

January 21, 1994

Mr. Rod Thomas
c/o Dresser Industrial Valve
P.O. Box 1430
Alexandria, LA 71509

Dear Mr. Thomas:

As you requested, I am forwarding a copy of two different documents. First is a photocopy of the July 31, 1991, *Federal Register* Notice for the amendments to 10 CFR 21 and §50.55(e). Second is a copy of a more readable version of 10 CFR 21. As we discussed, this is not the latest revision.

If I can be of further assistance, please contact me.

Sincerely,

William R. Jones
Reactor Operations Analysis Branch
Division of Safety Programs
Office for Analysis and Evaluation
of Operational Data

Enclosures: As stated

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UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS - ENERGY

21.1

21.3(a)

**PART
21**

REPORTING OF DEFECTS AND NONCOMPLIANCE

GENERAL PROVISIONS

- Sec.
- 21.1 Purpose.
- 21.2 Scope.
- 21.3 Definitions.
- 21.4 Interpretations.
- 21.5 Communications.
- 21.6 Posting requirements.
- 21.7 Exemptions.
- 21.8 Information collection requirements: OMB approval.

NOTIFICATION

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

PROCUREMENT DOCUMENTS

- 21.31 Procurement documents.

INSPECTIONS, RECORDS

- 21.41 Inspections.
- 21.51 Maintenance and inspection of records.

ENFORCEMENT

- 21.61 Failure to notify.

Authority: Sec. 161, 66 Stat. 946, as amended, sec. 234, 83 Stat. 696, as amended (42 U.S.C. 2201, 2262); sec. 201, as amended, 206, 88 Stat. 1242, as amended, 1246 (42 U.S.C. 5841, 5846).

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

For the purposes of sec. 273, 66 Stat. 956, as amended (42 U.S.C. 2273); §§ 21.1, 21.21(a) and 21.31 are issued under sec. 161b, 66 Stat. 946, as amended (42 U.S.C. 2201(b)); and §§ 21.21, 21.41 and 21.51 are issued under sec. 161c, 66 Stat. 950, as amended (42 U.S.C. 2201(c)).

GENERAL PROVISIONS

§ 21.1 Purpose.

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity falls to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial

safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

§ 21.2 Scope.

(s) The regulations in this part apply, except as specifically provided otherwise in parts 31, 34, 35, 39, 40, 60, 61, 70, or part 72 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high level radioactive waste, or to construct, manufacture, possess, own, operate or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS); and to each director and responsible officer of such a licensee. The regulations in this part apply also to each individual, corporation, partnership or other entity doing business within the United States, and each director and responsible officer of such organization, that constructs a production or utilization facility licensed for manufacture, construction, or operation pursuant to part 50 of this chapter, an ISFSI for the storage of spent fuel licensed pursuant to part 72 of this chapter, a MRS for the storage of spent fuel or high level radioactive waste pursuant to part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under part 60 of this chapter; or supplies basic components for a facility or activity licensed, other than for export, under parts 30, 40, 50, 60, 61, 70, 71, or part 72 of this chapter.

(b) For persons licensed to construct a facility under a construction permit issued under § 50.23 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under § 50.55(e) of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects

and failures to comply under this part and the responsibility of individual directors and responsible officers of such licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

(c) For persons licensed to operate a nuclear power plant under part 50 of this chapter, evaluation of potential defects and appropriate reporting of defects under §§ 50.72, 50.73 or § 73.71 of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects under this part and the responsibility of individual directors and responsible officers of such licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

(d) Nothing in these regulations should be deemed to preclude either an individual, a manufacturer, or a supplier of a commercial grade item (see § 21.3(e-1)) not subject to the regulations in this part from reporting to the Commission, a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure. NRC regional offices and headquarters will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers of the five regions (answered during regular working hours), are listed in appendix D to part 20 of this chapter. The telephone number of the NRC Operations Center (answered 24 hours a day—including holidays) is (301) 951-0550.

§ 21.3 Definitions.

As used in this part:

(a)(1) "Basic component," when applied to nuclear power reactors 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.

(2) "Basic component," when applied to other facilities and when applied to

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

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

(4) A commercial grade item is not a part of a basic component until after dedication (see § 21.3(o-1)).

(a-1) "Commercial grade item" means an item that is (1) not subject to design or specification requirements that are unique to facilities or activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and (2) used in applications other than facilities or activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and (3) 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).

(b) "Commission" means the Nuclear Regulatory Commission or its duly authorized representatives.

(c) *Constructing or construction* means the analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are safety related.

(c-1) "Dedication" of a commercial grade item occurs after receipt when that item is designated for use as a basic component.

(d) "Defect" means:
(1) A deviation (see § 21.3(e)) in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation (see § 21.3(g)), the deviation could create a substantial safety hazard; or

(2) The installation, use, or operation of a basic component containing a defect as defined in paragraph (d)(1) of this section; or

(3) A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of Part 50 of this chapter provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued pursuant to Part 50 of this chapter.

(e) "Deviation" means a departure from the technical requirements included in a procurement document (see § 21.3(i)).

(f) "Director" means an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity. In the case of an individual proprietorship, "director" means the individual.

(g) *Discovery* means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21. (a).

(h) *Evaluation* means the process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

(i) *Notification* means the telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

(j) *Operating or operation* means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to operations that are safety related.

(k) "Procurement document" means a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

(l) "Responsible officer" means the president, vice-president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

(m) "Substantial safety hazard" means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter.

(n) "Supplying" or "supplies" means contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

§ 21.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 21.5 Communications.

Except where otherwise specified in this part, all written communications and reports concerning the regulations in this part must be addressed to the Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555. In the case of a licensee, a copy must also be sent to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter.

§ 21.6 Posting requirements.

(a) Each individual, partnership, corporation or other entity 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.

(b) If posting of the regulations in this part or the procedures adopted pursuant to the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting section 206, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states when they may be examined.

(c) The effective date of this section has been deferred until January 6, 1978.

§ 21.7 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Suppliers of commercial grade items are exempt from the provisions of this part to the extent that they supply commercial grade items.

§ 21.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0035.

(b) The approved information collection requirements contained in this part appear in §§ 21.21 and 21.51.

NOTIFICATION

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

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

(1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, and

(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in § 21.21(c)(5). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(3) Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in § 21.21(a)(1) or § 21.21(a)(2) if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity—

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard, or

(ii) Contains a defect.

(b) If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to § 21.21(a).

(c)(1) A director or responsible officer subject to the regulations of this part or a person designated under § 21.21(c)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting—

(i) The construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter.

(2) The notification to NRC of a failure to comply or of a defect under paragraph (c)(1) of this section and the evaluation of a failure to comply or a defect under paragraphs (a)(1) and (a)(2) of this section, are not required if the director or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or the failure to comply.

(3) Notification required by paragraph (c)(1) of this section must be made as follows—

(i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at 301-492-8187 or by telephone at 301-951-0550 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(1) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile

has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in § 21.21(a)(2).

(ii) Written notification to the NRC at the address specified in § 21.5 within 30 days following receipt of information by the director or responsible corporate officer under paragraph (a)(3) of this section, on the identification of a defect or a failure to comply.

(4) The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

(5) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that, this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

(d) Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply. Commission action to obtain additional information may be based on reports of defects from other reporting entities.

56 FR 36081

56 FR 36081

42 FR 28911

43 FR 48671

49 FR 19623

55 FR 36081

PROCUREMENT DOCUMENTS

§ 21.31 Procurement documents.

Each individual, corporation, partnership or other entity subject to the regulations in this part shall assure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 5, 1978 specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

INSPECTIONS, RECORDS

§ 21.41 Inspections.

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

ENFORCEMENT

§ 21.61 Failure to notify.

Any director or responsible officer subject to the regulations in this part who knowingly and consciously fails to provide the notice required 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.

[Note removed 49 FR 19623]

§ 21.51 Maintenance and inspection of records.

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

(1) Retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation;

(2) Suppliers of basic components must retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of the notification.

(3) Suppliers of basic components must retain a record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.

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

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS
TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS - ENERGY

REPORTING OF DEFECTS AND NONCOMPLIANCE

**PART
21**

STATEMENTS OF CONSIDERATION

52 FR 8225
Published 3/17/87
Effective 7/14/87

Licenses and Radiation Safety
Requirements for Well Logging

See Part 39 Statements of Consideration

52 FR 31601
Published 8/21/87
Effective 8/19/87

Statement of Organization and General
Information

See Part 1 Statements of Consideration

53 FR 6137
Published 3/1/88
Effective 3/1/88

Relocation of Office of Nuclear
Reactor Regulation

See Part 19 Statements of Consideration

53 FR 31651
Published 8/19/88
Effective 9/19/88

Licensing Requirements for the
Independent Storage of Spent Nuclear
Fuel and High-Level Radioactive
Waste

See Part 72 Statements of Consideration

53 FR 43419
Published 10/27/88
Effective 10/27/88

Relocation of NRC's Public Document
Room; Other Minor Nomenclature
Changes

See Part 1 Statements of Consideration

54 FR 42287
Published 10/16/89
Effective 11/11/89

Change in Commercial Telephone
Number for Region III Office

See Part 20 Statements of Consideration

54 FR 52342
Published 12/21/89.

Amendatory Instructions; Correction

See Part 2 Statements of Consideration

56 FR 19253
Published 4/26/91
Effective 4/26/91.

Change in Commercial Telephone
Number for Region V

See Part 20 Statements of Consideration

➤ 56 FR 36081
Published 7/31/91
Effective 10/29/91

10 CFR Parts 21 and 50

RIN 3150-AA68

Criteria and Procedures for the
Reporting of Defects and Conditions
of Construction Permits

AGENCY: Nuclear Regulatory
Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations on the reporting of safety defects. The amendments are a result of the Commission efforts to apply the experience gained as a result of the Three Mile Island accident and also reflect Commission experience to date with the existing regulations. The amendments are applicable to Commission licensees, and to nonlicensees who construct facilities for, or supply basic components to facilities or activities licensed by the Commission. The amendments would reduce duplicate reporting of defects, clarify the criteria for reporting defects, and would establish uniform time periods for reporting and uniform requirements for the content of safety defect reports.

DATE: These amendments will be effective October 29, 1991.

FOR FURTHER INFORMATION CONTACT: W.R. Jones, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 492-4442.

SUPPLEMENTARY INFORMATION: On November 4, 1988, the Nuclear Regulatory Commission ("NRC" or "Commission") published in the Federal Register (53 FR 44594) for public comment proposed amendments to 10 CFR Part 21 (part 21), "Reporting of Defects and Noncompliance" and § 50.55 "Conditions of Construction Permits." The purpose of these proposed amendments was to reduce duplicate evaluation and reporting, establish

consistent time limits for reporting, establish a time limit for transfer of information from vendors to purchasers of basic components, more clearly define defects that must be reported, and establish consistent content for reporting. Other minor changes were proposed.

Public comments regarding the proposed amendments were received from thirty-five respondents. These comments were received from segments of the nuclear industry as follows: Twenty-three were received from utilities; five, from law firms representing members of the nuclear industry; three, from owners groups; two, from architect/engineers; and two were received from vendors. These comments have been evaluated and, where appropriate, incorporated into the final regulations. The public comments are discussed below in connection with the final regulations.

A detailed analysis of the public comments has been prepared and is available for public inspection in the NRC Public Document Room.

Background

The existing regulations contain several safety deficiency reporting requirements that apply to the construction and operation of nuclear power plants:

—Part 21 applies to all NRC licensees, as well as nonlicensees who construct facilities for or supply basic components or services associated with basic components to these licensees, and implements section 206 of the Energy Reorganization Act of 1974, as amended (ERA), (42 U.S.C. 5841 et seq.), which requires the reporting of defects that could create a "substantial safety hazard," and failures to comply related to a "substantial safety hazard" as defined in regulations.

—Section 50.55(e) applies solely to the holders of construction permits and currently requires the reporting of "significant deviations" or "significant deficiencies" which could have an adverse effect upon safety if they remain uncorrected.

—Sections 50.72 and 50.73 establish an event reporting system that applies uniformly to all operating nuclear power plants. These regulations require the licensee to make prompt telephone notification to NRC and to submit a written report for each operating event or adverse plant condition. As discussed below, changes to §§ 50.72 and 50.73 are not being made at this time.

—Section 73.71 applies to licensees and establishes a reporting system for

PART 21 • STATEMENTS OF CONSIDERATION

safeguards events, including any security failure, degradation, or discovered vulnerability of a safeguards system. As stated in § 73.71, a report under § 73.71 satisfies reporting requirements in both §§ 50.72 and 50.73. Section 73.71 is not being changed at this time.

Task II J.4 of the TMI Action Plan directed the NRC staff to evaluate and revise, if necessary, the existing requirements of part 21 and § 50.55(e) to assure prompt and comprehensive reporting. Over several years, the need for revision of these regulations has become apparent. Accordingly, based upon the staff experience with part 21 and § 50.55(e), the final rule will:

1. Reduce duplicate evaluation and reporting;
2. Establish uniform time limits for reporting;
3. Establish a time limit for transfer of information to end users when a substantial safety hazard determination by vendors is not possible;
4. More clearly and uniformly define the defects that need to be reported under § 50.55(e);
5. Establish uniform content for reports submitted under § 50.55(e) and part 21;
6. Clarify the definition of "basic component";
7. Clarify records retention requirements including the requirement for retention of records of evaluations of deviations that did not result in a finding of substantial safety hazard;
8. Establish time limits for evaluation of potential defects and failures to comply; and
9. Make other minor changes detailed below.

These revisions will reduce the amount of time and effort expended by industry in complying with existing reporting and evaluation requirements while still ensuring that safety deficiencies are identified and evaluated in a timely manner.

Part 21

Part 21 was intended to implement section 206 of the ERA. Section 206 requires directors and responsible officers of firms constructing, owning, operating, or supplying the basic components of any facility or activity licensed under the Atomic Energy Act of 1954, as amended, (AEA), (42 U.S.C. 2011 et seq.), to immediately report to the Commission the discovery of "defects" in "basic components" or failures to comply that could create a "substantial safety hazard." In addition to imposing obligations on the directors and responsible officers of NRC

licensees, section 206 of the ERA also imposes obligations on the directors and responsible officers of nonlicensees that construct facilities for or supply basic components to licensed facilities or activities. Any individual officer or director who knowingly fails to comply with the notification requirements is subject to civil penalties.

On March 3, 1975, the NRC published a proposed rule designed to implement section 206 (40 FR 8832), and on June 8, 1977, issued the final rule, adding part 21 to the Commission's regulations (42 FR 28893).

The regulations in part 21 impose reporting requirements on directors and responsible officers of firms which construct, own, operate, or supply basic components for any facility or activity licensed or otherwise regulated pursuant to the AEA or the ERA. Part 21 was amended on October 19, 1978 (43 FR 48721) to exempt "commercial grade items" from part 21 requirements until the items were "dedicated" for use as basic components in a nuclear facility.

Approximately 12,000 organizations, licensees, and nonlicensees, fall under the scope of part 21 reporting requirements. Part 21 covers licensees granted the following licenses: production and utilization facility licenses issued under part 50, including nuclear power plants and research and test reactors; byproduct material licenses issued under parts 30 through 35; well logging licenses issued under Part 39; source material licenses issued under Part 40; high-level radioactive waste disposal licenses issued under part 60; land disposal of radioactive waste licenses issued under part 61; special nuclear materials licenses issued under part 70; licenses for the packaging of radioactive materials for transport licenses issued under part 71; and spent fuel storage licenses issued under part 72.

The nonlicensee suppliers covered under part 21 are firms of many different sizes, supplying many different types of basic components and services associated with basic components to NRC licensees. For example, construction and operation of a nuclear power plant involves a many-level procurement chain. At the top of the chain is the electrical utility and the utility's major contractors such as the nuclear steam system supplier. The next level includes manufacturers who produce basic components specifically designed for nuclear use such as instrumentation, controls, major piping, pumps, and valves. These manufacturers in turn procure necessary parts, such as resistors, wiring, solid-state devices, and other hardware, from a multitude of

sources. For nuclear power reactors, part 21 applies to all tiers of the supply chain for basic components and to all activities which could create a substantial safety hazard. In the case of fuel cycle licensees and organizations supplying components to them, responsibility for complying with part 21 does not extend past the first tier of suppliers.

Approximately 300 reports have been submitted to the NRC annually under part 21. These reports of potential safety problems have resulted in generic communications such as NRC bulletins, generic letters, and information notices, and have contributed to the overall improved safety of the nuclear industry.

Section 50.55(e)

Section 50.55(e) of part 50, originally published as a final rule on March 30, 1972 (37 FR 8459), establishes requirements for reporting deficiencies occurring during the design and construction of nuclear power plants. The rule was designed to enable the NRC to receive prompt notification of deficiencies and to have timely information on which to base an evaluation of the potential safety consequences of the deficiency and determine whether regulatory action was required. Therefore, the holder of a permit for the construction of a nuclear power plant is required to notify the Commission of each significant deficiency found in design and construction, which if it were to have remained uncorrected, could have adversely affected the safety of operations of the nuclear power plant at any time throughout the expected lifetime of the plant.

Approximately 750 reports were submitted annually in the past to the NRC under § 50.55(e). As with part 21, these § 50.55(e) reports have formed the basis for generic communications such as NRC bulletins, generic letters, and information notices and have also contributed to the overall improved safety of the nuclear industry.

Action Being Taken

1. Reducing Duplicate Evaluation and Reporting Requirements

As stated above, the Commission regulations contain four different safety deficiency reporting requirements. Although distinctions exist between these requirements, staff experience indicates a need to reduce duplication in reporting or evaluation among part 21, and §§ 50.55(e), 50.72, 50.73, and 73.71.

