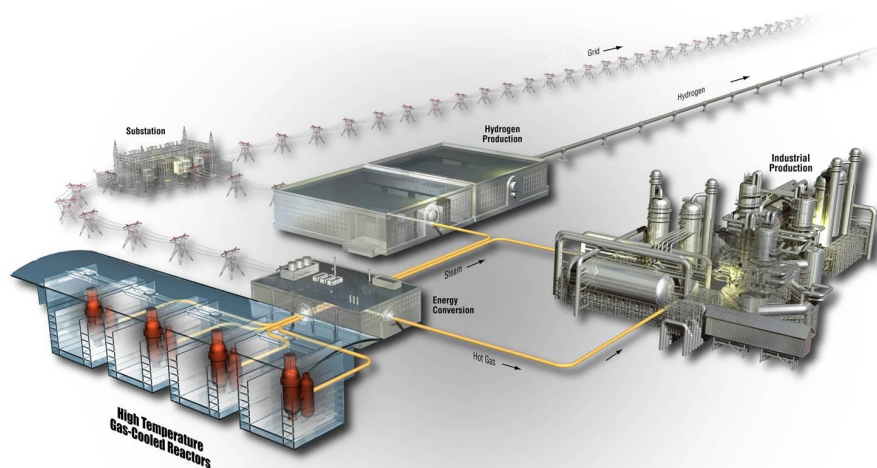


Guide

NQA-1 2008 1a 2009 NGNP Document Training: General

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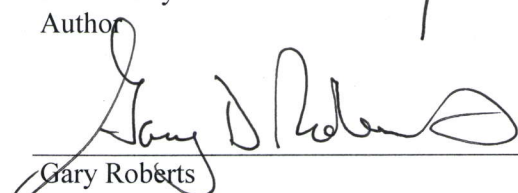
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NGNP Project	Guide	eCR Number: 591526
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Approved by:


Kirk Bailey
Author

4-7-2011
Date


Gary Roberts
NGNP QA Manager

4-7-2011
Date

REVISION LOG

[illegible]

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1. INTRODUCTION

This training guide describes how the Next Generation Nuclear Plant (NGNP) Project has implemented NQA-1 2008, 1a-2009 requirements into the program documents listed in Table 1. It also highlights these requirements and provides an overview of:

1. Documents used to develop this quality assurance program (QAP)
2. How the NGNP QAP fits within the INL site and regulatory structure
3. Hierarchy of documents within NGNP
4. All implementing documents currently affected
5. Modules created to provide training.

The latter part of this guide covers NQA-1 2008, 1a-2009 changes for the QAP and other areas that most people need to know about. Included in this module are the following documents:

Table 1. List of documents covered in this training module.

Program Requirements Documents	Management implementing Procedures
PRD-349, 1.0 NGNP Organization	MCP-3302 "NGNP Organization"
PRD-351, 2.1 NGNP Personnel Training and Qualification	MCP-3052 "NGNP Personnel Qualification and Certification"
PRD-350, 2.0 NGNP Quality Assurance Program	MCP-3303 "NGNP Quality Assurance Program"
PRD-368, 15.0 NGNP Control of Nonconforming Items	MCP-3060 "NGNP Control of Nonconforming Items"
PRD-372, 17.0 NGNP Records Management Procedure	MCP-3055 : NGNP Quality Assurance Records"

2. INSTRUCTIONS

NGNP documents were previously written to be in compliance to NQA-1 2000. This guide identifies the areas that have changed to be in compliance with NQA-1 2008, 1a-2009.

Take this training as follows:

1. Read this guide and sign for credit in the INL Electronic Document Management System (EDMS).
2. Read the documents listed in Table 1 above, and sign for credit in EDMS.
3. Refer any questions to your program's quality engineer.

