

Request for OMB Review

Important

Read instructions before completing form. Do not use the same SF 83 to request both an Executive Order 12291 review and approval under the Paperwork Reduction Act.

Answer all questions in Part I. If this request is for review under E.O. 12291, complete Part II and sign the regulatory certification. If this request is for approval under the Paperwork Reduction Act and 5 CFR 1320, skip Part II, complete Part III and sign the paperwork certification.

Send three copies of this form, the material to be reviewed, and for paperwork—three copies of the supporting statement, to:

Office of Information and Regulatory Affairs
Office of Management and Budget
Attention: Docket Library, Room 3201
Washington, DC 20503

PART I.—Complete This Part for All Requests.

1. Department/agency and Bureau/office originating request U.S. Nuclear Regulatory Commission	2. Agency code 3 1 5 0
3. Name of person who can best answer questions regarding this request William Jones	Telephone number (301) 492-4442
4. Title of information collection or rulemaking 10 CFR 21, Reporting of Defects and Noncompliance	

5. Legal authority for information collection or rule (cite United States Code, Public Law, or Executive Order)
42 USC 2201(o) or

5. Affected public (check all that apply)

1 <input type="checkbox"/> Individuals or households	3 <input type="checkbox"/> Farms	5 <input type="checkbox"/> Federal agencies or employees
2 <input type="checkbox"/> State or local governments	4 <input checked="" type="checkbox"/> Businesses or other for-profit	6 <input type="checkbox"/> Non-profit institutions
		7 <input checked="" type="checkbox"/> Small businesses or organizations

PART II.—Complete This Part Only if the Request is for OMB Review Under Executive Order 12291

7. Regulation Identifier Number (RIN)
____ or None assigned ☐

8. Type of submission (check one in each category)	Stage of development	Type of review requested
Classification		
1 <input type="checkbox"/> Major	1 <input type="checkbox"/> Proposed or draft	1 <input type="checkbox"/> Standard
2 <input type="checkbox"/> Nonmajor	2 <input type="checkbox"/> Final or interim final, with prior proposal	2 <input type="checkbox"/> Pending
	3 <input type="checkbox"/> Final or interim final, without prior proposal	3 <input type="checkbox"/> Emergency
		4 <input type="checkbox"/> Statutory or judicial deadline

9. CFR section affected
____ CFR

10. Does this regulation contain reporting or recordkeeping requirements that require OMB approval under the Paperwork Reduction Act and 5 CFR 1320? ☐ Yes ☐ No

11. If a major rule, is there a regulatory impact analysis attached? ☐ Yes ☐ No
If "No," did OMB waive the analysis? ☐ Yes ☐ No

Certification for Regulatory Submissions

In submitting this request for OMB review, the authorized regulatory contact and the program official certify that the requirements of E.O. 12291 and any applicable policy directives have been complied with.

Signature of program official	Date
Signature of authorized regulatory contact	Date

12. (OMB use only)

PART III.—Complete This Part Only if the Request is for Approval of a Collection of Information Under the Paperwork Reduction Act and 5 CFR 1320.

13. Abstract—Describe needs, uses and affected public in 50 words or less "Nuclear Facilities, Nuclear Reactors, Equipment"

This final rule change to 10 CFR 21.21 will clarify the procedures for reporting of defects and will reduce duplicative reporting, establish uniform time limits for reporting, and clarify records retention requirements.

14. Type of information collection (check only one)

Information collections not contained in rules

1 ☐ Regular submission

2 ☐ Emergency submission (certification attached)

Information collections contained in rules

3 ☐ Existing regulation (no change proposed)

6 Final or interim final without prior NPRM

4 ☐ Notice of proposed rulemaking (NPRM)

A ☐ Regular submission

5 ☒ Final, NPRM was previously published

B ☐ Emergency submission (certification attached)

7. Enter date of expected or actual Federal Register publication at this stage of rulemaking (month, day, year) _____

15. Type of review requested (check only one)

1 ☐ New collection

2 ☒ Revision of a currently approved collection

3 ☐ Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection

4 ☐ Reinstatement of a previously approved collection for which approval has expired

