

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

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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] Breitenberg, M. A., *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

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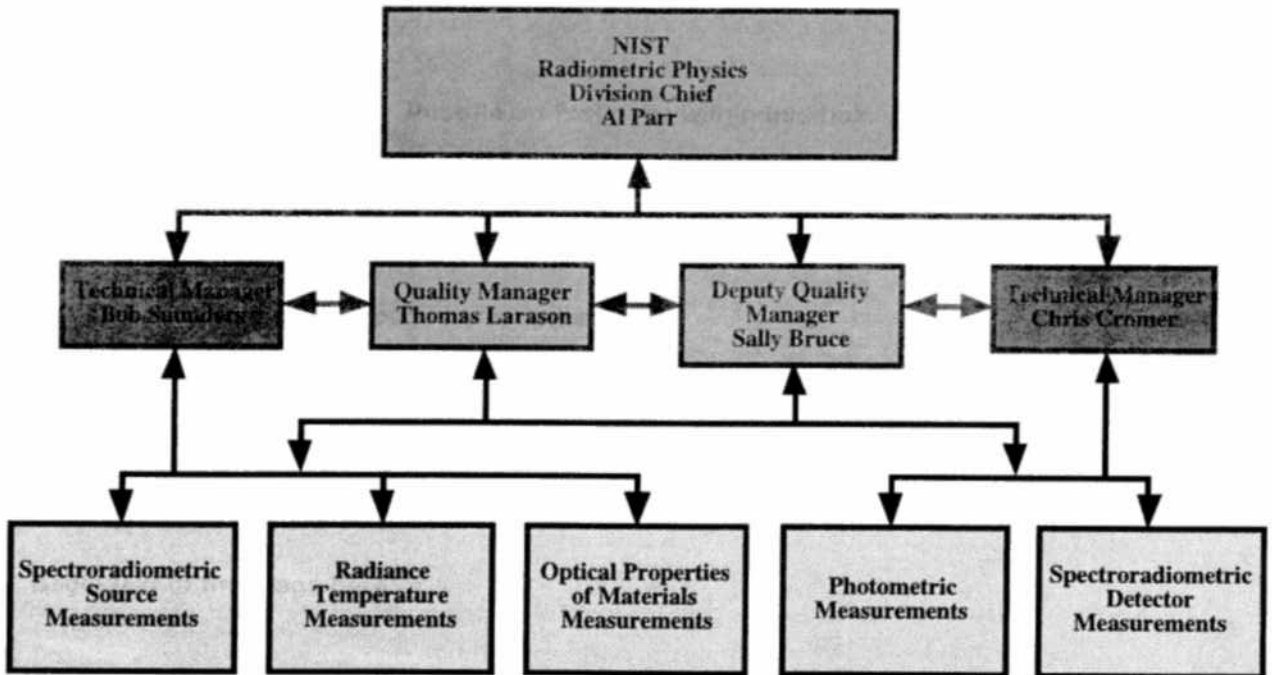


Figure 1. Radiometric Physics Division Calibration Services Organization Chart

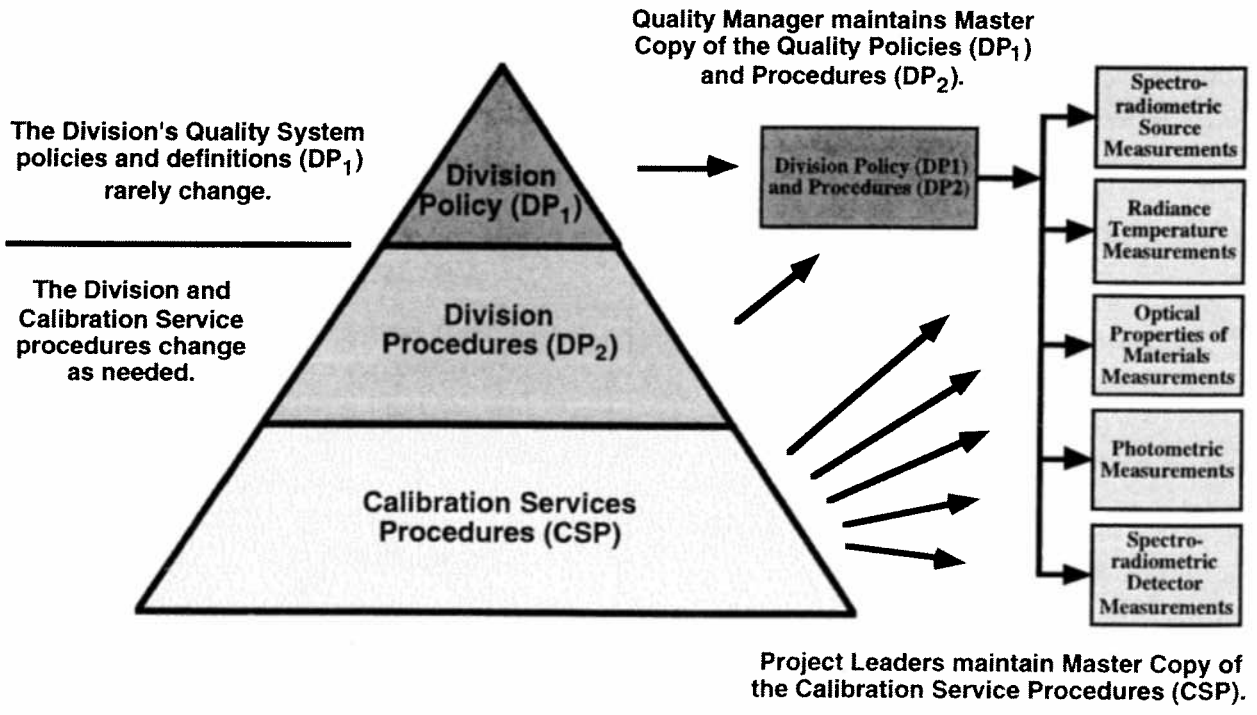


Figure 2. The structure of the Division's quality system documentation is shown.

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

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 (2 sigma) of the test or calibration.

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.)

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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

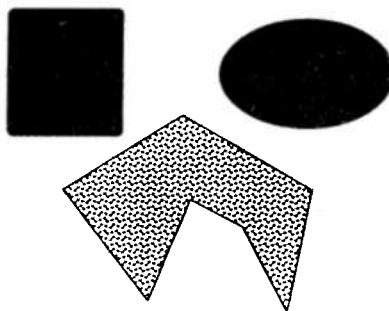


Table I
 Title of Table

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 x

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

Figure 4 b 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 Checklist that is included in the records for each calibration or test.