



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

PDR
AF 01- 426
042

September 7, 1994

NOTE TO: Greg Cwalina, Section Leader
RVIB/NRR

FROM: Sidney Feld, Section Leader
RAS/RDB/RES

SUBJECT: OFFICE RECONCURRENCE OF PROPOSED RULE - "PROCUREMENT OF
COMMERCIAL GRADE ITEMS BY NUCLEAR POWER PLANT LICENSEES; 10
CFR PART 21"

This proposed rule was previously transmitted for concurrence by our memorandum of June 7, 1994 but has been updated to accommodate the Office of General Counsel (OGC).

NRR's timely concurrence is requested on the enclosed Federal Register Notice, as concurrences from all the other offices, including OGC's no legal objection, have been obtained. A copy containing the comparative text is provided to facilitate your review.

A handwritten signature in cursive script that reads "Sid Feld".

Sidney Feld, Section Leader
RAS/RDB/RES

Enclosure:
As stated

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Enclosure 1

Federal Register Notice

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: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations in 10 CFR Part 21 to clarify and add flexibility to the process of procuring commercial grade items for safety-related service by nuclear power plant licensees. The proposed rule expands the scope of commercial grade items to encompass all items procured for use in safety-related service that are not designed and/or manufactured as basic components. This proposed rule is necessary to ensure that the procurement of commercial grade parts and their subsequent dedication are performed in a manner that avoids unnecessary delay and expense while maintaining an adequate level of plant safety. The proposed rule responds to a petition for rulemaking from the Nuclear Management and Resources Council (NUMARC), which is now incorporated into the Nuclear Energy Institute (NEI).

DATES: Submit comments by (75 days after publication in the Federal Register). Comments received after this date will be considered if it is

practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. ATTN: Docketing and Service Branch.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. on Federal workdays.

Examine comments received and the regulatory analysis at: The NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

Obtain single copies of the regulatory analysis from: M. L. Au, Office of Nuclear Regulatory Research, U. S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6181.

FOR FURTHER INFORMATION CONTACT: M. L. Au, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6181.

SUPPLEMENTARY INFORMATION:

Background

The Commission issued 10 CFR Part 21 on June 6, 1977 (42 FR 28893), to implement Section 206 of the Energy Reorganization Act of 1974. One of the purposes of Part 21 is to provide for the evaluation of deviations and reporting of defects, and failures to comply in safety-related parts and services for use in nuclear power plants. Part 21 is implemented in

conjunction with 10 CFR Part 50, Appendix B, which contains the quality assurance criteria to be applied to design, fabrication, construction, and testing of safety-related structures, systems, and components in nuclear power plants.

On October 14, 1993 (58 FR 53159), the Commission published a notice of receipt of a petition for rulemaking (PRM-21-2) from the Nuclear Management and Resources Council (NUMARC), which is now incorporated into the Nuclear Energy Institute (NEI). The NUMARC petition was docketed by the NRC on June 22, 1993.

The petitioner requested that the Commission amend 10 CFR Part 21 to clarify and add flexibility to the process of procuring commercial grade items for safety-related service by nuclear power plant licensees. Specifically, 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 reporting defects and failures to comply as required by Part 21.

Basis for Petition

The petitioner contends that many of the original equipment manufacturers and suppliers no longer maintain programs that meet the requirements in 10 CFR Part 50, Appendix B, due to the high cost of maintaining and implementing these programs relative to the diminishing demand for plant parts. Thus, an increasing number of safety-related parts are being purchased from manufacturers and suppliers who no longer maintain quality assurance programs pursuant to 10 CFR Part 50, Appendix B. Because, this is a relatively small market, the petitioner states that many vendors are unwilling to develop and maintain evaluation and notification procedures that meet Part 21 reporting requirements. With fewer vendors agreeing to comply with the requirements of Part 21, the petitioner claims that it is becoming difficult for nuclear power plant licensees to procure an increasing number of items and services for safety-related applications.

Part 21 currently provides an exemption for a subclass of component called "commercial grade." These components are defined as items that are

- (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 (for example, a catalog).

The petitioner believes that the provisions of Part 21 that relate to 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 believes 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 proposes the following three changes to 10 CFR Part 21:

First, the petitioner suggests that the NRC broaden the definition of "commercial grade item" in 10 CFR Part 21.3 to read as follows: "Commercial grade item means any item that has not been dedicated for use as a basic component." This definition essentially would include any item obtained on the open market. The petitioner believes 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 suggests a more flexible generic definition of "dedication" in 10 CFR Part 21.3: "Dedication is the evaluation process under-taken 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 and/or 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 proposes that the dedicating entity maintain documentation of the dedication process for the purpose of an audit or inspection.

The petitioner believes that the benefits of establishing this process are that the utility 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) would be 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 the effect of its performance in a safety-related application.

Third, the petitioner suggests that the responsibility for reporting defects and failures to comply for commercial grade items should reside with the entity responsible for performing the dedication process. The petitioner suggests that the following language be added to 10 CFR Part 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." The petitioner believes that it is appropriate to clarify that the responsibility for reporting defects and failures to comply for commercial grade items falls on the entity performing the dedication process because the suppliers and sub-tier suppliers do not necessarily know whether a commercial grade item is destined for a safety-related application.

Public Comments and Responses

The NRC received 23 letters in response to the publication of the notice of receipt of the petition. All but one letter supported the petition and called for a revision of the NRC's regulations consistent with the proposed amendments set forth in the petition.

Of the 22 letters that supported the petition, 17 supported the proposed amendments without any qualification. Fifteen of these letters were from nuclear utilities and two from nuclear vendors.

The five other supportive letters recommended minor changes to the specific language of the proposed amendments. With respect to the definition of dedication, one commenter recommended replacing "intended function" with "intended safety-related function." The intent here is to make it clear that a dedicating entity must focus on safety-related functions in determining whether an item will be suitable as a basic component. During the comment period, NUMARC indicated its support for this change. The NRC also concurs that this is an appropriate clarification. In addition, three commenters offered a clarifying second sentence that would establish the point in time that an item is considered dedicated. The sentence would indicate that, when dedication of a commercial grade item has been completed, the item may be used as a basic component. One of these commenters also recommended that the term "evaluation" be eliminated from the first sentence because the definition of "evaluation" is currently provided in 10 CFR Part 21.3 and has a different intent than its use here. The NRC supports inclusion of the additional sentence. The NRC also agrees with the commenter regarding removal of the term "evaluation." This term will continue to be used only in conjunction with a substantial safety hazard determination.

Two commenters recommended changes to the notification requirement to prevent confusion regarding the application of Part 21 only to basic components. The NRC agrees with the substance of the comment to provide for the notification of defects and failures to comply only subsequent to successful dedication of the commercial grade item as a basic component. The proposed amendment has been revised accordingly.

One commenter expressed concern that a supplier's responsibility for procurement documentation is not clear. The commenter recommended that

procurement documents specify that an item is commercial grade, that dedication would be performed by the purchaser, and that provisions of Part 21 would not apply to the supplier. The NRC believes 10 CFR Part 21.31 clearly states that only procurement documents for the purchase of basic components and dedication of commercial grade items need to require adherence to the provisions of Part 21.

The one letter in opposition to the petition was submitted by a private individual. This commenter believes that commercial grade dedication requires each utility to perform a comprehensive evaluation and to establish the appropriate engineering and quality requirements utilizing the provisions of Part 50, Appendix B. Further, this commenter also states that Part 21 should not be used as an instructional guide for the engineering analysis and procurement of items. The NRC believes that proposed revisions to Part 21 will reflect the current procurement situation faced by utilities while enhancing the requirement for ensuring proper qualification of commercial grade items used in safety-related applications.

Basis for Commission's Decision

The NRC has carefully reviewed the arguments presented by the petitioner and those that submitted public comments on the petition. The NRC is proposing to grant the petition in part with regard to 10 CFR Part 50 licensees by initiating this rulemaking. The proposed rule incorporates the petition in part, and modifies the petitioner's suggested language as indicated in the following discussion.

