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STATE HIGHWAY ADMINISTRATION

RESEARCH REPORT

DEVELOPMENT OF MATERIALS MANAGEMENT STRATEGIC PLAN

MACTEC ENGINEERING AND CONSULTING

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FINAL REPORT

January 2007

FINAL REPORT

Materials Management System Strategic Plan

Maryland State Highway Administration
Office of Materials Technology
Materials Management Division
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Lutherville, Maryland 21093

A product of the Materials Management Steering Committee

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16. Abstract

The core mission of the Maryland State Highway Administration is to efficiently provide mobility for our customers through a safe, well-maintained and attractive highway system that enhances Maryland's communities, economy and environment. As such, one of the most important roles we have is the design, construction, rehabilitation, and maintenance of over 14,600 lane-miles of highways throughout the State.

Due to the number of projects, large number of inputs to the process, and number of agencies, both private and public that contribute information, the Materials Clearance Process is a very complicated issue that is currently carried out in an effective, but perhaps inefficient manner due to its ad hoc nature. Therefore, it is recognized by MDSHA that there is a need to develop and implement a Materials Management System to meet the needs of the Materials Clearance program. The goal of this system will be to streamline all facets of the process so that information can be tracked and MDSHA personnel can manage the entire Materials Clearance Process more effectively and efficiently.

The following is a section-by-section look at the contents of this Strategic Plan.

Section 1: Vision and Mission. This section provides important background information on the topic. It discusses the genesis for Materials Management, a brief history of MD SHA MMS efforts, and a review of the State of the Practice in

Materials Management throughout the United States. It concludes with the Guiding Principles (MMS Definition, Vision, and Mission) which will be used to develop the MMS.

Section 2: Current Business Environment. This section takes an in-depth view of the current MDSHA Materials Clearance business environment. It describes the Materials Clearance process, details current laboratory information management procedures and explains how each piece of the system works today.

Section 3: Recommended Business Environment. This section outlines the recommended business environment for the future MMS system. The "critical capabilities" for the system are discussed along with detailed recommendations for system configuration including hardware and software.   Other issues such as training requirements and benefits of implementation of the system are also discussed.

Section 4: Implementation Strategy. The Implementation section outlines the specific tasks needed to develop the MMS. This section can be considered the Project Management Plan as it includes issues dealing within the scope, budget, and time requirements needed to fully develop the system.

Appendices and Reference Documents. The remainder of the document contains useful background information to support the Strategic Plan and can be used by future developers implementing the system.

This Strategic Plan has been developed in order to provide the roadmap for implementation of the MMS. Like a traditional roadmap it details the starting point of the trip (where we are), the end point (where we want to go) and many of the alternatives and considerations for the intended trip. Landmarks are outlined along the way to ensure we are moving in the right direction and progressing toward the goal in a timely manner. It should be understood that the route is dynamic and must be assessed at regular intervals. Due to the time it will require to implement the MMS it is inevitable that technology and business process revisions will occur during implementation of this system. This plan will be revisited at regular intervals and updated to reflect reality.

The implementation of a single Materials Management System will provide considerable benefits to MDSHA including the ability to:

- Store and retrieve data more efficiently and effectively
- Share data across Divisions and Offices
- Generate Business Plan progress reports easily
- Streamline Materials Clearance process
- Track long term material quality performance
- Link sources and materials used versus linear referencing system (spot on the road)
- Increase efficiency and reduce costs associated with Materials Clearance

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The input and assistance of the Maryland State Highway Administration Materials Management Steering Committee was instrumental in the development of this document and their work is appreciated. The members of the committee, in alphabetical order, are:

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Mr. Benjamin Gilardi was the Project Manager for this effort.

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The contents, opinions, findings, and conclusions expressed in this report are those of the author who is responsible for the facts and accuracy of the data represented in this document. The contents do not necessarily reflect the official views of the Maryland State Highway Administration or the Federal Highway Administration. This report does not constitute a standard, specification or regulation.

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Acronyms

AASHTO – American Association of State Highway and Transportation Officials

AMRL – AASHTO Materials Reference Laboratory

ASTM – American Society for Testing and Materials

BMS – Bridge Management system

COTS – Commercial off-the Shelf

FMIS – Financial Management Information System

GAB – Graded Aggregate Base

IDR – Inspector's Daily Report

JMF – Job Mix Formula

MARTCP – Mid-Atlantic Region Technician Certification Program

MCMS – Maryland Construction Management System

MMS – Materials Management System.

MPEL – Maryland Product Evaluation List

MSMT – Maryland Standard Method of Tests

NHS – National Highway System

PMS – Pavement Management System

QA – Quality Assurance

QC – Quality Control

QPL – SHA Qualified Products List

Foreword and Purpose

The Office of Materials Technology (OMT) has long recognized a need to implement an electronic Materials Management System (MMS) to better track, record, evaluate, analyze and review the quality of materials used on Maryland State Highway Administration (MDSHA) construction projects. In 1998, after several years of evaluation, MDSHA elected not to move forward with the purchase and implementation of the AASHTO Site Manager Construction management system which included a module to manage produced and delivered materials. As a result, MDSHA has not committed to a single approach to manage materials. Instead, a variety of approaches are being employed to manage materials ranging from electronic databases to proprietary systems to hardcopy records. Consequently, it is very difficult to integrate and share data across OMT teams and other MDSHA offices and to perform the critical Materials Clearance activities which are crucial to our overall mission.

This Strategic Plan for implementing the Materials Management System (MMS) has been developed to provide us with a roadmap to full implementation of the MMS, a process that will take a significant amount of time. It has been developed with input from many critical areas of MDSHA including many Divisions of OMT, Office of Construction, and the Office of Information Technology. This input was required in order to create a plan that represents and includes the perspectives of many of the key players in the Materials Management process.

The implementation of a single Materials Management System will provide considerable benefits to MDSHA including the ability to:

- Store and retrieve data more efficiently and effectively
- Share data across Divisions and Offices
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- Link sources and materials used versus linear referencing system (spot on the road)
- Increase efficiency and reduce costs associated with Materials Clearance

Please support us as we embark on the task of bringing this plan to life. Implementation of the MMS will provide many benefits to all MDSHA and provide increased efficiency and effectiveness to fulfill our core mission.

_____   _____
Woodrow Hood   Peter Stephanos, P.E.
Chief, Materials Management   Director, Office of Materials Technology

Executive Summary

The core mission of the Maryland State Highway Administration is to efficiently provide mobility for our customers through a safe, well-maintained and attractive highway system that enhances Maryland's communities, economy and environment. As such, one of the most important roles we have is the design, construction, rehabilitation, and maintenance of over 14,600 lane-miles of highways throughout the State.

The Materials Clearance process is a Federally mandated program documented in the Code of Federal Regulations, Title 23, Part 637, "Construction Inspection and Approval." The process is used to ensure that quality materials are being used on all Federal-aid highway projects on the National Highway System (NHS). To comply with Federal Highway Administration (FHWA) requirements, MD SHA, and all other states, must submit a materials certification for each construction project on the NHS System. This certification states, "Acceptance samples indicate the materials incorporated into the project and construction operations controlled by sampling and testing were in reasonably close conformity with the plans and specifications." While this is required for federally funded projects, this program has been extended to all construction projects undertaken by MD SHA regardless of the funding source.

Historically, MD SHA has conducted this process using a paper based system. Due to the number of projects, large number of inputs to the process, and number of agencies, both private and public that contribute information, the Materials Clearance Process is a very complicated issue that is currently carried out in an effective, but perhaps inefficient manner due to its ad hoc nature. Therefore, it is recognized by MD SHA that there is a need to develop and implement a Materials Management System (MMS) to meet the needs of the Materials Clearance program. The goal of this system will be to streamline all facets of the process so that information can be tracked and MD SHA personnel can manage the entire Materials Clearance Process more effectively and efficiently.

This Strategic Plan has been developed to outline the current material management state of the practice, review MD SHA's current business practices, determine Materials Clearance areas in need of improvement and provide an Implementation Plan to guide development of the Materials Management System.

MMS Guiding Principles

Based upon the examination of the state of the practice, it is evident that there is no dominant off-the-shelf MMS system that meets all MD SHA needs. There is also no nationally accepted standard with which to develop a MMS. The level of sophistication used by each DOT to manage the Materials Clearance process is variable and each DOT seems to be taking a unique approach to development of a MMS. The SiteManager product developed by AASHTO has been previously tested by MD SHA as a MMS and a decision made not to pursue this product for MMS functionality. A national effort to develop a standard MMS, besides SiteManager, does not appear to be on the horizon. Based upon market research conducted as part of the development of this Strategic Plan, there also does not appear to be a suitable commercial-off-the-shelf system for use by

MD SHA as a MMS. Thereby, a decision has been made to pursue development of a custom MMS to meet the unique needs of the MD SHA.

For the purposes of this program, the Materials Management System will be defined as follows:

> "An integrated electronic system used as a tool to manage the Materials Testing, Acceptance, and Clearance process within SHA."

The Vision for the Materials Management System will be as follows:

> The system will provide highway material sample tracking throughout the Materials Testing and Clearance life cycle, assist with source of supply acceptance, calculate pay factors, determine materials acceptability, generate sampling and testing schedules, and be used as a mechanism to determine when all Materials Clearance activities are complete. It will serve as the single data repository for all Materials Testing and Clearance activities including materials tested in central and field laboratories, consultant laboratories, manufacturing sites and project sites, as needed.   It will provide tools to managers in order to make decisions regarding the efficiency and effectiveness of the process, file storage, task tracking, and correspondence sharing.   It will also be capable of sharing data with SHA enterprise databases and other management systems such as PMS, BMS, TRNS*PORT, etc.

Key mission critical goals of the system will be as follow:

1. Management of the Materials Clearance Process
2. Allow data sharing and knowledge transfer among key SHA stakeholders
3. Allow one-stop data entry and status reporting on progress against Materials Clearance goals
4. Provide documentation of Materials Clearance compliance for FHWA certification
5. Allow lab managers to track the status and costs of testing within a given Technical Material Division
6. Provide up to date information on selected items related to SHA business plan objectives (Dashboard)

The definition, Vision and Mission form the Guiding Principles by which the MMS will be developed.

Current Business Practice

The Maryland State Highway Administration, Office of Materials Technology (OMT) has overall responsibility for managing the Materials Clearance process. At any one time, there may be as many as 400 active construction projects throughout the State and surrounding counties and municipalities for which OMT has direct materials testing responsibility. For State projects, MD SHA must certify that all materials used for each construction project have been adequately sampled and approved for use.

The generalized process for Materials Clearance within SHA is as follows:

Submittals: Once a construction contract has been awarded, the prime contractor provides the sources of materials intended to be used on the project. The source for each of these materials is listed with the company's name and address. The approval of these sources means that the producer has the necessary facilities to produce acceptable materials. It does not imply that the material is approved or accepted.

New Materials Sources: When the proposed source is one that has not recently or has never produced materials for MD SHA projects, the Administration may do a facility approval, and/or take representative samples of the materials being produced at the time of inspection. The Administration then evaluates the production process for quality control before the material is approved.

Qualified Products: The MD SHA allows the use of qualified products that have gone through a prescribed procedure for submittal, testing, and qualification. The Office of Materials and Technology maintains the Qualified Products List (QPL) for those products meeting specifications for use on Maryland State Highway Administration's construction projects. Prequalification does not imply that materials can be used on Maryland State Highway Administration projects without regard for normal Quality Assurance Testing and Procedures.

Materials Certification Program: The MD SHA follows a Materials Certification Program as outlined in the MD SHA Frequency Guide. A random process of sampling and testing is conducted to evaluate a manufacturer's and producer's material certificate of compliance.

Quality Assurance Program: The Maryland State Highway Administration makes appropriate distribution of density charts, job mix formulas, mix designs, etc. generated by the source submittals. The MD SHA staff follows the guidelines established by OMT to monitor the progress of the project, perform record keeping, and ensure proper communication.

Monthly Materials Clearance Procedures: The MD SHA Project Engineer prepares monthly submittal forms with estimate worksheet for each construction project. The required documentation such as certifications, laboratory test data, inspection reports, specifications etc. are reviewed and attached with the submittal. The Project Engineer reserves the right to withhold payment for items that don't have proper documentation as described above. The Project Engineer forwards this documentation to the Certification Engineer within 7 calendar days following the estimate due date with a copy of the estimate worksheet for review and comment. Within 14 days the Certification Engineer returns the submittal to the Project Engineer with copies to the Materials Engineer and Assistant District Engineer Construction with comments. The Contractor reviews and provides any missing information to the Project Engineer in order to get paid for material on that monthly estimate.

Materials Clearance, 30 Day Notice: At least 30 days before the completion of the project, the District Engineer will notify the District Materials Engineer in writing in accordance with MD SHA Construction Directive 72.1-10-12. This notification contains a list of bid items not used and where applicable quantities of materials were used. A request at that time for final reports is sent by OMT to all responsible centers and Districts providing inspection and/or testing for the project. After review completion, the appropriate personnel are requested to supply information to assist in resolving

exceptions. An exception is defined as, "any violation of the Specifications and /or Standards". All exceptions are addressed.

Materials Clearance Final Report: A final review of files is performed after receiving the copy of the Acceptance for Maintenance Letter. A copy of the certification or clearance correspondence is distributed to MD SHA's appropriate Districts and FHWA Office for NHS projects. The original is retained in the project file in the laboratory. The records are retained for three years after the final voucher is submitted to the Federal Highway Administration for approval.

The preceding discussion has outlined the current Materials Clearance processes. As mentioned early and often in this plan, the process as it currently stands is an effective process. The system works. However, system business processes can be streamlined and made more efficient through the use of improved processes and information technology. After analyzing the processes involved, discussing the current system with key stakeholders, and soliciting input on desired system characteristics, a series of 35 discrete Opportunities for Improvement were identified for the Materials Clearance process. In order to ameliorate these OFI's, a series of 54 critical capabilities were identified for the MMS. These critical capabilities were organized into a series of ten projects which are proposed for MMS Implementation over a five-year period.

Implementation Plan

Implementation of the MMS will be carried out through a series 10 individual projects (grouped together in six phases). Each project will produce aspects of the system that are useful on their own and will not require future projects to be functional. Therefore, if future projects are not completed (for whatever reason) there will be a system developed that is useful and expandable.

Each project will go through its own IT project life cycle development process including requirements documentation, budgeting, scheduling, planning, etc. In general, the initial planning work for each project can begin when the proceeding project is approximately 80% complete, or has a clear end in sight. These individual planning processes will incorporate the general aspects as outlined in this Strategic Plan as well as present business needs and new technologies.

A summary of each project is as follows:

Project 1 – Development of High-Level Requirements Document

The build-out of the MMS must follow the requirements of the Maryland System Development Lifecycle (SDLC) guidelines. The SDLC contains 10 phases for overall project development. Within the SDLC framework this Strategic Plan is considered to be the System Conceptual Development document. The scope of this project will be to perform the next phases of the SDLC which are the Planning stage (development of a general Project Management Plan) and the Requirements Analysis phase. [1] These phases will be combined in this project. These phases will be conducted for the MMS system as a whole and will not necessarily be concerned with the minutia of each project described

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[1] See chapters 3 and 4 of Volume 2 of the SDLC.

herein. The scope of the Planning document will be to plan, articulate and gain approval of the strategy to execute the management aspects of the MMS project. This document will expand and clarify the project work breakdown structure (WBS) as presented in this Strategic Plan. This project will have a ten-month duration and budget of $50,000.

Project 2 – MMS Functionality Pilot Study

Efforts have been underway to develop a basic prototype MMS and this effort has yielded a suitable framework system that can be expanded upon. The purpose of this project will be to carry out a pilot study to develop an internet portal that can access the prototype MMS. The effort is considered a pilot study to explore how the primary means of access to the MMS, the web, can be interfaced with back-end MMS databases. As the interface and access is critical to the success of the MMS, this pilot study is necessary to determine the areas of risk in this delivery mechanism and ameliorate one of the highest perceived risks of the MMS early on. The project is estimated to have an eight-month time duration and a budget of $50,000 and run concurrently with Project 1.

Project 3 – Development of Data Warehouse, Web Functionality, and Admin Tools

The purpose of this project is to develop the framework around which the MMS will be built. The first order of business will be to develop the prototype data model. Another important task will be to determine the location and licensing provisions of the Oracle software which will drive the system. The deliverables from this effort will include a data model, an active Oracle MMS database, and an active MMS internet presence. The MMS will also have the foundational administrative tools as documented previously. Documentation of the database model and system code will also be required. This project is expected to have a duration of twelve months and a budget of $175,000.

Project 4 - Project Management Application

The project management application will provide the means to enter Materials Clearance projects into the system. It will also handle notifications that projects have been initiated, and allow for manual and automated population of bid items and quantities. This application will have the capability to break-down lump sum items and enter these items into the database. It will also provide for automated development of the types, number of samples, and methods of acceptance for materials clearance. Development of this application is critical prior to development of all other MMS systems.   This project is expected to have a duration of eight months and a budget of $100,000.

Project 5 – Source of Supply Application

The Source of Supply application will be used by contractors to submit, and Area Materials Engineers to approve, sources used for each material. This project has the potential to quickly provide great efficiencies to the Materials Clearance process.   The project will have a duration of six months and a budget of $100,000.

Project 6 – Materials Clearance Application

The Materials Clearance Application will be the application where all materials clearance activities are monitored and managed. This system will assist the MMS with Materials Clearance activities and begin to allow reporting of progress and performance against

clearance goals. The Materials Clearance application will continue to be built out within the projects that follow. This project will have a twelve-month duration and a $150,000 budget

Project 7 – Laboratory Information Management System Application

The LIMS application will be used to provide sample management (receipt, testing status, and disposition), laboratory testing data storage, and laboratory equipment inventory capabilities. It is by far the largest and most complicated component of the MMS. During development of this Strategic Plan, a number of COTS LIMS were researched. As documented in the last section, it was determined that a custom LIMS system will be pursued by SHA. This project will have a twenty-four month duration and a budget of $200,000.

Project 8 – Field Data Management Application

The field data management application will be used to enter relevant data collected in the field that is used for materials clearance activities. This includes, but is not limited to, data entered through Form 14s, compaction data, and the Ride Tool. This project also envisions use of bar coding technology to log samples in the field and enter samples in the LIMS. This project has a time duration of eighteen months and a budget of $200,000.

Project 9 – Certified Materials Management Application

This portion of the MMS will be used to streamline the certified material acceptance process.   The application will have the capability to manage the list of certified materials and allow for automated population of the required stamps and certifications. It will also have an approval mechanism to allow the appropriate OMT agency to approve the material and allow it to go into clearance. This system will also have the capability to manage approved stockpile materials and approved lot quantities and maintain a list of approved stockpiles (producer, quantity, type of material, etc.), manage the quantity of material that has been used, inspection frequency, and provide notification of a stockpile's deviation from acceptable inspection cycles for each technical material division. This application has a duration of twelve months and a budget of $50,000.

Project 10 – Material Quality Approval Application

The Material Quality Approval Management application will be used to determine specification compliance and acceptance or rejection of test results. At the end of the day, this application will be able to link to all laboratory and field data elements and provide a judgment as to acceptance or rejection. This information will then be carried to the Materials Clearance application so that Clearance status can be updated and an electronic trail of acceptance or rejection of material created. This project has a duration of eight months and a budget of $200,000.

The MMS project has a total estimated duration of five years and a total estimated development budget (exclusive of hardware and system maintenance) of 1.275 million.

System Benefits

The implementation of a single Materials Management System will provide considerable benefits to MDSHA including the ability to:

- Store and retrieve data more efficiently and effectively
- Share data across Divisions and Offices
- Generate Business Plan progress reports easily
- Streamline Materials Clearance process
- Track long term material quality performance
- Link sources and materials used versus linear referencing system (spot on the road)
- Increase efficiency and reduce costs associated with Materials Clearance

Summary

This Strategic Plan has been developed in order to provide the roadmap for implementation of the MMS. Like a traditional roadmap it details the starting point of the trip (where we are), the end point (where we want to go) and many of the alternatives and considerations for the intended trip. Landmarks are outlined along the way to ensure we are moving in the right direction and progressing toward the goal in a timely manner. It should be understood that the route is dynamic and must be assessed at regular intervals. Due to the time it will require to implement the MMS it is inevitable that technology and business process revisions will occur during implementation of this system. This plan will be revisited at regular intervals and updated to reflect reality.

Introduction

The core mission of the Maryland State Highway Administration is to efficiently provide mobility for our customers through a safe, well-maintained and attractive highway system that enhances Maryland's communities, economy and environment. As such, one of the most important roles we have is the design, construction, rehabilitation, and maintenance of over 14,600 lane-miles of highways throughout the State.

It is estimated that during Fiscal Year 2005, MDSHA will undertake almost $600 million in construction to upgrade and maintain our system. At any given time we have hundreds of construction projects ongoing and for each project there is a systematic method with which to assess and approve the quality of over 800 different constituent materials. This method is formalized in what we know as the Materials Clearance process. For the purposes of this Strategic Plan, the Materials Management System will be the framework in which Materials Clearance activities will occur for MDSHA.

Due to the number of projects, large number of inputs to the process, and number of agencies, both private and public that contribute information, the Materials Clearance Process is a very complicated issue that is currently carried out in an effective, but perhaps inefficient manner due to its ad hoc nature. Therefore, it is recognized by MDSHA that there is a need to develop and implement a Materials Management System to meet the needs of the Materials Clearance program. The goal of this system will be to streamline all facets of the process so that information can be tracked and MDSHA personnel can manage the entire Materials Clearance Process more effectively and efficiently.

The following is a section-by-section look at what you will find in this Strategic Plan.

Section 1: Vision and Mission. This section provides important background information on the topic. It discusses the genesis for Materials Management, a brief history of MD SHA MMS efforts, and a review of the State of the Practice in Materials Management throughout the United States. It concludes with the Guiding Principles (MMS Definition, Vision, and Mission) which will be used to develop the MMS.

Section 2: Current Business Environment. This section takes an in-depth view of the current MDSHA Materials Clearance business environment. It describes the Materials Clearance process, details current laboratory information management procedures and explains how each piece of the system works today.

Section 3: Recommended Business Environment. This section outlines the recommended business environment for the future MMS system. The "critical capabilities" for the system are discussed along with detailed recommendations for system configuration including hardware and software. Other issues such as training requirements and benefits of implementation of the system are also discussed.

Section 4: Implementation Strategy. The Implementation section outlines the specific tasks needed to develop the MMS. This section can be considered the Project Management Plan as it includes issues dealing within the scope, budget, and time requirements needed to fully develop the system.

Appendices and Reference Documents. The remainder of the document contains useful background information to support the Strategic Plan and can be used by future developers implementing the system.

It is recognized that the development of a Materials Management system is likely viewed as an Information Technology project. In other words, manual systems or procedures are being automated to improve process and work flows. While a large portion of the contemplated system will be developed by information technology professionals, it should be emphasized that the successful implementation of the MMS will be dependent on a multi-disciplined team approach to the project with the users heavily involved in development of the system. User requirements must drive the system. This is stated early and often in the Strategic Plan.

This Strategic Plan has been developed in order to provide the roadmap for implementation of the MMS. Like a traditional roadmap it details the starting point of the trip (where we are), the end point (where we want to go) and many of the alternatives and considerations for the intended trip. Landmarks are outlined along the way to ensure we are moving in the right direction and progressing toward the goal in a timely manner. It should be understood that the route is dynamic and must be assessed at regular intervals. Due to the time it will require to implement the MMS it is inevitable that technology and business process revisions will occur during implementation of this system. This plan will be revisited at regular intervals and updated to reflect reality.

Section 1: Vision and Mission

The Materials Clearance process is a Federally mandated program documented in the Code of Federal Regulations, Title 23, Part 637, "Construction Inspection and Approval," (Appendix A). The process is used to ensure that quality materials are being used on all Federal-aid highway projects on the National Highway System (NHS). To comply with Federal Highway Administration (FHWA) requirements, MDSHA, and all other states, must submit a materials certification for each construction project on the NHS System. This certification states, "Acceptance samples indicate the materials incorporated into the project and construction operations controlled by sampling and testing were in reasonably close conformity with the plans and specifications." While this is required for federally funded projects, this program has been extended to all construction projects undertaken by MDSHA regardless of the funding source. FHWA periodically monitors performance of our organization to determine compliance with the Code (Appendix B).

MD SHA Historical Perspective

Historically, the Materials Clearance process has been paper-based and utilizes a series of log books to track samples and test results for each quality control sample taken on a project. Most, if not all, documentation for the process is originated in paper form, transmitted through the mail or other in-house courier methods, and stored in filing cabinets.

The need for an improved Materials Management process was recognized by OMT and its predecessors in the late 1980's. With growing access to relatively inexpensive computing power and introduction of networked computer work stations as well as robust PC-based office productivity tools (databases, spreadsheets, word processors, and proprietary systems), the vision was created to use these tools to provide for efficiencies throughout the process. A series of system specification documents was created throughout the early 1990's and this resulted in a well documented outline for an electronic Materials Management System.

During this timeframe, AASHTO was also in the midst of developing a Construction Management System called SiteManager (www.aashtoware.org) as part of the TRNS*PORT suite of products. SiteManager provides for data entry, tracking, reporting, and analysis of contract data from contract award through finalization and it includes a module for Materials Management. MDSHA decided to abandon the custom designed MMS and invested in the SiteManager product. Over time, interest in the SiteManager product waned as personnel realized that this system would not meet MDSHA's unique business environment and needs.

In the meantime, MDSHA Divisions with responsibility for Materials Management activities were creating standalone processes to assist them in their particular mission. This included use of spreadsheets, databases, proprietary systems and other electronic mediums to store and retrieve information. The systems developed by each party were, by necessity, developed within the business unit "silo" with differing data collection, processing, or reporting standards applied. In addition, paper was and remains the predominant form of communication and documentation within the Materials Management process. This ad hoc system of disparate computer tools meshed with paper

reporting forms the backbone of the Materials Clearance process within MDSHA to this day and it is an effective method – it works.

During formulation of the OMT's Business Plans goals in the 2002 and 2003 timeframe, it became evident once again that a formalized MMS was a top priority for MDSHA. As such, a series of scoping meetings were held to determine how to approach this task. In 2006, funding was allocated to develop a Strategic Plan to formally outline the scope and implementation phases necessary. This Strategic Planning document is the result of that effort.

Current DOT MMS Practice

In 2003, a project was undertaken by NCHRP (20-07, Task 157, "Materials Information Management Software Review") to assess the current state of the practice of Materials Management Systems throughout the United States (Appendix C). As part of the project, the investigator conducted a survey of State DOT MMS practice. They received quite a significant response with 48 AASHTO respondents of which 45 were state DOTs. The study found twenty-seven DOTs have some form of MMS in process or in-place. Ten of those entities report having a fully functional system in-place. Due to the unique needs of each DOT and the relative immaturity of the MMS marketplace, many reported developing custom systems using in-house resources supplemented with consultant staff. Five off-the-shelf systems were identified and the general consensus is that the majority of offered systems are Laboratory Information Management System (LIMS), and not integrated MMS. It should be noted again that the definition of MMS in this survey was quite broad and it is possible that a rudimentary LIMS was reported as a fully functioning MMS. From a critical review of the NCHRP document, it is doubtful that all but a handful of states actually have a functional MMS which includes all facets as proposed in this Strategic Plan.

The NCHRP study identified five LIMS/MMS vendors. These are:

- Beckman Coulter (FL, VA, and MI)
- Ciber Custom Solutions (SD)
- LabVantage Solutions (KY, MN, and NY)
- Perkin Elmer Labworks (NH)
- Visual Solutions, Inc. (WI and IN)

Thirty-five percent of the NCHRP respondents use SiteManager and 15 percent use the SiteManager Materials Module. Of those using the Materials Module, two-thirds found it difficult to use as a MMS.

A different MMS survey was conducted in February 2004 by the Ministry of Transportation, Ontario. This survey included 27 DOTs. A compilation of this data reveals the data shown in Figure 1-1. As seen in this figure, only 30 percent of DOTs use a readily available MMS package while 70 percent have chosen to develop a system in-house or have no system.

Figure 1-1. DOT MMS/LIMS Usuage
(source: Ontario Ministry of Trasnportation survey)
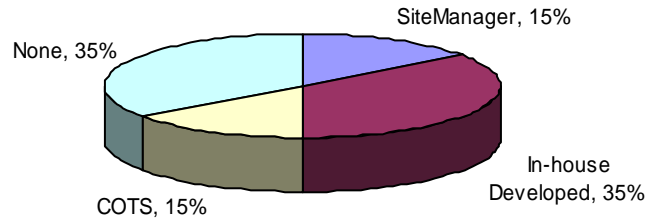
Again, this survey is not clear on the definition of MMS versus LIMS so it is difficult to assess if these states truly have an integrated MMS as per the definition presented previously.

Subsequently, MDSHA conducted an internal survey of vendors and States' experience with vendors. The results of this survey are shown in Table 1-1.

Table 1-1. SHA phone interview with selected states

Vendor	States Using	Conclusions
Atwood Systems	WI, IN	Both states praised both product and vendor. Includes LIMS, external links, interface to TRNS*PORT, etc.
LabVantage Solutions	KY, MN, NY	Kentucky not at all satisfied with product or vendor
Innerphase L.I.M.S formerly Beckman Coulter	FL, MI	Mainly a LIMS, no real Materials Management functionality
Ciber Custom Solutions	SD	Product is in very early states of in-house development
Perkins Elmer Life and Analytical Sciences	NH	Mainly a LIMS, no real Materials Management functionality
SAS Institute	IL	Most of system developed late 1980's, no GUI, etc., needs update
Virginia DOT	VA	In-house LIMS development designed to interface with SiteManager (VA is currently using SiteManager for construction management with the materials portion of the program turned off)
West Virginia DOT	WV	Developed late 1980's in-house / WV is looking to fix or replace

Based upon the examination of the state of the practice, it is evident that there is no dominant off-the-shelf MMS system, let alone a system that meets all DOT needs. There is also no nationally accepted standard with which to develop a MMS. The level of sophistication used by each DOT to manage the Materials Clearance process is variable and each DOT seems to be taking a unique approach to development of a MMS/LIMS. A national effort to develop a standard MMS, besides SiteManager, does not appear to be on the horizon.

Existing commercial systems in the marketplace require a fair amount of customization and development work to "shoe-horn" DOT business processes into the system. SiteManager is generally not suitable for MMS purposes without significant customization and in the current SiteManager environment, customization of this product is difficult to achieve. Lastly, from review of the literature, it is quite evident that collaboration between Information Technology and Engineering experts is critical to success. There must be a "meeting of the minds" and extensive collaboration in place to successfully implement a MMS. Appendix D contains a summary State of the Practice document developed as part of this plan for reference.

Materials Management System Guiding Principles

In our industry the term "Materials Management System" has many connotations and definitions. There seems to be confusion as to the true meaning of the term MMS as it is commonly, and incorrectly, referred to as a Laboratory Information Management System, or LIMS. NCHRP project 20-07, Task 157 offers relevant definitions for both terms:

> *Materials Management System (MMS). An integrated computerized database that keeps track of materials procured by the DOT. The system includes materials tested in central and field laboratories, on construction projects, and at manufacturing sites. The MMS is capable of providing sample tracking, quality assurance documentation, reports, and research analyses. An MMS may focus on: 1) the procurement process; 2) the performance process; or 3) both.*

> *An MMS aims to assist decision-makers in finding optimum strategies for specifying, procuring and evaluating materials as they relate to highway infrastructure performance in items such as pavements, bridges, embankments, and manufactured items such as paint, signs, guiderail, etc.*

> *Laboratory Information Management System (LIMS). A LIMS is a subset of a MMS that concentrates on sample identification, testing, and documentation of those products tested in a laboratory (as opposed to the field or to an off-site manufacturing facility). It is designed to allow the user to benefit from all the data that is collected within the laboratory environment. A LIMS should offer a range of functions for sample logging, tracking, reporting, archiving, querying, worklist generation, etc. In an analysis mode, a LIMS can be used to process results from instruments, trend data over a series of time points, automatically apply testing profiles to samples, result reporting along with numerous other sample-based activities. The benefits of a LIMS are to run the laboratory efficiently, reduce sample turnaround time, allow the rest of the organization to have improved access to information and eliminate duplication of work and errors.*

From a strategic standpoint, a MMS is an enterprise-wide tool used to manage the entire materials clearance process while the LIMS is a tool used within a MMS to manage the laboratory testing aspects of the materials clearance process. For example, a MMS might

be used to manage very high level goals in terms of number of projects cleared or track progress against SHA business plan goals while the LIMS is used to assess the status of a sample within the testing process, determine total monthly production, and individual test efficiency. <u>It is very important that this difference is understood.</u>

Definition

For the purposes of this program, the Materials Management System will be defined as follows:

"An integrated electronic system used as a tool to manage the Materials Testing, Acceptance, and Clearance process within SHA."

Vision

The Vision for the Materials Management System will be as follows:

The system will provide highway material sample tracking throughout the Materials Testing and Clearance life cycle, assist with source of supply acceptance, calculate pay factors, determine materials acceptability, generate sampling and testing schedules, and be used as a mechanism to determine when all Materials Clearance activities are complete. It will serve as the single data repository for all Materials Testing and Clearance activities including materials tested in central and field laboratories, consultant laboratories, manufacturing sites and project sites, as needed.   It will provide tools to managers in order to make decisions regarding the efficiency and effectiveness of the process, file storage, task tracking, and correspondence sharing.   It will also be capable of sharing data with SHA enterprise databases and other management systems such as PMS, BMS, TRNS*PORT, etc.

Mission

Key mission critical goals of the system will be as follow:

1. Management of the Materials Clearance Process
2. Allow data sharing and knowledge transfer among key SHA stakeholders
3. Allow one-stop data entry and status reporting on progress against Materials Clearance goals
4. Provide documentation of Materials Clearance compliance for FHWA certification
5. Allow lab managers to track the status and costs of testing within a given Technical Material Division
6. Provide up to date information on selected items related to SHA business plan objectives (Dashboard)

The definition, Vision and Mission form the Guiding Principles by which the MMS will be developed.

Section 2: Current Business Environment

Introduction

The Maryland State Highway Administration, Office of Materials Technology (OMT) has overall responsibility for managing the Materials Clearance process. At any one time, there may be as many as 400 active construction projects throughout the State and surrounding counties and municipalities for which OMT has direct materials testing responsibility. For State projects, MD SHA must certify that all materials used for each construction project have been adequately sampled and approved for use.

The MD SHA has a current Materials Clearance process that works. While some aspects of the system have evolved from a largely paper-based system to a database (electronic) environment on an ad hoc basis, the current process is still quite labor intensive. Also, there are significant barriers to sharing data among various participants and reporting of strategic level Materials Clearance progress is inefficient and time consuming.

Simply stated, the Materials Management System is meant to streamline the Materials Clearance procedure so that quality information is available in a timely manner to the appropriate personnel in order to make decisions and expedite the process.

There are currently 25 major offices within the Maryland State Highway Administration. Roughly half are significantly impacted in some manner by the Materials Clearance process. The primary SHA stakeholders for the Materials Clearance process are as follow:

- Office of Materials Technology (OMT)
- Office of Construction (OOC)
- Office of Finance (OOF)
- Office of Information Technology (OIT)
- All 7 Districts (D1 – D7)

The primary customers of the Materials Clearance process include the following:

- Office of Maintenance
- Office of Bridge Development
- Office of Traffic and Safety
- Federal Highway Administration
- Other MDOT modes (MTA, MAA, etc.)
- Counties, cities, and municipalities
- Contractors
- Major materials suppliers
- Materials producers
- Consultants

The Materials Clearance Process touches the core of MD SHA's mission, and the process has a wide variety and number of key stakeholders that must be included and involved in the Materials Management Process.

In order to implement the MMS, it is first important to understand the current business process to be modeled. Once the current business process is modeled and understood, gaps and weaknesses can be discovered and solutions developed.

Materials Clearance Procedure

The following is a detailed review of the Materials Clearance procedure. The process is illustrated in Figures 2-1, 2-2, and 2-3.

Project Initiation

All construction projects are identified by a unique contract number. This number is assigned before the project is advertised and is used throughout the duration of construction. Work on various phases of the project is identified by bid item number. Each bid item has a bid quantity that is the estimated amount of that particular item (e.g. tons of hot mix asphalt, cubic yards of borrow, cubic yards of concrete, linear feet of piling, etc.) needed to complete that phase of the project. Most contracts have a list of all bid item numbers, the various materials needed to construct the item, and the bid quantity, available from the Engineer's Estimate. This information is maintained in TRNS*PORT and is the basis for determining the list of materials needed for the contract.

As part of this process, lump sum items must be further broken down to represent the constituent components of the lump sum bid items. In addition, design/build projects have unique bid item needs that must be addressed in the Project Initiation phase. For example, a design/build project may involve a bridge structure. The entire structure is bid as a lump sum item but the various components that make up the bridge must be broken down so that the materials can be tracked, paid, and cleared.

It should be noted that Materials Clearance activities are not only conducted for SHA projects. SHA also performs clearance activities (primarily source approval, laboratory testing, field inspection, and materials certification) for other MDOT modes and federally sponsored projects in counties, cities, and municipalities.

Source of Supply

At the start of a project, a list of all materials used in the project is provided to the contractor. The contractor must name his sources of supply for all project materials and provide documentation of the approved mix design for various materials. The MDSHA provides guidance to general contractors for using a suggested format which must include the awarded contract number, project location, bid item number and materials to be used in each item. The source for each of these materials is listed with the company's name and address. The approval of these sources means that the producer has the necessary facilities to produce acceptable materials. It does not imply that the material is approved or accepted.
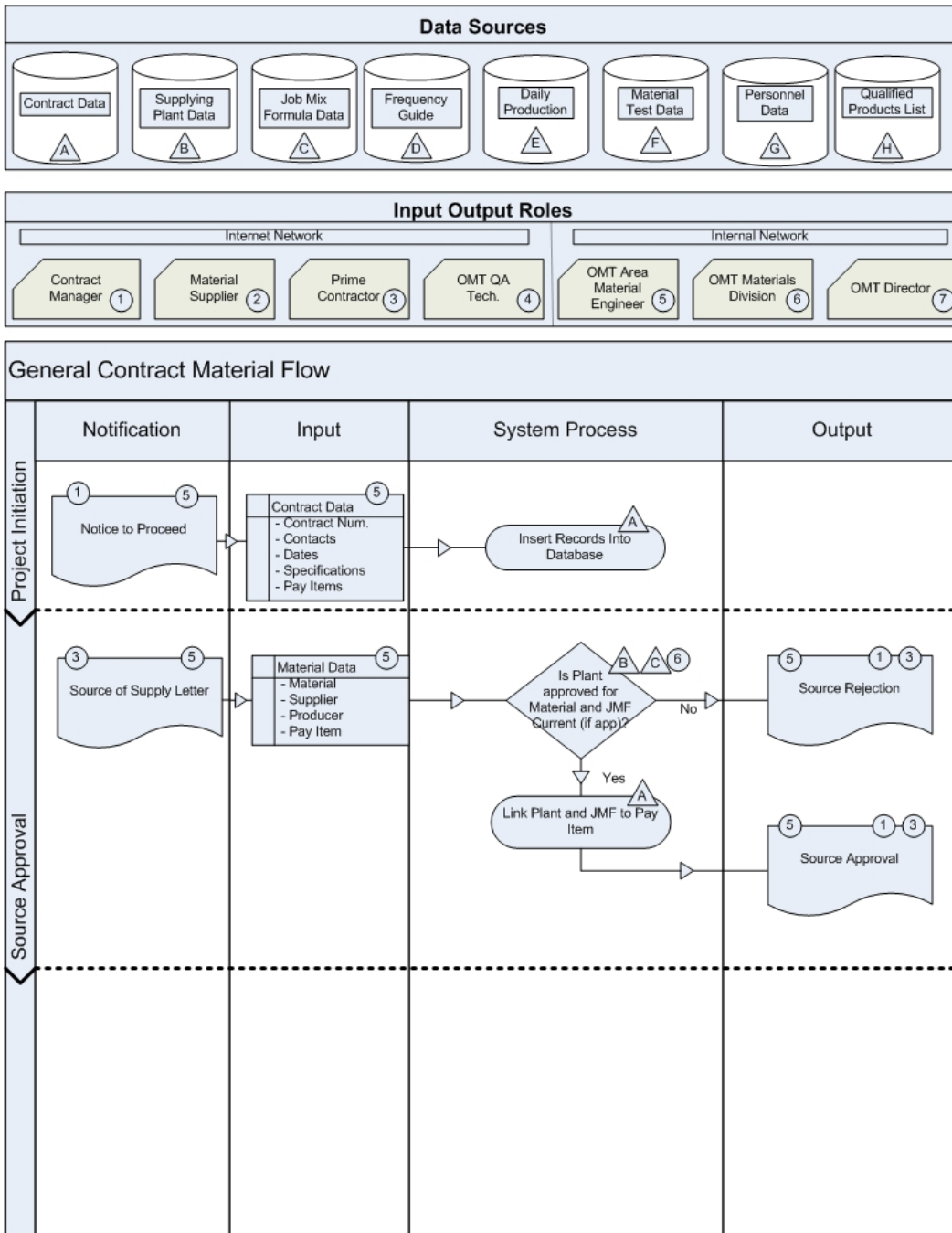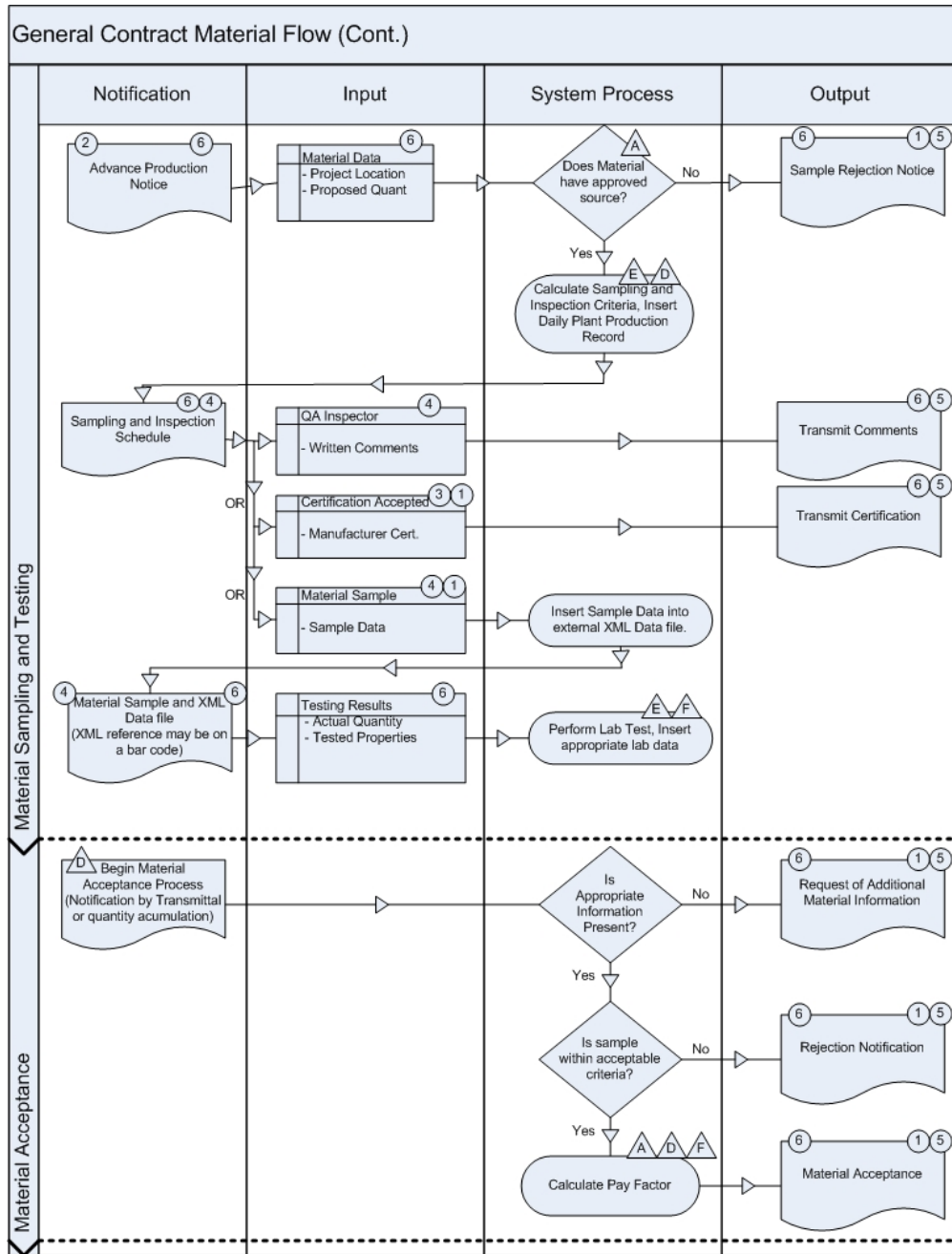
Figure 2-1. Materials Clearance flowchart, page 1

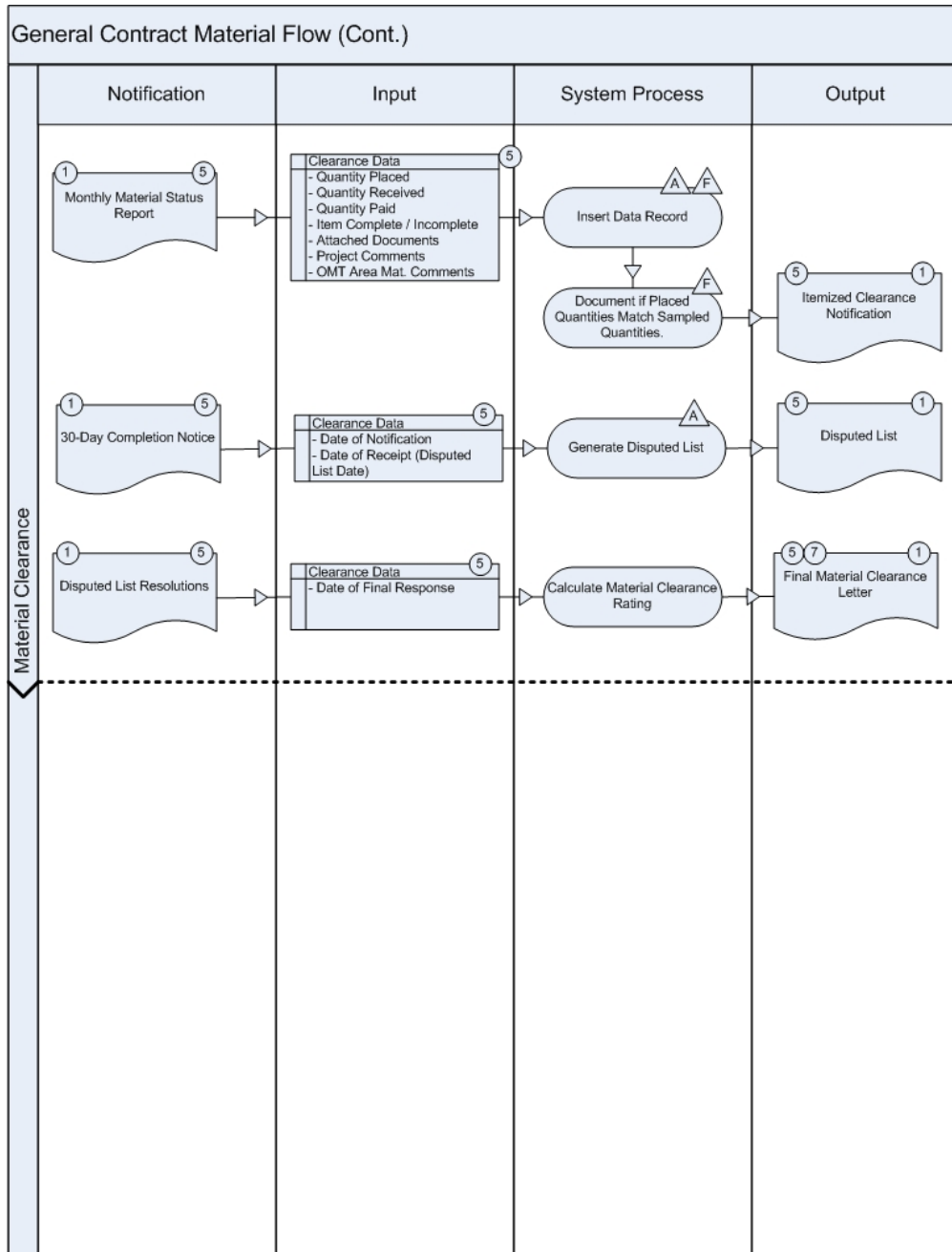Figure 2-2. Materials Clearance flowchart, page 2

Figure 2-3. Materials Clearance flowchart, page 3

As the sources are named, SHA approves or disapproves the supplier of choice. The contractor must change any disapproved sources of supply. This process may not be completed at the beginning of the contract. It may be on going and continue over the life of the contract. It is important to note that sources may change throughout the life of a contract. It is also possible that one material may have multiple sources of supply. This entire process is conducted using a paper-based system. The approved sources of supply are managed by each OMT technical materials division (Soils and Aggregates, Asphalt, Concrete, and Structural Materials).

When the proposed source is one that has not recently or has never produced materials for MDSHA projects, the Administration may do a facility approval, and/or take representative samples of the materials being produced at the time of inspection. The Administration then evaluates the production process for quality control before the material source is approved.

The MDSHA allows the use of qualified products that have gone through a prescribed procedure for submittal, testing, and qualification. The Office of Materials Technology maintains the Qualified Products List (QPL) for those products meeting specifications for use on Maryland State Highway Administration's construction projects. Prequalification does not imply that materials can be used on Maryland State Highway Administration projects without regard for normal quality assurance testing and procedures.

Determination of Acceptance Procedure, Type and Number of Tests

Contracts are bid and paid on the basis of bid item. Each bid item includes the quantity of that item needed to complete the project. The Frequency Guide lists the number of samples required for a specific quantity of an item's material and the acceptance procedure for that particular material. The total number of test samples required for each bid item is determined using the bid quantity and the frequency guide. This process of establishing the number of tests for materials clearance is currently performed in an ad hoc manner dependent on the person involved in the clearance activities. There is no system to perform this function automatically or consistently.

There are approximately 800 different types of materials that may be used in a highway construction project. The type of material is the primary characterization of any sample. The material's type and its use determine what tests are to be run on a sample. There are many ways in which materials are sampled, tested and approved for use on a project. These include materials which are:

1. Accepted on certification of the producer.
2. Rarely used in normal highway construction, while some may only be used once or twice a year.
3. Experimental or proprietary materials that are used for some unique purpose on a particular project. Although they may not be tested, they must be accounted for in the certification process. They are usually accepted on the manufacturer's certification or the Project Engineer's statement of satisfactory performance.
4. Inspected in the field rather than sampled. The inspector completes an inspection report which is treated just like a sample test report.

5. Tested in the field, such as compaction of base materials, by construction inspectors at the project site. These results are kept at the construction site until the project is completed. A tabulation of all tests run on the job site is compiled and sent to the Materials Engineer's office. This information is compared with the Frequency Guide to determine if the proper number of tests was performed.

6. Tested in the laboratory. This includes test procedures such as gradation, moisture content, etc. wherein a particular material is subjected to a laboratory procedure to ascertain acceptance or rejection. These results are retained in the technical material division in which they are received and data is usually stored in paper form. The approved results are sent back to the Area Materials Engineers for approval and subsequent release to the Project Engineer.

Regardless of the method used to accept or reject material, all information which supports the approval of the material is maintained and accounted for in the certification process. In order to keep track of tests conducted in the field, the Office of Construction is currently using a computer based Construction Management System (MCMS). The program is used by Project Engineers to track quantities of materials used on the project as well as to log material tests that are performed at the job site. Currently MCMS is a stand alone product which resides in the construction trailer or field site. It is not possible to electronically share information outside the project unless data is backed up on a web server (located outside SHA's firewall).

Many incidental materials are stocked by suppliers. These materials are sampled on a lot by lot basis. If the samples meet specification requirements, the lot is approved for use on state projects. This approval is good for one year from the original acceptance. Any material remaining in stock at the end of the approval period must be retested to be re-approved. The supplier notifies OMT when approved materials are shipped to projects. This notification contains contract, item number and quantity issued. A materials test report is issued to the project and the remaining stock quantity is calculated. This is done to ensure that shipments do not exceed the initial approved quantity.

The combination of contract, material type, and intended use define the tests to be run on the sample. Some material requires it to be sampled and physically tested in a laboratory. As construction progresses, samples of materials are taken throughout the life of the project. In addition to keeping track of job site tests and actual quantities used, the Construction Management System (MCMS) also generates a test sample description form to be used for samples taken at the job site and tested in the laboratory. The sample's identification form accompanies the sample to the laboratory. Each sample has a form, completed by the sampler, which provides pertinent information about the sample. The sample and form are delivered to the appropriate laboratory section for logging and testing.

Materials Specifications and Quality Assessment

Most materials must meet the requirements of the State Highway Administration's Standard Specifications for Construction and Materials. Section 900 of the specification book contains these materials specifications. This section specifies the following:

1. What standards the material must meet,
2. Tests to be run on each material,

3.   Methods of test to be used, and
4.   Specification limits required for the tests.

Elements of these general specifications are subject to revision at any time as new specifications are developed and existing specifications are revised or updated. It is important to note that the general specifications that apply to any particular contract are the versions which were in effect when the contract was advertised.

Every contract has a set of plans and special provisions that contain additions and/or exceptions to the general specifications. Materials indicated in the special provisions section apply only to those materials used in that specific contract.

Tests are performed according to prescribed methods. Section 900 of the SHA Standard Specifications for Construction & Material indicates the prescribed method of test or acceptance. These test methods originate from three primary sources including:

1. American Standards for Testing and Materials (ASTM),
2. American Association of State Highway and Transportation Officials (AASHTO), or
3. Maryland Standard Method of Tests (MSMT).

These test methods specify the apparatus to be used and procedures to be followed during the testing of a material. They are in printed form and are referred to by laboratory technicians as needed.

Tests which are required to be run on a sample are not necessarily performed in the same laboratory area. Some tests may need to be run in a different section or even in a different laboratory. Determination is made on the basis of which laboratory has the equipment to perform special tests. On occasion, samples may also be distributed to other laboratories in order to balance workloads. In addition, there is currently a movement within SHA to increase the outsourcing of materials testing to consultant laboratories. For example, the Asphalt Technology Division expects 75% of its testing to be outsourced within five years. There are some tests, such as aggregate gradation, which have a series of results associated with each test. These tests may have seven or more values resulting from one test.

Regardless of where or how the tests are performed, the results of all tests are supplied to the laboratory section that originally received the sample. As tests are completed, the results are compared with the appropriate test specifications to determine if the material has passed or failed. All test results are then logged. Tests may be repeated if the results are suspect or the material fails the prescribed test standard. Once results have been validated they are entered on a test data reporting form and forwarded to the appropriate Area Materials Engineer. Test results are stored in many forms. Some laboratory sections maintain all their records in ledger books while others use computers with a variety of database applications. This will be discussed in detail in a later section of this document.

When the test is complete, the Area Materials Engineer issues a report of the sample results, including recommendations for non-compliant materials to the Project and District Engineers. If the sample does not meet all specification requirements the

Materials Engineer makes recommendations as to the use or rejection of the questionable material. The ultimate decision to use, or reject, any material rests with the District Engineers. The final disposition of all failing samples is documented for the materials clearance process.

Because this process is de-centralized in nature, SHA may not know until the very end of the project if all materials have been accepted in accordance with the Materials Clearance procedure. This has contributed to long delays with final Materials Clearance in the past.

