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NUCLEAR REGULATORY COMMISSION

10 CFR Part 21

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

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).

1/9/95

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

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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 10 CFR 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. 10 CFR 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 10 CFR 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 10 CFR Part 21 reporting requirements. With fewer vendors agreeing to comply with these requirements, 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.

10 CFR Part 21 currently provides an exemption for a subclass of components 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 discussions in 10 CFR 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 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 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 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 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 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 10 CFR 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.

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 10 CFR Part 21 would not apply to the supplier. The NRC believes 10 CFR 21.31 clearly states that only procurement documents for the purchase of basic components and commercial grade items which have been designated for use as basic components through the dedication process must adhere to the provisions of 10 CFR 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 10 CFR Part 50, Appendix B. Further, this commenter also states that 10 CFR 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 10 CFR 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 the public comments that were submitted 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 CFR 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.

10 CFR 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 CFR Part 50, 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. Therefore, the NRC proposes to add the following sentence 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."

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. 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. 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, and analysis of historical records for acceptable performance. 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 petitioner also requested that the entity performing the dedication process be responsible for 10 CFR 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 10 CFR 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 10 CFR 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 identify and evaluate deviations, failure to report defects and 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, Criterion XV.

Critical Characteristics.

The NRC definition of the dedication process includes the term "critical characteristics." Given its import, the NRC believes it should be defined so as to assure proper and complete identification of those characteristics which need to be examined. Therefore, a definition of the term "critical characteristics" has been added. As noted in the proposed definition, the characteristics to be examined are selected design, material and performance characteristics.

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 and its responsibilities for the requirements associated with this process. Therefore, the NRC is proposing a definition of "dedicating entity."

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 and evaluating deviations, and reporting defects and failures to comply as required by 10 CFR 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). In addition, minor editorial changes have been made in Section 21.51(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 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 on 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 10 CFR 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 quality assurance 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 10 CFR Parts 30, 40, 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) 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).

(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 10 CFR Part 50, means a structure, system, component, or part thereof that is not designed and 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 10 CFR Parts 30, 40, 60, 61, 70, 71, or 72, 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 10 CFR Part 50, 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 pursuant to 10 CFR Part 50, 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 designed and manufactured under 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, or analyses of acceptable historical performance 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. 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 10 CFR Parts 30, 40, 60, 61, 70, 71, or 72, 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 10 CFR Part 50, 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 identifying and 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 identify and evaluate deviations, failure to report defects and failures 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) identifying and evaluating deviations, and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and (2) maintaining auditable records for the dedication process.

* * * * *

5. 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 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 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-

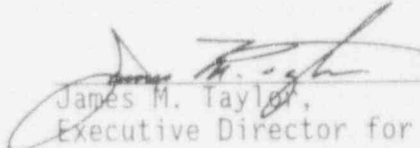
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(b) Each individual, corporation, partnership, or other entity (including dedicating entities) subject to the regulations in this part shall

permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

Dated at Rockville, Maryland, this 7th day of October, 1994.

For the Nuclear Regulatory Commission.


James M. Taylor,
Executive Director for Operations.