Commercial Grade item (CGI)

The NRC agrees in principle with the petitioner that the definition of a commercial grade item as it relates to 10 CFR Part 50 needs to be expanded to allow for a broader range of parts and services. In October 1978, when the NRC issued an immediately effective rule defining commercial grade item, it was for the purpose of exempting these items from the reporting requirements of Part 21 until their dedication as basic components. The NRC argued that this amendment was needed for safety reasons. Problems such as the inability to obtain needed supplies or to use the most qualified suppliers, and excessive delays in procurements were all cited as detriments to safety. The NRC believes that similar concerns are again present to some extent because the availability of basic components has declined and the current definition of commercial grade item is now unnecessarily restrictive.

The petitioner proposes 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 assure its qualification as a basic component. The Commission maintains that not all safety-related items can be properly dedicated after the manufacturing process is completed. For certain items, quality assurance is an integral part of the manufacturing process and cannot be attested to after the fact. The NRC believes that if the complexity of the design and/or manufacturing process of an item is such that dedication cannot reasonably assure the absence of a defect which could affect one or more critical characteristics of the item, the item must be designed and manufactured as a basic component. Items in this category include complex assemblies which generally have nuclear unique

requirements and applications and where the design and/or manufacturing process requires many in-process inspections and verifications to assure that defects are identified and corrected. Specific examples include, but are not limited to, fuel and control rod assemblies and pressure vessels. 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 results in very limited use of the commercial grade item designation. The NRC is proposing that, for 10 CFR Part 50 licensees, an item would qualify as a commercial grade item if it is not designed and/or manufactured as a basic component. This would effectively preclude inclusion of 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, 60, 61, 71, or 72 the existing definition is retained, although proposed revisions to 10 CFR Part 21 for non-reactor licensees are under development in a separate rulemaking.

The NRC's proposed definition of "Commercial Grade Item," when applied to facilities and activities licensed pursuant to 10 Part 50 of this chapter, means a structure, system, component, or part thereof that is not designed and/or manufactured as a basic component. A commercial grade item is not a basic component or part of a basic component, until the dedication process has been completed.

Basic Component

Because the NRC is now proposing a definition of commercial grade item for 10 CFR Part 50 licensees in terms of the standards involved during its design and manufacture, it is also appropriate to define basic component in a similar manner. The NRC therefore proposes to add the following to its definition of "basic component":

"This definition includes items designed and/or manufactured under a program complying with 10 CFR Part 50, Appendix B, and commercial grade items which have been successfully dedicated to be used as basic components pursuant to the dedication process described in this part". Thus the definition reads as follows:

When applied to facilities and activities licensed pursuant to Part 50 of this chapter, means a plant structure, system, component or part thereof necessary to assure (i) the integrity of the reactor coolant pressure boundary, (ii) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (iii) 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. This definition includes items designed and/or manufactured under a program complying with 10 CFR Part 50, Appendix B, and commercial grade items which have been successfully dedicated to be used as basic components pursuant to the dedication process described in this part.

Dedication Process

Dedication is an inspection and acceptance process by which a commercial grade item is designated for use as a basic component. By expanding the scope of commercial grade items for 10 CFR Part 50 licensees, it is anticipated that an increasing number of safety-related items will be procured as commercial grade items as opposed to basic components. This should result in increased reliance on dedication by licensees or third-party dedicating entities in lieu of the quality assurance programs of manufacturers and suppliers. Although such a transfer may be beneficial in some instances, the NRC needs greater assurance that 10 CFR Part 50 licensees or dedicating entities are performing meaningful and substantive dedication processes. In all cases, the licensee using the dedicated item is responsible for ensuring that the dedication process includes the identification and verification of critical characteristics and is to be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B of this chapter. As a result, the NRC believes that the rule needs to specify the key elements of such a dedication process. Specifically, the NRC maintains that this process must be performed in accordance with the applicable provisions of 10 CFR Part 50, Appendix B, and encompass inspections, tests, and/or analyses performed by the licensee or a third-party dedicating entity after delivery, supplemented as necessary, by a combination of commercial grade surveys, product inspections or witness/holdpoints. The four acceptance methods described in EPRI NP-5652, "Guidelines for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)," as conditionally endorsed by NRC Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs"

may be utilized as guidance for the dedication of commercial grade items for safety-related applications. The critical characteristics are those design, material, and performance characteristics that, when verified, will provide reasonable assurance that the item will perform its intended safety-related function.

The NRC's proposed definition of the dedication process is as follows: Dedication, when applied to facilities and activities licensed pursuant to Part 50 of this chapter, is an inspection and acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety-related function. In this respect, it is equivalent to an item obtained through a 10 CFR Part 50, Appendix B quality assurance program. This assurance is achieved by combination of commercial grade surveys, product inspections or witness/holdpoints at the manufacturer's facility supplemented as required by additional inspections or tests performed by a purchaser or a third-party dedicating entity after delivery. In all cases, the licensee using the dedicated item is responsible for ensuring that the dedication process includes the identification and verification of critical characteristics and is conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B of this chapter. The process is considered complete when the item is designated for use as a basic component. Due to the complexity of their design and/or manufacturing process, certain items must be designed and manufactured as basic components since the dedication process cannot reasonably assure the successful performance of the safety function (i.e., one or more critical characteristics of the item cannot be verified). Items in this category include complex assemblies which generally have nuclear unique

applications and where the design and/or manufacturing process requires many in-process inspections and verifications to assure that defects or failures to comply are identified and corrected. Specific examples include but are not limited to fuel and control rod assemblies and pressure vessels.

The petitioner also requested that the entity performing the dedication process be responsible for Part 21 evaluation and reporting requirements. The NRC concurs with this recommendation as it will add needed flexibility in the procurement of replacement parts. Further, the NRC believes that the dedicating entity would be the most qualified party to assume the responsibility for Part 21 requirements because in many cases the commercial grade supplier does not know the end application or safety function of the item. The dedicating entity will generate the necessary quality records during the dedication process, and should have a full understanding of the item's safety function to enable that entity to perform the deviation evaluation and defect reporting functions required under Part 21.

The dedicating entity, i.e., either (1) the manufacturer, (2) third-party entity, distributing a commercial grade item which it has successfully dedicated or (3) licensee, which has successfully dedicated a commercial grade item for its own use, would be subject to NRC enforcement action for failure to evaluate deviations, failure to report defects or failures to comply, or failure to maintain auditable records. In addition, if the dedicating entity identifies a defect which previously was not identified and which is attributable to a flaw in the dedication process, any known recipients of similar dedicated items using this process must be notified or included in the dedicating entity's notification to the Commission as currently required under the provisions of Part 50, Appendix B.

Critical Characteristics

The NRC definition of dedication process includes the term "critical characteristics." Given its import, the NRC believes it should be defined so as to identify those characteristics which need to be examined. As noted in the definition below, the characteristics to be examined are selected design, material and performance characteristics.

The NRC's proposed definition of "critical characteristics" is as follows: Critical characteristics, when applied to facilities and activities licensed pursuant to Part 50 of this chapter, are those 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.

Dedicating Entity

The NRC definition of the dedication process also includes the term "dedicating entity." Because the dedication process begins with the dedicating entity, the NRC believes that it is important to clearly identify the party responsible for the requirements associated with this process.

The NRC's proposed definition of "dedicating entity" is as follows: Dedicating entity, when applied to facilities and activities licensed pursuant to Part 50 of this chapter, means the organization that performs the dedication process to qualify a commercial grade item as a basic component. Dedication may be performed by either the manufacturer of the item, a third party organization, or the licensee itself. The dedicating entity is

responsible for evaluating deviations and reporting defects and failures to comply for the dedicated item and for maintaining auditable records for the dedication process. The dedicating entity may be subject to NRC regulatory enforcement for failure to evaluate deviations, failure to report defects or failures to comply, or failures to maintain auditable records.

