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US Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

Three Mile Island Nuclear Station, Unit 2
Operating License No. DPR-73
Docket No. 50-320
PDMS Quality Assurance Plan, Rev. 1

Dear Sir:

This letter transmits Revision 1 to the Post-Defueling Monitored Storage (PDMS) Quality Assurance Plan (QAP) for Three Mile Island, Unit 2 (Attachment 1). This revision is being forwarded in accordance with 10 CFR 50.54(a)(3) and 10 CFR 50.71. The changes made were to replace the word "should" with the word "shall" in the Introduction portion of the plan and to update titles in Sections 2.7 and 2.8 to reflect current organizations. The changes to the PDMS QAP do not reduce commitments to the NRC and are being forwarded to you for information only.

Sincerely,

R. L. Long
Director, Services Division

EDS/dlb
Attachment

cc: M. G. Evans - Senior Resident Inspector, TMI
T. T. Martin - Regional Administrator, Region 1
M. T. Masnik - Project Manager, PDNP Directorate
L. H. Thonus - Project Manager, TMI

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POST-DEFUELED MONITORED STORAGE
QUALITY ASSURANCE PLAN

Number
1000-PLN-7200.04

Title DPNCS Post-Defueling Monitored Storage Quality Assurance Plan for Three Mile Island Unit 2		Revision No. 1
Applicability/Scope This plan has TMI-2 Applicability		Responsible Office 6162
This Document is Within QA Plan Scope Safety Reviews Required		Effective Date *

List of Effective Pages

Page	Revision	Page	Revision	Page	Revision	Page	Revision
1.0	1	11.0	0	21.0	0	31.0	0
2.0	1	12.0	0	22.0	0	32.0	0
3.0	1	13.0	0	23.0	0	E1-1	0
4.0	1	14.0	0	24.0	0	E1-2	0
5.0	0	15.0	0	25.0	0		
6.0	0	16.0	0	26.0	0		
7.0	0	17.0	0	27.0	0		
8.0	1	18.0	0	28.0	0		
9.0	0	19.0	0	29.0	0		
10.0	0	20.0	0	30.0	0		

*Effective upon entry into PDMS phase.

	Signature	Concurring Organizational Element	Date
Originator	<i>[Signature]</i>	Director, Quality Assurance	2/18/93
Concurred By	N/A	Director, TMI-2	
	N/A	Director, Site Services	
	N/A	Director, Corporate Services	
	<i>[Signature]</i>	Director, Nuclear Assurance	2/24/93
	N/A	Director, Technical Functions Div.	
	N/A	Director, TMI-1 Division	
	N/A	Corporate Secretary	
	<i>[Signature]</i>	Staff Analyst, Policies/Procedures	5/11/92
	<i>[Signature]</i>	Responsible Technical Reviewer	4/1/93
Approved By	<i>[Signature]</i>	Office of the President	4/1/93

Title

DOCUMENT HISTORY

Revision No.

1

DOCUMENT HISTORY

REVISION	EFFECTIVE DATE	DESCRIPTION OF CHANGE	PREPARED BY: REVIEWED BY: APPROVED BY:
0		Initial Issue.	
1		<ul style="list-style-type: none">• Changed "should" to "shall" in second line of third paragraph of Introduction per commitment to NRC.• Updated titles in Sections 2.7 and 2.8 to reflect current organizations.• Made "Effective Date" contingent upon entry into PDMS phase.• Also, pagination changed due to conversion of document from WANG to Word Perfect Format.	

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Title

INTRODUCTION

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1

INTRODUCTION

At the completion of the TMI-2 Cleanup Program, the plant will be in a safe, stable condition that poses no risk to the health and safety of the public. The absence of any significant quantity or configuration of nuclear fuel assures that there is no potential for a nuclear criticality. This phase of plant life has been named Post-Defueling Monitored Storage (PDMS) and is suitable for an extended period.

During the PDMS period, GPUN will be licensed under 10 CFR 50 to "possess but not to operate" the TMI-2 facility. Since the plant will be in a non-operating and defueled status, there will no longer be any structures, systems, or components that perform a safety function. Therefore, the quality assurance (QA) requirements of 10 CFR 50, Appendix B, do not specifically apply. However, this Plan has been developed to provide TMI-2 with an appropriate scope PDMS QA Program based upon the guidance of Appendix B requirements. It replaces the "Recovery QA Plan for Three Mile Island Nuclear Station Unit 2" and shall be implemented according to NRC approved License conditions.

This Plan has been structured to correspond to the 18 criteria format of 10 CFR 50, Appendix B. The Plan shall be applied, as necessary, to assure that safe and stable PDMS conditions are maintained, while complying with all pertinent Licensing and other regulatory requirements. The TMI-2 PDMS Safety Analysis Report (SAR) provides rationale concerning the applicability of various regulatory requirements and should be consulted when implementing the Plan. Additionally, it is intended that the Plan be implemented to assure conformance with applicable 10 CFR 20; 10 CFR 71, Subpart H; and 49 CFR requirements. Any questions regarding the scope or interpretation of the Plan should be addressed to the Director, QA for determination.

Existing GPUN organizations and approved nuclear QA programs may be utilized to fulfill the requirements of the PDMS QA Plan since they will meet or exceed its intent.

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Revision No.

ORGANIZATION

0

1.0 ORGANIZATION**1.1 General**

1.1.1 It is the policy of GPUN to conduct PDMS activities at TMI-2 in such a manner as to ensure protection of the health and safety of the public and the personnel on site. To implement this policy, GPUN will adhere to the applicable QA requirements of the Nuclear Regulatory Commission (NRC) as presented in the Code of Federal Regulations (CFR) and appropriate Regulatory Guides, codes and standards; the ASME Boiler and Pressure Vessel Code as applicable to the State of Pennsylvania; other pertinent federal, state, and local QA regulatory requirements; and the GPUN corporate policies, as applicable.

1.1.2 To comply with these requirements, the Office of the President has authorized the establishment of a formal and comprehensive QA Program. This Program, which is described in the following sections, shall be implemented through documented and approved policies, procedures, and instructions which adhere to this Plan.

1.2 Responsibilities

1.2.1 The organizational elements responsible for the PDMS phase of TMI-2 are outlined in the following controlled documents: The GPUN Organizational Chart and the TMI-2 Technical Specifications identify the general structure of the on-site and off-site organizations supporting TMI-2. The GPUN Organization Plan sets forth specific responsibilities with regard to the requirements of this Plan and implementing procedures.

