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Fissile Materials Disposition Program

Plutonium Immobilization Project Development and Testing

Quality Assurance Program Description

February 1999

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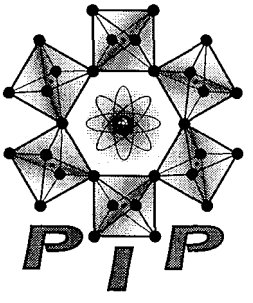
Fissile Materials Disposition Program



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LAWRENCE LIVERMORE NATIONAL LABORATORY

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QUALITY ASSURANCE PROGRAM DESCRIPTION

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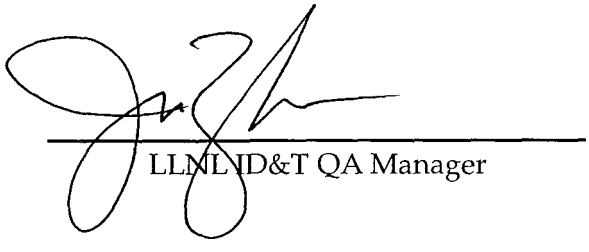

LLNL ID&T QA Manager

2-12-99

Date

LLNL ID&T Project Leader

2/14/99

Date

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REVISION HISTORY

REVISION	REVISION DESCRIPTION	REVISION DATE
0	Initial Issue	02/14/99

GLOSSARY

Activity	A directed process working toward a major program objective. Activities include programmatic functions; facility operations, scientific research experiments; development of prototype and test equipment and software, chemical processes; accelerator, computer and facility operations; and all forms of technical services and administrative functions.
Activity Leader	The line manager responsible for an activity or group of activities covered by a QA plan. The activity leader may be at any level with in the organization. Examples of activity leaders may include supervisors, division leaders, facility managers, group leaders, project leaders, project engineers, principal investigators, and lead experimenters.
Affected Organizations	An organization performing Program work subject to BARD requirements whose organizational relationships are defined in the ID&T Program documents. The Plutonium Immobilization Project sites are affected organizations.
Assessments	An audit, quality surveillance, readiness review or management performed by ID&T Program personnel and other independent quality professionals and technical specialists in order to verify and validate quality performance, evaluate the level of excellence an organization is providing and/or recommend quality improvement actions.
Document	Recorded information that describes, defines, specifies, reports, certifies, requires, or provides data or results. This information can be written, pictorial, photographic, or computer media form.
ES&H	Environmental, Safety & Health. Generally includes activities designed to protect the environment, ensure the safety and health of employees and the public, and to meet regulatory requirements in these areas.
Graded Approach	A method that provides for application of management controls commensurate with the consequences and probability of failure risk.
Implementing Procedure	A document that specifies or describes how an activity is to be performed.
Inspection	A quality assurance program verification that is used to verify whether an item conforms to specified technical criteria. An inspection is an examination or measurement to verify whether an item or process meets specified requirements.
ID&T	Immobilization Development and Testing.

Plan	A scheme or method formulated beforehand, for performing a specific activity.
Policy	A basic guiding principle provided by management.
Program	The Immobilization Development & Testing Program under the Plutonium Immobilization Project.
QA	Quality Assurance - All those planned and systematic actions necessary to provide adequate confidence that an item will perform satisfactorily
QA Plan	A facility-, site-, or activity-level document that details the implementation of QA. The plan may be referenced in other facility-, site-, or activity-level documents.
Quality	The degree to which an item or process meets or exceeds the user's requirements and expectations.
Quality Surveillance	This term is used interchangeably with 'surveillance' except when a conflict arises with the NRC use of the term 'surveillance'.
Record	A completed document or other media that provides objective evidence of an item or process.
Risk	A qualitative or quantitative expression of possible loss which considers both the probability of an occurrence and the consequences of that event.
Testing	(In an experiment or laboratory) The determination of the response of a material, item or system by subjecting it to a set of physical, chemical environment, or other conditions.
Validation	An activity that demonstrates that an item or process will perform under conditions of actual use and satisfy requirements of the user.
Work	Activities that are subject to the Quality Assurance Requirements Document. In addition, work is the process of performing a defined task or activity. Examples include research and development, operations, administration, software development and use, data collection, and analysis.

INTRODUCTION

Lawrence Livermore National Laboratory Immobilization Development & Testing organization (LLNL ID&T) is a Participant in the Plutonium Immobilization Project (PIP). The LLNL D&T has lead responsibilities for form characterization and qualification, ceramic form development, process/equipment development with plutonium, and process systems testing and validation for both conversion and immobilization. This work must be performed in accordance with the graded approach of a Quality Assurance (QA) Program.

A QA Program has been developed at LLNL to meet the requirements of the DOE/MD Quality Assurance Requirements. The LLNL QA Program consists of a Quality Assurance Program Description (QAPD) and Quality Implementing Procedures. These documents interface and are a subset of the overall PIP QA Program Documents. The PIP QA Program is described in the PIP ID&T QA Plan, PIP QAPD, and QA Procedures. Other Participant Organizations also must document and describe their PIP compliant QA Programs in a QAPD and implementing procedures. The purpose of this LLNL QAPD is to describe the organization, management processes, QA Controls for Grading, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the adequacy of work.

APPROACH

LLNL ID&T has established in the form of a QA Program an organizational structure and management process for the development of quality products. This QA Program is based on the requirements defined in 10 CFR 830.120, Energy/Nuclear Safety Management/Quality Assurance Requirements; DOE/RW-0333P, Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD); DOE/MD QARD for the Fissile Materials Disposition Program; and NQA-1, Quality Assurance Requirements for Nuclear Facilities. This program description provides an overview of the approach for meeting these requirements.

The QA Program described in this QAPD is based on the principles that work will be planned, documented, performed under controlled conditions, and periodically assessed to establish work item quality and process effectiveness and to promote improvement. Management and line personnel are responsible for planning, achieving, verifying, and assessing quality and promoting continuous improvement. This QAPD further describes the quality contributions expected of all personnel and encourages their active participation in implementing the ID&T QA Program.

As required by the aforementioned Federal Regulations and requirements documents, the implementation of this QA Program is mandatory unless specifically exempted by the methods and processes defined in this QAPD and applicable implementing documents. The implementation of this program will ensure that LLNL complies with all applicable laws and regulations and just as importantly assures that the program's products and deliverables meet the high standards of quality expected by our customers, the Department of Energy.

