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RULE NAME: PROCUREMENT OF COMMERCIAL GRADE ITEMS BY NUCLEAR POWER PLANT LICENSEES

PROPOSED RULE FED REG CITE: 59FR53372

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PART AFFECTED: PR-021

RULE TITLE: PROCUREMENT OF COMMERCIAL GRADE ITEMS BY NUCLEAR POWER PLANT LICENSEES

PROPOSED RULE SECY PAPER:	PROPOSED RULE SRM DATE: / /	DATE PROPOSED RULE SIGNED BY SECRETARY: 10/07/94
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DOCKET NO. PR-021
(59FR53372)

In the Matter of

PROCUREMENT OF COMMERCIAL GRADE ITEMS BY NUCLEAR
POWER PLANT LICENSEES

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
10/17/94	10/07/94	FEDERAL REGISTER NOTICE - PROPOSED RULE
11/28/94	11/20/94	COMMENT OF MARVIN I. LEWIS (1)
12/28/94	12/23/94	COMMENT OF WISCONSIN ELECTRIC POWER CO (BOB LINK) (2)
01/09/95	01/04/95	COMMENT OF MICHAEL HARRINGTON (3)
01/09/95	01/06/95	COMMENT OF DUKE POWER CO (H.L. ATKINS) (4)
01/10/95	01/09/95	COMMENT OF DETROIT EDISON (LYNNE S. GOODMAN) (5)
01/10/95	01/09/95	COMMENT OF NUCLEAR ENERGY INSTITUTE (THOMAS E. TIPTON) (6)
01/10/95	01/09/95	COMMENT OF SHAW, PITTMAN, POTTS & TROWBRIDGE (JAY E. SILBERG) (7)
01/12/95	01/09/95	COMMENT OF TU ELECTRIC (C. LANCE TERRY, GROUP VICE PRES.) (8)
01/13/95	01/09/95	COMMENT OF SOUTH CAROLINA ELECTRIC & GAS CO (GARY J. TAYLOR) (9)
01/17/95	01/09/95	COMMENT OF BOSTON EDISON CO (E.T. BOULETTE, PH.D.) (10)
01/17/95	01/09/95	COMMENT OF FLORIDA POWER & LIGHT CO (W.H. BOHLKE) (11)
01/17/95	01/09/95	COMMENT OF PECO ENERGY CO (G.A. HUNGER, JR.) (12)
01/17/95	01/13/95	COMMENT OF ENTERGY OPERATIONS, INC (JERROLD G. DEWEASE) (13)
01/19/95	01/12/95	COMMENT OF VIRGINIA POWER (M.L. BOWLING) (14)
01/31/95	01/25/95	COMMENT OF WESTINGHOUSE ELECTRIC CORP (N.J. LIPARULO) (15)

DOCKET NO. PR-021 (59FR53372)

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
02/07/95	01/31/95	COMMENT OF CAROLINA POWER AND LIGHT CO (R.E. ROGAN) (16)
02/07/95	02/01/95	COMMENT OF SOUTHERN NUCLEAR OPERATING CO (D.N. MOREY) (17)
02/08/95	02/01/95	COMMENT OF GEORGIA POWER CO (C.K. MCCOY) (18)
02/13/95	02/07/95	COMMENT OF FLORIDA POWER CORP (L.C. KELLEY) (19)
04/18/95	04/17/95	LTR FM NUCLEAR ENERGY INSTITUTE (ROBERT W. BISHOP) SUPPLEMENTING NEI'S 1/9/95 COMMENTS (COMMENT #6)
09/15/95	09/08/95	FEDERAL REGISTER NOTICE - FINAL RULE

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 21

RIN 3150-AF01

Procurement of Commercial Grade Items by Nuclear Power Plant Licensees

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

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

EFFECTIVE DATE: October 19, 1995 ~~[30 days following publication in the Federal Register.]~~

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

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

SUPPLEMENTARY INFORMATION:

Background

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

unwilling to develop and maintain evaluation and notification procedures that meet the reporting requirements in 10 CFR Part 21. With fewer vendors agreeing to comply with these requirements, the petitioner claimed that it is becoming increasingly difficult for nuclear power plant licensees to procure items for safety-related applications.

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

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

Second, the petitioner suggested a more flexible generic definition of "dedication" in 10 CFR 21.3 to read as follows: "Dedication is the evaluation process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended function." According to the petitioner, dedication methods could include testing,

inspection, surveying the commercial grade supplier to determine that the appropriate quality control is in place, observing the manufacturing process, and analyzing the historical record of the item for acceptable performance. The petitioner also proposed that the dedicating entity maintain documentation of the dedication process for an audit or inspection.

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

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

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

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

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

Third, the petitioner suggested that the responsibility for reporting defects and failures to comply for commercial grade items that have been dedicated should reside with the entity responsible for performing the dedication process. The petitioner suggested that the following language be added to 10 CFR 21.21(b): "The entity that performs the dedication is responsible for identifying, evaluating and reporting the deviations and failures to comply associated with substantial safety hazards of a commercial grade item." Since the manufacturers, suppliers, and sub-tier suppliers of commercial grade items do not necessarily know whether the item is destined for a safety-related application, the petitioner believes it is appropriate to clarify that the responsibility for reporting defects and failures to comply

found in commercial grade items falls on the entity performing the dedication process.

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

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

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

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

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

Public Comment

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

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

unnecessary delay and expense to the licensee while maintaining an adequate level of plant safety.

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

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

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

requires either the wholesale acceptance or rejection of specific rulemaking proposals contained in a 10 CFR 2.802 petition.

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

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

Comment. The proposed definition of "Commercial Grade Items" appears to be unnecessarily restrictive and could give rise to interpretational difficulties that could limit or preclude options available to the licensee, rather than enhance the flexibility of licensees or utilities in dedicating commercial grade items for safety-related applications. The difficulty with

the proposed definition of commercial grade item is that it would force utilities to always purchase a product as nuclear grade if a manufacturer with an Appendix B to 10 CFR Part 50 quality assurance program exists, which would result in a monopoly or a "captive market."

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

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

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

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

Response. Proposed changes to Part 21 regulatory requirements for non-reactor licensees are currently being considered.

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

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

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

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

Comment. In the definition of term "dedication," the example of "pressure vessels" does not meet the specific nuclear-unique requirement since

pressure vessels are used widely outside the nuclear industry and should be considered a potential candidate for dedication.

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

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

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

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

Response. The NRC believes it is important to define and codify "critical characteristics" because this term represents a subject of importance in the dedication process for commercial grade items. The Commission is aware that in the Electric Power Research Institute's (EPRI) "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications," EPRI NP-5652, "critical characteristics" is defined

primarily in procurement terms, i.e., that the item received is the item specified as verified by part number. However, in the Commission's view, this is an appropriate term by which to convey the intent of this rulemaking that the dedication process specify those characteristics important to the design, material, and performance of an item so that the verification of those characteristics will provide reasonable assurance that the item will perform its intended safety function.

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

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

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

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

Basis for Commission's Decision

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

When Part 21 was first issued in 1977, the suppliers of all parts making up a basic component were subject to the reporting requirements under Part 21. However, recognizing that the Commission lacked experience in implementing a reporting program of this scope, the Commission also pointed out in the Statement of Considerations accompanying this part that it would examine closely the implementation of Part 21 as the Commission gained experience. Following the issuance of Part 21, the NRC received many requests for clarification of the regulations. The NRC examined the issue of how far down the procurement chain Part 21 should be applicable and on October 19, 1978 (43 FR 4862), amended Part 21 to exempt commercial grade items from the reporting requirements of Part 21 until the items were dedicated for use as a basic component. The NRC held that the October 1978 rule was needed for safety

reasons. Problems such as the inability to obtain needed parts and services were all cited as detriments to safety. The NRC was challenged on this amendment and the court of appeals upheld the Commission's interpretation of section 206 of the ERA requiring the Commission to "draw a line somewhere to demarcate the outer boundaries of the duty to report" (Natural Resources Council v. NRC, 666 F.2d 595 (D.C. Cir. 1981)).

Problems such as the inability to obtain parts and services from the most qualified suppliers and excessive delays in procurements were all cited as detriments to safety. With the development of increased confidence in licensee implementation of dedication activities through NRC inspection and experience, and because the availability of basic components has further declined, the NRC believes that the current definition of commercial grade items has become unnecessarily restrictive.

The petitioner proposed that a commercial grade item be defined as any item that has not been dedicated for use as a basic component. Thus, any commercial grade item could be subject to a dedication process to verify its qualification as a basic component. The Commission maintains that not all commercial grade items can be properly dedicated for safety-related use after the manufacturing process is completed. In fact several commenters agreed that there is a limited category of components for which quality assurance is an integral part of the manufacturing process and that their critical characteristics cannot be attested to after-the-fact. The Commission believes that if the design or manufacturing process of an item is such that dedication cannot reasonably assure the absence of a defect that could affect one or more critical characteristics of the item, the item must be designed and manufactured as a basic component in accordance with 10 CFR Part 50, Appendix

B requirements. There are components in this limited category that generally have requirements and applications in which the design and manufacturing processes require in-process inspections and verifications to ensure that defects and failures to comply are identified and corrected. Thus, the NRC believes that commercial grade items cannot encompass the full spectrum of items envisioned by the petitioner.

Part 21 currently defines a commercial grade item as an item that is (1) not subject to nuclear-unique design or specification requirements; (2) used in applications outside the nuclear industry; and (3) ordered on the basis of specifications set forth in the manufacturer's published product description. This set of conditions resulted in very limited use of the commercial grade item designation. To provide added flexibility in using commercial grade items for safety-related service by nuclear power plant licensees, the NRC is replacing the set of conditions and adopted a new definition for commercial grade item. Under this new definition, a "commercial grade item," when applied to nuclear power plants, means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. The definition makes clear that a commercial grade item that is part of a basic component but does not affect a safety-related function need not be dedicated and that item is not considered a basic component. Commercial grade items do not include items in which their design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified). Typical examples include, but are not limited to, fuel assemblies, control rod assemblies, and reactor coolant pressure boundary components.

Thus the definition of "commercial grade item" does not include items whose quality assurance is an integral part of the manufacturing process and whose acceptance is based primarily on the vendor's certification of compliance with specific design requirements. For facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, the existing definition is retained, although proposed revisions to Part 21 for application to these facilities and activities (including those certified under 10 CFR Part 76) are under consideration in a separate rulemaking.

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

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

Section 21.61 has been amended to clarify the scope of this section. NRC licensees and their employees subject to Part 21 are also subject to the normal enforcement process and sanctions. In addition, Section 206 of the Energy Reorganization Act of 1974, as amended, and implemented by 10 CFR Part

21, imposes an obligation on firms and organizations that are involved in the nuclear industry, and further, imposes these obligations as a direct liability on certain individuals in these firms and organizations. The "knowingly and consciously" standard specified in § 21.61 applies only to non-licensees.

Environmental Impact: Categorical Exclusion

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

Paperwork Reduction Act Statement

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

Regulatory Analysis

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

Regulatory Flexibility Certification

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

Backfit Analysis

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

List of Subjects in 10 CFR Part 21

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

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

PART 21 -- REPORTING OF DEFECTS AND NONCOMPLIANCE

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

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

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

§ 21.2 [Amended]

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

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

§ 21.3 Definitions.

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

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

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

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

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

(2) When applied to other facilities and when applied to other activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear

power plants), 60, 61, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

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

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

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

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

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

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

* * * * *

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

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

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

Dedicating entity. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

* * * * *

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

§ 21.6 Posting requirements.

(a)(1) Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of --

(i) The regulations in this part;

(ii) Section 206 of the Energy Reorganization Act of 1974; and

(iii) Procedures adopted pursuant to the regulations in this part.

(2) These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.

* * * * *

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

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

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

* * * * *

(c) A dedicating entity is responsible for --

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

(2) Maintaining auditable records for the dedication process.

* * * * *

5. Section 21.31 is revised to read as follows:

§ 21.31 Procurement documents.

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

6. Section 21.41 is revised to read as follows:

§ 21.41 Inspections.

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

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

§ 21.51 Maintenance and inspection of records.

(a) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall prepare and maintain records necessary to accomplish the purposes of this part, specifically --

* * * * *

(b) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

8. Section 21.61 is revised to read as follows:

§ 21.61 Failure to notify.

(a) Any director or responsible officer of an entity (including dedicating entity) that is not otherwise subject to the deliberate misconduct provisions of this chapter but is subject to the regulations in this part who knowingly and consciously fails to provide the notice required as by § 21.21 shall be subject to a civil penalty equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

(b) Any NRC licensee subject to the regulations in this part who fails to provide the notice required by § 21.21 or otherwise fails to comply with the applicable requirements of this part shall be subject to a civil penalty as provided by section 234 of the Atomic Energy Act of 1954, as amended.

(c) The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records

of the dedication process. NRC enforcement action can be taken for failure to identify and evaluate deviations, failure to report defects and failures to comply, or failure to maintain auditable records.

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

For the Nuclear Regulatory Commission.

James M. Taylor,
Executive Director for Operations.

NUCLEAR ENERGY INSTITUTE

Robert Willis Bishop
VICE PRESIDENT &
GENERAL COUNSEL

April 17, 1995

Mr. John Hoyle, Secretary
Office of the Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

SUBJECT: Proposed Rule, *Procurement of Commercial Grade Items by Nuclear Power Plant Licensees*, (59 Fed. Reg. 53372; October 24, 1994)

Dear Mr. Hoyle:

On behalf of the nuclear industry, the Nuclear Energy Institute (NEI)[1] hereby supplements its previous comments, dated January 9, 1995, on the NRC's proposed rule, *Procurement of Commercial Grade Items by Nuclear Power Plant Licensees*, (59 Fed. Reg. 53372; October 24, 1994).

The industry supports the NRC's efforts to amend 10 CFR Part 21 to address the current problems with procuring commercial grade items for safety-related use by nuclear plant licensees. However, we would like to bring to the Commission's attention the industry's concerns about certain provisions of the proposed rule and our recommended modifications to the proposed rule to address those concerns.

