TOXCO

MATERIALS MANAGEMENT CENTER

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QUALITY ASSURANCE PROGRAM PLAN

DOC-001

Revision 7

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REVISION RECORD

REVISION NUMBER	DATE	PAGE(S)	DESCRIPTION
0	12/24/04	All	Initial Issue
1	3/2/06	iv and 5	Updated the reference from NQA-1-2000 to NQA-1-2004
		3	Deleted statement that Toxco Managers/Supervisors "Identify quality related activities within the department under their direction."
		29	Added "Gamma Streaming Testing" to the list of tests governed by Section 11, Test Control.
		34	Updated section 13.4.3 to reflect NQA 1-2004 requirements for special handling tools.
		48	Updated Exhibit 1 to better demonstrate the relationship between DOE QA and TMMC QA requirements.
2	7/24/09		Globally changed "Toxco Material Management Center" to "Toxco Materials Management Center"
		iv and 5	Updated the reference from NQA-1-2004 to NQA-1-2008
		iv	Updated the first paragraph to reflect TMMC's current capabilities.
			Globally changed TMMC VPM to Toxco, Inc. VPM.
		1	Revised section 1.3.1.4
		9	Updated TMMC RAM License ID
		7	Revised sections 2.5.2 , 2.5.2.1, 2.6.1.1 and 2.6.2.1
		7	Added section 2.6.1.2
		8	Revised section 2.6.3
		17	Revised section 6.2
		21	Revised section 7.5.2
		22	Revised section 8.3.1
		32	Revised sections 12.4.3 and 12.5.1
		35	Revised section 13.5.3
		38	Revised section 15.3.2 and 15.4.3
		39	Revised sections 15.5.3, 15.6.3 and 15.7.2
		42	Revised section 17.2.3
		43	Added sections 17.5.2 and 17.5.3
		43	Revised sections 17.6,
		46	Revised section 19.3.3
3	3/24/2010	6	Revised sections; 1.4.1; 1.4.1.3; through 1.4.1.5 and 1.4.2
		7	Revised section 1.4.3
		8	Revised section 1.4.4
		9	Revised section 2.3.1
		10	Revised section 2.3.3.5 and 2.3.4
		12	Revised sections 2.7.1 and 2.7.2
		13	Revised section 3.3.2
		20	Revised sections 5.6.2 and 5.6.3
		48	Revised section 17.9.1
		49	Updated Org Chart
4	3/30/2012	7	Revised section 2.6.1.1
		22	Revised section 8.2.1.3
		29	Revised section 11.2.3
5	12/12/2012	All	Globally changed "TMMC General Manager" to "Vice President – TMMC"
6	7/25/2013	iv, 5 and 48	Removed reference to 10 CFR 50 Appendix B and 10 CFR 71, Subpart H. TMMC does not provide nuclear safety related services and anticipates no preparation or shipment of materials requiring implementation of 10 CFR 71, Subpart H.
7	9/17/2013	ii, iv, 5 and 48	Changes are denoted by a revision bar in the right margin.

INTRODUCTION

The Toxco Materials Management Center (TMMC) is a division of Toxco, Inc. TMMC specializes in the handling and processing (e.g., decontamination, repackaging, volume reduction, and survey for release) of radioactive wastes and materials. TMMC also can repair and refurbish equipment or materials that have radioactive contamination. TMMC maintains a radioactive material processing license under the jurisdiction of the State of Tennessee Division of Radiological Health (TDRH).

The Quality Assurance Program Plan (QAPP) sections contained herein describe TMMC's basic policy for controlling the quality of products and services being provided by TMMC. The QAPP is consistent with the applicable requirements of ASME NQA-1-2008 "Quality Assurance Program Requirements for Nuclear Facility Applications," and Title 10 of the Code of Federal Regulations, Part(s), 830 Subpart A and as well as other comparable industry standards. Exhibit 1 identifies the correlation between the 18 criterion of NQA-1, and the ten elements of 10 CFR 830 Subpart A.

Notification of revision to the QAPP and all subsequent revisions shall be transmitted by an e-mail approved by the TMMC QA Manager.

SECTION 1.0
ORGANIZATION

1.1 Purpose

This section provides requirements for the organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality. Application of the QA program is illustrated on Exhibit 2.

1.2 General

Organizational structure, functional responsibilities, levels of authority and lines of communication shall be documented.

1.3 Specific Requirements

1.3.1 The organizational structure and responsibility assignments are such that:

1.3.1.1 Senior management establishes overall expectations for effective implementation of the QA program and is responsible for obtaining the desired end result;

1.3.1.2 Quality is achieved and maintained by those assigned responsibility for performing work;

1.3.1.3 Quality achievement is verified by individuals or organizations not directly responsible for performing the work; and

1.3.1.4 Those responsible for assuring that an appropriate quality assurance program has been established and those verifying activities affecting quality have sufficient authority, direct access to responsible levels of management, organization freedom and access to work to perform their function, including sufficient independence from cost and schedule when opposed to radiological safety considerations. These verification functions include the following:

- Identifying quality problems;
- Initiating, recommending or providing solutions to quality problems through designated channels;
- Verifying implementation of solutions; and
- Assuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency or unsatisfactory condition has occurred.

1.3.2 The systems and responsibilities for controlling further utilization of nonconforming items shall be documented in implementing procedures.

1.3.3 Whenever individual titles are used, the named individual has authority to designate another qualified individual within the company in writing, verbally, or in appropriate implementing procedures, but retains the ultimate responsibility for implementing the requirement.

1.4 Organization and Position Responsibilities

1.4.1 The responsibility and authority for organizational structure and definition are vested with the Vice President – TMMC (VP – TMMC). The VP – TMMC shall:

1.4.1.1 Provide assurance that all portions of this section have been established and implemented;

1.4.1.2 Assure that organizational charts utilized to define organizational structure and functional responsibilities are maintained and accurately depict the current operational structure of the company;

1.4.1.3 Assure that organizational changes are formally documented and communicated;

1.4.1.4 Have ultimate responsibility for the establishment and enforcement of the QA program at TMMC;

1.4.1.5 Assure operations are conducted in compliance with applicable licenses, rules, regulations and operational procedures;

1.4.1.6 Provide necessary operating instructions and procedures and for ensuring that TMMC personnel are adequately trained for work activities identified as Quality Related; and

1.4.1.7 Coordinate activities and personnel at the TMMC.

1.4.2 The Radiation Safety Officer (RSO) reports to the VP – TMMC on all matters regarding the radiological control program. The RSO shall:

1.4.2.1 Provide radioactive material license compliance oversight to assure that all site activities comply with radioactive material license/permit requirements ensuring the radiological health and safety of TMMC employees and protection of the environment;

1.4.2.2 Ensure that radioactive material license required employee training program is established and implemented;

1.4.2.3 Review/approve proposals/contracts and standard operating procedures to ensure radiological safety and radioactive material license requirements are met;

1.4.2.4 Stop or delay any operation if initiation or continuation of such work would result in a violation of radioactive material license condition or endanger personnel or the environment; and

1.4.2.5 Have overall responsibility for the radiation monitoring instrumentation calibration and maintenance program.

1.4.3 The Quality Assurance Manager (QAM) reports to the VP – TMMC on all matters associated to the Quality Assurance Program. The QAM shall:

1.4.3.1 Administer and coordinate TMMC's QA program;

1.4.3.2 Maintain the QAPP in compliance with the applicable Regulations, Codes, and Standards;

1.4.3.3 Coordinate external quality assurance audits performed by customers.

1.4.3.4 Execute Quality Assurance/Quality Control (QA/QC) activities in compliance with this QAPP and approved procedures, and contract documents;

1.4.3.5 Perform investigations, surveys, audits, inspections and reports of activities performed in accordance with this QAPP;

1.4.3.6 Review procurement documents for Quality Related items and services to ensure that the quality aspects are clearly and accurately defined and are in agreement with the QAPP and implementing procedures;