Materials Clearance

Monthly Materials Clearance procedures require the MDSHA Project Engineer to prepare a monthly submittal form with an estimate worksheet for each construction project. The Project Engineer reserves the right to withhold payment or take money back on the next estimate for items without proper documentation. Required documentation for review and submittal are: certifications, laboratory test data, inspection reports, and specifications. Seven (7) calendar days following the estimate due date, the Project Engineer forwards the documentation to the Area Materials Engineer for review and comment. The Area Materials Engineer then returns the submittal to the Project Engineer within fourteen (14) days. The Area Materials Engineer and Assistant District Engineer of Construction, hence, receive copies with comments. Payment is received for material on the monthly estimate after the contractor reviews and provides any missing information to the Project Engineer.

The Project Engineer notifies the Area Materials Engineer at least 30 days prior to the completion of the project. Notification is in accordance with MDSHA Construction Directive 72.1-10-12. The notification contains a list of bid items not used, and quantities of materials used. OMT sends a request for final reports to all responsible centers and districts providing inspection and/or testing for the project. After review completion, appropriate personnel are requested to supply information to resolve exceptions. An exception is defined as, "any violation of the Specifications and/or Standards." All exceptions are addressed.

After receiving a copy of the Acceptance for Maintenance Letter, a final review of files is performed and the final Materials Clearance approval is signed by the Director of OMT. A copy of the certification and clearance correspondence is distributed to the appropriate Districts, and the FHWA Office for all full-oversight Federal-Aid projects. The District Materials Engineer holds the original in the project file. Records are retained three (3) years after the final voucher is submitted to FHWA for approval.

Roles and Responsibilities

Many Offices within the MD SHA have a role in the Materials Clearance Process. The prominent Offices were listed at the beginning of the section and are repeated here for reference:

- Office of Materials Technology (OMT)
- Office of Construction (OOC)
- Office of Finance (OOF)
- Office of Information Technology (OIT)
- All 7 Districts (D1 – D7)

In the following discussion, we will briefly describe the role of the primary stakeholders.

Office of Materials Technology (OMT)

OMT has ultimate authority and responsibility for the Materials Clearance system. There are five key Divisions within OMT that perform core Materials Clearance process activities. These are:

- Materials Management Division
- Soils and Aggregate Technology Division
- Asphalt Technology Division
- Concrete Technology Division
- Structural Materials and Coatings Division

Materials Management Division

The Materials Management Division (MMD) is responsible for a wide variety of duties. In general this Division is responsible for District support, independent assurance testing, and materials management system development and implementation. Of critical note, District support services are provided through five Area Materials Engineers. These engineers serve as the first point of contact for District personnel on all material related matters. They attend many design milestone meetings, preconstruction and partnering meetings, and call on the four other technical material divisions (Soils and Aggregate, Asphalt, Concrete, and Structural Materials) as necessary to troubleshoot problems. Material Clearance responsibilities also come under this Division.

The services provided by MMD include:

- Materials management development and implementation
- Laboratory accreditation
- Area Materials Engineers
- Materials Clearance
- Independent Assurance
- Maintenance of the Qualified Products List (QPL)

The MMD is responsible for development of the Materials Management System (MMS) and a significant investment in resources has been dedicated to this effort. Once implemented, the MMS will drive the Materials Clearance process and be the sole system used to clear materials.

As discussed previously, the Area Materials Engineers are central figures in the Materials Clearance process. They are the "hub of the wheel" as it were and these personnel make sure the process runs smoothly. The Independent Assurance (IA) Team audits technicians and the field equipment that they use (nuclear gauges, infra-red thermometers, etc.). The IA team tracks, through the use of a database, all of the technicians certified to work on SHA projects. This is a critical function to meet FHWA guidelines.

The MMD also maintains the Qualified Products List. OMT maintains a listing of Qualified Materials used on Maryland State Highway Administration construction

projects. Qualified materials are those which have undergone a prescribed procedure for submittal, testing, and qualification. Qualification does not imply that materials can be used on SHA projects without regard for normal Quality Assurance testing and procedures.

The Materials Management division is involved in every phase of Materials Clearance activities and will have a very important role in the development of the MMS.

OMT Technical Material Divisions

Laboratory testing forms the core of the Materials Clearance process. Material tests are defined according to contract, material type, and intended use. The Construction Management System (MCMS) keeps track of job site tests and actual quantities used as construction progresses. The MCMS also generates a test sample description form to be used for samples taken at the job site and tested in the laboratory. The sampler completes a form for each sample with pertinent information about the sample. The sample identification form accompanies the sample to the laboratory. The appropriate laboratory section receives the sample and form for logging and testing.

Tests are performed according to the requirements outlined in Section 900 of the SHA Standard Specifications for Construction and Material and related MSMT's. Every contract has a set of plans and special provisions containing additions and/or exceptions to the general specifications. Indications in the special provisions section apply only to the materials used in each specific contract. Section 900 specifies the standards the material must meet, methods of test to be used, and specification limits required for the tests.

Required sample tests may be run in different sections of a lab or even in different labs. Samples may be distributed to other laboratories based on necessary equipment to perform special tests and sample testing workloads.

The results of all tests are supplied to the laboratory section that originally received the sample. Completed tests are compared with the appropriate test specifications to determine acceptance or failure. Validated test results are entered on the sample identification form that accompanied the sample to the laboratory, and then forwarded to the appropriate Area Materials Engineer. Laboratories keep records of test results via ledger books, various databases, or proprietary software.

There are four primary technical material divisions, all falling under the auspices of OMT. These are as follow:

- Soils and Aggregate Technology Division
- Asphalt Technology Division
- Concrete Technology Division
- Structural Materials and Coatings Evaluation Division

A review of each Division's role in the process is discussed in the following. A majority of this information was gleaned from on-site interviews with key staff in each Division.

Soils and Aggregate Technology Division

The responsibility of the Soils and Aggregate Technology Division is the acceptance of all soils, aggregate, and geo-textile materials used on MDSHA contracts. This includes the responsibility of laboratory and quality assurance as well as special studies and troubleshooting. The Division focuses its efforts on the acceptance of material sources and works closely with construction personnel in the placement of materials. The Area Materials Engineer within the Materials Management Division serves as the first point of contact with District personnel and can call on staff in the Soils and Aggregate Division when their expertise is required.   The Soils and Aggregate Technology Division provides the following services: approval of aggregate and soil sources, material acceptance, field QA (moisture and density equipment and technician verification), lab testing (soils), project site visits, troubleshooting, lab testing (preliminary design), aggregate bulletin, geo-textiles testing and acceptance, and material characterization testing.

Each year the Soils and Aggregate Technology Division is responsible for completion of 15,000 to 20,000 laboratory tests. This is accomplished primarily by in-house staff and facilities, however a small percentage of tests are outsourced. The outsourced tests are generally preliminary design test samples. The Division also outsources all geotextile testing.   While active construction samples form the core of this Division's testing efforts, it is by no means the only type of testing performed. It includes the following:

- Active construction quality assurance
- Geotechnical testing for preliminary design
- Source approval testing
- Graded Aggregate Base (GAB) production QA/QC
- GAB job-mix formula density testing
- Annual aggregate quality testing
- Bituminous surface course aggregate testing and approval

The goal is to login all received samples within one day of receipt, test all active construction samples within 15 calendar days and test all preliminary design samples within 45 days. Active construction samples are stored for approximately 45 days after testing and preliminary engineering samples are stored for approximately 6 to 12 months prior to disposal. Over 40 different tests are conducted by this Division. While stored in an Access database, almost all test results are ultimately reported in hardcopy form on standard data reporting forms.

The Soils and Aggregate Technology Division maintains several types of information storage and reporting solutions. These are:

- Approved Sources Database - Access
- Sample Logging and Test Cost Database - Access
- GeoSystem - Proprietary system used to record soils test results
- GAB Production/JMF Database - Access
- Aggregate Database - Access
- Aggregate Bulletin - Access
- Topsoil database - Access
- Geotextile database - Access

The approved sources database is an Access based system used to store a list of approved aggregate materials suppliers.

The sample logging and test cost database is used to log in samples for test, assign the costs associated with each test for billing purposes, and log out samples after it has been tested.

GeoSystem is a proprietary system used to record test data and calculate test results. The SHA and its consultants use this package and data can be electronically transferred between SHA and other users of Geosystems (outside consultants).

The GAB production and Job Mix Formula database is an Access based system that records daily GAB production results including tonnage, gradations and moisture contents. This database is also used to store approved GAB job-mix formulas.

The aggregate database is an Access based system used to record all aggregate test results for source of supply approval.

The aggregate bulletin contains a list of physical test values of samples taken from aggregate producers representing material submitted to the MD SHA for acceptance to use on SHA projects. The bulletin is stored in an Access database. The aggregate bulletin is subsequently placed as a PDF file on the SHA internet site and updated once per year. Currently, the aggregate bulletin and the aggregate database are being merged.

The topsoil database, an Access database, is used to store a list of eligible producers of topsoil.

The geotextile database is an Access based system used to track eligibility of geotextile products used on SHA projects.

The laboratory technology used in this Division is relatively modern. Many of the test systems (especially the scales and ovens) have the capability to output data directly from the test machine to a computer system for data processing and storage. Laboratory personnel's level of proficiency with computer systems ranges from intermediate to expert and most personnel are comfortable with current technology.

As can be seen by the above discussion, the Soils and Aggregates Division uses a wide variety of data storage solutions to perform its business functions, including a good deal of paper. Each solution has been developed to satisfy a certain need and to create efficiencies in business processes. These databases and their functions must be examined in great detail during development of the MMS.

Asphalt Technology Division

The responsibility of the Asphalt Technology Division is to accept all asphalt materials used on MDSHA contracts. This includes the responsibility of laboratory and quality assurance as well as special studies and troubleshooting. The Division's efforts are focused on the acceptance of materials provided by asphalt producers and to work closely with construction personnel in the placement of materials. The Area Materials Engineer within the Materials Management Division serves as the first point of contact with

District personnel and can call on staff in the Asphalt Division when their expertise is required. The Asphalt Division provides the following services: HMA plant approvals, mix design approvals, binder source approvals, evaluation of QC data, testing of QA data, project site visits, attend pre-pave meetings, specification development, mix acceptance, binder acceptance, participation in HMA roundtables, evaluation of new technology, partnering with industry, and lead state responsibilities.

The Asphalt Technology Division is responsible for testing the following types of materials:

- HMA pavement
- Slurry seals
- Recycled asphalt
- Performance-graded binders
- Emulsions
- Tack coats
- Joint sealant

Over the course of a year, the Asphalt Technology Division is responsible for conducting over 14,000 tests. Currently, this testing is performed almost exclusively in-house in four different laboratories disbursed throughout the State. There are plans to consolidate all asphalt testing to one location (the new OMT facility in Hanover, Maryland) and to outsource a significant amount of production testing (75 percent).

Similar to other testing Divisions, the Asphalt Technology Division performs many types of testing including:

- Active construction quality assurance
- Producer certification
- Mix design approval (design and sources)

Each laboratory uses a slightly different system to conduct its business operations. In general, this Division uses the following technology.

- Marylandware system used to store mix designs and QC/QA mix test results
- Pay Factor Program - Software
- Approved Job Mix Formula database – Access
- QC/QA database – Access
- Binder Database – Access
- Approved sources – Word
- HMAView – Web-based
- RideTool - Software

Marylandware is a product developed by the University of Maryland to store mix designs and asphalt quality control mix test results. The system is stand-alone and resides on individual computers within SHA (all four asphalt laboratories), producers, and contractors. Producers use Marylandware to record QC test results. Data can be imported and exported from Marylandware through email.

The Pay Factor Program is a system that compares QC and QA test results and develops asphalt pay factors. A pay factor is the amount of compensation a contractor receives based upon their ability to meet specification limits.

The approved job mix formula database contains a listing of the mix designs and their associated properties (gradation, asphalt content, etc.) that have been approved for use on SHA projects.

The QC/QA database is used to store QC/QA data and production quantities.

The binder database stores test results from binders produced by various manufacturers.

The approved sources database is used to store a list of approved HMA materials suppliers.

HMAView (http://hotmix.ce.washington.edu/md/) is a relatively new tool used for viewing data associated with Maryland's hot mix paving projects. It is currently not used in the materials clearance process and at this point is in the pilot stages of implementation. This system may take the place of Marylandware in the future. To populate HMAView, SHA must send data to the University of Washington and subsequently they populate the website with the data. SHA does not populate this site directly.

The RideTool application is used to import pavement surface roughness information and calculate ride quality pay factors for asphalt pavements.

Each of the four asphalt regional laboratories use slightly different systems to perform their day-to-day activities. This issue will be rectified when the division consolidates however the use of outsourcing will create other coordination and consistency issues.

The technology used in this Division is relatively modern. Many of the test systems, especially the relatively new SuperPave binder testing devices, have the capability to output data directly from the test machine to a computer system for data processing and storage. Laboratory personnel's level of proficiency with computer systems ranges from intermediate to expert.

Similar to other Divisions, the Asphalt Technology Division uses a wide variety of data storage solutions to perform its business functions, including a good deal of paper. Each of these solutions have been developed to satisfy a certain need and to create efficiencies in business processes. These databases and their functions must be examined in great detail during development of the MMS.

Concrete Technology Division

The responsibility of the Concrete Technology Division is to accept all concrete materials used on MDSHA contracts. This includes both laboratory and quality assurance responsibilities as well as special studies and troubleshooting. This division is responsible for acceptance of all produced concrete as well as pre-cast and pre-stressed concrete products. The Division's efforts are focused on the acceptance of materials provided by concrete producers and works closely with construction personnel in the

placement of materials. The Area Materials Engineer within the Materials Management Division serves as the first point of contact with District personnel and can call on staff in the Concrete Division when their expertise is required. The Concrete Division provides the following services: approval of plants, QA plant inspections, mix design approvals, concrete cylinder testing, cement testing, chemical testing, project site visits, attend pre-pour meetings, pre-cast material acceptance, concrete material acceptance, cement acceptance, paint acceptance, troubleshooting, and new technology evaluation.

Each year, the Concrete Technology Division is responsible for completion of up to 10,000 tests. This is accomplished primarily by in-house staff. However, a small percentage, about 10-15 percent, is currently outsourced. There are long-term plans to outsource a greater percentage of the work. The Division is responsible for a wide variety of materials tests - everything from one side of the right-of-way to the other.

Like other technical material divisions, the majority of testing performed is in support of active construction projects (QC/QA). However, they also evaluate products for the Qualified Products List, perform special studies and forensics on problem projects, perform long term monitoring of materials, and advise Project Engineers with technical issues on the job site.

For most testing applications, the goals is to log in all received samples within 24 hours and test all active construction samples within two weeks.   Samples are logged using paper-based methods.

The Concrete Technology Division maintains several types of information storage and reporting solutions. These are:

- Approved Sources/Approved Mix Design Database – Access
- Concrete cylinder test results – Excel
- Chemistry test results - Access
- Cement results - Access

The approved sources database is an Access solution that stores approved sources, as well as approved mix designs for concrete.

Concrete cylinder break test results are a large part of the work load for this Division. Currently, this data is stored in an Excel spreadsheet. In fact, each laboratory uses a different spreadsheet. This spreadsheet also calculates pay factors which determine contractor payment for placing concrete materials.

The chemistry laboratory has a fairly robust Access based system to store test results as does the cement laboratory.   The Division is very fond of both of these applications and would like to retain their functionality in any resulting MMS.

The Concrete Technology Division has a wide variety of data storage applications ranging from paper-based system to robust Access databases. At the end of the day, most of the test results are transmitted in hardcopy form, similar to the other technical material divisions.

Structural Materials and Coatings Evaluation Division

The Structural Materials and Coating Evaluation Division is responsible for the acceptance of all metal structural components, coating systems, pavement marking materials, and other materials not covered by the other three material divisions. Laboratory quality assurance as well as special studies and troubleshooting are also part of their responsibility. The efforts of this division are focused on the acceptance of material sources. The division works closely with construction personnel in the placement of materials. The Area Materials Engineer within the Materials Management Division serves as the first point of contact with District personnel and can call on staff in the Structural Materials and Coating Evaluation Division when their expertise is required. The Structural Materials & Coating Evaluation Division provides the following services: approval of fabrication shops, plant and manufacturer sources, verification of certified tests, product evaluation, structural materials testing, field investigations, QA plant inspections, QC and acceptance of non-structural items, project visits, troubleshooting, qualification of products, NTPEP testing, pavement marking QA testing, and constructability reviews.

This Division is divided into four major teams including:

1. Metals
2. Structural Materials
3. Coatings
4. Pavement Marking

The Division utilizes a wide variety of methods to test, accept, and otherwise qualify the quality of laboratory testing, testing in the field (i.e. pavement markings), evaluating production facilities and fabrication plants, and job site reviews. This division performs 500-600 fabrication and producer site visits each year to verify the quality control processes in-place or to accept materials produced at the facility (steel for example). Seventy percent of the on-site inspection is performed by consultants.

The Division is responsible for conducting (either in-house or out-sourced) over 17,000 tests per year. Most of the metals testing (90-95 percent) is currently outsourced. The Metals Team and Structural Materials Team each perform about 600 tests per year in-house. The testing turn-around time is targeted at 30 days. Samples are generally logged in within five business days of receipt (48 hours for reinforcing steel). Log books are used to record sample receipt.

The Division maintains a few systems to help manage their business processes, most are in hardcopy form. These are:

- Sample receipt system - hardcopy
- Approved sources list - hardcopy
- Test results - hardcopy
- Site certifications - hard copy
- Anchor bolt/washer test results - Access

The current sample receipt system is paper-based and varies based on the team using the system. This system is used to track samples and a log is created of acceptance or failure.

The approved sources list is also hardcopy. All test results are recorded and transmitted in hardcopy as are site certifications. There is a small database used to store anchor bolt and washer test results. It is only a data repository, so there are no analysis capabilities.

The technology used in this Division is relatively modern. Many of the test systems have the capability to output data directly from the test machine to a computer system for data processing and storage. Laboratory personnel's level of proficiency with computer systems ranges from average to expert.

A Note on Test Cost Tracking

The cost to test samples is charged to each contract according to a schedule of test costs. When testing of a sample is completed, the laboratory section adds the costs for each test run on the sample and enters the total on the report form. Information such as contract number, total cost, number of tests, and sample number are entered on the form.

Approximately once a month the data are analyzed to calculate the totals for each contract. This information is provided to the Office of Finance and the test costs are prorated and charged to the appropriate contracts through the Financial Management Information System (FMIS). From this same information, the total numbers of samples and tests are determined for the development of productivity charts. The process to account for and charge test costs to projects is a cumbersome and time-consuming process. A software program exists to update this information every month. During detailed design, this program should be investigated to determine it's applicability to the MMS process.

The current unit costs used to report test costs were developed in the 1960s through use of a time-motion study for each test procedure. The unit costs have been escalated each year in some form by each test center to reflect inflation. However, the actual underlying test costs have not been updated in over 40 years.

Office of Construction (OOC)

The Office of Construction has primary responsibility to oversee construction activities to expedite construction projects as safely as possible with minimum impact on the traveling public. The Office is composed of five major teams to support SHA's Construction Program. These are:

- Deputy Chief Engineer's Office
- Construction Inspection Division
- Utilities Team
- Contract Award Team
- Controls/MBE Team

The Office of Construction's major areas of responsibility include: contract processing (bid openings, contract award, notice to proceed), payments to contractors; establishment of MBE goals and Affirmative Action Plans, approval of change orders, construction inspection (administering the construction engineering manpower management system statewide, assignment of inspection, management of supplemental consultant inspection contracts), training, statewide utilities (relocation, determination of prior rights, billing,

coordination), claims avoidance/resolution, establishment of policies and procedures and related support functions.

The OOC works with OMT, Office of Finance, and all seven Districts in the Materials Clearance process. The OOC initiates all construction projects through issuance of Notice to Proceed, tracks all construction payments, and assures that projects are constructed with quality. This Office is involved in the entire materials clearance lifecycle.

Project Engineers, key players in the Materials Clearance process, are assigned by the OOC to construction projects throughout the State. While these personnel are members of the OOC, they work very closely with the District in which the project is located. The Project Engineers, and the team members on their projects, are responsible for making sure the Materials Clearance process is initiated, the correct number and type of samples are extracted and that all required field testing is performed. They also perform on-site field inspections to determine if material is performing as intended.

The primary tools used by the OOC to perform their duties are TRNS*PORT, and the Maryland Construction Management System (MCMS). TRNS*PORT is used to manage the construction bidding process and establish bid estimates (bid items and quantities). All construction contract phases are addressed with TRNS*PORT from the initial engineer's estimate, through award, and contractor payments. In addition, the system creates a database of historical contract data for bid monitoring and vendor analysis. MCMS is used to log construction activities, determine delivered materials quantities, generate sample information forms, and assist with management of the construction process.

Office of Finance (OOF)

The role of the Office of Finance is to develop and execute plans, programs and procedures to efficiently and effectively manage the financial resources of SHA. OOF manages the Financial Management Information System (FMIS) which is the primary accounting tool for the agency. The Office of Finance plays a key role in Materials Clearance activities by ensuring that the financial aspects of each project are captured and managed. Their role in development of the MMS will be a key to its success.

Office of Information Technology (OIT)

The Office of Information Technology (OIT) is in charge of ensuring that all information technology projects meet the development policies of the agency and is a key resource for all IT initiatives. The MMS will be a fairly large IT project and thus members of OIT should be involved in its development. The OIT can also assist with linking to other enterprise systems maintained by SHA including GIS, FMIS, TRNS*PORT, Asset Management, etc.

Districts

There are seven District offices located throughout Maryland. The mission of the District office is to provide the traveling public with a safe highway system. The District

Engineer is responsible for overseeing all areas of district operations which include: traffic, construction, maintenance, engineering systems, right-of-way, and utilities. The seven engineering districts cover all 23 counties of the state. The offices are located in Salisbury, Chestertown, Greenbelt, Lutherville, Annapolis, LaVale, and Frederick. The District offices and their locations are shown in Figure 2-4.

District offices play a key role in the Materials Clearance process by providing oversight to all Clearance activities. The District Engineer (or their designee) has a primary role working with the Project Engineer in accepting construction materials and ensuring that materials placed on the job site are of suitable quality. Another key role of the District is management of the "Sketchbook." The sketchbook is used to match material quantities with material delivery tickets. The sketchbook is a key input to determining contractor payment and ensuring payments to the contractor are accurate.

Districts have ultimate authority over the construction projects undertaken in their area and provide key approvals to all facets of the Materials Clearance process.

Figure 2-4. Location and county distribution of SHA district offices
(source: www.marylandroads.com)

Materials Clearance Systems

The Materials Clearance process currently utilizes a great variety of systems and procedures. These include paper-based systems, Access databases, Excel spreadsheets, and proprietary software systems. All of these systems will play a role in the Materials Management System and are under the responsibility of various SHA Divisions. In order to grasp the extent and number of systems used in the Clearance process, all tools have been consolidated in table 2-1 for ease of reference.

Table 2-1. Current MD SHA materials clearance systems

Owner	Tool	Description	Type	Location	Data Availability
OOF	Financial Information Management System (FMIS)	Software solution used as the primary accounting tool by SHA to charge cost centers for activities conducted.	Software	Central office	Statewide within SHA.
OOC	TRNS*PORT	Software solution used to manage construction estimating, bidding, and project initiation processes.	Software	Central office	Statewide within SHA. Consultants/contractors can access for estimating and bidding purposes.
OOC	Maryland Construction Management System (MCMS)	Software solution used to manage the construction process including contract items, usage of materials, inspector time, and contractor equipment and usage.	Software (Stand-alone)	Stand-alone on construction sites. Differing version resident dependent on when construction projects started.	Data only available within a construction project.
Various	Specifications	Paper based system used to define the quality of materials used on SHA projects.	MS Word	Various	Statewide via internet
Districts	Sketchbook	Paper-based system used to ensure construction pay items are accurate and match delivery tickets.	Paper-based	Each District	No access outside District
OMT/Materials Management Division	Qualified Products List (QPL)	System used to store a list of materials that have undergone a prescribed procedure for submittal, testing, and qualification.	MS Word	Each technical materials division.	Statewide via internet
OMT/Materials Management Division	Frequency Guide/SHA Quality Assurance Manual	Paper-based system used as the key document in determining the frequency of materials sampling and testing and method of acceptance for the Materials Clearance Process.	MS Word	Materials Management Division	Statewide via internet

Table 2-1. Current MD SHA materials clearance systems

Owner	Tool	Description	Type	Location	Data Availability
OMT/Soils and Aggregate Division	Approved Sources Database (Soils and Aggregate)	System used to manage Soils and Aggregate approved sources.	Access	Soils and Aggregate Technology Division	Within Technical Material Division
OMT/Soils and Aggregate Division	Sample Logging and Test Cost Database	System used to track samples received and charge contracts for testing.	Access	Soils and Aggregate Technology Division	Within Technical Material Division
OMT/Soils and Aggregate Division	GeoSystem	System used to record soils test results.	Software. Data stored in flat files (non-relational)	Soils and Aggregate Technology Division and consultant laboratories providing testing services to SHA. Data shared via import and export routines.	Within Technical Material Division to store test results and exchange information with consultants.
OMT/Soils and Aggregate Division	GAB Production/JMF Database	Used to store graded aggregate base production figures and store GAB job-mix formulas for easy reference.	Access	Soils and Aggregate Technology Division	Within Technical Material Division
OMT/Soils and Aggregate Division	Aggregate Database	Database used to store aggregate test results for source of supply approval.	Access	Soils and Aggregate Technology Division	Within Technical Material Division
OMT/Soils and Aggregate Division	Aggregate Bulletin	Contains physical test values of samples taken from aggregate producers.	Access	Soils and Aggregate Technology Division	Within Technical Material Division. Data can be accessed through internet
OMT/Soils and Aggregate Division	Topsoil Database	Stores list of eligible producers for top soil.	Access	Soils and Aggregate Technology Division	Within Technical Material Division.
OMT/Soils and Aggregate Division	Geotextile Database	Stores list of eligible geotextile products.	Access	Soils and Aggregate Technology Division	Within Technical Material Division.

Table 2-1. Current MD SHA materials clearance systems

Owner	Tool	Description	Type	Location	Data Availability
OMT/Asphalt Technology Division	MarylandWare	Stores mix designs and producer QC results.	Software (stand-alone)	Asphalt Technology Division (four regional laboratories), contractors and producers	Data shared between SHA and outsiders via email import and export.
OMT/Asphalt Technology Division	Approved Job Mix Formulas	Contains a list of mix designs and their associated properties that have been approved for use on SHA projects.	Access	Asphalt Technology Division	Within Technical Material Division
OMT/Asphalt Technology Division	QC/QA Database	Stores QC/QA data and production quantities.	Access	Asphalt Technology Division	Within Technical Material Division
OMT/Asphalt Technology Division	Binder Database	Stores test results from binders produced by various manufacturers.	Access	Asphalt Technology Division	Within Technical Material Division
OMT/Asphalt Technology Division	Approved Sources Database (Asphalt)	System used to manage HMA approved sources.	Access	Asphalt Technology Division	Within Technical Material Division
OMT/Asphalt Technology Division	HMAView	Tool used to view data associated with hot-mix paving projects.	Web-based Software	University of Washington	For approved users, through web portal.
OMT/Asphalt Technology Division	RideTool	Tool used to import pavement surface roughness information and calculate ride quality pay factors for HMA pavements.	Software (stand-alone)	OMT/Asphalt Technology Division	Within Technical Material Division
OMT/Concrete Technology Division	Approved Sources Database (Concrete)	System used to manage concrete materials approved sources.	Access	Concrete Technology Division	Within Technical Material Division
OMT/Concrete Technology Division	Concrete Cylinder Test Results Database	Database used to store cylinder break results. Excel used to calculate data and generate pay factors.	Access and Excel	Concrete Technology Division	Within Technical Material Division

Table 2-1. Current MD SHA materials clearance systems

Owner	Tool	Description	Type	Location	Data Availability
OMT/Concrete Technology Division	Chemistry Test Results	Robust and complex database used to store chemistry test results.	Access	Concrete Technology Division	Within Technical Material Division
OMT/Concrete Technology Division	Cement Test Results	Robust and complex database used to store cement test results.	Access	Concrete Technology Division	Within Technical Material Division
OMT/Structural Materials and Coatings Evaluation Division	Sample Receipt and Test Result System	Log book system used to record sample receipt and acceptance or failure of sample.	Paper-based	Structural Materials and Coatings Evaluation Division	Within Technical Material Division
OMT/Structural Materials and Coatings Evaluation Division	Approved Sources	System used to manage structural materials and coatings approved sources.	Paper-based	Structural Materials and Coatings Evaluation Division	Within Technical Material Division
OMT/Structural Materials and Coatings Evaluation Division	Site Certifications	System used to record results of site certifications.	Paper-based	Structural Materials and Coatings Evaluation Division	Within Technical Material Division
OMT/Structural Materials and Coatings Evaluation Division	Anchor Bolt and Washer Test Results	System used to record results of anchor bolt and washer test results.	Access	Structural Materials and Coatings Evaluation Division	Within Technical Material Division

Strengths and Opportunities for Improvement (OFIs)

The preceding discussion has outlined the current Materials Clearance processes and systems in use today. As mentioned early and often in this plan, the process as it currently stands is an effective process. The system works. However, system business processes can be streamlined and made more efficient through the use of improved processes and information technology.

After analyzing the processes involved, discussing the current system with key stakeholders, and soliciting input on desired system characteristics, the following outlines the primary Opportunities for Improvement for the Materials Clearance process.

Project Initiation

The current Project Initiation process is probably the most efficient part of the Materials Clearance process primarily because of the use of TRNS*PORT and MCMS. The notice of project initiation, while based upon electronic transmittal (email) could be improved.

1. Project Initiation information reaches most stakeholders, but not all. The possibility also exists for inconsistent notification.

2. After notice, there is no efficient method to track all projects in Materials Clearance and status of each project. Currently this information resides with the Area Materials Engineer. There is no method to view this data at a global level.

3. There exists no method to view active projects for other customers such as other MDOT modes and county/city/municipal customers.

4. Contract bid items and quantities can be entered in MCMS directly from TRNS*PORT, however this automated data transfer vehicle is not leveraged throughout the Materials Clearance process. All other parties must use paper-based or standalone spreadsheets to track materials. Once the data is in MCMS, updates to bid quantities and amount used are difficult to extract and use and this data cannot easily be shared outside OOC.

Source of Supply

The Source of Supply approval process is arguably the most inefficient process within the Materials Clearance process. This process is almost exclusively paper-based and involves the submittal and approval of literally hundreds of items for some projects. It has been stated that contractors sometimes must submit the same documentation three times or more before the source is finally approved. Almost all stakeholders agreed that this process is in need of automation to the extent possible.

1. Source of Supply approval process is paper based.

2. Current process may require multiple submissions by contractors

3. Approved source lists are maintained in an inconsistent manner (no standards)

4. There is no easy method to track changes in source over the construction life cycle

5. There is no easy method to develop reports of overall source use and quality of each source

6. There is no easy way to check if each material has had its source approved

7. There is no easy method to capture source of supply history

8. Source of supply records are not accessible outside the project

Determination of Acceptance Procedure/Type and Number of Tests

Determining the method of acceptance is an important part of the Materials Clearance process. Currently this process is paper-based.

1. The material type and quantities list (from TRNS*PORT) is not integrated with the Frequency Guide. Automated generation of initial planned sampling and testing type and frequency is not possible.

2. Data regarding planned Materials Clearance testing is not available easily to those outside OOC.

3. There is no efficient method to break down lump sum items to determine clearance goals.

4. There is no efficient method to update actual material types and quantities placed versus Materials Clearance goals.

5. MCMS is a stand-alone system with multiple versions running at any given time. MCMS data cannot be shared electronically.

6. It is difficult to determine, in a timely manner, the actual materials and quantities used in the contract.

Material Testing and Quality Assessment

1. Most, if not all, materials sampling and testing data (field and laboratory) ultimately processed using paper-based system.

2. Sample receipt, processing, and disposition system uneven between Divisions.

3. Laboratory systems are very uneven in sophistication, use, and management. Each laboratory uses a different (unique) system to conduct its business processes.

4. There are no procedures available to notify the laboratory of a sample's existence, and a method does not exist to capture needed sample information and test result data in a universal format.

5. Laboratory workload, sample status, and projected completion data are not easily assessed outside the laboratory division.

6. Laboratory test cost data is very hard to assemble and transmit. The current test cost data is out-of-date.

7. Personnel outside the laboratory division cannot determine the status of their test samples.

8. There are no automated controls of pre-approved material lot quantities.

9. There are no methods available to:

      a.   Capture off-site testing results,

      b.   Track the location of samples,

      c.   Capture material certifications,

      d.   View testing which occurs at other sites (cross testing),

      e.   Automatically determine if test results meet or don't meet the test standard criteria,

      f.   Easily determine if all material testing is complete for a contract,

      g.   Analyze historical test results,

      h.   There are no means available to provide the ability to look-up data on-line for sample information or test result data.

Materials Clearance

1. MD SHA is having difficulty clearing projects in a timely and efficient manner. This primarily impacts contractor payments and FHWA reimbursement for Federal-aid projects.

2. The monthly process used to reconcile contractor invoices with items that have been approved is slow and cumbersome. Tracking down deviations is very inefficient.

3. The current Materials Clearance process does not allow for easy access to all data elements related to Materials Clearance. Many processes are paper-based and many of the electronic systems used are not able to be shared across Divisions. Most data resides in filing cabinets or stand alone applications. Pulling together this enterprise-wide data to make strategic decision is not possible from a practical standpoint.

4. Development of Materials Clearance reports at the project and global level is time consuming and inefficient. Data provided as part of report generation is sometimes incomplete and erroneous.

5. The systems used for Materials Clearance were developed in an ad hoc manner to meet silo-based business needs. Most of the systems cannot interact with each other to share information. There is no standard data sharing protocol.

6. Many of the current electronic systems are not being managed or maintained according to SHA IT policy.

7. The process to generate high-level Materials Clearance reports supporting MDSHA Business Plan goals is inefficient and cumbersome.

8. There exists little opportunity to share materials clearance information with other enterprise systems such as FMIS, Pavement Management or the intended Asset Management System.

Summary

This section has outlined the current business practices used by MD SHA to perform the Materials Clearance process as it exists today. The Materials Clearance process was reviewed in detail and roles and responsibilities were discussed. Key systems currently

used to perform the process were outlined and discussed. Finally, each component of the system was analyzed and a series of Opportunities for Improvement were outlined.

The purpose of this section is to provide a basis for understanding the processes, procedures and tools used in an effort to form a foundation for development of the Materials Management System. It is also intended to provide the reader an understanding of where the system can be improved. The next section of this document will outline the identified critical capabilities and outline the framework for developing the Materials Management System.

Section 3: Recommended Business Environment

Introduction

The Materials Management process has been used for many years and works well. The obvious need is for tools to be employed to make the process more efficient and create a centralized framework under which to conduct Materials Clearance.

In order to address the Opportunities for Improvement presented in the previous section of this plan, Information Technology must be applied. IT applications, to the extent possible, will reduce the amount of paper-based processes and streamline the communication of results and resolution of issues.

This section outlines the recommended business environment for the Materials Management System. It begins with a discussion of the Critical Capabilities necessary to provide a solution that ameliorates as many of the OFIs as possible. The MMS framework and role of each part of the system are discussed in some detail. We then examine hardware and software issues. Keys to success for MMS implementation efforts are also identified.

Critical Capabilities

The envisioned Materials Management System will be designed to mitigate as many of the OFIs as possible. The intent of the system will be to streamline the Materials Clearance process and make more data available to more interested parties so that strategic decisions can be made using credible, real-time information. The following section will detail critical capabilities of the proposed system.

The system shall:

- Allow for electronic signatures to approve all facets of the materials clearance process.

- Adhere to State data archival policies.

- Provide a full training suite developed as the system progresses.

- Be "user friendly." In practice this means that users shall have input throughout the development life-cycle.

- Provide for an audit trail of all inquiries and changes to the database.

- Allow access rights based on need, authority, and right-to-know.

- Provide ability to retrieve information through the use of key word(s) (contextual searching) matched to the descriptive text in the data areas selected.

- Have a robust and secure document management system which allows the ability to store, track, index, and retrieve electronic files (PDF, digital pictures, etc.) linked to a particular materials clearance item. It is recognized that OIT is in the process of developing an enterprise level document management system. The MMS should be developed to be consistent with this enterprise system.

- Store five years of current data and "unlimited" number of years of archival data.

- Have ability to generate ad hoc reports.

- Comply with MDOT and MD SHA IT Policies.

- Track Materials Clearance work flows to ascertain Clearance status and performance against goals.

- Provide links to other enterprise systems such as FMIS, Asset Management, Pavement Management, etc.

- Export data to the Microsoft Office product suite (Word, Excel, Access) for off-line data processing and use.

Project Initiation

- Provide ability to automatically download information from TRNS*PORT and electronically notify all necessary stakeholders that a project has been initiated.

- Automatically download and generate bid item information from TRNS*PORT including:
  - Bid quantities
  - Item numbers
  - Category numbers

Source of Supply

- Provide for automated management (to the extent possible) of the Source of Supply approval process

- Allow for management and tracking of changes in Source of Supply throughout the project life-cycle

- Provide centralized tracking and maintenance of approved sources. Means to flag unapproved or new sources of supply.

- Allow management of approved job-mix formula data (JMFs)

- Track/Maintain the list of approved lot quantities

- Provide a link and management of QPL/MPEL/NTPEP data

Determination of Acceptance Procedure/Type and Number of Tests

- Provide an electronic database and management system for the Frequency Guide (Quality Assurance Manual)

- Ability to automatically (as feasible) generate numbers, types, and frequencies of tests required for the Materials Clearance process

- Have ability to break-down lump sum items (especially for Design/Build projects)

- Allow ad hoc import or manual insertion of new bid items

- Provide an automated method to enter field tests (Form - 14: Field Inspection Reports) and match them against Frequency Guide

Material Specification and Quality Assessment

- Maintain and store testing specifications and standards, such as:

  - general test specifications,

  - specific test methods used in the testing process

  - allow special testing provisions to be substituted or added as necessary,

  - determine which version of the specifications applies to the contract and the test specimen at time of testing and in the future (ability to reference specification used to test the material at a later date including ASTM, AASHTO, MSMT)

  - ability to track and submit test costs efficiently

- Provide a system to allow one time entry of sample information throughout the materials sampling, handling, testing, and disposition process. This is envisioned as a bar coding type system.

- Provide a system to manage laboratory equipment calibration processes and match test specimens/results with specific pieces of equipment

- Receive samples in the lab and assign tests to each sample as well as assign estimated completion dates

- Able to track project samples, design samples, special testing type samples, etc.

- Have the ability to track the location, status and disposition of each sample

- Generate progress reports of backlog, adherence to testing schedules, and efficiency of operations

- Where possible, output data directly from a test device to the LIMS

- Be able to add new test procedures easily and without having to know Oracle or web technologies (wizard)

- Allow the Project Engineer or other customer (pavement design, city, county, other MDOT modal, etc.) to view status of all testing for their projects

- Have the ability to update cost information for a given test

- Provide an automated link to FMIS to charge projects for testing performed

- Provide ability for outside laboratories to access LIMS portion of MMS for sample receipt, test assignment, test reporting, and sample disposition data entry.

- Provide an automated and instantaneous determination of meets/or does not meet specifications.

- Provide for electronic authorization of acceptable test results and a process to track exceptions or failures and log of final resolution

- Automatically calculate pay factors for each relevant material

- Provide a robust analysis tool set to report information and perform statistical analysis of data results including canned as well as an ad hoc reporting and analysis system.

Materials Clearance

- Provide an automated system to generate a report comparing progress against materials clearance goals and final materials clearance disposition of a project.

- Maintain a log of correspondence detailing decisions made regarding materials clearance including laboratory test rejection resolutions.

- Include the ability to extract sources, specific materials used, and location of materials for a given roadway section

- Contain a Materials Clearance Dashboard that contains summary information germane to a user's need and right to know.

- Provide a canned and ad hoc reporting system.

- Automatically notify and generate the 30-day Materials Clearance notice.

- Automatically notify and generate the Certification Letter at the end of the project.

Conceptual Materials Management System

The application sets identified for the development of an electronic Materials Management System (MMS) are as follow:

- MMS Framework
- Project Management
- Source of Supply
- Materials Quality Assessment
- Materials Clearance

The various application sets of the MMS along with their functions are presented in figure 3-1. It should be noted that the first order of business for MMS deployment should include a high level development document that takes this strategic plan one step further in terms of level of detail. This will be discussed further in section 4.
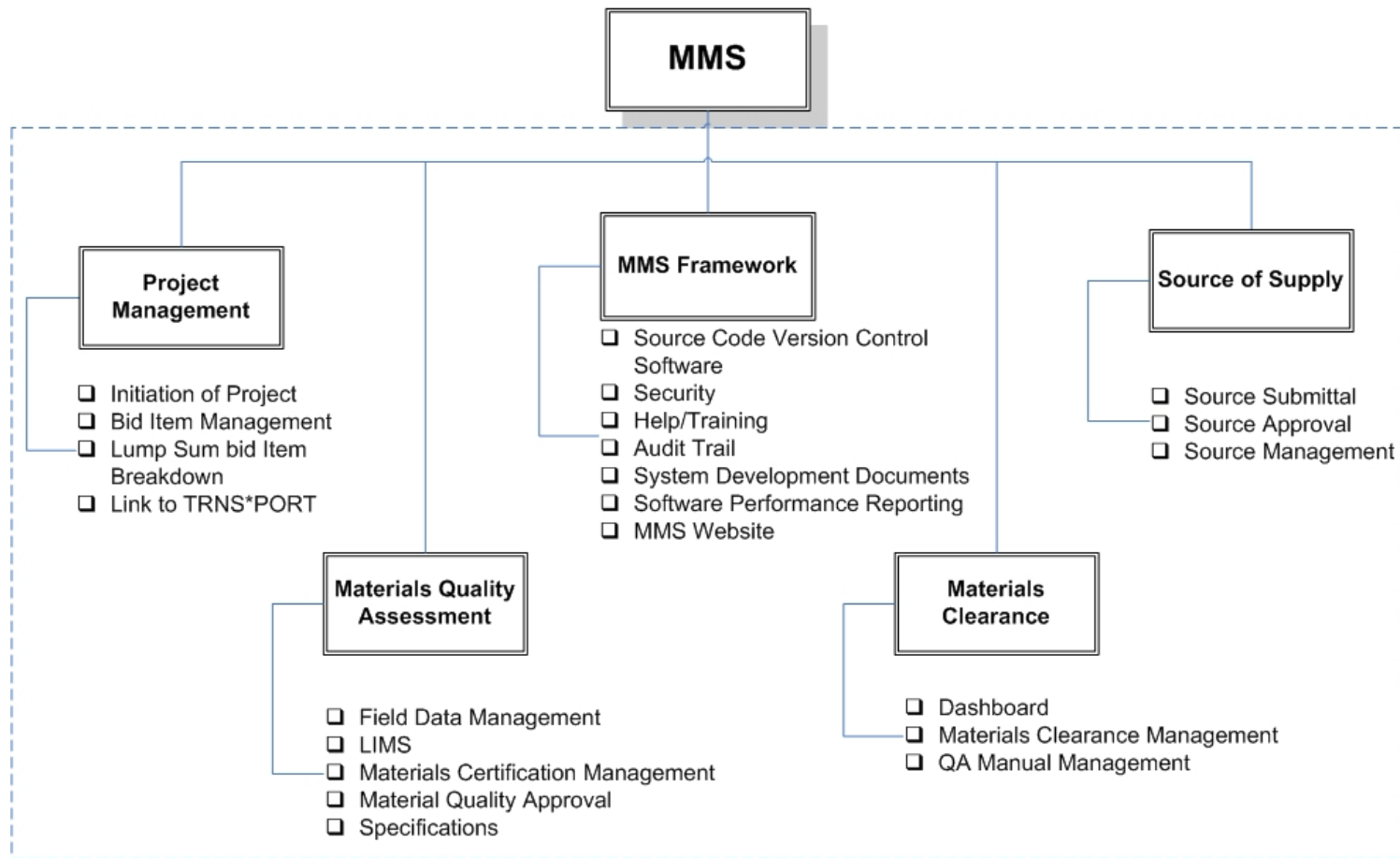
Figure 3-1. Conceptual Materials Management System

MMS Framework Application Set

The MMS Framework application set will form the backbone of the MMS. This is where the core MMS will be developed, documented, and communicated. This application set will contain two key facets critical to MMS functionality and security. These are the System Framework and Materials Management website applications.

The system framework set of applications will be used to develop and maintain the database structure, MMS HTML templates, and other system framework components. This is where the Oracle databases and the look and feel of the MMS will be developed and managed. <u>The System Framework will form the core and is the most critical aspect of the MMS.</u>

The System Framework will contain the following core components:

- Source Code Version Control Software
- Security
- Help/Training Software
- Audit Trail
- System Development Documentation
- Software Performance Report System (SPR)
- MMS Website

It is envisioned that the majority of the MMS will be custom designed and developed by perhaps a few different information technology vendors. It will also be built in an incremental manner with frequent updates. The source code version control software will contain a system that is used to store the core system source code and database structures so that they cannot be lost or corrupted. This system will include functionality to archive older versions of the source code to ensure that only the latest version of the code is used for updates. OIT has software to perform this function.

The security system will contain the database of user names, passwords, and access rights of all MMS user categories.

The help and training system will contain all files necessary to teach users how to utilize the system and provide on-demand help on most aspects of the system. It is envisioned that the training system will be present on the Materials Management website for on-demand training in the Materials Clearance process and each aspect of the MMS.

The audit trail aspect of the System Framework application set will contain software to track all database changes to the MMS. This will link the change with the user, date, and time. This application set will be important to verify approvals and rejections are tracked as well as to determine usage patterns of the database so as to improve functionality and performance.

The System Development Documentation system will contain Information Technology specifications, user guides, and other documentation used to develop the system. It will serve as a library to document all aspects of the MMS.

The System Framework application set will contain the Software Performance Report (SPR) system. This will be used to document problems with the system. It will also contain a tracking system to manage work orders output to fix a system problem. It will be available to all system users to provide feedback on the MMS.

The Materials Management website will form the portal through which all MMS activities are conducted. It will exist both on the MD SHA intranet and on the internet. As such, portions will exist both inside and outside the MD SHA firewall. The website will be configured to include all of the application sets included in the conceptual design. All current Materials Management functions that exist in various parts of the current MD SHA intra and internets will be consolidated under this website. All databases and specifications will be managed and accessed through this portal including such items as the Aggregate Bulletin, the Maryland Product Evaluation Listing (MPEL), and the Qualified Products Listing (QPL), to name but a few. Some portions will be open to all (such as MPEL and QPL) while others will be password-protected (such as Source of Supply and Project Management). The website will contain links to all sections of the MMS in one easy to use interface. **All transactions involved in the Materials Clearance process will be conducted through the MMS website portal.**

Project Management Application Set

The Project Management Application Set provides the means to manage the list of active construction, maintenance, design, research, and special projects for which the MMS will be utilized. Data for a given project must be input in this application set first, prior to entry of any data in other MMS areas.

The core processes will be as follow:

1. Initialization of Project within MMS
2. Transmittal of Project Initiation to Appropriate Parties
3. Input of Project Information (automated and manual)
4. Update of Project Information
5. Creation of Bid Items
6. Update of Bid Items
7. Breakout of Lump Sum Items

The first step in any project included in the MMS will be entry of appropriate project information into the MMS database and transmittal of Project Initiation information to appropriate parties. In order to do that, two systems will be employed. The first, applicable to the majority of construction and perhaps maintenance projects, is automated input of information from the TRNS*PORT system.

The TRNS*PORT system is a trade name for a series of construction management products sponsored by AASHTO. The Maryland SHA is currently utilizing several of the available products including PES - Proposal and Estimates System; LAS - Letting and Awards System; CAS - Construction Administration System, and DSS - Decision Support System. MD SHA is also using Estimator, which is a software package to assist Design Engineers in developing estimates, and Expedite, which assists the Contracts Award Team with inputting bid information. All construction contract phases are

addressed with TRNS*PORT from the initial engineer's estimate, through award, and contractor payments.

When a project has been given Notice of Award, the Office of Construction (Project Engineer), the District and the Materials Management Division (Area Materials Engineer and the Certification Engineer) will be notified. MMD personnel will then query TRNS*PORT (through a tool present in the MMS) to determine if project information is present. If it is, then personnel will be allowed to automatically download appropriate information for the project including contract number, prime contractor name, address, contact information, bid items, bid quantities, etc. If the project is not in TRNS*PORT (e.g. County project), then Materials Management personnel will manually input the information into the system using an appropriate data entry screen. Once the project is successfully initialized, an electronic notice will be sent out to appropriate personnel to inform them that the project has been set-up in the MMS and is active. The distribution list for each type of project will need to be finalized during detailed development operations.

Once a project is setup, the bid items and quantities will need to be input. If the project is present in TRNS*PORT, this information shall be downloaded from this system. In some cases, automated data download will not be possible (primarily for 3rd party managed projects). Therefore, manual bid item data entry functionality must be incorporated.

After download, lump sum bid items may need to be broken out into their constituent components so they may be tracked for clearance purposes. For some types of projects, such as design/build, entire projects may be bid as lump sum and these projects will also need to be broken down into their constituent bid items. This process may be long and involved for larger design/build projects. In order to facilitate this process, there must be an automated system developed to conduct this interaction with TRNS*PORT as well as a data entry form that allows access to the downloaded information and the ability to break down lump sum items. It would be useful to design the automated and manual data entry system with some intelligence to list potential constituent lump sum bid items based on past lump sum breakdown experience. Responsibility for the lump sum bid item breakdown process will reside with the Area Materials Engineer.

This system must also have the capability to automatically generate the number and method of tests for each bid item. This is determined from use of the Frequency Guide.

After project set-up, updates will need to be solicited from the MCMS system on a regular basis (i.e. monthly). It is thought that the MMD Certification Engineer would be responsible for this activity. MCMS is the only system that has up to-date information on bid items and quantities used on the project. This is expected to be a complex system to develop. As touched on previously, MCMS exists in various versions on stand-alone computers located on project sites. The version used is usually the latest version of the software when the project was started. Once present on a job site, the MCMS software is rarely updated to a new version. Also, MCMS does not currently have the capability to broadcast data to other users, except for (in some later versions) the capability to write data to a web server for back-up purposes. Currently, construction trailers have a wide variety of data communication capabilities ranging from none to high speed access lines. These limitations will need to be overcome during MMS implementation in concert with

the Office of Construction. Projects not tracked using MCMS will need to have their updates performed by hand.

It is possible during data update that new items have been entered into the system and it is possible there are lump sum bid items present. In this case, the lump sum item breakdown process must be repeated.

Once all bid item information has been established and the project is set-up and approved by the Area Materials Engineer, a notification should be sent to appropriate personnel (same personnel as originally notified) that the project is setup. Once this occurs, the project, and all its information, should be viewable in the Materials Clearance system (described later) as an active project in clearance.

It is envisioned that the Project Management system will reside behind the SHA firewall.

Source of Supply Application Set

Sources of supply must be approved for all constituent materials on a construction project. The Source of Supply application set will provide a means for the Area Materials Engineer and Prime Contractor to coordinate review and approval of Sources of Supply at the initiation of a project and thereafter throughout the project life-cycle.

It is envisioned that once a project is established through the Project Management system, the contractor will have access to bid items over the internet through the MMS web portal. They may then electronically select the source of supply for each bid item and transmit the list to the Area Materials Engineer. An automated approval will be generated almost instantaneously for many items. A system must be implemented to track the correspondence between the contractor and the Area Materials Engineer, and to issue final approval of the source for those bid items that need review.

Additionally, the system must allow for notification of source changes and update of sources for new bid items. A historical record of the source for each material and the history of source per bid item throughout the project life-cycle must be maintained. A system must also be developed to notify personnel when a previously approved source being used on an active construction project is subsequently dropped from the approved sources list. This system must be developed with heavy user involvement from the contractor and SHA in order for it to succeed. The final result will be a database of source approvals, rejections, and exceptions for a project.

This will require development of a single electronic warehouse of approved sources and job-mix formulas for SHA (currently the approved source list for each laboratory technical division is stored and maintained separately). The lists will still be maintained by their current owner. However all the information will be maintained in a consistent electronic medium. The developer must also determine how and when to access the QPL and NTPEP databases (if needed) to develop this system.

The transition from a paper based source of supply approval system to an electronic form of source approval and tracking has the potential to create significant advances in efficiency in the Materials Clearance system in a very short timeframe. It will be a significant "win" for the MMS and should be given a high priority.

Materials Quality Assessment Application Set

The Materials Quality Assessment Application Set is the central clearinghouse for determining the quality of materials used by SHA. It is comprised of five areas:

1. Field Data Management,
2. Laboratory Information Management System (LIMS),
3. Material Certification Management,
4. Material Quality Approval, and
5. Specifications.

Field Data Management

The Field Data Management application will be the central receipt, storage, and management center for all relevant QC/QA testing that occurs in the field or in producer facilities that is used for Materials Clearance. It will receive data from Form 14's (Field Inspection Form), density test results, MDWare and the RideTool (or similar applications), as a minimum.

Form 14 is the standard method used by Project Engineers and Inspector's to certify material in the field. Many materials are placed on a project and verified as "performing as intended" by field inspectors. Besides approval of the source of supply, this is the only means to clear a material on a project. Therefore, it will allow entry of Form 14 data directly into the MMS. During initial development efforts, this will be performed using a data entry screen. Subsequent development should move the Form 14 process from a paper-based system to an electronic system whereby the form is completed in the field on a portable computing device (PDA, ruggedized laptop, etc.) and digitally transmitted to the MMS. Provisions must also be made for field test data entries from third-party sources (e.g. counties) as well.

Another key piece of the Field Data Management System will be entry of field QC/QA results in the MMS. Currently, this primarily involves density testing of prepared subgrade and base materials (we will discuss HMA in a moment). For initial implementation a data entry screen will be developed and manual data entry will occur. Subsequently, a digital solution should be used to allow one-stop data capture and transmittal to the MMS. Provisions must be made for entry of data from external sources such as counties or other DOT modals.

It must be recognized that implementation of this system will require a fair bit of change on the part of Project Engineers and field inspectors to move from a paper-based system to an electronic system. Also, this application will require an investment in rugged field data capture equipment and a means to transmit data from the handheld device to the MMS. The equipment needed must also be able to output laboratory sample information and bar codes for the LIMS portion of the system.   This system is perceived as high risk due to the many interactions and equipment investment decisions that need to be made. This will be discussed in more detail in the Implementation Plan section of this document.

This system must also interface with two critical QC/QA programs, the MDWare suite of programs and the RIDETOOL. MDWare is currently used to capture QC data related to

placement of HMA, among other functions. An interface must be created to extract relevant data from MDWare and import it into the MMS. Also, the RIDETOOL is used to capture and access ride quality of new pavements and is used to calculate incentive payments based on ride quality. The resultant data from this tool needs to be incorporated into the MMS.

Laboratory Information Management System

The Laboratory Information Management System (LIMS) will be used to manage all aspects of laboratory testing both within SHA and testing conducted by outside laboratories. It will have the following capabilities:

- Sample management (receipt, test assignment, tracking, disposition)
- Test data input and storage of results
- Reporting (workload, goal attainment, test cost determination, and test cost charges to projects)
- Management of lab equipment (inventory, calibrations)
- Certification by lab manager of test results
- Link between test result and specification

Because of the number and diversity of tests performed to determine the quality of materials, the LIMS will be the largest application of the MMS in terms of effort to develop and database size. The LIMS will offer the benefit of consistent sample management among laboratories as well as consistent data entry and storage features among all laboratories conducting materials testing for the SHA. It will be accessed through the intranet and the internet. It is intended that the LIMS be used only for test reporting. Determination of specification compliance will occur in another application set (Material Quality Approval).

Responsibility for all laboratory testing currently occurs in one of the four material technical divisions at OMT. These are:

- Soils and Aggregate Technology Division
- HMA Technology Division
- Concrete Technology Division
- Structural Materials and Coatings Technology Division.