5 ☐ Existing collection in use without an OMB control number

16. Agency report form number(s) (include standard/optional form number(s))

N/A

22. Purpose of information collection (check as many as apply)

1 ☐ Application for benefits

2 ☐ Program evaluation

3 ☐ General purpose statistics

4 ☒ Regulatory or compliance

5 ☐ Program planning or management

6 ☐ Research

7 ☐ Audit

17. Annual reporting or disclosure burden

1 Number of respondents

100

2 Number of responses per respondent

2.2

3 Total annual responses (line 1 times line 2)

220

4 Hours per response

84.5

5 Total hours (line 3 times line 4)

18,600

18. Annual recordkeeping burden

1 Number of recordkeepers

100

2 Annual hours per recordkeeper

20

3 Total recordkeeping hours (line 1 times line 2)

1,995

4 Recordkeeping retention period

Life years

19. Total annual burden

1 Requested (line 17-5 plus line 18-3)

20,595

2 In current OMB inventory

27,988

3 Difference (line 1 less line 2)

- 7,393

Explanation of difference

4 Program change

- 7,393

5 Adjustment

20. Current (most recent) OMB control number or comment number

3150-0035

21. Requested expiration date

4/30/92

23. Frequency of recordkeeping or reporting (check all that apply)

1 ☒ Recordkeeping

Reporting

2 ☒ On occasion

3 ☐ Weekly

4 ☐ Monthly

5 ☐ Quarterly

6 ☐ Semi-annually

7 ☐ Annually

8 ☐ Biennially

9 ☐ Other (describe): _____

24. Respondents' obligation to comply (check the strongest obligation that applies)

1 ☐ Voluntary

2 ☐ Required to obtain or retain a benefit

3 ☒ Mandatory

25. Are the respondents primarily educational agencies or institutions or is the primary purpose of the collection related to Federal education programs? ☐ Yes ☒ No

26. Does the agency use sampling to select respondents or does the agency recommend or prescribe the use of sampling or statistical analysis by respondents? ☐ Yes ☒ No

27. Regulatory authority for the information collection

10 CFR 21

; or

FR

; or, Other (specify): _____

Paperwork Certification

In submitting this request for OMB approval, the agency head, the senior official or an authorized representative, certifies that the requirements of 5 CFR 1320, the Privacy Act, statistical standards or directives, and any other applicable information policy directives have been complied with.

Signature of program official

Date

Signature of agency head, the senior official or an authorized representative

Date

Gerald E. Cranford, DSO for Information Resources Management

June 5, 1991

OMB SUPPORTING STATEMENT
FOR PROPOSED AMENDMENTS TO 10 CFR PART 21,
REPORTING OF DEFECTS AND NONCOMPLIANCE AND
10 CFR 50.55(E), CONDITIONS OF CONSTRUCTION PERMITS

Description of Information Collection

10 CFR Part 21 requires directors and responsible officers of firms and organizations, building, operating, owning, or supplying safety-related components to NRC licensed facilities, or conducting NRC licensed activities, to report defects in components and failures to comply that could create a substantial safety hazard (SSH). 10 CFR 50.55(e) is being amended to require the holder of a facility construction permit to report any defect found in the final design or construction, or any significant breakdown in quality assurance program.

A. Justification

1. Need for the Collection of Information. Part 21 implements 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 basic components of any facility or activity licensed under the Atomic Energy Act to immediately report to the Commission the discovery of defects in basic components or failures to comply that could create a SSH. 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 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.

Section 50.55(e) of 10 CFR Part 50 establishes requirements for reporting deficiencies occurring during the design and construction of nuclear power plants. The regulation is 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 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 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.

The revisions to the exiting regulations have the following objectives:

- a. Reduce duplicative evaluation and reporting;
- b. Establish uniform time limits for evaluation, transfer of information, and reporting;
- c. More clearly and uniformly define the defects to be reported;
- d. Establish a uniform content for reporting; and
- e. Clarify records retention requirements.

The amendments contain reporting and recordkeeping requirements which are necessary in order that the NRC be informed of safety defects so that the agency can take appropriate regulatory action. Records are required to be maintained so that technical issues may be effectively resolved and for enforceability of the regulations. The Supplementary Information in the *Federal Register* notice starting on Page 6 of the rule provides the basis for this rulemaking action.