1.4.3.7 Interpret and implement the QAPP and associated procedures;

1.4.3.8 Review adverse conditions with appropriate management and recommend courses of corrective action, when required, including initiation of Stop Work Orders;

1.4.3.9 Provide for timely identification and corrective action of conditions adverse to quality;

1.4.3.10 Ensure that QA/QC inspection and surveillance personnel are qualified and/or certified for their assigned work activity, and that any required qualification/certification records are on file;

1.4.3.11 Identify quality weakness, initiate, recommend or provide solutions to quality problems, and verify implementation of resolution; and

1.4.3.12 Develop, maintain and issue the Approve Suppliers List (ASL).

1.4.4 All Toxco Managers/Supervisors report to the VP – TMMC. Each responsible Manager/Supervisor shall:

1.4.4.1 Assure appropriate quality is achieved in deliverables, services and/or operations under their direction;

1.4.4.2 Assure organizational compliance with QA requirements as specified in this QAPP and implementing procedures;

1.4.4.3 Assure that TMMC personnel are trained, qualified and/or certified, as applicable to perform Quality Related assignments;

1.4.4.4 Arrange for adequate facilities and test equipment needed to achieve Quality Related program objectives;

1.4.4.5 Assure that appropriate administrative and technical procedures and instructions are approved, current and available at the work area;

1.4.4.6 Initiate corrective action within their areas of responsibility when deficiencies are identified;

1.4.4.7 Assess the adequacy of those portions of the QA program for which they are responsible; and

1.4.4.8 Have overall responsibility for the procurement of items and services for Quality Related applications.

SECTION 2.0
QUALITY ASSURANCE PROGRAM

2.1 Purpose

2.1.1 This section establishes requirements for planning, implementation and maintenance of TMMC's QA program. The TMMC QA program is established to be consistent with the appropriate elements of:

- ASME NQA-1-2008 – "Quality Assurance Requirements for Nuclear Facility Applications"; and
- Title 10, Part 830, Subpart A of the CFR – "Nuclear Safety Management - QA Requirements" (Department of Energy).

2.1.2 Furthermore, the QA program is designed to implement TMMC's commitment to the appropriate elements of:

- Title 49, Parts 100-177 and 178-199 of the CFR – (Transportation);
- Title 10, Part 61 of the CFR – "Licensing Requirements for Land Disposal of Radioactive Wastes" (Nuclear Regulatory Commission);
- Tennessee Radioactive Materials License R-01037-E16 (as amended); and
- Tennessee State Regulations for Protection Against Radiation, Tennessee Department of Health and Environment (0400-20-5).

2.2 General

2.2.1 The QA Program shall be documented with written requirements and reflect the policies of this QAPP. Written procedures will be used to further describe implementation of the requirements of the QA program.

2.2.2 TMMC shall implement additional QA requirements as identified in client procurement documents.

2.3 Responsibilities

2.3.1 The VP – TMMC is responsible for endorsing the QA Program and for providing the necessary resources for its implementation.

2.3.2 The QAM is responsible for review and approval of the QA Program and for providing administrative and/or technical support as applicable.

2.3.3 The QAM is responsible for establishing, implementing and/or verifying implementation of the QA Program to assure that the objectives are met. QAM responsibilities include:

2.3.3.1 Documentation, review and maintenance of the QAPP;

2.3.3.2 Supervision and training of QA/QC personnel;

2.3.3.3 Surveillance and audit of activities which are Quality Related;

2.3.3.4 Reporting to the VP – TMMC on the status and adequacy of the QA program and significant conditions adverse to quality.

2.3.4 The QAM is responsible for the identification of Quality Related systems, components, or services and may confer with the RSO for interpretation of and application of radioactive material license requirements in making Quality Related determinations. The VP – TMMC has the final decision in disputed designations.

2.3.5 Each responsible Manager/Supervisor shall ensure:

2.3.5.1 The preparation, control and implementation of written policies, procedures and instructions for the performance of activities affecting quality;

2.3.5.2 That persons verifying acceptability of items or activities in their areas of responsibility are qualified in the principles, techniques and requirements; and

2.3.5.3 That appropriate indoctrination and training is provided and that proficiency of personnel in performing activities affecting quality is achieved and maintained.

2.4 Program Requirements

2.4.1 The QA Program requires that:

2.4.1.1 The organizational structure is defined and responsibilities and authority are clearly established within the organization;

2.4.1.2 Activities that are Quality Related are documented and conducted under controlled conditions including the use of appropriate test equipment, suitable environmental conditions and satisfying all prerequisites.

2.4.1.3 Nonconformances are identified, documented, dispositioned, and corrective actions are verified.

2.4.1.4 The quality of procured items or services, which are Quality Related, are controlled to assure compliance with the QA program.

2.5 Program Application

2.5.1 The QA Program applies to all activities that are "Quality Related."

2.5.2 Quality Related is defined as an all-inclusive term that identifies items, systems, or services that:

2.5.2.1 Prevent, control or mitigate radioactive material release from the TMMC site (e.g., radiological controlled HVAC systems, radioactive material handling and transportation, etc…).

2.5.2.2 Directly establish or maintain conditions or activities necessary to be in compliance with radioactive material license conditions (e.g. radiation survey instrumentation, calibration sources, etc…).

2.5.3 The extent to which the QA Program is applied to any activity is dependent on:

2.5.3.1 Contractual requirements;

2.5.3.2 The designation of the activity as Quality Related;

2.5.3.3 The nature and scope of the work to be performed.

2.5.4 The QAM is responsible for establishing specific QA requirements for routine Quality Related activities as well as project specific activities.

2.6 Indoctrination/Training

2.6.1 Indoctrination

2.6.1.1 Managers/Supervisors shall assure that personnel performing or managing Quality Related activities receive indoctrination in their job responsibilities and authority; general criteria, including applicable codes and standards, regulatory commitments, applicable company procedures and quality assurance requirements.

2.6.1.2 The QAM shall assure that QA indoctrination is provided to TMMC personnel.

2.6.2 Training

2.6.2.1 Managers/Supervisors shall assure that training is provided to their personnel performing Quality Related activities.

2.6.2.2 Personnel assigned to perform Quality Related activities shall be trained in the principles and techniques of the activity being performed.

2.6.2.3 Training shall be provided, as necessary, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities.

2.6.2.4 On-the-job training shall be used if direct hands-on applications or experience is needed to achieve and maintain proficiency.

2.6.3 Records shall be maintained of indoctrination and training. Records of indoctrination/training shall include one or more of the following:

- attendance sheets;
- training logs;
- personnel training records.

2.7 QA Program Status Reporting

2.7.1 The QAM shall periodically report to cognizant TMMC management including the VP – TMMC on the status and adequacy of the QA Program.

2.7.2 An annual report shall be issued to the VP – TMMC containing a summary of external and internal audits, internal surveillance activities, nonconformance report and corrective action issuance, QA/QC Inspection activities and quality concerns.

SECTION 3.0
DESIGN CONTROL

3.1 Purpose

Toxco Materials Management Center does not conduct Quality Related design activities. As Quality Related design needs are identified, TMMC shall utilize the services of suppliers approved by the QAM in accordance with SECTION 7.0 of this QAPP. If TMMC should decide to implement an internal design program, this section establishes requirements, responsibilities and administrative controls for design activities associated with those processes and items used during operations, which are identified as Quality Related.

3.2 General

3.2.1 Design controls shall assure that applicable regulatory requirements and the design basis are correctly translated into design documents such as specifications, drawings, calculations, procedures and instructions.

3.2.2 Design control activities shall be performed using design reviews, alternate calculations, tests, or application of appropriate codes, standards, or regulatory requirements.

3.2.3 Procedures shall be established for the review, approval, release, distribution and revision of design control documents.

