# *Draft*
# Standard Administrative Procedures

## July 1996

Please submit comments and suggestions to:

Georgia L. Harris
NIST Office of Weights and Measures
Bldg 820, Rm 232
Gaithersburg, MD 20899

FAX: 301/926-0647

Acknowledgment:
The NIST Office of Weights and Measures expresses appreciation to the State of Minnesota for providing copies of its Standard Administrative Procedures and Standard Laboratory Procedures.

**Table of Contents**

**Standard Administrative Procedure 1**
**Protection of Client Confidentiality and Proprietary Rights**

## 1 Introduction

This is the laboratory procedure for protection of client confidentiality and proprietary rights. The laboratory will use the system outlined in this standard administrative procedure to protect client confidentiality and proprietary rights to the extent allowed by law. All laboratory data and records are considered official public record according to State Statute. The laboratory will not release records except in accordance with official request procedures.

## 2 Purpose

Protection of client confidentiality and proprietary rights is an accreditation requirement as well as a legal concern; however, legal requirements take precedence over accreditation criteria.

## 3 Responsibility and Authority

The Laboratory Supervisor has direct responsibility to ensure that 1) all requests for client information (other than requests from the client) are presented properly in writing and 2) reports or other information are not disseminated without following procedures described here with proper authorization given.

## 4 Operations

4.1 The following information is considered confidential or proprietary and will not be released without proper request and authorization:

- 4.1.1 information regarding submission of specific test items for calibration or numbers of items submitted;
- 4.1.2 test artifact condition of receipt, test or calibration data and results, calibration or test reports, or any adjustment data;
- 4.1.3 proprietary artifact design information;
- 4.1.4 client names, addresses, and contacts; and
- 4.1.5 any other questionable information or data issued to a specific client.

4.2 All telephone, facsimile, or e-mail requests for information listed in this procedure as confidential or proprietary will be refused. Requestor will be asked to present his request in writing, on official letterhead of the organization making the request, to the director stating specific questions or requests along with reason or justification for such requests.

4.3 Formal requests will be given to the Division legal staff for review against State requirements. A status letter will be sent to the requestor pending legal review.

4.3.1 An official letter of denial from the director will be sent to the requestor in the event that requests do not meet State requirements.

4.3.2 An official letter from the director detailing the requested information will be sent to the requestor by certified mail, return receipt requested, along with any required copies of laboratory records if the request meets State requirements.

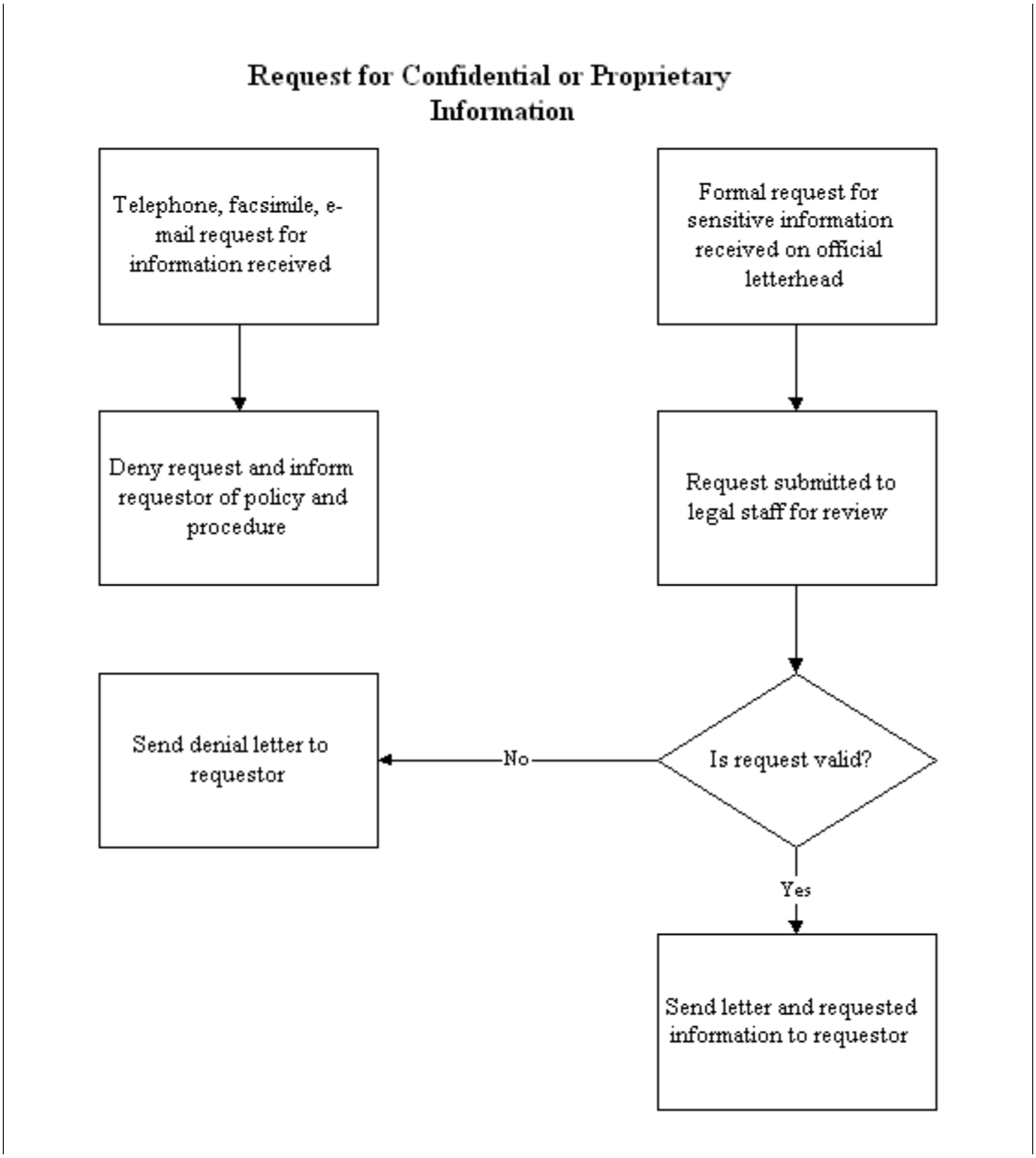


**Figure 1 SAP 1 Flowchart**

**Standard Administrative Procedure 2**
**Impartial Service**

## 1 Introduction

This is the laboratory policy/procedure to ensure that clients received impartial service. The laboratory will follow the policies outlined in this standard administrative procedure to ensure that all clients receive fair and equal treatment.

## 2 Purpose

The laboratory is a government agency entrusted with public service responsibilities. It is of the utmost importance to deliver fair, unbiased, impartial service to calibration clients to ensure that the integrity of the laboratory remains unquestioned.

## 3 Responsibility and Authority

The Laboratory Supervisor will ensure that all procedures and process used in the laboratory accord fair and equitable treatment to all clients.

## 4 Operations

4.1 The following policy guidelines and procedures will be strictly adhered to:

4.1.1 All submissions for test and calibration will be received and logged according to the laboratory handling and tracking procedure and scheduling procedure.

4.1.2 Calibration items will not receive preferential treatment with regard to customer status, calibration type, schedule, or fees charged of the customer, except as noted in the scheduling procedure.

4.1.3 Laboratory staff may not accept gratuities, gifts, or other special treatment in lieu of modifying laboratory policies.

4.2 All other State policies regarding laboratory operation with regarding to maintaining an unbiased position will be highlighted in a policy handbook as available.

**Standard Administrative Procedure 3**
**Contract Review**

## 1 Introduction

This is the laboratory procedure for contract review. The laboratory will follow this standard administrative procedure to ensure that requests for test and calibration are properly documented by the customer and that the laboratory delivers the expected calibration and report.

## 2 Purpose

Laboratory customers expect a given service when they request a test or calibration and often use language that is unclear as to the specific test or calibration they are requesting.

Laboratory staff must evaluate each request for calibration to ensure that the proper standards, equipment, and trained staff perform the test or calibration. Laboratory staff must also prepare specific reports based on customer requests and needs.

## 3 Responsibility and Authority

3.1 The laboratory technical manager or trained metrologist will ensure the following, in consultation with the customer as needed:

3.1.1 evaluate each request for calibration to ensure that it is properly documented;

3.1.2 assign specific staff to use specific procedures that will clearly identify standards and equipment; and

3.1.3 determine the appropriate type of report for the test or calibration.

3.2 The laboratory quality manager will randomly review the paperwork for the contract review process to ensure that these steps are being followed by the technical manager and by technical staff assigned to the test or calibration. Discrepancies will be detailed according to SAP 7 on Audits and Reviews.

## 4 Operations

4.1 The laboratory receives requests for calibration in writing (often through a purchase order), by telephone, or by submission of test/calibration items without accompanying paperwork.

4.2 Laboratory staff review the request and complete a laboratory work order according to SAP 4, Handling Calibration and Test Items. The form indicates whether appropriate paperwork was submitted. If appropriate paperwork was not submitted, staff indicate whether this is a repeat calibration which the customer was satisfied with or if the customer was contacted directly (by telephone, facsimile, e-mail, or mail) to agree to the type of test that will be conducted.

4.3 The laboratory quality manager will randomly select work orders during technical audits to ensure that proper contract review has been completed.

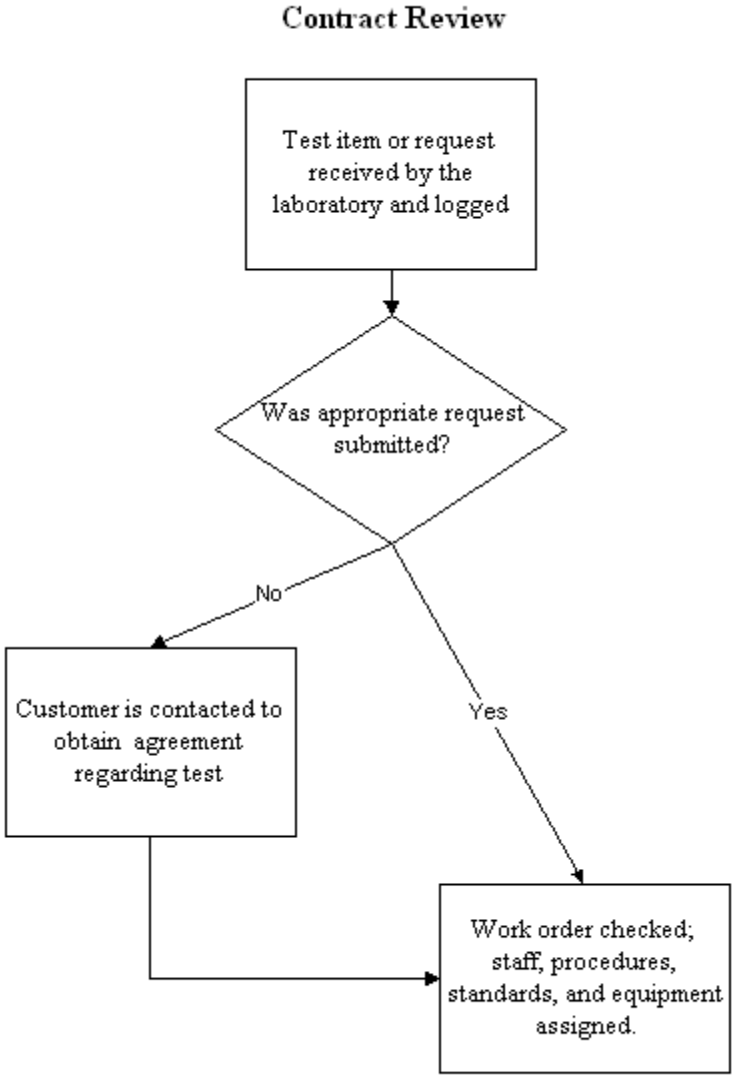


**Figure 2 SAP 3 Flowchart**

**Standard Administrative Procedure 4**
**Handling Calibration and Test Items**

## 1 Introduction

This procedure describes the management and tracking of artifacts submitted for calibration. A laboratory log documents the assigned work order number, status and location of each artifact, or group of artifacts. Each artifact, or group of artifacts, is assigned a work order which is circulated with the artifact during its stay in the laboratory.

## 2 Purpose

The handling and tracking system will ensure that services are provided on schedule, allow the metrology laboratory staff to provide customers with up-to-date information on the status of artifacts and help prevent loss, accidental damage, incorrect return of artifacts, or theft of artifacts.

## 3 Responsibility and Authority

Trained metrology staff manage the tracking system. Metrology laboratory staff provide accurate tracking information by making entries in the laboratory log, and completing and attaching work orders to all artifacts, or groups of artifacts. All entries are sufficiently detailed so that anyone with familiarity with the laboratory operation can evaluate the identification and calibration status of any customer item.

## 4 Operations

4.1 Artifacts are submitted and received.

Customers and Weights and Measures Division Investigators submit artifacts for calibration. The artifacts are received, logged, stored, calibrated, and returned according to the following procedures:

4.1.1 All artifacts are tracked through the laboratory log. The log contains the following information about each artifact, or group of artifacts, submitted for calibration:

4.1.1.1 State test number(s) assigned to this artifact or group of artifacts;

4.1.1.2 Name of the company or individual, contact, address and phone number;

4.1.1.3 Source (i.e. whether the artifacts were submitted by the Weights and Measures Division, a registered placing-in-service agent, or other customer);

4.1.1.4 Description of the artifacts that includes the following information:

4.1.1.4.1 Quantity included in the group of artifacts;

4.1.1.4.2 Denominations, values, or range of values of the artifacts;

4.1.1.4.3 Manufacturer of the artifacts;

4.1.1.4.4 Any flaws, damage, or irregularities noticed when the artifacts were received.

4.1.1.5 Additional descriptive information (if needed). Additional information must be written on an attachment that includes the state test number. The attachment must be stapled to the log;

4.1.1.6 Location where the artifacts are stored;

4.1.1.7 Date the artifacts were received from the customer, and the initials of the receiving metrologist;

4.1.1.8 Calibration date, and the initials of the calibrating metrologist;

4.1.1.9 Date the artifacts were shipped or returned to the customer, and the initials of the metrologist who shipped or returned them.