It must be recognized that each Division has specific needs with respect to the LIMS and each Division must be consulted in detail during development.

The sample management system will provide the ability to receive and log samples from the originator, assign test procedures to the sample/specimen, track the sample as it is tested, and report the final disposition of the sample. First, the sample management system will primarily be a manual process where samples are received and logged using a data input screen consistent among all laboratories. The data input screen will be tied to the Field Management system so that basic sample information can be imported into the LIMS easily. Eventually, the system will use bar-coded sample tags which will be scanned to automatically input sample data in the MMS database.

Test data input and storage will be handled through the use of data input screens. Automated transfer of data results from equipment to the MMS is not deemed feasible at present due to equipment capability issues and the vast variety of equipment in use. Automated transfer of testing data may become feasible as this project in the future and new equipment is purchased. This capability should be re-visited as implementation progresses. It is thought the data input portion will follow data reporting sheets currently in use by the laboratory. In addition, some of the laboratories already use an Access data input interface. These should be leveraged during implementation efforts.

The LIMS system should contain a wizard (template) so users have the flexibility to change a screen or add new test data reporting screens as needed. Test procedures change quite often and new tests are added on a regular basis based on technological advances in the industry.

This system must have the flexibility to modify data entry without the use of IT professionals whenever possible. It will also contain a link to test specifications so technicians can pull up the specification related to the test(s) they are performing. The technician performing the test should also be recorded. Finally, there should be a robust quality assurance capability flagging entries that do not seem reasonable (e.g. data range checks) and checking for logic in data entry (e.g. sieve size percent passing values are equal to or less than successive sieve percent passing). This functionality must be accessed through the internet so that outside laboratories can input data.

The LIMS will have the ability to provide laboratory managers a means to access many reports regarding workload, productivity, and progress against goals. A laboratory management system must be developed to facilitate management of the testing process. This should include a canned system of static reports (e.g. number of samples processed per month, testing backlog, etc) and an ad hoc data reporting tool to extract data deemed necessary by the laboratory manager. The needs of each laboratory manager may vary somewhat so this system (canned reports) must be developed with input from all four technical material divisions.

Another system to be incorporated in this application set is the equipment inventory and calibration feature. Most SHA laboratories have an inventory of their equipment, but no central repository or consistent method exists to track this information. Therefore, this system will be used as a central equipment inventory center. Calibration data associated with the equipment will also be maintained in this system.

After laboratory data is entered and all laboratory testing is complete for a sample, the laboratory manager will need a method to approve the test result. The test result management system will allow the manger to view test results and approve them for transmittal to the Materials Clearance system. This will include electronic signature capability. It should also have the ability to request re-testing or re-sampling if necessary, and this process should be tracked until the test result issue is resolved.

The LIMS, of all the MMS application sets, has the greatest potential to be developed using a Commercial Off-the-Shelf (COTS) system, because it is the system most used by other DOT and testing laboratories. For reference, table 3-1 contains a sampling of COTS LIMS solutions. The data contained in this table was developed based on a review of several vendors' websites. The point of the table is to illustrate that there are many LIMS solutions in the marketplace with a wide variety of functionality.

Table 3-1. Sample LIMS solutions and critical capabilities

	User Friendly	Security	Archiving Cap.	Multiple Users	Query Searches	Export to Microsoft Office	Barcoding Capability	Instrument Extr.	Windows / Oracle	Audit Trail	Pass / Fail	Sample Tracking	Website Links
SLIM - H&A Scientific		X				X			X	X			http://www.hascientific.com/slim01.html
AIS Lims		X		X				X			X		http://www.ais-lims.co.uk/lims/features.shtml
Bio Tracker		X						X	X	X		X	http://www.ubi.ca/cart/index.php/cPath/34
Blaze Systems		X	X		X		X	X	X	X		X	http://www.blazesystems.com
Horizon Lims		X						X	X	X	X		http://www.chemware.com
LabAnalyst.net	X	X		X	X		X	X	X	X	X	X	http://www.labanalyst.net
Timeless Lims		X		X			X		X				http://www.timelessmedical.com/products/lims/
LabPas		X					X		X			X	http://www.labpas.com/labpas/labpas.html
Lab Pro 2000		X						X					http://www.labpro2000.com
Autoscribe Matrix Gemini	X	X		X					X				http://www.autoscribe.co.uk/upgrades.shtml
Novatek		X		X	X					X		X	http://www.novatekeurope.com/x/rma.html
NWA Lims		X			X	X	X	X	X	X			http://www.nwasoft.com/lims.htm
CCLAS EL		X						X	X				http://www.comlabs.com.au/en/products.htm
Labsoft Lims		X		X			X		X				http://www.labsoftlims.com/Features/capabilities.htm
STIS		X	X						X	X			http://www.chemistry-software.com/pdf/STIS.pdf
Starfruit		X	X		X				X	X		X	http://www.duii.com/SF_Capability.htm
Starlims		X			X	X		X					http://www.starlims.com/solutions/lims_Sampling_to_Reporting.htm
Aspen Enterprise		X		X				X	X	X	X		http://www.telecation.com/go.aspx?p=aspene.htm
ABB Lims		X	X	X		X				X		X	http://www.abb.com
Tribal Software		X	X	X	X	X	X		X				http://www.tribalsoftware.com/product/ldms.html
Matware		X		X		X	X		X				http://www.mat-ware.com/more.html#moreOverview
Labware		X	X			X	X	X		X			http://www.labware.com/LWWeb.nsf/lp/en04
WinLims		X					X						http://www.lims-software.co.uk/lims.asp
LabMate		X						X	X	X	X		http://www.yullin.com/home/english/product/ePdLabMate.asp
Wavefront		X		X	X		X						http://www.wavefrontsoftware.com/lims_products/Wavefront_LIMS_Enterprise.htm
LogBook	X	X						X					http://www.techwareinc.com/LogBook_Discovery.htm
Sample Master iLims		X			X				X	X		X	http://www.atlab.com/Products%20and%20Services/Products/samplemasterilim.html
SQL Lims		X						X	X			X	https://products.appliedbiosystems.com/ab/en/US/adirect/ab?cmd=catNavigate2&catID
LimsExpress		X					X					X	http://www.dynamicdatabases.com

It is expected that almost all other parts of the MMS will be developed using a custom approach. No software exists in the marketplace to perform these functions considering Maryland's unique business processes. Thereby, it is appropriate to debate developing the LIMS using existing commercial software versus taking a custom design approach.

Table 3-2 contains a matrix of pros and cons associated with developing a custom LIMS versus employing a COTS solution. Based on discussions held during preparation of this plan, it was decided that SHA should pursue a custom designed and implemented LIMS solution. The primary reasons for this decision were as follow:

- A custom LIMS offers greater flexibility and opportunity to integrate with the remainder of the MMS,
- It offers higher potential of meeting all of SHA's needs, and
- It offers the most potential to provide SHA with more flexibility and control of the final system.

It is recommended that this issue be re-visited during the system requirements stage of the development of the LIMS. In any case, consideration should be given by the developers to use the LIMS framework described in ASTM E1578, "Standard Guide for Laboratory Information Management Systems," and ASTM E 2066, "Standard Guide for Validation of Laboratory Information Management Systems." These documents are located in Appendix E for reference. These documents contain a robust blueprint for assessing needs and establishing requirements for the LIMS.

Materials Certification Management

Materials quality assessment is not restricted to laboratory testing. Many materials are certified at fabrication plants and approved for use prior to reaching the construction project. This can include steel, paint, bolts, etc. OMT performs 500 to 600 site inspections each year to certify materials in this manner. As explained in a previous section of the document, the certification procedure is primarily paper-based. This portion of the MMS will be used to streamline the certified material acceptance process.

The first step in the certified materials acceptance procedure is for the source of supply to be approved. Next, the producer must have an approved quality control plan in place and on file with OMT. In most cases, the material must be inspected and approved by the manufacturer's quality control team prior to shipment to the job site. Also, in some cases a MD SHA inspector must examine the certifications, inspection reports, and shipping tickets/bill of lading prior to shipment to the job site or on the job site itself. After the inspector is satisfied, they attach their certified stamp to the Shipping Ticket or Bill of Lading to the product. They then send all information to the responsible OMT office for review (usually the Structural Metals and Coatings Team) and subsequent transmittal to the certification engineer for clearance.

This portion of the MMS will manage this process more effectively. It must have the capability to manage the list of certified materials and allow for automated population of the required stamps and certifications. It should also have an approval mechanism to allow the appropriate OMT agency to approve the material and allow it to go into clearance.

Table 3-2. Comparison of COTS versus Custom Designed LIMS

LIMS	PRO	CON
COTS	Lower initial cost	Potentially higher long-term maintenance and upgrade costs
	Shorter implementation cycle	Tied to proprietary system (lack of flexibility to modify to meet present and future business needs). May have to modify MMS to meet LIMS functionality.
	Choose a vendor that will work with the organization to reduce the risks inherent in the vendor's product	Vendor may not be willing to allow access to artifacts of the Software Engineering Process – Source code
	Vendor agrees to support product from a security and viability perspective over the long term	May have limited economic or legal protection for product performance – Is the vendor economically viable for at least the length of the support agreement?
	Vendor expertise	No direct control of system management and operations
	History of Use – Vendor ratings and certifications.	Unbounded domain i.e., Internet. May lack control and visibility of system behavior under various circumstances.
	Ensured Evolution – Third party testing and analysis of product performance may be available. May be able to leverage other DOT experience/processes.	Minimal Product Information: Purchase Price, License Agreement, an application programming interface (API) specification, own experience or third party experience with product.
	Control of number of copies to purchase	May have to purchase more copies than necessary. Or, extra copies are more expensive. Could be significant for consultant laboratories.
	Technical Support as needed depending upon organization's capabilities	Limited ability to change software attributes such as long-term viability, security, reliability, performance, safety, usability

Table 3-2. Comparison of COTS versus Custom Designed LIMS

LIMS	PRO	CON
CUSTOM DESIGN	Product developed and maintained according to specific SHA business practices. Custom product to meet all SHA needs.	Higher development risk.
	Long-term system viability more likely because database and scripts are developed with the specific functionality and security necessary to meet changing functional needs	Full control and visibility of artifacts and engineering process, system management and operations
	Can control your risk tolerance: background and reference checks of product designer can help reduce risk	Can never be completely aware of the background and skill of the personnel building your system
	In-house domain experts (labs) and IT group can be directly involved in the product evolution/design.	Greater initial cost
	Vendor agrees to support product from a security and viability perspective over the long term. If designed properly, not tied to one vendor.	No third party testing or analysis available for product to provide quality assurance
	No unwanted features of a "one size fits all" software	Greater time commitment from SHA for the development of product
	Less overall risk than COTS-based system because designed specifically for needs of SHA	Longer implementation time versus ready to use COTS
	Ability to better control potential for data loss or corruption	Depending upon economic health of the custom designer – what is the economic survivability of the vendor. Is the vendor economically viable for at least the length of the support agreement?
	Content and detail of system documentation can be fully controlled.	Increased need for thorough system documentation so that system can be maintained no matter who the vendor. Very high level of IT Project Management experience needed to ensure successful implementation.

This system must also have the capability to manage approved stockpile materials and approved lot quantities. In some cases, contractors or producers may be allowed to maintain stockpiles of material for use on other projects. These stockpiles are inspected and approved for one year. Therefore, it must maintain a list of approved stockpiles (producer, quantity, type of material, etc.), manage the quantity of material that has been used, inspection frequency, and notification of a stockpile's deviation from acceptable inspection cycles for each technical material division.

Material Quality Approval

The material quality approval system will be used to manage the test approval or rejection cycle. At the conclusion of the LIMS process, the data is approved by the laboratory manager for release to the Material Quality Approval application. In this system the test result is matched with the appropriate specification and material acceptance or rejection occurs. When the result is accepted, data is released to all interested parties through the MMS. If the result is rejected, the system must manage the dispute resolution process, track what actions were taken, and record the final resolution.

This system has been purposefully split from the Field Data Management and the LIMS system to allow a one-stop source for approving test results and allowing release of the data from the MMS to the Project Engineer or entity awaiting the laboratory test result. The Area Materials Engineer will have final say over test result approval.

Specifications

The specifications system will be used to manage and store materials quality assurance specifications. It will include the specification itself along with the limits of acceptance for each material. This database will have the capability to electronically store the specification and to archive old versions of specifications for future reference. It is critical laboratory tests, or other QA specifications, be matched with the specification used to determine acceptance. The specifications system should be able to be assessed within and outside SHA (for use by consultant inspectors or outside laboratories for example).

Materials Clearance Application Set

The Material Clearance Application Set will tie data from all other parts of the MMS to perform the Materials Clearance function. The Material Clearance System will manage the list of projects in clearance, bid items, quantities, clearance status, material approvals, disputed list resolutions, monthly material status reports, 30 day clearance notices, final material clearance letters, and the frequency guide. A dashboard providing canned or ad hoc reports will be developed as well. The Material Clearance application set will also provide the ability to store correspondence related to specific contracts/projects bringing together the entire MMS. The capabilities of the Materials Clearance application set will be contained in three applications and they are:

1. Materials Clearance Dashboard
2. Materials Clearance Management
3. Quality Assurance Manual Management (Frequency Guide)

Materials Clearance Dashboard

The Materials Clearance Dashboard will be used by various managers of the materials clearance process to view data needed to assist them in their particular role. It will be flexible enough to provide information based on the user's need to know and their right to know as well as their particular business plan goals. For example, managers within OMT may want to see data related to laboratory backlog, overall materials quality, and percent asphalt constructed meeting density, percent of concrete meeting strength, and so on. Another Division may have other needs. The Dashboard should contain real-time information and is envisioned to be a tool to quickly look at high level data within the Material Management and Clearance process. It should also contain functionality on order to drill down into the details of the materials clearance process. The developers must obtain heavy user input to determine each party's needs. Potential users of the Dashboard may include the following:

- OMT Management
- Certification Personnel
- Project Engineers
- Contractors
- Districts
- Other Customers (cities, counties, etc.)

The Dashboard will be the "face" of the MMS to some users. For example, OMT Management may use it to view strategic reports of Materials Clearance activities.   The Dashboard will contain summary reports unique to the type of user, detailed data where necessary and an ad hoc report generator to develop strategic reports based on user need and right to know. A great deal of care must be used developing the user interface of the Dashboard as it will be the interface most users use to access their data. This data will be assessed through the Materials Management website.

Materials Clearance Management

The Materials Clearance Management system is the area where all of the details related to materials clearance are stored and viewed through the MMS web interface. This includes the following:

- List of projects in Clearance
- Bid items
- Quantities
- Required testing and certification and progress against Clearance goals
- Clearance status
- Approvals
- Disputed test results and documented resolution
- Monthly Clearance reports/resolutions
- 30-day Clearance Notice generation
- Final Materials Clearance Notice generation
- Canned and ad hoc report generator

Most, if not all of the data used to populate this portion of the MMS will be extracted from other parts of the MMS. For example, initial project information and bid items will be extracted from the project management system. Progress against Clearance goals will be extracted from the Material Quality Approval system, and monthly Clearance reports will be generated from extracting data from almost all parts of the MMS.

The Materials Clearance Management system should be developed in close coordination with Certification engineers to make sure it meets their user requirements.

Quality Assurance Manual Management (Frequency Guide)

This application will be used to manage and up-date the Frequency Guide. It will primarily be comprised of a database of bid items organized by category code along with the type of acceptance criteria (e.g. laboratory testing, producer certification, functioning as intended, etc.) and frequency of quality assurance testing. This database will be used to develop the materials clearance requirements for a particular project. Developers can use the Frequency Guide present in the Quality Assurance Manual to develop the Frequency Guide database.

Information Technology Framework

Materials Clearance is a very complicated process involving literally hundreds of people and many different organizations. The system will have many customers inside and outside of SHA. The previously discussed MMS framework lends itself to development as a web services application. In other words, all transactions, interfaces, and business processes will occur on a web base platform that can be assessed from within SHA via the intranet (within the firewall) and by the outside world via the internet (outside the firewall). This type of application also lends itself to instantaneous update of software functionality and update of core software. To use the system, all a user will need is a connection to the internet and a browser.

For this application, a robust and scalable database platform must be used. Access is one such tool however this program has many limitations with respect to scalability and is limited in its ability to store large quantities of information. Oracle software is a set of tools that provides the user with a quick and easy way of creating and managing large enterprise quality databases. Oracle is the de facto database standard application for SHA and SHA currently has a site license managed by the Office of Information Technology. The Materials Management Division would have to contact OIT to obtain a license or possibly create a MMS database instance on one of the existing Oracle servers. This decision will be discussed during development of the Implementation Plan.

The application development environment used to access the database and provide the tools to be used as part of the MMS is expected to utilize many different types of software and languages including VB.NET, Crystal Reports, Java, and other web based development tools. Attempting to list the tools to be used is not germane to the purpose of this Strategic Plan – that decision is best left to the developers of the system.

Some of the advantages of utilizing a server type web based application are as follow[1]:

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[1] Partially extracted from www.masternewmedia.org

Cross-platform compatibility. Web-based applications have a much easier path to successful cross-platform compatibility than downloadable software applications. Several technologies including Java, Flash, and ASP allow effective development of programs supporting all of the major operating systems.

Updating. Web-based applications are always updated to the last release, without requiring the user to take pro-active action, and without needing to prompt or interfere with user work habits in the hope that they will initiate new downloads and installation procedures (sometimes impossible when working inside a large organization).

Immediacy of access. Web-based applications need not be downloaded, installed and configured. You access your account online and are ready to work no matter what your setup or hardware is.

Reduced memory requirements. Web-based applications have far more reasonable demands on end-user RAM memory than locally installed programs. By residing and running off a server, these web-based applications use in most cases the memory of the computers they run on, leaving more space for running multiple applications at the same time.

Reduced number of bugs. Web-based applications should be less prone to crashing and creating technical problems due to software or hardware conflicts with other existing applications, protocols or internal custom software. With web-based applications, everyone uses the same version, and all bugs can be fixed as soon as they are discovered. This is the reason why web-based applications should have far fewer bugs than traditional downloadable desktop software.

Data is safer. While hard disk crashes will not disappear, it is likely that users will hear a lot less about them. All of the data involved in the MMS will be stored, backed-up and secured using SHA enterprise standards.

The only apparent drawback to use of such a system is the limitations some construction trailers have with access to the internet. In addition some field crews do not have access to any computing device in the field yet alone one with a wired or wireless connection to the internet. This issue will need to be explored more fully during system implementation. The use of the MMS will require all users to have access to the internet on a consistent and regular basis.

Critical Success Factors

The MMS is a large software project. Large software projects have a long and well-documented history of facing significant challenges and have large impediments to success. The Maryland Software Development Life Cycle (SDLC) process has been developed to minimize the chance of failure and maximize the chance of success. The SDLC, as applicable, should form the basis for implementation of the MMS. At this point though, it is useful to review some of the factors that will be keys to success for this project.

The Standish Group, located in West Yarmouth, Massachusetts is a research firm that focuses on mission critical project management applications. This group conducted a

widely referenced and accepted study in 1994, CHAOS, that has been published annually since that year outlining the reasons information technology (IT) projects were successful. The Standish study categorized projects into three resolution types: 1. Successful – project is completed on time and on budget, with all features and functions originally specified; 2. Challenged – project is completed and operational, but over budget, late, and with fewer features and functions than initially specified; and 3. Failed – project is cancelled before completion, or never implemented.

Table 3-3 presents the original critical success factors the Standish Group CHAOS study identified in 1994.

Table 3-3: Recipe for Success: CHAOS Ten

Order of Importance	Project Success Factors
1.	Executive Support
2.	User Involvement
3.	Experienced Project Manager
4.	Clear Business Objectives
5.	Minimized Scope
6.	Standard Software Infrastructure
7.	Firm Basic Requirements
8.	Formal Methodology
9.	Reliable Estimates
10.	Other Criteria

Let's review each of these as extracted from the CHAOS study.

Executive support was rated the most important because without it a project will fail. This factor influences a project's process and progress.

User Involvement affects project success because if the project doesn't meet the user's needs or expectations then the project will fail.

Experienced project managers have the ability to translate business and technical requirements between people from their respective disciplines. They have the competency to decrease project scope reducing time frames. They have the ability to organize all participants and can provide direction, motivation, and inspiration through ingenuity. Experienced project managers also have the ability to convey project requirements and progress. In other words they can clearly and concisely communicate the needs of the project without sacrificing performance.

Clear business objectives are critical to success because this allows project milestones to be outlined concretely. There is no guessing as to whether an objective has been achieved.

Minimized scope is a critical success factors because it allows objectives to be clearly focused. Objectives are not mixed together rather they can be clearly identified and therefore can be obtained with less uncertainty.

Standard software infrastructure is a key to project success because it provides stability for the software infrastructure.

Firm basic requirements provide clear obtainable goals that will reduce the effect of change. Less interruption to daily processes that provide quick results for improved efficiency allow greater user involvement, and therefore create an attitude of success.

Formal Methodology provides consistency in procedures. Go and no-go checkpoints can allow for the incorporation of lessons learned.

Reliable Estimates utilize collective knowledge. Realistic estimates must reflect the real cost of a project so budgeting and other financial factors can be controlled.

Other criteria such as competent staff, proper planning and ownership provide a roadmap of essential tools for the success of a project.

Software projects are successful if specific criteria are followed. The purpose of the project must be specific and the objectives of the project must be kept small. Realistic small milestones that provide quick results and enhance the present work processes are what help a project succeed.

The project should be grown. Each phase should be planned with specific milestones that can be measured. Measuring the milestones is a key to success because management can have concrete information for estimating the evolution of a project. Management is a critical component because they determine the attitude toward a project. If the leaders of an organization do not view the project as a potential success, then personnel below management will not be very involved in the project.

Proper planning and accounting for impacts of business functions such as reorganization will affect the success of a project. If management is distracted with other priorities, a software project may fail because the infrastructure/middleware/connectivity/data integration/measurable development/project management skills necessary for the project's success are being utilized elsewhere. An organization's leadership cannot spread itself too thin by managing various high level projects at once. Finding balance in managing human resources valuable for the success of a project is a key to having a successful project. This balance is obtained through flexibility and lessons learned. Being able to redirect course throughout the evolution of a project to incorporate unforeseen challenges is also important to the success of a project. This is achieved through progressive management skills. Therefore, measurable milestones, a flexible yet focused management approach and the ability to evolve/grow the software as it is being developed to incorporate unforeseen circumstances are factors that will affect the potential success of the MMS project.

Section 4: Implementation Plan

Introduction

The preceding sections of this document have laid the foundation for implementation of the Materials Management System. This section provides an in-depth description of the proposed implementation plan for development of the MMS. It discusses the team structure necessary to guide and develop the MMS. A summary review of the scope of work is then presented.

If one looks at the development of the MMS as one contiguous project it can quickly become a long and complicated process with high risk and high cost. In an effort to reduce the overall complexity of the project, we plan to implement the full system through a series 10 individual projects (grouped together in six phases). Each project will produce aspects of the system that are useful on their own and will not require future projects to be functional. Therefore, if future projects are not completed (for whatever reason) there will be a system developed that is useful and expandable.

Each project will go through its own IT project life cycle development process including requirements documentation, budgeting, scheduling, planning, etc. In general, the initial planning work for each project can begin when the proceeding project is approximately 80% complete, or has a clear end in sight. These individual planning processes will incorporate the general aspects as outlined in this strategic plan as well as present business needs and new technologies.

Team Structure

Development of the Materials Management System is going to be a long and complicated process. As mentioned previously, two of the primary keys to success will be the involvement of Senior Management and extensive user input on each facet of MMS development. In order to guide the process, three Committees should be utilized for MMS development.

The first committee should be the overall MMS Steering Committee. This committee already exists and its function should be continued. The committee should meet quarterly to provide guidance on OMT polices and procedures, answer questions, and provide direction that cannot be answered at a lower level. These committee meetings will provide a forum to present on progress of MMS development and provide an avenue to obtain upper management support.

The committee should be made up of the OMT Director and Materials Management Chief who will act as the primary decision makers on the Committee. OMT technical material division Chiefs (or appointees) are members of the committee as well and these personnel will be invited to express their opinions. Directors (or appointees) of other offices that are involved in present development efforts would also be invited to attend.

An Oversight Committee should also be formed. This committee will be charged with managing day-to-day Project Management issues which arise during the course of the

Project and will be responsible for the direction of the project, programming decisions, and adherence to standards.

This committee will be a smaller group who will assist the Project Manager and guide efforts on a short-term basis. It is essential that a strong and capable Project Manager be appointed from the outset to manage the development of the MMS. The Materials Management Division of OMT will be the primary owner and developer of the MMS and thus should house the Project Manager. The Team Leader in charge of MMS development should be appointed as Project Manager of the MMS.

The Oversight Committee should be composed of the MMD Chief, MMS Project Manager, a representative from the Information Technology Division, and IT developers who are involved with the project. The Committee should meet on a schedule determined by the MMS Project Manager and communicate frequently on progress, successes, and challenges.

For each significant work task of the MMS a user group should be formed. These user groups will be comprised of two or three key users of the application being developed and their job is to assist with user requirements, provide feedback on the user interface, and perform beta testing of the application(s) under their purview. User groups will be defined based on the project being developed (cross-section of personnel that will use the development efforts) but will always include the MMS Project Manager and the IT Developer personnel involved in the development effort. This interaction with the user community will be essential to overall MMS adoption and use of the system.

These committees will meet and communicate on an informal basis and there existence may last for as short as a few weeks to possibly as long as the entire project duration.

Scope of Work

The scope of work for development of the MMS is predicated on developing the MMS in a phased and incremental manner. Development of the system will be conducted through six phases and ten clearly defined projects. Each phase will build on the next in order to provide increased functionality as the project progresses. This work plan focuses on efforts to build out the system using the conceptual MMS framework presented in Section 3 of this document. The generalized scope of work and time frame for developing the MMS is presented in figure 4-1. Table 4-1 contains a summary of the estimated budget and time duration for each project.

Phase 1 – System Initiation Projects

Phase 1 of the MMS project will be concerned with performing more detailed planning into the scope and data models to be used for overall MMS development. It will also include performing a small pilot study to further evolve the understanding of the Materials Management Division with respect to how the MMS will interact with agency intranet and internet protocols and further refine the MMS web based concept.
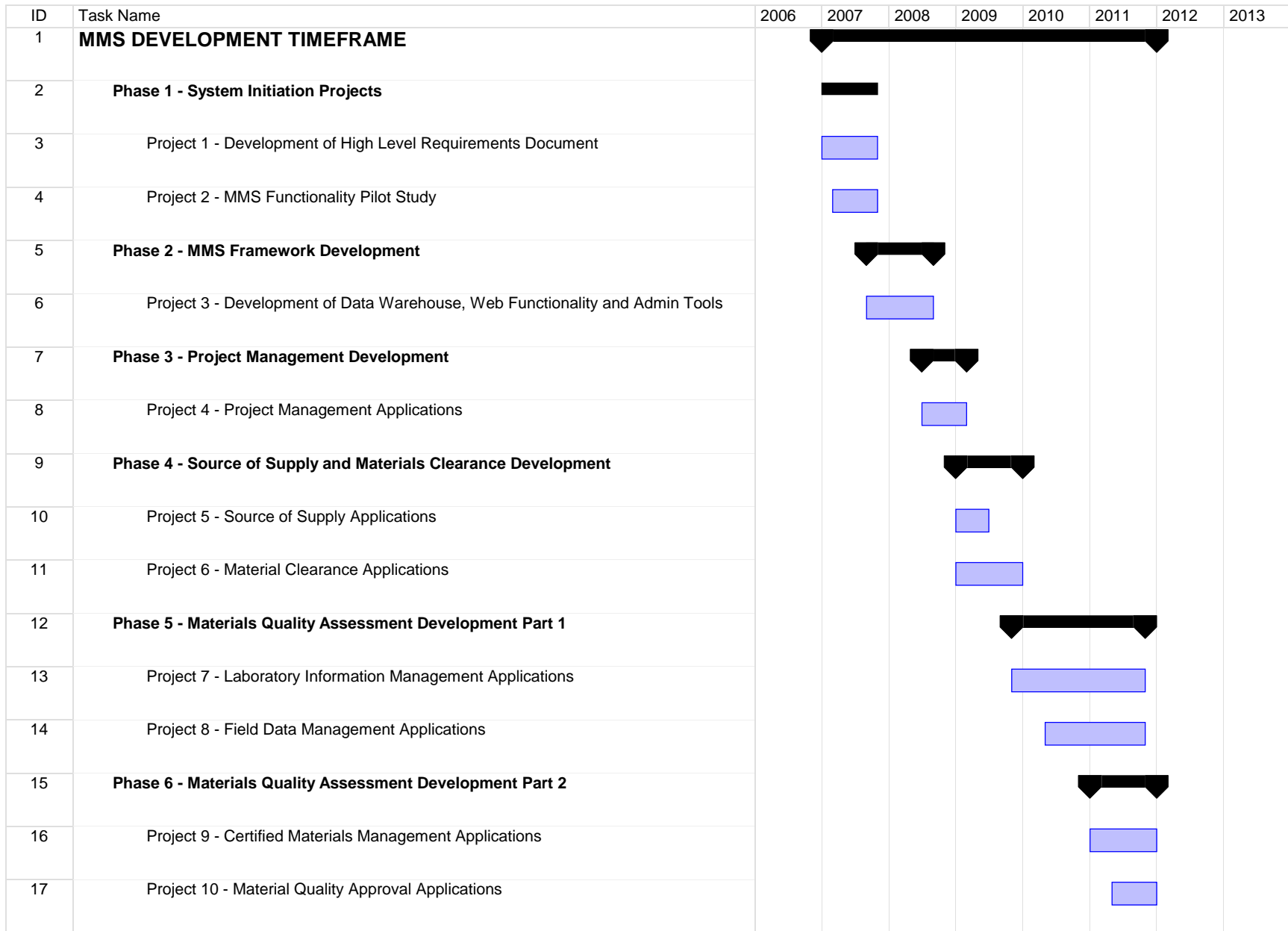
ID	Task Name	2006	2007	2008	2009	2010	2011	2012	2013
1	**MMS DEVELOPMENT TIMEFRAME**								
2	**Phase 1 - System Initiation Projects**								
3	Project 1 - Development of High Level Requirements Document								
4	Project 2 - MMS Functionality Pilot Study								
5	**Phase 2 - MMS Framework Development**								
6	Project 3 - Development of Data Warehouse, Web Functionality and Admin Tools								
7	**Phase 3 - Project Management Development**								
8	Project 4 - Project Management Applications								
9	**Phase 4 - Source of Supply and Materials Clearance Development**								
10	Project 5 - Source of Supply Applications								
11	Project 6 - Material Clearance Applications								
12	**Phase 5 - Materials Quality Assessment Development Part 1**								
13	Project 7 - Laboratory Information Management Applications								
14	Project 8 - Field Data Management Applications								
15	**Phase 6 - Materials Quality Assessment Development Part 2**								
16	Project 9 - Certified Materials Management Applications								
17	Project 10 - Material Quality Approval Applications								

Figure 4-1. Generalized MMS scope of work.

Table 4-1. Estimated project development budget and time duration

Project	Budget, $	Duration, months
Project 1 – Development of High-Level Requirements Document	50,000	10
Project 2 – MMS Functionality Pilot Study	50,000	8
Project 3 – Development of Data Warehouse, Web Functionality, and Admin Tools	175,000	12
Project 4 - Project Management Application	100,000	8
Project 5 – Source of Supply Application	100,000	6
Project 6 – Materials Clearance Application	150,000	12
Project 7 – Laboratory Information Management System Application	200,000	24
Project 8 – Field Data Management Application	200,000	18
Project 9 – Certified Materials Management Application	50,000	12
Project 10 – Material Quality Approval Application	200,000	8

Project 1 – Development of High-Level Requirements Document

The build-out of the MMS must follow the requirements of the Maryland System
Development Lifecycle (SDLC) guidelines. The SDLC contains 10 phases for overall
project development. Within the SDLC framework this Strategic Plan is considered to be
the System Conceptual Development document. The scope of this project will be to
perform the next phases of the SDLC which are the Planning stage (development of a
general Project Management Plan) and the Requirements Analysis phase. [1] These phases
will be combined in this project. These phases will be conducted for the MMS system as
a whole and will not necessarily be concerned with the minutia of each project described
herein.

The scope of the Planning document will be to plan, articulate and gain approval of the
strategy to execute the management aspects of the MMS project. This document will
expand and clarify the project work breakdown structure (WBS) as presented in this
Strategic Plan.

To conduct the high-level Requirements Analysis Phase, the system shall be defined in
more detail with regard to system inputs, processes, outputs, and interfaces (both internal
and external). This definition process occurs at the functional level. The system shall be
described in terms of the functions to be performed, not in terms of computer programs,
files, and data streams. The emphasis in this phase is on determining what functions must
be performed rather than how to perform those functions. This is best done through first
identifying outputs, inputs, and processes. During the Requirements Phase, the Project
Team will:

- Further define and refine functional and data requirements,
- Complete business process engineering of the functions to be supported,
- Develop detailed data and process models,
- Define functional and system requirements that are not easily expressed in
  data and process models. Functional and system requirements also include
  the requirements of the business process, the user requirements, and
  operational requirements (once the system is completed, what does it require
  to keep running?),
- Refine the high level architecture and logical design to support the system
  and functional requirements, and
- Continue to identify and mitigate risk that the technology can be phased-in
  and coordinated with the business.

This project is estimated to have a ten-month time duration and a budget of $50,000. It
will involve direct stakeholders of the MMS process such as the technical material
divisions, Office of Construction, and the Office of Information Technology, as a
minimum. The OIT official assigned for oversight of the MMS will need to approve the
document so that the MMS project can proceed.

The deliverable from this effort will be a Project Management Plan and the high-level
System Requirements document. This effort will require the involvement of the MMS

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[1] See chapters 3 and 4 of Volume 2 of the SDLC.

Project Manager and perhaps consultant assistance with development of the aforementioned deliverables.

<u>Project 2 – MMS Functionality Pilot Study</u>

Efforts have been underway to develop a basic prototype MMS and this effort has yielded a suitable framework system that can be expanded upon. The purpose of this project will be to carry out a pilot study to develop an internet portal that can access the prototype MMS. The effort is considered a pilot study to explore how the primary means of access to the MMS, the web, can be interfaced with back-end MMS databases. As the interface and access is critical to the success of the MMS, this pilot study is necessary to determine the areas of risk in this delivery mechanism and ameliorate one of the highest perceived risks of the MMS early on. The pilot study will also have a focus on delivering the Asphalt Technology team a method to deliver their QC/QA tools and pay factor programs more efficiently and effectively. The scope of work of this project will also include development of an intranet data entry and access tools to interact with the prototype MMS for internal OMT use.

The project is estimated to have an eight-month time duration and a budget of $50,000 and run concurrently with Project 1.

Besides the efforts of the MMD, this project will require the assistance of the Asphalt Technology Division and asphalt producers (primarily through the efforts of the existing Asphalt Electronic Data Exchange Team). OIT will be involved with coordinating and approving development of the intranet/internet portal.

This project will require the services of a consultant developer with experience working within SHA software development guidelines and with experience developing internet tools for SHA. The system must be developed to meet all OIT standards in terms of internet development applications. The MMD will be responsible for performing the intranet pilot study.

This pilot study will be an essential risk mitigation tool in that many lessons will be learned concerning the underpinning assumptions of this MMS plan and practical lessons learned on how the web can be leveraged to deliver the MMS.

Phase 2 – MMS Framework Development

Phase 2 of the project will be focused on formally building out the framework of the MMS. This will include development of the data model, Oracle database implementation, and creation of system administration tools.

<u>Project 3 – Development of Data Warehouse, Web Functionality, and Admin Tools</u>

The purpose of this project is to develop the framework around which the MMS will be built. Besides developing the detailed design document as required by the SDLC, the first order of business will be to develop the prototype data model. Another important task will be to determine the location and licensing provisions of the Oracle software which will drive the system. The MMS Project Manager will need to work with the Information and Technology Division to determine the appropriate server configuration and purchasing options.

The MMS will be developed over a period of time by perhaps many IT developers. It is essential that source code version control tools be employed to store and access the code. This tool must provide the capability to provide version control to source code and provide security features to back-up and limit access to the system source code.

Another key to success for the MMS will be to develop training modules for each subset of the system as it is developed. Under this project, the overall format and description of contents for a generic sub-system should be developed. These system training requirements will be used during development of each application to ensure a consistent approach to MMS training.

Another task within this project is development of an audit trail system to capture changes to the database and determine who made changes and when they occurred. This system will be useful to determine where approvals originated and who authorized changes to the database.

Development of the MMS will require a substantial investment in documentation. Therefore there must be a central storage area for all development documentation. This will allow the Project Manager to keep track of system development, allow the development vendor(s) access to documentation of all applications, and provide a series of legacy documents useful to future users and managers of the system. This aspect of the MMS should not be overlooked. It is key that all documents be kept in an organized, easily referenced database for future use.

During MMS development, implementation, and maintenance, it is inevitable that performance issues, or bugs, arise. Therefore, it is prudent to allow users of the system to notify the Project Manager and system developer of known issues as soon as possible. The Software Performance Reporting software should perform this function and allow managers to track the issues and resolutions for each bug, or issue with the software.

The Materials Management website is designed to be the only portal used to access Materials Management information on the intranet and internet. The interface will allow access to all portions of the MMS on a need and right to know basis. The design of the portal is critical as it will provide the primary interface for all users. A critical early win for the MMS will be to consolidate all of the existing information which resides on the intranet and internet into the MMS portal. User input should be solicited early and often in development of the web portal. The intent of this task is not to populate the entire website, but rather to develop the framework with which to format and present data. This project will extend the work under Project 2 to result in a full-time internet presence for the MMS.

This project is expected to have a duration of twelve months and a budget of $175,000. This effort will require the direct involvement of an Oracle DBA, a software developer(s), and coordination with OIT to locate, setup, and administer the server. This project will leverage the lessons learned from Project 2 to create a MMS portal that is robust, meets SHA security and access standards, and forms the initial presence of the MMS within the SHA community.

The deliverables from this effort will include a data model, an active Oracle MMS database, and an active MMS internet presence. The MMS will also have the

foundational administrative tools as documented previously. Documentation of the database model and system code will also be required.

Phase 3 – Project Management Development

Phase 3 will begin the process of creating MMS functionality that can be used for the Materials Clearance process. This will start with development of Project Management applications.

<u>Project 4 - Project Management Application</u>

The project management application will provide the means to enter Materials Clearance projects into the system. It will also handle notifications that projects have been initiated, and allow for manual and automated population of bid items and quantities. This application will have the capability to break-down lump sum items and enter these items into the database. It will also provide for automated development of the types, number of samples, and methods of acceptance for materials clearance. Therefore, it must be linked to the Frequency Guide. Development of this application is critical prior to development of all other MMS systems.

In order to initiate Projects within the MMS, it will be necessary to establish interactions with TRNS*PORT and MCMS. MCMS already interacts with TRNS*PORT so this process has been successfully completed before. However, MCMS is a stand-alone system (individual versions of software reside on individual computers in the construction trailer). It is possible that major modifications are required to MCMS in order to allow automated update of bid items and quantities. The benefits and costs of interacting with MCMS must be weighed when developing detailed specifications for this application to determine if this is a viable option.

The core processes will be as documented in the Project Management Application Set described in section 3 of this document. The deliverable from this project will be an internet based system that provides the following functionality:

1. Initialization of Project within MMS
2. Transmittal of Project Initiation to Appropriate Parties
3. Input of Project Information (automated and manual)
4. Update of Project Information
5. Creation of Bid Items
6. Update of Bid Items
7. Breakout of Lump Sum Items

This tool will also feature the first implementation of the Letter Generation System that will be a standard MMS tool to manage the flow of information and document activities occurring within the Materials Clearance process. Further, this tool will feature implementation of a task management application that allows users to map their work flows and easily determine the MMS tasks they need to complete. It will also contain a Folder Application that will save all relevant correspondence for ease of extraction by users. This particular application will need to be coordinated with the Enterprise Document Management system under development within SHA.

This project is expected to have a duration of eight months and a budget of $100,000. This effort will require the use of a consultant developer(s) that understands the MMS framework application and understands MCMS and the TRNS*PORT system. Assistance will be needed from OIT, OOC, and OOF to assist with linkages to their products.

Phase 4 – Source of Supply and Materials Clearance Development

Phase 4 will be concerned with developing the Source of Supply application and initial development of the Materials Clearance tracking application. It will consist of two specific projects.

Project 5 – Source of Supply Application

The Source of Supply application will be used by contractors to submit, and Area Materials Engineers to approve, sources used for each material. The first critical task in this application will be consolidation of the approved sources lists in each technical area into one cohesive database. It should be stressed that the owners of the data will remain the laboratory technical centers and they shall continue to have rights to manage the data. These managers should have direct input, through the User Group process, into development of this application.

The Source of Supply application shall also contain links between category codes and approved sources. When a category code (bid item) is selected, a list of applicable suppliers should be presented so as to facilitate selection of the source in an efficient manner.

At this point, the Qualified Products List must be transferred to the Oracle system and systems developed to manage the QPL database. The current owners of the process should be retained and each technical materials division should be allowed access to manage their list. This must be integrated with the MPEL system as needed.

The user interface used to approve sources should be developed with input from a contractor(s) and the Area Materials Engineers. Their input is critical to developing a system that works for the user and provides the most benefit for all involved.

The project will have a duration of six months and a budget of $100,000. It will require use of a consultant developer familiar with the MMS system and the MPEL system.

This is the first application of the MMS that will use the MMS web interface extensively by outside sources.

Project 6 – Materials Clearance Application

The Materials Clearance Application will be the application where all materials clearance activities are monitored and managed. This system will assist the MMS with Materials Clearance activities and begin to allow reporting of progress and performance against clearance goals. The Materials Clearance application will continue to be built out within the projects that follow.

This application will contain detailed Materials Clearance reports and will be the area in which all aspects of the MMS come together. The primary components of the system include:

- Materials Clearance Dashboard
- Materials Clearance status interface
- Monthly Clearance report interface
- 30-day Clearance Management System
- Final Materials Clearance Management System

The Dashboard will be an information center used to produce strategic level reports on Materials Clearance activities. User involvement in defining the types and detail of reports will be critical to success. Most of the task activities relate to defining the reports to be developed and deploying a user-friendly interface.

The clearance status interface will contain all of the detailed information concerning the status of all materials clearance efforts. It will contain such information as:

- List of projects in clearance
- Bid items and quantities
- Project progress
- Source of supply status
- List of disputed items and resolutions

This application will also manage the monthly, 30-day and final Materials Clearance reporting process. It will have a canned report generator and an ad hoc report generator. This will facilitate querying the database at a detailed level within a given project. It will also be capable of generating reports that assist in tracking source quality over time, contractor's performance over time and various productivity reports to assist with managing the entire process. As with all of the other tools, user involvement is critical to success.

This tool must also be able to output data to other SHA management systems. Bridge, Pavement, Maintenance and the proposed Asset Management systems all have need for data from the MMS. The primary purpose of this linkage identified at this time is to allow constituent source materials (aggregate base for example) to be tracked back through the system to identify supplier, test results, etc. associated with the material placed on the project.   In the future, all of this information may be linked to the GIS for data analysis purposes.

It is not envisioned that all Materials Clearance activities be incorporated during this effort. For example, the LIMS or Field Data Management applications will not be deployed yet and therefore test results will not be available. However, this project will focus on laying the groundwork for incorporation of all Materials Clearance activities as described in Section 3 of this report.

This project will have a twelve-month duration and a $150,000 budget. It will likely require the services of a consultant developer. Involvement by many groups within OMT, especially the MMD and upper management, will be necessary to assist with defining the contents of the Materials Clearance tool set. The Office of Construction may

also be involved as the manner in which Materials Clearance is performed will begin to change dramatically during this development effort.

Phase 5 – Materials Quality Assessment Development Part 1

This phase will focus on build-out of the Laboratory Information Management System and the Field Data Management applications. Both of these systems will provide key Materials Clearance data.

Project 7 – Laboratory Information Management System Application

The LIMS application will be used to provide sample management (receipt, testing status, and disposition), laboratory testing data storage, and laboratory equipment inventory capabilities. It is by far the largest and most complicated component of the MMS. During development of this Strategic Plan, a number of COTS LIMS were researched. As documented in the last section, it was determined that a custom LIMS system will be pursued by SHA. This matter should be investigated further once a system developer is on board to gauge the complexity and chances of success of a custom LIMS deployment. The LIMS will be designed to the extent possible to simply be a data capture and test approval system; it will not determine specification acceptance or rejection. The framework of the LIMS has been developed as part of an earlier prototyping effort. Some of this work can be leveraged in the creation of the production LIMS.

The LIMS must have the capability to store laboratory equipment information such as the type, location, and number of test apparatus in a given laboratory. This inventory system must also be tied to an equipment calibration monitoring and feedback system that allows calibration data to be recorded and a reminder output when a piece of equipment needs to be calibrated.

It will also contain a test cost reporting system to allow charges to be placed against construction or engineering design contracts for testing of materials. This will entail development of a database to store test cost information. This database will be linked to FMIS to charge the contract for approved tests (the initial linkage with FMIS may be performed as part of Project 4).

A sample management system will be developed such that sample receipt, processing, and disposition occur within a consistent database environment across technical material divisions. This will first be developed using data entry screens and manual data entry. Once a bar-coding system is in-place, this process will be automated so that when a sample is logged in the field; its identification information will not need to be entered again. It is expected that implementation of a bar-coding sample tracking system may take some time to research, procure, and implement. Therefore, a phased approach will allow for early implementation of the LIMS without having to wait for full system integration. The sample management system should provide for various productivity and summary reports necessary for the laboratory manger to run their operations in an efficient and effective manner.

The next task will be to develop a test assignment system. This may be challenging as there may be multiple possible testing regimes for a given material dependant on its intended use. The laboratory managers will need to be consulted on this issue in order to develop test assignment parameters for each material.

After the sample management system has been created, it will be necessary to develop test data input screens to log test results and match them against test assignments. The test data input screens and associated databases should be constructed using a wizard if at all possible. The wizard will allow modification or creation of new test result data capture screens without the need for re-programming.

Each test result data entry screen should be enabled with QC/QA tools to ensure accurate data is populated. For example, automated range and logic checks will potentially cut down on erroneous data entry.

After test data is input, the laboratory manager will require a means to approve or reject test results. Once tests are approved, the resultant summary data will be transferred to the materials quality approval application (to be developed in the next phase for specification compliance determination).

This project will have a twenty-four month duration and a budget of $200,000. It will require the services of a consultant programmer.

Project 8 – Field Data Management Application

The field data management application will be used to enter relevant data collected in the field that is used for materials clearance activities. This includes, but is not limited to, data entered through Form 14s, compaction data, and the Ride Tool.

The first phase of the development of the application will be to develop a system for manual entry of field data. This will allow rapid deployment while waiting on implementation of automated field data collection and reporting.

The manual system will entail development of entry forms for Form 14s and compaction data. It will also allow for integration with the Ride Tool analysis program for input of asphalt smoothness data. Development of this phase of the system will not result in lost work when automated data entry is enacted as data entry sheets will be necessary in the future in order to capture data that is not or cannot be automated (data from third parties perhaps). Again, during development of this application, user input by field personnel (Project Engineer) is critical to success.

Development of automated data capture and reporting will entail providing handheld devices, possibly with wireless capabilities, to field personnel with which to enter Form 14 and other data collected in the field. Research will be needed to determine the types and costs of devices to be used in the field. This phase should be implemented as a pilot study on a few projects followed by full implementation after all of the issues have been worked out with the system.

This project has a time duration of eighteen months and a budget of $200,000. A consultant programmer(s) with hand held data entry device experience will be required.

Phase 6 – Materials Quality Assessment Development Part 2

Phase 6 will concentrate on building the final core applications for the MMS. This will include deployment of a certified materials management system and material quality approval applications.

Project 9 – Certified Materials Management Application

This portion of the MMS will be used to streamline the certified material acceptance process as described in Section 3 of this document.   The application must have the capability to manage the list of certified materials and allow for automated population of the required stamps and certifications. It should also have an approval mechanism to allow the appropriate OMT agency to approve the material and allow it to go into clearance. This system must also have the capability to manage approved stockpile materials and approved lot quantities and it must maintain a list of approved stockpiles (producer, quantity, type of material, etc.), manage the quantity of material that has been used, inspection frequency, and provide notification of a stockpile's deviation from acceptable inspection cycles for each technical material division.

This application has a duration of twelve months and a budget of $50,000.

Project 10 – Material Quality Approval Application

The Material Quality Approval Management application will be used to determine specification compliance and acceptance or rejection of test results. To develop this application it will be necessary to link to the specifications (discussed later) to determine the specification limits for each test, or suite of tests. An algorithm must be developed to conduct this comparison and output the results.

In some cases, results may fail the specification limits. In this event, the Area Materials Engineer must resolve the test result with the laboratory manager and ultimately the District and Project engineers. The results of this resolution process must be documented in the database.

A specifications database will be used to store the specifications used to perform a certain test. The acceptance limits must also be codified so as to match results with specifications. The capability must exist to link specifications with the test result for archival purposes so that future users can determine the exact specification used.

The Frequency Guide must also be managed under this project. This guide is a primary input to the Materials Clearance process and is critical to development of the Materials Management System. The current Frequency Guide (paper-based) must be converted into an electronic database so that all aspects of the Materials Clearance process can be automated. A user interface must be developed so that the Guide can be updated. A link between the Frequency Guide in use for a project should be made for archival purposes and so future users can relate a project to the correct Frequency Guide version.

At the end of the day, this application must be able to link to all laboratory and field data elements and provide a judgment as to acceptance or rejection. This information will then be carried to the Materials Clearance application so that Clearance status can be updated and an electronic trail of acceptance or rejection of material created.

This project has a duration of eight months and a budget of $200,000.

Implementation Schedule

In order to develop the short-term and long-term scope of work, it is first important to review the tasks and assign priorities, level of effort and impact of each project on the overall development of the MMS. Table 4-2 contains a matrix comparing each project against cost, risk and impact to the Materials Management process. The following scale is used for each recommendation.

Cost – measure of estimated cost. A more accurate or detailed cost will be necessary prior to starting each task after this plan is implemented. This matrix provides a ballpark cost for each recommendation. Final costs will depend on options selected, whether hardware and software exists or needs to be purchased and additional functionality that comes out of the detailed requirements specification.

Low	< $50,000
Medium	$50,000 - $200,000
High	>$200,000

Risk - measure of task difficulty

Low	Task is not complicated
Medium	Task moderately difficult. Some dependencies between this task and other tasks.
High	Very difficult and complex task. A more detailed design needs to be performed prior to starting task.

Impact - a scale determining the level of benefit of a particular recommendation and is derived by the level of efficiency gained through implementation of the task.

Low	Increase in efficiency is minimal.
Medium	This will have a significant impact on efficiency.
High	This will provide a significant impact in terms of productivity or this is a critical project for completion of the MMS.

The overall implementation schedule has been presented previously in figure 4-1. This figure contains a conceptual time schedule for development of all major applications. As shown, a five-year timeframe is proposed for MMS implementation.

Table 4-2. Project development cost, risk, and impact assessment matrix

Project	Cost	Risk	Impact
Project 1 – Development of High-Level Requirements Document	Low	Low	High
Project 2 – MMS Functionality Pilot Study	Low	Med	High
Project 3 – Development of Data Warehouse, Web Functionality, and Admin Tools	Med	Med	High
Project 4 - Project Management Application	Med	Med	Med
Project 5 – Source of Supply Application	Med	Low	Med
Project 6 – Materials Clearance Application	Med	High	Med
Project 7 – Laboratory Information Management System Application	Med	Med	High
Project 8 – Field Data Management Application	Med	High	Med
Project 9 – Certified Materials Management Application	Low	Med	Low
Project 10 – Material Quality Approval Application	Med	Med	High

The overall budget for development of the Materials Management System is presented in table 4-3. This budget table is derived from the cost estimates presented previously in table 4-1. These costs denote costs for system development and do not include expenditures for equipment such as bar code scanners and field data input devices as these costs are very difficult to estimate at this time.

Table 4.3 – Overall project budget

Project	Estimate
Project 1 – Development of High-Level Requirements Document	$50,000
Project 2 – MMS Functionality Pilot Study	$50,000
Project 3 – Development of Data Warehouse, Web Functionality, and Admin Tools	$175,000
Project 4 - Project Management App	$100,000
Project 5 – Source of Supply App	$100,000
Project 6 – Materials Clearance App	$150,000
Project 7 – Laboratory Information Management System App	$200,000
Project 8 – Field Data Management App	$200,000
Project 9 – Certified Materials Management App	$50,000
Project 10 – Material Quality Approval App	$200,000
TOTAL	**$1,275,000**

More refined estimates will be developed during the system requirements stage of MMS development (Project 1).

Total budget is not the only issue. The MMS will be developed over a number of years. As such, an estimated cash flow analysis was conducted to determine the level of effort each year. To perform this analysis, an estimate was developed of the amount of work, on a percentage basis, on a particular project for a particular year. This is presented in table 4.4

Table 4.4– Percentage project completion per year

Project	Y 1	Y 2	Y 3	Y 4	Y 5
Project 1 – Requirements Document	100				
Project 2 – MMS Functionality Pilot Study	100				
Project 3 – Data Warehouse, Web Functionality, and Admin Tools		30	70		
Project 4 - Project Management Apps		80	20		
Project 5 – Source of Supply Apps			100		
Project 6 – Materials Clearance Apps			100		
Project 7 – LIMS Apps				70	30
Project 8 – Field Data Management Apps				60	40
Project 9 – Certified Materials Management Apps				10	90
Project 10 – Material Quality Approval Apps					100

These values were then multiplied by the estimated budget amount to yield the data shown in figure 4-2.

Figure 4-2. Cash flow analysis.

	1	2	3	4	5
Yearly	100000	132500	392500	240000	410000
Culmulative	100000	232500	625000	865000	1275000
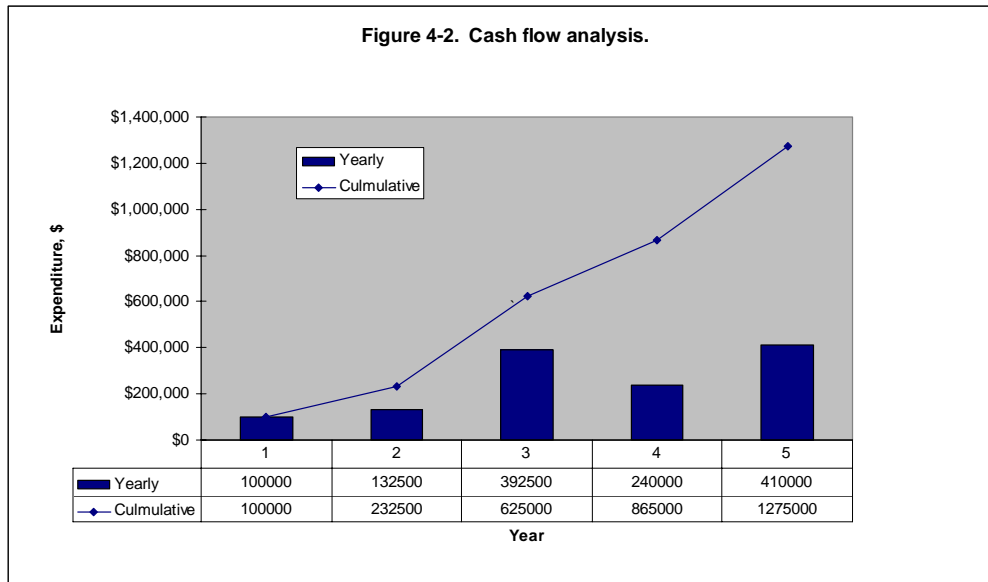
Once each project is complete, it should be recognized that the system will need regular maintenance and update. During the detailed requirements phase of the project, a plan and budget for system maintenance should be developed.