Duplicate reporting has been primarily a problem for part 21 and § 50.55(e).

PART 21 • STATEMENTS OF CONSIDERATION

A. Part 21 and § 50.55(e)

A number of instances have occurred where the same deficiency in a basic component was evaluated and reported by two different organizations, one attempting to satisfy the criteria of part 21, and the other attempting to meet the differently worded criteria of § 50.55(e). The fact that reporting criteria are different for each requirement and that there is a lack of any explicit framework in the regulations to preclude duplicate reporting have led to duplication of both licensee and NRC staff effort. The revised rule makes the relationship between these two regulations straightforward. Construction permit holders will perform evaluations, report as appropriate, and keep records under § 50.55(e). If deviations are evaluated under § 50.55(e) and result in either a negative reportability determination or reportable defect, then this satisfies requirements of part 21.

Additionally, the scope of § 50.55(e) is being expanded from covering only the construction of nuclear power plants to cover all construction permits issued under § 50.23 for any production or utilization facility. This action will provide uniform reporting of defects and failures to comply associated with a substantial safety hazard found during construction for all production and utilization facilities. In summary, construction permit holders will be required to report under § 50.55(e) rather than under part 21.

For research reactors, (non-power reactors), which are currently covered by part 21, such facilities for which future construction permits are issued will report defects and non-compliance found during construction under § 50.55(e). No expansion of current reporting requirements is taking place. The regulation under which research reactors would report is being shifted from part 21 to § 50.55(e).

Special consideration has been given to those holders of construction permits issued prior to the effective date of these amendments. Section 50.55(e)(10), allows these construction permit holders to continue to report and evaluate defects under part 21 if they so choose. This provision is intended to avoid requiring these construction permit holders to change reporting procedures.

B. Part 21 and §§ 50.72 and 50.73

In the Supplementary Information for the proposed amendments published for public comment in November, 1988, (53 FR 44594) a brief discussion was presented on duplicate reporting by operating license holders under § 50.73

[Licensee Event Reports (LERs)] and part 21. The statement was made that § 50.73 would not be changed at this time and that the duplication of reporting was minimal for these two regulations. Licensee Event Reports and reports made under part 21 were reviewed for 1988. The amount of duplication was small. Approximately 55 percent of the part 21 reports submitted in 1988 were submitted by licensees. Of these, only a few were submitted by an LER.

Most of the respondents commenting on the proposed amendments stated that in actual practice there is some duplication of evaluation and reporting effort between part 21 and §§ 50.72 and 50.73 and many respondents urged the Commission to adopt amendments to §§ 50.72 and 50.73 at the same time as those for part 21.

Amendment of §§ 50.72 and 50.73 has been reconsidered. Other changes to §§ 50.72 and 50.73 unrelated to these issues are also under consideration and broad changes cannot be accomplished on a schedule consistent with the present changes to part 21 and § 50.55(e). A piecemeal approach would be burdensome and confusing. Hence, changes to §§ 50.72 and 50.73 to eliminate duplicate evaluation and reporting are not being made at this time. They are currently being evaluated.

To eliminate possible confusion created by the brief discussion in the Supplementary Information for the proposed amendments, the following discussion addresses the concerns raised by numerous commentors to the proposed rule, and describes the relationship between §§ 50.72 and 50.73 and part 21.

The criterion for reporting a defect under part 21 for nuclear reactors is that a deviation in a basic component under reasonably expected operational circumstances, including expected normal operation, transients, and design basis accidents, could create a substantial safety hazard. Basic components are plant structures, systems, or components necessary to ensure the (i) integrity of the reactor coolant pressure boundary; (ii) capability to shut down the reactor and keep it in a safe shutdown condition; or (iii) prevent or mitigate the consequences of an accident which could result in potential offsite exposures comparable to those referred to in § 100.11.

The criteria for determining the existence of a substantial safety hazard and, consequently, whether a defect is reportable under part 21 are given in NUREG-0302, Revision 1, "Remarks

Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR part 21) for Reporting of Defects and Noncompliance, July 12-26, 1977," as:

- Moderate exposure to or release of licensed material. Moderate exposure is further clarified as exposure in excess of 25 rem to the whole body and exposure to an individual in an unrestricted area of 0.5 rem;
- Major degradation of essential safety-related equipment. This phrase is considered to represent a loss of redundancy if, in conjunction with a single failure, a required safety function could not be performed; or
- Major deficiencies involving design, construction, inspection, test, or use. "Major deficiency" means a condition or circumstance which under normal operating conditions, an anticipated transient, or postulated design basis accident could contribute to exceeding a safety limit or cause an accident or in the event of an accident due to other causes could, considering an independent single failure, result in a loss of safety function necessary to mitigate the consequences of the accident.

For operating nuclear plants, events or conditions are reported under §§ 50.72 and 50.73. Basic components or services associated with basic components which are installed in the plant which have deviations and, thus, could be potential defects (i.e., could create substantial safety hazards), should be evaluated under appropriate criteria of §§ 50.72 and 50.73 to determine if the deviations are a reportable event or condition. That is, where deviations in basic components do produce potentially reportable events or conditions, the deviations should be evaluated under the criteria of §§ 50.72 and 50.73. Several paragraphs of §§ 50.72 and 50.73 contain criteria on reporting of possible defects and are comparable to the criteria for part 21. Section 50.73(a)(2)(ii) and the companion § 50.72(b)(1)(ii) provide the criteria:

Any event or condition that resulted in the condition of the nuclear power plant, including its principal safety barriers, being seriously degraded, or that resulted in the nuclear power plant being:

- (A) In an unanalyzed condition that significantly compromised plant safety;
- (B) In a condition that was outside the design basis of the plant; or
- (C) In a condition not covered by the plant's operating and emergency procedures.

Additionally, § 50.73(a)(2)(vii) provides the criteria:

Any event where a single cause or condition caused at least one independent

PART 21 • STATEMENTS OF CONSIDERATION

train or channel to become inoperable in multiple systems or two independent trains or channels to become inoperable in a single system designed to:

- (A) Shut down the reactor and maintain it in a safe shutdown condition;
- (B) Remove residual heat;
- (C) Control the release of radioactive material; or
- (D) Mitigate the consequences of an accident.

Substantial safety hazard evaluations of potential defects in basic components must consider failure of functionally redundant basic components in determining whether a loss of safety function could occur. A condition, circumstance, or deviation which could cause a failure of the functionally redundant component must be considered in evaluating potential losses of safety function or major reduction in the degree of protection provided the public health and safety.

This requirement is similar to § 50.72(b)(2)(iii) and § 50.73(a)(2)(v) and (vi):

(v) Any event or condition that alone could have prevented the fulfillment of a safety function of structures or systems that are needed to:

- (A) Shut down the reactor and maintain it in a safe shutdown condition;
- (B) Remove residual heat;
- (C) Control the release of radioactive material; or
- (D) Mitigate the consequences of an accident.

(vi) Events covered in paragraph (a)(2)(v) of this section may include one or more personnel errors, equipment failures, and/or discovery of design, analysis, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to this paragraph if redundant equipment in the same system was operable and available to perform the required safety function.

However, as discussed in NUREG-1022, "Licensee Event Report System", September, 1983, if a basic component contains a defect, and the defect could occur in the functionally redundant component, then this second failure must be considered in the evaluation of reportability. Thus, these two requirements, one in part 21 to include failure of the functionally redundant component in evaluation of a substantial safety hazard, and one in §§ 50.72 and 50.73 to include failure of the functionally redundant component, are compatible.

Operating license holders can reduce duplicate evaluation and reporting effort by evaluating deviations in basic components installed in operating plants which produce events which could meet the criteria of §§ 50.72 and 50.73. If the

evaluation of events using the criteria of §§ 50.72 or 50.73 results in a finding that the event is reportable and the event is reported via these sections, then as indicated in § 21.2(c), the evaluation, notification, recordkeeping, and reporting obligations of part 21 are met. If the event is determined not to be reportable under §§ 50.72 or 50.73, then the obligations of part 21 are met by the evaluation.

As indicated in the discussion of the substantial safety hazard criterion above, evaluation under the substantial safety hazard criteria requires evaluation of possibilities of events which, because of the defect in the basic component, would lead to a moderate exposure, a major degradation, or a major deficiency. This evaluation must include consideration of the defect in conjunction with the worst operational transient or design basis accident. This requirement is somewhat different than that in either § 50.72 or § 50.73. However, §§ 50.72 and 50.73, in the paragraphs discussed above, require explicit evaluation of loss of safety function. Such an evaluation would be adequate to determine if the safety function would be lost during the worst transient or accident.

As stated in § 21.2(c), the evaluation of the deviation in a basic component which causes an event which is evaluated using criteria of either §§ 50.72 or 50.73, satisfies the required evaluation and reporting requirements of part 21. Thus, to the extent possible by changing part 21, § 21.2(c) would explicitly relieve the officers and directors of holders of operating licenses under part 50 from the part 21 evaluation, notification, and reporting requirements if potential defects which produce events are evaluated and defects are reported under §§ 50.72 and 50.73. The reporting requirements associated with §§ 50.72 and 50.73 would be deemed to satisfy the corresponding requirements of part 21.

The defect reporting requirements of section 206 of the Energy Reorganization Act as amended would be met by part 50 operating licensees, for defects which produce reportable events, by reporting under appropriate paragraphs of §§ 50.72 and 50.73.

Even though the Commission need not be notified of defects more than once, where previously reported defects create reportable events as defined in §§ 50.72 and 50.73, these events must be reported pursuant to §§ 50.72 and 50.73 for each nuclear power plant facility licensed under part 50 where they occur. For licensees with more than one facility with an operating license, each containing the same defect, the

Commission need only be notified once of the defect. However, §§ 50.72 and 50.73 requires reports of any events associated with the defect for any facility at which they occur. There is no intention to eliminate any reporting currently required under §§ 50.72 or 50.73.

For utilities with two facilities, one with a construction permit and one with an operating license, each having the same defect, the Commission can be notified via appropriate reporting under §§ 50.72 and 50.73 for the operating plant if the defect creates a reportable event. This reporting will satisfy the requirements of §§ 50.72 and 50.73 for the operating plant and § 50.55(e) for the facility with a construction permit.

It should be noted, as stated in NUREC-0302, Revision 1, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR part 21) for Reporting of Defects and Noncompliance, July 12-26, 1977," October 1977, on pages 21.3(d)-1 and 21.3(d)-2, that deviations or potential defects discovered during receipt inspection are not reportable by the purchaser if the purchaser returns the basic component to the vendor for evaluation. If the purchaser chooses to keep the basic component because of unavailability of another component, or for whatever reason, then the purchaser should evaluate the potential defect under part 21.

Thus, one category of defects which will still be reported by power plant operating license holders under part 21 rather than §§ 50.72 and 50.73 are those defects discovered by licensees in equipment which has never been installed or used in the nuclear plant. Defects in these basic components cannot create situations which are reportable under § 50.72 or § 50.73 since these components cannot create a reportable event or condition. Basic components which are delivered and accepted by the purchaser but are not installed in the plant should be evaluated under part 21 and reported under part 21 if found to be reportable.

As a final point regarding the relationship between part 21 and §§ 50.72 and 50.73, since these sections are not being changed at this time, failures to comply associated with a substantial safety hazard should still be reported under part 21 by licensees.

C. Part 21 and § 73.71

Section 21.2(c) will explicitly relieve the officers and directors of holders of operating licenses under part 50 from the part 21 evaluation, notification, and reporting requirements when defects

PART 21 • STATEMENTS OF CONSIDERATION

associated with safeguards events are reported under § 73.71. The reporting requirements associated with § 73.71 would be deemed to satisfy the corresponding requirements of part 21.

D. Vendors

In addition to relief of licensees and construction permit holders, § 21.21(c)(2) relieves vendors subject to the reporting requirements of part 21 from reporting to the Commission. If the Commission has been previously notified of a defect under either part 21, §§ 50.73, 50.55(e), or § 73.71. That is, for any defect identified, evaluated, and for which the Commission has been notified by any entity under any of the four regulations, the related vendor will not be required to provide initial notification to the Commission. However, all entities covered by these regulations should be aware that the NRC will continue to evaluate notifications made to determine if additional information is required. If the Commission determines that additional information is required, the Commission will contact appropriate vendors, licensees, or construction permit holders under § 21.21(e), to obtain adequate information. Based on this information, the staff will then determine appropriate regulatory action. Such action may consist of direct contact or generic communication such as an Information Notice.

One commentator stated that the proposed amendments did not eliminate the requirement for contractors who perform evaluations for licensees or construction permit holders to report defects even though the defects were reported by licensees or construction permit holders. The following discussion is provided to clarify this issue. When a vendor (including architect-engineers or other service organizations) performs an evaluation of a deviation for a licensee or construction permit holder under the direction of the licensee and under contract, the reporting obligation lies with the licensee or construction permit holder. When the evaluation is complete, the evaluation satisfies the licensee's obligation under the regulations if either (1) the deviation is determined to be a defect and is reported or (2) the deviation is determined not to be reportable. Under the circumstances described here, the contractor has no reporting obligation provided the licensee fulfills its reporting obligation. If subsequent to the evaluation, the evaluating organization (vendor, architect-engineer, or service organization) discovers that the evaluation itself contained a defect, as opposed to the original deviation, then

the evaluating organization has the obligation to report the defect.

E. Enforcement

Responsible officers and directors of a part 50 construction permit or operating licensee would still be subject to the civil penalty provisions of section 206 (b) of the ERA as set forth in § 21.61 for the failure to notify the Commission of a defect or failure to comply. However, as noted above, notification under any one of these four regulations (part 21, §§ 50.55(e), 50.73, and 73.71) satisfies reporting obligations under section 206.

F. Relationship to Other Reporting Regulations

Several respondents commenting on the proposed amendments stated that the relationship of part 21 and § 50.55(e) to § 50.4, 50.9 and part 20 should be discussed in these amendments. Regarding § 50.9, the last sentence of § 50.9 states, "This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements."

Regarding § 50.4, which provides administrative details of written communications to the Commission, § 50.55(e) and part 21 contain their own written communication directions and reference to § 50.4 is not required. Review of part 20 indicates that no changes to the regulations are necessary.

Thus, based on the above discussions, §§ 50.72 and 50.73 will be used by operating license holders to report defects which create events or conditions reportable under these sections. Section 50.55(e) will be used by part 50 construction permit holders for reporting of defects and failures to comply associated with a substantial safety hazard discovered by construction permit holders or contractors hired by construction permit holders (or referred to construction permit holders by vendors who cannot evaluate the defect). Part 21 will be used by part 50 vendors and by materials licensees and their vendors covered under parts 30 through 35, 36, 40, 60, 61, 70, 71, and 72 to report defects and failures to comply associated with a substantial safety hazard. Part 50 non-power reactor operating license holders will use part 21 for reporting of defects and failures to comply associated with a substantial safety hazard. It should be noted that nuclear power plant operating license holders will still use 10 CFR part 21 to report failures to comply associated with a substantial safety hazard.

While no requirement is being placed in these regulations to require the notification of vendors of the existence of a defect by construction permit or operating license holders and no requirement is being placed in the regulations to require vendors to inform purchasers of a defect (unless the vendor cannot perform the evaluation of the potential defect), it is expected that licensees, construction permit holders, and vendors will continue to communicate about defects with each other. Entities covered by these regulations are encouraged to continue to communicate so that all appropriate entities will be aware of defects.

Research reactors with operating licenses will continue to report under part 21 since they are not subject to §§ 50.72 and 50.73.

2. Establishing Uniform Time Limits for Reporting

Both § 50.55(e) and part 21 currently require an initial notification and a follow-up written notification. In the case of part 21, if the initial notification was a written report, no follow-up notification is required. There are differences between the current part 21 and § 50.55(e) for the time limits for both these notifications. In order to improve consistency between the two regulations uniform time limits are being implemented.

Regarding the initial time limit, part 21 allows two days from the time the determination has been made that a defect exist. Currently § 50.55(e) requires the initial notification to be made in 24 hours. The final amendments to § 50.55(e) will extend the period for notification of the Commission under § 50.55(e) from one day to two days. In Petition for Rulemaking (PRM) 50-36, filed by the Nuclear Utility Backfitting and Reform Group (48 FR 28282), dated April 20, 1983, petitioners proposed revising § 50.55(e) reporting requirements to eliminate the 24 hour initial report (Issue III). Alternatively, the petition recommended adoption of a deadline of five days for an initial report. In addition to this PRM, four respondents commenting on the proposed amendments stated that the two-day notification was too short.

This final rule extends the initial reporting deadline under § 50.55(e) from 24 hours to two days. The Commission believes that the two-day requirement will provide industry with more flexibility while still allowing sufficient warning of safety problems and is consistent with the objective of establishing uniform reporting criteria. The Commission believes that the five-day recommendation proposed by PRM-

PART 21 • STATEMENTS OF CONSIDERATION

50-36 and recommended by the commentators mentioned above is too long considering staff's need to be provided with early notification of potentially generic conditions at construction permit facilities which could affect operating facilities. This two-day time limit will be consistent with the current part 21 time limit. Accordingly, the two-day time limit in the final rule addresses and resolves Issue III of PRM 50-36.

Additionally, the use of the same initial notification period for both part 21 and § 50.55(e) is consistent with the objective of establishing uniform reporting time frame.

In the current part 21, submittal of the required written report within the five day time limit has been difficult to accomplish. In addition, the incremental information available during the subsequent three day interval following the initial report does not provide a meaningful addition to the information already available to the Commission. The extension to 30 days for the time limit for submittal of the written followup report would allow submittal of a complete report. Thus, the final rule will change the time limit for submission of the required followup written report from five days to 30 days. This time limit for the written report submittal is consistent with that in § 50.55(e) and § 50.73.

