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**Developing Quality System
Documentation Based on
ANSI/NCSL Z540-1-1994
- - The Optical Technology
Division's Effort**

**Sally S. Bruce
Thomas C. Larason**

U.S. DEPARTMENT OF COMMERCE
Technology Administration
National Institute of Standards
and Technology
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Gaithersburg, MD 20899-0001

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August 1996



U.S. DEPARTMENT OF COMMERCE
Michael Kantor, Secretary
TECHNOLOGY ADMINISTRATION
Mary L. Good, Under Secretary for Technology
NATIONAL INSTITUTE OF STANDARDS
AND TECHNOLOGY
Arati Prabhakar, Director



Preface

The Optical Technology Division, formerly known as the Radiometric Physics Division, at the National Institute of Standards and Technology (NIST) began a project in 1993 to develop a quality system that is based on the American National Standard for Calibration - Calibration Laboratories and Measuring and Test Equipment, ANSI/NCSL Z540-1-1994. We embarked on this effort at the request of our customers and our National Research Council Review Panel. Although quality procedures were previously in place, they varied from calibration service to calibration service within the Division. One goal of this project is to unify all the calibration services in the Division with standard formats and similar procedures. Another goal is to improve the quality of our measurement services. Quality system documentation is an essential component of an overall effort to improve the quality of our measurement services.

Documenting a quality system can seem overwhelming and perplexing at first, due to the lack of specific examples of the standard. The intent of this publication is that it serve as a useful guide to individuals who are embarking on the task of documenting a quality system. Actual sections of the Optical Technology Division's Calibration Service Quality Manual will be shown as well as forms and checklists used routinely within the quality system. It is not intended that this example of quality system documentation be interpreted as an official NIST standard for quality manuals but rather as a complement to the NCSL "Handbook for the Interpretation and Application of ANSI/NCSL Z540-1-1994" and to provide guidance to other calibration services at NIST, particularly those starting to develop their quality systems.

The appendix of this publication contains a reprint of a paper entitled, "Building a Quality System Based on ANSI/NCSL Z540-1-1994 -An Effort by The Radiometric Physics Division at NIST." Originally it was published in the Proceedings of the National Conference of Standards Laboratories (NCSL) 1995 Workshop and Symposium, Dallas, TX, July 16-20, 1995. This paper summarizes the work that went into developing the Optical Technology Division quality system documentation.

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Abstract

The Optical Technology Division, formerly known as the Radiometric Physics Division, at the National Institute of Standards and Technology (NIST) began a project in 1993 to develop a quality system that is based on the American National Standard for Calibration - Calibration Laboratories and Measuring and Test Equipment, ANSI/NCSL Z540-1-1994. This document is intended to complement the NCSL "Handbook for the Interpretation and Application of ANSI/NCSL Z540-1-1994" and to provide guidance to other calibration services at NIST, particularly those starting to develop their quality systems.

Key Words:

accreditation
ANSI/NCSL Z540-1-1994
calibration and testing laboratories
documentation
ISO/IEC Guide 25
quality manual
quality system

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Introduction

A quality system can be looked upon as the mechanism to provide confidence that a product or service meets the customer's requirements. This confidence in meeting the requirements is both internal to the management and external to the customer.

The ANSI/NCSL Z540-1-1994 (hereafter referred to as Z540) is a generic system for managing quality assurance that is based on the ISO/IEC General Requirements for the Competence of Calibration and Testing Laboratories, Guide 25, an internationally recognized standard for calibration laboratories. The Z540 requires that a quality system be documented. The foremost purpose of quality system documentation is to improve a product and/or service. It is not simply to meet the requirements of an auditor. For improvement to really happen you need to study your organization, this includes all levels of the organization (from senior management to support services, e.g., accounting and shipping) that affect the quality of your product and/or service. Only after you have analyzed your work processes can appropriate policies, procedures, and instructions be written. A lot of effort goes into developing documentation that "fits" your organization. The documentation should describe what is happening now, not what happened in the past, nor what is planned for the future. The quality manual is a living document and the structure of the documentation should be designed with easy updating in mind. Copies of other organization's documentation are of little benefit since they do not take into account the unique situations of your own organization. The Z540 is a generic system, it allows for flexibility so an organization can tailor its quality system to effectively match its needs.

Compliance with a quality system standard (ISO 9000, ANSI/NCSL Z540, ISO/IEC Guide 25, etc.) is a continuing process. It is not a "one-shot deal." The requirements for internal audits and corrective actions provide the tools needed for continuous process improvement. There are resources available to help with quality system documentation. Several organizations offer classes on documenting a quality system. Additionally, if an organization is planning to apply for accreditation, the chosen accrediting body will often provide information and help with the interpretation of the requirements of the standard.

The description of our process of building quality system documentation is given in the appendix, but the steps can be summarized as follows: First, and most important, was a commitment from management. Second, a quality manager and deputy quality manager were chosen. The quality manager and deputy quality manager then studied the organization and defined what would be included in the quality system and defined the documentation structure. A working group was formed of those involved with and affected by the quality system. Next, the Z540 was reviewed and the work organized (and prioritized). A schedule was developed and work assignments were made. Finally, the documentation was audited (and reviewed) for improvement.

Training should be included for everyone involved, from managers to laboratory personnel. At a minimum, training should cover what the Z540 is and the fact that it is now a continuing part of laboratory operations. Also, specific training exercises may be needed on how to document or flowchart processes, how to conduct an audit, etc.

From our experience in quality system documentation we strive to adhere to these basic principles: a) fix only what is broken, that is, only make changes where problems have occurred in the past; b) don't create bureaucracy; c) don't write procedures for vague possibilities or rare occurrences -- address these topics in a general way (e.g., if something out of the ordinary happens, identify who has the authority to make decisions and give instructions); d) take the minimalist view -- adequately cover a subject and move on; e) look to examples from others and adapt them to your individual situation.

Frequently the areas that require the most attention when documenting a quality system are: a) ensuring that all the requirements of the Z540 are adequately met; b) adequately describing traceability and uncertainties; c) establishing document control; d) defining all critical procedures; e) documenting software; and f) developing a formalized complaint process. Software validation is an area where we have yet to find a definite answer. How and to what extent should software be validated? Currently, software validation varies from laboratory to laboratory but typically involves using known data sets or manual calculations to verify automated algorithms.

In summary, quality system documentation describes what you do. It contains (or references) the focus and scope of your quality system, your quality policy, an outline of your organization (an organization chart), a description of your process, and the procedures you use to produce your product and/or service. The whole process of quality system documentation can be thought of as documenting good business practice and good laboratory practice. It can be succinctly stated as:

Say what you do.
Do what you say.
Review what you do.
Improve what you do.

Sections of the Optical Technology Division's Calibration Service Quality Manual including forms and checklists used routinely within the quality system are provided for example and are found on pages 3 to 36.

Section 1: Scope

Written By: Sally Bruce / Thomas Larason

Version: 1.1

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1 Scope

1.1 This document describes the requirements that a calibration service within Division 844, the Optical Technology Division, formerly the Radiometric Physics Division, at NIST, must demonstrate it meets if it is to be recognized as competent to carry out specific calibrations outlined in the SP 250 Users Guide. The calibration services offered to our customers are of the highest accuracy obtainable in the United States. The practices documented in this **Quality System Manual** are followed by the calibration services personnel to assure that our customers receive optical radiation calibrations of the highest accuracy.

The **Quality System Manual** for the calibration services offered by Division 844 is based on the ANSI/NCSL Z540-1-1994 Standard and the ISO/IEC Guide 25. The **Quality System Manual** is organized into three sections. The three sections form a pyramidal shape. The top section is the division quality system policies, the middle section contains the division procedures that uniformly apply to all calibration services, and the bottom section is the calibration service procedures for each calibration service.

1.2 Figure 1 shows the pyramidal structure of Division 844's quality system documentation.

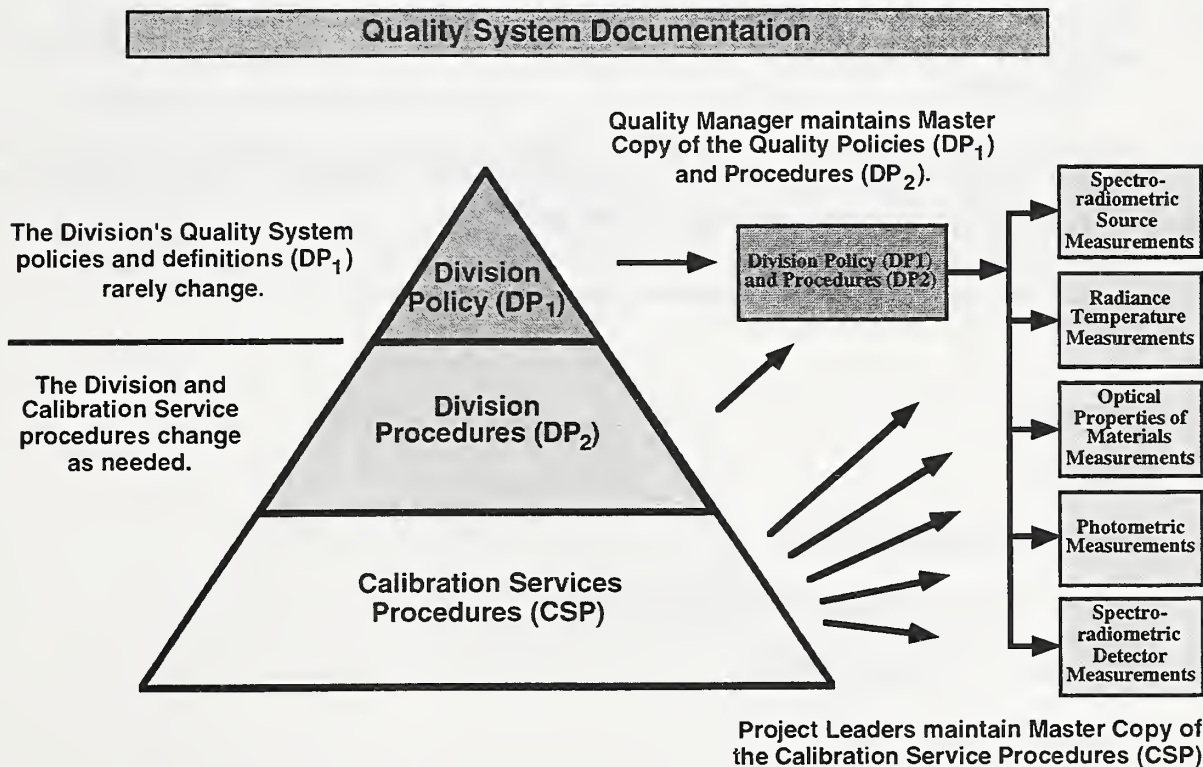


Figure 1

1.3 The following sections of the ANSI Z540-1-1994 and ISO Guide 25 are documented within the calibration services quality system for Division 844:

- Section 1 Scope
- Section 2 References
- Section 3 Definitions
- Section 4 Organization and management
- Section 5 Quality system, audit and review
- Section 6 Personnel
- Section 7 Accommodation and environment
- Section 8 Equipment and reference materials
- Section 9 Measurement traceability and calibration
- Section 10 Calibration methods
- Section 11 Handling of calibration items
- Section 12 Records
- Section 13 Certificates and records
- Section 15 Supplies
- Section 16 Complaints

Note: Section 14 is not included in the Division 844 calibration services quality system. The services offered by Division 844 are performed by our own personnel and not contracted to outside parties.

1.4 The following sections are Part I of the Quality Manual and are found in the Division Quality System Policy and Procedures Manual (white notebook). Part I contains the Division Policy (DP₁) and Division Procedures (DP₂).

Section

- 1. Scope
- 2. References
- 3. Definitions
- 4. Organization and Management
- 5. Quality system, Audit and Review (Part I)
- 13. Certificates and Reports (Part I)
- 16. Complaints

- 1.5 The following sections are Part II of the Quality Manual and are found in Calibration Service Procedures Manual (blue notebook) for each Calibration Service in the Division. Part II contains the Calibration Service Procedures (CSP).

Section

5. Quality system, Audit and Review (Part II)
 6. Personnel
 7. Accommodation and Environment
 8. Equipment and Reference Materials
 9. Measurement Traceability and Calibration
 10. Calibration Methods
 11. Handling of Calibration Items
 12. Records
 13. Certificates and Reports (Part II)
 14. Sub-contracting of calibration (Does not apply to Division.)
 15. Outside Support Services and Supplies
 16. Calibration Service Complaint Logs
Calibration Service Complaint Records
- 1.6 The **Quality System Manual** does not cover research and development, contract, CRDA, or other cooperative activities unless a calibration or special test is specified.

Section 2: References

Written By: Sally Bruce / Thomas Larason Version: 1.1 Page 1 of 1

Approved By: _____ Date: _____

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2 References

ANSI/NCSL Z540-1-1994, American National Standard for Calibration - Calibration Laboratories and Measuring and Test Equipment - General Requirements

ISO Guide 25: 1990, *International Organization for Standardization / International Electrotechnical Commission General Requirements for the Competence of Calibration and Testing Laboratories*

ISO Guide 2: 1986, *General Terms and their definitions concerning standardization and related activities*

International Vocabulary of Basic and General Terms in Metrology (VIM) : 1993, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML.

Guide to the Expression of Uncertainty in Measurement: 1993, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML.

NIST Technical Note 1297: 1994 Edition, Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results, by B. N. Taylor and C. E. Kuyatt.

NIST Special Publication 811: 1995 Edition, Guide for the Use of the International System of Units (SI), by B. N. Taylor.

NIST Handbook 150, National Voluntary Laboratory Accreditation Program (NVLAP) Procedures and General Requirements, by J. L. Cigler and V. R. White, editors, March 1994.

NIST Handbook 150-2 (Draft), National Voluntary Laboratory Accreditation Program (NVLAP) Calibration Laboratories Technical Guide, by J. M. Crickenberger, editor, August 1995.

