

Document is uncontrolled in printed form.

**NIST Ceramics Division
Quality Manual**

for

**Standard Reference Material
Production Projects**

QM-III-852.01

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	1 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

Table of Contents (linked)

1.	INTRODUCTION.....	5
1.1	Commitment to Quality.....	5
1.2	Scope.....	5
1.3	Outline of CD Project Level Quality Manual.....	5
2.	REFERENCES.....	6
2.1	Normative Reference	6
2.2	Informative References	6
3.	DEFINITIONS	6
4.	MANAGEMENT REQUIREMENTS	6
4.1	The Ceramics Division.....	6
4.1.1	Description.....	6
4.1.2	Physical Locations	6
4.1.3	Organizational Structure of CD	7
4.1.3.1	Organizational Chart.....	7
4.1.3.2	Responsibilities, Authorities, and Delegations	7
4.2	CD Quality System.....	7
4.2.1	CD Quality Policy.....	7
4.2.2	CD Quality Objectives.....	7
4.2.3	Organizational Structure of the CD QS	7
4.2.3.1	Organizational Chart of Quality Managers.....	7
4.2.3.2	Responsibilities, Authorities, and Delegations	7
4.3	Control of Documents, Records, and Data	8
4.3.1	Quality Documents	8
4.3.2	Quality Document Approval and Issue.....	8
4.3.3	Quality Document Changes	8
4.3.4	Technical Documents, Records, and Data	8
4.4	Administrative Requirements.....	9
4.4.1	Review and Approval of Requests for Measurement Services.....	9
4.4.1.1	Reference Material Activities	9

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	2 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

4.4.1.2	Other CD Measurement Services.....	9
4.4.2	Procuring Products and Services from External Sources	9
4.4.3	Interaction with NIST Supporting Divisions	9
4.4.4	Subcontracting of Measurement Services.....	10
4.4.5	Planning and Control of Measurement Service Delivery	10
4.5	Corrective and Preventive Actions.....	10
4.5.1	Non-Conformity and Corrective Actions.....	10
4.5.2	Customer Feedback and Concerns.....	10
4.5.3	Preventive Actions	10
4.6	Assessments and Management Reviews.....	10
4.6.1	Assessments	10
4.6.1.1	NIST-Level Assessments.....	10
4.6.1.2	CD-Level Assessments	11
4.6.2	Reviews by CD Management	11
4.6.2.1	Quality Documents	11
4.6.2.2	Technical Competence.....	11
4.7	Service to the Client.....	11
5.	TECHNICAL REQUIREMENTS	11
5.1	Introduction.....	11
5.2	Personnel.....	11
5.2.1	Competence.....	12
5.2.2	Education and Training Goals	12
5.2.3	Job Descriptions.....	12
5.2.4	Collaborators.....	12
5.3	Accommodations and Environmental Conditions	12
5.4	Measurement Procedures and Procedure Validation	12
5.4.1	Measurement Procedures	12
5.4.2	Method Validation	12
5.4.3	Estimation of Uncertainty	13
5.4.4	Evaluation and Control of Data	13
5.5	Equipment	13
5.6	Traceability.....	13
5.7	Sampling, Preparation, Homogeneity, and Stability for Reference Materials	13
5.8	Handling of Test and Calibration Items	13

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	3 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

5.9	Quality Assurance Practices	13
5.10	Reporting Results.....	14
APPENDICES.....		14
Appendix A: Acronyms		14
Appendix B: Definitions		14

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	4 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

INTRODUCTION

QM-III-852.01 (the present document) is the project-level quality manual (QM) for the production of Standard Reference Materials (SRMs) in the Ceramics Division (CD). This document conforms to the requirements of the National Institute of Standards and Technology (NIST) Quality Manual (NIST-QM-I) and expands the policy and objectives of the NIST-level quality manual, NIST-QM-I, and the Division-level quality manual, QM-II-852, to provide a framework within which CD staff members realize these quality objectives. CD is committed to the use of good laboratory practices and quality management.

1.1 Commitment to Quality

The provision, production, and certification of SRMs (known generally as “measurement services” or “services” in this document) is an essential element of the work performed by the CD in fulfilling its mission. In the conduct of this vital work, as in all its efforts, the CD is committed to performance excellence characteristic of a global leader in measurements and standards. Our goal is to provide measurement services that meet the needs of our customers and, through continuous improvement, to strive to anticipate their needs, exceed their expectations, and deliver outstanding value to the Nation. All staff members whose activities affect the quality of our services are expected to be familiar with the CD Quality System (QS), including the provisions of the present document, and to be conscientious in their implementation. The CD strives to maintain its Quality System in conformity with the international standard ISO/IEC 17025, to the extent allowed by statute and regulation.