Summary

Section 4 provided a detailed overview of the proposed implementation plan for development of the MMS. This section discussed the team structure necessary to guide and develop the MMS. A summary review of the scope of work was presented at the project level. Then a conceptual implementation schedule was illustrated. Lastly, a conceptual budget was discussed along with a summary analysis of cash flows for system development.

Like any plan, this section outlines the conceptual framework for development of the MMS. It should be revisited often and modified as necessary to reflect the successes and challenges that will undoubtedly be faced during development of the Maryland SHA Materials Management System.

Appendix A

Federal Regulations

be in writing and that the contracting agency intends to make award without obtaining further revisions.

§ 636.510 Can the competitive range be further defined once discussions have begun?

Yes, you may further narrow the competitive range if an offeror originally in the competitive range is no longer considered to be among the most highly rated offerors being considered for award. That offeror may be eliminated from the competitive range whether or not all material aspects of the proposal have been discussed, or whether or not the offeror has been afforded an opportunity to submit a proposal revision. You must provide an offeror excluded from the competitive range with a written determination and notice that proposal revisions will not be considered.

§ 636.511 Can there be more than one round of discussions?

Yes, but only at the conclusion of discussions will the offerors be requested to submit a final proposal revision, also called best and final offer (BAFO). Thus, regardless of the length or number of discussions, there will be only one request for a revised proposal (*i.e.*, only one BAFO).

§ 636.512 What is the basis for the source selection decision?

(a) You must base the source selection decision on a comparative assessment of proposals against all selection criteria in the solicitation. While you may use reports and analyses prepared by others, the source selection decision shall represent your independent judgment.

(b) The source selection decision shall be documented, and the documentation shall include the rationale for any business judgments and tradeoffs made or relied on, including benefits associated with additional costs. Although the rationale for the selection decision must be documented, that documentation need not quantify the tradeoffs that led to the decision.

§ 636.513 Are limited negotiations allowed prior to contract execution?

Yes, after the source selection but prior to contract execution, you may conduct limited negotiations with the selected design-builder to clarify any remaining issues regarding scope, schedule, financing or any other information provided by that offeror. You must comply with the provisions of § 636.507 in the exchange of this information.

§ 636.514 How may I provide notifications and debriefings?

You may provide pre-award or post-award notifications in accordance with State approved procedures. If an offeror requests a debriefing, you may provide pre-award or post-award debriefings in accordance with State approved procedures.

PART 637—CONSTRUCTION INSPECTION AND APPROVAL

Subpart A [Reserved]

Subpart B—Quality Assurance Procedures for Construction

Sec.
637.201 Purpose.
637.203 Definitions.
637.205 Policy.
637.207 Quality assurance program.
637.209 Laboratory and sampling and testing personnel qualifications.
APPENDIX A TO SUBPART B OF PART 637— GUIDE LETTER OF CERTIFICATION BY STATE ENGINEER

AUTHORITY: Sec. 1307, Pub. L. 105–178, 112 Stat. 107; 23 U.S.C. 109, 114, and 315; 49 CFR 1.48(b).

SOURCE: 60 FR 33717, June 29, 1995, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 637 appear at 67 FR 75934, Dec. 10, 2002.

Subpart A [Reserved]

Subpart B—Quality Assurance Procedures for Construction

§ 637.201 Purpose.

To prescribe policies, procedures, and guidelines to assure the quality of materials and construction in all Federal-

aid highway projects on the National Highway System.

§ 637.203 Definitions.

Acceptance program. All factors that comprise the State transportation department's (STD) determination of the quality of the product as specified in the contract requirements. These factors include verification sampling, testing, and inspection and may include results of quality control sampling and testing.

Independent assurance program. Activities that are an unbiased and independent evaluation of all the sampling and testing procedures used in the acceptance program. Test procedures used in the acceptance program which are performed in the STD's central laboratory would not be covered by an independent assurance program.

Proficiency samples. Homogeneous samples that are distributed and tested by two or more laboratories. The test results are compared to assure that the laboratories are obtaining the same results.

Qualified laboratories. Laboratories that are capable as defined by appropriate programs established by each STD. As a minimum, the qualification program shall include provisions for checking test equipment and the laboratory shall keep records of calibration checks.

Qualified sampling and testing personnel. Personnel who are capable as defined by appropriate programs established by each STD.

Quality assurance. All those planned and systematic actions necessary to provide confidence that a product or service will satisfy given requirements for quality.

Quality control. All contractor/vendor operational techniques and activities that are performed or conducted to fulfill the contract requirements.

Random sample. A sample drawn from a lot in which each increment in the lot has an equal probability of being chosen.

Vendor. A supplier of project-produced material that is not the contractor.

Verification sampling and testing. Sampling and testing performed to validate the quality of the product.

§ 637.205 Policy.

(a) *Quality assurance program.* Each STD shall develop a quality assurance program which will assure that the materials and workmanship incorporated into each Federal-aid highway construction project on the NHS are in conformity with the requirements of the approved plans and specifications, including approved changes. The program must meet the criteria in § 637.207 and be approved by the FHWA.

(b) *STD capabilities.* The STD shall maintain an adequate, qualified staff to administer its quality assurance program. The State shall also maintain a central laboratory. The State's central laboratory shall meet the requirements in § 637.209(a)(2).

(c) *Independent assurance program.* Independent assurance samples and tests or other procedures shall be performed by qualified sampling and testing personnel employed by the STD or its designated agent.

(d) *Verification sampling and testing.* The verification sampling and testing are to be performed by qualified testing personnel employed by the STD or its designated agent, excluding the contractor and vendor.

(e) *Random samples.* All samples used for quality control and verification sampling and testing shall be random samples.

§ 637.207 Quality assurance program.

(a) Each STD's quality assurance program shall provide for an acceptance program and an independent assurance (IA) program consisting of the following:

(1) Acceptance program.

(i) Each STD's acceptance program shall consist of the following:

(A) Frequency guide schedules for verification sampling and testing which will give general guidance to personnel responsible for the program and allow adaptation to specific project conditions and needs.

(B) Identification of the specific location in the construction or production operation at which verification sampling and testing is to be accomplished.

(C) Identification of the specific attributes to be inspected which reflect the quality of the finished product.

(ii) Quality control sampling and testing results may be used as part of the acceptance decision provided that:

(A) The sampling and testing has been performed by qualified laboratories and qualified sampling and testing personnel.

(B) The quality of the material has been validated by the verification sampling and testing. The verification testing shall be performed on samples that are taken independently of the quality control samples.

(C) The quality control sampling and testing is evaluated by an IA program.

(iii) If the results from the quality control sampling and testing are used in the acceptance program, the STD shall establish a dispute resolution system. The dispute resolution system shall address the resolution of discrepancies occurring between the verification sampling and testing and the quality control sampling and testing. The dispute resolution system may be administered entirely within the STD.

(iv) In the case of a design-build project on the National Highway System, warranties may be used where appropriate. See 23 CFR 635.413(e) for specific requirements.

(2) The IA program shall evaluate the qualified sampling and testing personnel and the testing equipment. The program shall cover sampling procedures, testing procedures, and testing equipment. Each IA program shall include a schedule of frequency for IA evaluation. The schedule may be established based on either a project basis or a system basis. The frequency can be based on either a unit of production or on a unit of time.

(i) The testing equipment shall be evaluated by using one or more of the following: Calibration checks, split samples, or proficiency samples.

(ii) Testing personnel shall be evaluated by observations and split samples or proficiency samples.

(iii) A prompt comparison and documentation shall be made of test results obtained by the tester being evaluated and the IA tester. The STD shall develop guidelines including tolerance limits for the comparison of test results.

(iv) If the STD uses the system approach to the IA program, the STD shall provide an annual report to the FHWA summarizing the results of the IA program.

(3) The preparation of a materials certification, conforming in substance to Appendix A of this subpart, shall be submitted to the FHWA Division Administrator for each construction project which is subject to FHWA construction oversight activities.

(b) In the case of a design-build project funded under title 23, U.S. Code, the STD's quality assurance program should consider the specific contractual needs of the design-build project. All provisions of paragraph (a) of this section are applicable to design-build projects. In addition, the quality assurance program may include the following:

(1) Reliance on a combination of contractual provisions and acceptance methods;

(2) Reliance on quality control sampling and testing as part of the acceptance decision, provided that adequate verification of the design-builder's quality control sampling and testing is performed to ensure that the design-builder is providing the quality of materials and construction required by the contract documents.

(3) Contractual provisions which require the operation of the completed facility for a specific time period.

[60 FR 33717, June 29, 1995, as amended at 67 FR 75934, Dec. 10, 2002]

§ 637.209 Laboratory and sampling and testing personnel qualifications.

(a) Laboratories.

(1) After June 29, 2000, all contractor, vendor, and STD testing used in the acceptance decision shall be performed by qualified laboratories.

(2) After June 30, 1997, each STD shall have its central laboratory accredited by the AASHTO Accreditation Program or a comparable laboratory accreditation program approved by the FHWA.

(3) After June 29, 2000, any non-STD designated laboratory which performs IA sampling and testing shall be accredited in the testing to be performed

by the AASHTO Accreditation Program or a comparable laboratory accreditation program approved by the FHWA.

(4) After June 29, 2000, any non-STD laboratory that is used in dispute resolution sampling and testing shall be accredited in the testing to be performed by the AASHTO Accreditation Program or a comparable laboratory accreditation program approved by the FHWA.

(b) Sampling and testing personnel. After June 29, 2000, all sampling and testing data to be used in the acceptance decision or the IA program shall be executed by qualified sampling and testing personnel.

(c) Conflict of interest. In order to avoid an appearance of a conflict of interest, any qualified non-STD laboratory shall perform only one of the following types of testing on the same project: Verification testing, quality control testing, IA testing, or dispute resolution testing.

APPENDIX A TO SUBPART B OF PART 637—GUIDE LETTER OF CERTIFICATION BY STATE ENGINEER

Date _____
Project No. _____
This is to certify that:
The results of the tests used in the acceptance program indicate that the materials incorporated in the construction work, and the construction operations controlled by sampling and testing, were in conformity with the approved plans and specifications. (The following sentence should be added if the IA testing frequencies are based on project quantities. All independent assurance samples and tests are within tolerance limits of the samples and tests that are used in the acceptance program.)

Exceptions to the plans and specifications are explained on the back hereof (or on attached sheet).

_____
Director of STD Laboratory or other appropriate STD Official.

PART 645—UTILITIES

Subpart A—Utility Relocations, Adjustments, and Reimbursement

Subpart B—Accommodation of Utilities

AUTHORITY: 23 U.S.C. 101, 109, 111, 116, 123, and 315; 23 CFR 1.23 and 1.27; 49 CFR 1.48(b); and E.O. 11990, 42 26961 (May 24, 1977).

EDITORIAL NOTE: Nomenclature changes to part 645 appear at 65 FR 70311, Nov. 22, 2000.

Subpart A—Utility Relocations, Adjustments, and Reimbursement

SOURCE: 50 FR 20345, May 15, 1985, unless otherwise noted.

§ 645.101 Purpose.

To prescribe the policies, procedures, and reimbursement provisions for the adjustment and relocation of utility facilities on Federal-aid and direct Federal projects.

§ 645.103 Applicability.

(a) The provisions of this regulation apply to reimbursement claimed by a State transportation department (STD) for costs incurred under an approved and properly executed transportation department (TD)/utility agreement and for payment of costs incurred under all Federal Highway Administration (FHWA)/utility agreements.

(b) Procedures on the accommodation of utilities are set forth in 23 CFR part 645, subpart B, Accommodation of Utilities.

(c) When the lines or facilities to be relocated or adjusted due to highway construction are privately owned, located on the owner's land, devoted exclusively to private use and not directly or indirectly serving the public, the provisions of the FHWA's right-of-way procedures in 23 CFR 710.203,

Appendix B

FHWA Materials Clearance Review

U.S. Department of Transportation
Federal Highway Administration

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Maryland State Highway Administration and Federal Highway Administration Maryland Division

September 16, 2004

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PURPOSE

The purpose of this review was to examine the policies, procedures, and overall performance of Material Clearance Procedures of Maryland State Highway Administration (MDSHA). This review was also intended to insure that the Materials Clearance Procedures of MDSHA are in place, including policies, procedures and guidelines to comply with the FHWA Quality Assurance Program in meeting the requirements as stated in 23 CFR 637 for all Federal-aid Highway Projects on the National Highway System (NHS).

To comply with Federal Highway Administration (FHWA) requirements, the State must submit a materials certification for each construction project on the NHS System. This certification states, "Acceptance samples indicate the materials incorporated into the project and construction operations controlled by sampling and testing were in reasonably close conformity with the plans and specifications."

SCOPE

During the months October 2003 thru January 2004, a statewide process review was performed on different construction projects administered by Maryland State Highway Administration in Baltimore, Montgomery and Washington Counties in Maryland. The projects inspected were both Exempt and Non-exempt projects. This process review documents the sampling and testing performed, including Independent Assurance

Audits, and the disposition of failing and untested materials. This also includes discussions with personnel from SHA's Central and Regional Materials Laboratories as well as a detailed review of the project records, including organizational manuals, charts, delegation, directives, procedures, instructions, training materials, correspondence files, project records etc. The items reviewed included MDSHA Materials Clearance Program, Laboratory and Field Procedures, Quality Control and Quality Assurance Program, Frequency Guide and Compliance with Federal Regulations (23 CFR 637). This process review was limited to the MDSHA Materials Clearance Procedures program only.

REVIEW TEAM

- Azmat Hussain, FHWA
- Woody Hood, SHA CNRL
- Scott Stomps, SHA District 3
- Stuart Jones, SHA District 4
- Jack Zies, SHA District 6

BACKGROUND

The State Highway Administration has the responsibility for the direct supervision of all construction activities, including quality assurance as outlined in the provisions of 23 CFR 637, which includes an Acceptance Program and an Independent Assurance program. The FHWA Policy (23 CFR 637.205) states that each State shall develop a quality assurance program, which assures that the materials and workmanship incorporated into each Federal-aid Highway construction project on the NHS, are in conformity with the approved plans and specifications, including approved changes. This program must meet the criteria as described in Section 23 CFR 637.207, and approved by the FHWA. The State Highway Administration had maintained an adequate qualified staff, which was part of this review. The State had also maintained a Central Laboratory, which meets the requirements as stated in CFR 637.209.

EXECUTIVE SUMMARY

The results of this Process Review indicate that Maryland State Highway Administration's Materials Clearance Procedure is overall satisfactory and that the MDSHA is making a conscientious effort to insure the quality of the end product. This report contains several recommendations, if implemented will further enhance the Materials Clearance Procedures. MDSHA's adoption of the recommendation in this report will strengthen this procedure and the quality of the end product.

MDSHA OFFICE OF MATERIALS & TECHNOLOGY TECHNICAL DIVISION/TEAMS

The MDSHA Office of Materials & Technology teams play an important role in the delivery of the Federal-aid program to ensure the quality control/ quality assurance of materials being incorporated into MDSHA projects. The Office of Materials & Technology controls the following teams:

- Metals and Coatings Concrete
- Precast/Prestressed Cement
- Chemicals Hot Mix Asphalt Soils
- Aggregates Materials Management
- Area Materials & Evaluation Engineers

MDSHA MATERIALS CLEARANCE PROCEDURES

The MDSHA procedures for Materials Clearance were implemented prior to its use on Federal-aid projects. The procedures were revised on May 20, 2003, which includes but not limited to the Source of Supply Letters (SOS), Suggested Formats, General Instructions for Source Materials, Accessing OMT Qualified Products List via Internet, MDSHA Stamps, Monthly Clearance Process, Status Report Format, and Completion of Various Forms. The Frequency Guide was also found on all construction projects inspected during this review and was used by the Project Engineers for Materials Clearance. The Materials Clearance Procedures are as follow:

Submittals:

Once a construction contract has been awarded, the prime contractor provides the sources of materials intend to be used on this project. The MDSHA provides tips to the General Contractors for using a suggested format, which must include, the awarded contract number, project location, bid item number and materials to be used in each item (see attachment #1). The source for each of these materials is listed with company's name and address. The approval of these sources means that the producer has the necessary facilities to produce acceptable materials. It does not imply that the material is approved or accepted.

New Materials Sources:

In case, when the proposed source is one that has not recently or never produced materials for MDSHA projects, the Administration may do a facility approval and/or take representative samples of the materials being produced at the time of inspection to evaluate the production process for quality control before the material is approved.

Qualified Products:

The MDSHA also allows the use of qualified products, which have gone through a prescribed procedure for submittal, testing, and qualification. The Office of Materials & Technology maintains the Qualified Products List (QPL) for those products, which have met specifications for use on Maryland State Highway Administration's construction projects. Prequalification does not imply that materials can be used on Maryland State Highway Administration projects without regard for normal Quality Assurance Testing and Procedures.

Materials Certification Program:

In addition, the MDSHA follows a Materials Certification Program as outlined in the MDSHA Frequency Guide. A random process of sampling and testing is conducted to evaluate a manufacturer's and producer's material certificate of compliance. (The verification of certifications is done in accordance with the schedule outlined in attachment #2 (table 4) which is also part of the Frequency Guide).

Quality Assurance Program:

The Maryland State Highway Administration makes appropriate distribution of any density charts, job mix formulas, mix designs, etc. generated by the source submittals. The MDSHA staff follows the guidelines established by the Maryland State Highway's, Office of Materials and Technology, to monitor the progress of the

project, record keeping, communicating, etc.

Monthly Materials Clearance Procedures:

On each construction project, the MDSHA Project Engineer prepares the monthly submittal form with estimate worksheet. The required documentation such as certifications, laboratory test data, inspection reports, specifications etc. are reviewed and attached with this submittal. The Project Engineer reserves the right to withhold payment (or take back money on the next estimate) for items that don't have proper documentation as described above. The Project Engineer forwards this documentation to the Evaluation Engineer within 7 calendar days following the estimate due date with a copy of the estimate worksheet for review and comment. Within 14 days the Evaluation Engineer returns the submittal to the Project Engineer with copies to the Area Engineer and Assistant District Engineer Construction with comments. The Contractor reviews and provides any missing information to the Project Engineer in order to get paid for material on that monthly estimate. (A copy of this document is shown in attachment #3).

Materials Clearance, 30 Day Notice:

At least 30 days before the completion of the project, the District Engineer will notify the Regional Materials Engineer in writing in accordance with MDSHA Construction Directive 72.1-10-12. This notification contains a list of bid items not used and where applicable quantities of materials used. At that time a request for final reports is sent by OMT to all responsibility centers and Districts which are providing inspection and/or testing for the project. After review completion, the appropriate personnel are requested to supply information to assist in resolving exceptions. An exception is defined as," any violation of the Specifications and /or Standards". All exceptions are addressed.

Materials Clearance Final Report:

A final review of files is performed after receiving the copy of the Acceptance for Maintenance Letter. A copy of the certification or clearance correspondence is distributed to MDSHA's appropriate Districts and FHWA Office for NHS projects. The original is retained in the project file in the Regional Laboratory. The records are retained for three years after the final voucher is submitted to the Federal Highway Administration for approval.

INSPECTIONS

After reviewing the existing specifications, technical materials, charts, directives, procedures, instructions, training manual, and correspondence files, the team carefully selected three projects for inspections at different locations to complete this process review. The projects are as follow:

l Cherry Hill/Randolph Road on US 29, Montgomery County F.A.P No. AC/HP-0359 (001) N (MO836B51)
l Replacement of Deck for Bridge No. 3952 on Cold Bottom Road, Baltimore County F.A.P No. AC-BH-83-2 (200) N (BA 384B51)

ı US 40 Alternate, West of MD 67 to Frederick County Line, Washington County F.A.P
   No. AC-STP-G-225-1 (7) E (WA101B51)

INTERVIEWS

During this review process several interviews were conducted with MDSHA personnel,
including the Evaluation Engineers, Project Engineers, Office Managers and Inspectors.
Some open-ended questions were asked that filled in the gaps in the existing information
available at the time of this process review.

OBSERVATIONS AND DISCUSSIONS

A.

Observation:

The material clearance tracking time period of 30 days after receipt of the 30 day

notice might not be sufficient time to clear project.

Discussion: Under the new "Monthly Materials Clearance Process" projects are

generally 98% cleared at the time this notice is received. OMT has been providing

training in this new process to all Construction Project Personnel, Consultants,

Contractors and Suppliers since May 2003. As projects start using the new process,

OMT has been tracking the time to clear projects as part of the OMT business plan.

Recommendation:

Continue to provide training to those new to the process and provide refresher

training at regular intervals. Consider making training a mandatory part of the overall

MDSHA/OMT/CID Training Programs for Technicians/Project personnel.

Resolution: OMT to continue monitoring time required to clear projects under new

process and offer training/resources to address issues related to materials clearance.

B.

Observation:

The final acceptance of landscaping and pavement markings pay items are held up

at the end of the project due to the nature of their construction procedures.

Sometimes, this causes delays in the final acceptance of these materials.

Discussion: Previously this was the case, but OMT has instituted a new policy where

landscape and pavement markings are addressed by the District, with the contractor,

without holding up final materials clearance.

Recommendation:

OMT to continue to monitor projects for possible delays due to problems with

landscape or pavement markings when clearing projects.

Resolution: OMT process has addressed this issue. No further action is required at this time.

C.

Observation:

The materials clearance items, which were not completed on each monthly estimate were not carried over or shown on the next monthly estimate as completed. Discussion: This has been a problem with the software program carrying over the items needing additional documentation. Project Engineer must write this in by hand on each monthly estimate for items carried over.

Recommendation:

OMT has been working with the Office of Construction (OOC) to address issues with the software program relative to the Materials Clearance Process. The carryover of items not completed on the monthly estimate will be discussed with OOC and changes to software program will be made to address this issue.

Resolution:

OMT is working with OOC to have software program modified to address this issue.

D.

Observation:

The Contractor may not agree with some of the pay quantities on each monthly estimate as stated on the Inspector's Daily Report (IDR), which is used by the Project Engineer for preparing the sketch book. This results in delays to the contractor in getting payment for those pay items. This should be discussed and agreed upon with contractor before submittal of estimate.

Discussion:

The project personnel must collect all necessary tickets, paperwork, etc. for processing each monthly estimate regarding the pay items/materials being used on the project. Contractor must ensure that all documentation is given to the project personnel. Contractor needs to be aware that any agreement of pay quantities is not final until approved by Sketchbook. Maryland State Highway Administration (MDSHA) and Maryland Highway Contractors Association (MHCA) Leadership Council is looking into this problem. Recommendation: MDSHA/Maryland Highway Contractor's Association (MHCA) Team to address issues of how to address sketchbook/contractor disagreement over quantities. Resolution: Awaiting recommendations from MDSHA/MHCA Leadership Council.

E.

Observation:

The Contractor/MDSHA must keep track of the materials list, which is supplied to MDSHA for approval prior to the construction.

Discussion:

This matter must be discussed in the pre-construction meeting and the materials list should be established for this purpose. It shall be updated on monthly basis to check the status of each item. Source of supply submittals are approved by OMT and it is then up to project engineer/contractor to verify/use the source submitted unless a request for a source change is approved by OMT.

Note:

On Design Build projects agreement between the Contractor and Project Engineer on the development of the materials item list is critical to tracking materials and final materials clearance at end of project.

Recommendation:

OMT should continue to provide training and refresher courses in Materials Clearance to all project/contractor personnel involved in the submittal/approval of material sources. The Office of Traffic should be included in this training effort.

Resolution:

OMT will be providing this training at CID Expo and various other locations throughout State for those needing refresher training or who are new to the Materials Clearance Process.

F.

Observation:

The HMA pay quantities reported by the plant were found different compared to the total quantities delivered on one project as of 10/21/03. The quality control reports of plant shows a total of 1900 tons of HMA delivered on a job, whereas, the HMA tickets show a total of 4000 tons delivered on the site. The quality control records (copies of plant reports) of 2100 tons HMA placed was missing from the project files along with QC/QA testing information. This may have happened due to the lack of knowledge of contractor and project personnel in the importance of collecting tickets, paperwork, etc. and the process for handling paperwork. The Contractor was paid based upon the tonnage showed on HMA tickets received on site without verifying the quality control data.

Discussion:

This had been a problem previously, but producers of HMA are now required to have MDWare installed at their facilities before being approved. Samples are now entered daily into the program and matching up quantity of material shipped to a particular project versus what was actually paid for has not been an issue.

Recommendation:

> The Project Engineer should verify the quantity of HMA delivered to the project through review of delivery tickets. The HMA Team should compare QC/QA data using MDWare and e-mail evaluations to the Project Engineer during construction. The quantity listed in MDWare will represent the quantity produced and shipped to the project each day, this may differ from quantity placed due to the weather or equipment breakdown.
>
> When the HMA Team and District Sketchbook agree on the HMA pay quantities, the HMA Team will submit an HMA Summary packet to the District Engineer and Evaluation Engineer with the Quantities, Test Results, Incentive/Disincentive, with recommendation for payment.

Resolution:

> The Procducer must use MDWare to submit pay quantities and test results to HMA Team for evaluation. HMA Team will then forward results of evaluation to Project Engineer for payment.

G.

Observation:

> In some cases it was noted that the test data collected for the density/core test analysis did not have information regarding the total tonnage placed on that particular day. Due to the lack of this information, the frequency of testing as stated in the Contract documents may not have been followed.

Discussion:

> In most instances the Contractor or their representative is drilling the cores. The Project Engineer must ensure that the State inspectors taking possession of the cores follow the specifications as provided in the Contract documents based on the tonnage placed that day. This issue should be discussed at the pre-pave meeting and during HMA construction.

Recommendations:

> Project personnel should be responsible for keeping track of the HMA tonnage placed on any one particular day and must follow the specifications as stated in the Contract documents to ensure the correct number of random test cores is obtained.

Resolution:

> The MDSHA Office of Construction (OOC) will give this responsibility to the Project Engineer to assure the proper number of samples is obtained as required by the Contract documents.

H.

Observation:

The adjustment factor of HMA cores test results received from the laboratory was not applied to the HMA pay quantities in the next monthly estimate. Adjustment Factors were applied at the end of the project.

Discussion:

Under the present system, HMA is paid for at each monthly estimate based on tonnage/bid price and any adjustments are applied at the end of project. District does not want to do change orders every month. They would rather do one change order at end of project. In addition, not all test results are received at each monthly estimate to allow applying adjustment factors at that time. OMT has begun requiring HMA producers to use a new software program, MDWare, to track samples.

Recommendations:

OMT should continue to require MDWare be installed at any HMA facility approved to provide material to MDSHA projects and address any discrepancies in tonnage/adjustment factors at the end of project.

Resolution:

MDWare will address this issue and allow for better correlation of tonnage placed versus actual material paid for on each monthly estimate.

I.

Observation:

Redline Revisions and Change Orders have the potential to negatively impact the time required to clear a project based on the 30 day notice.

Discussion:

This has been a problem in the past and had a major impact on the OMT goal of clearing projects within 60 days of when the 30 day notice was received; since many of the Redline Revisions/Change Orders are received after the 30 day notice.

Recommendation:

OMT has requested that District issue a new 30 day notice when there is a Redline Revision and/or Change Order on a project.

Resolution:

Issue has been resolved with District, a new 30 day notice is issued whenever a Redline Revision and/or Change Order is processed.

J.

Observation:

The minimum frequency for the verification of certifications as contained in Table 4 of the Sample Frequency Guide is not being adhered to for all the materials listed.

Discussion:

> The inability to meet these minimum frequencies can be attributed to an increase in the number of manufacturers/suppliers and the reduction of staff at the Office of Materials and Technology (OMT).

Recommendations:

> The Office of Materials & Technology (OMT) investigate the possibility of sharing resources with other state agencies to perform these audits utilizing standard auditing forms developed by such organizations as NTPEP. Where that is not practical develop the ability to utilize contractual services to perform the audits. Also revise the table to reflect not only the frequency interval, but also the volume of material supplied by any one source.

Resolution:

> The Office of Materials & Technology (OMT) will investigate the recommendations, consider alternates and report back to FHWA.

Best Practices of MDSHA/OMT:

> As SHA has relied on the Consultant Industry to assume more of the role of the Project Engineer, with SHA providing the oversight. Providing the necessary resources to perform those roles has fallen on OMT in the area of Materials Clearance.

In that regard OMT has taken the initiative through the following actions (Best Practices):

- A team of individuals from D-3 Construction and OMT's Southern Regional Laboratory revised the Materials Clearance Process to what is now known as the "Monthly Materials Clearance Process"
- OMT has developed a training program for this new process complete with manual and CD-rom to train individuals from the submittal of material sources at the start of a project; through the final materials clearance at the end of the project
- OMT has offered this training to our Consultant Industry, Contractors, Producers, Suppliers, SHA employees, etc. starting in May 2003. To date OMT has trained over 350 individuals in this new process.
- Materials Clearance has been made one of the key rating areas on the "Partnering Rating Form" filled out each month by the Project Engineer and Contractor on a majority of MDSHA Projects.
- Refresher classes are held each year at our Construction Inspection Division (CID) Expo
  OMT will continue to offer this training on a regular basis throughout each year based on demand.
- In the area of Verification of Certifications: OMT will make a determination if agency and/or consultants can provide the resources to meet the frequency specified.

ACKNOWLEDGEMENTS

The Maryland Division Office expresses its sincere appreciation to MDSHA and their staff for their input and participation in this process review.

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FHWA

United States Department of Transportation - **Federal Highway Administration**

Appendix C

NCHRP MMS Report

Materials Information Management System Software Review
Final Report

Project: NCHRP 20-07, Task 157, Final Report

By: Ted Ferragut, PE

             TDC Partners, Ltd.

Date: February 17, 2003

To: Edward Harrigan, Senior Program Manager

             National Cooperative Highway Research Program

This final report is presented to the National Cooperative Highway Research Program under NCHRP 20-7, Task 157, Materials Information Management System Software Review. The Executive Summary and the Conclusions and Recommendations have been refined to reflect Panel comments and concerns. It also includes survey results from a Materials Management survey conducted by the NM State Highway and Transportation Department.

Materials Information Management System Software Review

Table of Contents

I. Executive Summary

The AASHTO Subcommittee on Materials (SOM) has recognized materials management as an important function that can help to improve data collection, storage, and analysis for both contract management and research purposes. While the SOM saw benefits in organizing collective efforts among the members, several initiatives to build off the AASHTOWare Trns*port SiteManager Module have not materialized. Several DOTs had initiated their own local programs with various levels of detail. The SOM's MaterialsManager Task Force decided to survey the DOTs to determine current status and to present a course of action. A contractor was hired by the National Cooperative Highway Research Project 20-7, Task 157.

The survey response was exceptional, with 45 state DOTs responding. The survey showed a wide array of individual DOT programs and initiatives. However, ten DOTs have initiated and implemented programs with five commercial Laboratory information Management System (LIMS) vendors, not including the SiteManager vendor. This expansion of the experienced vendor list should now allow other DOTs to piggyback and benefit from these pioneer efforts. This vendor option supplements the current AASHTOWare option, giving the DOTs the opportunity to 1) join in a national effort with licensing fees; or 2) develop and implement their own contract.

The respondents see sample tracking, quality assurance, and to a lesser extent data analysis as components of a materials management system. While 35% of the respondents use SiteManager, only 15% use the SiteManager Materials Module. The survey went on to show that there is a wide variation in materials management knowledge and application within the DOTs. The survey also showed that 40% of the respondents consider themselves novices in understanding material management systems while 50% see themselves as proficient.

Nearly all respondents see the need for a national coordination effort to further the development of Materials Management, though not necessarily through the adoption of a single software program or a central control organization.

Based on the survey results and the subsequent interviews with various DOTs and vendors, the following recommendations are offered to the Subcommittee on Materials:

1) Define a Material Management System so that individual DOTs can establish a program and direction. Include key strategic elements for developing a plan.
2) Do not identify or promote a single software solution. Do not establish a central controlled organization. There are sufficient experienced DOTs and software companies that other DOTs can draw of that experience and customize the software to their individual programs and needs.
3) Develop a support program that will give guidance to individual DOTs in the procurement of their own software, building off the work that the pioneer states

have accomplished. The support program should include Trns*port SiteManager Materials Module as one of the software programs.

4) Develop and share guide documents for the procurement of Materials Management software.

Expanding on these recommendations:

1) Develop a summary document that defines a Materials Management System and includes clear, unambiguous benefits. The SOM should look to AASHTO documents on pavement, bridge, and asset management for guidance. The document should clearly define terms such as materials management, laboratory information systems, and commercial off-the-shelf to minimize confusion. The document should also include an outline of the key elements of a strategic plan.

Provide guidance to the individual DOT Materials Offices in developing a structured approach. The Plan should recognize changing roles and responsibilities in quality control and assurance among contractor's suppliers, and DOTs. The Plan should also address linkages to other management systems – pavements, bridge, construction, asset, traffic, and safety, for example.

2) Develop a comprehensive technology transfer and sharing program. The program should include a website, list serve, case studies, hardware technology advances, etc. The AASHTO SOM should consider developing a "fair" to expand DOT knowledge of the various software systems.

3) Organize and share guideline procurement documents should DOTs elect to procure commercially available of software in lieu of using SiteManager Materials Module.

These recommendations do not preclude the use of the SiteManager Materials Module. There is enough evidence that it can be adapted to meet most of the needs of the Materials Offices. However, respondents and interviewees note that it takes a lot of patience and working through various AASHTO committee activities.

Materials Management Systems are one of the least developed of all the DOT management systems. Materials, however, may account for over 75% of the expenditures in a typical construction contract. Sample identification, tracking, and interpretation as to compliance are extremely important in the conduct of a construction contract. This need to track and report on samples on accelerated construction projects, for example, are becoming more critical.

Additionally, strategic decisions made from pavement and bridge management systems, ultimately come down to materials and material combinations. Fact-based decisions in the materials area should not rely on a collection of disconnected databases or spreadsheets but on a professionally organized approach to data collection and interpretation.

Lastly, the transfer of roles and responsibilities from the DOTs to contractors for inspection, quality control, and quality assurance require a shift in thinking of the

conventional ways to document programs. The future may even include contractor tests for acceptance and payment. It is important that the DOTs have a vision that includes this effort. A materials management system needs to be flexible to adapt to this evolution.

II. Background

Overview

In January 2000, the AASHTO Subcommittee on Materials (SOM) was balloted to gauge interest in a Trns*port MaterialsManager Development Project. This project was to develop an improved MaterialsManager module as an add-on component to the AASHTOWare Trns*port SiteManager module. Only 13 States agreed to participate in the MaterialsManager enhancement project at that time, less than the number required for implementation. Since that time, some States have developed their own Materials Management System (MMS) using COTS (Commercial Off-the-Shelf) software as a core. Some of these have been at costs well below what was proposed for the MaterialsManager proposal.

The MaterialsManager Task Force of the AASHTO SOM met August 2, 2001 to discuss the future of a joint effort to develop software for the management of materials tests and suppliers. It was identified at that meeting that some States had already implemented their own material systems using commercially available Laboratory Information Management Systems (LIMS). It was agreed that a comprehensive review of existing technology and currently available solutions is necessary before embarking on a totally new system. It should be noted that the original "MaterialsManager Project Proposal" included a proposed LIMS review, but at that time actual DOT implementation was limited.

Tasks

Task 1. Survey DOT to identify existing materials management programs and any associated COTS systems.

Task 2. Develop a list of 5-6 States that have successfully implemented a materials management system.

Task 3. Review those DOTs with successful materials management systems using site visits, telephone interviews, and documentation reviews.

Task 4. Prepare a final report identifying those issues related to the current options and providing a recommendation on a course of action.

Contract Award Date

The contract was awarded in June 2002.

III. Study Approach

TDC Partners discussed the issue in depth with the MaterialsManager Task Force shortly after award to discuss the issue and to collect all the appropriate background. TDC Partners then developed a detailed questionnaire that addressed the above Tasks. The questionnaire was sent out to the DOTs via the AASHTO SOM listserv. Forty-seven (47) of the AASHTO Subcommittee members responded to the questionnaire.

TDC Partners also did a thorough literature search and conducted face-to-face and telephone interviews with companies that provide commercial off-the-shelf LIMS software.

TDC Partners conducted on-site visits to four DOTs – Colorado, Michigan, Texas, and Wisconsin. Finally, TDC Partners conducted a telephone interviews with Missouri DOTs and a detailed review of Florida and West Virginia DOT documentation.

IV. Survey Results

Overview

The survey was sent out in July and held open through September 2003. Survey results are included in Appendix 8. There were forty-eight AASHTO respondents with forty-five representing state DOTs. Other respondents included the District of Columbia, Ontario Province, and an FHWA Division office. This was considered an exceptionally good response, showing significant interest in the subject.

In response to Task 1, to identify existing Materials Management Systems and associated COTS Systems, the following companies were identified as providing commercially off-the-shelf LIMS systems:

- Beckman Coulter (FL, VA, and MI)
- Ciber Custom Solutions (SD)
- LabVantage Solutions (KY, MN, and NY)
- Perkin Elmer Labworks (NH)
- Visual Solutions, Inc. (WI and IN)

It is worth noting that many DOTs are developing in-house programs, using a combination of in-house Information Technology (IT) and materials expertise, supplemented with software developers.

Twenty-seven (27) DOTs have some sort of formal computerized materials management information program underway. Of the twenty-seven (27), approximately ten might be defined as having a fully operational system. However, there is no universally accepted definition of a Materials Management System and it is not clear how a DOT rates its system compared to other DOTs.

TDC Partners conducted in-depth interviews with Wisconsin, Missouri, Colorado, Texas, and Michigan. West Virginia was found to have extensive documentation on their system. TDC Partners elected to interview two states in transition – Colorado and Texas – as both were considering options for commercial off-the-shelf LIMS versus in-house development.

There was no "silver bullet" in selecting any singular commercial system. All systems require extensive involvement by DOT personnel with both material and IT skills.

Some of the statistics have been rounded for clarity. Exact values can be found in the appendices. In addition, it should be noted that some respondents did not complete all the questions, or did not answer them exactly as instructed. In general, however, the trends that resulted were clear.

Respondents Profile

60% described themselves as technical, 50% as managerial. Some described themselves as both.

60% described their organizations as centrally managed, 40% as decentralized.

40% described themselves as novices in their knowledge of MMS, 50% considered themselves proficient, and 10% considered themselves experts.

Material Management System Functions

80% of the respondents believe that a Materials Management System should include sample tracking, quality assurance, and data analysis elements.

Of these three functions, sample tracking and quality assurance were equally considered important; data analysis was measured slightly less.

Status of Materials Management within the DOTs

60% of the respondents have computerized materials management in their DOT business plan.

70% of the respondents have some type of Materials Management System under consideration, development or in place. Nearly all see Materials Management as a continuing process.

80% see materials management as a function that will eventually be integrated with other DOT management systems. These systems include pavement, bridge, and asset management as well as traffic and safety systems.

Nearly all see total electronic entry (paperless) as the ultimate data entry mode.

Site Manager Usage

35% of the respondents use SiteManager.

15% use the SiteManager Materials Module. Of those using the Materials Module, approximately two-thirds found it inadequate for materials management and consider it more appropriate for construction management. Approximately 50% of those familiar with it judge it difficult to use.

Internal Management of MMS

75% see internal staffing and time availability as a major obstacle to full implementation.

65% see funding as a major obstacle for future development.

45% see internal implementation (coordination with other offices) as a major obstacle.

75% see the startup element as the primary challenge, 25% see sustaining the system as a significant challenge, once it is up and running.

75% of the respondents have adequate access to IT personnel.

70% of the respondents expect that data input will eventually be outsourced.

75% see highway contractors eventually entering test data into the MMS.

Brainstorming and Master Planning

75% would attend an organized brainstorming session. The session could include a thorough review of the MMS status, discuss MMS issues with the private vendors, discussion of a national strategy, develop detailed guidelines and best practice documents, or other such issues.

Benefits of the System

Improve overall quality assurance needs and improve business information practices were considered equally as the major benefits to be received from an MMS. One state identified the major benefit succinctly as "fact-based decision making". Other benefits include efficient use of personnel, integration with other management systems, and eventual linkage with contractor quality control systems.

Knowledge, Procurement, and Use of COTS

60% of the respondents had little or no knowledge of commercially available COTS systems.

20% of the respondents have experience with COTS. Those that use COTS obtained the services competitively. Nearly all believe it was a major effort to initiate the procurement and a major effort to execute it. It took continued evaluation and adaptation.

V. Field Visits, Interviews, and Literature Reviews

Based on the survey results, TDC Partners elected to interview Wisconsin, Missouri, and Michigan as states that had implemented or nearly implemented MMS. TDC Partners also reviewed West Virginia's extensive documentation of their system. TDC elected to interview states in transition – Colorado and Texas – as both had extensively evaluated their options for LIMS versus in-house development. The full reports are included in the Appendices.

In each interview, TDC Partners asked the DOT to provide a chronological description of how their system evolved. They were asked about the institutional barriers they faced and the depth of upper management support they received. The DOTs were also asked about future initiatives and how the system might be modified to accommodate changes.

Following are brief highlights of the interviews:

Wisconsin DOT (WisDOT)

In the late 80's, the DOT had a first generation material management system on a mainframe. While trend setting at the time, it proved to be difficult to input data, make programming changes, and report findings. A second-generation materials management system was initiated in 1995 in conjunction with a construction project management initiative. After attempting to have the original mainframe programmer modify the system to connect to the new system, the DOT ultimately decided to hire a second consultant to: 1) use some of the old data; and 2) provide new software that could be used more widely within the department within the framework of the new system.

WisDOT eventually developed three systems under the umbrella Material Tracking System (MTS). It addresses both field construction and laboratory material requirements in one system. The system allows for sample tracking, quality assurance, and some reasonable data analysis. The MTS system is available to the DOT, contractor, and suppliers' personnel, although only DOT employees may enter data at this time. Firewall security issues require significant software connections to link the field data to the mainframe.

The software system developer was retained to operate the MTS. One task was to maintain the system and provide user support to handle the replicate process from the field and the website posting. They are currently at a dedicated 1.5 to 2 full-time equivalent (FTE) effort, which should reduce to 1.0 FTE shortly. The developer also has been retained to do modifications and enhancements to the system – hard coding issues. However, the DOT has required the developer to allow the system to accept friendly "text" entry changes, minimizing the need for programming. This "text" entry system is able to accommodate nearly all changed to existing test procedures. With the system relatively stable now, WisDOT is considering releasing the developer and maintaining the system with their own forces.

WisDOT has probably been impacted more by the changing roles and responsibilities associated with quality assurance, independent assurance, contractor quality control, and new terms such as contractor assurance and quality verification. They consider the defining and freezing of quality definitions and programs as critical to easing the future software development.

Overall, they are pleased they decided to hire a developer and build the system from scratch. They found the Trns*port products difficult to use. While it did take time for the developer to gain an understanding of WisDOT language, needs, and operational flow, the DOT is pleased with the overall coordination.

As the quality umbrella is redefined, the system will be updated. The Materials Management System cannot, however, communicate efficiently with the other management systems in the DOTs, as they are on different platforms. This is a major initiative for the future.

Michigan DOT (MDOT)

In the early 90's, MDOT went to Total Quality Management, which included a major reorganization. This reorganization placed IT personnel in the various business areas including construction and materials functions. Under the concept of "business-process" reengineering, FieldManager was conceived, in part also to serious staff cuts. FieldManager connected the existing construction project system with additional materials requirements. The major thrust was to prove that a test result had been conducted and that material being recommended for payment had been approved. Eventually, FieldManager was incorporated into the AASHTOWare family of products.

While the initial MMS covered just field activities, it was only an "accident" that the laboratory effort was initiated. The process began with the construction and materials divisions being combined under reorganization, along with the general need for more automation. The existing laboratories already had their own systems, but it was difficult to: 1) make the data available for research, forensics, or performance analysis; and 2) move personnel from one laboratory to another without having to conduct relatively extensive training.

After evaluating SiteManager, MDOT opted to procure independent services. They chose Beckman-Coulter, even though Beckman-Coulter had no experience with highway materials management systems. Beckman-Coulter had LIMS credentials, but mostly in the medical field. Slowly but surely and with patience on both sides, the DOT and the developer established common language and, as a result, have developed a system to the point where it will be implemented early next year in the central laboratories and then the field laboratories. The system captures nearly all of the testing being done in the laboratory.

MDOT believes they will eventually have an all encompassing MMS, integrating the laboratory system with the field activities. However, MDOT is heavily into construction warranties and an asset management program. These two subjects really highlight the need for an all-encompassing material management system that is fully integrated with other systems - pavements, bridges, and traffic, for example. Since all are on the same database platform, this could be done. It would be a challenging task, but clearly in their future plans.

MDOT is pleased with the development of their own system. They believe that the learning curve the developer went through could be very beneficial for other states that desire to hire them for services. MDOT also believes that other states could combine resources and effectively use a standard product such as SiteManager; they will have to work hard on terminology and give-and-take. MDOT believes the lab and field systems are not as different as some like to claim – from a computer system standpoint.

Texas Department of Transportation (TxDOT)

In response to an internal need for a MMS, TxDOT recently began the development task by an evaluation of the various options available to them. This included their own survey of the states, where they found that the majority of the responders that had an MMS program underway were developing the system in-house. Although TxDOT uses the SiteManager system, they feel that there are limitations to using the SiteManager Materials Module, and desire to have a version that is more compatible with TxDOT test standards.

TxDOT is currently weighing the two development options:
1. Adoption and customization of a COTS LIMS; or
2. In-house development.

As part of their investigative phase, they have spoken with other states such as Florida, regarding their experience with a commercial vendor.

As part of this preliminary phase, TxDOT has developed a prototype of a LIMS system for the asphalt binder lab. This prototype is a functional system that allows the asphalt laboratory technicians to enter all of their test values and perform routine calculations.

With the prototype LIMS development for the central asphalt laboratory close to 100% complete, prototypes will also be developed for the remaining seven central labs. All the

laboratory prototype systems will capture current business practices, but are being developed with enough flexibility to add new test standards if and when they come online. Additional functionality will also be added, including direct connections to handheld data entry units and automated test equipment. The prototypes, as well as the final product, will be tied to the SiteManager system. TxDOT believes that even if a commercial LIMS is eventually selected, the work done in the development of this prototype will not be wasted, since it would serve as the basis for procurement standards for the commercial vendor.

Regardless of the procurement system they eventually deploy, TxDOT plans to address the development of LIMS for the soils, concrete and hot-mix lab functions, since these are the most common laboratory functions within the districts. The plan is to get the system functional in the central lab, and then migrate to the districts. TxDOT's policy is to lessen the load on the districts, so the central office wants to foolproof the systems prior to expanding the system to the districts.

If the prototypes are considered viable, the next step in the process is to develop a Project Management Plan. This Plan will include a detailed cost analysis of the various options. If the Plan is approved, a project team will be assembled that will oversee either the in-house development or work with a commercial LIMS vendor.

Finally, the one key TxDOT vision is to be able to call up a specific section of highway that will present all the technical information on that section. That will require integration with the Pavement Management Information System, the LIMS, and SiteManager. They envision being at that point sometime in the next 5 to 10 years.

Colorado DOT (CDOT)

CDOT has not implemented an MMS or a LIMS. However, they have conducted a very thorough review of their development and implementation options. Currently, CDOT uses Trns*port SiteManager, but not the Materials Module. A key CDOT objective for a MMS is to maintain compatibility and linkage to SiteManager. They recognize the need to organize their laboratory data, but they also recognize the need to analyze the data as well.

One of the reoccurring employee complaints about SiteManager is that it is difficult to use. Many CDOT employees are still not comfortable with computers technology, making the implementation of any system rather difficult. No matter what computerized option is eventually developed for the MMS, CDOT will not eliminate the paper process until they have employee trust in the new system.

Currently, the various central and regional labs use their own software applications to do materials test reporting, with most using spreadsheets. However, there is currently no connecting program and no overall master database. CDOT envisions that hot mix asphalt will be the first subject of a more formal MMS. Even though HMA is rather complex subject for computerization, the payoff could be extremely high.

CDOT has considered participating in a multi-state program, but feels that there are inherent problems with that approach. Since CDOT would not use AASHTO test procedures, they feel that there is no real cost savings to a pooled-fund effort. As a result, the most promising alternative to date will be to procure and customize a COTS LIMS. No matter which option is eventually selected, CDOT has already proceeded with developing flowcharts of their laboratory processes. These will be handed to the developer, who can use them to customize the system to best suit the needs of the department.

Some more progressive CDOT managers want to link wireless technology, handhelds, and automated equipment with the future MMS development. However, there are a number of fundamental requirements that are equally as important. These include the ability to update the test standards frequently in the software.

CDOT feels that the transition time for implementation should be short (maybe six months), or else people won't switch easily. One implementation plan is for CDOT to use one region as a model – to show how it can connect to control database, followed by implementation at the other regions. Alternatively, implementation can begin with HMA for all regions – followed by PCC, and so on. CDOT believes that implementation must be as seamless as possible.

CDOT recognizes that staffing the execution of the MMS will be an issue. They believe that employees would be preferred over outsourcing. Realistically however, a combination of resources would be acceptable, with a vendor to do some maintenance, and CDTO staff to do the rest.

One of the first data applications of the system will be to link MMS to pavement performance (PMS). This will allow the department to identify the quality characteristics that should govern the acceptance criteria and to determine the incentive/disincentive as well.

Missouri DOT (MoDOT)

MoDOT has been involved in the development of a MMS since the late 80's. When MoDOT decided to implement SiteManager in the mid-90's, it raised the need to link it to the existing MMS system. At about the same time, "year 2000" issues were also of concern; the DOT had to either update the existing in-house software or to seek out an alternative.

The driving question that needed to be answered was "what do you want the new system to do?" To answer this, MoDOT identified the numerous operations undertaken both in the field and the lab. After a thorough analysis of SiteManager, it was decided to develop the necessary management tools within the custom "test template" framework inherent in the SiteManager system. MoDOT further identified the need for additional third-party tools for more advanced queries and calculations not possible with SiteManager. After an internal evaluation, it was determined that enhancements to the MaterialsManager module within the SiteManager system would be the best approach.

MoDOT admits that SiteManager is not as easily customizable as what most users want. Although it includes a number of AASHTO test procedures, many agencies do not routinely use them, making SiteManager difficult to use "out of the box". Furthermore, there are some flaws in the SiteManager system that makes using even the default test procedure capabilities difficult or even impossible. It has been MoDOT's experience that many of the "limitations" can be overcome, but it will take some hard work and perseverance. For MoDOT, the hard work has generally paid off.

MoDOT believes that the biggest reason more states are not using the materials management capabilities of SiteManager come from preconceived notions about its limitations. States also have been investing in other alternative solutions, preventing them from considering the SiteManager alternate.

While some privately question the level of support provided by AASHTOWare for SiteManager, MoDOT believes that the SiteManager developers have provided them adequate support. However, MoDOT has expressed disappointment and frustration when the developers release the software to users without a more thorough debugging. As a result, it has taken them a long time and a fair amount of resources to work out the bugs once deployed within the department.

In general, MoDOT believes there would never be the same satisfaction with an outsourcing effort as there would be for an in-house effort. When bugs are encountered, or changes are needed, what could have been accomplished in a matter of hours within the department, now takes days or even weeks. Furthermore, if MoDOT decides that they would like a major enhancement, their options include 1) doing the work internally; or 2) go through the SiteManager task force and other official channels. If they make modifications to their version of SiteManager, the next upgrade of SiteManager generally eliminates the previous modification.

Within reason, MoDOT believes that SiteManager Materials Module can be connected to other department databases (e.g. pavement management). Eventually, it is expected that all databases within MoDOT will be connected. This will allow a particular pavement section will be tied to the materials used during the construction.

VI. Conclusions and Recommendations

While there are many conclusions in the report, the following capture the most significant:

1. No Single System. It was clear from the survey and interview responses that collectively the DOTs do not see the overall need for a single national Materials Management System computer program. There were two reasons given: 1) uniqueness of each materials program within the DOT; 2) desire to have tighter, more local control of the software development and implementation. Why are there no overriding reasons to procure SiteManager? Even though several DOTs believe that SiteManager Materials Module can meet most, if not all, the needs of individual DOTs, they do admit it takes

significant involvement in committee work and a clear understanding of licensing agreements in order to "localize" the software. This same effort would have to be applied with a local procurement.

2. Lack of Internal DOT Management Support. While the survey showed that some Materials Offices included MMS as part of their DOT's business plan, Materials Offices do not appear to have strong internal organizational support for the concept of an MMS.

3. Less than Proficient. Nearly 40% of the respondents rated themselves as novices in their understanding of materials management systems, with 50% rating themselves as proficient. Only 10% rated themselves as experts. In the "trickle up theory" it is believed that the managers above the materials function have an even lesser understanding of the concept.

4. Three Purposes, No Clear Winner. Overall, DOTs believe that MMS should include sample tracking, quality assurance, and data analysis. However, individual DOTs weigh each one differently.

5. Materials AND Information Technology Skills. While many respondents stated they had connections to IT specialists, the Michigan DOT actually assigned IT personnel to specifically work with the engineering and technician staff during the development of their program. Wisconsin DOT and Texas DOT both had personnel that had sufficient understanding of the computer science and materials skills. Both skill sets need to cooperate throughout the process.

6. Effective Pioneering Work. Several DOTs have done important pioneer work with commercial vendors. There effort should provide benefit to the other DOTs and as the vendors now have the "learning curve" behind them.

7. Vendors Speak Out. In confidential interviews with several vendors, they note a significant knowledge gap from one DOT to another. Most experienced vendors can easily detect whether a DOT is just beginning or has a clear plan. Unfortunately, few appear to have a plan in hand. This should not be interpreted as critical of the DOTs, just recognition that there are few guidance documents that DOTs can draw from.

8. One Vendor versus Another. There are no overriding quality reasons to select one LIMS Vendor over another, as long as they have highway materials experience. This includes the SiteManager Materials Module vendor.

9. Language and Definitions. There is confusion in the use of MMS language and definitions, resulting in misunderstanding among DOTs. Terms such as LIMS, COTS, MMS, are not the same among DOTs, and even within the DOTs. It is somewhat embarrassing to say that even the authors of this report tended to interchange terminology in the survey and in the interviews.

10. Wireless, PDA, etc. Several respondents discussed advanced computer technology that would be included in the MMS. They include wireless communication, automated lab equipment, PDA, and intelligent construction systems. While these cutting edge

ways of communicating and transferring data can impact the should be considered, getting a system up and running is many times more important than these system enhancers.

11. Benefits from Sharing. Even though the materials functions vary dramatically across the country, there was a sense that this might minimize the value of sharing information across state lines. In reality, there are many areas in MMS and LIMS that are common. What is not common across DOTs lines is a clear unambiguous description of the MMS process, flow, goals, and objectives. While it is too simple to say, "a lab is a lab", there are routine practices common to all. DOTs can share information and should continue to find appropriate ways to share ideas and to possibly economize in the procurement process.

Recommendations:

The following recommendations have been organized for the AASHTO Subcommittee on Materials and for individual DOTs.

AASHTO Subcommittee on Materials

1. No Software Dominates. The AASHTO Subcommittee on Materials (SOM) should not recommend to their members that they procure the Trns*port Site Manager Materials Module, should that member elect to develop a Materials Management System. Rather, the SOM should inform their members that there are companies that can effectively bid on and develop a Materials Management System that can be integrated with the other aspects of AASHTO's Trns*port software. Vendors now have products and experience with adapting their original software to DOT needs.

Once one or more DOTs procure from a single vendor they should develop a "user group" with that vendor to identify potential cost and time saving advancements that could be shared. The SOM should not establish a central control organization.

2. "What and Why Materials Management". The SOM should develop a generic paper on "What is Materials Management and Why it is Needed" The paper would include the overall description, goals, objectives, inputs and outputs, relationships to engineering, contract and project management, relationships to other management systems, the relationship to research, etc. This paper would be aimed at two audiences: the materials engineers themselves and higher management.