3.3 Responsibilities

3.3.1 Managers/Supervisors are responsible for ensuring that appropriate design requirements are clearly established and documented.

3.3.2 The VP – TMMC is responsible for assessing and approving design requirements for processes and equipment impacting public safety.

3.3.3 The QAM is responsible for reviewing procurement documents for Quality Related items or services to ensure that design requirements have been established and are documented and that QA standards and controls are identified and documented.

3.3.4 The RSO is responsible for assessing and approving design requirements for processes and equipment impacting radiological safety.

3.4 Design Input

3.4.1 Design requirements shall be established and defined in drawings, specifications or design change packages for Quality Related applications. Design input shall include the following as applicable:

- Design Basis;
- Performance Requirements;
- Regulatory Requirements;
- Codes and Standards;
- Environmental Conditions;
- Interfaces with Structures/Equipment; and
- Quality Requirements.

3.4.2 The level of detail of design input shall be sufficient to assure that the activity will be carried out correctly, providing a basis for making design decisions, accomplishing verification measures and evaluating any changes to the design.

3.5 Design Verification

3.5.1 Designs shall be reviewed to verify that design objectives have been satisfied including regulatory requirements and material/equipment compatibility.

3.5.2 The verification/design review process shall be performed by individuals other than those who performed the original design.

3.5.3 Verification methods may include one or more of the following methods: modeling, design analysis, evaluation of historical performance data, qualification testing, alternate calculations, or independent review.

3.5.4 The extent of the design verification required for a particular design or design activity is determined and documented in procurement documents, instructions, procedures, or

3.5.4.1 If independent reviews are used, a general evaluation of the design is conducted by a competent person other than the original designer;

3.5.4.2 If design reviews are used, reviews are held at intervals necessary to ensure a satisfactory design process;

3.5.4.3 If alternate calculations are used, the input data used and the computer program or other calculation method shall be reviewed;

3.5.4.4 If qualification testing is used, the tests are identified, their configuration is defined and documented, and they shall demonstrate adequacy of performance under conditions that simulate the most adverse operational conditions.

3.5.5 Design review/verification activities shall be identified and documented appropriately.

3.5.6 Design verification must be completed prior to the structure or items being relied upon to perform the function.

3.6 Design Change Control

All design changes shall be subjected to the same control measures as the initial designs. All associated documentation of design changes shall be carried out in accordance with initial documentation requirements.

3.7 Design Documentation

Design documentation and records which provide evidence that design requirements have been satisfied and that the design or design activity was performed in accordance with requirements shall be identified, stored and maintained in accordance with SECTION 17.0 of this QAPP.

SECTION 4.0
PROCUREMENT DOCUMENT CONTROL

4.1 Purpose

This section establishes requirements for initiating and controlling procurement documents of Quality Related items and services by TMMC. Excluded from application are office supplies, standard types of operational and maintenance tools and supplies, and administrative services.

4.2 General

4.2.1 Procurement documents shall be controlled to assure that applicable design bases and other requirements necessary to assure adequate quality is included or referenced in documents for procurement of Quality Related items and services.

4.2.2 The requirements for procurement document control shall be implemented using approved, written procedures.

4.2.3 Quality Related items and services as determined by the QAM shall be purchased from approved suppliers. The requirements for the control of suppliers supplying items or services are contained in SECTION 7.0 of this QAPP.

4.2.4 Contractors or subcontractors procuring items and services within the scope of this section shall comply with the requirements as specified within.

4.2.5 Procurement documents and changes thereto shall be reviewed to assure inclusion of the appropriate requirements prior to transmittal to prospective suppliers or subcontractors.

4.3 Responsibilities

4.3.1 The requester is responsible for completing the procurement document and shall accurately describe the item or service needed and define the applicable requirements.

4.3.2 Each responsible Manager/Supervisor is accountable for ensuring that applicable regulatory requirements, technical/quality assurance requirements, design basis and other requirements are suitably included or referenced in the procurement documents.

4.3.3 The QAM is responsible for reviewing and approving Quality Related procurement documents to assure that applicable requirements are identified. Additionally, the QAM is responsible for the approval of suppliers providing such items or services.

4.3.4 The RSO is responsible for reviewing and approving Quality Related procurement documents to ensure that radioactive material license requirements are satisfied.

4.4 Procurement Requirements

4.4.1 The procurement of items and services for Quality Related applications shall be accomplished through the preparation of written documents such as material requisitions, purchase orders, specifications or contracts.

4.4.2 Quality Related procurement documents shall contain, as applicable:

4.4.2.1 A clear, concise statement of the scope of the work to be performed by the supplier;

4.4.2.2 Technical requirements such as drawings, codes, specifications, standards, regulations, procedures or instructions that describe the items or services to be furnished;

4.4.2.3 Identification of appropriate test, inspection and acceptance requirements of the purchaser for determining acceptability of the item and for monitoring and evaluating the supplier's performance;

4.4.2.4 Quality assurance program requirements;

4.4.2.5 The requirement that the subcontractor or supplier have a documented QA program that implements the appropriate requirements of this QAPP;

4.4.2.6 Requirements for the supplier to incorporate applicable quality assurance requirements in subtier procurement documents;

4.4.2.7 Provisions for access to the supplier's facilities and records for source inspection and/or audits;

4.4.2.8 Identification of the documentation required to be submitted for information, review or approval and the time for submittal;

4.4.2.9 Specific QA records to be maintained by the supplier and the retention times and disposition requirements;

4.4.2.10 Requirements for reporting and approving disposition of nonconformances;

4.4.2.11 Provisions for quantitative as found conditions of measuring & test equipment; and

4.4.2.12 Requirements for the supplier to control the calibration of tools, gauges, instruments and testing devices to standards traceable to National Institute of Standards (NIST), or equivalents.

4.4.3 Quality Related procurement document changes affecting the technical or quality assurance program requirements shall be subject to the same review and approval as the original document.

4.4.4 Procurement documents for Quality Related application shall be retained in accordance with SECTION 17.0 of this QAPP.

SECTION 5.0
INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 Purpose

This section establishes requirements for preparation, review, approval, and use of instructions, procedures and drawings controlling Quality Related activities.

5.2 General

5.2.1 The following Quality Related activities shall be accomplished in accordance with documented, approved instructions, procedures or drawings;

- Radioactive material packaging, packages and shipping activities;
- Radioactive material licensed activities;
- Radiation control activities;
- Sample analysis/counting;
- QA/QC activities for inspection, surveillance and audit performance; and
- Procurement of Quality Related items and services.

5.2.2 Basic requirements for Quality Related activities shall be specified in approved procedures. These documents shall describe the appropriate requirements and primary responsibilities for controlling activities that affect radiological safety as well as the quality of items and services.

5.3 Responsibilities

5.3.1 Managers/Supervisors are responsible for ensuring that Quality Related activities, for their areas of responsibility, are identified and accomplished in accordance with approved instructions, procedures or drawings.

5.3.2 The QAM as a minimum shall review Quality Related procedures and drawings to ensure that QA program requirements are addressed including quantitative and qualitative acceptance criteria as applicable.

5.3.3 The RSO as a minimum shall review Quality Related procedures, and drawings to ensure that radioactive material license requirements are satisfied.

5.4 Requirements

5.4.1 Instructions, procedures and drawings shall be prepared and detailed to the extent necessary to carry out the task or operation.

5.4.2 Instructions, procedures and drawings shall include appropriate quantitative or qualitative acceptance criteria to permit independent verification that the activity was performed correctly.

5.4.3 Completed instructions, procedures and drawings shall be reviewed for accuracy and completeness by a qualified individual other than the preparer.

5.4.4 When documents have been reviewed and approved per the requirements of this section, they shall be released for issue and controlled in accordance with SECTION 6.0 of this QAPP.

5.4.5 Revisions to documents shall be prepared, reviewed, approved and distributed in the same manner as the original issue.

