the left ear an approved metal eartag bearing a serial number and the inscription ''U.S. Reactor'', or a similar State reactor tag. Cattle must also be:

(1) Branded with the letter ''J,'' at least 5 by 5 centimeters (2 by 2 inches) in size, high on the left hip near the tailhead; or

(2) Accompanied directly to slaughter by an APHIS or State representative; or

(3) Moved in vehicles closed with official seals applied and removed by an APHIS representative, State representative, accredited veterinarian, or an individual authorized for this purpose by an APHIS representative.

* * * * *

Done in Washington, DC, this 13th day of September 1995.

Patricia Jensen,

Acting Assistant Secretary, Marketing and Regulatory Programs.

[FR Doc. 95–23191 Filed 9–18–95; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 21

RIN 3150–AF01

Procurement of Commercial Grade Items by Nuclear Power Plant Licensees

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to provide added flexibility in procuring commercial grade items for safety-related service by nuclear power plant licensees. This action provides the requirements for the procurement of basic components, which will be procured initially as commercial grade items with subsequent dedication for safety-related service, in a manner that avoids unnecessary delay and expense while maintaining an adequate level of plant safety.

EFFECTIVE DATE: October 19, 1995.

ADDRESSES: Copies of the public record, including the final regulatory analysis and any public comments received on the proposed rule, may be examined and copied for a fee in the Commission's Public Document Room at 2120 L Street, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: M. L. Au, P.E., Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–6181; E-mail MLA@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

On October 24, 1994 (59 FR 53372), the NRC published a proposed rule in the Federal Register that would clarify and add flexibility to 10 CFR Part 21 requirements for the procurement of commercial grade items for safety-related service by nuclear power plant licensees. This action was in response to a petition for rulemaking (PRM–21–2) from the Nuclear Management and Resources Council (NUMARC), which has been incorporated into the Nuclear Energy Institute (NEI). The notice of receipt of the petition for rulemaking was published on October 14, 1993 (58 FR 53159). The petitioner contended that many of the manufacturers and suppliers of original equipment no longer maintain programs that meet the requirements of Appendix B, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' to 10 CFR Part 50, ''Domestic Licensing of Production and Utilization Facilities,'' because of the high cost of maintaining and implementing these programs relative to the diminishing demand for plant parts. Thus, according to NEI, an increasing number of safety-related items are being purchased as commercial grade items from manufacturers and suppliers who no longer maintain quality assurance programs required by Appendix B to 10 CFR Part 50. Because this is a relatively small market, the petitioner stated that many vendors are unwilling to develop and maintain evaluation and notification procedures that meet the reporting requirements in 10 CFR Part 21. With fewer vendors agreeing to comply with these requirements, the petitioner claimed that it is becoming increasingly difficult for nuclear power plant licensees to procure items for safety-related applications.

The petitioner believed that the sections in 10 CFR Part 21 that relate to procurement of commercial grade items, the dedication of these items for use in safety-related applications, and the reporting requirements associated with these items are unworkable and ineffective and consequently may adversely affect safety. Furthermore, the petitioner believed that the effect of these provisions has been to discourage vendors from maintaining programs that meet NRC requirements and to even refuse to provide parts to licensees. To alleviate these problems, the petitioner proposed the following three changes to 10 CFR Part 21:

First, the petitioner suggested that the NRC broaden the definition of ''commercial grade item'' in 10 CFR 21.3 to read as follows: ''Commercial grade item means any item that has not been dedicated for use as a basic component.'' Essentially this definition would cover any item obtained on the open market. The petitioner believed that allowing commercially available items to qualify as commercial grade items would result in more reasonable prices and delivery times with no adverse impacts on safe plant operations.

Second, the petitioner suggested a more flexible generic definition of ''dedication'' in 10 CFR 21.3 to read as follows: ''Dedication is the evaluation process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended function.'' According to the petitioner, dedication methods could include testing, inspection, surveying the commercial grade supplier to determine that the appropriate quality control is in place, observing the manufacturing process, and analyzing the historical record of the item for acceptable performance. The petitioner also proposed that the dedicating entity maintain documentation of the dedication process for an audit or inspection.