Section 21.21(a)(1) requires the vendor (not an NRC licensee), or licensee to evaluate deviations and failures to comply potentially causing an SSH to determine if the deviations or failures to comply could cause an SSH. Depending upon the outcome of the evaluation, the evaluation may be submitted to NRC as discussed under Section 21.21(c)(3)(ii) below.

Section 21.21(a)(2) requires that if the vendor (not an NRC licensee) or licensee cannot complete an evaluation of either the failure to comply or a potential defect within 60 days of its discovery, then, an interim written report should be submitted to the Commission describing the defect or the failure to comply. The report must be submitted within 70 days of discovery of the potential defect or the failure to comply.

Section 21.21(a)(3) requires that a director or responsible official of a company covered by 10 CFR Part 21 be notified within 5 days of the determination (based on the evaluation under Section 21.21(a)(1) above) that a defect or failure to comply associated with an SSH exists.

Section 21.21(b) requires that a vendor that cannot perform an evaluation of a deviation transmit information to the purchasers of basic components containing a deviation. The purchaser is then expected to evaluate the information as discussed under Section 21.21(a)(1) above.

Section 21.21(c)(3)(i) requires the Commission be notified by the vendor (not an NRC licensee) or licensee via telephone or facsimile within two days following receipt of information by a director or responsible office that a defect or failure to comply associated with an SSH hazard exists.

Section 21.21(c)(3)(ii) requires the submittal of a written report by the vendor (not an NRC licensee) or licensee to the Commission within 30 days of identification of a defect or failure to comply associated with an SSH. The report contents are defined in the current Section 21.21(b)(3).

Section 21.51(a)(1) requires vendors (these suppliers are not NRC licensees) or licensees to retain records of evaluations of deviations and failures to comply for 5 years from the date of the evaluation.

Section 21.51(a)(2) requires vendors (these suppliers are not NRC licensees) of components to retain notifications of potential defects or failures to comply that were sent to affected licensees for 5 years from the date of the notification.

Section 21.51(a)(3) requires vendors (these suppliers are not NRC licensees) of components to retain a record of purchasers of components for 10 years after delivery of the component.

Section 50.55(e)(1)(i) requires CP holders to evaluate deviations and failures to comply potentially causing an SSH to determine if the deviations or failures to comply could cause an SSH. Depending upon the outcome of the evaluation, the evaluation may be submitted to NRC as discussed under Section 50.55(e)(6)(ii) below.

Section 50.55(e)(1)(ii) requires that if the CP holder cannot complete an evaluation of the failure to comply or the potential defect within 60 days of its discovery, then an interim written report should be submitted to the Commission describing the defect or failure to comply. The report must be submitted within 70 days of discovery of the potential defect or failure to comply. The requirement to submit an interim report exists in the current subsection 50.55(e)(3)(ii). However, a specific time period for submittal has been added.

Section 50.55(e)(1)(iii) requires that a director or responsible official of a CP holder be notified within 5 days of the determination (based on the evaluation under Section 50.55(e)(1)(i) above) that a defect or failure to comply associated with an SSH exists.

Section 50.55(e)(6)(i) requires that the Commission be notified via telephone or facsimile within 2 days following receipt of

information by a director or responsible officer that a defect or failure to comply associated with an SSH hazard exists.

Section 50.55(e)(6)(ii) requires the submittal of a written report to the Commission within 30 days of identification of a defect or failure to comply associated with an SSH. The report contents are defined in Section 50.55(e)(8).

Section 50.55(e)(9)(i) requires CP holders to retain procurement documents (records) defining the requirements that facilities or basic components must meet for the lifetime of the basic component.

Section 50.55(e)(9)(ii) requires CP holders to retain records of evaluations of deviations and failures to comply for 5 years from the date of the evaluation.

2. Agency Use of the Information. Part 21 and Section 50.55(e) reports have contributed to improved safety of nuclear power plants and have resulted in NRC generic communications and NRC inspections. All reports received are reviewed and acted upon.
3. Reduction in Burden Through Information Technology. There are no legal obstacles to reducing the burden associated with this information collection. Industry organizations are urged to share and distribute such information to all affected parties as it becomes available. NRC disseminates significant generic information to all affected parties via generic communications. Elimination of duplicate reporting is encouraged. Automated systems for tracking reports are being used to the extent possible.
4. Effort to Identify Duplication. Commission regulations contain several safety deficiency reporting requirements. Although distinctions exist between these requirements, duplication of reporting has occurred. This rulemaking activity will reduce duplicate evaluation, reporting, and recordkeeping in the regulations.
5. Effort to Use Similar Information. There is no information identifying defects and failures to comply associated with SSHs which exists outside these regulations.
6. Efforts to Reduce Small Business Burden. No CP holders affected by Section 50.55(e) are small businesses. Licensees affected by Part 21 are not small businesses. A majority of the vendor/suppliers are not considered small businesses. This rulemaking activity will reduce the burden on the regulated industry.
7. Consequences of Less Frequent Collection. The rule requires reporting of defects or failures to comply which could create