3. Links with Pavement and Bridge Management. The SOM should look for guidance from the other management systems, especially pavements and bridge, to draw comparisons, needs, and interrelationships. The SOM should clearly note that both pavement and bridge management systems will be limited in the future without a cohesive, integrated materials management system. The AASHTO Pavement Management Guide is a good reference document.

If memory serves the author, the AASHTO Joint Task Force on Pavements benefited from a cooperative effort with FHWA's Pavement Management Office and various technology transfer efforts under the old Demonstration Projects. The Subcommittee on Bridges and Structures likewise benefited from FHWA's joint efforts with Caltrans of PONTIS. The SOM should explore a cooperative venture with the FHWA to see if any technology services could be developed in an organized way.

4. Definitions. Within the framework of "What is Materials Management and Why it is Needed," it is recommended that the SOM develop clear, unambiguous definitions. In Appendix 1, some preliminary definitions have been offered for Task Force consideration. It is also recommended that a definition for "Materials Management System" be developed and serve as the umbrella over subordinate terms such as LIMS and COTS.

5. Technology Transfer. The SOM should develop a technology transfer mechanisms to better share experiences, best practices, and new technology. Several other ideas that should be explored include:

o Develop "How to ..." papers
o Develop a website, with interactive list serve capabilities.
o Collect and distribute a document that describes Site Manager much more clearly to the DOTs
o Collect and distribute procurement documents developed by various DOTs
o Conduct a "fair" at the Subcommittee on Materials and ask both experienced DOTs and vendors to present their programs.
o Share information on how the use of MMS-generated information has identified issues and resolved problems within the state.
o Share how DOTs and construction contractors and suppliers are working together in information sharing.
o Share how new hardware and communication technologies are being integrated with MMS.

Individual DOTs

The following recommendations are offered to individual DOTs, but should be included in the SOM's papers recommended above.

6. Long Range Plan – Each DOT. Individual DOT Materials Office should develop a long range plan for materials management that includes the definitions, purpose, goals, objectives, benefits, stakeholders, roles and responsibilities, and a timeline for development and implementation. It is problematic whether the strategic plan is endorsed by the DOT or just the Materials Office. The strategic plan serves two purposes: 1) to help the Materials Office organize a complex process; and 2) to help the Materials Office gain management's technical and financial support.

The stakeholders would include senior managers, central and district personnel, other database stakeholders, FHWA, construction contractors and suppliers.

7. Linkage with Other Systems. The strategic plan should clearly link the MMS to as many other management systems as possible – pavements, bridges, traffic, etc. As a minimum, is recommended that the MMS should use the same database platforms as the pavement and bridge systems and be linked through key fields such as mileposts, stations, GPS, etc.

It is recommended that these technologies be included in the strategic plan and be phased properly. It is probably more critical that the Materials Office have a skeleton program first and then supplement it with these advancements.

7. The Procurement Process – Well Defined. The DOT Materials Office should clearly define the procurement specification in as much detail as possible in order to obtain the services efficiently. This should include clearly flowcharting the operating system and laboratory functions. The DOT must also have a clear, staged implementation strategy.

It is important to clearly define the differences in the terms "LIMS Vendor", and "LIMS Vendor with Highway Materials Experience." A LIMS vendor has experience with large volumes of lab data, generally from the medical or food industry. A "LIMS Vendor with Highway Materials Experience" should have this same experience but with some additional experience with highway materials functions.

If a DOT elects to procure services, it is recommended they include a requirement for "prior experience with other DOTs" in the proposal.   Each vendor should clearly be able to identify this work experience to the procuring DOT.

8. Future Integration Efforts. It is recommended that the DOT Materials Office include in their strategic plan potential future roles and responsibilities among their organization and the construction contractors and suppliers. One major issue facing DOTs is the change in roles and responsibilities associated with all quality assurance programs. Flexible options should be considered for any future contractor role in quality control, quality assurance, independent assurance, etc.

9. Skills. It is recommended that the DOT Materials Office, in their strategic plan, identify the key skill sets required and assure that the resources are available before and during procurement of services.

10. First Things First. Earlier in the report, it was recommended that the DOT Materials Office develop an overall strategic plan. The question of what portion of the MMS should be implemented first, as it is highly likely that the procurement and development of a full system would be cost prohibitive. Starting points could include project generated sample tracking, central laboratory test documentation for certification lists, materials, central laboratory testing only, etc. There was no persuasive evidence that one starting point is better than another when implementing an MMS.

For a Materials Office that wishes to start with a laboratory option, a step-by-step is presented:

1. Develop an overall MMS framework, with definitions and upper management acceptance (implicit or explicit, as the case may be).
2. Develop LIMS framework with one central laboratory used as a model, for example, asphalt mix testing.
3. Add a second central laboratory once there is common knowledge, experience and actual benefits gained.
4. Add all central laboratories.
5. Integrate with all district laboratories.
6. Integrate with contractor and commercial laboratories

Checklist:
- ✓ Identify clearly the differences between PRODUCT tracking and PROJECT Tracking.
- ✓ Identify the test procedures that will be included.
- ✓ Identify individual test results requirements.
  - ▪ Option 1. Test Results Outputs
  - ▪ Option 2. Test Inputs, Calculations, and Outputs
- ✓ Identify personnel that will have INPUT rights.
- ✓ Identify personnel that will have OUPUT rights.
- ✓ Identify data population strategies, including data quality checks.
- ✓ Identify simple reporting needs first, followed by more complex reporting as required.

1. Appendix 1. Proposed Definitions

TDC Partners developed the first three proposed definitions:

Materials Management System (MMS). An integrated computerized database that keeps track of materials procured by the DOT. The system includes materials tested in central and field laboratories, on construction projects, and at manufacturing sites. The MMS is capable of providing sample tracking, quality assurance documentation, reports, and research analyses. An MMS may focus on: 1) the procurement process; 2) the performance process; or 3) both.

An MMS aims to assist decision-makers in finding optimum strategies for specifying, procuring and evaluating materials as they relate to highway infrastructure performance in items such as pavements, bridges, embankments, and manufactured items such as paint, signs, guiderail, etc.

Laboratory Information Management System (LIMS). A LIMS is a subset of a MMS that concentrates on sample identification, testing, and documentation of those products tested in a laboratory (as opposed to the field or to an off-site manufacturing facility). It is designed to allow the user to benefit from all the data that is collected within the laboratory environment. A LIMS should offer a range of functions for sample logging, tracking, reporting, archiving, querying, worklist generation, etc. In an analysis mode, a LIMS can be used to process results from instruments, trend data over a series of time points, automatically apply testing profiles to samples, result reporting along with numerous other sample-based activities. The benefits of a LIMS are to run the laboratory efficiently, reduce sample turnaround time, allow the rest of the organization to have improved access to information and eliminate duplication of work and errors.

Commercial Off-the-Shelf (COTS) Software. A software product that is available to a variety of users. COTS software is developed and sold for general use, as opposed to a specific user. A single user, however, can dictate the composition of or changes to the software. The developer has the ultimate freedom to control the software, whether to issue a new release or to otherwise modify the software without regard to the user. *Note: Currently, COTS software is available with LIMS functionality, but not MMS within a highway environment.*

The following definitions were taken from AASHTO literature:

AASHTOWare. This is AASHTO's joint software development technical service program. AASHTO member agencies have an opportunity to pool their resources and produce complex software solutions at a cost generally lower than custom in-house development, while allowing the users to develop a best practice approach as well. Included in AASHTOWare family is ***AASHTO Trns*port***. It consists of 12 components that address an agency's pre-construction and construction contract information and management needs.

Trns*port SiteManager*.*   A comprehensive client/server based construction management tool provided as one of 12 components within ***Trns*port***. It provides for data entry, tracking, reporting and analysis of contract data from contract award through finalization.   ***SiteManager*** is built on the same multi-tier architecture as the rest of the Trns*port suite allowing for easy integration and data transfer. It can be used by all levels of construction personnel such as field inspectors, technicians, project managers, clerks, auditors, lab personnel, management, producer/suppliers, contractors and the FHWA.

FieldManager*.* This is an electronic construction management system for managing and tracking construction projects, documenting construction progress, initiating contractor payments and communicating with an agency's central office contract administration system. It was designed for use by state departments of transportation, local government agencies, engineering consultants, large contractors or any organization that manages construction projects. The FieldManager suite contains three companion products that work together to comprise this powerful construction management system. They are, ***FieldBook***, ***FieldBuilder,*** and ***FieldPad***. The three work together to link field office and field inspection together. These products allow communication, data sharing, information management, and record keeping aimed at reducing inspector administrative time and costs.

Appendix 2. Missouri DOT Report

10 December 2002 (telephone interview)

<u>Participants</u>

Ted R. Ferragut, P.E. – President, TDC Partners, Ltd.
Robert Otto Rasmussen, Ph.D., P.E. – Vice President / Chief Engineer, The Transtec Group, Inc.
Denis Glascock – Missouri DOT

<u>Meeting Objectives</u>

The objectives for the meeting are to develop a chronology of the process of developing/implementing the MMS used by Missouri DOT, with a focus on decisions made along the way.

<u>How was the need established for the development of a MMS for MoDOT?</u>

In the late 80's, thru the 90's, in-house software was developed by MoDOT for materials tracking. SiteManager came along, and a goal was established to integrate the two software tools. As the year 2000 approached, issues with legacy software came up, partly due to the Y2K issues that many software programs were facing at the time. This spurred a need for an update to the in-house software – or else, to find an alternative.

<u>What was the preferred alternative for the MMS?</u>

After an internal evaluation, it was determined that enhancements to the MaterialsManager module within the SiteManager system would be the best approach. SiteManager was already helping with contract administration. The original developers of the SiteManager system recognized that an enhanced MaterialsManager module would be of assistance to a number of the then current users. The MaterialsManager module identifies if a particular material is approved, but there was a need to transition to more of a LIMS that could do routine tracking of materials. What many people didn't (and still don't) recognize is that materials tracking in SiteManager does NOT have to be project specific.

<u>What were the steps taken in developing the LIMS capabilities within SiteManager via MaterialsManager?</u>

The first question that needed to be answered was "what do you want it to do?" We needed to identify the numerous operations undertaken both the field inspectors and the lab technicians. Nearly 300 test procedures in total were identified. Interim tools for accessing the SiteManager have been developed and are continue to be used. These

third-party tools allow us to perform queries of the data that is more advanced than what SiteManager currently allows for.

What do you feel most current users of SiteManager feel about the materials tracking capabilities?

SiteManager is not as easily customizable as what most users want. It includes a number of AASHTO test procedures, but many agencies do not routinely use the ones that are included. In addition, many states have adopted test specifications that differ from the AASHTO standards, making SiteManager difficult to use "out of the box". Furthermore, there are some flaws in the SiteManager system that make using the default test procedure capabilities difficult or impossible.

How have MoDOT and other agencies overcome these limitations?

MoDOT has taken advantage of the "test template" feature of the SiteManager software. Some DOT's employ spreadsheets and other interface programs that go back-and-forth with SiteManager. This has allowed for straightforward customization. It should be pointed out that MoDOT's system is maybe 80% in functionality, although there really is no "100%" system out there. It is believed that the tie to construction is pretty good in the current system.

What are some of the specific strengths and weaknesses of the current system?

Periodic sampling of materials based on quantities of that material is handled well by SiteManager. However, sampling based on "construction units" such as per day or by station is more difficult. The sample tracking is not extensive in SiteManager – but is of enough detail to tell if a sample had been tested and checked. One benefit is the ability to check "approved materials lists"

How is the SiteManager system tied to other databases within the DOT?

Within certain limitations, the SiteManager data can now be connected to data from other databases (e.g. pavement management). Eventually, it is expected that all databases within the development and control of the DOT will be connected. This will allow a particular section along a pavement to be tied to the materials used during the construction.

Why are other states not enhancing the SiteManager materials capabilities like Missouri has?

The biggest reason is probably preconceived notions that people have about the limitations of the SiteManager software. It has been MoDOT's experience that many of the "limitations" identified by other users of the SiteManager system can be overcome. Another roadblock for other states may be that they have already invested resources in alternative solutions, and don't wish to stray from the decisions that have already been

made. Politics may also be a factor in the decision-making process. Of course, MoDOT would like to see other states take a more active interest in the MaterialsManager module, since Missouri can leverage its effort with others.

What advice would you offer for those still in the decision-making process?

It takes a lot of time and effort to understand a system as complex as a MMS. Many of the sales people of other LIMS systems may tend to over-represent the capabilities of their systems in order to make the sale, but a lot of work will remain in customizing the system for use by the DOT.

What about the support provided by the SiteManager developers and sponsors?

The support for SiteManager has come via a number of sources. AASHTO has not provided the level of support that was expected, from our perspective. The developers of SiteManager (InfoTech) have provided adequate levels of support. In general, they are available to the DOT when a call is made. However, it was disappointing that the developers released the software to the users without a more thorough debugging. It took a long time and a fair amount of resources to work out the bugs once deployed within the department. There is some concern with the "warranty" oversight by AASHTO.

In general, MoDOT wouldn't be satisfied with any vendor, compared to the responsiveness that they could have done in-house. Gone are the days of working all night to fix the bug. Now, they are at the mercy of the developer, which can take days or even weeks to address a bug. If MoDOT decides that they would like an enhancement – they either have to pay for it internally, or else go through the task force and other official channels.

Any last words of wisdom from your experience?

It is better to fix something that we have, then to start from the ground up. It has been very beneficial to have other states as "friends" in this process. Discussing issues with other states has led to better solutions. Maybe for the "common good", the DOT's should set aside the need to have a "100%" system, and pool their resources to develop a workable solution.

Appendix 3. Colorado DOT Report

19 June 2002 (Site Interview)

Participants

Ted R. Ferragut, P.E. – President, TDC Partners, Ltd.
Robert Otto Rasmussen, Ph.D., P.E. – Vice President / Chief Engineer, The Transtec Group, Inc.
Dan K. Rozycki – President, The Transtec Group, Inc.
Tim Aschenbrener – Materials Engineer, Colorado DOT
Gary Dewitt – Region IV Materials Engineer, Colorado DOT

Meeting Objectives

The objectives for the meeting are to develop a chronology of the process of developing/implementing the MMS used by Colorado DOT, with a focus on decisions made along the way.

What are CDOT's objectives related to MMS development?

CDOT wants to develop a system that maintains compatibility and linkage to Trns*Port SiteManager. We will have to push to get it thru – some at CDOT and others have reservations. We need to work with the regions. A good example is AASHTO 2002 – where we are working with Region II on implementation strategies. We need to speed up the learning process of how to work with data. We also need a way to better organize our data. It should be recognized that some people still don't like to use computers.
A big complaint about SiteManager is that it has a very "busy" screen – it is difficult to use. We will need to slowly take paper out of the process – to gain trust in the system that comes online.

What are some of the factors being considered during the MMS development?

An IT management team was formed for implementation because IS staff was overwhelmed. The current state focus is on financial systems, however in September '02, there will be a shift to asset management including MMS. It is envisioned that HMA would be first to come online. We plan to connect to SuperBase99 in Phase II (as well as links with other programs). We now use Millennium Asphalt instead of SuperBase99. Until then, we will use disks with other software in Phase I. Currently, the various central and regional labs use their own software applications to do reporting – some spreadsheet-based. There is currently no tie-in program or a master database.

<u>What features do you want in an MMS?</u>

Interested in Handheld OS (Palm or PocketPC) interface – there should be "considerable" emphasis on this in the near future. It may be easier to work with a handheld instead of a PC for many applications.   The success to this will be synchronization of the handheld with a desktop. We would like to have equipment w/ RS232 connected directly to system, since it is the standard protocol. It is desirable to have internal mechanisms in the software to alert users on outstanding items.

We also need to have ability to update the standards <u>frequently</u> in the software. This will require staff on board to do support. Government employees are preferred over outsourcing for support, unless there is a long-term commitment.   However, a combination would be good – with a vendor to do some maintenance, and staff in CDOT to do rest. CDOT just made decision to switch from Sybase to Oracle. This will impact the development process.

<u>What is your approach toward implementation of the MMS?</u>

There needs to be a seamless flow during implementation.   As an example, PMS implementation in CDOT has been painful – specifically data mining. The DOT really wants to link the MMS to PMS to find what QC's (Quality Characteristics) are the best ones to pay for. The QA program for PMS has been a critical issue. A big problem with SiteManager has been communication with remote locations.   Solutions considered include T1 and satellite. The LIMS should allow for maintenance off-line, and the ability to upload it later.

One implementation plan is for CDOT to use one region as a model – to show how it can connect to control database, followed by implementation at the other regions. Another implementation plan is to begin with HMA for all regions – followed by PCC. SiteManager was rolled out en masse – this caused problems. We need to implement in stages!

<u>What are your thoughts about a multi-state development effort for a MMS?</u>

A multi-state program has problems, since there are dissimilarities on data entry & handling. CDOT would not use AASHTO procedures – they use their own. Would the cost savings of a pooled-fund effort be an incentive? If it requires the DOT to change their procedures, they are not interested. Based on this, the preferred alternative has been to go with off-the-shelf software, and customize it.   Why should they pay development through AASHTO, and then pay again to customize it for CDOT? SiteManager has been difficult to get changes made. In preparing for development of the MMS, flowcharts have already developed for the processes in the labs – there will be handed to the developer.

Have you spoken with any of the commercial LIMS vendors?

We are aware of Beckman/Coulter working with Florida DOT. They have met with CDOT a couple of times to discuss their operations. These meetings have resulted in brainstorming to fully document the processes that aren't already on flowcharts. CDOT need to spend time in this process, since it is important that the final outcome be readily usable.

Is there a connection with Construction and Contractor QC?

How will construction people be involved? The first step is to insure that data is entered electronically. The forms would need to be specified. There should be restricted access by contractors. The project engineer has complete authority on project. Payment on materials via SiteManager would be there. This link would help the state not to have to pay without testing to support the quality. This would help to identify problems early on. Notification is key. QC/QA software could interface with the LIMS directly.

Any final suggestions and thoughts?

It is believed that a vision should be established prior to a MMS development – one that links PMS, QC/QA, PRS, etc. SiteManager was sold to "managers" – too little emphasis was placed on human interaction and maintenance. The transition time should be short (maybe 6 months). It must be short, or people won't switch easily. There is a need to emphasize the savings, not just the costs.

HMA's labs are probably most difficult process to deal with since they have the most information. The opposite (simplest) is probably guardrail inspection. PDA's should be considered. They work now, especially for inspectors in the field measuring things like asphalt yield. Both Palm & CE are good platforms – CE is preferred if there are calculations. It is believed that Connecticut has a system using Palm OS on the field. IS doesn't completely support Palm yet – they see it as an extra border – no staff or interest. It is recommended that we have more discussions with FL and WI.

Appendix 4. Texas DOT Report

25 October 2002 (Site Interview)

<u>Attendees</u>

J. Jeffrey Seiders, P.E. – Assistant Director, TxDOT Materials and Pavement Section
Ahmed Eltahan, Ph.D., P.E. – Engineer / Supervisor, TxDOT Materials and Pavement Section
Hisham Makkouk – LIMS Prototype Developer, TxDOT
Robert Otto Rasmussen, Ph.D., P.E. – Vice President / Chief Engineer, The Transtec Group, Inc.
Dan K. Rozycki – President, The Transtec Group, Inc.

<u>Meeting Objectives</u>

The objectives for the meeting were to develop a chronology of the process of developing/implementing the LIMS and the future MMS and to focus on the decisions made along the way.

<u>Beyond the NCHRP study, are you aware of other ongoing work in this area?</u>

TxDOT had conducted their own survey of the states recently (via the AASHTO listserv) regarding MMS. The final results were assembled in September. The results of the survey were used to develop trends of LIMS vs. in-house development of a MMS. There were 27 responses to TxDOT's survey. (11 responses indicated internal development, 8 indicated external (COTS) development, 8 indicated no development)

<u>TxDOT uses SiteManager. Why are they pursuing a Materials Management System (MMS)?</u>

Several years back, Bobby Templeton started the process for SiteManager. It was quickly recognized that SiteManager needed a materials "add on". AASHTO balloted for a better materials manager – which did not pass. An in-house initiative was made at TxDOT due to the slow scheduling of the national (AASHTO) initiative. Mr. Seiders served on the TxDOT team to implement the SiteManager system and saw some of the limitations of the system first-hand.

<u>What options is TxDOT considering for the development of the LIMS?</u>

Two options are being considered for the Laboratory Information Management System (LIMS): in-house development and procurement and customization of a Commercial Off

The Shelf (COTS) Software. In this investigative phase, TxDOT has spoken with Florida DOT re Beckman-Coulter's LIMS system. Beckman-Coulter has also made presentations to TxDOT, including a recent follow-up visit. Ahmed and Hisham are spearheading the in-house evaluation of LIMS options.

How is TxDOT beginning the decision making process in how to develop the LIMS?

A prototype of a LIMS system for the asphalt (binder) lab has recently been completed. Note that this is a prototype and not a "program" which requires numerous TxDOT approvals. The prototype is a functional system that allows the asphalt lab to enter all of their test values, and performs routine calculations – storing all of the interim and final values. If a LIMS is procured – there would have to be customization anyway. The prototype work that is being done now will not be wasted, since no matter what option is selected (off-the-shelf or in-house), the functionality will be clearly defined. Ahmed and Hisham believe that a COTS would likely not save much development time, since customization and population of data fields is extensive.

How will the Prototype LIMS be developed?

The current prototypes are being developed to 100% for current business practices, but are developed flexible enough if/when new standards come online. More advanced functionality – such as direct connections to handheld data entry units and test equipment via their ports – is envisioned for the next phase.

The asphalt lab is the first of eight (8) labs that will require development. The prototype essentially "automates the paperwork" in the lab. The asphalt lab was selected first due to an internal initiative for better automation. The prototype is being developed with a tie to the SiteManager system – but it is important to note that testing in the (central) lab is often categorized by producer, where SiteManager is by project. Hisham has been assigning both project IDs and Unique IDs to the data, so that the data can be sorted by either project or producer. Work is underway in developing a prototype system in the chemistry lab (30-35% complete); the soils lab (30-35% complete); and just underway at the concrete and hot-mix labs.

What is the connection between the Central Lab and the Districts regarding the LIMS?

More emphasis will be made in prototype development for the soils, concrete, and hot-mix labs since these are the most common within the districts, and will expedite implementation there. Three or four districts are very interested in the LIMS system – and attended Beckman-Coulter's presentations. The plan is to get the system functional in the central lab, then migrate to the districts. The policy of the department is to lessen the load on the districts, so the central office is minimizing promises about the system until it is proven.

<u>What will be the form and functionality of the LIMS?</u>

Sybase PowerBuilder is being used in the development of the prototype system. SiteManager was a "something for everybody" system. What was needed was a LIMS plug-in for materials. The plug-in should be flexible enough to quickly customize to Texas' test methods. Some of the features in the current COTS systems are nice, but not necessary – e.g. the more sophisticated statistical analysis features. The more advanced user should also be able to make modifications to the inputs – to update it to changing specifications, methods, or equipment.

<u>Who will use the LIMS data and how?</u>

If the LIMS is done right, it will allow the user to plot trends in the data. Researchers for TxDOT also believe that the LIMS data will be very valuable. For example, Amy Epps of Texas A&M is currently performing an analysis on asphalt producers – the LIMS data would save time and money in this type of analysis. The big vision is to allow for a specific section of a specific highway to be called up with the various TxDOT databases – giving a full picture of what is there. This includes the PMIS database, LIMS, and SiteManager. The LIMS data will be used in three places: management, SiteManager, and the mainframe. TxDOT envisions being at a place to tie all of the databases together within 5-10 years.

<u>What are the next steps for the development, deployment, and implementation of the LIMS</u>? The basic position of the department is to try things out on some projects – and expand only if successful, or if the appropriate changes have been made. After the prototype concept is complete, the next step for the department is to initiate a Project Management Plan, which them has a cost analysis done, and if selected, proceeds to where a team is assembled. Version control has already been built into the development of the prototype to assist in the development. Changes that are made to the system will automatically be disseminated. TxDOT wants to complete the prototypes for the central lab, and to begin working with some of the districts before deciding on whether to do in-house development, or to go with a LIMS vendor.

Appendix 5. Michigan DOT Report

6 September 2002 (Site Interview)

<u>Attendees</u>

Marty Forster, MDOT FieldManager Technical Specialist (MF)
Kevin Fox, MDOT System Administrator (KF)
Mike Ledyard, MDOT Systems Support Manager (Acting CIO) (ML)
Judy Ruszkowski, MDOT LIMS Project Manager (JR)
Ted Ferragut, TDC Partners, Ltd.
Rob Rasmussen, The Transtec Group, Inc.

<u>Meeting Objectives</u>

The objectives for the meeting are to develop a chronology of the process of developing/implementing the LIMS and the future MMS and to focus on decisions made along the way.

Ted gave an introduction to this project and our role and discussed some of the general findings from the questionnaire. Only a few states, Michigan being one of them, have structures in place to develop a full and integrated system. Ted mentioned that the "Intelligent Construction Systems (ICS)" concept is being discussed in earnest within the F-SHRP Rapid Renewal initiative. The ICS initiative is a vision for the future – an automated process to help the industry build things better and access information more efficiently. MMS is a step to this.

<u>Can you describe how the LIMS and FieldManager concepts began?</u>

In 1992/1993, MDOT went to Total Quality Management (TQM). At the same time, MDOT was involved in a major reorganization. Information Technology (IT) was decentralized and moved into the various business areas.

Once a year, there is a call for IT projects with the goal of developing projects to simplify work. These ideas are filtered through various departments and prioritized. The second-to-highest level includes a combination of IT and management types. Final recommendations are given to highest management level for approval and funding. This overall process is not unlike other approval processes in MDOT.

By the time the idea has made it to the highest level, a lot of background work has been done (e.g. questionnaires). A business needs analysis is done early on, often done by an outside group. A technical needs analysis is then done.

For each project, there is a business project manager (engineer-type person) and a technical project manager (IT-type person). Nearly always there is a project "champion" are in place at higher management levels.

The FieldManager project was conceived around 1994 or 1995. Business-process reengineering came at about the same time as significant staff cuts – this led to more automation.

Can you expand upon FieldManager and its background?

It needs to be stated that materials are looked at from two perspectives. Construction looks at materials much differently than the different laboratories. The needs are very different. Additionally, each laboratory (e.g. concrete, bituminous) was uniquely independent. They all had their own way of tracking and storing data.

An early system - Construction Project Record Keeping System (CPRKS) - helped the construction folks to look at the tracking of material use for a given pay-item. This was in response to the need to control the usage of the material and to prove that a test report existed approving that material.

FieldManager was viewed as requiring more materials detail in the construction effort, beyond CPRKS. At this time, a closer look was taken on the laboratory automation requirements as well.

FieldManager has been a success due to the partnership with the developer, InfoTech. There was constant communication between all parties. Even the individual programmers were involved in the business meetings – and were made to understand the business process.

One of the requirements of a business review was that the LIMS and the FieldManager needed to be tied together at some point in the future.

And then MDOT moved toward a LIMS?

The process began by essentially "stumbling onto each other" when the construction and materials divisions were combined. Test report automation also came out of the high demands for quick turnaround of test results. Automation was also looked at to make things more efficient – starting with small computer programs and spreadsheets.

During the LIMS concept development, there was always the question of how much information to capture into the existing databases (e.g. tare weights). The review included an assessment of where data was coming from, especially "hand keyed" data entry. It was not a new issue within the department. As far back as 1972, entering and processing laboratory data was a multi-stage process requiring a number of individuals.

<u>Was there any momentum to move in this direction from anything being done nationally?</u>

Yes there was. The MDOT initiative was just about the time that AASHTO had major initiatives in these areas - BAMS and the TrnsPort.

<u>Was any area particularly difficult to capture?</u>

One area that was difficult to capture at the source was the materials acceptance. At that time there was only LIMS, which had the goal of automating it, but was being phased in. At times, it seemed like that construction was only interested if the specimen passed, not necessarily the test result itself.

<u>Have you addressed the field testing issue yet?</u>

MDOT has not tackled the field testing issue yet. So far, it only includes lab testing. Field testing will be addressed in the next phase.

It was noted that the error rates can be quite high in this process.

<u>What was the catalyst for the LIMS?</u>

The Division recognized the need to improve overall division-wide coordination. Part of the problem was that the individual labs had already established their own databases. The impetus for the LIMS was to make things more efficient for those individuals that needed access to data for each of the labs. For example, if somebody wanted to consolidate the information for a given project, under the existing system, this would be quite difficult.

The LIMS process started with automating the test reports, followed by automating the reporting system, then automating data entry, calculations, pass/fail, and data storage/mining.

ML says that the various divisions in MDOT began to move towards a more process-oriented approach: how is data flowing from one division to another? Automation is being done to work within this process.

<u>Was there a top down master plan for the process?</u>

While there is no big master plan, there is a constant reevaluation of the business practices including short-term and long-term solutions. MDOT is trying to get new systems up and operational in a shorter period of time. This has resulted in more phased approaches.

How was the LIMS justified?

Two approaches were used in justifying the LIMS: 1) make the data available long-term for research/forensics/performance analysis; and 2) with so many little databases and levels of automation in each of the labs, a need was there to have a common system in place in order to more efficiently move people and data from one lab to another if needed. Even the regional labs were storing and processing data different than the central lab. The regional labs do more of the routine, low-tech tests. Central does a much greater variety of tests.

How did you select in-house versus commercial off-the-shelf?

An analysis was done in-house to determine how the system should be developed – in-house versus commercial off-the-shelf. SiteManager was also evaluated as an option, including the MateralsManager component of SiteManager.

MDOT released an "Invitation for Bids" (IFB) and interviewed various vendors. The IFB included a lot of detail. The vendor demonstrations required in the IFB led the Department to believe that one or more could be easily configurable to MDOT requirements. The decision was then made to adapt off-the-shelf software to MDOT requirements. By the way, the detail in the invitation to bid eventually became the contract language.

And you chose Beckman-Coulter?

Yes. They meet the requirements and price. The next highest bidder was four to five times higher in cost. However, even after Beckman-Coulter was selected, it was very difficult since they did not come in with any experience in the highway area. In hindsight, it probably would have been better to require Beckman to bring on engineers and materials people. Beckman probably didn't know how much work was going to be involved, and once they got into it, they had to be very careful so as not to go beyond their costs. Beckman doesn't get paid until they deliver the project as specified. Overall, MDOT is pleasantly surprised with Beckman's product.

Where are we in the LIMS contract?

The LIMS has both a client-server and a web interface – acceptance testing for the contract has been completed for the client-server, and is about to begin for the web interface. MDOT is looking to close out the contract at the end of the year, implement it in the central lab, and then roll it out to the regions.

MDOT believes they are very close to capturing most of the processes being done in the lab. The key has been to set up the various test protocols. Once setup, entering the data is easy.

Overall, both parties have been very patient with each other. They both recognize the difficulty of the task but also recognize the enormous long-term payoff.

Where there any major changes in the scope since the contract began?

The only real change from the original scope of the LIMS project had included direct-entry of the data from automated test equipment. Beckman is adaptable to do this in the future, even though this element has been cut from the first phase of the project.

Where are you in developing an overall Materials Management System?

We are in the process of establishing the business requirements for their MMS. MDOT is very strongly dedicated to warranties and asset management, which requires the power that a MMS can provide.

How much data will be captured?

The question is constantly being asked: how much do we need to capture in the database? The answer comes down to the cost-benefit analysis. Simple calculations can be done easily. More complex calculations can be exported to other software for processing, making it better to export it in those cases to more efficient calculation programs. Some of the researchers most definitely want more data than what is reasonable to capture, so they are constantly reminded that the system is for capturing data – not for sophisticated data analysis.

Can you describe the security or quality control of the data entry?

The LIMS system has 3 levels for security/quality control – data entry by the lab tech, verification of the results, and approval of the results.

Who will do the populating of the LIMS database?

Beckman is setting up the database, MDOT does the population. After the contract, MDOT could update the database, adding new tests, for example. Alternatively, Beckman may be hired to do it. Beckman supplies tools to make the changes and updates to the database (e.g. LIMS Builder). The department had to train staff on how to enter the data into the system.

As a minimum, Beckman will be in place on a technical support contract. The first contract will be for one year, and annually renewable.

Data entry starts with data generated today. One of the elements of the Beckman contract is to look at the older databases and see how it can be included. That would be a separate project though.

Can you share the cost for the B-C contract?

The Beckman contract is for $358,000. However, it's important to note that MDOT supplies about two FTE's to help in development and implementation.

<u>What is the platform for the database?</u>

MDOT's LIMS and other databases are Oracle-based. This allows us eventually to link all new databases.

<u>Who will have access to the LIMS?</u>

The LIMS will only be available to MDOT in the first phase – consultants may have access to it later on, if laboratory testing becomes more privatized.

<u>How have the LIMS intellectual property rights been handled?</u>

The State of Michigan owns their LIMS, but Beckman may be able to go to another DOT or private testing labs to sell their system.

<u>Have you talked with other DOTs on your work?</u>

We are in contact with FLDOT's Phil Lancaster. The FLDOT has a contract with Beckman as well. Analysts from MDOT and FLDOT are working together as well. Florida has a much broader scope than Michigan. Florida wanted a system to include data input and extraction by contractors and consultants.

When talking with other DOTs, there has to be a strict definition of terms: "LIMS", "MMS", and other terms need strict definitions for proper communication.

<u>Do other departments have access to the LIMS and FieldManager data?</u>

Currently, much of this data will be put into the same physical database – so the pavement management people will have access to the LIMS and/or the FieldManager data. Data has to be shared between the divisions – this is paramount to the overall system architecture. There is always the need to better link the various divisions in the organization.

A platform is being setup so that data from virtually every source can be brought together at a future date for any reason.

<u>Are you sharing your databases with private contractors?</u>

FieldManager is out and available to the contractors in the field right now. As part of a pilot project next season, everybody on a project will have access to the raw data (read only) from the FieldManager.

<u>There is the term "Intelligent Construction Systems" that seems to be catching on, with one part of the definition to utilize test data as real-time feedback – to</u>

<u>improve the construction operations more efficiently. Have you addressed this concept?</u>

LIMS is a key to getting there, a part of long-term systems performance knowledge. Spatially referencing materials along a construction project is very important. Having a common database for materials and construction is also important.

It should be noted that safety is major issue within the Department. It is an important linkage to prioritizing and financing future elements of the program. Eventually, this database will provide key information to trace how materials may affect safety.

ML says that with the LIMS, the taxpayers' money is being spent more efficiently. This is a necessary step since the workforce is decreasing.

<u>How are you connected to AASHTO's work?</u>

The Department is looking at replacing some of the existing databases with SiteManager. MDOT is pushing AASHTO to ensure that FieldManager continues to be supported.

The solution MDOT needs will need to work with both the LIMS and FieldManager – and hopefully AASHTO will adopt this type of solution.

<u>What is your biggest challenge facing MDOT?</u>

A new Department of Information Technology has been recently established by the governor. The MDOT is now assigned IT people from this new department. It appears there is a state, if not national, movement to recombine IT personnel. However, in order to be successful on a large project like this, all agreed that the IT people need to be partnered closely with the business people.

Believe it or not, this is one of the biggest challenges current facing MDOT IT is the consolidation of IT into a new state department. The current system of IT personnel being assigned to the operating division has been very successful.

<u>Do you think each DOT needs to fire an individual contractor? Or can a DOT adapt from a standard product to their particular use? What about different DOTs cooperating?</u>

For Michigan, a standard AASHTO product could probably work. It seems that if flexible enough, a DOT can adapt it for its own use. Differences in terminology could be an issue – especially if a DOT uses different standards than the AASHTO's standards. While everyone always says there are a lot of differences between the various DOTs, their experience in working with other DOTs really boils down to differences in terminology. The major issue is the different categories for tests, especially those for research and development.

<u>There are Pavement Management Systems, Bridge Management Systems, LIMS, MMS, Safety Systems, SiteManager, etc. How will this all work together?</u>

It would be a daunting task to attempt to link at all these systems as one integrated system. It is important to recognize that eventually it will and should be done. There are even databases outside MDOT that will be linked with other state governmental agencies. MDOT is using the same platform and recognizes that eventually all will be integrated. It was important to MDOT that each incremental step be done well, recognizing the bigger linkage is still ahead.

Appendix 6. Wisconsin DOT Report

25 November 2002 Site Interview

<u>Attendees</u>

John Volker, WI DOT
Tom Brokaw, WI DOT
Ted Ferragut, TDC Partners, Ltd.

<u>Meeting Objectives</u>

The objectives for the meeting are to develop a chronology of the process of developing/implementing the LIMS and the future MMS and to focus on decisions made along the way.

Ted gave an introduction to this project, TDC Partners' role, and an overview of the general findings from the questionnaire. Only a few states, Wisconsin being one of them, have structures in place to develop a full and integrated system. Ted mentioned that the "Intelligent Construction Systems (ICS)" concept is being discussed in earnest within the F-SHRP Rapid Renewal initiative. The ICS initiative is a vision for the future – an automated process to help the industry build things better and access information more efficiently. MMS is a step in this direction.

<u>Can you describe how the LIMS and FieldManager concepts began?</u>

In the late 80's, the DOT had a first generation materials system on a mainframe computer. It was developed using a difficult programming language (by today's standards) and was not conducive to changes. It was construction project oriented, with test data entry. While it allowed data entry, it would not allow any program changes, and had no sorting or data reporting capabilities.

At the same time, there was another emerging issue on project management and data entry. The DOT was looking at electronic data entry in the field. The DOT attempted to use the same consultant that managed the mainframe system to design the new system, but ran into serious problems.

In 1995, the DOT wanted to get materials testing information out to the districts and to integrate this information with the districts' material testing information. The DOT looked into a web-based system, but had a number of technical issues. The consultant (same as the one managing the main frame project) was hired to do the project had two tasks: one for contract administration, and the other for materials control. The materials office wanted the same look and feel, since the data came from one office. Eventually, the DOT had to hire a second consultant. The new consultant was able to

use some of the old data, and came up with some very good software that was usable and widely accepted within the department.

Where do you stand now on your program?

The DOT has three integrated systems. The umbrella is the Material Tracking System (MTS). It is a computerized filing and reporting system for construction materials tests. It is on a permanent database (Oracle), with all data stored on a mainframe and uses a Windows environment. The MTS can be accessed via a wide area network (WAN) in the central lab and in the districts' main labs via the Web.

Within the MTS is the MIT – (Material Information Tracking) System. This is Field Manager. It transmits data from the field via PC to central office. Only authorized personnel can enter test data.

To view the overall test data, field and remote uses can view reports that include all laboratory data from central and from the districts. This is the called the Material Tracking Web (MTW) site. Anyone with access to the Internet can register to view the site.

Currently, the MTS is on the other side of the firewall from the MIT to maximize security. There is an automatic connection that links the systems and examines QA issues. Outsiders can download MIT data through the MTW stand-alone package provided by the DOT. This is and will be the primary access technique for suppliers and contractors.

The entire issue is about four years old.

The next generation will be the Material Report System (MRS).

When you started the system, did you do it lab by lab?

The DOT's original focus was on the entire laboratory, rather than the asphalt laboratory, then concrete, etc. We have approximately 24 different test forms currently in the MTS. This would vary by each section of the lab. For example, the asphalt binder is considered one test result with all of the "subtest" components entered. Many engineers and technicians have data and calculations on Excel files; we are attempting to eliminate as much of this as possible. In some cases, where a PC is doing the testing and the calculations, we are trying to transmit this information directly to the MTS. This has helped with laboratory certification.

What do you mean by "data analysis"?

Data Analysis is looking at the components of test information that makes up the test and looks at how these results impact the quality system. It is currently calling up data and transmitting it to one report file for analysis. It can be a routine or a canned analysis. For example, this may include looking at changes in aggregate source data

over time. Some of the analyses would get formal file names and could be called up routinely.

What do you see as the major benefits?

Quality assurance is the number one need and the system helps us enormously. We are looking to adding better reporting which will also help us.

What new refinements are coming on board?

The DOT will be adding additional material types, improve the reporting and analysis techniques.

How is the system managed?

Basically, the original firm that designed the system now operates it. The DOT has two elements within the contract:

1. Maintenance. A maintenance clause that calls for user support, at the rate of 1.5 to 2 person-years of effort. They handle the replicate process with data from the field and the website posting. The DOT would like to move it back in-house, as the workload is diminishing significantly. This should eventually move to 1 person-year of effort.

2. Modifications and enhancements to the original MRS, MITS, and MRS. There is also less to do as time goes by, with a fairly consistent work load. One issue is to update changes to the testing specifications. The DOT is trying to eliminate hard coding programming. On some of the test procedures, the DOT can make the changes by adding text files. This would include footnotes or embellishments to the test program, but not to the test calculations or results. It would include updates to approved supplier lists, etc. The workload is fairly consistent, with 2 person-years working on the modifications.

If I used the term sample tracking, what would it mean to you?

Sample Tracking is the ability to track samples from the date sampled, received, tested, verified, etc. The dates are currently in the database. By March 2003, we should be able to search and sort, through a canned report procedure, any of those dates. However, we will not include MUST HAVE dates in the system. This will be done manually, via telephone or email, outside the system.

<u>Let's talk about the how the quality system and software? How will it work together?</u>

Good question. First of all, WDOT defines *Quality Assurance* as the <u>overall</u> assurance process of meeting the requirements, the umbrella, if you will, over the entire program. It falls under the DOT's Quality Management Program (QMP). It consists of three parts:

1. **Quality Control Data.** This is the testing and monitoring of the product by the contractors and suppliers[1]. In the MRS, the DOT eventually wants this all this data in electronic formatting. This decision will require a ten-fold increase in database size and reporting requirements. Currently, the DOT is getting the information on paperwork only. We really need to look at what we are going to do with all this information prior to initiating the effort.
2. **Contractor Assurance (CA).** This is a new approach, similar to quality verification testing by the DOT. It calls for the contractor to conduct second level evaluation of the QC program. It too will be put into the computer.
3. **Quality Verification (QV) Testing.** These are DOT tests that are done on the final product to substantially accept the results from the contractor quality control testing. It also includes some second stage testing, where there is no actual contractor testing, for example, traffic striping.

While the Independent Assurance Program (IAP) is part of the overall QMP, it is very tricky program. It is not project-related. The results go into the MTS. It is a basically a checklist of qualifications and the test results to see if the independent checks are within tolerances. It is done on a program-by-program basis.

<u>What are your thoughts on Trns*Port?</u>

The DOT had some problems adapting to it. It was difficult to work with. The DOT believed it would take more effort to customize it. It was almost easier to start from scratch.

<u>What about future integration with other Management Systems – Pavements, Bridges, Safety, etc?</u>

We have the Materials Management System, Project Tracking System, Bridge Management (Pontis), Pavement Management, and Traffic Databases. We would like to say we have integration resolved but we don't. Unfortunately, we have different platforms. The Materials Systems Tracking (MTS) will have linkage with the Project Tracking System through project numbers. It is a major future challenge to connect the other systems together.

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[1] The DOT does no quality control. It is all done by the private sector.

<u>What would your recommendation be to the other DOT material engineers?</u>

If you are initiating a system, it could be approached first from a LIMS perspective or from a Materials Management System. Our focus was on the districts and considering them as customers. This allowed for the development of integrated laboratory and materials management systems, with a lot of focus on the overall materials management systems approach.

The second recommendation is to look to the future and make sure that the materials management system is fully linked to the other databases. That will allow for future linkage.

Appendix 7. Additional Information

The following appendices are available on request:

1. "Proposed Enhancement of the Material Function of SiteManager by MoDOT," dated April 3, 2001
2. AASHTO Trns*Port Materials Manager Solicitation, dated November 22, 1992
3. "The Role of the Materials Specialty within SiteManager," by Colorado DOT, dated April 12, 2001
4. Laboratory Information Management System Contract P0304, Florida DOT, dated June 6, 2000
5. Michigan Department of Transportation Materials Testing System, Contract Number 071B1001378, dated 2001.
6. Wisconsin DOT Material Tracking System User Guide, dated September 4, 2001.
7. WVDOT Materials Management System (website last accessed December 13, 2002)

Appendix 8. Summary of Survey Results

This appendix includes two versions of the survey. The first is a summary of all the survey results. The second includes all the comments included in the response.

Appendix 9. New Mexico State Highway Department Survey Results

This appendix includes a recent survey completed by the new Mexico State Highway Department.

Appendix D

SHA MMS State of the Practice Report

Materials Management System
State of the Practice Review

Prepared for:

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MACTEC Project Number 6420040001, Task 8.2

May 10, 2006

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APPENDIX A – REFERENCES

INTRODUCTION

This document provides an overview of the State of the Practice review concerning Materials Management Systems (MMS) conducted by MACTEC. Primary sources for this review included information compiled by the Maryland SHA as part of its implementation efforts including results of a NCHRP study on this subject, as well as internal SHA meeting minutes, notes, and working documents. An internet search was also conducted on the subject including review of the Transportation Research Information Service (TRIS) and Research in Progress (RIP) databases. This document serves as a compilation and summary of this information.

MATERIALS MANAGEMENT SYSTEM FUNDAMENTALS

In our industry the term "Materials Management System" has many connotations and definitions. There seems to be confusion as to the true meaning of the term MMS as it is commonly, and incorrectly, referred to as a Laboratory Information Management System, or LIMS. NCHRP project 20-07, Task 157 (1) offers relevant definitions for both terms:

> *"**Materials Management System (MMS)**. An integrated computerized database that keeps track of materials procured by the DOT. The system includes materials tested in central and field laboratories, on construction projects, and at manufacturing sites. The MMS is capable of providing sample tracking, quality assurance documentation, reports, and research analyses. An MMS may focus on: 1) the procurement process; 2) the performance process; or 3) both.*
>
> *An MMS aims to assist decision-makers in finding optimum strategies for specifying, procuring and evaluating materials as they relate to highway infrastructure performance in items such as pavements, bridges, embankments, and manufactured items such as paint, signs, guiderail, etc.*
>
> ***Laboratory Information Management System (LIMS)**. A LIMS is a subset of a MMS that concentrates on sample identification, testing, and documentation of those products tested in a laboratory (as opposed to the field or to an off-site manufacturing facility). It is designed to allow the user to benefit from all the data that is collected within the laboratory environment. A LIMS should offer a range of functions for sample logging, tracking, reporting, archiving, querying, worklist generation, etc. In an analysis mode, a LIMS can be used to process results from instruments, trend data over a series of time points, automatically apply testing profiles to samples, result reporting along with numerous other sample-based activities. The benefits of a LIMS are to run the laboratory efficiently, reduce sample turnaround time, allow the rest of the organization to have improved access to information and eliminate duplication of work and errors."*

This NCHRP report seems to be the only substantive work in this subject in the recent past. It will be a useful document throughout this project.

From a strategic standpoint, a MMS is an enterprise-wide tool used to manage the entire materials clearance process while the LIMS is a tool used <u>within a MMS</u> to manage the <u>laboratory</u> testing

aspects of the materials clearance process. For example, a MMS might be used to manage very high level goals in terms of number of projects cleared or track progress against SHA business plan goals while the LIMS is used to assess the status of a sample within the testing process, determine total monthly production, and individual test efficiency. <u>It is very important that this difference is understood as we undertake this project.</u>

CURRENT PRACTICE

The NCHRP project conducted a survey of State DOT MMS practices in 2003. They received quite a significant response with 48 AASHTO respondents of which 45 were state DOTs. Twenty-seven DOTs have some form of MMS in process or in-place. Ten of those entities report having a functional system in-place. Due to the unique needs of each DOT and the relative immaturity of the MMS marketplace, many reported developing custom systems using in-house resources supplemented with consultant staff. Five off-the-shelf systems were identified and the general consensus is that the majority of the offered systems are LIMS, and not integrated MMS. It should be noted again that the definition of MMS in these surveys is quite broad and it is possible that a rudimentary LIMS is being reported as a fully functioning MMS. From a critical review of the NCHRP document, it is doubtful that all but a handful of states actually have a functional MMS as described in the definition above.

Five vendors were noted as marketing LIMS/MMS products. These are:

- Beckman Coulter (FL, VA, and MI)
- Ciber Custom Solutions (SD)
- LabVantage Solutions (KY, MN, and NY)
- Perkin Elmer Labworks (NH)
- Visual Solutions, Inc. (WI and IN)

Also significant, thirty-five percent of the respondents use SiteManager and 15 percent use the SiteManager Materials Module. Of those using the Materials Module, two-thirds found it difficult to use as a MMS. (1)

A different MMS survey was conducted in February 2004 by the Ministry of Transportation, Ontario. This survey included 27 DOTs. A compilation of this data reveals the following statistics on system usage:

- SiteManager: 15%
- In-house System: 35%
- COTS   15%
- None   35%

Again, this survey is not clear on the definition of MMS versus LIMS so it is difficult to assess if these states truly have an integrated MMS as per the definition presented previously. (2)

An internal SHA survey of vendors and States' experience with vendors is shown in Table 1.

Table 1 - SHA phone interview with selected states

Vendor	States Using	Conclusions
Atwood Systems	WI, IN	Both states praised both product and vendor. Includes LIMS, external links, interface to Tport, etc.
LabVantage Solutions	KY, MN, NY	Kentucky not at all satisfied with product or vendor
Innerphase L.I.M.S formerly Beckman Coulter	FL, MI	Mainly a LIMS, no real Materials Management functionality
Ciber Custom Solutions	SD	Product is in very early states of in-house development
Perkins Elmer Life and Analytical Sciences	NH	Mainly a LIMS, no real Materials Management functionality
SAS Institute	IL	Most of system developed late 1980's, no GUI, etc. needs update
Virginia DOT	VA	In-house LIMS development designed to interface with SiteManager (VA is currently using SM for construction management with the materials portion of the program turned off)
West Virginia DOT	WV	Developed late 1980's in-house / WV is looking to fix or replace

Based upon these studies, several things are fairly clear.

1. There is no single off-the-shelf system that meets all DOT needs
2. Each DOT seems to be taking their own unique approach to development of a MMS/LIMS
3. Each of the commercial systems in the marketplace require a fair amount of customization and development work to "shoe-horn" DOT business processes into the system
4. SiteManager is generally not suitable for MMS purposes without <u>significant</u> customization (in the current SiteManager environment, customization of this product is difficult to achieve)
5. Collaboration between IT and Engineering experts critical to success
6. Incremental development is a key
7. A new system should run parallel to existing system for six months to a year to work out bugs and process flows

SHA BACKGROUND MATERIALS

SHA has been pursuing a Materials Management System for many years and as such, a great deal of information has been developed within SHA on this topic.

Strategic Level

The Office of Materials and Technology has a well defined Business Plan (BP). The goals present in the OMT BP have a direct tie to overall SHA Business Plan goals. The Materials Management System will directly impact the following OMT Plan objectives:

OBJECTIVE	DESCRIPTION
3.1	Maintain annually at least 83% (CY 2002 pavement conditions) of the MD SHA pavements in acceptable ride quality condition.
3.3	Maintain annually at least "XX" percent of the SHA pavement network in acceptable condition.
4.3	Accomplish more work for lower cost for appropriate SHA services through partnerships by December 31, 2006

The following Business Plan objectives will be impacted in an indirect manner by implementation of a MMS.

OBJECTIVE	DESCRIPTION
2.7	Improve travel time by "XX" percent between US Route 1 and I-370.
4.12	Improve efficiencies in our business processes in a fiscally responsible manner.
5.8	Implement an SHA Environmental Stewardship Program involving all offices and Districts by the end of 2004

It is clear from these tables that Implementation of the MMS will have a broad impact on SHA OMT Business Plan goals. Materials Management not only directly affects the laboratories at OMT but indirectly affects a wide variety of customers including Construction, Pavement Management, Bridge Management, contractors, etc.

Tactical Level

SHA has proceeded with many activities related to moving MMS forward within OMT. The following presents a brief summary of the information and conclusions put forth by SHA to-date.

Scope of Issue

The scope of testing in a given year is as follows:

- 54,000 tests
- 2550 QA site visits per year
- Evaluation of 49 new products
- Clear 150 projects
- Complete 300 design recommendations

Maryland State Highway Administration   *Materials Management Systems (MMS) Strategic Plan*
MACTEC Reference No. 6420040001   *State of the Practice/Literature Review Report*
May 10, 2006

As a result of these activities, the following data must be stored, retrieved and managed:

- Logging of samples
- Source approvals
- Test results
- Plant production records
- Electronic storage of letters, documents, digital photos
- Test cost data
- Failure resolutions
- Approved mixes
- Pay factors
- Field inspection reports
- Certified test reports from producers
- Materials clearance processing information
- Prequalified lists

The ultimate stated goal of the MMS is to provide an electronic system to be used to manage the Materials Clearance process. The following Divisions will be directly impacted by the MMS:

- Asphalt Technology
- Concrete Technology
- Soils and Aggregate
- Structural Materials and Coatings Evaluation Division
- Materials Management Division

Currently, technical areas may use one system, or a combination of off the shelf, in-house or consultant developed software programs or log books to manage the logging, tracking and processing of samples, test reports and final materials clearance on projects. There is some limited use of electronic transfer of test data, certifications and inspection reports. Some of the issues related to this approach are:

- Each Technical Team uses various programs and methods to collect and store data.
- Hand logging of materials into a logbook is still in use in many areas.
- There is basically no electronic integration of test data from one Technical area to another; when testing is performed on the same sample by different Technical areas, other than by hard copies.
- Some data is stored by date, other by project, by plant and/or mix, and other data is stored by manufacturer/producer/supplier.

For each Division, the following is a general summary of the status of MMS within their Division.

Soils and Aggregate
- Test results recorded by contract number in Access
- Geo-System uses Access to record yearly quantities, polish values and ASR results
- Geo-System can be attached to files on N drive by Pavement Division
- Samples are logged on S drive
- Aggregate Bulletin in Access

- Program has checklist on when qualities need to be run
- Quality Control results from production facilities are sent to CNRL
- Private lab could send test results to CNRL by Zip file which can be retained in Geo-System

Cement
- Data is saved in Access file on M drive by Dave Kalendek
- Distribution of test results by hard copy

Chemical
- Samples logged in database file coded for specific materials
- Test results manually calculated and stored in test area
- Test cost are manually entered into system

Concrete
- Cylinder test results are in Excel file on N drive
- Plastic results and compressive strengths files maintained by region
- Separate file per mix and region
- Source approvals uses list of approved mixes on server
- Mix designs stored by plant and mix

HMA
- Uses Marylandware for storing QC results
- Producers can use system and electronically transfer data
- QC results will be sent by producer
- Program will generate pay factors

A detailed list of pros and cons associated with some of the Division's practices are contained in Table 2.

SHA MMS PLANNING

Through review of SHA documents, the following are excerpts of the current status of MMS in SHA and the stated desired outcomes.