The petitioner believed that the benefits of establishing this approach would be that the licensee or third-party performing the dedication:

(1) Understands the safety significance and function of the proposed component;

(2) Is able to identify the characteristics necessary to perform its intended function better than the manufacturer; and

(3) Is responsible for the quality of the commercial grade item.

This would require the party performing the dedication to determine the suitability of the component by analyzing its ability to perform successfully in a safety-related application.

Third, the petitioner suggested that the responsibility for reporting defects and failures to comply for commercial grade items that have been dedicated should reside with the entity responsible for performing the dedication process. The petitioner suggested that the following language be added to 10 CFR 21.21(b): ''The entity that performs the dedication is responsible for identifying, evaluating and reporting the deviations and failures to comply associated with substantial safety hazards of a commercial grade item.'' Since the manufacturers, suppliers, and sub-tier suppliers of commercial grade items do

not necessarily know whether the item is destined for a safety-related application, the petitioner believes it is appropriate to clarify that the responsibility for reporting defects and failures to comply found in commercial grade items falls on the entity performing the dedication process.

To sum up, the petitioner requested that 10 CFR Part 21 be amended to:

(1) Replace the existing definition of commercial grade item with a more inclusive definition;

(2) Include a flexible generic process for dedication of commercial grade items for safety-related use; and

(3) Clarify that the entity performing the dedication of a commercial grade item is responsible for discovering and evaluating deviations and for reporting defects and failures to comply as required by 10 CFR Part 21.

The rule grants in part and denies in part the petition for rulemaking (PRM–21–2) from the NEI and completes action on the petition.

Public Comment

The NRC received 23 letters of public comments in response to the Federal Register notice announcing the receipt of the petition for rulemaking. All but one letter supported the petition and called for a revision of the NRC's regulations consistent with the proposal set forth in the petition. The NRC considered these comments in the development of the proposed rule that was published in October 1994.

The NRC received 19 letters of comment in response to the proposed rule. The NRC considered these comments in developing the final rule, the objective of which is to provide requirements for the procurement of basic components, initially procured as commercial grade items and subsequently dedicated for safety-related service, in a timely and cost effective manner that avoids unnecessary delay and expense to the licensee while maintaining an adequate level of plant safety.

The 19 letters of comment received in response to the proposed rule can be categorized as follows: 1 from an interested individual, 1 from an individual in a citizen's group, 1 from the Nuclear Energy Institute (NEI) with a supplemental letter re-emphasizing comments important to NEI, 1 from a law firm, 14 from nuclear power plant licensees, and 1 from a nuclear power plant supplier. Many of the letters contained comments that were similar in nature. The majority of the commenters were supportive of the proposed rule. Only one commenter, an individual from a citizens group, objected to the proposed rule. The following section summarizes the public comments received and provides NRC's responses to the concerns expressed.

Comment. The proposed rule contains changes developed by NRC staff which differ from the proposal originally submitted by NEI (formerly NUMARC), and in addition, codifies new prescriptive requirements for the dedication process.

Response. Part 21 currently does not contain a regulatory definition of ''dedication,'' indicating only the time when dedication occurs; however, the NEI petition sought, among other matters, to define and establish by rulemaking a standard for the dedication process. As such, it was appropriate for the Commission to consider the elements of a dedication process for commercial grade items which assure the protection of the health and safety of the public rather than limit this standard to the industry's proposal. Therefore, it is not inappropriate for the NRC to consider ''provisions not sought by the petitioner.'' The NRC has never interpreted, nor has it implemented, the 10 CFR 2.802 rulemaking petition process in a manner which requires either the wholesale acceptance or rejection of specific rulemaking proposals contained in a 10 CFR 2.802 petition.