Debra L. Kaiser, Ph.D.
Chief, Ceramics Division

1.2 Scope

QM-III-852.xx documents conform to QM-II-852 and NIST-QM-I and describe CD quality policies, procedures, and objectives specific to the SRM production and certification activities of the CD.

1.3 Outline of CD Project-Level Quality Manual

The CD project-level quality manual (QM-III-852.01, this document) is a third-level document as described in NIST-QM-I section 1.3. It contains policies and procedures established and maintained by the CD to meet its quality goals for Standard Reference Materials developed by the CD. QM-III-852.01 contains quality-specific policies and procedures established and maintained for: each SRM produced by the CD; technical procedures for measurement services; definitions of measurement service specific terms; list of personnel responsible for this

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	5 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

measurement service; technical training requirements for measurement personnel; procedures for observations, data acquisition, and data analysis; list of laboratory requirements; description of uncertainty analyses; and other technical issues relevant to the quality system for this measurement service.

2. References

2.1 Normative References

NIST Quality Manual (NIST-QM-I)
Ceramics Division Quality Manual (QM-II-852)

2.2 Informative References

NIST Special Publication 811 – “Guide for the Use of the International System of Units (SI)” – <http://physics.nist.gov/Pubs/SP811/contents.html>

NIST Technical Note 1297 – “Guideline for Evaluating and Expressing the Uncertainty of NIST Measurement Results” – <http://physics.nist.gov/Document/tn1297.pdf>

3. Definitions

General definitions are given in QM-II-852, Section 3. More specialized definitions required for the present document are given in Appendix B.

4. Management Requirements

4.1 The Ceramics Division

4.1.1 Description

Description of CD management requirements are given in QM-II-852, Section 4.

4.1.2 Physical Locations

CD measurement services are conducted in NIST facilities in the Materials Science and Engineering Laboratory (Building 223), the Advanced Measurement Laboratory (Buildings 217 and 219), and the Center for Neutron Research (Building 235) in Gaithersburg, Maryland, and in the National Synchrotron Light Source at Brookhaven National Laboratory, Upton, New York.

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	6 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

4.1.3 Organizational Structure of the CD

CD is part of the Materials Science and Engineering Laboratory (MSEL) of the National Institute of Standards and Technology (NIST) which is an agency within the Technology Administration of the Department of Commerce.

4.1.3.1 Organizational Chart

The current NIST organizational charts are found at the following website: <http://orgchart.nist.gov>. The management chain for CD is given in the chart for the Materials Science and Engineering Laboratory <http://www.msel.nist.gov/mselorg.html>.

4.1.3.2 Responsibilities, Authorities, and Delegations

General responsibilities in the CD are described in QM-II-852, Section 4.1.3.2, and general responsibilities for SRM development and production are described in the NIST Administrative Manual Subchapter 5.19. Any specific responsibilities, authorities, or delegations unique to the provision of a particular measurement service are documented in the SRM statement of work.

4.2 CD Quality System

4.2.1 CD Quality Policy

CD SRM projects are committed to following the NIST Quality System outlined in QM-I, section 4.2.1.

4.2.2 CD Quality Objectives

The CD quality objectives are those put forth in QM-I, Section 4.2.2.

4.2.3 Organizational Structure of the CD QS

4.2.3.1 Organizational Chart of Quality Managers

The CD organizational chart of quality managers is set forth in QM-II-852, Section 4.2.3.1.

4.2.3.2 Responsibilities, Authorities, and Delegations

Responsibilities, authorities, and delegations are set forth in QM-II-852, Section 4.2.3.2.

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	7 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

Additional responsibilities of Quality Managers may be included in SRM statements of work.

4.3 Control of Documents, Records, and Data

4.3.1 Quality Documents

Quality documents (including reports from internal assessments, reviews by management, and records of non-conformities and corrective and preventive actions) are managed following the specifications in NIST-QM-I and the NIST [Administrative Manual Subchapter 2.06 on Records Management](#). CD staff comply with Subchapter 11.02 (www-i.nist.gov/admin/mo/adman/1102.HTM) governing computer and information security.

4.3.2 Quality Document Approval and Issue

The Technical Project Leader (TPL) for any CD SRM project is responsible for obtaining managerial approval of proposed revisions of QM-III-852.01 prior to implementation. The official version of QM-III-852.01 is maintained by the Division Quality Manager on the CD web site. This official version of QM-III-852.01 is accessible as a read/print-only document. This copy is updated (replaced) with each new and approved version of QM-III-852.01, and previous versions and dates of applicability are retained. Printed copies are clearly marked as uncontrolled documents.

4.3.3 Quality Document Changes

Changes to QM-III-852.01 are processed in conformity with QM-II-852, Section 4.3.3.

The Division Quality Manager notifies CD personnel when a revised version of QM-III-852.01 is official and available on the CD web site.