3. Establishing Time Limit for Transfer of Information

Currently, § 21.21(e)(1)(ii) does not explicitly address time limits for transfer of information in situations for which vendors of basic components are unable to evaluate whether deficiencies or failures to comply could create substantial safety hazards. This inability to evaluate may be due to the vendor's lack of knowledge of how the basic component is utilized by the end user or for other reasons. The change to § 21.21(b) will explicitly add a time limit provision to correct this problem.

Two commentators stated that the five working day time limit was too short and was arbitrary. The Commission believes that the five day time limit is not arbitrary. It begins after the formal evaluation process has reached the conclusion that the vendor cannot determine if a defect exists. Additionally, this time period is comparable to the two day initial reporting requirement when a defect is determined to exist.

Thus, the final rule requires that if, during the evaluation period, the supplier which discovers a deviation or failure to comply that could potentially

create a substantial safety hazard determines that it is unable, due to insufficient information or other reasons, to perform the evaluation, then that entity must inform the purchasers of the "basic component" within five days of this determination.

Transfer of information from vendors to purchasers or affected licensees is expected to be a formal process which should involve records retention discussed below and will trigger the start of the evaluation process by the purchasers or affected licensees.

4. Defining Defects To Be Reported

Section 206 of the ERA requires the reporting of "defects which could create a substantial safety hazard." Existing § 21.3(k) defines substantial safety hazard as "a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to parts 30, 40, 50, 60, 61, 70, 71, or 72 * * *." In addition, the supplementary information for the original part 21 final rulemaking, June 6, 1977 (42 FR 2689), contained the following guidance on what constitutes a "substantial safety hazard":

- Moderate exposure to, or release of, licensed material, or
- Major degradation of essential safety-related equipment, or
- Major deficiencies involving design, construction, inspection, test, or use.

Existing § 50.55(e) requires the reporting of deficiencies in design and construction which could adversely affect the safety of operations of a nuclear power plant and which represent the following:

- A significant breakdown in any portion of the quality assurance program, or
- A significant deficiency in a final design, or
- A significant deficiency in the construction of, or significant damage to a structure, system, or component requiring corrective action involving extensive effort, or
- A significant deviation from performance specifications requiring corrective action involving extensive effort.

NRC experience with § 50.55(e) reports has indicated that clarification of the type of deviation that is required to be reported would be advantageous. Accordingly, the reporting criteria in § 50.55(e) are amended to be the same as those contained in part 21.

As stated above, duplication of evaluation and reporting has primarily been a problem for § 50.55(e) and part

21. This increase in the reporting threshold and extension of § 50.55(e) application to all construction permit holders will allow the Commission to obtain the proper level of reporting with no loss of significant safety information, i.e., the amendment raising the § 50.55(e) threshold will facilitate eliminating duplicate reporting by making the definition of defects reported under § 50.55(e) identical to those reported under part 21. This reduction of duplication will be accomplished with no loss in critical safety information and will reduce unnecessary industry burden.

It should be pointed out that a slight difference exists between the current definition of "deviation" in part 21 and that in the amendments to § 50.55(e). In the current part 21, "procurement documents" are specifically referred to as determining the requirements of a basic component. However, in § 50.55(e), procurement documents are not mentioned as determining these requirements. The basis for this difference is that in applying § 50.55(e), basic components will have requirements imposed on them not only by their procurement documents, but also by other licensee documents. In the case of part 21, application of the regulation to vendors will require the use of procurement documents to determine the requirements which the purchaser placed on the basic component.

5. Reporting Content

The final revisions to § 50.55(e)(6) will require the content of the information reported under § 50.55(e) to be consistent with that required by current § 21.21(b)(3). These revisions will assure that the Commission obtains all the information necessary to evaluate and take corrective action, in reference to a particular defect.

6. Clarification of "Basic Component"

Current § 21.3(a)(3), which clarifies items which are to be considered as "basic components," includes:

* * * design, inspection, testing, or consulting services important to safety that are associated with the component hardware whether these services are performed by the component supplier or others.

That paragraph is being modified to further clarify what is intended to be significant items. The terms "analysis," "fabrication," and "replacement parts," are being added to the definition of "basic component." The subsection is revised to read

* * * safety related design, analysis, inspection, testing, fabrication, replacement

PART 21 • STATEMENTS OF CONSIDERATION

parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

The proposed rule published November 4, 1988, for public comment contained the additional items "quality assurance," "training," and "maintenance" in the definition of basic component. These items have been eliminated from the definition based on public comment. Eleven commentors responding to the November 4, 1988 request for public comment stated that the additional items were not clarifications, but, actually expanded the scope of part 21 and § 50.55(e). One commentor stated that the addition of the items to the definition of basic component exceeded the legal authority granted the NRC by section 206 of the ERA. As discussed below, the legal authority provided in section 206 is not exceeded.

The Commission regards the additional items as clarification. The items "analysis," "fabrication," and "replacement parts" are clearly within the scope of the present part 21. They do not expand the scope of part 21.

The final amendments retain the coverage of significant quality assurance breakdowns in § 50.55(e). Such breakdowns in the quality assurance programs may not actually result in a defect being created in a basic component. However, such breakdowns may be severe enough or extensive enough to indicate that the overall program is deficient to the extent that the program itself represents a defect. In such cases, these programmatic breakdowns are reportable as defects because they could clearly have produced substantial safety hazards. Enforcement action resulting from reports of these quality assurance breakdowns will be consistent with ordinary enforcement policies.

Also, it should be noted that, as stated in the current definition of basic component in § 21.3(a)(1), "systems" are properly considered as "basic components." These systems are those systems which are safety-related. Examples are the auxiliary feedwater system for pressurized water reactors and the high pressure coolant injection system for boiling water reactors.

The Supplementary Information accompanying the proposed amendments discussed the reporting of the fire protection system and the security system defects under part 21. Seven commentors stated that fire and security systems were not safety related systems and that the components are purchased as commercial grade items.

Where fire and security systems are not basic components, defects are not reportable under part 21. However, to the extent that basic components are involved, defects in fire protection and security systems are reportable under part 21. In addition, a deficiency in either of these systems could produce a reportable event under § 50.72, 50.73 or § 73.71 even though a "basic component" is not involved.

In addition, vendors, construction permit holders, and licensees are encouraged to voluntarily report potential defects in components for these systems and in the systems themselves.

7. Clarifying Records Retention Requirements

Section 50.55(e)(9) in the final rule and final revisions to § 21.51 clarify the specific records that must be maintained and their retention period to assure compliance with the regulations. These include records of evaluations, including records of evaluations of deviations which were not judged to cause substantial safety hazards. These records are identical to records currently required to be retained under part 21 and § 50.55(e). Also, for vendors, notifications and a list of purchasers of basic components are required to be retained. Several commentors responding to the request for public comments stated that the requirement for vendors to retain a list of purchasers of basic components for the lifetime of the component was impractical. The main reason was that vendors did not know what happened to basic components in licensed facilities and, thus, did not know how long the lifetime would be. Additionally, since services are included in basic components, lifetime retention requirements for these components were difficult to implement because the lifetime of a service at a licensed facility was impossible for vendors to ascertain. The NRC has recent experience with records review performed as part of our regulatory function. Based on the above, the time period for retention of records of purchasers of basic components has been reduced to 10 years.

Some persons commenting on the proposed amendments also stated that the records requirements for evaluations and notifications should be discussed in more detail. The purpose of the requirement to retain evaluations for 5 years assures that vendors, licensees, and construction permit holders maintain records of evaluations of deviations which were found reportable and also those found not reportable. The records of notifications required to be

maintained under § 21.51 are notifications which vendors have sent informing purchasers or licensees that a deviation has been found and the vendor is unable to complete the substantial safety hazard evaluation.

Also based on public comments, clarifying phrases have been added to the records retention requirements. The phrase, "after the date of the evaluation" has been added to § 21.51(a)(1) and § 50.55(e)(9)(ii) to clarify this requirement. The phrases "after the date of the notification" and "after delivery" have been added to §§ 21.51(a)(2) and 21.51(a)(3) respectively to clarify these requirements.

8. Evaluation Time Limit

Under existing § 21.21(b)(2), the initial notification of a defect or failure to comply must be made to the NRC within two days of the time a director or responsible officer obtains information on the existence of a reportable defect. However, the existing rule is silent concerning the time period between the discovery of a potential defect and the time when an evaluation of the potential defect should be completed. Similarly, no deadline is established prescribing when the director or responsible officer must be informed of a potentially reportable defect.

In the proposed amendments published for public comment in November, 1988, no amendment to part 21 was proposed to prescribe a specific length of time allowed for the evaluation. However, a time period of 30 days was discussed as a reasonable time to complete evaluations in the Supplementary Information accompanying the proposed amendments published in November, 1988.

The Commission is aware of a number of cases where an inordinate length of time passed between the initial discovery of a potential defect and when the Commission was informed of the existence of a defect. In addition, NRC discussions held with utility personnel indicate that they generally believe a time limit for evaluations is necessary to ensure that defects or failures to comply which create substantial safety hazards are brought to the attention of the Commission. Also, section 206 of the ERA indicates that the Commission should be notified immediately of defects and failures to comply associated with a substantial safety hazard. Thus, in order to ensure consistency in the evaluation of the less complex issues, the final amendments to § 21.21(e)(1) require that, except in certain instances discussed below, the

PART 21 • STATEMENTS OF CONSIDERATION

evaluation of deviations be completed within 60 days after the date of discovery of the deviation. Instances of allowing long lapses in the evaluation process due to administrative problems or personnel absence must be avoided.

The final amendment to § 21.21(a)(3) also requires that a director or responsible officer be informed within 5 working days of completion of the evaluation identifying existence of a defect or failure to comply associated with a substantial safety hazard.

Over half of the persons responding to the proposed amendments published for public comment were concerned with the time limit for evaluation. Industry comments concerning the establishment of a specific time limit for evaluation were in general concerned that the 30 day period was insufficient to adequately evaluate more complex issues. The commentators stated that the time period would result in over-reporting of issues due to lack of adequate time for evaluation. Additionally, several commentators recommended that a reasonableness standard should be applied which was based on the complexity of the issue being evaluated.

In general, the Commission believes that most deviations should be evaluated within 60 days. However, the Commission agrees that there are deviations and failures to comply which require complex evaluations and, as such, an evaluation may not be completed within 60 days. When completion of the evaluation is not possible within the 60-day evaluation time limit, the amended § 21.21(b) would require that an "interim" written report be submitted within 60 days of the date of discovery. No telephonic (2 day) notification is required for interim reports.

The interim report must contain available information about the deviation or failure to comply describing it and contain a statement telling when the evaluation of the deviation or failure to comply will be completed.

Existing § 50.55(e) (2) and (3) establish time frames only for reporting. The final amendments to § 50.55(e)(1)(i) would require the holder of a construction permit to evaluate deviations within 60 days. As with final amendments to part 21, if completion of the evaluation is not possible within 60 days, the final amended § 50.55(e)(1)(ii) would require that an "interim" written report be submitted within 60 days of the date of discovery of the defect or failure to comply. The final amendment to § 50.55(e)(1)(iii) would require that a director or responsible officer be

informed within 5 working days after completion of the evaluation identifying a defect or failure to comply associated with a substantial safety hazard.

9. Other Changes

(a) For consistency with §§ 50.55(e) and 50.73, part 21 has been changed to direct correspondence to the Document Control Desk with appropriate copies. Also, telephone communications have been specifically directed to the NRC Operations Center. In addition, in part 21, the number of copies required to be submitted has been reduced by eliminating copies to specific NRC offices.

(b) Section 21.2, which sets forth the scope of part 21 coverage, has been revised to include part 60 facilities.

The existing rule already applies to part 60 licensees (as an entity licensed to possess, use, and/or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel) and to those entities that supply basic components for an activity licensed under part 60. The extension of part 21 to organizations that construct geologic repositories will complete the part 21 coverage by extending it to all the major activities or facilities licensed by the Commission.

(c) Additional changes to definitions in part 21 and § 50.2 for § 50.55(e) are being made in response to comments received. First, the definition of "construction" and "constructing" is being added to § 50.2. This definition was omitted from the previously published proposed amendment.

The definition of "discovery" is being added to the regulations. The time limit for evaluation of deviations and failures to comply begins on the date a deviation or failure to comply is discovered. Thus, in order to complete the documentation, some evaluation must take place to identify a deviation or failure to comply. Further, the "discovery" process is intended to be included in the procedures necessary to comply with part 21 or § 50.55(e).

The definition of "notification" is being added to part 21 and § 50.2 for § 50.55(e). The purpose of this addition is to clarify understanding that the Commission must be notified by vendors, construction permit holders and licensees by letter or telephone call. Second party information or word of mouth information to unspecified members of the NRC staff does not constitute notification.

(d) In response to public comment, § 50.55(e)(10)(iii) was added to ensure understanding that recordkeeping in

accordance with § 50.55(e) satisfies the requirements of part 21.

Environmental Impact: Categorical Exclusion

The NRC has determined that this regulation is the type of action described in categorical exclusion in § 51.22(c) (1) and (3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final regulation.

Paperwork Reduction Act Statement

The final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget approval numbers 3150-0011 and 3150-0035.

Public reporting burden for this collection of information is estimated to average 85 hours per part 21 response and 95 hours per § 50.55(e) response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Information and Records Management Branch (MNBB-7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-3019 (3150-0011 and 3150-0035), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission has prepared a regulatory analysis on the final regulation. The analysis identifies and examines the costs and benefits of the final regulation and its alternatives. The analysis is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW, (Lower Level), Washington, DC 20555. Single copies may be obtained from William R. Jones, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone (301) 492-4442.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b) et seq., the Commission certifies that this rule, will not have a significant economic impact on a substantial number of small entities. The revision to § 50.55(e) applies solely to the holders of construction permits issued under § 50.23, none of which can be

PART 21 • STATEMENTS OF CONSIDERATION

considered small entities. Although the revision to Part 21 could potentially affect a substantial number of small entities (see NRC size standards published December 9, 1985, 50 FR 50241) who supply basic components to NRC licensees, the economic impact on these firms is expected to be slight. Approximately 80 percent of the 300 annual nuclear-power-plant-related 10 CFR part 21 reports have been submitted by licensees; the remaining 20 percent have been submitted by nonlicensee suppliers and vendors. Section 21.2 eliminates duplicate reporting for those organizations subject to the defect reporting requirements, and therefore should reduce the economic impact on these organizations, including small businesses.

Backfit Analysis

The Commission has determined that the final rule, when effective, does not impose new safety reporting requirements on part 50 licensees. Therefore, a Backfit Analysis is not required for this final rule pursuant to § 50.109.

List of Subjects

10 CFR Part 21

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

10 CFR Part 50

Antitrust, Classified information penalty, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, 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 parts 21 and 50.

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS - ENERGY

**PART
21**

REPORTING OF DEFECTS AND NONCOMPLIANCE

PROPOSED RULE MAKING

➤ 53 FR 44594
Published 11/4/88
Comment period expires 1/3/89.

10 CFR Parts 21 and 50

Criteria And Procedures for the
Reporting of Defects

AGENCY: Nuclear Regulatory
Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission proposes to amend its regulations on the reporting of safety defects. The proposed revisions are a result of the Commission efforts to apply the experience gained as a result of the Three Mile Island accident and also reflect Commission experience to date with the existing regulations. The proposed amendments would be applicable to Commission licensees, and to nonlicensees who construct facilities for, or supply components to facilities or activities licensed by the Commission. The amendments would eliminate duplicative reporting of defects, clarify the criteria for reporting defects, and would establish uniform time periods for reporting and uniform requirements for the content of reports of defects.

DATES: Submit comments by January 3, 1989. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Submit written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Deliver comments to: 11555 Rockville Pike, Rockville, MD 20852 between 7:30 a.m. and 4:15 p.m. Federal workdays. Copies of comments received and the regulatory analysis may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT:
W.R. Jones, Office for Analysis and
Evaluation of Operational Data, U.S.
Nuclear Regulatory Commission,
Washington, DC 20555, Telephone: (301)
492-4442.

SUPPLEMENTARY INFORMATION:

Background

Existing Commission regulations contain several safety deficiency reporting requirements applicable to the construction and operation of nuclear power plants:

- 10 CFR Part 21 applies to all NRC licensees, as well as nonlicensees who construct facilities for or supply components to these licensees, and requires the reporting of defects that could create a "substantial safety hazard," as defined in regulations.
- 10 CFR 50.55(e) applies solely to the holders of construction permits and currently requires the reporting of "significant deviations" or "significant deficiencies" which could adversely affect safety.
- 10 CFR 50.72 and 50.73 establish reporting system that applies uniformly to all operating nuclear power plants. These regulations require the licensee to make prompt telephone notification to NRC and to submit a written report for each significant operating event or adverse plant condition. Section 50.73 replaced previous Licensee Event Report (LER) requirements in § 50.36.
- 10 CFR 73.71(c) applies to licensees and establishes a reporting system for security failure, degradations, or discovered vulnerability in a safeguard systems. As stated in § 73.71(c), a report under § 73.71(c) satisfies reporting requirements in both § 50.72 and 10 CFR Part 21.

Task II J.4 of the TMI Action Plan directed the NRC staff to evaluate and revise, if necessary, the existing requirements of 10 CFR Part 21 and § 50.55(e) to ensure prompt and comprehensive reporting. Over several years, the need for revision of these regulations has become apparent. Accordingly, based upon the staff experience with Part 21 and § 50.55(e), the proposed revision would:

1. Eliminate duplicative evaluation and reporting;
2. More clearly and uniformly define the defects that need to be reported under § 50.55(e).