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General Purpose Module

March 2011

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NGNP Mission

- The mission of the NGNP Project is to broaden the environmental and economic benefits of nuclear energy technology to the United States and other economies by demonstrating its applicability to market sectors not served by light water reactors (LWRs). Those markets, which typically use fossil fuels to fulfill their energy needs, can use high temperature gas-cooled reactors (HTGRs) like the NGNP to reduce this dependence and the resulting carbon footprint.

INL/EXT-09-17505, Next Generation Nuclear Plant Project 2009 Status Report



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NGNP QA Program Development

- NGNP created a QAP that meets the requirements of 10 CFR Part 50, Appendix B “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.”
- NGNP used ASME NQA-1-2008, 1a-2009, “Quality Assurance Requirements for Nuclear Facility Applications” as the NRC endorsed standard for meeting the requirements of Appendix B (above).

NOTE: Regulatory Guide 1.28. Rev 4. is the NRC endorsing document for ASME NQA-1-2008, 1a-2009.

- The NGNP Quality Assurance Program Description (QAPD) PDD-172 describes the QAP. It follows the format of Nuclear Energy Institute. (NEI) 11-xx draft c (currently under NRC review).



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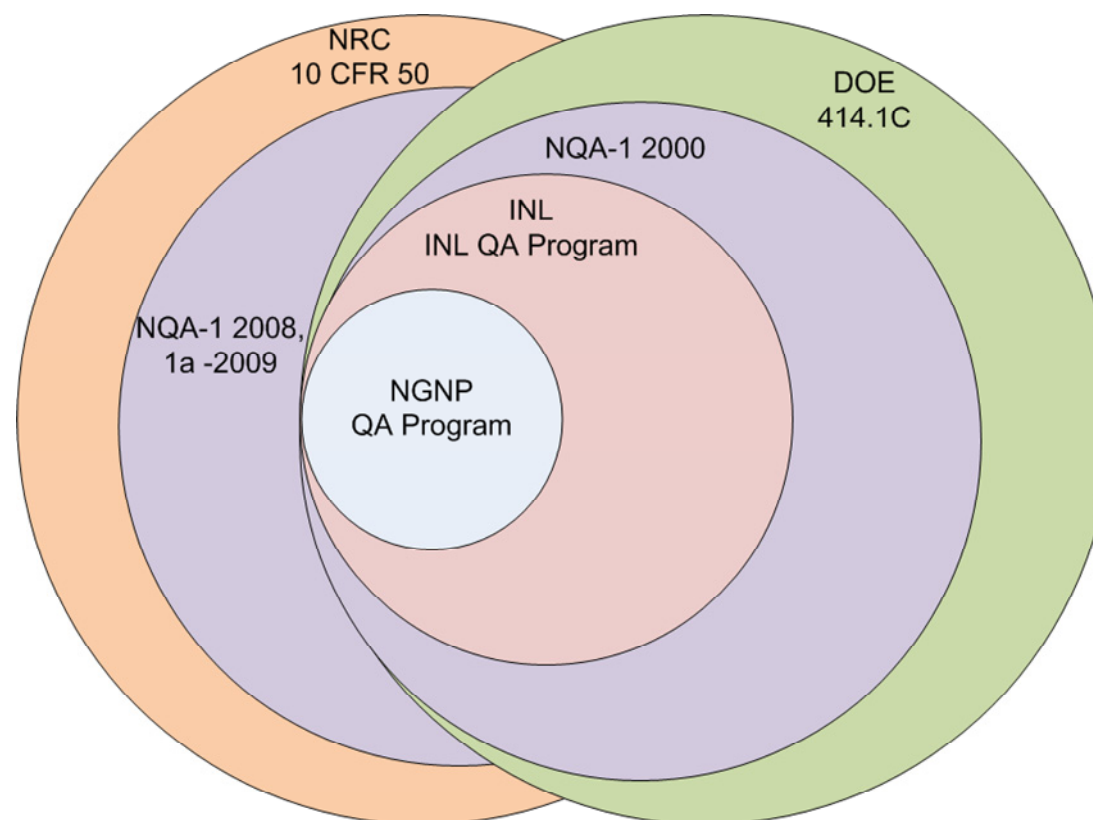
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Requirements Track