The subsequent sections of this QAPD describe the LLNL QA Program in terms of the principal QA criteria described in DOE/RW-0333P Quality Assurance Requirements and Description.

CRITERION 1—ORGANIZATION

1.1 Interfaces With Outside Organizations

LLNL is the DOE technical lead organization for the Plutonium Immobilization Project. In addition to LLNL, the main laboratory participants in the project are:

- Westinghouse Savannah River Company (WSRC),
- Argonne National Laboratory (ANL) , and
- Pacific Northwest National Laboratory (PNNL).

The interfaces and relationships among the main participants at the project level will be discussed in the PIP QAPD. The interfaces at the LLNL level with the main laboratory participants will be defined in specific Activity Plans, Test Plans, Scientific Notebooks, or other project memoranda.

The following subcontracting organizations support the Immobilization ID&T Program through LLNL:

- **Australian National Science and Technology Organization (ANSTO)** - ANSTO provides ceramic formulation development, characterization and testing.
- **Lawrence Berkeley National Laboratory (LBNL)** - LBNL provides chemical valence state measurements.
- **Sandia National Laboratory (SNL)** - SNL provides materials characterization measurements.
- **Massachusetts Institute of Technology (MIT)** - MIT provides studies of thermodynamic properties of neutron absorbers.
- **University of California at Davis (UC-Davis)** - UC Davis provides studies of thermodynamic properties of constituents in titanate ceramic.
- **Brigham Young University (BYU)** - BYU provides studies of thermodynamic properties of constituents in titanate ceramic.

Each of these LLNL support organizations will be directed by and report to a LLNL Task or Activity Lead. The LLNL Task or Activity Lead will develop the scope of work, deliverable list, schedules, and methods of interface. Each of these participating support organizations will implement LLNL ID&T QA procedures or equivalent QA procedures. For QA purposes, these organizations will be treated as extensions of LLNL rather than suppliers that must be qualified and regularly re-qualified. The main interface document with these organizations will be a contract or other procurement document, supplemented by applicable test plans, activity plans, or project memoranda as defined in the contract document.

LLNL and its direct support contractors will also use various organizations for specific analyses, testing, or calibration functions. For QA purposes, a subset of these organizations (ones that perform quality affecting tasks or produce a quality affecting item) will be considered suppliers that must be qualified and re-qualified in accordance with LLNL QA procedures. The main interface document with these organizations will be a contract or other procurement document.

1.2 ID&T Responsibilities

1.2.1 ID&T Project Leader

The ID&T Project Leader is responsible for approving this QAPD and for maintaining an organizational environment conducive to the effective implementation of the ID&T QA Program. Authority for the execution of the ID&T QA function, including the verification of effective implementation, is delegated to the ID&T QA Manager. The ID&T Project Leader position is currently filled by the same person as the PIP Program Leader. If and when a transition of the Program function to the selected Immobilization Facility site occurs, a LLNL ID&T Project Leader will become a separate position. Because one person currently fills these two positions, a Deputy LLNL ID&T Project Leader will implement many of the ID&T Project Leader's duties and responsibilities.

1.2.2 ID&T Management (Activity and Task Leads)

The ID&T Management Team, comprising activity and task leaders, has overall responsibility for the successful accomplishment of the ID&T objectives. ID&T Management provides the necessary planning, organization, direction, control, resources, and support to achieve its mission objectives. Management is responsible for planning, performing, and improving the quality of work.

ID&T Management is responsible for establishing and implementing policies, plans, and procedures that control the quality of work, consistent with the provisions of this QAPD. Management is responsible for defining quality, developing appropriate plans to attain quality, providing support of the workers in pursuit of quality, and verifying quality achievement.

ID&T Management has various QA responsibilities that include:

- ensuring that adequate technical and QA training is provided for personnel performing activities important to the satisfaction of ID&T objectives;
- ensuring compliance with all applicable regulations and requirements pertaining to ID&T activities, and appropriate state and local laws;
- ensuring that personnel adhere to procedures for the development, identification, control, and protection of QA records;
- exercising the authority and responsibility to stop unsatisfactory work such that cost and schedule do not override environmental, safety, or health considerations;

- developing, implementing, and maintaining plans, policies, and procedures that implement this QAPD; and

- identifying, investigating, reporting, and correcting quality problems.

1.2.3 LLNL ID&T QA Manager

The LLNL ID&T QA Manager reports to the ID&T Project Leader and has the authority and overall responsibility to independently assess the effective implementation of the LLNL ID&T QA Program. Additional authorities and responsibilities of the LLNL ID&T QA Manager include the following:

- scheduling and conducting QA assessments;

- coordinating LLNL QA activities with the overall PIP QA Manager;

- maintaining liaison with other program QA organizations and other affected organizations;

- preparing, as appropriate, and reviewing internal procedures that implement the provisions of this QAPD;

- reviewing and approving, with line management concurrence, supplier and sub-tier participant QA plans;

- tracking, performing trend analysis, and reporting quality problem areas; and

- providing for the processing of documentation concerning conditions adverse to quality.

The ID&T QA Manager will have direct access to responsible management at a level where appropriate action can be affected; be sufficiently independent from cost and schedule considerations; have the organizational freedom to communicate with management; and have no other responsibilities unrelated to the quality assurance program that would prevent full attention to quality assurance matters.

ID&T management policy grants the QA organization sufficient authority, access to work areas, and organizational freedom to identify quality problems, recommend solutions, verify implementation of solutions, and assure that unsatisfactory conditions are controlled until proper disposition has occurred.

Additionally, the ID&T QA Manager will:

- develop, establish, and interpret ID&T QA policy to ensure effective implementation;

- prepare, issue, and maintain the ID&T QAPD and quality implementing procedures;

- interface with ID&T staff, and others, relating to quality assurance matters;

- assist other ID&T organizations with quality planning, documentation, quality measurement, and problem identification and resolution; and
- provide guidance to all ID&T organizations concerning identification, control, and protection of QA records.

1.2.4 ID&T Staff

Effective implementation of the ID&T QA Program is dependent upon the efforts of individuals at all levels of the organization. The ID&T organization is structured such that the individual performing the work is responsible for achieving and maintaining quality.