5.5 Instructions

5.5.1 Work instructions are step-by-step instructions that provide detailed information on carrying out job specific activities (e.g., operation of processing, count room equipment). Work instructions shall be reviewed and approved by the responsible Manager/Supervisor and a technical reviewer as a minimum.

5.6 Procedures

5.6.1 Standard Operating Procedures (SOP's) shall be developed to implement the requirements of this QAPP. Each applicable Manager/Supervisor is responsible for identifying the need and developing procedures for appropriate activities.

5.6.2 The GM, RSO, and QAM shall review Quality Related SOP's as a minimum.

5.6.3 The VP – TMMC shall approve procedures in writing prior to their controlled issuance in accordance with SECTION 6.0 of this QAPP.

5.7 Drawings

5.7.1 Drawings that describe a radioactive material licensed process, shall be identified, developed, approved and controlled.

5.7.2 Original drawings shall be controlled in accordance with SECTION 6.0 of this QAPP.

SECTION 6.0
DOCUMENT CONTROL

6.1 Purpose

This section establishes requirements and responsibilities for controlling the preparation, issue and change of documents that specify quality requirements or prescribe activities affecting quality. Documentation includes but is not limited to work instructions, procedures, drawings, contract documents, specifications and the QAPP.

6.2 General

Documents are controlled to the extent necessary to assure appropriate preparation or receipt, review for adequacy, completeness, approval and distribution for use and document revision and/or deletion.

6.3 Responsibilities

Managers/Supervisors originating Quality Related documents that prescribe activities affecting quality shall identify distribution requirements to assure that documents are distributed to and used at the location where the activity is being performed.

6.4 Requirements

6.4.1 A system shall be established and implemented through procedures for the control of documents that provides for the following:

6.4.1.1 Identification of documents to be controlled;

6.4.1.2 Specified distribution of controlled documents for use at the appropriate location;

6.4.1.3 Identification of individuals responsible for preparing, reviewing, approving, issuing, and distributing documents and revisions to those documents;

6.4.1.4 Review of documents and changes for technical adequacy, quality requirements, completeness and correctness prior to approval and issuance;

6.4.1.5 Method(s) to ensure the correct documents are being used.

6.4.2 Document Changes

6.4.2.1 Changes to controlled documents which either affect how work is completed or affect the results shall be reviewed and approved by the same organizations that reviewed and approved the documents originally. Review and approval can be delegated to other qualified organizations.

6.4.2.2 Changes to controlled documents which neither affect how work is conducted nor affect the results shall not require the same level of review and approval required in 6.4.2.1 (e.g., editorial changes). Document control procedures shall indicate persons authorized to make minor changes.

6.4.2.3 Records that document the quality requirements, their verification and acceptance, shall be generated and maintained in accordance with SECTION 17.0 of this QAPP.

SECTION 7.0
CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 Purpose

The purpose of this section is to establish requirements for the control of purchased items and services for Quality Related applications, and to assure conformance to the procurement document(s).

7.2 General

7.2.1 Procedures for the control of purchased items and services shall be established to ensure conformance to specified requirements in procurement documents.

7.2.2 Procurement controls shall provide for the following as appropriate;

- source evaluation and selection;
- evaluation of objective evidence of quality furnished by the Supplier;
- source inspection;
- audit; and
- examination of items or services upon delivery or completion.

7.2.3 Procurement activities shall be planned and documented to ensure a systematic approach to the procurement process.

7.2.4 Evaluation of supplier capabilities shall be performed and documented prior to issuance of a purchase order or contract.

7.2.5 Proposal evaluations shall be performed as applicable, to assess the extent of conformance to procurement documents by the bidder prior to placement of a purchase order or subcontract.

7.2.6 Supplier generated documents shall be controlled, handled and approved in accordance with established methods.

7.2.7 Measures shall be established for accepting an item or service furnished by the supplier.

7.2.8 Changes to procurement documents shall be controlled and documented.

7.2.9 Measures shall be established to ensure the proper disposition of items or services that do not conform to procurement requirements.

7.2.10 Records that contain documenting evidence that sufficiently identifies the specific procurement requirements (e.g., codes, standards and specifications) met by the purchased item shall be retained.

7.3 Responsibilities

7.3.1 The requester and appropriate Manager/Supervisor are responsible for completing procurement documents for Quality Related items and services. A complete procurement document will include required reviews and approvals and clearly define quality and technical requirements.

7.3.2 Managers/Supervisors are responsible for determining and documenting the need for an approved supplier.

7.3.3 Managers/Supervisors and Purchasing Personnel are responsible to assure that only suppliers listed on the Approved Suppliers List (ASL) are used for Quality Related procurement.

7.3.4 The QAM is responsible for:

7.3.4.1 The review of appropriate purchase documents to assure that appropriate quality and technical requirements are defined;

7.3.4.2 Performing QA/QC inspection planning, as applicable;

7.3.4.3 Evaluating and qualifying suppliers; and

7.3.4.4 The re-evaluation of suppliers on a periodic basis, not to exceed three years.

7.4 Evaluation and Approval of Suppliers

7.4.1 Supplier evaluation and selection shall be documented and shall include one or more of the following techniques:

7.4.1.1 Supplier's history of providing an identical or similar product or service which performs satisfactorily in actual use. The supplier's history shall reflect current capability;

7.4.1.2 Supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated;

7.4.1.3 Supplier's technical and quality capability as determined by direct evaluation (i.e., audit, surveillance) of the facilities, personnel and implementation of a quality program; and

7.4.1.4 A client's formal acceptance (i.e., audit) of a supplier's quality assurance program, specific to the item or service provided.

7.4.2 Suppliers shall be selected based on their capability to provide items or services in accordance with applicable requirements of the procurement document.

7.4.3 Suppliers of Quality Related items or services shall be selected from the TMMC ASL.

7.4.4 Approved suppliers shall be monitored periodically to ensure that the quality of the item or service provided is maintained. When audits are used as the basis of qualification, the supplier must be audited triennially as a minimum.

7.4.5 Suppliers may be conditionally approved to supply items or services after the completion of a satisfactory audit and prior to the issuance of the audit report.

7.4.6 Suppliers evaluated and approved by TMMC shall be added to the ASL. Suppliers found to be unacceptable shall be removed from the ASL.

7.5 Verification and Acceptance of Items and Services

7.5.1 QA/QC inspection personnel shall perform receipt inspections as required by client contracts or associated procurement documents, to verify that procured items and services conform to specified requirements.

7.5.2 Verification activities shall be conducted using applicable procedures, drawings, procurement documents or checklists. The method used to verify the item or service shall be determined based on its complexity or supplier's past performance. One or a combination of the following methods may be used:

- Supplier Certificate of Conformance;
- Source verification;
- Receiving inspection; or
- Post installation testing.

7.5.3 Documents generated by TMMC or submitted by the supplier which assure the quality of a procured item or service shall be controlled in accordance with Procurement Procedures and SECTION 17.0 of this QAPP.

SECTION 8.0
IDENTIFICATION AND CONTROL OF ITEMS

8.1 Purpose

This section establishes requirements for identification and control of items for Quality Related applications.

8.2 General

8.2.1 The following items shall be identified and controlled, as a minimum:

8.2.1.1 Client items received for decontamination, repackaging, survey-for-release, volume reduction, refurbishment, shipment to disposal site and/or return to client;

8.2.1.2 Radioactive waste generated as a result of processing client items;

8.2.1.3 Reusable TMMC and client containers (e.g., boxes, sea/land and roll-off containers, etc.); and

8.2.1.4 Procured items controlled by SECTION 7.0 of this QAPP.

8.2.2 Client items that have been determined by TMMC to be fit for reuse and are unconditionally released are not considered Quality Related and not subject to the requirements of this section, unless otherwise dictated by contract.

8.2.3 The marking and identification system shall identify the acceptability of procured items for use, and maintain item traceability throughout all stages of processing.