Notification, Inspection, and Reporting Responsibilities

Section 21.21 (c)(1) and (2) have been added to clarify that the dedicating entity of a commercial grade item is responsible for identifying, evaluating, and reporting defects and failures to comply as required by Part 21, as well as maintaining auditable records of the dedication process.

Sections 21.21, 21.41, and 21.51 contain the NRC's requirements for notification, inspections, records, and maintenance and inspection of records, respectively. The NRC proposes, for clarification purposes, that these sections explicitly identify dedicating entities as being subject to the regulations in these sections. The phrase, "(including dedicating entities)" has been added to §§ 21.6(a), 21.21(a), 21.31, 21.41, and 21.51(a) and (b).

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed regulation is the type of action described in the categorical exclusion in 10 CFR Part 51.22(c)(3)(iii). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

Paperwork Reduction Act Statement

This proposed 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 draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the analysis may be obtained from M. L. Au, Office of Nuclear Regulatory Research, U. S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6181.

The Commission requests public comment on the draft analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

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 upon a substantial number of small entities. The proposed 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 Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121. In addition, the rule, if promulgated, would potentially 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 Part 50.109, does not apply to this proposed rule. These amendments do not involve any provision that would impose additional requirements requiring a backfit analysis as defined in 10 CFR Part 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. 553, the NRC is proposing to adopt 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 (42 U.S.C. 2201, 2282); 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)

2. Section 21.3 is amended by removing the paragraph designations from each of the defined terms and arranging the definitions in alphabetical order; revising the terms Basic component, Commercial grade item, and Dedication, and adding the terms Critical characteristics, and Dedicating entity to read as follows:

§ 21.3 Definitions.

Basic component. (1) When applied to facilities and activities licensed pursuant to Part 50 of this chapter, means a plant structure, system, component or part thereof necessary to assure (i) the integrity of the reactor coolant pressure boundary, (ii) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (iii) 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. This definition includes items designed and/or manufactured under a program complying with 10 CFR Part 50, Appendix B, and commercial grade items which

have been successfully dedicated to be used as basic components pursuant to the dedication process described in this part.

(2) When applied to other facilities and when applied to other activities licensed pursuant to parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter, means a component, structure, system, or part thereof that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect (see § 21.3(d)) or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard (see § 21.3(k)).

(3) In all cases, basic component includes safety related design, analysis, inspection, testing, fabrication, replacement 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 facilities and activities licensed pursuant to Part 50 of this chapter, means a structure, system, component, or part thereof that is not designed and/or manufactured as a basic component. A commercial grade item is not a basic component, or part of a basic component, until the dedication process has been completed.

(2) When applied to facilities and activities licensed pursuant to Parts 30, 40, 60, 61, 70, 71, or 72 of this chapter, 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 facilities and activities licensed pursuant to Part 50 of this chapter, 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 facilities and activities licensed to Part 50 of this chapter, is an inspection and acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety-related function and, in this respect, is equivalent to an item obtained through a 10 CFR Part 50, Appendix B quality assurance program. This assurance is achieved by a combination of commercial grade surveys, product inspections or witness/holdpoints at the manufacturer's facility supplemented as required by additional inspections or tests performed by the purchaser or a third-party dedicating entity after delivery. In all cases, the licensee using the dedicated item is responsible for ensuring that the dedication process includes the identification and verification of critical characteristics and is conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B of this chapter. The process is considered complete when the item is designated for use as a basic

component. Due to the complexity of their design and/or manufacturing process, certain items must be designed and manufactured as basic components since the dedication process cannot reasonably assure the successful performance of the safety function (i.e., one or more critical characteristic of the item cannot be verified). Items in this category include complex assemblies which generally have nuclear unique applications and where the design and/or manufacturing process requires many in-process inspections and verifications to assure that defects or failures to comply are identified and corrected. Specific examples include but are not limited to fuel and control rod assemblies and pressure vessels.

(2) When applied to facilities and activities licensed pursuant to Parts 30, 40, 60, 61, 70, 71, or 72 of this chapter, occurs after receipt when that item is designated for use as a basic component.

Dedicating entity. When applied to facilities and activities licensed pursuant to Part 50 of this chapter, means the organization that performs the dedication process to qualify a commercial grade item as a basic component. Dedication may be performed by either the manufacturer of the item, a third party dedicating entity, or the licensee itself. The dedicating entity pursuant to Section 21.21 (c) of this part, is responsible for evaluating deviations, reporting defects and failures to comply for the dedicated item and maintaining auditable records for the dedication process. NRC enforcement action can be taken for failure to evaluate deviations, failure to report defects or failure to comply, or failure to maintain auditable records.

* * * * *

3. In Section 21.6, the introductory text of paragraph (a) is revised to read as follows:

§ 21.6 Posting requirements.

(a) Each individual, partnership, corporation or other entity (including dedicating entities) subject to the regulations in this part, shall post current copies of the following documents in a conspicuous position on any premises, within the United States where the activities subject to this part are conducted (1) the regulations in this part, (2) section 206 of the energy Reorganization Act of 1974, and (3) procedures adopted pursuant to the regulations in this part.

* * * * *

4. In Section 21.21, the introductory text of paragraph (a) is revised, new paragraph (c) is added, and original paragraphs (c) and (d) become (d) and (e) respectively as follows:

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

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

* * * * *

(c) A dedicating entity is responsible for (1) assessing deviations, identifying 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. In Section 21.31, text of this paragraph is revised to read as follows:

§ 21.31 Procurement documents.

Each individual, corporation, partnership or other entity (including dedicating entities) subject to the regulations in this part shall assure 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 or other entity (including dedicating entities) subject to the regulations in this part shall permit the Commission to inspect its records, premises, activities, and basic components as necessary to accomplish the purposes of this part.

7. In Section 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, or other entity (including dedicating entities) 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, or other entity (including dedicating entities) subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the discovery 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.

Dated at Rockville, Maryland, this ____ day of _____, 1994.

For the Nuclear Regulatory Commission.

James M. Taylor,
Executive Director for Operations.

[Document Name: G:AU\PR21-9X9.PET]

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* See Previous Concurrence ←

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erection, installation, operation, maintenance, modification, or inspection of a basic component.

Dated at Rockville, Maryland, this ____ day of _____, 1994.

For the Nuclear Regulatory Commission.

James M. Taylor,
Executive Director for Operations.

[Document Name: G:AU\PR21-9X3.PET]

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Enclosure 2

Draft Regulatory Analysis

DRAFT REGULATORY ANALYSIS

Proposed Amendment to 10 CFR Part 21, "Reporting of Defects and Noncompliance"

1.0 INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend 10 CFR Part 21, "Reporting of Defects and Noncompliance" ("Part 21"), as it relates to the procurement of commercial grade items (CGIs) for safety-related use for 10 CFR Part 50 Licensees. The proposed rule expands the scope of CGIs, provides greater assurance that the dedication process is substantive and meaningful, and clarifies the reporting and evaluation requirements of the entities performing dedication. The staff believes this action is necessary due to the severe decline in the number of safety-related component manufacturers with a 10 CFR Part 50, Appendix B ("Appendix B"), quality assurance program.

This regulatory analysis of the proposed rulemaking was prepared according to the guidance in Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG/BR-0058 (Rev. 1), 1984. Section 1.0 includes background information, a statement of the problem to be addressed by the proposed rulemaking, and the objectives of the proposed rulemaking. Section 2.0 identifies and discusses reasonable alternatives for meeting the regulatory objectives. Section 3.0 contains a discussion of the projected values and impacts associated with alternatives. Section 4.0 contains the decision rationale.

1.1 BACKGROUND

During the development of the Energy Reorganization Act of 1974, Congress identified a need for an effective means to anticipate problems before they occurred. Section 206 of the Energy Reorganization Act (42 U.S.C. 5846) requires that the NRC be notified of defects and failures to comply affecting basic components used in nuclear facilities that could potentially

create a substantial safety hazard. Part 21 establishes the procedural guidance and requirements for implementing Section 206. Also, Part 21, in conjunction with Part 50, Appendix B, addresses the procurement of parts for nuclear power plants, including basic components and CGIs to be used in safety-related applications.