Each employee, including contractor personnel working to ID&T QA procedures, is responsible for the mandatory implementation of project requirements documents and for promptly reporting all existing, developing, or potential conditions adverse to quality, to the responsible management for evaluation and action.

CRITERION 2—QA PROGRAM

LLNL has established a Quality Assurance Program that defines the management processes and controls on work performed in support of the PIP ID&T Program. This QA Program is defined by this Quality Assurance Program Description, QA and technical implementing procedures, an assortment of plans (test, task, activity, QA, Records, etc.), and management policies and directives that are documented in LLNL memoranda.

This QA Program has been developed in a structured manner that provides for top down implementation of the applicable requirements documents. This QA Program accommodates the size, location, organizational structure, and nature of the work to be performed by LLNL. This structured and graded approach ensures that the management processes and controls are carried out efficiently and effectively. Because LLNL will not directly perform all of the technical work for the ID&T, this QA Program addresses the positive controls needed for external and internal interfaces.

Some of the work performed by LLNL personnel will be performed under controls established by overall LLNL Management. These controls include both quality assurance and administrative policies and procedures. The overall LLNL QA Program is defined and described in the LLNL Quality Assurance Plan - "Quality Assurance Program, M-078, Rev. 2, July 1994", and "Quality Assurance Program for Nuclear Facilities and Nuclear Facility Support Functions - M-078-NF, Revision 4."

The ID&T QA Program structure and general description of the management processes that are in place to ensure that program objectives are achieved, are discussed in the following sections that are generally based on the eighteen quality assurance elements of NQA-1 and supplements of DOE/RW -0333P QARD.

2.1 Quality Assurance Controls

The results of scientific investigations, testing, and engineering studies on the ID&T Program have varying levels of use. Some results will be used directly for license application, whereas other results will be used to investigate a concept, determine the feasibility of an approach, or assemble and test a prototype design. To determine the correct level of controls that are applicable to the work being performed, the LLNL QA Program will go through a process of classification and grading of the work.

2.1.1 QA Grading

The application of quality assurance management controls will be determined during the planning of assigned work, and will depend on the relative importance of an activity or its end result. The extent or level of controls (grading) to be applied to an activity performed by ID&T will be commensurate with the risk posed to Program objectives by that activity, considering such factors as:

- impact on the health and safety of the public, workers, or the environment;
- importance of the data generated or analyzed;
- ability to demonstrate functional compliance through inspection or test;
- function or end use of the item.
- complexity of design or fabrication of the item or design or implementation of the activity;
- reliability of the process;
- reproducibility of the results;
- uniqueness of the item or degree of standardization;
- history of the item or service quality;
- necessity for special controls or processes; and
- impact on cost and or/schedule.

The application of management controls for ID&T activities and tasks is identified in **Table 1**, "Application of Quality Assurance Management Controls." QA controls (grading) shall be applied to the degree commensurate with the following:

2.1.2 Classifying Items and Work

The QA program shall apply to the following:

- Items important to public radiological safety as described in 10 Code of Federal Regulations (CFR) Parts 60, 71, and 72.
- Items and natural barriers important to waste isolation as described in 10 CFR Part 60.
- Items required for the control and management of site-generated radioactive waste other than spent fuel and high-level waste.
- Items required for the protection of items important to safety and waste isolation from the hazards of fire.
- Items not intended to perform a safety function but whose failure could impair the capability of other items to perform their intended safety or waste isolation function.
- Items required for physical protection as defined by 10 CFR Part 73.
- Items required to control occupational radiological exposure.

2.1.3 Controlling Activities

The QA program shall apply to immobilization form and their characterization data. Note: Characterization for the purpose of QA applicability includes activities related to sample collection and the collection and analysis of data or immobilization form samples that support performance confirmation or performance assessments.

The QA program shall apply to activities related to the items on a *Q-List* (such as design, procurement, construction, fabrication, production, handling, packaging, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification, and decontamination).

The QA program shall apply to those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.

The QA program shall apply to activities related to the high-level waste form development through qualification, production, and acceptance.

2.2 Planning

The LLNL ID&T Management will to some extent plan all work that will be performed in support of the ID&T Program. A documented plan could be in the format of an overall Project Plan, or subdivided into Activity or Task plans. Additional documented plans may be developed as necessary to provide for more detail or describe a lower level of work below the Work Breakdown Structure of the Project. LLNL Management will determine the appropriate level of planning at these more detailed levels. Some of these plans have already been determined by management and are included in implementing procedures. At the program level, the Immobilization Project has developed and is implementing and Integrated D&T Plan that covers all of the ID&T activities and tasks in the program.

For some work that is to be performed to meet RW-0333P requirements, specific planning information must be included in a plan or set of plans for each defined work activity to ensure work is accomplished under suitably controlled conditions. These planning elements include

- Definition of the work scope, objectives, and a listing of the primary tasks involved.
- Identification of scientific approach or technical methods used to collect, analyze, or study results of applicable work.
- Identification of applicable standards and criteria.
- Identification and selective application, or development, of appropriate implementing documents.
- Identification of field and laboratory testing equipment, or other equipment.

- Identification of, or provisions for the identification of, required records and the recording of objective evidence of the results of the work performed.
- Identification of QA program verifications of the work performed.
- Identification of prerequisites, special controls, environmental conditions, processes, or skills.
- Identification of computer software.

2.3 Readiness Reviews

Readiness reviews will be conducted at critical Program phases to verify that work prerequisites have been satisfied; detailed technical and QA procedures have been reviewed for adequacy and appropriateness; personnel have been trained and qualified, and the proper equipment, material, and resources are available.

2.4 Peer Reviews

Peer reviews will be conducted when the adequacy of information or the suitability of implementing documents and methods essential to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards and practices. The primary use of peer reviews will be to establish a QA pedigree for previously collected or generated data. The Project Lead will assess the need to perform a peer review.

2.5 Management Assessments

The ID&T Project Leader will on an annual basis supplement the audit and surveillance activities of LLNL with an assessment of available resources, QA procedure adequacy, and QA program effectiveness. This assessment will place emphasis on the use of human and material resources to achieve program goals and objectives. The management assessment will include an introspective evaluation to determine if the entire integrated management system effectively focuses on meeting strategic goals.

The LLNL ID&T Project Leader will retain overall responsibility for management assessments. Direct participation by senior management is essential to the success of the process because management is in the position to view the organization as a total system. This assessment may interface with QA personnel but should not be confused with quality assurance audits and surveillances.