The industry's first concern relates to the definition of commercial grade item (CGI). By defining a CGI as "a structure, system or component, or part thereof *which is not designed and manufactured as a basic component*"(emphasis added), the NRC has unnecessarily restricted the items which may be obtained as CGIs and then dedicated. As was noted in the industry's petition for rulemaking filed June 21, 1993, one of the industry's objectives for requesting that the definition of CGI be modified is to address the fact that there are fewer manufacturers which produce Appendix B-qualified safety related parts. However, another objective is to permit licensees to obtain an item of suitable quality as a commercial grade item at a significantly lower cost. Unfortunately, the definition of CGI in the proposed rule

[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

ecg\general\21recmts

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would preclude a licensee from obtaining an item available on the open market at a significantly reduced cost solely because another vendor designed or manufactured the item as a basic component. The industry recommends that the NRC revise the definition of commercial grade item by deleting the reference to items "designed and manufactured as a basic component." Instead, the NRC should define commercial grade items as items which are not "basic components;" they will only become basic components once the dedication process is complete.

While the industry believes it clearly is appropriate to be able to obtain items as commercial grade based upon their cost and then dedicate them, we do not advocate permitting such a process to be applied to all items used in a nuclear power plant. We believe that the rule should be modified both to address our concern about the restrictiveness of the proposed definition of commercial grade item and to ensure that some types of items that simply are inappropriate for dedication are not encompassed by the rule. To address the NRC's concern that the dedication process may not assure the performance of the safety function of certain types of items, we recommend that the definition of commercial grade item identify the categories of items which the industry agrees should be, *per se*, excluded. The NRC already has set out a description of the categories of items which should be excluded in the definition of "Dedication." This description simply should be moved to the definition of "Commercial grade item." Our recommended revision to Section 21.3, "Commercial grade item" is as follows:

> *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 does not qualify as a basic component under Section 21.3. For the purpose of this definition, a commercial grade item does not include items with complex assemblies which generally have nuclear unique applications and where the design and manufacturing process requires many in-process inspections and verifications to assure that defects or failures to comply are corrected. Specific examples include, but are not limited to fuel and control rod assemblies and primary system pressure vessels.** (modified text in bold type.)

Our final concern is that the NRC's statement of what is necessary for the dedication process in the Statement of Considerations differs from that which is contained in the definition of "Dedication" in the rule. The result is an apparently inadvertent, but nonetheless substantial, change in the requirements for the commercial grade item dedication process. The rule would require that the

dedication process be conducted in accordance with the applicable provisions of 10 CFR 50, Appendix B, and "include commercial grade surveys, product inspections or witness/holdpoints, and analysis of historical record for acceptable performance supplemented, as necessary, by inspections tests, and/or analyses performed by the licensee or a third party dedicating entity after delivery." By contrast, the Statement of Considerations more appropriately would allow the dedicating entity greater flexibility by requiring that the process 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, but permit the dedicating entity to supplement the dedication process, as necessary, by a combination of commercial grade surveys, product inspections or witness/holdpoints.

The approach set out in the Statement of Considerations appears to be that which was intended for the rule itself. And consistent with the industry's significant experience and expertise with dedicating commercial grade items, the Statement of Considerations approach permits licensees to determine the actions and resources necessary to adequately dedicate a particular commercial grade item. It would be counterproductive for the rule rigidly to require that specific actions be taken for each dedication because, as has been demonstrated through the industry's procurement initiative, the dedication process should be tailored to the item undergoing dedication. Otherwise, through prescriptive rule language the licensee may be forced to expend unnecessary resources on the dedication process without any increased safety benefit.

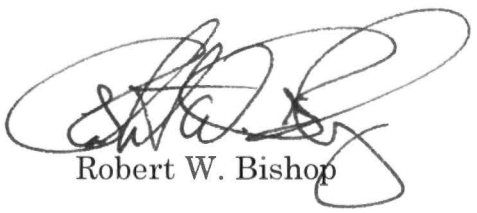
The problem can be easily remedied by inserting into the definition of "Dedication" the same language as is contained in the Statement of Considerations (59 Fed. Reg. 53372, 53374.) Our recommended revision to the second sentence of "Dedication," as defined in Section 21.3 is as follows:

> This assurance is achieved by **a dedication process which is performed in accordance with the applicable provisions of 10 CFR 50, Appendix B, and encompasses 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 record for acceptable performance**. (modified text in bold type.)

We appreciate your consideration of these additional comments on the draft rule and would like to meet with NRC staff to discuss these and our earlier comments.

If you have any questions regarding our views, please do not hesitate to contact Ellen Ginsberg, NEI Assistant General Counsel, at 202-739-8140, or me.

Sincerely,



Robert W. Bishop

RWB/ECG/bjb
c: Mr. Martin Malsch (Office of General Counsel)

Florida Power
CORPORATION

February 7, 1995
NL95 0006

Mr. John C. Hoyle
Acting Secretary
Office of the Secretary
U.S. Nuclear Regulatory Commission
Washington, CD 20555

Attention: Docketing and Service Branch

Subject: Proposed Rulemaking to 10CFR21
59 Federal Register 53372

Florida Power Corporation (FPC) has reviewed the subject proposed rulemaking issued for public comment in the October 24, 1994 Federal Register. We are aware also that your office has been forwarded a letter dated January 9, 1995 from Mr. Thomas Tipton of the Nuclear Energy Institute (NEI), containing an industry response to the proposed rulemaking. The following comments are additional comments submitted by Florida Power Corporation for your consideration.

With minor exceptions, FPC agrees with most of the comments expressed in the above referenced letter from Mr. Tipton relative to differences between the June, 1993 NUMARC petition for rulemaking and NRC's proposed rulemaking. Some NEI comments indicate they have concerns with the potential impact of codifying "critical characteristics" and "dedication". FPC has less concern to the codification of these terms since NRC appears to have adopted the terms consistent with the NUMARC Comprehensive Procurement Initiative (NUMARC 90-01). Although we would have preferred the definition of critical characteristics to be the same as that contained in EPRI NP-5652, it should be pointed out that on page 19 of the proposed rulemaking, the actual definition does incorporate the term "reasonable assurance" with respect to the selection and verification of critical characteristics. With regard to "dedication", we do not object to the term's codification, but to the attempt by NRC to equate a dedicated item with one designed and manufactured under a 10CFR50 Appendix B QA program. Perhaps the rule should state that a reasonably dedicated item will perform its intended safety function in a manner equivalent to an item purchased as a basic component.

The section of the proposed rulemaking titled "Basis for Commission's Decision" requires clarification in several areas as follows:

1. On page 11, NRC states it needs greater assurance that 10CFR Part 50 licensees or dedicating entities are performing meaningful and substantive dedication processes. This statement is inconsistent with the statements made subsequent to finalization of NRC Inspection Module 38703 which indicated NRC planned to utilize the module for performance-based inspections based on CGI's which have failed in service. This "position" resulted from the conclusion of the Pilot Program for Procurement Inspections. FPC questions the basis for NRC's need for greater assurance in view of the fact that utilities have implemented the NUMARC Comprehensive Procurement Initiative and are now responsible for assessing its effectiveness as part of their internal assessment programs.

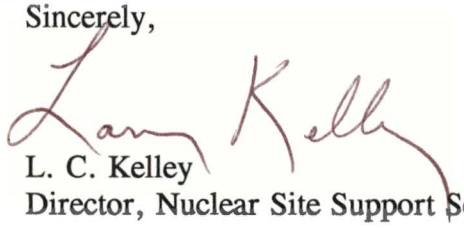
2. FPC understands the reasons why NRC chose to reference Generic Letter 91-05 (Page 12) in its basis for decision regarding the four methods of acceptance described in EPRI NP-5652. However, FPC wishes to point out once again, that the guidance contained in Generic Letter 91-05 goes beyond that described in industry initiatives for dedication.

3. NRC should clarify their intent with regard to the responsibility of a dedicating entity as described on Page 13. FPC understands how a manufacturer or a third party dedicating entity would be able to identify other users of items they sell. However, for a defect identified by a Part 50 licensee, FPC is unsure how a utility would "know" of a recipient of similar dedicated items. We are encouraged to utilize the INPO Network system for exchange of parts and material and QA information, but to what extent is NRC expecting to focus on the notifying utility for purpose of identifying other users of the item? Does NRC assume any obligation to notify the supplier of reviews subject to 10CFR21?

4. In several areas, NRC refers to 10 CFR Part 50 licensees. Since the changes made to 10CFR21 are clearly intended to apply to more than operating utilities, this reference should be clarified as subject to the general provisions of 10CFR21 which encompasses any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954 or the Energy Reorganization Act of 1974.

We appreciate the opportunity to provide our comments. Please contact Ken Wilson (904-563-4549) if you have any questions regarding these comments, or if you require additional information.

Sincerely,



L. C. Kelley
Director, Nuclear Site Support Services

TWC

cc: P.M. Beard
W.C. Conklin

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(18)

C. K. McCoy
Vice President, Nuclear
Vogtle Project

Georgia Power
the southern electric system

February 1, 1995

Docket Nos. 50-321 50-424 HL-4774
50-366 50-425 LCV-0556

John C. Hoyle, Acting Secretary
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Comments on
Procurement of Commercial Grade Items by Nuclear Power Plant Licensees
(59 Federal Register 53372 of October 24, 1994)

Dear Sir:

Georgia Power Company has reviewed the proposed rule, "Procurement of Commercial Grade Items by Nuclear Power Plant Licensees," published in the Federal Register on October 24, 1994. In accordance with the request for comments, Georgia Power Company is in total agreement with the NEI comments that are to be provided to the NRC. Additionally, Georgia Power would like to offer the following comment: The NRC indicates that the new definitions of Basic Component, Commercial Grade Item, Critical Characteristic, Dedication and Dedicating Entity would apply only to Part 50 licensees while the current definitions of the Basic Component, Commercial Grade Item and Dedication would continue to be applicable to Part 30, 40, 60, 61, 71 and 72 licensees. Furthermore, the definitions of Critical Characteristics and Dedicating Entity would not be applicable to licensees except those under Part 50. It will be confusing and costly for nuclear plant operators to procure and dedicate equipment under different regulatory requirements due to the fact that many Part 50 licensees have additional licenses. The current wording of the regulations indicate that a Part 50 licensee that holds additional licenses would be working under differing definitions. The evaluation and reporting of potential defects would also be more difficult. It is recommended that the new definitions be applicable and consistent to licensees who hold other licenses as well as a Part 50 license.

Should you have any questions, please advise.

Respectfully submitted,

CKM'G

C. K. McCoy

CKM/JMG

cc: Georgia Power Company
Mr. J. T. Beckham, Jr., Vice President, Plant Hatch
Mr. J. B. Beasley, General Manager - Plant Vogtle
Mr. H. L. Sumner, Jr., General Manager - Plant Hatch

U. S. Nuclear Regulatory Commission, Washington, DC
Mr. K. N. Jabbour, Licensing Project Manager - Hatch
Mr. D. S. Hood, Licensing Project Manager - Vogtle

U. S. Nuclear Regulatory Commission, Region II
Mr. S. D. Ebneter, Regional Administrator
Mr. B. L. Holbrook, Senior Resident Inspector - Hatch
Mr. B. R. Bonser, Senior Resident Inspector - Vogtle

HL-4774
LCV-0556
File G.02.07

Southern Nuclear Operating Company
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17

Southern Nuclear Operating Company
the southern electric system

Dave Morey
Vice President
Farley Project

February 1, 1995

Docket Nos. 50-348
50-364

John C. Hoyle, Acting Secretary
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Comments on
Procurement of Commercial Grade Items by Nuclear Power Plant Licensees
(59 Federal Register 53372 of October 24, 1994)

Dear Sir:

Southern Nuclear Operating Company has reviewed the proposed rule, "Procurement of Commercial Grade Items by Nuclear Power Plant Licensees," published in the Federal Register on October 24, 1994. In accordance with the request for comments, Southern Nuclear is in total agreement with the NEI comments that are to be provided to the NRC. Additionally, Southern Nuclear would like to offer the following comment: The NRC indicates that the new definitions of Basic Component, Commercial Grade Item, Critical Characteristic, Dedication and Dedicating Entity would apply only to Part 50 licensees while the current definitions of the Basic Component, Commercial Grade Item and Dedication would continue to be applicable to Part 30, 40, 60, 61, 71 and 72 licensees. Furthermore, the definitions of Critical Characteristics and Dedicating Entity would not be applicable to licensees except those under Part 50. It will be confusing and costly for nuclear plant operators to procure and dedicate equipment under different regulatory requirements due to the fact that many Part 50 licensees have additional licenses. The current wording of the regulations indicate that a Part 50 licensee that holds additional licenses would be working under differing definitions. The evaluation and reporting of potential defects would also be more difficult. It is recommended that the new definitions be applicable and consistent to licensees who hold other licenses as well as a Part 50 license.

Should you have any questions, please advise.

Respectfully submitted,

D. N. Morey

DNM/JMG

U.S. NUCLEAR REGULATORY COMMISSION
DOCKETING & SERVICE SECTION
OFFICE OF THE SECRETARY
OF THE COMMISSION

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cc: Southern Nuclear Operating Company
Mr. R. D. Hill, Plant Manager

U. S. Nuclear Regulatory Commission, Washington, DC
Mr. B. L. Siegel, Licensing Project Manager

U. S. Nuclear Regulatory Commission, Region II
Mr. S. D. Ebneter, Regional Administrator
Mr. T. M. Ross, Senior Resident Inspector

(16)

CP&L

Carolina Power & Light Company
PO Box 1551
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January 31, 1995

FILE: X-X-1075

NL&RAS-95-002

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Subject: Comments on Proposed Rule - Procurement of Commercial Grade Items by Nuclear Power Plant Licensees (59 FR 53372, October 24, 1994)

Dear Sir:

These comments are submitted on behalf of the Carolina Power & Light Company (CP&L) and support the Nuclear Energy Institute (NEI) response to the NRC concerning the proposed rule - Procurement of Commercial Grade Items by Nuclear Power Plant Licensees (59 FR 53372, October 24, 1994).