On October 14, 1993, the Commission published a notice of receipt of a petition for rulemaking (58 FR 53159) from the Nuclear Management and Resources Council (NUMARC), which is now incorporated into the Nuclear Energy Institute (NEI). The petitioner requested that the Commission amend its regulations contained in Part 21 to clarify and add flexibility regarding the procurement of CGIs for safety-related service by nuclear power plant licensees.

1.2 STATEMENT OF THE PROBLEM

Equipment in nuclear power plants continue to need replacement or refurbishment. Currently, Part 21 requirements allow nuclear utilities to procure a safety-related part as a basic component or CGI that will be appropriately dedicated for use as a basic component. Many original suppliers and manufacturers no longer maintain Appendix B qualified programs because of the diminishing demand for parts and the burden of maintaining such a quality assurance program. As a result, fewer items are available as basic components and must be procured as CGIs. The current definition of a CGI [Part 21.21.3(4)(a-1)] requires that all three of the following provisions be satisfied:

1. The CGI is not subject to design or specification requirements that are unique to nuclear facilities;
2. The CGI is used in applications other than nuclear facilities; and
3. The CGI is to be ordered from the manufacturer/supplier based on specifications set forth in the manufacturer's published product description.

This restrictive, three-pronged definition of a CGI may preclude a nuclear utility from obtaining appropriate parts in the most cost- and time-efficient manner. To the extent that the purchaser cannot obtain a needed item from the most qualified supplier and must turn to other less qualified suppliers, a nuclear licensee may experience unnecessary delays, expense, design changes, and associated detriments to safety.

1.3 OBJECTIVE OF THE PROPOSED RULEMAKING

The objective of the proposed rulemaking is to alleviate the current regulatory problems associated with procurement and dedication of CGIs on the part of power reactor licensees without decreasing the responsibility for discovering and evaluating deviations in addition to reporting defects and failures to comply.

To alleviate the problems, the petitioner proposes three changes to Part 21. These include a new definition of a CGI that would include any item obtained on the open market, clarifications on the dedication process, and clarification of the responsibility for reporting deficiencies in a CGI.

The staff has reviewed the changes proposed by the petitioner and supports their main objective. However, the staff believes the petitioner's definition of CGI may be too broad. The petitioner defines a commercial grade item as any item that has not been dedicated for use as a basic component. A commercial grade item would thus be subject to a dedication process, to determine its qualification as a basic component. The staff is proposing that, for 10 CFR Part 50 licensees, an item would qualify as a commercial grade item if it is not designed and/or manufactured as a basic component. This would effectively preclude inclusion of 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. The staff's proposed definition of "Commercial Grade Item," when applied to facilities and activities licensed pursuant to 10 Part 50 of this chapter, means a structure, system, component, or part thereof that is not designed and/or manufactured as a basic component. A commercial grade item is not a basic component, or part of a basic component, until the dedication process has been completed. Thus the staff believes that

commercial grade items should not encompass the full spectrum of items envisioned by the petitioner.

2.0 REASONABLE ALTERNATIVES FOR ACHIEVING THE REGULATORY OBJECTIVE

Most of the changes proposed by the petitioner and the staff are intended to clarify existing requirements and should not impact licensees. The only change that results in an impact is the redefinition of a CGI. The three alternatives presented below relate only to the CGI definitions.

Alternative 1 -- No change. Do not revise the current definition of a CGI and retain the three-pronged definition.

Alternative 2 -- Replace the current definition of a CGI with the definition proposed by NUMARC. This definition would include all items that are commercially available.

Alternative 3 -- Replace the current definition of a CGI with the definition proposed by the staff. When applied to facilities and activities licensed pursuant to Part 50 of this chapter, means a structure, system, component, or part thereof that is not designed and/or manufactured as a basic component. A commercial grade item is not a basic component, or part of a basic component, until the dedication process has been completed.

3.0 CONSEQUENCES

The safety and cost impacts of the three alternatives are discussed in the following sections.

3.1 Safety Impacts

The alternatives potentially affect two safety issues. The first issue relates to quality and the second issue relates to availability.

3.1.1 Quality

All safety-related items in nuclear power plants must meet the quality assurance standards set forth in Appendix B of Part 50. For certain items, the quality assurance is an integral part of the manufacturing process that cannot be verified after the fact. For this reason, the dedication process may not be adequate especially for one-of-a-kind, uniquely designed items without a performance history. The safety impact due to item quality is discussed below for each alternative.

Alternative 1. If no changes are made to Part 21, the quality of items should remain the same. However, this will result in very limited use of CGIs due to the restrictive definition.

Alternative 2. The dedication process may not be capable of verifying all items. Some items that successfully complete a dedication process may prove to be unreliable and cause failure rates to increase. Items that have quality verification as an integral part of the manufacturing process and little or no performance history are the most susceptible.

Alternative 3. Items that cannot be adequately verified during the dedication process are likely to be nuclear-unique equipment. Items used outside the nuclear industry normally have some performance history. However, excluding all equipment that have a nuclear-unique design or specification requirement may preclude items that could be verified during dedication.

Safety Risk Impact Due to Item Quality

Alternative 1	Alternative 2	Alternative 3
No Change	Small Risk Increase	No Change

3.1.2 Availability

As parts become more difficult to obtain, repairs may become delayed. Yet, these delays should not significantly affect plant safety because of administrative controls and limiting conditions for operation (LCOs). These controls and limiting conditions are intended to maintain plant safety. Safety risk normally increases only a small amount when an LCO is reached. The main impact from reaching an LCO is a shutdown of operations. The cost impacts due to shutdowns are discussed later in Section 3.2.2. The safety impact due to item availability is discussed below for each alternative.

Alternative 1. The availability of parts is already a problem for the nuclear industry. As the number of Appendix B qualified suppliers continues to decrease, the current procurement problems will escalate. This may cause more LCOs to be reached, slightly increasing safety risk, and result in unnecessary or prolonged downtime.

Alternative 2. This provides the best protection for ensuring item availability because of the broad definition proposed for a CGI. Improving item availability may prevent an LCO, thus decreasing safety risk.

Alternative 3. Similar to Alternative 2, the availability of items is improved because of the expanded definition proposed for a CGI. This is only true for safety-related items that do not have nuclear-unique specifications or requirements.

Safety Risk Impact Due to Item Availability

Alternative 1	Alternative 2	Alternative 3
Small Increase	Small Decrease	Small Decrease (Less than #2)

Based on the safety impact, the staff concludes Alternative 3 is the best. The staff believes that Alternative 3 will meet the needs of the industry without increasing the safety risk by introducing less quality parts. Alternative 3 is also preferred over Alternative 1 because increasing item availability should improve safety risk.

Overall Impact on Safety Risk

	Alternative 1	Alternative 2	Alternative 3
Quality	None	Small Increase	None
Availability	Small Increase	Small Decrease	Smaller Decrease
"Net Impact"	Small Increase	None	Smaller Decrease

3.2 Cost Impacts

An important objective of Alternatives 2 and 3 is to allow nuclear utilities to obtain appropriate parts in a more cost- and time-efficient manner. Increasing the availability of safety-related parts may reduce procurement cost and reduce the risk of unscheduled or extended downtime.

3.2.1 Procurement Cost

NUMARC's petition states that the procurement cost of a CGI in lieu of a basic component is significantly less. Many nuclear power reactor licensees have expressed this view in their public comments to the NUMARC petition. There is often a large cost differential because manufacturers of a CGI are not required to have the degree of quality control, inspections, tests, documentation, etc., that is required of a basic component. The procurement cost of a basic component is usually three to seven times greater than a CGI for an expensive component (e.g., over \$1 million) and up to 100 times greater

for a less expensive component.¹ When a CGI is purchased in lieu of a basic component and the item is determined to be safety-related, the CGI must be dedicated for use as a basic component. In theory, the cost required to dedicate a CGI can be more than the procurement cost differential. Some of the determining factors include the quantity of parts to be dedicated, the level of effort required to dedicate an individual component, the expertise available, and market demand for the component.