The desired <u>benefits</u> of the system are as follow:

- Consistently store data
- Calculate test costs more accurately
- Share data across Division and Offices
- Provide easier access to data
- Streamline clearance process
- Track long term performance against material quality
- Integrate with producer/supplier/fabricator systems
- Increased Efficiency and Reduced Costs

Table 2 - Summary of pros and cons of current MMS processes in selected divisions

Chem/Cen/Conrete	
Strengths	**Weakness**
Cem	
Samples & tests kept electronically	Only Dave K. (user) can see them
	Limited to inventory systems
Chem	
Information stored electronically	Limited to inventory system
Does generate test cost	Must know cat. Code generated by lab
	Limited to chem
	Wasted space
	Cumbersome program
	Manually transfer information
Concrete	
Plastic & strength results stored together	User must know what to do exactly
Calculations performed electronically	Add front end
Mix source approval statewide	Multiple files. Results & approved mixes
Mix source approval in database	Not in database
Mix approval stored electronically	Elect. pull data from field
	Can't link to other databases
Soils/Agg.	
Computerized to calculate	Proprietary database
Transfer of info to consultant	
Electronically stored GAB mix designs	Not in database (GAB)
Aggregate Bulletin	Compaction test results from CID are hard copied
GAB gradations in database & geosystems format	Gradations keyed in from outside
Samples tracked electronically	Can't import information from geosystems
	Not statewide function
	Computer dedicated to test equip. Doesn't transfer data
	Dedicated computer equipment is not networked
Structural Materials	
Electronic record of anchor bolts, nuts, washers samples and test results	Only an inventory system. No link to spec.
Has front end to make data entry easier	Test results are not stored electronically
Logging system to track samples and if the sample passes or fail	Approved sources are in hard copy

The desired <u>outcomes</u> of the MMS are as follow:

- Managing lab test results
- Receiving and approving certified test results
- Referencing approved sources
- Managing materials acceptance process
- Clearing materials on projects
- Reporting and tracking during a project
- Storing Project Information

Identified strengths present in the existing system are as follow:

- A good deal of data is stored electronically
- Some calculations are done electronically
- Data relatively available within a team
- In some cases SHA can share data electronically with consultants

Identified opportunities for improvement of the current system are as follow:

- We can not share data across teams/Divisions or with others
- Some systems are cumbersome and not straightforward
- A good deal of data is still not stored in databases, but in hardcopy
- Inconsistent referencing
- Some proprietary systems
- Multiple products
- Materials Clearance process is not automated
- Data mining and statistical analysis difficult
- Archival and retrieval of data is difficult

Of particular note, a detailed set of specifications were written for implementation of a Laboratory Information Management System (LIMS) in 1995. Some of the information contained in this document is still relevant and this document should be referenced in later stages of this project.

SUMMARY

This document provided an overview of the State of the Practice review concerning Materials Management Systems (MMS) conducted by MACTEC. Primary sources for this review included information compiled by the Maryland SHA as part of its implementation efforts including results of a NCHRP study on this subject and internal SHA meeting minutes, notes, and working documents. An internet search was also conducted on the subject including review of the Transportation Research Information Service (TRIS) and Research in Progress (RIP) databases.

There are three important documents that should be referenced throughout this project. They are the NCHRP 20-07, Task 157 Final Report, the LIMS specifications developed in 1995, and the PowerPoint presentation titled mmsproposala.ppt. A draft outline of the suggested MMS Strategic Plan is also available.

APPENDIX A – REFERENCES

1. Ferragut, Ted, "***Materials Information Management System Software Review Final Report***," National Cooperative Research Program Project 20-07, Task 157, National Academy of Sciences, February 2003.
2. Anonymous, "***MMS Survey***," Ministry of Transportation, Ontario, February 2004.

Appendix E

ASTM LIMS Standards

Standard Guide for
Laboratory Information Management Systems (LIMS)[1]

This standard is issued under the fixed designation E 1578; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide describes computer systems used to manage laboratory information. The term Laboratory Information Management Systems (LIMS) describes this class of computer systems.

1.2 This guide covers LIMS ranging from small laboratories with simple requirements to large multi-site laboratories with complex requirements. The elements of the LIMS guide may be selected based on specific laboratory requirements.

1.3 The audience of this document includes: (*1*) end users of LIMS, (*2*) implementers of LIMS, (*3*) LIMS vendors, (*4*) instrument vendors, and (*5*) individuals who must approve LIMS funding.

1.4 The purpose of this guide includes: (*1*) help educate new users of Laboratory Information Management Systems (LIMS), (*2*) provide standard terminology that can be used by LIMS vendors and end users, (*3*) establish minimum requirements for primary LIMS functions, (*4*) provide guidance for the specification, evaluation, cost justification, implementation, project management, training, and documentation, and (*5*) provide an example of a LIMS function checklist.

1.5 Information contained in this guide will benefit a broad audience of people who work or interact with a laboratory. New LIMS users can use this guide to understand the purpose and functions of LIMS. The guide can help prospective LIMS users in understanding terminology, configurations, features, design, and costs. Individuals who are purchasing a LIMS can use this guide to identify functions that are recommended for specific laboratory environments. LIMS vendor Research and Development staffs can use the guide as a tool to evaluate, identify, and correct areas that need improvement. LIMS vendor sales staffs can use the guide to accurately represent functions of their LIMS product to prospective customers. This guide does not define laboratory instrument interfaces.

1.6 This guide can be used by laboratories of all sizes. The guide addresses complex issues that impact primarily large LIMS implementations. Small laboratories should review issues that may impact their environments. The implementation times and recommendations listed in this guide are directed at medium and large laboratories.

2. Referenced Documents

2.1 *ASTM Standards:*

E 622 Generic Guide for Computerized Systems[2]

E 625 Guide for Training Users of Computerized Systems[2]

E 627 Guide for Documenting Computerized Systems[2]

E 730 Guide for Developing Functional Designs for Computerized Systems[2]

E 731 Guide for Selection and Acquisition of Commercially Available Computerized Systems[2]

E 792 Guide for Computer Automation in the Clinical Laboratory[2]

E 919 Specification for Software Documentation for a Computerized System[2]

E 1013 Terminology Relating to Computerized Systems[2]

E 1029 Guide for Documentation of Clinical Laboratory Computer Systems[2]

E 1340 Guide for Rapid Prototyping of Computerized Systems[2]

E 1381 Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems[2]

E 1394 Specification for Transferring Information Between Clinical Instruments and Computer Systems[2]

2.2 *IEEE Standards:*

100—Standard Dictionary of Electrical and Electronic Terms[3]

610—Standard Glossaries of Computer-Related Terminology[3]

729—Glossary of Software Engineering Terminology[3]

730.1—Standard for Software Quality Assurance Plans[3]

730.2—Guide for Software Quality Assurance Plans[3]

828—Standard for Software Configuration Management Plans[3]

829—Standard for Software Test Documentation[3]

830—Guide to Software Requirements Specifications[3]

1008—Standard for Software Unit Testing[3]

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[1] This guide is under the jurisdiction of ASTM Committee E13 on Molecular Spectroscopy and Chromatography and is the direct responsibility of Subcommittee E13.15 on Analytical Data.

Current edition approved Oct. 15, 1993. Published December 1993.

[2] *Annual Book of ASTM Standards*, Vol 14.01.

[3] Available from IEEE, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331.

2.3 *ANSI Standards:*

X3.172 American National Dictionary for Information Processing Systems (ANDIS)[4]

X3.135 Standard for Structured Query Language (SQL-2)[4]

X3.168 Standard for Embedding Structured Query Language in Three GL Programs[4]

2.4 *ISO Standards:*

International Standards Organization (ISO) 9000 Standards[5]

2.5 *Other Standards:*

Data Communication Standard for Chromatography[6]

Data Communication Standard for Mass Spectrometry[6]

CAALS-I Communication Specification[7]

3. Terminology

3.1 This guide defines terminology used in the LIMS field. Paragraph 3.3 defines LIMS terms specific to this guide. Paragraph 3.1 provides references to other computer-related technical terms used in this guide. LIMS vendors use many different terms to define the items listed in 3.3. Users of this document should request a terminology list from each vendor with a cross reference to the terms used in this guide.

3.2 *Definitions*—For definitions of terms relating to computerized systems, refer to Terminology E 1013, Guide E 622, Glossaries IEEE 100, IEEE 610, IEEE 729, and ANSI X3.172.

3.3 *Definitions of Terms Specific to This Standard:*

3.3.1 *archive (1)*, *n*—data from a working database that has been transferred to storage media for long term storage.

3.3.1.1 *Discussion*—Information stored in the archive can be retrieved for reporting or additional processing.

3.3.2 *archive (2)*, *v*—the process of making an archive (*1*).

3.3.2.1 *Discussion*—Allows erasure of data from the working database in order to free space for additional data.

3.3.3 *audit trail*, *n*—a record of events related to a transaction including the original information and any changes to the information.

3.3.3.1 *Discussion*—The audit trail may be composed of manual or computerized records of events and information, or both. The audit trail is used to reconstruct a series of related events that have occurred.

3.3.4 *data*, *n*—record observations used for producing information.

3.3.5 *data analysis*, *n*—the ability to display, manipulate, transform, and verify LIMS database information.

3.3.6 *data/information capture*, *v*—the uni/bi-directional communication of data/information to/from a LIMS.

3.3.7 *data integrity*, *n*—the concept that information is not corrupted during communication, transfer, manipulation, storage, and recall functions.

3.3.8 *determination*, *n*—a single result, the lowest level of information in a LIMS.

3.3.8.1 *Discussion*—A LIMS example of a determination is a pH result.

3.3.9 *dynamic table(s)*, *n*— LIMS database table(s) or file(s) where sample and result information are stored.

3.3.9.1 *Discussion*—The storage of LIMS sample and result data/information can be in one or more database tables. Synonyms: LIMS database, active database.

3.3.10 *event-triggering*, *v*— action(s) performed following a specific condition(s).

3.3.10.1 *Discussion*—Event triggering conditions can be initiated by way of data, process, or other external events.

3.3.11 *information*, *n*—data plus context.

3.3.11.1 *Discussion*—Data are of little value without context. The information value of a LIMS is related not only to the quality of data stored, but also the context or relationships that are maintained within the system.

3.3.12 *LIMS*, *n*—acronym for Laboratory Information Management System. Computer application(s) [software] and hardware that can acquire, analyze, report, and manage data and information in the laboratory.

3.3.13 *laboratory management*, *n*—the monitoring and control of a laboratory's data management, and to a lesser degree, laboratory resources.

3.3.14 *login*, *n*—registration of a sample in a LIMS.

3.3.15 *profile*, *n*—a group of one or more tests.

3.3.15.1 *Discussion*—A predefined list of tests that are assigned to a LIMS sample during login.

3.3.16 *raw data*, *n*—the original record of an observation.

3.3.16.1 *Discussion*—Data entered into the system directly from original observations (not from a source document) by keyboard or automatically by laboratory test devices are considered raw data. Raw data is recorded on laboratory worksheets, memoranda, notes, notebooks, and are the result of original observations and activities related to laboratory testing. Raw data may include photographs, microfilms, computer printouts, magnetic media, and recorded data from automated instruments.

3.3.17 *results*, *n*—smallest unit of test data input into the LIMS.

3.3.17.1 *Discussion*—For example, an individual pH result. See *determination*.

3.3.18 *reporting*, *v*—extracting, organizing, and presenting information stored in a LIMS.

3.3.19 *sample*, *n*—a small part of portion of a material or product intended to be a representative of the whole.
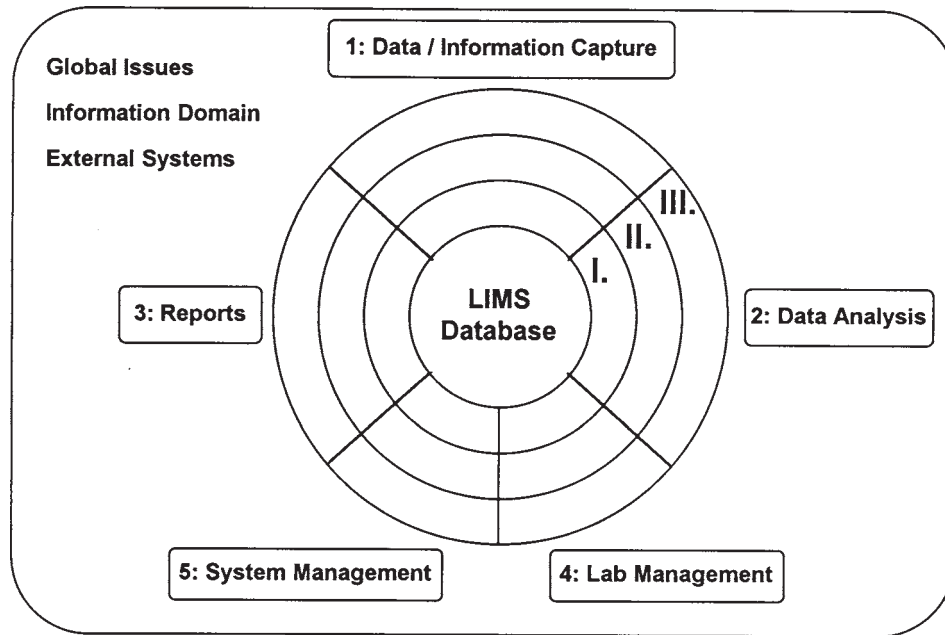
3.3.19.1 *Discussion*—A LIMS sample may be further subdivided into sub samples or aliquots.

NOTE 1—**LIMS Database:** A computer database application that can acquire, analyze, report, and manage data and information in the laboratory.
Functional Areas: 1: Data/Information Capture, 2: Data Analysis, 3: Reporting, 4: Laboratory Management, 5: System Management.
Level Definitions: I: Minimum Core LIMS functions, **II:** Intermediate LIMS functions, and **III:** Advanced LIMS functions.
Global Items: Issues that have an impact on all LIMS functions. The global issues have different capability levels (I–III). Specific global items include: Change Control (Configuration Management), Communication Infrastructures, Documentation, Performance, Quality, Security, Training, User Interface, and Validation.
Information Domain: The environment into which LIMS delivers information.
External Systems: Computer systems that send and receive data/information to/from a LIMS.
FIG. 1 LIMS Concept Model

3.3.20 *static tables*, *n*—descriptive LIMS database tables where profiles, tests, calculations, specifications, and related information are defined and stored (commonly found in "look up/reference/dictionary" tables).

3.3.20.1 *Discussion*—LIMS stores look up information to speed login and test assignments. Generally prior to login the static tables need to be configured. Some LIMS implementations can enter static table information directly from login step.

3.3.21 *system management*, *n*—monitoring and maintaining the computer system.

3.3.22 *test*, *n*—operation performed on a sample. A test may result in one or more determinations. A test may include specifications and procedures for the determinations involved plus sample preparation and biographical information.

3.3.23 *validation*, *n*—establishing documented evidence which provides a high degree of assurance that a specific implementation of a LIMS will consistently meet its predetermined specifications and quality attributes.

3.3.24 *verification*, *n*—process of checking the accuracy of manually, or automatically (electronically) entered information.

3.3.25 *work flow*, *n*—description of tasks performed within a laboratory, including sample flow, inputs, process and outputs.

4. Significance and Use

4.1 This guide includes information on LIMS terminology, a concept model, LIMS functions/work flow model, LIMS

database technology and structures, computer hardware platforms, LIMS life cycle, LIMS costs and benefits, LIMS implementation guide and LIMS functions checklist. This guide will aid in LIMS selection, implementation, and use. This guide will improve the effectiveness of implemented LIMS through a better understanding of the LIMS structures and functions, and by expanding the horizon of the LIMS information domain.

5. LIMS Concept Model

5.1 The LIMS concept model is a graphical representation of the major components that comprise a LIMS. The concept model can be used as a communication tool for defining LIMS functions to people in different disciplines. The diagram (Fig. 1) is composed of a circle in the middle representing a LIMS computer database. The LIMS database is surrounded by five functional components: (*1*) Data/Information Capture, (*2*) Data Analysis, (*3*) Reporting, (*4*) Laboratory Management, and (*5*) System Management. Three concentric rings expand out from the center and represent degrees of LIMS capabilities. Level 1 depicts core (mandatory) LIMS functions. Level 2 represents intermediate functions. Level 3 represents advanced functions and technology. The box that surrounds the inner circles represents global issues that have an impact on all parts of the LIMS model. Global issues include: change control (configuration management), communication infrastructure, documentation, performance, quality, security, training, user interface, and validation.

TABLE 1 LIMS Concept Model Sections

Level I—Minimum LIMS Functions

Global Issues	LIMS Database	Data/Information Capture	Data Analysis	Reporting	Lab Management	System Management
Change Control		Manual Sample Login	Result Verification	Pre-Defined Reports	Sample/Order Status	Backup and Recovery
Documentation	Fixed Database Structure				Sample/Order Tracking	
Quality		Manual Result Entry	Basic Calculations	Sample Labels	Backlog Report	
Security	Limited Capacity					
User-Interface	Limited Performance					
Validation						

Level II—Intermediate LIMS Functions

Global Issues	LIMS Database	Data/Information Capture	Data Analysis	Reporting	Lab Management	System Management
On-Line Documentation	Intermediate Capacity and Performance	On-Line from instruments (one-way)	Comparison of Result to Specification	User Defined Reports	Scheduling of Lab Work	Archiving
Group Security			Predefined Math Functions	Queries, Sorts, Filters	Location of Sample	Manual Performance Tuning
On-Line Training	Referential Integrity	File Transfers (one-way)			Workload Prediction	System Fault Tolerance
Graphic User Interface	User-Definable Fields	Bar Code Entry			Pricing/Invoicing	
Validation Tools					Time (shelf life) Schedule	
Chain of Custody	User-Definable Indices		Intra-Test Calculations	Basic Graphics		
Configuration Tools	User-Definable Tables	User Qualification Checking	Graphical Presentation	Ad Hoc Querying and Reporting	Sample Inventory	
Audit Trail	Transactional Integrity		Basic Statistics QA/QC on Samples			

Level III—Advanced LIMS Functions

Global Issues	LIMS Database	Data/Information Capture	Data Analysis	Reporting	Lab Management	System Management
Version Control	SQL-2 Compatibility	Bidirectional Communications to/from Instruments	Inter Test/Sample Calculations	Natural Language Reporting Methods	Resource Management	Dynamic Performance Tuning
Static Table Revision Control	High Capacity and Performance		Advanced Math Functions	Batch Reports	External System Scheduling Work	Advanced System Fault Tolerance
Security by Object	Natural Language Based	IR, UV, NMR Spectra File Transfers	User–Defined Functions	Event Triggers Export to External Systems		Redundant Systems
Advanced Validation Tools	Client Server Transaction Rules	Two Way Links to External Systems	3–D Graphs	Bulk Data Transfers	AI Decision Making Tools	
Multitasking User Interface	Distributed and Central Information and Processing		Advanced Statistics	Advanced Graphics	Revenue/Cost Tracking	
Multimedia Advanced Configuration Tools		Multimedia/Imaging	Dynamic Links to Prior Results and Other Systems	Multi-Site LIMS Reports	Advanced QC Management	Advanced Communication Links to External Systems
		Electronic Notebook			Multi-Site LIMS Management	

5.2 The boundaries between each section of the model define distinct classes of LIMS functions. Data and information flow between sections through the LIMS database at the hub of the model. The LIMS concept model functional sections delineate the breadth of a specific LIMS implementation. The three concentric rings represent the capabilities of a LIMS. The LIMS concept model focuses on functions, not technology. The LIMS concept model is modular in design reflecting that LIMS requirements vary from laboratory to laboratory.

5.3 *Using the LIMS Concept Model*—The primary purpose of the LIMS model is to educate people who are not familiar with LIMS functions. For example; how to explain what a LIMS is to approvers of funding. A second use of the LIMS concept model is to serve as a checklist of functions that can be used in specifying LIMS requirements for specific laboratory environments. The concept model can be used to construct a modular representation of the primary LIMS functions and the

level of sophistication required to meet a specific LIMS implementation. The LIMS concept model, combined with the remaining sections of this guide can be used to aid work flow redesign, specification, selection, implementation, and life cycle issues.

5.4 The LIMS concept model subsections are defined in Table 1 in a tabular form for additional detail and clarity.

5.5 Global issues impact all segments of the LIMS concept model. The global issues have three levels of capabilities (see Table 1). The global issues are:

5.5.1 *Change Control*—Change control covers LIMS software version/revision control, LIMS results (sample and determinations), LIMS static table information, LIMS screens (design, query, inputs and outputs) and reports, hardware, standard operating procedures (SOPs), facilities, and people. Change control can also be described by the term configuration

management. Formal change control is essential for data integrity. See IEEE 828.

5.5.2 *Communication Infrastructure*—Network communication links between the LIMS and clients, including Local Area Network (LANs), Wide Area Network (WANs), public and private phone systems, etc.

5.5.3 *Documentation*—User manuals, programmer technical reference manuals, training manuals, SOPs, on-line documentation, vendor-supplied validation documents, vendor-supplied system development SOPs, and source code. See Specification E 919.

5.5.4 *Performance*—Responsiveness of all LIMS functions.

5.5.5 *Quality*—Pertaining to the overall LIMS product. See IEEE-730.1 and IEEE-730.2.

5.5.6 *Security: Physical, System, Application*—Physical security is linked to the facility and equipment accessibility. System security is built into the operating system used by the computer hardware. Application security is provided by the LIMS application and can be backed up by LIMS audit trails. Total system security includes backup, fault-tolerant functions, hot spares and support contracts (hardware and software).

5.5.7 *User Interface*—The user interface includes what appears on the computer screen and what the user physically interacts with (input devices: keyboards, bar codes readers). Examples include: command-driven, menu systems, graphic user interface (GUI)/window systems, multi-media, hand-held input devices, bar code readers, and voice input.

5.5.8 *Validation*—The LIMS validation issue is primarily a concern of laboratories using LIMS in industries regulated by the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), Nuclear Regulatory Commission (NRC) and the International Standards Organization (ISO). Validation of a LIMS requires extra time and resources. Benefits of validation are real. Recommendation: Don't assume everything is working correctly. Prove it by formal validation testing. Document the validation testing. Keep the validation document up to date with strict change control, audits, and annual reviews.

5.5.9 *Training*—Users and system administrators need to be trained in all authorized LIMS functions. Training and training resources can be provided by in-house staff, vendors, or consultants. Training should be ongoing and documented. See Guide E 625.

5.6 *LIMS Concept Model Functional Segments*:

5.6.1 *LIMS Computer Database*—The LIMS database is the hub for all LIMS interactions. The database is generally composed of two sections: (*1*) static and (*2*) dynamic. The static area is where descriptive information about tests, profiles, calculations, specifications, etc. are stored. The dynamic area is where sample and result information is stored.

NOTE 1—Some laboratories enter static LIMS information in a dynamic fashion during login. The database technology used can range from simple flat files to advanced object-oriented systems with enforced integrity and transaction rules. The database and hardware technologies employed for a specific LIMS implementation determine the primary performance characteristics of the system. A large LIMS is more flexible when built on a high-level database management system. See the sections on LIMS database technology and computer hardware platforms.

5.6.2 *Data/Information Capture*—The Uni/Bidirectional communication of information to/from LIMS. Level 1 data/information capture into a LIMS is represented by manual keyboard entry. Manual keyboard entry is one of the most common LIMS input methods. Level 2 data/information capture includes one-way electronic transfer of information from subordinate and independent systems (instrument uploads/transfers are a common LIMS input method). Level 3 involves bidirectional communication between the LIMS and external systems (instruments, balances, other computer systems). The bidirectional communication includes instrument control, run lists, multi-instrument workstations, trigger LIMS functions from external systems and run parameters.

5.6.3 *Data Analysis*—The process of verifying, manipulating, transforming, and displaying existing database information. Level 1 data analysis includes simple range checking for inputs (for example; pH physical limits for inputs are 1 to 14 pH units), and simple calculations. Level 2 includes specification checking, intra-test calculations, descriptive statistics, and basic graphical presentation. Level 3 includes advanced user-defined functions, inter/intra-test/sample calculations, advanced graphical presentation, and dynamic links to prior results and external systems.

5.6.4 *Reporting*—Extracting, organizing, and presenting information stored in a LIMS. Level 1 reporting includes predefined reports and sample labels. Level 2 reports include user-defined reports and queries. Level 3 reports include advanced natural language reporting tools, batch reports, event-triggered reports, exports to external systems, bulk data transfers, and advanced graphics.

5.6.5 *Laboratory Management*—The monitoring and control of a laboratory's data, and to a lesser degree, laboratory resources. Level 1 functions include sample/order status, sample/order tracking and backlog information. Level 2 includes scheduling of laboratory work, location tracking of samples, work load prediction, pricing, and invoicing. Level 3 functions include laboratory resource management, artificial intelligence (AI) decision-making tools, revenue/cost tracking, and auto workload balancing.

5.6.6 *System Management*—Monitoring and maintaining LIMS computer systems. Level 1 functions include backup and recovery. Level 2 functions include archiving, manual performance tuning, and system fault tolerance. Level 3 functions include dynamic performance tuning and advanced system fault tolerance functions.

5.6.7 A detailed breakdown of typical LIMS functions is found in Table 1.

6. LIMS Database Technology and Structures

6.1 The database technology and structure of the database tables are critical to the overall success of the LIMS implementation.

6.2 The database technology employed by LIMS vary with each vendor and implementer. The LIMS database tables are divided into two broad areas: (*1*) LIMS *static* database tables where descriptive information is defined (for example, profiles, tests, calculations, specifications, and related information (commonly found in "look up/reference/dictionary" tables)) and (*2*) *dynamic* tables where sample and result/determination

information is stored as samples are logged and results are entered. The terms *static* and *dynamic* represent general characterization of LIMS database tables; specific LIMS implementations use LIMS static tables in a dynamic fashion. The LIMS user needs to closely study how the current laboratory information organization and work flow match the two database areas (*static* and *dynamic*). The time required to implement a LIMS is dependent on tools and structure of the static database tables.

6.3 Examples of LIMS database technologies include: (*1*) network, (*2*) relational, and (*3*) object. Structured query language (SQL) is an ANSI standard for relational databases. Fourth generation languages (4GLs) are used by some LIMS vendors to develop LIMS applications on top of the underlying database technology. The 4GL tools can be very powerful and allow your Laboratory or MIS staff to customize your LIMS application to meet your changing requirements. Exercise caution when customizing a vendor-supplied LIMS to ensure that your system is compatible with future vendor software upgrades.

6.4 General database recommendations on selecting a LIMS include the following:

6.4.1 Select a LIMS where the combination of the LIMS application and its underlying technology closely matches your laboratory work flow requirements and information structure.

6.4.2 Select a LIMS based on a commercial database management system or database toolbox that is reliable, effective and supported external to your LIMS vendor (this is especially true if there is a chance that you may change your LIMS in the future). Proprietary LIMS database management systems may be required to meet specific performance requirements. Portability of data is a key factor in selecting a LIMS, including compatibility with an industry standard for accessing data.

6.4.3 Select a LIMS based on database technology that permits the end-user to add/modify fields, indexes, relationships, tables, codes.

6.4.4 Select a LIMS where the database structure of the static tables/files (profiles, tests, calculations, specifications and related information) closely matches your current information structures and work flows.

6.4.5 Select a LIMS where the database structure of the dynamic tables/files matches the information types (numeric, date, memo) used in your laboratory.

6.4.6 Select a LIMS that permits third party tools to be used for report generation, export, import, links to external systems, security, and monitoring beyond functionality built directly into the LIMS.

6.4.7 *Advanced LIMS Technology*—Several technologies are classified as advanced LIMS functions because of their newness in the LIMS field rather than because they have been demonstrated to have advanced utility. These include:

6.4.7.1 *Object-Based Systems*—This is a programming technique as opposed to a LIMS feature. Proponents claim reduced programming and maintenance efforts, and better handling of complex relationships. Current object-based systems suffer from a lack of standards and may have poor performance in transaction-processing environments. Since

these are development tools, not LIMS features, significant advantages have yet to be shown for the LIMS purchaser. Object-based LIMS products will emerge as the technology matures.

6.4.7.2 *Multimedia/Imaging*—This technology incorporates video and sound into end user software. Useful integration of multimedia into LIMS have yet to be delivered, but is likely to prove useful when extensive document scanning is required or where on-line training is valuable. When investigating this technology, balance the benefits against the knowledge that in a laboratory, graphical data are often needed in numeric format rather than an image bitmap, and that increased complexity and, therefore, increased training may be the result. This area should not be confused with simply using image-related media such as CD-ROM/WORM for storing data.

6.4.7.3 Artificial intelligence (AI) techniques in LIMS are in two predominant forms expert systems and natural language interfaces. Expert systems can choose actions based upon a *knowledge base* of rules. Expert systems will provide additional utility to laboratories requiring automated decision making with more complex criteria or that require fully-automated control. The cost of creating appropriate rule bases and establishing sufficiently consistent procedures should be weighed against the human time required to perform the same tasks and the fact that many commercial LIMS have already been programmed to automatically perform functions based upon criteria that have been proven to be useful.

6.4.7.4 Natural language systems use assumptions about languages to convert typed questions into more rigorous database queries. The cost of a natural language interface is justified if frequent ad-hoc queries must be performed that are not otherwise provided within a LIMS, and should be weighed against other simplifying query mechanisms such as query-by-example and query-by-form.

6.4.7.5 *Multi-Tasking User Interface*—This technique allows a user to leave one LIMS function to perform another function, then switch back without losing work. This is desirable for *power* users, those who are frequently interrupted to change LIMS functions or where laboratory work varies dramatically from day to day, and during the LIMS installation when the database has not yet been completely configured. Negative aspects are that some users find such interfaces more confusing, so training costs may be slightly higher, and that most LIMS users only use a small subset number of LIMS functions, making the additional learning curve more difficult to justify.

6.4.7.6 The overall fit of a LIMS to laboratory operations is generally more important than specific advanced technology.

7. Computer Hardware Platforms

7.1 The criteria for LIMS selection should be driven by the software function. Hardware should be a second priority behind overall software functionality. Computer hardware technology and price-performance ratios used to support LIMS are changing rapidly. The LIMS implementer should start with vendor guidelines for sizing computer hardware to match projected needs. The implementer should follow up vendor hardware sizing recommendations with site visits and performance testing on pilot systems in-house (Vendors sometimes
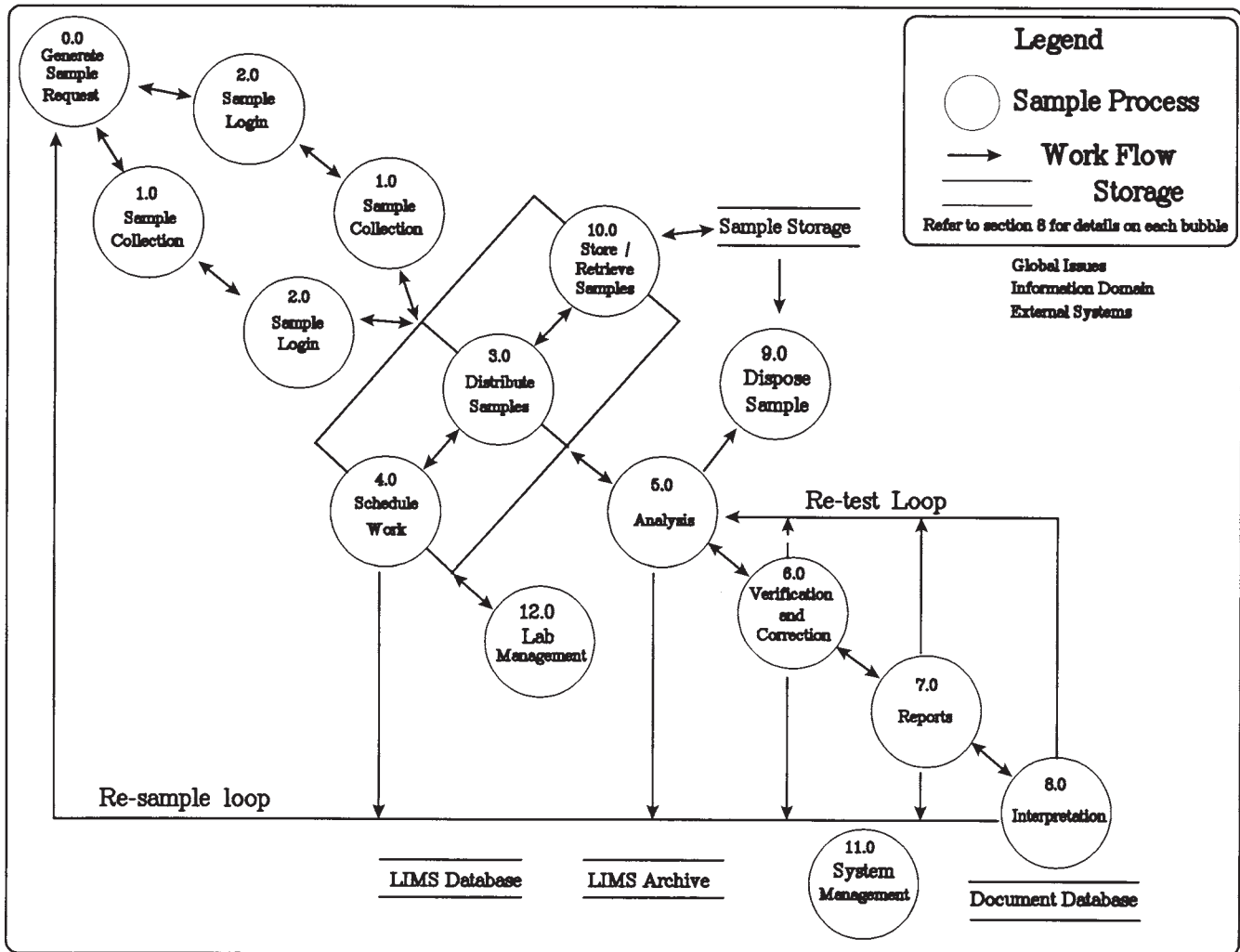
FIG. 2 Generic LIMS Work Flow

under-specify the hardware to keep initial costs low in order to capture your business). Hardware sizing is dependent on many factors. Important factors include: (*1*) number of concurrent users, (*2*) number of records (sample and determinations) per year, (*3*) number of records to be maintained on-line, (*4*) archive requirements, (*5*) type of reporting required and, (*6*) external loads on the system from non LIMS applications. Hardware sizing includes CPU, clock speeds, bus data width, memory, disk capacity, disk I/O, archive media capacity, and network communication rates. The first-time LIMS users should be aware that LIMS (database) transactions often place demanding loads on computer hardware. Reports that are required to summarize data for large data sets can take minutes to hours to run. The user needs to plan the implementation goals, schedules, and resources. For example, the LIMS may take 6 to 24 plus months to implement in a large laboratory. The laboratory may be better off buying a small processor for implementation and upgrading to a faster platform near the end of the implementation (when hardware prices should be cheaper). Plan for growth 1 to 3 years ahead. Business cycles do not always result in laboratory expansion. Consider whether the LIMS you evaluate can be scaled back to a smaller, simpler

system as well as to a larger, more complex one. Database software vendors often have significant surcharges for scaling licenses back to smaller systems, and hardware and software discounts may be heavily affected by downsizing. Portability of software between hardware systems is important if you expect to change hardware platforms over the life of the LIMS. The ability to transfer data between different computer systems is vital in a heterogeneous computing environment. Select a hardware system that can be scaled up (CPU speed and storage capacity) to meet changing requirements.

8. Generic LIMS Work Flow Model

8.1 The LIMS work flow model provides a generic representation work flow in a typical laboratory. The purpose of the work flow diagram (Fig. 2) is to elucidate the LIMS functions and interaction points with typical laboratory work flow (processing of samples). Specific laboratory requirements will vary widely from one laboratory to another. The individual's own laboratory work flow should be defined as part of the LIMS life cycle. Fig. 3 describes a LIMS work flow for a large complex laboratory. The following description explains the basic LIMS functions and work flow interactions. The numbers
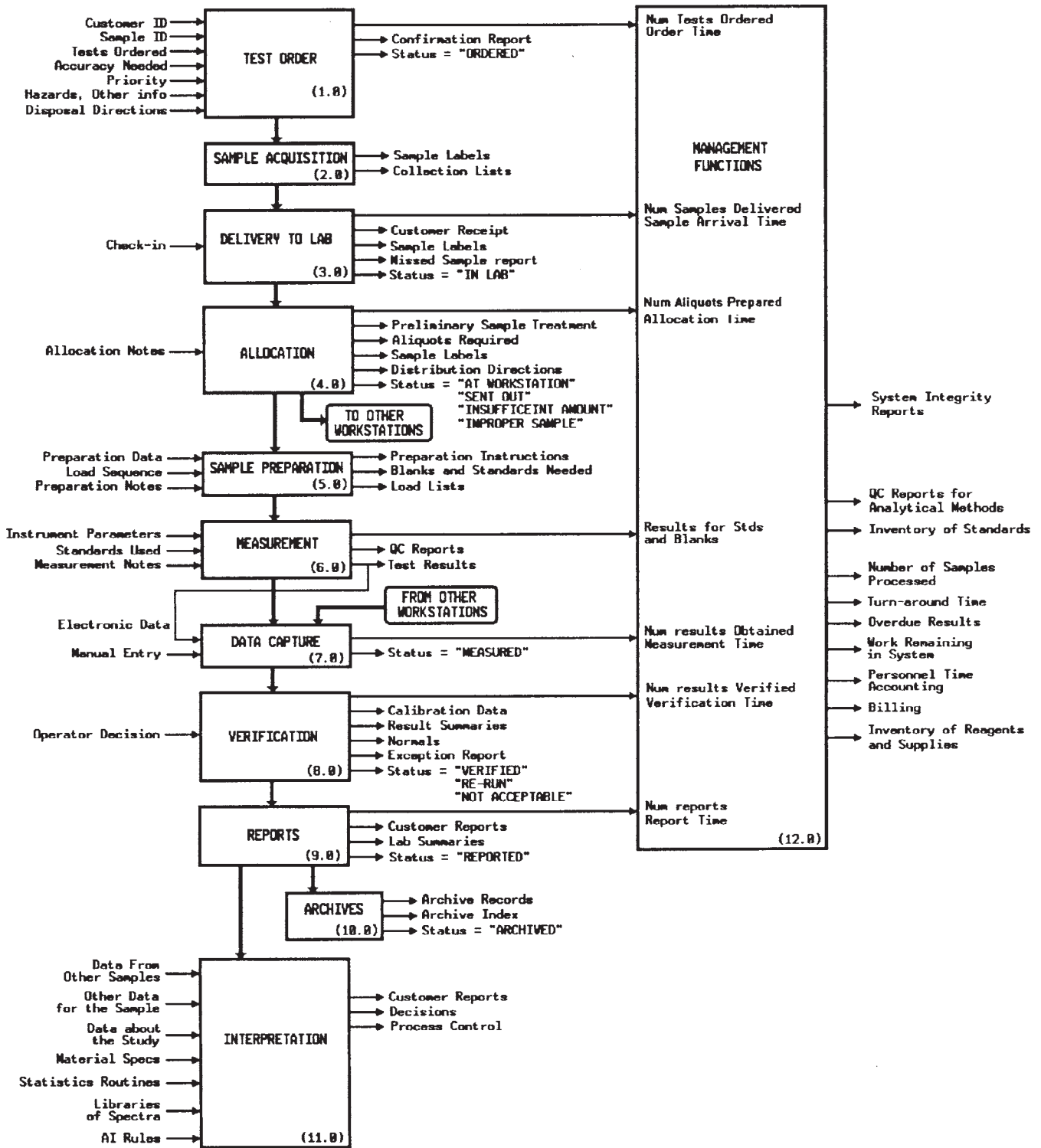
FIG. 3 An Example of a Complex Laboratory Work Flow

in the parentheses in Section 8 refer to specific work flow processes (bubbles) in Fig. 2. To provide clear examples of what may be performed in each of the work flow model functions, items from all three levels of the LIMS concept model are used. The following description does not include every concept model function and is not limited to a particular level.

NOTE 2—The generic LIMS work flow model presented in Section 8 provides a general description of work performed in the laboratory. The LIMS work flow model tries to avoid high level technical terms and concepts found in rigorous information models. Detailed information system analysis may be required for complex laboratory environments. Rigorous information model techniques can be found in De Marco (**1**)[8] and Yourdon (**2**). For additional information in this area, see Mahaffey (**3**), McDowall (**4**, **5**), McGinnis (**6**), and Nakagawa (**7**).

8.2 *LIMS Statuses*—LIMS are capable of maintaining information on the status of samples, individual test/determinations, comparison of results to specifications, verification of results, approval of samples/orders, and much more. Status information is updated as each LIMS transaction takes place. The functions/work flows all have an impact on LIMS status information. Examples of sample/order statuses include: new, ordered, active, received in the lab, verified, reported, approved, released, rejected. Examples of test/determination statuses include: new, done, verified, out of specification 1, out of specification 2. Select a LIMS that maintains the statuses that you need for running your laboratory. Selected reports generated by LIMS retrieve information based on statuses.

8.3 *Generate Sample Request (0.0)*— The initiation of a request for testing/sampling starts the process. Examples of sample requests include manual forms, phone requests, process-driven requests, time or calendar-based requests, ad-hoc requests, and LIMS-generated requests. Information obtained from the sample request includes biographical, client, requested test(s), and safety information. Some LIMS implementations require the ability to post-log samples.

8.4 *Sample Collection (1.0)*—Sample collection may be a manual, automated, or robotic process. The sample collection can be assisted by the LIMS (post login) in some environments by printing collection lists and generating labels (bar code) for the sample containers. Sample collection can precede login or follow login; the actual order will vary from laboratory to laboratory. LIMS statuses can be updated (post login) during the sample collection step. The LIMS can provide information on how to collect samples, specific sample plans, container requirements, safety (Material Safety Data Sheets (MSDS)) information, sample storage requirements, and sample routing information. Chain of custody for the sample can be tracked by the LIMS, although this may not supplant legal chain of custody requirements.

8.5 *Login (2.0)*:

8.5.1 The LIMS must first be properly configured and the relatively fixed information about personnel, customers, tests, reports, and the like must be entered into the static tables. The LIMS configuration time can be 1 to 24 plus months depending on laboratory size and implementation approach. Some LIMS implementations are able to add static table information from the sample log screens. After the LIMS is configured, the process begins with a sample order login. Where the sample is not naturally uniquely identified, the LIMS assigns a unique number(s) to each sample/order that is registered (login). The unique number can be a sequential integer or a user-defined sequence. Multiple samples can be logically linked in one LIMS order or submission. The system captures who submitted the sample(s), costs, how the sample is identified, and what tests are to be done on the sample. Other information may also be important, such as the priority of the tests, what level of accuracy and precision is needed, what hazards the sample might present to the laboratory personnel, what approximate levels of components are expected, and what should be done with the sample when analysis is complete. Login can precede or follow sample collection. Fig. 2 shows the two possible paths. The LIMS login function should be a simple, straightforward process with a friendly and efficient user interface.

8.5.2 A confirmation report is often issued to ensure users the system accepted the sample order. LIMS statuses are updated for the sample/order. The management function (MF) needs to record the fact that an order was made (for keeping operational statistics) and when it was made so the MF can begin to track the time intervals for the remaining steps of the process. This will also allow laboratory management to determine turnaround time and various overdue conditions.

NOTE 3—The following three sections; Distribute Samples 3.0, Schedule Work 4.0, and Store/Retrieve Samples 10.0 are closely related. Fig. 2 shows how samples can move prior to actual analysis in the typical laboratory. The actual flow of samples will vary from laboratory to laboratory. For example, a simple ad-hoc sample may be logged in and results entered into the LIMS directly, bypassing the distribute samples, schedule work and store/retrieve samples all together. The rectangle encompassing these functions in Fig. 2 implies optional paths that are sample dependent.

8.6 *Distribute Samples (3.0)*:

8.6.1 The distribute samples process includes important LIMS functions of work list, sample routing, custody, and labeling. Nearly all LIMS will have an explicit or implied check-in step. At this point, the LIMS is informed that a sample has arrived. The status of the sample/order can indicate its arrival. Sometimes the customer is issued a receipt to confirm delivery and to tell the submitter the laboratory number that was assigned to the sample. A laboratory label will be applied if it has not already happened. Chain-of-custody may be required to track sample containers and their contents. Examples of chain-of-custody requirements include regulated controlled substances, evidence supporting legal court cases, or radioactive materials. When collection lists are generated, a missed sample report indicates those samples which could not be obtained for whatever reason. The management function records the arrival so it can report the number of samples processed, and the arrival time for its monitoring of the remaining processes. LIMS statuses are updated for the sample/order.

8.6.2 It is frequently necessary to divide the sample for simultaneous analysis at different workstations. The LIMS knows all the tests that must be performed and can tell the technician what aliquots are needed, how much material must go in each one, and where they are to be sent. Additional labels are needed for the individual aliquots. Sometimes a preliminary treatment is performed on some or all of the sample, such as adding a preservative. If so, directions can be given to the technician to assist this step. The status of the test changes. It may be sent to a workstation in the laboratory or off site to a remote facility for analysis. Sample problems may also be

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[8] The boldface numbers in parentheses refer to the list of references at the end of the standard.

noted at this point. There may be insufficient sample to prepare all aliquots, or the technician may notice a problem with the sample, such as a wrong color or improper physical state. The management function needs to know about aliquot preparation for its counts-of-work-done. The time is important, because it marks when the sample becomes available to the various laboratory workstations.

8.7 *Schedule Work (4.0)*—The LIMS automatically schedules work (tests) for each sample/order. The laboratory management can adjust sample priorities and reassign work as required. The LIMS can add laboratory standards, control samples, and QC samples to the scheduled work flow. LIMS statuses are updated for the sample/order.

8.8 *Analysis (5.0) (Sample Preparation, Measurement, and Data Capture)*:

NOTE 4—Analysis (5.0) contains multiple subjects. Subjects addressed in Analysis include sample preparation, measurement, QC samples, and data capture. The analysis activity will vary from laboratory to laboratory. Fig. 2 also shows a re-test and re-sample loop. A more detailed discussion of these topics follows:

8.8.1 *Sample Preparation*—Most samples need some preparation before analysis. The LIMS can provide directions for the sample preparation, as well as suggest the standards and blanks needed to calibrate or verify operation of the method. In some cases, preparation requires entering experimental data, such as tare weight and final weight from a balance. The LIMS computes experimental factors from this data. Other times, preparation parameters are calculated separately and entered by the technician. For multi-sample instruments, the samples, standards, QC samples and blanks in the tray need to be identified. The role of LIMS QC samples needs to be examined closely. Related QC issues include calibrations, spikes, spike duplicates, sample duplicates, and audit reports. This can be determined by the technician who informs the LIMS, or by the LIMS which tells the technician how to load the tray. Any irregularities or exceptions can be entered here as preparation notes. They can be tagged on to the reports and may help explain any unusual results. LIMS statuses are updated for the sample/order.

8.8.2 *Measurement*—Certain supporting data should be collected as part of the measurement process. This may include instrument settings, standards and blanks used, and any irregularities, difficulties, and unusual behavior. This information helps document the procedures used, and may help explain unusual results. Test results/determinations are the main output of the measurement process. Test results may be printed or sent electronically to the next step. In addition, the measurement process may produce values for blanks, standards, and instrument self-checks. These can be reported to the technician, and also to the management functions which may be maintaining a history file of QC data for each workstation. The concepts of what is raw data and what needs to be retained for legal evidence may be defined differently for each client or agency involved.

8.8.3 *Data Capture*—The results of the measurement must be entered into the LIMS. It may be entered by way of electronic interfaces or, in low volume applications, typed in by technicians. When a test result/determination is entered, the statuses of the sample/order and result determination are updated. The management functions record the fact and time that results were captured so that they can keep statistics of work accomplished and track the progress of each test order. Audit trails record biographical information about each LIMS transaction.

8.9 *Verification and Correction (6.0)*— A laboratory may require that results be reviewed by a qualified person (this is industry specific and dependent on regulatory requirements). To help in this process, the LIMS may show the results for standards and blanks. The technician can judge whether the method was in control. The LIMS can show summaries of work done for review. Unusual or out-of-range results can be flagged for more careful scrutiny. If normal values are known for the substance being tested, they can be displayed. Also, any results outside of normal can be highlighted or displayed separately for closer review. Corrections to LIMS data can be made during the verification step. The LIMS can enforce laboratory SOPs that require the reviewer to be a different person from the tester. Changes to LIMS results should be audit trailed and a reason given for why a correction has been made. The original data must be retained, and all changes appended to the result record. After examining the data, the user must make a decision. Results can be approved, changing the result status. A test (one or more determinations) can be scheduled for re-test, or if that is not possible, the result can simply be marked as NOT-ACCEPTABLE. Management functions need to know when results are verified—another milestone in the progress of a test/sample/order. LIMS statuses are updated for the sample/order. Not all LIMS implementations require audit trails. The LIMS implementer needs to determine whether audit trails are important, what information should be audited, and whether reasons for changes should be recorded.

8.10 *Re-Test Loop*—Retests can be initiated at multiple points in the LIMS work flow. Fig. 2 shows possible re-test paths. A re-test is defined as one or more additional determinations on the original sample/order container.

8.11 *Re-Sample Loop*—Re-samples can be initiated at multiple points in the LIMS work flow. Fig. 2 shows possible re-sample paths. A re-sample is defined as one or more additional samples. The LIMS needs to establish forward and backward links to samples that are added by way of the re-sample loop.

8.12 *Reports (7.0)*—Once test results are verified, they can be reported to the customer. This can take a variety of forms, including printed output, electronic mail, and response to on-line queries. Reports can also include summaries for laboratory use. Different reports can be issued depending on the requirements. Management functions are told when the reports are issued, because this marks the end of the turn-around time. LIMS statuses are updated for the sample/order.

8.13 *Interpretation (8.0)*:

8.13.1 The laboratory exists to generate information for the parent/client organization. Some of the LIMS today are configured to better assist that ultimate purpose. They may organize and configure results to make interpretation and decision making easier. This can be done by combining results

from many samples, adding additional non-laboratory-generated information to the reports, and including generic information related to the test or activity that caused the samples to be analyzed in the first place. Sometimes analysis is done to confirm quality or properties of a material. In this case, material specifications can be entered into the LIMS so that results can be checked against acceptable values. Sometimes statistical routines can be used with collections of results to determine trends and make other conclusions. Spectral libraries can be used to identify materials. Artificial intelligence is used in some cases to help understand the results. LIMS statuses are updated for the sample/order.

8.13.2 The output of the interpretation segment can be reports, decisions based on predefined criteria, or direct process control actions.

8.14 *Dispose of Samples (9.0)*—The proper documentation of sample disposal following analysis is an increasing concern. The LIMS can be used to track final sample disposition and waste removal.

8.15 *Store/Retrieve Samples (10.0)*— Samples can be retained in fixed storage rooms/locations while awaiting analysis. LIMS statuses are updated for the sample/order. Inventories can be maintained for reference samples, laboratories reagents, standards, QC samples, time-based samples (shelf life stability), in addition to normal samples.

8.16 *Laboratory Management (11.0)*:

8.16.1 By collecting statistics and time-stamps at various points in the process, the management functions can prepare reports for the laboratory managers. Number of samples processed at each workstation by shift, day of week, and hour of day can be prepared. This can help identify peak demands, roadblocks, and other problems. It provides good documentation to justify new instruments or personnel. Turnaround times document the laboratory's responsiveness to customer needs. Overdue results and work remaining in the system help managers to determine how well the laboratory is responding to current demands. Personnel time accounting can be tracked by the time each sample is at each workstation. This can be used to bill by project, and to monitor personnel performance. Billing outputs are needed in those labs that charge customers for work done (as opposed to corporate blanket funding). The number of tests done can be used to estimate the consumption of reagents and supplies. Instrument calibration and maintenance records can be maintained and reported by the LIMS.

8.16.2 Quality control issues are also scattered throughout the LIMS. The management functions can correlate these results into suitable reports. An inventory of standard materials can be maintained, with suitable outputs when the supply of any particular reagent is running low and replacement is advised. Also included in QC, is the LIMS itself. System diagnostics and database integrity checks are performed routinely and reports given.

8.17 *System Management (12.0)*—System management functions include backup and recovery, manual performance tuning, system maintenance, user maintenance (accounts, training, help desk), and archives. Permanent legal archives are prepared after all work is done. The archive is typically recorded on paper, microfilm, magnetic media, or optical disk.

Even if the archive itself is not machine readable, there may be archive indexes prepared in computer usable form. System management responsibilities may include formal document archive functions. The ability to read archives after LIMS software updates is an important consideration with a possible considerable cost factor.

9. LIMS Life Cycle

9.1 The LIMS life cycle defines the normal steps that are taken to acquire, implement, and maintain a LIMS. First time LIMS implementers will gain understanding of the basic steps. Seasoned LIMS users can use the LIMS life cycle to maintain existing LIMS and prepare for the implementation of the next generation LIMS. See IEEE 1074. The following LIMS life cycle lists the major steps in a LIMS life time and gives specific references to sources for more detailed information.

9.2 The LIMS life cycle steps 9.7 to 9.9 can be slow and expensive to complete. These steps produce the best results for companies that understand LIMS and can support the implementation of those functional requirements that are not met by their selected product. Smaller companies may benefit from alternatives to the formal techniques listed in Sections 9.7 to 9.9. Alternatives include (*1*) installing and trying each of several LIMS that meet the basic requirements, (*2*) simply evaluating LIMS against the LIMS Guide Checklist in Appendix X1 and (*3*) changing laboratory operations to fit a selected LIMS.

9.3 *Definition of Business Requirements*—Organizational missions and objectives should be clearly defined. LIMS requirements should not conflict with core organizational missions.

9.4 *Project Definition*—A project definition document should be developed outlining the objectives for the LIMS (see Guide E 622).

9.5 *Model Current State Laboratory Practices*—Meet with LIMS users, end users, laboratory managers, external users of laboratory information. Diagram sample work flow and information captured in the laboratory (see LIMS work flow diagrams). Time required to model current laboratory practices can range from a few days to several months. Extended modeling may be counterproductive, if the time exceeds several weeks. See Guide E 730. Rapid prototyping may be more productive (see Guide E 1340).

9.6 *Model Future State Laboratory Practices*—The future state for laboratory practices needs to be defined prior to LIMS implementation/selection. Failure to perform this step may lead the user to automate a "broken wheel." First fix the wheel (laboratory work flow) and then automate the optimum work flow. LIMS should not be used to set laboratory policy or procedures, but LIMS may be used to enforce them.

9.7 *Functional Requirements*:

9.7.1 Develop functional requirements for a LIMS. The functional requirements should meet current and future state work flow and information requirements. The functional requirements can be in the form of a checklist of major features and functions performed in the laboratory (see the LIMS Guide Checklist in Appendix X1). The LIMS concept model can be used as a starting point in developing a list of LIMS functions. See Guide E 622, IEEE 830, IEEE 1016, and IEEE 1228.

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9.7.2 Determine if your laboratory has specific hardware/software standards. For example your laboratory may have standardized on a specific hardware platform (mainframe, mini, local area network). Include references to existing laboratory computers and instruments.

9.7.3 Rapid prototyping of LIMS can aid in defining functional requirements. See Guide E 1340.

9.7.4 Time required for developing functional requirements for a LIMS range from one week for a small laboratory to several months for a large laboratory.

9.8 *Request for Proposals (RFP)*—Issue a request for proposals (RFP) to LIMS vendors. The RFP should include a summary of your functional requirements, annual sample quantity, test complexity and sample work flow/model to define your specific needs. The LIMS concept model can be used to identify your requirements to the LIMS vendors. The sample work flow models found in Fig. 2 and Fig. 3 and Appendix X1 can be used directly if they match your laboratories' requirements. Time required to write and issue a LIMS RFP can range from a week to a month or more. See Guide E 731.

Note 5—Custom LIMS can be built in-house. Custom-built LIMS are recommended only if unique requirements demand it. The cost of building and maintaining a LIMS in-house needs to be compared to the cost of purchasing a LIMS. The functions in commercial LIMS need to be compared to your specific laboratory functional requirements.

9.9 *Evaluation & Selection*—Quotations received from LIMS vendors should be evaluated against the functional requirements document. Objective judgments of the advantages and disadvantages of each LIMS product should be made. Weights can be assigned to each LIMS function for complex systems. Refer to LIMS Checklist in Appendix X1 as a starting point and add your own functional requirements. The people who will be interacting with the LIMS should take an active role in the evaluation and selection steps. Site visits to installed systems are recommended. See section on LIMS database technology and hardware platforms for additional issues. See Guide E 622, Guide E 627, and Guide E 731.

9.10 *Purchase*—The purchase order must contain conditions and provisions that are required by the end users. Typical items include delivery dates, acceptance testing, payment schedules, source code, software support and update policies, required documentation, training, installation, warranties, listing of all hardware and software. Formal contracts can be attached to the purchase orders. See Guide E 731.

9.11 *Implementation*—The implementation time for LIMS is variable. Typical implementation periods range from 1 to 24 plus months. The actual implementation time is dependent on the complexity and size of the laboratory's sample and test structure. See the LIMS implementation section (Section 11) for a list of issues that impact the laboratory during LIMS start up. See Section 9 on Implementation Designs of Guide E 622. Training is an ongoing requirement for LIMS. Time required for training should be scheduled during the implementation period. See Guide E 625.