1.3 Office of President - GPUN

1.3.1 The Office of President - GPUN has the overall responsibility for the establishment, implementation, and effectiveness of the TMI-2 PDMS QA Program. This responsibility is administered through management staff.

1.3.2 The Organization Plan shall define responsibilities for the following functions:

- 1.3.2.1 Operations and Maintenance
- 1.3.2.2 Engineering Support
- 1.3.2.3 Radiation Controls
- 1.3.2.4 Environmental Controls
- 1.3.2.5 Licensing
- 1.3.2.6 Independent Review
- 1.3.2.7 Quality Assurance

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2.0 QUALITY ASSURANCE PROGRAM

2.1 The PDMS QA Plan is the primary document which establishes the policies, goals, and objectives of the QA Program for TMI-2 and is an integral part of the PDMS SAR. This Plan is authorized by the Office of the President and requires that the appropriate levels of management implement the PDMS QA Program. The purpose of this Plan is to establish the principal requirements which, when implemented, will provide that level of assurance necessary to meet and maintain secure PDMS conditions while complying with all pertinent License requirements.

2.2 The scope of the PDMS QA Program includes all items and activities which are necessary for safe PDMS operations, maintenance, and surveillance. These items and activities are designated as within "QA Plan Scope" and include:

- 2.2.1 Structures, systems, and components required to be operable by the TMI-2 Technical Specifications.
- 2.2.2 Operations associated with any of the structures, systems, and components included in 2.2.1 above, including chemistry activities.
- 2.2.3 Surveillance testing and maintenance of structures, systems, and components included in 2.2.1 above.
- 2.2.4 Modifications of structures, systems, and components included in 2.2.1 above.
- 2.2.5 Radiological monitoring (including on-site and environmental monitoring).
- 2.2.6 Radiological protection.
- 2.2.7 Radioactive waste management.
- 2.2.8 Emergency planning.
- 2.2.9 Training.
- 2.2.10 Security.
- 2.2.11 Fire protection.
- 2.2.12 Additional items/activities deemed necessary by plant management.

NOTE: The SAR should be referred to for descriptions of the Security, Emergency, and Radiation Protection Plans established for PDMS.

2.3 Procedures, or portions thereof, for controlling activities within QA Plan Scope shall be identified as such. Systems and major components, but not parts thereof, will be identified as within QA Plan Scope in a Quality Classification List (QCL) document. The QCL shall be established, maintained, and controlled by the assigned TMI-2 and support organizations.

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QUALITY ASSURANCE PROGRAM

Revision No.

0

The significance of an item or activity to quality shall be considered in its classification. Procedures shall be prepared which establish the requirements for identification and control of items and activities within QA Plan Scope. Activities affecting structures, systems, and components within QA Plan Scope shall be considered to be within QA Plan Scope unless otherwise specified.

- 2.4 Assigned organizations shall implement the requirements of the Plan through written policies, procedures, or instructions appropriate to the circumstances. The degree to which the requirements of this Plan and its implementing documentation are applied will be based upon considerations such as:
- 2.4.1 The importance of a malfunction or failure of the item to the maintenance of safe and stable PDMS conditions.
 - 2.4.2 The design and fabrication complexity or uniqueness of the item.
 - 2.4.3 The need for special controls and surveillance or monitoring of processes, equipment, and operational activities.
 - 2.4.4 The degree to which functional compliance can be demonstrated by inspection or test.
 - 2.4.5 The quality history and degree of standardization of the item or activity.
 - 2.4.6 The intended life during which the item performs a quality-related function.
- 2.5 GPU: is committed to a comprehensive QA Program consisting of up to three levels of verification to assure satisfactory and complete implementation of the program commensurate with its requirements for maintaining PDMS conditions. The Program's foremost considerations are the protection of the general public's health and safety.
- 2.5.1 Level I - Activities at this level consist of independent inspections, checks, and tests. Where first-level activities involve independent inspection for purposes of acceptance and/or verification of modifications to systems within QA Plan Scope, the activity will be performed by the QA Department or by organizations authorized to perform the activity by the QA Department.
 - 2.5.2 Level II - The activities at this level are primarily those of surveillance or monitoring and are performed as deemed necessary by the QA Department. The level of surveillance/monitoring applied is consistent with the importance of the item to maintaining the function and intent of activities and equipment within QA Plan Scope, and the extent of administrative controls utilized for the Level I activity.

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- 2.5.3 Level III - The purpose of this level of activity is to assure, through a comprehensive program of review and auditing, that the first and second levels of the program are properly functioning. This level also establishes that all organizations are properly satisfying all the requirements of the PDMS QA Program.
- 2.6 This Plan is supported by a Statement of Policy which is signed by the President - GPUN. The Statement of Policy provides authorization and evidence of management commitment to the QA Program. The Plan shall be approved by the Office of the President and shall be reviewed for concurrence by the affected division heads.
- 2.7 The Director, QA, with the assistance of the Licensing and Regulatory Affairs Director, shall, for each revision to this QA Plan, determine if the changes reduce or do not reduce the commitments previously accepted by the NRC.
- 2.8 Revisions to the QA Plan that do not reduce the commitments to the NRC shall be submitted by the Director, QA on a Document History page; concurred with by the Director, Nuclear Assurance; and approved by the Office of the President. Revisions of this type do not require approval by the NRC prior to issuance, but must be submitted to the NRC at least annually.
- Revisions to the QA Plan that reduce the commitments to the NRC shall be submitted to the NRC and receive NRC approval prior to issuance. Revisions shall be regarded as approved by the NRC upon receipt of a letter to this effect from the appropriate reviewing office or 60 days after submittal to the NRC whichever comes first. Revisions of this type shall be submitted by the Director, QA on a revised Cover Page, concurred with by the Division Directors, and approved by the Office of the President.
- 2.9 The PDMS QA Plan shall be maintained in accordance with written procedures that comply with appropriate regulatory requirements. Copies of the Plan may be distributed as "Controlled" or "Uncontrolled" copies in accordance with approved document control procedures. Changes to this Plan shall be incorporated into implementing procedures within 60 days of issuance unless an alternative implementation schedule is approved in writing by the Director, QA.
- 2.10 The effectiveness of the QA Program is evaluated and reported by the QA Department through the surveillance, monitoring, and auditing functions. The Director, QA shall be responsible for evaluating deficiencies for the detection of any adverse quality trends.
- 2.11 Records of commitments to regulatory requirements are maintained by the Licensing organization. The TMI-2 PDMS SAR and associated License form the initial basis of these commitments. They must be complied with in conjunction with this QA Plan.
- 2.12 The GPUN QA Program includes requirements for formal indoctrination and training/retraining programs of personnel performing or verifying activities within QA Plan Scope. These programs are implemented by appropriate training plans and procedures.