CP&L endorses NEI's comments on the proposed rule. In order to operate its plants safely, reliably, and efficiently CP&L must be able to obtain quality replacement items in spite of the diminishing number of Appendix B manufacturers. Therefore, we fully support NEI in its efforts to promulgate a rule that allows licensees increased flexibility to obtain quality replacement parts which provide reasonable assurance that they will perform their intended safety functions.

Sincerely,

R. E. Rogan
Manager, Nuclear Licensing and
Regulatory Affairs

FAE/alr

cc: Mr. H. W. Habermeyer, Jr.
Mr. L. E. Jones
Mr. W. H. Rasin (NEI)
Mr. J. Presley
Ms. S. Flynn
Mr. K. Jury
Mr. L. Rowell

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NTD-NRC-95-4394

Westinghouse
Electric Corporation

Energy Systems

Nuclear Technology Division

Box 355
Pittsburgh Pennsylvania 15230-0355

January 25, 1995

Mr. John C. Hoyle
Acting Secretary
Office of the Secretary
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch

Subject: Procurement of Commercial Grade Items by Nuclear Power Plant Licensees
Proposed Rule; Request for Public Comment (59 F. R. 53372, Oct. 24, 1994)

Dear Mr. Hoyle:

Westinghouse Electric Corporation ("Westinghouse") files these comments in response to the Proposed Rule; Request for Public Comment ("Proposed Rule") of the U. S. Nuclear Regulatory Commission ("Commission" or "NRC") with regard to the "Procurement of Commercial Grade Items by Nuclear Power Plant Licensees". In the Proposed Rule, the NRC requests public comment on its proposed revision to 10 CFR Part 21, including its proposed expansion of the definition of "commercial grade item," 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 responds to a Petition for Rulemaking submitted to the NRC on June 22, 1993 by the Nuclear Management and Resources Council ("NUMARC"), which is now incorporated into the Nuclear Energy Institute ("NEI"). Westinghouse submitted comments fully endorsing NUMARC's petition by letter dated December 28, 1993 (ET-NRC-93-4033). Westinghouse continues to support those comments and the need to amend Part 21 to remove restrictions on the definition of "commercial grade item" currently contained therein and to provide for a flexible dedication process to qualify commercial grade items for safety-related use in a manner that would not result in a degradation of safety. As a result, Westinghouse agrees with the Commission's adoption of much of NUMARC's original proposals in the Proposed Rule, including the additional changes and modifications proposed by other commenters that supported the NUMARC petition and which the Commission has included in the Proposed Rule.

While the Proposed Rule addresses some of the problems identified in the NUMARC petition and incorporates some of the proposed changes to Part 21 to address those problems, it does not include all of the changes NUMARC originally proposed and also contemplates the codification of certain new requirements for the Part 21 dedication process. Comments on these aspects of the Proposed Rule have been filed by NEI on behalf of the commercial nuclear power industry; and Westinghouse fully supports those NEI comments. In addition, the purpose of the following comments is to reflect Westinghouse's position on those specific areas of the Proposed Rule that vary from the original NUMARC petition and which Westinghouse, in its position as a major vendor of equipment, parts

and services to the nuclear industry, finds fundamentally problematic and in need of further consideration by the Commission.

Definition of "Commercial Grade Item"

In addition to replacing the constraints contained in the existing definition of "commercial grade item" in Part 21 as requested by the NUMARC petition, the Proposed Rule seeks to add a new restriction in the definition that an item could not be designated as a commercial grade item if it is designed and/or manufactured as a "basic component" (as defined in proposed Part 21, section 21.3). The NRC's rationale is that such a restriction is necessary to preclude the commercial dedication of items requiring nuclear-unique or specific manufacturing processes, such as [reactor] pressure vessels, and fuel or control rod assemblies.

As a major vendor of safety-related basic components, including commercial nuclear fuel assemblies, Westinghouse agrees that these types of items, due to their unique nuclear applications, should and will continue to be designed, manufactured and procured as basic components in the future. This would likely be the case even under the flexible change in the commercial grade item definition originally proposed by NUMARC, i.e., to any item that is not procured for use as a basic component, which Westinghouse continues to endorse. Westinghouse remains committed to ensuring that equipment of this nature continues to be readily available for use by 10 CFR Part 50 licensees in their operating nuclear plants. To this end, Westinghouse and its major sub-vendors and suppliers will continue to maintain programs and procedures under Part 21 and 10 CFR Part 50, Appendix B to supply this type of equipment as basic components.

Westinghouse believes, however, that the additional restriction the NRC proposes to add to the commercial grade item definition is overly restrictive and detracts from the needed flexibility in any dedication process. Today, many replacement items originally designed or manufactured as basic components are suitable for commercial dedication. This includes items originally manufactured by Westinghouse as basic components, such as electrical and instrumentation systems. Despite this fact, one possible interpretation of the restriction in the definition of commercial grade item proposed by the NRC could be to prohibit the dedication of any replacement item that, in the past, had been produced and supplied by a manufacturer under a 10 CFR Part 50, Appendix B program. Like its utility customers, Westinghouse is often finding it increasingly difficult to procure quality replacement components from certain of its preferred sub-vendors and suppliers who have ceased operating under Appendix B programs. These entities, however, in many instances are still willing to supply replacement components as commercial grade items for Westinghouse to dedicate for ultimate sale to its Part 50 licensee customers.

In support of the proposed restriction, the Proposed Rule states that quality assurance requirements that can not be attested to after-the-fact are so integral to the manufacturing and/or design process of certain commercial grade items that dedication is not a feasible alternative. Even were this category of items large (which Westinghouse does not believe to be the case), the dedication process addressed in the EPRI guidance document, "Guidelines for the Utilization of Commercial-Grade Items in Nuclear Safety Related Applications" (NP-5652), as endorsed in Commission guidelines (NRC Generic Letter 91-05) and adopted by the NRC in the Proposed Rule as an acceptable means of dedication, clearly includes acceptable dedication methods, such as surveys and source verifications and inspections, that would allow for a dedicating entity to observe a suppliers' manufacturing process and quality controls. Thus, appropriate dedication methods clearly do exist even for the category of commercial grade item for which the NRC is concerned. Westinghouse, through its Nuclear Services Division ("WNSD"), has actually adopted a flexible commercial dedication program (WCAP 12885, Rev. 0, March 28, 1991) that includes these dedication methods to provide assurance that even a dedicated commercial grade item for which quality assurance is an integral part of the manufacturing

and/or design process will meet the technical and quality requirements of its intended safety-related application in a manner that maintains overall plant safety. Westinghouse's increased use of its WNSD commercial dedication program has occurred without any evidence of a reduction in procurement quality or the operating safety of its customers' plants.

For the above reasons, Westinghouse believes that the Commission should reconsider any further restrictions on the definition of commercial grade item as contained in the Proposed Rule. At the most, if the Commission believes it needs to specifically exclude a category of nuclear-unique items that should not qualify as a dedicated commercial grade item, it should exclude those items by name from the revised definition. Even if the Commission incorporates its proposed definition of commercial grade item into revised Part 21, the regulation should provide a dedicating entity with discretion to determine whether or not a commercial item has manufactured or quality characteristics that make it unsuitable for dedication under the dedicator's established program.

The Dedication Process

The Proposed Rule indicates that the NRC desires greater assurance that 10 CFR licensees and other dedicating entities, such as Westinghouse, are performing meaningful and substantive dedication processes. It indicates that EPRI NP-5652 and NRC Generic Letter 91-05 may be utilized as guidance to such entities for the dedication of commercial grade items for safety-related applications. As previously noted, Westinghouse, through WNSD's commercial dedication program, has patterned its dedication approach on these guidance documents. The Westinghouse dedication program is designed to provide objective evidence and reasonable assurance that items purchased by Westinghouse and dedicated for ultimate safety-related use conform to key procurement requirements and Appendix B criteria (including Criterion VII, "Control of Purchased Material Equipment and Services"), and will be suitable for their intended function. WNSD's program has been reviewed by many of Westinghouse's utility customers, the Nuclear Utility Procurement Issues Committee ("NUPIC") and the NRC and has been found to be acceptable. Westinghouse agrees that the time is now appropriate for the Commission to acknowledge these existing and accepted industry dedication programs, including its own WNSD program, as part of the revision to Part 21 to codify commercial grade item dedication.

As noted by NEI in its comments to the Proposed Rule, however, the NRC's proposed definition of "dedication" in revised section 21.3 states that a dedication process must involve "commercial grade surveys, product inspections... supplemented as required by additional inspections or tests, or analyses of acceptable historical performance...." This is in conflict with the above-noted dedication guidance documents which provide that any combination of the identified dedication methods may be used. Westinghouse urges the Commission to remain true to the documents it acknowledges provide appropriate guidance for the dedication process and incorporate this guidance, which already has obtained review and acceptance in the industry, unchanged into its definition of "dedication" in revised section 21.3 and the revised dedication process under amended Part 21.

Critical Characteristics

Similarly, the definition of "critical characteristics" contained in the Proposed Rule, if necessary to be codified at all, should follow the definition of this concept as contained in the above-noted guidance documents. Those documents acknowledge that, given a specific commercial grade item and its performance, a variety of characteristics can be identified as being critical, but the focus for dedication purposes should remain on those critical characteristics that are "important" and that, once verified, will provide "reasonable assurance" that the item will perform its intended safety function. As noted in its comments on NUMARC's original petition, Westinghouse continues to have the required detailed knowledge of the safety function, design and manufacturing characteristics and

ultimate application of nuclear replacement equipment, parts and services to identify those important critical characteristics necessary to properly dedicate commercial grade items for safety-related, basic component use. Based on its experience and knowledge, Westinghouse should therefore be provided with sufficient flexibility in any revision to Part 21 to select those important critical characteristics from the list of all potential characteristics for the item being dedicated to reasonably assure its intended safety-related function and application.

Applicability to 10 CFR Part 50 Licensees Only

Finally, the Proposed Rule indicates that the revised definition of a "commercial grade item" and the other proposed changes to Part 21 will apply to procurement activities of or on behalf of 10 CFR Part 50 licensees only. The Proposed Rule also indicates that proposed revisions to Part 21 for non-reactor licensees are under development in a separate rulemaking. As a major vendor of commercial nuclear fuel, Westinghouse believes that the Part 21 revisions contained in the Proposed Rule, as modified by the above comments, would be equally beneficial for other NRC licensees. Westinghouse therefore urges the Commission to extend its instant proposal to all categories of licensees or to issue substantially similar proposed rules to cover commercial dedication methods by such licensees as soon as possible.

Westinghouse appreciates the opportunity to submit the foregoing comments and respectfully requests that the Commission consider these comments as it finalizes a clear and practical regulation that provides the utmost flexibility for knowledgeable licensees and nuclear vendors to effectively utilize commercial dedication processes to assure the continued supply of quality equipment, parts and services for safety-related application in nuclear power plants. Westinghouse would be pleased to discuss these comments further with the Commission and members of the NRC staff.

Very truly yours,

N. J. Liparulo, Manager
Nuclear Safety Regulatory and Licensing Activities

5000 Dominion Boulevard
Glen Allen, Virginia 23060

(14)

VIRGINIA POWER

January 12, 1995

Office of the Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Serial No. GL 94-061
NL&P/GSS R0

Attn: Docketing and Service Branch

Dear Sir:

**COMMENTS ON PROPOSED RULE
PROCUREMENT OF COMMERCIAL GRADE ITEMS
BY NUCLEAR POWER PLANT LICENSEES**

In the October 24, 1994 Federal Register, the NRC requested comments on the proposed rule to amend its regulations in 10 CFR Part 21 to add flexibility to the process of procuring commercial grade items for safety-related applications. The purpose of the rule is to ensure that the procurement of commercial grade parts and their subsequent dedication for use in a safety-related application are performed in such a manner that avoids unnecessary delay and expense while maintaining an adequate level of plant safety.

While the NRC has made significant progress in improving the wording in 10 CFR Part 21, we feel that additional flexibility is needed to resolve procurement conflicts that impact commercial grade procurement and dedication processes. The restrictions proposed in the definitions of a "Commercial Grade Item" and "Dedication" are vague and open to interpretation. Therefore, we offer the following specific changes to the proposed wording in addition to endorsing the comments sent separately to the NRC by the Nuclear Energy Institute (NEI).

- Delete the proposed wording for the definition of a "Commercial Grade Item" - 10 CFR 21.3 and replace it with the original proposed NEI wording. The NEI's proposed wording was developed by a consortium of utilities and represents the flexibility needed to function in today's nuclear procurement environment.

- Delete the last three sentences ("Due to the complexity ... control rod assemblies and pressure vessels.") in the definition of "Dedication" 10 CFR 21.3 (1). While we agree in principle with the NRC's concerns, we feel that these controls are achieved through the existing program controls.

- Delete the term "consulting service" in the definition of "Basic Component" - 10 CFR 21.3 (3). Consulting services have no impact on a basic component's ability to serve a safety function and adds no value to the procurement process.

We appreciate the opportunity to make comments on the proposed rule. If you have any questions, please contact us.

Very truly yours,

M. L. Bowling, Manager
Nuclear Licensing and Programs

cc: Mr. William Rasin
Nuclear Energy Institute
Suite 400
1776 I Street, N.W.
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Mr. Thomas E. Tipton
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ENTERGY

DOCKET NUMBER
PROPOSED RULE PR 21
(59FR53372)

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DOCKETED
USNRC

95 JAN 17 A11 :40

Jerrold D. Dewease
Vice President
Operations Support

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

(13)

January 13, 1995

Mr. John C. Hoyle
Acting Secretary
Office of the Secretary
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTN: Docketing and Service Branch

Subject: Comments on Proposed Revision to 10 CFR Part 21

CNRO-95/00002

Dear Mr. Hoyle:

On October 24, 1994, the Nuclear Regulatory Commission published for comment in the *Federal Register* (59 Fed. Reg. 53372) a proposed revision to 10 CFR Part 21. The proposed change involving the dedication process and definition of "commercial-grade item" is an important issue for the industry. The Nuclear Energy Institute (NEI), in interaction with and in behalf of the industry, has submitted pertinent comments for the NRC's consideration.

Entergy Operations, Inc. provided review comments to NEI in preparation of its submittal. Please consider this to be our formal endorsement of the NEI comments and our request for the NRC's careful consideration of the same.