NIST Administrative Manual

Section 3: Definitions

Written By: Sally Bruce / Thomas Larason

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3 Definitions

3.1 The following definitions are unique to the NIST Optical Technology Division (844) Quality System Manual.

- a. **Accounting:** Within the Administration unit of NIST the accounting department is responsible for billing the customers.
- b. **Calibration Advisory Group (CAG):** As defined by the Administrative Manual, the CAG was established by the NIST Director to provide broad oversight for the Calibration Program and related calibration activities. The membership of the CAG is the Organizational Unit Directors or their designate.
- c. **Calibration Program:** The office that handles the purchase orders and test folders for routine calibrations and special tests. They are the interface between Division 844 and Customers (external to NIST). Within the NIST organization structure, the Calibration Program is a part of Technology Services within the Office of Measurement Services.
- d. **Calibration Report:** The formal report issued to the Customer describing the results of a **regularly offered test** (i.e., established calibration service). The Report becomes the property of the Customer after payment has been made. This Report is also referred to as a "**Report of Calibration**" or sometimes generically called a Test Report. (Condensed from the NIST Administrative Manual.)
- e. **calibration service:** A physical measurement service listed in NIST SP 250. The service may consist of several different regularly offered tests (calibrations) and special tests.
- f. **Customer:** Person (corporate or individual) whom requests a calibration or test. This is usually someone external to NIST, but could be another NIST calibration service or researcher which will use the measurement results/data for their own reporting of official results. (i.e., NIST photometers measured in spectral comparator facility.)
- g. **days in process:** The number of days elapsed since the receipt of the purchase order. (Sometimes referred to as "days in progress.")
- h. **point of contact [POC]:** Person at the customer site to contact for more information. In the context of calibration services, it typically refers to the individual who requested and/or can answer questions regarding a requested calibration/measurement.
- i. **Quality System Manual:** The document describing the requirements that a calibration service must demonstrate it meets if it is to be recognized as competent to carry out calibrations and special tests. It does not cover research and development, contract, CRDA, or other cooperative activities unless a calibration or special test is specified. The Manual is organized into three sections the Division Quality System Policy Manual, the Division Quality System Procedures Manual, and the Division Quality System Calibration Service Procedures Manual. The first two sections are

the same throughout the Division and are combined into one notebook. The Calibration Service Procedures are unique for each calibration service and are kept in a separate notebook(s) from the Division Quality System Policy and Procedures Manual.

- i.1 (Quality System) Policy Manual [DP1]:** Describes the policies, references, and definitions used by calibration services.
- i.2 (Quality System) Procedures Manual [DP2]:** Describes the procedures that uniformly apply to all calibration services (e.g., complaint procedures).
- i.3 (Quality System) Calibration Service Procedures Manual [CSP]:** Describes the unique procedures, references, and information for a particular calibration service.
- i.4 (Quality System) Secretary's Manual:** Describes the policies, references, and definitions used by the secretaries from the groups that provide calibration services within the Optical Technology Division. The Secretary's Manual is basically the Policy Manual [DP1] and Procedures Manual [DP2] with relevant sections from the Calibration Service Procedures Manual [CSP].
- j. NIST Administrative Manual:** Currently a two volume set that contains essentially the operations manual of NIST. The manual contains the descriptions and overviews of operations throughout NIST, including calibration services.
- k. NIST Special Publication 250 (SP 250):** NIST Special Publication 250 is called the NIST Calibration Services User's Guide. The SP 250 provides detailed descriptions of NIST calibrations, special tests, and measurement assurance programs that are available to Customers. A separate Fee Schedule is issued annually providing current prices for the services offered, updates on points-of-contact, and information on measurement seminars. The SP 250 is a "catalog" which describes the measurement services offered to NIST customers along with NIST policies and instructions for ordering these services.
- l. NIST 64:** NIST form 64 is called the Test Record. Upon receipt of customer purchase order, the Calibration Program issues NIST form 64 by serial number in a test folder (see definition for test folder below).
- m. Project Leader:** Within the Optical Technology Division and its Quality System for Calibration Services, the project leader is the individual responsible for the day-to-day operations within their calibration laboratory. They typically have responsibility for scheduling the measurements, making sure the measurements are completed using appropriate calibration procedures, completing the test reports, signing the test reports and making sure the customer's equipment is packaged and ready for shipping. The project leader is also responsible for maintaining the records of test folders pending, the completed test reports, and computer records. The project leader is typically responsible for maintaining and upgrading their calibration laboratories and equipment.
- n. records:** Within the Quality System for the Optical Technology Division records are forms that are completed and data files from the computers used for retrieval and analysis of test results.
- o. Secretary:** Within the Optical Technology Division the secretaries from the groups that provide calibration services are responsible for preparing the Calibration/Test Reports.

- p. **Shipping and Receiving:** Within the Facilities Services Division the NIST Shipping and Receiving department is responsible for delivering and shipping packages and parcels for NIST. Shipping and Receiving ships and delivers calibration and test artifacts which is why their department is included within the definitions of the Optical Technology Division. It should be noted that we do not control the quality of their operations, just that artifacts covered within this quality system are handled by their department.
- q. **special test:** This is a unique test that does not justify the characterization of the measurement process (e.g., pooled statistics); or can be requested by a Customer which is not a regularly offered test (calibration); or is a measurement method which is being refined or modified. (Condensed from the NIST Administrative Manual.)
- r. **test folder:** The document from the Calibration Program which indicates an official calibration or test has been requested by a Customer (external to NIST). This document is absolutely necessary before any measurements are to be conducted on a Customer's test item. The test folder contains five numbered forms of NIST 64: 1) Acceptance, 2) Division Record, 3) Fee Record, 4) Shipping Record and 5) Packing Slip.
- s. **Test Folder Coordinator:** The Secretary who is responsible for mailing Calibration/Test Reports and filing them in the Division Calibration file after the Division Chief approves the report. Currently, the Optical Sensor Group Secretary is the Test Folder Coordinator. In the event of the Test Folder Coordinator's absence, the Group Leaders of the calibration service efforts will assign a substitute. The procedure for the duties of the Test Folder Coordinator are found in 844SOP 2.
- t. **Test Report:** The formal report issued to the Customer describing the results of a **special test**. The Report becomes the property of the Customer after payment has been made. This Report is also referred to as a "**Report of Test**" or sometimes generically called a Test Report along with Calibration Reports. (Condensed from the NIST Administrative Manual).
- u. **Technical Manager:** The Group Leader to which the calibration service is assigned. The Technical Manager provides technical and managerial direction for the calibration service.
- v. **verification**¹: Evidence by calibration or examination that specified requirements have been met.

3.2 The following definitions are common generic metrology terms and come from the *International Vocabulary of Basic and General Terms in Metrology (VIM)* : 1993, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML unless otherwise noted.

- a. **calibration**²: The set of operations which establish, under specific conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

¹This definition is closer in meaning to the definition in ISO/IEC Guide 25 : 1990, General Requirements for the Competence of Calibration and Testing Laboratories than the definition in ANSI/NCSL Z540-1-1994, American National Standard for Calibration - Calibration Laboratories and Measuring and Test Equipment - General Requirements.

²In this Quality System Manual "calibration" will be used generically to refer to all test numbers listed in the NIST SP 250, that is "regularly offered tests (calibrations)" and "special tests," unless otherwise noted.

- b. **laboratory/calibration laboratory^{3†}**: Body [facilities and staff] that calibrates or performs calibrations and verifications. Note: In cases where a laboratory forms part of an organization that carries out other activities besides calibration, the term "laboratory" refers only to those parts of that organization that are involved in the calibration process.
- c. **measurement**: The set of operations having the object of determining a value of a quantity.
- d. **national standard**: The standard recognized by a national decision to serve, in a country, as the basis for assigning values to other standards of the quantity concerned.
- e. **primary standard**: A standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standard of the same quantity.
- f. **quality manual[†]**: The section of the quality system documentation that states the quality policy, quality system and quality practices of the organization.
- g. **quality system[†]**: The organizational structure, responsibilities, procedures, processes and resources for implementing quality throughout the calibration service laboratories.
- h. **reference standard**: A standard, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived.
- i. **secondary standard**: A standard whose value is assigned by comparison with a primary standard of the same quantity.
- j. **traceability**: The property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of [direct] comparisons all having stated uncertainties.
- k. **transfer standard**: A standard used as an intermediary to compare standards. Note: The term **transfer device** should be used when the intermediary is not a standard.
- l. **working standard**: A standard that is used routinely to calibrate or check material measures, measuring instruments or reference materials. Notes: 1) A working standard is usually calibrated against a reference standard. 2) A working standard used routinely to ensure that measurements are being carried out correctly is called a **check standard**.

³In this Quality System Manual "laboratory" will refer to the NIST Optical Technology Division (844). Not to be confused with the NIST Physics Laboratory. In a few instances "laboratory" will be used generically to mean the physical room where measurement equipment is located or other cases where the context is not confusing (e.g., lab notebook, good laboratory practice, etc.).

[†]ANSI/NCCL Z540-1-1994, American National Standard for Calibration - Calibration Laboratories and Measuring and Test Equipment - General Requirements.

Section 4: Organization and Management

Written By: Sally Bruce

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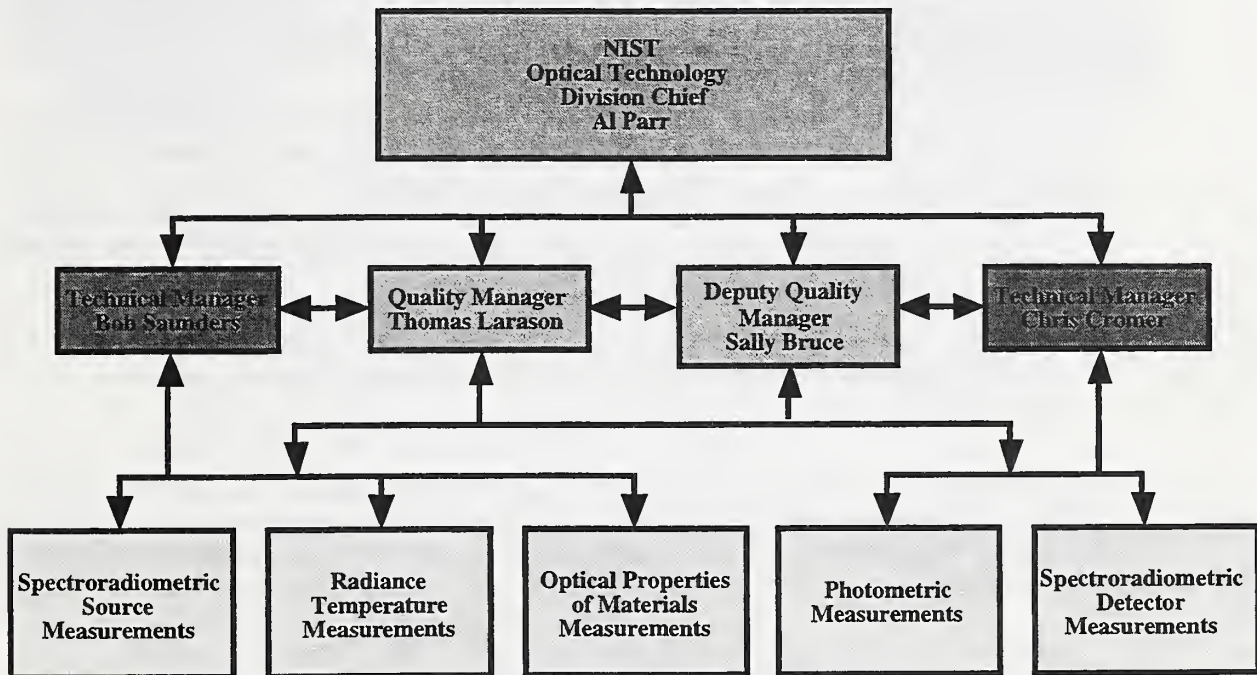
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4 Organization and Management

- 4.1 The Optical Technology Division (844) of NIST offers five primary calibration services in the field of optical radiation measurements. These calibration services are: Spectroradiometric Source Measurements, Radiance Temperature Measurements, Optical Properties of Materials Measurements, Photometric Measurements, and Spectroradiometric Detector Measurements.
- 4.2 The organizational chart of the Quality System for the calibration services offered by the Optical Technology Division at NIST is shown below.

Optical Technology Division Calibration Services Organization Chart



- 4.3 The technical managers are designated as each other's alternates in the event of either of their absence. The deputy quality manager will be designated as alternate quality manager in the event of his/her absence.
- 4.4 Section 5.2.c describes the chain of communication between the layers of management within the quality system.

Section 5: Quality System, Audit and Review

Written By: Sally Bruce / Thomas Larason

Version: 1.2 Page 1 of 10

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Date: _____

5 Quality System, Audit and Review

5.1 This section documents the Laboratory's (Division 844) quality system. This documentation shall be available for use by the calibration service personnel. This section documents the Laboratory's policies and objectives for, and its commitment to, good laboratory practice and quality of calibration services. The Laboratory management shall ensure that these policies and objectives are documented, communicated, understood, and implemented by all calibration service personnel concerned. The quality manual shall be maintained current under the responsibility of the Quality Manager.

5.2 The Laboratory's (Division 844) policies and operational procedures related to quality management are documented below. The calibration services offered by the Optical Technology Division (844) include Spectroradiometric Source Measurements, Radiance Temperature Measurements, Optical Properties of Materials Measurements, Photometric Measurements, and Spectroradiometric Detector Measurements. Each calibration service has its own subsection where appropriate. This section is referred to as the "**quality manual.**"

- a) **Quality Policy Statement.** The Optical Technology Division of NIST maintains the National Standards for radiation thermometry, spectroradiometry, photometry, and spectrophotometry. These standards are disseminated to customers requiring calibrations of the highest accuracy obtainable in the United States and requiring reference to the national standards of optical radiation maintained at NIST. The Optical Technology Division's quality policy is:

We shall provide the highest accuracy optical radiation tests and calibrations obtainable in the United States to our customers.

