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RULES AND REGULATIONS

42 FR 28891

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Rule
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ADDITIONAL MATERIAL

Title 10—Energy
CHAPTER 1—NUCLEAR REGULATORY
COMMISSION
Reports to the Commission Concerning
Defects and Noncompliance
AGENCY: U.S. Nuclear Regulatory
Commission.

9201140279

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to require directors and responsible officers of firms and organizations building, operating or owning NRC-licensed facilities, or conducting NRC-licensed activities, to report failures to comply with regulatory requirements and defects in components which may result in a substantial safety hazard. Also covered under the new regulations are directors and responsible officers of firms and organizations supplying safety-related components, including safety-related design, testing, inspection and consulting services.

NRC licensees and other firms and organizations covered by the new regulations must adopt internal procedures to assure that safety-related defects and noncompliance are brought to the attention of responsible officers and directors. Those individuals, in turn, will be required to notify the Commission within two days, and file a written report within five days, of learning of the defect or noncompliance. Directors and responsible officers may designate an employee to provide on their behalf the notification to NRC.

EFFECTIVE DATE: July 6, 1977. Certain obligations under this effective rule are not imposed until January 6, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. W. E. Campbell, Jr., Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Phone 301-443-6917.

SUPPLEMENTARY INFORMATION: On March 3, 1975, the Nuclear Regulatory Commission published in the Federal Register (40 FR 8832) for public comment proposed amendments to 10 CFR Parts 2, 31, 35, and 40 of its regulations and a proposed new Part 21 to its regulations, "Reporting of Defects and Noncompliance."

The purpose of these proposed amendments and the new proposed Part 21 is to implement section 206 of Pub. L. 93-438, the Energy Reorganization Act of 1974, as amended.

Section 206 of the Energy Reorganization Act of 1974 as amended, reads as follows:

"NONCOMPLIANCE"

Sec. 206 (a) Any individual director, or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or pursuant to this Act, who obtains information reasonably indicating that such facility or activity or basic components supplied to such facility or activity—

(1) 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

(2) Contains a defect which could create a substantial safety hazard, as defined by regulations which the Commission shall promulgate, shall immediately notify the Commission of such failure to comply or of such defect, unless such person has actual

knowledge that the Commission has been adequately informed of such defect or failure to comply.

(b) Any person who knowingly and consciously fails to provide the notice required by subsection (a) of this section shall be subject to a civil penalty in an amount equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

(c) The requirements of this section shall be prominently posted on the premises of any facility licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended.

(d) The Commission is authorized to conduct such reasonable inspections and other enforcement activities as needed to insure compliance with the provisions of this section."

The new Part 21 requires that the directors and responsible officers of organizations that construct, own, operate or supply components of a facility or activity that is licensed or otherwise regulated by the Nuclear Regulatory Commission inform the Commission if they obtain information reasonably indicating that such facility, activity or basic component fails to comply with regulatory requirements relating to substantial safety hazards or that such facility, activity, or basic component contains a defect which could create a substantial safety hazard. Part 21 additionally requires that these organizations establish procedures to evaluate deviations from the technical requirements of the procurement documents or inform the purchaser concerning the deviation in order that the purchaser evaluate the deviation or have it evaluated. The organizations subject to the regulations in Part 21 may be many procurement tiers away from the holder of a license to construct or operate a nuclear power reactor. If the license is other than to construct or operate a nuclear power reactor, then the organizations subject to the regulations are those organizations that directly supply the licensee of the facility or activity. The directors and responsible officers of these organizations will be subject to a fine of up to \$5,000 for each deliberate failure to notify the Commission of the existence of such a defect or noncompliance. The organizations subject to Part 21 regulations must also maintain records, post copies of specific documents, inform procurement sub-tier suppliers of their responsibility under Part 21 and allow inspection of their premises, facilities and activities by duly authorized representatives of the Commission.

The Commission requires that a number of reports and notifications be submitted by licensees. These include licensee's report of incidents required by 10 CFR § 20.403, permit holder's notification of design or construction deficiencies required by 10 CFR § 50.55(e)(1), and licensee's report of theft or attempted theft of special nuclear material required by 10 CFR § 70.52. Other Commission regulations provide for receipt of various kinds of requests for information. For example, 10 CFR § 2.802 provides for petitions to issue, amend or rescind regulations, and 10 CFR § 19.16 provides for notifications from workers in regard to radiological hazards. These communica-

tions from licensee and the public are methods of securing information concerning the implementation effectiveness of Commission regulations. This information is an essential ingredient of sound regulation. The regulations in Part 21 add another required notification. Moreover, a longstanding Commission policy encourages individuals not subject to the Commission's regulations to report to the Commission a known or suspected defect or failure to comply, as authorized by law. The identity of anyone so reporting will be withheld from disclosure.

The Commission intends to examine closely the implementation of new Part 21 with a view to making any clarifying or other changes that may be warranted in light of experience. In particular, insufficient experience has been accumulated to permit the writing of a detailed regulation at this time that would provide a precise correlation of all factors pertinent to the question of what is a significant safety hazard. Part 21 is intended in this regard as an initial effort to identify a number of the factors involved with the question of significant safety hazard. Further, additional guidance in the form of regulatory guides may be developed should experience with the application of Part 21 indicate the need for such guidance. In this regard, we expect that the implementation efforts of the staff and those subject to the rule, and the views of interested members of the public, should provide the necessary data base for such further guidance.

During the development of the Energy Reorganization Act, Congress identified a need for an effective means to "anticipate problems before the event." Section 206 was developed to fill that need.

Interested persons have been afforded an opportunity to participate in the development of Part 21 and the associated amendments. The more important changes made to Part 21 are listed below and are based largely on consideration of public comments.

(1) The individuals subject to the notification requirement of Part 21 have been restricted to (a) directors and (b) officers vested with executive authority over activities subject to this part. These individuals may identify as individual that is authorized to provide notification to the Commission.

This new part is only one of many of the reporting channels that concerns defects or noncompliance, e.g., 10 CFR 50.55(e). Individuals that are subject to the requirements of this part that become aware of a defect or noncompliance that is outside the responsibility of their organization and individuals that are not subject to the requirements of any part of Title 10 are encouraged, but not required, to report to the Commission known or suspected defects or failure to comply. As authorized by law, the identity of anyone so reporting will be withheld from disclosure.

(2) Part 21, as adopted, does not specify whether firms may reimburse directors or responsible officers for civil penalties imposed pursuant to these regulations, and instead allows this question

to be resolved in accordance with applicable state law.

(3) The definition of "defect," as applied to components themselves, has been restricted to include those deviations in delivered components from technical requirements included in the procurement document that could, on the basis of an evaluation, create a substantial safety hazard. Defect also includes a deviation in a portion of the facility subject to the construction permit or manufacturing licensing requirement of Part 50 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. Whether such deviation could result in a substantial safety hazard is determined during the deviation evaluation. Defect also includes, for facilities licensed for operation under Part 50, any condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit as set forth in the operating license technical specifications.

(4) The definition of basic components has been divided into two parts: one part is applicable to power reactors licensed under Part 50 and the second part is applicable to activities licensed pursuant to Parts 30, 40, 70 or 71 and to other Part 50 facilities. For power reactors the definition is based on the guidance given in Regulatory Guide 1.20. For other facilities and activities basic component has been defined as components that are directly procured by a licensee.

(5) Substantial safety hazard has been defined in terms of a major reduction in the degree of protection provided to the public health and safety. Criteria that are appropriate for determination of creation of a substantial safety hazard include:

Moderate exposure to, or release of, licensed material.

Major degradation of essential safety-related equipment.

While agreeing with all other aspects of this Notice, Commissioner Gilinsky believes there should be barred from reimbursing directors or responsible officers for civil penalties imposed pursuant to Part 21, on grounds that Section 206 of the Energy Reorganization Act is designed to impose personal responsibility, a goal undermined by corporate indemnification. The Commission majority believes that, in accordance with the general practice of federal regulatory bodies in analogous matters, the question of the reimbursability of such penalties should be governed by applicable state law. It notes that the adverse publicity attendant on being subjected to a civil penalty for knowingly concealing significant safety information would be a major incentive to compliance, irrespective of whether the person so penalized was later reimbursed by the company. The majority also recognizes the serious practical difficulty in attempting to differentiate between a properly awarded salary increase or bonus and an improper reimbursement. If Part 21 does not in practice appear to be accomplishing its purpose, the Commission will, of course, propose changes deemed appropriate in light of experience.

Major deficiencies involving design, construction, inspection, test or use of licensed facilities or material.

To the extent that failures to comply or defects in a security system can contribute to a substantial safety hazard, such failures and defects are within the scope of Part 21.

(6) Clarification has been added in regard to which organizations are subject to the regulations in this part. In order that the implementation of Section 206 may be responsive to anticipation of problems before the event, a broad interpretation of "firm constructing, owning, operating or supplying the components" has been used. This interpretation includes not only licensees and organizations that physically construct facilities and physically supply components but also includes organizations that only supply safety-related services such as design, inspection, testing or consultation; e.g., site geological investigations.

This interpretation is intended to bring within the regulations in this part those various organizations that can create a substantial safety hazard considering the various methods available for consultation, procurement, design, construction, testing, inspection and operation. These methods include not only the option where design and construction are accomplished by one organization but also the option where one organization does safety-related consultation, another safety-related design and another the actual construction. Each of these organizations has the capability to generate a defect and a potential for failing to comply.

If a basic component is fabricated by one organization using a design from another organization, the possibility of creating a substantial safety hazard, based upon a faulty design, exists upon the delivery of the design that fails to comply or contains a defect. A substantial safety hazard, based upon faulty fabrication, exists upon delivery of the item that fails to comply or contains a defect. In many instances the competent fabricating organization possesses neither the capability nor the responsibility for design.

It is realized that during the activities of design and consultation there may be a stage of conceptual design or consultation in regard to feasibility. Only when such a design or consultation can result in the creation of a substantial safety hazard is it appropriate to specify the applicability of Part 21 in the procurement document.

(7) The organizations subject to this part must establish procedures to provide for correction of deviations, or evaluation of deviations or informing purchasers of the deviation so the purchaser may evaluate the deviation. These procedures must also provide for informing a responsible officer or director of the organization of any resulting defect or failure to comply.

(8) The provisions of Part 21 imposing requirements that procurement documents state, when applicable, that Part 21 applies would be applicable only to future procurements of facilities,

components or services; i.e., procured on or after six months after the effective date of Part 21.

The effective date of 4216 dealing with posting requirements, 4212(a) dealing with adopting procedures, and 42131 dealing with maintenance of records has been deferred until January 6, 1978, to allow organizations to establish and implement procedures.

(9) The organizations subject to the regulations in Part 21 are required to prepare records in connection with their activities to assure compliance with this part. Prior to destruction of such records they shall be offered to the purchaser. It is not anticipated that these documentation requirements will necessitate any change in the documentation procedures of organizations that are presently complying with 10 CFR 50 Appendix B, "Quality Assurance Criteria."

(10) Clarification has been added in regard to the applicability of Part 21 to the licensed activity of exporting persons who are only licensed to export nuclear facilities or materials and who do not otherwise construct or operate facilities or activities or supply components are not subject to the new part. Individuals subject to this part need report only defects or failures to comply which could create a substantial safety hazard in facilities and activities within the United States. Further, any notification submitted in accordance with Part 21 may be exempt from public disclosure as authorized by law.

After consideration of the comments received and other factors, the Commission has adopted the amendments to Parts 2, 31, 34, 35, 40, and 70, and the new Part 21 set forth below.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following new Part 21 of Title 10, Chapter I of the Code of Federal Regulations, and amendments to Parts 2, 31, 34, 35, 40, and 70 are published as a document subject to codification to be effective on July 6, 1977.

PART 2—RULES OF PRACTICE

Paragraph (b) of § 2.200 is amended to read as follows:

§ 2.200 Scope of subpart.

(a) This subpart also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to section 204 of the Act and section 206 of the Energy Reorganization Act of 1974.