9.12 *Validation*—The validation of LIMS is a mandatory step for regulated industries. Specific validation requirements exist for industries regulated by the FDA, EPA, and NRC. Validation of LIMS can add three to twelve months to the implementation time. Documentation plays an important role in the validation process for LIMS. See Guide E 627, IEEE 829, IEEE 1008, IEEE 1012, and IEEE 1028.

9.13 *Operation*—The normal operation of a LIMS includes the routine login, result entry, result verification and reports. Routine system tasks include backup, recovery and user account maintenance. Logs are maintained on system functions, maintenance, service, software problems, and security. Change control/configuration management plays an important role during LIMS operations. Changes in hardware, software, laboratory staff, and laboratory environment need to be carefully monitored and controlled. The LIMS software is generally updated periodically by the vendor. LIMS software updates need to be tested/validated prior to live use of the new software. Ongoing training is needed to keep existing LIMS users current with new features and to train new LIMS users. Data integrity checking is a continuous task. Special system software, audit trails, and LIMS reports are used to monitor the fidelity of LIMS data and information. New instruments are connected to the LIMS for transferring information. Links to external systems are maintained and serviced. The archive of LIMS data is periodically performed to manage system storage space and performance. Service contracts are maintained and renewed. Preventive maintenance tasks are performed per predefined schedule. Repairs are conducted on failed hardware units. Software support is conducted with the LIMS vendor using voice, FAX, mail, and modem support. See IEEE 1042.

9.14 *Retirement or Replacement (or both) of a LIMS*—Planning for the replacement of LIMS should begin early in the LIMS life cycle. Technology (software and hardware) changes very rapidly. The technology cycle is often shorter than the typical LIMS implementation cycle. The ease of changing from one LIMS to another is very important with a short technology cycle. Issues include how to retrieve, edit, and report on LIMS data collected from an older LIMS. Questions to be addressed include: do you convert the old data, maintain old hardware to retrieve data on a limited basis, or dump all data to a third party system for archive?

10. LIMS Costs and Benefits

10.1 Good LIMS cost-benefit analysis requires time, solid understanding of the laboratory environment, and comprehension of the benefits realized. Care must be taken not to over analyze the cost-benefit factors beyond the precision required for the project. Cost-benefit factors need to be addressed with other non-cost factors in making the decision to install a LIMS. The cost-benefit components of *not* implementing LIMS should also be addressed. See the Stein articles for additional information (**8, 9**).

10.2 *LIMS Costs*—LIMS costs can be classified in several ways: (*1*) direct versus indirect costs, (*2*) initial versus ongoing, (*3*) purchase versus implementation, and (*4*) tangible versus intangible.

10.2.1 *Purchase Cost (initial costs)*— Purchase cost includes computer hardware, software, installation, cabling, electrical wiring, power condition, climate control, furniture, and on-site spares, and taxes.

10.2.2 *Implementation Cost (initial costs)*—Implementation cost includes: personnel to manage acquisition and installation, disruption due to installation, loss of space taken up by the new LIMS equipment, writing of new standard operating procedures (SOPs), loss of incompletely depreciated equipment, laboratory staff time required to build LIMS tests, specifications, calculations, reports, links to instruments and external computer systems, validation time and the customizing of existing LIMS code to meet functional requirements. Initial training costs should be carefully examined and calculated not only for the project team installing the system, but for each staff member who will use the system. A factor should also be included to provide for retraining of staff unable to learn the protocols during the first pass.

10.2.3 *Cost of Ownership (ongoing)*—Cost of ownership includes service contracts, software support contracts, rental/lease fees, software license fees, consumable supplies (paper, toner, labels, backup media (tape)), personnel to manage the system and to supervise and train new LIMS users, power depreciation costs, ongoing technical training sessions, user group meetings, and ongoing costs related to validation testing for implementation and change.

10.3 *LIMS Benefits Can Be Broken Down Into Tangible, Intangible, and Unpredictable*:

10.3.1 Tangible benefits include items that can be assigned a dollar amount; examples include turn-around time, labor, laboratory throughput, and improved resource utilization.

10.3.2 Intangible benefits include use of state-of-the art information processing, better service management, and easer compliance with regulatory requirements.

10.3.3 Unpredictable benefits include the non-routine problem solving and process improvement that occurs as a result of improvement information processing tools being available with the LIMS.

10.3.4 *Laboratory Throughput and Turnaround*:

10.3.4.1 Labor savings,

10.3.4.2 Data management,

10.3.4.3 Laboratory management,

10.3.4.4 Quality of data,

10.3.4.5 Quality of laboratory operations,

10.3.4.6 Regulatory compliance,

10.3.4.7 Reduction in manufacturing losses (if applicable), and

10.3.4.8 Reduction in manufacturing inventory cost (if applicable).

10.4 *Common Errors in LIMS Cost-Benefit Analysis*:

10.4.1 Expecting immediate increase in productivity,

10.4.2 Expecting turnkey products,

10.4.3 Expecting a paperless office,

10.4.4 Expecting lower maintenance costs,

10.4.5 Expecting improved reliability of automated systems,

10.4.6 Underestimating laboratory staff time required to build LIMS test tables and format the system to user specifications. Vendor must carefully describe actual time required, and

10.4.7 Failure to have strategic planning (funds, personnel, and space) for expansion/replacement of the LIMS.

11. LIMS Implementation Guide

11.1 The impact of installing a LIMS should be carefully evaluated prior to implementation. The time required by laboratory personnel to implement a LIMS is generally *underestimated* (by a factor of 2), especially by first time LIMS users. The underestimation of LIMS implementation time is much more severe in large installations. See Guide E 622. Also see Mahaffey (**3**), McDowall (**4, 5**), and McGinnis (**6**). Formal project management skills are important to a successful LIMS implementation. See Kerzner (**10**) and King (**11**).

11.2 *Purpose and Goals of a LIMS*—The purpose and goals of implementing a LIMS need to be clearly understood by all potential LIMS users. A project definition stating in writing the purpose and goals of the LIMS is helpful (see Guide E 622).

11.3 *Business Aspects of a LIMS*—The business aspects of a LIMS need to be considered; for example, total resources (funding available, number, and skills of laboratory staff), time requirement (for implementation, processing laboratory samples), short and long-range business plans, and objectives.

11.4 *Boundaries Placed on the LIMS*— The scope of the LIMS should be defined. Examples of questions that should be addressed include: (*1*) will all labs within a department or organization be included or just a few; (*2*) is there more than one physical site included in the LIMS; (*3*) are there any time boundaries on LIMS implementation/operation; (*4*) are there any staffing limitations; (*5*) are there any training/skills limitations; (*6*) are communication links to external computer systems required; (*7*) are laboratory instruments going to be directly linked to the LIMS?

11.5 Get buy-in from users during each phase of LIMS implementation.

11.6 *LIMS Staffing Requirements*—Staffing requirements vary widely for LIMS. Staffing requirements are generally divided into implementation and operation phases. Staff resources required to implement a LIMS are generally higher that routine operation. A majority of medium to large LIMS implementations supporting over 50 laboratory staff members require a minimum of one full time person dedicated to maintaining the LIMS. Larger LIMS implementations can have two to five full time staff supporting LIMS and laboratory automation. The LIMS staff generally supports lab automation including LIMS, data acquisition, and robotics. Organizations with data processing departments must decide where to locate the LIMS support staff, in the laboratory organization, or in the data processing organization. Small laboratories may absorb the LIMS staff functions with the existing laboratory staff. The implementation tasks require additional staff resources. Implementation teams can be three to ten people working part time over the implementation phase. The computer and system skills required of the LIMS staff vary with the technology employed. Systems implemented with mainframes or mini computers generally require additional staff resources with higher skill levels compared to PC/LAN based solutions. The ideal candidates for LIMS staff include personnel with both laboratory and computer experience. Finding suitable candidates with both laboratory and computer experience can be difficult. Laboratories have been successful in retraining existing laboratory personnel to acquire new computer skills.

11.7 Have one main party with decision authority responsible for implementation. See IEEE 1058.1 and Kerzner **(10)** and King **(11)** on project management.

11.8 *Loading of Test, Calculation, Specification, and Other Static Information*—The loading of an individual laboratory's tests, calculations, specifications, and other static information into the LIMS database is usually the most time consuming step in implementing a LIMS. A large laboratory with hundreds of tests, calculations, and specifications can spend 6 to 24 plus months on entering and verifying tests. Smaller laboratories with fewer tests, calculations, and specifications can reduce the implementation time to one to six months. This area of planning is consistently the least clearly understood or planned area in LIMS implementation. The failure to clearly quantify the costs and time associated with this single LIMS implementation phase can place the entire project at risk. The total cost in person hours required to enter the test, calculation, and specification information can exceed the total cost of hardware and software. Detailed planning and prototyping is recommended to maximize efficiency in this area. Research and contract labs may have less work than a large QA laboratory. Each laboratory needs to address this task on a case by case basis.

11.9 *Instrument Configuration and Links to LIMS*—The electronic transmission of data and information between a LIMS and laboratory instrumentation offers significant improvements in laboratory efficiencies. Implementing instrument links with LIMS can take many forms. The two broad categories include file transfers and direct capture by way of RS-232 outputs. Common approaches to linking instruments include building standard libraries of import routines designed to read data directly from the output of certain laboratory instruments. Real time data acquisition uses bidirectional communication between the LIMS and the instrument. Advanced LIMS-instrument links include LIMS generated run-list that combine QA/control/standard samples mixed in with LIMS samples. The LIMS determines the order of vials in an autosampler tray. Results from an autosampler/chromatography session are passed to the LIMS for further calculations and reports. Selected LIMS vendors market data acquisition systems that are tailored to work closely with their own LIMS product. Vendor assistance is generally needed to configure instrument cabling and import routines. Data acquisition systems (primarily chromatography based) perform a majority of the instrument data capture tasks. Intermediate data/information is passed from the data acquisition systems to the LIMS for final calculations and reports. A simple example of real time data acquisition would be an RS-232 link between a balance and PC based LIMS terminal. Linking instruments to LIMS can take one to three months depending on the number of instruments, type of instruments, number of custom libraries required for import, and the type of preprocessing performed by the instrument/data acquisition system. Sample preparation steps can also be linked to the LIMS, for example an automated robotic sample preparation station. Standards defining links between instruments and LIMS are beginning to appear. Standards defining links between clinical LIMS and instruments have been published. See Specification E 1394, the

ADISS/AIM, AIA, NIST CALS standards, and the Net CDF Unidata work by Rew **(12–14)**.

11.10 *Information Stewardship*—Organizations should consider fresh new ideas on how to effectively use the LIMS tool. Replicating outdated paper systems should be avoided. New policies will be needed to protect the valuable information assets. Examples of policies include security, data backup, data archive, and disaster recovery. The new LIMS should be designed to make the data request and reports formats as transparent to the end users as possible, so that disruption of services is kept to a minimum. The importance of a clearly defined alternate method of reporting is critical, and this alternative (manual backup) should be tested on a periodic basis. Laboratory information maintained in the LIMS needs to be freely available to client users who are authorized to use the information.

11.11 *Data Integrity*—LIMS data integrity is linked to data entry verification, physical security, system backup, change control, validation, and database maintenance.

11.12 *Training*—End user and system manager training is critical to successful LIMS and should be given highest priority and continued support. Although system management training is usually comprehensive, care must be given to provide sufficient end user training to avoid continual telephone or written queries to the laboratory. Training needs to cover all aspects of LIMS operation from user training on how to login, enter results and report results, to system manager training on how to maintain complex computer systems. User qualification testing is becoming standard for regulated laboratories. Training documents maintained for each user can include personnel backgrounds, education, qualifications, job experience, job descriptions, and formal testing of specific LIMS functions. See Guide E 625.

11.13 *Documentation*—Documentation is critical to the operation of a LIMS. Documentation includes manuals supplied by the vendor and user-developed documents. Examples of vendor-supplied documentation include manuals, technical reference manuals, validation manuals, QC documentation and vendor staff curriculum vitae. User-developed documents include all standard operating procedures (SOPs), training documents, change control forms, definitions, acceptance-testing records, problem report logs, backup and recovery logs, audit reports, and security records. See Guide E 627 and IEEE 1063.

11.14 *Maintenance and Support*—Commercial LIMS generally have maintenance agreements and services that cover technical support with varying degrees of service. The service agreements can include written or implied provisions for software upgrades and training, and clear definitions of both user and vendor support expectations for the life of the arrangement. The service agreement should spell out how disagreements over service will be mediated, and should be made a part of the contract with the LIMS vendor.

11.15 *Change Control*—Procedures for LIMS change control need to be in place at the start of implementation. Change control procedures should define persons authorized to approve changes (hardware and software). Standard forms should be developed to track and manage changes. Information tracked during changes should include requirements to be met before

approval of changes, revision numbers of all codes undergoing change, responsibilities for documenting testing, approving of changed versions, and moving changed versions to the production environment.

11.16 *Legal Issues—Hard Copy Required?* Legal constraints on how your laboratory uses information need to be addressed. Regulatory requirements may require specific LIMS features like audit trails of LIMS transactions. Business requirements may require signed hard copies for all laboratory documents. Legal departments (if they exist) should be consulted on how you are planning to use the LIMS. Concepts of "Best Available Evidence" for laboratory records need to be reviewed and understood by LIMS users. Careful examination of regulations should be done to determine if there is a need for: (*1*) reported results to have provisions for two verifications, (*2*) reported results changed during on-line operations to generate an audit trail, and (*3*) provision that archived data and test/requester tables be loaded into present system for retrieval of information. Retention periods for both raw data and LIMS resident data need to be evaluated and defined.

11.17 *Clinical Laboratory Issues*—Standards have been published on automation in clinical laboratories. See Guides E 792 and E 1029 and Specifications E 1381 and E 1394. Also see list of references at the end of this standard.

12. LIMS and Instrument Standards and Regulations

12.1 Standards are emerging as the LIMS/instrumentation field becomes more mature. The standardization of analytical data formats and the communication of the information from instrumentation to LIMS is critical to free and efficient information flow in the laboratory. The Analytical Data Interchange and Storage Standards Analytical Information Model (ADISS AIM) is one example of the object oriented standards that are under development in the laboratory.

12.2 The International Standards Organization (ISO) has established the 9000 series of standards. LIMS vendors are beginning to adopt the ISO 9000 standards. LIMS vendors must pass a ISO audit to be registered as a ISO 9000 supplier. The ISO 9000 series of standards establishes a minimum level of quality. The ISO 9000 registration is required to do business in the European Community (EC).

12.3 The Analytical Instrument Association has issued a Data Communication Standard for chromatography. The AIA standard is based on the NetCDF toolkit and file transfer methods.

12.4 The U.S. National Science Foundation Unidata Program Center has developed the Network Common Data Form (netCDF) data access library to support the creation, access, and sharing of scientific data in a form that is self-describing and network-transparent. The net CDF data form includes information defining the data it contains. The netCDF data sets can be accessed by computers that have different representations for integers, characters, and floating-point numbers. The netCDF data form supports a variety of scientific data types, including point values, soundings, multidimensional grids, and images. Data sets conforming to netCDF file requirements can be written on one type of computer and read on another without explicit conversion. See Rew and Davis (**12–14**).

12.5 The United States Environmental Protection Agency (EPA) has issued the Good Automated Laboratory Practices (GALP) (**15**) regulation. The GALP document describes acceptable data management practices in laboratories that provide data to the EPA. The GALP is divided into two sections. The first section formally establishes the agency's recommended practices for laboratories to follow in automating their operations. The second section provides laboratory management and personnel with recommendations and examples for complying with the GALP. The EPA combined a number of principles and policies into one integrated document to endure the integrity of health and environmental data for automated laboratories.

12.6 The ADISS Analytical Information Model (ADISS AIM) (**16**) is a formal, standardized taxonomy of analytical data objects. The ADISS model is a conceptual and logical model that is independent of implementation. It starts at a high level of abstraction and works down to very specific instances of analytical data sets. The ADISS AIM is both global to and independent of particular analytical techniques.

12.7 The ADISS information model is part of a global, public-domain architecture for analytical data interchange and storage standards, called the ADISS Architecture. The generalized nature of the ADISS Architecture makes it easier to specialize to common analytical techniques than previous approaches based on particular data exchange or storage formats, query languages, or tool sets. It has been adopted industry-wide to solve specific problems of analytical data interchange and storage.

12.8 The ADISS AIM, by itself, does not address details of machine architectures, application architectures, file formats, or exchange, storage, or archival mechanisms. It can be readily used in flat file, relational, or object-oriented databases. Its typical uses are data exchange (communication), analytical instrument data system software design, laboratory information management system (LIMS) design, integrated spectral database design, spectral library databases, and interfacing laboratory information systems with corporate databases. The top-level information classes in the ADISS AIM are given below. Virtually any analytical dataset can be derived from these classes. Within these classes, materials and their properties can be fully described, along with all specimen preparation and test and measurement procedures needed to give full reports from an analysis.

12.9 *ADISS Information Classesmed:*

12.9.1 Administrative,

12.9.2 Measurement-Description,

12.9.3 Instrument-ID,

12.9.4 Instrument-Configuration,

12.9.5 Sample-Description,

12.9.6 Instrument-Control-Method,

12.9.7 Detection-Method,

12.9.8 Analog-Data-Conversion-Method,

12.9.9 Raw-Data Global,

12.9.10 Raw-Data Per-Scan,

12.9.11 Library-Data Per-Scan,

12.9.12 Peak-Processing-Method,

12.9.13 Peak-Processing-Results,

12.9.14 Instrument-Calibration-Method,

12.9.15 Component-Quantitation-Method,

12.9.16 Component-Quantitation-Results,

12.9.17 Sequence-Information,

12.9.18 Reprocessing-Method, and

12.9.19 Reprocessing-Results.

12.10 These information classes are filled out for particular analytical techniques by looking at data elements from a large cross-section of datasets from that technique. This model is being applied to the major instrumental techniques, such as nuclear magnetic resonance, infrared, ultraviolet, inductively coupled plasma, and atomic absorption and atomic emission mass spectrometry, chromatography, thermal analysis, X-ray spectroscopy, and others. The ADISS Analytical Information Model is the foundation of data communications and storage standards being used by the Analytical Instrument Association's Data Communications Standards Committee, the American Society of Mass Spectrometry, the American Vacuum Society, and other standards developing organizations. See the AIA standards referenced. The ADISS AIM is used to build data dictionaries for individual analytical techniques. From these data dictionaries, implementation templates can be built, for things as data exchange systems (including formats and the tools needed to access data in various formats), instrument interfacing systems, data storage models, and reporting systems.

12.11 The National Institute of Standards and Technology (NIST) conceived the Consortium on Automated Analytical Laboratory Systems (CAALS) to foster the development of automation for analytical chemistry. The CAALS-I Communication Specification describes a set of platform-independent standards for message interchange between analytical instruments (modules) and their controlling computers (controllers).

12.12 These emerging LIMS and instrument standards have been endorsed by a number of important organizations. Commercial products are beginning to enter the marketplace that conform to these standards. Spectroscopic and chromatographic instruments will be the first to adopt the emerging standards.

13. Keywords

13.1 automation; computerized systems; data analysis; information capture; laboratory information management system; laboratory management; LIMS; system management; validation

APPENDIX

(Nonmandatory Information)

X1. LIMS GUIDE FUNCTION CHECKLIST

X1.1 The LIMS Guide Function Checklist (See Fig. X1.1.) should be used as a starting point. Supplement this list with your own specific LIMS functions. A checklist should be prepared for each vendor under evaluation. The LIMS Function Checklist should be part of a formal request for proposal (RFP) document. The LIMS Guide Checklist is set up to be used as a spreadsheet. Each LIMS function is assigned a weight (0–3 for normal functions, and 10 for mandatory functions, where 0 = not required, 1 = preferred, 2 = important, 3 = very important, and 10 = mandatory function). A rank is assigned to each function for how the function compares between vendors (for example three vendor's login functions would be compared head to head, the vendor with the best login functions is ranked with a 3, second best a 2 and third best a 1. A relative score is calculated by taking the weight by rank for each specific function. Each category is summed to compare vendor to vendor by LIMS function. The categories are summed to calculate a final score. This process can be simplified (to one page per vendor) by using only the major category summary items (see Fig. X1.2) without the second level of detail. The method outlined here can be modified to meet specific requirements.

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Vendor Contact Information	
Vendor Name:	Vendor Contact:
Product Name:	Evaluation Date:
Phone #	FAX #:

LIMS Function / Feature	Wt. 0 to 3,10	Rank 1 to n	Score W * R
Login			
Single sample login			
Unique LIMS number automatically assigned to each sample			
Group or Batch sample login			
Routine Schedule login			
Create Login schedule by pattern			
Create Login schedule by calendar marking (stability shelf life)			
List schedule by login template (tabular and calendar image)			
List schedule by test (tabular and calendar image)			
Login from external systems or files			
LIMS Resample Login			
Event Trigger Login			
Modify tests assigned to samples during login			
Ad-hoc login and test assignments			
Register Sample Receipt for prelogged sample			
Add or delete tests or profiles from logged in sample			
User definable login methods			
User definable login screens			
Ease of login			
Login reports			
LIMS Function / Feature			
Labels			
Print container label (with and without bar codes)			
Print container requirements report from schedule			
Print labels from logged in samples (with bar codes)			
Print labels from Schedule			
Print sample receipt			
Print sampling route list from Schedule			
User definable label formats			
Ease of label functions			
Sample Distribution			
Distribution Lists			
Chain of Custody			
Sample routing			
Sample storage and retrieval			
Sample storage inventory management			
Sample disposition / disposal management			
On-line access to sample distribution, storage & safety information			

FIG. X1.1 LIMS Guide Checklist

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LIMS Function / Feature	Wt. 0 to 3,10	Rank 1 to n	Score W * R
Assigning Work			
Select and assign tasks			
Select tasks by analyst, work group, instrument, test, priority			
Print work list by work group, instrument, test, sample			
Work list by test			
Print test backlog			
Print instrument backlog from schedule			
Print instrument backlog from active samples			
Section/Analyst Work lists			
Print work group backlog			
Print analyst backlog			
Specialized Sample group work list			
Print backlog of expiring samples in time order			
Instrument sequence or control file generation			
Tray loading list			
Transmit sequence file to instrument			
User definable work assignment methods			
Analyst Worksheets			
Printed worksheets			
Electronic worksheets			
Sample Preparation			
LIMS Function / Feature			
Data Capture - Entering Data & Information			
Manual Keyboard Data Entry			
Single sample by sample (can use bar code for sample id)			
Single sample by test (bar code sample id)			
Multi sample by work list			
Multi sample by test backlog			
Worksheet single sample data entry (spreadsheet)			
Worksheet multiple sample data entry (spreadsheet)			
User definable result entry methods			
Spreadsheet or auto-entry limit and status checking			
Automated Instrument Data Entry			
RS-232 Instruments			
Acquisition Systems (Down / Up Loads)			
Instrument Control (Bidirectional)			
Auto sampler control			
Robotic Systems			
Review auto entered results			
File transfers			
User definable instruments import / export methods			
Data Import			
Enter results from samples sent out			
Enter results from foreign systems			

FIG. X1.1 LIMS Guide Checklist *(continued)*

LIMS Function / Feature	Wt. 0 to 3,10	Rank 1 to n	Score W * R
Specification Checking			
One level			
Two levels			
Three + levels			
Missing specifications			
Approximate specification checking <,>			
Limit of instrument detection issues			
User definable specification checking functions			
Ad-hoc specification definition post login			
Specifications based on test results			
Warning to user for out of specification (audible, screen message, color, flag)			
Custom user defined algorithms used for specification checking			
Calculations			
Inter Test			
Intra Test			
Intra Sample			
Inter Sample			
Descriptive Statistics			
Advanced Math Functions			
User Defined Functions			
Links to prior results			
Trigger/Event Functions			
Library of math subroutines			
Sample preparation factors			
Linear calibration & method-of-addition calculations			
LIMS Function / Feature			
Quality Control Monitoring			
QC Templates			
Automatic Generation of Control Charts			
Automatic Trend Analysis			
Automatic Calculation of % Accuracy of Controls			
Automatic Calculation of % Spikes			
Automatic Calculation of % Recovered			
Automatic Calculation of % Difference of Duplicates			
Graphics			
2D			
3D			
Data Edit / Correction			
Edit sample information			
Edit Test Results			
Audit trail changes (keep original data plus info on changes)			
Force comments for all changes			

FIG. X1.1 LIMS Guide Checklist *(continued)*

LIMS Function / Feature	Wt. 0 to 3,10	Rank 1 to n	Score W * R
Reviewing and Approving Results			
Review / Verify Tests			
Reschedule a test			
Reschedule a sample			
Approve Samples			
Communicate status to external systems			
User definable review and approval methods			
Reporting Results			
Single Sample Reports			
Group Analysis Reports			
Multi sample reports			
Summary Reports			
Certificate of Analysis Reports			
Graphical Results Reports			
Chain of custody report			
Link to E-Mail Report Distribution			
User definable reports			
Ad-hoc Reports			
Report tools (standard or proprietary)			
Export data sets (small and large) to external systems			
Audit trail reports			
Comment reports			
Control Chart Reports			
Reports to files (disks)			
Contract Laboratory Program Reports & Diskette			
LIMS Function / Feature			
Managing Lab Operations			
Sample status reports			
Workload reports			
Overdue reports			
Instrument loading reports			
Tests performed on instruments by operator			
Tests by instrument for inst utilization and PM			
Instrument calibration management			
Personnel loading reports			
Accounting reports			
Cost allocation report: total costs allocated by account			
Proforma invoices			
Cumulative charges per account			
Quality Assurance reports			
Capability Catalog			
Transaction Log listing and maintenance			
Inventory management			
Instrument Calibration Reports			
Exception Reports			
Reagent & standards inventory reports			

FIG. X1.1 LIMS Guide Checklist *(continued)*

LIMS Function / Feature	Wt. 0 to 3,10	Rank 1 to n	Score W * R
System Maintenance			
System Data maintenance			
Archiving Result Data			
Result Data Export			
Information Access - On-line			
SOPs			
Method development			
Method validation			
Supporting technical information			
Historical QA Data			
Database Structure			
Flat File			
Relational			
Client Server / Distributed database			
Match to current information structure/relationships			
Match to current laboratory material/test/specification structure			
LIMS sample / result data base structure: Assess fit to laboratory			
Sample structure			
Result structure			
Material structure			
Profile structure			
Test structure			
Result structure			
Specification structure			
Relationship between samples and tests			
LIMS Function / Feature			
Data Integrity			
Transactional integrity			
Referential integrity			
Data integrity report			
Data recovery after fault			
Data integrity during concurrent development			

FIG. X1.1 LIMS Guide Checklist (continued)

LIMS Function / Feature	Wt. 0 to 3,10	Rank 1 to n	Score W * R
LIMS (database/system) Performance			
Benchmark tests on live production systems			
Test Database Size (# sample and result records, # fields/record, # of indexes)			
Test hardware environment			
Time to login in 1 sample with 1 test 1 result			
Time to login 10 samples with 10 tests (with 1 result/test) each			
Time to enter results into 1 sample & 1 test (with 1 result/test)			
Time to enter results into 10 samples with 10 tests (1 result/test) each			
Time to enter results into 1 sample & 1 test (with 1 calculated result/test)			
Time to enter results into 10 samples with 10 tests (1 calculated result/test) each			
Time to print final report			
Ad hoc query time (test matrix)			
Time to re-index database (1000, 10000 & 100000 records)			
Number of concurrent users during testing			
Maximum number of users supported			
Multi User Stress Testing - Record locking / contention			
Time to archive records (1000, 10000, 100000)			
Time required to configure LIMS database Static Tables (see "Configuration Tools")			
Are the end users (from site visits) happy with performance?			
Overall Performance Summary			
Database Tools			
User definable tables			
User definable fields			
User definable indexes			
User definable field expressions			
User definable field authorities by data type, category, group, user			
Import / Export LIMS modules (login/result entry methods, screens formats, reports)			
Automatic restructure of old data into new structure			
Configuration Tools (configuration of LIMS to meet work flow requirements).			
Material definitions			
Test definitions			
Tests tied to specific materials			
Standard tests			
Ad-hoc test definition during login			
Pass/Fail tests			
Free Comment tests			
Menu choice tests			
Numeric tests			
Numeric with calculations			
Result/Observation definition			
Algorithm definition			
Tools for building algorithms			
Profile definition			
Time Study definition			
Specification definition			
Revision Control			
Audit Trail changes			
Configuration Reports			
Time required to add one LIMS material with one test and specification			

FIG. X1.1 LIMS Guide Checklist *(continued)*

LIMS Function / Feature	Wt. 0 to 3,10	Rank 1 to n	Score W * R
Time required to add one material with 10 tests and specifications			
Time required to interface instruments to LIMS			
Correct association of specification with historical records after a change in specification			
Correct association of information with historical records after a change in reference information			
Numerical Representation			
Internal representation of numeric values			
number of digits			
picture statements			
Rounding Issues			
User definable rounding rules			
Odd - Even			
Five and greater			
Comparison Operators (<,>,+,-)			
Data Types			
Text			
Integer			
Floating Point			
Fixed point			
Scientific notation			
Logical			
Date			
Integer			
String Manipulation Functions			
Audit Trails			
Result level edits			
Sample level edits			
LIMS database structure edits			
Test Structures			
Specifications			
LIMS methods			
Change Control			
Code Change			
Static Table and specification			
LIMS methods (login, result entry...)			
LIMS Reports			
Security			

FIG. X1.1 LIMS Guide Checklist *(continued)*

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LIMS Function / Feature	Wt. 0 to 3,10	Rank 1 to n	Score W * R
Hardware			
CPU size (data path, clock speed, ...)			
Disk IO			
Network IO			
Printer IO			
Workstation			
UPS			
Physical plant requirements (space, cooling, power, cabling,...)			
Warranty			
Hardware components			
Software			
System Reliability and Maintenance Requirements			
Reliability / Redundancy			
Mean time between failures			
Manual work flow provisions during failure			
Self-tests and diagnostics			
Repair / Replace policy			
Time to repair			
Maintenance training level required			
Preventive maintenance			
Spare recommendations			
Software maintenance & updates			
Frequency of updates			
Install new release in parallel for testing			
Migration of data to new release			
Documentation on software update			
Ease of update process			
Security			
LIMS by group			
LIMS by users			
LIMS by data type			
LIMS by field			
by LIMS function			
by OS System (mini/LAN)			
by facility (physical security)			
by network (WAN)			
by electronic identification (passwords, badges, bar codes)			
by electronic signature (biometric verification, ie retina scan)			
automatic terminal time out			

FIG. X1.1 LIMS Guide Checklist *(continued)*

LIMS Function / Feature	Wt. 0 to 3,10	Rank 1 to n	Score W * R
Vendor Rating			
Voice Support			
Modem Support			
Help Desk Support			
Training Support			
Installation support			
Documentation			
Established Software Development Standards			
Formal Change Control			
Software Revision Control			
Software portability			
Access to source code			
Quality and skills of staff			
Quantity of support staff for customer support			
Quantity of staff dedicated to R&D on future LIMS functions			
Ability of vendor to apply new technology to LIMS product			
Financial stability			
Number of LIMS installed			
Number of years in the LIMS business			
Meet GMP/GALP or other regulatory requirements			
Problem resolution time			
Cost (note: cost can be ranked relative to other vendors or listed in actual amounts)			
Hardware costs			
Hardware cost of ownership (service / maintenance contracts)			
Software costs			
Software cost of ownership (support / updates)			
Cable costs			
Implementation costs			
Training costs			
Links to general purpose tools			
Word Processing			
Spreadsheet			
Pop-up Calculator(s)			
Statistical Analysis			
Graphic Presentation			
Vendor Reference List (obtain the following information from each customer)			
Software Revision No.			
Hardware Platform			
No of concurrent users			
Samples per year			
Industry			
Years of operation			
Contact name			
Phone			
Feedback from end users on LIMS support from vendor			
Feedback from end users on LIMS functions			
Observe LIMS in operation			
Access to source code			
Amount of custom coding required to meet requirements			

FIG. X1.1 LIMS Guide Checklist (continued)

ASTM LIMS Guide Check List Summary

Vendor Contact Information

Vendor Name:	Vendor Contact:
Product Name:	Evaluation Date:
Phone #	FAX #:
Evaluator Name:	Date:

LIMS Function / Feature	Wt. 0 to 3,10	Rank 1 to n	Score W * R
Login			
Labels			
Sample Distribution			
Assigning Work			
Sample Preparation			
Data Capture			
Specification Checking			
Calculations			
Quality Control Monitoring			
Graphics			
Data Edit / Corrections			
Reviewing and approving results			
Reporting results			
Managing Lab Operations			
System Maintenance			
Information Access			
Database Structure			
Data Integrity			
LIMS Performance			
Database Tools			
Static Table configuration tools			
Numerical Representation			
String Manipulation			
Audit Trails			
Change Control			
Hardware			
Warranty			
System Reliability and Maintenance Requirements			
Security			
Vendor Rating			
Costs			
Links to general purpose tools			
Vendor Reference			
ASTM LIMS Guide Score Total			
Attach comments, trip reports, performance testing results, quotations from vendor.			

FIG. X1.2 LIMS Guide Checklist Summary

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Standard Guide for
Validation of Laboratory Information Management Systems[1]

1. Scope

1.1 This guide describes an approach to the validation process for a Laboratory Information Management System (LIMS).

1.2 This guide is for validation of a commercial LIMS purchased from a vendor. The procedures may apply to other types of systems, but this guide makes no claim to address all issues for other types of systems. Further, in-house developed LIMS, that is, those developed by internal or external programmers specifically for an organization, can utilize this guide. It should be noted that there are a number of related software development issues that this guide does not address. Users who embark on developing a LIMS either internally or with external programmers also should consult the appropriate ASTM, ISO, and IEEE software development standards.

1.3 This guide is intended to educate individuals on LIMS validation, to provide standard terminology useful in discussions with independent validation consultants, and to provide guidance for development of validation plans, test plans, required standard operating procedures, and the final validation report.

2. Referenced Documents

2.1 *ASTM Standards:*
E 622 Guide for Developing Computerized Systems[2]
E 623 Guide for Developing Functional Requirements for Computerized Systems[3]
E 624 Guide for Developing Implementation Designs for Computerized Systems[3]
E 627 Guide for Documenting Computerized Systems[2]
E 919 Specification for Software Documentation for a Computerized System[2]
E 1013 Terminology Relating to Computerized Systems[2]
E 1384 Guide for Content and Structure of the Electronic Health Record (EHR)[2]
E 1578 Guide for Laboratory Information Management Systems (LIMS)[2]
E 1639 Guide for Functional Requirements of Clinical Laboratory Information Management Systems (CLIMS)

2.2 *IEEE Standards:*[4]
100 Standard Dictionary of Electric and Electronic Terms
610 Standard Glossaries of Computer-Related Terminology
729 Glossary of Software Engineering Terminology
730.1 Standard for Software Quality Assurance Plans
730.2 Guide for Software Quality Assurance Plans
828 Standard for Software Configuration Management Plans
829 Standard for Software Testing Documentation
830 Guide for Software Test Documentation
1008 Standard for Software Unit Testing
1012 Standard for Software Verification and Validation Plans
1016 Recommended Practice for Software Design Descriptions
1028 Standard for Software Reviews and Audits
1042 Guide to Software Configuration Management
1058-1 Standard for Software Project Management Plans
1063 Standard for Software User Documentation
1074 Standard for Developing Software Life Cycle Processes
1228 Standard for Software Safety Plans

2.3 *ISO Standards:*[5]
9000 Quality Management and Quality Assurance Standards - Guidelines for Selection and Use
9000-3 Guidelines for Application of ISO 9001 to Development, Supply, and Maintenance of Software
9001 Quality Systems—Model for Quality Assurance in Design, Production, Installation, and Servicing
9002 Quality Systems—Model for Quality Assurance in Production and Installation
9003 Quality Systems—Model for Quality Assurance in Final Inspection and Test
9004 Quality Management and Quality System Elements—Guidelines
9004-2 Quality Management and Quality System Elements, Part 2 Guidelines for Services
9004-4 Guidelines for Quality Improvements

3. Terminology

3.1 *Definitions*—This guide defines terminology used in the validation of computerized systems. The standards listed in Section 2 provide additional definitions that the reader may want to review before beginning their validation process.

3.1.1 *acceptance criteria*, *n*—the specifications used to accept or reject a computer system, application, function, or test action.

3.1.2 *change control*, *n*—the process, authorities for, and procedures to be used to manage changes made to a computerized system or a system's data, or both. Change control is a vital activity of the Quality Assurance (QA) program within an establishment and should be described clearly in the establishment's SOPs.

3.1.3 *configuration management*, *n*—a discipline applying technical and administrative direction and surveillance to identify and document the functional and physical characteristics of a configured item, to control changes to those characteristics, to record and report change implementation status, and to verify compliance with specified requirements.

IEEE

3.1.4 *customization*, *n*—the process of adding new software to or altering a LIMS so that it may perform functions not planned by the original system designers. This entails creating new software, compiling software modules, and linking modules to produce new executable programs. If done by the vendor, it may be considered and validated as part of the vendor system. See related definition for "customized system" in Terminology E 1013.

3.1.5 *delivered system*, *n*—the LIMS, as initially supplied by the vendor before any static configuration data have been added. In some cases, the vendor may contract with the laboratory to enter some configuration data on behalf of the laboratory, in which case the delivered system is still considered to be the default system before such customer-specific information has been added. When the vendor performs this task, they are an agent of the laboratory, and the customer shall meet the on-site validation requirements in Section 7.

3.1.6 *dynamic testing*, *n*—the actual testing of various functions and procedures using the LIMS software while in operation.

3.1.7 *installation qualification (IQ)*, *n*—documented verification that all key aspects of the installation adhere to approved design intentions as defined in system specifications and that manufacturers' recommendations are suitably considered.

3.1.8 *LIMS*, *n*—acronym for Laboratory Information Management System that refers to computer software and hardware that can acquire, analyze, report, store, manage data, and process information in the laboratory.

3.1.9 *LIMS data loading (configuration)*, *n*—the process of entering static data into appropriate data structures, such as tables or database records, to make a LIMS suitable for operation in a particular laboratory. This information may include items like names and addresses of laboratory customers, names of laboratory personnel, descriptions of tests performed by the laboratory, specifications, calculations, templates, or descriptions of LIMS reports, etc. In this process, no new functionality is added to the LIMS that was not originally planned by the system designers. Addition of configuration data may affect the behavior of the system.

3.1.10 *LIMS tailoring*, *n*—see *LIMS data loading (configuration)*.

3.1.11 *operational qualification (OQ)*, *n*—documented verification that each unit or the entire system operates as intended throughout its full operating range.

3.1.12 *quality assurance unit (QAU)*, *n*—the body of individuals responsible for design and interpretation of quality standards, such as validation procedures and processes (not product testing).

3.1.13 *source code*, *n*—a computer program expressed in human-readable form (programming language) that shall be translated into machine-readable form (object code) before it can be executed by the computer.

3.1.14 *static testing*, *n*—a structured review of the source code.

3.1.15 *stress testing*, *n*—the running of test protocols designed to test the limits of LIMS functions.

3.1.16 *test plan*, *n*—see *test protocol*.

3.1.17 *test protocol*, *n*—a written procedure describing a set of actions and their expected outcomes that when executed provides documentary evidence that specific functional requirements for the LIMS work as specified.

3.1.18 *validation*, *n*—the process of establishing documented evidence that provides a high degree of assurance that a specific process, system, or item consistently meets its predetermined specifications or quality attributes.

3.1.19 *validation plan*, *n*—the document that identifies all systems and subsystems involved in a specific validation effort and the approach by which they will be qualified and validated, including identification of responsibilities and expectations.

3.1.20 *validation team*, *n*—the group of individuals responsible for the validation process. This team may consist of representatives of the laboratory, QAU, Management Information System (MIS) organizations, or outside consultants.

3.1.21 *vendor audit*, *n*—an independent review and examination of system records and activities in order to test the adequacy and effectiveness of data security and data integrity procedures, to ensure compliance with established policy and operational procedures, and to recommend any necessary changes.

ANSI

3.1.22 *vendor audit team*, *n*—a team made up of individuals who are knowledgeable in computer system engineering, auditing practices, computer system quality methods, regulatory compliance, validation practices, business and legal policies and procedures (applicable only to computer hardware and

software procurement and related services). **(1)**[6]

3.1.23 *version control, n*—control of all associated software and document versions. This also includes all documents associated with implementation, validation, or operation of a LIMS.

4. Significance and Use

4.1 Validation is an important and mandatory activity for laboratories that fall under regulatory agency review. Such laboratories produce data upon which the government depends to enforce laws and make decisions in the public interest. Examples include data to support approval of new drugs, prove marketed drugs meet specifications, enforce environmental laws, and develop forensic evidence for trial. This also extends to LIMS used in environmental laboratories. In some cases these systems may need to be interoperable with CLIMS and computer-based patient records (CPR) for reporting environmental exposures and clinical laboratory testing for biologic measure of stressor exposure. The enormous financial, legal, and social impact of these decisions requires government and public confidence in laboratory data. To ensure this confidence, government agencies regularly review laboratories operating under their rules to confirm that they are producing valid data. Computer system validation is a part of this review. This guide is designed to aid users validating LIMS and incorporating the validation process into their LIMS life cycle.

4.2 Validation must provide evidence of testing, training, audit and review, management responsibility, design control, and document control, both during the development of the system and its operation life **(2)**.

5. The LIMS Life Cycle and the Validation Process

5.1 The process of validation should start at the beginning of the LIMS life cycle as defined in Guide E 1578. Adding validation to the end of the LIMS implementation could add from three to twelve months to the LIMS project. Further, adding validation to the end of the process would prevent the organization from using the LIMS during validation. Fig. 1 represents points where validation may impact the procurement of LIMS. Validation will not have an impact on all of the LIMS life cycle, and the amount of interaction with the validation team will vary during each life cycle phase.

5.1.1 *Validation Team Formation Phase*—This phase is typically not a separate phase in the LIMS life cycle, however, it is a critical part of the validation process. A typical team consists of representatives from the laboratory, MIS group, and QAU. There may be other team members depending on the scope of the project and resources within the organization. If required, the identified validation team members should begin to identify training courses on computer systems validation at this time. No training should take place until those who have been selected for the validation team have their management's full agreement to participate in this activity. These courses can be either in-house or outside-developed courses. The vendor audit team may consist only of the validation team or it may be a specific subgroup within the organization. It is recommended that the vendor audit team should include organizational members from the QAU, MIS, and the laboratory **(1)**.

5.2 *Business Requirements Definition Phase*—The business unit, specifically the laboratory, shall contact the QAU to determine current good manufacturing practices (cGMPs), good manufacturing practices (GMPs), good automated laboratory practices (GALPs), and other requirements that shall be addressed with this project. An initial selection of validation team members is made at this time.

5.3 *Project Definition Phase*—Final agreement and management acceptance for all validation team members should be obtained. Because validation is complex and can take a long time, each team member should have the full support of their management. It is critical that management understands and agrees to the time commitment for these individuals. Without agreement from each member's management chain, the probability for developing and validating the LIMS successfully will diminish. Once formed, the validation team can start to address high-level issues such as the existence of corporate standard operation procedures (SOPs) needed for validation. Time constraints and inexperience of team members can be a limiting factor in the validation process. This is when the team should identify outside consultants that may be needed in the validation process and begin developing the validation plan. Appropriate training of validation team members also should be carried out during this phase of the LIMS life cycle.

5.4 *Model of Current State of Laboratory Practice*—The validation team typically is not part of this process.

5.5 *Model of Future State of Laboratory Practices*—The validation team typically is not part of this process.

5.6 *Functional Requirements Development Phase*—The validation team should work with the group responsible for developing functional requirements. At this time the team can also begin to develop and revise, as necessary, a high-level draft of the organization's validation plan for this project. The validation team may want to begin developing the high-level test protocols during this phase. Further this activity begins to focus attention on validation at the start of the project. Each identified functional requirement should be the subject of one or more test protocols.

5.7 *Request for Proposal (RFP) Phase*—The validation team shall ensure that the RFP includes both a request to audit the vendor and their validation requirements. People using this document for acceptance testing who are in unregulated industries may not require this audit process. Also, the validation team should request that the vendor's development process and LIMS application have undergone independent evaluation/validation. If another company, that is, a third party consultant or another corporation, has validated the vendor operation and LIMS development process, it does not mean that the prospective buyer can assume that the software is validated. During this time the team should specify what actions to take if a LIMS vendor denies them the right to an audit. The validation team should review the RFP prior to its submission to the vendor.

5.8 *Evaluation and Selection Phase*—The validation team should identify those people who will participate in vendor

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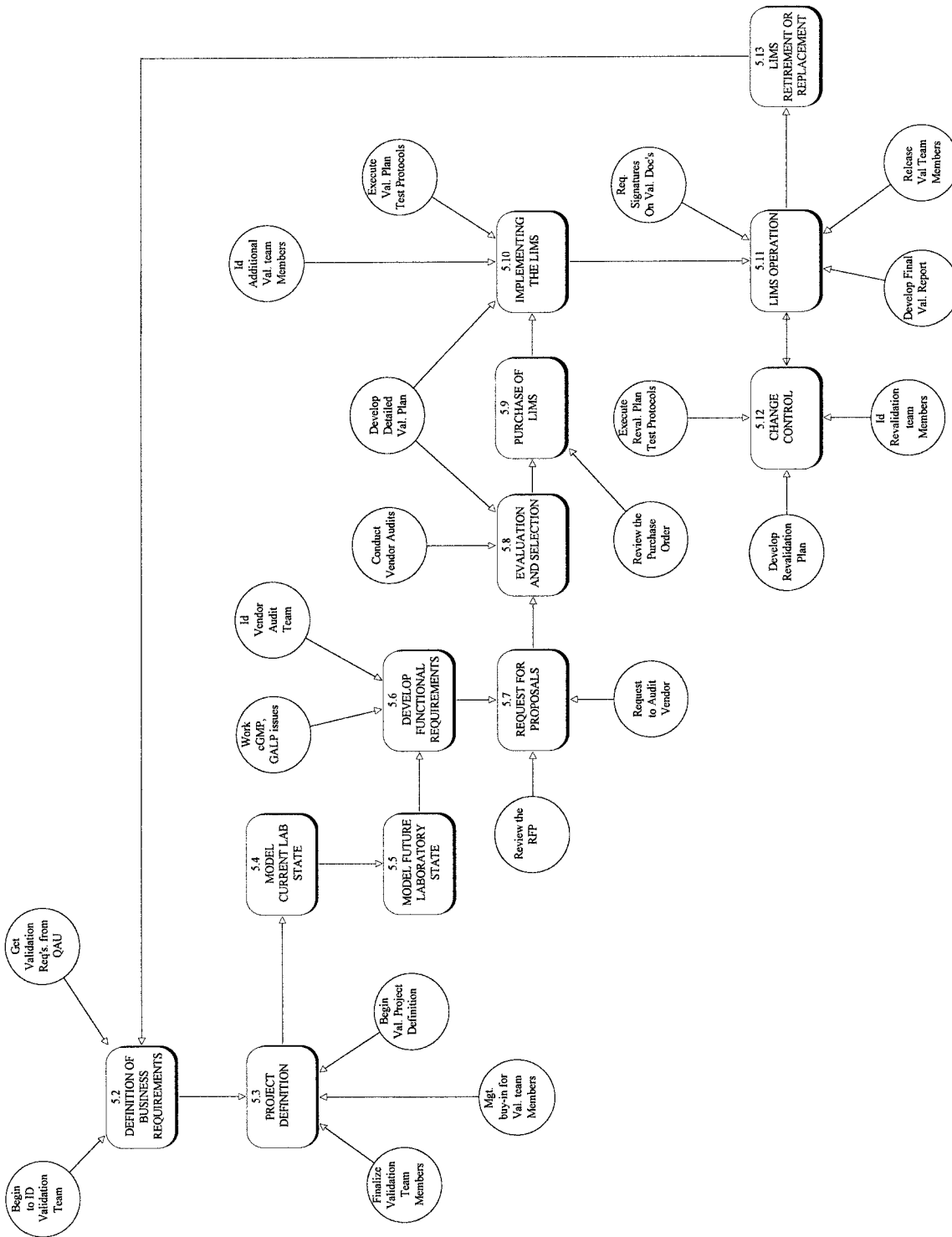[6] The boldface numbers in parentheses refer to the list of references at the end of this standard.

FIG. 1 LIMS Life Cycle

reviews. Since this process can take from one to several days, only those LIMS manufacturers targeted by LIMS team should be visited. The prioritized selection of LIMS shall be based upon the vendor's answers to the RFP. The RFP answers will normally emphasize the stated functional requirements. Perform a vendor audit to find the built-in quality. Continue vendor audits until an acceptable vendor for both quality and function is found. The audit results are useful in assessing the buyer's exposure to risk when system functionality is balanced against quality of system development. See Section 6 for more auditing of the LIMS vendor.

5.9 *Purchase*—Validation team members should review and be part of the purchase order approval process to ensure validation issues and criteria outlined in 5.8 are met and to begin the early stages of configuration management.

5.10 *Implementation Phase*—The validation team shall finalize the validation plan and other documentation that must be approved by the system owner and authorized by QAU before the plan is carried out. A schedule of events is developed. Testing protocols will be executed and the results documented. When all test protocols have been executed and documented, the final validation report is developed and the required signatures are obtained to approve this report. The final approval will be obtained from the system owner as authorized by QAU.

5.11 *Operational Phase*—When all validation tasks have been completed, the validation team can be disbanded. Tasks in this area include the following:

5.11.1 Ongoing training of new users.

5.11.2 Modification of SOPs to address necessary changes to the LIMS or its operational environment.

5.11.3 Review of procedures and their adherence to existing SOPs, documenting compliance with SOPs.

5.11.4 Maintenance of change control procedures for the existing system.

5.11.5 Maintenance of the system.

5.11.6 Upgrades to the LIMS hardware or software. This also includes all associated hardware or software in the LIMS operating environment, that is, the LAN, computers' operating system, etc. See the change control phase in 5.12.

5.12 *Change Control*—The LIMS Manager will face change control issues often during the normal operation of a LIMS. The LIMS Manager must understand that all minor and major changes to the system shall be subject to change control, assessment of consequences, and revalidation after the change takes place. Upgrades in software as well as changes in how the system is used may require revalidation. The change control committee may determine the system changes require revalidation. All changes shall be documented, as well as assessment of the need to validate the change and the extent of the revalidation. The level of detail for the revalidation process depends upon the type of change. A new validation team may be needed. This team may wish to include some test protocols from the original validation process. The degree of revalidation is highly dependent upon the impact of the identified change. Change requests and problems should be documented (see Appendix X6) (3).

5.13 *Retirement/Replacement of the LIMS*—The process starts over with the establishment of a new validation team.

6. LIMS Vendor Assessment/Audit

6.1 Industry regulators require laboratories to ensure that computer applications, such as LIMS, are validated. It is the responsibility of the laboratory owner to demonstrate that specific applications are developed, tested, operated, and maintained according to accepted quality practices.

6.2 The regulatory authorities expect that organizational personnel will follow the formal policies governing operations, as well as, comply with the proper levels of control and documentation. Further, they expect vendors to use the same level of quality control and quality practices as the customers they are supplying. It is the system owner's responsibility to investigate the vendor's operation and verify that they have accepted practices in place and that they are using them. The system owner can use the vendor audit to inspect and evaluate the vendors quality assurance programs, practices, and documentation procedures.

6.3 An organization may want to outsource vendor audits when they lack the organizational expertise, see it as a more cost effective, or they want a more objective or thorough audit. The use of audit results from a third party not associated with the user's organization, or those performed by another corporation, may not be used as a substitute for auditing the vendor. Alternatively, an audit that is jointly conducted by a consortium of corporations all looking to use a particular vendor's application has been used in the past with regulatory authority approval.

6.4 Vendor assessment should occur during the evaluation and selection phase of the LIMS life cycle and before final vendor selection. If the organization already has a vendor audit team established, this group should review their system functional requirements with the LIMS validation team. If the organization does not have such a team already established, they may want to have members of the LIMS validation team perform the vendor auditing. The audit team should be comprised of an experienced software auditor internal or external to the company and one or more individuals from the LIMS team. In general, there should be someone on the audit team responsible for the long-term relationship with the vendor. Typically, this person is the system or application owner.

6.5 The primary goal of the audit is to ensure that the vendor's software development and management procedures are consistent with the accepted practices, that is, those which are traceable back to a reference point and to which these practices adhere. This means that the audit team shall assess the vendor's quality measures, which affect the product they sell and the quality support they provide in the future. The audit team can meet this objective by gathering evidence, which demonstrates that the LIMS vendor is adhering to well-defined and documented software development and maintenance standards or practices (4).

6.6 In addition to these objectives, the auditing organization should evaluate the vendor's financial health and stability (1). It should be noted that even though a LIMS vendor organization is registered as meeting national or international requirements, for example, ISO 9001, the vendor is not exempt from

being audited by their customers. The purchasing organization is still responsible for auditing the prospective LIMS vendor. See Fig. 2 for the GAMP 96(5) guideline on the auditing process flowchart.

6.7 The vendor assessment should cover software development, software maintenance, quality and control issues (4).

Key areas that should be targeted for inspection include documentation that supports system testing, preventive maintenance, operation and maintenance manuals and administrative procedures (1). The source code review process should be limited to a random sampling of the source code modules that the customer selects. Each item should be ranked for the
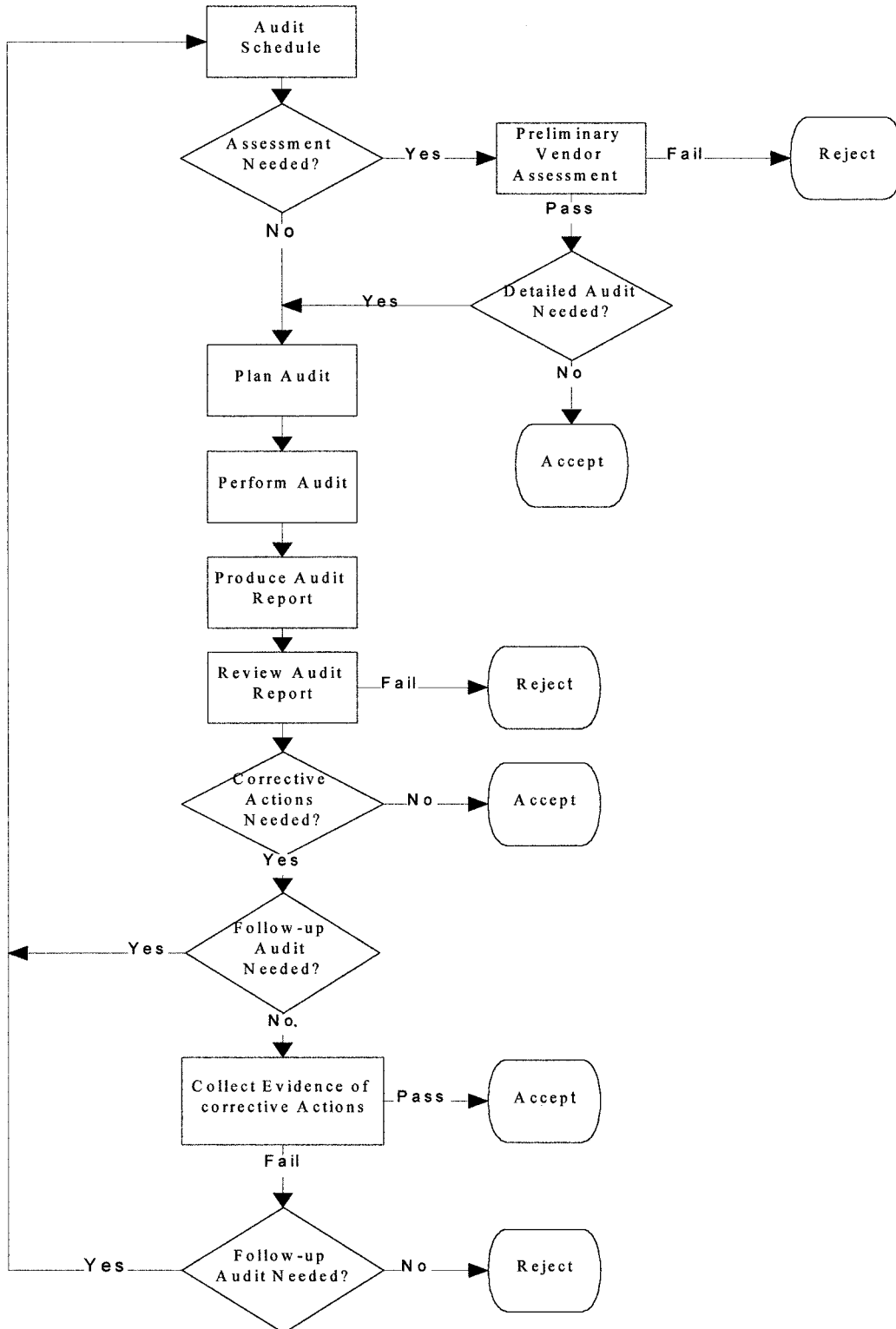

FIG. 2 Auditing Process

vendor's ability to meet that particular audit point. For example, a major discrepancy would indicate that the vendor had little or no compliance to the audit point/area. A minor discrepancy indicates that the vendor has some compliance. Both ISO 9000-3 and IEEE standards are detailed and may be used to create individualized checklists. It is important to remember that there are many different ways to accomplish compliance, and the auditor must take great care to understand how the audited company works and compare that to the standard instead of comparing it to his or her own quality system. See Appendix X1 for an overview of software items that should be investigated.

