

Global Quality Management System Supplement for Nuclear Requirements of the United States Nuclear Regulatory Commission's 10 CFR 50 Appendix B, and 10 CFR 21

1. SCOPE

1.1. Content

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 established design and documentation criteria and with specified contractual and regulatory requirements. The requirements of this document must be implemented in conjunction with the requirements of Quality Specification TEC-1000, and the supporting tier two specifications. This Quality Specification; while superseding Quality Specification 102-152 (K), Additional Total Quality Management (TQM) Requirements for Products Sold for Nuclear Applications; elevates the geographic scope of this document from Regional / United States to Global relevance. The regulatory and contractual requirements and the statements of compliance established in the preceding Quality Specification 102-152 (K) are maintained in this document

2. APPLICABLE DOCUMENTS

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

2.1. Documents

TEC-1000 Global Quality Management System

2.2. Reference Industry Regulations

- A. 10 CFR 50 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. 10 CFR 21 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-610C Acceptability for Electronic Assemblies

3. DEFINITIONS

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

4. QUALITY MANAGEMENT SYSTEM

4.1. Quality System – General Requirements

- A. If nuclear product is produced or a service is provided by another business/site, one or more of the following controls shall be exercised:
 - 1. The employees shall temporarily report into the site manager/team leader or quality manager during the performance of the activity and shall perform the activity in accordance with documented specifications and procedures.
 - 2. The site quality manager shall arrange for an audit of the quality system to ensure that functions affecting quality of the nuclear activity are conducted in a planned and systematic manner and comply with applicable documents and standards.
 - 3. The site quality manager shall impose the applicable nuclear quality standard requirements on the site and individuals performing nuclear activities.
 - 4. Commercial grade products may be converted to nuclear grade by following a documented “dedication process.”
- B. The interfaces, responsibilities, and authorities for nuclear activities performed by another business or site must be documented.
- C. Regardless of the business, site or individual performing the activity, the ultimate responsibility for quality of nuclear products and for the disposition and shipment of nuclear product remains with the site manager and team leader of Tyco Electronics Corporation.

4.2. Documentation Requirements

- A. The site quality assurance manager is responsible for notifying Engineering Practices and Standards department of Tyco Electronics Corporation regarding nuclear customers should receive controlled distribution of copies of Quality Specification TEC-1000, and of this quality specification. A subsequent controlled distribution shall be completed whenever any of these documents are changed.
- B. The site quality assurance manager is responsible for assuring records of all activities affecting nuclear product quality are maintained for a minimum of ten (10) years, in the responsible department.

5. MANAGEMENT RESPONSIBILITY

5.1. Management Commitment

- A. The site manager and team leader, in conjunction with the operations and engineering management, has the ultimate responsibility for nuclear quality within the manufacturing site. Activities affecting quality shall be conducted in a planned, systematic manner. Organizational structures shall assure that individuals performing activities affecting quality have sufficient freedom and authority to perform those activities, including identification and resolution of problems and conditions adverse to quality, verification of problem resolutions, implementation of the total quality management process, and authority to withhold from continued production or release for shipment products not in conformance with acceptance criteria.
- B. The site quality assurance manager is the management representative with the responsibility for ensuring that all employees engaged in the production of products for the nuclear industry are familiar with the quality program defined in Quality Specification TEC-1000, and in this document. This individual also has the authority to ensure that these requirements are implemented and maintained. Additionally, the quality assurance manager is responsible for organizing verification activities, setting training requirements for nuclear certified personnel, facilitating a continual improvement program, and conducting the management review of the quality system.

- 5.2. Customer Focus
- 5.3. Quality Policy
- 5.4. Planning
- 5.5. Responsibility, Authority and Communication
- 5.6. Management Review

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 applicable education and training requirements. Each department shall be responsible for issuing and maintaining the certification status of their personnel.

- 6.3. Infrastructure
- 6.4. Work Environment

7. PRODUCT REALIZATION

- 7.1. Planning of Product Realization
- 7.2. Customer Related Processes

Order entry for nuclear products shall be processed through customer service, Tyco Electronics, Fuquay-Varina, North Carolina. This function shall maintain procedures to ensure that the applicable functions review nuclear orders for quality requirements and acknowledge all purchase orders, requests for quote, and customer contracts for nuclear products. Refer to the flow diagram, Figure 1 of this document.

- 7.3. Design and Development

Independent verification is accomplished through the engineering review process. Signature approval (either electronic or hand original) is interpreted as an acknowledgement that the document is correct and satisfactory.