2. A new Part 21 is added to read as follows:

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

GENERAL PROVISIONS

Sec.	Purpose
21.1	Purpose
21.2	Scope
21.3	Definitions
21.4	Interpretations
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NOTIFICATION

- 21.21 Notification of failure to comply or existence of a defect

PROCUREMENT DOCUMENTS

- 21.31 Procurement documents

INSPECTIONS, RECORDS

- 21.41 Inspections
21.51 Maintenance of records

EXPORTMENT

- 21.61 Failure to notify

AUTHORITY: Sec. 161, Pub. L. 85-703, 68 Stat. 946, sec. 234, Pub. L. 91-161, 83 Stat. 434, sec. 206, Pub. L. 93-433, 88 Stat. 1246 (42 U.S.C. 2201, 2282, 2846).

GENERAL PROVISIONS

§ 21.1 Purpose.

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity 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 defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

§ 21.2 Scope.

The regulations in this part apply, except as specifically provided otherwise in Parts 31, 34, 35, 40, or 70 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, and/or transfer within the United States source, byproduct and/or special nuclear materials, or to construct, manufacture, possess, own, operate and/or transfer within the United States, any production or utilization facility, and to each director (see § 21.3(f)) and responsible officer (see § 21.3(j)) 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 (see § 21.3(c)) a production or utilization facility licensed for manufacture, construction or operation (see § 21.3(h)) pursuant to Part 50 of this chapter or supplies (see § 21.3(i)) basic components (see § 21.3(k)) for a facility or activity licensed, other than for export, under Parts 30,

40, 50, 70, or 71. Nothing in these regulations should be deemed to preclude an individual 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.

§ 21.3 Definitions.

As used in this part, (a) "Basic component," when applied to nuclear power reactors means a plant structure, system, component or part thereof necessary to assure (1) the integrity of the reactor coolant pressure boundary, (2) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (3) 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; "Basic component," when applied to other facilities and when applied to other activities licensed pursuant to Parts 30, 40, 50, 70 or 71 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)). In all cases "basic component" 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.

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

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

(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

*NRC Regional Offices will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers (for nights and holidays as well as regular hours) are listed below:

Region	
I (Philadelphia).....	(215) 337-1150
II (Atlanta).....	(404) 221-4503
III (Chicago).....	(312) 858-2640
IV (Dallas).....	(817) 374-2841
V (San Francisco).....	(415) 486-3141

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(j)).

(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) "Evaluation" means the process accomplished by or for a licensee to determine whether a particular deviation could create a substantial safety hazard.

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

(i) "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.

(j) "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.

(k) "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, 70 and 71.

(l) "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 communications and reports concerning the regulations in this part, should be addressed to the Director.

Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, or to the Director of a Regional Office at the address specified in Appendix D of Part 20 of this chapter. Communications and reports also may be delivered in person at the Commission's offices at 1717 H Street NW., Washington, D.C.; at 7920 Norfolk Avenue, Bethesda, Md.; or at a Regional Office at the location specified in Appendix D of Part 20 of this chapter.

§ 21.6 Posting requirements.

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.

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.

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.

NOTIFICATION

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

(a) Each individual, corporation, partnership or other entity subject to the regulations in this part shall adopt appropriate procedures to: (1) provide for (i) evaluating deviations or (ii) informing the licensee or purchaser of the deviation in order that the licensee or purchaser may cause the deviation to be evaluated unless the deviation has been corrected; and (2) assure that a director or responsible officer is informed 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. The effective date of this paragraph has been deferred until January 6, 1978.

(b) (1) A director or responsible officer subject to the regulations of this part or a designated person shall notify the Commission when he 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, 70 or 71 and that is within his organization's responsibility or (ii) a basic component that is within his 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, 70 or 71. The above notification is not required if such individual has actual knowledge that the Commission has been adequately informed of each defect or failure to comply.

(2) Notification required by this paragraph shall be made within two working days of the receipt of the information. Notification shall be made to the Director, Office of Inspection and Enforcement, the Director of a Regional Office, and notification is by means of other written communication. A written report shall be submitted to the appropriate Office within 5 days after the information is obtained. Three copies of each report shall be submitted to the Director, Office of Inspection and Enforcement.

(3) 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 involved 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.

(4) 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.

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

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

§ 21.51 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.

§ 21.52 Maintenance of records.

(a) Each licensee of a facility or activity subject to the regulations in this part shall maintain such records in connection with the licensed facility or activity as may be required to assure compliance with the regulations in this part.

(b) Each individual, corporation, partnership, or other entity subject to the regulations in this part shall prepare records in connection with the design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of any facility, basic component supplied for any licensed facility or to be used in any licensed activity sufficient to assure compliance with the regulations in this part. After delivery of the facility or component and prior to the destruction of the records relating to evaluations (see § 21.3(g)) or notifications to the Commission (see § 21.21), such records shall be offered to the purchaser of the facility or component. If such purchaser determines any such records:

(1) Are not related to the creation of a substantial safety hazard, he may authorize such records to be destroyed; or

(2) Are related to the creation of a substantial safety hazard, he shall cause such records to be offered to the organization to which he supplies basic components or for which he constructs a facility or activity.

If such purchaser is unable to make the determination as required above then the responsibility for making the determination shall be transferred to the individual, corporation, partnership, or other entity subject to the regulations in this part that issued the procurement document to the purchaser. In the event that the determination cannot be made at that level then the responsibility shall be transferred in a similar manner to another individual, corporation, partner-

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ship, or other entity subject to the regulations in this part, until, if necessary, the licensee shall make the determination.

(c) Records that are prepared only for the purpose of assuring compliance with the regulations in this part and are not related to evaluations or notifications to the Commission may be destroyed after delivery of the facility or component.

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

ENFORCEMENT

§ 21.61 Failure to notify.

Any director or responsible officer subject to the regulations in this part who knowingly and consciously fails to provide the notice required by § 21.21 shall be subject to a civil penalty in an amount not to exceed \$5,000 for each failure to provide such notice and a total amount not to exceed \$25,000 for all failures to provide such notice occurring within any period of thirty consecutive days. Each day of failure to provide the notice required by § 21.21 shall constitute a separate failure for the purpose of computing the applicable civil penalty.

NOTE—The reporting and record keeping requirements contained in this part have been approved by the General Accounting Office under B-180225 (NO 446).

PART 31—GENERAL LICENSES FOR BYPRODUCT MATERIAL

§§ 31.2, 31.5, 31.7, 31.8, 31.10, and 31.11 [Amended]

3. In 10 CFR Part 31, § 31.2(a) is amended by changing the words "Parts 19, 20, and 36" to read "Parts 19, 20, 21, and 36."

4. In 10 CFR Part 31, § 31.5(c)(10), § 31.7(b), § 31.8(c), § 31.10(b)(3), and § 31.11(f) are amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

PART 34—LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

§ 34.31 [Amended]

5. In 10 CFR Part 34, § 34.31(a)(2) is amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

§ 35.31 [Amended]

6. In 10 CFR Part 35, § 35.31(c) is amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

PART 40—LICENSING OF SOURCE MATERIAL

§§ 40.22 and 40.23 [Amended]

7. In 10 CFR Part 40, § 40.22(b) is amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

8. In 10 CFR Part 40, § 40.23(c) is amended by changing the words "Part 20" to read "Parts 20 and 21."

PART 70—SPECIAL NUCLEAR MATERIAL

§ 70.11 [Amended]

9. In 10 CFR Part 70, § 70.11(c) is amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

Dated at Washington, D.C., this 1st day of June 1977.

For the Nuclear Regulatory Commission.

SAMUEL J. CHALK,

Secretary of the Commission.

[PR Doc 77-15987 Filed 6-3-77; 8:45 am]

RULES AND REGULATIONS

Title 10—Energy
CHAPTER 1—NUCLEAR REGULATORY COMMISSION

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

Reports to the Commission Concerning Defects and Noncompliance

Correction

In FR Doc 77-15987 appearing in the issue for Monday, June 6, 1977 on page 28891, on page 28894 § 21.3-d-11 should read as follows:

§ 21.3 Definitions.

(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

PART 2—RULES OF PRACTICE

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

PART 31—GENERAL LICENSES FOR BYPRODUCT MATERIAL

PART 34—LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

PART 40—LICENSING OF SOURCE MATERIAL

PART 70—SPECIAL NUCLEAR MATERIAL

Reports to the Commission Concerning Defects and Noncompliance: Extension of Effective Date

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Change of effective date of final rule.

SUMMARY: The Nuclear Regulatory Commission is changing from July 6, 1977 to August 10, 1977, the effective date

of its recently published regulations which require directors and responsible officers of firms and organizations building, operating or owning NRC-licensed facilities, or conducting NRC-licensed activities, or supplying safety related components to report failures to comply with regulatory requirements and defects in components which may result in a substantial safety hazard. No change is being made in those portions of the regulations now subject to the deferred effective date of January 6, 1978. This change in effective date will give persons subject to the rule additional time to establish implementing procedures.

EFFECTIVE DATE: August 10, 1977. Certain obligations under the effective rule are not imposed until January 6, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. W. E. Campbell, Jr., Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. (phone: 301-443-6917).

SUPPLEMENTARY INFORMATION: On June 6, 1977, the Nuclear Regulatory Commission published in the Federal Register (42 FR 28891-28896, FR Doc. 77-15937) amendments to 10 CFR Parts 2, 31, 34, 35, 40 and 70 of its regulations and a new Part 21—Reporting of Defects and Noncompliance to implement section 206 of the Energy Reorganization Act of 1974, as amended (Public Law 93-438, 88 Stat. 1246-1247). As stated in the Federal Register notice, the effective date of the final rule was July 6, 1977, thirty days after the date of publication, except for certain portions of the rule for which the effective date was specifically deferred until January 6, 1978. The purpose of the deferred effective date was to allow organizations to establish and implement procedures to comply with certain provisions of the rule. On June 9, 1977, the NRC staff announced that five public meetings, hosted by each of its five regional offices, would be held during the period July 12 through July 28, 1977, for the purpose of explaining the provisions of the rule and answering any questions which might be raised concerning its implementation. As the effective date of the rule approached, several organizations expressed concern that they would not be able to have adequate interim procedures in place before the rule became effective, that they needed clarification of certain provisions of the rule and that it would be particularly helpful if the effective date of the rule were deferred for a period of approximately sixty days after the date of the last scheduled regional meeting.

As noted in the recently expanded delegation of authority to the Commission's Executive Director for Operations (42 FR 33290-33291, June 30, 1977, FR Doc. 77-18988), there are at the present time only two qualified members of the Nu-

clear Regulatory Commission. Since the Commission lacks a quorum for the transaction of business, the requests of organizations to postpone the effect date of 10 CFR Part 21 must be addressed, if they are to be addressed at all, by the Executive Director for Operations. Upon review of the final rule in the light of the concerns expressed and after consultation with the incumbent Commissioners in accordance with the provisions of his delegated authority, the Executive Director for Operations has determined that it would be in the public interest to postpone the effective date of the final rule until August 10, 1977. This extension would give persons and organizations affected by the rule an additional fifteen days after the date of the last NRC public informational meeting in which to put interim implementing procedures in place. The Executive Director for Operations has also determined that this change in the effective date of the final rule is a minor amendment which does not substantially modify existing regulations affecting the public health and safety, the common defense and security, or substantive or procedural rights and that he has been delegated authority to issue it. Since the purpose of this change in the effective date of the final rule is to allow organizations to obtain more information about its provisions prior to implementation, the Executive Director for Operations also finds that notice and public procedure thereon are contrary to the public interest and that there is good cause to make this change in the effective date of the final rule effective immediately upon publication in the Federal Register without the customary thirty day notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following change in the effective date of Title 10, Code of Federal Regulations, Part 21 is published as a document subject to modification.

1. In FR Doc. 77-15937 appearing at page 28891 in the Federal Register of June 6, 1977, the Effective Date paragraph appearing on page 28892 in column 1 is revised to read as follows:

EFFECTIVE DATE: August 10, 1977. Certain obligations under the effective rule are not imposed until January 6, 1978.

(Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); Sec. 201, as amended, Pub. L. 93-438, 88 Stat. 1243, Pub. L. 94-79, 89 Stat. 413 (42 U.S.C. 5841).)

Dated at Bethesda, Md., this 6th day of July 1977.

For the Nuclear Regulatory Commission.