4.1.1.10 The receiving metrologist assigns a state test number, and enters the number into the laboratory log under the heading "State Test Number."

4.1.1.10.1 The state test number is taken from one of the pre-numbered inspection report forms issued to the metrology laboratory by the Weights and Measures Division Billing Clerk.

4.1.1.10.2 The pre-numbered inspection report form is placed in the vertical wall file in the metrology laboratory office. The slots in the wall file correspond to storage locations A, B, C, and D.

4.1.1.11 The metrologist completes a work order and attaches it to the artifact or group of artifacts.

4.1.1.12 The metrologist enters the customer identity and description of the artifacts into the laboratory log under the headings "submitted by", "source", and "description".

4.1.1.13 The metrologist places the artifacts in a secure storage area (A, B, C, or D) and notes the location in the laboratory log (see Section 4.1.1.5) under "storage location".

4.1.1.14 The metrologist checks the vertical wall file in the metrology laboratory office to ensure that the pre-numbered inspection report was placed in the slot that corresponds to the storage location.

4.2 Artifacts are stored.

The metrology laboratory has four storage areas designated as A, B, C, and D. Areas A, B, and C are subdivided into numbered locations. Artifacts are assigned to these shelves. Artifact storage locations (letter and number) are recorded in the laboratory log.

4.2.1 Storage area A is located in the small mass laboratory.

4.2.2 Storage area B is located in the large mass laboratory.

4.2.3 Storage area C is located in the small volume laboratory.

4.2.4 Storage area D is located in the large volume laboratory.

4.3 Artifacts are calibrated.

4.3.1 A metrologist checks the work schedule to find the next assignment. The metrologist removes the artifacts from storage (if the artifacts are stored in storage area A, B, or C, the metrologist takes an "In Calibration" marker and places it in the position

where the artifacts were stored). The metrologist proceeds to the calibration process.

4.3.2 Upon completing calibration, the metrologist notes the calibration date, and the metrologist's initials, in the laboratory log under the heading "Tested".

4.3.3 The metrologist returns the artifacts to the storage area from which they were taken (and, in the case of storage areas A, B, and C, places the "In Calibration" marker on the cabinet door).

4.3.4 The metrologist completes all of the test documentation, including the pre-numbered inspection report, and gives the documents to the Technical Manager for review.

4.3.5 The Technical Manager reviews and signs the calibration report if it is complete and correct.

4.3.6 The metrologist forwards the calibration report to administrative staff for copying, filing, customer notification, and shipping.

4.4 Artifacts are returned to the customers

4.4.1 Metrology staff arrange shipping or return of the artifacts.

4.4.2 Artifacts are removed from storage at the time they are shipped or returned to the customer's representative.

4.4.3 The metrologist who supervises shipping of the artifacts enters and initials the date in the laboratory log under the heading "Returned".

4.5 Multiple delivery dates

In some cases, a single customer may submit several artifacts, or groups of artifacts, as part of one large calibration project that may extend over several days. A single state test number is assigned to all of the artifacts received as part of the project, unless there are more artifacts than lines on the numbered report. In that case additional numbered reports may be used.

4.5.1 As each artifact in the project is calibrated, the calibrating metrologist will:

4.5.1.1 Return the completed artifact to its original storage location;

4.5.1.2 Complete a test report for the artifacts calibrated in each phase of the project;

4.5.1.3 Give the original calibration report to the Technical Manager for review;

4.5.1.4 Update the laboratory log as each phase of the project is completed.

4.5.2 As each phase of the project is completed, the metrologist consults the original work order specifications and:

4.5.2.1 Ships or returns the calibrated articles to the customer; or,

4.5.2.2 Holds the calibrated artifacts until the entire project is completed.

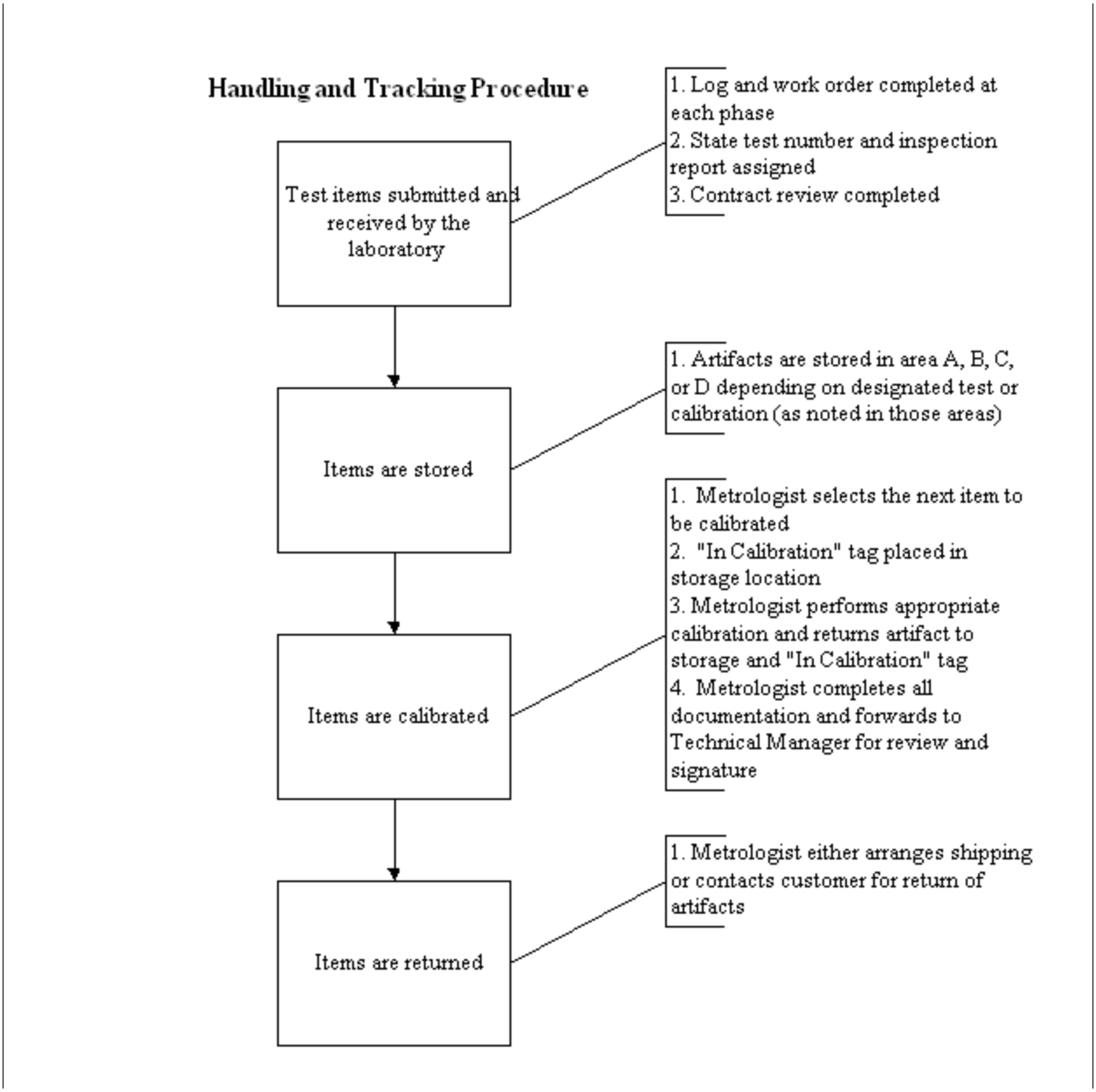


**Figure 3 SAP 4 Flowchart**

**Standard Administrative Procedure 5**
**Scheduling**

## 1 Introduction

This is the metrology laboratory policy and procedure for scheduling tests. The metrologists maintain a work schedule that accommodates work requests from customers, allows sufficient time for standards surveillance and instrument monitoring, and provides annual calibration for the standards and equipment used by the Weights and Measures Division field staff.

## 2 Purpose

Effective scheduling is necessary to ensure efficient use of the metrology staff and laboratory resources. Effective scheduling of the laboratory workload provides timely service to customers, and ensures that the laboratory staff will have sufficient time for instrument monitoring and laboratory standards surveillance. Effective scheduling promotes good measurement services, and reduces unnecessary deadline pressures that may lead to safety problems and shortcuts in procedures.

## 3 Responsibility and Authority

All metrologists have responsibility for scheduling work and are authorized to accept and schedule work orders within the parameters set by this policy. The Laboratory Supervisor has the authority to change the work schedule upon consultation with laboratory staff as needed.

## 4 Operations

4.1 Service Goal
The metrology laboratory will attempt to schedule all work requests so that the work can be completed within 15 days once the artifacts are received.

4.2 Desk calendar (laboratory may implement 4.2 or 4.3 or both)
A desk/wall calendar is maintained as the primary instrument for accepting and scheduling work orders. The calendar is available to staff members at all times.

4.3 Electronic calendar
The metrologists will update, maintain and print an electronic calendar that is posted for all staff to use. The electronic calendar is an instrument for recording whether a work order is received, and when the order is completed.

4.4 Scheduling

4.4.1 Customer work requests received via telephone. The metrologist who receives a work request by telephone must:

4.4.1.1 Check the desk calendar to find the available dates and times;
4.4.1.2 Determine the nature of the work request and the amount of time required;
4.4.1.3 Discuss the available dates and times with the customer and set a mutually agreeable date and time;
4.4.1.4 Enter the work order on the desk calendar at the agreed upon date.

4.4.2 Customer work requests received by fax or mail. The metrologist who receives a work request by fax or mail must:

4.4.2.1 Check the desk calendar to find the available dates and times;
4.4.2.2 Determine the nature of the work request and the amount of time required. If the request is not clear, the metrologist must call the customer and request additional information;
4.4.2.3 Enter the work order on the desk calendar;
4.4.2.4 Notify the customer by telephone, fax or mail. The notice to the customer must include the date that the work will be completed.

4.4.3 Internal surveillance and monitoring. The Quality Manager, with the Laboratory Supervisor, must schedule surveillance and monitoring on the following:

4.4.3.1 Standards;
4.4.3.2 Processes;
4.4.3.3 Equipment;
4.4.3.4 Round robins.

4.4.4 Weights and Measures Division field equipment. The metrologists schedule calibration services for Weights and Measures Division field equipment.

4.4.4.1 In the first week of each month, the metrologist identifies Weights and Measures Division field inspectors who have equipment that was calibrated 11 months earlier.
4.4.4.2 The metrologist contacts the appropriate Regional Supervisor and sets a calibration date for the inspectors. The date must be set to ensure that the field equipment will be calibrated within 12 months of the previous calibration date.
4.4.4.3 The metrologist asks the appropriate Regional Supervisor to notify the inspectors of the equipment calibration date.

4.5 Project Status

The metrologists transfer data from the desk calendar to the electronic calendar. The log sheet is used to inform the metrology laboratory staff about the status of all work requests, including arrival date, test date and departure date of artifact(s). The electronic calendar is used to:

4.5.1 Indicate that a work assignment has been completed;
4.5.2 Indicate when a work order has not been delivered to the metrology laboratory on time.

4.6 Work order information

4.6.1 Customer work orders

Each customer work order received and listed on the calendar must include the following information. The information must be obtained from the customer and entered on the desk calendar:

4.6.1.1 Company Name;
4.6.1.2 Contact Person;
4.6.1.3 Telephone Number;
4.6.1.4 Description of items to be calibrated:

4.6.1.4.1 Denominations;
4.6.1.4.2 Quantity;
4.6.1.4.3 Class (weights);
4.6.1.4.4 Descriptive information.

4.6.2 Surveillance and monitoring

Each standards surveillance or instrument monitoring project listed on the calendar must include the description of work to be performed.

4.6.3 Weights and Measures Division field equipment

Each Weights and Measures Division field equipment calibration project listed on the calendar must include the following information:

4.6.3.1 Inspector to whom the equipment is assigned.
4.6.3.2 Description of the items to be calibrated.

4.6.3.2.1 Denominations;
4.6.3.2.2 Quantity;
4.6.3.2.3 Class (weights);
4.6.3.2.4 Descriptive information.

4.7 Scheduling priority

The Laboratory, as required by State Statutes, Section xxx.xx provides calibration services to all companies and individuals that request services. When sufficient staff time is available to complete all work requests, the requests will be placed on the schedule in the order in which they were received. Occasionally, a large volume of work requests are received, and sufficient staff time may not be available to complete work on all of the requests within 15 days. In these cases, the metrologists follow this order of priority to prevent scheduling conflicts:

4.7.1 Standards surveillance and instrument monitoring projects.
4.7.2 Requests for emergency service, where a company must receive calibration services in order to:

4.7.2.1 Fulfill a requirement for a contract with a government agency or with another company;
4.7.2.2 Meet requirements to market a product or service;

4.7.3 Weights and Measures Division field equipment that is due for calibration (i.e. last calibration was 12 months previous).

4.7.4 Field equipment, operated by a registered placing-in-service agent, that is due for calibration (i.e. last calibration was 12 months previous).

4.7.5 All other scheduled work requests.

4.7.6 All work received without an scheduled appointment.

4.8 Unscheduled work requests

The Metrology Laboratory will occasionally receive work orders that have not been scheduled. The metrologists place these work orders on the schedule calendar at the earliest possible date, without delaying the completion of scheduled work orders. When the unscheduled work is completed, the metrologists notify the company or person by telephone to point out that better service and faster turn-around times are available if work is scheduled in advance.

