

Request for OMB Review

DUPLICATE ORIGINAL

Smith

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

Roberta Ingram

Telephone number

301 504-1219

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)

6. Affected public (check all that apply)

1 ☐ Individuals or households

3 ☐ Farms

5 ☐ Federal agencies or employees

2 ☐ State or local governments

4 ☒ Businesses or other for-profit

6 ☐ Non-profit institutions

7 ☒ 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)

Classification

1 ☐ Major

2 ☐ Nonmajor

Stage of development

1 ☐ Proposed or draft

2 ☐ Final or interim final, with prior proposal

3 ☐ Final or interim final, without prior proposal

Type of review requested

1 ☐ Standard

2 ☐ Pending

3 ☐ Emergency

4 ☐ 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?

1 ☐ Yes 2 ☐ No

If "No," did OMB waive the analysis?

3 ☐ Yes 4 ☐ 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)

FOI
11

U.S. NUCLEAR REGULATORY COMMISSION

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

AGENCY: U.S. Nuclear Regulatory Commission (NRC)

ACTION: Notice of the Office of Management and Budget (OMB) review of
information collection.

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

1. Type of submission, new, revision, or extension:
Revision
2. The title of the information collection: 10 CFR Part
21, "Reporting of Defects and Noncompliance."
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: All directors and responsible officers of firms and organizations building, operating, or owning NRC licensed facilities as well as directors and responsible officers of firms and organizations supplying basic components and safety related design, analysis, testing, inspection, and consulting services to NRC licensed facilities or activities.
6. An estimate of the number of responses: 350 annually (150 initial notifications, 150 written reports, and 50 interim reports,
7. An estimate of the average burden hours per response: 66 hours
8. An estimate of the total number of hours needed to complete the requirement or request: 22,988 (19,300 reporting hours and 3,688 recordkeeping hours)
9. An indication of whether Section 3504(h), Pub. L. 96-511 applies: Not applicable

10. Abstract: 10 CFR Part 21 implements Section 206 of the Energy Reorganization Act of 1974, as amended. It requires directors and responsible officers of firms and organizations building, operating, owning, or supplying basic components to NRC licensed facilities or activities to report defects and noncompliances that could create a substantial safety hazard at NRC licensed facilities or activities. Organizations subject to 10 CFR Part 21 are also required to maintain such records as may be required to assure compliance with this regulation.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC 20555.

Comments and questions should be directed to the OMB reviewer:

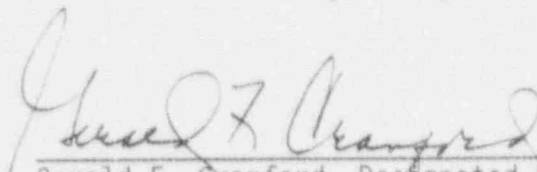
Ronald Minsk
Office of Information and Regulatory Affairs (3150-0035)
NEOB-3019
Office of Management and Budget
Washington, DC 20503

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 22th day of June 1992.

For the Nuclear Regulatory Commission

A handwritten signature in cursive script, appearing to read "Gerald F. Cranford".

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

SUPPORTING STATEMENT FOR 10 CFR PART 21,
"REPORTING OF DEFECTS AND NONCOMPLIANCE"

Description of the Information Collection

10 CFR Part 21.21 requires directors and responsible officers of firms and organizations building, operating, owning, or supplying basic 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 21.51 requires each organization subject to 10 CFR Part 21 to maintain such records as may be required to assure compliance with 10 CFR Part 21.

A. JUSTIFICATION

1. Need for the Collection of Information

Part 21, "Reporting of Defects and Noncompliance," 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.

Part 21 contains 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.

Section 21.21(a)(1) requires the vendor (not an NRC licensee) or licensee to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards. 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 or licensee cannot complete an evaluation of either the failure to comply or deviation within 60 days of its discovery, then an interim written report should be submitted to the Commission describing the deviation or the failure to comply. The report must be submitted within 60 days of discovery of the deviation 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 within 5 working days of the determination. 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 or licensee via telephone or facsimile within two 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 21.21(c)(3)(ii) requires the submittal of a written report by the vendor 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 Section 21.21(c)(4).

Section 21.21(d) provides for the Commission to obtain from individuals subject to 10 CFR Part 21 any needed additional information related to a defect or failure to comply.

Section 21.51(a)(1) requires vendors 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 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 of components to retain a record of purchasers of components for 10 years after delivery of the component.

2. Agency Use of Information

10 CFR Part 21 reports are reviewed by the NRC staff to determine whether the reported defects or noncompliances in basic components at NRC licensed facilities or activities are potentially generic safety problems. These reports have been the basis for the issuance of numerous NRC information notices, generic letters and bulletins that have contributed to the improved safety of the nuclear industry.