LEE V. GOSSICK

Executive Director for Operations

(FR Doc. 77-19539 Filed 7-6-77; 10:47 am)

REPORTS TO THE COMMISSION CONCERNING DEFECTS AND NONCOMPLIANCE

Correction

In FR Doc. 77-15987 appearing on page 28891 in the issue for Monday, June 6, 1977, on page 28894, § 21.3 (a)(3) should read as follows:

(3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 150.11 of this chapter.

Section 21.3(d)(1) should read as follows:

§ 21.3 Definitions.

(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

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REMARKS PRESENTED AT
PUBLIC REGIONAL MEETINGS
TO DISCUSS REGULATIONS (10 CFR PART 21)
FOR REPORTING OF
DEFECTS AND NONCOMPLIANCE

July 12 - 26, 1977



U. S. Nuclear Regulatory Commission

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National Technical Information Service

PB-269 215

Remarks Presented at Public Regional Meetings to
Discuss Regulations (10 CFR Part 21) for Reporting of
Defects and Noncompliance, July 12-26, 1977

Nuclear Regulatory Commission, Washington, D C

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT
WASHINGTON, DC 20555

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PDR

December 31, 1985

IE INFORMATION NOTICE NO. 85-101: APPLICABILITY OF 10 CFR 21 TO CONSULTING
FIRMS PROVIDING TRAINING

Addressees:

All nuclear power facilities holding an operating license (OL) or a construction permit (CP).

Purpose:

This information notice is provided to inform licensees and consultants of a potential generic problem concerning the applicability of 10 CFR 21 to certain training activities provided by consultants. It is expected that recipients will review the information for applicability to their facilities and consider actions, if appropriate, to preclude similar problems from occurring at their facilities. However, suggestions contained in this information notice do not constitute NRC requirements; therefore, no specific action or written response is required.

Discussion:

Recently, the NRC performed a vendor inspection of a company that supplies consulting services, including training, to the nuclear industry. During this inspection, it was noted that licensees had failed to appropriately impose 10 CFR 21 on the consultant providing training. The Commission is taking this opportunity to remind licensees of their responsibilities under 10 CFR 21.

Paragraph 21.3(a)(3) of 10 CFR 21 states: "In all cases 'basic component' includes design, inspection, testing, or consulting services...." Training, which is provided as a consulting service, is therefore subject to the provisions of 10 CFR 21 when the training is associated with a basic component as defined in paragraph 21.3(a)(1) of 10 CFR 21 [for example, nondestructive examination training, inservice inspection (ISI) or testing (IST) training]. Licensee procurement of such training services must therefore specify the applicability of 10 CFR 21. Any "deviations" found in the training material by consultants must be evaluated by the contractor or reported to the licensee for evaluation, and any "defects" which could have an impact on the component hardware must be reported to the NRC as provided in 10 CFR 21.

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16. Abstracts Nureg-0302 includes remarks by NRC representative on the rule 10 CFR Part 21 (included). Remarks are provided by the Regional Director and representatives of the Offices of the Executive Legal Director, Standards Development, Nuclear Reactor Regulation, Nuclear Materials Safety and Safeguards, International Programs, and Inspection and Enforcement. Staff remarks cover the legislative and legal aspects of the rule, how the rule impacts on reactor, material, fuel cycle and export licenses and related suppliers and inspection and enforcement of the rule.				
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NUREG-0302

REMARKS PRESENTED AT
PUBLIC REGIONAL MEETINGS
TO DISCUSS REGULATIONS (10 CFR PART 21)
FOR REPORTING OF
DEFECTS AND NONCOMPLIANCE

July 12 - 26, 1977

Manuscript Completed: June 1977
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Office of Inspection and Enforcement
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

REMARKS PRESENTED AT PUBLIC REGIONAL MEETINGS
(DALLAS, ATLANTA, SAN FRANCISCO, CHICAGO, PHILADELPHIA)
TO DISCUSS REGULATIONS (10 CFR PART 21)
FOR REPORTING OF DEFECTS AND NONCOMPLIANCE

JULY 12-26, 1977

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ADDITIONAL MATERIAL

1. Copy of Federal Register Notice 42FR28891-28896 of June 6, 1977

1.

Remarks by Regional Directors
Office Inspection and Enforcement
To Public Regional Meetings on 10 CFR Part 21
July 12-26, 1977

Boyce H. Grier, Region I
Norman C. Moselvy, Region II
James G. Keppler, Region III
E. Morris Howard, Region IV
Robert H. Engelken, Region V

Welcoming Keynote Address

Good morning, ladies and gentlemen. Welcome to this meeting. I appreciate the opportunity to meet with you here today in one of the five Regional Workshop Sessions that the Nuclear Regulatory Commission is sponsoring to explain and discuss the provisions of its new regulation, 10 CFR Part 21, "Reports to the Commission Concerning Defects and Noncompliance".

I'm sure that most of you are aware of the major provision of Part 21. It has been the subject of considerable review, discussion, comment, revision and refinement since the proposed rule was first published in the Federal Register in March 1975. It is no secret that it has been one of the most controversial rules ever promulgated by the Commission and it has potentially significant implications for all members of the nuclear community, from power plant operators, nuclear steam suppliers, architect engineers and constructors to consultants and component vendors. I am certain that even the regulators will face a learning period concerning some of the legal and technical nuances of this rule as they become more involved in the enforcement of it in the months ahead. I sincerely hope that our discussions today will help us all develop a clear and common understanding of the objectives and requirements of this important new rule.

As the objective of Part 21 is to implement Section 206 of the Energy Reorganization Act, I believe stating the specific words of Section 206 will be helpful in establishing the background for the panel discussions that will follow. Section 206, as enacted, reads as follows:

"NONCOMPLIANCE"

Sec. 206.(a) Any individual director, or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or pursuant to this Act, who obtains information reasonably indicating that such facility or activity or basic components supplied to such facility or activity--

- (1) 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
 - (2) contains a defect which could create a substantial safety hazard, as defined by regulations which the Commission shall promulgate,
- shall immediately notify the Commission of such failure to comply, or of such defect, unless such person has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.
- (b) Any person who knowingly and consciously fails to provide the notice required by subsection (a) of this section shall be subject to a civil penalty in an amount equal to the amount provided by Section 234 of the Atomic Energy Act of 1954, as amended.
 - (c) The requirements of this section shall be prominently posted on the premises of any facility licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended.
 - (d) The Commission is authorized to conduct such reasonable inspections and other enforcement activities as needed to insure compliance with the provisions of this section."

In approving 10 CFR Part 21 as the means for implementing Section 206 of the Energy Reorganization Act of 1974, the Commission is requiring directors and responsible officers of certain firms and organizations building, operating or owning NRC-licensed facilities, or conducting NRC-licensed activities, to report any defects in components and failures to comply with NRC requirements that could result in a substantial safety hazard. Directors and responsible officers may designate an employee to notify the NRC on their behalf but they may not be relieved of the responsibility for notification of the NRC.

The reporting requirement is intended to assure that the NRC receives prompt notification concerning defects or failures to comply with NRC requirements for facilities or activities licensed by the Commission which could present a substantial safety hazard. The purpose of this reporting requirement is to further enhance our "defense in depth" measures for assuring public health and safety and protection of the environment.

Now I'm sure that even from your reading of the rule and from this brief discussion you have made some important observations. For instance, you have no doubt noted that, unlike provisions of the Atomic Energy Act which impose obligations on licensees, Section 205 imposes obligations on firms and organizations who are involved in the nuclear industry as well as on firms and organizations who are NRC licensees and, further, imposes these obligations as a direct liability on certain individuals

in these firms and organizations. No doubt you are also pondering some of the other important issues and questions that were considered by the staff and commented upon profusely by many of you during the years that this rule has been in preparation. Questions, for example, like:

1. What levels of individuals in an organization are required to notify the Commission on defects and noncompliance?
2. How is a defect defined?
3. How does the Commission define a "basic component," i.e., how far down the tiers of suppliers should Part 21 be applied?
4. How should a supplier be advised of the applicability of Part 21?
5. Should reporting individuals be required to identify all facilities or activities, including exported facilities, at which a defect or failure to comply may exist?

Well, that's precisely why we are all here today - to discuss such questions. I hope that our workshop discussions today will provide answers to most, if not all, of these questions so that we can all approach the implementation of this important new rule with a common understanding of what the law requires of us.

Thank you for meeting here with us today. I hope that your visit here will be both enjoyable and profitable.

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REMARKS BY
THE OFFICE OF THE EXECUTIVE LEGAL DIRECTOR
TO PUBLIC REGIONAL MEETINGS ON 10 CFR PART 21

BY
JAMES K. ASSELSTINE
MARC R. STAENBERG

JULY 12-26, 1977

The Legislative and Legal Aspects of Part 21

The Regional Director, in his keynote address, explained the relationship of Section 206 of the Energy Reorganization Act to the new Part 21 and the basic purpose of the rule. It is interesting to note that Section 206 was not part of the Act as it was passed by the House of Representatives. This section was added by the Senate committee. The purpose of the section as explained by the Senate committee in its report was:

to upgrade the system of detecting and anticipating the defects that increasingly have plagued the nuclear power industry and threatens its safety record on a daily basis. The application of this provision to component suppliers is intended to benefit electric utilities in particular, which usually have no way of knowing that a sealed, prefabricated part is defective until it triggers a shutdown costing tens of thousands of dollars a day in lost generating capacity.

In addition, Section 206 as enacted by the Congress was made expressly applicable to all facilities and activities which are licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

Section 206 in its final form was a substitute added by the Joint House Senate conference committee on the Energy Reorganization Act. Of interest is the fact that, as originally drafted, a failure to report could have resulted in criminal prosecution. The criminal penalties were dropped in the House Senate conference in favor of civil penalties.

Section 206 is a broadly worded statute by which Congress intended to give the NRC responsibility to flesh out the bare bones of the statutory language and to develop workable definitions of terms and a workable implementation program. Part 21 is the result of the Commission's efforts in this regard and, of necessity, goes into considerable detail in many areas where the statute did not. But even as the final rule was published on June 6, 1977, the Commission recognized that future experience and further information might warrant clarifying or other changes to the rule. It is thus not possible in these short remarks to anticipate and answer every circumstance which might arise.

With this in mind, several things about Section 206 are particularly worthwhile emphasizing. First, it imposes obligations on individuals. The language of the section refers specifically to individual directors or responsible officers, and these terms are further defined in the Commission's Part 21. Thus, under Part 21, it is individuals who may be subject to civil penalties. Our Office of Standards Development representative will be providing examples of who these individuals are.

The statute is silent on the question whether an individual director or responsible officer who has been compelled to pay a civil penalty may be reimbursed by his employer. Unlike the proposed rule, the effective Part 21 does not address the reimbursement question. The explanation which accompanied publication of the rules in the Federal Register indicates that the matter of reimbursement would be governed by State law. Second, the section clearly applies to persons not licensed or previously directly regulated by the Nuclear Regulatory Commission. Section 206 specifically mentions suppliers of components. Third, Section 206 is not unique. Other statutes impose sanctions for failure to report defects or hazards; for example, the Federal Boat Safety Act of 1971, the Consumer Product Safety Act and the National Traffic and Motor Vehicle Safety Act.

Part 21 is presently effective and binding insofar as the obligation to provide the required notification is concerned. Should any of you have the misfortune to be cited for a civil penalty under Part 21, the opportunities available to you to argue for different language in the Part in the enforcement proceeding against you will likely be very limited. Thus, if you have problems, it is better to raise them now rather than later. While the rule is presently in effect, you have a right under federal law to petition the Nuclear Regulatory Commission to amend the rule. The rule also provides that an exemption may be granted by the Commission upon application of an interested person when the Commission determines that such exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest. A person may also seek an interpretation from the General Counsel of a particular section or matter covered by the rule, thereby indicating areas of concern to him. These avenues wouldn't relieve you of the obligation to comply with the Part before the petition or request was acted upon, but they would be the proper way to get your concerns before the Nuclear Regulatory Commission.

REMARKS BY
THE OFFICE OF STANDARDS DEVELOPMENT
TO PUBLIC REGIONAL MEETINGS ON 10 CFR PART 21
BY
W. E. CAMPBELL, JR
JULY 12-26, 1977

Development of the Part 21 Regulations

My objective is to provide information concerning the Part 21 rule making and related amendments to other Parts of Title 10. It may be helpful if you have available your copy of the Federal Register notice concerning this effective rule making because I and other speakers will be making some references to various sections.