8.3 Responsibilities

8.3.1 Managers/Supervisors are responsible for maintaining the identification of client items at the TMMC facility. This also includes maintaining the identification of appropriate TMMC and client shipping containers.

8.3.2 The QAM is responsible for verifying by inspection/surveillance that items are identified and controlled.

8.4 Identification

8.4.1 The identification requirements for client items, radioactive waste, procured items, and shipping containers shall be defined in procedures or instructions. The identification shall be unique such as lot, batch, package number, serial number or sample location.

8.4.2 The identification of Quality Related items shall be maintained to assure traceability of items from receipt to final use.

8.4.3 The identification may be written on tags or labels, written directly on the item, container or sample, or bar codes may be used and affixed to the item. When direct identification is impractical, segregation of items may be used.

8.4.4 The mechanism used to identify the item, container or sample, shall not degrade the function or service life of the item.

8.4.5 The markings placed on items, tags and labels shall be legible and durable.

8.4.6 The identification at any stage of processing shall relate the item to a specific job number.

8.4.7 Documentation generated during processing which provides relevant processing/ inspection information shall be unique and traceable to the item.

8.4.8 The identification of items and containers shall be maintained at all times. Identification of items and associated documentation should be verified periodically throughout the processing sequence.

8.4.9 When items and samples are subdivided, identification shall be transferred to each subpart or record traceable to the subpart.

8.4.10 Items without proper identification shall be considered in an indeterminate condition and controlled in accordance with SECTION 15.0 of this QAPP.

8.5 Inventory Control

8.5.1 Inventory records shall be maintained on shipments of items received at TMMC for processing. At the completion of processing, the disposition of the items and radioactive waste shall be documented.

8.5.2 The TMMC radionuclide inventory shall be maintained in accordance with the radioactive material license requirements.

SECTION 9.0
CONTROL OF SPECIAL PROCESSES

9.1 Purpose

The purpose of this section is to establish the requirements and responsibilities for assuring that special processes for Quality Related applications are controlled and carried out by qualified personnel using qualified procedures. Special processes include those processes that could affect the properties of material, for which routine inspection is not an adequate means for determining acceptability of results. Examples of special processes include: specification (e.g., code) welding, heat treating and non-destructive examination.

9.2 General

Processes used at TMMC for decontamination or refurbishment of Quality Related items are evaluated to determine which method(s) will not affect the integrity of the item, as appropriate. Process evaluation methods are commensurate with the level of importance of individual items. When new methods are used which are identified as "special," the requirements of this section shall apply.

9.3 Responsibilities

Managers/Supervisors are responsible for identifying the need for special processes and for assuring that qualified personnel, procedures and equipment are used.

9.4 Qualification/Performance

9.4.1 Special processes shall be controlled using approved and qualified procedures.

9.4.2 Special processes shall be conducted by or under the supervision of qualified personnel.

9.4.3 Where required, equipment and material used during the performance of processes shall be qualified and measuring and test equipment shall be appropriately calibrated.

9.4.4 Personnel, processes and equipment must be qualified prior to the performance of special processes using written and approved procedures or instructions. Special processes shall be conducted by or under the supervision of qualified personnel.

9.4.5 Procedures and instructions shall incorporate applicable codes, standards and specifications providing detailed information on processing techniques, equipment and materials to be used and requirements for documentation, evaluation and acceptance criteria.

9.4.6 Requirements for special processes performed by TMMC subcontractors and vendors shall be specified in procurement documents.

9.5 Records

9.5.1 Records which provide documentary evidence of personnel, process and equipment qualification, shall be maintained per contractual or procedural requirements.

9.5.2 Performance records shall be maintained which provide documentary evidence that qualified personnel conducted the special processes using qualified procedures, with qualified equipment.

9.5.3 Records shall be maintained in accordance with SECTION 17.0 of this QAPP.

SECTION 10.0
INSPECTION

10.1 Purpose

This section establishes requirements for the control of inspection activities conducted at TMMC while evaluating Quality Related items against applicable specifications, instructions, procedures, drawings or other technical requirements.

10.2 General

10.2.1 Receiving, in-process, and final inspections shall be performed using instructions, procedures or checklists that clearly identify the acceptance criteria to be used, when the inspection activity is to be performed and the documentation required.

10.2.2 Inspections that verify acceptance of an item or activity to specified requirements shall be planned and performed by qualified persons other than those who performed or directly supervised the item or activity being inspected.

10.2.3 Provisions for identifying mandatory inspection hold points, requiring witnessing by the inspector, shall be incorporated in the appropriate documents, such as procurement specifications and test procedures.

10.2.4 The following inspection activities shall be conducted in accordance with the requirements of this section as a minimum:

10.2.4.1 Receipt inspection of procured items and equipment controlled under SECTION 7.0 of this QAPP;

10.2.4.2 Inspection of shipping containers after refurbishment, repair, or modification (e.g., Sea/Land and roll-off containers, etc…);

10.2.4.3 Inspection of radioactive material packaging processes;

10.2.4.4 Inspection of outgoing radioactive material shipments, including a limited vehicle inspection;

10.2.4.5 Inspection of processed materials to be returned to the client (e.g., decontaminate and return); and

10.2.4.6 Inspection of materials presented for release (e.g., unconditional, conditional and alternative disposal).

10.3 Responsibilities

10.3.1 The QAM shall be responsible for the training and qualification of QC inspection personnel. The QAM shall be responsible for providing qualified inspection personnel when special process inspections are required (e.g., specification welding, NDE).

10.3.2 Managers/Supervisors are responsible for assuring that client-specific and other hold points are identified and notification is made to QA to provide QA/QC inspection support.

10.3.3 Managers/Supervisors are responsible for notifying the QA Department to coordinate receipt inspection of items that are controlled under SECTION 7.0 of this QAPP.

10.4 Inspection Techniques

10.4.1 Inspection techniques shall be based on applicable specifications or standards. The quality characteristics to be verified shall be identified, as well as qualitative and quantitative acceptance criteria.

10.4.2 When sampling is used to verify the acceptability of a group of items, the sampling method shall be based on valid statistical methods.

10.4.3 When direct inspection is not possible, monitoring processing methods, equipment and personnel where applicable shall provide indirect control of the inspection process.

10.5 Inspector Qualification

QA/QC inspection personnel who are qualified in accordance with internal procedures or applicable standards shall conduct final inspections.

10.6 Inspection Performance

10.6.1 Inspections shall be performed using approved instructions, procedures or checklists.

10.6.2 Results of inspections shall be documented. Records shall provide traceability to the item inspected. Documentation shall include:

- Item or activity inspected;
- Date of inspection;
- Name of inspector;
- Description of the item(s) or activity inspected;

- Identification and calibration status and equipment (e.g., special tools, gauges) used;
- Acceptance criteria (e.g., procedure, instruction, standard, etc.);
- Results or acceptability;
- Reference to information on action taken in connection with any nonconformance noted.

10.6.3 Nonconforming items identified as a result of inspection activities shall be dispositioned in accordance with SECTION 15.0 of this QAPP.

10.6.4 Programmatic deficiencies/deviations identified as a result of this inspection will be dispositioned in accordance with SECTION 16.0 of this QAPP.

10.6.5 Inspection records shall be maintained in accordance with SECTION 17.0 of this QAPP.

SECTION 11.0
TEST CONTROL

11.1 Purpose

This section establishes requirements for control of tests conducted on Quality Related items to demonstrate satisfactory performance or conformance to applicable specifications, instructions, procedures, drawings or other technical requirements.

11.2 General

11.2.1 When items are required to be tested according to material specifications, contractual requirements, or procurement documentation, testing shall be conducted using approved procedures or instructions by personnel who are qualified to perform the task.

11.2.2 When testing requires specialized qualifications and skills, the personnel performing the tests shall meet the applicable codes/standards.