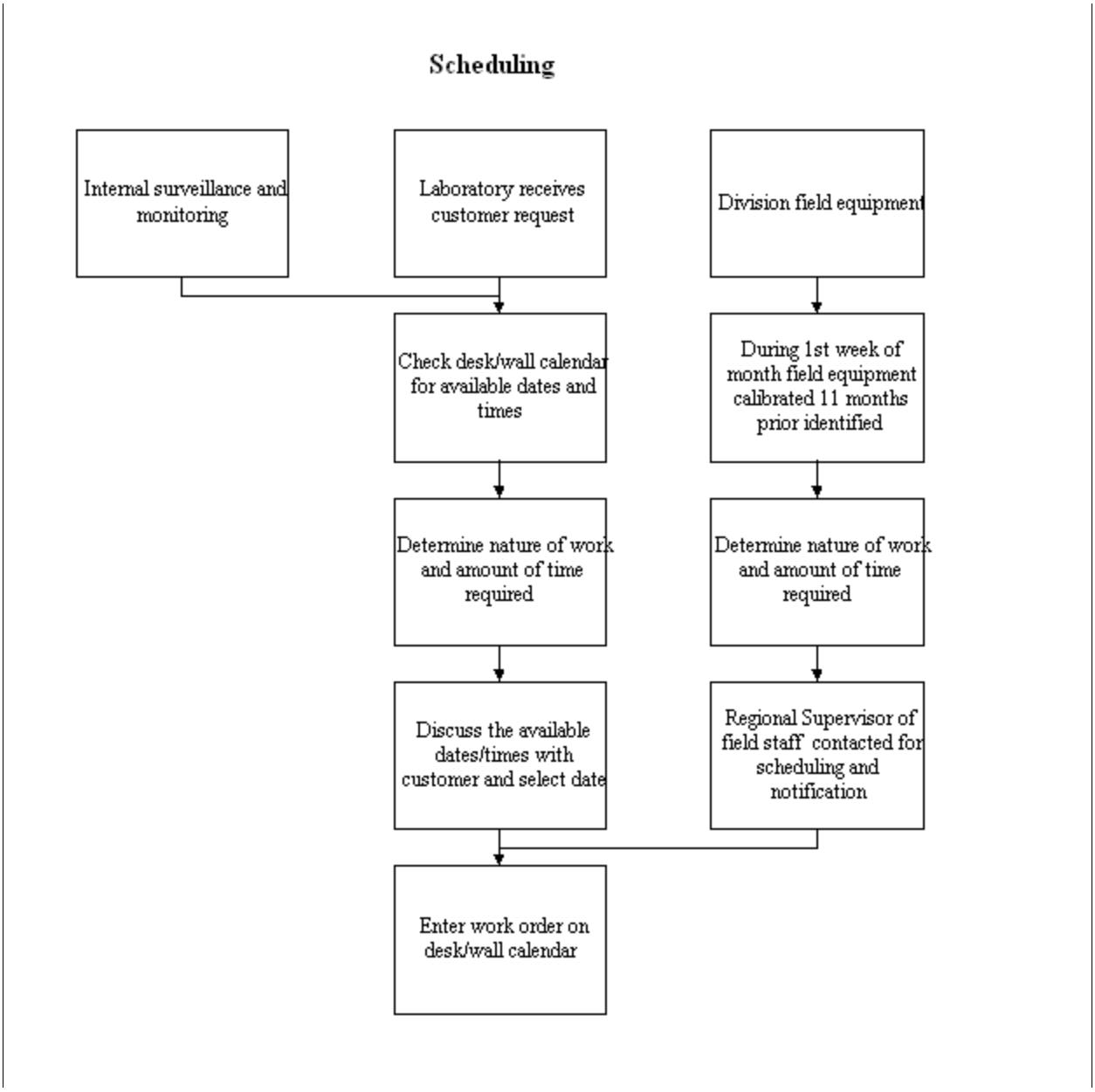


**Figure 4 SAP 5 Flowchart**

**Standard Administrative Procedure 6**
**Document Control**

## 1 Introduction

This is the metrology laboratory procedure for document control. Controlled documents include:

1.1 Standard administrative procedures;
1.2 Good laboratory procedures;
1.3 Good measurement practices;
1.4 Standard operating procedures;
1.5 Statistical process control charts;
1.6 All data collection forms and reporting forms are controlled by their inclusion in the standard procedures and charts listed in 1.1 above.

NOTE: The document control of the laboratory quality manual is integral to the quality manual. Items identified above that are included in NIST Handbook 145 are not part of the laboratory document control system except as modified by the laboratory.

## 2 Purpose

The metrology laboratory controls documents to ensure that the laboratory has uniform and consistent procedures for all calibrations and tests performed in the laboratory, laboratory staff consistently use the correct procedures to perform calibrations and tests and that reports sent to customers are uniformly clear, consistent, and understandable.

## 3 Responsibility and Authority

Responsibility and authority for document review and control are distributed according to the type of document. Following, are the categories of documents that must be reviewed and signed, and the names and titles of the responsible persons:

3.1 Standard administrative procedures must be reviewed by the Laboratory Supervisor;
3.2 Good laboratory practices, good measurement practices, standard operating procedures and associated forms must be reviewed and signed by the Technical Manager of the metrology laboratory;
3.3 Statistical process control charts and forms must be reviewed and signed by the Quality Manager for the metrology laboratory.

## 4 Operations

4.1 Document review system

All documents and forms must be reviewed annually, or more often if a need for change is identified by a metrology laboratory staff member. The following questions must be addressed and answered for each document and form reviewed:

4.1.1 Has the National Institute of Standards and Technology recommended any changes to a standard document or form?

4.1.2 Have there been any changes in laboratory equipment which will require corresponding changes in a document or form?

4.1.3 Have metrology laboratory staff members suggested any changes to a document or form?

4.1.4 Have metrology laboratory customers requested any changes to a document or form?

4.1.5 How frequently has the document or form been used in the last year?

4.1.6 Can this document or form be combined with another document or form?

4.1.7 Can this document or form be eliminated?

4.2 Document identification system

In order to ensure that documents are not changed without review, and to ensure that the correct documents are used in the metrology laboratory, the following information must be included in each document and form:

4.2.1 An accurate descriptive title at the top of each document or form;

4.2.2 An up-to-date revision number, located in the footer at the bottom of each document or form;

4.2.3 The date that the document was last revised, located in the footer at the bottom of each document or form;

4.2.4 A unique form number, located in the footer at the bottom of each document.

4.3 Document review and revision process

4.3.1 Annual review.

4.3.1.1 Each controlled document and form must be reviewed each year.

4.3.1.2 For the annual review process, the Laboratory Supervisor or designee will:

4.3.1.2.1 Schedule the document and form review sessions;

4.3.1.2.2 Schedule the calibration and testing workload to ensure that the staff will have sufficient time to complete the review process;

4.3.1.2.3 In May of each year, notify the metrology laboratory staff of dates for the upcoming review sessions in July;

4.3.1.2.4 Schedule staff leave requests to ensure that the entire metrology laboratory staff will be present for the review sessions.

4.3.1.3 Each controlled document will be reviewed according to the criteria in paragraph 4.1, above.

4.3.1.4 If the staff agree that a change is needed, the Laboratory Supervisor directs the person responsible for the document (see paragraphs 3.1 through 3.4 above) to prepare a draft of the document or form, including the suggested change, for the next weekly staff meeting.

4.3.1.5 The Laboratory Supervisor implements the document and removes all previous revisions after the following criteria have been met:

4.3.1.5.1 If the draft meets all of the criteria in sections 4.1 and 4.2 above;

4.3.1.5.2 If the staff agree to accept the draft;

4.3.1.5.3 When the person responsible for the document (see paragraphs 3.1 through 3.4 above) has signed and approved the document.

4.3.2 Intermediate reviews.

4.3.2.1 Any controlled document or form may be reviewed during any weekly meeting of the metrology laboratory staff.

4.3.2.2 The Laboratory Supervisor will ask the laboratory staff, at each staff meeting, if anyone has discovered a problem or need for change in any controlled document or form.

4.3.2.3 If the staff agree that a change is needed, the Laboratory Supervisor directs the person responsible for the document (see paragraphs 3.1 through 3.4 above) to prepare a draft of the document or form, including the suggested change, for the next weekly staff meeting.

4.3.2.4 The Laboratory Supervisor implements the document and removes all previous revisions after the following criteria have been met:

4.3.2.4.1 If the draft meets all of the criteria in sections 4.1 and 4.2 above

4.3.2.4.2 If the staff agree to accept the draft

4.3.2.4.3 When the person responsible for the document (see paragraphs 3.1 through 3.4 above) has signed and approved the document

4.4 Implementing revised documents

To implement revised versions of controlled documents and forms, the Laboratory Supervisor:

4.4.1 Places the revised document, including any forms that are part of the document, in the appropriate laboratory manual;

4.4.2 Removes the complete previous revision of the document from the laboratory manual and any other locations where documents may be used;

4.4.3 Stores the previous revision in the document archive;

4.4.4 Provides a supply of revised data collection or reporting forms for use in the metrology laboratory;

4.4.5 Removes and recycles the existing supply of the previous revision of the form.

4.5 Document archive

4.5.1 The Laboratory Supervisor maintains an archive of all previous revisions of controlled documents and forms filed in the following order:

4.5.1.1 By form number;

4.5.1.2 By revision level for each form number.

4.5.2 The Laboratory Supervisor will maintain the controlled document and form archive indefinitely.

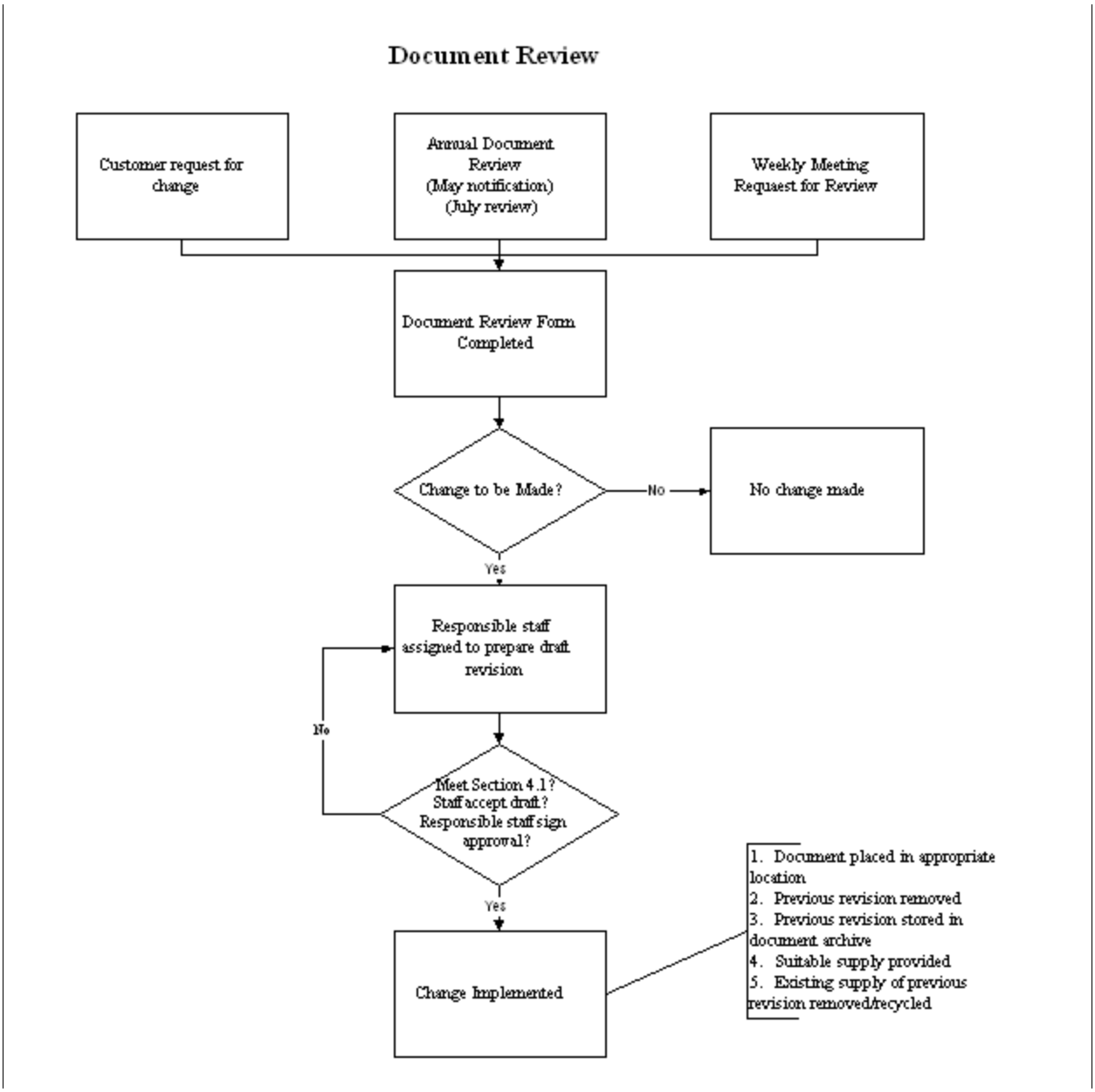


**Figure 5 SAP 6 Flowchart**

**Form 1 Document Review**

| Document Review |
|---|
| Date: |
| Document Title: |
| Document Number: |
| **Review Questions:** |
| 1. Has the National Institute of Standards and Technology recommended any changes to a standard document or form? Yes No |
| 2. Have there been any changes in laboratory equipment which will require corresponding changes in a document or form? Yes No |
| Explain if yes |
| |
| 3. Have metrology laboratory staff members suggested any changes to a document or form? Yes No |
| Explain if yes |
| |
| 4. Have metrology laboratory customers requested any changes to a document or form? Yes No |
| Explain if yes |
| |
| 5. How frequently has the document or form been used in the last year? |
| 6. Can this document or form be combined with another document or form? Yes No |
| Explain if yes |
| 7. Can this document or form be eliminated? Yes No |
| 8. Do staff agree on the need for a change? Yes No |
| Staff assigned if yes: |
| Revision date of approval/implementation per section 4.4: |
| Signature of responsible staff: |

**Standard Administrative Procedure 7**

## Data Management

## 1 Introduction

This is the metrology laboratory policy for data management. The metrology laboratory will use the data management system outlined in this SAP to maintain records of standards control, process control and quality control, and of the calibrations and tests performed by the laboratory. The data management system includes filed paper copies of documents and digital information stored on a computer hard disk drive. All records are secured.