Sincerely,

Jerrold D Dewease

JGD/jlt-b
cc: (See Next Page)

Acknowledged by card FEB 24 1995

cc: Mr. R. P. Barkhurst
Mr. J. L. Blount
Mr. L. J. Callan
Mr. J. L. Colvin
Mr. S. D. Ebneter
Mr. C. R. Hutchinson
Mr. G. Kalman
Mr. H. W. Keiser
Mr. J. R. McGaha
Mr. R. B. McGehee
Mr. P. W. O'Connor
Mr. C. Patel
Mr. N. S. Reynolds
Mr. D. L. Wigginton
Mr. J.W. Yelverton
Central File (GGNS)
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Records Center (WF-3)
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Corporate File [10]

PECO ENERGY

PECO Energy Company
Nuclear Group Headquarters
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January 9, 1995

Mr. Samuel J. Chilk
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Subject: PECO Energy Company
Comments Concerning NRC Proposed Rule 10CFR21,
"Procurement of Commercial Grade Items by Nuclear
Power Plant Licensees" (59FR53372)

Dear Mr. Chilk:

This letter is being submitted in response to the NRC's request for comments concerning the Proposed Rule 10CFR21, "Procurement of Commercial Grade Items by Nuclear Power Plant Licensees," published in the Federal Register (i.e., 59FR53372, dated October 24, 1994). PECO Energy Company appreciates the opportunity to comment on this proposed rule intended to add flexibility and clarification to the process of procuring commercial grade items for safety-related applications by nuclear power plant licensees. In response to this request, we offer the following comments for consideration by the NRC.

General Comments

1) **10CFR21.3, "Definitions"**

a) **Commercial Grade Item** - The NRC's proposed definition of commercial grade item should not replace the new definition proposed by the Nuclear Energy Institute (NEI). Rather than enhancing a utility's ability to use the commercial grade dedication process, the NRC's proposed definition could have the exact opposite result. The difficulty with the NRC's proposed definition is that it would force utilities to always purchase a product nuclear grade if a manufacturer with a 10CFR50, Appendix B program exists. Therefore, if only one 10CFR50, Appendix B, manufacturer existed for a particular product, this manufacturer would have a monopoly and prices would be based accordingly. The option to buy the item commercial grade from the manufacturer or a similar item commercial grade from another manufacturer, and then dedicate the item is precluded by the NRC's proposed definition.

b) **Critical Characteristics** - We recommend that the NRC delete the definition of "Critical Characteristics." This term comes from EPRI NP-5652 and not 10CFR50, Appendix B. This term is not appropriate for a regulation associated with reporting requirements.

c) **Dedication (1)** - Instead of providing a simple definition, the NRC has provided a detailed discussion of the dedication process. 10CFR21 is a regulation for reporting defects and noncompliances, and should not be used for providing guidance for implementing 10CFR50, Appendix B, requirements. Therefore, we recommend that the NRC modify its definition to be very specific. An example is provided below for consideration by the NRC.

> "Dedication 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. When the dedication of the commercial grade item has been completed, the item may be used as a basic component."

d) **Dedication (2)** - We request that the NRC clarify this particular definition. The present wording is unclear since the sentence is missing a subject and the references to the other 10CFR Parts do not seem to be appropriate. We offer the following definition as an example for consideration by the NRC.

> "Once a commercial grade item is dedicated, deficiency reporting becomes the responsibility of the party performing the dedication."

e) **Dedicating Entity** - On the fifth line of the definition, we recommend that the word "accept" replace the word "qualify." We consider this word substitution necessary to ensure that the dedication process is differentiated from the equipment qualification process.

2. **10CFR21.31, "Procurement Documents"**

In the second and third line we consider the phrase "(including dedicating entities)" to be unnecessary. This paragraph addresses purchase orders for basic components, and not commercial grade items.

If you have any questions, please do not hesitate to contact us.

Very truly yours,

G. A. Hunger, Jr.

G. A. Hunger, Jr.

Florida Power & Light Company, P.O. Box 14000, Juno Beach, FL 33408-0420

L-95-14

JAN 9 1995

Mr. John C. Hoyle, Acting Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Attn: Docketing and Service Branch

Re: Procurement of Commercial Grade Items
by Nuclear Power Plant Licensees
59 Fed. Reg. 53372, October 24, 1994
Request for Comments

On October 24, 1994 (59 FR 53372), the Nuclear Regulatory Commission (NRC) published for public comment a proposed rule, "Procurement of Commercial Grade Items by Nuclear Power Plant Licensees." The following comments are submitted on behalf of Florida Power and Light Company (FPL), a licensed operator of two nuclear power plant units in Dade County, Florida and two units in St. Lucie County, Florida.

The Nuclear Energy Institute (NEI) is offering comments on this proposed rule. FPL endorses the NEI comments and recommendations.

As noted in NEI's response, the major purpose of NUMARC's petition on June 23, 1993, was to remove restrictions on the definition of "commercial grade item" currently contained in Part 21, in order to provide for increased use of utility or third-party dedication of commercial grade parts. This change was sought as a means to address changes in the marketplace, primarily the decreasing availability of replacement parts from manufacturers with 10 CFR 50, Appendix B programs.

However, as currently proposed, the new rule goes too far by codifying new prescriptive requirements for the dedication process. There is no need to codify procurement processes and terminology that have been successfully incorporated into utility programs through the NUMARC procurement initiatives. FPL requests that the NRC revise these sections of the proposed rule to agree with the industry comments supplied by NEI. It is imperative that the NRC provide a clear and practical regulation that creates the necessary flexibility for licensees to obtain quality replacement items in light of the decreasing availability of Appendix B manufacturers.

Very truly yours,

W. N. Paduano Jr.

for W. H. Bohlke
Vice President
Nuclear Engineering and Licensing

BOSTON EDISON
Pilgrim Nuclear Power Station
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E. T. Boulette, PhD
Senior Vice President — Nuclear

January 9, 1995

(10)

BECo Ltr. #95-002

Secretary, U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attn: Docketing and Service Branch

Pilgrim Station Comments on the Proposed Rule on the Procurement of Commercial Grade Items by Nuclear Power Plant Licensees, 10 CFR Part 21 59FR53372)

We have reviewed the NRC proposed rule amending 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. We do not agree with some of the additional definitions and wording added by the NRC staff to the original NEI (formerly NUMARC) petition for rulemaking as published in the October 14, 1993, Federal Register (58 FR53159).

We endorsed the original NEI petition scope that sought to remove restrictions on the definition of "commercial grade item" currently contained in Part 21 in order to provide for increased use of utility or third-party dedication of commercial grade parts. The petition proposed three changes. The first would broaden the definition of a commercial grade item to allow utilities to obtain certain items of acceptable quality on the open market where such an item would likely be obtained relatively quickly at a more reasonable cost. The second change would define dedication as the process applied to qualify a commercial grade item as a basic component and require the dedicating entity to reasonably assure the item will perform its intended function. And the third change clarified that the dedicating entity is responsible to meet Part 21 reporting requirements if it discovers a defect that could create a substantial safety hazard.

The changes proposed by the NRC, in several cases, alter the objectives of the original petition . Our comments on these changes are as follows:

Commercial Grade Item (CGI)
The NRC staff is concerned that the NEI petition definition of commercial grade item is too broad. The NRC believes that commercial grade items should not encompass the full spectrum of items envisioned by the petition. For example, 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. Items in this category include complex assemblies that generally have nuclear unique requirements and applications. Also, the design and/or manufacturing process for these items may require 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. To address this concern, the NRC proposes that an item would qualify for commercial grade consideration only if it is not designed and/or manufactured as a basic component. The NRC intent is to preclude inclusion of items as CGI whose quality assurance is an integral part of the manufacturing process.

We agree with the NRC intent to place restrictions for those items whose quality assurance is an integral part of the manufacturing process such as given in the above examples. However, the NRC proposed definition is somewhat confusing and could potentially be interpreted to preclude the option of purchasing CGIs from one vendor if another vendor manufactures the item as a basic component. Or, it might possibly restrict use of commercially available piece parts of components that were originally manufactured as basic components. One of our objectives in endorsing the original proposal was to allow the utility the option of purchasing CGIs even in cases where items are available from an Appendix B qualified vendor. We request the NRC's reconsideration of their proposed wording and ask that this definition be further refined through continued interactions with NEI as the focal point for the industry.

Basic Component

We agree with the NRC proposal 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

The NRC anticipates that an increasing number of safety-related items will be procured as commercial grade items as opposed to basic components due to expanding the scope of commercial grade items. As a result, the NRC is seeking greater assurance that 10 CFR Part 50 licensees or dedicating entities are performing meaningful and substantive dedication processes. The NRC believes that the rule needs to specify the key elements of such a dedication process.

While we agree that the industry should have consistent standards for the application of dedications, we disagree with the need to include the level of detail in the rule as proposed by the NRC. Several industry guidance documents are in existence and have recognition and endorsement from the NRC as acceptable means for the dedication of commercial grade items for safety-related applications. We suggest the NRC consider other mechanisms available such as Regulatory Guides or Generic Letters for putting forth NRC staff positions and guidance. Alternatively, NEI could be requested to prepare and issue such guidance as it has in the past for other regulatory issues.

Critical Characteristics

The NRC added this definition to the proposed rule so as to ensure proper and complete characteristics that should be examined in the dedication process.

We agree with the NRC objective for defining this term. We point out however, that this term is defined and clarified in existing industry guidance documents as noted above in our discussion regarding the dedication process. Therefore, we question the need to include this level of detail in the regulation itself.

Dedicating Entity

The NRC is proposing a definition of "dedicating entity" because the NRC believes it important to clearly identify the party and its responsibilities for the requirements associated with this process.

We agree with the NRC's rationale for adding this definition in the regulation.

We appreciate the opportunity to comment on this important rule revision. We suggest a continued dialogue with NEI and the NRC on the NRC revisions and additions to the original petition to help bring any remaining differences to quick closure.

E T Boulette

E. T. Boulette, PhD

ETB/JDK/nas/Rap94/Commgrad

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Gary J. Taylor
Vice President
Nuclear Operations

DOCKET NUMBER
PROPOSED RULE PR 21
(59FR53372)

January 9, 1995
Refer to: RC-95-0009

(9)

Mr. S. J. Chilk, Secretary,
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Attention: Docketing and Service Branch

Dear Mr. Chilk:

Subject: VIRGIL C. SUMMER NUCLEAR STATION
DOCKET NO. 50/395
OPERATING LICENSE NO. NPF-12
COMMENTS ON PROPOSED AMENDMENTS TO 10 CFR PART 21

South Carolina Electric & Gas Company (SCE&G) has reviewed the proposed amendments to 10 CFR Part 21 (59 Fed. Reg. 53372). SCE&G is in agreement with the proposed amendments; however, we believe that inter-utility transfers should also be specifically addressed at this time by the amendment to 10 CFR Part 21.

10CFR21 does not clearly address the 10CFR21 obligations associated with a safety-related "complex" item (manufactured under an appendix B program) which was purchased from a qualified vendor by utility "A", then transferred to utility "B" for use as a basic component. Problems arise in the case where utility "A" is unwilling to accept 10CFR21 provisions on the transfer procurement documents.

If utility "A" is unwilling to accept 10CFR21 responsibility in the transfer, the 10CFR21 amendment (section 21.31) should address that the transfer is allowed, if utility B can document their acceptance of the qualification of the vendor during the time of original manufacture and sale of the item.

We suggest the following sentence addition to 21.31: "In the case of inter-utility transfer of basic component items an exception is made to the imposition of 10CFR21 provisions on the inter-utility transfer documents, in the cases where the receiving utility can document their acceptance of the qualification of the originally supplying vendor".

Inter-utility transfers provide an opportunity to obtain qualified equipment/material when manufacturers or vendors are not able to meet immediate needs. Inter-utility transfers are not currently addressed by 10 CFR Part 21 and SCE&G believes this is an excellent opportunity to provide guidance in this area.

SCE&G appreciates the opportunity to provide comments on this proposed rule.

Very truly yours,

Gary J. Taylor

JDH:ews

c: O. W. Dixon
R. R. Mahan
R. J. White
G. F. Wunder
NSRC
CFS
RTS (PR 920036)
File (811.02, 21.003)

TU ELECTRIC

Log # TXX-95001
File # 10185
Ref. # 10 CFR Part 21

January 9, 1995

C. Lance Terry
Group Vice President

Mr. John Hoyle
Secretary of the Commission
U. S. Nuclear Regulatory Commission,
Washington, DC 20555
Attn: Docketing and Service Branch

SUBJECT: PROPOSED RULE CHANGE TO 10 CFR PART 21

REF: 1) 10 CFR Part 21, Proposed Rulemaking, Federal Register, Volume 59, No. 204, October 24, 1994, Pages 53372 through 53377.

Dear Mr. Hoyle:

By Federal Register notice dated October 24, 1994, (Reference) the NRC solicited comments for amending 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. These comments are submitted by TU Electric in response to the NRC notice of October 24, 1994 (Reference 1).

TU Electric commends the Commission for its improvement in the rule. TU Electric supports a change to 10 CFR Part 21 to broaden the current definition of commercial grade items. This change as modified below provides the flexibility needed to procure items necessary to support Nuclear Power plants in a shrinking Nuclear market. However, we believe the specific language could be improved further to prevent unnecessary limitations which will hinder the procurement of parts and materials necessary to support Nuclear Power Plants and Nuclear Safety.

The following are specific comments on the proposed change:

Page 53375, third column, Definition of Basic Component:

The proposed change states: "...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."

This phrase provides no additional guidance in the determination of basic components. The criteria for a basic component is stated later which is those items necessary to assure integrity of the reactor coolant pressure boundary, capability to shut down the reactor and maintain it in a safe shut down condition, or the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred in §100.11 of this chapter. In addition, this proposed change can lead to confusion and defeat the purpose of the proposed change by implying that items which were originally manufactured under an Appendix B program can not be dedicated. This concern is discussed further in our comments on the definition of Commercial Grade Item.

Recommendation:

Delete this proposed phrase.

Page 53376, first column, Definition of Commercial Grade Items:

The proposed change states: "...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."