Alternatives 2 and 3 make additional items available for procurement as safety-related components. However, these additional items provide a cost savings to the industry only if their procurement and dedication are more economical. As licensees become increasingly more responsible and experienced in the dedication process, and as more competitive markets emerge because of the increased procurement options available to the nuclear utilities, the potential for cost savings will increase.

For the purpose of this regulatory analysis, the NRC assumes these costs are unaffected. Until more information becomes available, the potential cost savings for procuring and dedicating a CGI as opposed to procuring a basic component are assumed to be small.

3.2.2 Downtime

Item availability can affect the frequency and duration of shutdowns at nuclear power plants. Replacement energy cost estimates have been prepared for the NRC in Replacement Energy Costs for Nuclear Electricity-Generating Units in the United States: 1992-1996, NUREG/CR-4012, ANL-AA-30, Vol. 3, 1992. This report estimates the average daily cost for replacement energy for individual power reactors to range from \$20,000 to \$624,000, assuming nominal capacity factors of 62-65%. The wide variation reflects differences in reactor sizes and in the fuels and types of generating plants used to replace the lost nuclear generation.

It is difficult to accurately estimate the number of days a nuclear power plant will be shutdown due to reduced item availability. For example,

¹ Letter to Chairman Selin from Mr. John Brons, dated September 18, 1992. See Attachment 5 of NUMARC's petition for rulemaking PRM-21-2.

item availability varies with market supply and demand, reliability of components, future regulations, and new innovative designs. Today, the trend is toward decreasing item availability. Alternative 2 provides better item availability than Alternative 3, but Alternative 2 may use less quality components and cause additional shutdowns. The net number of shutdowns for Alternatives 2 and 3 is assumed to be similar. The average number of shutdown days prevented each year by selecting Alternative 2 or 3 over Alternative 1 (no action) is assumed to range from 0 to 2 per nuclear power plant. Assuming 112 nuclear power plants and an average cost of \$300,000 per day shutdown (NUREG/CR-4012), the estimated savings to the nuclear utility industry would range over the following:

Minimum = \$0 per year

Maximum = (112 power plants) * (2 days) * (\$300,000/day/power plant)
 = \$67 Million per year

To estimate the total cost savings over the remaining life, a 5% discount rate and a 23-year average remaining life are assumed. The present worth factor for 5% compound interest over 23 years is approximately 13.5. The maximum remaining life cost savings are calculated as follows:

Maximum life cost savings = \$67 Million * 13.5
 = \$900 Million

Cost Savings due to Shutdowns Days Avoided (Millions)

	Alternative 1	Alternative 2	Alternative 3
Annual	\$0	\$0 - \$67	\$0 - \$67
Life	\$0	\$0 - \$900	\$0 - \$900

3.3 NRC Costs

NRC costs for processing, tracking, and closeout activities of Part 21 are assumed to be unaffected in this regulatory analysis.

4.0 DECISION RATIONALE

The recommended action is to proceed with the NRC's proposed rule (Alternative 3). The key factors influencing the decision are discussed for each alternative.

Alternative 1. This alternative, no change, will cause item availability to continue shrinking, which may lead to a slight increase in safety risk. The unavailability of items may cost up to \$67 million per year in unscheduled or prolonged downtime.

Alternative 2. This alternative could result in less quality parts passing the dedication process, slightly increasing safety risk. This may be offset by the small decrease in safety risk from increasing item availability. Increasing item availability may prevent up to \$67 million in unscheduled or prolonged downtime. Alternative 2 would become the preferred alternative if the availability of items that are excluded in NRC's proposed definition (nuclear- unique equipment) became a serious problem.

Alternative 3. This alternative is preferred because item quality is not sacrificed and item availability is improved. Increasing item availability slightly decreases safety risk and may prevent up to \$67 million in unscheduled or prolonged downtime.

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Enclosure 3
Congressional Letters



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

The Honorable Philip R. Sharp, Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

In the near future, the Nuclear Regulatory Commission (NRC) intends to publish in the Federal Register the enclosed proposed amendment to the Commission's rules in 10 CFR Part 21. The NRC is proposing to amend its regulations to clarify and add flexibility to the process of procuring commercial grade items for safety-related service by nuclear power plant licensees. The proposed rule expands the scope of commercial grade items to encompass all items procured for use in safety-related service that are not designed and/or manufactured as basic components. This proposed rule is necessary to ensure that the procurement of commercial grade parts and their subsequent dedication is performed in a manner to avoid unnecessary delays and expense while maintaining an adequate level of plant safety. The proposed rule responds to a petition for rulemaking from the Nuclear Management and Resources Council (NUMARC), which is now incorporated into the Nuclear Energy Institute (NEI).

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Michael Bilirakis



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555-0001

The Honorable Joseph I. Lieberman, Chairman
Subcommittee on Clean Air and Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

In the near future, the Nuclear Regulatory Commission (NRC) intends to publish in the Federal Register the enclosed proposed amendment to the Commission's rules in 10 CFR Part 21. The NRC is proposing to amend its regulations to clarify and add flexibility to the process of procuring commercial grade items for safety-related service by nuclear power plant licensees. The proposed rule expands the scope of commercial grade items to encompass all items procured for use in safety-related service that are not designed and/or manufactured as basic components. This proposed rule is necessary to ensure that the procurement of commercial grade parts and their subsequent dedication is performed in a manner to avoid unnecessary delays and expense while maintaining an adequate level of plant safety. The proposed rule responds to a petition for rulemaking from the Nuclear Management and Resources Council (NUMARC), which is now incorporated into the Nuclear Energy Institute (NEI).

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Senator Alan K. Simpson



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

The Honorable Richard H. Lehman, Chairman
Subcommittee on Energy and Mineral Resources
Committee on Natural Resources
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

In the near future, the Nuclear Regulatory Commission (NRC) intends to publish in the Federal Register the enclosed proposed amendment to the Commission's rules in 10 CFR Part 21. The NRC is proposing to amend its regulations to clarify and add flexibility to the process of procuring commercial grade items for safety-related service by nuclear power plant licensees. The proposed rule expands the scope of commercial grade items to encompass all items procured for use in safety-related service that are not designed and/or manufactured as basic components. This proposed rule is necessary to ensure that the procurement of commercial grade parts and their subsequent dedication is performed in a manner to avoid unnecessary delays and expense while maintaining an adequate level of plant safety. The proposed rule responds to a petition for rulemaking from the Nuclear Management and Resources Council (NUMARC), which is now incorporated into the Nuclear Energy Institute (NEI).

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Representative Barbara Vucanovich

Enclosure 5

Federal Register Notice

Proposed Rule with comparative text

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: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations in 10 CFR Part 21 that would to clarify and add flexibility to the process ~~NRC regulations regarding~~ of procuring commercial grade items for safety-related service by nuclear power plant licensees. The proposed rule expands the scope of commercial grade items to encompass all items procured for use in safety-related service that are not designed and/or manufactured as basic components. This proposed rule is necessary to ensure that the procurement of commercial grade parts and their subsequent dedication ~~is~~ are performed in a manner that avoids unnecessary delay and expense while maintaining an adequate level of plant safety. The proposed rule responds to a petition for rulemaking from the Nuclear Management and Resources Council (NUMARC), which is now incorporated into the Nuclear Energy Institute (NEI).

DATES: Submit comments by (75 days after publication in the Federal Register). Comments received after this date will be considered if it is

practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. ATTN: Docketing and Service Branch.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. on Federal workdays.

Examine comments received, the environmental assessment and finding of no significant impact, and the regulatory analysis at: The NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

Obtain single copies of the environmental assessment and finding of no significant impact and the regulatory analysis from: M. L. Au, Office of Nuclear Regulatory Research, U. S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6181.

FOR FURTHER INFORMATION CONTACT: M. L. Au, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6181.