## 2 Purpose

Proper data management aids in maintaining quality standards, managing customer records, and scheduling metrology laboratory operations.

## 3 Responsibility and Authority

3.1 The Laboratory Supervisor will review and maintain:
- 3.1.1 Work order records;
- 3.1.2 Standard Administrative Procedures (SAPs);
- 3.1.3 Instrument status records;
- 3.1.4 Training records;
- 3.1.5 Artifact and calibration records;
- 3.1.6 Scheduling calendars and records;
- 3.1.7 A file of customer complaints received by the metrology laboratory.

3.2 The Technical Manager will review and maintain:
- 3.2.1 SOPs and Round Robin records;
- 3.2.2 GLPs and GMPs;
- 3.2.3 Statistical Process Control Charts.

3.3 The Quality Manager will review:
- 3.3.1 SOPs;
- 3.3.2 and maintain all audit records and Statistical Process Control Charts.

3.4 The Weights and Measures Division MIS Coordinator (or suitably trained metrologist) will:
- 3.4.1 Assist the metrology laboratory staff in the design, installation, and maintenance of the computerized records system;
- 3.4.2 Perform regular backups of metrology laboratory records and data, and ensure safe storage of backup tapes;
- 3.4.3 Restore files from tape as requested by metrology laboratory staff.

3.5 Metrology Laboratory Staff will perform routine filing tasks and update computerized records as directed by the Technical Manager, the Laboratory Supervisor, or the Quality Manager.

## 4 Operations

4.1 Files -- Paper Copies.

4.1.1 The metrology laboratory maintains paper copies of:
Quality System Manual
Operations Manual
Standard Administrative Procedures
Standard Operating Procedures
Standard Laboratory Practices
Calibration Data
State Test Reports
Laboratory Log
Statistical Process Control Data

4.1.2 These records are kept in controlled file drawers that can be accessed only by metrology laboratory staff, and the Weights and Measures Division Director.

4.1.3 Records will be kept for a minimum of seven years unless otherwise noted in the appropriate SAP.

4.2 Files -- Computer Hard Disk Drive.

4.2.1 The metrology laboratory maintains electronic copies of:
Quality System Manual
Operations Manual
Standard Administrative Procedures
Standard Operating Procedures
Standard Laboratory Practices
Calibration Reports
State Test Reports
Statistical Process Control Data

4.2.2 The electronic records are maintained on a hard disk drive that can be accessed only by the metrology laboratory staff, the MIS Coordinator, and the Weights and Measures Division Director.

4.2.3 Formats follow accepted templates. Templates use:

4.2.3.1 Times New Roman (12 pt) for body text, unless otherwise noted in the corresponding SAP;

4.2.3.2 Times New Roman (14 pt) and Times New Roman (16 pt) for title text;

4.2.3.3 Times New Roman (10 pt) for footers and pagination.

4.2.4 Monday through Friday of each week, the MIS Coordinator performs a hard disk drive backup to tape. The tapes are stored by the MIS Coordinator. If the MIS coordinator is absent, the backup is performed by the Weights and Measures Division Director.

**Standard Administrative Procedure 8**
**Preparation of Calibration and Test Reports**

## 1 Introduction

This is the Metrology Laboratory procedure for preparing calibration reports and test reports. Test reports are the only permanent written records of the services provided by metrology laboratory. To the customer, test reports represent the services they receive. It is imperative that these items satisfy customer needs and expectations, and reflect the high quality of service provided by the metrology laboratory.

## 2 Purpose

In order to provide uniform and understandable information to the customer, the content of the test reports produced by the metrology laboratory must comply with ANSI/NCSL Z540-1-1994 (ISO/IEC Guide 25). They must be prepared with care to ensure that they accurately convey all information pertaining to the calibration or test. Carefully prepared test reports must contain all the necessary information to justify the test results. The test report must be generated from the information collected on standardized data sheets specific to each SOP. The calibration report may include narrative information for special calibrations.

## 3 Responsibility and authority

The Technical Manager has primary responsibility for the content and accuracy of calibration and test reports. The Quality Manager is responsible for ensuring that the reports comply with the metrology laboratory quality system and with ANSI/NCSL Z540-1-1994 (ISO/IEC Guide 25). The Technical Manager has authority to edit and modify all reports.

## 4 Operations

Each calibration report or report of test must contain essential information about the metrology laboratory, the customer, and the calibrations or tests performed by the metrology laboratory.

4.1 Required test report contents:

4.1.1 The report title, as follows:

4.1.1.1 “Calibration Report"; or,

4.1.1.2 “Report of Test".

4.1.2 The name and address of the metrology laboratory, as follows:

4.1.3 Customer identification and contact information:

4.1.3.1 Name;

4.1.3.2 Address;

4.1.3.3 Contact person (if the customer gives a contact name);
4.1.3.4 Telephone number;
4.1.3.5 Purchase order number (if the customer gives a number).

4.1.4 Description and unambiguous identification of the artifacts to be calibrated:
4.1.4.1 Model number (if a model number is available);
4.1.4.2 Serial number (if a serial number is available);
4.1.4.3 Manufacturer name (if a name is available).

4.1.5 Characterization and condition of the artifacts:
4.1.5.1 Poor - the artifact displays very significant wear or other degradation that will greatly reduce effectiveness as a standard;
4.1.5.2 Fair - the artifact displays significant wear or other degradation;
4.1.5.3 Good - the artifact displays some wear or other degradation;
4.1.5.4 Excellent - the artifact displays little wear or other degradation;
4.1.5.5 New - the artifact displays no wear or other degradation;
4.1.5.6 Contaminated - the artifact displays contamination (include a description of the contamination);
4.1.5.7 Other - include a description of any other condition which may effect the integrity of the standard.

4.1.6 Required dates:
4.1.6.1 Date that the artifacts were received;
4.1.6.2 Calibration date;
4.1.6.3 Date that the report is produced and signed.

4.1.7 Identification of the operating procedure used for the calibration or test:
4.1.7.1 The name and number of the Standard Operating Procedure used for the calibration or test; or,
4.1.7.2 A description of a non-standard operating procedure used for the calibration or test. If a non-standard procedure is requested by the customer (or required for an unusual artifact or instrument) the Technical Manager will establish the procedure and confirm acceptance with the client. A non-standard procedure will be concisely documented and described in the calibration report.

4.1.8 Deviations from standard methods
Deviations from, additions to, or exclusions from the standard method must be noted on the report.

4.1.9 Test or calibration results
The Metrology Laboratory does not employ sampling procedures. All artifacts submitted by a customer must be calibrated or tested, and the results noted on the report.

4.1.10 Other relevant information

Any information, such as an environmental condition relevant to a specific calibration, must be noted on the report.

4.1.11 Uncertainty

The report must include an uncertainty statement with the following information:

4.1.11.1 A statement of the estimated expanded uncertainty of the calibration result;

4.1.11.2 The method used to calculate the uncertainty;

4.1.11.3 The confidence level associated with the calibration result.

4.1.12 Signature

Reports require two signatures. The metrologist responsible for the contents of a report must sign and submit the report to the Technical Manager or the Laboratory Supervisor for review. The Technical Manager or Laboratory Supervisor must review and sign the report.

4.1.13 Test results -- application restriction

The report must include a statement that the results apply only to the artifacts calibrated.

4.1.14 Limitations of use

If an artifact (a thermometer, for example) is calibrated in only part of its range, or if only some artifacts in a group of artifacts (10 out of 30 weights, for example) are calibrated, the report must include a statement that clearly explains that use of the artifact or artifacts is limited by the extent of the calibration performed.

4.1.15 Reports -- restriction on reproduction

The report must include a statement that the report must not be reproduced, except in full, without written approval from the metrology laboratory.

4.1.16 Traceability statement

The report must include a traceability statement with the following information:

4.1.16.1 The standards to which the calibrated artifacts are traceable;

4.1.16.2 Information referring to the test number of the standards to which the artifacts are traceable (indicating that records are on file);

4.1.16.3 The calibration or test methods used to ensure that the results are traceable.

4.1.17 Accreditation number

The report must include the metrology laboratory accreditation number if available.

4.2 Test report design

4.2.1 Arrangement and presentation of the calibration data must allow for ease of use by the client.

4.2.2 The specific standard report format must be used for each calibration procedure.

4.3 Typeface and font size

4.3.1 Test reports must use the Times New Roman typeface, font size 12.

4.3.2 Test reports produced using the MASSCODE software program must use the Courier W1 typeface.

4.4 Test report distribution, storage, and retention

4.4.1 A copy of the report must be distributed to the customer via mail, courier, or in person.

4.4.2 Each test report must be filed:

4.4.2.1 By the calendar year in which the report was produced;

4.4.2.2 Alphabetically by customer name within the calendar year group.

4.4.3 An original, signed, paper copy of each test report must be retained for a minimum of seven years.

4.5 Corrections or amendments to reports

4.5.1 A report shall not be considered to have been issued, until it has left the metrology laboratory. Any change to a report before it leaves the laboratory will not be considered an amendment.

4.5.2 A report may be modified to correct a recorded error, omission, or action by the Metrology Laboratory. A report may be modified only according to the following criteria and restrictions:

4.5.2.1 The verbiage of a report may be corrected if the changes do not affect the numerical values provided;

4.5.2.2 Incorrect entries from the data sheet may be corrected under the Technical Manager's supervision;

4.5.2.3 Changes to numeric values are not allowed unless the artifacts are recalibrated;

4.5.2.4 After a report is corrected:

4.5.2.4.1 The report must be reviewed again by the Technical Manager;

4.5.2.4.2 The Technical Manager must send a corrected report to the customer;

4.5.2.4.3 The Technical Manager must attach a copy of the corrected report to the filed copy of the original report.

4.5.2.5 The corrections must be noted in the Corrective Action/Complaint record.

4.5.3 Amendments to reports, resulting from requests or changes made by the customer, may be made according to the following criteria:

4.5.3.1 A report may be changed if the technical validity of the calibration or test is maintained;

4.5.3.2 When a report is amended:

4.5.3.2.1 The report must be reviewed again by the Technical Manager;

4.5.3.2.2 The Technical Manager must send the amended report to the customer;

4.5.3.2.3 The Technical Manager must attach a copy of the amended report to the filed copy of the original report.

4.5.3.3 The original contract must be reviewed to determine if the contract was correctly followed.

**Standard Administrative Procedure 9**
**Audits and Reviews**

## 1 Introduction

This is the metrology laboratory procedure for conducting internal audits, and for cooperating in external audits. This is the only procedure that the metrology laboratory will use to conduct audits or cooperate with external auditors.

## 2 Purpose

The purpose of this procedure is to ensure that the metrology laboratory maintains a high level of service quality, and a high level of compliance with laboratory procedures, by conducting regular internal audits, and by cooperating with external audits, within the limits set by the procedure.

## 3 Responsibility and authority

3.1 The Quality Manager is authorized to operate a continuous internal audit program.
3.2 The Technical Manager is authorized to:
3.2.1 Respond to requests from customers for external audits;
3.2.2 Arrange external audits to be performed, at the discretion of the metrology laboratory, by recognized accreditation organizations;
3.2.3 Respond to requests, received through the Weights and Measures Division Director, for performance or financial audits conducted by the State Legislative Auditor.

## 4 Operations

4.1 Internal audits
The Quality Manager will organize and complete periodic and special audits as outlined below:
4.1.1 A Quality System Audit will be conducted semiannually.
4.1.1.1 The Quality Manager will evaluate the Quality Manual and the Standard Administrative Procedures (SAPs) for compliance with ISO Guide 25 requirements.
4.1.1.2 The Quality Manager will then observe operations to determine compliance with the requirements of the Quality Manual and the SAPs.
4.1.1.3 The Quality Manager will meet with the Technical and Laboratory Supervisors to report the findings of the audit.
4.1.1.4 The Technical and Laboratory Supervisors will address the findings to the Quality Manager's satisfaction, and will implement any necessary changes before the next Quality System Audit.
4.1.1.5 The Quality Manager will make a written report of the audit results and distribute copies to the Technical and Laboratory Supervisors, and to the Weights and Measures Division

Director. The Quality Manager will keep a copy of this report on file.

4.1.2 A Technical System Audit will be conducted semiannually in the quarters when the Quality System Audit is not conducted.

4.1.2.1 The Quality Manager will evaluate the Standard Operating Procedures (SOPs) and the Standard Laboratory Procedures (SLPs) for compliance with the requirements of NIST Handbook 143, NIST Handbook 150, and the laboratory Quality Manual.

4.1.2.2 The Quality Manager will then observe operations to determine compliance with the requirements outlined in the SOPs and SLPs.

4.1.2.3 The Quality Manager will meet with the Technical and Laboratory Supervisors to report the findings of the audit.

4.1.2.4 The Technical and Laboratory Supervisors will address the findings to the Quality Manager's satisfaction, and will implement any necessary changes before the next Technical System Audit.

4.1.2.5 The Quality Manager report the audit results in writing to the Technical and Laboratory Supervisors, and to the Weights and Measures Division Director. The Quality Manager will maintain a copy of this report on file.

4.1.3 A Safety Audit will be conducted annually.

4.1.3.1 The Quality Manager with work with the Weights and Measures Division Safety Coordinator to evaluate the SOPs, SAPs, and SLPs for compliance with safety requirements.

4.1.3.2 The Quality Manager and the Safety Coordinator will observe operations to determine compliance with the safety procedures outlined in the SOPs, SAPs, and SLPs.

4.1.3.3 The Quality Manager and the Safety Coordinator will meet with the Technical and Laboratory Supervisors to report the findings of the audit.

4.1.3.4 The Technical and Laboratory Supervisors will address the findings to the satisfaction of both the Quality Manager and the Safety Coordinator, and will implement any necessary changes within a reasonable time limit to be determined by the Safety Coordinator.

4.1.3.5 The Quality Manager will report the audit results, in writing, to the Technical and Laboratory Supervisors, the Safety Coordinator, and the Weights and Measures Division Director. The Quality Manager will maintain a copy of this report on file.