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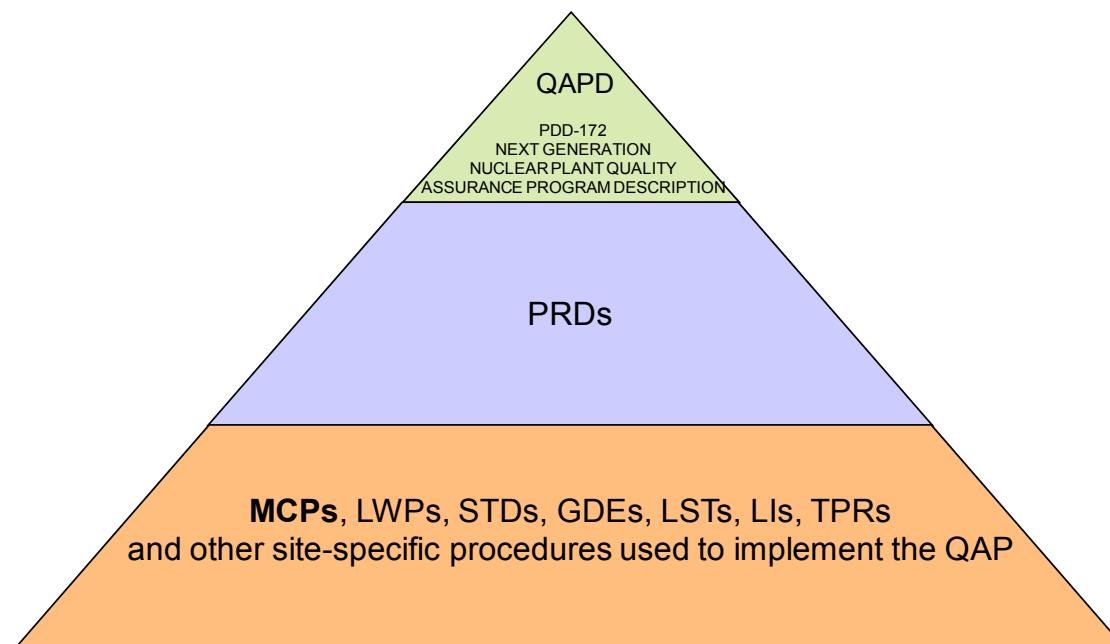
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NGNP QAP Implementing Documents



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PRDs and MCPs: Phase 1

Program Requirements Documents	Management implementing Procedures
PRD-349, 1.0 NGNP Organization	MCP-3302 "NGNP Organization"
PRD-351, 2.1 NGNP Personnel Training and Qualification	MCP-3051 "NGNP Audit Personnel Training and Qualification"
PRD-351, 2.1 NGNP Personnel Training and Qualification	MCP-3052 "NGNP Personnel Qualification and Certification"
PRD-350, 2.0 NGNP Quality Assurance Program	MCP-3303 "NGNP Quality Assurance Program"
PRD-354, 3.1 NGNP Software Quality Assurance	MCP-3058 "NGNP Software Quality Assurance"
PRD-363, 10.0 NGNP Inspection	MCP-3063 "NGNP Inspection"
PRD-364, 11.0 NGNP Test Control	MCP-3064 "NGNP Test Control"
PRD-365, 12.0 NGNP Control of Measuring and Test Equipment	MCP-3066 "NGNP Control of M&TE"
PRD-368, 15.0 NGNP Control of Nonconforming Items	MCP-3060 "NGNP Control of Nonconforming Items"
PRD-372, 17.0 NGNP Records Management Procedure	MCP-3055 : NGNP Quality Assurance Records"
PRD-373, 18.0 NGNP Audits	MCP-3062 "NGNP Quality Assurance Audits"