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QUALITY ASSURANCE PROGRAM

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0

- 2.13 QA programs and implementing procedures for suppliers or contractors providing materials and services for GPUN which are covered under the scope of this QA Program shall be subject, when specified in procurement documents, to review and acceptance by the QA Department prior to the commencement of any activity within QA Plan Scope.
- 2.14 It is the responsibility of the Director, QA, supported by his staff, to provide for the effective administration of this Plan. Accordingly, all queries regarding the scope or interpretation of the Plan shall be addressed to the Director or other appropriate QA management for determination.
- Disputes involving quality arising from a difference of opinion between QA/QC personnel and other organization (engineering, procurement, manufacturing, construction, operations, maintenance, etc.) personnel shall, if possible, be resolved at the level at which such disputes occur. If this is not possible, the difference of opinion shall be escalated through supervisory/management levels until resolution is achieved.
- 2.15 The Director, QA shall make the decision on matters concerning inspection and acceptance to established requirements. The director of the applicable engineering group shall make the decision on matters concerning interpretation of technical requirements or design changes.
- 2.16 Existing GPUN organizations that are implementing approved nuclear QA Programs may apply those programs, as necessary, in support of this Plan.

Title

DESIGN CONTROL

Revision No.

0

3.0 DESIGN CONTROL

- 3.1 TMI-2 was originally designed and constructed in compliance with appropriate 10 CFR 50 Codes and Standards. Due to the non-operating and defueled status of TMI-2 during PDMS, there will no longer be any structures, systems, or components which perform a safety function. However, the TMI-2 Technical Specifications do identify certain structures, systems, and components required to be operable. Such structures, systems, and components are considered within QA Plan Scope and, thus, require the application of QA design controls on a graded basis should modifications be required. Systems and major components within QA Plan Scope are identified in a Quality Classification List (QCL) document.
- 3.2 To the extent defined in Section 2.0, measures shall be established for PDMS to ensure design criteria are included or correctly translated into design documents. These measures, as a minimum, shall ensure that applicable design inputs are identified and documented. Changes from approved design inputs shall be identified, approved, documented, and controlled. Inputs shall be translated into design output documents containing the technical and quality requirements that must be satisfied.
- 3.3 To the extent necessary, design control measures shall be implemented by controlled written procedures. Such procedures may address the following design activities:
- 3.3.1 The organizational structure, authority, and responsibility of personnel involved in preparing, reviewing, and approving design documents.
 - 3.3.2 Design input requirements necessary to permit the correct performance of design process activities. ALARA considerations, if appropriate, shall be specified.
 - 3.3.3 Design process activities sufficient to ensure that design inputs are correctly translated into specifications, drawings, procedures, or instructions.
 - 3.3.4 Internal and external design interface controls and lines of communication among participating design organizations and across technical disciplines.
 - 3.3.5 Design verification methods such as design review or alternate calculations. Verification may be performed by any competent party not responsible for the original design.
 - 3.3.6 Design and specification changes, including field changes, subject to design control measures.
 - 3.3.7 Records of design activities shall be generated in sufficient detail to permit QA auditing as required by this Plan.

Title

DESIGN CONTROL

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0

- 3.4 Methods shall be employed to ensure that adequate precautions or evaluations are in place during PDMS activities (including the installation and/or removal of hardware) to preclude damaging, impeding operational movements, or in any way adversely impacting the ability of items required by the Technical Specifications to maintain the plant in a safe and stable PDMS condition.
- 3.5 Measures shall be provided to assure that responsible plant personnel are made aware of design changes and/or modifications which may affect the performance of their duties.

Title

PROCUREMENT DOCUMENT CONTROL

Revision No.

0

4.0 PROCUREMENT DOCUMENT CONTROL

- 4.1 During the PDMS period, minimal procurement activities are anticipated. Nevertheless, QA measures shall apply to the procurement of materials including new and spare parts, replacement parts, and consumables, as established by Engineering and consistent with the scope of this Plan.
- 4.2 Procurement of material, equipment, and services which are considered within QA Plan Scope shall be performed in accordance with written policies, procedures, and instructions which shall establish methods to comply with applicable regulatory requirements.
- 4.3 Procurement documents shall, as applicable:
 - 4.3.1 Provide, where necessary, a description of the items or services to be provided by the supplier.
 - 4.3.2 Specify technical requirements by reference to the specific drawings, specifications, codes, regulations, procedures, or instructions including revisions thereto that describe the items or services to be furnished.
 - 4.3.3 Specify QA requirements commensurate with the importance to quality of the items and services within QA Plan Scope being performed.
 - 4.3.4 Provide for GPUN access to supplier and lower-tier supplier facilities and records for inspection or audit.
 - 4.3.5 Identify those records which suppliers shall retain, maintain, and control and those which shall be delivered prior to use or installation of the item.
- 4.4 Review of procurement documents shall:
 - 4.4.1 Be performed by competent personnel who have access to pertinent information.
 - 4.4.2 Ensure that appropriate technical, quality, and administrative requirements have been included.
 - 4.4.3 Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents.

Title

INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Revision No.