As a result of the enactment of the Energy Reorganization Act, the Nuclear Regulatory Commission was required to promulgate new regulations. It was decided to prepare one new Part to cover all aspects of the regulations required under Section 206 instead of preparing a separate Part for each type of license that we issue; for example, a Part 30 License or a Part 40 License or a Part 50 License. The rule making required under Section 206 of the Energy Reorganization Act could have been accomplished by making appropriate changes to the present Parts 30, 40, 50 etc., but it was felt that a better way to do it would be to have one new Part. The proposed rule, which was published on March 3, 1975 in 40 FR 8832, was the subject of a large number of comments. My first illustration indicates the source of the comments on this proposed rule.

**PROPOSED PART 21
COMMENT SOURCE**

1 JAN. 1976

UTILITY	25
NUCLEAR STEAM	
SUPPLY SYSTEM	1
INDIVIDUALS	4
LAW FIRMS	4
EDUCATIONAL	2
ARCHITECT	
ENGINEER	10
CONSTRUCTOR	10
SUPPLIER	10
SOCIETY	
ASSOCIATION	2
CONSULTANTS	4
GOVERNMENTAL	4
TOTAL COMMENTS	134

Of these comments, 114 were received prior to the expiration of the extended comment period. When the comment period closed the review and resolution of these comments commenced. This review and resolution included those that were on time and those that were late. To proceed to an effective rule a number of courses were available.

- 1) Enter into a rule making hearing.
- 2) Revise the rule taking into account the comments received and publish the rule again as a proposed rule for comment.
- 3) Revise the rule taking into account the comments received and publish as an effective rule.

Because the significant issues regarding the proposed rule were adequately discussed in the many comments received a hearing was not deemed necessary and the staff proceeded, with Commission approval, to draft an effective regulation. As you are aware the rule has been noticed on June 6, 1977. / ←

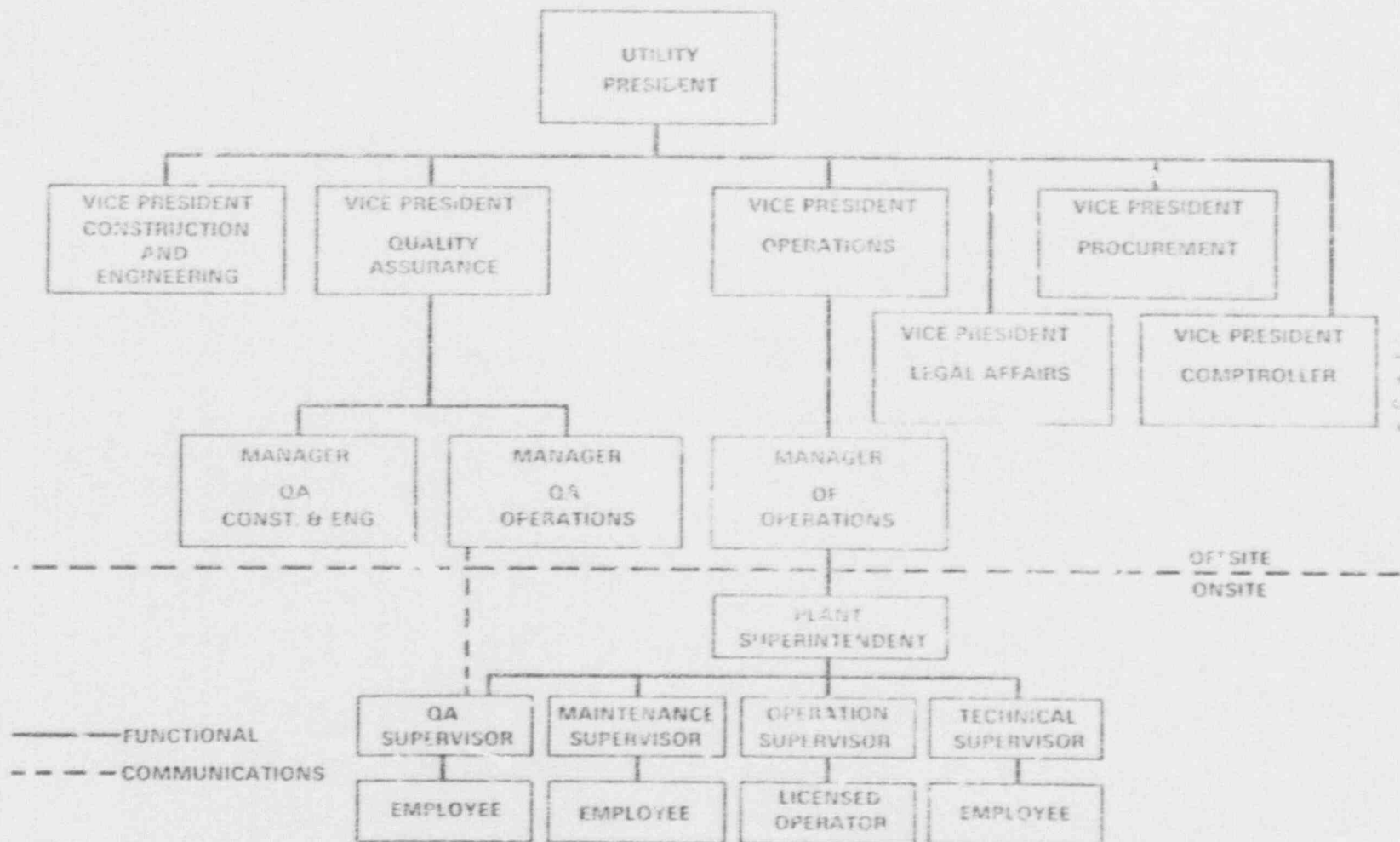
I am attempting to achieve an effective rule that was responsive to Section 206 of the Energy Reorganization Act a number of major and minor issues were addressed. I will address some of these issues.

"What level of individuals in an organization should be required to notify the Commission of defects and noncompliance?"

The notice of proposed rule making requested specific comment in this regard. This illustration shows a "typical utility organization" (see next page). It is indicative of the organization of most licensees in that there are numerous tiers and numerous titles but in very few organizations would the titles in one organization relate to the functional descriptions in other organizations where the same title was used.

As used in Part 21, "director" was defined as 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, that individual is the director. Responsible officer was defined to mean the president, vice president or other individuals in the organization of a corporation, partnership or other entity who is vested with executive authority over activities subject to Part 21. Activities such as design, construction, operation are included. An officer, for example the Vice-President in Charge of Community Affairs may not be a responsible officer in regard to Part 21. An individual subject to this part may authorize another individual to provide notification for him but the individual subject to Part 21 will remain responsible for compliance with Part 21.

"How should a defect be defined?"



The Energy Reorganization Act uses the phrase "defect which could create a substantial safety hazard." It is necessary that important or significant defects be differentiated from the inconsequential defects. Deviation and defect are interrelated. For example, a procured item is required to meet certain requirements. If the item does not meet its prescribed requirements a deviation exists. Some deviations can create a substantial safety hazard and others can not. The deviations that exist at time of delivery or become known after delivery must be evaluated to determine ability to create a "substantial safety hazard". These relationships will be discussed more fully as the remarks are presented.

Part 21 has provided four definitions of defect as follows: (1) a defect is a deviation in a basic component delivered to a purchaser where on the basis of an evaluation the deviation could create a substantial safety hazard (This definition is primarily directed at the offsite supplier) or (2) a defect means the installation, use or operation of a basic component containing a defect as defined above. (This definition is primarily directed at the recipient, e.g. user, of the component or service) or (3) a defect is a deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of Part 50 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 (This definition is primarily directed at the on-site supplier) or (4) a defect is 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 (This definition is primarily directed at a specific class of licensees).

It should be noted that the definitions applicable to suppliers are pertinent only upon delivery of an offsite fabrication component. Deviations that are identified by a supplier when the product is within his control, by definition are not a defect unless they remain uncorrected upon delivery of the defective component or service.

The Procurement Document is defined in Part 21 as "A contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser."

The definition includes both an inter-organizational and an intra-organizational document that defines the technical requirements. This document is the vehicle by which a supplier is informed that the procurement action is within the regulation. To a responsible pressure vessel supplier it should be obvious his product has significant safety importance thus is within the scope of the regulation but to a supplier of nuts and bolts the safety significance is not clear thus the applicability of Part 21 may not be known without the procurement document notification.

Substantial safety hazard means the loss of a safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety. Applicable criteria for the determination of substantial safety hazard are given in the statement of consideration. These include a) moderate exposure to, or release of, licensed material b) major degradation of essential safety-related equipment and c) major deficiencies involving design, construction, inspection, test or use.

"What types of business that are not licensed or otherwise regulated are within the scope of Part 21?"

The legislation is explicit in regard to owning, constructing, operating and supplying the components. Due to the diverse nature of this industry there are many "build to print" contracts and many "design and build," "Design only" or "consult only" contracts. The entire supply chain involved in the production of a basic component for a power reactor that could create a substantial safety hazard, because of a defect in the component, is within the scope of Part 21. The safety-related operations of constructing, owning, operating and supplying components each have within themselves safety-related activities, e.g., consultation, design, inspection and test. The definition of "basic component" and "operation" have been defined so as to include these safety-related activities. This aspect of the proposed rule was the subject of numerous comments.

The relationship of one person subject to Part 21 to another from a different organization, who was also subject to Part 21, received many comments. Also the relationship of individuals not subject to this part was also the source of many comments.

"Should an officer or director of a organization responsible for procuring or producing a component be required to make a Part 21 notification to the Commission concerning either a defect or non-compliance not within responsibility of his organization?"

If an individual or individuals subject to Part 21 becomes aware of a defect that is not within the responsibility of his organization he is not required by this part to submit a notification. In such cases, the individual that gains the knowledge of a defect in an item outside his organization's area of responsibility would be encouraged to report but would not be subject to a civil penalty if he did not report it.

An individual, such as employee, who is not subject to the Part 21 is not required to make a Part 21 notification when he gains information concerning a defect a noncompliance and therefore not subject to civil penalties. It is anticipated that the organizations within the scope of Part 21 will establish, if they have not already done so, a management concept such that the individual will feel free to identify his safety-related concerns in house.

"§ 21.2 Nothing in these regulations should be deemed to preclude an individual 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."

This policy is in line with the long standing Commission policy for securing safety-related information as mentioned in the statement of considerations.

"Moreover, a longstanding Commission policy encourages individuals not subject to the Commission's regulations to report to the Commission a known or suspected defect or failure to comply; as authorized by law, the identity of anyone so reporting will be withheld from disclosure."

The time of notification is another subject concern. The sequence of events and timing subsequent to deviation identification, evaluation and providing information to the responsible officer or director is shown on this illustration.



The rule presently is silent in regard to the time from when identification of a deviation occurs to the time of notification to the Nuclear Regulatory

Commission. At present this is deemed unquantifiable for all facets of the regulated industry. The times identified are those after the responsible officer or director receives the information of the evaluation. In the event that the time between identification of the deviation and notification is provided to NRC must be quantified then it will be the subject of future regulatory action.

Part 21 is not the "last word" in the prevention of safety hazards. It will not cure the problem of an inadequate procurement document, or inspector who doesn't inspect or faulty design. This rule is only one of a number of the reporting and notification tools presently utilized by the Nuclear Regulatory Commission to insure that we have the necessary safety-related information.

I would like at this time to call to your attention the stated Commission intentions regarding Part 21 as stated in the statement of consideration and as discussed by the representative of the Office of the Executive Legal Director.

"The Commission intends to examine closely the implementation of Part 21 with the view to making any clarifying or other changes that may be warranted in the light of experience. In particular, insufficient experience has been accumulated to permit the writing of a detailed regulation at this time that would provide a precise correlation of all factors pertinent to the question of what is a significant safety hazard. Part 21 is intended in this regard as an initial effort to identify a number of the factors involved with the question of significant safety hazard."