Comment. Amendments to the definitions are ambiguous and do not provide a clear demarcation between basic components and commercial grade items. The definition of ''basic component'' raises two problems involving wording. The definition states that it ''includes'' two categories of items, i.e., those designed ''or'' manufactured under Appendix B to 10 CFR Part 50 quality assurance programs, and commercial grade items successfully dedicated as basic components. The first problem is the use of the term ''includes'' in the definition of basic component. This opens the possibility that other categories of items could also exist which is not the intent. The second problem is the use of the word ''or'' between ''design'' and ''manufactured.'' An item designed under an Appendix B quality assurance program, but manufactured commercial grade should not be categorized as a basic component. It requires dedication to be categorized as a basic component.

Response. The NRC agrees with the commenter's observation that the Commission's intent was for the definition of basic component to be limited to only two categories of items: (1) those designed and manufactured under 10 CFR Part 50, Appendix B quality assurance programs, and (2) those commercial grade items successfully dedicated as basic components. The definition of ''basic component'' has been revised to address the commenter's concern.

Comment. The proposed definition of ''Commercial Grade Items'' appears to be unnecessarily restrictive and could give rise to interpretational difficulties that could limit or preclude options available to the licensee, rather than enhance the flexibility of licensees or utilities in dedicating commercial grade items for safety-related applications. The difficulty with the proposed definition of commercial grade item is that it would force utilities to always purchase a product as nuclear grade if a manufacturer with an Appendix B to 10 CFR Part 50 quality assurance program exists, which would result in a monopoly or a ''captive market.''

Response. The new definition is not intended to restrict the licensee from purchasing commercial grade items for subsequent dedication for safety-related applications even though a basic component designed and manufactured under an Appendix B to 10 CFR Part 50 quality assurance program is currently available. The commercial grade item, when properly and successfully dedicated, is deemed by the NRC to be equivalent in its safety function performance to the same or a similar item designed and manufactured under an Appendix B to Part 50 quality assurance program.

Comment. The phrase ''or part of a basic component'' should be deleted from the definition of commercial grade items because it could be interpreted to mean that all commercial grade items used in basic components are required to be dedicated for safety-related use.

Response. To address this comment, the NRC has modified the definition of ''commercial grade item'' to clarify that a commercial grade item that is part of a basic component but does not affect a safety-related function need not be dedicated. Therefore, a commercial grade item which is part of a basic component is considered to be a basic component after it has been dedicated prior to installation only if it affects a safety function.

Comment. The proposed new definition of ''commercial grade item'' and other changes to Part 21 should not be limited to only nuclear power plant licensees under Part 50, and their vendors, since these entities hold other licenses and would benefit from changes to Part 21.

Response. Proposed changes to Part 21 regulatory requirements for

nonreactor licensees are currently being considered.

Comment. The definition of the term ''dedication'' needs to be clarified as it lacks flexibility for dedication of a commercial grade item for safety-related applications. The graded approach should be used for applying Appendix B to 10 CFR Part 50.

Response. The dedication process must be performed using the applicable quality assurance criteria of Appendix B to 10 CFR Part 50. Appendix B already allows the level of quality assurance implemented to be consistent with the item's importance to safety (i.e., the graded approach).

Comment. The complexity of an item's design or manufacturing process should not be a criterion for excluding commercial grade items from eligibility to undergo a dedication process.

Response. To the extent the term ''complexity'' has caused confusion, the language of the rule has been modified to remove that term. The NRC maintains that if the design of an item and its manufacturing process are such that the dedication process cannot reasonably ensure the absence of a defect or failure to comply that affects one or more critical characteristics of the item, then the item cannot be dedicated, and must be designed and manufactured as a basic component. Included are items for which the manufacturing process requires in-process inspections and verifications to ensure that defects are identified and corrected. Typical examples include, but are not limited to, fuel assemblies, control rod assemblies, and reactor coolant pressure boundary components.

Comment. In the definition of term ''dedication,'' the example of ''pressure vessels'' does not meet the specific nuclear-unique requirement since pressure vessels are used widely outside the nuclear industry and should be considered a potential candidate for dedication.

Response. The example is no longer included in the definition. In the Statement of Considerations, ''pressure vessel'' has been replaced with ''reactor coolant pressure boundary components'' since the NRC believes such components, due to their importance to safety, should continue to be designed and manufactured as basic components under an Appendix B quality assurance program.