PART 21 PROPOSED RULE MAKING

3. Establish consistent time limits for reporting;

4. Establish a time limit for transfer of information to end users when a substantial safety hazard determination is not possible;

5. Establish a uniform content for reporting for § 50.55(e) and Part 21; and

6. Make other more minor changes detailed below.

These revisions will reduce the amount of time and effort expended by industry in complying with existing reporting and evaluation requirements while still ensuring that safety deficiencies are identified and evaluated in a timely manner. The proposed revision is aimed at improving the evaluation and reporting of safety defects from the nuclear industry.

Part 21

Part 21 was intended to implement section 206 of the Energy Reorganization Act of 1974 (42 U.S.C. 5846). Section 206 requires directors and responsible officers of firms constructing, owning, operating, or supplying the components of any facility or activity licensed under the Atomic Energy Act to report to the Commission the discovery of "defects" in "basic components" that could create a "substantial safety hazard." The purpose of section 206 was to ensure that the Commission has prompt information concerning safety defects. In addition to imposing obligations on the directors and responsible officers of NRC licensees, section 206 also imposes obligations on the directors and responsible officers of nonlicensees that construct facilities for or supply components to licensed facilities or activities. Any individual officer or director who knowingly fails to comply with the notification requirements is subject to civil penalties.

On March 3, 1975, the NRC published a proposed rule designed to implement Section 206 (40 FR 8832), and on June 6, 1977, issued the final rule, adding Part 21 to the Commission's regulations (42 FR 28893).

The regulations in 10 CFR Part 21 impose reporting requirements on directors and responsible officers of firms constructing, owning, operating, or supplying components for any facility or activity licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended. Part 21 was amended on October 19, 1978 (43 FR 48721) to exempt "commercial grade items" from Part 21 until the items were "dedicated" for use as a basic component for a nuclear facility.

Approximately 12,000 organizations, licensees, and nonlicensees, are under the scope of Part 21 reporting requirements. Licensees include those granted licenses under the following parts: production and utilization facility licenses issued under 10 CFR Part 50, including nuclear power plants and research and test reactors at various stages in the licensing process; byproduct material licenses issued under Parts 30 through 35; source material licenses issued under Part 40; high-level radioactive waste disposal issued under Part 60; land disposal of radioactive waste issued under Part 61; special nuclear materials licenses issued under Part 70; the packaging of radioactive materials for transport under Part 71; and spent fuel storage under Part 72.

The nonlicensee suppliers covered under Part 21 are firms of many different sizes, supplying many different types of basic components and services to NRC licensees. For example, construction and operation of a nuclear power plant involves a many-level procurement chain. At the top of the chain is the electrical utility and the utility's major contractors such as the nuclear steam system supplier. The next level includes manufacturers who produce components specifically designed for nuclear use such as instrumentation, controls, major piping, pumps, and valves. These manufacturers in turn procure necessary parts, such as resistors, wiring, solid-state devices, and other hardware, from a multitude of sources. For nuclear power reactors, Part 21 applies to all tiers of the supply chain to all activities which could create a substantial safety hazard. Approximately 300 reports are submitted to the NRC annually under Part 21. These reports of potential safety problems have resulted in generic communications such as NRC bulletins, generic letters, and information notices, and have contributed to the overall improved safety of the nuclear industry.

Section 50.55(e)

Section 50.55(e) of 10 CFR Part 50, originally published as a final rule on March 30, 1972 (37 FR 6459), establishes requirements for reporting deficiencies occurring during the design and construction of nuclear power plants. The rule was designed to enable the NRC to receive prompt notification of deficiencies and to have timely information on which to base an evaluation of the potential safety consequences of the deficiency and determine if further regulatory action is required. Therefore, the holder of a permit for the construction of a nuclear power plant is required to notify the

Commission of each significant deficiency found in the processes of design and construction, which if it were to have remained uncorrected, could have adversely affected the safety of operations of the nuclear power plant at any time throughout the expected lifetime of the plant.

Approximately 900 reports are submitted to the NRC annually under § 50.55(e). As with Part 21, these § 50.55(e) reports have formed the basis for generic communications such as NRC bulletins, generic letters, and information notices and have also contributed to the overall improved safety of the nuclear industry.

The Proposed Action

1. Eliminating Duplicative Evaluation and Reporting Requirements. As stated above, Commission regulations contain several safety deficiency reporting requirements. Although distinctions exist between these requirements, staff experience indicates a need to eliminate duplication in reporting or evaluation among Part 21, § 50.55(e), and § 50.73. A number of instances have occurred where the same deficiency in a component was evaluated and reported by two different organizations, one attempting to satisfy the criteria of Part 21, and the other attempting to meet the differently worded criteria of § 50.55(e). The fact that the reporting criteria are different for each requirement and the lack of any explicit framework in the regulations to preclude duplicative reporting have led to duplication of both licensee and NRC staff effort.

The proposed revision to § 21.2 would relieve holders of construction permits under § 50.23 from their Part 21 evaluation, notification, and reporting responsibilities if they report a defect under § 50.55(e). The proposed revision to § 50.55(e) establishes the applicable evaluation and reporting procedures, as well as recordkeeping requirements, for construction permit holders. Compliance with these § 50.55(e) requirements would be deemed to satisfy the corresponding requirements of Part 21.

In order to make the reporting of defects found during construction consistent for all production or utilization facilities, the scope of § 50.55(e), which formerly covered only the construction of nuclear power plants, is being expanded to include all construction permits issued under § 50.23. Thus, the reporting of defects found during construction at these facilities would be shifted from 10 CFR Part 21 to § 50.55(e). These facilities were previously covered by Part 21. Thus, no increase in reporting

PART 21 PROPOSED RULE MAKING

requirement is being imposed on these facilities.

Likewise, proposed § 21.2 would explicitly relieve the officers and directors of the holders of operating licenses under Part 50 from the Part 21 evaluation, notification, and reporting requirements because defects will be reported by holders of operating licenses under § 50.73 or § 73.71. The reporting procedures and recordkeeping requirements currently in § 50.73, would be deemed to satisfy the corresponding requirements of Part 21.

Thus, the defect reporting requirements of section 206 of the Energy Reorganization Act would be met by Part 50 licensees by reporting under either § 50.55(e) or § 50.73, as appropriate. However, responsible officers and directors of a Part 50 licensee would still be subject to the civil penalty provisions of section 206(b) of the Energy Reorganization Act as set forth in § 21.61 for the failure to notify the NRC of a defect.

In addition, proposed revisions to § 21.21 would relieve vendors subject to the reporting requirements of Part 21 from reporting to the Commission under Part 21 if a defect has been previously reported under §§ 50.55(e), 50.73, or 73.71. That is, in proposed § 21.21(b)(2), for any defect identified, evaluated, and reported by a CP or OL holder pursuant to §§ 50.55(e), 50.73, or 73.71, the related vendor would not be required to provide a report.

Proposed § 50.55(e)(8) will relieve the holders of construction permits under Part 50 from reporting a defect if it has previously been reported under Part 21.

The NRC staff will continue to evaluate notifications made to NRC under Part 21, §§ 50.55(e), 50.72, 50.73 or 73.71. Where necessary, NRC staff will contact the licensee and appropriate vendor to obtain additional information. Additional vendor information obtained by NRC direct contact under the proposed amendment to § 21.21(c) would consist of information on additional locations of basic components containing the defect, corrective actions required, and advice provided to recipients of the basic components. Based on this information, the staff will then determine appropriate regulatory action. For cases in which the vendor notifies NRC and has not notified licensee purchasers, NRC would evaluate the need to notify licensees based on safety significance of the defect or noncompliance. Where warranted, NRC would notify the appropriate licensees, either directly or via a generic communication such as an Information Notice, of the existence of such a defect. NRC staff will evaluate

the need to notify vendors of a licensee notification, where warranted by the safety significance and generic aspects of the defect or noncompliance, in order that vendors are aware of the existence of a defect.

Relief for holders of operating licenses from reporting under § 50.73 similar to that in proposed § 50.55(e) outlined above will be implemented in the near future. However, the original intent of NRC defect reporting requirements was that reporting under only one of the requirements would satisfy the other requirements. Additionally, it should be noted that staff experience with reporting under § 50.73 indicates that there is minimal duplication between this section and Part 21 and § 50.55(e). The staff is currently reviewing the reporting experience with § 50.73 since it became effective in January 1984. Changes may be required as a result of this review and this issue will be addressed at that time.

The intent of these revisions is to establish the filing of one report by a vendor, operating license holder, or construction permit holder for each separate defect, with the reporting obligation resting on the entity that discovers the defect. It is intended that § 50.55(e) will be exclusively used for the reporting of defects discovered by construction permit holders (or referred to them by a vendor who is unable to evaluate the defect); and § 50.73 will be exclusively used for the reporting of defects discovered by the holders of operating licenses (or referred to them by a vendor who cannot evaluate the defect). Part 21 will be exclusively used for reporting defects discovered by materials licensees covered under Parts 30, 31, 34, 35, 40, 60, 61, 70, 71, 72; Part 50 licensees other than nuclear power plant licensees and holders of construction permits; and vendors involved in constructing or supplying components for any facility or activity licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended.

In order to facilitate the elimination of duplicate reporting, the proposed revision also establishes § 50.55(e) content similar to that contained in 10 CFR Part 21. It is anticipated that this proposed revision will significantly reduce the reporting burdens on the regulated industry, as well as improve the Commission staff evaluation of these reports, without any loss of relevant safety information.

In addition to the reporting of defects in basic components, Part 21 also requires the reporting of failures to comply with the Atomic Energy Act of

1954, as amended, or any applicable rule, regulation, order, or license of the Commission related to a substantial safety hazard. To further make reporting more consistent, holders of construction permits would notify the Commission of failures to comply under § 50.55(e) instead of Part 21 under the proposed amendments.

2. *Defining Defects To Be Reported.* Section 206 of the Energy Reorganization Act requires the reporting of "defects which could create a substantial safety hazard." Existing § 21.3(v) defines substantial safety hazard as "a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72." In addition, the supplementary information for the original Part 21 final rulemaking, June 6, 1977 (42 FR 2886), contained the following guidance on what constitutes a "substantial safety hazard":

- Moderate exposure to, or release of, licensed material, or
- Major degradation of essential safety-related equipment, or
- Major deficiencies involving design, construction, inspection, test, or use.

Existing § 50.55(e) requires the reporting of deficiencies in design and construction which could adversely affect the safety of operations of a nuclear power plant and which represent the following:

- A significant breakdown in any portion of the quality assurance program, or
- A significant deficiency in a final design, or
- A significant deficiency in the construction of, or significant damage to a structure, system, or component requiring corrective action involving extensive effort, or
- A significant deviation from performance specifications requiring corrective action involving extensive effort.

NRC experience with § 50.55(e) reports has indicated that clarification of the type of deviation that is required to be reported would be advantageous. Accordingly, the reporting criteria in proposed § 50.55(e) are the same as those contained in § 21.3.

This increase in the reporting threshold to all construction permit holders will allow the Commission to obtain the proper level of reporting with no loss of significant safety information, i.e., the proposed amendment raising the § 50.55(e) threshold will facilitate

PART 21 PROPOSED RULE MAKING

eliminating duplicative reporting by making the definition of defects reported under § 50.55(e) identical to those reported under Part 21. This elimination of duplication will be accomplished with no loss in critical safety information and will reduce unnecessary industry burden.

It should be pointed out that a slight difference exists between the current definition of "deviation" in Part 21 and that in the proposed § 50.55(e). In the current Part 21, "procurement documents" are specifically referred to as determining the requirements of a basic component. However, in § 50.55(e), procurement documents are not mentioned as determining these requirements. The basis for this difference is that in applying § 50.55(e), basic components will have requirements imposed on them not only by their procurement documents, but other licensee documents. In the case of Part 21, application of the regulation to vendors will require the use of procurement documents to determine the requirements which the purchaser placed on the basic component.

3. *Establishing Uniform Time Limits for Reporting.* In the current Part 21, submittal of the required written report within the five day time limit has been difficult to accomplish. In addition, the incremental information available during the subsequent 3 day interval following the initial report does not provide a meaningful addition to the information already available to the Commission. The proposed extension to 30 days for the time limit for submittal of the written followup report would allow submittal of a complete report. Also, addition of time limits for evaluation of defects will further ensure that the staff is informed regarding significant safety hazards. Thus, the proposed rule would change the time limit for submission of the required followup written report from five days to 30 days.

As outlined above, the proposed amendments would establish uniform reporting deadlines for Part 21 and § 50.55(e). Initial notification to the NRC is required within two days of identification of a defect. A difference exists between this requirement and § 50.72 where initial reporting of events or conditions is required within one to four hours depending on the event or condition. The staff believes this difference is justifiable in that § 50.72 reports involve problems at operating facilities for which remedial actions may be needed very quickly. Rapid notification is required because the NRC has a responsibility to respond rapidly to protect the health and safety of the

public when there is an event or condition that could pose a potential threat of a release of radiation above normal operating levels.

Part 21 reports by vendors and § 50.55(e) reports by construction permit holders, on the other hand, involve reporting of defects which could create a substantial safety hazard if a specific event or failure should occur. Although Part 21 and § 50.55(e) reports may involve generic substantial safety hazards, the relative risk of potential failures is less than the risks of failures evidenced by actual events or conditions of plants having operating licenses. Finally, the reporting experience with §§ 50.72 and 50.73 versus Part 21 and § 50.55(e) indicates that more issues which directly affect the health and safety of the public are discovered from analyses of operating reactor events than from Part 21 and § 50.55(e) reports. Accordingly, the staff has proposed a two-day initial reporting time limit for Part 21 and § 50.55(e) as an adequate means for providing sufficient warning of potential safety problems.

4. *Establishing Time Limit for Transfer of Information.* Currently, Part 21 (§ 21.21(a)(3)(ii)) does not explicitly address time limits for transfer of information in situations for which vendors or other suppliers of components are unable to evaluate whether deficiencies could create substantial safety hazards. This inability to evaluate may be due to the vendor's or supplier's lack of knowledge of how the component is utilized by the end user or for other reasons. The proposed change to Part 21 would explicitly add a time limit provision to correct this problem. The proposal would require that if, during the evaluation period, the entity which discovers a deviation that could potentially create a substantial safety hazard determines that it is unable, due to insufficient information or other reasons, to evaluate the deficiency, then that entity must notify the purchasers of the "basic component" within five days of this determination.

5. *Reporting Content.* Proposed revisions to § 50.55(e)(8) would require the content of the information reported under § 50.55(e) to be consistent with that required by § 21.21(b)(3). These revisions will ensure that the Commission obtains all the information necessary to evaluate and take corrective action, in reference to a particular defect.

6. *Other Changes.* In addition to these major revisions, minor changes are being proposed to improve the overall quality and coherence of Part 21 and § 50.55(e).

(a) The proposed revision to § 50.55(e) would extend the period for notification of the Commission from one day to two days. In Petition for Rulemaking (PRM) 50-36, filed by the Nuclear Utility Backfitting and Reform Group (48 FR 28282), dated April 20, 1983, petitioners propose revising 10 CFR 50.55(e) reporting requirements to delete the 24 hour initial report entirely (Issue III). Alternatively, the petition recommends adoption of a deadline of five days for an initial report. This proposed rulemaking extends the initial reporting deadline under § 50.55(e) from 24 to 48 hours. The staff believes that the proposed two-day requirement will provide industry with more flexibility while still allowing sufficient warning of safety problems and is consistent with the objective of establishing uniform reporting criteria. The staff agrees that the current § 50.55(e) initial reporting requirement may be restrictive; however, the five-day recommendation proposed by PRM-50-36 is believed to be too long considering staff's need to be provided with early notification of potentially generic conditions at construction permit facilities which could affect operating facilities. This time limit will be consistent with the current Part 21 time limit. Accordingly, the proposed two-day versus 24-hour current reporting requirement addresses and resolves Issue III of PRM 50-36.

(b) Proposed § 50.55(e)(7) and revisions to § 21.51 clarify the specific records that must be maintained and their retention period to ensure compliance. Retention of procurement documents would be retained either by the vendor or the purchaser of the basic component. The vendor would be required to retain a list of the purchasers of the basic component.

(c) For consistency with §§ 50.55(e) and 50.73, Part 21 would be changed to direct correspondence to the Document Control Desk with appropriate copies to regional and headquarters offices. Also, telephone communication has been specifically directed to the NRC Operations Center.

(d) Current § 21.3(e)(3), which clarifies items which are to be considered as "basic components," includes:

"design, inspection, testing, or consulting services important to safety."

That subsection is being modified to further clarify what are intended to be significant items. The proposed subsection would be revised to include:

"safety related design, analysis, inspection, testing, quality assurance, fabrication, training, maintenance, replacement parts, or consulting services that are associated with the

PART 21 PROPOSED RULE MAKING

basic component hardware whether these services are performed by the component supplier or others."

Also, it should be noted that, as stated in the current definition of basic component in § 21.3(a)(1), "systems" are properly considered as "basic components." These would include but not be limited to such "systems" as security and fire protection systems among other systems which can affect the safety of the facility. As an example, for power reactors, the rationale is that a defect or noncompliance in the security system is one which could allow access of an unauthorized individual into a vital area without being detected by the security system. The staff's view is that this represents a major reduction in the degree of protection afforded the health and safety of the public and is, therefore, a substantial safety hazard and would require notification.

These clarifications are consistent with current NRC practice and previous guidance provided in both NUREG 0302, Rev. 1: Remarks Presented at Public Regional Meetings to Discuss Regulations (10 CFR 21) for Reporting of Defects and Noncompliance, October, 1977; and in NRC Office of Inspection and Enforcement Information Notice 85-101: Applicability of 10 CFR 21 to Consulting Firms Providing Training.