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Training Modules

- General Purpose Module:
 - Organization
 - Quality Assurance Program
 - Personnel Training and Qualification
 - Control of Nonconforming Items
 - Records Management
- Software Quality Assurance Module:
 - Software Quality Assurance
- Test Control Module:
 - Test Control and Control of Measuring and Test Equipment
- Inspection Module:
 - Inspection
- Audit Module:
 - Audit and Audit Personnel Test and Qualification



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NGNP Training

- PRD changes because of new requirements
- All changes incorporated into MCPs
- Useful information
- Document read and sign-off



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REFERENCES: Requirements, Standards and Guides

- 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"
- 10 CFR 830, "Nuclear Safety Management," Subpart A, "Quality Assurance Requirements"
- DOE Order 414.1C, "Quality Assurance"
- ASME NQA-1-2008, 1a-2009, "Quality Assurance Requirements for Nuclear Facility Applications"; Parts I; II; Part III subpart 3.3, "Nonmandatory guidance Appendix 3.3: "Guidance on Qualification of Existing Data"; Part IV, Subpart 4.2, "Graded Approach Application of Quality Assurance Requirements for Research and Development"
- ASNT-SNT-TC-1A, 'The American Society of Nondestructive Testing Recommended Practice"
- ANSI/NCCL Z540-1, "American National Standard for Calibration-Calibration Laboratories and Measuring and Test Equipment-General Requirements"
- ISO-17025, "General Requirements for the Competence of Testing and Calibration Laboratories"
- DOE Guide 414.1-3, *Suspect/Counterfeit Items*



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Training Content

- Identify changes resulting in compliance to NQA-1-2008, 1a-2009 from an NQA-1 2000 compliant program and,
- Regulatory Guide 1.28, Rev 4

NOTES:

All changes were evaluated on the perceived impact to the user. They were rated on an importance scale of Low, Medium, and High. Changes with a Medium or High rating are presented in this module.

Changes of a low rating were typically of a clarification nature that did not introduce a significant new, or change to an existing, requirement.



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General Purpose module

- This module provides training for the following documents:

PRD-349, "1.0 NGNP Organization"

MCP-3302, "NGNP Organization"

PRD-350, "2.0 NGNP Quality Assurance Program"

MCP-3303, "NGNP Quality Assurance Program"

PRD-351, "2.1 NGNP Personnel Training and Qualification"

MCP-3052, "NGNP Personnel Training and Qualification"

PRD-372, "17.0, "NGNP Records Management Procedure"

MCP-3055, "NGNP Quality Assurance Records"

PRD-368, "15.0 NGNP Control of Nonconforming Items"

MCP-3060, "NGNP Control of Nonconforming Items"



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Module Use Instructions

- Each entry is comprised of two parts:

Requirements	Where implemented
A requirements section that lists the requirement source and content	An implementation section that lists where the requirement has been addressed in NGNP documents

Use this module to quickly focus on the changes to NGNP documentation.



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ORGANIZATION

<p>NGNP Project Director Roles and Responsibilities: NQA-1-2008 Requirement 1, para. 201(d). (d)"those responsible for assuring that an appropriate quality assurance program has been established and those verifying activities affecting quality achievement have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform this their function, including sufficient independence from cost and schedule when opposed to safety function considerations. These verification functions include the following: (1) identifying quality problems (2) initiating, recommending, or providing solutions to quality problems through designated channels (3) verifying implementation of solutions (4) assuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.</p>	<p>PRD-349 3.3.D MCP-3302, 4.1.2 MCP-3302, 4.1.2 MCP-3302, All MCP-3302, 4.1,7 MCP-3302, 4.1.2</p>
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No other requirements affect Organization