SSHs. There is no specific periodic reporting. It is not possible to collect the required information less frequently without compromising the Commission's safety function.

8. Circumstances which Justify Variation from OMB Guidelines. Records are required to be retained beyond the 3 year limit established by OMB. This longer retention is required because review of recent experience with existing records in recent reviews indicates that a 3 year retention would not be adequate for review and evaluation of recurring defects. It is necessary to be able to verify that the deviation has adequately been evaluated and corrected as required. Records of evaluations are therefore retained for 5 years. Procurement documents have long been retained for the lifetime of the components. This is standard industry practice. It is necessary so that the records of component characteristics and performance can be reviewed when needed.
9. Consultations Outside NRC. The staff has utilized comments from the industry on the existing Part 21 and Section 50.55(e) and those received for this proposed rulemaking. In addition, the recommendations of the Presidential Commission on the Accident at Three Mile Island on the safety defect reporting system have also been considered and used as appropriate.
10. Confidentiality of Information. Information which is identified as proprietary, which by being disclosed will do substantial harm to an organization's competitive position, could be withheld from disclosure under a Freedom of Information Act request if the Commission determines that it is in the public interest to do so.
11. Justification for Sensitive Questions. The proposed and current rules do not request sensitive information.

12. Estimated Annualized Cost to the Federal Government.

<u>ACTIVITY</u>	<u>NRC ANNUAL BURDEN</u>		<u>COST (@ \$92/HR)</u>
	<u>HOURS PER SUBMITTAL</u>	<u>TOTAL HOURS</u>	
Review interim reports (20 per year)	7.5	150	\$ 13,800
Receive and review initial telephone FAX notification (400 per year)	2	800	\$ 73,600
Review written reports (400 per year)	8	3200	\$294,400
Review records of evaluations, transmittals, lists of purchasers, and procurement		2000	\$184,000
TOTAL BURDEN		6150	\$565,800

13. Estimate of Burden

Shown in Table I.

14. Reasons for Change in Burden. The burden estimated here represents a programmatic decrease in the burden hours estimated under the current clearance for this rulemaking. This is due to reduced number of duplicate reports compared to those historically submitted under the current rule. This decrease is due to the limitation of duplicate reporting. The estimate more accurately represents burden to respondents based on discussions with respondents and includes a correction and re-estimate of the actual burden imposed by current CFR requirements. There has been a historic decrease in the number of responses under both 10 CFR Part 21 and §50.55(e). This decrease is reflected in Table I.
15. Publication of Statistical Use. Data collected through this rule provides the input for generic information notices and bulletins. Each report is tabulated in a computerized data base and tracked to resolution. The data contained in the computerized system is not published except as it is reflected in notices and bulletins.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in the collection of information.

TABLE I
BURDEN (ANNUALIZED CHANGE)
REPORTING REQUIREMENTS

<u>SECTION</u>	<u>NUMBER SUBMITTALS ANNUALLY</u>	<u>HOURS PER SUBMITTAL</u>	<u>TOTAL HOURS</u>	<u>COST (\$92/HR)</u>
21.21(a)(1)	Covered under 21.21(c)(3)(ii)	--	--	--
21.21(a)(2)	20 interim reports per year-increase in burden	95	1900	\$174,800
21.21(a)(3)	Covered under 21.21(c)(3)(ii)	--	--	--
21.21(b)	Covered under 21.21(c)(3)(ii)	--	--	--
21.21(c)(3)(i)	100 fewer telephone or FAX notifications per year due to decrease in reporting and reduction in duplication	1	-100	(\$ 9,200)
21.21(c)(3)(ii)	100 fewer written reports per year due to decrease in reporting and reduction in duplication	75*	-7500	(\$690,000)
PART 21 REPORTING SUBTOTAL REDUCTION			-5700	(\$524,400)

* Use of average burden per response of 75 hours for this calculation accounts for change in burden from previous clearance.