0

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

- 5.1 During the PDMS period, activities within QA Plan Scope shall be prescribed by and accomplished in accordance with written instructions, procedures, or drawings of a type appropriate to the circumstances. Procedural adherence shall be mandatory.
- 5.2 Standard guidelines for the format, content, review, and approval of instructions, procedures, and drawings shall be specified in division/ department administrative procedures. Procedural documentation shall be prepared, reviewed, and approved by individuals knowledgeable in the area affected by the procedure. Technical and independent reviews shall be in accordance with the GPU: Review and Approval Matrix.
- 5.3 Typical procedure types that shall be established, as necessary, are:
- 5.3.1 Administrative Procedures - Organizational responsibilities, interface relationships, and QA Program and general plant administrative implementation controls are specified.
- 5.3.2 Operating Procedures - Provide instructions in sufficient detail to safely operate plant systems and components required to be operable per the PDMS Technical Specifications.
- 5.3.3 Surveillance and Test Procedures - Provide detailed instructions for implementing PDMS Technical Specification surveillance and test requirements.
- 5.3.4 Maintenance Procedures - These include both corrective and preventive maintenance. Skills normally possessed by qualified maintenance personnel may not require detailed step-by-step delineation in written procedures.
- 5.3.5 Radiation Protection Procedures - Provide for implementation of the Radiation Protection Plan.
- 5.3.6 Engineering Procedures - Provide administrative controls for the technical activities necessary to support a safe PDMS condition.
- 5.3.7 Chemistry Procedures - Provide laboratory procedures and administrative controls necessary to support a safe PDMS condition.
- 5.3.8 QA/QC Procedures - Provide detailed implementation requirements governing the quality verification activities of monitoring, inspection, surveillance, audit, and review.
- 5.4 If appropriate, instructions, procedures, and drawings shall include quantitative (such as dimensions, tolerances, and operating limits) and qualitative (such as workmanship samples) acceptance criteria sufficient for determining that activities within QA Plan Scope have been satisfactorily accomplished.

Title

INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Revision No.

0

- 5.5 Instructions, procedures, and drawings shall be reviewed and approved in accordance with administrative requirements prior to their implementation. Review and approval activities shall be documented.
- 5.6 Procedural documentation shall be periodically reviewed for adequacy as set forth in administrative procedures. A revision of a procedure may fulfill the periodic review requirement provided the results of the review are documented.
- 5.7 Applicable procedures shall be reviewed following any significant operator error, malfunction, or system/component modification.

Title	Revision No.
DOCUMENT CONTROL	0

6.0 DOCUMENT CONTROL

- 6.1 Documents which specify quality requirements or prescribe activities within QA Plan Scope shall be controlled in a manner appropriate to the circumstances. Such documents include, but are not limited to, those instructions, procedures, and drawings necessary to implement the QA Program defined in Section 2.0 of this Plan.
- 6.2 Document control measures shall be established in written procedures. These procedures shall address the following elements of document control, as necessary:
 - 6.2.1 Measures to assure that documents within QA Plan Scope, including changes thereto, have been reviewed and approved for release by authorized personnel.
 - 6.2.2 Changes to documents have been reviewed and approved by the same organizations that performed the original review and approval unless otherwise specified by those organizations.
 - 6.2.3 Distribution lists shall be established and maintained current. Organizations participating in activities within QA Plan Scope shall receive or have convenient access to documentation governing that activity.
 - 6.2.4 The issuance of documents within QA Plan Scope is performed in a controlled manner in accordance with written procedures.
 - 6.2.5 A system to identify the latest issue of documents shall be established in written procedures. Master lists identifying current document revision levels may be issued to user personnel for reference. Alternatively, documents may be stamped in a permanent manner to indicate their level of control. A system which combines the use of master lists and stamping techniques is acceptable provided that all documents within QA Plan Scope are included.
 - 6.2.6 The user of a document is responsible for ensuring that the latest issue of the document is used to perform work within QA Plan Scope. Users are also responsible for removing voided, superseded, or obsolete documents from the work place to prevent their inadvertent use.
 - 6.2.7 Measures to ensure that the periodic and mandatory (e.g., a system modification) document reviews required by Section 5.0 of this Plan have been conducted.
 - 6.2.8 In the special case of documents containing information pertaining to plant security, provisions shall be made to prohibit unauthorized disclosure of certain safeguards information. These provisions shall include identification of the documents, restrictions on their distribution, and storage in locked security storage containers.
 - 6.2.9 Documents that are distributed for information purposes only shall not be utilized to perform activities within QA Plan Scope.

Title	Revision No.
CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES	0

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

- 7.1 During the PDMS period, measures shall be established to assure that purchased material, equipment, and services conform to the procurement documents. The degree to which control measures will be employed shall be based upon the significance to quality of the item or service being supplied.
- 7.2 Procurement sources shall be evaluated and selected considering the item or service being supplied. Methods may include any or all of the following:
 - 7.2.1 Review of supplier histories
 - 7.2.2 Evaluation of current quality records.
 - 7.2.3 Direct evaluation of the supplier's facilities.
- 7.3 If appropriate, a manufacturing assurance program will be implemented. This program may include:
 - 7.3.1 If required by procurement documents, GPUN approval of supplier's drawings, procedures, and manufacturing plans.
 - 7.3.2 Review of supplier records documentation for completeness and acceptability.
 - 7.3.3 Source inspection, surveillance, or audit of supplier quality activities relative to the procurement specifications.
- 7.4 Material acceptance requirements shall be established at the plant site to assure that:
 - 7.4.1 The item's handling and shipping requirements have been observed by the supplier and maintained by the carrier.
 - 7.4.2 The items provided meet the technical and quality requirements specified in applicable receiving inspection plans.
 - 7.4.3 The item's quality records package or compliance certification is complete and adequate.
 - 7.4.4 Items delivered which are not in compliance with procurement documents are identified and controlled in accordance with nonconformance control procedures.
- 7.5 Sufficient records documentation shall be maintained at the plant site to identify the specific requirements, such as codes, standards, and specifications met by purchased material and equipment within QA Plan Scope.

Title

IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND
COMPONENTS

Revision No.

0

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, & COMPONENTS

- 8.1 Materials, parts, and components, including partially fabricated subassemblies, necessary to support a safe PDMS condition, shall be identified and controlled in accordance with written procedures appropriate to the circumstances.
- 8.2 Item identification requirements, when specified by Engineering in procurement documents, shall be verified prior to installation as a condition of acceptance.
- 8.3 Physical identification shall be used to the maximum extent possible. The location and method of identification shall be specified so as not to affect the form, fit, function, or quality of the item being identified. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed.
- 8.4 When required by codes, standards, or specifications, traceability of materials, parts, or components to specific inspection, test, or other records shall be provided for and verified.
- 8.5 Where specified, items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.
- 8.6 Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as:
- 8.6.1 Maintenance or replacement of markings and identification records, if necessary, due to aging.
- 8.6.2 Protection of identifications on items subject to excessive deterioration due to environmental exposure.
- 8.7 Correct identification of materials, parts, and components shall be verified prior to release for fabrication, shipping, installation, or testing.