SUPPLEMENTARY INFORMATION:

Background

The Commission issued 10 CFR Part 21 on June 6, 1977 (42 FR 28893), to implement Section 206 of the Energy Reorganization Act of 1974. One of the purposes of Part 21 is to provide for the evaluation of deviations and

reporting of ~~deviations~~, defects, and failures to comply in safety-related parts and services for use in nuclear power plants. Part 21 is implemented in conjunction with 10 CFR Part 50, Appendix B, which contains the quality assurance criteria to be applied to design, fabrication, construction, and testing of safety-related structures, systems, and components in nuclear power plants.

On October 14, 1993 (58 FR 53159), the Commission published a notice of receipt of a petition for rulemaking (PRM-21-2) from the Nuclear Management and Resources Council (NUMARC), which is now incorporated into the Nuclear Energy Institute (NEI). The NUMARC petition was docketed by the NRC on June 22, 1993.

The petitioner requested that the Commission amend 10 CFR Part 21 to clarify and add flexibility ~~regarding the~~ to the process of ~~procurement~~ of commercial grade items for safety-related service by nuclear power plant licensees. Specifically, the petitioner requested that 10 CFR Part 21 be amended to

(1) Replace the existing definition of commercial grade item with a more ~~practical~~ 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 ~~deficiencies~~ ~~defects~~ and failures to comply as required by Part 21.

Basis for Petition

The petitioner contends that many of the original equipment manufacturers and suppliers no longer maintain programs that meet the requirements in 10 CFR Part 50, Appendix B, due to the high cost of maintaining and implementing these programs relative to the diminishing demand for plant parts. Thus, an increasing number of safety-related parts are being purchased from manufacturers and suppliers who no longer maintain quality assurance programs pursuant to 10 CFR Part 50, Appendix B. ~~Under these circumstances, the nuclear plant licensee is responsible for assuring the qualification of the part for safety related service. This transfer of responsibilities is permissible under Appendix B of Part 50. However, under Part 21, vendors are required to evaluate and report defects. These responsibilities are not transferable to purchaser.~~ Because, this is a relatively small market, **the petitioner states that** many vendors are unwilling to develop and maintain evaluation and notification procedures that meet Part 21 reporting requirements. With fewer vendors agreeing to comply with the requirements of Part 21 ~~regulation~~, **the petitioner claims that** it is becoming difficult for nuclear power plant licensees to procure an increasing number of items and services for safety-related applications.

Part 21 currently provides an exemption for a subclass of component called "commercial grade." These components are defined as ~~catalog~~ items that are

- (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 (for example, a catalog).

The petitioner believes that the provisions of Part 21 that relate to 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 believes 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 proposes the following three changes to 10 CFR Part 21:

First, the petitioner suggests that the NRC broaden the definition of "commercial grade item" in 10 CFR Part 21.3 to read as follows: "Commercial grade item means any item that has not been dedicated for use as a basic component." This definition essentially would effectively include any item obtained on the open market. The petitioner believes 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 suggests a more flexible generic definition of "dedication" in 10 CFR Part 21.3: "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 and/or 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 proposes that the dedicating entity maintain documentation of the dedication process for the purpose of an audit or inspection.

The petitioner believes that the benefits of establishing this process are that the utility 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) would be 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 the effect of its performance in a safety-related application.

Third, the petitioner suggests that the responsibility for reporting ~~deficiencies~~ defects and failures to comply for commercial grade items should reside with the entity responsible for performing the dedication process. The petitioner suggests that the following language be added to 10 CFR Part 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." The petitioner believes that it is appropriate to clarify that the responsibility for reporting ~~deficiencies~~ in defects and failures to comply for commercial grade items falls on the entity performing the dedication process because the suppliers and sub-tier suppliers do not necessarily know whether a commercial grade item is destined for a safety-related application.

Public Comments and Responses

The NRC received 23 letters in response to the publication of the notice of receipt of the petition. All but one letter supported the petition and called for a revision of the NRC's regulations consistent with the proposed amendments set forth in the petition.

Of the 22 letters that supported the petition, 17 supported the proposed amendments without any qualification. Fifteen of these letters were from nuclear utilities and two from nuclear vendors.

The five other supportive letters recommended minor changes to the specific language of the proposed amendments. With respect to the definition of dedication, one commenter recommended replacing "intended function" with "intended safety-related function." The intent here is to make it clear that a dedicating entity must focus on safety-related functions in determining whether an item will be suitable as a basic component. During the comment period, NUMARC indicated its support for this change. The NRC also concurs that this is an appropriate clarification. In addition, three commenters offered a clarifying second sentence that would establish the point in time that an item is considered dedicated. The sentence would indicate that, when dedication of a commercial grade item has been completed, the item may be used as a basic component. One of these commenters also recommended that the term "evaluation" be eliminated from the first sentence because the definition of "evaluation" is currently provided in 10 CFR Part 21.3 and has a different intent than its use here. The NRC supports inclusion of the additional sentence. The NRC also agrees with the commenter regarding removal of the

term "evaluation." This term will continue to be used only in conjunction with a substantial safety hazard determination.

Two commenters recommended changes to the notification requirement to prevent confusion regarding the application of Part 21 only to basic components. The NRC agrees with the substance of the comment to provide for the notification of defects and failures to comply only subsequent to successful dedication of the commercial grade item as a basic component. The proposed amendment has been revised accordingly.

One commenter expressed concern that a supplier's responsibility for procurement documentation is not clear. The commenter recommended that procurement documents specify that an item is commercial grade, that dedication would be performed by the purchaser, and that provisions of Part 21 would not apply to the supplier. The NRC believes 10 CFR Part 21.31 clearly states that only procurement documents for the purchase of basic components and dedication of commercial grade items need to require adherence to the provisions of Part 21.

The one letter in opposition to the petition was submitted by a private individual. This commenter believes that commercial grade dedication requires each utility to perform a comprehensive evaluation and to establish the appropriate engineering and quality requirements utilizing the provisions of Part 50, Appendix B. Further, this commenter also states that Part 21 should not be used as an instructional guide for the engineering analysis and procurement of items. The NRC believes that proposed revisions to Part 21 will reflect the current procurement situation faced by utilities while enhancing the requirement for ensuring proper qualification of commercial grade items used in safety-related applications.

Basis for Commission's Decision

The NRC has carefully reviewed the arguments presented by the petitioner and those that submitted public comments on the petition. The NRC is proposing to grant the petition in part with regard to 10 CFR Part 50 licensees by initiating this rulemaking. The proposed rule incorporates the petition in part, and modifies the petitioner's suggested language as indicated in the following discussion.

Commercial Grade item (CGI)

The NRC agrees in principle with the petitioner that the definition of a commercial grade item as it relates to 10 CFR Part 50 needs to be expanded to allow for a broader range of parts and services. In October 1978, when the NRC issued an immediately effective rule defining commercial grade item, it was for the purpose of exempting these items from the reporting requirements of 10 Part 21 until their dedication as basic components. ~~which~~ The NRC argued that this amendment was needed for safety reasons. Problems such as the inability to obtain needed supplies or to use the most qualified suppliers, and excessive delays in procurements were all cited as detriments to safety. The NRC believes that similar concerns are again present to some extent because the availability of basic components has declined and the current definition of commercial grade item is now unnecessarily prescriptive restrictive.

The petitioner ~~defines~~ proposes that a commercial grade item be defined as any item that has not been dedicated for use as a basic component. Thus,

any a commercial grade item ~~would~~ could thus be subject to a dedication process to assure its qualification as a basic component. The Commission maintains that not all safety-related items can be properly dedicated after the manufacturing process is completed. For certain items, quality assurance is an integral part of the manufacturing process and cannot be attested to after the fact. ~~Such items should be manufactured as basic components and would not require a dedication activity.~~ The NRC believes that if the complexity of the design and/or manufacturing process of an item is such that dedication cannot reasonably assure the absence of a defect which could affect one or more critical characteristics of the item, the item ~~should~~ must be designed and manufactured as a basic component. Items in this category include complex assemblies which generally have nuclear unique requirements and applications and where the design and/or manufacturing process requires many in-process inspections and verifications to assure that defects are identified and corrected. Specific examples include, but are not limited to, fuel and control rod assemblies, and pressure vessels, ~~heat exchangers,~~ ~~certain complex electrical items,~~ etc. Thus, the NRC believes that commercial grade items ~~should~~ 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 results in very limited use of the commercial grade item designation. The NRC is proposing that, for 10 CFR Part 50 licensees, an item would qualify as a commercial grade item if it is

not designed and/or manufactured as a basic component. This would effectively preclude inclusion of 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, 60, 61, 71, or 72 the existing definition is retained, although proposed revisions to 10 CFR Part 21 for non-reactor licensees are under development in a separate rulemaking.