Management assessments should focus on the identification and resolution of both systematic and management issues and problems. Strengths and weaknesses affecting the achievement of organizational objectives should be identified so that meaningful action can be taken to improve quality.

2.6 Completion of a QA Matrix

LLNL has completed a matrix of where the DOE/RW-0333P QARD requirements are directly addressed in LLNL QA Implementing Procedures or other QA documents. This matrix will be updated as changes are made to the DOE/RW QARD or to LLNL QA Implementing documents. This matrix will be reviewed internally at LLNL and by the PIP QA Lead. Where exceptions or clarifications are needed, LLNL has and will continue to document these exceptions/clarifications in the comments section for the specific QARD section.

2.7 Personnel Training and Qualification

LLNL has developed a program for the training and qualification of LLNL and support staff that ensures that personnel are trained and qualified to perform their assigned work. Training will be provided to ID&T personnel on an "as-needed" basis to ensure that job proficiency is maintained.. These requirements for the training and qualification of personnel fall into two general categories based on the level of "Graded QA" requirements.

All LLNL staff will comply with University of California LLNL administrative requirements for a variety of site training, including security, health and safety, and general administrative functions. In addition to this standard practice training and documentation of qualification requirements, all LLNL and support staff performing work on the LLNL ID&T program will receive general program and QA program indoctrination. This indoctrination will cover the general PIP ID&T program goals, purpose, plans, and organization. It will also address the general QA requirements imposed on the program.

In addition to the above, individuals that must comply with RW-0333P requirements will be trained and qualified as follows:

Qualification requirements for ID&T personnel will be established for activities important to the licensing application. The training requirements and results will be documented. These positions include but are not limited to managers, scientists, and assessment personnel.

The responsible organization will analyze each key job position to determine the responsibilities of the position, and select personnel that have education, experience, and training, commensurate with the minimum requirements to perform or verify activities that are subject to the QAPD. The qualification of an individual will be based upon an evaluation of education and experience and will be compared to those established for the position. Verification of personnel qualifications will be performed for key staff whose work could be used to support a license application for Yucca Mountain or the Immobilization Plant.

CRITERION 3—DESIGN

LLNL ID&T personnel will be responsible for some immobilization process and equipment development. This development activity will result in design work that will be documented in equipment specifications and design drawings. LLNL will primarily be involved in development activities for Plutonium Conversion Process/Equipment and First-stage Immobilization Process/Equipment. LLNL work will encompass the design and testing of pre-prototypic and prototypic process equipment. Since this developmental work will not involve design of plant equipment, the implementation of strict QA requirements for design, as defined in DOE/RW-0333P Quality Assurance Requirements and Description, will not be required during equipment development and testing. Subsequent design work for plant equipment systems that may involve LLNL ID&T personnel will be performed in accordance with a developed Quality Implementing Procedure that meets the applicable requirements of this QA criteria.

3.1 Design Standards and Interfaces

However, design work that leads to equipment that will in the LLNL Plutonium Building will meet requirements for design review required by Plutonium Building Quality and Administrative policies and procedures. In either case, the general requirements include the following controls:

3.2 Design Verification

Items and processes will be designed using sound engineering and scientific principles and appropriate standards. Design work, including changes, will incorporate appropriate requirements such as general design criteria and design bases. Design interfaces will be identified and controlled.

3.3 Software Design

The adequacy of design products will be verified by individuals or groups other than those who performed the work. Required verification and validation work will be completed before approval and implementation of the design.

Software design requirements are included and discussed in Supplement I, Software QA, of this QAPD.

CRITERIA 4 AND 7—PROCUREMENT AND RECEIVING

LLNL administrative policies and procedures ensure that items and services are procured in accordance with all Federal and State laws and regulations. These administrative requirements ensure that items and services are procured from qualified suppliers, that specifications are defined and controlled, and that items or services received are meet procurement specifications. For critical items and quality-affecting services, additional requirements based on DOE/RW-0333P - QARD are implemented as follows:

4.1 Procurement Planning

Procurement activities will be planned as early as possible and documented to ensure a systematic approach to the procurement process. Procurement planning will identify procurement methods and organizational responsibilities; identify what is to be accomplished, who is to accomplished it, how and when it is to be accomplished; and document the sequence of actions and milestones needed to effectively complete the procurement.

4.2 Receiving

D&T will ensure that procured items and services meet established technical and QA requirements and that they are performed as specified.

4.3 Supplier Evaluation

Prospective suppliers will be evaluated on the basis of documented criteria. ID&T will verify that approved suppliers continue to provide acceptable items and services.

CRITERION 5—IMPLEMENTING PROCEDURES

To ensure that work is performed under controlled conditions and to aid in work repeatability, LLNL ID&T work activities will be performed using implementing procedures, scientific notebooks, and/or other documented instructions. LLNL has instituted management controls for the development, review, revision, and approval of implementing procedures. A "graded approach"will be taken in the application of these implementing procedures such that some LLNL ID&T personnel may need to only implement general University of California requirements or policies for work controlling documents, others may need to implement specific LLNL facility procedure requirements (e.g. Pu Building Pu handling requirements), while others will need to implement more stringent DOE/RW-0333P compliant Quality Assurance Procedures. These QA procedures allow for the direct adoption of existing Yucca Mountain Program Participant implementing procedures, conversion of American Society of Testing and Materials (ASTM) or similar nationally accepted procedures, or the development of ID&T specific implementing procedures.

Drawing control is also covered by this QA criterion; however, LLNL has not identified any controls necessary at this time for drawings created by LLNL. LLNL is currently and will continue to create drawings for prototype equipment. These drawings will be controlled in accordance with LLNL standard practices and Plutonium Building procedures rather than a specific DOE/RW-0333P compliant QA implementing procedure. Note that scientific notebooks are controlled in accordance with Supplement III requirements described in this QAPD. General requirements for control of implementing procedures are as follows:

Work will be performed under controlled conditions using approved procedures and instructions, scientific notebooks, and administrative controls. Items will be identified and controlled to ensure proper use is maintained to prevent damage, loss, or deterioration. Equipment used for process monitoring or data collection will be calibrated and maintained.