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QUALITY ASSURANCE PROGRAM

NQA-1-2008 Requirement 2, para. 202, Training. The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities. On-the-job training shall be used if direct hands-on applications or experience is needed to achieve and maintain proficiency.	PRD-351 r0 3.2.3 MCP-3052r0 4.1.3.6
NQA-1-2008 Requirement 2, para. 301, Nondestructive Examination. This requirement specifies requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MP), ultrasonic (UT), liquid penetrant (PT), electromagnetic (ET), neutron radiographic (NR), leak testing (LT), acoustic emission (AE), and visual testing (VT) to verify conformance to the specified Requirements. The American Society of Nondestructive Testing (ASNT) Recommended Practice or Standards provide acceptable qualification Requirements for NDE personnel. Applicable Codes and Standards or design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable ASNT qualification requirement and edition or to specify an equivalent alternative requirement. SNT TC 1 A, December 1988 Edition, and its applicable Supplements shall apply as Requirements to NDE.	PRD-351 3.4.1 MCP-13425 1. MCP-13425 4.2
NQA-1-2008 Requirement 2, para. 303.3, Audit Preparation. Prospective Lead Auditors shall participate in a minimum of five quality assurance audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification. “Participation in independent assessments including team assessment activities such as operations readiness reviews and regulatory inspections/surveys may be used to satisfy up to four of the five required quality assurance audits, provided that the activities can demonstrate the following: (a) independence from the functional areas being assessed (b) planning that establishes the scope of the activities and associated evaluation criteria (c) performance by technically qualified and experienced personnel (d) results that are documented and reported to management (e) appropriate corrective action initiated and tracked to resolution. Such participation shall be subject to review and acceptance by the organization responsible for quality assurance audits and/or the certifying authority prior to their use for qualification”	PRD-351 3.5.3 MCP-3051, 4.3.1

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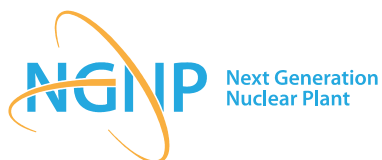
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QUALITY ASSURANCE PROGRAM

NQA-1-2008 Requirement 2, para. 305, <i>Technical Specialists</i> "Technical Specialists – The responsible auditing organization shall establish the qualifications and requirements for use of technical specialists to accomplish the auditing of quality assurance programs."	PRD-351 3.7 MCP-3051, 4.6.1
NQA-1-2008 Requirement 2, Section 500, <i>Records</i>. Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records. Records of qualification, including requalification, for Auditors and Lead Auditors and for inspection and test personnel shall be established and maintained by the employer and for indoctrination and training. Records of indoctrination and training shall include one or more of the following: (a) attendance sheets (b) training logs (c) personnel training records. The employer shall establish and maintain records for indoctrination and training; Auditor and Lead Auditor qualification and requalification; and inspection and test personnel qualification and requalification.	PRD-351 3.9.2, 3.9.3 MCP-3052, 5.2

No other requirements affect Quality Assurance Program



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CONTROL OF NONCONFORMANCE

NQA-1-2008 Requirement 15, para. 405, Reexamination

Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria

Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

MCP- 3060,
Section 4.6.3.4
(E) Note.

No other requirements affect Control of Nonconformance



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QUALITY ASSURANCE RECORDS

<p>NQA-1-2008, Requirement 17, Section 100, Basic The control of quality assurance records shall be established consistently with the schedule for accomplishing work activities. Quality assurance records shall furnish documentary evidence that items or activities meet specified quality Requirements. Quality assurance records shall be identified, generated, authenticated, and maintained, and their final disposition specified. Requirements and responsibilities for these activities shall be documented. The term records, used through out this requirement, is to be interpreted as <i>quality assurance records</i>. Record control requirements and responsibilities for these activities shall be documented.</p>	<p>PRD-372r0 3.1.1.3 MCP-3055 procedure MCP-3055 4.2.2.1</p>
<p>NQA-1-2008 Requirement 17, Section 200 (c), Generation of Records. (c) Records to be generated, supplied, or maintained shall be specified in applicable documents, such as design specifications, procurement documents, test procedures, and operational procedures</p>	<p>PRD-372r0 3.1.2.3 TEM – 5, Section 5 MCP-3055, 4.7</p>
<p>NQA-1-2008 Requirement 17, Section 300 Authentication of Records. a) Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Corrections to documents shall be reviewed and approved by the responsible individual from the originating or authorized organization. b) Electronic documents shall be authenticated with comparable information as in para. 300(a), as appropriate: (1) with identification on the media; or (2) with authentication information contained within or linked to the document itself.</p>	<p>PRD-372r0 3.1.3.2 MCP-3055, 4.3.3.1.4 4.3.3.6 MCP-3055, 4.3.4</p>