Title

CONTROL OF SPECIAL PROCESSES

Revision No.

0

9.0 CONTROL OF SPECIAL PROCESSES

- 9.1 During the PDMS period, special processes associated with items and activities within OA Plan Scope shall be controlled by written procedures or instructions. Special processes, as defined by Engineering, are those that require interim in-process controls in addition to final inspection to assure quality including, but not limited to, such processes as welding, heat treating, chemical cleaning, and nondestructive examination (NDE).
- 9.2 Special process procedures or instructions shall be established to assure that special processes are accomplished under controlled conditions in accordance with applicable codes, standards, applications criteria, and other special requirements including the use of qualified personnel, procedures, and equipment, if necessary.
- 9.3 Procedures or instructions for the control of special processes shall contain appropriate process acceptance criteria and be reviewed and approved by qualified personnel.
- 9.4 Personnel, procedures, and equipment performing special processes may require qualification. Organizational responsibilities for defining qualification requirements and for implementing qualification programs shall be specified.
- 9.5 For special processes not covered by the existing codes or standards or when item quality requirements exceed the requirements of established codes or standards, the necessary qualifications of personnel, procedures, and equipment shall be defined in the procedures.
- 9.6 Qualification records of personnel, procedures, and equipment associated with special processes shall be established, maintained, and kept current. Records of the performance of special processes shall be maintained in accordance with applicable requirements.

Title

Revision No.

INSPECTION

0

10.0 INSPECTION

- 10.1 A program for the inspection of activities within QA Plan Scope conducted during the PDMS period shall be established. This program shall provide for suitable levels of independent verification to assure quality, and is a Level I verification activity as defined in Section 2.0 of this Plan. Inspection program activities will be controlled by written procedures appropriate to the circumstances.
- 10.2 Inspection personnel (including NDE specialists) who verify conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task. Qualification levels shall be established in accordance with applicable codes, standards, and GPUN training programs. Records of personnel qualification and certification shall be maintained and kept current. If individuals assigned to perform inspections are not part of the responsible GPUN QA organization, applicable procedures and personnel qualification criteria shall be reviewed and concurred with by the responsible QA organization prior to commencing the inspection activity.
- 10.3 Inspections may be conducted by second-line supervisory personnel or by other qualified personnel not assigned first-line supervisory responsibility for the conduct of work. Inspections to verify quality shall not be conducted by individuals who performed the work or the first-line supervisor responsible for the activity.
- 10.4 Work authorizing documents used to implement work in the field within QA Plan Scope shall be reviewed by QA Department personnel when the need for the following is determined by Engineering:
- 10.4.1 Inspections and/or process monitoring.
 - 10.4.2 Hold and/or witness points.
- 10.5 The inspection program shall require inspection and/or test of items for work operations where such is necessary to verify conformance to applicable instructions, procedures, and drawings for accomplishing the activity. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of process shall be required. Both inspection and process control shall be performed when required by applicable code, standard, or specification.
- 10.6 Mandatory inspection hold points shall be included in appropriate documentation. When QA hold points have been established, either contractually, by procurement, or internally by plant procedures, work may not proceed beyond the hold point until either inspection is performed or waived by the responsible QA organization.
- 10.7 Inspection activities shall be planned and controlled by procedures, instructions, or checklists. These documents shall include, as required:

Title

INSPECTION

Revision No.

0

- 10.7.1 The characteristic or activity to be inspected.
 - 10.7.2 Prerequisites and/or special conditions associated with the inspection.
 - 10.7.3 Measuring and test equipment needed and the accuracy requirements.
 - 10.7.4 Inspection methods or procedures to be used. Where verification of prior inspection is to be performed, a sampling inspection plan approved by QA may be used.
 - 10.7.5 Provisions for recording the results of inspection hold points and approvals for work to continue.
 - 10.7.6 Acceptance criteria for evaluating results.
 - 10.7.7 Provisions for recording inspection data evaluation results and administrative information.
- 10.8 Inspection data and results shall be evaluated by qualified personnel to assure that inspection requirements have been satisfied. Inspection results shall be approved by authorized personnel.
- 10.9 Items and activities failing to conform to inspection requirements shall be identified and controlled in accordance with established nonconformance control procedures.

Title

TEST CONTROL

Revision No.

0

11.0 TEST CONTROL

- 11.1 A test program shall be established to assure that items will perform satisfactorily in service and that a safe and stable PDMS condition is maintained. Test procedures shall incorporate or reference the requirements and acceptance limits contained in applicable design and licensing documents.
- 11.2 The PDMS test program shall cover required tests including:
 - 11.2.1 Surveillance tests and inspections required by the PDMS Facility License and Technical Specifications to demonstrate conformance with operability requirements.
 - 11.2.2 Tests required to demonstrate satisfactory performance following plant maintenance and modifications within QA Plan Scope. Testing shall be sufficient to confirm that the changes reasonably produce expected results and that the change does not reduce the safety or stability of the PDMS condition.
- 11.3 A schedule for all identified tests and inspections within QA Plan Scope shall be established and maintained. This schedule shall be monitored, as necessary, to ensure that required tests and inspections are performed, evaluated, and reported on a timely basis.
- 11.4 Test procedures or instructions shall provide for the following, as required:
 - 11.4.1 A description of test objectives.
 - 11.4.2 Test prerequisites (e.g., calibrated instrumentation, environmental conditions, trained personnel, etc.).
 - 11.4.3 Instructions for performing the test or surveillance inspection including cautionary or safety notes and equipment control measures.
 - 11.4.4 Identification of mandatory hold or witness points.
 - 11.4.5 Documentation of corrective actions performed on nonconformances identified.
 - 11.4.6 Acceptance criteria for evaluating test results.
 - 11.4.7 Documenting the evaluation of test results.
- 11.5 Results shall be evaluated and their acceptability determined by an authorized individual or group.
- 11.6 Unacceptable test results shall be identified in accordance with established nonconformance control procedures.
- 11.7 Records of PDMS testing activities shall be maintained as required by the Technical Specifications.