To ensure that the person performing the work achieves their goal, management is responsible for establishing processes and procedures to ensure that all work is planned and performed under controlled conditions by personnel who are knowledgeable of the work requirements, and that these individuals are capable of accomplishing the work in accordance with specified requirements.

Management is involved in work processes through their interactions with personnel performing the work and through their review and verification of ongoing and completed work. This will help ensure that the definition of "acceptable work performance" is clearly communicated and that personnel are provided the necessary training, resources, and administrative controls to properly accomplish their tasks.

Cross references to the applicable LLNL QA implementing procedures are documented in **Table 2** and **Table 3**.

CRITERIA 6 & 17—DOCUMENTS AND RECORDS

Certain documents must be controlled to ensure that the user of the document has the latest, most up-to-date procedure or drawing. LLNL has developed and implemented a formal control system that requires procedures and some other documents be prepared, reviewed, approved, and distributed in a controlled manner. The distribution system includes a requirement for the use of a receipt acknowledgement form to help ensure that each holder of the document has the latest revision of the document.

LLNL has also implemented controls for the identification, preparation, transmittal, handling, and retention of project records. LLNL has developed a system to assist in the retreivability and ensure the traceability of project records. LLNL has determined that the dual storage method of long-term records retention is the most economical method of records storage. The use of one-hour fire-rated file cabinets will be used for short-term storage while QA records are being processed and for storage of non-QA project records.

Some of the requirements that the LLNL Document Control Center will implement include:

ID&T will prepare, review, approve, issue, use, and revise documents that prescribe processes and specify requirements. ID&T will specify, prepare, authenticate, and maintain sufficient records to accurately reflect completed work.

ID&T has established and is implementing processes to control the preparation, review, approval, and revision of documents that establish policies, prescribe work, or specify requirements.

ID&T has established and is implementing processes to control the issuance and distribution of documents that prescribe work or specify requirements to ensure that correct, applicable, and current documents are available to personnel performing prescribed activities prior to the commencement of work, at the location where the work is performed.

ID&T has established and is implementing processes to ensure that sufficient records are specified, prepared, authenticated, and maintained to accurately reflect completed work. The maintenance of records will include provisions for retention, protection, preservation, traceability, accountability, and retrievability.

CRITERION 8—CONTROL OF ITEMS CRITERION 13—SPECIAL HANDLING STORAGE AND SHIPPING

These QA criteria establish requirements to ensure that only correct and accepted items are used or installed and that they are handled with appropriate care. It includes requirements for the identification of items from the time of initial fabrication, or receipt, up to and including installation and use. Other controls include: development of documentation to ensure that the item can be traced at all times from its source through installation or end use; controls for the use of physical markings; methods for control of items with limited operating or shelf life specifications, and methods for item storage. LLNL ID&T has developed quality implementing procedures that require the development of specific technical implementing procedures that identify the methods needs to meet these requirements. LLNL ID&T has not identified any items that must be controlled in accordance with the stringent requirements defined in DOE/RW-0333P QARD. However, the intent of these requirements will be implemented for prototype equipment that is developed or procured and for plutonium test materials being used to test and validate equipment designs. Implementing procedures that address these general controls are in place for any work being conducted in the LLNL Plutonium facility.

CRITERION 9—SPECIAL PROCESSES

There are no currently defined special processes at LLNL that need to be controlled. However, at some future point, special processes like welding, nondestructive testing, feed blending, or other work whose results are highly dependent on the control of the process or skill of the operator will be controlled under QA and Technical Implementing Procedures to be developed.

CRITERIA 10, 11, 14—INSPECTION AND TESTING

Some LLNL ID&T developed or procured items will require inspection or testing to ensure that they meet identified specifications. These items will primarily be prototype equipment for use in the LLNL Plutonium Building. Any inspections or tests that must be performed to verify items meet specifications will be completed in accordance with Plutonium Building quality and administrative procedures. These procedures are based on the intent of the following DOE/RW-0333P requirements. LLNL ID&T has developed quality implementing procedures that include requirements related to items that must comply with the DOE/RW-0333P QARD requirements. LLNL ID&T has not identified any items that must be inspected or tested in accordance with these requirements, but subsequent "QA grading" or items/methods development may reveal a need to implement ID&T developed procedures that meet the following general requirements.

10.1 Inspection Performance

Inspections and testing will be performed in accordance with approved implementing procedures. An essential part of the work planning process is to identify the items and processes to be inspected or tested, the parameters or characteristics to be evaluated, the techniques to be used, the acceptance criteria, any hold points, and the group responsible for performing the tests and inspections.

Inspection for acceptance will be performed by personnel other than those who performed or directly supervised the work being inspected. Inspection and testing of specified items and processes will be conducted using established acceptance and performance criteria. The acceptance of items and processes will be made and documented by qualified authorized personnel. Equipment used for inspections and tests will be calibrated and maintained.

10.2 Inspector and Testor Qualification

Personnel who perform inspections or specific tests will be qualified and certified to meet certain inspector or tester qualification requirements. These qualification requirements include both education and specific experience criteria. The responsible LLNL organization will qualify and certify the inspector or tester. For Inspectors, generally the QA Manager will perform this assessment of qualification and certification. And the Responsible technical organization will certify technical area testers.

10.3 Inspection and Testing Tags

In addition to the use of inspection or test procedures and the certification of inspectors and testers, the controls of these QA criteria also require the use of inspection and testing tags or other identifiers to prevent the inadvertent bypassing of required inspections or tests, or the inadvertent changing of inspection or test conditions.

CRITERION 12—CONTROL OF MEASURING AND TEST EQUIPMENT

This QA criterion covers the selection, identification, calibration, use, and handling of measuring and test equipment. The goals of the requirements of this criterion are to reduce the risk of unknowingly obtaining invalid or incorrect test results or data; reduce the risk of introducing unknown measurement error; to ensure that the required accuracy and precision is realized; and to make it possible to identify data from out of calibration M&TE. The LLNL ID&T has two levels of controls for equipment that will be used in tests or used to collect data. For equipment that is related to data used to support a license application, the rigorous requirements of DOE/RW-0333P will control be implemented. Similar requirements will be implemented for measuring and test equipment related to plutonium processing in the LLNL Plutonium Building. All other equipment used for testing or the collection of data will be controlled in accordance with good engineering and scientific practices, some of which are defined in University of California LLNL policies and administrative procedures. These controls will not be applicable for certain commercial equipment, such as, rulers, tape measures, levels, and other normal commercial equipment that provides adequate accuracy.