(e) Section 21.2, which sets forth the scope of Part 21 coverage has been revised to include Part 60 facilities.

The existing rule already applies to Part 60 licensees (as an entity licensed to possess, use, and/or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel) and to those entities that supply basic components for an activity licensed under Part 60. The proposed extension of Part 21 to organizations that construct geologic repositories would complete the Part 21 coverage by extending it to all the major activities or facilities licensed by the Commission.

Timeliness of Evaluations

Under existing § 21.21(b)(2), the initial notification of a defect must be made to the NRC within *two days* of the time a director or responsible officer obtains information on the existence of a reportable defect. However, the existing rule is silent concerning the time period between the discovery of a potential defect and the time when an evaluation of the potential defect should be completed and the NRC notified. Similarly, no deadline is established for when the director or responsible officer must be informed of a potentially reportable defect. The Commission is

aware of a number of cases where an inordinate length of time passed between the initial discovery of a potential defect and when the Commission was informed. While no amendment is being proposed to set a time limit for evaluation of deviations, and informing directors or responsible corporate officers, and the NRC, in general, under most circumstances, 30 days is believed to be a reasonable time to evaluate deviations to determine if reportable defects exist. Should a more lengthy evaluation be required, it may indicate the need to report the potential defect.

Existing 10 CFR 50.55(e) (2) and (3) establish time frames only for the reporting of defects. Proposed § 50.55(e) would also require the holder of a construction permit to evaluate deviation within 30 days and extend initial notification of the Commission from 24 hours to two days. The extension of the initial notification time from 24 hours to 2 days in proposed 10 CFR 50.55(e), provides the industry with more flexibility, while still allowing sufficient warning of potential safety problems. The use of the same initial notification period for both 10 CFR Part 21 and 10 CFR 50.55(e) is consistent with the objective of establishing uniform reporting time frames.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis of the proposed regulation. The analysis identifies and examines the costs and benefits of the proposed regulation and its alternatives. The draft analysis is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW., Washington, DC 20555.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed regulation is the type of action described in categorical exclusions 10 CFR 50.22(c) (1) and (3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 107 hours per 10 CFR Part 21 response and 28 hours per § 50.55(e) response, including the time for reviewing instructions searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments

regarding this burden estimate or any other aspects of this collection of information, including suggestion for reducing this burden to Records and Reports Management Branch, Division of Information Support Services, Office of Administration and Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. The proposed revision to § 50.55(e) applies solely to the holders of construction permits issued under 10 CFR 50.23, none of which can be considered small entities. Although the proposed revision to Part 21 could potentially affect a substantial number of small entities (See NRC size standards published December 9, 1985, 50 FR 50241) who supply components to NRC licensees, the economic impact on these firms is expected to be slight. Approximately 80 percent of the 300 annual nuclear-power-plant-related Part 21 reports have in the past been submitted by licensees; the remaining 20 percent have been submitted by nonlicensed suppliers and vendors. Proposed § 21.2 eliminates duplicative reporting for those organizations subject to the defect reporting requirements, and therefore should reduce the economic impact on these organizations, including small businesses.

Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates the following:

(a) The size of their business and how the proposed regulations would result in significant economic burden upon them as compared to larger organizations in the same business community.

(b) How the proposed regulations could be modified to take into account their differing needs or capabilities.

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulations were modified as suggested by the commenter.

(d) How the proposed regulations, as modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to

PART 21 PROPOSED RULE MAKING

providing special advantages to any individuals or groups.

(e) How the proposed regulations, as modified, would still adequately protect the public health and safety.

The comments may be submitted to the NRC as indicated under the ADDRESSES heading.

Backfit Analysis

The Commission has determined that a backfit analysis is not required for this proposed rule, because these amendments do not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects

10 CFR Part 21

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

10 CFR Part 50

Antitrust, Classified information, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalty, Radiation protection, Reactor siting criteria, Reporting and record keeping 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 Parts 21 and 50.

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

1. The authority citation continues to read as follows:

Authority: Sec. 161, 68 Stat. 946, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2201, 2282); sec. 271, as amended, 206, 86 Stat. 1242, as amended, 1246 (42 U.S.C. 5841, 5846).

Section 21.2 also issued under Secs. 135, 141, Pub. L. 97-425, 90 Stat. 2232, 2242 (42 U.S.C. 10135, 10181).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 21.6, 21.21(a) and 21.31 are issued under sec. 161b, 68 Stat. 946, as amended (42 U.S.C. 2201(b)); and §§ 21.21, 21.41 and 21.51 are issued under sec. 161c, 68 Stat. 950, as amended (42 U.S.C. 2201(c)).

2. Section 21.2 is revised to read as follows:

§ 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise in Parts 31, 34, 35, 39, 40, 60, 61, 70, or 72 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess,

use, or transfer within the United States source material, byproduct material, special nuclear material, or spent fuel, or to construct, manufacture, possess, own, operate or transfer within the United States, any production or utilization facility or independent spent fuel storage installation, or a geologic repository for the disposal of high-level radioactive waste under Part 60 of this chapter; and to each director and responsible officer of such a licensee. The regulations in this part apply also to each individual, corporation,

partnership or other entity doing business within the United States, and each director and responsible officer of such organization, that constructs a production or utilization facility licensed for manufacture, construction, or operation pursuant to Part 50 of this chapter or an independent spent fuel storage installation for the storage of spent fuel licensed pursuant to Part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under Part 60 of this chapter; or who supplies basic components for a facility or activity licensed, other than for export, under Parts 30, 40, 50, 60, 61, 70, 71 or 72 of this chapter.

(b) For persons licensed to construct a facility under a construction permit issued under § 50.23 of this chapter, reporting defects under § 50.55(e) of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects under this part and the responsibility of individual directors and responsible officers of such licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

(c) For persons licensed to operate a nuclear power plant under Part 50 of this chapter, reporting defects under § 50.73 or § 73.71 of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects under this part and the responsibility of individual directors and responsible officers of such licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

(d) Nothing in these regulations should be deemed to preclude either an individual, a manufacturer, or a supplier of a commercial grade item (see § 21.3(a-1)) not subject to the regulations in this part from reporting to the Commission a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure.

(e) NRC regional offices and headquarters will accept collect telephone calls from individuals who wish to speak to NRC representatives

concerning nuclear safety-related problems. The location and telephone numbers of the five regions (answered during regular working hours), are listed in Appendix D to Part 20 of this chapter. The telephone number of the NRC Operations Center (answered 24 hours a day—including holidays) is (202) 951-0550.

3. In § 21.3 paragraphs (a)(3), (c) and (h) are revised to read as follows:

§ 21.3 Definitions.

(a) * * *
(3) In all cases, "basic component" includes safety related design, analysis, inspection, testing, quality assurance, fabrication, training, maintenance, replacement parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

(c) "Constructing" or "construction" means the design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are safety related.

(h) "Operating" or "operation" means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to operations that are safety related.

4. Section 21.5 is revised to read as follows:

§ 21.5 Communications.

Except where otherwise specified in this part, all written communications and reports concerning the regulations in this part should be addressed to the Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Additionally, if the communication is related to a nuclear power reactor, non-power reactor, or other utilization facility licensed under Part 50, a copy shall be sent to the Director, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555. If the communication is related to an activity licensed under Part 50 such as a fuel reprocessing plant or other production facility, a copy of the communication shall be sent to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington,

PART 21 PROPOSED RULE MAKING

DC 20555. A copy of communications related to activities licensed under Parts 30, 31, 34, 35, 40, 60, 61, 70, 71, or 72 must be sent to the Director, Office of Nuclear Material Safety and Safeguards. In the case of a licensee, a copy shall also be sent to the appropriate Regional Administrator at the address specified in Appendix D to Part 20 of this chapter.

5. In § 21.21, paragraphs (b)(2) through (b)(4) are redesignated (b)(3) through (b)(5); new paragraph (b)(2) is added; and the section heading and paragraphs (a), (b)(1), (b)(3) and (c) are revised to read 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 subject to the regulations in this part shall adopt appropriate procedures to—

(1) Evaluate deviations to identify defects as soon as practicable. If, during the evaluation period, the organization discovering the deviation determines that it does not have the capability to perform the evaluation, the organization shall notify the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation, pursuant to the applicable reporting regulation, and

(2) Ensure that a director or responsible officer is informed as soon as practicable, if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity—

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard, or

(ii) Contains a defect.

(b)(1) A director or responsible officer subject to the regulations of this part or a person designated under § 21.21(b)(5) shall notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting—

(i) The construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 60, 70, 71, or 72 of this chapter.

(2) The notification to NRC of a failure to comply or of a defect under

paragraph (b)(1) of this section, is not required if the director or responsible officer has actual knowledge that the Commission has been notified of the defect or the failure to comply.

(3) Notification required by paragraph (b)(1) of this section must be made as follows—

(i) Initial notification by telefax, which is the preferred method of notification, to the NRC Operations Center at 301-492-8187 or by telephone at 301-851-0550 within two days following receipt of information by the director or responsible corporate officer under paragraph (b)(1) of this section, on the identification of a defect or a failure to comply. Verification that the telefax has been received should be made by calling the NRC Operations Center.

(ii) Written notification to the NRC at the address specified in § 21.5 within 30 days following receipt of information by the director or responsible corporate officer under paragraph (a)(2) of this section, on the identification of a defect or a failure to comply.

(c) Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply. Such Commission action to obtain additional information may be based on reports of defects from other reporting entities.

§ 21.41 [Removed]

6. Section 21.41 is removed.

7. Section 21.51 is revised to read as follows:

§ 21.51 Maintenance and inspection of records.

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

(1) Retain evaluations of all deviations for a minimum of five years.

(2) Suppliers of basic components shall retain any notifications sent to purchasers and affected licensees for a minimum of five years.

(3) Suppliers of basic components shall retain a record of the purchasers of basic components for the lifetime of the basic component.

(b) Each individual, corporation, partnership, or other entity subject to the regulations in this part shall afford the Commission, at all reasonable times, the opportunity to inspect records pertaining to basic components that relate to the discovery, evaluation, and reporting of deviations and defects, including any advice given to purchasers or licensees on the placement, erection,

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

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

8. The authority citation for Part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 101, 182, 183, 186, 188, 68 Stat. 936, 937, 938, 946, 953, 954, 955, 956, and amended, sec. 232, 87 Stat. 1244, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2256, 2239, 2282); secs. 201, as amended, 202, 206, 68 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5641, 5642, 5646).

Section 50.7 also issued under Pub. L. 85-671, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 165, 68 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.25, 50.35, 50.55, 50.56 also issued under sec. 185, 66 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a, and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 68 Stat. 1245 (42 U.S.C. 5644). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 99 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80-50.81 also issued under sec. 184, 66 Stat. 954, as amended (42 U.S.C. 2234). Section 50.103 also issued under sec. 106, 66 Stat. 939, as amended (42 U.S.C. 2138). Appendix F also issued under sec. 187, 66 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 66 Stat. 956, as amended (42 U.S.C. 2273), §§ 50.10 (e), (b) and (c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 66 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 50.10 (b) and (c) and 50.54 are issued under sec. 161i, 66 Stat. 948, as amended (42 U.S.C. 2201(i)); and §§ 50.8, 50.55(e), 50.59(b), 50.70, 50.71, 50.72, 50.73, and 50.78 are issued under sec. 161o, 66 Stat. 950, as amended (42 U.S.C. 2201(o)).

9. Section 50.2 is amended by adding the following definitions in alphabetical order to read as follows:

§ 50.2 Definitions

"Basic component" means, for the purposes of § 50.55(e) of this chapter:

(1) When applied to nuclear power reactors, any plant structure, system, component, or part thereof necessary to ensure (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.

(2) When applied to other types of facilities or portions of such facilities for

PART 21 PROPOSED RULE MAKING

which construction permits are issued under § 50.23 of this chapter, a component, structure, system or part thereof that is directly procured by the construction permit holder for the facility subject to the regulations of this part and in which a defect could create a substantial safety hazard.

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

"Defect" means, for the purposes of § 50.55(e) of this chapter:

(1) A deviation in a basic component delivered to a purchaser for use in a facility or activity subject to a construction permit under this part, if on the basis of an evaluation, the deviation could create a substantial safety hazard at any time throughout the expected lifetime of the facility, were it to remain uncorrected or,

(2) The installation, use, or operation of a basic component containing a defect as defined in paragraph (1) of this definition; or

(3) A deviation in a portion of a facility subject to the construction permit of this part provided the deviation could, on the basis of an evaluation, create a substantial safety hazard at any time throughout the expected lifetime of the facility, were it to remain uncorrected.

"Deviation" means, for the purposes of § 50.55(e) of this chapter, a departure from the technical, quality assurance, or quality control requirements defined in procurement documents, safety analysis report, construction permit, or other documents provided for basic components installed in a facility subject to the regulations of this part.

"Director" means, for the purposes of § 50.55(e) of this chapter, an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity.

"Discovery" means, for the purposes of § 50.55(e) of this chapter, the first identification of a deviation by any individual within the organization.

"Evaluation" means, for the purposes of § 50.55(e) of this chapter, the process accomplished by or for a construction permit holder to determine whether a particular deviation could create a substantial safety hazard.

"Procurement document" means, for the purposes of § 50.55(e) of this chapter, a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

"Responsible officer" means, for the purposes of § 50.55(e) of this chapter, the president, vice-president, or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

"Substantial safety hazard" means, for the purposes of § 50.55(e) of this chapter, a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility of activity authorized by the construction permit issued under this part.

10. In § 50.55, paragraph (e) is revised to read as follows:

§ 50.55 Conditions of construction permits.

(e)(1) Each individual, corporation, partnership, or other entity holding a facility construction permit subject to this part shall adopt appropriate procedures to—

(i) Evaluate deviations as soon as practicable, and in all cases within 30 days discovery, in order to identify a reportable defect that could create a substantial safety hazard at any time throughout the expected lifetime of the plant were it to remain uncorrected.

(ii) Ensure that a director or responsible officer is informed as soon as practicable, and in all cases within the initial 30-day period allowed for evaluation of deviations pursuant to paragraph (e)(1)(i) of this section, if the construction of a facility or activity, or a basic component supplied for such facility or activity—

(A) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard, or

(B) Contains a defect.

(2) The holder of a facility construction permit subject to this part who obtains information reasonably indicating that the facility fails to comply with the Atomic Energy Act of 1954, as amended or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard shall notify the Commission through a director or

responsible officer of the failure to comply.

(3) The holder of a facility construction permit subject to this part shall notify the Commission through a director or responsible officer if the holder obtains information reasonably indicating the existence of any defect found in construction or any defect found in the final design of a facility as approved and released for construction.

(4) This notification requirement applies to all defects regardless of whether extensive evaluation, redesign, or repair is required to conform to the criteria and bases stated in the safety analysis report or construction permit. Reporting under this section satisfies the responsibility of individual directors or responsible officers of holders of construction permits issued under § 50.23 of this chapter to report defects under Section 206 of the Energy Reorganization Act and under 10 CFR Part 21.

(5) The notification required by paragraph (e)(3) of this section must consist of—

(i) Initial notification by telefax, which is the preferred method of notification, to the NRC Operations Center at 301-492-8187 or by telephone at 301-451-0550 within two days following receipt of information by the director or responsible corporate officer under paragraph (e)(1)(ii) of this section, on the identification of a defect or a failure to comply. Verification that the telefax has been received should be made by calling the NRC Operations Center.

(ii) Written notification submitted to the Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with a copy to the appropriate Regional Administrator at the address specified in Appendix D to Part 20 of this chapter, a copy to the appropriate NRC resident inspector within 30 days following receipt of information on the identification of a defect or failure to comply.

(iii) If insufficient information is available for a complete evaluation of a deviation or potential failure to comply within 30 days of discovery of the deviation, prepare and submit an interim report to the Commission that contains all available information, and a statement as to when a complete report will be filed. Submit the interim report within 30 days of discovery of the deviation.

(6) The written notification required by paragraphs (e)(5)(ii) and (iii) of this section must clearly indicate the notification is being submitted under paragraph (e) of this section and include

PART 21 PROPOSED RULE MAKING

the following information, to the extent known—

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which contains a defect or fails to comply.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at the facility subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to other entities.

(7) The holder of a construction permit shall prepare and maintain records necessary to accomplish the purposes of this section, specifically—

(i) Retain procurement documents, which define the requirements that facilities or basic components must meet in order to be considered acceptable, for the lifetime of the basic component.

(ii) Retain evaluations of all deviations for a minimum of five years.

(8) The requirements of this § 50.55(e) are deemed to be satisfied when the defect has been previously reported under Part 21 of this chapter or under § 50.73 of this part.

* * * * *

Dated at Rockville, MD, this 31st day of October 1988.

For the Nuclear Regulatory Commission,
Samuel J. Chilk,
Secretary of the Commission.

➤ 55 FR 50008
Published 12/4/90.
Comment period expires 3/4/91

Licenses and Radiation Safety
Requirements for Large Irradiators

See Part 36 Proposed Rule Making

this section shall not apply to individual packages of avocados weighing four pounds or less, net weight, in master containers.

Dated: July 25, 1991.

William J. Doyle,

Acting Deputy Director, Fruit and Vegetable Division.

[FR Doc. 91-18088 Filed 7-30-91; 8:47 am]

BILLING CODE 3410-93-M

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 21 and 50

RIN 3150-AA68

Criteria and Procedures for the Reporting of Defects and Conditions of Construction Permits

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations on the reporting of safety defects. The amendments are a result of the Commission efforts to apply the experience gained as a result of the Three Mile Island accident and also reflect Commission experience to date with the existing regulations. The amendments are applicable to Commission licensees, and to nonlicensees who construct facilities for, or supply basic components to facilities or activities licensed by the Commission. The amendments would reduce duplicate reporting of defects, clarify the criteria for reporting defects, and would establish uniform time periods for reporting and uniform requirements for the content of safety defect reports.

