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QUALITY SYSTEM SUPPLEMENT

10CFR21 AND 10CFR50 APPX B

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Abstract:

This document describes supplemental requirements for compliance with NRC regulations 10CFR21 and 10CFR50 Appendix B.

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1. SCOPE

1.1 Theory

This specification defines the additional nuclear requirements that apply only to the activities affecting nuclear product and service quality to assure that nuclear grade products are in conformance with



2. APPLICABLE DOCUMENTS

The following documents constitute a part of this specification to the extent specified herein. Unless otherwise specified, the latest revision of the document applies.

2.1. Company Documents

Quality Manual

2.2. Reference Industry Regulations

- A. 10CFR50 Appendix B: US NRC Regulation 10, Code of Federal Regulations Part 50, Appendix B: Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- B. 10CFR21: US NRC Regulation 10, Code of Federal Regulations Part 21: Reporting Of Defects and Noncompliance
- C. ASME NQA-1: Quality Assurance Requirements for Nuclear Facility Applications
- D. ANSI/ISO/IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories
- E. ANSI/ASME Standard N45.2: Quality Assurance Program Requirements for Nuclear Facilities
- F. EPRI NP-5652: Guidelines for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications
- G. IPC-A-610: Acceptability for Electronic Assemblies

3. DEFINITIONS

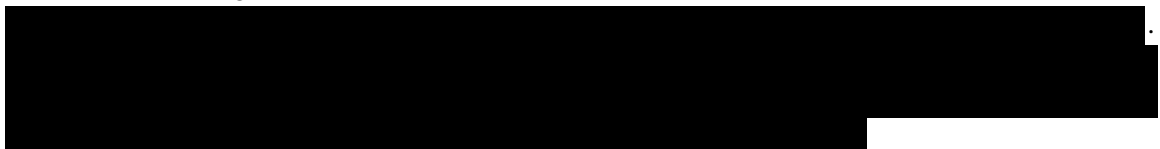
Definitions contained in the above mentioned documents and industry regulations are applicable herein.

4. QUALITY MANAGEMENT SYSTEM

4.1. Quality System – General Requirements

- A. If nuclear product is produced or nuclear service is provided by the Company or Subcontractor, one or more of the following controls shall be exercised:

- 1.
- 2.



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- 3. [Redacted]
- 4. [Redacted]
- B. [Redacted]
- C. [Redacted]

4.2. Documentation Requirements

- A. The Quality Manager is responsible for [Redacted]
- B. The Quality Manager is responsible for [Redacted]

5. MANAGEMENT RESPONSIBILITY

5.1. Management Commitment

- A. The Company Quality Manager has the ultimate responsibility for [Redacted]
- B. The Company Quality Manager is the management representative with the responsibility for [Redacted]

6. RESOURCE MANAGEMENT

6.1. Provision of Resources

6.2. Human Resources

Each department that is responsible for performing activities that require certification shall establish the [Redacted]

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7. PRODUCT REALIZATION

7.1 Customer Related Processes

Orders for nuclear products shall be processed through the Contracts department. This function shall

[REDACTED]

(See Proposal Development and Contract Review Procedure)

7.2 Design and Development

Independent verification is accomplished through

[REDACTED]

7.3 Purchasing

Quality personnel are responsible for

[REDACTED] s.

7.4 Production and Service Processes

A. A unique identification number shall

[REDACTED]

B. Industry specification IPC-A-610 is used when

[REDACTED]

7.5 Control of Inspection, Measuring and Testing Devices

A. The calibration of inspection, measuring and test equipment shall

[REDACTED]

B. With regard to safety related products, measuring and test equipment (M&TE) calibration requirements apply to

[REDACTED]

C. Calibration service suppliers that are used in support of dedicated measuring and test equipment shall

[REDACTED]

D. Alternatively, suppliers of commercial-grade calibration services that have been accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) or the American Association for Laboratory Accreditation (A2LA) may

[REDACTED] provided each of the following conditions are met:

1. [REDACTED]

- [REDACTED]
- [REDACTED]

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- [Redacted]
- 2. [Redacted]
- [Redacted]
- [Redacted]

8. Measurement, Analysis and Improvement

8.1. Inspection and Testing

- A. For nuclear grade items, final inspection is [Redacted]
- B. Computer programs used to determine conformance or acceptability of a product shall [Redacted]
- C. Items and components that are approved and designated for Class 1 safety applications shall [Redacted]

8.2. Monitoring and Measurement

Auditors performing audits of the nuclear product line are qualified according to the Company's training program.