This definition seems to imply that items which were originally designed or manufactured under an Appendix B program are excluded from commercial dedication. Many items were originally designed or manufactured under an Appendix B program; but, a similar item is commercially available and can be easily dedicated. In addition, this does not provide the flexibility necessary to buy replacement parts from manufacturers who originally had an Appendix B QA program but have dropped them due to commercial considerations. For example, T J Cope originally designed and manufactured cable tray under an Appendix B QA program. Several years ago, they dropped their Appendix B QA program. This definition could be interpreted to restrict a utility from dedicating cable tray manufactured commercially by T J Cope or an equivalent product from another commercial cable tray manufacturer. Another example is NEI Peebles. This company originally designed and manufactured generators for emergency diesel generators under an Appendix B QA program. NEI Peebles has recently decided to drop their Appendix B program. Replacement parts are available commercially from Peebles or equivalent products from other manufacturers without an Appendix B program. Many of these products can be easily dedicated.

Recommendation:

Change the definition of commercial grade items to: "Commercial grade item means any item that has not been dedicated for use as a basic component."

Page 53376, first column, Definition of Dedication paragraph (1):

The proposed change states: "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."

This sentence implies that the dedication process requires a commercial grade survey (EPRI NP-5652 method 2) or source inspection (EPRI NP-5652 method 3) at the manufacturer's facility and the other methods, special test and inspections (EPRI NP-5652 method 1) or vendor history (EPRI NP-5652 method 4), are only used to supplement this process. Requiring some form of inspection or survey at the commercial manufacturer's facility would defeat the purpose of the proposed change. Many items can be adequately dedicated by testing after receipt of the item. In addition, many manufacturers will not allow survey or source inspection of their products due to the competitive nature of their business and low volume of sales to Nuclear customers. Enforcement of this proposed sentence would restrict commercial dedication rather than improve the procurement process which is the reason for the proposed change to 10 CFR Part 21.

Moreover, this sentence is inconsistent with the discussion which preceded the proposed changes. Specifically, page 53374, bottom of the second column of the same volume of the Federal Register, states: "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, test, and/or analysis performed by the licensee or a third-party dedication entity <u>after delivery</u>, <u>supplemented</u> 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."

This discussion states that commercial grade surveys are to supplement as necessary activities that are performed after receipt of the item. In addition, neither EPRI NP-5652 nor Generic Letter 89-02 "Actions To Improve The Detection Of Counterfeit And Fraudulently Marked Products" which conditionally endorsed NP-5652 suggest that survey or source inspection are the primary means of commercial dedication and the other methods are only supplementary.

Recommendation:

The sentence should be changed to read: "This assurance is achieved by test, inspection and/or analysis performed by the licensee or a third-party dedication entity, supplemented as required by a combination of commercial grade surveys, product inspections or witness/holdpoints at the manufacturer's facility, or analyses of acceptable historical performance."

Page 53376, second column, Definition of Dedication paragraph (1):

The proposed change states: "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."

The complexity of an item or the manufacturing process should not be the criteria to exclude items from commercial dedication. There are many complex products that should be dedicated. Many of these products are manufactured commercially and have manufacturing processes that require many in-process inspections. For example, controllers, governors, integrated circuits, semiconductors, printed circuit cards, and computers are not manufactured or designed under an Appendix B QA program. Other industries such as Aerospace and Military have strict quality requirements that should satisfy the Nuclear industry. The actions necessary to provide reasonable assurance through dedication that an item will perform its intended safety related function should be base on a number of considerations which include complexity, manufacturing process, safety significance, and performance history. Items which would require extensive activities to perform commercial grade item dedication would naturally guide utilities to procuring those items from Appendix B suppliers, if available. In addition, there are parts and subassemblies to complex items used as examples by the NRC in the proposed change which were procured commercially and dedicated. This change to 10 CFR Part 21 may be interpreted as restricting the dedication of commercial grade parts of a complex nuclear unique assembly.

Recommendation:

Delete these sentences from the proposed change to 10 CFR Part 21.

TU Electric appreciates this opportunity to comment on the proposed rule change and requests that the Commission or NRC staff contact Carl B. Corbin at (214) 812-8859 if there are any questions.

Sincerely,

C. L. Terry

By: 
D. R. Woodlan
Docket Licensing Manager

CBC/cbc

c - L. J. Callan
Resident Inspector, CPSES
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(7)

January 9, 1995

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Attn: Docketing and Service Branch

Re: Proposed Rule to Amend 10 CFR Part 21 on Procurement of Commercial Grade Items by Nuclear Power Plant Licensees, 59 Fed. Reg. 53372

Gentlemen:

On October 24, 1994, the Nuclear Regulatory Commission published in the Federal Register a proposed rule to amend 10 CFR Part 21. The proposed rule, arising out of a petition for rulemaking submitted by the Nuclear Management and Resources Council (now incorporated into the Nuclear Energy Institute), would modify Part 21 to provide flexibility in the procurement of "commercial grade items" by nuclear power plant licensees. Having represented many licensees and their suppliers of goods and services with respect to Part 21 issues since that regulation was originally promulgated, we are pleased to submit the following comments on the proposed rule.

In general, we agree with the Commission's conclusions that a problem exists with the procurement of commercial grade items, that the problem has gotten worse since the concept of commercial grade items was initially added to Part 21, and that an appropriate solution to the problem would be to broaden the definition of commercial grade items and to place greater emphasis on the dedication of commercial grade items. We do, however, believe that the amendments as proposed are ambiguous and do not provide a clear demarcation between basic components and commercial grade items. This lack of clarity will result in considerable uncertainty among licensees and their suppliers as to the allocation of responsibility for Part 21 compliance. This uncertainty will in turn continue to make it difficult for licensees to obtain basic components from qualified suppliers.

The Commission recognizes that the definition of commercial grade item as it relates to nuclear power reactors needs to be expanded to allow for a broader range of parts and services. As the Commission points out, the availability of basic components has declined and the current

definition of commercial grade item is unnecessarily restrictive, resulting in a very limited use of the commercial grade designation.

The Commission proposes to solve this dilemma by changing the definitions in Part 21. The revised definition for commercial grade item does not, by itself, cause difficulty since it merely defines commercial grade item as a structure, system or component which "is not designed and manufactured as a basic component." The definition of basic component, however, raises a number of problems. The first problem is that the definition begins by stating that it "includes" two categories of items, i.e. those designed and/or manufactured under 10 CFR Part 50, Appendix B quality assurance programs, and those commercial grade items successfully dedicated as basic components. By using the term "includes", the definition leaves open the possibility that other categories of items may also be included. This ambiguity can readily be cured by adding "only" to the definition, so that the term basic component would "only include" the two categories of items identified.

A second, perhaps more significant problem with the basic component definition, is its use of the phrase "designed and/or manufactured". As written, the language could be interpreted as bringing within the scope of a basic component any item that was either designed or manufactured under an Appendix B quality assurance program. This would be inconsistent with the Commission's view, expressed in the Supplementary Information accompanying the proposed rule, that basic components need only include components where 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." If, for example, a licensee (or a supplier) designed an item which was sufficiently simple such that dedication could "reasonably assure the absence of a defect which could affect one or more critical characteristics" of the item, and that design work took place under an Appendix B quality assurance program, the item would appear to be treated as a basic component both as to the licensee, the supplier, and sub-tier suppliers. And it would be treated as a basic component regardless of how simple and uncomplicated the item might be. Notwithstanding the ability to ascertain all of the item's critical characteristics in the dedication process, the licensee or supplier would still be required to treat the item as a basic component. Since nuclear plant licensees conduct essentially all of their activities under Appendix B quality assurance programs, and particularly their design activities, almost every item procured for a nuclear plant could be considered a basic component. This would be inconsistent with the concerns expressed in the original NUMARC petition, concerns with which the Commission agreed, that the use of the commercial grade concept was too limited. If the Commission's concern is that the dedication process is not adequate for "one-of-a-kind, uniquely designed items without a performance history" (NRC Draft Regulatory Analysis, p. 5), the proposed rule clearly is too broad.

One way to solve this dilemma would be to revise the basic component definition to include only those items which are either (1) designed and manufactured under an Appendix B quality assurance program, or (2) commercial grade items successfully dedicated as basic

components. Since commercial grade items are already defined as items which are not designed and manufactured as basic components, this revised basic component definition would assure that if an item could not be successfully dedicated, it would still be considered a basic component. This would resolve the Commission's concern that items such as fuel and control rod assemblies and pressure vessels should not be treated as commercial grade items. This slight modification to the definition as proposed would also assure that vendors who operate under Appendix B quality assurance programs and whose products are treated as basic components within their organizations and when sold to purchasers, would be able to treat as commercial grade items those sub-components that they procure from third parties (or from related entities which do not operate under Appendix B quality assurance programs) so long as those components can be successfully dedicated.

In addition, we would suggest that in finalizing the rule, care should be taken that the rule use consistent terminology. For example, the proposed definition of "critical characteristics" in § 21.3 uses the phrase "intended safety function", while the proposed definition of "dedication" in § 21.3 uses the phrase "intended safety-related function" as well as the phrase "safety function". Slight differences in terminology will only cause confusion in the application of Part 21.

We appreciate the opportunity to comment on the proposed amendments to 10 CFR Part 21. Should the Commission or the Staff have any questions concerning these comments, please feel free to contact us.

Very truly yours,

SHAW, PITTMAN, POTTS & TROWBRIDGE

by: Jay Silberg
Jay E. Silberg

NUCLEAR ENERGY INSTITUTE

Thomas E. Tipton
VICE PRESIDENT,
OPERATIONS & ENGINEERING

January 9, 1995

Mr. John C. Hoyle
Acting Secretary
Office of the Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

ATTENTION: Docketing and Service Branch

SUBJECT: Industry Comments on Proposed Revisions to 10 CFR Part 21

Dear Mr. Hoyle:

The Nuclear Energy Institute (NEI)[1] has reviewed the proposed revision to 10 CFR Part 21 issued for public comment in the October 24, 1994, *Federal Register* (59 Fed. Reg. 53372). The proposed revisions, involving the dedication process and the definition of "commercial grade item," are issues of significance for the industry, and we would appreciate the NRC's careful consideration of the following comments.

On June 22, 1993, NUMARC petitioned NRC to revise Part 21. The major purpose of the petition was to remove restrictions on the definition of "commercial grade item" currently contained in Part 21, in order to provide for increased use of utility or third-party dedication of commercial grade parts in a manner that would not result in a degradation of safety. The change requested in the petition was sought to address changes in the marketplace, primarily the decreasing availability of replacement parts from manufacturers with 10 CFR 50, Appendix B programs. The proposed change was further supported by the fact that utility procurement programs and capabilities for dedication have been significantly enhanced through implementation of the NUMARC procurement initiatives, which included guidelines for the dedication process.

Following NRC publication of the NUMARC petition on October 14, 1993, NRC received and reviewed public comments, and subsequently developed a revised version of the

[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry. NEI is the successor organization to the Nuclear Management and Resources Council (NUMARC).

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proposal originally submitted by NUMARC. This revised version included changes developed by NRC staff that were not reflected in the public comments for the original petition. While the NRC proposed rule addresses some of the problems identified in the industry's petition, it does not include all the changes originally proposed, and also codifies new prescriptive requirements for the dedication process. We are concerned that the proposed revisions will not address the fundamental concerns that resulted in the industry's petition. Specific comments are as follows:

Definition of "Commercial Grade Item" (proposed § 21.3)

While the industry petition sought to remove existing restrictions on the definition of "commercial grade item" to recognize the realities of the current marketplace, the NRC's proposed rule would replace the existing restrictions with a new restriction that an item could not be designated as a commercial grade item if it is designed and/or manufactured as a basic component (as defined in proposed § 21.3). This definition would appear to further limit, rather than enhance, utility flexibility in dedicating commercial grade items. The NRC proposed rule states that such a restriction is necessary to prevent the attempted dedication of certain items requiring nuclear-unique or specific manufacturing processes, such as pressure vessels (we assume this is intended to mean reactor pressure vessels, as there is no reason pressure vessels in general could not be candidates for dedication), and fuel or control rod assemblies. We agree in principal that these types of items should not be considered for dedication by utilities or third party dedicators. However, we are concerned that the wording proposed by NRC would unnecessarily limit dedication of a far broader range of items, and would result in frequent interpretational difficulties.

The proposed restriction would result in the establishment of a "captured market." If a manufacturer or supplier provided an item under a 10 CFR 50, Appendix B program, utilities would be required to purchase the item from that manufacturer or supplier. The definition could be interpreted to prohibit dedication of any item that had been produced by any manufacturer under an Appendix B program. Many manufacturers have dropped Appendix B programs but still provide replacement components as commercial grade items. Under the proposed definition, utilities would be excluded from dedicating these replacement components and would be left with no alternative to support continuing operation of existing equipment. Our member utilities have estimated the proposed change would exclude up to 80 percent of the items being dedicated under the current definition, with impacts in the millions of dollars per year per plant.

Further examples of potential confusion with regard to applicability of this restriction could include: (1) items manufactured as basic components by one manufacturer, but available commercially through others; (2) commercially available piece parts of basic components; and (3) non-safety-related piece parts of basic components.

In support of the proposed restriction, the proposed rule states that for certain items, quality assurance is an integral part of the manufacturing process that cannot be attested to after the fact. We would note that this category of items is a small subset of all items designed and manufactured as basic components. Further, even for those items that do fall into this category, the dedication process, as addressed in the NUMARC procurement initiatives, includes provisions for observation of the manufacturing process and quality controls through surveys and source verifications. We believe proper consideration of these dedication methods should provide a sound basis to support commercial grade treatment of items for which quality assurance is an integral part of the manufacturing process.

For the above reasons, it is imperative that the proposed restriction on the definition of commercial grade item be reconsidered. Changing the restriction on commercial grade items to explicitly exclude limited categories of components, such as primary system pressure boundary components within containment, reactor pressure vessel, reactor core and internals, and fuel assemblies, would be an appropriate alternative to the currently proposed far-ranging exclusion.