11.2.3 The following tests, as a minimum, shall be conducted under the requirements of this section;

- On site equipment calibrations;
- Performance testing of shipping containers (as applicable);
- Computer program testing; and
- DOP testing of HEPA systems.

11.3 Responsibilities

11.3.1 Managers/Supervisors shall:

- Establish and implement controls to ensure that tests performed in support of quality related activities are conducted in accordance with specified requirements;
- Develop test plans and procedures;
- Identify test requirements;
- Ensure that tests are performed by qualified personnel;
- Document and evaluate test results, and
- Identify, protect and store test records.

11.3.2 The QAM is responsible for:

- Reviewing test procedures to ensure that applicable quality standards, regulations or design specifications are identified;
- Assuring that tests performed in support of quality related activity are conducted in accordance with specified requirements;
- Monitoring and auditing the test control process;
- Assuring that test plans and procedures are reviewed and approved; and
- Participating in verification of test results, as needed.

11.4 Testing Requirements

11.4.1 Testing shall be performed in accordance with approved procedures which include provisions for ensuring that all prerequisites and suitable environmental conditions have been met, that adequate test equipment/instrumentation is available and used and that necessary monitoring is performed.

11.4.2 Prerequisites shall include the following as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to tested, suitable environmental conditions and provisions for data acquisition.

11.4.3 Test results shall be documented and evaluated by a technically knowledgeable person to ensure that requirements have been satisfied.

11.4.4 Items that do not pass required tests shall be identified, physically segregated as required, labeled as nonconforming, and dispositioned according to the requirements of SECTION 15.0 of this QAPP.

11.4.5 Inspection records shall be maintained in accordance with SECTION 17.0 of this QAPP.

SECTION 12.0
CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Purpose

This section establishes requirements for controlling devices used in measuring and testing activities that affect the quality of items or process measurements at TMMC.

12.2 General

12.2.1 Calibration and control measures are not required for rulers, tape measures, and other such devices, if normal commercial equipment provides adequate accuracy.

12.2.2 Appropriate calibrated measuring and test equipment (M&TE) with the proper range and accuracy shall be used to ensure that accurate measurements are made.

12.2.3 M&TE shall have a unique identification to ensure traceability and determination of calibration status.

12.2.4 M&TE that is used frequently and may be susceptible to calibration drift shall be checked periodically using a secondary standard to verify equipment is within accuracy range.

12.2.5 Calibrations shall be performed using approved calibration procedures. When suppliers are used for calibration services, they shall be approved by the QAM in accordance with SECTION 7.0 of this QAPP.

12.2.6 The following M&TE as a minimum shall be controlled by the requirements of this section:

- Radiation Monitoring Equipment;
- Count Lab Equipment;
- Aerosol Photometer;
- Scales;
- Electrical Test Equipment; and
- Torque Wrenches.

12.3 Responsibilities

12.3.1 Managers/Supervisors responsible for:

12.3.1.1 Preparation of calibration procedures which identify the type of equipment, calibration frequency, traceability, standards and associated documentation; and

12.3.1.2 Maintaining traceability of measuring and test equipment to calibration records by recording a unique serial number on the equipment and documentation.

12.3.2 The QAM is responsible for:

12.3.2.1 Review of calibration procedures;

12.3.2.2 Periodic surveillance, inspection and/or internal audits of the M&TE control program; and

12.3.2.3 Review and approval of suppliers used for calibration services.

12.4 Control System

12.4.1 A system shall be established, maintained and documented by procedure for measuring and test equipment controlled by this section.

12.4.2 The system shall provide for:

12.4.2.1 Establishment of calibration requirements for each controlled device to include frequency of calibration, accuracy and range;

12.4.2.2 Administrative controls to ensure that each device is checked for calibration and adjusted accordingly; and

12.4.2.3 Administrative controls to ensure that each device is checked for calibration and adjusted accordingly.

12.4.3 M&TE, which is overdue for calibration or found to be out of calibration, shall be tagged and/or segregated, or removed from service, and not used for acceptance until it has been calibrated.

12.4.4 When M&TE is found to be out of calibration, an evaluation of the validity of previous inspection and test results and the acceptability of items previously inspected or tested is made and documented by written report in accordance with approved procedures.

12.5 Calibration Requirements

12.5.1 M&TE shall be calibrated at scheduled frequencies against certified equipment having known valid relationships to nationally recognized standards e.g., National Institute of Standards (NIST) or to international standards known to be equivalent to and verified against corresponding nationally recognized standards. If no such standards exist, the basis for calibration shall be documented.

12.5.2 The calibration method and frequency for each item shall be based on the type of equipment, stability characteristics, required accuracy, frequency of usage and environment to which it will be subjected.

12.5.3 Calibration shall be conducted by trained, qualified personnel.

12.5.4 Special controls shall be documented and applied as required for controlling environmental conditions such as temperature, humidity, cleanliness or radiation/electrical background to ensure and maintain the accuracy and operating characteristics of the device.

12.5.5 Calibration records shall be maintained in accordance with SECTION 17.0 of this QAPP.

SECTION 13.0
HANDLING, STORAGE AND SHIPPING

13.1 Purpose

This section establishes requirements for the controls implemented at TMMC for handling, storage, shipping, cleaning and preservation of Quality Related items.

13.2 General

13.2.1 Handling, storage, packaging and shipping of quality related items shall be conducted in accordance with radioactive material license and contractual requirements and applicable regulations, codes, and standards.

13.2.2 Requirements for handling, storage, packaging, shipping, cleaning and preservation of items controlled by this section shall be documented in approved procedures or instructions.

13.2.3 As a minimum, this section shall control radioactive material handling, storage, packaging and shipping activities.

13.3 Responsibilities

13.3.1 Managers/Supervisors are responsible for the preparation and implementation of instructions and procedures for the handling, storage, shipping and packaging of items controlled by this section for their respective areas of responsibility.

13.3.2 The QAM shall be responsible for reviewing procedures and instructions developed for handling, storage, shipping and packaging of items controlled by this section.

13.3.3 The QAM shall be responsible for verifying implementation of procedural requirements through periodic inspections, surveillances and audits of the activities.

13.4 Handling

13.4.1 Handling equipment shall be in a safe condition and adequate for its intended use.

13.4.2 Special tools and equipment shall be used, as necessary, to ensure safe and non-damaging handling of heavy or bulky items, items that are highly radioactive or items that are sensitive.

13.4.3 Special handling tools and equipment shall be inspected and tested in accordance with procedures at specified time intervals or prior to use.

13.4.4 Operators of special handling or lifting equipment shall be properly trained and qualified.

13.5 Packaging

13.5.1 Appropriate packaging such as strong tight shipping containers shall be provided for the containment of radioactive and/or hazardous items.

13.5.2 Packaging instructions shall identify and describe important operations such as pre-packaging, container inspections, compaction, solidification and post packaging checks.

13.5.3 Packaged items and the packaging of containers shall provide positive identification or traceable records to such information as applicable.

13.6 Shipping

13.6.1 Shipping instructions shall identify the items shipped, any special handling and packaging requirements, radiation control requirements, shipping mode and destination, and any special requirements for handling and storage at the destination.

13.6.2 Shipping package and container labels/markings shall be in conformance with applicable regulatory and/or disposal site requirements.

13.6.3 Shipping documents shall be prepared in compliance with specified requirements, (e.g., 49CFR, NRC, disposal site criteria, etc…).

13.7 Storage

13.7.1 Identification of stored items shall be in accordance with the requirements of SECTION 8.0 in this QAPP.

13.7.2 Storage controls shall be in accordance with applicable specifications, regulatory and special permit requirements.

13.7.3 Stored packages shall be inspected periodically to detect damage or deterioration; to verify the adequacy of item identification; to ensure maintenance of containment or other special requirements; and to ensure that specified exposure and environmental controls are maintained.

13.7.4 Wherever possible, storage facilities should include areas for segregation or control of items found nonconforming.