Title

CONTROL OF MEASURING AND TEST EQUIPMENT

Revision No.

0

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

- 12.1 A program to control the measuring and test equipment (M&TE) used to support PDMS activities within QA Plan Scope shall be established. M&TE includes tools, gauges, instruments, reference and transfer standards, and other measuring and testing devices, including NDE equipment. The M&TE control program shall be implemented by use of written procedures.
- 12.2 Major elements of the control program are:
- 12.2.1 Identification of all M&TE within the scope of the program.
 - 12.2.2 Inspection and verification of accuracy upon receipt of equipment calibrated off site.
 - 12.2.3 Measures to control, calibrate, adjust, and maintain M&TE at prescribed intervals or prior to use.
 - 12.2.4 Traceability of calibration test data to nationally recognized standards or approved and documented alternatives.
- 12.3 Installed operations M&TE requiring calibration shall be labeled, tagged, or otherwise controlled in accordance with written procedures to ensure that approved calibration intervals are not exceeded. Portable M&TE may be similarly controlled but shall, as a minimum, be clearly labeled to indicate the date on which the current calibration expires. M&TE that has exceeded the approved calibration interval shall not be used for measurements or tests until recalibrated.
- 12.4 The calibration frequency for M&TE shall be based on required accuracy, purpose, degree of usage, stability characteristics, and/or any other condition which may affect the measurement. A calibration recall system shall be implemented to assure recalibration within the required period for each piece of M&TE covered under the scope of this program.
- 12.5 Calibration procedures shall delineate any necessary environmental controls, limits, or compensations in excess of those which may be inherent to the general program. Calibration of M&TE shall be against standards that have an accuracy that assures the equipment being calibrated will be within required tolerance.
- 12.6 NDE equipment shall be controlled and calibrated in accordance with the industry code governing its use.
- 12.7 When M&TE is found to be out of calibration, the validity of previous tests and calibrations that utilized the item since its last calibration shall be evaluated. Such evaluations shall be documented in suitable form. Corrective actions shall be taken as necessary. If any item of M&TE is consistently found to be out of calibration, it shall be repaired or replaced.

Title

CONTROL OF MEASURING AND TEST EQUIPMENT

Revision No.

0

- 12.8 Special calibrations shall be performed should the accuracy of any item of M&TE become questionable.
- 12.9 Rulers, tape measures, levels, and other such devices may not be included in the M&TE control program if normal commercial practices provide for adequate accuracy.
- 12.10 Sufficient records shall be maintained to provide objective evidence that M&TE control program activities have been implemented.

Title	Revision No.
HANDLING, STORAGE AND SHIPPING	0

13.0 HANDLING, STORAGE AND SHIPPING

- 13.1 The handling, storage, shipping, cleaning, and preservation of material and equipment within QA Plan Scope necessary to support PDMS shall be controlled in accordance with written instructions, procedures, and drawings to prevent damage, deterioration, or loss.
- 13.2 Special handling tools and equipment shall be provided where necessary to assure that items can be handled safely and without damage. Handling operations will be performed by suitably trained personnel.
- 13.3 Storage practices shall provide for methods of storage and the control of items in storage which will minimize the possibility of damage or deterioration during storage. The release of items for installation shall be procedurally controlled.
- 13.4 Special measures shall be established for the storage of chemicals, reagents, lubricants, and other consumable materials.
- 13.5 Controls shall be established to ensure that items whose shelf life has expired will not be used.
- 13.6 Shipping control measures shall be established that conform to standard industry practices appropriate to the item involved.
- 13.7 Cleaning requirements shall be included in design and procurement documents, specifications, and procedures, if appropriate.
- 13.8 Preservation requirements shall be included in design and procurement documents, specifications, and procedures, if appropriate.

Title	Revision No.
INSPECTION, TEST, AND OPERATING STATUS	0

14.0 INSPECTION, TEST AND OPERATING STATUS

- 14.1 During PDMS, a program to identify the inspection, test, and operating status of structures, systems, components, and individual items within QA Plan Scope shall be established and implemented by written procedures.
- 14.2 The inspection and test status of individual items shall be maintained through the use of status indicators such as physical location and tags, markings, shop travelers, stamps, inspection records, labels, routing cards, or other suitable means. Only items that have passed required inspections and tests are used, installed, or operated.
- 14.3 Procedures shall be provided to require identification of the operating status of structures, systems, components, controls, or support equipment in order to prevent inadvertent or unauthorized operation. These procedures shall require control measures such as locking or tagging to secure and identify equipment in a controlled status. The procedures shall also require that the status of inspections and test performed upon individual items be indicated by the use of markings such as stamps, tags, labels, routing cards, or other suitable means.
- 14.4 Permission to release equipment or systems for maintenance or modification shall be granted by designated operating personnel. Granting of such permission shall be documented. After permission has been granted to remove equipment from service, it shall be made safe to work on. Measures shall provide for the protection of equipment and workers.
- 14.5 When equipment is ready to be returned to service, operating personnel shall place the equipment in operation and verify and document its functional acceptability.
- 14.6 Control measures for temporary modifications, such as temporary bypass lines, electrical jumpers, lifted electrical leads, and temporary trip point settings, shall be established. A log shall be maintained of the current status of temporary modifications.
- 14.7 The use of status indicators shall be controlled by written procedures. These procedures will specify the authority for application and removal of tags, markings, labels, stamps, or other indicators.
- 14.8 Where required documentary evidence of acceptability is not available, the associated equipment or materials will be considered nonconforming. Items not installed shall be appropriately controlled. Nonconforming items shall be identified in accordance with established nonconformance control procedures.

Title

Revision No.

NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

0

15.0 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

- 15.1 Nonconforming materials, parts, components, services, or activities within the scope of the GPU: PDMS QA Program shall be identified and controlled in accordance with written procedures. The procedures shall include instructions for identification, documentation, segregation, review, disposition, and notification to affected organizations, as appropriate.
- 15.2 Nonconformances include both hardware problems involving materials, parts, components, or systems which do not comply with established requirements and non-hardware problems such as failure to comply with the Facility License and Technical Specifications, procedures, regulations, and/or other established requirements. It is the responsibility of all organizations and individuals involved with TMI-2 PDMS functions to identify and report nonconformances which may affect structures, systems, equipment, materials, parts, and components within QA Plan Scope.
- 15.3 Nonconformance reports shall be used to identify nonconforming materials, parts, components, and activities; and shall be used to identify items or activities whose status is indeterminate due to lack of documentation. Nonconformance report documentation shall provide for the following, as necessary:
- 15.3.1 Identification of the nonconforming item or activity.
 - 15.3.2 Description of the nonconformance.
 - 15.3.3 Cause of the nonconformance.
 - 15.3.4 Disposition of the nonconformance.
 - 15.3.5 Notification to the affected organization of the nonconformance.
 - 15.3.6 Documenting the controls applied to nonconforming items (e.g., hold tags, segregation, etc.)
 - 15.3.7 Evidence of review for reportability per the Technical Specifications.
 - 15.3.8 Administrative data, including reviews and approvals.
- 15.4 Measures shall be established to procedurally control further processing, delivery or installation of a nonconforming item or continuation of a nonconforming service or activity, pending a decision on its disposition. Nonconforming items shall be appropriately identified and controlled until their acceptability for use has been established. In order to prevent their inadvertent use or installation, nonconforming items shall be identified by marking or tagging and shall be physically segregated, where practical. If physical segregation is not practical, identification of items as nonconforming by marking or tagging shall be acceptable.

Title

NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Revision No.

0

- 15.5 The responsibility and authority for the evaluation and disposition of nonconforming items, services, and activities shall be procedurally defined. Personnel performing evaluations to determine a disposition shall be competent in the specific area being evaluated. Nonconforming items, services or activities shall be reviewed and accepted, rejected, repaired, or reworked. Appropriate administrative corrective actions shall be applied to non-hardware issues.
- 15.6 Repaired or reworked items shall be reinspected and/or retested in accordance with original inspection and test requirements, or acceptable alternatives as determined by Engineering. For items dispositioned "repair" or "use-as-is," a description of the change, waiver, or deviation shall be documented to record the change and, if applicable, denote the as-built condition. Documentation verifying the acceptability and approval of such items shall be required.
- 15.7 When all necessary actions associated with the disposition of nonconforming items, services, or activities have been completed and verified, nonconformance reports shall be administratively closed. Records of nonconformance report documentation shall be maintained in accordance with the Technical Specifications and governing administrative procedures.

Title

CORRECTIVE ACTION:

Revision No.

0

16.0 CORRECTIVE ACTION

- 16.1 Section 15.0 of this Plan describes the program that will be established to identify and control nonconforming items, services, and activities within QA-Plan Scope during the PDMS period. Integral to the program to control nonconformances, requirements to accomplish prompt and effective corrective action shall be established. Requirements for the corrective action program shall be included in appropriate written procedures.
- 16.2 Nonconformances shall be evaluated to determine the cause of the condition and the need for corrective action. Evaluations and resulting dispositions shall be made by competent personnel. Nonconformances shall be dispositioned "scrap," "repair," "rework," "use-as-is," or an appropriate administrative correction. Corrective action necessary to preclude recurrence of nonconformances shall also be determined and implemented, as appropriate.
- 16.3 Management controls shall be established to ensure that required corrective actions are being addressed by responsible organizations in a timely manner. Disputes regarding corrective action issues shall be escalated to appropriate levels of management for resolution, if necessary. Follow-up activities shall be conducted to verify implementation of corrective actions and to close-out corrective action documentation.
- 16.4 Significant nonconformances (e.g., violations reportable to the NRC) shall be documented and reported to appropriate levels of GPUN management. Such reports shall identify the nonconformance, its cause, and the corrective action taken.
- 16.5 Records of nonconformances and their associated corrective actions shall be maintained in accordance with the Technical Specifications and governing administrative procedures. Periodically, these records shall be reviewed and analyzed to identify adverse quality trends, if any. Results of these reviews shall be reported to management.

Title

Revision No.

QUALITY ASSURANCE RECORDS

0

17.0 QUALITY ASSURANCE RECORDS

- 17.1 Records of items and activities within QA Plan Scope shall be generated, supplied, and maintained during PDMS in accordance with written procedures. Sufficient records and documentation shall be maintained to provide evidence of the quality of items or activities.
- 17.2 The TMI-2 Technical Specifications, design specifications, procurement documents, and GPUN procedures identify the records necessary to comply with regulatory requirements, industry codes and standards, and GPUN management control requirements. Documents that are designated records shall be legible, accurate, and completed appropriate to the work accomplished. Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.
- 17.3 Records within QA Plan Scope shall be included in an indexing system with sufficient information to permit identification between the record and the item(s) or activities to which it applies. The system shall also include retention times and the location of the record within the record system.
- 17.4 Records shall be classified as either "lifetime" or nonpermanent records and retained accordingly. Retention times for nonpermanent records shall be specified in writing and shall be of sufficient duration to assure the ability to reconstruct significant events and satisfy statutory requirements.
- 17.5 Records within QA Plan Scope may be corrected subject to the review and approval of the originating organization or as authorized in written procedures.
- 17.6 Organizations responsible for receiving records shall be identified and shall implement an appropriate receipt control system. These organizations shall provide for the protection of records from damage or loss while the records are in their custody.
- 17.7 Records shall be stored in predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies. Appropriate single or dual facility methods of storage may be used. The facilities shall be constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:
- 17.7.1 Natural disasters such as winds, floods, or fires.
 - 17.7.2 Environmental conditions such as high and low temperatures and humidity.
 - 17.7.3 Infestation of insects, mold, or rodents.

Title

QUALITY ASSURANCE RECORDS

Revision No.

0

- 17.8 Storage methods shall protect records from damage due to moisture, temperature, or pressure. Provisions, as required, shall be made for special processed records, (such as radiographs, photographs, negatives, and microfilm) to prevent damage from excessive light, stacking, electromagnetic fields, and temperature. Measures shall be established to preclude the entry of unauthorized personnel into storage areas.
- 17.9 Records shall be identifiable and retrievable. Lists shall be established and maintained identifying those personnel having access to record files. The removal of records from storage areas shall be controlled.

Title

Revision No.