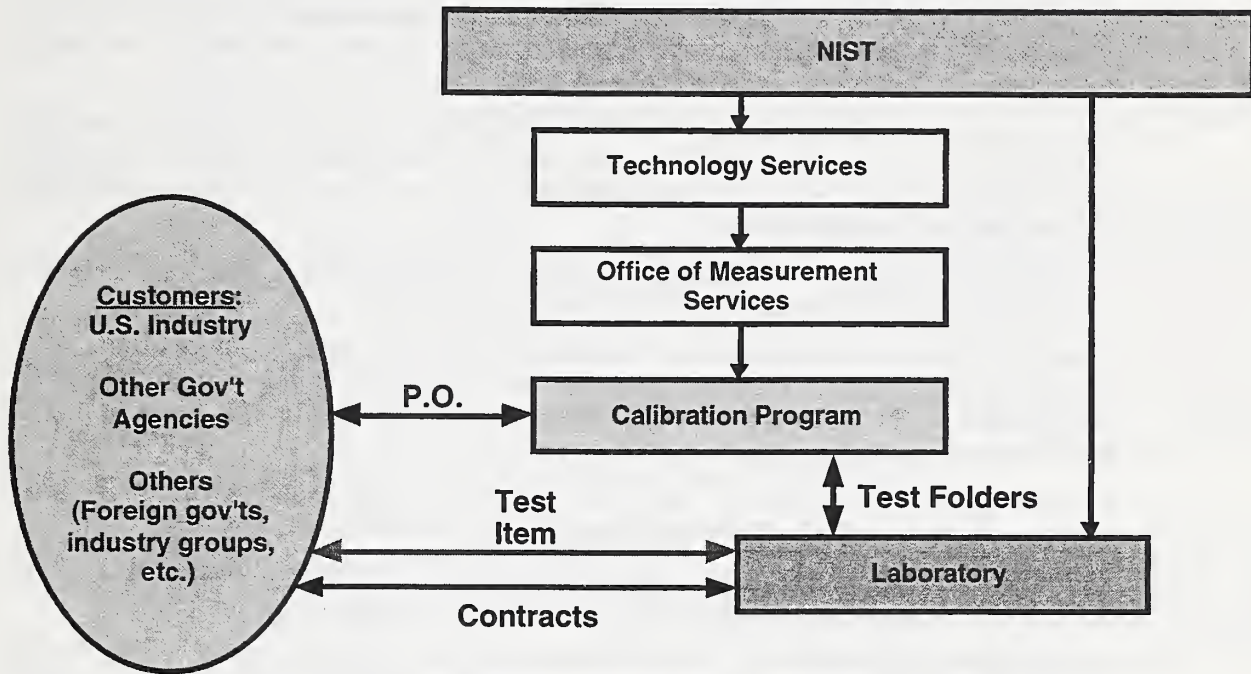
Responsibility for implementing this policy has been delegated to the staff through the technical management chain. This manual contains the quality objectives endorsed by the entire technical management chain. Management in the Optical Technology Division is committed to:

providing each calibration service with the time, resources, and materials necessary to carry out these services.

- b) The organization and management structure for the calibration services offered by the Optical Technology Division at NIST are documented in the Division Quality System Policy and Procedures Manual, Section 4.
- c) Relationships between organizational parts are defined in the following manner: The Division Chief maintains the overall authority and responsibility of the calibration services offered within the Optical Technology Division (844). The Quality Managers and the Technical Managers have direct, uninterrupted communication with the Division

Chief. The calibration service personnel have direct, uninterrupted communication with the Technical Managers and the Quality Managers.

The relationship between NIST and Calibration Service Customers is shown in the following diagram.



- d) Procedures for control and maintenance of documents are handled in the following manner:

The Optical Technology Division's Quality Systems Manual is organized into three sections. The three sections form a pyramid shape, growing progressively larger from top to bottom. The top section is the **Division Quality System Policies** (and definitions). The middle section contains the **Division Procedures** that uniformly apply to all calibration services (e.g., complaint procedures). The bottom section is the **Calibration Service Procedures** for each calibration service.

Each calibration service Project Leader will maintain a copy of their own Calibration Service Procedures Manual which will reside in the particular calibration service laboratory. These documents will be maintained by referencing version numbers on an index log sheet located in the front of the manual. Only current versions of the document shall remain in the manuals.

The Quality Manager maintains the master copy of the Division Quality Policies and Procedures. The Division Quality System Policies rarely change, but the Division Procedures change as needed. These procedures are reviewed and approved by the Quality Manager and Division Chief.

The Project Leaders maintain the master copies of the Calibration Service Procedures for their calibration service. These procedures are revised as needed and reviewed and approved by the Technical Manager. A copy of the approved procedures is kept by the Quality Manager.

The Quality System Manuals are numbered and assigned to individuals, who are responsible for maintaining the manual under their control. The Quality Manager maintains the list of all the individuals assigned a Quality System Manual. Every section of the Quality System Manual is identified by version numbers. Current version numbers are listed at the front of each manual. The Quality System Manual is reviewed annually by the Quality Manager to ensure its suitability and effectiveness. The Quality System Manual is a document that evolves over time and is continually being refined.

- e) Job Descriptions of Key Staff. See each individual Calibration Service Procedures Manual for the job descriptions of the key staff for that calibration service. Typically there will be descriptions for the Technical Manager, Project Leader, Calibration Technician/Staff, and Secretary.

The Project Leaders in the calibration services have the responsibility for the quality system compliance as part of their NIST performance plan.

- f) Approved Signatories. See each individual Calibration Service Procedures Manual for the approved signatories for that calibration service. Typically the signatories will be the Division Chief, Technical Manager, and Project Leader. And in the event of any of their absences alternates shall be named.
- g) Traceability of Measurements. See each individual Calibration Service Procedures Manual for the traceability of measurements for that calibration service.
- h) Scope of Calibrations and Tests. See each individual Calibration Service Procedures Manual for the scope of the calibrations and tests for that calibration service.
- i) Arrangement for New Work. All new work (defined by the receipt of a Test Folder from the NIST Calibration Program) is reviewed and logged by the Project Leader. The use of the Calibration - Special Test Checklist (see the example at the end of this section) is initiated at this point. The Project Leader will also return the Acceptance Notice to the Customer. If there is a question about the appropriateness of the request, that is, if the Customer's request is beyond the calibration service's capability or time schedule, the Project Leader will contact the Customer to discuss the situation in the event that the Customer's requirements can be changed to meet current capabilities. (Usually this discussion happens before the Customer sends a purchase order, thus before any Test Folder is issued.) If necessary the Project Leader can discuss the request with the Technical Manager. If a Customer's request is determined to be beyond the calibration service's capability the Test Folder will not be accepted and the Acceptance Notice will be sent to the Customer explaining that the request is beyond the calibration service's capability.

Unique test situations are accepted from time to time for Special Tests that are beyond the tests listed in the NIST Calibration Services Users Guide SP 250 and the scope of measurements listed in part h above since NIST is the nation's research/technology leader (in radiometry). In this situation the Project Leader, Technical Manager, and Customer shall all agree on the test conditions and uncertainty level prior to accepting the Test Folder and taking any measurements. Conditional acceptance may be given if the suitability of a Customer's test item is in question. In this situation, preliminary tests will be made to determine the suitability of the test item. Again, the Project Leader, Technical Manager, and Customer shall all agree and document their conclusions in advance to any measurements on the amount of preliminary testing (i.e., the cost to the Customer).

It shall be a goal of the Optical Technology Division (844) to have routine calibrations completed, and the Test Folder returned to the NIST Calibration Program within 180 days. If a test is in progress more than 270 days, the Project Leader shall furnish to the Quality Manager a written plan for the completion of the test. The Project Leader shall monitor, schedule, and accept new tests according to a plan which will comply with the time constraints defined in this section. Should a test be in progress more than 1 year, the Project Leader shall prepare a memorandum describing the circumstances and if additional time is needed, the Division Chief shall approve or disapprove the submitted memorandum. This memorandum shall be routed through the appropriate Technical Manager for approval.

Test reports shall be given the same priority as other work, first in - first out, unless there is a bonafide emergency. A priority or emergency test will be documented as such by a memorandum from the Project Leader to the Technical Manager stating the circumstances of urgency. A copy of that memo will reside in the Test Folder and be kept in the Records of that test. Only in these instances will the Test Report generation be given highest priority. It shall be the goal of the Division to have a one week turn around on a Test Report from time of submission for typing to signatures of approval and ready for shipment. (Appendix A contains the NIST Administrative Manual Section 14.01 "Procedure for Handling Customer Orders".) A flowchart depicting the steps taken for all new work is shown at the end of this section.

- j) Calibration and Test Procedures. As a general rule, official NIST calibrations shall be performed only by the designated calibration specialist who is the employee of the U.S. Government. In particular, the customer or his representatives shall not participate in a calibration endeavor unless circumstances require it and approval of the Division Chief is obtained in advance. The presence of unofficial participants in a calibration shall be noted in the official calibration or test report.

See each individual Calibration Service Procedures Manual for the description and flow chart depicting the calibration and test procedures used for that calibration service.

- k) Handling of Test and Calibration Items. See each individual Calibration Service Procedures Manual for the handling of test and calibration items for that calibration service.
- l) Major equipment and reference measurement standards. See each individual Calibration Service Procedures Manual for the major equipment and reference measurement standards for that calibration service.
- m) Procedures for Calibration, Verification, and Maintenance of Equipment. See each individual Calibration Service Procedures Manual for the procedures for calibration, verification, and maintenance of equipment for that calibration service.
- n) Quality Assurance Practices. See each individual Calibration Service Procedures Manual for the quality assurance practices for that calibration service.
- o) Procedures for Corrective Action when Discrepancies are Detected or Departures from Documented Policy Occur. If a discrepancy is detected the Project Leader and Technical Manager shall work with everyone involved to determine if the discrepancy still exists and what measurements were affected. All Customers (external and internal) shall be notified and all efforts should be made to provide corrected data or remeasure the Customer's test item.

If a departure from documented policy occurs the Project Leader and Technical Manager shall work with everyone involved to determine if the departure affected any measurements. If any measurements were affected the Customers (external and internal) shall be notified and all efforts should be made to provide corrected data or remeasure the Customer's test item.

In both cases the Project Leader and Technical Manager shall determine what needs to change to prevent the situation from occurring again.

- p) Arrangements for Permitting Departures from Documented Policies and Procedures. Departure from the policies and procedures documented in the Quality System Manual shall be permitted by the Division Chief for exceptional situations. The Technical Manager and Project Leader shall request an exception in writing and the Division Chief shall permit or deny the request in writing also. The situations involved are occasional and unexpected, like catastrophic failure of equipment, loss of personnel, or an unusual test request. Approved requests shall be kept in the Test Folder.
- q) Complaint Handling. The Laboratory's (Division 844) procedures for handling complaints are documented in the Division Quality System Policy and Procedures Manual, Section 16.
- r) Protecting Confidentiality and Proprietary Rights. All records of Customer tests are property of the U.S. Government. Any draft test reports containing the Customer's name, address, or reference to their test item are shredded. The final versions of the test reports shall be kept in an appropriately secure area. All data whether in a lab notebook, on floppy disk, or a hard disk shall also be made appropriately secure. This not only means from unauthorized use, but also from inadvertent loss (i.e., hard disk crash).

Reports on calibrations and special tests are regarded as the property of the Customer. Copies are not supplied to other parties except as required by federal law or requested in writing by the Customer.

In order to insure privacy and confidentiality, visitors and guests (i.e., guest scientists) shall not become involved in official calibration activities except as approved by the appropriate Technical Manager.

See each individual Calibration Service Procedures Manual for the location of test reports and laboratory notebooks for that calibration service.

- s) Audit and Review Procedures. The procedures for audit and review are documented in Section 5.3 below.
- t) Establishing and Changing Calibration Intervals. All equipment critical to the measurements of each calibration service shall have a calibration or verification interval. See each individual Calibration Service Procedures Manual for the equipment and intervals for that calibration service.

Calibration/verification intervals shall be the manufacturer's recommended interval. If there is no recommended interval the Project Leader and Technical Manager shall determine a conservative interval (e.g., six months) with input from the appropriate NIST technical staff until a statistical interval can be established (i.e., several initial intervals have passed). If it is the Project Leader and Technical Manager's experience that the manufacturer's recommended interval is not appropriate (too long or too short) they can change the interval based on statistical analysis of the history of that item.

The Division's policy on establishing and changing calibration/verification intervals is:

Calibration/verification intervals shall be the manufacturer's recommended interval. If there is no recommended interval a conservative interval shall be established until a statistical interval can be established. If experience shows that the manufacturer's recommended interval is not appropriate, the interval can be changed based on statistical analysis of the history of that item.

- u) Measurement Uncertainty Policy. The technique for determining measurement uncertainty is defined in NIST Technical Note 1297, Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results, by B. N. Taylor and C. E. Kuyatt. The Laboratory's policy on the expression of measurement uncertainty is:

All measurement uncertainties reported in calibration and test reports shall be 2 sigma as determined by NIST Technical Note 1297, Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results.

- 5.3 Each calibration service shall be audited annually by the Technical Manager to insure the correctness or validity of the calibration service's measurements. Where the audit findings cast doubt on the validity of the calibration service's measurements immediate corrective action shall be taken and any Customer whose work may have been affected shall immediately be notified in writing.
- 5.4 The quality system of each calibration service shall be reviewed annually by the Quality Manager or designate. The quality system of the Laboratory as a whole shall be reviewed annually by the Quality Manager and management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.
- a) The General Operations Checklist found in NIST Handbook 150-2, NVLAP Calibration Laboratories Technical Guide, may be used as part of the annual audit by the Quality Manager or designate. All sections of the checklist may be used that are applicable as defined by the scope and intent of the quality system documentation.
- b) The Quality System Audit Checklist (see the example at the end of this section) shall be used by the Quality Manager or designate as part of the annual audit.
- 5.5 All audit and review findings and any corrective actions that arise from them shall be documented by the Quality Manager. The Technical Manager or designate shall ensure that these actions are discharged within the agreed time frame.
- 5.6 In addition to periodic audits the calibration service shall ensure quality measurements by any of the following:
- a) Internal Quality Control;
- b) Interlaboratory Comparisons;
- c) Use Of Reference Materials;
- d) Using Different Methods;
- e) Correlation Of Results.