The NRC's proposed definition of "Commercial Grade Item," when applied to facilities and activities licensed pursuant to 10 Part 50 of this chapter, means a structure, system, component, or part thereof that is not designed and/or manufactured as a basic component. A commercial grade item is not a basic component, or part of a basic component, until the dedication process has been completed.

Basic Component

Because the NRC is now proposing a definition of commercial grade item for 10 CFR Part 50 licensees in terms of the standards involved during its design and manufacture, it is also appropriate to define basic component in a similar manner. ~~terms to avoid any confusion between the two definitions.~~ The NRC therefore proposes to add the following to its definition of "basic component": ~~When applied to facilities and activities licensed pursuant to Part 50 of this chapter, is an item designed and/or manufactured under a program complying with Appendix B of Part 50 of this chapter or a Commercial grade item which has been successfully dedicated pursuant to this chapter. If the complexity of the design and/or manufacturing process of an item is such~~

~~that dedication can not reasonably assure the absence of a defect which could affect one or more critical characteristics of the item, the item shall be designed and manufactured as a basic component. Items in this category include complex assemblies which generally have nuclear unique applications and where the design and/or manufacturing process requires many in-process inspections and verifications to assure that defects are identified and corrected. Specific examples include fuel and control rod assemblies, pressure vessels.~~

"This definition includes items designed and/or manufactured under a program complying with 10 CFR Part 50, Appendix B, and commercial grade items which have been successfully dedicated to be used as basic components pursuant to the dedication process described in this part". Thus the definition reads as follows:

When applied to facilities and activities licensed pursuant to Part 50 of this chapter, means a plant structure, system, component or part thereof necessary to assure (i) the integrity of the reactor coolant pressure boundary, (ii) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (iii) 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. This definition includes items designed and/or manufactured under a program complying with 10 CFR Part 50, Appendix B, and commercial grade items which have been successfully dedicated to be used as basic components pursuant to the dedication process described in this part.

Dedication Process

Dedication is an inspection and acceptance process by which a commercial grade item is designated for use as a basic component. By expanding the scope of commercial grade items for 10 CFR Part 50 licensees, it is anticipated that an increasing number of safety-related items will be procured as commercial grade items as opposed to basic components. This should result in increased reliance on dedication by licensees or third-party dedicating entities in lieu of the quality assurance programs of manufacturers and suppliers. ~~The petitioner contends that this is appropriate because the licensee understands the safety significance of the proposed component better than the manufacturer.~~ Although such a transfer may be beneficial in some instances, the NRC needs greater assurances that 10 CFR Part 50 licensees or dedicating entities are performing meaningful and substantive dedication processes. In all cases, the licensee using the dedicated item is responsible for ensuring that the dedication process includes the identification and verification of critical characteristics and is to be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B of this chapter. As a result, the NRC believes that the rule needs to specify the key elements of such a dedication process. Specifically, the NRC maintains that this process must be performed in accordance with the applicable provisions of 10 CFR Part 50, Appendix B, and encompass inspections, tests, and/or analyses performed by the licensee or a third-party dedicating entity after delivery supplemented, as necessary, by a combination of commercial grade surveys, product inspections or witness/holdpoints. The four acceptance methods described in EPRI NP-5652, "Guidelines for the Utilization of Commercial-Grade Items in

Nuclear Safety-Related Applications (NCIG-07)," as conditionally endorsed by NRC Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs" may be utilized as guidance for the dedication of commercial grade items for safety-related applications. The critical characteristics are those design, material, and performance characteristics that, when verified, will provide reasonable assurance that the item will perform its intended safety-related function.

The NRC's proposed definition of the dedication process is as follows: Dedication, when applied to facilities and activities licensed pursuant to Part 50 of this chapter, is an inspection and acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety-related function. In this respect, it is equivalent to an item obtained through a 10 CFR Part 50, Appendix B quality assurance program. This assurance is achieved by combination of commercial grade surveys, product inspections or witness/holdpoints at the manufacturer's facility supplemented as required by additional inspections or tests performed by a purchaser or a third-party dedicating entity after delivery. In all cases, the licensee using the dedicated item is responsible for ensuring that the dedication process includes the identification and verification of critical characteristics and is conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B of this chapter. The process is considered complete when the item is designated for use as a basic component. Due to the complexity of their design and/or manufacturing process, certain items must be designed and manufactured as basic components since the dedication process cannot reasonably assure the successful performance of the safety function (i.e., one

or more critical characteristics of the item cannot be verified). Items in this category include complex assemblies which generally have nuclear unique applications and where the design and/or manufacturing process requires many in-process inspections and verifications to assure that defects or failures to comply are identified and corrected. Specific examples include but are not limited to fuel and control rod assemblies and pressure vessels.

The petitioner also requested that the entity performing the dedication process be responsible for Part 21 evaluation and reporting requirements. The NRC concurs with this recommendation as it will add needed flexibility in the procurement of replacement parts. Further, the NRC believes that the dedicating entity would be the most qualified party to assume the responsibility for Part 21 requirements because in many cases the commercial grade supplier does not know the end application or safety function of the item. The dedicating entity will generate the necessary quality records during the dedication process, and should have a full understanding of the items's safety function to enable that entity to perform the deviation evaluation and defect reporting functions required under Part 21. ~~The dedicating entity may be subject to NRC regulatory action for failure to evaluate deviations, failures to report defects or failures to comply, or failures to maintain auditable records. In addition, a deviation or defect is attributable to a flaw in the dedication process. The recipients of similar dedication using this process would need to be notified or included in the dedicating entity's notification to the Commission as currently required under the provisions of Part 50, Appendix B.~~

~~The NRC's proposed definition of the dedication process is as follows:~~
Dedication, when applied to facilities and activities licensed pursuant to

~~Part 50 of this chapter, is the process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function. Dedication may be performed by either the manufacturer of the item, a third party dedicating entity, or the licensee itself. The dedication process includes the identification and verification of critical characteristics and shall be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B of this chapter. The process is considered complete when the item is designated for use as a basic component. In all cases, the licensee using the dedicated item is responsible for ensuring that the applicable provisions of 10 CFR Part 50, Appendix B have been complied with and the item has been dedicated in compliance with the dedication requirement of this chapter. Responsibility for evaluating deviations and for reporting defects or failures to comply under this part begins with the dedicating entity at the time the dedication process is complete. The dedicating entity may be subject to NRC regulatory action for failure to evaluate deviations, failures to report defects or failures to comply, or failures to maintain auditable records.~~

The dedicating entity, i.e., either (1) the manufacturer, (2) third-party entity, distributing a commercial grade item which it has successfully dedicated or (3) licensee, which has successfully dedicated a commercial grade item for its own use, would be subject to NRC enforcement action for failure to evaluate deviations, failure to report defects or failures to comply, or failure to maintain auditable records. In addition, if the dedicating entity identifies a ~~deviation or~~ defect which previously was not identified and which is attributable to a flaw in the dedication process, any known recipients of similar dedicated items using this process must be notified or included in the

dedicating entity's notification to the Commission as currently required under the provisions of Part 50, Appendix B.

Critical Characteristics

The NRC definition of dedication process includes the term "critical characteristics." Given its import, the NRC believes it ~~too needs to~~ should be defined so as to identify those characteristics which need to be examined. As noted in the definition below, the characteristics to be examined are selected design, material and performance characteristics.