The general requirements for the control of measuring and test equipment include:

12.1 Calibration Standards

Measuring and test equipment including equipment shall be calibrated, adjusted, and maintained as a unit at prescribed intervals, or prior to use, against reference calibration standards having traceability to nationally recognized standards. Calibration standards shall have a greater accuracy than the required accuracy of the measuring and test equipment being calibrated.

12.2 Calibration Interval

The method and interval of calibration for each device shall be defined.

12.3 Equipment Tagging

Calibrated measuring and test equipment shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration. Calibrated measuring and test equipment shall be uniquely identified to provide traceability to its calibration data.

12.4 Documentation of the Use of Calibrated Equipment

The use of measuring and test equipment shall be documented to include M&TE identification, traceability information, calibration data, the identification of the individual performing the calibration and the date of calibration and date due,

results of the calibration and statement of acceptability, reference to any actions taken in connection with out-of-calibration equipment, identification of the implementing document used.

12.5 Out of Calibration Equipment

Out-of-Calibration measuring and test equipment shall be tagged, segregated, or otherwise controlled to prevent use until they have been recalibrated. When measuring and test equipment is found out-of-calibration during recalibration, the validity of results obtained using that equipment since its last valid calibration shall be evaluated.

CRITERIA 15 & 16—NONCONFORMANCES AND CORRECTIVE ACTIONS

ID&T has established and will implement procedures to detect and prevent quality problems and to ensure quality improvement. Processes that do not establish requirements will be identified, controlled and corrected. Corrections will include identifying the root cause of the problem and taking action to prevent recurrence. Process implementation and information derived from overview activities will be reviewed and the data analyzed to identify processes needing improvement. Items that do not conform to specifications or procedural requirements will be documented in accordance with a Quality Implementing procedure for the control of Nonconformances that include the following general requirements.

ID&T management is responsible for building a culture in which continuous improvement is a fundamental and integral part of the organizations' mission. ID&T will establish and implement processes to detect and prevent conditions adverse to quality, to ensure continuous improvement.

Corrective action for significant conditions adverse to quality will include identification of the causes of adverse conditions and provisions to preclude recurrence. Item reliability, process implementation, and other relevant information will be reviewed and the data analyzed to identify items and processes needing improvement.

All personnel will be responsible for identifying nonconforming items, activities, and processes and will be encouraged by management to suggest improvements. Management at all levels should foster a "no fault" attitude to encourage the identification of nonconforming items and processes. Nonconformances will be documented, evaluated, and dispositioned.

ID&T will emphasize the detection and prevention of problems before they occur as a critical part of the quality improvement process. The ID&T QA Manager will schedule QA audits and surveillance to assess implementation of the ID&T quality assurance program.

CRITERION 18—INDEPENDENT ASSESSMENT

One of the basic tenets of a good QA program is the implementation of an effective independent assessment program. The two primary methods of implementation of this QA criterion are the conduct of audits and surveillances. LLNL ID&T has instituted a system of assessment or oversight that is planned, conducted in a prescribed manner, and focuses on the results of work. These audits and surveillance will be performed to verify compliance with procedural requirements, but more focus will be placed on the verification of the overall quality of the LLNL ID&T deliverables. This assessment of overall quality will be achieved through the use of "performance-based" audits and technical surveillances evaluate the results of LLNL ID&T work more than the implementation of procedural steps. However, to ensure that customer requirements that are defined in implementing documents are implemented and to aid in the improvement of implementing procedures, compliance audits will be performed at least annually for all LLNL ID&T quality affecting activities. Some of the general requirements for the LLNL ID&T program include:

Planned and periodic independent assessments will be conducted to measure item and service quality, process effectiveness, and to promote improvement. The LLNL ID&T QA organization will have sufficient authority and freedom from the activities being assessed to carry out responsibilities. Individuals performing assessments will be technically qualified and knowledgeable of the items and activities being assessed.

The types and frequencies of independent assessments will be based upon the relevant control levels assigned to the items or services under the cognizance of the organization.

The program will be planned and documented and include routine surveillance of those activities, and audits to verify compliance of all aspects of the quality assurance program and determine its adequacy and effectiveness.

SUPPLEMENT I—SOFTWARE QA AND CONFIGURATION MANAGEMENT

The purpose of the requirements defined in this QA criterion is to ensure that: software programs and routines used by the LLNL ID&T are appropriately defined or selected to achieve its intended purpose; the software is adequately tested on the platform for which it will be used; the documentation is adequate and complete so that another user would know what the software was qualified and tested to do; the latest, most correct version of the software is used and distributed; and any discovered problems are corrected and other users are notified.

Software programs that must comply with the stringent documentation requirements from DOE/RW-0333P QARD will be limited to those programs and routines that are used to collect or support the collection or processing of data that will be delivered to support an NRC licensing application. For non-DOE/RW related software, some of these controls are identified in University of California LLNL administrative procedures. Those software programs that are used to control some equipment used in the LLNL Plutonium facility will additionally be documented and tested in accordance with Plutonium Building implementing procedures.

The general QA controls for the development, use, revision, testing, transfer, problem resolution, and retirement of software programs and software routines are described below:

I.1 Software Requirements

Software requirements will be specified, documented, and reviewed. These requirements will pertain to functionality, performance, design constraints, data attributes, and external interfaces. Each requirement will be specified in sufficient detail to permit the accomplishment of design and validation activities. Software requirements will be traceable throughout the software development cycle, and a verification and validation plan will be prepared at the conclusion of documenting and approving software requirements.

I.2 Software Design

The software design will be based on the software requirements, and will be documented and reviewed. The design will specify the overall structure and the reduction of the overall structure into physical solutions. The design may necessitate the modification of the requirements documentation and the verification and validation plans.

I.3 Software Configuration Management

A software configuration management system will be established to include configuration identification and configuration control and status accounting. Software will be placed under configuration management as each baseline element is approved.