Calibration _____ Special Test _____ Checklist

Customer: High Priority (memo must be attached) _____
 PO #: Test #:
 Model #: Test Folder #:
 Serial #: Storage Location:

| <u>No.</u> | <u>Item</u> | <u>Initials</u> | <u>Date</u> |
|-------------------------|--|-----------------|-------------|
| 1. | Test item received | _____ | _____ |
| 2. | PO received | _____ | _____ |
| 3. | PO sent to Calibration Program | _____ | _____ |
| 4. | Test Folder received | _____ | _____ |
| 5. | Schedule measurement | _____ | _____ |
| 6. | Acceptance Form mailed | _____ | _____ |
| 7. | Measure test item | _____ | _____ |
| Test Dates: | | | |
| Working Standards Used: | | | |
| 8. | Analyze data | _____ | _____ |
| 9. | Write report | _____ | _____ |
| 10. | Preparer's signature: report finished, data checked, and test item checked. | _____ | _____ |
| 11. | To Technical Manager for signature | _____ | _____ |
| 12. | To Division Chief for signature | _____ | _____ |
| 13. | Mail original test report(s) to Customer Send paperwork to Accounts and to Calibration Services | _____ | _____ |
| 14. | Pack test item w/ shipping items: packing list, test report, POC, etc. | _____ | _____ |
| 15. | Take test item to Shipping | _____ | _____ |

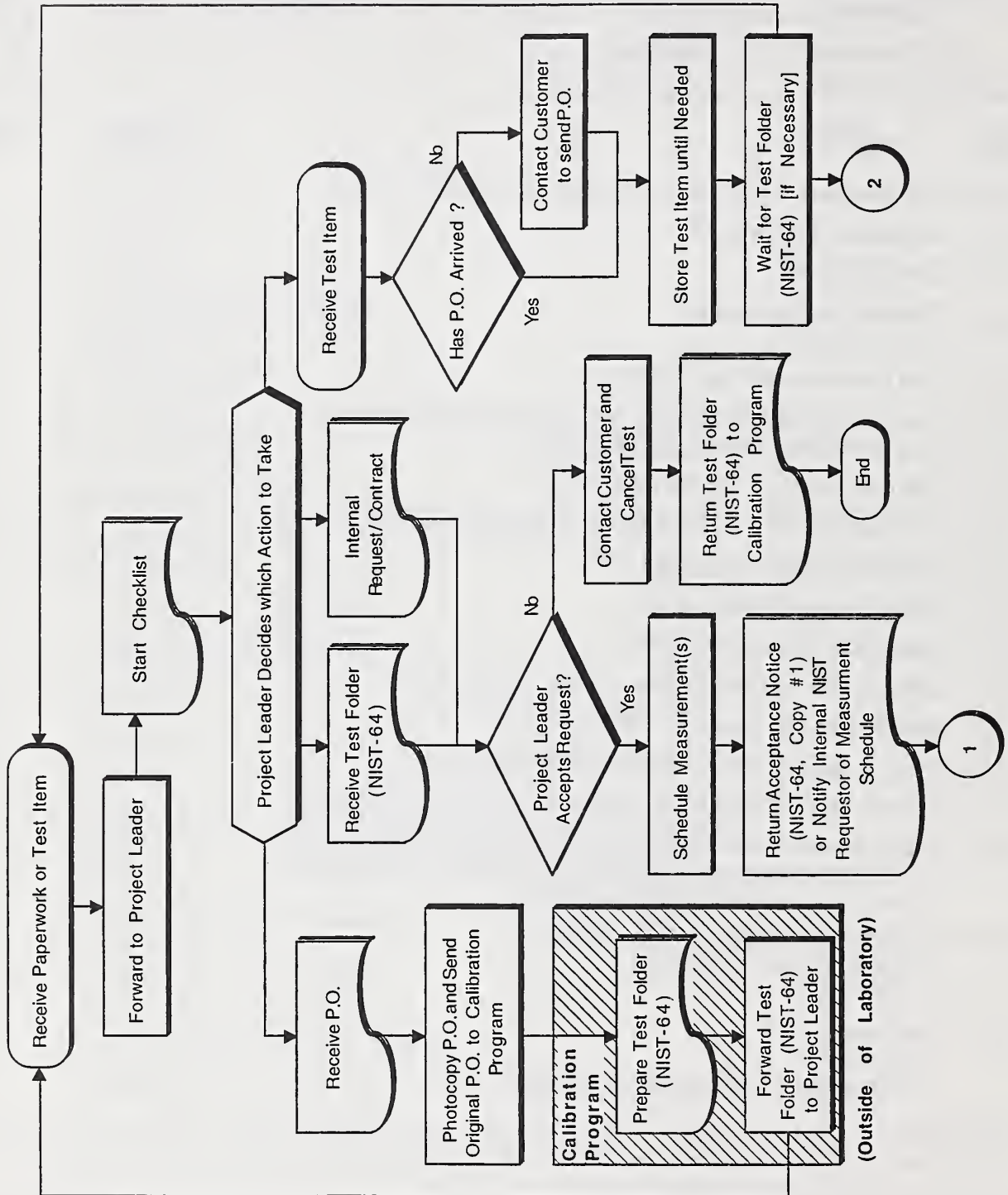
Quality System Audit Checklist

Calibration Service Laboratory: _____ Date: _____
 Auditors: _____
 Cal. Personnel: _____
 Laboratory Room #: _____

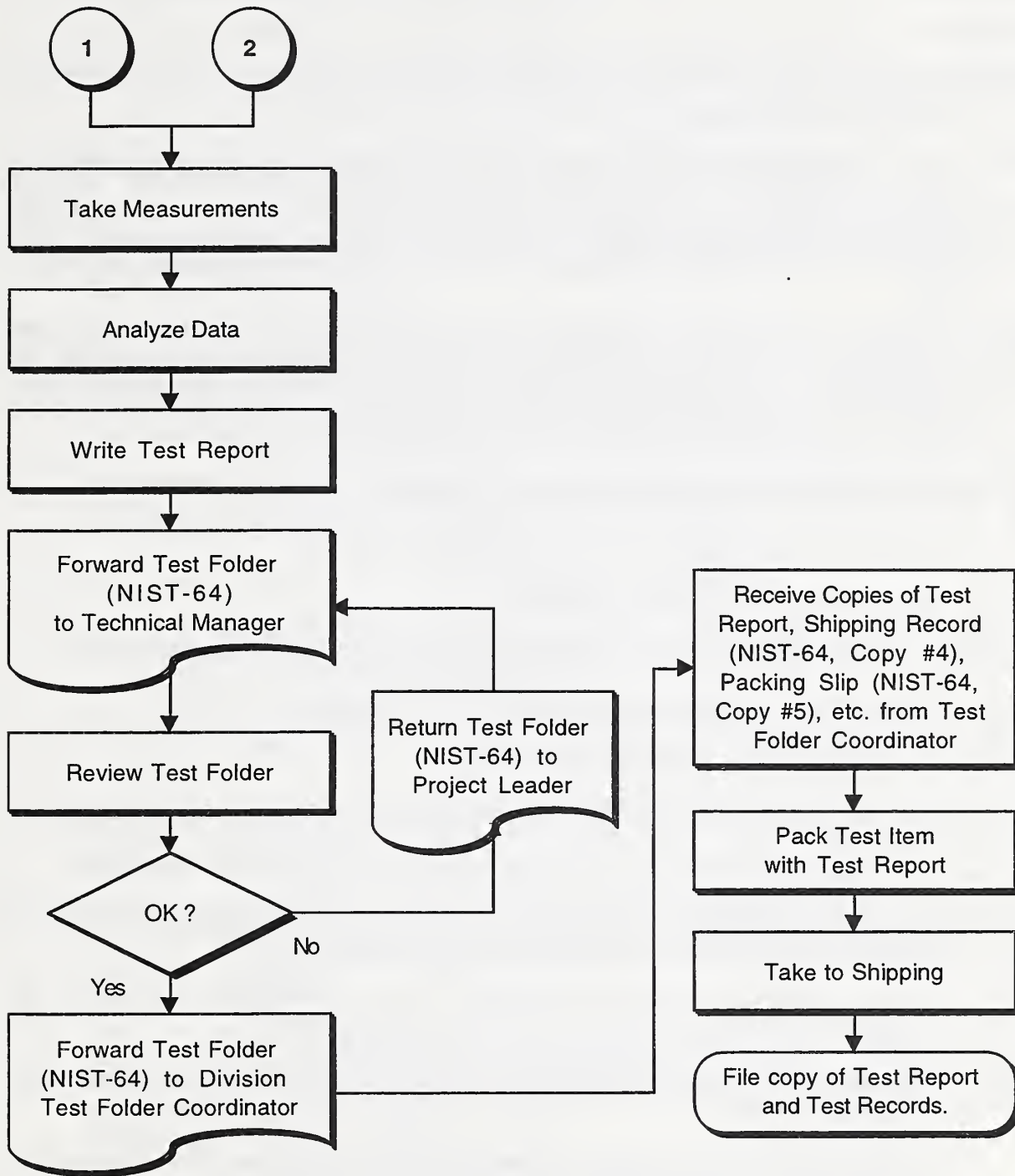
| <u>No.</u> | <u>Item</u> | <u>Satisfactory</u> | <u>Unsatisfactory</u> |
|------------|---|---------------------|-----------------------|
| 1. | Cal. Personnel understand and can explain Quality System? | _____ | _____ |
| 2. | Acceptance Forms sent? | _____ | _____ |
| 3. | Checklists used? | _____ | _____ |
| 4. | Physical log or schedule? Is it visible? | _____ | _____ |
| 5. | Test Folders visible and orderly? | _____ | _____ |
| 6. | Able to find data (in lab book and computer), Test Folder (or records in files), and log for test items? | _____ | _____ |
| 7. | Lab book kept per Physics Lab policy? | _____ | _____ |
| 8. | Is a phone log kept of Customer calls concerning Cal. Services? | _____ | _____ |
| 9. | Test items stored per Section 11? | _____ | _____ |
| 10. | Records kept per Section 12? | _____ | _____ |
| 11. | Complaint Records up to date? | _____ | _____ |
| 12. | Always follows test procedures from start to finish? | _____ | _____ |
| 13. | Review one test item from "In Process" list. | _____ | _____ |
| 14. | Review one recently completed test/calibration item. | _____ | _____ |
| 15. | Review (walk-through) one current test/calibration procedure. | _____ | _____ |
| 16. | Cal. Personnel understand and can explain Cal. Service Scale? Scale realization data available and compared to older scales? Last Scale realization within 2 years? | _____ | _____ |
| 17. | Manuals have current section versions? Table of Contents current? All pages? | _____ | _____ |
| 18. | Facilities clean? Orderly? Professional looking (lights working?). | _____ | _____ |

Comments: _____

New Work Flowchart



New Work Flowchart (con't)



Section 13: Certificates and Reports

Written By: Sally Bruce / Thomas Larason

Version: 1.1 Page 1 of 7

Approved By: _____

Date: _____

Revised By: _____

Date: _____

13 Certificates and Reports

- 13.01 Section 13 of the Quality System Manual refers to Test Reports issued by the Laboratory as a result of the initiation of a Test Folder. The Test Folder is either issued by the NIST Calibration Program upon receipt of a Customer's Purchase Order, or is issued by the Laboratory upon receipt of other U.S. Government Agency Funds, or internal NIST requests from either another Calibration Service or another organizational unit within NIST.
- 13.1 Test Reports issued by the Laboratory shall present results that are accurate, clear, and unambiguous. The Test Report shall include all the information necessary for the interpretation of the results and all the information required by the method used. Information may include reference to NIST SP250 documents, papers published by NIST authors, or other appropriate documents (ANSI, CIE, etc.).
- 13.2 Each Test Report shall contain the following information:
- a) the test title, e.g. "Report of Test" or "Report of Calibration";
 - b) the first page shall be on NIST letterhead;
 - c) the NIST Calibration Services Guide SP250 test number and the test folder number;
 - d) name, address, and purchase order number of the customer;
 - e) description and identification of the test item;
 - f) the characteristics of the test item shall be described in Section 1 of the Test Report;
 - g) final date of performance of the test shall be noted in the footer of the Test Report;
 - h) Section 2 of the Test Report shall describe the test method and sampling procedure and any deviations from the referenced procedures or methods;
 - i) where appropriate, influence parameters (e.g. environmental conditions like temperature and humidity) shall be reported in the Test Report;
 - j) the data shall be presented in Section 3 and supported by either tables or graphs or other appropriate method;
 - k) a statement of the measurement uncertainty shall be included in the Test Report, and its presentation shall follow NIST Technical Note 1297 (1994 edition);

- l) the Project Leader shall sign the Test Report - under the designation: "Prepared by";
 - m) the Technical Manager shall sign the Test Report - between the designations: "Approved by" and "for the Director of NIST";
 - n) where relevant, a statement that the results relate only to the items tested;
 - o) the Test Report contains a statement that the report shall not be reproduced except in full, without the written approval of the Laboratory;
 - p) the Test Report shall describe the NIST scale for which it is traceable to.
- 13.3 The Laboratory has standardized its Test Report format. Test Reports and Calibration Reports issued by the Laboratory shall use "Times" font. Appendix 13-A contains the sample "Report of Test" for the Laboratory. Appendix 13-B contains a sample "Report of Calibration" for the Laboratory.
- 13.4 Each Calibration Service shall have a sample "Report of Calibration" for each Test Number listed in the SP 250 User's Guide and a sample "Reports of Test" for each Special Test listed in the SP 250 User's Guide. These sample Test Reports shall follow the samples shown in Appendixes 13 A & B. See each individual Calibration Service Procedures Manual for their sample Test Reports.
- 13.5 Amendments to the Test Reports shall be made in the form of a document which includes the statement, "Supplement to Test Report" and the test report number shall follow. Any amendment shall contain the relevant parts of the format in 13.2.
- 13.6 The Laboratory shall notify Customers promptly, in writing, of:
- a) any event such as the identification of defective equipment that casts doubt on the validity of results given in any Test Report. Such notification shall quantify the magnitude of error created in the results.
 - b) any customer's equipment found significantly out-of-tolerance during the testing process. Measurement data shall be reported so that the appropriate action can be taken.
- 13.7 Reports on calibrations are regarded as the property of the Customer. Copies are not supplied to other parties except as required by federal law or requested in writing by the Customer.
- 13.8 When Customers require transmission of test results by telephone, fax, or other electronic or electromagnetic means, the Calibration Staff shall ensure that confidentiality is preserved. A written record of such transmissions shall be kept in the file with the Test Report and Records.
- 13.9 Each Test Report or Calibration Report issued by the Laboratory shall have a cover letter. The cover letter shall reference the NIST Calibration Services test folder number, the Customer's purchase order number, the date of the purchase order, the customer name, address, and the point of contact name (if known), and the signature of the Division Chief. Appendix 13-C contains a sample cover letter.



UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-0001

REPORT OF TEST

Test Number as listed in SP250

for

Test Item Identification, Model #, Serial #

Submitted by:

Mr. John Doe
Any Company
123 Calibration Court
Measurement City, MD 00000-0000

(See your Purchase Order No. PO 98765 dated January 1, 1993)

1. Description of Test Item

In this section give a description and unambiguous identification of the Test Item. The characteristics and condition of the Test Item as appropriate.

2. Description of Test

In this section give a brief description of the test referring to other documents where appropriate (i.e. SP250's, ASTM standards, etc.). Appropriate influence parameters such as, environmental conditions (temperature and humidity are at the bottom) and S/N of working standards used.

3. Results of Test

In this section give the results: tables, graphs, sketches, etc. (or refer to them if placed at the end of the report); and the estimated uncertainty ($k = 2$) of the test.

Prepared by:

Approved by:

(Name of Person Writing Report)
Optical Technology Division
Physics Laboratory
(301) 975-xxxx

(Name of Group Leader)
For the Director,
National Institute of
Standards and Technology
(301) 975-xxxx

Laboratory Environment:

Temperature: $23.x \text{ }^\circ\text{C} \pm 0.3 \text{ }^\circ\text{C}$
Relative Humidity: $4x \% \pm 2.2 \%$

Test Date: May 16, 1993

NIST Test No.: 844/123456-93/y (/y if more than one item)

Page 1 of 2

REPORT OF TEST

Test Number as listed in SP250
 Any Company

Manufacturer: xxxx
 Model #: abcd
 Serial #: 1234

References:

- [1] E. F. Smith "The First Example Reference," National Bureau of Standards (U.S.), Special Publication 250-17 (1988).
- [2] G. Laurel and J. E. Hardy, "The Second Example Reference," Applied Optics 30, 3091-3099 (1991).

Figure 1
 Title of Figure



Table 1
 Title of Table

| Wavelength (nm) | Response (A/W) | Wavelength (nm) | Response (A/W) | Wavelength (nm) | Response (A/W) |
|-----------------|----------------|-----------------|----------------|-----------------|----------------|
| 400 | 1.825E-01 | 435 | 2.114E-01 | 470 | 2.357E-01 |
| 405 | 1.871E-01 | 440 | 2.151E-01 | 475 | 2.389E-01 |
| 410 | 1.916E-01 | 445 | 2.186E-01 | 480 | 2.422E-01 |
| 415 | 1.959E-01 | 450 | 2.223E-01 | 485 | 2.455E-01 |
| 420 | 1.999E-01 | 455 | 2.257E-01 | 490 | 2.485E-01 |
| 425 | 2.039E-01 | 460 | 2.291E-01 | 495 | 2.517E-01 |
| 430 | 2.077E-01 | 465 | 2.323E-01 | 500 | 2.548E-01 |

Test Date: May 16, 1993
 NIST Test No.: 844/123456-93/y (/y if more than one item)

Page 2 of 2



UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-0001

REPORT OF CALIBRATION

Test Number as listed in SP250

for

Calibration Item Identification, Model #, Serial #

Submitted by:

Mr. John Doe
Any Company
123 Calibration Court
Measurement City, MD 00000-0000

(See your Purchase Order No. PO 98765 dated January 1, 1993)

1. Description of Calibration Item

In this section give a description and unambiguous identification of the Calibration Item. The characteristics and condition of the Calibration Item as appropriate.

2. Description of Calibration

In this section give a brief description of the calibration referring to other documents where appropriate (i.e. SP250's, ASTM standards, etc.). * Appropriate influence parameters such as, environmental conditions (temperature and humidity are at the bottom) and S/N of working standards used.

3. Results of Calibration

In this section give the results: tables, graphs, sketches, etc. (or refer to them if placed at the end of the report); and the estimated uncertainty ($k = 2$) of the calibration.

Prepared by:

Approved by:

(Name of Person Writing Report)
Optical Technology Division
Physics Laboratory
(301) 975-xxxx

(Name of Group Leader)
For the Director,
National Institute of
Standards and Technology
(301) 975-xxxx

Laboratory Environment:

Temperature: $23.x \text{ }^\circ\text{C} \pm 0.3 \text{ }^\circ\text{C}$
Relative Humidity: $4x \% \pm 2.2 \%$

Calibration Date: May 16, 1993
NIST Test No.: 844/123456-93/y (/y if more than one item)

Page 1 of 2

NIST

REPORT OF CALIBRATION

Test Number as listed in SP250
 Any Company

Manufacturer: xxxx
 Model #: abcd
 Serial #: 1234

References:

- [1] E. F. Smith "The First Example Reference," National Bureau of Standards (U.S.), Special Publication **250-17** (1988).
- [2] G. Laurel and J. E. Hardy, "The Second Example Reference," Applied Optics **30**, 3091-3099 (1991).

Figure 1
 Title of Figure

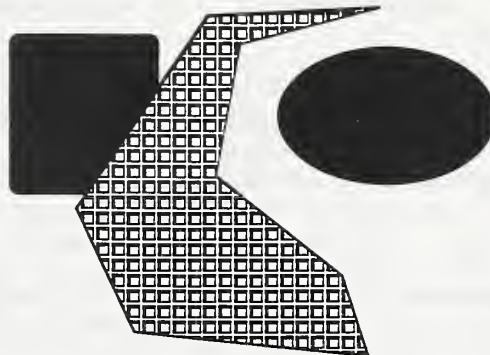


Table 1
 Title of Table

| Wavelength (nm) | Response (A/W) | Wavelength (nm) | Response (A/W) | Wavelength (nm) | Response (A/W) |
|-----------------|----------------|-----------------|----------------|-----------------|----------------|
| 400 | 1.825E-01 | 435 | 2.114E-01 | 470 | 2.357E-01 |
| 405 | 1.871E-01 | 440 | 2.151E-01 | 475 | 2.389E-01 |
| 410 | 1.916E-01 | 445 | 2.186E-01 | 480 | 2.422E-01 |
| 415 | 1.959E-01 | 450 | 2.223E-01 | 485 | 2.455E-01 |
| 420 | 1.999E-01 | 455 | 2.257E-01 | 490 | 2.485E-01 |
| 425 | 2.039E-01 | 460 | 2.291E-01 | 495 | 2.517E-01 |
| 430 | 2.077E-01 | 465 | 2.323E-01 | 500 | 2.548E-01 |

Calibration Date: May 16, 1993
 NIST Test No.: 844/123456-93/y (/y if more than one item)

Page 2 of 2



UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-0001

(Date stamped here.)

In reply refer to: 844/123456-93/1
844/123456-93/4

Any Company
(Attention: Name of person to receive test report, if known)
123 Calibration Court
Measurement City, MD 00000-0000

Subject: <Calibration or Test Item> Report(s) of <Calibration or Test>

Order No.: PO 98765 dated January 1, 1993

Dear Madam/Sir: (or name of person to receive the report, if known)

Enclosed are the results of the <Calibration or Test Item> <calibration or test> for Test Number (as listed in SP250) and associated documentation you requested. Please refer to the above file numbers in any later communication concerning these tests. (Wording doesn't need to be exact, but something to this effect.)

Sincerely,

Albert C. Parr, Chief
Optical Technology Division
Physics Laboratory

Enclosure(s): (as applicable)

Four Reports of <Calibration or Tests>

ACP/rlc

NIST Cost Center 844xxxx

NIST

Section 16: Complaints

Written By: Thomas Larason / Sally Bruce

Version: 2.1 Page 1 of 4

Approved By: _____

Date: _____

Revised By: _____

Date: _____

16 Complaints

16.1 The Laboratory's (Division 844) policy on complaints is:

All complaints received from Customers or other parties are important and every effort shall be made to resolve the complaints in a prompt and professional manner. A record shall be maintained of all complaints and of the actions taken by the Laboratory.

- 16.2 When a complaint, or any other circumstance, raises doubt about the Laboratory's compliance with the Laboratory's policies, procedures, or otherwise concerning the quality of the Laboratory's calibrations, the Laboratory shall promptly resolve the complaint. If necessary, all Laboratory personnel involved (i.e. technicians, Technical Manager, Project Leader, etc.) shall meet and decide on the best way to resolve the complaint to the satisfaction of the Customer.
- 16.3 The individual Laboratory personnel receiving the complaint (either by fax, phone, mail, or in person) shall follow procedure 844SOP 1.
- 16.4 If the complaint is received by personnel not directly involved with the complaint (i.e., the Division Chief, secretaries, etc.) then the Complaint Response Form shall be filled out as completely as possible listing the Customer's name, telephone number, and a description of the complaint. If possible, any immediate and reasonable action should be taken to resolve the complaint. These should be recorded and dated on the Complaint Response Form. (These are 844SOP 1 steps 5.1, 5.2, and 5.3.) The complaint shall then be forwarded to the Project Leader of the calibration service involved, who shall proceed to resolve the complaint.
- 16.5 If the complaint involves personnel at NIST outside of the Laboratory's direct control (e.g., Calibration Program, Shipping), the complaint shall be forwarded to them in writing requesting their help in resolving the complaint.
- 16.6 Each calibration service shall maintain a Complaint Log and file of Complaint Response Records (completed Forms).
- 16.7 The Quality Manager shall maintain the Laboratory's Complaint Log and file of Complaint Response Forms from each calibration service in the Laboratory. The Laboratory's Complaint Log and file of Complaint Response Forms shall be kept in the Division Office. The Division Secretary shall be responsible for the location of the Laboratory's Complaint Log and file of Complaint Response Records (completed Forms).
- 16.8 The Quality Manager (or Deputy) shall monitor the progress of each complaint response to insure a timely resolution to all complaints. After each complaint has been resolved, the Quality Manager (or Deputy) shall contact the Customer to thank them for their input and inquire if the situation that initiated the complaint has satisfactorily been addressed. This "follow-up" communication shall be documented and any further needed action shall be directed to the appropriate Laboratory personnel.

- 16.9 New Laboratory and Calibration Service Complaint Logs will be started each October 1 (each new fiscal year). The old logs and complaint records will be retained for 3 years.
- 16.10 A complaint is usually caused by the action (or inaction) of Laboratory personnel involved with calibration services. But sometimes a complaint concerns the inability of the Laboratory to perform a desired action (i.e., provide a service, meet the Customer's schedule, reported uncertainties are too high) or concerns a matter which the Laboratory has little or no control (e.g., service fees). These complaints have no immediate solutions, but they should be treated in a similar manner to other complaints. That is, they should be forwarded to the Project Leader, Technical Manager, and Quality Manager as described.

Annually the Quality Manger (or Deputy) shall review the Complaint Records and report to the Laboratory management on all Complaints without immediate solutions (i.e., concerning the Laboratory's inability to perform a desired action or matters which the Laboratory had little or no control). This input will be submitted to the Laboratory management for future planning consideration.

Complaint Log [FY] For:

| No. | Customer, POC, and Telephone Number | Project Leader | Date Received | Date Closed |
|-----|-------------------------------------|----------------|---------------|-------------|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |
| 5 | | | | |
| 6 | | | | |
| 7 | | | | |
| 8 | | | | |
| 9 | | | | |
| 10 | | | | |
| 11 | | | | |

Complaint Response Form

Lab Complaint Number: _____

Calibration Service Complaint Number: _____

**Lab Personnel
Receiving
Complaint:** _____

Date Received: _____

Ext.: _____

Project Leader: _____

Date Forwarded: _____

Ext.: _____

Forwarded To: _____

Date Forwarded: _____

Ext.: _____

Customer: _____

Phone Number: _____

Point of Contact: _____

FAX Number: _____

Complaint:

Action Taken:

Date Closed: _____

Project Leader Initials: _____

Technical Manager Initials: _____

Quality Manager Initials: _____

**Optical Technology Division (844)
Standard Operating Procedure**

844SOP001

Written By: Thomas Larason / Sally Bruce

Version: 1.4

Approved By: _____

Date: _____

Revised By: _____

Date: _____

Subject: Calibration Service Complaints

Page 1 of 4

Table of Contents

1. Scope
2. Introduction
3. Definitions
4. Related Documents
5. Complaints Process [ANSI/NCSL Z540, Section 16]
6. Flowchart

1. Scope

- 1.1 This document covers all the calibration services offered by the Optical Technology Division (844) and the personnel involved with these calibration services.
- 1.2 This document does **not** cover research and development, contract, CRDA, or cooperative activities unless a calibration or special test is specified.

2. Introduction

- 2.1 This procedure describes the way complaints are to be handled by the Laboratory (Division 844) personnel.

3. Definitions

- 3.1 **Complaint:** Customer expression of dissatisfaction with a requested calibration service. Complaints can be broken, damaged, or missing test items, excessive delay from the estimated completion date without a reasonable explanation, or missing data in the report.