Codification of the dedication process and the term "critical characteristics"

The proposed revision to § 21.3 includes new definitions of "critical characteristics" and a revised definition of "dedication." We have two areas of concern with respect to the inclusion of these new definitions. First, we do not believe it is necessary or beneficial to codify the processes and terminology that have been successfully incorporated into utility programs through the NUMARC procurement initiatives. NRC has already developed and implemented appropriate inspection programs to ensure proper utility dedication practices in accordance with the NUMARC initiatives. The proposed level of prescriptive detail in rulemaking is simply not warranted, particularly in Part 21, a rule that pertains to reporting of defects and noncompliances.

Our second concern is that the terms proposed for definition were originally developed by the industry to support improved dedication and procurement programs under the NUMARC procurement initiatives. The definitions proposed for inclusion in Part 21 are inconsistent with the terms as defined in the referenced guidance document for the NUMARC procurement initiatives (EPRI NP-5652), which discusses critical characteristics as follows:

> "Critical characteristics are identifiable and measurable attributes/variables of a commercial grade item which once verified, provide reasonable assurance that the item received is the item specified.

> Based on the performance and design basis for an item, a variety of characteristics can be identified that are critical for satisfactory performance. However, for purposes of establishing critical characteristics for acceptance, only certain of these must be verified to provide reasonable assurance that the item specified is the item received."

The second paragraph of the definition is important, as demonstrated by NRC pilot assessments and inspections of dedication programs following utility implementation of the NUMARC initiatives. Questions have arisen regarding determinations of critical characteristics for particular items and the amount of verification necessary to provide reasonable assurance. The second paragraph of the above definition allows for appropriate use of reasonable assurance, such that lack of verification of postulated critical characteristics having remote or insignificant correlations to safety functions would not be a basis for a violation.

With regard to the definition of "dedication" proposed for § 21.3, we have discussed above our concerns with respect to limitations on items that would be subject to dedication under this definition. In addition, we would note that the proposed definition states that a dedication process must involve "commercial grade surveys, product inspections...supplemented as required by additional inspections or tests, or analyses of acceptable historical performance..." This is in conflict with the NUMARC industry initiatives, which provides that any combination of the four acceptance methods may be used. In fact, testing and inspection is the most commonly used dedication method.

The proposed definition of "dedication" states that the process must be carried out under the "applicable provisions of 10 CFR 50, Appendix B." We would note that the "applicable provisions" for dedication may be defined by the licensee in the quality assurance program description, and that not all Appendix B criteria should necessarily apply to dedication of every item. As provided by Appendix B, the licensee should be permitted to consider a graded approach in application of Appendix B criteria for dedication, commensurate with the safety significance of the item being dedicated.

The definition notes that with respect to safety function, item performance should be "equivalent to an item designed and manufactured under Appendix B." We agree that the dedication and Appendix B manufacturing processes should share the same objective - to achieve reasonable assurance that the item will perform its intended safety function. Overall, we believe this objective has been met. We would note, however, that practical implementation of the above requirement on a case by case basis could be subjective, and that it would be difficult to measure or establish "equivalent" quality.

Again, we emphasize the importance of promulgating a clear and practical regulation that provides the necessary flexibility for licensees to obtain quality replacement items in light

of diminishing numbers of Appendix B manufacturers. Please contact Biff Bradley (202-739-8083) or Alex Marion (202-739-8080) of the NEI staff, or myself (202-739-8107), if you have any questions regarding these comments, or if additional information is desired.

Sincerely,

Thomas E. Tipton

TET/REB/ljw

c: NRC: Rules Review and Directives Branch,
Freedom of Information and
Administration and Publications Services

Douglas R. Gipson
Senior Vice President
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Detroit Edison

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January 9, 1995
NRC-95-0001

Secretary,
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

References: 1) Fermi 2
NRC Docket No. 50-341
NRC License No. NPF-43

2) NRC Proposed Rule, 10 CFR 21, Procurement of Commercial Grade Items by Nuclear Power Plant Licensees, dated October 24, 1994 (59 FR 53372)

Subject: Detroit Edison Comments on the Proposed Rule 10 CFR 21, Procurement of Commercial Grade Items by Nuclear Power Plant Licensees

The purpose of this letter is to submit Detroit Edison's comments on the proposed rule on 10 CFR 21 (Reference 2). The comments are provided in the Enclosure of this letter.

If you have any questions, please contact Mr. Girija S. Shukla at (313) 586-4270.

Sincerely,

Lynne S. Goodman
Director, Nuclear Licensing

Enclosure

cc: T. G. Colburn
A. Marion (NEI)
J. B. Martin
M. P. Phillips
A. Vegel

Detroit Edison Comments on NRC Proposed Rule 10 CFR 21, Procurement of Commercial Grade Items by Nuclear Power Plant Licensees

In general, Detroit Edison supports the NUMARC petition of October 14, 1993 and endorses NEI's comments on the proposed rule. Detroit Edison's specific comments are given below:

- The proposed rule provides a definition of dedication which reads that Dedication is an inspection and acceptance process by which a commercial grade item is designated for use as a basic component.

  This definition could cause confusion when compared with the activities of inspections, tests, and/or analyses. We suggest the definition be changed to reads that dedication is an acceptance process which includes inspections, tests, and/or analyses by which a commercial grade item is designated for use as a basic component.

- Under Dedicating entity, the new rule implies that if the licensee is the dedicating entity, the dedicated item is to be used only by the dedicating licensee.

  We suggest the definition be changed to read that dedication may be performed by either the manufacturer of the item, a third party dedicating entity, or a licensee. This change would permit one licensee to also dedicate for other licensees.

- Also under Dedicating entity, clarification should be added that reporting requirements apply for the dedicated item once it has been designated for use as a basic component.

  This would clarify that the dedicating entity need not report defects identified during the dedication process and prior to designating the dedicated item a basic component.

- New requirements are being specified for dedication, hence, a backfit analysis should be required.

- Under Dedication, the text should be changed to read that the dedication process should provide assurance that a commercial grade item to be used as a basic component will perform its intended safety-related function, but not that the item is equivalent to an item designed and manufactured under a 10 CFR 50, App. B Quality Assurance Program. Also, items currently required to be designed and manufactured as basic components, such as fuel and control rod assemblies and pressure vessels, should be allowed to be dedicated if they are built to acceptable standards.

Duke Power Company
Electric Center
P.O. Box 1006
Charlotte, N.C. 28201-1006

DUKE POWER

January 6, 1995

The Secretary of the Commission
US Nuclear Regulatory Commission
Washington, DC 20555

Attn: Docketing and Service Branch

Subject: Proposed Rule 10CFR Part 21
Procurement of Commercial Grade Items by Nuclear Power Plant Licensees

We support the petition submitted by the Nuclear Management and Resources Council (NUMARC) which was docketed by the NRC on June 22, 1993. We have participated in developing and support the comments the Nuclear Energy Institute has made regarding the proposed rule as issued by the NRC on October 24, 1994.

While we endorse the NEI comments, we offer the following specific comments relative to the proposed rule:

1. In paragraph 21.3, the definition of "Commercial Grade Item" should be revised to delete the sentence which reads, "(1) When applied to facilities and activities licensed pursuant to 10CFR Part 50, means a structure, system, component, or part thereof that is not designed and manufactured as a basic component." This sentence can easily be misconstrued to prohibit dedication of an item if the item is available anywhere in the marketplace as a basic component even though the item meets all the other traditional tests for commercial grade acceptability. The NRC and the industry should cooperate at the highest levels to preclude such misinterpretations by eliminating the sentence. The Commission's concerns that nuclear unique, complex components cannot be assured to function without design and manufacture as basic components are addressed by the current rule and definition of commercial grade items.

2. In paragraph 21.3, the definition of "Critical Characteristics" should be removed from the proposed rule. Since fundamental differences remain between NRC staff and much of the nuclear industry in interpretation of the term "critical characteristics", codifying the term will inevitably change industry performance in this area. The performance of industry in this arena does not warrant a change in practice. We are concerned that the proposed rule will kick-off a round of inspection activity by the NRC field and vendor division inspectors which is not warranted by industry performance.

3. In paragraph 21.3, the definition of "Dedication" should be revised to clarify the intent and to reduce the possibility of conflicting interpretations between the industry and the commission. Delete "....is equivalent to an item designed and manufactured under 10CFR 50 Appendix B Quality Assurance Program" which is the last phrase of the first sentence. Commercial Grade items are not typically equivalent to an item manufactured under Appendix B QA program. For instance, the audit assurance, the personnel qualification assurance, and the equipment calibration assurance typically provided by a commercial manufacturing facility, while adequate to provide reasonable assurance that an item will perform its intended safety function, are not equivalent to the level of assurance provided by Appendix B QA programs. Also in the same paragraph the sentence, "This assurance is achieved by a combination of commercial grade surveys...." should be revised. It should read, "This assurance may be provided by...." to make it clear that the rule does not require a particular combination of methods or supplements. In short, no guidance or rule is needed to improve performance in this arena beyond the guidance provided by the industry initiatives. The level of detail provided by the proposed rule will likely generate additional discussion and controversy between the industry and the NRC that is not warranted in view of current performance.

   Further, in the definition of "Dedication", the phrase, "(i.e one or more critical characteristics of the item cannot be verified)", which appears in the second paragraph, should be deleted. The dedication process provides reasonable assurance an item will perform its safety related function. Inclusion of this phrase may lead to disputes over adequacy of selection and verification of "critical characteristics" which are not warranted.

H.L. Atkins
Manager, Procurement Engineering
Nuclear Generation Department
Duke Power Company

hla/rab

cc: G.A. Copp
File

(3)

Michael Harrington
Star Route
Barrington, N.H. 03825

January 4, 1995

Secretary, U.S. Nuclear Regulatory Compliance
Washington, D.C. 20555

Attention: Docketing and Service Branch

I am writing to provide comments to the proposed change to 10CFR21 as published in Volume 59, No.# 204, 10/24/94 issue of the Federal Register.

The need to change 10CFR21 to expand the definition of commercial grade items has been apparent for a number of years but continues to become more acute as more vendors drop their nuclear programs. While this proposed change attempts to address this need, it contains at least one major problem and a few minor ones. These problems are addressed below.

Section	**Problems**
Dedication.(1)	1). In discussing how reasonable assurance that a commercial grade item will perform its intended safety function is achieved, this section states "This assurance is achieved by a combination of commercial grade surveys, product inspections or witness/hold points at the manufacturer's facility supplemented as required by additional inspections or tests, or analysis of acceptable historical performance by the purchaser...". This statement implies that achievement of assurance requires that as a minimum, a survey, inspection or witness point be performed at the manufacturer's facility. This would then be supplemented as required by additional test and inspections or an analysis of the vendors historical performance. This is contrary to current industry practice, the NUMARC Comprehensive Procurement Initiative and NRC Generic Letters 89-02 and 91-05. The most common single method of dedication used since the issuance of these documents is method 1 "Special tests and Inspections" from EPRI 5652" which does not involve any surveys, inspections or witness points at the manufacturers facility. This section **needs to be changed** to allow for use of any of the four (4) methods (or a combination thereof) listed in EPRI 5652.

2). The proposed change would not eliminate all restrictions on what items could be dedicated as was the case in the NUMARC Petition. The licensee who is ultimately responsible for the quality of the dedicated item should be allowed to decide when an item should be designed and manufactured as a basic component. The licensee could use documented engineering judgement (as is now allowed in selecting critical characteristics in NRC Inspection Procedure 38703, Section a(1)), to determine when the dedication process could provide reasonable assurance that an item can perform its safety function. It should be noted that dedicating an item does not preclude having its design be classified as a basic component or the use of in process controls and inspections.

3). One of the specific examples, pressure vessels, does not meet the requirement of having a very complex design and/or manufacturer processing. If the intended example is reactor pressure vessels, this should be clearly stated. Almost all other pressure vessels are used widely outside the nuclear industry and should be considered potential candidates for dedication.

In conclusion, the proposed revision to 10CFR21 is a large improvement over the present, providing the comments in item 1 above are incorporated. Without these changes it represents a large step backward. The comments listed in items 2 and 3, while not absolutely essential, would greatly improve the proposed revision.

Sincerely,

Michael D. Harrington

(2)

Wisconsin Electric
POWER COMPANY

231 W. Michigan, P.O. Box 2046, Milwaukee, WI 53201-2046

(414) 221-2345

VPNPD-94-136
NRC-94-093

December 23, 1994

Secretary, Docketing & Service Branch
U.S. NUCLEAR REGULATORY COMMISSION
Mail Station P1-137
Washington, DC 20555

Dear Secretary:

WISCONSIN ELECTRIC POWER COMPANY COMMENTS ON PROPOSED RULEMAKING AMENDMENTS TO 10 CFR 21
59 FEDERAL REGISTER 53372

These comments are submitted by Wisconsin Electric Power Company in response to the request for public comments on the proposed rule-making to amend 10 CFR Part 21 which was published at 59 Federal Register 53372 on October 24, 1994.

Wisconsin Electric Power Company, which owns and operates the Point Beach Nuclear Plant, supports the intent of the proposed amendments to 10 CFR Part 21. We commend the Commission's efforts toward alleviating current regulatory problems associated with procurement and dedication of commercial grade items for nuclear safety-related applications. The proposed amendments serve to clarify and add flexibility to the process while not adversely impacting safety. Wisconsin Electric appreciates the opportunity to review and comment on the proposed amendments.

While Wisconsin Electric supports the intent of the proposed amendments to 10 CFR Part 21, we believe clarification of some of the language in the proposed rule is necessary. Our comments, presented in the order in which the subject appears in the proposed rule, follow.

Commercial Grade Item

The proposed definition of a commercial grade item states, in part, that "...A commercial grade item is not a basic component, or part of a basic component, until the dedication process has been completed." We recommend that the phrase "or part of a basic component," be removed from the definition since the definition of basic component already addresses parts. Wisconsin Electric is concerned that the proposed wording could be interpreted to mean that all commercial grade items used in a basic component require dedication. The current practice is that noncritical parts of a basic component need not be dedicated. Removing the phrase clarifies the intent of this portion of the definition.