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QUALITY ASSURANCE RECORDS

NQA-1-2008 Requirement 17, para. 402, Nonpermanent Records Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable Requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. Nonpermanent records shall be maintained for the identified retention period.	PRD-372r0 3.1.6 MCP-3055, 4.4.4
NQA-1-2008, Requirement 17, Section 500, Receipt Control of Records. Records shall be retained in accordance with the above classifications. The retention period for nonpermanent records shall be established in writing. Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing a system of receipt control controls of records for permanent and temporary storage. Receipt controls shall provide a method for identifying the records received, receipt and inspection of incoming records, and submittal of records to storage.	PRD-372r0 3.1.7 MCP-3055, 4.1.12 MCP-3055, 4.1.13
NQA-1-2008 Requirement 17, Section 600, STORAGE as para. 601, General (a) Records shall be stored in at predetermined location(s) in facilities, containers, or a combination thereof, constructed and maintained in a manner which minimizes the risk of loss , damage, or destruction from the following: (1) natural disasters such as winds, floods, or fires (2) environmental conditions such as high and low temperatures and humidity (3) infestation of insects, mold, or rodents (4) dust or airborne particles (b) Dual facilities, containers, or combination thereof shall be provided for records storage if a single facility, container, or combination thereof is not capable of providing adequate protection (b) Activities detrimental to the records shall be prohibited in the storage area. (c) Access to the processing, storage, and retrieval of records shall be limited to authorized personnel. (d) Provisions shall be made to prevent damage from harmful conditions (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage	PRD-372r0 3.1.8 MCP-3055, 4.4.5 MCP-3055, 4.4.5.7 MCP-3055, 4.4.5.2 MCP-3055, 4.4.5.6

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QUALITY ASSURANCE RECORDS

NQA-1-2008, Requirement 17, para 602, Facility Types There are two equally satisfactory methods of providing storage, single or dual. 602.1 Single storage consists of a storage facility, vault, room, or container(s) with a minimum two-hour fire rating. The design and construction of a single storage facility, vault room, or container shall be reviewed for adequacy by a person competent in fire protection or contain a certification or rating from an accredited organization. 602.2 Dual facilities, containers, or a combination thereof shall be at locations sufficiently remote from each other to eliminate the chance exposure to a simultaneous hazard. Facilities used for dual storage are not required to satisfy the requirements of para. 602.1, but shall meet the Requirements of para. 601.	PRD-372r0 3.1.9 MCP-3055, 4.4.5.10
NQA-1-2008 Requirement 17, para.603, Temporary Storage When temporary storage of records (such as for processing, review, or use) is required, the storage facility or container shall provide a one-hour fire rating, unless dual storage requirements of para. 602.2 are met.	PRD-372r0 3.1.10 MCP-3055, 4.4.5.11
NQA-1-2008 Requirement 17, Section 800, MAINTENANCE OF RECORDS (a) Records shall be protected from damage or loss (b) Records shall be retrievable Record controls shall provide for retrievability within planned retrieval times based upon the record type or content. (c) The methods for record changes shall be documented. (d) Provisions shall be made for specially processed records (such as radiographs, photographs, negatives, microfilm, and magnetic and optical media) to prevent damage from excess light, stacking, electromagnetic fields, temperature, and humidity. Provisions shall be established to ensure that no unacceptable degradation of the electronic record media occurs during the established retention period (e) Provisions shall be made to ensure that the records remain retrievable after hardware, software, or technology changes. (f) Provisions shall be established to ensure the following when records are duplicated or transferred to the same media or to a different media for the purposes of maintenance or storage: (1) duplication or transfer is appropriately authorized (2) record content, legibility, and retrievability are maintained	PRD-372r0 3.1.12 MCP-3055, 4.4.5.8, 4.4.5.9 MCP-3055, 4.4.6.17 PLN-883 PLN-884 MCP-3055, 4.4.5.9 PLN-883 PLN-884