- 7.4. Purchasing

Procurement and supplier quality assurance are responsible for reviewing purchasing documents prior to or upon issuance to ensure that requirements are adequately defined and documented, and that the supplier has the capability to ensure compliance with the requirements. Paragraph 4.1.A.3. also applies to purchased products or services.

- 7.5. Production and Service Processes

- A. A unique identification number shall be assigned to each batch and item type. This identification shall accompany the item throughout the processing cycle, from receipt to installation. When practical, the identification is marked directly on the item. When direct marking is not practical, items are labeled or tagged with identification.
- B. Soldering is a special process. The industry specification IPC-A-610C Class 2 is used, when applicable, for soldering and soldering quality requirements and acceptability.

7.6. Control of Inspection, Measuring and Testing Devices

- A. The calibration of inspection, measuring and test equipment shall be controlled in accordance with the Tyco Electronics company calibration program. Calibration services are only allowed to be supplied by suppliers listed on the Tyco Electronics metrology function or manufacturing site's approved supplier list.
- B. With regard to safety related product a metrology function that provides calibration services to a manufacturing site is viewed as a "supplier" to the manufacturing site. As such, it is listed on the manufacturing site's approved supplier list for safety related products. Measuring and test equipment (M&TE) calibration requirements apply toward equipment used to dedicate product for safety-related applications.
- C. A commercial-grade survey of calibration service suppliers, which are used in support of dedicated measuring and test equipment, shall be performed to verify that the supplier has adequate controls over the instrument's critical characteristics affected by the services, and to assure a written quality program is in place to control similar services in the future.
- 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 be utilized without a commercial-grade survey being performed, provided each of the following conditions are met:
 1. A documented review of the supplier's accreditation shall be performed and shall include a verification of each of the following:
 - The calibration or laboratory holds an accreditation by NVLAP or A2LA
 - The accreditation is based on ANSI/ISO/IEC 17025.
 - The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.
 2. The purchase documents impose any additional technical and administrative requirements, as necessary, to satisfy the Tyco Electronics quality assurance program and technical provisions, including:
 - The calibration certificate or report includes identification of the laboratory equipment and standard used.
 - The calibration certificate/report includes reporting as-found and as-left data and record as-found out-of-tolerance condition.

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1. Inspection and Testing

- A. For nuclear grade items, final inspection is performed and documented by quality assurance personnel. Persons other than those who performed or directly supervised the work shall complete inspection for acceptance.
- B. Computer programs used to determine conformance or acceptability of a product shall be evaluated prior to use. The results of this evaluation shall be documented.
- C. Products and product components that are approved and designated for Class 1 safety applications shall be considered dedicated upon successful completion of in-process testing and audit test verification of the final assembly. Factory orders (and their components) that are designated for the manufacture of safety related products will receive additional in-process controls, checks, and verifications to assure compliance with 10 CFR 50 Appendix B program requirements upon completion of each unit. This is in compliance with EPRI NP-5652, methods 1 and 2. Prior to the completion of all in-process testing and audit test verifications, all products are considered commercial in nature and shall conform to all applicable Tyco Electronics quality systems requirements.

8.2. Monitoring and Measurement

Auditors performing audits of the nuclear product line are qualified in accordance with Quality Specification TEC-1000, Paragraph 8.2.

8.3. Control of Nonconforming Product

See Appendix A

8.4. Measurement and Analysis of Organizational Performance

8.5. Improvement

The site quality assurance manager is responsible for implementing the requirements of 10 CFR 21 for potential safety related defects of nuclear grade products. All Part 21 evaluations shall be presented for management review.