4.3.4 Technical Documents, Records, and Data

It is the responsibility of individual staff members to maintain appropriate technical records in support of the development and certification of SRMs in the CD and to provide all such records as needed to the Technical Project Leader. Records sufficient to reproduce assigned values from analysts' determinations are maintained by the TPL and are readily retrievable. Technical records include:

- Statements of work;
- Notes, notebooks, and/or documents that describe material handling, sample selection, sample preparation, measurement equipment, measurement conditions, and data analysis;
- Data used to produce final measurement results and certified values.

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	8 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

Observations and data are recorded, annotated with the date and time data, and identified as to the specific task. When mistakes occur in written records, particularly in laboratory notebooks, each mistake is crossed out and the correct information entered alongside or as near to the original as practicable. Alterations to records are initialed by the person making the correction. Records are legible and stored to prevent damage and minimize deterioration. Each TPL is responsible for maintaining back-up copies of electronic files, and at least one back-up copy must be in a location that is physically different from the location of the original files, such as a different building.

Records are maintained as described in NIST Administrative Manual Subchapter 2.06 (<http://www-i.nist.gov/admin/mo/adman/206.htm>) or for a minimum of ten years if not otherwise specified. CD staff comply with Subchapter 11.02 (www-i.nist.gov/admin/mo/adman/1102.HTM) governing computer and information security.

4.4 Administrative Requirements

4.4.1 Review and Approval of Requests for Measurement Services

4.4.1.1 Reference Material Activities

Technical Project Leaders are responsible for assessing customer needs and for ensuring the technical feasibility of proposed SRMs. CD annually develops a list of potential reference material projects, including both production (WCF) and prototype (SD) types of projects, in response to customer needs. Each proposed project is described in the form of an SRM Statement of Work. CD management reviews and prioritizes the SRM Statements of Work. CD follows the procedures regarding reference materials activities set forth in the NIST Administrative Manual Subchapter 5.19 for all funded SRM projects.

4.4.1.2 Other CD Measurement Services

CD measurement services outside the scope of Section 4.4.1.1 must be approved by the CD Chief and must conform to all policies and practices detailed in QM-II-852.

4.4.2 Procuring Products and Services from External Sources

CD follows the policies prescribed in QM-II-852, Section 4.4.2 for the procurement of products and services from sources external to NIST.

4.4.3 Interaction with NIST Supporting Divisions

NIST-QM-I Section 4.3.3 and the NIST Administrative Manual govern interactions with supporting services. It is the responsibility of the TPL to communicate to CD management

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	9 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

concisely and clearly the actions desired/required of NIST supporting services to allow SRM project and quality goals to be achieved.

4.4.4 Subcontracting of Measurement Services

CD follows NIST policy on subcontracting of measurement services as delineated in QM-I, Section 4.4.4.

4.4.5 Planning and Control of Measurement Service Delivery

CD follows the policies and procedures established in QM-II-852, Section 4.4.5.

4.5 Corrective and Preventive Actions

4.5.1 Non-Conformity and Corrective Actions

The procedures for handling corrective and preventive actions are described in QM-II-852, Section 4.5.1 and NIST-QM-I, Section 4.5.1.

4.5.2 Customer Feedback and Concerns

The procedures for handling customer feedback and concerns are described in QM-II-852, Section 4.5.2 and NIST-QM-I, Section 4.5.2.

4.5.3 Preventive Actions

The procedures for handling preventive actions are described in QM-II-852, Section 4.5.3 and NIST-QM-I, Section 4.5.3.

4.6 Assessments and Management Reviews

4.6.1 Assessments

4.6.1.1 NIST-Level Assessments

CD participates in the NIST-level assessments described in NIST-QM-I Section 4.6.1.

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	10 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

4.6.1.2 CD-Level Assessments

The procedures for handling CD-level assessments are described in QM-II-852, Section 4.6.1.2.

4.6.2 Reviews by CD Management

The procedures for handling reviews by CD management are described in QM-II-852, Section 4.6.2.

4.6.2.1 Quality Documents

QM-III-852.01 is reviewed annually by the Technical Project Leader and the Division Quality Manager for consistency with QM-II-852 and NIST-QM-I. Each SRM Statement of Work is reviewed at the time of its proposal by the Technical Project Leader and the Division Quality Manager for consistency with QM-II-852 and NIST-QM-I.

4.6.2.2 Technical Competence

The policies and procedures for ensuring technical competence are described in QM-II-852, Section 4.6.2.2.

4.7 Service to the Client

CD follows the policies and procedures established in NIST-QM-I Section 4.7 and QM-II-852, Section 4.7.

5. Technical Requirements

5.1 Introduction

The policies and procedures included in this manual (QM-III-852.01) with respect to technical requirements are only those that apply to SRM production in the CD. All other technical requirements will be found in, or referenced in, NIST-QM-I and QM-II-852.