The records required to be maintained in accordance with 10 CFR 21.51 are subject to inspection by the NRC to determine compliance with the subject regulation. These records fall into four categories: records relating to evaluations defined by 10 CFR 21.3, records of previously submitted reports pursuant to 10 CFR 21.21, records of procedures required to assure compliance with 10 CFR Part 21, and procurement documents necessary to ensure that background specifications are available to evaluate potential defects and noncompliances.

Industry organizations, such as the Institute for Nuclear Operations (INPO) and the Nuclear Management and Resources Council (NUMARC), are urged to share and distribute such information to all affected parties as it becomes available. The NRC further disseminates significant generic information to all affected parties via NRC information notices, generic letters, and bulletins and encourages the elimination of duplicate reporting. Computer databases are used extensively by the NRC and the nuclear industry for tracking these reports.

3. Reduction of 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. 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. Distinctions exist between these requirements. The revised 10 CFR Part 21 which became effective October 29, 1991, clarified the reporting and evaluation requirements to reduce duplication among 10 CFR Part 21, 10 CFR Part 50.55(e), 10 CFR Part 50.72, 10 CFR Part 50.73 and 10 CFR Part 73.71.

5. Effort to Use Similar Information

10 CFR Part 21 implements Section 206 of the Energy Reorganization Act of 1974, as amended (U.S.C. 5846). It is the only regulation that currently requires directors and responsible officers of firms and organizations building, operating, or owning NRC licensed facilities, or conducting NRC licensed activities, to report defects and noncompliances that could create substantial safety hazards. Similar information is not currently available within the NRC or industry to accomplish the intent of Section 206.

6. Effort to Reduce Small Business Burden

Approximately 12,000 licensees and other organizations are under the scope of 10 CFR Part 21. The majority of these respondents are not considered to be small businesses. The revised 10 CFR Part 21, effective October 29, 1991, has reduced the reporting burden for these licensees and other organizations.

7. Consequences of Less Frequent Collection

10 CFR Part 21 has no specific period for reporting; instead, it requires the reporting of defects and noncompliances immediately after it is determined that they could create a substantial safety hazard. Less frequent collection of such information could reduce the NRC effectiveness in the area of assessing potentially generic safety issues and in disseminating such information to affected parties.

8. Circumstances which Justify Variation from OMB Guidelines

10 CFR Part 21 requires the reporting of defects and noncompliances that could create a substantial safety hazard in facilities or activities licensed by the NRC. This information is needed within 30 days to ensure that the NRC receives prompt notification of these defects and noncompliances, evaluates them, and is able to promptly disseminate information regarding those defects and noncompliances that are determined to be potentially generic safety problems.

In addition, 10 CFR Part 21 requires records 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 been adequately evaluated and corrected as required. Records of evaluations are therefore retained for 5 years. Supplier notifications to purchasers/affected licensees are retained for 5 years. Supplier records of purchasers of basic components are retained for 10 years after delivery of basic component.

9. Consultation Outside the NRC

The staff has utilized comments from licensees and other organizations regarding the requirements of 10 CFR Part 21. 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 that is identified as proprietary or confidential, which is defined as information that if disclosed could do substantial harm to an organization's competitive position, would be withheld from disclosure under a Freedom of Information Act request if the NRC determines that it is in the public interest to withhold it.

11. Justification for Sensitive Questions

This rule does not request sensitive information.

12. Estimate of the Cost to the Federal GovernmentNRC ANNUAL BURDEN

<u>ACTIVITY</u>	<u>HOURS PER SUBMITTAL</u>	<u>TOTAL HOURS</u>	<u>COST @\$115/H.R</u>
Review interim reports (50 per year)	12	600	\$69,000
Receive and review initial telephone FAX notification (150 per year)	2	300	34,500
Review written reports (150 per year)	12	1800	207,000
Review records of evaluations, transmittals, lists of purchasers, and procurement		1000	115,000
TOTAL BURDEN		3700	425,500

13. Estimate of Industry Burden

The total burden to respondents for reporting and recordkeeping in accordance with 10 CFR Part 21 is estimated to be 22,988 hours based on 150 initial notifications, 150 written reports, and 50 interim reports, annually from 100 respondents, or \$2,643,620 at \$115 per hour of professional staff time. Details are included in the attached table.

14. Reasons for Change in Burden

The estimate reflects the number of reports expected in the next few years, 200 (150 written reports, 50 interim reports) annually based on the number received in the last few years and the Part 21 interim report requirement. It also reflects a new estimate that more accurately represents the burden to respondents based on discussions with respondents and includes a correction and new estimate of the actual burden imposed by the current regulations.

15. Publication for Statistical Use

The data collected through this regulation provides input for generic communication issued by the NRC such as information notices, generic letters, and bulletins. Each report received is coded and entered into a computer database system that is used for tracking these reports. A printout of the information in the database is distributed to NRC offices monthly to inform them of the 10 CFR Part 21 reports that have been received by the NRC, their review status, and the reason for closeout. The data 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.