DATES: These amendments will be effective October 28, 1991.

FOR FURTHER INFORMATION CONTACT: W.R. Jones, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 492-4442.

SUPPLEMENTARY INFORMATION: On November 4, 1988, the Nuclear Regulatory Commission ("NRC" or "Commission") published in the Federal Register (53 FR 44594) for public comment proposed amendments to 10 CFR Part 21 (part 21), "Reporting of Defects and Noncompliance" and § 50.55 "Conditions of Construction Permits." The purpose of these proposed amendments was to reduce duplicate evaluation and reporting, establish

consistent time limits for reporting, establish a time limit for transfer of information from vendors to purchasers of basic components, more clearly define defects that must be reported and establish consistent content for reporting. Other minor changes were proposed.

Public comments regarding the proposed amendments were received from thirty-five respondents. These comments were received from segments of the nuclear industry as follows: Twenty-three were received from utilities; five, from law firms representing members of the nuclear industry; three, from owners groups; two, from architect/engineers; and two were received from vendors. These comments have been evaluated and, where appropriate, incorporated into the final regulations. The public comments are discussed below in connection with the final regulations.

A detailed analysis of the public comments has been prepared and is available for public inspection in the NRC Public Document Room.

Background

The existing regulations contain several safety deficiency reporting requirements that apply to the construction and operation of nuclear power plants:

—Part 21 applies to all NRC licensees, as well as nonlicensees who construct facilities for or supply basic components or services associated with basic components to these licensees, and implements section 206 of the Energy Reorganization Act of 1974, as amended (ERA), (42 U.S.C. 5841 et seq.), which requires the reporting of defects that could create a "substantial safety hazard," and failures to comply related to a "substantial safety hazard" as defined in regulations.

—Section 50.55(e) applies solely to the holders of construction permits and currently requires the reporting of "significant deviations" or "significant deficiencies" which could have an adverse effect upon safety if they remain uncorrected.

—Sections 50.72 and 50.73 establish an event reporting system that applies uniformly to all operating nuclear power plants. These regulations require the licensee to make prompt telephone notification to NRC and to submit a written report for each operating event or adverse plant condition. As discussed below, changes to §§ 50.72 and 50.73 are not being made at this time.

—Section 73.71 applies to licensees and establishes a reporting system for

safeguards events, including any security failure, degradation, or discovered vulnerability of a safeguards system. As stated in § 73.71, a report under § 73.71 satisfies reporting requirements in both §§ 50.72 and 50.73. Section 73.71 is not being changed at this time.

Task II J.4 of the TMI Action Plan directed the NRC staff to evaluate and revise, if necessary, the existing requirements of part 21 and § 50.55(e) to assure prompt and comprehensive reporting. Over several years, the need for revision of these regulations has become apparent. Accordingly, based upon the staff experience with part 21 and § 50.55(e), the final rule will:

1. Reduce duplicate evaluation and reporting;
2. Establish uniform time limits for reporting;
3. Establish a time limit for transfer of information to end users when a substantial safety hazard determination by vendors is not possible;
4. More clearly and uniformly define the defects that need to be reported under § 50.55(e);
5. Establish uniform content for reports submitted under § 50.55(e) and part 21;
6. Clarify the definition of "basic component;"
7. Clarify records retention requirements including the requirement for retention of records of evaluations of deviations that did not result in a finding of substantial safety hazard;
8. Establish time limits for evaluation of potential defects and failures to comply; and
9. Make other minor changes detailed below.

These revisions will reduce the amount of time and effort expended by industry in complying with existing reporting and evaluation requirements while still ensuring that safety deficiencies are identified and evaluated in a timely manner.

Part 21

Part 21 was intended to implement section 206 of the ERA. Section 206 requires directors and responsible officers of firms constructing, owning, operating, or supplying the basic components of any facility or activity licensed under the Atomic Energy Act of 1954, as amended, (AEA), (42 U.S.C. 2011 et seq.), to immediately report to the Commission the discovery of "defects" in "basic components" or failures to comply that could create a "substantial safety hazard." In addition to imposing obligations on the directors and responsible officers of NRC

licensees, section 206 of the ERA also imposes obligations on the directors and responsible officers of nonlicensees that construct facilities for or supply basic components to licensed facilities or activities. Any individual officer or director who knowingly fails to comply with the notification requirements is subject to civil penalties.

On March 3, 1975, the NRC published a proposed rule designed to implement section 206 (40 FR 8832), and on June 6, 1977, issued the final rule, adding part 21 to the Commission's regulations (42 FR 28893).

The regulations in part 21 impose reporting requirements on directors and responsible officers of firms which construct, own, operate, or supply basic components for any facility or activity licensed or otherwise regulated pursuant to the AEA or the ERA. Part 21 was amended on October 19, 1978 (43 FR 48721) to exempt "commercial grade items" from part 21 requirements until the items were "dedicated" for use as basic components in a nuclear facility.

Approximately 12,000 organizations, licensees, and nonlicensees, fall under the scope of part 21 reporting requirements. Part 21 covers licensees granted the following licenses: production and utilization facility licenses issued under part 50, including nuclear power plants and research and test reactors; byproduct material licenses issued under parts 30 through 35; well logging licenses issued under Part 39; source material licenses issued under Part 40; high-level radioactive waste disposal licenses issued under part 60; land disposal of radioactive waste licenses issued under part 61; special nuclear materials licenses issued under part 70; licenses for the packaging of radioactive materials for transport licenses issued under part 71; and spent fuel storage licenses issued under part 72.

The nonlicensee suppliers covered under part 21 are firms of many different sizes, supplying many different types of basic components and services associated with basic components to NRC licensees. For example, construction and operation of a nuclear power plant involves a many-level procurement chain. At the top of the chain is the electrical utility and the utility's major contractors such as the nuclear steam system supplier. The next level includes manufacturers who produce basic components specifically designed for nuclear use such as instrumentation, controls, major piping, pumps, and valves. These manufacturers in turn procure necessary parts, such as resistors, wiring, solid-state devices, and other hardware, from a multitude of

sources. For nuclear power reactors, part 21 applies to all tiers of the supply chain for basic components and to all activities which could create a substantial safety hazard. In the case of fuel cycle licensees and organizations supplying components to them, responsibility for complying with part 21 does not extend past the first tier of suppliers.

Approximately 300 reports have been submitted to the NRC annually under part 21. These reports of potential safety problems have resulted in generic communications such as NRC bulletins, generic letters, and information notices, and have contributed to the overall improved safety of the nuclear industry.

Section 50.55(e)

Section 50.55(e) of part 50, originally published as a final rule on March 30, 1972 (37 FR 6459), establishes requirements for reporting deficiencies occurring during the design and construction of nuclear power plants. The rule was designed to enable the NRC to receive prompt notification of deficiencies and to have timely information on which to base an evaluation of the potential safety consequences of the deficiency and determine whether regulatory action was required. Therefore, the holder of a permit for the construction of a nuclear power plant is required to notify the Commission of each significant deficiency found in design and construction, which if it were to have remained uncorrected, could have adversely affected the safety of operations of the nuclear power plant at any time throughout the expected lifetime of the plant.

Approximately 750 reports were submitted annually in the past to the NRC under § 50.55(e). As with part 21, these § 50.55(e) reports have formed the basis for generic communications such as NRC bulletins, generic letters, and information notices and have also contributed to the overall improved safety of the nuclear industry.

Action Being Taken

1. Reducing Duplicate Evaluation and Reporting Requirements

As stated above, the Commission regulations contain four different safety deficiency reporting requirements. Although distinctions exist between these requirements, staff experience indicates a need to reduce duplication in reporting or evaluation among part 21, and §§ 50.55(e), 50.72, 50.73, and 73.71.

Duplicate reporting has been primarily a problem for part 21 and § 50.55(e).

A. Part 21 and § 50.55(e)

A number of instances have occurred where the same deficiency in a basic component was evaluated and reported by two different organizations, one attempting to satisfy the criteria of part 21, and the other attempting to meet the differently worded criteria of § 50.55(e). The fact that reporting criteria are different for each requirement and that there is a lack of any explicit framework in the regulations to preclude duplicate reporting have led to duplication of both licensee and NRC staff effort. The revised rule makes the relationship between these two regulations straightforward. Construction permit holders will perform evaluations, report as appropriate, and keep records under § 50.55(e). If deviations are evaluated under § 50.55(e) and result in either a negative reportability determination or reportable defect, then this satisfies requirements of part 21.

Additionally, the scope of § 50.55(e) is being expanded from covering only the construction of nuclear power plants to cover all construction permits issued under § 50.23 for any production or utilization facility. This action will provide uniform reporting of defects and failures to comply associated with a substantial safety hazard found during construction for all production and utilization facilities. In summary, construction permit holders will be required to report under § 50.55(e) rather than under part 21.

For research reactors, (non-power reactors), which are currently covered by part 21, such facilities for which future construction permits are issued will report defects and non-compliance found during construction under § 50.55(e). No expansion of current reporting requirements is taking place. The regulation under which research reactors would report is being shifted from part 21 to § 50.55(e).

Special consideration has been given to those holders of construction permits issued prior to the effective date of these amendments. Section 50.55(e)(10), allows these construction permit holders to continue to report and evaluate defects under part 21 if they so choose. This provision is intended to avoid requiring these construction permit holders to change reporting procedures.

B. Part 21 and §§ 50.72 and 50.73

In the Supplementary Information for the proposed amendments published for public comment in November, 1988, (53 FR 44594) a brief discussion was presented on duplicate reporting by operating license holders under § 50.73

[Licensee Event Reports (LERs)] and part 21. The statement was made that § 50.73 would not be changed at this time and that the duplication of reporting was minimal for these two regulations. Licensee Event Reports and reports made under part 21 were reviewed for 1988. The amount of duplication was small. Approximately 55 percent of the part 21 reports submitted in 1988 were submitted by licensees. Of these, only a few were submitted by an LER.

Most of the respondents commenting on the proposed amendments stated that in actual practice there is some duplication of evaluation and reporting effort between part 21 and §§ 50.72 and 50.73 and many respondents urged the Commission to adopt amendments to §§ 50.72 and 50.73 at the same time as those for part 21.

Amendment of §§ 50.72 and 50.73 has been reconsidered. Other changes to §§ 50.72 and 50.73 unrelated to these issues are also under consideration and broad changes cannot be accomplished on a schedule consistent with the present changes to part 21 and § 50.55(e). A piecemeal approach would be burdensome and confusing. Hence, changes to §§ 50.72 and 50.73 to eliminate duplicate evaluation and reporting are not being made at this time. They are currently being evaluated.

To eliminate possible confusion created by the brief discussion in the Supplementary Information for the proposed amendments, the following discussion addresses the concerns raised by numerous commentors to the proposed rule, and describes the relationship between §§ 50.72 and 50.73 and part 21.

The criterion for reporting a defect under part 21 for nuclear reactors is that a deviation in a basic component under reasonably expected operational circumstances, including expected normal operation, transients, and design basis accidents, could create a substantial safety hazard. Basic components are plant structures, systems, or components necessary to ensure the (i) integrity of the reactor coolant pressure boundary; (ii) capability to shut down the reactor and keep it in a safe shutdown condition; or (iii) prevent or mitigate the consequences of an accident which could result in potential offsite exposures comparable to those referred to in § 100.11.

The criteria for determining the existence of a substantial safety hazard and, consequently, whether a defect is reportable under part 21 are given in NUREG-0302, Revision 1, "Remarks

Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR part 21) for Reporting of Defects and Noncompliance, July 12-26, 1977," as:

- Moderate exposure to or release of licensed material. Moderate exposure is further clarified as exposure in excess of 25 rem to the whole body and exposure to an individual in an unrestricted area of 0.5 rem;
- Major degradation of essential safety-related equipment. This phrase is considered to represent a loss of redundancy if, in conjunction with a single failure, a required safety function could not be performed; or
- Major deficiencies involving design, construction, inspection, test, or use. "Major deficiency" means a condition or circumstance which under normal operating conditions, an anticipated transient, or postulated design basis accident could contribute to exceeding a safety limit or cause an accident or in the event of an accident due to other causes could, considering an independent single failure, result in a loss of safety function necessary to mitigate the consequences of the accident.

For operating nuclear plants, events or conditions are reported under §§ 50.72 and 50.73. Basic components or services associated with basic components which are installed in the plant which have deviations and, thus, could be potential defects (i.e., could create substantial safety hazards), should be evaluated under appropriate criteria of §§ 50.72 and 50.73 to determine if the deviations are a reportable event or condition. That is, where deviations in basic components do produce potentially reportable events or conditions, the deviations should be evaluated under the criteria of §§ 50.72 and 50.73. Several paragraphs of §§ 50.72 and 50.73 contain criteria on reporting of possible defects and are comparable to the criteria for part 21. Section 50.73(a)(2)(ii) and the companion § 50.72(b)(1)(ii) provide the criteria:

Any event or condition that resulted in the condition of the nuclear power plant, including its principal safety barriers, being seriously degraded, or that resulted in the nuclear power plant being:

- (A) In an unanalyzed condition that significantly compromised plant safety;
- (B) In a condition that was outside the design basis of the plant; or
- (C) In a condition not covered by the plant's operating and emergency procedures.

Additionally, § 50.73(a)(2)(vii) provides the criteria:

Any event where a single cause or condition caused at least one independent

train or channel to become inoperable in multiple systems or two independent trains or channels to become inoperable in a single system designed to:

- (A) Shut down the reactor and maintain it in a safe shutdown condition;
- (B) Remove residual heat;
- (C) Control the release of radioactive material; or
- (D) Mitigate the consequences of an accident.

Substantial safety hazard evaluations of potential defects in basic components must consider failure of functionally redundant basic components in determining whether a loss of safety function could occur. A condition, circumstance, or deviation which could cause a failure of the functionally redundant component must be considered in evaluating potential losses of safety function or major reduction in the degree of protection provided the public health and safety.

This requirement is similar to § 50.72(b)(2)(iii) and § 50.73(a)(2)(v) and (vi):

(v) Any event or condition that alone could have prevented the fulfillment of a safety function of structures or systems that are needed to:

- (A) Shut down the reactor and maintain it in a safe shutdown condition;
- (B) Remove residual heat;
- (C) Control the release of radioactive material; or
- (D) Mitigate the consequences of an accident.

(vi) Events covered in paragraph (a)(2)(v) of this section may include one or more personnel errors, equipment failures, and/or discovery of design, analysis, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to this paragraph if redundant equipment in the same system was operable and available to perform the required safety function.

However, as discussed in NUREG-1022, "Licensee Event Report System", September, 1983, if a basic component contains a defect, and the defect could occur in the functionally redundant component, then this second failure must be considered in the evaluation of reportability. Thus, these two requirements, one in part 21 to include failure of the functionally redundant component in evaluation of a substantial safety hazard, and one in §§ 50.72 and 50.73 to include failure of the functionally redundant component, are compatible.

Operating license holders can reduce duplicate evaluation and reporting effort by evaluating deviations in basic components installed in operating plants which produce events which could meet the criteria of §§ 50.72 and 50.73. If the

evaluation of events using the criteria of §§ 50.72 or 50.73 results in a finding that the event is reportable and the event is reported via these sections, then as indicated in § 21.2(c), the evaluation, notification, recordkeeping, and reporting obligations of part 21 are met. If the event is determined not to be reportable under §§ 50.72 or 50.73, then the obligations of part 21 are met by the evaluation.

As indicated in the discussion of the substantial safety hazard criterion above, evaluation under the substantial safety hazard criteria requires evaluation of possibilities of events which, because of the defect in the basic component, would lead to a moderate exposure, a major degradation, or a major deficiency. This evaluation must include consideration of the defect in conjunction with the worst operational transient or design basis accident. This requirement is somewhat different than that in either § 50.72 or § 50.73. However, §§ 50.72 and 50.73, in the paragraphs discussed above, require explicit evaluation of loss of safety function. Such an evaluation would be adequate to determine if the safety function would be lost during the worst transient or accident.

As stated in § 21.2(c), the evaluation of the deviation in a basic component which causes an event which is evaluated using criteria of either §§ 50.72 or 50.73, satisfies the required evaluation and reporting requirements of part 21. Thus, to the extent possible by changing part 21, § 21.2(c) would explicitly relieve the officers and directors of holders of operating licenses under part 50 from the part 21 evaluation, notification, and reporting requirements if potential defects which produce events are evaluated and defects are reported under §§ 50.72 and 50.73. The reporting requirements associated with §§ 50.72 and 50.73 would be deemed to satisfy the corresponding requirements of part 21.

The defect reporting requirements of section 206 of the Energy Reorganization Act as amended would be met by part 50 operating licensees, for defects which produce reportable events, by reporting under appropriate paragraphs of §§ 50.72 and 50.73.

Even though the Commission need not be notified of defects more than once, where previously reported defects create reportable events as defined in §§ 50.72 and 50.73, these events must be reported pursuant to §§ 50.72 and 50.73 for each nuclear power plant facility licensed under part 50 where they occur. For licensees with more than one facility with an operating license, each containing the same defect, the

Commission need only be notified once of the defect. However, §§ 50.72 and 50.73 requires reports of any events associated with the defect for any facility at which they occur. There is no intention to eliminate any reporting currently required under §§ 50.72 or 50.73.

For utilities with two facilities, one with a construction permit and one with an operating license, each having the same defect, the Commission can be notified via appropriate reporting under §§ 50.72 and 50.73 for the operating plant if the defect creates a reportable event. This reporting will satisfy the requirements of §§ 50.72 and 50.73 for the operating plant and § 50.55(e) for the facility with a construction permit.