2-1

REMARKS BY
THE OFFICE OF NUCLEAR REACTOR REGULATION
TO PUBLIC REGIONAL MEETINGS ON 10 CFR PART 21
BY
WILLIAM T. RUSSELL

JULY 12-26, 1977

HOW PART 21 IMPACTS
REACTOR LICENSING, LICENSEES AND SUPPLIERS

My name is William Russell and I am a Project Manager in the Office of Nuclear Reactor Regulation's Division of Operating Reactors. My objective is to provide some insight as to the scope of reactor activities to which Part 21 applies, the general criteria that we will be using in our evaluation of reported Part 21 items and how we will factor this information into the reactor licensing process. I will also discuss the impact of this new rule on reactor licensees, vendors, contractors and consultants.

Background

The Energy Reorganization Act of 1974, which established the Nuclear Regulatory Commission, provided a specific review function to include "monitoring, testing and recommending upgrading of systems designed to prevent substantial health or safety hazards." In partial fulfillment of this, NRC reviews operating experience, including reports from NRC inspectors, reactor licensees and vendors. We also review information obtained from NRC research and from foreign exchange agreements. As new technical information and operating experience become available the Office of Nuclear Reactor Regulation determines whether such information could significantly alter previously determined levels of reactor safety. When we conclude that the level of safety has been or may be degraded, timely licensing action is taken. The action taken varies based upon the potential hazard to the public health and safety. These actions can range from an order to shut down a reactor to a request that affected licensees determine the effect of the new technical information or operating experience upon their facilities. Through this process of identifying and resolving technical issues and applying this information to operating reactors, a data base of experience is evolving that is having a positive impact on new plant designs.

Typical Part 21 Report Scenario

The reporting of defects and non-compliance pursuant to 10 CFR Part 21 will be incorporated into the reactor licensing process in a similar manner. A typical scenario for a safety-related defect reported by a basic component supplier for a reactor facility may start with the discovery that a basic component already furnished by the supplier deviates from the procurement document specifications. The supplier would evaluate the deviation or would report the deviation to the purchaser to allow the purchaser to determine if a substantial safety hazard is involved. It is expected that in most instances the supplier's evaluation would require discussion with the purchaser. If, based upon this evaluation, it is concluded that the deviation could create a substantial safety hazard then the deviation must be reported as a defect to the NRC. Before describing how the NRC evaluates and uses Part 21 reports, I will discuss a substantial safety hazard.

The general criteria which we will use in evaluating a substantial safety hazard are identified in the statement of consideration which was published with the new rule. These criteria include: moderate exposure to, or release of, licensed material; major degradation of essential safety-related equipment; and major deficiencies in design, construction, inspection, test or operation. For a power reactor, Regulatory Guide 1.29, identifies the essential safety-related equipment which must remain functional during the Safe Shutdown Earthquake. These safety-related equipments are necessary to ensure (1) the integrity of the reactor coolant pressure boundary, (2) the capability to shutdown the reactor and maintain it in a safe shutdown condition and (3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposure comparable to the guideline exposure of 10 CFR Part 100. Under the new rule these essential safety-related equipments are defined as "basic components." Major degradation of such basic components, or a condition or circumstance involving a basic component that could contribute to exceeding a safety limit is considered a substantial safety hazard. In the case of a redundant basic component, a condition, circumstance or deviation which could cause a failure of that component must be evaluated to determine if there maybe a loss of safety function for the affected basic component or a major reduction in the degree of protection provided to public health and safety. Therefore, a defect in a basic component, even though a redundant component exists, could be reportable under Part 21.

The Office of Inspection and Enforcement will perform the initial evaluation of the safety significance of the reported defect or non-compliance and will evaluate the action being taken by the supplier

and licensee. I&E also determines whether an unreviewed safety issue may exist, if a licensing action is required or if inspection or enforcement action is necessary. If a licensing action or unreviewed safety issue is involved, NRR would be advised and would assume lead responsibility for further NRC action. Within NRR, the Division of Operating Reactors has the responsibility to collect and evaluate experience with operating reactors to assure that appropriate and timely corrective action is taken and to feed back information to other NRR divisions conducting evaluations of proposed reactor facilities. The reported defect is also evaluated to determine if it is common to several reactor facilities. Our review may require the affected reactor licensees to submit additional information and analysis. Interim licensing action may be taken to assure the public health and safety during our review. The interim licensing action could be an order to shutdown, reduce power or other restrictions or conditions on reactor operation pending final resolution of the problem. The final licensing action could require replacement of the defective component or appropriate restrictions on reactor operation. The scenario I have just described is an example of the feedback of reports of defects and noncompliance into reactor licensing.

Impact on Reactor Licensees and Supplier Organizations

I would like to shift gears for a moment to discuss the impact of the new rule on reactor licensees and upon private industry involved in design, construction, test, inspection and consultation for nuclear reactors. For several years we have been requiring permit holders to report significant deficiencies and deviations discovered which could adversely affect the safety of future operation. This reporting is required as a condition of the facility construction permit under 10 CFR 50.55(e). Similarly, the Technical Specifications issued as a part of every power reactor operating license require the reporting of significant failures, malfunctions, degradation and deviations as Licensee Event Reports. Regulatory Guide 1.16 identifies the type of information to be reported in Licensee Event Reports. Therefore, for the power reactor licensee, the notification requirements of the new rule are different only in scope from reporting requirements which are already in place. Duplicate reporting under Part 21 is not required. For example, a Licensee Event Report, which includes all appropriate information required for a Part 21 Notification, would satisfy the requirement that the licensee's director or responsible officer has actual knowledge that the Commission has been adequately informed and a separate Part 21 Notification would not be required. Most research and test reactor licensees are subject to similar reporting requirements as conditions of their construction permits and their operating license Technical Specifications.

The notification of defects and noncompliance which could create a substantial safety hazard is necessary to insure that potential reactor safety hazards are promptly identified, evaluated and resolved. It is for this reason that the notification requirements of Part 21 include organizations supplying safety-related equipment and safety-related services. Safety-related services include design, engineering, testing, inspecting and consulting services which could, if they contained defects, create a substantial safety hazard. Examples of these types of safety-related services and software are:

- . Nondestructive examination of safety-related welds,
- . Design of safety-related pipe hangers and supports,
- . Seismic and geologic surveys for a reactor site,
- . Specification of safety-related hardware characteristics,
- . Computer codes for reactor analysis,
- . Emergency procedures, and
- . Fire protection inspections by fire consultants

Organizations providing these types of safety-related services, as well as licensees and firms that physically construct facilities or supply basic components, must establish procedures to identify deviations from technical requirements and must provide for evaluations to determine if defects exist. These procedures must also assure that directors and responsible officers are informed of the existence of defects in delivered products. For some organizations the implementation of new internal procedures for evaluation of deviations will not be required to accommodate Part 21. Company procedures for the evaluation of deviations which were previously performed as part of good engineering and management practice may be sufficient. Records in connection with design, manufacture, fabrication, placement, erection, test and inspection of basic components and facilities, sufficient to insure compliance with the new rule shall be maintained. The records required to be kept for the design, construction, test, inspection and operation of power reactors under the quality assurance programs specified under 10 CFR Part 50 Appendix B should satisfy the record keeping requirements of the new rule.

Tie-In With Safeguards Rule

Before I conclude I would like to address one additional item. When Part 21 was published in the Federal Register, the statement of considerations addressed failures to comply or defects in a security system.

The NRC recently adopted a new regulation which identified additional requirements for the physical security of nuclear power reactors. The primary safeguards concern for nuclear power reactors is for potential acts of sabotage or terrorism. Such acts are of concern because they could lead to the release of significant amounts of radioactive material which could endanger the public health and safety. Therefore, failures to comply or defects in a security system can contribute to the creation of a substantial safety hazard and are within the scope of Part 21. For example, a defect or noncompliance which allows or could allow an unauthorized individual to gain access to a vital area of a nuclear power plant without being detected by means other than visual surveillance, including remote visual-electronic surveillance, is considered to be a substantial safety hazard and is therefore reportable under Part 21.

Conclusion

In conclusion, I have outlined the basic method by which operating experience including reports of defects and noncompliance are reviewed and as appropriate fed back into the licensing process. I have also discussed the impact of the notifications and record keeping requirements of the new rule upon both reactor licensees and others in the nuclear reactor industry. The process of identifying deviations, conducting evaluations and notifying the NRC of substantial safety hazards will require additional effort and some additional costs. However, the long term benefit of being able to anticipate potential safety problems is substantial.

REMARKS BY
THE OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
TO PUBLIC REGIONAL MEETING ON 10 CFR PART 21

BY
W. A. NIXON
J. E. ROTHFLEISCH

JULY 12-26, 1977

The Impact of Part 21 on Material
and Fuel Cycle Licensees and Suppliers

As a staff member of the Office of Nuclear Material Safety and Safeguards, I am going to describe, briefly, how the new regulation, Part 21, applies to material and fuel cycle licensees.

When the proposed version of Part 21 was first published, I believe many people thought it applied only to nuclear reactors. In fact, Part 21 applies, with a few exemptions I will describe later, to:

- 1) all byproduct material licenses issued under Part 30 to 36
- 2) source material licenses issued under Part 40
- 3) special nuclear material licenses covered by Part 70
- 4) the packaging of radioactive material for transport, Part 71 and
- 5) fuel cycle facilities licensed under Part 50.

In earlier talks this morning, the history and legal aspects of Part 21 have been discussed and the application of Part 21 to nuclear power reactors has been described. Rather than repeat information already presented on the general content and applicability of the rule, I will concentrate on the specific aspects of the rule that are important for determining how the rule is applied to material and fuel cycle licensees.

The definition of basic component as it applies to material and fuel cycle licensees is extremely important. Basic component, for these licensees, is defined in paragraph 21.3 as "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 or failure to comply with any applicable regulation in this chapter, order or license issued by the Commission could create a substantial safety hazard." This definition limits the supplier organizations subject to Part 21 to those that directly supply the licensee. Let me repeat this, responsibility for complying with Part 21

does not, in the case of organizations supplying material and fuel cycle licensees, extend past the first tier of suppliers. The term basic component does include design, inspection, testing or consulting services important to safety that are associated with component hardware, and organizations supplying such services directly to the licensee would be subject to Part 21.

Other aspects of the new rule apply to material and fuel cycle licensees and first tier suppliers just as they do to power reactor licensees and suppliers. Of particular importance are the requirements for posting, notification, procurement documents and inspection and records. We believe that most evaluations of deficiencies and reports to the Commission of defects will be made by licensees, because many suppliers would not have all of the information needed to evaluate the significance of a deviation. We believe appropriate criteria for determination of the existence of a substantial safety hazard include:

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

To the extent that failures to comply or defects in a security system could contribute to a substantial safety hazard, such failures and defects could be within the scope of Part 21. Components of security systems that do not meet performance standards or which fail could present the potential for safety hazards. When such anomalies are noted to exist they should be evaluated pursuant to Part 21.

I mentioned earlier that there were a few exemptions from Part 21. These exemptions are for some uses of radioactive materials authorized by General Licenses in 10 CFR Parts 31, 35, and 40. The exemptions in Part 31 apply to small quantity uses in safety devices, gauges, ice detection equipment and clinical or laboratory testing. The exemption in Part 35 applies to medical use of specified quantities of by-product material. Under Part 40, users of small quantities of source material and the use of depleted uranium in certain industrial products or devices are exempt. The specific exemptions are identified in changes to the regulations associated with the adoption of Part 21.

That completes my formal presentation. We will be available this afternoon to answer any questions you may have. Thank you.

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REMARKS BY
THE OFFICE OF INTERNATIONAL PROGRAMS
TO PUBLIC REGIONAL MEETINGS ON 10 CFR PART 21
AT SAN FRANCISCO, CHICAGO AND PHILADELPHIA
BY
DR. J. D. LAFLEUR, JR.
JULY 19-26, 1977

Part 21 and its Effect on Exporters

As you know, Section 206 requires reporting of defects and non-compliance in "licensed" facilities and activities.

The first version of the rule was quite worrisome to many exporters, who seemed to be placed in the role of having to report to NRC on defects in certain foreign nuclear power plants. It is not the intent of NRC to assume the responsibility for the safety of nuclear energy overseas, nor do we intend to make U. S. vendors, who happen to know about safety problems overseas, report them to us, if these problems do not affect safety in the United States.