U.S. NUCLEAR REGULATORY COMMISSION
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Definition

Wisconsin Electric strongly agrees that the dedication of a commercial grade item to be used as a basic component will provide reasonable assurance that it will perform its intended safety-related function. However, Wisconsin Electric maintains that a licensee must have available the flexibility to apply appropriate controls to a component manufacturer who may not maintain a 10 CFR 50 Appendix B program such that, at the conclusion of the dedication process, the objective evidence supporting the item's ability to perform its safety function is sufficiently demonstrated. That evidence may come from either a fully implemented Appendix B qualified design and manufacturing process or from evidence derived from inspections, surveys, and testing performed in support of dedication.

The proposed wording of this rule does not appear to allow for such flexibility. The proposed wording states that "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." Literally interpreted, these words could require the use of surveys or inspections or holdpoints at the manufacturer's facility in all cases. Although this level of assurance may be appropriate for some items, it is not required for simple, commodity items. For example, many items can be dedicated based solely on receipt inspection/testing at the licensee's facility with no vendor inspections required. We believe the proposed wording is overly restrictive and does not reflect current practices.

Based upon our understanding of the Commission's position as described in the proposed rule's statement of considerations, Wisconsin Electric believes that the Commission's intent in listing the possible means of dedication would be better communicated if worded as follows:

> "This assurance is achieved by one or more of the following acceptance methods: (1) commercial grade surveys, (2) product inspections or witness/holdpoints at the manufacturer's facility, (3) receipt inspections or special tests, (4) analyses of acceptable historical performance of a manufacturer."

Our proposed wording supports the industry guidance on acceptance methods currently in use, EPRI NP-5652, "Guidelines for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)," which was conditionally endorsed by the NRC in Generic Letter 91-05. Reasonable assurance of an items' ability to perform its intended safety-related function is the baseline requirement. The means by which this assurance is demonstrated should be flexible.

Dedication (latter portion of definition)

While Wisconsin Electric agrees that there are certain items which must be designed and manufactured as basic components, we believe that the sentence beginning with "Due to the complexity of their design and/or manufacturing process," may be too restrictive and could be difficult to interpret and implement. The proposed wording implies that "complexity of the design and/or manufacturing process" is the determining factor in whether an item can be dedicated or must be manufactured as a basic component.

Complexity of a design or process does not, in and of itself, determine whether an item can be dedicated. Such an interpretation may unnecessarily limit the dedication of many items. Although the NRC states that for certain items quality assurance is an integral part of the manufacturing process that cannot be attested to after the fact. Wisconsin Electric notes that current industry guidance on the dedication process provides for observations of the manufacturing process and quality controls through surveys and source verifications.

Wisconsin Electric believes that the intent would be better communicated as follows:

> "When the dedication process cannot reasonably assure the successful performance of an item's safety function (i.e., one or more critical characteristics of the item cannot be verified), that item must then be designed and manufactured as a basic component. Specific examples include, but are not limited to, fuel, control rod assemblies, and reactor pressure vessels."

Wisconsin Electric appreciates this opportunity to provide comments on the proposed amendments to 10 CFR Part 21. Should you have any questions regarding our comments or if we can be of further assistance as you review our comments, please call Tom Jessessy at (414)755-6594.

Sincerely,

Bob Link
Vice President
Nuclear Power

TJJ/jg

cc: NRC Resident Inspector
NRC Regional Administrator
NEI

Marvin I. Lewis
3133 Fairfield Street
Philadelphia, PA 19136
(215)676 1291

Secretary of the Commission
Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Secretary:

Please accept this letter as my comments on 10CFR Part 21, Amending Requirements Governing Procurement of Safety-Related Items for Nuclear Power Plants.

1. Considering the recent fiasco with Rosemont controllers wherein people may actually go to jail, the "unnecessary delays" may actually be a benefit increasing the safety of nuclear power plants.

2. "commercial grade items" were never meant for nuclear power plants. If OEM, original equipment manufacturers, no longer have the demand to keep an adequate quality assurance program, the answer is to shut down nuclear power plants rather than lower the level of safety required by 10CFR50 Appendix B.

3. NEI should not be leading the NRC into "a more flexible process." The NRC should be requiring NEI and its members to increase safety.

Respectfully submitted,

M. I. Lewis.

11-20-94

Critical Mass

Volume 4, No. 1 | Public Citizen's Critical Mass Energy Project | February 1994

See No Evil, Hear No Evil, Speak No Evil

What The NRC Won't Tell You About America's Nuclear Reactors

by Matthew Freedman and Jim Riccio

America's nuclear reactors have more serious safety, training, and equipment problems than government regulators acknowledge, according to secret internal industry documents obtained by Public Citizen's Critical Mass Energy Project. Examination of these documents reveals long-standing deficiencies at nuclear reactors across the nation that could jeopardize public health and safety. These findings conflict with public assessments made by the Nuclear Regulatory Commission (NRC), the federal agency in charge of regulating commercial nuclear power operations.

The internal documents are significant because they show that aging atomic reactors are plagued by a variety of management and technical problems, many of which have not been revealed in NRC's public assessments. The range and frequency of NRC's omissions raise serious concerns about the credibility of regulators and their willingness to acknowledge potential safety hazards at nuclear reactors.

"These documents show that citizens need greater access to accurate information about nuclear power plants," said Bill Magavern, director of Public Citizen's Critical Mass Energy Project. "The time has come to lift the veil of secrecy that shrouds this industry. There's just no good excuse to keep the public in the dark when our health and safety may be at risk."

The internal documents obtained by Public Citizen are plant evaluations performed by the Institute of Nuclear Power Operations (INPO), an Atlanta-based group founded by nuclear utilities in the wake of the 1979 accident at Three Mile Island, near Harrisburg, PA. INPO routinely sends inspection teams to operating reactors, reviews significant operating problems and equipment malfunctions, and maintains data bases on nuclear power plant operation.

The detailed findings compiled by INPO, while required reading for NRC inspectors, have been withheld from the public by NRC. As a result, the relationship between INPO and NRC has been controversial. Public interest groups charge that INPO acts as a "shadow" regulator by serving as a buffer between the nuclear utilities and the NRC. The information INPO provides is used by NRC to determine proper regulatory policy and sometimes substitutes for NRC's own investigations into safety issues. INPO thus shields the nuclear industry from additional regulation and ensures that information passed on to NRC avoids public scrutiny.

"When NRC leaves it up to the industry to correct the problems, they don't get corrected, and the public has no way of knowing the adequacy of the resolution," said Robert Pollard, a former NRC inspector now working as a nuclear safety watchdog for the Union of Concerned Scientists in Washington, D.C.

Although NRC contends that its relationship with INPO does not inhibit public access to the regula-

Continued on page 4

Clinton and Congress Urged to Boost Efficiency and Renewables, Cut Nuclear and Fossil Dollars

by Bill Magavern

After suffering through the Reagan-Bush years when federal energy dollars went largely to nuclear and fossil fuel boondoggles, sustainable energy advocates are waging an intensive campaign to shift funding to energy efficiency and renewable technologies. While the Clinton Administration generally supports such a shift, it has not been as steadfast or as effective as it should be in pushing new energy funding priorities through the nuclear and fossil barons on Capitol Hill.

The final budget for 1994 improves upon the previous year, substantially increasing funding for efficiency and renewables. However, the efficiency budget requested by the president was not fully funded by Congress.

Another great disappointment was Congress' failure to cut the nuclear budget, a problem caused primarily by the decision to continue full funding for the **Advanced Liquid Metal Reactor (ALMR)**, a dangerous and expensive breeder reactor. President Clinton had first proposed terminating, then scaling back the ALMR. Then, the Department of Energy actually undermined the administration's position by advocating the breeder to Congress. Although the House voted overwhelmingly to "bag the breeder," the Sen-

Continued on page 3

Inside this Issue

NOTES OF INTEREST

THREE MILE ISLAND 15th ANNIVERSARY CONFERENCE

This March marks the 15th anniversary of the Three Mile Island accident, and safe-energy activists will commemorate the occasion with a major conference. Three Mile Island Alert is sponsoring the conference, which will be held on the weekend of March 26-27 at the State Capitol Complex in downtown Harrisburg, PA. Registration costs only $35 and includes two meals.

The aim of the conference is not so much to look back as to strategize on meeting present and future challenges like license renewal, decommissioning, and especially radioactive waste. Activists will be able to participate in issue discussions and skills development sessions on a variety of topics.

Since Pennsylvania is planning a "low-level" waste dump for its own wastes and those of Maryland, Delaware and West Virginia, attendees from those states are encouraged to lobby the Pennsylvania State Legislature on Monday, March 28. Activists from other states may wish to make the two-hour trip to Washington, D.C. to lobby Congress and the Clinton Administration. For more information, contact *TMI Alert, 315 Peffer Street, Harrisburg, PA 17120 (Phone: 717-233-7897).*

SUN DAY 1994

Organized to be a national celebration of renewable energy and energy efficiency, SUN DAY 1994 is gearing up for a round of events that will include the participation of public interest groups, businesses, trade organizations, state officials and federal agencies. The official date for SUN DAY is Sunday, April 24. Local and national groups will hold events around that day focused on educating the general public on the status, potential, and benefits of renewable energy and efficient technologies. Originally founded by Public Citizen, SUN DAY is an ongoing campaign which can be contacted (if you would like to affiliate your group or just want more information) at *315 Circle Avenue #2, Takoma Park, MD 20912-4836 (Phone: 301-270-2258 / Fax: 301-891-2866).*

RENEW '94 CONFERENCE

The Northeast Sustainable Energy Association (NESEA) will be hosting the RENEW '94 conference in Stamford, CT on April 11-13 of this year. The meetings will focus on the near-term commercialization of renewable energy technologies in the northeastern United States. Topics for discussion include: a status report on the renewable energy industry in the northeast, utility-scale and demand-side applications for renewable technologies, environmental and resource issues, economics of renewable energy, and the impact of recent federal policies on renewable energy development. Attendees will include activists, utility staff, policy makers, financiers, independent power producers and others. According to its organizers, the conference will be "a watershed event in ensuring a sustainable energy future for the northeastern United States." For more information, contact *Paul Lipke at NESEA, 23 Ames Street, Greenfield, MA 01301 (Phone: 413-774-6051/Fax: 413-774-6053)*

EARTH DAY ENERGY FAST

The Earth Day Energy Fast campaign, a new project tied to the observance of Earth Day, is promoting individual actions that can be taken to incorporate energy conservation and efficiency techniques into daily routines. From Earth Day (Friday, April 22) to the following Sunday, Energy Fast will call on concerned citizens to examine their own relationship to six different issue areas and ask them to determine what they can do to participate in the observance. Categories included in the Energy Fast are: Transportation, Climate-Control, Lighting, Food-Preparation, Water, and Communication. The Energy Fast Campaign will include renewable energy and efficiency trade associations, activists, and policy makers in coordinating a series of local events which educate about simple and cost-effective efficiency technologies, incentives offered by local utilities, and options for installing renewable energy systems. For more information or to affiliate your group with the Energy Fast campaign, contact *Jeff Softley at Earth Day Energy Fast, 1002 1/2 N. Sweetzer Avenue, Los Angeles, CA 90069 (Phone: 213-654-6237).* ◆

SUSTAINABLE ENERGY BUDGET (SEB)

Recommendations for the Department of Energy (in millions)

Program Area	FY'93 Actual	FY'94 Actual	FY'95 SEB Recomm.	Change from FY'94 Actual
Energy Efficiency	$575.3	$685.3	$1,177.0	+$491.7
Renewable Energy	$210.0	$291.0	$611.5	+$320.5
Nuclear Power	$1,012.0	$1,012.8	$259.1**	-$753.7
Fossil Fuels	$1,225.2	$1,111.3	$632.6*	-$478.7
EIA	$33.3	$86.9	$94.9	+$8.0
Total	**$3,055.8**	**$3,187.3**	**$2,775.1**	**-$412.2**

** does not include reprogrammed funds from FY'94*

***does not include $80 million from the increase in nuclear waste fund fee*

BUDGET *continued from front cover*

ate kept it alive by a narrow 8-vote margin, and the House-Senate conference committee ignored the House position and fully funded this slab of nuclear pork.

Now targeting the fiscal year 1995 and 1996 budgets, Public Citizen and other environmental, consumer and labor groups have launched the **Clean Energy Campaign**, which is building support both in Washington and at the grassroots for a major shift in spending from outdated and polluting nuclear and fossil programs to the cleaner technologies of the future.

As part of the campaign, hundreds of grassroots organizations have written to President Clinton urging support for redirecting at least $1 billion from the Department of Energy's current budget, including nuclear and fossil programs, to efficiency and renewables projects. The letter to Clinton points out that sustainable energy benefits the economy:

"Substantial investments in energy efficiency and renewable energy resources can mean economic growth, expansion of international export markets, and the creation of over one million jobs in the U.S. while decreasing total energy use per unit of economic output by 20 percent over and above current trends. In addition, such action can save consumers money, improve public health, and protect the environment while helping you achieve your commitment of reducing greenhouse gases to 1990 levels by the year 2000 and continuing with further reductions thereafter."

The Clean Energy Campaign is also seeking Congressional cosponsors for **House Concurrent Resolution 188**, introduced by Representative Phil Sharp (D-IN) with Reps. Dick Swett (D-NH), Connie Morella (R-MD), Blanche Lambert (D-AR), and Sherwood Boehlert (R-NY). H. Con. Res. 188 calls for a national policy of:

1) Increasing energy efficiency and reducing energy use per unit of Gross Domestic Product by at least 30 percent by the year 2010, to replicate progress made since 1973;

2) Ensuring that by 2010 renewable energy technologies (wind, solar, hydropower, biomass, and geothermal) account for at least 20 percent of the overall national energy mix; and

3) Achieving these goals by adopting a national strategy which changes priorities within the DOE's overall budget, by fiscal year 1996, to shift $1,000,000 from the DOE's budget for conventional energy and other programs to spending on efficiency, conservation, and renewable energy programs, consistent with the aim of lowering the Federal deficit.

The sponsors of H. Con. Res. 188 are not calling for an overall increase in government spending, but for a shift of support from polluting and ineffective energy sources to cleaner, safer, job-creating domestic technologies.

The **"Sustainable Energy Budget"**, written and endorsed by dozens of public-interest, business, and government organizations at the national, state and local levels, calls for a similar funding shift that would result in an overall reduction in DOE spending.