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QUALITY ASSURANCE RECORDS

Reg Guide -1.28 Section C. Regulatory Position 1.a(1), Lifetime and Nonpermanent Records: Paragraph 400, "Classification," of Requirement 17, "Quality Assurance Records," provides guidance on the retention of "lifetime" and "nonpermanent" records. Paragraph 401, "Lifetime Records," discusses the scope and responsibilities related to these records. The owner or an authorized agent must maintain lifetime records for the life of the particular item while it is installed in the plant or stored for future use.	PRD-372r0 3.1. MCP-3055, 4.4.
Reg Guide -1.28 Section C. Regulatory Position 1.a(2), Lifetime and Nonpermanent Records: Paragraph 402, "Nonpermanent Records," identifies nonpermanent records as those records that "...show evidence that an activity was performed in accordance with the applicable requirements"... The owner or an authorized agent does not need to retain these records for the life of the item because they do not meet the criteria for lifetime records. However, Paragraph 700, "Retention," specifies that document retention periods are documented and records maintained for their retention period.	PRD-372r0 3.1.4, 3.1.6 MCP-3055, 4.4.4
Reg Guide -1.28 Section C. Regulatory Position 1.a(3), Lifetime and Nonpermanent Records: NQA-1 Part III, Nonmandatory Appendix 17A-1, "Guidance on Quality Assurance Records," in Paragraph 200, "List of Typical Lifetime Records," lists typical lifetime records containing information that meets Requirement 17 of Part I. The list of typical lifetime records in nonmandatory Appendix 17A-1 should be considered for guidance purposes only. Note that the nomenclature of these records may vary. For records not listed in Appendix 17A-1, the type of record that most nearly describes the record in question should be followed with respect to its retention classification. The applicant or licensee should be cognizant that the list is not considered to be all-inclusive. The applicant or licensee itself is responsible for ensuring, in accordance with QA Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50, that it maintains sufficient records to furnish evidence of activities affecting quality.	MCP-3055, 4.4.4



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QUALITY ASSURANCE RECORDS

Regulatory Guide – 1.28 Regulatory Position 1.b.(1): In Regulatory Issue Summary (RIS) 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," dated October 23, 2000 (Ref. 9), the NRC staff provided applicants and licensees with a way to satisfy the requirements for the maintenance of QA records. The guidance should also be applied to the recordkeeping and maintenance requirements in other parts of the regulations that accept the storage of records in the form of electronic media. The NRC reminds licensees and applicants that the guidance in Generic Letter (GL) 88-18, "Plant Record Storage on Optical Disks," dated October 20, 1988 (Ref. 10), remains relevant and acceptable.	MCP-3055, 4.3.3.3
Regulatory Guide – 1.28 Regulatory Position 1.b.(2): Attachment 1 to RIS 2000-18 lists guidance documents on establishing an electronic recordkeeping system to maintain the integrity, authenticity, and acceptability of QA records during their required retention period in accordance with requirements of Appendix B to 10 CFR Part 50 and other regulations for the storage of QA records in electronic media. These guidance documents also describe methods that the licensee or applicant can use to authenticate electronic records; to prevent their alteration or falsification; to protect them from, or to recover them following, a disaster; and to manage their software configuration. Although the complete set of guidance documents referenced in Attachment 1 to RIS 2000-18 constitutes an acceptable method for satisfying the provisions of Appendix B to 10 CFR Part 50 and other regulations for the storage of QA records in electronic media, this guidance does not supersede current QA record commitments in an applicant's or licensee's QA program description."]PRD-372r0 3.1.12 Note 2

No other requirements affect Quality Assurance Records



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Questions ?

See your program QE for additional information