4.1.4 A Special Internal Audit may be called at any time by the Weights and Measures Division Director, the Weights and Measures Division Safety Coordinator, or any of the Metrology Department's Staff if there is concern that some portion of the metrology system is generating discrepant results or unsafe conditions.

4.1.4.1 The Quality Manager will conduct the audit with assistance from the Safety Coordinator, if necessary.

4.1.4.2 The procedures for the audit will depend upon the nature of the discrepancy or condition, and will be determined by the Quality Manager at the time of the audit.

4.1.4.3 The Quality Manager will meet with the Technical and Laboratory Supervisors, the

Safety Coordinator (if necessary), and the person who requested the special audit to report the findings of the audit.

4.1.4.4 The Technical and Laboratory Supervisors will address the findings to the satisfaction of the Quality Manager. They will implement any necessary changes within a reasonable time limit set by the Quality Manager.

4.1.4.5 The Quality Manager will report the audit results, in writing, to the Technical and Laboratory Supervisors, the Safety Coordinator (if necessary), and to the Weights and Measures Division Director. The Quality Manager will maintain a copy of this report on file.

4.2 External audits requested by laboratory customers

The Metrology Laboratory will submit to audits requested by laboratory customers. The metrology laboratory will respond to the following audit requests with the following procedures:

4.2.1 When the Technical Manager receives a written request from a customer for documents or information relating to metrology laboratory procedures, calibrations, or tests:

4.2.1.1 Write to the customer to acknowledge receipt of the request;

4.2.1.2 Review the customer's request and, if necessary, place a telephone call to the customer's representative to clarify any requested items that may not be clearly identified in the request;

4.2.1.3 Compile the requested information and send it to the customer within thirty days after receiving and clarifying the request.

4.2.2 When the Technical Manager receives a formal written request for an on-site audit to be conducted by a customer's audit team:

4.2.2.1 Place a telephone call to the customer's representative and schedule a mutually agreeable date and duration for the audit, not more than forty-five days after the date of the request, unless the customer specifies a later date;

4.2.2.2 Write to the customer to acknowledge receipt of the customer's request, to confirm the audit date and duration, and to extend an invitation to the customer's audit team;

4.2.2.3 In the letter (required in 4.2.2.2 above), ask the customer's representative to provide written questions, a list of the documentation the audit will review, a complete description of the customer's audit criteria, and a deadline by which the requested information must be received;

4.2.2.4 When the requested information is received, assign metrology laboratory staff to an audit team that will work with the customer's audit team;

4.2.2.5 If the requested information is not received by the deadline, write to the customer and cancel the audit;

4.2.2.6 Assign audit preparation tasks and deadlines to ensure that the Metrology Laboratory will be fully prepared for the audit;

4.2.2.7 Meet with the customer's audit team and assist them in completing their audit as quickly and efficiently as possible;

4.2.2.8 Set a mutually agreeable deadline, in writing, for the customer's audit team to report their audit results;

4.2.2.9 Respond to any follow-up questions or requests the customer's audit team submits prior to the agreed upon deadline. Respond to follow-up questions and requests within five days after they are received;

4.2.2.10 Receive and file the customer's audit report;

4.2.2.11 Meet with the metrology laboratory staff and the Weights and Measures Division Director to decide whether to implement any suggestions in the auditor's report, or how to correct any problems that may have been discovered in the auditor's report;

4.2.2.12 Implement any changes according to standard administrative procedures;

4.2.2.13 Report the results to the Weights and Measures Division Director.

4.3 External audit by an accreditation organization

The metrology laboratory may request an audit by an external accreditation organization. The Technical Manager must use the following procedure to make such a request, and to respond to the audit results:

4.3.1 Select an appropriate accreditation organization;

4.3.2 Determine the scope of the audit (by producing a list of laboratory procedures or operations that are to be audited);

4.3.3 Receive permission from the Weights and Measures Division Director to request an external audit by the selected accreditation organization;

4.3.4 Submit a formal written request for an audit to the selected accreditation organization;

4.3.5 Place a follow-up telephone call to a representative of the accreditation organization to set a mutually agreeable date for the audit;

4.3.6 Notify the metrology laboratory staff of the audit dates, and organize an audit team to assemble the necessary information and to work with the audit team from the accreditation organization;

4.3.7 Respond to any pre-audit requests from the accreditation organization audit team (send documents and other information as requested);

4.3.8 Schedule the metrology laboratory staff so that the entire staff will be available to answer questions, provide documents, and demonstrate procedures during the audit;

4.3.9 Work with the accreditation organization audit team to set a deadline for completing the audit report;

4.3.10 Respond to any follow-up questions or information requests from the audit team;

4.3.11 Receive and file the audit report;

4.3.12 Meet with the metrology laboratory staff and the Weights and Measures Division Director to decide how to implement any suggestions in the auditor's report, and how to correct any problems that may have been discovered in the auditor's report;

4.3.13 Implement the changes according to standard administrative procedures;

4.3.14 Report the results to the Weights and Measures Division Director.

4.4 External audits by the State Legislative Auditor

The metrology laboratory will respond to any request for a performance or financial audit by the State Legislative Auditor. Such requests will be passed to the metrology laboratory by the Weights and Measures Division Director. The Technical Manager will

use the following procedure to respond to the audit request:

4.4.1 Meet with the Weights and Measures Division Director, Finance Manager, and the audit team from the State Legislative Auditor's office to:

4.4.1.1 Determine the scope of the audit;

4.4.1.2 Receive requests for information;

4.4.1.3 Set a deadline for responding to the auditors' requests.

4.4.2 Organize an audit response team to assemble the requested information within the deadlines set by the State Legislative Auditor;

4.4.3 Provide the requested information to the Weights and Measures Division Director;

4.4.4 Schedule the metrology laboratory staff to respond to any requests from the auditor for interviews or demonstrations;

4.4.5 Respond to any follow-up information requests by providing the requested information to the Weights and Measures Division Director;

4.4.6 Receive the audit report from the Weights and Measures Division Director;

4.4.7 Discuss the report with the Division Director and the Finance Manager to determine how to implement any changes or suggestions;

4.4.8 Implement changes according to the standard administrative procedures.

**Table 1 Audit Summary**

| **Audit Summary** | | | |
|---|---|---|---|
| Section | Audit type | Frequency | Responsible Manager |
| 4.1.1 | Quality System (QS) | Alternating Quarters (from TS) | Quality Manager |
| 4.1.2 | Technical System (TS) | Alternating Quarters (from QS) | Quality Manager |
| 4.1.3 | Safety | Annually | Quality Manager |
| 4.1.4 | Special Internal | As requested or needed | Quality Manager |
| 4.2.1 | Customer Requested | As requested | Technical Manager |
| 4.3 | Accreditation On-site | Determined by Accrediting Agency | Technical Manager |
| 4.4 | State Legislative Audit | As requested | Director, Technical Manager |
| | | | |

**Standard Administrative Procedure 10**
**Software Quality Assurance**

## 1 Introduction

This is the metrology laboratory procedure for protecting and validating the accuracy of computer software. Software is classified as primary, secondary, or tertiary, according to its potential for introducing errors into calibration results. Each classification has an associated validation and security protocol. Reference NCSL RP 13, Computer Systems in Metrology.

## 2 Purpose

The purpose of this procedure is to ensure that software does not contribute errors or additional uncertainty to any measurement process and to ensure that computer systems are adequately secure.

## 3 Responsibility and authority

3.1 The Technical Manager will classify new software and validate the numerical and computational integrity of primary and secondary software. Validation records are maintained in the laboratory for primary software.

3.2 For primary software that does not have built in protections to prevent accidental changes during routine use, the Technical Manager and the MIS Coordinator will implement a system of templates, cell protection, read only access, or other security measures to protect the programming.

3.3 The MIS Coordinator will employ the following security measures to maintain the security of the disk partition where primary software resides:

3.3.1 Passwords to limit disk access. Only the metrology laboratory staff, the Weights and Measures Division Director; and the MIS Coordinator will have access to the disk;

3.3.2 Regular backups of the entire disk partition;

3.3.3 Restoration of software in the event of a disk failure.

3.4 The Quality Manager is authorized to ensure that this procedure is followed and that all software associated with a measurement result has been validated. The Quality Manager is responsible to validate, or arrange to have another metrologist validate, any primary or secondary software written by the Technical Manager.

## 4 Operations

4.1 Computer Software -- Classified
Software is classified as primary, secondary, or tertiary, according to its potential for introducing errors into calibration results.

4.1.1 Primary Software - Software that contributes numeric data to a calculation algorithm.

The following primary software is used in the metrology laboratory:

| Software | Purpose | Program Source |
|---|---|---|
| LAB WIZARD | Mass Calibration | NIST |
| MASSCODE.DOS | Mass Calibration | NIST |
| 3-1WEIGH.W** | Mass Calibration | NIST |
| VolLPG | LPG Volume Calibration | NIST |
| 5GALGRAV | 5 Gal Gravimetric Calibration | NIST |
| VOLUME.W** | Volume Calibration | NIST |

4.1.1.1 Primary software -- exception

Primary software does not include software that performs basic arithmetic procedures such as multiplication and division. Software that performs basic arithmetic procedures is indirectly validated through the validation of the primary and secondary programs in which it is utilized.

4.1.1.2 Firmware -- exception

Firmware (algorithms or programming coded into the circuitry of a device or instrument, and provided with the device or instrument by the original manufacturer) is also excepted from the definition of primary software.

4.1.2 Secondary Software

Programming developed in the metrology laboratory that contributes numeric data to a calculation algorithm through a series of basic arithmetic procedures specified by the metrologist who designed the program. These basic calculations are performed by tertiary software that is indirectly validated through the validation of the secondary software. The possibility of error arises mainly from the metrologist's program itself. Examples include spontaneously written spreadsheets to calculate a mean, or standard deviation. These internally developed programs are not stored or listed.

4.1.3 Tertiary Software

Acquired software that is produced outside of the metrology laboratory, including:

4.1.3.1 Software that does not contribute numeric data to a calculation algorithm;

4.1.3.2 Software that performs such basic mathematical functions that its accuracy can be assumed and indirectly validated through the validation of the primary and secondary software in which it is utilized.

The following tertiary software is used in the metrology laboratory:

| Software | Purpose | Program Source |
|---|---|---|
| Microsoft Word v 6.0a | Word processing | Microsoft |
| Word Perfect 6.1 | Word processing | Corel |
| Microsoft Excel v 5.0 | Spreadsheet | Microsoft |
| Microsoft PowerPoint v 4.0 | Presentation | Microsoft |
| Lotus 1-2-3 v 3.1 | Spreadsheet | Lotus |
| Quattro Pro | Spreadsheet | Corel |
| Labview v 3.0 | Instrument Control and Data Acquisition | National Instruments |
| Microsoft Windows v 3.1 | Secondary Operating System | Microsoft |
| IBM PC DOS v 6.1 | Operating System | IBM |
| Math Cad v 4.0 | Calculation | Math Soft |

4.2 Computer Software -- Validation System

4.2.1 Primary Software

Primary software is validated upon initial acceptance, and after any modification, or platform transfer. The validation procedure includes:

4.2.1.1 Checking for data entry errors; and,

4.2.1.2 Verifying the accuracy for all extremes using accepted standards such as recognized data sets; or,

4.2.1.3 Verifying the accuracy for all extremes by hand calculation. Differences must be << less than the uncertainty of the measurement process. The Technical Manager is responsible for determining what "<< less" means in each case.

4.2.2 Secondary Software

Validation includes an examination of formulae, checking significant digits, and verifying cell or variable names. This validation is performed by:

4.2.2.1 The Technical Manager validates secondary software written by laboratory staff.

4.2.2.2 The Quality Manager validates secondary software written by the Technical Manager, or arranges to have the software validated by another metrologist (this may involve a third party metrologist from another organization).

4.2.3 Tertiary Software

4.2.3.1 Tertiary software that performs basic arithmetic functions is indirectly validated through the primary and secondary software in which it is utilized.

4.2.3.2 Tertiary software that does not contribute numerically is not validated because it does not contribute to measurement results

4.3 Computer Software -- Security

4.3.1 Primary Software

Upon successful validation, primary software is secured so that it cannot be altered without an intentional action by the Technical Manager. Software may be secured through compilation, cell protection, read only templates or other measures as deemed necessary by the Technical Manager and the MIS Coordinator. Current primary software is secured as follows:

| Software | |
|---|---|
| LAB WIZARD | Compiled by NIST |
| MASSCODE.DOS | Compiled by NIST |
| 3-1WEIGH.W** | Cell protection, read only template |
| 5GALGRAV.W** | Cell protection, read only template |
| VolLPG.W* | Cell protection, read only template |
| Volume.W** | Cell protection, read only template |
| Vol40 | Cell protection, read only template |
| Density | Cell protection, read only template |

4.3.2 Secondary Software

Secondary software is not stored and therefore not secured.

4.3.3 Tertiary Software

Tertiary software is indirectly validated through the validation of any primary or secondary software which utilizes it.

**Standard Administrative Procedure 11**
**Purchase and Evaluation of Supplies and Services**

## 1 Introduction

This is the metrology laboratory procedure for purchase, storage, and evaluation of supplies and services. Obtaining products or services from organizations registered to ISO 9000 or accredited to ISO Guide 25 is recommended where possible; however, this is no guarantee of acceptable quality. The laboratory inspects and evaluates products or services and identifies any unique storage requirements when products are received or returned.

## 2 Purpose

It is imperative that supplies and services obtained by the laboratory reflect the expected quality of service and that they do not adversely contribute to the quality of measurement results.

## 3 Responsibility and Authority

3.1 The Technical Manager is responsible for ensuring that suitable specifications are used to purchase supplies and services.

3.2 The Quality Manager is responsible for ensuring that products and services meet designated specifications.

## 4 Operations

4.1 The laboratory will use national or international specifications for standards where available and inspect the standards upon receipt to determine that standards meet specifications. Examples include:

- 4.1.1 Mass standards: OIML R 111 or ASTM E 617;
- 4.1.2 Mass field standards: NIST Handbook 105-1;
- 4.1.3 Volumetric field standards: NIST Handbook 105-2, 105-3; and
- 4.1.4 Thermometers: ASTM E 1 or NIST Handbook 105-6.