It should be noted, as stated in NUREG-0302, Revision 1, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR part 21) for Reporting of Defects and Noncompliance, July 12-28, 1977," October 1977, on pages 21.3(d)-1 and 21.3(d)-2, that deviations or potential defects discovered during receipt inspection are not reportable by the purchaser if the purchaser returns the basic component to the vendor for evaluation. If the purchaser chooses to keep the basic component because of unavailability of another component, or for whatever reason, then the purchaser should evaluate the potential defect under part 21.

Thus, one category of defects which will still be reported by power plant operating license holders under part 21 rather than §§ 50.72 and 50.73 are those defects discovered by licensees in equipment which has never been installed or used in the nuclear plant. Defects in these basic components cannot create situations which are reportable under § 50.72 or § 50.73 since these components cannot create a reportable event or condition. Basic components which are delivered and accepted by the purchaser but are not installed in the plant should be evaluated under part 21 and reported under part 21 if found to be reportable.

As a final point regarding the relationship between part 21 and §§ 50.72 and 50.73, since these sections are not being changed at this time, failures to comply associated with a substantial safety hazard should still be reported under part 21 by licensees.

C. Part 21 and § 73.71

Section 21.2(c) will explicitly relieve the officers and directors of holders of operating licenses under part 50 from the part 21 evaluation, notification, and reporting requirements when defects

associated with safeguards events are reported under § 73.71. The reporting requirements associated with § 73.71 would be deemed to satisfy the corresponding requirements of part 21.

D. Vendors

In addition to relief of licensees and construction permit holders, § 21.21(c)(2) relieves vendors subject to the reporting requirements of part 21 from reporting to the Commission, if the Commission has been previously notified of a defect under either part 21, §§ 50.73, 50.55(e), or § 73.71. That is, for any defect identified, evaluated, and for which the Commission has been notified by any entity under any of the four regulations, the related vendor will not be required to provide initial notification to the Commission. However, all entities covered by these regulations should be aware that the NRC will continue to evaluate notifications made to determine if additional information is required. If the Commission determines that additional information is required, the Commission will contact appropriate vendors, licensees, or construction permit holders under § 21.21(e), to obtain adequate information. Based on this information, the staff will then determine appropriate regulatory action. Such action may consist of direct contact or generic communication such as an Information Notice.

One commentator stated that the proposed amendments did not eliminate the requirement for contractors who perform evaluations for licensees or construction permit holders to report defects even though the defects were reported by licensees or construction permit holders. The following discussion is provided to clarify this issue. When a vendor (including architect-engineers or other service organizations) performs an evaluation of a deviation for a licensee or construction permit holder under the direction of the licensee and under contract, the reporting obligation lies with the licensee or construction permit holder. When the evaluation is complete, the evaluation satisfies the licensee's obligation under the regulations if either (1) the deviation is determined to be a defect and is reported or (2) the deviation is determined not to be reportable. Under the circumstances described here, the contractor has no reporting obligation provided the licensee fulfills its reporting obligation. If subsequent to the evaluation, the evaluating organization (vendor, architect-engineer, or service organization) discovers that the evaluation itself contained a defect, as opposed to the original deviation, then

the evaluating organization has the obligation to report the defect.

E. Enforcement

Responsible officers and directors of a part 50 construction permit or operating licensee would still be subject to the civil penalty provisions of section 206 (b) of the ERA as set forth in § 21.61 for the failure to notify the Commission of a defect or failure to comply. However, as noted above, notification under any one of these four regulations (part 21, §§ 50.55(e), 50.73, and 73.71) satisfies reporting obligations under section 206.

F. Relationship to Other Reporting Regulations

Several respondents commenting on the proposed amendments stated that the relationship of part 21 and § 50.55(e) to § 50.4, 50.9 and part 20 should be discussed in these amendments. Regarding § 50.9, the last sentence of § 50.9 states, "This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements."

Regarding § 50.4, which provides administrative details of written communications to the Commission, § 50.55(e) and part 21 contain their own written communication directions and reference to § 50.4 is not required. Review of part 20 indicates that no changes to the regulations are necessary.

Thus, based on the above discussions, §§ 50.72 and 50.73 will be used by operating license holders to report defects which create events or conditions reportable under these sections. Section 50.55(e) will be used by part 50 construction permit holders for reporting of defects and failures to comply associated with a substantial safety hazard discovered by construction permit holders or contractors hired by construction permit holders (or referred to construction permit holders by vendors who cannot evaluate the defect). Part 21 will be used by part 50 vendors and by materials licensees and their vendors covered under parts 30 through 35, 39, 40, 60, 61, 70, 71, and 72 to report defects and failures to comply associated with a substantial safety hazard. Part 50 non-power reactor operating license holders will use part 21 for reporting of defects and failures to comply associated with a substantial safety hazard. It should be noted that nuclear power plant operating license holders will still use 10 CFR part 21 to report failures to comply associated with a substantial safety hazard.

While no requirement is being placed in these regulations to require the notification of vendors of the existence of a defect by construction permit or operating license holders and no requirement is being placed in the regulations to require vendors to inform purchasers of a defect (unless the vendor cannot perform the evaluation of the potential defect), it is expected that licensees, construction permit holders, and vendors will continue to communicate about defects with each other. Entities covered by these regulations are encouraged to continue to communicate so that all appropriate entities will be aware of defects.

Research reactors with operating licenses will continue to report under part 21 since they are not subject to §§ 50.72 and 50.73.

2. Establishing Uniform Time Limits for Reporting

Both § 50.55(e) and part 21 currently require an initial notification and a follow-up written notification. In the case of part 21, if the initial notification was a written report, no followup notification is required. There are differences between the current part 21 and § 50.55(e) for the time limits for both these notifications. In order to improve consistency between the two regulations uniform time limits are being implemented.

Regarding the initial time limit, part 21 allows two days from the time the determination has been made that a defect exist. Currently § 50.55(e) requires the initial notification to be made in 24 hours. The final amendments to § 50.55(e) will extend the period for notification of the Commission under § 50.55(e) from one day to two days. In Petition for Rulemaking (PRM) 50-36, filed by the Nuclear Utility Backfitting and Reform Group (48 FR 28282), dated April 20, 1983, petitioners proposed revising § 50.55(e) reporting requirements to eliminate the 24 hour initial report (Issue III). Alternatively, the petition recommended adoption of a deadline of five days for an initial report. In addition to this PRM, four respondents commenting on the proposed amendments stated that the two-day notification was too short.

This final rule extends the initial reporting deadline under § 50.55(e) from 24 hours to two days. The Commission believes that the two-day requirement will provide industry with more flexibility while still allowing sufficient warning of safety problems and is consistent with the objective of establishing uniform reporting criteria. The Commission believes that the five-day recommendation proposed by PRM-

50-36 and recommended by the commentors mentioned above is too long considering staffs need to be provided with early notification of potentially generic conditions at construction permit facilities which could affect operating facilities. This two-day time limit will be consistent with the current part 21 time limit. Accordingly, the two-day time limit in the final rule addresses and resolves Issue III of PRM 50-36.

Additionally, the use of the same initial notification period for both part 21 and § 50.55(e) is consistent with the objective of establishing uniform reporting time frames.

In the current part 21, submittal of the required written report within the five day time limit has been difficult to accomplish. In addition, the incremental information available during the subsequent three day interval following the initial report does not provide a meaningful addition to the information already available to the Commission. The extension to 30 days for the time limit for submittal of the written followup report would allow submittal of a complete report. Thus, the final rule will change the time limit for submission of the required followup written report from five days to 30 days. This time limit for the written report submittal is consistent with that in § 50.55(e) and § 50.73.

3. Establishing Time Limit for Transfer of Information

Currently, § 21.21(a)(1)(ii) does not explicitly address time limits for transfer of information in situations for which vendors of basic components are unable to evaluate whether deficiencies or failures to comply could create substantial safety hazards. This inability to evaluate may be due to the vendor's lack of knowledge of how the basic component is utilized by the end user or for other reasons. The change to § 21.21(b) will explicitly add a time limit provision to correct this problem.

Two commentors stated that the five working day time limit was too short and was arbitrary. The Commission believes that the five day time limit is not arbitrary. It begins after the formal evaluation process has reached the conclusion that the vendor cannot determine if a defect exists. Additionally, this time period is comparable to the two day initial reporting requirement when a defect is determined to exist.

Thus, the final rule requires that if, during the evaluation period, the supplier which discovers a deviation or failure to comply that could potentially

create a substantial safety hazard determines that it is unable, due to insufficient information or other reasons, to perform the evaluation, then that entity must inform the purchasers of the "basic component" within five days of this determination.

Transfer of information from vendors to purchasers or affected licensees is expected to be a formal process which should involve records retention discussed below and will trigger the start of the evaluation process by the purchasers or affected licensees.

4. Defining Defects To Be Reported

Section 206 of the ERA requires the reporting of "defects which could create a substantial safety hazard." Existing § 21.3(k) defines substantial safety hazard as "a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to parts 30, 40, 50, 60, 61, 70, 71, or 72 * * *." In addition, the supplementary information for the original part 21 final rulemaking, June 6, 1977 (42 FR 2889), contained the following guidance on what constitutes a "substantial safety hazard":

- Moderate exposure to, or release of, licensed material, or
- Major degradation of essential safety-related equipment, or
- Major deficiencies involving design, construction, inspection, test, or use.

Existing § 50.55(e) requires the reporting of deficiencies in design and construction which could adversely affect the safety of operations of a nuclear power plant and which represent the following:

- A significant breakdown in any portion of the quality assurance program, or
- A significant deficiency in a final design, or
- A significant deficiency in the construction of, or significant damage to a structure, system, or component requiring corrective action involving extensive effort, or
- A significant deviation from performance specifications requiring corrective action involving extensive effort.

NRC experience with § 50.55(e) reports has indicated that clarification of the type of deviation that is required to be reported would be advantageous. Accordingly, the reporting criteria in § 50.55(e) are amended to be the same as those contained in part 21.

As stated above, duplication of evaluation and reporting has primarily been a problem for § 50.55(e) and part

21. This increase in the reporting threshold and extension of § 50.55(e) application to all construction permit holders will allow the Commission to obtain the proper level of reporting with no loss of significant safety information, i.e., the amendment raising the § 50.55(e) threshold will facilitate eliminating duplicate reporting by making the definition of defects reported under § 50.55(e) identical to those reported under part 21. This reduction of duplication will be accomplished with no loss in critical safety information and will reduce unnecessary industry burden.

It should be pointed out that a slight difference exists between the current definition of "deviation" in part 21 and that in the amendments to § 50.55(e). In the current part 21, "procurement documents" are specifically referred to as determining the requirements of a basic component. However, in § 50.55(e), procurement documents are not mentioned as determining these requirements. The basis for this difference is that in applying § 50.55(e), basic components will have requirements imposed on them not only by their procurement documents, but also by other licensee documents. In the case of part 21, application of the regulation to vendors will require the use of procurement documents to determine the requirements which the purchaser placed on the basic component.

5. Reporting Content

The final revisions to § 50.55(e)(8) will require the content of the information reported under § 50.55(e) to be consistent with that required by current § 21.21(b)(3). These revisions will assure that the Commission obtains all the information necessary to evaluate and take corrective action, in reference to a particular defect.

6. Clarification of "Basic Component"

Current § 21.3(a)(3), which clarifies items which are to be considered as "basic components," includes:

* * * design, inspection, testing, or consulting services important to safety that are associated with the component hardware whether these services are performed by the component supplier or others.

That paragraph is being modified to further clarify what is intended to be significant items. The terms "analysis," "fabrication," and "replacement parts," are being added to the definition of "basic component." The subsection is revised to read

* * * 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.

The proposed rule published November 4, 1988, for public comment contained the additional items "quality assurance," "training," and "maintenance" in the definition of basic component. These items have been eliminated from the definition based on public comment. Eleven commentors responding to the November 4, 1988 request for public comment stated that the additional items were not clarifications, but, actually expanded the scope of part 21 and § 50.55(e). One commentor stated that the addition of the items to the definition of basic component exceeded the legal authority granted the NRC by section 206 of the ERA. As discussed below, the legal authority provided in section 206 is not exceeded.

The Commission regards the additional items as clarification. The items "analysis," "fabrication," and "replacement parts" are clearly within the scope of the present part 21. They do not expand the scope of part 21.

The final amendments retain the coverage of significant quality assurance breakdowns in § 50.55(e). Such breakdowns in the quality assurance programs may not actually result in a defect being created in a basic component. However, such breakdowns may be severe enough or extensive enough to indicate that the overall program is deficient to the extent that the program itself represents a defect. In such cases, these programmatic breakdowns are reportable as defects because they could clearly have produced substantial safety hazards. Enforcement action resulting from reports of these quality assurance breakdowns will be consistent with ordinary enforcement policies.

Also, it should be noted that, as stated in the current definition of basic component in § 21.3(a)(1), "systems" are properly considered as "basic components." These systems are those systems which are safety-related. Examples are the auxiliary feedwater system for pre-saturated water reactors and the high pressure coolant injection system for boiling water reactors.

The Supplementary Information accompanying the proposed amendments discussed the reporting of the fire protection system and the security system defects under part 21. Seven commentors stated that fire and security systems were not safety related systems and that the components are purchased as commercial grade items

Where fire and security systems are not basic components, defects are not reportable under part 21. However, to the extent that basic components are involved, defects in fire protection and security systems are reportable under part 21. In addition, a deficiency in either of these systems could produce a reportable event under § 50.72, 50.73 or § 73.71 even though a "basic component" is not involved.

In addition, vendors, construction permit holders, and licensees are encouraged to voluntarily report potential defects in components for these systems and in the systems themselves.

7. Clarifying Records Retention Requirements

Section 50.55(e)(9) in the final rule and final revisions to § 21.51 clarify the specific records that must be maintained and their retention period to assure compliance with the regulations. These include records of evaluations, including records of evaluations of deviations which were not judged to cause substantial safety hazards. These records are identical to records currently required to be retained under part 21 and § 50.55(e). Also, for vendors, notifications and a list of purchasers of basic components are required to be retained. Several commentors responding to the request for public comments stated that the requirement for vendors to retain a list of purchasers of basic components for the lifetime of the component was impractical. The main reason was that vendors did not know what happened to basic components in licensed facilities and, thus, did not know how long the lifetime would be. Additionally, since services are included in basic components, lifetime retention requirements for these components were difficult to implement because the lifetime of a service at a licensed facility was impossible for vendors to ascertain. The NRC has recent experience with records review performed as part of our regulatory function. Based on the above, the time period for retention of records of purchasers of basic components has been reduced to 10 years.

Some persons commenting on the proposed amendments also stated that the records requirements for evaluations and notifications should be discussed in more detail. The purpose of the requirement to retain evaluations for 5 years assures that vendors, licensees, and construction permit holders maintain records of evaluations of deviations which were found reportable and also those found not reportable. The records of notifications required to be

maintained under § 21.51 are notifications which vendors have sent informing purchasers or licensees that a deviation has been found and the vendor is unable to complete the substantial safety hazard evaluation.

Also based on public comments, clarifying phrases have been added to the records retention requirements. The phrase, "after the date of the evaluation" has been added to § 21.51(a)(1) and § 50.55(e)(9)(ii) to clarify this requirement. The phrases "after the date of the notification" and "after delivery" have been added to §§ 21.51(a)(2) and 21.51(a)(3) respectively to clarify these requirements.

8. Evaluation Time Limit

Under existing § 21.21(b)(2), the initial notification of a defect or failure to comply must be made to the NRC within two days of the time a director or responsible officer obtains information on the existence of a reportable defect. However, the existing rule is silent concerning the time period between the discovery of a potential defect and the time when an evaluation of the potential defect should be completed. Similarly, no deadline is established prescribing when the director or responsible officer must be informed of a potentially reportable defect.

In the proposed amendments published for public comment in November, 1988, no amendment to part 21 was proposed to prescribe a specific length of time allowed for the evaluation. However, a time period of 30 days was discussed as a reasonable time to complete evaluations in the Supplementary Information accompanying the proposed amendments published in November, 1988.

The Commission is aware of a number of cases where an inordinate length of time passed between the initial discovery of a potential defect and when the Commission was informed of the existence of a defect. In addition, NRC discussions held with utility personnel indicate that they generally believe a time limit for evaluations is necessary to ensure that defects or failures to comply which create substantial safety hazards are brought to the attention of the Commission. Also, section 208 of the ERA indicates that the Commission should be notified immediately of defects and failures to comply associated with a substantial safety hazard. Thus, in order to ensure consistency in the evaluation of the less complex issues, the final amendments to § 21.21(a)(1) require that, except in certain instances discussed below, the

evaluation of deviations be completed within 60 days after the date of discovery of the deviation. Instances of allowing long lapses in the evaluation process due to administrative problems or personnel absence must be avoided.

The final amendment to § 21.21(a)(3) also requires that a director or responsible officer be informed within 5 working days of completion of the evaluation identifying existence of a defect or failure to comply associated with a substantial safety hazard.

Over half of the persons responding to the proposed amendments published for public comment were concerned with the time limit for evaluation. Industry comments concerning the establishment of a specific time limit for evaluation were in general concerned that the 30 day period was insufficient to adequately evaluate more complex issues. The commentors stated that the time period would result in over-reporting of issues due to lack of adequate time for evaluation. Additionally, several commentors recommended that a reasonableness standard should be applied which was based on the complexity of the issue being evaluated.

In general, the Commission believes that most deviations should be evaluated within 60 days. However, the Commission agrees that there are deviations and failures to comply which require complex evaluations and, as such, an evaluation might not be completed within 60 days. When completion of the evaluation is not possible within the 60-day evaluation time limit, the amended § 21.21(b) would require that an "interim" written report be submitted within 60 days of the date of discovery. No telephonic (2 day) notification is required for interim reports.