The NRC's proposed definition of "critical characteristics" is as follows: Critical characteristics, when applied to facilities and activities licensed pursuant to Part 50 of this chapter, 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.

Dedicating Entity

The NRC definition of the dedication process also includes the term "dedicating entity." Because the dedication process begins with the dedicating entity, the NRC believes that it is important to clearly identify the party responsible for the requirements associated with this process.

The NRC's proposed definition of "dedicating entity" is as follows: Dedicating entity, when applied to facilities and activities licensed pursuant to Part 50 of this chapter, means the organization that performs the

dedication process to qualify a commercial grade item as a basic component. Dedication may be performed by either the manufacturer of the item, a third party organization, or the licensee itself. The dedicating entity is responsible for evaluating deviations and reporting defects and failures to comply for the dedicated item and for maintaining auditable records for the dedication process. The dedicating entity may be subject to NRC regulatory enforcement for failure to evaluate deviations, failure to report defects or failures to comply, or failures to maintain auditable records.

Notification, Inspection, and Reporting Responsibilities

Section 21.21 (c)(1) and (2) have been added to clarify that the dedicating entity of a commercial grade item is responsible for identifying, evaluating, and reporting defects and failures to comply as required by Part 21, as well as maintaining auditable records of the dedication process.

Sections 21.21, 21.41, and 21.51 contain the NRC's requirements for notification, inspections, records, and maintenance and inspection of records, respectively. The NRC proposes, for clarification purposes, that these sections explicitly identify dedicating entities as being subject to the regulations in these sections. The phrase, "(including dedicating entities)" has been added to §§ 21.6(a), 21.21(a), 21.31, 21.41, and 21.51(a) and (b).

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed regulation is the type of action described in the categorical exclusion in 10 CFR Part 51.22(c)(3)(iii). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

Paperwork Reduction Act Statement

This proposed 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 draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the analysis may be obtained from M. L. Au, Office of Nuclear Regulatory Research, U. S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6181.

The Commission requests public comment on the draft analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

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 upon a substantial number of small entities. The proposed 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 Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121. In addition, the rule, if promulgated, would potentially 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. small entities.~~

Backfit Analysis

The Commission has determined that the backfit rule, 10 CFR Part 50.109, does not apply to this proposed rule. These amendments do not involve any provision that would impose additional requirements requiring a backfit analysis as defined in 10 CFR Part 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. 553, the NRC is proposing to adopt 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 (42 U.S.C. 2201, 2282); 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)

2. Section 21.3 is amended by removing the paragraph designations from each of the defined terms and arranging the definitions in alphabetical order; revising the terms Basic component, Commercial grade item, and Dedication, and adding the terms Critical characteristics, and Dedicating entity to read as follows:

§ 21.3 Definitions.

Basic component. ~~(1) When applied to facilities and activities licensed pursuant to Part 50 of this chapter, is an item designed and/or manufactured under a program complying with Appendix B of Part 50 of this chapter or a Commercial grade item which has been successfully dedicated pursuant to this~~

~~chapter. If the complexity of the design and/or manufacturing process of an item is such that dedication can not reasonably assure the absence of a defect which could affect one or more critical characteristics of the item, the item shall be designed and manufactured as a basic component. Items in this category include complex assemblies which generally have nuclear unique applications and where the design and/or manufacturing process requires many in-process inspections and verifications to assure that defects are identified and corrected. Specific examples include fuel and control rod assemblies, pressure vessels, heat exchangers, certain complex electrical items, etc.~~

(1) ~~(2)~~ When applied to facilities and activities licensed pursuant to Part 50 of this chapter, means a plant structure, system, component or part thereof necessary to assure (i) the integrity of the reactor coolant pressure boundary, (ii) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (iii) 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. This definition includes items designed and/or manufactured under a program complying with 10 CFR Part 50, Appendix B, and commercial grade items which have been successfully dedicated to be used as basic components pursuant to the dedication process described in this part.

(2) ~~(3)~~ When applied to other facilities and when applied to other activities licensed pursuant to parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter, means a component, structure, system, or part thereof that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect (see § 21.3(d)) or failure to comply with any applicable regulation in this chapter, order, or license

issued by the Commission could create a substantial safety hazard (see § 21.3(k)).

(3) ~~(4)~~ In all cases, basic component includes safety related design, analysis, inspection, testing, fabrication, replacement 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 facilities and activities licensed pursuant to Part 50 of this chapter, means a structure, system, component, or part thereof that is not designed and/or manufactured as a basic component. A commercial grade item is not a basic component, or part of a basic component, until the dedication process has been completed.

(2) When applied to facilities and activities licensed pursuant to Parts 30, 40, 60, 61, 70, 71, or 72 of this chapter, 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 facilities and activities licensed pursuant to Part 50 of this chapter, 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 facilities and activities licensed to Part 50 of this chapter, is an inspection and acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety-related function and, in this respect, is equivalent to an item obtained through a 10 CFR Part 50, Appendix B quality assurance program. This assurance is achieved by a combination of commercial grade surveys, product inspections or witness/holdpoints at the manufacturer's facility supplemented as required by additional inspections or tests performed by the purchaser or a third-party dedicating entity after delivery. In all cases, the licensee using the dedicated item is responsible for ensuring that the dedication process includes the identification and verification of critical characteristics and is conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B of this chapter. The process is considered complete when the item is designated for use as a basic component. Due to the complexity of their design and/or manufacturing process, certain items must be designed and manufactured as basic components since the dedication process cannot reasonably assure the successful performance of the safety function (i.e., one or more critical characteristic of the item cannot be verified). Items in this category include complex assemblies which generally have nuclear unique applications and where the design and/or manufacturing process requires many in-process inspections and verifications to assure that defects or failures to comply are

identified and corrected. Specific examples include but are not limited to fuel and control rod assemblies and pressure vessels.

(2) When applied to facilities and activities licensed pursuant to Parts 30, 40, 60, 61, 70, 71, or 72 of this chapter, occurs after receipt when that item is designated for use as a basic component.

Dedicating entity, when applied to facilities and activities licensed pursuant to Part 50 of this chapter, means the organization that performs the dedication process to qualify a commercial grade item as a basic component. Dedication may be performed by either the manufacturer of the item, a third party dedicating entity, or the licensee itself. The dedicating entity, pursuant to Section 21.21 (c) of this part, is responsible for evaluating deviations, reporting defects and failures to comply for the dedicated item and ~~for evaluating deviations and maintaining auditable records for the dedication process, and may be subject to~~ NRC regulatory enforcement action can be taken for failure to evaluate deviations, failure to report defects or failures to comply, or failures to maintain auditable records.

* * * * *

3. In Section 21.6, the introductory text of paragraph (a) is revised to read as follows:

§ 21.6 Posting requirements.

(a) Each individual, partnership, corporation or other entity (including dedicating entities) subject to the regulations in this part, shall post current copies of the following documents in a conspicuous position on any premises, within the United States where the activities subject to this part are conducted (1) the regulations in this part, (2) section 206 of the energy Reorganization Act of 1974, and (3) procedures adopted pursuant to the regulations in this part.

* * * * *

4. In Section 21.21, the introductory text of paragraph (a) is revised, added new paragraph (c), and original paragraphs (c) and (d) become (d) and (e) respectively as follows:

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

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

* * * * *

(c) A dedicating entity is responsible for (1) assessing deviations, identifying 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. In Section 21.31, text of this paragraph is revised to read as follows:

§ 21.31 Procurement documents.

Each individual, corporation, partnership or other entity (including dedicating entities) subject to the regulations in this part shall assure 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 or other entity (including dedicating entities) subject to the regulations in this part shall permit the Commission to inspect its records, premises, activities, and basic components as necessary to accomplish the purposes of this part.

7. In Section 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, or other entity (including dedicating entities) 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, or other entity (including dedicating entities) subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the discovery 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.

Dated at Rockville, Maryland, this ____ day of _____, 1994.

For the Nuclear Regulatory Commission.

James M. Taylor,
Executive Director for Operations.

[Document Name: G:AU\PR21-9X8.PET]

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