8.3. Control of Nonconforming Product

See Appendix A

8.4 Improvement

The Company Quality Manager is responsible for [Redacted]

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APPENDIX A

1. SCOPE

1.1. Theory

To provide guidance for the Company and Subcontractors that supply products and/or services to the nuclear industry in compliance with the requirements outlined in the United States Nuclear Regulatory Commission (USNRC) Rules and Regulations 10CFR21, Reporting of Defects and Noncompliance. The primary objective of this guideline is to [REDACTED]

1.2. Application

- A. This document implements the nuclear product investigation, evaluation and reporting procedures necessary for conformance with 10CFR21.
- B. The Company and Subcontractors shall have a local procedure documenting the process for investigating, evaluating and reporting 10CFR21 issues. The procedure should address at a minimum:
 - 1. [REDACTED]
 - 2. [REDACTED]
 - 3. [REDACTED]

(See Control of Nonconforming Product Procedure)

1.3. Purpose

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires [REDACTED]

[REDACTED] who obtains information reasonably indicating:

- (a) [REDACTED]
- (b) [REDACTED]

2. APPLICABLE DOCUMENT

US NRC Rules and Regulation 10CFR21, Reporting of Defects and Noncompliance

3. REQUIREMENTS

- A. Nothing in these regulations should be deemed to preclude [REDACTED]






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B. Except where otherwise specified in this part, all written communications and reports concerning the regulations in this part must be addressed to the Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555. In the case of a licensee, a copy must also be sent to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter. (56 FR 36089, July 31, 1991)

C. Posting requirements:


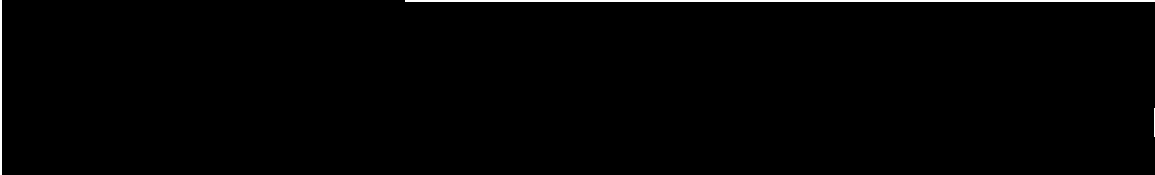
1. Each individual, partnership, corporation, dedicating entity or other entity subject to the regulations in this part shall post current copies of:
 - (i) 
 - (ii) 
 - (iii) 
2. These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.
3. If posting of the regulations in this part or the procedures adopted pursuant to the regulations in this part is not practicable, the licensee or firm, 
4. 

NOTE: Each provider may develop specific postings as long as they comply with the requirements of 10CFR21.

D. Exemptions:

The Commission may, upon application of any interested person or upon its own initiative, 


E. Notification:

1. Each individual, corporation, partnership, dedicating entity or other entity subject to the regulations in this part shall adopt appropriate procedures to:
 - a. 
 - b. 

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c.

d.

2. A dedicating entity is responsible for

3. A Responsible Authority subject to the regulations of this part or a person designated under §21.21(d)(5) must

a.

b.

c. Notification required by paragraph (d)(1) of this section must be made as follows:

(i)

(ii)

d. The written report required by this paragraph shall include

(i)

(ii)

(iii)

(iv)

(v)

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(vi) [Redacted]

(vii) [Redacted]

(viii) [Redacted]

e. The Responsible Authority may authorize an individual to provide [Redacted]

4. Individuals subject to this part may be required [Redacted]

F. Records:

1. Inspections - Each individual, corporation, partnership, dedicating entity or other entity subject to the regulations in this part shall [Redacted]

2. Maintenance and inspection of records - Each individual, corporation, partnership, dedicating entity or other entity subject to the regulations in this part shall [Redacted]

a. [Redacted]

b. [Redacted]

c. [Redacted]

3. Each individual, corporation, partnership, dedicating entity or other entity subject to the regulations in this part shall [Redacted]

G. Enforcement:

1. Failure to Notify:

a. Any Responsible Authority of an entity (including dedicating entity) [Redacted] shall [Redacted]

b. [Redacted]

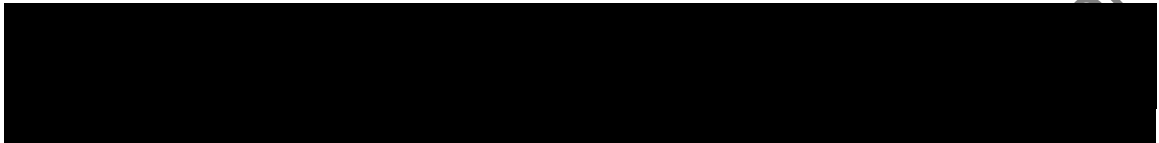
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c.



2. Criminal Penalties:

a.



b.



Authority: Sec. 161, 68 Stat. 948, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2953 (42 U.S.C. 2201, 2282, 2297f); secs. 201, as amended, 206, 88 Stat. 1242, as amended, 1246 (42 U.S.C. 5841, 5846).

Section 21.2 also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

Source: 42 FR 28893, June 6, 1977, unless otherwise noted.

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