TABLE I (cont.)
BURDEN (ANNUALIZED CHANGE)
REPORTING REQUIREMENTS

<u>SECTION</u>	<u>NUMBER SUBMITTALS ANNUALLY</u>	<u>HOURS PER SUBMITTAL</u>	<u>TOTAL HOURS</u>	<u>COST (@\$92/HR)</u>
50.55(e)(1)(i)	Covered under 50.55(e)(6)(ii)	--	--	--
50.55(e)(1)(ii)	20 interim reports per year-no increase over current reduction	0	0	\$ 0
50.55(e)(1)(iii)	Covered under 50.55(e)(6)(ii)	--	--	--
50.55(e)(6)(i)	50 fewer telephone or FAX notifications per year	1	-50	(\$ 4,600)
50.55(e)(6)(ii)	50 fewer written reports per year due to decrease in reporting and reduction in duplication	19*	-950	(\$ 87,400)
50.55(e) REPORTING SUBTOTAL REDUCTION			-1000	(\$ 92,000)
REPORTING SUBTOTAL (Part 21 and 50.55(e))			-6700	(\$616,400)

* Use of average burden per response of 19 hours for this calculation accounts for change in burden from previous clearance.

TABLE I (cont.)
BURDEN (ANNUALIZED CHANGE)
RECORDKEEPING REQUIREMENTS

<u>SECTION</u>	<u>NUMBER RECORDS RETAINED ANNUALLY</u>	<u>HOURS PER RECORD</u>	<u>TOTAL HOURS</u>	<u>COSTS (\$45/HR)</u>
21.51(a)(1)	340 EVALUATION RECORDS	0.375	-127.5	(\$ 5,738)
21.51(a)(2)	250 NOTIFICATIONS	0.375	- 93.75	(\$ 4,219)
21.51(a)(3)	11,500 PURCHASER DOCUMENTS	0.128	-1472	(\$ 66,240)
PART 21 REDUCTION SUBTOTAL			-1693.25	(\$ 76,196)
50.55(e)(9)(i)	0 PROCUREMENT DOCUMENTS*	0.15	0	
50.55(e)(9)(ii)	275 EVALUATION RECORDS	0.375	-103.125	(\$ 4,641)
50.55(e) REDUCTION SUBTOTAL			-103.125	(\$ 4,641)
OVERALL RECORDS RETENTION SUBTOTAL			-1796.375	(\$ 80,837)
OVERALL REDUCTION (REPORTING AND RECORDKEEPING)			-8496.375	(\$697,237)

* No reduction in procurement document retention is expected.

9. An indication of whether Section 3504(h), Pub. L. 96-511 applies: Applicable
10. Abstract: Proposed amendments to 10 CFR Part 21 and Section 50.55(e) rules will clarify the criteria and procedures for reporting of safety defects by licensees and nonlicensees. The proposed revised criteria and procedures to the existing rules would (1) reduce duplicate evaluation and reporting, (2) establish uniform time limits for evaluation, transfer of information, and reporting, (3) more clearly and uniformly define the defects to be reported, (4) establish a uniform content for reporting; and (5) clarify records retention requirements.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street, N.W. Lower Level, Washington, D.C. 20555.

Comments and questions can be directed by mail to the OMB reviewer:

Ronald Minsk
Office of Information and Regulatory Affairs, (3150-0011 and 3150-0035)
NEOB-3019
Office of Management and Budget
Washington, D.C. 20503.

Comments can also be submitted by telephone at (202) 395-3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 492-8132.

Dated at Bethesda, Maryland, this _____ day of _____, 1991.

For the Nuclear Regulatory Commission.

Gerald F. Cranford, Designated Senior
Official for Information Resources
Management

Distribution: See attached

*See previous concurrence:

ROAB	AEOD	C:ROAB
WJones:mmk	GThompson	JRosenthal
5/15/91*	5/20/91*	5/16/91*

OGC *Pyramid Reduction*
GM *Guino* IRM *CR*
6/3/91 GCranford
6/5/91

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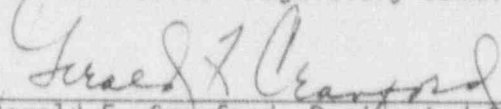
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Dated at Bethesda, Maryland, this 5th day of June, 1991.