Comment. In the definition of ''dedicating entity,'' the word ''qualify'' should be replaced with the word ''accept'' to ensure that the dedication process is differentiated from equipment qualification.

Response. The NRC agrees that the word ''qualify'' could lead to misinterpretation. The definition of ''dedicating entity'' has been revised.

Comment. The proposed definition of ''critical characteristics'' should not be codified for two reasons. First, it is not necessary or beneficial to codify the processes. Second, the term was originally developed by industry to support improved dedication and procurement programs under NUMARC procurement initiatives. There are fundamental differences in the interpretation of the term ''critical characteristics'' between the NRC and much of the nuclear industry.

Response. The NRC believes it is important to define and codify ''critical characteristics'' because this term represents a subject of importance in the dedication process for commercial grade items. The Commission is aware that in the Electric Power Research Institute's (EPRI) ''Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications,'' EPRI NP–5652, ''critical characteristics'' is defined primarily in procurement terms, i.e., that the item received is the item specified as verified by part number. However, in the Commission's view, this is an appropriate term by which to convey the intent of this rulemaking that the dedication process specify those characteristics important to the design, material, and performance of an item so that the verification of those characteristics will provide reasonable assurance that the item will perform its intended safety function.

Comment. One utility commented that a backfit analysis should be required because new requirements for dedication are being specified.

Response: The current Part 21 regulation already provides for the dedication of commercial grade items to be used in safety-related applications. The final rule provides for a broadening of the definition of commercial grade items and their subsequent dedication for safety-related service. The rule does not impose a more restrictive requirement upon any licensee or dedicating entity; therefore, it does not constitute a backfit as defined in 10 CFR 50.109(a)(1), and no backfit analysis is necessary.

Comment. Part 21 does not clearly address the responsibilities for reporting defects and failures to comply associated with the purchase and subsequent transfer of a basic component by one utility to another. A provision should be included in the rulemaking allowing one utility to accept an item as a basic component when the utility supplying the item is unwilling to accept the Part 21 responsibilities associated with this kind of transaction. The utility purchasing the item should document the qualification of the vendor during the time of original manufacture and sale of the item.

Response: The NRC does not agree with the position set forth in this comment. The Part 21 regulation specifies the responsibilities of any individual or corporation and each director and responsible officer of such organization that supplies basic components. Those responsibilities are also applicable to utilities which supply basic components to other utilities. Nothing in the regulation prevents a utility from contacting the original supplier or manufacturer for the direct transfer of information regarding the item.

Basis for Commission's Decision

The NRC has reviewed the public comments that were submitted on the proposed rule. The final rule has taken into consideration many of the suggested changes as indicated in this Statement of Considerations.

When Part 21 was first issued in 1977, the suppliers of all parts making up a basic component were subject to the reporting requirements under Part 21. However, recognizing that the Commission lacked experience in implementing a reporting program of this scope, the Commission also pointed out in the Statement of Considerations accompanying this part that it would examine closely the implementation of Part 21 as the Commission gained experience. Following the issuance of Part 21, the NRC received many requests for clarification of the regulations. The NRC examined the issue of how far down the procurement chain Part 21 should be applicable and on October 19, 1978 (43 FR 4862), amended Part 21 to exempt commercial grade items from the reporting requirements of Part 21 until the items were dedicated for use as a basic component. The NRC held that the October 1978 rule was needed for safety reasons. Problems such as the inability to obtain needed parts and services were all cited as detriments to safety. The NRC was challenged on this amendment and the court of appeals upheld the Commission's interpretation of section 206 of the ERA requiring the Commission to ''draw a line somewhere to demarcate the outer boundaries of the duty to report'' (*Natural Resources Council* v. *NRC,* 666 F.2d 595 (D.C. Cir. 1981)).

Problems such as the inability to obtain parts and services from the most qualified suppliers and excessive delays

in procurements were all cited as detriments to safety. With the development of increased confidence in licensee implementation of dedication activities through NRC inspection and experience, and because the availability of basic components has further declined, the NRC believes that the current definition of commercial grade items has become unnecessarily restrictive.