SUPPLEMENT II—SAMPLES

LLNL ID&T will use samples of various materials for the testing of prototype equipment, and for the evaluation of the waste form. Therefore; some controls on these samples will be implemented to ensure that the pedigree of samples can be traced to prove credibility of data, to reduce the risk of using or basing conclusions on incorrect or unidentifiable or untraceable samples, and to reduce the risk that qualification data will be attributed to samples other than those the user believes it came from. LLNL ID&T has developed a Quality Implementing procedure that prescribes controls that need to be included in a technical procedure or scientific notebook. Each LLNL ID&T Activity or Task Leader is required to develop a sample control system that addresses the specific methods for sample control including the following elements:

- development of documentation to ensure that the sample can be traced at all times from its source through installation or end use;
- controls for the use of physical markings;
- methods for control of samples limited shelf life specifications,
- methods for sample handling, storage, and shipping, and
- methods to control nonconforming samples.

SUPPLEMENT III.1—SCIENTIFIC PLANNING AND USE OF SCIENTIFIC NOTEBOOKS

The scope of LLNL ID&T work includes a significant amount of research and development, as well as scientific investigations. Because of the nature of the work, detailed acceptance specifications cannot always be defined prior to the implementation of the work. The work that LLNL ID&T has been tasked to perform requires that LLNL ID&T staff be allowed some flexibility to change approaches or methods of achieving the results that LLNL ID&T has bee tasked to complete. However, management needs to ensure that their goals and objectives will be achieved in the timeframe needed and within the project budget constraints. Therefore, a planning document that describes the various elements and processes that will be implemented to achieve the desired results. The PIP program has developed an overall ID&T test Plan to describe the overall goals, objectives, and (to some extent) the methods of achieving these goals and objectives. LLNL ID&T personnel will develop more detailed plans to describe and control the planned work that is described in PIP test plan. This detailed plan will be documented in a LLNL Technical Report, separate LLNL detailed plan, or in a scientific notebook.

The implementation of these plans can be performed in accordance with technical implementing procedures. However, some of LLNL 's work does not always allow the use of prescribed methods as found in technical implementing procedures. Therefore, scientific notebooks will be utilized to document the general planned approaches and to document the evolving methods and approaches being developed by the LLNL ID&T staff. Some of the requirements for the control of these methods development or scientific investigations that will be implemented for LLNL ID&T work include:

Scientific investigations will be defined, controlled, verified, and documented. Process variables affecting scientific investigations will be measured and controlled. Scientific investigations will be performed in accordance with requirements documented in test plans, procedures, and scientific notebooks. If deviation from standards or the establishment of specially prepared test procedures is deemed appropriate, the modified or new test procedures will be documented in sufficient detail to be repeatable, and will be justified, evaluated, and approved by the responsible individual.

SUPPLEMENT III.2—DATA TRACEABILITY, REVIEW, AND QUALIFICATION

LLNL ID&T will produce a significant amount of data that may be used in a license application for a proposed geologic repository, and potentially for the Plutonium Immobilization Plant. Therefore it is important that LLNL staff control these data so that it can be traced by to its source, and be shown to technically accurate and correct through a review process. The general requirements for the control of data include the following:

III.2.1a Data Traceability

All data will be recorded so that it is clearly identifiable and traceable to the test, experiment, study, or other source from which it was generated. Identification and traceability of the data will be documented and maintained.

III.2.1b Data Controls

The method of data recording will be controlled to avoid data loss and permit data retrievability. Controls will be established to ensure that data integrity and security are maintained wherever data are stored. Controls will prescribe how specific types of data will be stored with respect to media, conditions, location, retention time, security, and access. Data will be suitably protected from damage and destruction during their prescribed lifetime and will be readily retrievable.

SUPPLEMENT V—CONTROL OF THE ELECTRONIC MANAGEMENT OF DATA

Processes will be developed to control and verify that data that is stored, processed, and used electronically is correct, accurate, and complete. These methods will ensure that data transmitted from one source or media to another that all data were transferred without corruption and reduce the risk that data retrieved through the use of a query language produce the desired information and results. LLNL ID&T has developed a QA implementing procedure that prescribes the minimum requirements for the development and documentation of procedural or scientific notebook controls for the management of these databases.

Table 1. LLNL WBS activity graded QA level assessment matrix.

Activity and Task	FY99	FY00	FY01	FY02
1.0 Program Management				
1.1 Project Office				
1.2 QA				
1.3 Technical Documentation				
1.4 Plutonium Facility				
2.0 Technical Support				
2.1 Feed Materials Characterization and Blending				
2.2 Proliferation Resistance				
2.3 System Integration and Cross-cutting Functions				
3.0 Immobilized Form Development				
3.1 Coordination and Facilities	Q	Q	Q	Q
3.2 Basic Formulation and Process Parameters	Q	Q	Q	Q
3.3 Form Qualification Samples and Data	Q	Q	Q	Q
3.4 Product Control Model Development	Q	Q	Q	Q
4.0 Perf Testing and Qual for Repos				
4.1 Form Performance Testing and Dissolution Modeling	Q	Q	Q	Q
4.1.1 Radiation-damage Sample Synthesis	Q	Q	Q	Q
4.1.2 Short-term Corrosion Tests	Q	Q	Q	Q
4.1.3 Long-term Corrosion Tests	Q	Q	Q	Q
4.1.4 Integrated Corrosion Tests	Q	Q	Q	Q
4.1.5 Single-pass Flow-through (SPFT) Tests	Q	Q	Q	Q
4.1.6 Dissolution Model Development	Q	Q	Q	Q
4.1.7 Physical Property Measurements	Q	Q	Q	Q
4.2 Thermodynamic Data Determination and Validation	Q	Q	Q	Q
4.2.1 Aqueous Solubility/Speciation Meas	Q	Q	Q	Q
4.2.2 Solid Phase Enthalpy and Entropy Meas	Q	Q	Q	Q
4.3 Form Qualification and Repository Interactions	Q	Q	Q	Q
5.0 Pu Conversion Process/Equipment Dev				
5.1 Material Receipt & Storage	q	q	q	q
5.2 Oxide Fuel Feed Preparation	q	q	q	q
5.3 Material Size Reduction				
5.4 Material Unpackaging and Sorting	q	q	q	q
5.5 Metal Fuel Feed Preparation	q	q	q	q
5.6 Metal Conversion	q	q	q	q
5.7 Impure Oxide Feed Preparation	q	q	q	q
5.8 Materials Characterization	q	Q	Q	Q
5.9 Material Control and Accountability				
5.10 In-process Storage Vault				

Table 1. LLNL WBS activity graded QA level assessment matrix. (cont.)