Note: A complaint is usually caused by the action (or inaction) of Laboratory personnel involved with calibration services. But sometimes a complaint concerns the inability of the Laboratory to perform a desired action (i.e., provide a service) or concerns a matter which the Laboratory has little or no control (e.g., fees). While these complaints have no immediate solutions (the Laboratory can not immediately create a new calibration service or lower our fees) they should be treated in a similar manner to other complaints. That is, they should be forwarded to the Project Leader, Technical Manager, and Quality Manager as described.

- 3.2 **Discrepancy:** Customer expression of disagreement or divergence (an inconsistency) in measurement results from a Calibration Service. This is different than a complaint but should be handled in essentially the same manner, since this could indicate a problem with the Calibration Service's data handling or reference scale.

Note: Many times discrepancies are the result of the Customer's inappropriate use of the test item or misunderstanding how to apply the calibration data. Laboratory personnel should determine if the Calibration Service in question is operating according to proper procedures and is under control (i.e., everything is OK with the Calibration Service) or if the Customer is having a problem on their end. The latter is often impossible to

determine completely, but a reasonable effort should be made as resources allow (i.e., you can't go and take the measurements for them).

4. Related Documents

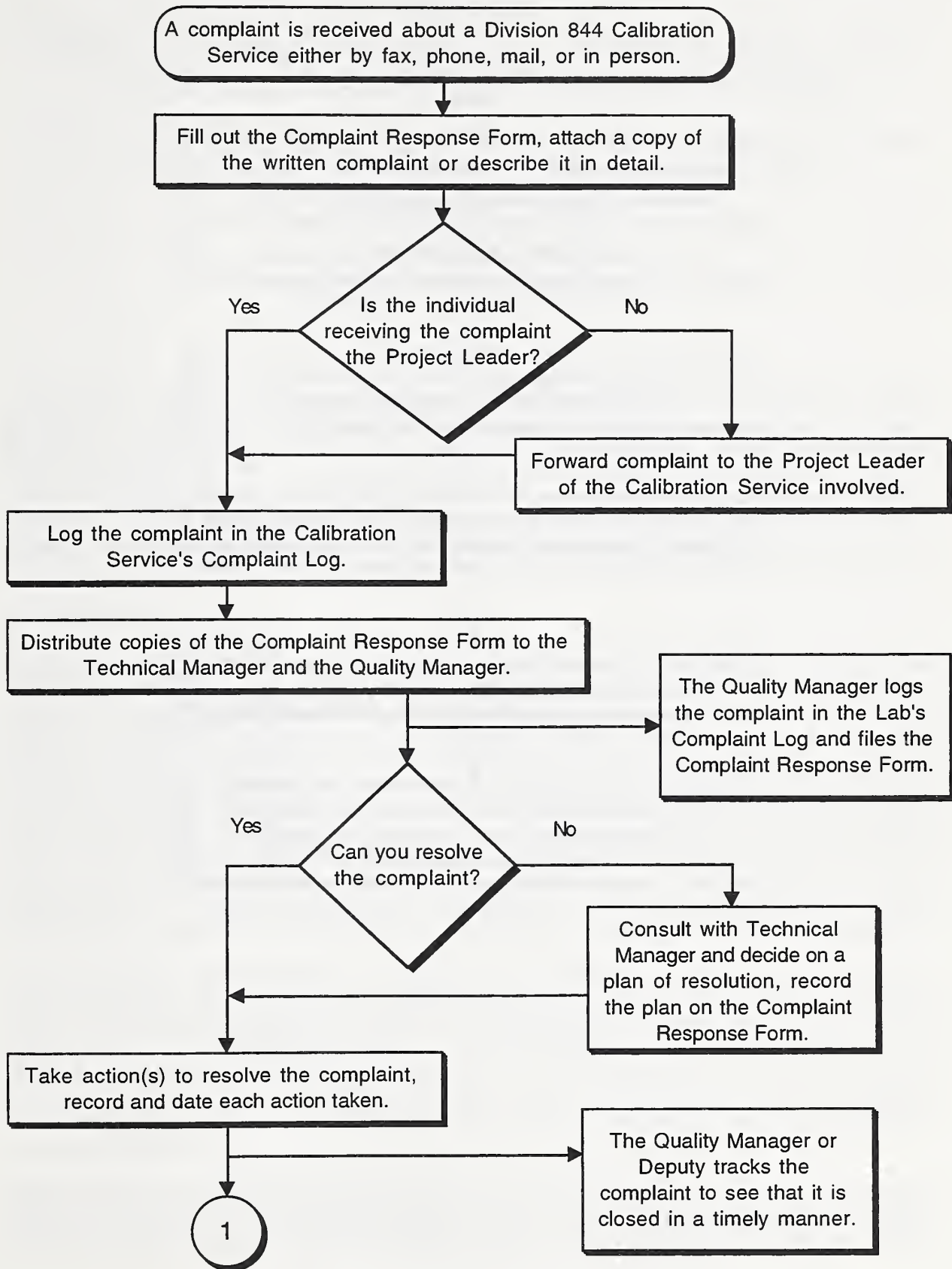
- 4.1 Calibration Service Procedures Manual(s)
- 4.2 Complaint Response Form
- 4.3 Complaint Log Sheets

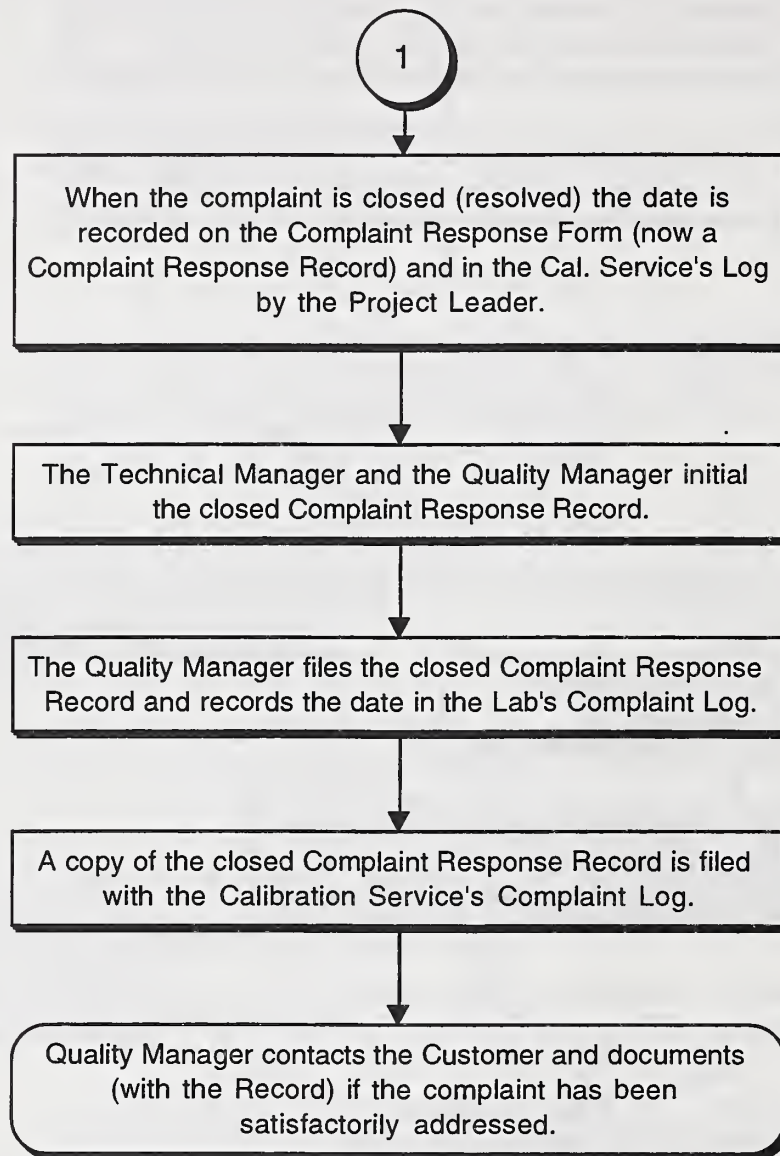
5. Complaints Process [ANSI/NCSL Z540, Section 16]

- 5.1 Fill out a Complaint Response Form as completely as possible listing the Customer (company or organization complaining), the name of the Point Of Contact (POC), and their telephone number. Also, describe their complaint or attach a copy of the fax, letter, or phone log communicating the complaint.
- 5.2 Take any and all immediate and reasonable actions to resolve complaint.
- 5.3 Record and date each action taken to resolve the complaint.
- 5.4 If the individual receiving the complaint is not the Project Leader, forward the complaint to the Project Leader who shall be responsible for resolving the complaint (if it has not already been resolved).
- 5.5 The Project Leader logs the complaint into the Calibration Service's Complaint Log.
- 5.6 List all Laboratory personnel involved and distribute copies of the Complaint Response Form to the Technical Manager and Quality Manager.
- 5.7 In most cases the complaint can not be immediately resolved by the individual receiving the complaint. In those cases the Project Leader shall be responsible for resolving the complaint. If necessary, the Technical Manager and all Laboratory personnel involved will meet to decide on a plan of action to resolve the complaint. Record or attach the plan to the Complaint Response Form.
- 5.8 The Quality Manager shall log the complaint into the Laboratory's Complaint Log and file the Complaint Response Form. The Quality Manager or Deputy shall follow up on all complaints and see that they are closed (resolved) in a timely manner.
- 5.9 When the complaint is closed (resolved) the date shall be recorded on the Complaint Response Form and in the Calibration Service's Complaint Log by the Project Leader. A completed Complaint Response Form is now a Complaint Response Record.
- 5.10 The Technical Manager and Quality Manager shall initial the closed (resolved) Complaint Response Record.
- 5.11 The Quality Manager shall file the closed (resolved) Complaint Response Record and record the date the Complaint Response Record was closed in the Laboratory's Complaint Log.
- 5.12 A copy of the initialed (resolved) Complaint Response Record shall be filed with the Calibration Service's Complaint Log.
- 5.13 The Quality Manager shall contact the Customer and document (with the Record) whether the situation that initiated the complaint has been satisfactorily addressed.

6. Flowchart

- 6.1 The following flowchart depicts the Complaints Process described above in section 5.





Appendix:

Building a Quality System Based On ANSI/NCSL Z540-1-1994 -An Effort by The Radiometric Physics Division at NIST

Originally published in the Proceedings of the National Conference of Standards Laboratories (NCSL) 1995 Workshop and Symposium, Dallas, TX, July 16-20, 1995.

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Abstract

The Radiometric Physics Division of the National Institute of Standards and Technology (NIST) is developing a quality system for the calibration services it offers based on the American National Standard for Calibration - Calibration Laboratories and Measuring and Test Equipment, ANSI/NCSL Z540-1-1994. A description of the overall quality system structure and the organization of the documentation is given. Several essential areas of the quality system are briefly described. These essential areas are the quality manual, equipment records, calibration methods, computer software documentation, test report format, and complaint handling procedures. The experience to date of developing the quality system is described and specific examples are shown.

Introduction

The Radiometric Physics Division (hereafter the Division) at the National Institute of Standards and Technology (NIST) began a project in 1993 to develop a quality system that is based on the American National Standard for Calibration - Calibration Laboratories and Measuring and Test Equipment, ANSI/NCSL Z540-1-1994 [1]. Although quality procedures were previously in place, they varied from calibration service to calibration service within the Division. The goal of the project is to unify all the calibration services in the Division with standard formats and similar procedures. A quality manager and deputy were selected to head the project. They developed the quality system structure, unified the documentation with standardized formats, and assigned tasks to the managers, scientists, engineers, and technicians involved with calibration services within the Division. The Division has five calibration services that it offers: 1) spectroradiometric source measurements, 2) radiance temperature measurements, 3) optical properties of materials measurements, 4) photometric measurements, and 5) spectroradiometric detector measurements.

Six essential areas were identified and focused on first. These essential areas are the quality manual, equipment records, calibration methods, computer software documentation, test report format, and complaint handling procedures. The documentation of these six areas is the beginning of the process toward full implementation of the ANSI/NCSL Z540-1-1994 (here after the Z540) for the calibration services offered by the Division. The second phase of the documentation effort focused on the remaining areas of the Quality System. These areas include: personnel, accommodation and environment, handling of calibration items, records, measurement traceability, and outside support.

Balance between functionality and bureaucracy was a concern from the start. Efforts were directed toward developing a useful and practical quality system. Excessively sophisticated and complex procedures were avoided, along with redundant documentation. Tools such as checklists, forms,

and flowcharts were used where they were applicable. The description of the Z540 implementation in this paper serves only as an indication of a particular effort for developing a quality system for calibration services and does not constitute a recommendation by NIST of procedures for other laboratories to follow. Each implementation of the Z540 should be tailored to the unique circumstances and requirements of the individual laboratory.

Description of a Quality System

A competent testing or calibration laboratory should have a well-documented quality system. A quality system is [2], "The process, organizational structure, procedures, and resources that manufacturers and suppliers use to control these (product quality) variables to produce a product of consistent quality which meets defined specifications." Quality systems change with time as processes are improved, equipment is added, etc. Quality system documentation describes what is happening now, not what happened in the past, nor what is planned for the future.

For a laboratory developing a quality system, specific real world examples are difficult to find. There are many books on quality, but few have examples of quality system documentation. Until recently, laboratories rarely showed their quality system documentation to those outside of its organization or explained how it was developed. Good sources of information for those beginning the documentation process are the Recommended Practices from the National Conference of Standards Laboratories (NCSL) [3] and the NIST Handbook 150-2, the National Voluntary Laboratory Accreditation Program (NVLAP) Calibration Laboratories Technical Guide [4].

Radiometric Physics Division Quality System Structure

Definitions

The first step in developing the quality system structure was to follow the Z540 as appropriate to the operation of the Division. After reviewing the Z540 sections 3 (definitions) and 4 (organization and management), three principal terms were defined: (1) laboratory, (2) technical manager, and (3) quality manager.