As we go to press, indications are that President Clinton will follow some but not all of the recommendations in the "Sustainable Energy Budget." Clinton will again propose significant hikes in the efficiency and renewables budgets, probably about 30 percent above current levels. And he will propose a reduction in spending for programs that promote a future generation of nuclear reactors, but will seek to continue some of those projects despite his announced opposition to building any more atomic power plants.

The president's budget request only begins the decisionmaking process. A Washington adage states that "the president proposes, and Congress disposes." Funding decisions go through Congress' complex, arcane, and frequently secretive budget and appropriations process. ◆

HEAR NO EVIL *continued from front cover*

tory process, a 1991 report by the General Accounting Office (GAO), the investigative arm of Congress, came to some disturbing--and contrary--conclusions. GAO found 12 instances in the previous two years where "NRC decided not to issue its own information notice because INPO had already alerted the industry to a potential problem." GAO concluded that as a result of this relationship "information that may be important to the public's understanding of nuclear power operations is not publicly available."

Critical Mass staffers examined a total of 57 plant-specific internal INPO evaluations dating from 1991 through early 1993 for 86 nuclear reactors, or about 80 percent of all U.S. commercial units, located in 31 states. The documents assess performance in eight areas: operations, maintenance, engineering, worker training, chemistry, radiological protection, organization-administration, and operating experience.

The INPO reports leaked to Public Citizen contain important information that is unavailable from any other source. The sheer mass of this data leads to a far better understanding of some generic problems afflicting many plants across the country. Most importantly, the evaluations reveal that the aging of nuclear plant systems and components is causing widespread problems which reduce the margin of safety at operating reactors. Furthermore, utility efforts to prevent further degradation have been only partially successful.

Other findings include:

* **Deficiencies in worker qualification and training programs at a startlingly high number of plants.** This is particularly noteworthy in light of Public Citizen's long battle with the NRC over whether or not it is appropriate to turn over the management of such programs to INPO;

* **Problems maintaining the pools that hold highly radioactive spent fuel at reactor sites.** NRC has cited fuel pool problems as potentially leading to breakage of the fuel rods, which would result in extremely high levels of worker exposures to radiation; and

* **Insufficient attention by many nuclear plant managers to underlying causes of repeated equipment failures and emergency shutdowns.** Consequently, many of the same problems recur.

To determine whether NRC has addressed the issues identified in the INPO reports, Critical Mass researchers examined the publicly available evaluations of each nuclear power plant, known as the Systematic Assessment of Licensee Performance (SALP). The SALP is widely viewed as a report card on the condition of the plant and is studied by analysts ranging from Wall Street investment firms to public interest groups. Unlike most tests, the SALP contains no failing grades for inadequate compliance. Instead, the NRC decides whether the plant should receive less regulation, the same level, or more in the future, based on its level of current performance.

The INPO reports reveal that deficiencies in the management of aging are widespread in the industry and are causing potentially serious incidents at many American reactors.

Critical Mass discovered that despite a requirement that NRC inspectors read INPO reports, many SALP evaluations fail to address a number of key safety concerns raised by INPO. Critical Mass also found that by comparing INPO and NRC documents, NRC regulators often recommend reduced oversight at reactors where INPO has identified serious deficiencies.

Altogether, NRC's SALP reports only managed to report on about one-third of the total findings identified by INPO, while forty percent were left unaddressed and one quarter were directly contradicted.

The INPO reports reveal that deficiencies in the management of aging are widespread in the industry and are causing potentially serious incidents at many American reactors. In contrast, NRC's SALP evaluations have an uneven record of identifying weaknesses in utilities' efforts to address aging issues. Safety lapses and station malfunctions are often judged by NRC to be isolated incidents and not indicative of the broader management issues that INPO frequently cites as the cause of many plant failures. For example, NRC identified weaknesses at only two of five plants cited by INPO for maintenance deficiencies that were causing emergency shutdowns and equipment failures that challenge reactor safety systems.

NRC relies on accumulated industry experience to help utilities understand the effects of aging on specific reactor components. The Nuclear Performance and Reliability Data System (NPRDS), a computerized database that INPO runs, is designed to track industry experience. It will serve a central role in industry's efforts to create maintenance programs based around "probablistic risk assessment," which estimates risks of component and system failure based on information provided through operating reactor experience. But INPO reports concede that more than one-quarter of the reactors studied are inadequately reporting component failures to the database.

These gaps bring into question the usefulness of the NPRDS and its ability to serve as a basis for any reliable form of risk assessment. Moreover, it undermines the NRC's contention that there is enough data accumulated to allow for less regulation and more industry self-policing on maintenance issues.

Discrepancies between INPO and NRC assessments of worker training have been both substantial and common. These discrepancies

are particularly significant because NRC has delegated responsibility for worker training programs to INPO (see related story). INPO's own findings cast doubt on the wisdom of NRC's decision to let the industry decide what kind of training is appropriate.

Despite glaring omissions in NRC's SALP program, the agency already has taken steps to reduce the scope and breadth of its examinations. When the program was initiated in 1982, SALP reports covered and rated plants in 11 functional areas. By 1988, the number of areas addressed was reduced to seven. This year, NRC consolidated the seven areas into four main categories.

As a result of the initial reduction in the SALP from 11 to seven categories, assessments of reactor chemistry programs were folded into the area of radiological protection, which evaluates management's actions to protect workers from unnecessary exposures to radiation. Chemistry programs, if improperly run, can cause reactor piping to corrode and reduce the operating life of numerous components. Out of the 54 findings at 35 reactors cited by INPO for deficient chemistry programs, SALP reports addressed only two. This experience indicates that reducing the scope of SALP evaluations even further could cause other areas to be underevaluated.

What often gets lost in NRC's efforts to "streamline" regulation is the importance of giving the public meaningful access to information. "Since the SALPs already fail to give an accurate assessment of the condition at operating plants, the result of cutting back the program will be that more safety issues go undetected," said Magavern. "This means that while the industry is kept appraised of safety problems by INPO, NRC leaves the public in the dark."

Yet despite abundant evidence that the industry fails to address important problems on its own, NRC continues to chant the mantra of deregulation, hoping to solve deeply rooted problems that have dogged commercial nuclear power since it was born on the failed promise of "energy too cheap to meter."

With the release of these documents, Public Citizen called for the disclosure of all INPO materials used by NRC. In addition, Critical Mass recommended that the SALP program, now slated to suffer a slow death, instead be resurrected and strengthened to ensure that all operations of each nuclear power plant receive evaluations that are tough, fair, and thorough.

Critical Mass also has called for a Congressional investigation into the discrepancies between INPO's plant assessments and NRC's SALP reports.

Finally, Public Citizen has urged President Clinton to appoint safety-minded Commissioners to the Nuclear Regulatory Commission. "We have had too much of cozy industry relations and toothless regulation," remarked Magavern. "The public demands government regulators who will keep the industry honest. Right now, most citizens' groups see NRC as a partisan promoter of the nuclear industry. The agency's credibility problem will persist until it gains new leaders who make a clean break with the past."◆

PUBLIC CITIZEN TAKES NRC TO COURT

Public Citizen has challenged the Nuclear Regulatory Commission's relationship with INPO on a number of occasions, citing the inaccessibility of critical information as a barrier to public participation in nuclear regulation.

In 1984, Public Citizen filed suit against the NRC after being denied access to important INPO documents filed sought under the Freedom of Information Act (FOIA). The reports described events and significant operating experiences contained in INPO's Significant Event Evaluation and Information Network (SEE-IN).

Eight years later, the U.S. Court of Appeals for the District of Columbia Circuit held in Critical Mass Energy Project v. Nuclear Regulatory Commission that because INPO makes available to NRC on a voluntary basis information normally withheld from the public, it should not be subject to release under FOIA.

According to David Vladeck, director of Public Citizen's Litigation Group, this case was "a significant defeat for those of us who rely on government documents to monitor closely the performance of federal agencies, particularly where the NRC is involved."

Public Citizen has also criticized the NRC's penchant for abandoning regulation in the nuclear industry's internal programs. A good example lies in NRC's handling of worker training programs.

In response to the partial core meltdown at Three Mile Island in 1979, Congress passed a requirement that the NRC write regulations for the training and qualification of nuclear reactor operators.

Despite a clear mandate from Congress, NRC refused to issue such a rule. Instead, the Commission released a general policy statement that praised the industry programs set up by INPO while reserving the right to create a rule if the industry's performance was not sufficient.

When NRC again avoided issuing a rule during a 1988 reexamination of the subject, Public Citizen sued to force the Commission to comply with the requirements of the

Continued on page 8

Copies of Hear No Evil, See No Evil, Speak No Evil: What the NRC Won't Tell You About America's Nuclear Reactors are 168 pages and available for $20 to Public Citizen members and activists, $80 for others.

Twenty Years After the Embargo

Understanding and Treating America's Oil Addiction

by Christopher Dyson

This past October was the twentieth anniversary of the Arab Oil Embargo, an event that first alerted Americans to the dangers of dependency on foreign oil. In mid-October, 1973, Arab nations imposed an oil export embargo on the United States and some of its allies for supporting Israel in the Yom Kippur War. The embargo caused the world oil price to quadruple -- from $3 per barrel to nearly $12 per barrel. Many U.S. consumers were also forced to wait in long lines for their gasoline, causing frustration and even fistfights.

To mark this anniversary, Public Citizen and the American Council for an Energy Efficient Economy (ACEEE) have published a report, **Twenty Years After The Embargo: The Costs of U.S. Oil Import Dependence and How They Can Be Reduced**. This report examines whether the United States has learned anything from its wake-up call in 1973, and explains what must be done so that these gasoline lines never reappear.

The report finds that the United States is now more dependent on foreign oil than it was during 1973. Net oil imports now account for 43 percent of U.S. oil consumption, compared to 35 percent in 1973. In recent years, oil imports have accounted for 70 percent of the total U.S. merchandise trade deficit. This means that the U.S. oil import deficit is even bigger than the U.S. trade deficit with Japan.

"The United States has done little to change its gas guzzling ways," said Joan Claybrook, President of Public Citizen. "In fact, the country has slid backwards."

Costs of the Oil Import Addiction

Addiction to foreign oil seriously harms the U.S. economy in a number of ways. By purchasing imported oil, the United States transfers tens of billions of dollars every year to foreign oil producers. These are dollars that the United States might otherwise use to invest in its own economy.

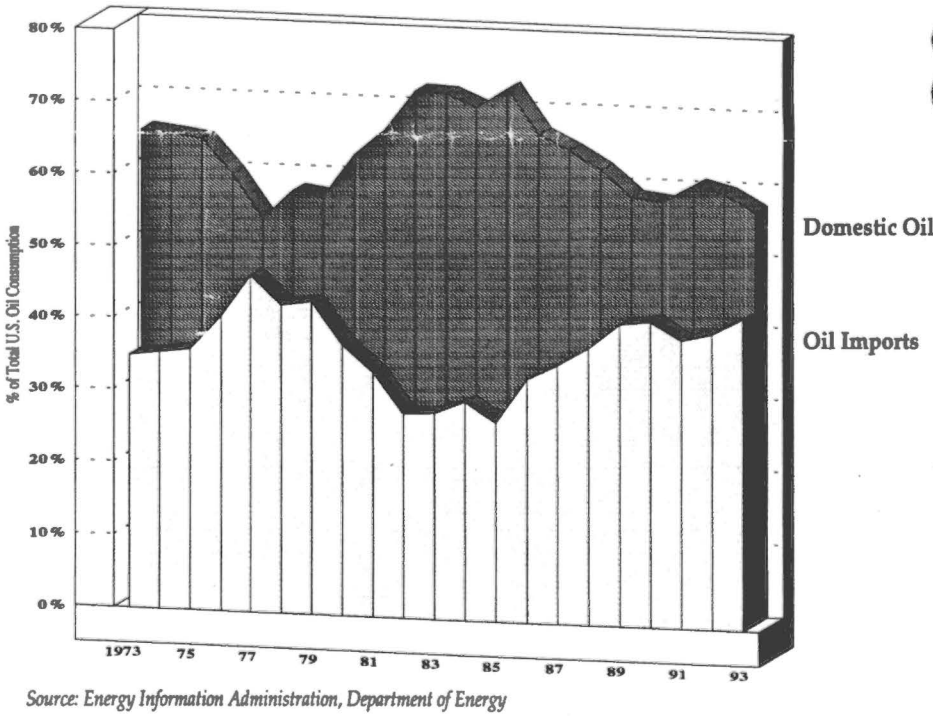
U.S. oil imports create many of the conditions that cause political instability and oil price spikes. For example, the United States, through its oil imports, paid for many of the military weapons that Sadaam Hussein used in 1990 to invade Kuwait. By being the world's largest oil importer, the United States also gives the Organization of Petroleum Exporting Countries (OPEC) enough market power to set oil prices much higher than they would be in a competitive market.

These oil price spikes and general high oil prices have devastated the U.S. economy over the past twenty years. **From 1973 to 1993, the United States has had four economic recessions -- in 1974, in 1980, in 1981-82, and in 1990-91. Every one occurred right after an oil price spike.** Some economists estimate that high oil prices have cost the U.S. over $4 trillion dollars since 1972.

Imported oil also costs a lot to defend. The report estimates that the United States spends $35 billion a year to defend the Persian Gulf. This does not even count the billions of dollars the United States spent in Operations Desert Shield and Desert Storm. The United States has also spent over $40 billion dollars since 1976 building and filling its Strategic Petroleum Reserve.

The Public Citizen/ACEEE report blames oil imports for almost 20 percent of the 4.1 million barrels that are spilled in world seas every year. Overdependence on oil also increases local and regional air pollution, as well as global warming due to the greenhouse effect. "While the gas lines have disappeared," said Critical Mass Director Bill Magavern, "our

U.S. Oil Dependence
1973-1993



Source: Energy Information Administration, Department of Energy

Rulemaking item –

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 21

RIN 3150-AF01

Procurement of Commercial Grade Items by Nuclear Power Plant Licensees

AGENCY: Nuclear Regulatory Commission.

ACTION: 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

Pub 10/24/94

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-

* * * * *

(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.