Activity and Task	FY99	FY00	FY01	FY02
6.0 First Stage Immob Process/Equip Dev				
6.1 Ceramic Feed Batching				
6.2 Ceramification Subsystem Development and Testing				
6.2.1 Ceramification Process Dev	q + Q	q + Q	q + Q	q + Q
6.2.2 Ceramification Equipment Dev	q	q	Q	Q
6.3 Ceramic Puck Handling				
6.4 NDE for Process Control	q	q	q	q
6.5 SNM Material Accountability	q	q	q	q
6.6 Sintering	q	q	q	q
6.7 Recycle of Unacceptable Materials	q	q	q	q
6.8 Can Loading				
6.9 Can NDE and MC & A				
6.10 Can Storage Vault				
7.0 Second Stage Immob Proc/Equip Dev				
7.1 Canister pour analysis and testing				
7.1.1 Canister Design and Assembly				
7.1.2 Canister pour analysis and testing	q	q	q	q
7.2 Can in Canister Design and Assembly				
7.3 Canister Transport System				
7.4 DWPF Receipt and Handling				
8.0 Plant Equipment Testing and Demos				
8.1 Ceramic Process Test Facility				
8.2 Plutonium Process Support Laboratory				
8.3 Integrated Equipment Test Facility				
9.0 NEPA				
10.0 DOCDR				

Note:

Q the full LLNL D&T QA Program (all applicable QA Elements from DOE/RW-0333P)

q implementation of select QA Program elements for good management practices, inlcuding organization ,training, scientific notebooks and records.

Table 2. Cross reference of DOE/RW-0333P elements to LLNL implementing procedures.

QARD Criterion	Criterion Title	LLNL Procedure
1.0	Organization	LQIP 1.1 - Organization
2.0	QA Program	
	Planning	LQIP SIII.1 - Scientific Notebooks
	Classifying Items/Activities	LQIP 3.1 - Applying QA Controls
	Surveillances	LQIP 18.2 - Surveillances
	Management Assessments	LQIP 2.2 - Management Assessment
	Readiness Reviews	LQIP 2.4 - Readiness Review
	Peer Reviews	LQIP 2.3 - Peer Review
	Document Reviews	LQIP 6.2 - Document Review
	Training & Qualifications	LQIP 2.1 - Training
3.0	Design Control	LQIP 3.2 - Design
4.0	Procurement Document Control	LQIP 4.1 - Procurement
		LQIP 7.1 - Supplier Qualification
5.0	Implementing Documents	LQIP 5.1 - LQIP Development
		LQIP 5.2 - Technical Procedures
6.0	Document Control	LQIP 6.1 - Document Control
		LQIP 6.2 - Document Review
7.0	Control of Purchased Items	LQIP 7.1 - Supplier Qualification
		LQIP 7.2 - Receiving Inspection
8.0	Control of Items	LQIP 13.1 - Handling, Storage, Shipping
9.0	Special Processes	N/A
10.0	Inspection	LQIP 10.1 - Inspection
11.0	Test Control	LQIP 11.1 - Test Control
12.0	Measuring and Test Equipment	LQIP 12.1 - M&TE
13.0	Handling, Shipping, and Storage	LQIP 13.1 - Handling, Storage, Shipping
14.0	Inspection, Test, and Operating Status	LQIP 14.1 - Test Status
15.0	Nonconformances	LQIP 15.1 - NCRs
16.0	Corrective Actions	LQIP 16.1 - Corrective Actions
		LQIP 16.2 - Trending
17.0	QA Records	LQIP 17.1 - QA Records
18.0	Audits	LQIP 18.1 - Audits
		LQIP 18.2 - Surveillances
		LQIP 18.3 - Auditor Qualification
SI	Supplement I - Software	LQIP SI.1 - Software QA
SII	Supplement II - Samples	LQIP 8.1 - Samples
SIII	Supplement III-Scientific Investigations	LQIP SIII.1 - Scientific Notebooks
		LQIP SIII.2 - Data Traceability
SV	Supplement V- Control of Electronic Management of Data	LQIP SV.1 - Electronic Data Management

Table 3. Cross reference of 10 CFR 830.120 QA requirements to LLNL Plutonium Facility–Bldg. 332 QA program documents.

10 CFR 830.120 Section and QA Criteria	LLNL Pu Facility QA Program Documents
Section 1 - Management	
(i) Program	LLNL Quality Assurance Plan - Quality Assurance Program, M-078, Rev. 2, July 1994, Quality Assurance Program for Nuclear Facilities and Nuclear Facility Support Functions - M-078-NF, Revision 4. Plutonium Facility QA Plan (QAP) (M-078-020 Rev. 2, May 1994) Section 3.1.3 through 3..1.3.16
(ii) Training and Qualification	Facility Safety Procedure (FSP) Section 7 and Appendix K Safety Training Program (STP) for Plutonium Workers - Section 3; and Training Implementation Matrix (TIM)
(iii) Quality Improvement	FSP Sec. 3, 8, & Appendix F Plutonium Facility - Building 332 Quality Implementing Procedure QIP 3 - Corrective Action Record Procedure
(iv) Documents and Records	QAP Section 3.4 Plutonium Facility - Building 332 QIP 6 - Document and Record Control Procedure
Section 2 Performance	
(i) Work Processes	QAP Sec. 4.1, Sec. 8.1.2, 8.2.5 FSP Sec. 2, 4, & 8, and Appendix C, D, F, & L Plutonium Facility Maintenance & Operations Manual (MOM) - UCRL-MA-127630
(ii) Design	QAP Sec. 4.2 QIP 1- Design Review procedure
(iii) Procurement	QAP Sec. 4.3 QIP 7 - Procurement control procedure
(iv) Inspection and Acceptance Testing	QAP Sec 4.4 QIP 5- Inspection and Acceptance Testing procedure QIP 8 - Calibration Program for Measuring and Test Equipment
Section 3 - Assessment	
(i) Management Assessment	QAP Sec. 5.1 Self-Assessment and Deficiency - Correction Implementation Plan
(ii) Independent Assessment	performed by Univ. of Ca. - LLNL- Assurance Review Office in accordance with their quality procedures and by LLNL D&T QA Organization in accordance with LLNL D&T QIPs 18.1, 18.2, 18.3, and 7.2