The petitioner proposed that a commercial grade item be defined as any item that has not been dedicated for use as a basic component. Thus, any commercial grade item could be subject to a dedication process to verify its qualification as a basic component. The Commission maintains that not all commercial grade items can be properly dedicated for safety-related use after the manufacturing process is completed. In fact several commenters agreed that there is a limited category of components for which quality assurance is an integral part of the manufacturing process and that their critical characteristics cannot be attested to after-the-fact. The Commission believes that if the design or manufacturing process of an item is such that dedication cannot reasonably assure the absence of a defect that could affect one or more critical characteristics of the item, the item must be designed and manufactured as a basic component in accordance with 10 CFR Part 50, Appendix B requirements. There are components in this limited category that generally have requirements and applications in which the design and manufacturing processes require in-process inspections and verifications to ensure that defects and failures to comply are identified and corrected. Thus, the NRC believes that commercial grade items cannot encompass the full spectrum of items envisioned by the petitioner.

Part 21 currently defines a commercial grade item as an item that is (1) Not subject to nuclear-unique design or specification requirements; (2) used in applications outside the nuclear industry; and (3) ordered on the basis of specifications set forth in the manufacturer's published product description. This set of conditions resulted in very limited use of the commercial grade item designation. To provide added flexibility in using commercial grade items for safety-related service by nuclear power plant licensees, the NRC is replacing the set of conditions and adopted a new definition for commercial grade item. Under this new definition, a ''commercial grade item,'' when applied to nuclear power plants, means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. The definition makes clear that a commercial grade item that is part of a basic component but does not affect a safety-related function need not be dedicated and that item is not considered a basic component. Commercial grade items do not include items in which their design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified). Typical examples include, but are not limited to, fuel assemblies, control rod assemblies, and reactor coolant pressure boundary components. Thus the definition of ''commercial grade item'' does not include items whose quality assurance is an integral part of the manufacturing process and whose acceptance is based primarily on the vendor's certification of compliance with specific design requirements. For facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, the existing definition is retained, although proposed revisions to Part 21 for application to these facilities and activities (including those certified under 10 CFR Part 76) are under consideration in a separate rulemaking.

The new definition is not intended to restrict the licensee from purchasing commercial grade items for subsequent dedication for safety-related applications even though a basic component designed and manufactured under an Appendix B to 10 CFR Part 50 quality assurance program is currently available. The commercial grade item, when properly and successfully dedicated, is deemed by the NRC to be equivalent in its safety function performance to the same or a similar item designed and manufactured under an Appendix B to Part 50 quality assurance program.

Sections 21.6, 21.21, 21.31, 21.41, and 21.51 contain the NRC's requirements for posting, notification, inspection, records, and maintenance and inspection of records, respectively. The NRC is clarifying these sections to point out that dedicating entities are subject to the regulations in these sections. In addition, minor editorial changes have been made in § 21.51(b).

Section 21.61 has been amended to clarify the scope of this section. NRC licensees and their employees subject to Part 21 are also subject to the normal enforcement process and sanctions. In addition, Section 206 of the Energy Reorganization Act of 1974, as amended, and implemented by 10 CFR Part 21, imposes an obligation on firms and organizations that are involved in the nuclear industry, and further, imposes these obligations as a direct liability on certain individuals in these firms and organizations. The ''knowingly and consciously'' standard specified in § 21.61 applies only to non-licensees.

Environmental Impact: Categorical Exclusion

The NRC has determined that this regulation is the type of action described in the categorical exclusion in 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this regulation.

Paperwork Reduction Act Statement

This rule does not contain a new information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget approval number 3150–0035.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies may be obtained from (See **FOR FURTHER INFORMATION CONTACT.**)

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The rule primarily impacts nuclear power plant licensees because they are expected to assume a greater role in the dedication process. The companies that own these plants do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810). In addition, the rule, when promulgated, will allow small entities to more effectively compete in providing components and services to nuclear power plants, and to the extent this occurs, the rule is advantageous to them.