4.2 In addition to specifications, and if specifications are not available, the following criteria will be used in purchase considerations:

- 4.2.1 Accuracy, stability, contribution to measurement uncertainty (quality factor);
- 4.2.2 Familiarity with the product, word of mouth experience from other laboratories (quality factor);
- 4.2.3 Prior relationship with supplier, supplier's reputation, and commitment to customer satisfaction;
- 4.2.4 Availability of product, parts, or services.

4.3 Maintenance of records

The laboratory will maintain purchase and warranty records and maintain performance history files. In situations where the quality of product or services are not adequate for the intended purpose, the laboratory will investigate the issue prior to additional purchases.

4.4 List of acceptable suppliers

The laboratory will maintain a list of acceptable suppliers for laboratory standards, equipment, supplies, and services where the quality of such products or services may affect the quality of the measurements. Each supplier will be evaluated initially and annually thereafter according to criteria in section 4.2.

4.5 Examples of purchases affecting quality of measurement results

4.5.1 Laboratory supplies affecting measurement quality

4.5.1.1 Chemicals
4.5.1.2 Wipes
4.5.1.3 Weight handling equipment - gloves, forceps, filter paper
4.5.1.4 Meniscus reading tools, magnifiers

4.5.2 Standards

4.5.2.1 Weights
4.5.2.2 Volumetric
4.5.2.3 Thermometers
4.5.2.4 Barometers
4.5.2.5 Hygrometers
4.5.2.6 Tapes

4.5.3 Equipment

4.5.3.1 Balances
4.5.3.2 Water purification system

4.5.4 Services

4.5.4.1 Calibration of standards
4.5.4.2 Balance repair and/or maintenance

4.6 Inspection prior to use

All products and services are inspected or validated prior to use of equipment or supplies.

**Form 3 Supplier Evaluation**

| Supplier Evaluation | |
|---|---|
| Date: | |
| Supplier: | |
| Supplier products: | |
| **Evaluation Questions:** | |
| Applicable specification | Yes No |
| Title of applicable specification: | |
| Supplier registration/accreditation: | |
| Accuracy, stability, uncertainty evaluation: | |
| | |
| Familiarity with product, word of mouth experience from other laboratories: | |
| | |
| Prior relationship, supplier reputation, commitment: | |
| | |
| Availability of products, parts, service: | |
| | |
| | |
| Other comments regarding supplier: | |
| | |
| | |
| | |
| | |
| | |
| Signature of responsible staff: | |

**Form 4 List of Acceptable Suppliers**

| Supplier | Product(s) | Acceptance Date |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Standard Administrative Procedure 12**
**Corrective Action and Complaint Resolution**

## 1 Introduction

This is the metrology laboratory procedure for resolving customer complaints and for correcting errors discovered by the laboratory staff. This procedure will be used to correct all errors and resolve all customer complaints.

## 2 Purpose

2.1 The purpose of the customer complaint resolution system is to ensure that:
- 2.1.1 All customer complaints are resolved quickly and effectively;
- 2.1.2 Metrology laboratory customers are satisfied with the services provided by the laboratory.

2.2 The purpose of the internal error correction system is to ensure that:
- 2.2.1 All errors discovered by the laboratory staff are corrected and prevented from occurring again;
- 2.2.2 Services provided to our customers are of the highest quality possible.

## 3 Responsibility and authority

3.1 The Laboratory Supervisor:
- 3.1.1 Receives customer complaints;
- 3.1.2 Investigates customer complaints;
- 3.1.3 Takes corrective action to resolve customer complaints;
- 3.1.4 Initiates corrective recalls as outlined in SAP No. 17 if needed.

3.2 The Technical Manager:
- 3.2.1 Determines the source, magnitude, extent, and significance of all errors discovered and reported by the laboratory staff;
- 3.2.2 Determines whether a recall is necessary;
- 3.2.3 Instructs the Laboratory Supervisor to contact all affected customers in the event of a recall.

3.3 The Quality Manager:
- 3.3.1 Performs internal audits as outlined in SAP No. 09;
- 3.3.2 Informs the Technical and Laboratory Supervisors of any discrepancies or errors uncovered by these audits.

3.4 The Laboratory Supervisor, Technical Manager, and Quality Manager are responsible

for maintaining a working environment that:

3.4.1 Encourages error discovery and correction;

3.4.2 Strongly supports error reporting, by all metrology laboratory staff members, without regard for the source of the error.

3.5 The entire metrology laboratory staff is responsible for reporting errors to the Technical Manager.

## 4 Operations

4.1 Customer complaints -- initial contact

A metrologist who receives a customer complaint must request the following information:

4.1.1 Company name;

4.1.2 The name of the person making the complaint;

4.1.3 The state test number;

4.1.4 A telephone number for the contact person;

4.1.5 A fax number;

4.1.6 The nature of the complaint.

4.2 Customer complaints -- resolution

Below is a list of potential customer complaints and methods of resolution:

4.2.1 When a work order has not been given timely placement on the metrology laboratory work schedule, the Laboratory Supervisor will:

4.2.1.1 If possible, reschedule the work for an earlier date within the parameters outlined in SAP 12;

4.2.1.2 If rescheduling is not possible, explain the metrology laboratory work load to the customer and assure the customer that the laboratory will complete the work as soon as possible.

4.2.2 When the metrology laboratory has not completed work on time, the Laboratory Supervisor will:

4.2.2.1 Determine when the work was scheduled to be completed;

4.2.2.2 Determine whether the work was completed at the time promised to the customer;

4.2.2.3 If the work was delayed:

4.2.2.3.1 Determine the cause of the delay;

4.2.2.3.2 Explain the cause of the delay to the customer;

4.2.2.3.3 Take corrective action to prevent further problems.

4.2.3 If the metrology laboratory failed to comply with the specifications in a work order, the Laboratory Supervisor will:

4.2.3.1 Review the work order;

4.2.3.2 Review all of the reports produced for the work order;

4.2.3.3 If the metrology laboratory failed to comply with the customer's specifications:

4.2.3.3.1 Ask the customer to re-submit the work order;

4.2.3.3.2 Re-schedule and complete the work as soon as possible;
4.2.3.3.3 Supervise the re-scheduled work to ensure that the metrology meets the customer's specifications;
4.2.3.3.4 Take corrective action to prevent future problems.

4.2.4 If there are errors in reports produced by the metrology laboratory, the Laboratory Supervisor will:
4.2.4.1 Review reports to determine if errors were made;
4.2.4.2 If the metrology laboratory made an error:
4.2.4.2.1 Correct the error;
4.2.4.2.2 Provide a corrected copy of the report to the customer;
4.2.4.2.3 File a corrected copy of the report with the original test reports;
4.2.4.2.4 Determine the cause of the error;
4.2.4.2.5 Take corrective action to prevent future errors.

4.2.5 When a customer reports a discrepancy between test results reported by the Minnesota metrology laboratory and results reported by another laboratory, the Technical Manager will:
4.2.5.1 Determine whether the differences in the reported values are within the uncertainty ranges reported by both laboratories;
4.2.5.2 If the differences in the reported values are within the uncertainty ranges, explain the measurement uncertainty concept to the customer;
4.2.5.3 If the differences in the reported values exceed the uncertainty ranges, and if the reason for the discrepancy is unclear, contact the other laboratory and discuss the discrepancy to determine the cause and possibly conduct an Interlaboratory Comparison;
4.2.5.4 If the cause of the discrepancy cannot be determined, ask the customer to re-submit the work order so that the test procedure can be reproduced.

4.3 Complaint file
The Laboratory Supervisor will maintain a complaint file that includes that following information for each complaint received by the metrology laboratory:
4.3.1 Complainant name;
4.3.2 Date complaint was received;
4.3.3 Nature of the complaint;
4.3.4 Disposition of the complaint.

4.4 Internally discovered errors
4.4.1 Any member of the metrology laboratory staff who discovers an error must report the error to the Technical Manager.
4.4.2 Upon receiving a report of an error, the Technical Manager will:
4.4.2.1 Determine the source of the error as categorized below:
4.4.2.1.1 Human errors, such as an incorrect reading, transcription, or manual computation, are usually one-time errors that affect one artifact;

4.4.2.1.2 Procedure errors may be a long term problem that may affect many calibrations;

4.4.2.1.3 An instrument malfunction, or poor performance, may be a long term problem that may affect many calibrations.

4.4.2.2 Determine the time-frame within which the error occurred;

4.4.2.3 Determine the range of artifacts that may have been affected (for example, a specific equipment performance problem may only affect mass standards less than three grams);

4.4.2.4 Notify the Laboratory Supervisor of the error, and instruct the Laboratory Supervisor to research the metrology laboratory records to identify customers that may have been affected by the error;

4.4.2.5 Work with the metrology laboratory staff, Quality Manager and Laboratory Supervisor to correct the problem that led to the error.

4.4.3 Upon receiving notice of an error from the Technical Manager, the Laboratory Supervisor must:

4.4.3.1 Research the metrology laboratory records for all calibration and test records:

4.4.3.1.1 Produced during the time-frame the error is known to have occurred;

4.4.3.1.2 Produced by the staff member who is known to have made the error;

4.4.3.1.3 Produced using an instrument that is known to have caused the error;

4.4.3.1.4 Produced using an incorrect or inappropriate procedure.

4.4.3.2 Identify the customers and the artifacts affected by the errors;

4.4.3.3 Send one written notice to each customer affected by the error. The notice must include:

4.4.3.3.1 The identity of the artifacts affected by the error;

4.4.3.3.2 The magnitude and nature of the error;

4.4.3.3.3 A request to recall the artifacts for recalibration;

4.4.3.3.4 A statement that all recalibration services will be provided without charge;

4.4.3.3.5 A statement that it is the customer's option to decide whether to recalibrate.

4.4.3.4 If the written notice is returned as undeliverable, the Laboratory Supervisor must place a telephone call to the affected customer's representative (as identified on each calibration report);

4.4.3.5 Receive and schedule, as quickly as possible, all recalibration requests from customers affected by the error.

4.4.4 The Technical Manager must work with the Quality Manager, the Laboratory Supervisor, and the metrology laboratory staff to correct the error and prevent recurrences.

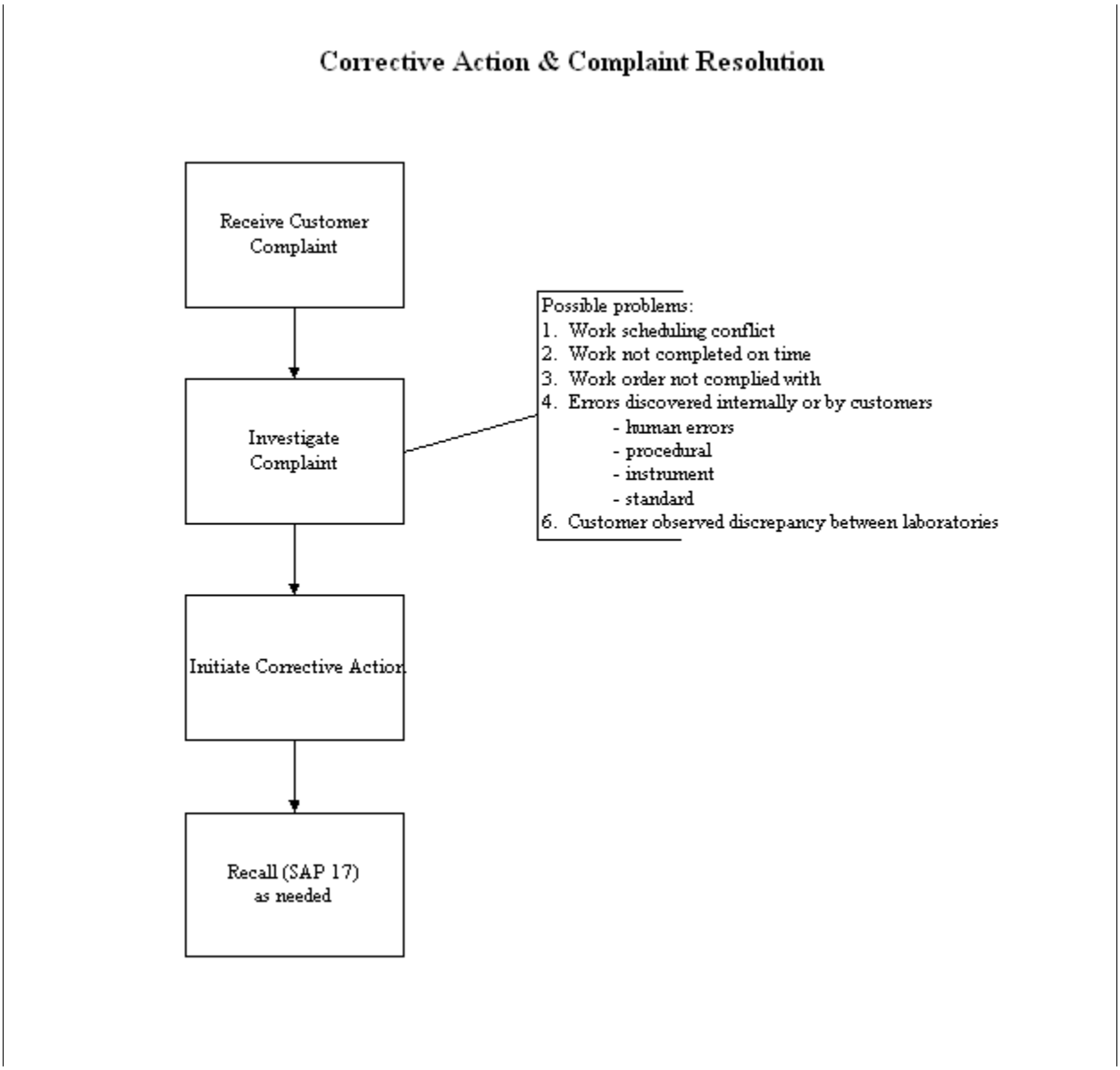


**Figure 6 SAP 12 Flowchart**

**Standard Administrative Procedure 13**
**Laboratory Maintenance**

## 1 Introduction

This is the metrology laboratory policy and procedure for maintenance. Cleanliness is a vital component of metrology laboratory operations. Dust and dirt, that may enter the metrology laboratory environment from any source, will increase measurement uncertainties, contaminate standards, damage measurement instruments, adversely affect the health and safety of the staff, and generally degrade the measurement capabilities of the laboratory.