Z540 section 3.1 defines a laboratory as a "Body that calibrates and/or tests." The Division was defined as the "laboratory" for the purpose of the quality system documentation. The different calibration services in the Division are described in a separate subsection (where appropriate) in the quality system documentation. Each calibration service is called a "calibration laboratory" within the Division quality system documentation.

Z540 refers to technical and quality managers in sections 4.2.f and 4.2.g. In the Division, the technical manager is defined as the group leader for that calibration laboratory. A group leader is the NIST first line supervisor and is responsible for the technical, financial, and personnel management of the staff assigned to that particular group. The group leader allocates resources (people) and materials (equipment) for the calibration laboratory. The technical manager is responsible for the accuracy of the measurements provided by the laboratory.

The quality manager and deputy are responsible for developing, documenting, implementing, and maintaining the quality system with the help of the technical managers and the calibration laboratory personnel. The quality manager is not responsible for the accuracy of the measurements in the calibration service laboratories.

Two other positions, division chief and project leader, were defined within the quality system of the Division. The division chief maintains the overall authority and responsibility of the calibration services offered by the Division. The project leader is responsible for the day-to-day technical operation of the calibration laboratory, including schedules, maintenance, and record keeping.

Organizational Chart

Sections 5.2.b and 5.2.c of the Z540 discuss the laboratory organization and the relationships between the parts of the organization. The Division offers five areas of calibration services: 1) spectroradiometric source measurements, 2) radiance temperature measurements, 3) optical properties of materials measurements, 4) photometric measurements, and 5) spectroradiometric detector measurements. Each calibration laboratory involves two to four individuals: project leader, technical manager, and possibly one or two staff personnel. Figure 1 shows the organization of the calibration services offered by the Division at NIST. There is usually only one technical manager for a laboratory. The Division has two technical managers because of the existing organization structure in the Division. Independent of the quality system organization structure, there are groups within the Division. Each group has a group leader for administrative purposes.

Documentation Organization, Control, and Maintenance

The Division's quality systems manual is organized into three sections. The three sections form a pyramid shape, with the top section being the Division's quality system policies. The middle section contains the Division's procedures that uniformly apply to all calibration service laboratories (e.g., complaint procedures). The bottom section is the laboratory procedures for each calibration service. The top and middle section reside in the Division Quality System Policy and Procedure Manual. The bottom section resides in the Calibration Service Procedures Manual. The structure of the Division's quality system documentation is shown in Figure 2.

The quality manager maintains the master copy of the Division's quality policies and procedures. The Division's quality system policies rarely change, but the Division's procedures change as needed. These procedures are reviewed and approved by the quality manager and division chief. The project leaders maintain the master copies of the laboratory procedures for their calibration service. These procedures are revised as needed and reviewed and approved by the technical manager. Copies of the approved procedures are kept by the quality manager.

The quality system manuals are numbered and assigned to individuals, who are responsible for maintaining the manual under their control. The quality manager maintains the list of all individuals assigned a quality system manual. Every section of the quality system manual is identified by version numbers. Current version numbers are listed at the front of each manual. The quality system manual is reviewed annually by the quality manager to ensure its suitability and effectiveness. The quality system manual is a document that evolves over time and is continually being refined.

Six Essential Areas of a Quality System

Six essential areas were identified first as requiring documentation (or standardization of documentation) after reviewing the Z540. Described below are the six essential areas identified: quality manual, equipment records, calibration methods, computer software documentation, test report format, and complaint handling procedures. These are the first sections of the quality manual that were documented.

1) Quality Manual

The quality manual follows the framework of section 5.2 of the Z540. Parts (a) through (d) describe the objectives and commitments by management to quality and contains a quality policy statement (see Figure 3), the organization structure and relationship among the various parts, and the procedures for document control and maintenance. Procedural topics are addressed in parts (i) and (o) through (s), such as, review of all new work, feedback and corrective actions when

discrepancies are detected, complaints, protecting the confidentiality and proprietary rights of customers, and audit and review of the calibration laboratory. These subsections of 5.2 are the same for all the calibration service laboratories.

Parts (e) through (h) and (j) through (n) of section 5.2 were written specifically for each calibration laboratory. They cover such topics as: job descriptions, the scope of measurements for the calibration laboratory, calibration procedures, major equipment, and method for determining the basis of the measurements (i.e., measurement scale).

2) Equipment Records

Z540 section 8.4 describes laboratory equipment record requirements. The equipment records in the Division's quality system manual contain the following: type of equipment, manufacturer, serial number, NIST identification number, current location, date of last calibration, and due date of next calibration. The location of calibration and maintenance records and equipment manuals is also listed in the quality system manual.

3) Calibration Methods

Section 10 of the Z540 stipulates the inclusion of calibration and test methods. Many calibration services at NIST are documented in the NIST Special Publication 250 series (SP250). The SP250 document describes a specific calibration service, including, the technical background, calibration method, and uncertainty estimates. The quality system manual combines the information in the appropriate SP250 with additional detail pertinent to the quality management effort. The SP250 describes a calibration service at a specific time and is not continually revised; whereas, the quality system manual is a "living document"; which is revised whenever a change is made in any part of the process or quality system.

4) Computer Software Documentation

Part 7 of Section 10 of the Z540 covers the requirements regarding the use of computers when used as part of the calibration process. A major element of part 7 concerns the documentation of the software used. The Division's software documentation consists of five elements: documented computer code, flow chart, defined input and output for the program and subroutines, data location and format, and user manual.

Configuration control of calibration software is a fundamental ingredient of quality management. Calibration software is changed infrequently, and only after new versions of programs are verified with test data or some other means to confirm that the software functions as expected. The calibration software version is identified and listed with the test records kept for each calibration.

An important part of maintaining a computer is taking appropriate steps to prevent unauthorized use, and protection from inadvertent loss of data (i.e., a hard disk crash). To minimize loss, all data is backed up on a regular schedule.

5) Test Report Format

Z540 section 13 concerns test certificates and reports. In particular, section 13.2 lists several items that should be included in test certificates and reports. The more significant items are the following: name of the laboratory, unique identification of the test certificate or report, description and unambiguous identification of the test item, calibration method used, test results (tables, graphs, etc.), estimated uncertainty, and the names of the person(s) responsible for the content of the test report. The more significant requirements of section 13 were already a part of the Division's report structure.

The objective for the Division was to unify the test report format for each of its calibration laboratories. A common format is used by each calibration laboratory, with only minor changes being made to suit a particular requirement. The standard test report issued by the Division is easier for our customers to understand, particularly since some of them receive reports from several calibration service laboratories within the Division. An example of the test report format is shown in Figure 4.

In the Division's quality system, section 13 is divided into two sections: 13A and 13B. Section 13A resides in the Division Policy and Procedure manual. The generic samples, "Report of Test" and "Report of Calibration", are located in the appendixes of Section 13A. The specific examples of "Report of Test" and "Report of Calibration" for each Calibration Service are located in the Calibration Service Procedures Manual in part 13B.

6) Complaint Handling Procedures

Section 16 of the Z540 requires the laboratory to have a documented policy and procedure for resolving complaints and recording the actions taken in resolving the complaint. The Division's policy on complaints is located in the Division Policy and Procedures Manual section 16. Section 16 also contains the standard operating procedure to follow when documenting a complaint, and includes a complaint response form and complaint log. An example of the complaint response form is shown in Figure 5. Each Calibration Service has in its Calibration Service Procedures Manual the complaint response form log for that service. A master list is maintained by the Division Secretary.

The Division employs a number of practices to decrease the chance of errors and complaints. The input and output of every calibration laboratory are defined, measurements are not taken until clearly defined criteria are met. These definitions help eliminate misunderstandings among the calibration staff members or between the staff and customers. Every calibration laboratory in the Division posts a schedule of calibrations and tests and has a test item checklist to track the progress of each test or calibration. The checklist is included in the records for that test item. An example of the test item checklist is shown in Figure 6. Every calibration staff member keeps a phone log of communications with customers, a practice that is essential in reconstructing events and resolving a complaint if one is ever made.

The remaining sections of the Quality System Documentation

Records

Section 12 of the Z540 stipulates that the records of the calibration or test must be maintained in sufficient order to reproduce the measurement if necessary. The Division had already maintained the records of the test reports and associated administrative paperwork in a central location. This was another example of an established system that just needed to be documented. Section 12 of the Division's Quality System resides in the Calibration Service Procedures Manual. Each project leader is responsible for maintaining the records of each measurement. Each calibration service has a unique laboratory notebook where records of the measurement are kept. Section 12 describes the location of where to find these records.

Sub-contracting

The Division does not sub-contract its calibration work. Section 14 of the Z540 is not included in the Division's Quality System.

Personnel, Accommodation and Environment, and Handling of Test Items

The Division Calibration Staff had prepared similar sub-sections for the NIST Handbook 150-2. We updated and verified our recommendations. Section 6 of the Z540 documents personnel records and files. All of the Division's personnel records are maintained by the NIST Administration. In order not to duplicate effort, Section 6 points to the location of these files. Section 6 also contains a resume of each of the calibration staff. Since the sub-sections are unique to each calibration service, these sections are found in the Calibration Service Procedures Manual.

Measurement traceability

Section 9 of the Z540 deals with the requirements of documenting the measurement traceability. The establishment of the Calibration Service's measurement scale and lists of round robins and interlaboratory comparisons with other national laboratories are found in Section 9.

Outside support

Section 15 specifies requirements for purchases of outside support materials and services directly effecting the measurements. The records for all purchases have been maintained by the Division. The Calibration Service Procedures Manual will contain a list of specifications for such equipment and will point to where the existing records are located.

The Experience of Building a Quality System

The critical first step to building a quality system based on the Z540 was a commitment from management. It is through commitment from management that time, resources, and materials are allocated for the substantial documentation effort that is required to be compliant with Z540.

The second step was designating a quality manager and deputy to coordinate the effort. This team, in conjunction with Division management, identified the persons to be involved and described their relationships in the quality management structure. Once the appropriate structure was in place, the duty of allocating writing and organizing tasks could be assigned and its progress monitored. Setting specific completion deadlines for various aspects of the quality system implementation was essential.

The experience of the Division in building a quality system is probably similar to other calibration and testing facilities. Many parts of the quality system existed (i.e., uncertainty estimates, records, documented procedures, etc.), but had not been uniformly organized. The work in building a quality system is in documenting procedures and processes now done by memory (e.g., when to calibrate a piece of equipment or equipment maintenance procedures) or handled on a case by case basis (e.g., complaints).

The documentation of a quality system seems to be an overwhelming task at first. It can seem perplexing in the beginning, principally due to the lack of specific real world examples to follow. Dividing the Z540 documentation process into sections made the task less intimidating.

Building a quality system based on Z540 in the Radiometric Physics Division has begun. Once the construction ends, the never ending maintenance of a quality system begins. It is important to remember that a competent quality system is continually being reviewed and improved as the laboratory is continually improving and modifying its services.

References

[1] American National Standard for Calibration - Calibration Laboratories and Measuring and Test Equipment, ANSI/NCSL Z540-1-1994

[2] M. A. Breitenberg, *Questions and Answers on Quality, the ISO 9000 Standard Series, Quality System Registration, and Related Issues*, NISTIR 4721 (U.S. Government Printing Office, Washington, DC, 1993), pp. 2.

[3] The Recommended Practices from the National Conference of Standards Laboratories (NCSL) can be obtained from the NCSL Secretariat, 1800 30th Street, Suite 305B, Boulder, Colorado, USA 80301.

[4] NIST Handbook 150-2, The National Voluntary Laboratory Accreditation Program Calibration Laboratories Technical Guide.

Acknowledgments

The authors are indebted to J. Cigler and J. Crickenberger from the National Voluntary Laboratory Accreditation Program (NVLAP) for their instruction on the subject of the Z540; P. Wychorski from Eastman Kodak Company and K. Jaeger from Lockheed Missile and Space Company for their encouragement; C. Cromer, A. Parr, and B. Saunders for their motivation and support. The authors would like to give special thanks to the calibration laboratory staff in the Radiometric Physics Division for their assistance, Y. Barnes, C. Gibson, J. Jackson, and Y. Ohno.