Burden TableReporting Requirements

<u>Section</u>	<u>No. of Responses Annually</u>	<u>Hours Per Response</u>	<u>Total Hours</u>	<u>Cost @\$115/hr</u>
21.21(a)(1)	Included in 21.21(c) (3)(ii)			
21.21(a)(2)	50	95	4,750	\$546,250
21.21(a)(3)	Included in 21.21(c) (3)(ii)			
21.21(b)	Included in 21.21(c) (3)(ii)			
21.21(c)(3)(i)	150	2	300	34,500
21.21(c)(3)(ii)	150	95	14,250	1,638,750
21.21(d)	Included in 21.21(c) (3)(ii)			
<hr/>			<hr/>	<hr/>
Total Reporting Burden			19,300	\$2,219,500

Recordkeeping Requirements

There are 100 licensees maintaining records.

<u>Section</u>	<u>No. of Records</u>	<u>Burden Per Record</u>	<u>Total Hours</u>	<u>Cost @\$115/hr</u>
21.51(a)(1)	8	.375	300	\$34,500
21.51(a)(2)	5	.375	198	21,620
21.51(a)(3)	250	.128	<u>3,200</u>	<u>368,000</u>
Total Recordkeeping Burden			3,688	\$424,120

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS

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

21.1

21.3(a)

**PART
21**

REPORTING OF DEFECTS AND NONCOMPLIANCE

GENERAL PROVISIONS

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

NOTIFICATION

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

PROCUREMENT DOCUMENTS

- 21.31 Procurement documents.

INSPECTIONS, RECORDS

- 21.41 Inspections.
21.51 Maintenance and inspection of records.

ENFORCEMENT

- 21.61 Failure to notify.

Authority: Sec. 161, 66 Stat. 948, as
amended; sec. 234, 63 Stat. 424, as amended
(42 U.S.C. 2201, 2282); sec. 201, as amended,
206, 66 Stat. 1242, as amended, 1246 (42 U.S.C.
5841, 5846).

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

For the purposes of sec. 223, 66 Stat. 950, as
amended (42 U.S.C. 2273); §§ 21.3, 21.21(a)
and 21.31 are issued under sec. 161b, 66 Stat.
948, as amended (42 U.S.C. 2201(b)); and
§§ 21.21, 21.41 and 21.51 are issued under sec.
161c, 66 Stat. 950, as amended (42 U.S.C.
2201(c)).

GENERAL PROVISIONS

§ 21.1 Purpose.

The regulations in this part estab-
lish procedures and requirements for
implementation of section 206 of the
Energy Reorganization Act of 1974.
That section requires any individual
director or responsible officer of a
firm constructing, owning, operating
or supplying the components of any
facility or activity which is licensed or
otherwise regulated pursuant to the
Atomic Energy Act of 1954, as amend-
ed, or the Energy Reorganization Act
of 1974, who obtains information rea-
sonably indicating: (a) That the facili-
ty, activity or basic component sup-
plied to such facility or activity 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 substantial

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

§ 21.2 Scope.

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

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

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

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

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

§ 21.3 Definitions.

As used in this part:

(a)(1) "Basic component," when ap-
plied to nuclear power reactors means
a plant structure, system, component
or part thereof necessary to assure (i)
the integrity of the reactor coolant
pressure boundary, (ii) the capability
to shut down the reactor and maintain
it in a safe shutdown condition, or (iii)
the capability to prevent or mitigate
the consequences of accidents which
could result in potential offsite expo-
sures comparable to those referred to
in § 100.11 of this chapter.

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

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

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

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

(a-1) "Commercial grade item" means an item that is (1) not subject to design or specification requirements that are unique to facilities or activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and (2) used in applications other than facilities or activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and (3) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example a catalog).

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

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

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

(d) "Defect" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 21.4 Interpretations.

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

§ 21.5 Communications.

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

§ 21.6 Posting requirements.

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

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

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

§ 21.7 Exemptions.

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

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

§ 21.8 Information collection requirements: OMB approval.

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

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

NOTIFICATION

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

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

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

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

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

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

(ii) Contains a defect.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply.

Commission action to obtain additional information may be based on reports of defects from other reporting entities.

PROCUREMENT DOCUMENTS

§ 21.31 Procurement documents.

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

INSPECTIONS, RECORDS

§ 21.41 Inspections.

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

ENFORCEMENT

§ 21.51 Failure to notify.

Any director or responsible officer subject to the regulations in this part who knowingly and consciously fails to provide the notice required by § 21.21 shall be subject to a civil penalty equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

[Note removed 49 FR 19623]

§ 21.51 Maintenance and inspection of records.

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

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

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

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

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