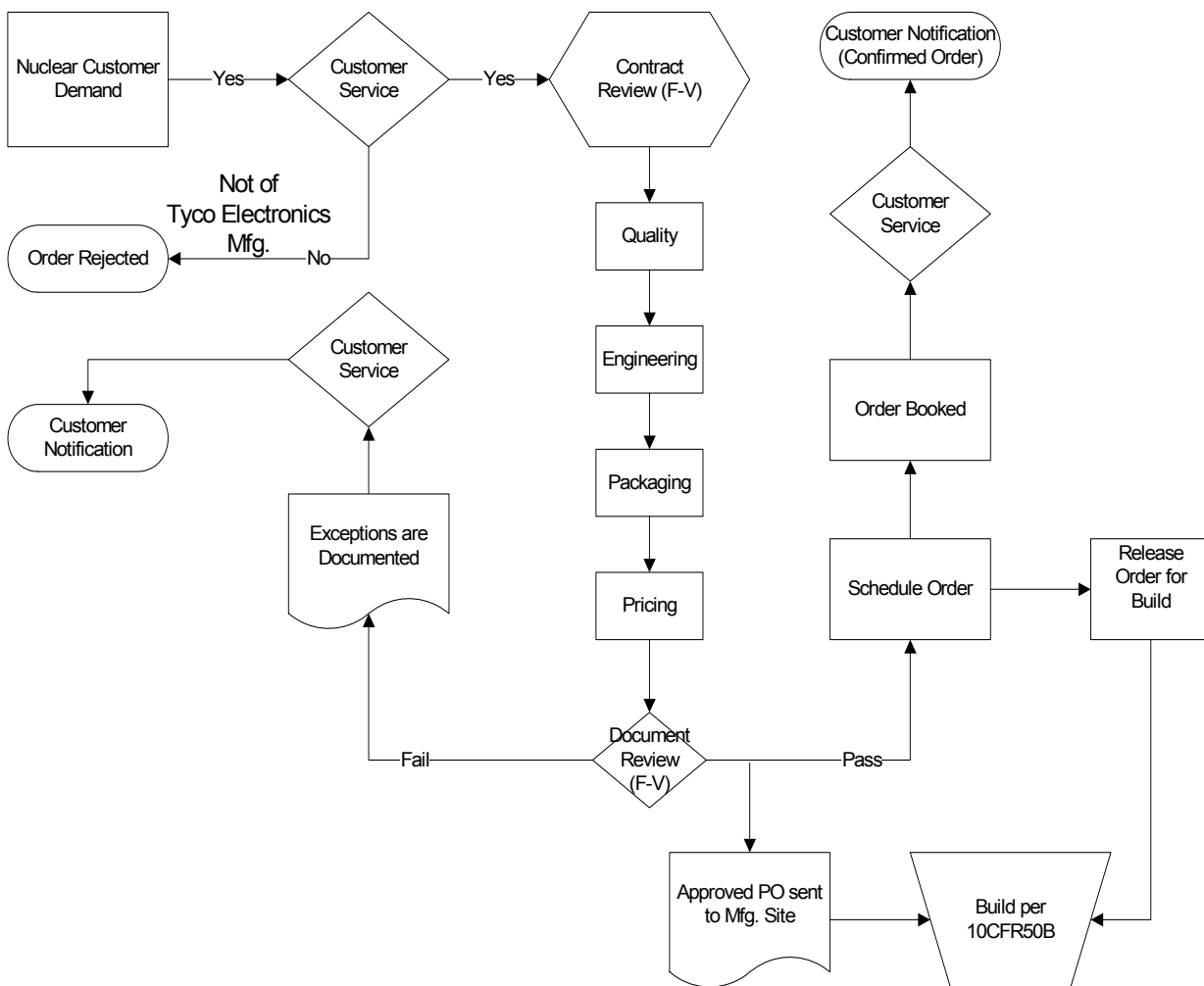


Figure 1

APPENDIX A

1. SCOPE

1.1. Content

To provide guidance for those groups or divisions supplying 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 10 CFR 21, Reporting of Defects and Noncompliance.

The primary objective of this guideline is to ensure that any potential product defect, as the term is defined in 10 CFR 21, and any potential noncompliance with the Atomic Energy Act of 1954 are documented and investigated sufficiently to assure compliance with Section 206 of the Energy Reorganization Act of 1974 regarding reporting and noncompliance.

1.2. Application

- A. This document as a guide implements the nuclear product investigation, evaluation, and reporting procedures necessary for conformance with 10 CFR 21.
- B. Each facility that produces nuclear products shall have a local procedure documenting their process for investigating, evaluating and reporting of 10 CFR 21 issues. The procedure should address at a minimum, the following:
 - 1. Responsible individuals at the facility
 - 2. Timeframe for evaluations and reporting
 - 3. Record maintain and retention.

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 any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

2. APPLICABLE DOCUMENTS

USNRC Rules and Regulation 10 CFR 21, Reporting of Defects and Noncompliance

3. REQUIREMENTS

- A. Nothing in these regulations should be deemed to preclude either an individual, a manufacturer, or a supplier of a commercial grade item not subject to the regulations in this part from reporting to the Commission, a known or suspected defect or failure to comply and as authorized by law, the identity of anyone so reporting will be withheld from disclosure. NRC regional offices and headquarters will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers of the four regions (answered during regular working hours), are listed in appendix D to part 20 of this chapter. The telephone number of the NRC Operations Center (answered 24 hours a day -- including holidays) is (301) 816 - 5100.
- 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) The regulations in this part;
 - (ii) Section 206 of the Energy Reorganization Act of 1974; and
 - (iii) Procedures adopted pursuant to the regulations in this part.
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 subject to the regulations in this part may, in addition to posting section 206, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.
4. The effective date of this section has been deferred until January 6, 1978. [42 FR 28893, June 6, 1977, as amended at 60 FR 48374, Sept. 19, 1995]

NOTE

Each site may develop site specific postings as long as they comply with the requirements of 10 CFR 21.