The interim report must contain available information about the deviation or failure to comply describing it and contain a statement telling when the evaluation of the deviation or failure to comply will be completed.

Existing § 50.55(e) (2) and (3) establish time frames only for reporting. The final amendments to § 50.55(e)(1)(i) would require the holder of a construction permit to evaluate deviations within 60 days. As with final amendments to part 21, if completion of the evaluation is not possible within 60 days, the final amended § 50.55(e)(1)(ii) would require that an "interim" written report be submitted within 60 days of the date of discovery of the defect or failure to comply. The final amendment to § 50.55(e)(1)(iii) would require that a director or responsible officer be

informed within 5 working days after completion of the evaluation identifying a defect or failure to comply associated with a substantial safety hazard.

B. Other Changes

(a) For consistency with §§ 50.55(e) and 50.73, part 21 has been changed to direct correspondence to the Document Control Desk with appropriate copies. Also, telephone communications have been specifically directed to the NRC Operations Center. In addition, in part 21, the number of copies required to be submitted has been reduced by eliminating copies to specific NRC offices.

(b) Section 21.2, which sets forth the scope of part 21 coverage, has been revised to include part 60 facilities.

The existing rule already applies to part 60 licensees (as an entity licensed to possess, use, and/or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel) and to those entities that supply basic components for an activity licensed under part 60. The extension of part 21 to organizations that construct geologic repositories will complete the part 21 coverage by extending it to all the major activities or facilities licensed by the Commission.

(c) Additional changes to definitions in part 21 and § 50.2 for § 50.55(e) are being made in response to comments received. First, the definition of "construction" and "constructing" is being added to § 50.2. This definition was omitted from the previously published proposed amendment.

The definition of "discovery" is being added to the regulations. The time limit for evaluation of deviations and failures to comply begins on the date a deviation or failure to comply is discovered. Thus, in order to complete the documentation, some evaluation must take place to identify a deviation or failure to comply. Further, the discovery process is intended to be included in the procedures necessary to comply with part 21 or § 50.55(e).

The definition of "notification" is being added to part 21 and § 50.2 for § 50.55(e). The purpose of this addition is to clarify understanding that the Commission must be notified by vendors, construction permit holders and licensees by letter or telephone call. Second party information or word of mouth information to unspecified members of the NRC staff does not constitute notification.

(d) In response to public comment, § 50.55(e)(10)(iii) was added to ensure understanding that recordkeeping in

accordance with § 50.55(e) satisfies the requirements of part 21.

Environmental Impact: Categorical Exclusion

The NRC has determined that this regulation is the type of action described in categorical exclusion in § 51.22(c) (1) and (3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final regulation.

Paperwork Reduction Act Statement

The final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget approval numbers 3150-0011 and 3150-0035.

Public reporting burden for this collection of information is estimated to average 95 hours per part 21 response and 95 hours per § 50.55(e) response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Information and Records Management Branch (MNBB-7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-3019 (3150-0011 and 3150-0035), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission has prepared a regulatory analysis on the final regulation. The analysis identifies and examines the costs and benefits of the final regulation and its alternatives. The analysis is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW, (Lower Level), Washington, DC 20555. Single copies may be obtained from William R. Jones, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone (301) 492-4442.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b) et seq., the Commission certifies that this rule, will not have a significant economic impact on a substantial number of small entities. The revision to § 50.55(e) applies solely to the holders of construction permits issued under § 50.23, none of which can be

considered small entities. Although the revision to Part 21 could potentially affect a substantial number of small entities (see NRC size standards published December 9, 1985, 50 FR 50241) who supply basic components to NRC licensees, the economic impact on these firms is expected to be slight. Approximately 80 percent of the 300 annual nuclear-power-plant-related 10 CFR part 21 reports have been submitted by licensees; the remaining 20 percent have been submitted by nonlicensee suppliers and vendors. Section 21.2 eliminates duplicate reporting for those organizations subject to the defect reporting requirements, and therefore should reduce the economic impact on these organizations, including small businesses.

Backfit Analysis

The Commission has determined that the final rule, when effective, does not impose new safety reporting requirements on part 50 licensees. Therefore, a Backfit Analysis is not required for this final rule pursuant to § 50.109.

List of Subjects

10 CFR Part 21

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

10 CFR Part 50

Antitrust, Classified information, Civil penalty, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, 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 parts 21 and 50.

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, 2262); 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, 98 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 21.6, 21.21(a) and 21.31 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and

§§ 21.21, 21.41 and 21.51 are issued under sec. 1610, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

Section 21.2 is revised to read as follows:

§ 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise in parts 31, 34, 35, 39, 40, 60, 61, 70, or part 72 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high level radioactive waste, or to construct, manufacture, possess, own, operate or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS); and to each director and responsible officer of such a licensee. The regulations in this part apply also to each individual, corporation, partnership or other entity doing business within the United States, and each director and responsible officer of such organization, that constructs a production or utilization facility licensed for manufacture, construction, or operation pursuant to part 50 of this chapter, an ISFSI for the storage of spent fuel licensed pursuant to part 72 of this chapter, a MRS for the storage of spent fuel or high level radioactive waste pursuant to part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under part 60 of this chapter; or supplies basic components for a facility or activity licensed, other than for export, under parts 30, 40, 50, 60, 61, 70, 71, or part 72 of this chapter.

(b) For persons licensed to construct a facility under a construction permit issued under § 50.23 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under § 50.55(e) of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects and failures to comply under this part and the responsibility of individual directors and responsible officers of such licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

(c) For persons licensed to operate a nuclear power plant under part 50 of this chapter, evaluation of potential defects and appropriate reporting of defects under §§ 50.72, 50.73 or § 73.71 of this chapter satisfies each person's evaluation, notification, and reporting

obligation to report defects under this part and the responsibility of individual directors and responsible officers of such licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

(d) Nothing in these regulations should be deemed to preclude either an individual, a manufacturer, or a supplier of a commercial grade item (see § 21.3(a-1)) not subject to the regulations in this part from reporting to the Commission, a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure. NRC regional offices and headquarters will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers of the five regions (answered during regular working hours), are listed in appendix D to part 20 of this chapter. The telephone number of the NRC Operations Center (answered 24 hours a day—including holidays) is (301) 951-0550.

3. In § 21.3 paragraphs (h) through (l) are redesignated as paragraphs (j) through (n); paragraph (g) is redesignated as paragraph (h); new paragraphs (g) and (i) are added; and paragraphs (a)(3) and (c), and newly redesignated (h) and (j) are revised to read as follows:

§ 21.3 Definitions.

(a) * * *

(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.

(c) *Constructing or construction* means the analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are safety related.

(g) *Discovery* means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21, (a).

(h) *Evaluation* means the process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

(i) *Notification* means the telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

(j) *Operating or operation* means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to operations that are safety related.

4. Section 21.5 is revised to read as follows:

§ 21.5 Communications.

Except where otherwise specified in this part, all written communications and reports concerning the regulations in this part must be addressed to the Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555. In the case of a licensee, a copy must also be sent to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter.

5. In § 21.21, paragraph (b)(1) is redesignated (c)(1); paragraphs (b)(2) through (b)(4) are redesignated (c)(3) through (c)(5); paragraph (c) is redesignated (d); new paragraphs (b) and (c)(2) are added; and the section heading and paragraphs (a), and newly designated (c)(1), (c)(3) and (d) are revised to read 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 subject to the regulations in this part must adopt appropriate procedures to—

(1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, and

(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or

responsible officer or designated person as discussed in § 21.21(c)(5). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(3) Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in § 21.21(a)(1) or § 21.21(a)(2) if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity—

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard, or

(ii) Contains a defect.

(b) If the deviation or failure to comply is discovered by a supplier of basic components or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to § 21.21(a).

(c)(1) A director or responsible officer subject to the regulations of this part or a person designated under § 21.21(c)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting—

(i) The construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter.

(2) The notification to NRC of a failure to comply or of a defect under paragraph (c)(1) of this section and the evaluation of a failure to comply or a defect under paragraphs (a)(1) and (a)(2) of this section, are not required if the director or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or the failure to comply

(3) Notification required by paragraph (c)(1) of this section must be made as follows—

(i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at 301-492-8187 or by telephone at 301-951-0550 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(1) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in § 21.21(a)(2).

(ii) Written notification to the NRC at the address specified in § 21.5 within 30 days following receipt of information by the director or responsible corporate officer under paragraph (a)(3) of this section, on the identification of a defect or a failure to comply.

(d) Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply. Commission action to obtain additional information may be based on reports of defects from other reporting entities.

6. Section 21.51 is revised to read as follows:

§ 21.51 Maintenance and inspection of records.

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

(1) Retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation;

(2) Suppliers of basic components must retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of the notification.

(3) Suppliers of basic components must retain a record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.

(b) Each individual, corporation, partnership, or other entity subject to the regulations in this part must afford the Commission, at all reasonable times, the opportunity to inspect records pertaining to basic components that relate to the discovery, evaluation, and reporting of deviations, failures to comply and defects, including any advice given to purchasers or licensees on the placement, erection, installation,

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

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

7. The authority citation for part 50 continues to read as follows:

Authority: Secs. 162, 103, 104, 105, 161, 162, 183, 186, 189, 88 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 88 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91-190, 83 Stat. 653 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 106, 88 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 88 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a, and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 653 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2236). Section 50.78 also issued under sec. 122, 88 Stat. 939 (42 U.S.C. 2152). Sections 50.80 through 50.81 also issued under sec. 184, 88 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 68 Stat. 953, as amended (42 U.S.C. 2273); §§ 50.46 (a) and (b), and 50.54(c) are issued under sec. 161b, 161i and 161o, 68 Stat. 948, as amended (42 U.S.C. 2201(b)). §§ 50.7(a), 50.10(a)-(c), 50.34 (a) and (e), 50.44(a)-(c), 50.46 (a) and (b), 50.47(b), 50.48 (a), (c), (d), and (e), 50.49(a), 50.54 (a), (i), (j)(1), (l)-(n), (p), (q), (t), (v), and (y), 50.55(f), 50.55e(a), (c)-(e), (g), and (h), 50.59(c), 50.60(a), 50.62(c), 50.64(b), and 50.80 (a) and (b) are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 50.49 (d), (h), and (j), 50.54 (w), (z), (bb), (cc), and (dd), 50.55(e), 50.59(b), 50.61(b), 50.62(b), 50.70(a), 50.71 (a)-(c) and (e), 50.72(a), 50.73 (a) and (b), 50.74, 50.78, and 50.80 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

8. Section 50.2 is amended by adding the following definitions in alphabetical order to read as follows:

§ 50.2 Definitions

Basic component means, for the purposes of § 50.55(e) of this chapter:

(1) When applied to nuclear power reactors, any 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.

(2) When applied to other types of facilities or portions of such facilities for which construction permits are issued under § 50.23, a component, structure, system or part thereof that is directly procured by the construction permit holder for the facility subject to the regulations of 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 parts, or consulting services that are associated with the component hardware, whether these services are performed by the component supplier or other supplier.

Construction or constructing means, for the purposes of § 50.55(e), the analysis, design, manufacture, fabrication, quality assurance, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are safety related.

Defect means, for the purposes of § 50.55(e) of this chapter:

(1) A deviation in a basic component delivered to a purchaser for use in a facility or activity subject to a construction permit under this part, if on the basis of an evaluation, the deviation could create a substantial safety hazard; or

(2) The installation, use, or operation of a basic component containing a defect as defined in paragraph (1) of this definition; or

(3) A deviation in a portion of a facility subject to the construction permit of this part provided the deviation could, on the basis of an evaluation, create a substantial safety hazard.

Deviation means, for the purposes of § 50.55(e) of this chapter, a departure from the technical or quality assurance requirements defined in procurement documents, safety analysis report, construction permit, or other documents provided for basic components installed

in a facility subject to the regulations of this part.

Director means, for the purposes of § 50.55(e) of this chapter, an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity.

Discovery means, for the purposes of § 50.55(e) of this chapter, the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 50.55(e)(1).

Evaluation means, for the purposes of § 50.55(e) of this chapter, the process of determining whether a particular deviation could create a substantial safety hazard or determining whether a failure to comply is associated with a substantial safety hazard.

Notification means the telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

Procurement document means, for the purposes of § 50.55(e) of this chapter, a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

Responsible officer means, for the purposes of § 50.55(e) of this chapter, the president, vice-president, or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

Substantial safety hazard means, for the purposes of § 50.55(e) of this chapter, a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity authorized by the construction permit issued under this part.

9. In § 50.55, paragraph (e) is revised to read as follows:

§ 50.55 Conditions of construction permits.

(e)(1) Each individual, corporation, partnership, or other entity holding a facility construction permit subject to this part must adopt appropriate procedures to—

(i) Evaluate deviations and failures to comply to identify defects and failures

to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (e)(1)(ii) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.

(ii) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in paragraph (e)(7) of this section. The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(iii) Ensure that a director or responsible officer of the holder of a facility construction permit subject to this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraph (e)(1)(i) or (e)(1)(ii) of this section, if the construction of a facility or activity, or a basic component supplied for such facility or activity—

(A) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard,

(B) Contains a defect, or

(C) Undergoes any significant breakdown in any portion of the quality assurance program conducted pursuant to the requirements of appendix B to 10 CFR part 50 which could have produced a defect in a basic component. Such breakdowns in the quality assurance program are reportable whether or not the breakdown actually resulted in a defect in a design approved and released for construction or installation.

(2) The holder of a facility construction permit subject to this part who obtains information reasonably indicating that the facility fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard must notify the Commission of the failure to comply through a director or responsible officer or designated person as discussed in paragraph (e)(7) of this section.

(3) The holder of a facility construction permit subject to this part who obtains information reasonably indicating the existence of any defect found in construction or any defect found in the final design of a facility as approved and released for construction must notify the Commission of the defect through a director or responsible officer or designated person as discussed in paragraph (e)(7) of this section.

(4) The holder of a facility construction permit subject to this part who obtains information reasonably indicating that the quality assurance program has undergone any significant breakdown discussed in paragraph (e)(1)(ii)(C) of this section must notify the Commission of the breakdown in the quality assurance program through a director or responsible officer or designated person as discussed in paragraph (e)(7) of this section.

(5) The notification requirements of paragraphs (e)(2), (e)(3), and (e)(4) of this section apply to all defects and failures to comply associated with a substantial safety hazard regardless of whether extensive evaluation, redesign, or repair is required to conform to the criteria and bases stated in the safety analysis report or construction permit. Evaluation of potential defects and failures to comply and reporting of defects and failures to comply under this section satisfies the construction permit holder's evaluation and notification obligations under part 21 of this chapter and, satisfies the responsibility of individual directors or responsible officers of holders of construction permits issued under § 50.23 of this chapter to report defects, and failures to comply associated with substantial safety hazards under section 206 of the Energy Reorganization Act of 1974.

(6) The notification required by paragraphs (e)(2), (e)(3), and (e)(4) of this section must consist of—

(i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at 301-492-8187 or by telephone at 301-951-0550 within two days following receipt of information by the director or responsible corporate officer under paragraph (e)(1)(iii) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in paragraph (e)(1)(ii).

(ii) Written notification submitted to the Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with a copy to

the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter and a copy to the appropriate NRC resident inspector within 30 days following receipt of information by the director or responsible corporate officer under paragraph (e)(1)(iii) of this section, on the identification of a defect or failure to comply.

(7) The director or responsible officer may authorize an individual to provide the notification required by this section, provided that this must not relieve the director or responsible officer of his or her responsibility under this section.

(8) The written notification required by paragraph (e)(6)(ii) of this section must clearly indicate that the written notification is being submitted under § 50.55(e) and include the following information, to the extent known—

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for the facility or the activity within the United States which contains a defect or fails to comply.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all the components in use at the facility subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to other entities.

(9) The holder of a construction permit must prepare and maintain records necessary to accomplish the purposes of this section, specifically—

(i) Retain procurement documents, which define the requirements that facilities or basic components must meet in order to be considered acceptable, for the lifetime of the basic component.

(ii) Retain evaluations of all deviations and failures to comply for a minimum of five years.

(iii) Maintaining records in accordance with this section satisfies the construction permit holders recordkeeping obligations under part 21 of this chapter. The recordkeeping obligations of responsible officers and directors under part 21 of this chapter are met by recordkeeping in accordance with this section.

(10) The requirements of this § 50.55(e) are satisfied when the defect or failure to comply associated with a substantial safety hazard has been previously reported under Part 21 of this chapter or under § 73.71 of this chapter under § 50.55(e) or § 50.73 of this part. For holders of construction permits issued prior to October 29, 1991, Evaluation, reporting and recordkeeping requirements of § 50.55(e) may be met by complying with the comparable requirements of Part 21 of this chapter.

Dated at Rockville, Md. this 24th day of July, 1991.

For the Nuclear Regulatory Commission,

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 91-17994 Filed 7-30-91; 8:45 am]

BILLING CODE 7580-01-8

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 21 and 25

[Docket No. NM-53; Special Conditions No. 25-ANM-45]

Special Conditions: British Aerospace Public Limited Company Model 4100 Airplane, Main Cabin Aisle Arrangement

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the British Aerospace, Public Limited Company (BAe), Model 4100 airplane. This airplane will have a novel or unusual design feature associated with the main cabin aisle arrangement. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this particular design feature. These special conditions contain the additional safety standards which the Administrator finds necessary to establish a level of safety equivalent to that established by the airworthiness standards of part 25 of the Federal Aviation Regulations (FAR)

EFFECTIVE DATE: August 30, 1991.