Backfit Analysis

The Commission has determined that the backfit rule, 10 CFR 50.109, does not apply to this rule. These amendments do not involve any provision that would impose additional requirements requiring a backfit analysis as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 21

Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 21.

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

1. The authority citation for Part 21 continues to read as follows:

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).

§ 21.2 [Amended]

2. Section 21.2 (d) is amended by revising the reference reading ''(see § 21.3(a–1)'' to read ''(as defined in § 21.3),'' and in the third sentence of this section, change the word ''five'' to ''four.''

3. Section 21.3 is amended by removing the paragraph designations from each of the defined terms and arranging the definitions in alphabetical order, removing the words ''paragraph (d)(1) of'' in paragraph (2) of the term *Defect,* removing the parenthetical references in the terms *Defect* and *Deviation,* revising the terms *Basic component, Commercial grade item,* and *Dedication,* and adding the terms *Critical characteristics* and *Dedication entity* to read as follows:

§ 21.3 Definitions.

Basic component. (1)(i) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

(A) The integrity of the reactor coolant pressure boundary;

(B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 100.11 of this chapter.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with 10 CFR Part 50, Appendix B, or commercial grade items which have successfully completed the dedication process.

(2) When applied to other facilities and when applied to other activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(3) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

Commercial grade item. (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, commercial grade item means an item that is:

(i) Not subject to design or specification requirements that are unique to those facilities or activities;

(ii) Used in applications other than those facilities or activities; and

(iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

* * * * *

Critical characteristics. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedication. (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B. The process is considered complete when the item is designated for use as a basic component.

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

Dedicating entity. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. 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.

* * * * *

3. In § 21.6, paragraph (a) is revised to read as follows:

§ 21.6 Posting requirements.

(a) (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.

* * * * *

4. In § 21.21, the introductory text of paragraph (a) is revised, paragraphs (c) and (d) are redesignated as paragraphs (d) and (e), and a new paragraph (c) is added to read as follows:

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

(a) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to—

* * * * *

(c) A dedicating entity is responsible for—

(1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and

(2) Maintaining auditable records for the dedication process.

* * * * *

5. Section 21.31 is revised to read as follows:

§ 21.31 Procurement documents.

Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

6. Section 21.41 is revised to read as follows:

§ 21.41 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.

7. In § 21.51 the introductory text of paragraph (a) and paragraph (b) are revised to read as follows:

§ 21.51 Maintenance and inspection of records.

(a) 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—

* * * * *

(b) 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.

8. Section 21.61 is revised to read as follows:

§ 21.61 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.

Dated at Rockville, Maryland, this 8th day of September 1995.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 95–23179 Filed 9–18–95; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1000 and 1002

[Docket No. 82N–0273]

RIN 0905–AD78

Records and Reports Regulations for Radiation Emitting Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations regarding the requirements for recordkeeping and reporting of adverse experiences and other information relating to radiation emitting electronic products. This rule reduces recordkeeping and reporting requirements for some products, requires only abbreviated reporting for other products, and clarifies certain requirements. The timing and content of certain reports will be revised to enhance the usefulness of the information. These amendments will improve protection of the public health while reducing regulatory burdens on manufacturers, dealers, and distributors of radiation emitting electronic products.

EFFECTIVE DATE: October 19, 1995.

FOR FURTHER INFORMATION CONTACT: Joanne Barron, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4654.

SUPPLEMENTARY INFORMATION:

I. Background

The Regulatory Flexibility Act (5 U.S.C. 601) and Executive Order 12866 require FDA to periodically conduct a comprehensive review of existing regulations. This review is to analyze alternative regulatory approaches and to identify regulations that need to be revised or revoked because they impose an unnecessary burden on specific segments of the public, such as manufacturers, dealers, small businesses, or the general public. In the Federal Register of July 2, 1982 (47 FR 29004), FDA announced its plan to review the records and reports regulations in part 1002 (21 CFR part 1002). FDA recognized that, although part 1002 does not appear to have a major impact on the overall radiation emitting electronic products industry, its impact on small manufacturers