Under international agreements we now receive a large amount of important nuclear safety information, on facilities similar to US facilities, from foreign regulatory authorities. Exporters, who also happen to have the safety responsibility for similar US plants, are, of course, involved in the analysis and correction of any defects and non-compliances in the affected plants. Most of these foreign governments do not make early announcements of all safety problems that occur in their nuclear facilities, and they do not wish to have NRC make premature announcements of those foreign problems for them. We do not wish to lose these foreign sources of important safety information, nor do we wish to antagonize these friendly governments. Nor do we wish to make US vendors the source of information of foreign plants against the will of the foreign governments involved, if such information is not necessary for domestic safety. The new rule, and the Federal Register notice announcing it, contain clarification in regard to the applicability of Part 21 to the licensed activity of exporting. Persons who are only licensed to export nuclear facilities or materials and who do not otherwise construct or operate facilities or activities or supply components are not subject to the new part. Individuals subject to this part need report only defects or failures to comply which could create a substantial safety hazard in facilities and activities within the United States. In other words, they must report on defects or failures to comply in the U. S. facilities for which they are responsible parties, not in overseas plants they happen to know about. Further, any notification submitted in accordance with Part 21 may be withheld from public disclosure if the notification falls within one of the exemptions of the Freedom of Information Act, or if withholding is otherwise authorized by law.

Let's look at a specific example:

Suppose a U. S. vendor has a contract to do work in a foreign country (or possibly is an exporter of a foreign plant). In the course of this overseas work, that vendor learns of a defect in a foreign plant that reflects a similar defect in a U. S. domestic plant. Suppose, also, that that vendor is a "responsible" party under 21, for the domestic plant. This vendor reports to NRC the defect in the domestic reactor, but does not provide certain details about the applicable foreign experience because his overseas client or the foreign government has not given him permission to disclose the information publicly.

First, does the vendor have to supply these details?

No, he does not, providing enough explanation is given to NRC to make the information usable in NRC safety work.

This leads to another question: If this vendor requests that information about the foreign experience not be publicly disclosed, will NRC honor this request? Yes, if the information is exempt from public disclosure under U. S. law, and the NRC determines that it is in the public interest to protect it.

I have two examples of such information that could be exempt from public disclosure under U. S. law.

a) If the information is proprietary information, that is, information given in confidence, the disclosure of which would do substantial harm to the vendor's competitive position, the documents containing that information could be withheld under Exemption 4 of Freedom of Information Act.

b) If there is a clear statement from the involved foreign government that the information can be given to NRC only under condition that it be protected from public disclosure, that information may be withheld under either Exemption 4 or Exemption 1 of Freedom of Information Act.

REMARKS BY
OFFICE OF INSPECTION AND ENFORCEMENT
TO PUBLIC REGIONAL MEETINGS ON 10 CFR PART 21
BY
G. W. REINMUTH
JULY 12-26, 1977

The Inspection and Enforcement of Part 21

In the past, when a new rule or requirement was written into our regulations, we have noted that those who must apply the rule to their activities will often have difficulty in translating the requirement in the intended manner. Frequently the user will react to one extreme or the other, depending upon whether the company is the buyer or the seller.

As an example, when the 10 CFR Part 50, Appendix B quality assurance criteria were initially applied, we felt licensees frequently responded by asking more of their suppliers than was intended. On the other hand, when we inspected the licensee's own QA programs and those of his principal contractors, we noted the tendency to require less of themselves than was called for. I suppose this a normal reaction and is the consequence of writing a good portion of our rules in the form of criteria rather than in specification-type requirements.

From the words that you have heard this morning, you are by now aware that Part 21 will probably also present problems in application. It was a difficult rule to write - parts of it include words such as reasonably indicating, responsible officer, could create a substantial safety hazard, etc. Any time one has to apply these kinds of words to a specific work action, reasonable men will differ in their understandings of precisely what the words mean. The message I'm trying to convey is that Part 21 is a complex rule that must be read, studied, comprehended, judgment applied and perhaps more than a reasonable effort put forth to live with it in our everyday affairs.

With respect to the Office of Inspection and Enforcement's role in inspecting against the rule, we do not intend setting up a special new inspection program identified as the Part 21 Inspection Program. We look upon this rule as another requirement which must be covered by our current inspection programs. Those programs cover both reactor and material licensees, and the inspection of reactor contractors and vendors. Basically Part 21 is a reporting requirement, thus our inspectors will not only be investigating and evaluating those things that are reported, but will be looking for situations or conditions which may not have been reported but should have been.

Obviously, there are other specific requirements in the rule which can and will require verification - such things as:

- Proper posting of requirements.
- Preparation and implementation of administrative procedures to assure that Part 21 type events are appropriately identified, evaluated and reported.
- Inclusion of Part 21 requirements in procurement documents.
- Maintenance of records,

and others. These, of course are the relatively easy items to address.

With respect to our enforcement of Part 21 matters, again we do not see the need for modifying our present criteria. For those of you not familiar with our practices, we define noncompliance as a failure to comply with a regulatory requirement whether that requirement is a 10 CFR regulation, a license condition or any other form of requirement. Noncompliance items are further categorized into three categories of severity: violations, infractions, and deficiencies, with a violation being the most severe category. By definition, failure to report constitutes a violation. Sanctions applied to noncompliance items are again imposed according to severity thresholds. These same rules and criteria will be applied to activities falling within the scope of Part 21.

You may note that the rule permits a six month delay in implementation of the posting requirements, the preparation of internal administrative procedures and inclusion of Part 21 provisions in procurement documents. This delay was intended to allow sufficient time for planning and preparation. I must emphasize however, that after January 6, 1978, my office is obligated to enforce the rule as written, therefore our inspectors will expect to see these provisions in place after that date.

In my view, the real difficulty with Part 21 will be to decide what is or what isn't reportable under the rule. It is impossible for any of us on this panel or you in the audience to anticipate all the conditions or situations which might be reportable - or even typical ones. None of the reportable events will be black or white cases - each will require a substantial application of sound engineering judgment and evaluation - on your part and on ours. For guidance, reactor licensees may wish to review their existing procedures currently applied to the reporting of 10 CFR 50.55(e) type deficiencies, since the administrative controls that are necessary to assure satisfaction of those requirements might also be used to satisfy the Part 21 requirements. Keep in mind, however, that Part 21 covers a much broader range of activity, unlike 50.55(e) which is limited to holders of construction permits only.

For those companies not directly licensed by the NRC, but nevertheless subject to Part 21, may I suggest that you establish with your customers and suppliers a clear understanding of how you intend to administer your affairs in order to comply with the rule. Even though compliance with Part 21 may not be a requirement of current in-house contracts and may not show up in new contracts during the next several months, since this provision of the rule is not fully effective until January 6, 1979, defined suppliers of nuclear products and services should be aware that they are still subject to the Part 21 requirements. Further, the responsibility for reporting cannot automatically be delegated or assumed to be the sole responsibility of the buyer.

Since the Office of Inspection and Enforcement is the designated receiving office for Part 21 reports, I would like to point out the key details of the reporting requirements and the mechanics for doing so. This information is shown in Attachment A.

Also the names, titles, addresses and phone numbers of our Headquarters and Regional Directors are provided for your convenience in Attachment B. We hope that your need for them will be negligible.

In summary, I would like to re-emphasize that Part 21 represents a new rule - broad in its implications - but mandated by Congress. Therefore, it is in your interest to assure yourselves that you are familiar with it, difficult as it might be. We, on the other hand, are obliged to inspect for compliance and enforce its provisions.

Attachment A

Part 21 Reporting Requirements

When and how

Within two days following receipt of information.
(Written or other)

Written report within five days.

To whom

Director, Office of Inspection and Enforcement

Regional Director, Office of Inspection and
Enforcement

By whom

Individual director, responsible officer or
authorized individual.

Detail required

See Part 21, Paragraph 21.21(b)(3)
Other as requested by Commission Paragraph 21.21(c).

Attachment B

Office of Inspection and Enforcement

Mailing Addresses and Phone Numbers

Ernst Volgenau, Director Office of Inspection and Enforcement U. S. Nuclear Regulatory Commission Washington, D. C. 20555	(301) 492-7397
Boyce H. Grier, Director, Region I Office of Inspection and Enforcement U. S. Nuclear Regulatory Commission 631 Park Avenue King of Prussia, Pennsylvania 19406	(215) 337-1150
James P. O'Reilly, Director, Region II Office of Inspection and Enforcement U. S. Nuclear Regulatory Commission 230 Peachtree Street, N. W., Suite 1217 Atlanta, Georgia 30303	(404) 221-4503
James G. Keppler, Director, Region III Office of Inspection and Enforcement U. S. Nuclear Regulatory Commission 799 Roosevelt Road Glen Ellyn, Illinois 60137	(312) 858-2660
E. Morris Howard, Director, Region IV Office of Inspection and Enforcement U. S. Nuclear Regulatory Commission 611 Ryan Plaza Drive, Suite 1000 Arlington, Texas 76012	(817) 334-2841
Robert H. Engelken, Director, Region V Office of Inspection and Enforcement U. S. Nuclear Regulatory Commission 1990 N. California Boulevard, Suite 202 Walnut Creek, California 94596	(415) 486-3141

RULFS AND REGULATIONS

20001

ADDITIONAL MATERIAL

Title 10—Energy
CHAPTER 1—NUCLEAR REGULATORY
COMMISSION
Reports to the Commission Concerning
Defects and Noncompliance
AGENCY: U.S. Nuclear Regulatory
Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to require directors and responsible officers of firms and organizations building, operating or owning NRC-licensed facilities, or conducting NRC-licensed activities, to report failures to comply with regulatory requirements and defects or components which may result in a substantial safety hazard. Also covered under the new regulations are directors and responsible officers of firms and organizations supplying safety-related components, including safety-related design, testing, inspection and consulting services.

NRC licensees and other firms and organizations covered by the new regulations must adopt internal procedures to assure that safety-related defects and noncompliance are brought to the attention of responsible officers and directors. Those individuals, in turn, will be required to notify the Commission within two days, and file a written report within five days, of learning of the defect or noncompliance. Directors and responsible officers may designate an employee to provide on their behalf the notification to NRC.

EFFECTIVE DATE: July 6, 1977. Certain obligations under the effective rule are not imposed until January 6, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. W. E. Campbell, Jr., Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Phone 202-442-6917.

SUPPLEMENTARY INFORMATION: On March 3, 1975, the Nuclear Regulatory Commission published in the *Federal Register* (40 FR 8837) for public comment proposed amendments to 10 CFR Parts 2, 31, 35, and 40 of its regulations and a proposed new Part 21 to its regulations, "Reporting of Defects and Noncompliance."

The purpose of these proposed amendments and the new proposed Part 21 is to implement section 206 of Pub. L. 93-433, the Energy Reorganization Act of 1974, as amended.

Section 206 of the Energy Reorganization Act of 1974 as amended, reads as follows:

"NONCOMPLIANCE"

Sec. 206. (a) Any individual director, or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed, or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or pursuant to this Act, who obtains information reasonably indicating that such facility or activity or basic components supplied to such facility or activity—

(1) 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

(2) Contains a defect which could create a substantial safety hazard as defined by regulations which the Commission shall promulgate, shall immediately notify the Commission of such failure to comply, or of such defect, unless such person has actual

knowledge that the Commission has been adequately informed of such defect or failure to comply.

(b) Any person who knowingly and recklessly fails to provide the notice required by subsection (a) of this section shall be subject to a civil penalty in an amount equal to the amount provided by section 204 of the Atomic Energy Act of 1954, as amended.

(c) The requirements of this section shall be prominently posted on the premises of any facility licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended.

(d) The Commission is authorized to conduct such reasonable inspections and other enforcement activities as needed to insure compliance with the provisions of this section."