For the Nuclear Regulatory Commission.


Gerald F. Cranford, Designated Senior
Official for Information Resources
Management

Distribution:

AAP EMB

subj-circ-chron

GCranford, IRM

GMizuno, OGC

SHudson, OC

BShelton, IRM

WJones, ROAB

JRosenthal, ROAB

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*See previous concurrence:

ROAB
WJones:mmk
5/15/91*

AEOD
GThompson
5/20/91

C:ROAB
JRosenthal
5/16/91*

OGC
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5/ /91

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subj-circ-chron

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WJones, ROAB

JRosenthal, ROAB

ROAB

WJones:mmk

5/15/91

AEOD

GThompson

5/ /91

ROAB

JRosenthal

5/16/91

OGC

GMizuno

5/ /91

IRM

PNorry

5/ /91

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping
Requirements: Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission (NRC)

ACTION: Notice of the OMB review of information collection

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of Paperwork Reduction Act (44 U.S.C. Chapter 35).

1. Type of submission, new, revision, or extension: Revision
2. Title of the information collection: 10 CFR 21, "Reporting of Defects and Noncompliance," and 10 CFR 50.55(e), "Reporting of Defects in Design and Construction."
3. The form number if applicable: Not applicable
4. How often the collection is required: On occasion
5. Who will be required or asked to report: NRC licensees and directors or responsible officers of non-licensees that supply components to licensed facilities or activities.
6. An estimate of the number of responses:
Part 21 - Reduction of 100 reports annually
§50.55(e) - Reduction of 50 reports annually
7. An estimate of the total number of hours needed to complete the requirements or request:
Part 21 - Reduction of 7393 hours per year
§50.55(e) - Reduction of 1103 hours per year
8. The average burden per response is: Part 21 - 95 hours
§50.55(e) - 95 hours

this action shall not apply to individual packages of exicator 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. 91-18008 Filed 7-30-91; 8:45 am]

BILLING CODE 3110-02-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 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

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

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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 8632), and on June 6, 1977, issued the final rule, adding part 21 to the Commission's regulations (42 FR 26893).

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 46721) 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 § 50.72 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: (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, therefore, 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 12-20, 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 the 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 defects were reported by a licensee or construction permit holder. 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 50 (b) of the ERA 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 28262), 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 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 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 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 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) or 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)(3), "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 commenters 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(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 flowing 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 commenters stated that the time period would result in over-reporting of issues due to lack of adequate time for evaluation. Additionally, several commenters 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(c) (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.

g. 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 1990 (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 1990, 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 § 50.73, 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, 85 Stat. 444, 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).

Section 21.2 also issued under secs. 135, 141, Pub. L. 97-425, 96 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, 60 Stat. 996, as amended (42 U.S.C. 2201(c)).

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, 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 paragraph (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. 102, 103, 104, 105, 161, 162, 163, 166, 169, 66 Stat. 930, 937, 938, 946, 953, 954, 955, 956, as amended, sec. 234, 63 Stat. 1244, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2262); sec. 201, as amended, 202, 206, 66 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, 165, 66 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91-190, 63 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 106, 66 Stat. 939, as amended (42 U.S.C. 2136). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 165, 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, 63 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 66 Stat. 1246 (42 U.S.C. 5844). Sections 50.56, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 66 Stat. 939 (42 U.S.C. 2152). Sections 50.80 through 50.81 also issued under sec. 164, 66 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 167, 66 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 66 Stat. 956, as amended (42 U.S.C. 2273): §§ 50.46 (a) and (b), and 50.54(c) are issued under sec. 161b, 161i and 161o, 66 Stat. 946, as amended (42 U.S.C. 2201(b)). §§ 50.7(e), 50.10(e)-(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), (j)(5), (p), (q), (r), (v), and (y), 50.55(f), 50.55a(e), (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, 66 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, 50.76, and 50.90 are issued under sec. 161o, 66 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 (c) 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 301-491-0550 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. Chalk,
Secretary of the Commission.
[FR Doc. 91-17994 Filed 7-30-91; 8:45 am]
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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.