D. Exemptions

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. Suppliers of commercial grade items are exempt from the provisions of this part to the extent that they supply commercial-grade items. [42 FR 28893, June 6, 1977, as amended at 43 FR 48622, Oct. 19, 1978].

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. Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, and
 - b. Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in §21.21(d)(5). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.
 - c. Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and in all cases, within the five working days after completion of the evaluation described in §21.21(a)(1) or §21.21(a)(2) if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity.
 - d. If the deviation or failure to comply is discovered by a supplier of basic components or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to §21.21(a).

2. A dedicating entity is responsible for identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items and maintaining auditable records for the dedication process.
3. A director or responsible officer subject to the regulations of this part or a person designated under §21.21(d)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting.
 - a. A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 60, 61, 63, 70, 71, or 72 of this chapter.
 - b. The notification to NRC of a failure to comply or of a defect under paragraph (d)(1) of this section and the evaluation of a failure to comply or a defect under paragraphs (a)(1) and (a)(2) of this section is not required if the director or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or the failure to comply.
 - c. Notification required by paragraph (d)(1) of this section must be made as follows:
 - (i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816 - 5151 or by telephone at (301) 816 - 5100 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(1) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in §21.21(a)(2).
 - (ii) Written notification to the NRC at the address specified in §21.5 within 30 days following receipt of information by the director or responsible corporate officer under paragraph (a)(3) of this section on the identification of a defect or a failure to comply.
 - d. The written report required by this paragraph shall include, but need not be limited to, the following information to the extent known:
 - (i) Name and address of the individual or individuals informing the Commission.
 - (ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.
 - (iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.
 - (iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.
 - (v) The date on which the information of such defect or failure to comply was obtained.
 - (vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations in this part.
 - (vii) The corrective action which has been, is being, or will be taken, the name of the individual or organization responsible for the action, and the length of time that has been or will be taken to complete the action.
 - (viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.
 - e. The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

4. Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply. Commission action to obtain additional information may be based on reports of defects from other reporting entities. [42 FR 28893, June 6, 1977, as amended at 46 FR 58283, Dec. 1, 1981; 47 FR 57480, Dec. 27, 1982; 52 FR 31611, Aug. 21, 1987; 56 FR 36089, July 31, 1991; 59 FR 14086, Mar. 25, 1994; 60 FR 48374, Sept. 19, 1995]
- F. Inspections, Records
1. Inspections - Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission to inspect records, premises, activities, and basic components as necessary to accomplish the purposes of this part. [60 FR 48374, Sept. 19, 1995]
 2. Maintenance and inspection of records - Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall prepare and maintain records necessary to accomplish the purposes of this part, specifically.
 - a. Retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation;
 - b. Suppliers of basic components must retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of the notification.
 - c. Suppliers of basic components must retain a record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.
 3. Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component. [56 FR 36090, July 31, 1991, as amended at 60 FR 48374, Sept. 19, 1995]

G. Enforcement

1. Failure to Notify

- a. Any director or responsible officer of an entity (including dedicating entity) that is not otherwise subject to the deliberate misconduct provisions of this chapter but is subject to the regulations in this part who knowingly and consciously fails to provide the notice required as by §21.21 shall be subject to a civil penalty equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.
- b. Any NRC licensee subject to the regulations in this part who fails to provide the notice required by §21.21 or otherwise fails to comply with the applicable requirements of this part shall be subject to a civil penalty as provided by section 234 of the Atomic Energy Act of 1954, as amended.
- c. The dedicating entity, pursuant to §21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process. NRC enforcement action can be taken for failure to identify and evaluate deviations, failure to report defects and failures to comply, or failure to maintain auditable records. [60 FR 48374, Sept. 19, 1995]

2. Criminal Penalties

- a. Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 21 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.
- b. The regulations in part 21 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§21.1, 21.2, 21.3, 21.4 21.5, 21.7, 21.8, 21.61, and 21.62. [57 FR 55071, Nov. 24, 1992]

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.