The new Part 21 requires that the directors and responsible officers of organizations that construct, own, operate or supply components of a facility or activity that is licensed or otherwise regulated by the Nuclear Regulatory Commission inform the Commission if they obtain information reasonably indicating that such facility, activity or basic component fails to comply with regulatory requirements relating to substantial safety hazards or that such facility, activity, or basic component contains a defect which could create a substantial safety hazard. Part 21 additionally requires that these organizations establish procedures to evaluate deviations from the technical requirements of the procurement documents or inform the purchaser concerning the deviation in order that the purchaser evaluate the deviation or have it evaluated. The organizations subject to the regulations in Part 21 may be many procurement users away from the holder of a license to construct or operate a nuclear power reactor. If the licensee is other than to construct or operate a nuclear power reactor, then the organizations subject to the regulations are those organizations that directly supply the licensee of the facility or activity. The directors and responsible officers of these organizations will be subject to a fine of up to \$5,000 for each deliberate failure to notify the Commission of the existence of such a defect or noncompliance. The organizations subject to Part 21 regulations must also maintain records, keep copies of specific documents, inform procurement, supplier documents of their responsibility under Part 21 and allow inspection of their premises, facilities and activities by duly authorized representatives of the Commission.

The Commission requires that a number of reports and notifications be submitted by licensees. These include licensee's report of incidents required by 10 CFR § 20.403, permit holder's notification of design or construction deficiencies required by 10 CFR § 20.55(e)(1), and licensee's report of theft or attempted theft of special nuclear material required by 10 CFR § 20.62. Other Commission regulations provide for receipt of various kinds of requests or information. For example, 10 CFR § 20.62 provides for petitions to issue, amend or rescind regulations, and 10 CFR § 19.16 provides for notifications from workers in regard to radiological hazards. These communica-

tions from licensee and the public are methods of securing information concerning the implementation effectiveness of Commission regulations. This information is an essential ingredient of sound regulation. The regulations in Part 21 add another required notification. Moreover, a longstanding Commission policy encourages individuals not subject to the Commission's regulations to report to the Commission a known or suspected defect or failure to comply, as authorized by law, the identity of anyone so reporting will be withheld from disclosure.

The Commission intends to examine closely the implementation of new Part 21 with a view to making any clarifying or other changes that may be warranted in light of experience. In particular, insufficient experience has been accumulated to permit the writing of a detailed regulation at this time that would provide a precise correlation of all factors pertinent to the question of what is a significant safety hazard. Part 21 is intended in this regard as an initial effort to identify a number of the factors involved with the question of significant safety hazard. Further, additional guidance in the form of regulatory guides may be developed should experience with the application of Part 21 indicate the need for such guidance. In this regard, we expect that the implementation efforts of the staff and those subject to the rule, and the views of interested members of the public should provide the necessary data base for such further guidance.

During the development of the Energy Reorganization Act, Congress identified a need for an effective means to "anticipate problems before the event." Section 206 was developed to fill that need.

Interested persons have been afforded an opportunity to participate in the development of Part 21 and the associated amendments. The more important changes made to Part 21 are listed below and are based largely on consideration of public comments.

(1) The individuals subject to the notification requirement of Part 21 have been restricted to (a) directors and (b) officers vested with executive authority over activities subject to this part. These individuals may identify an individual that is authorized to provide notification to the Commission.

This new part is only one of many of the reporting channels that concerns defects or noncompliance, e.g., 10 CFR 20.55(e). Individuals that are subject to the requirements of this part that become aware of a defect or noncompliance that is outside the responsibility of their organization and individuals that are not subject to the requirements of any part of Title 10 are encouraged, but not required, to report to the Commission known or suspected defects or failure to comply. As authorized by law, the identity of anyone so reporting will be withheld from disclosure.

(2) Part 21, as adopted, does not specify whether firms may reimburse directors or responsible officers for civil penalties imposed pursuant to these regulations, and instead allows this question

to be resolved in accordance with the applicable state law.

(3) The definition of "deviation" as applied to components the purchaser has restricted to include "the 1974 Act as delivered components (in 1974 model) requirements included in a purchaser's document that could, at the time of an evaluation, create a substantial safety hazard. Defect also includes a deviation in a portion of the facility subject to the construction permit or manufacturing licensing requirement of Part 50 provided the deviation could, at the time 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. Whether such deviation could result in a substantial safety hazard is determined during the deviation evaluation. Defect also includes, for facilities licensed for operation under Part 50, any condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit as set forth in the operating license technical specifications.

(4) The definition of basic components has been divided into two parts. The first part is applicable to power reactors licensed under Part 50 and the second part is applicable to activities licensed pursuant to Parts 30, 40, 70 or 71 and to other Part 50 facilities. For power reactors the definition is based on the guidance given in Regulatory Guide 1.20. For other facilities and activities, basic component has been defined as components that are directly procured by a licensee.

(5) Substantial safety hazard has been defined in terms of a major reduction in the degree of protection provided to the public health and safety. Criteria that are appropriate for determination of creation of a substantial safety hazard include:

Moderate exposure to, or release of, licensed material.

Major degradation of essential safety-related equipment.

While agreeing with all other aspects of this Notice, Commissioner Gilliam believes there should be turned from reimbursing direct or responsible others for civil penalties imposed pursuant to Part 21, on grounds that Section 206 of the Energy Reorganization Act is designed to impose personal responsibility, a goal not permitted by corporate indemnification. The Commission majority believes that in accordance with the general practice of Federal regulatory bodies in analogous matters, the question of the reimbursement of such penalties should be governed by applicable state law. It notes that the adverse publicity attendant on being subjected to a civil penalty for knowingly concealing significant safety information would be a major incentive to compliance. Irrespective of whether the person so penalized was later reimbursed by the company, the majority also recognizes the serious practical difficulty in attempting to differentiate between a properly awarded salary increase or bonus and an improper reimbursement. If Part 21 does not in practice appear to be accomplishing its purpose, the Commission will, of course, propose changes deemed appropriate in light of experience.

Major deficiencies involving design, construction, inspection, test or use of licensed facilities or material.

To the extent that failures to comply or defects in a security system can contribute to a substantial safety hazard, such failures and defects are within the scope of Part 21.

(6) Clarification has been added in regard to which organizations are subject to the regulations in this part. In order that the implementation of Section 206 may be responsive to anticipation of problems before the event, a broad interpretation of "firm constructing, owning, operating or supplying the components" has been used. This interpretation includes not only licensees and organizations that physically construct facilities and physically supply components but also includes organizations that only supply safety-related services such as design, inspection, testing or consultation; e.g., site geological investigations.

This interpretation is intended to bring within the regulations in this part those various organizations that can create a substantial safety hazard considering the various methods available for consultation, procurement, design, construction, testing, inspection and operation. These methods include not only the option where design and construction are accomplished by one organization but also the option where one organization does safety-related consultation, another safety-related design and another the actual construction. Each of these organizations has the capability to generate a defect and a potential for failing to comply.

If a basic component is fabricated by one organization using a design from another organization, the possibility of creating a substantial safety hazard, based upon a faulty design, exists upon the delivery of the design that fails to comply or contains a defect. A substantial safety hazard, based upon faulty fabrication, exists upon delivery of the item that fails to comply or contains a defect. In many instances the competent fabricating organization possesses neither the capability nor the responsibility for design.

It is realized that during the activities of design and consultation there may be a stage of conceptual design or consultation in regard to feasibility. Only when such a design or consultation can result in the creation of a substantial safety hazard is it appropriate to specify the applicability of Part 21 in the procurement document.

(7) The organizations subject to this part must establish procedures to provide for correction of deviations, or evaluation of deviations or informing purchasers of the deviation so the purchaser may evaluate the deviation. These procedures must also provide for informing a responsible officer or director of the organization of any resulting defect or failure to comply.

(8) The provisions of Part 21 imposing requirements that procurement documents state, when applicable, that Part 21 applies would be applicable only to future procurements of facilities,

components or services, i.e., procured on or after six months after the effective date of Part 21.

The effective date of 4218 dealing with posting requirements, 42121(a) dealing with adopting procedures, and 42151 dealing with maintenance of records has been deferred until January 6, 1978, to allow organizations to establish and implement procedures.

(9) The organizations subject to the regulations in Part 21 are required to prepare records in connection with their activities to assure compliance with this part. Prior to destruction of such records they shall be offered to the purchaser. It is not anticipated that these documentation requirements will necessitate any change in the documentation procedures of organizations that are presently complying with 19 CFR 20 Appendix B, "Quality Assurance Criteria."

(10) Clarification has been added in regard to the applicability of Part 21 to the licensed activity of exporting. Persons who are only licensed to export nuclear facilities or materials and who do not otherwise construct or operate facilities or activities or supply components are not subject to the new part. Individuals subject to this part need report only defects or failures to comply which could create a substantial safety hazard in facilities and activities within the United States. Further, any notification submitted in accordance with Part 21 may be exempt from public disclosure as authorized by law.

After consideration of the comments received and other factors, the Commission has adopted the amendments to Parts 2, 31, 34, 35, 40, and 70, and the new Part 21 set forth below.

Pursuant to the Atomic Energy Act of 1954 as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following new Part 21 of Title 10, Chapter 1 of the Code of Federal Regulations, and amendments to Parts 2, 31, 34, 35, 40, and 70 are published as a document subject to codification to be effective on July 6, 1977.

PART 24—RULES OF PRACTICE

Paragraph (b) of § 2.293 is amended to read as follows:

§ 2.293 Scope of subpart.

(b) This subpart also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to section 234 of the Act and section 206 of the Energy Reorganization Act of 1974.

2. A new Part 21 is added to read as follows:

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

GENERAL PROVISIONS

Sec.	
21.1	Purpose.
21.2	Scope.
21.3	Definitions.
21.4	Interpretations.
21.5	Communications.
21.6	Posting requirements.
21.7	Exemptions.

NOTIFICATION

§ 21.21 Notification of failure to comply or existence of a defect

PROCUREMENT DOCUMENTS

§ 21.22 Procurement documents

INSPECTIONS, RECORDS

§ 21.41 Inspections

§ 21.51 Maintenance of records

ENFORCEMENT

§ 21.61 Failure to notify

APPROVED: Dec 161, Pub. L. 85-705, 88 Stat. 245, sec. 234, Pub. L. 91-181, 84 Stat. 444, sec. 216, Pub. L. 93-433, 88 Stat. 1249 (42 U.S.C. 2201, 2282, 5846).

GENERAL PROVISIONS

§ 21.1 Purpose.

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity 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 defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

§ 21.2 Scope.

The regulations in this part apply, except as specifically provided otherwise in Parts 31, 34, 35, 40, or 70 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, and/or transfer within the United States source, byproduct and/or special nuclear materials, or to construct, manufacture, possess, own, operate and/or transfer within the United States any production or utilization facility, and to each director (see § 21.3(f)) and responsible officer (see § 21.3(j)) 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 (see § 21.3(e)) a production or utilization facility licensed for manufacture, construction or operation (see § 21.3(h)) pursuant to Part 50 of this chapter or supplies (see § 21.3(i)) basic components (see § 21.3(a)) for a facility or activity licensed, other than for export, under Parts 30,

40, 50, 70, or 71. Nothing in these regulations should be deemed to preclude an individual 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.

§ 21.3 Definitions.

As used in this part, (a) "Basic component," when applied to nuclear power reactors means a plant structure, system, component or part thereof necessary to assure (1) the integrity of the reactor coolant pressure boundary, (2) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (3) 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; "Basic component," when applied to other facilities and when applied to other activities licensed pursuant to Parts 30, 40, 50, 70 or 71 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(a)). In all cases "basic component" includes design, inspection, testing, or engineering services important to safety that are associated with the component hardware, whether these services are performed by the component supplier or others.

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

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

(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(a)), the deviation could create a substantial safety hazard, or

(2) The installation, use, or operation of a basic component containing a defect

*NRC Regional Offices will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers (for nights and holidays as well as regular hours) are listed below:

Region	
I (Philadelphia).....	(215) 397-1150
II (Atlanta).....	(404) 221-4500
III (Chicago).....	(312) 854-3500
IV (Dallas).....	(214) 335-2841
V (San Francisco).....	(415) 485-3141

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(f)).

(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) "Evaluation" means the process accomplished by or for a licensee to determine whether a particular deviation could create a substantial safety hazard.

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

(i) "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.

(j) "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.

(k) "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, 70 and 71.

(l) "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 communications and reports concerning the regulations in this part should be addressed to the Director.

Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, or to the Director of a Regional Office at the address specified in Appendix D of Part 20 of this chapter. Communications and reports also may be delivered in person at the Commission's offices at 1717 H Street NW., Washington, D.C., at 5920 Norfolk Avenue, Bethesda, Md., or at a Regional Office at the location specified in Appendix D of Part 20 of this chapter.