13.8 Preservation

13.8.1 Special preservation measures shall be provided for processing, storage, or shipping of materials and equipment, as necessary.

13.8.2 Preservation methods may include special passive protection such as packaging, coverings, radiation shielding, or environmental controls.

13.8.3 Special preservation methods shall be verified periodically to determine their effectiveness.

SECTION 14.0
INSPECTION, TEST AND OPERATING STATUS

14.1 Purpose

This section establishes requirements for indicating the inspection, test and operating status of Quality Related items at TMMC and to ensure that the items have passed the required inspections and tests prior to installation, use or further processing.

14.2 General

After the completion of inspection and test activities, the status of items shall be indicated as conforming (accepted) or rejected using markings such as stamps, tags, labels or entries on transfer documentation.

14.3 Responsibilities

14.3.1 Managers/Supervisors shall be responsible for applying appropriate markings to items and completing required documentation for Quality Related activities.

14.3.2 QA/QC inspection personnel shall be responsible for the application of a status indicator (e.g., QC accept/reject labels) on items after completion of the required inspection and/or test.

14.4 Status Indication and Control

14.4.1 The inspection, test and operating status of Quality Related items and equipment shall be known at all times throughout the process or activity.

14.4.2 The requirements for the use of status indicators and associated transfer documentation shall be indicated in written procedures and instructions.

14.4.3 Items and equipment that are not operating or out of calibration shall be tagged accordingly to prevent inadvertent use.

14.4.4 Tags or other out-of-service indicators shall be located so they are clearly visible. The removal of tags shall be documented and controlled by procedure.

14.4.5 Items that do not satisfactorily pass inspection and tests shall be dispositioned in accordance with SECTION 15.0 of this QAPP.

SECTION 15.0
CONTROL OF NONCONFORMING ITEMS

15.1 Purpose

This section establishes requirements and responsibilities for identification, documentation, segregation and disposition of nonconforming items in order to prevent their inadvertent use or installation.

15.2 General

15.2.1 A nonconformance is a deficiency in characteristic, documentation, or procedure that renders the quality of an item unacceptable or indeterminate.

15.2.2 The requirements for identification, documentation, segregation, and disposition of nonconforming items and notification to affected organizations shall be implemented using approved, written procedures.

15.2.3 Nonconforming items may be identified as the result of internal and client audits, surveillances and inspections or daily observations.

15.3 Responsibilities

15.3.1 All TMMC personnel are responsible for identifying nonconforming items and reporting them to their immediate Manager/Supervisor and/or QAM.

15.3.2 The QAM is responsible for developing a procedure for the identification, documentation and control of nonconforming items.

15.4 Internal Nonconformances

15.4.1 When an item is found to be nonconforming to specified requirements, the nonconforming condition shall be documented on a nonconformance report (NCR).

15.4.2 The responsible organization or individual identified on the NCR shall provide a disposition of nonconforming items, which may include use-as-is, repair, rework, or reject.

15.4.3 The QAM shall verify implementation of the nonconforming item disposition as appropriate.

15.5 Supplier Nonconformances

15.5.1 Suppliers of Quality Related items to TMMC are required to immediately notify TMMC of deviations from procurement requirements.

15.5.2 Nonconformances should be documented and controlled in accordance with the supplier's QA program.

15.5.3 Supplier nonconformances shall be dispositioned with TMMC concurrence.

15.6 Client Nonconformance Notification

15.6.1 The QAM shall make notification to client personnel when their items are determined to be nonconforming. This determination may be made through receipt inspection, testing, or surveillance activities.

15.6.2 Client items determined to be nonconforming shall be identified and segregated as necessary to prevent inadvertent use.

15.6.3 The QAM or appropriate Manager shall initially contact the client via phone, fax or e-mail. NCR's that document client nonconforming items shall be transmitted to the client for review and concurrence, if required by contract.

15.7 Nonconformance Assessment and Tracking

15.7.1 The QAM shall ensure that NCR documentation is complete, and NCR's are tracked to disposition verification.

15.7.2 NCR documentation shall be maintained in accordance with SECTION 17.0 of this QAPP.

SECTION 16.0
CORRECTIVE ACTION

16.1 Purpose

This section establishes requirements and responsibilities for corrective action measures that assure conditions adverse to quality are promptly identified and corrected to prevent their recurrence.

16.2 General

16.2.1 Conditions adverse to quality include: failures or malfunctions, program deficiencies and deviations, defective items and recurring deficiencies or nonconformances.

16.2.2 Conditions adverse to quality shall be evaluated; corrective action determined and implemented in accordance with approved procedures.

16.3 Responsibilities

16.3.1 TMMC employees are responsible for identifying and reporting conditions adverse to quality to appropriate management.

16.3.2 Managers/Supervisors are responsible for evaluating conditions adverse to quality and completing corrective actions for their respective areas.

16.3.3 The QAM is responsible for verifying that conditions adverse to quality have been corrected.

16.4 Corrective Action Requirements

16.4.1 Identified conditions that are adverse to quality are documented and reported by the use of Condition Reports (CR).

16.4.2 An investigation of the deficiency and corrective action shall be promptly initiated when it is determined that a condition adverse to quality exists.

16.4.3 For significant conditions adverse to quality, measures shall include:

- Determination of the root cause;
- Corrective action to be taken;
- Action taken to prevent recurrence.

16.4.4 Examples of conditions adverse to quality, which may under certain conditions be significant, include:

- deficiencies in design, manufacturing, construction testing or process requiring substantial rework, repair or replacement;
- damage to a structure, system, component or process requiring substantial repairs;
- a nonconservative error detected in a Quality Related computer program after it has been released for use;
- loss of essential data; and
- repeated failure to implement a portion of an approved procedure.

16.4.5 For significant conditions adverse to quality, the cause of the condition and the corrective action taken shall be reported to appropriate TMMC management for review.

SECTION 17.0
QUALITY ASSURANCE RECORDS

17.1 Purpose

This section establishes requirements and responsibilities for the identification, generation, authentication, retention and disposition of QA records that furnish documentary evidence of the implementation of this QAPP.

17.2 General

17.2.1 QA records shall provide adequate documentary evidence of those TMMC activities controlled by this QAPP.

17.2.2 QA records shall include those records that are specified in applicable regulations, facilities radioactive material licenses, or by contract.

17.2.3 The storage of QA records shall be accomplished in a manner that provides timely retrieval and prevents damage, deterioration or loss.

17.2.4 A schedule for retention of QA records shall be established.

17.3 Responsibilities

17.3.1 Each responsible Manager/Supervisor shall:

- Establish and implement controls to ensure that QA records generated in support of quality affecting activities are in accordance with this section and contract requirements; and
- Identify, protect, store and validate QA records.

17.3.2 The QAM shall be responsible for verifying that QA records are prepared, collected and filed in accordance with specified requirements.

17.3.3 The QAM is responsible for establishing a system for maintaining QA records according to the requirements of this section.

17.4 Generation of QA Records

17.4.1 QA records shall be legible, accurate and complete.

17.4.2 QA records shall be traceable to associated items and activities and accurately reflect the work accomplished or information required.

17.5 Authentication of QA Records

17.5.1 Documents shall be considered valid QA records only if stamped, initialed or signed and dated by authorized personnel or otherwise authenticated.

17.5.2 Corrections to documents shall be reviewed and approved by the responsible individual from the originating or authorized organization.

17.5.3 Electronic documents shall be authenticated with comparable information as in section 17.5.1 above, as appropriate:

17.5.3.1 With identification on the media; or

17.5.3.2 With authentication information contained within or linked to the document itself.

17.6 Control of QA Records

QA records generated shall be identified and controlled to ensure timely retrieval and prevent loss or damage.

17.7 QA Record Files

17.7.1 A file system shall be established and maintained for the following documents:

- Current and previous revisions of the QAPP;
- Current and previous revisions of TMMC procedures;
- Records of proficiency training including qualification/certification records for personnel;
- QA records generated for client projects; and
- Other records generated in support of compliance with regulatory, contractual, or procedural requirements.