5.2 Personnel

The authorized project team for each SRM is listed in the SRM Statement of Work. A copy of the Statement of Work is maintained by the Technical Project Leader (a.k.a. Technical Project Manager) and the Group Leader. Others may participate in this work under the direction of the

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	11 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

Technical Project Leader with the approval of the Group Leader who provides administrative oversight for the project.

5.2.1 Competence

The qualifications of the members of the project team comply with QM-II-852, Section 5.2.1.

5.2.2 Education and Training Goals

Education and training requirements comply with QM-II-852, Section 5.2.2.

5.2.3 Job Descriptions

CD follows the policies and procedures established by NIST in NIST-QM-I Section 5.2.3.

5.2.4 Collaborators

CD follows the policies and procedures established by NIST in NIST-QM-I Section 5.2.4.

5.3 Accommodations and Environmental Conditions

The accommodations and environmental conditions comply with QM-II-852, Section 5.3 and with the specifications and constraints of the MATERIAL ACQUISITION/ACCEPTANCE/PACKAGING PLAN and the EXPERIMENTAL DESIGN/CERTIFICATION PLAN in the SRM Statement of Work.

5.4 Measurement Procedures and Procedure Validation

CD follows the policies and procedures established in QM-II-852, Section 5.4.

5.4.1 Measurement Procedures

CD follows the policies and procedures established in QM-II-852, Section 5.4.1 and the EXPERIMENTAL DESIGN/CERTIFICATION PLAN of the SRM Statement of Work.

5.4.2 Method Validation

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	12 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

CD follows the policies and procedures established in QM-II-852, Section 5.4.2 and the EXPERIMENTAL DESIGN/CERTIFICATION PLAN of the SRM Statement of Work.

5.4.3 Estimation of Uncertainty

CD follows the policies and procedures established in QM-II-852, Section 5.4.3.

5.4.4 Evaluation and Control of Data

CD follows the policies and procedures established in QM-II-852, Section 5.4.4 and NIST Administrative Manual, Subchapter 14.05.

5.5 Equipment

CD follows the policies and procedures established in QM-II-852, Section 5.5 and the EXPERIMENTAL DESIGN/CERTIFICATION PLAN of the SRM Statement of Work.

5.6 Traceability

CD follows the policies and procedures established in QM-II-852, Section 5.6.

5.7 Sampling, Preparation, Homogeneity, and Stability for Reference Materials

CD follows the policies and procedures established in QM-II-852, Section 5.7, NIST Administrative Manual, Subchapter 14.05, and the MATERIAL ACQUISITION/ACCEPTANCE/PACKAGING PLAN and the STABILITY MONITORING PLAN in the SRM Statement of Work.

5.8 Handling of Test and Calibration Items

CD follows the policies and procedures established in QM-II-852, Section 5.8, and the MATERIAL ACQUISITION/ACCEPTANCE/PACKAGING PLAN and the STABILITY MONITORING PLAN in the SRM Statement of Work.

5.9 Quality Assurance Practices

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	13 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

CD follows the policies and procedures established in QM-II-852, Section 5.9, NIST Administrative Manual, Subchapter 14.05, and the EXPERIMENTAL DESIGN/CERTIFICATION PLAN of the SRM Statement of Work.

5.10 Reporting Results

CD follows the policies and procedures established in QM-II-852, Section 5.10 and NIST Administrative Manual, Subchapter 14.05. At the end of each SRM production project, a Project Completion Memorandum (QM-II-852, Appendix B) is issued.

Appendices

Appendix A: Acronyms

Only acronyms specific to QM-III-852.01 are given here. Other acronyms are given in QM-II-852, Appendix A.

Acronym	Meaning
CD	Ceramics Division
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
NIST	National Institute of Standards and Technology
NIST SP	NIST Special Publication
QM	Quality Manual
QS	Quality System
RM	Reference Material
SD	Service Development
SRM	Standard Reference Material
TPL	Technical Project Leader
WCF	Working Capital Fund

Appendix B: Definitions

Only definitions specific to QM-III-852.01 are given here. Other definitions are given in QM-II-852, Section 3.

service development: a project type preparatory to developing a Standard Reference Material and typically involves the refinement or validation of materials preparation procedures, measurement methods, or prototype specimens.

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	14 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.

NIST Division 852 Quality Manual [QM-III-852.01]

Document is uncontrolled in printed form.

Technical Project Manager: a term used by the NIST Measurement Services Division for the SRM Technical Project Leader.

working capital fund: a project type dedicated to the production of a Standard Reference Material under the auspices of the NIST Measurement Services Division.

Version	Date Approved	Author	Approval	Page	Filename
02	10/03/05	CD Quality Committee	CD Div Chief, Debra L. Kaiser	15 of 15	QM-III-852.01.doc

Document is uncontrolled in printed form.