§ 21.6 Posting requirements.

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.

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.

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.

Notification

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

(a) Each individual, corporation, partnership or other entity subject to the regulations in this part shall adopt appropriate procedures to: (1) provide for (i) evaluating deviations or (ii) informing the licensee or purchaser of the deviation in order that the licensee or purchaser may cause the deviation to be evaluated unless the deviation has been corrected; and (2) assure that a director or responsible officer is informed 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. The effective date of this paragraph has been deferred until January 6, 1978.

(b)(1) A director or responsible officer subject to the regulations of this part or a designated person shall notify the Commission when he 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, 70 or 71 and that is within his organization's responsibility; or (ii) a basic component that is within his 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, 70 or 71. The above notification is not required if such individual has actual knowledge that the Commission has been adequately informed of such defect or such failure to comply.

(2) Initial notification required by this paragraph shall be made within two days following receipt of the information. Notification shall be made to the Director, Office of Inspection and Enforcement, or to the Director of a Regional Office. If initial notification is by means other than written communication, a written report shall be submitted to the appropriate Office within 5 days after the information is obtained. Three copies of each report shall be submitted to the Director, Office of Inspection and Enforcement.

(3) 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 purchaser or licensee.

(4) 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 (1) paragraph.

(c) Individuals subject to paragraph (b) may be required by the Commission to supply additional information related to the defect or failure to comply.

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.

§ 21.51 Maintenance of records.

(a) Each licensee of a facility or activity, subject to the regulations in this part shall maintain such records in connection with the licensed facility or activity as may be required to assure compliance with the regulations in this part.

(b) Each individual, corporation, partnership, or other entity subject to the regulations in this part shall prepare records in connection with the design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of any facility, basic component supplied for any licensed facility or to be used in any licensed activity sufficient to assure compliance with the regulations in this part. After delivery of the facility or component and prior to the destruction of the records relating to evaluation (see § 21.31) or notifications to the Commission (see § 21.21), such records shall be offered to the purchaser of the facility or component. If such purchaser determines any such records:

(1) Are not related to the creation of a substantial safety hazard, he may authorize such records to be destroyed; or

(2) Are related to the creation of a substantial safety hazard, he shall cause such records to be offered to the organization to which he supplies basic components or for which he constructs a facility or activity.

If such purchaser is unable to make the determination as required above then the responsibility for making the determination shall be transferred to the individual, corporation, partnership, or other entity subject to the regulations in this part that issued the procurement document to the purchaser. In the event that the determination cannot be made at that level then the responsibility shall be transferred in a similar manner to another individual, corporation, partner-

RULES AND REGULATIONS

this, or other entity subject to the regulations in this part, until, if necessary, the licensee shall make the determination.

(c) Records that are prepared only for the purpose of assuring compliance with the regulations in this part and are not related to evaluations or notifications to the Commission may be destroyed after delivery of the facility or component.

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

ENFORCEMENT

§ 21.61 Failure to notify.

Any director or responsible officer subject to the regulations in this part who knowingly and consciously fails to provide the notice required by § 21.21 shall be subject to a civil penalty in an amount not to exceed \$5,000 for each failure to provide such notice and a total amount not to exceed \$25,000 for all failures to provide such notice occurring within any period of thirty consecutive days. Each day of failure to provide the notice required by § 21.21 shall constitute a separate failure for the purpose of computing the applicable civil penalty.

Note.—The reporting and record keeping requirements contained in this part have been approved by the General Accounting Office under H-160925 (60-448).

PART 31—GENERAL LICENSES FOR HYPRODUCT MATERIAL

§§ 31.2, 31.5, 31.7, 31.8, 31.10, and 31.11 (Amended)

3. In 10 CFR Part 31, § 31.2(a) is amended by changing the words "Parts 19, 20, and 21" to read "Parts 19, 20, 21, and 22."

4. In 10 CFR Part 31, §§ 31.5(c)(1), 31.7(b), 31.8(c), 31.10(b)(3), and 31.11 (f) are amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

PART 34—LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

§ 34.31 (Amended)

1. In 10 CFR Part 34, § 34.31(a)(2) is amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

§ 35.31 (Amended)

6. In 10 CFR Part 35, § 35.31(c) is amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

PART 40—LICENSING OF SOURCE MATERIAL

§§ 40.22 and 40.23 (Amended)

7. In 10 CFR Part 40, § 40.22(b) is amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

8. In 10 CFR Part 40, § 40.23(c) is amended by changing the words "Part 20" to read "Parts 20 and 21."

PART 70—SPECIAL NUCLEAR MATERIAL

§ 70.19 (Amended)

9. In 10 CFR Part 70, § 70.19(c) is amended by changing the words "Parts 19 and 20" to read "Parts 19, 20, and 21."

Dated at Washington, D.C., this 1st day of June 1977.

For the Nuclear Regulatory Commission.

SAMUEL J. CHALK,
Secretary of the Commission.

(PR Doc 77-15887 Filed 6-3-77; 8:45 AM)

END

DATE

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8-9-77

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8-9-77
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UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
WASHINGTON, D.C. 20555

July 24, 1987

NRC INFORMATION NOTICE NO. 87-33: APPLICABILITY OF 10 CFR PART 21
TO NONLICENSEES

Addressees:

All NRC licensees.

Purpose:

This notice is provided to inform addressees of a potential generic problem concerning the applicability of 10 CFR Part 21 to certain fabrication, erection, installation, modification, inspection, testing, and training services provided to licensees. It is expected that recipients will review the information for applicability to their facilities and consider actions, if appropriate, to preclude similar problems. However, suggestions contained in this information notice do not constitute NRC requirements; therefore, no specific action or written response is required.

Description of Circumstances:

During recent NRC inspections at the Byron Station, Units 1 and 2, it was noted that the licensee, Commonwealth Edison Company (CECo), had failed to appropriately apply the requirements of 10 CFR Part 21 to onsite contractors. These contractors provided fabrication, erection, installation, modification, maintenance, inspection, and testing services for the Byron facility. During interviews with senior CECo management, the NRC was informed that CECo had made the decision not to specify applicability of the requirements of 10 CFR Part 21 for any of their onsite contractors. During a separate NRC inspection, it was also noted that Iowa Electric Light and Power Company (IELP) had failed to appropriately apply the requirements of 10 CFR Part 21 to a local vendor that had repaired/rewound Class 1E electrical equipment for the Duane Arnold Nuclear Power facility. IE Information Notice 85-101, "Applicability of 10 CFR 21 to Consulting Firms Providing Training," was previously issued on December 31, 1985, to inform licensees and consultants of a potential generic problem concerning the applicability of 10 CFR Part 21 to certain training activities provided by consultants. The notice was issued after an NRC vendor inspection of a company which provided consulting services, including training, to the nuclear industry disclosed that licensees had failed to appropriately apply the requirements of 10 CFR Part 21 to the consultant providing the training.

Discussion:

The Commission is taking this opportunity to emphasize the responsibilities of licensees under the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance." 10 CFR Part 21 establishes procedures and requirements for the implementation of Section 206 of the Energy Reorganization Act of 1974, as amended. Section 206 imposes reporting responsibilities on directors and responsible officers of firms constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended. The focus of Section 206 goes beyond those entities licensed or regulated by the Commission to all entities that engage in the activities described in the regulation.

10 CFR 21.3(c) states that the terms "constructing" or "construction" include the design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity that is subject to 10 CFR Part 21 and consulting services which are related to the facility or activity that are important to safety. 10 CFR 21.3(1) states that the terms "supplying" or "supplies" means contractually responsible for a basic component used or to be used in a facility or activity subject to 10 CFR Part 21. 10 CFR 21.3(a)(3) states that "in all cases 'basic component' 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." Hence, onsite and offsite construction services are subject to the provisions of 10 CFR Part 21 whenever these services are associated with a basic component as defined in 10 CFR 21.3(a)(1). Although 10 CFR Part 21 obligations are applicable, whether or not the contractor has been contractually obligated to the provisions of 10 CFR Part 21, licensee procurement of such services should nevertheless specify the applicability of 10 CFR Part 21 as stated in 10 CFR 21.31 unless such services fall under the definition of "commercial grade item" as defined in 10 CFR 21.3(a)(4). Any deviation discovered following the suitability for application review performed to dedicate a commercial grade item for a safety-related application would be required to be evaluated by the dedicating or subsequent user organization and, if appropriate, reported pursuant to the requirements of 10 CFR Part 21.

Further discussion and guidance on this matter is provided 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," published in October 1977.* This publication provides NRC staff remarks on 10 CFR Part 21 as well as some legislative and legal discussions on 10 CFR Part 21 and its impact upon reactor, material, fuel cycle, and export licensees and related suppliers.

*NUREG-0302, Rev. 1, is available through the NRC/GPO Sales Program, U.S. NRC, Washington, D.C. 20555, (202) 275-2060.

No specific action or written response is required by this information notice. If you have any questions about this matter, please contact the Regional Administrator of the appropriate regional office or this office.

Charles E. Rossi
Charles E. Rossi, Director
Division of Operational Events Assessment
Office of Nuclear Reactor Regulation

Technical Contacts: Jaime Guillen, NRR
(301) 492-8933

M. P. Phillips, RIII
(312) 790-5530

R. S. Love, RIII
(312) 790-5593

Attachment: List of Recently Issued NRC Information Notices

November 3, 1988

4A 68-2

PDR

The Honorable John B. Breaux, Chairman
Subcommittee on Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

8901120437
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PDR

Dear Mr. Chairman:

Enclosed for your information are copies of proposed rulemaking to be published for public comment in the Federal Register. Also enclosed is a public announcement concerning the rulemaking.

The Commission is proposing to amend its regulations regarding the reporting of safety defects in 10 CFR 21 and 10 CFR 50.55(e). The proposed revisions are a result of Commission efforts to apply the experience gained at Three Mile Island and also to reflect Commission experience with existing regulations. The proposed Amendments concentrate on reporting of significant safety defects in the construction and operation of nuclear power plants.

The revisions will eliminate duplicate reporting by different entities within the nuclear industry; establish consistency of reporting requirements, and clarify the criteria for reporting.

Sincerely,

Original signed by
E. L. Jordan

Edward L. Jordan, Director
Office for Analysis and Evaluation
of Operational Data

Enclosure:
As stated

cc: Senator Alan K. Simpson

Distribution:

DCS JRosenthal
ROAB R/F GLanik
AEOD R/F KBlack
ELJordan MWilliams
CJHeltemes WJones
TMNovak
VBenaroya

Identical Letters Sent To:

Rep. Morris K. Udall
Rep. Manuel Lujan, Jr.
Rep. Philip Sharp
Rep. Carlos J. Moorhead
Rep. Mike Synar
Rep. William F. Clinger, Jr.

*SEE PREVIOUS CONCURRENCE

4A
EN
10/29/88

DFC	:*ROAB:DSP	:*ROAB:DSP	:*ROAB:DSP	:*DSP	:*D:DSP	:DD:AEOD	:D:AEOD
NAME	:WJones	:GLanik	:JRosenthal	:VBenaroya	:TMNovak	:CJHeltemes	:ELJordan
DATE	:8/2/88	:8/4/88	:8/5/88	:8/5/88	:8/8/88	:9/1/88	:9/1/88

Accession#	Docket	Author Name	Affil	Issued	Microfiche Address
B901120443		JORDAN,E.L.	NEXD	BB1103	69615-071/69615-021
(#)	49	Forwards proposed rulemaking re reporting of safety defects in 10CFR21 & 50.55(e),for info.Public announcement re rulemaking			
B901120437		JORDAN,E.L.	NEXD	BB1103	69614-223/69614-223
(#)	7	Forwards proposed rulemaking re reporting of safety defects in 10CFR21 & 50.55(e),for info.Public announcement re rulemaking			
B901120420		JORDAN,E.L.	NEXD	BB1103	69614-219/69614-219
(#)	0	Forwards proposed rulemaking re reporting of safety defects per 10CFR21 & 50.55(e) & public announcement.Proposed amends			
B901120415		JORDAN,E.L.	NEXD	BB1103	69614-215/69614-215
(#)	1	Forwards proposed rulemaking re reporting safety defects in 10CFR21 & 50.55(e),for info.Proposed amends concentrate on			