17.8 QA Record Storage

17.8.1 Records shall be stored in a manner to minimize the risk of damage or destruction. One-hour fire rated cabinets shall be used for the temporary storage of records during processing.

17.8.2 When duplicate records are maintained the original and duplicate record shall be maintained at locations sufficiently remote from each other to eliminate the chance of destruction by the same event.

17.9 Retention Time and Disposition of Record

17.9.1 Records shall be retained in accordance with established retention requirements. Under no circumstances shall records be destroyed unless approved by the QAM and the VP – TMMC.

17.9.2 QA records to be turned over to clients shall be transmitted utilizing a cover letter that identifies the QA records and provides for acknowledgment of receipt.

SECTION 18.0
AUDITS

18.1 Purpose

This section establishes requirements and responsibilities for a comprehensive system of planned and periodic audits that evaluate the effectiveness and verify compliance with all aspects of the QA Program.

18.2 General

18.2.1 The Audit program (Independent Assessment) includes the following elements:

18.2.1.1 Audit of the QAPP to ensure implementation of the requirements;

18.2.1.2 Surveillance of Quality Related activities to ensure compliance with site procedures, applicable regulations, codes and standards; and

18.2.1.3 Pre-award surveys and audits of suppliers who supply Quality Related items/services to ensure qualification and compliance with procurement documents.

18.3 Responsibilities

18.3.1 The QAM shall ensure that internal and/or external QA audits are performed to provide coverage and coordination with ongoing QA program activities. Audits shall be scheduled at a frequency commensurate with the status and importance of the activity.

18.3.2 The QAM shall also ensure that auditors are selected and assigned who are independent of any direct responsibility for performance of the activities which they will audit.

18.3.3 The QAM shall assign auditors to the audit team when required, who have experience and training commensurate with the scope and complexity of the activities to be audited.

18.3.4 The QAM shall assure that auditors are trained and qualified in accordance with approved procedures.

18.3.5 The QAM is responsible for planning, scheduling and conducting audits and internal surveillances.

18.3.6 TMMC managers shall assess their management processes to determine effectiveness in achieving objectives, and to promote improvement. Management Assessments shall be scheduled and performed by all Manager/Supervisors at least annually.

18.4 Audit/Surveillance Performance

18.4.1 Audits shall be planned and conducted in accordance with written procedures and checklists to assure that all requirements of the activity audited are addressed during the audit and that associated procedures are adequate to control the activity.

18.4.2 Audit conduct and auditor qualifications shall be in accordance with written procedures.

18.4.3 Surveillances shall be planned and conducted in accordance with written procedures and checklists to assure that all requirements of the activity evaluated are addressed during the surveillance.

18.5 Audit Reporting

18.5.1 A written report shall be prepared upon completion of the audit or surveillance detailing the results including the scope, date, participants, and recommendations for correcting deficiencies. The report shall be distributed to the responsible departments and appropriate management.

18.5.2 Manager/Supervisors shall review audit/surveillance reports, evaluate findings and schedule corrective actions.

18.6 Follow-up and Closeout

18.6.1 The Lead Auditor or person performing the audit/surveillance shall follow-up to ensure corrective action is completed as scheduled and is effective.

18.6.2 The Lead Auditor shall close out the audit when findings, observations or nonconformances have been resolved in a satisfactory manner.

18.6.3 All audit/surveillance documentation shall be maintained as QA records in accordance with SECTION 17.0 of this QAPP.

SECTION 19.0
SOFTWARE QUALITY ASSURANCE

19.1 Purpose

Where applicable, this section establishes requirements for the validation, verification and control of computer programs that are generated or procured by TMMC for internal use.

19.2 General

Computer programs which are in Quality Related applications shall be validated, verified and controlled according to the requirements of this section.

19.3 Responsibilities

19.3.1 The QAM shall verify that procurement documents for computer programs specify applicable requirements. The QAM is responsible for the performance of periodic surveillances and/or audits to verify implementation of this section.

19.3.2 The QAM or Designee is responsible for storage and maintenance of program documentation including computer tapes, diskettes, CD's, and user manuals.

19.3.3 Managers/Supervisors are responsible for the development of new computer programs or modification to existing programs according to specifications. Validation test problems shall be prepared for new and modified programs.

19.4 Computer Program Development, Validation and Verification

19.4.1 Computer programs shall be developed by qualified programmers identifying and documenting applicable design inputs.

19.4.2 Verification tests shall be developed and run to test all applicable program options. Acceptance limits for verification testing shall be defined. Results shall be documented in writing.

19.4.3 User manuals shall be prepared or modified (for revised programs) by the program developer.

19.4.4 An independent reviewer shall verify that the program has been developed and tested in accordance with associated requirements, that the user manual is adequate, and that associated documentation is complete. The reviewer shall indicate approval in writing.

19.4.5 Revised programs shall require the same testing, documentation and review as required for the original program development.

19.5 Validation of Procured Computer Programs

19.5.1 When validation of purchased computer programs exists, technically competent individuals shall review the validation documents. Review and approval shall be documented.

19.5.2 When validation documentation for purchased computer programs does not exist, validation problems shall be run by a competent individual to test all program options related to the Quality Related function and demonstrate satisfactory operation for the program application. Results and approval shall be documented accordingly.

19.5.3 Computer Program Documentation Maintenance

The storage and maintenance of program documentation, including computer tapes, diskettes, cassettes, CD's, etc., shall be in accordance with the requirements of SECTION 17.0 of this QAPP.

Exhibit 1
Correlation of QA Reference Standards to the TMMC QAPP

Criteria of: ASME NQA-1	Criteria of: 10 CFR 830 Subpart A (DOE)	Applicable TMMC QAPP Section
1. Organization	1. Management/Program 10 Assessment/Independent Assessment	QAPP Section 1 and Organization Charts
2. Quality Assurance Program	1. Management/Program 2. Management/Personnel Training and Qualification 3. Management/Quality Improvement 9. Assessment/Management Assessment 10. Assessment/Independent Assessment	QAPP Section 2
3. Design Control	6. Performance/Design	QAPP Sections 3 and 19
4. Procurement Document Control	7. Performance/Procurement	QAPP Section 4
5. Instructions, Procedures, and Drawings	4. Management/Documents and Records 5. Performance/Work Process	QAPP Section 5
6. Document Control	4. Management/Documents and Records	QAPP Section 6
7. Control of Purchased Items and Services	7. Performance/Procurement	QAPP Section 7
8. Identification and Control of Items	5. Performance/Work Process	QAPP Section 8
9. Control of Special Processes	5. Performance/Work Process 8. Inspection and Acceptance Testing	QAPP Section 9
10. Inspection	8. Inspection and Acceptance Testing 10. Assessment/Independent Assessment	QAPP Section 10
11. Test Control	8. Inspection and Acceptance Testing 10. Independent Assessment	QAPP Section 11
12. Control of Measuring and Test Equipment	5. Performance/Work Process 8. Inspection and Acceptance Testing	QAPP Section 12
13. Handling, Storage, and Shipping	5. Performance/Work Process	QAPP Section 13
14. Inspection, Test, and Operating Status	5. Performance/Work Process 8. Inspection and Acceptance Testing	QAPP Section 14
15. Control of Nonconforming Items	3. Management/Quality Improvement 10. Assessment/Independent Assessment	QAPP Section 15
16. Corrective Action	3. Management/Quality Improvement 10. Assessment/Assessment/Independent Assessment	QAPP Section 16
17. Quality Assurance Records	4. Management/Documents and Records	QAPP Section 17
18. Audits	9. Assessment/Management Assessment 10. Assessment/Independent Assessment	QAPP Section 18

Exhibit 2
Organizational Chart
TOXCO Materials Management Center