Cleaning responsibilities must be carried out by the metrology laboratory staff. Cleaning by an untrained person could result in damage to standards, instruments, or the laboratory environment.

## 2 Purpose

The Metrology Laboratory cleaning and maintenance program has four main purposes:

2.1 To ensure that calibration and testing results are not affected by dust and dirt;

2.2 To ensure that measurement instruments are not damaged, or their performance degraded, by dust and dirt;

2.3 To maintain safe and healthful working conditions in the metrology laboratory and in the areas surrounding the laboratory;

2.4 To maintain dust free conditions in the small mass calibration room by:

2.4.1 Regularly removing all dust and dirt within the small mass calibration room;

2.4.2 Regularly cleaning the areas surrounding the metrology laboratory to eliminate potential sources of dust and dirt incursion into the small mass calibration room.

## 3 Responsibility and authority

The Laboratory Supervisor is responsible for maintaining the metrology laboratory and the areas surrounding the metrology laboratory. The Laboratory Supervisor will assign cleaning responsibilities on a rotating schedule to all laboratory staff. These cleaning assignments will be listed on the metrology laboratory schedule.

## 4 Operations

4.1 Levels of cleanliness -- defined

Three distinct levels of cleanliness are required for the metrology laboratory and the areas surrounding the metrology laboratory. These three levels are:

4.1.1 The LEVEL 1 environment is a dust free, restricted access environment:

4.1.1.1 Access is restricted to prevent incursion of dust;

4.1.1.2 Loose papers, reports, manuals and reference documents must be removed upon completion of each calibration assignment;

4.1.1.3 At each scheduled cleaning event:

4.1.1.3.1 All surfaces and instruments must be thoroughly wiped with a damp cloth to remove dust;

4.1.1.3.2 The floor must be mopped (wet mop if Friday, else dry dust mop);

4.1.1.3.3 The adhesive-surfaced dust removal mat must be checked and replaced if necessary.

4.1.2 The LEVEL 2 environment is a clean, limited access environment. At each scheduled cleaning event:

4.1.2.1 Dust must be removed from all surfaces;

4.1.2.2 Floors must be vacuumed;

4.1.2.3 Wastebaskets must be emptied;

4.1.2.4 Recycling containers must be emptied;

4.1.2.5 Loose papers must be put away or recycled;

4.1.2.6 Manuals and reference documents not in use must be reshelved.

4.1.3 The LEVEL 3 environment includes clean, limited access and open access environments.

4.1.3.1 If dirt or dust is present in the calibration work area, the area must be cleaned and swept at the beginning of each calibration or test assignment.

4.1.3.2 At each scheduled cleaning event:

4.1.3.2.1 All floors must be swept;

4.1.3.2.2 Wastebaskets must be emptied;

4.1.3.2.3 Tools and other articles must be put away.

4.2 Levels of cleanliness -- applied

The Metrologists will maintain three distinct levels of cleanliness in the Metrology Laboratory and surrounding areas. The three levels of cleanliness (defined in section 4.1 above) will be applied to the Metrology Laboratory and surrounding areas as follows:

4.2.1 A LEVEL 1 environment will be maintained in the small mass calibration room.

4.2.2 A LEVEL 2 environment will be maintained in:

4.2.2.1 The small mass tolerance testing area;

4.2.2.2 The thermometry calibration area;

4.2.2.3 The metrology laboratory office area.

4.2.3 A LEVEL 3 environment will be maintained in:

4.2.3.1 The large mass calibration and tolerance testing room;

4.2.3.2 The work room between the loading dock and large mass room;

4.2.3.3 The volume transfer calibration area;

4.2.3.4 The loading dock area outside the metrology laboratory office;

4.2.3.5 The storage and shipping room adjacent to the metrology laboratory office;

4.2.3.6 The garage area adjacent to the loading dock area.

4.3 Cleaning and maintenance schedule

The Laboratory Supervisor will assign metrology laboratory staff members to clean the metrology laboratory and surrounding areas on Friday (on Thursday if staff work a 4-day week).

4.4 Unscheduled maintenance

When a calibration or testing assignment generates dust or dirt in the metrology laboratory, or in the areas surrounding the metrology laboratory, the metrologist who completed the assignment will clean the area according to the appropriate level of cleanliness defined in section 4.1. This maintenance task must be completed when the calibration or testing assignment is completed. The accumulated dust or dirt must not be left for the next scheduled cleaning day.

4.5 Volume transfer calibration areas

When a metrologist completes a volume transfer calibration assignment (in the volume calibration area inside or above the entrance to the petroleum laboratory) the metrologist will:

4.5.1 Clean the volumetric prover platform, if used during the calibration or test;

4.5.2 Clean the sink area and counter top if used during the calibration or test of a small volume test measure;

4.5.3 Dry the loading dock floor below the volumetric prover platform;

4.5.4 Dry the floor inside the entrance to the petroleum laboratory;

4.5.5 Dry the surfaces of the volumetric provers used for the calibration or test.

4.6 Additional maintenance

The Laboratory Supervisor will perform the following maintenance tasks at the intervals indicated with each task:

4.6.1 Check the supply of clean gloves, lab coats, and lint-free cloth squares on the first working day of each month and submit a request to purchase any supplies that must be replenished.

4.6.2 Charge the electric pallet mover each Friday at the end of the workday.

**Standard Administrative Procedure 14**
**Laboratory and Data Security**

## 1 Introduction

This is the metrology laboratory policy for physical security and data security. The Laboratory Supervisor will use this policy to ensure the security of the metrology laboratory.

## 2 Purpose

The purpose of the laboratory security procedure is to:

2.1 Protect the state standards of mass, length, volume, temperature and density in order to:
2.1.1 Protect the validity of the original NIST calibrated values;
2.1.2 Protect the validity of all of the subsequent surveillance work performed on the standards;
2.1.3 Ensure that the standards are safe from:
2.1.3.1 Accidental damage or breakage;
2.1.3.2 Exposure to harmful environmental effects;
2.1.3.3 Theft or vandalism.
2.2 Protect the instruments and equipment used in the metrology laboratory in order to:
2.2.1 Ensure the continuing validity of measurements produced with the instruments;
2.2.2 Ensure that there are no environmental or other factors which will degrade the validity of the control chart data produced and maintained for the instruments;
2.2.3 Ensure that the instruments are safe from;
2.2.3.1 Accidental damage or breakage;
2.2.3.1.1 Exposure to harmful environmental effects;
2.2.3.1.2 Theft or vandalism.
2.3 Protect laboratory reports, records, documents and electronic data relating to:
2.3.1 Calibration and test data for all artifacts calibrated or tested in the metrology laboratory;
2.3.2 Standard procedure documents;
2.3.3 Statistical process control charts;
2.3.4 Archival data, reports, and procedure documents.
2.4 Ensure the physical security of the metrology laboratory staff.

## 3 Responsibility and authority

3.1 The Laboratory Supervisor is responsible for the security of:
3.1.1 The state standards;
3.1.2 Laboratory instruments and equipment;
3.1.3 Laboratory records and electronic data;
3.1.4 The laboratory staff.

3.2 The Laboratory Supervisor is authorized to seek assistance from:

3.2.1 The Weights and Measures Division Director and Regional Supervisors for guidance and direction on security and safety issues;

3.2.2 The Division's Management Information Systems Coordinator to ensure the security of electronic data.

## 4 Operations

The Laboratory Supervisor will implement procedures to provide a secure working environment for the protection of the metrology laboratory staff, standards, equipment, and documentation.

4.1 Levels of security defined.

4.1.1 LEVEL 1 security means that access is restricted by a code lock or key operated lock. The doors to LEVEL 1 areas are locked at all times. Only the metrology laboratory staff and the Weights and Measures Division Director have access to the code or key to enter a LEVEL 1 area.

4.1.2 LEVEL 2 security means that access is restricted by a code lock. The doors to the LEVEL 2 area are locked at all times except when equipment is moved from one area to another. Only Weights and Measures staff stationed at this locations have access to the entry code for the LEVEL 2 area.

4.1.3 LEVEL 3 security means that access is limited. LEVEL 3 areas are locked except as noted below. Doors to a LEVEL 3 area are kept closed but not locked when they are not in use during normal working hours - 6:00 AM through 5:30 PM, Monday through Friday. During normal working hours, and when the areas are in use, LEVEL 3 areas can be accessed from the dock area (a LEVEL 4 area).

4.1.4 LEVEL 4 security means that the area is open to the public during normal working hours - 6:00 AM through 5:30 PM, Monday through Friday. LEVEL 4 areas are locked at night. During normal working hours, LEVEL 4 areas can be accessed through the garage service door at the rear of the building, or through the front entrance to the Weights and Measures Division office.

4.2 Laboratory security

4.2.1 The following areas are LEVEL 1 security areas:

4.2.1.1 The metrology laboratory office;

4.2.1.2 The small mass tolerance testing area;

4.2.1.3 The temperature calibration area;

4.2.1.4 The large volume calibration platform above the entrance to the petroleum laboratory.

4.2.2 The following areas are LEVEL 2 security areas:

4.2.2.1 The large mass calibration room. (The large mass room also has a key lock, allowing access by metrology and managerial staff only);

4.2.2.2 The length bench area;

4.2.2.3 The work room between the loading dock area and the large mass calibration room.

4.2.3 The following areas are LEVEL 3 security areas:

4.2.3.1 The shipping room adjacent to the metrology laboratory office;

4.2.3.2 The work room area where calibrations are performed with the 5 gallon slicker plate measure.

4.2.4 The following areas are LEVEL 4 security areas:

4.2.4.1 The garage area and loading dock area;

4.2.4.2 The Weights and Measures Division office.

4.3 Fire protection

4.3.1 All areas outside the small mass calibration room are protected by an automatic sprinkling system and warning system that meets State fire codes. The system was professionally installed when the building was constructed. It is maintained and regularly tested by the building owner in accordance with local fire codes.

4.3.2 The interior of the small mass calibration room is protected by an automatic Halon fire quenching and warning system that meets State fire codes. The system was professionally installed when the small mass calibration room was constructed inside the metrology laboratory. The system is professionally maintained and tested in accordance with local fire codes.

4.3.3 Portable fire extinguishers are located in the loading dock area, the shipping room, the small mass tolerance room, and the petroleum laboratory in accordance with local fire codes. The fire extinguishers are maintained in accordance with local fire codes.

4.4 Environmental controls

4.4.1 The main HVAC system for the building maintains stable temperature and humidity in the:

4.4.1.1 Metrology laboratory office;

4.4.1.2 Small mass tolerance room between the laboratory office and the small mass calibration room;

4.4.1.3 Large mass room;

4.4.1.4 Workroom between the loading dock and the large mass room;

4.4.1.5 Shipping room;

4.4.1.6 Loading dock and garage areas.

4.4.2 Metrologists will prevent large temperature swings in the metrology laboratory and large mass calibration room when the overhead garage doors are opened by:

4.4.2.1 Closing the doors to the work room and the large mass calibration room;

4.4.2.2 Keeping the door to the metrology laboratory office, and the double air-lock door to the small mass calibration room closed at all times.

4.4.3 A separate HVAC system maintains the temperature and humidity within tightly controlled parameters in the small mass calibration room.

4.5 Special security considerations

The state standards and metrology laboratory records and data must be carefully handled, securely stored, and carefully maintained according to the following procedures:

4.5.1 Handling and storage of the state standards

4.5.1.1 The state standards of mass, length, volume, and temperature must be handled according to Standard Operating Procedures.

4.5.1.2 Standards that are normally stored in a LEVEL 1 security area must never be left unattended when they have been removed from the area. Standards removed from a LEVEL 1 security area must be returned to a LEVEL 1 security area at any time when the metrologist using the standards will not have direct control and supervision of the standards.

4.5.1.3 All standards must be immediately returned to their designated secure storage areas when a metrologist completes a calibration or test assignment.

4.5.1.4 The primary one-kilogram mass standards, designated **P1•** and **P1••**, are stored in a locked container in a locked cabinet in a LEVEL 1 security area.

4.5.2 Secure storage of documents and paper records

4.5.2.1 Documents and records are maintained in the metrology laboratory office, a LEVEL 1 security area.

4.5.2.2 The door access code is known only to metrology staff and the Weights and Measures Division Director.

4.5.3 Computer data security

4.5.3.1 Metrology laboratory files and data are stored within a single disk partition on a network server in the Weights and Measures Division office.

4.5.3.2 The disk partition is accessible only from computers operated by:

4.5.3.2.1 The metrology laboratory staff;

4.5.3.2.2 The Weights and Measures Division Director;

4.5.3.2.3 The Management Information Systems Coordinator.

4.5.3.3 A user name and user defined password are required to access the operating systems of the computers (listed in 4.5.3.2 above) that are mapped to the metrology laboratory disk partition on the network server.

4.5.3.4 Physical access to the computers used by the metrology laboratory staff is restricted. The computers are located in the metrology laboratory office, a LEVEL 1 security area.

**Standard Administrative Procedure 15**
**Departure from Documented Policies and Procedures**

## 1 Introduction

This is the metrology laboratory policy for departure from documented policies and procedures. The Laboratory Supervisor will use this policy to ensure that policies and procedures are followed and updated as needed. The laboratory will not deviate from documented policies and procedures unless authorized.

## 2 Purpose

The laboratory quality system and procedures have been developed and implemented to ensure consistent quality of measurement results and good laboratory practices. Deviation from laboratory policies and procedures may contribute to measurement errors.

## 3 Responsibility and Authority

3.1 The Technical Manager, Quality Manager, and Laboratory Supervisor must all evaluate possible consequences of requested departures and approve departures prior to their occurrence as follows:

3.1.1 The Technical Manager is responsible for evaluating the effect of deviations on measurement accuracy and traceability.