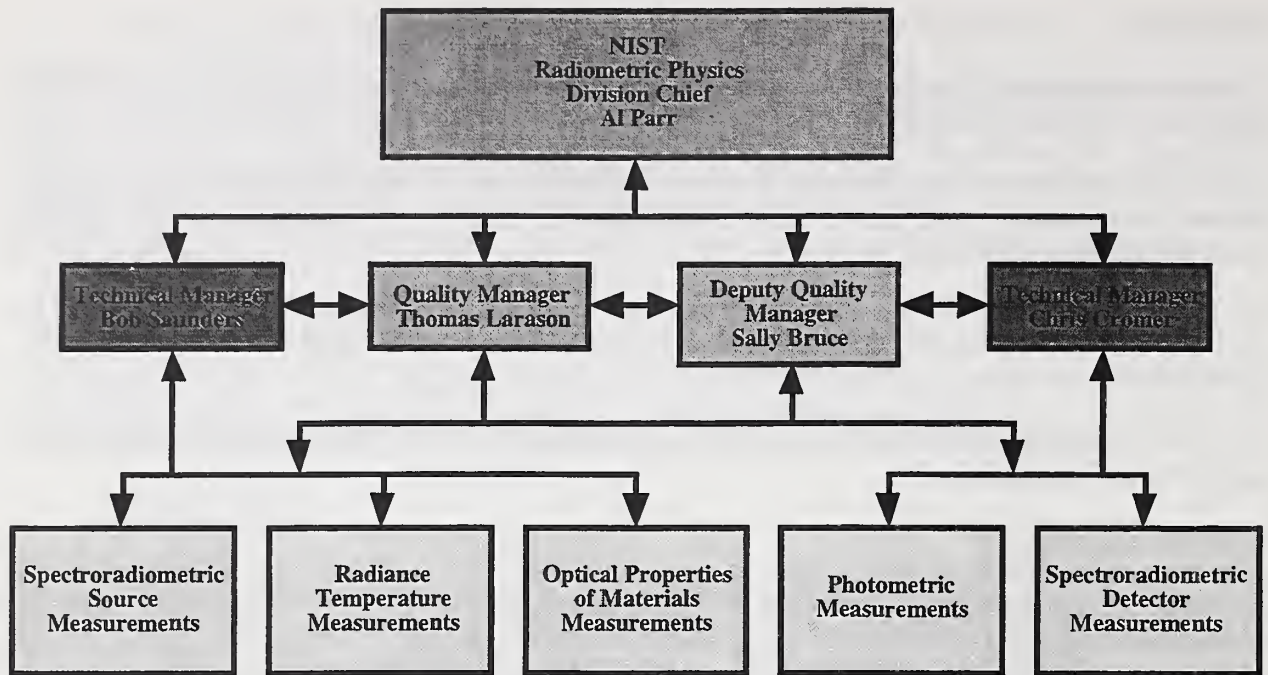


Figure 1. Radiometric Physics Division Calibration Services Organization Chart

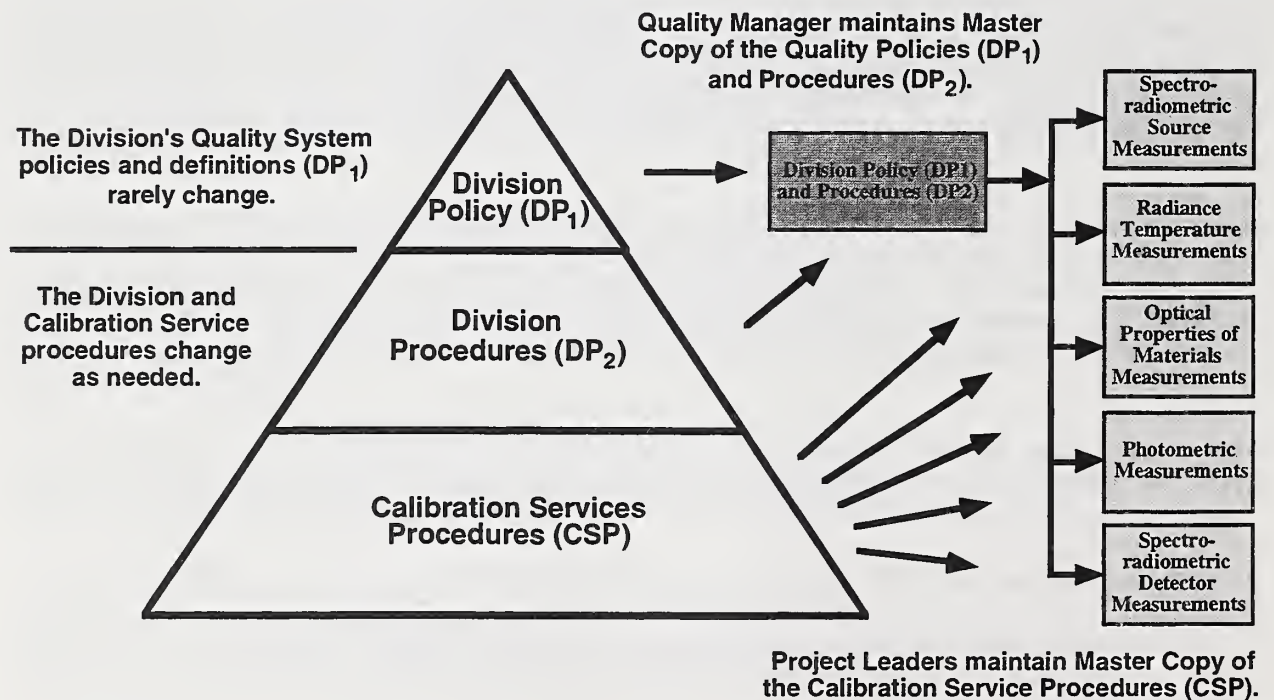


Figure 2. The structure of the Division's quality system documentation is shown.

Section 5: Quality System, Audit and Review

Written By: Sally Bruce

Version: 1.0

Approved By: _____

Date: _____

Revised By: _____

Date: _____

5 Quality System, Audit and Review

5.1 This section documents the Laboratory's (Division 844) quality system. This documentation shall be available for use by the calibration service personnel. This section documents the Laboratory's policies and objectives for, and its commitment to, good laboratory practice and quality of calibration services. The Laboratory management shall ensure that these policies and objectives are documented and communicated to, understood, and implemented by all calibration service personnel concerned. The quality manual shall be maintained current under the responsibility of the Quality Manager.

5.2 The Laboratory's (Division 844) policies and operational procedures related to quality management are documented below. The calibration services offered by the Radiometric Physics Division (844) include Spectroradiometric Source Measurements, Radiance Temperature Measurements, Optical Properties of Materials Measurements, Photometric Measurements, and Spectroradiometric Detector Measurements. Each calibration service has its own subsection where appropriate. This section is referred to as the "quality manual."

- a) **Quality Policy Statement.** The Radiometric Physics Division of NIST maintains the National Standards for radiation thermometry, spectroradiometry, photometry, and spectrophotometry. These standards are disseminated to customers requiring calibrations of the highest accuracy obtainable in the United States and requiring reference to the national standards of optical radiation maintained at NIST. The Radiometric Physics Division's quality policy is:


We shall provide the highest accuracy optical radiation tests and calibrations obtainable in the United States to our customers.

Responsibility for implementing this policy has been delegated to the staff through the technical management chain. This manual contains the quality objectives endorsed by the entire technical management chain. Management in the Radiometric Physics Division is committed to:

providing each calibration service with the time, resources, and materials necessary to carry out these services.

- b) The organizational chart of the Quality System for the calibration services offered by

Figure 3. The Quality Policy Statement from the Radiometric Physics Division's Quality Manual is shown.

| | | |
|---|--|--|
|  | NIST | <small>UNITED STATES DEPARTMENT OF COMMERCE National Institute of Standards and Technology Gaithersburg, Maryland 20899-0001</small> |
| REPORT OF TEST Test Number as listed in SP250 for Test Item Identification, Model #, Serial # Submitted by: Mr. John Doe Any Company 123 Calibration Court Measurement City, MD 00000-0000 (See your Purchase Order No. PO 98765 dated January 1, 1993) | | |
| 1. Description of Test Item | | |
| In this section give a description and unambiguous identification of the Test Item. The characteristics and condition of the Test Item as appropriate. | | |
| 2. Description of Test | | |
| In this section give a brief description of the test or calibration referring to other documents where appropriate (i.e. SP250's, ASTM standards, etc.). Appropriate influence parameters such as, environmental conditions (temperature and humidity are at the bottom) and S/N of working standards used. | | |
| 3. Results of Test | | |
| In this section give the results: tables, graphs, sketches, etc. (or refer to them if placed at the end of the report); and the estimated uncertainty ($k = 2$) of the test. | | |
| Prepared by: | Approved by: | |
| (Name of Person Writing Report) Radiometric Physics Division Physics Laboratory (301) 975-xxxx | (Name of Group Leader) For the Director, National Institute of Standards and Technology (301) 975-xxxx | |
| Laboratory Environment: Temperature: $23.x \pm 0.3$ °C Relative Humidity: $4x \pm 2.2$ % | | |
| Test Date: May 14, 1993 NIST Test No.: 844/123456-93/y (y if more than one item with test folder.) | | |
| | | Page 1 of 2 |

13B-1

Macintosh HD:Public:ISO:[13] ISO Quality System.844

Figure 4a. Example of the Test Report first page Format for the Radiometric Physics Division

REPORT OF TEST

Test Number as listed in SP250
Any Company

Model #: abcd
Serial #: 1234

References:

- [1] E. F. Smith "The First Example Reference." National Bureau of Standards (U.S.), Special Publication 250-17 (1988).
- [2] G. Laurel and J. E. Hardy, "The Second Example Reference." Applied Optics 30. 3091-3099 (1991).

Figure 1
Title of Figure



Table 1
Title of Table

| Wavelength (nm) | Response (A/W) | Wavelength (nm) | Response (A/W) | Wavelength (nm) | Response (A/W) |
|-----------------|----------------|-----------------|----------------|-----------------|----------------|
| 400 | 1.825E-01 | 435 | 2.114E-01 | 470 | 2.357E-01 |
| 405 | 1.871E-01 | 440 | 2.151E-01 | 475 | 2.389E-01 |
| 410 | 1.916E-01 | 445 | 2.186E-01 | 480 | 2.422E-01 |
| 415 | 1.959E-01 | 450 | 2.223E-01 | 485 | 2.455E-01 |
| 420 | 1.999E-01 | 455 | 2.257E-01 | 490 | 2.485E-01 |
| 425 | 2.039E-01 | 460 | 2.291E-01 | 495 | 2.517E-01 |
| 430 | 2.077E-01 | 465 | 2.323E-01 | 500 | 2.548E-01 |

Test Date: May 14, 1993
NIST Test No.: 844/123456-93/y (y if more than one item with test folder.)

Page 2 of 2

13B-2

Macintosh HD:Public:ISO:[13] ISO Quality System.844

Figure 4b. Example of the Test Report Format second page for the Radiometric Physics Division

Complaint Response Form

Lab Complaint Number: _____

Calibration Service Complaint Number: _____

Lab Personnel
Receiving
Complaint: _____

Date Received: _____

Ext.: _____

Project Leader: _____

Date Forwarded: _____

Ext.: _____

Forwarded To: _____

Date Forwarded: _____

Ext.: _____

Customer: _____

Phone Number: _____

Point of Contact: _____

FAX Number: _____

Complaint:

Action Taken:

Date Closed: _____

TM Initials: _____

Project Leader Initials: _____

QM Initials: _____

16-3

Larason HD:ISO Guide 25:ISO Section 16:[16] ISO Complaints

Figure 5. The Complaint Response Form allows the calibration staff and management to track customer complaints to resolution.

Checklist

___ Calibration ___ Special Test

PO #: _____ Test #: _____
 Model #: _____ Test Folder #: _____
 Serial #: _____ Storage Location: _____

| <u>No.</u> | <u>Item</u> | <u>Initials</u> | <u>Date</u> |
|------------|--|-----------------|-------------|
| 1. | Test item received | _____ | _____ |
| 2. | PO received | _____ | _____ |
| 3. | Test Folder received | _____ | _____ |
| 4. | Schedule measurement | _____ | _____ |
| 5. | Acceptance Form mailed | _____ | _____ |
| 6. | Measure test item | _____ | _____ |
| | Test Dates: | | |
| | Working Standards Used: | | |
| 7. | Analyze data | _____ | _____ |
| 8. | Write report | _____ | _____ |
| 9. | Preparer's signature: report finished, data checked, and test item checked. | _____ | _____ |
| 10. | To Technical Manager for signature | _____ | _____ |
| 11. | To Division Chief for signature | _____ | _____ |
| 12. | Mail original Test Report(s) to Customer Send paperwork to Accounts and to Calibration Services | _____ | _____ |
| 13. | Pack test item w/ shipping items: packing list, test report, POC, etc. | _____ | _____ |
| 14. | Take to Shipping | _____ | _____ |

Figure 6. An Example of the Test Item Check-off List that is included in the records for each calibration or test.



NIST

UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-0001

REPORT OF TEST

Test Number as listed in SP250

for

Test Item Identification, Model #, Serial #

Submitted by:

Mr. John Doe
Any Company
123 Calibration Court
Measurement City, MD 00000-0000

(See your Purchase Order No. PO 98765 dated January 1, 1993)

1. Description of Test Item

In this section give a description and unambiguous identification of the Test Item. The characteristics and condition of the Test Item as appropriate.

2. Description of Test

In this section give a brief description of the test or calibration referring to other documents where appropriate (i.e. SP250's, ASTM standards, etc.). Appropriate influence parameters such as, environmental conditions (temperature and humidity are at the bottom) and S/N of working standards used.

3. Results of Test

In this section give the results: tables, graphs, sketches, etc. (or refer to them if placed at the end of the report); and the estimated uncertainty ($k = 2$) of the test.

Prepared by:

Approved by:

(Name of Person Writing Report)
Radiometric Physics Division
Physics Laboratory
(301) 975-xxxx

(Name of Group Leader)
For the Director,
National Institute of
Standards and Technology
(301) 975-xxxx

Laboratory Environment:
Temperature: $23.x \pm 0.3$ °C
Relative Humidity: $4x \pm 2.2$ %

Test Date: May 14, 1993
NIST Test No.: 844/123456-93/y (y if more than one item with test folder.)

Page 1 of 2

REPORT OF TEST

Test Number as listed in SP250
 Any Company

Model #: abcd
 Serial #: 1234

References:

- [1] E. F. Smith "The First Example Reference," National Bureau of Standards (U.S.), Special Publication **250-17** (1988).
- [2] G. Laurel and J. E. Hardy, "The Second Example Reference," Applied Optics **30**, 3091-3099 (1991).

Figure 1
 Title of Figure



Table 1
 Title of Table

| Wavelength (nm) | Response (A/W) | Wavelength (nm) | Response (A/W) | Wavelength (nm) | Response (A/W) |
|-----------------|----------------|-----------------|----------------|-----------------|----------------|
| 400 | 1.825E-01 | 435 | 2.114E-01 | 470 | 2.357E-01 |
| 405 | 1.871E-01 | 440 | 2.151E-01 | 475 | 2.389E-01 |
| 410 | 1.916E-01 | 445 | 2.186E-01 | 480 | 2.422E-01 |
| 415 | 1.959E-01 | 450 | 2.223E-01 | 485 | 2.455E-01 |
| 420 | 1.999E-01 | 455 | 2.257E-01 | 490 | 2.485E-01 |
| 425 | 2.039E-01 | 460 | 2.291E-01 | 495 | 2.517E-01 |
| 430 | 2.077E-01 | 465 | 2.323E-01 | 500 | 2.548E-01 |

Test Date: May 14, 1993
 NIST Test No.: 844/123456-93/y (y if more than one item with test folder.)

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