AUDITS

0

18.0 AUDITS

- 18.1 During PDMS, a system of planned and scheduled audits shall be established for both GPUN and supplier functions which affect items and activities within QA Plan Scope. Audits include an objective evaluation of practices, procedures, and instructions including an independent review of activities, items, and records within QA Plan Scope which demonstrate effective implementation. The audit system shall be defined and implemented in accordance with written procedures and is a Level III verification activity as defined in Section 2.0 of this Plan.
- 18.2 Audit areas required by the TMI-2 Technical Specifications shall be scheduled and conducted in compliance with the specified frequencies. Audit schedules shall be periodically reviewed and revised, as necessary, to ensure that appropriate audit coverage is maintained. Unscheduled audits may be conducted at any time or as requested by responsible GPUN management.
- 18.3 An individual audit plan describing the audit to be performed shall be developed and documented by the auditing organization. This plan shall identify the audit scope, the requirements, the activities to be audited, the applicable documents, and written procedure or checklists to be used in performing the audit.
- 18.4 Audits shall be performed by trained and qualified personnel not having direct responsibilities in the areas being audited. Qualification and training requirements shall be established and documented, and records of qualifications shall be maintained and kept current. Personnel selected for QA audit assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. For each audit, an appropriately qualified individual shall be appointed as audit team leader. Other audit team members shall be utilized as required and will be classified as either auditors or technical specialists, depending on their function on the audit team.
- 18.5 Audits shall be conducted in accordance with approved procedures and/or checklists. Audited organizations shall provide sufficient support to assure the accuracy of audit results. Selected elements of the QA program shall be audited to the depth necessary to determine whether or not they are being implemented effectively. Objective evidence shall be examined. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization. At the conclusion of the audit, a post-audit conference shall be held with management of the audited organization to discuss audit results and present any adverse audit findings (i.e., nonconformances).
- 18.6 Audit reports shall be issued in a timely manner following performance of the audit. Reports shall contain a summary of audit results, an evaluation of QA Program implementation, and a description of adverse findings, if any. Audit reports shall be distributed to responsible management in both the audited and the auditing organizations.

Title

AUDITS

Revision No.

0

- 18.7 Management of the audited organization or activity shall review and investigate any adverse audit findings to determine and schedule appropriate corrective action including action to prevent recurrence. A response shall be made as requested by the audit report, giving results of the review and investigation. Responsible QA organizations shall conduct follow-up activities to verify that appropriate corrective actions have been taken in a timely manner.
- 18.8 Audit findings shall be periodically reviewed and analyzed to identify adverse quality trends, if any. Results of these reviews shall be reported to management. Section 16.0 of this Plan addresses trending activities associated with other types of nonconformance report documentation.
- 18.9 Records of audit activities shall be maintained as required by the Technical Specifications and GPUN audit system implementing procedures.

Title

TERMS AND DEFINITIONS

Revision No.

0

EXHIBIT 1

Terms and Definitions

This Exhibit contains certain terms and their definitions needed to achieve a uniform understanding of PDMS QA Program requirements. It is not intended that this Exhibit be considered as a comprehensive listing of terminology used in the Program. Therefore, additional terms and their definitions may be included in related GPUN policies, plans, and procedures.

ACCEPTANCE (as used in relation to acceptance of a document): Generally approved, believed, or recognized. Does not require signature of person accepting.

ACCEPTANCE CRITERIA: Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

ALARA: (Acronym for As Low As Reasonably Achievable) - a method of analysis of the performance of activities in radiological areas to determine specific methods for reducing man-rem exposure.

ARCHITECT/ENGINEERING (A/E): A firm under contract to provide engineering or design services.

APPROVAL: An act of endorsing and adding positive authorization (signature) to a document by the person(s) responsible for the document.

AS-BUILT DATA: Documented data that describes the condition actually achieved in a product.

CONCURRENCE: Written agreement that the provisions in a document for which review has been requested are acceptable for implementation within, or from the standpoint of, the signer's area of responsibility.

CONTRACTOR: Any organization under contract for furnishing items or services. It includes the term vendor, supplier, subcontractor, fabricator and subcontractor levels, where appropriate.

CONTROLLED DOCUMENT: A document which is assigned and distributed to an individual or organization and requires that individual or organization to be accountable for the document and to acknowledge receipt of the document in writing. The distributing agent is responsible for providing the recipients with current revisions to the document and for maintenance of the return acknowledgment receipts.

CORRECTIVE ACTION: Measures taken to rectify conditions adverse to quality end, where necessary, to preclude repetition.

DOCUMENT: Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures or results. A document is not considered to be a QA record until it is completed and contains the required signatures.

EXTERNAL ORGANIZATIONS: Any organization participating in the project which is not a part of GPUN or the TMI-2 on-site organization. This term includes vendors, A/E's, and contractors.

Title

Revision No.

TERMS AND DEFINITIONS

0

FIELD CHANGE REQUEST (FCR): A document which is generated in the field requesting engineering approval of a drawing, specification, or procedure change.

MONITORING/SURVEILLANCE: An act of assuring compliance of activities to program requirements by direct observation or record review. Generally, monitoring is performed on site and surveillance is performed at a vendor's facility.

PROCUREMENT DOCUMENT: Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

QA PLAN (Plan): The basic document which describes the method and extent of compliance of the QA Program to the applicable regulatory and GPUN requirements.

QA PROGRAM (Program): The planned and systematic actions which constitute compliance with regulatory quality assurance requirements and the controlled documents which describe and prescribe those actions.

QA RECORD: A completed document that furnishes evidence of the quality of items and/or activities affecting quality.

QUALIFICATION (Personnel): The characteristics or abilities gained through education, training, or experience as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

QUALIFICATION (Procedures): An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

QUALITY CLASSIFICATION LIST (QCL): The controlled document used to record the identification of systems and major components subject to the requirements of the PDMS QA Plan.

SPECIAL PROCESS: A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

SUPPLIER: Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtler levels.

SUPPLIER QUALITY CLASSIFICATION LIST (SQCL): A list of suppliers who have been evaluated by the GPUN QA Department for their capabilities to produce or provide items, equipment, or services for nuclear power plants.

TRACEABILITY: The ability to trace the history, application, or location of an item and like items or activities by means of recorded information.

TREND ANALYSIS: A quantitative method of collecting and analyzing nonconformance/deviation events with the goal of systematically determining programmatic/procedural weaknesses.

VERIFICATION: An act of confirming, substantiating, and assuring that an activity or condition has been implemented in conformance with the specified requirements.