6.8 The organization should have established corporate auditing guidelines that describe in detail the procedures to which the vendor audit team shall adhere. These procedures should cover all activities from the initial vendor contact to the final meeting with the vendor. The overall auditing cycle can be divided generally into four stages: preliminary audit, detailed audit, follow-up audits, and surveillance audits (5). Each of these stages has its place within the overall auditing process.

6.8.1 *Preliminary Audits (Preaudit Activities)*—The goal of this stage is to gather enough documented evidence to determine if a detailed audit is required. The tool used to perform this auditing stage is typically a questionnaire. The questionnaire can be divided into the majors areas of concern, such as general corporate background information, sales information on the LIMS application (version-specific), vendor's software development life cycle (SDLC) procedures, and the product development history. Specifically, the buyer should request that the vendor supply, in advance, those standards, procedures, and plans that are associated with the LIMS application being investigated (1). The audit team should look for technical standards, manuals, or guides covering the following: development methodologies, software quality assurance practices, change control procedures, configuration management procedures, personnel training procedures, user support documentation, testing procedures, technical review practices, and security procedures (1).

6.8.2 *Detailed Audit*—When conducting these audits the organization should cover all aspects of interest relating to the application of LIMS. The validation team should plan their audit before actually performing it. The plan should establish the scope of the audit, who will be auditing, and the timing agreed to with the LIMS vendor. The audit notification should specify the purpose, timing, targeted system, scope, and the measurement criteria of the audit (1). The audit process itself can be divided into three major steps: the opening meeting, the review and inspection, and the closing meeting (5).

6.8.2.1 *Opening Meeting*—The opening meeting establishes the basic ground rules of the audit. Items to be addressed include, but are not limited to, introductions of everyone involved in this audit activity, the scope, purpose, agenda, schedule, location of the validation team meeting room, arrangements for accessing specific documents, and the signing of any confidentiality agreements by the LIMS vendor or the validation team members.

6.8.2.2 *Review and Inspection*—The audit team examines the LIMS vendor's records and their practices in accordance

with these documents. The goal is to establish documented evidence that the LIMS vendor operations show adherence to their quality procedures during the LIMS development. The audit team can perform the audit using a checklist based on the scope of the audit. A successful auditor should use a "show me" approach when auditing. The required depth for coverage of each audit item will vary, but in general the audit team should identify one or two items that they will cover in great detail (5). The audit team may want to hold daily wrap-up sessions designed to capture that day's activities. Any observations made and their impact on quality issues should be addressed at this time. The audit team also should begin developing a list for tracking follow-up action items (1). This guide will aid in creation of the final audit report.

6.8.2.3 *Closing Meeting*—The lead audit team member will list all observations that the team noted during their audit. This should include positive results as well as issues of concern (5). The vendor's response to the observations should be included in the documentation used to develop the audit report. The audit report is important because it serves as documented evidence of the audit and its findings, as well as the basis for determining corrective actions required by the vendor. As such, the report shall present the data accurately and objectively. Because it is sensitive, the audit report should be treated as a confidential document. The audit team should close the audit with the following next steps: *(1)* the lead auditor will produce an audit report, *(2)* the audit report will be reviewed by the audit team and management, who will devise a set of corrective actions, and *(3)* the LIMS vendor should be contacted by the lead auditor and devise a plan to implement the identified corrective actions (5). Individuals receiving the audit report will be identified. Expected response times to address the identified weakness shall be included in the audit report (1).

6.8.3 *Follow-Up Audit*—Follow-up audits review the progress made by the LIMS vendor on those items identified as areas of concern on the previous audit. The organization looking to purchase the LIMS has a few options they can pursue based on the outcome of the audit report. These options include the following (5):

6.8.3.1 Use the LIMS supplier unconditionally.

6.8.3.2 Use the LIMS supplier for certain LIMS products only, for example, specific versions.

6.8.3.3 Use the LIMS supplier only after specific corrective actions have been carried out.

6.8.3.4 Prohibit the use of the LIMS vendor.

6.8.4 If the LIMS vendor agrees to make the necessary corrective actions outlined in the audit report, the organization purchasing the LIMS should obtain the necessary documentation from the vendor for the changes made.

6.8.5 *Surveillance Audit*—These audits focus on weaknesses found during previous audits and any new features or LIMS products, for example, a new stability study module. These audits should follow the same general guidelines adhered to by the original audit. The frequency of these audits will depend on previous audit results and criticalness of the issues that need to be addressed.

6.9 The validation team, in concert with management, should establish an action plan for those instances in which the

LIMS vendor refuses to allow an audit. The LIMS validation team must remember that it can not test quality into the system. Further, the amount of testing is proportional to the level of risk the organization will take for implementing the LIMS. Options available to the organization include the following:

6.9.1 The organization accepts the business risk and performs a much greater degree and depth of validation for the LIMS.

6.9.2 The organization rejects the LIMS vendor and moves the selection process towards alternate LIMS vendors.

7. Validation of LIMS Installed at Customer Site

7.1 The customer shall validate their use of the LIMS, independent of any vendor audit, in the operational environment in which the LIMS will be residing. The fact that a vendor's LIMS development process has been validated by the vendor or other organizations has little bearing on validating the organization's LIMS application. Further, the fact that a vendor's LIMS software has been validated by one of their other customers does not obviate the need for an organization to validate their implementation of the application.

7.2 As key functional requirements are identified and evaluated during the product evaluation phase, their results should be recorded. These results may be used in development, execution and documentation of the official LIMS test protocols. Any testing done during development of the LIMS test protocols or overall validation plan should be further refined once a specific LIMS has been selected. It should be noted that the level of testing and evaluation done during the evaluation and selection process generally will not contain enough detail to replace the test protocol used in the validation plan documentation.

7.3 The LIMS validation team may begin to identify additional resources to test the LIMS. Any new individuals selected should be familiar with the laboratory's requirements and its operation. Further, they should be knowledgeable about cGMP, GMP, GLP, GALP, or other requirements that the laboratory shall follow.

7.4 The LIMS typically is delivered as an empty database, that is, devoid of site-specific data. Configuration data and fixed laboratory information must be entered before the system can be validated. At this point, the organization starts to model their laboratory practices in LIMS. This includes test and workstation definitions and laboratory and customer personnel data. It should be noted, that during this step the laboratory may encounter additional functional requirements that were not captured initially. If the organization chooses to implement such functionality, the LIMS requirement document shall be revised to reflect these changes. Further, during this step the organization may uncover requirements that the LIMS cannot meet. The organization should document these facts and include what actions, if any, they will take to solve this problem. There are several strategies that can be used to validate a LIMS. These include, but are not limited to, the following:

7.4.1 Configure the LIMS specifically for testing with only enough configuration data to permit testing. In this case, the test system is identical to the production system, specifically, it is functioning in the same operational environment as the production system. Generally, this means that it is operating on the same computer on which the production system will reside. The configuration used in the test system shall exactly match the production system. Specifically, all reports, entry screens, queries, etc., must be identical. Furthermore, all features that are to be used in the production LIMS shall be checked for proper operation in the test system.

7.4.2 Configure the LIMS for regular operations, then isolate it from normal service while testing it. A system configured for use is called the production system. This can be accomplished by copying the production database to the test system. The LIMS program executables are the same, for example, the validation data may be part of a separate set of database tables that use the same program executables as the production LIMS, or the validation data may be part of different data group that uses the same database tables and executables as the production LIMS. The difference is in the sample data tables. If there are no problems, this approach saves time. The LIMS does not have to be configured twice, once for testing and again for production. If problems are found, partial or complete reconfiguration may be required after repairs are made. Documentation verifying that the production system is equivalent to the test system shall be provided, and the data generated during the validation process should be retained and identified as validation data.

7.4.3 A separate computer system may be used for testing.

7.4.3.1 The separate computer may be configured specifically for validation, as in 7.4.1, or it may be a copy of the production system, as in 7.4.2.

7.4.3.2 If a separate computer is used, it should have identical hardware, software, and operating system. The operating environment shall be identical to the one used for the production system. Instrument interfaces may be difficult to install on such a test system, but if they are part of the production system, they must be part of the test system as well. Ultimately, the test system could provide backup hardware for the production system.

7.4.3.3 The production and test systems may exist on the same computer, if it is sufficiently powerful, running independently. In this case, both software systems may have access to the instrument interfaces.

7.4.3.4 A subset of tests is needed when the test system is converted to the production system. These tests are used to confirm that the system still functions properly in production mode. No artificial data needs to be loaded into the active system. This subset of tests may consist of vendor-supplied diagnostic routines and little more, as long as they reliably test all parts of the proposed system. While some vendors supply these types of tools, many do not. There is no standard for their construction and execution. The use of such tools should not be the only means of testing the LIMS, but rather augment a more rigorous set of test protocols. In some cases the organization may require the tools themselves be validated prior to their use.

7.4.4 Parallel testing may be used. For a new LIMS, the manual systems can be used simultaneously with the LIMS and the results compared. If the new LIMS is a replacement, both old and new systems can be used in parallel for some period of time to compare them. The existing validated system is the

production system, while the new LIMS is the test system. Validating interfaces to instruments are an issue with a parallel testing approach, since they cannot usually be connected to both systems at the same time. In this case, the organization shall develop an approach that allows for the testing of these interfaces. The organization may want to connect these interfaces to the system undergoing validation after all other tests have been executed and just prior to the development of the final validation report. Another approach is to incorporate these interfaces as their own validation project conducted after the initial validation has been concluded.

7.5 *Response to Errors*:

7.5.1 Error handling and acceptance criteria shall be defined and described in the validation protocol and followed during the testing and reporting of results. The definition shall include criteria to be used to assess severity of errors.

7.5.2 Critical errors, such as system crashes or fatal errors, located during validation tests should be corrected or repaired immediately, before additional testing is done. Often the correction of such errors requires that most or all of the validation tests be run again. These are errors for which there is no work-around. These errors seriously threaten the integrity of the LIMS data.

7.5.3 Noncritical errors should be accumulated during the validation tests. When testing is complete, the team may decide these errors do not compromise the integrity of the information. These are errors which could result in the possibility that unacceptable result data would be accepted by the LIMS. There may be an acceptable work-around for such errors.

7.5.4 The validation team may wish to use an error grading system that helps to take action when errors are encountered. Each error would be identified by grade, and a decision would be made on what follow-up, if any, is necessary. The following are examples of grades and the errors that fall into those grades (**6**):

7.5.4.1 *Grade 0*—Typographical errors and other errors not related to the computer system.

7.5.4.2 *Grade 1*—Minor errors such as the use of upper and lower case letters used in fields not constructed for them.

7.5.4.3 *Grade 2*—Tolerable errors that must be communicated to the vendor.

7.5.4.4 *Grade 3*—Major errors that must be immediately reported to the vendor and the QA manager. All validation efforts should be suspended until QA has discussed the problem.

7.5.4.5 *Grade 4*—Disastrous errors such as relational errors in the database. These are reported the same as Grade 3 but the validation effort should be aborted. QA could still decide that the effort continue after thorough discussions.

7.6 *Standard Operating Procedures (SOPs)*:

7.6.1 SOPs are necessary for validation and ongoing operation of an organization's LIMS. These documents cover several areas, from the operation of the LIMS application through to the hardware on which the application resides. The SOPs formalize the procedures used to maintain the LIMS in a validated state by describing specific procedures to be followed. These procedure help ensure that the organization maintains a quality operation. SOPs are detailed in 11.4.

8. Validation Plan Design

8.1 The validation plan provides the overall direction of the validation process. The validation plan includes, but is not limited to, the overall objectives, a description of the system, any test boundaries or assumptions under which the validation team will be operating, the participants' responsibilities, and any general instructions for the execution of installation qualification (IQ) or operational qualification (OQ) test protocols. The validation plan needs to include a listing and description of all software and hardware components. Sometimes software modules associated with the LIMS are changed by the installation of other software. These changes could be from operating system upgrades, an upgrade to the LIMS, or other unrelated software. Further, the addition of hardware components, video cards, modems, sound cards etc., and their associated software can affect the initial LIMS validation state. The detailed listing of software and hardware components associated with the LIMS is essential as it makes up the LIMS initial configuration and describes the beginning state from which all change control is based. All test protocols for both the IQ and OQ of the associated hardware and software components are included in the validation plan. The last part of the validation plan is the signatures of the individuals responsible for ensuring that validation plan meets the organization and regulatory requirements. Typically, these signatures include the QAU validation manager, a laboratory manager, LIMS manager, and others.

8.2 IQ testing should be based on manufacturer's specifications, or recommendations, or both. Application-specific configuration will be verified as part of the IQ/OQ testing.

8.3 Vendor-supplied diagnostics can be used as part of IQ/OQ testing. IQ/OQ protocols based on vendor-supplied diagnostics shall include step-by-step verification of diagnostic procedures, recording of all results, and acceptance criteria for each result.

8.4 IQ/OQ protocol documents and test results should be produced for all hardware and software used with the LIMS, that is, operating system, database, report generators, statistical packages, network, connected instruments, computers including terminals, PCs, clients and servers, printers and plotters, bar code readers, etc. If the LIMS application is being loaded on an existing computer system, the original hardware IQ documentation may be used.

8.5 A suggested format of the IQ/OQ protocol document can be found in Appendix X2.

9. Test Protocol Design

9.1 Each organization should determine which LIMS features may attract the largest amount of attention by the auditing agencies. The organization shall determine what level of risk they are willing to accept. To validate every feature is too costly in terms of resources and time. McDowall has suggested that the organization divide the LIMS functions into one of the following three categories: must validate, should validate, and could validate (**2**).

9.1.1 The validation test protocols need to identify critical LIMS functions that will be tested. Critical LIMS functions should be based on core functions and the intended use of the

LIMS application. Rationale should be provided for not testing portions of the LIMS.

9.2 The development and execution of test protocols (TP) takes the largest amount of time in the validation effort. This fact often is overlooked when the validation project plan is developed. Many factors affect TP development and execution. First, good familiarity with the new LIMS and how it operates are essential. The less familiar the user is the longer it takes to develop detailed TPs. The validation team should build sufficient time into the project schedule for the personnel developing TPs to develop familiarity with the new system. A second factor affecting TP development is how long the TP developers have to focus upon the validation project. Not focusing enough on the TP development effort will add a significant number of additional months to the validation project. The execution of the TPs also is affected significantly by focusing the testers on the execution of the TP. A third factor affecting TP development is the number of resources available to work on the TPs. Last, the experience level of the individuals writing and executing the TPs will affect the time necessary for these activities. If possible, the organization should have at least one experienced individual working with those developing and executing the TPs.

9.3 The number of TPs necessary for validating the LIMS depends on the complexity of the LIMS and the level of detail required to adequately test the key features. TPs can be as simple as one or two lines of execution instructions or as complex as several hundred lines. The level of complexity will depend on the direction that the organization takes in the design of their TPs. Each organization should have an organizational SOP that describes how TPs are to be designed. The design can be as simple as very high level and general instructions on what testers should do and what they should expect as their acceptance criteria. TPs designed in this manner generally require the tester to write down, in detail, what they have done. At the opposite end of the spectrum are those TPs that instruct testers step by step on what to do. TPs designed in this manner typically require the testers to answer yes/no or true/false to the acceptance criteria. In either case, complex TPs can take several days to execute and document. The detail captured by testers for each TP should be sufficient enough to ensure that the LIMS function or the process being tested is under control. See Appendix X3.

9.4 In addition to execution of the TP, the validation team shall incorporate the time necessary to review TP results and to solve any identified problems. The review process can take almost as long as the execution of the TP, if the test is extremely complex. The time necessary to carry out this validation step often is underestimated. The review of each TP is necessary to ensure that the content makes sense and that it adheres to GMP documentation requirements. Specifically, all errors should have a single line drawn through them; the tester should initial, date, and give a reason why the word or group of words were crossed out. In some cases the reviewer may be responsible for deciding if the TP has met its acceptance criteria successfully, and thus, either passes or fails.

9.5 The validation team should address in the validation plan how they will handle failed TPs. This shall be addressed before the testing begins. They also should address early on how they will allow changes to the TPs after approved by the QAU. There are times when testers will need to make changes to the TP during the execution phase of a TP. Testers should be provided a way to incorporate these changes into the existing TP. The procedure shall be approved by the QAU and incorporated into the validation plan. It is essential to giver testers freedom to further design and follow additional test steps when executing the TP. This freedom allows them to explore why a particular step or set of steps did not meet its acceptance criteria. Without this freedom the entire validation project can be delayed.

9.6 All TPs shall be designed to test the given LIMS feature or function. The actual design of TPs will vary from organization to organization. The designer of the TP may wish to include any or all of the following in the design of the TP:

9.6.1 *Test Protocol Header Information*—This section contains the name of the corporation using the LIMS, the department name of the LIMS owner, date the TP was designed, statement if the TP is for IQ or OQ, TP revision number, and what system is being tested (for example, ABC LIMS Version 7.1).

9.6.2 *Test Protocol Identification Number*—Each TP should have a unique identification number. This number is only unique to the associated validation plan for the TP.

9.6.3 *Purpose*—What the TP is designed to test. For example, the purpose is to verify that new users can be added, modified, or deleted from LIMS.

9.6.4 *Requirements Under Test*—These are the functional requirements that are being tested by the TP. The TP may be designed for more than one functional requirement. Any functional requirement that was not included into the validation plan should not be included in the development of the TPs.

9.6.5 *Special Needs/Requirements*—This section lists special items that are needed to execute the TP, including specific skills the testers must have or links to other test protocols or other applications.

9.6.6 *Test Step Procedures*—Each test step should include a step number, a test procedure, and acceptance criteria for that step. Further, the test steps should be divided into and have a set of test steps for each of three categories: normal testing, stress testing, and robustness testing. Normal testing steps test the LIMS function using all common user commands. Test steps that test the function at its boundaries are stress testing. An example would be entering 20 characters into a 20 character field. Robustness testing represents testing the feature outside its boundaries. For example, a user's password may only accept character and numbers, so testers are instructed to enter special characters or punctuation characters for a newly created user's password. Testers shall identify if the test step passed of failed acceptance criteria. Typically, this is a simple yes/no statement.

9.6.7 *Comments Section*—This section is used by testers to enter their comments on any unexpected results obtained while executing the TP. Users also can capture how these unexpected results were resolved.

9.6.8 *Tester Sign-off*—The tester should sign and date the TP at the end of the testing process. If the TP covers several pages, the tester only should sign and date the page when they have completed the test steps on that page. In some organizations testers are responsible for determining if the TP passes or fails. If the TP fails, testers should document in the comments section why the TP fails. If they have identified a possible resolution, testers should document this as well.

9.6.9 *Reviewer Sign-off*—The TP reviewer should sign and date the TP only after reviewing the data and concurring that the TP has been completed. If questions exist, the reviewer should not sign the TP until the questions are answered. In some cases, it is the responsibility of the reviewer to determine if the TP passes or fails. If the TP fails, the reviewer should use the comments section to explain why. The reviewer should not make changes to the document. If changes need to be made, the original tester should be contacted to make the changes.

9.6.10 *Attachments*—All attachments that are part of the execution of the TP should contain the following pieces of information: the TP identification number, the step number, initials of who created the attachment, and the date the attachment was created. Furthermore, the tester may want to highlight or explain certain items on the attachment. Any handwritten item requiring change shall follow the same criteria as the TP and include a single line through the item, initials of the person making the change, date, and a reason for the change.

9.7 As TPs are finished they should be forwarded for review. After they have been reviewed and signed, they should be given to the validation team leader. This will facilitate the development of the final validation report. Furthermore, if there are identified system outages to be addressed, the validation team leader can start to address these issues without impeding the progress of the testing team members.

9.8 The validation team members can use several approaches to design and test their LIMS implementation. The test team may wish to include the following additional approaches in the TP design:

9.8.1 Running vendor supplied diagnostic tests (supplied tools/test set may need to be validated prior to their use).

9.8.2 Running automated testing tools, if available, for that particular LIMS (supplied tools/test set may need to be validated prior to their use).

9.8.3 Log results manually along with the LIMS for a given time period, and compare the results.

9.8.4 If the LIMS has telephone access, test the associated telephone security measures thoroughly.

9.8.5 Introduce errors deliberately, and determine if the system properly identifies and rejects them.

9.8.6 Stress the system by artificially and completely filling it with data, or running many activities at once.

9.8.7 If operating in a windows environment, for example, open all the windows at once.

9.8.8 Schedule heavy loads.

9.8.9 Test security by trying to break in or use prohibited functions. Look for "back-door" entry points.

9.8.10 Try to abort an input to see if the system behaves as specified.

9.8.11 Visually observe interfaces and other aspects that produce a discernible action.

9.8.12 Vary load sequences of automated instruments.

9.8.13 Review every output screen for completeness, correct data in every field, and adherence to specification.

9.8.14 Use screen capture or keystroke capture techniques to review system operation.

9.8.15 Test all event triggers by forcing them to happen. Include scheduled events and, as much as possible, exception events.

9.8.16 Disconnect the power to interfaced instruments, servers, and other parts of the system.

9.8.17 Use protocol testers for network performance, including adherence to protocol, timing, and data integrity.

9.8.18 Use instrument simulators, if available, to test exceptions and errors in interfaces.

10. LIMS Operation

10.1 Once the LIMS has been validated, operational system maintenance begins. At this stage the validation team members can be disbanded. From this point on those responsible for daily operation have the responsibility to maintain it in a validated state. The critical issues that face the organization, and more importantly the LIMS Manager, are as follows (**2, 7**):

10.1.1 *Configuration Management*—The purpose of configuration management is to ensure that any changes to the hardware, firmware, network, LIMS executable code, or any other component that was part of the initial LIMS validation process are identified and controlled. All LIMS applications and the hardware platforms on which they reside will change. It is essential that the organization controls and documents these changes. The procedures for managing these changes fall under configuration management. Configuration management starts during the development and execution of the LIMS hardware and software IQs and OQs. At that time the validation team established a listing of all hardware and software in the LIMS setup and configuration, including part numbers, release numbers, serial numbers, and software version numbers. All these items together make up the initial LIMS configuration. This is the baseline for configuration management. Additional items that should be considered are DLLs used by the LIMS application and any associated software. In this case the user shall track DLL names, dates installed/written, and versions. This is crucial to ensure that no other software changed the DLLs used by the LIMS. The objective is to show that the organization is in control of the LIMS. The organization must show that once the initial configuration has been established, all changes to that configuration are authorized, tested, and documented. It is essential that if responsibilities for the various parts of the LIMS configuration are shared by other organizational groups, for example, information services, maintains the network infrastructure, they must be aware that they cannot make changes to their area of responsibility without first checking with the LIMS manager and the organization.

10.1.2 *Change Control*—Changes to the LIMS are a fact of life. It is imperative that all the implemented changes go through change control. Change control involves several steps: change request, analyze impact, review/approve, implement,

and validate (**2**). The organization should have an SOP describing the procedures to be followed by those requesting the change. Furthermore, the organization should have a change control board that reviews all proposed change controls. The membership of this board will vary from organization to organization. Key members include QAU personnel familiar with validation of computerized systems and personnel from the various business areas. The board's role is to review all proposed changes and determine if the approach adheres to both the organizational and regulatory requirements. In addition, the board reviews and assesses the impact of the change on operations. When preparing to make the decision to request a change to the LIMS, consider the following: will the changes provide big enough benefits to offset the time and resources needed to revalidate the LIMS; what other systems will be impacted by the change; how much time will be required to successfully implement the change; what resources shall be made available to implement the change; and, what effects will not implementing the change have on both the laboratory and the organization. In addition, LIMS applications that reside on a PC-based server must be controlled carefully because a user's PC may use different DLLs and update versions of the LIMS DLLs in a noncontrolled manner.

10.1.3 *SOPs*—See 11.4 for details on SOPs.

10.1.4 *Operational Log Records*—The organization should use log books to document the proper ongoing operation of the LIMS. Records can be as simple as a predefined form that is filled out and filed, to as complex as a specialized recordkeeping application. In general, the organization's goal in utilizing these logs is to show evidence of control over the LIMS operation. In some cases, these records can be used to show trends in the performance of software or hardware components. Operational logs should cover the following areas (**7**):

10.1.4.1 *Backup of Data Log*—This document provides evidence that the LIMS application is being backed up in accordance with the organization's SOP. This log should contain, but not be limited to, such items as who performed the backup, the time of the backup, to what extent the LIMS was backed up (for example, full system backup including the LIMS and the operating system it resides on or partial where only the LIMS data directories are backed up), where the tapes are stored, and if the backup was successful.

10.1.4.2 *Error and Error Resolution Log*—The organization should maintain an error and error resolution log. This log helps to determine if there are trends in the errors, as well as provide evidence that errors are addressed as they are captured. The organization shall determine if it can resolve the error. If there are ways to fix it in-house the organization should contact the LIMS vendor. In either case, the organization should state what they have done to resolve the error. When errors are identified as bugs, the organization should obtain a time commitment from the vendor for resolving the bug. This data should be entered into the log. If the LIMS vendor states that the bug has been fixed in an upgrade of the software, the organization should record this data. Revalidation of the fixed bug should be a key area addressed in the revalidation effort upon implementation of the upgrade.

10.1.4.3 *Hardware Maintenance Logs*—These logs deal specifically with the hardware components of the LIMS, including any associated networking peripherals. The user should track the serial/part number of the component being replaced, the manufacturer's name of the replaced board, if known, the serial/part number of the new part, the manufacturer of the new board, the printed name and signature of the serviceman, the date the replacement took place, a reason why the component was replaced, and other data that will be helpful to debug problems later (**6**).

10.1.5 *Revalidation*—All changes must be assessed for their impact on the validation of LIMS. Changes that impact the integrity or accuracy of data in LIMS require the LIMS to be revalidated. The revalidation effort need not be as major as the original validation effort, assuming the changes are minor in nature. The effort involved can be shortened by using some of the original TPs from the initial validation effort. The design and amount of documentation will vary from one organization to the other, as each has their own change control SOP. The user can design a shortened version of the original LIMS validation plan.

10.1.6 *Periodic Audits*—The organization should conduct periodic audits of their LIMS. This audit verifies that the LIMS complies with the established policies and procedures. These audits, typically, are not carried out by the LIMS or laboratory personnel. Generally, they are handled by QAU personnel. While these audits are not part of the LIMS manager's direct responsibilities, this person does not have responsibility for maintaining the LIMS in a validated state. The areas of greatest concerns for those auditing include: security procedures, error logs, maintenance logs, change control procedures, training records, operational logs, if used, back-up and recovery procedures, disaster recovery procedures, and documentation management procedures.

11. Documentation

11.1 There are many types of documents associated with validation. Each document must be version–controlled to ensure that users can identify the specific versions they used in their validation process.

11.2 The validation documentation should include, but is not limited to, the following (**8**):

11.2.1 *Validation Plan (see Appendix X2)*—The master plan that outlines roles, responsibilities, and the course of action to be followed by the validation team.

11.2.2 *Functional Requirements*—Contains the requirements the LIMS is expected to meet. This is a key essential document used in the validation process of LIMS (see 11.5 for more details).

11.2.3 *Prevalidation Systems Acceptance Test Documents*—This document can be used to determine the validity of the LIMS, based on the functional requirements document. The difference in this case is that the functional requirements are not tested as stringently as in a normal protocol testing environment.

11.2.4 *Complete System Specifications* (database schema, user interface designs, wiring diagrams, etc.).

11.2.5 *IQ, OQ Protocol Documents (see Appendix X2)*—These documents comprise the bulk of the validation activity.

The goal in each case is to design a test protocol that tests one or more functional requirements. Each set of tests shall contain what the user considers the acceptance criteria for that test step.

11.2.6 *Test Protocols (see Appendix X3)*—These are part of the IQ/OQ document. Each test protocol will test one or more functional requirement. All test protocol attachments, that is, hard copies of screen layout, paper reports, etc., all become part of the IQ/OQ documentation package.

11.2.7 *SOPs*—See 11.4.

11.2.8 *LIMS System Manual*.

11.2.9 *Final Validation Report-Qualification Report (see Appendix X4)*—This report completes the validation plan, which has been executed. It shall document any system limitations identified during the execution of the associated testing protocols. It must record the formal decision to accept the system with sign-off. It should note if acceptance is for limited operation because some tests failed. It should document how the identified limitations are to be handled.

11.2.10 The following is other miscellaneous supporting documentation the user may want to include **(8)**:

11.2.10.1 All purchase orders associated with the LIMS application, hardware, software, consulting services, etc.

11.2.10.2 The vendor audit status report.

11.2.10.3 The escrow agreement for the LIMS source code.

11.2.10.4 Source code maintenance requirements for any in-house customization work accomplished.

11.2.10.5 Structural testing documentation for the source code.

11.2.10.6 Service contract and support agreements.

11.2.10.7 User and LIMS administrator training records.

11.2.10.8 The LIMS implementation plan.

11.2.11 The user should have the following additional documentation for customization work **(8)**:

11.2.11.1 System development life cycle.

11.2.11.2 Programming standards and conventions document.

11.2.11.3 Configuration management records created during the development of the system.

11.2.11.4 Documented evidence of structural testing on the source code.

11.2.11.5 Procedure to release the system from development phase to validation phase.

11.2.11.6 Documented evidence verifying the adherence to procedures.

11.2.11.7 Procedure to address problems found after the system is implemented.

11.3 *Documentation Strategies*—Several schemes exist for tracking progress during validation.

11.3.1 All activities should be documented, especially tests that fail and must be subsequently repeated.

11.3.2 A logbook may be kept, where all tests are recorded chronologically along with their results and dispositions. Each entry should record when the test was done, who did it, what results were obtained, and how problems were resolved.

11.3.3 There may be a protocol opened when each test is begun. If a test fails, the protocol must be closed with unsatisfactory results. After repairs, a new protocol for that test may be opened and the test repeated.

11.4 *Standard Operating Procedures That Are Specific to the Operation of the LIMS*:

11.4.1 SOPs shall be in place to ensure that the organization has well defined procedures. The number, the design, and the focus of SOPs will vary considerably across organizations and LIMS applications. For example, if the LIMS runs on a server versus a stand-alone PC, the organization will need a different SOP for each. The following list gives general SOPs that organizations may wish to develop. The user of this guide should not assume that the list below is complete or required.

11.4.2 *SOP on SOPs*—Describes how SOPs shall be designed, including specific required sections and types of information, who has responsibility for what, and a numbering system for all corporate SOPs.

11.4.3 *Validation of Computerized System*—This is a corporate level SOP that describes the ins and outs involved in the development of a validation plan for a computerized system. This SOP should be targeted at a specific class of computer systems.

11.4.4 *Training*—Covers who shall train, who shall be trained, what is to be covered, and version control of training material. Include who has responsibilities for informing trainers and trainees. The extent of the training depends upon what access the person needs in the system. Changes in access, or responsibilities, or both, may require more training. The training should include theoretical and practical use of the system, and how to document training records, etc.

11.4.5 *Backup and Restore*—Includes procedures for backup, use of the journal log, off-site copies, policy on keeping earlier versions of the database (for missed errors), and restoration procedures.

11.4.6 *Disaster Recovery*—This SOP covers those procedures that should be followed in case of major disasters, such as fire, flood, sabotage, and major system or equipment failures. These procedures include defining the interim laboratory operation for how the business will be conducted during the loss of the LIMS. Further, this SOP should cover how to resume business once the LIMS is operational again.

11.4.7 *Security*—Includes system policy, corporate policy, and enforcement policy. Minimum password policy should be specified, such as maximum lifetime of a password, avoidance of trivial passwords, who assigns passwords, expiration dates, maximum number of tries before lock-out, and access logs. Policy should include when security reviews are conducted, who performs them, who reviews the results, how security policy revisions are made, and who assigns responsibilities and rights. The need for securing physical access to the system also should be incorporated into the SOP. Other procedures may exist, such as keyboard locking, biological identifications, etc. These should be addressed as necessary in this SOP.

11.4.8 *Change Control*—Includes version identification, maintenance of static data still needed to document older results, change policies, sign-offs required, retesting and re-validation needed, and the documentation required. The effect of changes on more general information should be considered, such as research studies, material specifications or formulations, analysis techniques, and method parameters. Change control is needed any time LIMS performance may be affected,

for example, changes to the operating system, the local area network, the database engine, the server hardware or software, the LIMS software, any interface, all major repairs, and many minor repairs.

11.4.9 *LIMS Operation*—This SOP should include the operating policies and responsibilities of each user from the LIMS manager down to the end user. If the LIMS operates over a local area or wide area network, these functions may be under different management. The LIMS manager and the organization shall ensure that the SOP addresses these issues in order to provide proper support for their LIMS. Further, the SOP shall address other LIMS items, such as start-up and shut-down procedures, ownership of supplies, routine problem resolution, etc. Some organizations have specific job descriptions for their personnel. As such, these job descriptions may be referenced in this SOP.

11.4.10 *Maintenance*—Includes who did the service, when it was performed, what was done, and what documentation that should be created. This should apply to both routine and unscheduled maintenance. Documentation is also required for who approved on completion of service, what retesting was done, and if necessary, what level of revalidation was performed and documentation required. In some industries, repairs shall follow the organization's established change control procedures.

11.4.11 *LIMS Usage*—Emphasizes responsibilities. This may refer to the manual(s), if they exist, but a user handbook or manual should not be written in this SOP. The understanding is those using this SOP will already be trained and know how to use the LIMS. It is not necessary to rewrite the SOP if the system changes appearance, for example if " log the samples by batch" appears instead of, "Log - <return> <return> <down-arrow> highlight "by batch" and <return>."

11.4.12 *Error Handling*—Addresses how LIMS errors are to be handled. This can be a separate SOP or it can be incorporated into the LIMS Operational SOP. In either case, LIMS errors should be documented. Further, the SOP should describe the course of action that LIMS users should take when they encounter a problem.

11.4.13 *Building Static Data Templates*—Includes nomenclature to be used in the design of the various static tables. For example, this SOP may state that all test methods will be coded into LIMS using a specific method numbering system or that all test result templates will track certain data elements (test initials, tester lab notebook number, etc.).

11.4.14 *Instrument Interfacing*—Describes how new instruments are connected to the LIMS, how they are tested, how they are validated, and how they are to be used.

11.5 *Functional Requirements Document*:

11.5.1 This a key document in the validation process of LIMS. This document is used to ensure that the LIMS does what it purports to do and will continue to do so once validated (**9**). This document should outline the business and regulatory needs and policies. While the development of the functional requirements document is the responsibility of the LIMS project team, it is essential that the LIMS validation team know and understand what should be contained in this document.

11.5.2 The functional requirements document puts into common language the required LIMS functionalities and LIMS performance issues (**9**). It is a communication device for conveying requirements to the LIMS vendor. In addition, the functional requirements document aids in the development of the qualification documents and their associated test protocols. When the test protocols are executed they will be compared to requirements detailed in this document.

11.5.3 This document should contain detailed information that covers the system description, systems constraints, vendor-related requirements, detailed system information, general systems performance requirements, system implementation and other operational requirements, and other documentation for custom-developed software (**9**).

11.5.3.1 The system description should include, but is not limited to, a main purpose, essential features system environment and associated interfaces critical to the system operation, and projected completion schedule (**9**). Additional items also include a glossary of terms, acronyms, and abbreviations specific to the LIMS and references to other corporate standards.

11.5.3.2 System constraints should include, but are not limited to, a preferred platform for the hardware and software, system interfaces to other systems (instruments, LAN, WAN, etc.), future system expandability requirements, environmental requirements, life expectancy of the system, scheduling requirements, source code availability, and maintenance requirements (**9**).

11.5.3.3 Vendor-related requirements should include, but are not limited to, vendor audit requirements, vendor systems deliverables (hardware, source code, etc.), user manuals, training manuals, vendor service deliverables for bug support, maintenance, and training (**9**).

11.5.3.4 The overall objective and task requirements are outlined in the detailed system information document. Systems functionalities should be divided into three main blocks: input, processing, and output requirements. Each block should describe subfunctionalities specific to each area. For example, an input subfunctionality would include requirements for migrating data from the current system to the new LIMS (**9**).

11.5.3.5 General system performance requirements should cover the expected response time for specific tasks using the system, expected maintenance downtime, error handling requirements during start-up and shut-down, and backup and recovery requirements (**9**).

11.5.3.6 System implementation and other operational-related requirements should cover support and service needs, supporting documentation, such as user's manual, an administrator's manual, as well as archival and data-retention requirements (**9**).

11.5.3.7 For customized LIMS, the functional requirements document should include the systems development life cycle used, the SDLC phase and required deliverables for each phase, the quality assurance plan, documentation for prototyping, requirements for configuration management and items to be included, requirements for change control, required testing

and documentation to be performed during development testing, and requirements for any additional documentation for post-implementation activities (**9**).

12. The Quality Assurance Unit (QAU)

12.1 The QAU conducts or assists quality assurance activities in the interpretation of the various regulatory requirements. This extends to issues relating to the validation of computerized systems, such as LIMS. Additional roles that the QAU has that affect the LIMS and its validation include vendor audits, review and final sign-off of the LIMS validation plan and final validation report, ongoing monitoring of the LIMS via audits and change control requests, and assistance in the development and maintenance of the LIMS related SOPs.

12.2 QAU personnel who are responsible for the validation of computerized systems should have a sound technical understanding of both the regulations and computer technology. QAU individuals can use in-house or industry training course, read technical literature on this subject, or work in conjunction with an experienced computerized systems validation QAU expert to obtain the required level of expertise. It is imperative that QAU personnel stay abreast of the technology changes.

12.3 The validation team should have a QAU member at the start of the project. Early involvement will aid validation in many ways. First, the QAU representative can gain an understanding of the LIMS project. Second, they can indicate which regulatory requirements the team needs to work against. This allows the validation team ample time to design these requirements into the validation plan versus reworking the issues later in the project. Third, as the validation plan is created the QAU representative can review and suggest corrections to the document. When QAU is included from the start of the project, the validation team will be better able to meet the project timelines.

12.4 The QAU also is responsible for the ongoing evaluation of the LIMS. They should periodically review procedures for operating the LIMS. The goal is to ensure that the proper controls are used. The LIMS manager and others should be aware of the need to follow the outlined procedures. Areas that draw the most QAU attention are those that directly affect data integrity, its accuracy, or its security. QAU representatives will be checking for prescribed change control procedures and documentation after any changes. Error and operational logs must be kept up to date. This can be a monumental effort if the responsibilities for maintaining the LIMS is spread across several organizational groups (laboratory, IS server operations, IS database manager, etc.).

12.5 Representatives from the QAU may be involved in the following LIMS project steps:

12.5.1 Project definition.

12.5.2 Functional requirements.

12.5.3 *Investigation of Vendors*—The QAU may perform a vendor audit to ensure good software practices were followed while developing the LIMS. They should at least review the vendor audit report if they did not participate in the actual audit.

12.5.4 *Vendor Negotiations*—The QAU may be involved as functional requirements are added, dropped, and revised. This often occurs to resolve differences between ideal requirements and available features in commercial systems.

12.5.5 *Vendor Selection*—A revised validation plan should be part of the contract with the vendor.

12.5.6 *Validation Phase*—The QAU will monitor compliance to the validation plan and review conclusions and approvals. This includes authorizations of the validation IQ/OQ protocol, including the TPs prior to execution. Further, it includes authorization of the qualification report after the execution of the IQ/OQ protocol.

13. Management's Role

13.1 Management's key role is to commit and support the appropriate resources to the validation project, which include both labor and money. Furthermore, management shall help define the level of risk the business is willing to accept. Management should strongly support the quality assurance unit and their involvement from the start of the LIMS project, as well as ensure that all necessary SOPs are in place and that those responsible for the LIMS validation project have received the necessary training to conduct their job.

13.2 Management may act as the project sponsor with overall project sign-off responsibilities, which includes responsibility for being involved in all major decision points during the validation project. Management needs to ensure that the proper resources are allocated to maintain the LIMS and any associated systems in a validated state. Management may be called upon to resolve issues across organization boundaries and to ensure that all those involved in the LIMS daily operation are aware of the organizational and regulatory requirements.

APPENDIXES

(Nonmandatory Information)

X1. VENDOR ASSESSMENT INFORMATION

Vendor Name:	Vendor Contact:
Product Name:	Evaluation Date:
Phone #:	FAX #:
Audited By:	

AUDIT ITEMS	LEVEL OF EVIDENCE 1=NONE, 2= SOME; 3=COMPLETE	COMMENTS / REFERENCE DOCUMENTS
Software Development		
Review standards/guides/procedures (software Life Cycle)		
Evidence of technical reviews		
Evidence of standard coding practices		
Development documentation exists for:		
Requirements phase		
Design phase		
Source Code phase		
Testing phase		
Installation and Checkout phase		
Operation and Maintenance phase		
Source Code Module Structure includes:		
Header Information		
Program name		
Program description		
Development date-time stamp		
Developer(s) name(s)		
Inputs		
Outputs		
Program and subroutine calls		
Data parameters		
Revision-control sections		
Annotated Code		
Testing		
Structural Testing (tests the code)		
Functional Testing (tests the design)		
Validation Test Data Sets		
Documented Test Results/Exceptions		
Software Maintenance		
Customization of Standard Software		
Revision control		
Synchronization between vendor/client		
Configuration Control		
Software Quality and Control Issues		
Software Quality Assurance Group		
Security Controls to Access Software		
Error-Detection/Problem-Resolution Procedures and Outcome Records		
Distribution Controls		
Records Retention Schedule		
Disaster Recovery		
Software Quality Plan		
Software Functional Requirements		

FIG. X1.1 Vendor Assessment Information Sample Form

AUDIT ITEMS	LEVEL OF EVIDENCE 1=NONE, 2= SOME; 3=COMPLETE	COMMENTS / REFERENCE DOCUMENTS
Software Quality and Control Issues Continued		
Software Development Life Cycle Defined		
Software Developer Training Requirements		
Software Validation Plan		
General Facility Issues		
Security Controls for Building Access		
General Cleanliness		
Organizational Quality and Control Issues		
Standard Operating Procedures (organizational & departmental)		
SOP Utilization		
Training Program		
Personnel Qualification Records		
Personnel Training Records		
Contract Programmers Training/Supervision Records		
Internal Auditing Program		
Quality Policy		
Quality Manual		
Documentation Control		
Product Life Cycle Model		
Product Project Plan		

FIG. X1.1 Vendor Assessment Information Sample Form *(continued)*

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X2. VALIDATION PLAN

{Project or Equipment Name under going validation}
{date}

(I) INTRODUCTION

A) **Objective** *(State the objective(s) of the qualification plan)*
B) **System Description** *(A description of the purpose, location, and method of operation for the system being qualified)*
C) **Test Assumptions/Boundaries** *(Narrative describing base assumptions associated with the qualification. Clearly state boundaries of the system and the operating conditions which the qualification will evaluate)*
D) **Responsibilities** (Listing of individuals name and what they are responsible for)
E) **Development Summary** *(Summary of the developer testing and results ---relates to in-house developed. systems)*
F) **General Instructions** *(Provide detailed instructions, by inclusion or reference, on how to execute IQ/OQ tests).*

(II) INSTALLATION QUALIFICATION (IQ) *(Involves establishing documented evidence that the LIMS is installed and configured to meet design intent and user requirements. IQ does not typically include operation of the system.)*

G) **Equipment List & Description** *(List of all major hardware and software components with a brief description of the function/construction of each. This list will include the make/model and revision number as appropriate).*
H) **Engineering Specifications**
    1) **Spec's** *(Include any specifications of components needed for the effective installation of the system or sub-system.)*
    2) **Drawing list** *(Flow diagrams, data models etc. - whatever gives a clear picture of the system or subsystem).*
    3) **Environmental requirements** *(Discuss anything outside the LIMS which it needs to operate effectively. This shall include utility requirements such as power, air conditioning, other software, other hardware, and anything else needed for the LIMS.)*
I) **IQ Test Plan/Protocol**
    1) **Test Plan/Protocol** *(Detail here the test plan to verify that the LIMS is installed and configured according to the design and user requirements. The test plan shall provide sufficient instruction to assure that the task is carried out correctly. Each Test plan/protocol shall include the requirement(s) being tested, the test procedure, and the acceptance criteria for each test procedure).*
        A) **Calibrations**
        B) **Initial Set-up Procedures**
        C) **Test Tools**

(III) OPERATIONAL QUALIFICATION (OQ) *(Involves establishing documented evidence that the LIMS operates as intended throughout anticipated ranges. This activity requires evaluation of the LIMS under dynamic operational conditions. Full OQ need not be repeated for each new installation as long as installation is conducted within originally qualified operational ranges and functional requirements. Limited OQ, however, is required)*

J) **Critical Factors** *(List of critical factors for the LIMS identified during design and development process, vendor information, or technical judgment. The critical factors listed shall be verified via test plans.)*
K) **OQ Test Plan/Protocol** *(Detail here the test plan/protocol to verify that the LIMS operates according to the design and user requirements. The test plan/protocol shall provide sufficient instruction to assure that the task is carried out correctly. The test plan/protocol must specify expected outcome and acceptance criteria for each critical factor and function. Testing encompasses not only the expected range of input values and volume (normal conditions testing) but also how the LIMS will respond to unusual or extreme operating ranges/conditions (stress testing) and invalid operating ranges/conditions (robustness testing).*
    1) **Standard Operational Procedures(SOPs)**

(IV) Signatures *(This shall include who is submitting the plan for the validation team and will include the name and date of the individuals responsible for reviewing the validation document and concurring that validation was completed correctly. Typically these signatures include someone from the QAU, the laboratory responsible for the LIMS, a representative for the information management group).*

FIG. X2.1 Validation Plan Example

X3. TEST PROTOCOL DESIGN EXAMPLE

ABC Corp., City, State USA		Your Department Name	
Date: 06/05/96 Operational Qualification Protocol		Revision: 1.0	
Subject: XZY LIMS Application			

K.1 OQ TEST PLAN: Administrator Functions

Verify that the LIMS Administrator Function operates as originally designed. Further, to ensure that LIMS users gain the correct access authority level.

	PROCEDURE	ACCEPTANCE CRITERIA	MET ACCEPTANCE CRITERIA YES/NO?
	NORMAL CONDITIONS		
1.	Log into LIMS with Administrator Authority and add a new user to LIMS with User authority. Log out and then log back into LIMS with the User identification just setup.	New user to be added to LIMS with User Authority level. The new user just setup will be able to login LIMS and will have the proper authorities set.	
2.	Log into LIMS with Administrator Authority and change the user from Step 1 from User authority to Stability Group Authority. Log into LIMS with the changed user identification	System will allow this change. User will now have Stability Group Authority rights.	
3.	Change and verify the change of an existing users password. Next log into LIMS using the user id that was just changed and use the changed password.	LIMS will allow the password to be changed and verified. The user will be able to log into LIMS using the changed password.	
4	User added in step 1 logs into LIMS with their current password. Record the screen contents.	The users password will not be displayed and the user will be able to log into LIMS.	
5	User added in step 1 logs into LIMS, changes their password and then verifies the change.	The user will be able to log into LIMS, change their password and verify the change.	
	STRESS CONDITIONS		
6.	Add a new user with same name as the user added in step 1.	System will not allow the same user name to be added to LIMS.	
7.	Add a new user with the same name as a the user created in step 1 but with a different authority level.	System will not allow the same user name to be added regardless of the difference in authority levels.	
8.	User logs into LIMS and selects the change password button. They enter their current password and enter the new password and then verify the new password using a password which is different than the new password just entered.	System will accept the current password and the new password entered but will issue an error message and reject the verification of the password.	

All Acceptance Criteria met (circle one) YES NO	
Tested By / Date:	
Reviewed By / Date:	
Comments:	

FIG. X3.1 Test Protocol Design Example

X4. QUALIFICATION REPORT

{Project or Equipment Name under-going validation}
{DATE}

A. **<u>CONCLUSIONS</u>**

B. **<u>DISCUSSION</u>**

(1) Compliance within the IQ/OQ Qualification Protocol:
Make reference to the protocol and indicate whether it was followed completely or not. Clearly explain and document any deviations from the protocol and their impact on the system.

(2) Results vs. Success Criteria:
Attach the completed Test Protocols with document signoffs. Discuss results that may not be obvious in the test plan. Identify system limitations and how they will be handled.

(3) Documentation:
Verify that the system documentation is complete and filed for validation purposes.

C. **<u>SIGNATURES</u>**

Submitted by: _____ for the _____Team

By signing below, we indicate that we have reviewed the attached Qualification Report and concur that the protocol was followed, all protocol requirements have been satisfied and documented, and acceptance criteria were met except as noted.

_____   _____
(Name / Title)   Date   (Name / Title)   Date

_____   _____
(Name / Title)   Date   (Name / Title)   Date

FIG. X4.1 Qualification Sample Report

X5. LIMS VALIDATION ERROR REPORT (6)

User Identification:_____   Date: _____

Error Type: User_____   Program_____   Other_____

Evaluation of error: Emergency_____   Normal_____   Other_____

Error Number (system generated): _____
                                  _____

Error Message: _____
               _____
               _____
               _____
               _____
               _____
               _____
               _____
               _____
               _____

Error description and suggested solution/actions:

_____
_____
_____
_____
_____
_____
_____
_____
_____

Date   Signature

To be filled in by the system manager

Error Type: _____

Degree of Seriousness: _____

Action: _____

Conclusion: _____

FIG. X5.1 LIMS Sample Validation Error Report (6)

X6. CHANGE REQUEST/PROBLEM LOG (3)

_____
(Log ID)

A. Title: System ID: _____ System Name: _____ Version: _____

B. Nature of the Request or Problem (operational/error, change in business/technology requirements, preventive maintenance, requested change, re-assignment of colleagues, change in documentation or SOPs etc.)

C. Date of Request/Date Problem Encountered: ___ / ___ / ___

D. Person Requesting Change/Person Reporting Problem: _____

E. Findings:

Assessor: _____ Date: ___ / ___ / ___

F: Possible Decisions:

Decisions	Check One	Decided By	Date
Cancel Request/Postpone	_____	_____	___ / ___ / ___
Defer Until Next Version	_____	_____	___ / ___ / ___
Proceed	_____	_____	___ / ___ / ___
Other (Specify Below)	_____	_____	___ / ___ / ___

FIG. X6.1 Sample Change Request/Problem Log (3)

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G: Resolution:

Action	Check All Those Required To Be Done	Completed By	Date
Change to System & Change Made(see attached)	_____	_____	___ / ___ / ___
Update/Approve Requirements	_____	_____	___ / ___ / ___
Update/Approve Design Specifications	_____	_____	___ / ___ / ___
Update/Approve Validation Plan	_____	_____	___ / ___ / ___
Revalidate System	_____	_____	___ / ___ / ___
Update/Approve/Distribute User Manual	_____	_____	___ / ___ / ___
Train Users	_____	_____	___ / ___ / ___
Update/Approve/Distribute SOPs	_____	_____	___ / ___ / ___
Move Change Into Production	_____	_____	___ / ___ / ___
Notify Users	_____	_____	___ / ___ / ___
Other (Specify Below)	_____	_____	___ / ___ / ___

H: Reviewed By: _____ on ___ / ___ / ___
                      (responsible Party)   (Review Date)

FIG. X6.1 Sample Change Request/Problem Log (3) (continued)

SECTION AREA	SECTION FIELD NAMES	NAME EXPLANATION
A	Log ID	Unique ID assigned to each entry. The assignment should be in some type of order that provides evidence that none are missing.
	System ID	The system's identification number, if it has one.
	System Name	The application's name, for example, ABC LIMS.
	Version	Version of the application, for example, Version 1.2.4.
B	Nature of Request	Description of what is being requested.
C	Date of Request/Problem	The date the problem was discovered or request was made.
D	Person Requesting/Reporting Problem	The person who identified the problem or who is making the request.
	Findings	For change requests, the assessment of findings may include, but is not limited to, requirements, recommendation(s), estimate of work, possible schedule/timeframes, verification testing required, and validation impact. For problems encountered, findings could include what caused the problem, recommended resolution, estimate of work, possible schedule/timeframe, verification testing required, and validation impact. If minor changes are made, then minimal localized and regional tests are recommended.
	Assessor	The person who completed the findings.
	Date	The date the assessor signed.
F	Possible Decision	Check one of the available options.
	Decided by	Signature of the person making the decision.
	Other (page 1)	Other decision made about the event.
G	Resolution	Check all that apply. If the decision was made to proceed, the responsible user party then identifies any one or more items that need to be completed before closing out the entry. If no items are selected, this event could be closed out by having the responsible party sign and date the bottom of the form.
	Completed by	Signed by the person responsible for completing the specific action items.
	Date	Date the action was completed.
	Change to System	This section may have to be completed by the IS professional, either alone, or in close collaboration with the responsible user party for the system. This section could describe briefly and refer to other, more extensive documentation.
	Update/Approve Requirements	This would be checked as a result of finding an error in requirements, an error in the system that impacts the requirements, or an enhancement which requires that the requirements be updated.
	Update/Approve Design Specifications	This could be checked as a result of correcting an error in or clarifying the design specifications, resolving a bug that required a modified design, or an enhancement which requires that the design specifications be updated.
	Update/Approved Validation Plan	If a bug were found or enhancement made that required updating the requirements or design specifications, the validation plan may need to be updated—if only to add/modify test cases.
	Revalidate System	At the time of change, the responsible person in collaboration with the IS person may decide that the system needs to be revalidated.
	Update/Approve/Distribute User Manual	This could be checked due to finding an error in or needing to clarify instructions in the manual, an enhancement, or correcting an error in the system.
	Train Users	This would be checked if the users needed retraining or initial training.
	Update/Approve/Distribute SOPs	During changes or as functional/organization changes are made in the department.
	Move Change into Production	Document exactly what was done to move change into production or reference other documentation.
	Notify Users	Indicate who, how, and when they were notified or reference other documentation.
	Other (page 2)	Indicate here, or reference other documentation, anything else needing to be completed that is not covered elsewhere.
	Responsible Party	Person, typically in the user department, responsible for the validated state of the system. This signature indicates that all resolution actions have been completed and that this log entry is now closed.
	Date	Date the responsible party signed the document.

FIG. X6.1 Sample Change Request/Problem Log (3) *(continued)*

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