3.1.2 The Quality Manager is responsible for evaluating the potential impact on the quality system, including identifying deviations in other policies or procedures.

3.1.3 The Laboratory Supervisor is responsible for evaluating the impact on laboratory operations, staff safety, and customer expectations.

3.2 If a deviation occurs without prior approval, it will be recorded as an audit finding and treated as such.

## 4 Operations

4.1 Any staff member requesting a deviation is responsible for obtaining authorization from laboratory managers using the Deviation Request Form.

4.2 The request is evaluated for whether or not policies or procedures should be changed if approval is granted.

4.3 The completed form is placed in the Deviations file for review during audits.

4.4 If all approvals are granted, the deviation may proceed.

**Form 5 Deviation Request Form**

| Deviation Request Form | | |
|---|---|---|
| Date: | | |
| Requested deviation: | | |
| Reason for deviation: | | |
| **Evaluation Questions:** | | |
| What is the impact of this request on accuracy and traceability of measurements and report? | | |
| | | |
| Approved: | Yes | No |
| Signature of Technical Manager: | | |
| What is the impact of this request on the quality system? Will this deviation affect other policies or procedures? If so, which ones? | | |
| | | |
| Approved: | Yes | No |
| Signature of Quality Manager: | | |
| What is the impact of this request on laboratory operations? Staff safety? Customer expectations? | | |
| | | |
| Approved: | Yes | No |
| Signature of Technical Manager: | | |
| Should a policy or procedure be changed as a result of this request? | Yes | No |
| Describe proposed change if yes: | | |
| | | |
| | | |
| | | |
| | | |
| Signature of staff requesting deviation: | | |

**Standard Administrative Procedure 16**
**Staff Training**

## 1 Introduction

This is the metrology laboratory procedure for staff training. It is the Weights and Measures Division Director's goal to have a highly trained and effective staff in the metrology laboratory. The Laboratory Supervisor has the full support of the Division Director to provide and arrange high quality training for the entire staff of the metrology laboratory.

## 2 Purpose

A highly trained and effective staff will ensure that the metrology laboratory will:

2.1 Maintain its certifications and accreditations;

2.2 Fulfill the Weights and Measures Division statutory mandate to provide high quality measurement services to its customers.

## 3 Responsibility

The Laboratory Supervisor is responsible for:

3.1 Locating appropriate training opportunities for the metrology laboratory staff;

3.1.1 Assigning the staff to required training courses, including NIST metrology seminars;

3.1.2 Notifying the staff of optional training opportunities;

3.1.3 Encouraging the staff to take advantage of training opportunities.

3.2 Receiving training requests from metrology laboratory staff members;

3.3 Coordinating training activities with the Weights and Measures Division Training Coordinator;

3.4 Ensuring that the metrology laboratory staff complete NIST metrology training, including NIST assigned Laboratory Audit Problems.

## 4 Operations

4.1 Types of training

The Laboratory Supervisor must offer and arrange the following types of training for the metrology laboratory staff:

4.1.1 Formal training that includes courses, seminars, and classroom training sessions presented by NIST/OWM, Regional MAP, NCWM, NCSL, universities, colleges, and other organizations offering academic, scientific, and professional development courses.

4.1.2 On the job training on the quality system and procedures that includes:

4.1.2.1 Individual instruction;

4.1.2.2 Group discussion sessions;

4.1.2.3 Informal instructional sessions conducted by one member of the metrology laboratory staff

to convey information from a formal training course;

4.1.2.4 Team working sessions conducted by one member of the metrology laboratory staff to demonstrate a procedure.

4.2 Training information sources

The Laboratory Supervisor must read bulletins and newsletters from NIST, NCWM, NCSL, and other organizations to find appropriate training opportunities for the metrology laboratory staff.

4.3 Training activities -- coordination

The Laboratory Supervisor must coordinate all training activities with the Weights and Measures Division Training Coordinator, as follows:

4.3.1 Set training priorities and, if necessary, determine funding availability;

4.3.2 Submit departmental training requests to the Training Coordinator for approval by the Training Coordinator, Division Director, and Department Personnel Manager;

4.3.3 Submit out-of-state travel requests, if necessary, to the Training Coordinator for approval by the Division Director, Department Accounting Director, and Department Commissioner;

4.3.4 Receive all necessary approvals for training;

4.3.5 Ask the Training Coordinator to make travel arrangements, if necessary.

4.4 Supervision of training

The Laboratory Supervisor must schedule and supervise training for the metrology laboratory staff as follows:

4.4.1 Enroll staff members in training courses and seminars;

4.4.2 Supervise completion of any course work assigned as part of the training course or seminar. This is particularly important in the case of NIST metrology training. For NIST metrology training, the Laboratory Supervisor must:

4.4.2.1 Impose a firm deadline to complete Laboratory Audit Problems following the NIST metrology training seminar;

4.4.2.2 Schedule sufficient time for a metrologist to work on the Laboratory Audit Problems during normal working hours, and to complete the problems by the deadline;

4.4.2.3 Work with the Technical Manager to act as advisors to a metrologist who is completing the Laboratory Audit Problems;

4.4.2.4 Ensure that the deadline is met, and that the completed Laboratory Audit Problems are submitted to NIST/OWM.

4.5 Training records

The Laboratory Supervisor maintains records of all training completed by the metrology laboratory staff. The record includes a complete training log, and copies of diplomas or certificates, if available. A record is maintained for the following types of training:

4.5.1 NIST/OWM metrology training;

4.5.2 NIST special discipline training in the measurement of mass, volume, temperature, length,

density, and other fields related to metrology;

4.5.3 NIST/OWM training offered annually at the National Conference on Weights and Measures;

4.5.4 Participation in Regional MAP seminars;

4.5.5 Participation in other work-related seminars;

4.5.6 Work-related academic training or courses;

4.5.7 Professional developmental programs that may improve skills utilized in a laboratory;

4.5.8 Undergraduate and graduate degrees, and other academic or work-related course work completed prior to employment with the metrology laboratory.

4.6 Minimum level of training required:
In addition to the coursework required for employment as a Laboratory Metrologist or a Metrology Laboratory Manager, all metrology laboratory staff members must complete the following training courses and seminars:

4.6.1 Quality Awareness Training - an overview of quality system requirements;

4.6.2 NIST/OWM basic metrology training, including successful completion of the Laboratory Audit Problems;

4.6.3 Annual participation, to the extent allowed by budget and travel limitations, in Regional MAP training and meetings.

**Standard Administrative Procedure 17**
**Recall Procedure**

## 1 Introduction

This is the metrology laboratory procedure for recalling a calibrated artifact when an error is discovered after the artifact is returned to the customer. The metrology laboratory staff will use this procedure for all recalls.

## 2 Purpose

The purpose of the recall procedure is to correct errors when they are discovered. This will be accomplished by:

2.1 Informing customers when a calibration error is discovered;
2.2 Working with customers to correct calibration errors made by the metrology laboratory.

## 3 Responsibility and Authority

3.1 The Laboratory Supervisor, Technical Manager, and Quality Manager are responsible for maintaining a working environment that:
3.1.1 Encourages error discovery and correction;
3.1.2 Strongly supports error reporting, by all metrology laboratory staff members, without regard for the source of the error.

3.2 The entire metrology laboratory staff is responsible for reporting errors to the Technical Manager.

3.3 The Technical Manager is responsible for:
3.3.1 Determining the magnitude, extent, and significance of all errors discovered and reported by the laboratory staff;
3.3.2 Determining whether a recall is necessary;
3.3.3 Determining the source of all reported errors;
3.3.4 Determining the time frame within which the error occurred;
3.3.5 Instructing the Laboratory Supervisor to search the calibration records for customers that may have been affected by the error.

3.4 The Laboratory Supervisor is responsible for:
3.4.1 Researching records to find customers that may have been affected by the error;
3.4.2 Contacting all affected customers to recall artifacts affected by the error;
3.4.3 Scheduling the metrology laboratory staff to correct errors on recalled artifacts.

## 4 Operations

When an error is discovered, it must be corrected as soon as possible. The following procedure will be used to correct errors:

4.1 Any member of the metrology laboratory staff who discovers an error must report the error to the Technical Manager.

4.2 Upon receiving a report of an error, the Technical Manager will:

4.2.1 Determine the source of the error:

4.2.1.1 Human errors, such as an incorrect reading, transcription, or manual computation, are usually one-time errors that affect one artifact;

4.2.1.2 Procedure errors may be a long term problem that may affect many calibrations;

4.2.1.3 An instrument malfunction, or poor performance, may be a long term problem that may affect many calibrations.

4.2.2 Determine the time-frame within which the error occurred;

4.2.3 Determine the range of artifacts that may have been affected (for example, a specific equipment performance problem may only affect mass standards less than three grams);

4.2.4 Notify the Laboratory Supervisor of the error, and instruct the Laboratory Supervisor to research the metrology laboratory records to identify customers that may have been affected by the error;

4.2.5 Work with the metrology laboratory staff, Quality Manager and Laboratory Supervisor to correct the problem that led to the error.

4.3 Upon receiving notice of an error from the Technical Manager, the Laboratory Supervisor must:

4.3.1 Research the metrology laboratory records for all calibration and test records:

4.3.1.1 Produced during the time-frame the error is known to have occurred;

4.3.1.2 Produced by the staff member who is known to have made the error;

4.3.1.3 Produced using an instrument that is known to have caused the error;

4.3.1.4 Produced using an incorrect or inappropriate procedure.

4.3.2 Identify the customers and the artifacts affected by the errors;

4.3.3 Send one written notice to each customer affected by the error including:

4.3.3.1 The identity of the artifacts affected by the error;

4.3.3.2 The magnitude and nature of the error;

4.3.3.3 A request to recall the artifacts for recalibration;

4.3.3.4 A statement that all recalibration services will be provided without charge;

4.3.3.5 A statement that it is the customer's option to decide whether to recalibrate.

4.3.4 If the written notice is returned as undeliverable, the Laboratory Supervisor must place a telephone call to the affected customer's representative (as identified on each calibration report);

4.3.5 Receive and schedule, as quickly as possible, all recalibration requests from customers affected by the error;

4.3.6 Work with the metrology laboratory staff, Quality Manager and Technical Manager to correct the problem that led to the error.

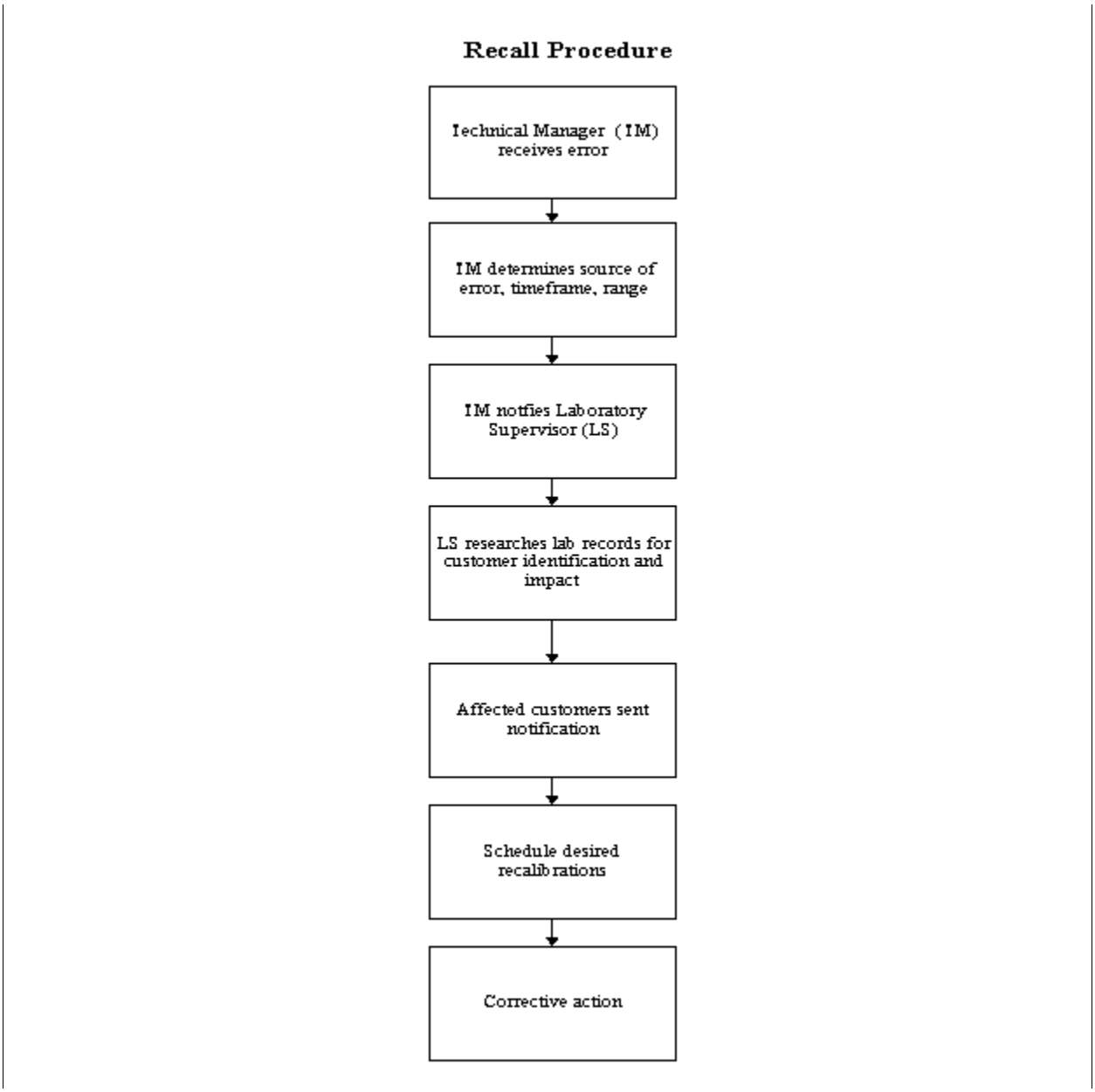


**Figure 7 SAP 17 Flowchart**