

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

June 17, 1991

NRC INFORMATION NOTICE NO. 91-39: COMPLIANCE WITH 10 CFR PART 21,
"REPORTING OF DEFECTS AND NONCOMPLIANCE"

Addressees:

All Nuclear Regulatory Commission (NRC) material licensees.

Purpose:

The purpose of this notice is to remind licensees of the requirements contained in 10 CFR Part 21, "Reporting of Defects and Noncompliance" (Attachment 1). It is expected that licensees will review this information, distribute this notice to responsible staff, and consider actions, if appropriate, to ensure compliance with applicable requirements. However, this notice does not in itself establish any new requirements.

Description of Circumstances:

Past inspections at materials licensees indicate that many licensees are not complying with all the requirements of Part 21 and are unclear about the applicability of Part 21 to their licensed programs.

In one case, a company supplying teletherapy units discovered a failure in a timer which could have resulted in a substantial safety hazard. Although the failure was evaluated and the timer was determined to require replacement, an evaluation to determine if a substantial safety hazard could exist was not performed. As a result, a responsible officer or director in the licensee's organization was not informed that the timer contained what NRC later determined to be a defect, and NRC was not notified of the defect, as required by 10 CFR 21.21(b). A contributing factor in this case was the failure to establish appropriate procedures to evaluate whether a deviation could represent a substantial safety hazard, as required by 10 CFR 21.21(a).

In another case a radiographic equipment manufacturer reviewed circumstances surrounding separation of a source assembly from the drive cable. Although the licensee took actions to recall the defective source, it failed to report the defect to NRC and had not developed procedures for evaluating manufacturing defects, to determine applicability to Part 21 reporting.

Discussion:

Part 21 was issued in June 1977, and applies to all licensees and certain unlicensed vendors. The requirements in Part 21 are to ensure that equipment deficiencies or failures that could create a substantial safety hazard involving NRC-regulated activities are reported to NRC. Prompt licensee reporting of

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defects will enable NRC to determine if a defect is generic in nature, so that appropriate measures can be taken to ensure protection of the public health and safety.

The requirements are based on Section 206 of the Energy Reorganization Act, which states, in part, "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..., or (2) Contains a defect which could create a substantial safety hazard, ... shall immediately notify the Commission of such failure to comply, or of such defect...."

The principal requirements of Part 21 include the following:

- (1) Licensees must post required documents related to Part 21 in a conspicuous location. These include a copy of the regulation, Section 206 of the Energy Reorganization Act of 1974, and any procedures developed pursuant to Part 21. [10 CFR 21.6(a) and (b)]
- (2) Licensees must develop procedures for identifying and evaluating deviations, or informing affected customers, so that the customer can evaluate the deviation; and must also develop procedures for reporting defects to a director or responsible officer. [10 CFR 21.21(a)]
- (3) Licensees must report defects to NRC, within certain time frames. [10 CFR 21.21(b)]
- (4) Procurement documents issued by the licensee for basic components must state that Part 21 applies to the procurement. [10 CFR 21.31]

NRC staff recognizes that these requirements are very broad and require considerable licensee judgment to implement. As a minimum, licensees should determine which aspects of their licensed activity could result in a substantial safety hazard from a defect in a basic component. Attachment 2 provides guidelines for determining what constitutes a substantial safety hazard. NUREG-0302, Revision 1, published in October 1977, provides responses to questions on Part 21 raised in public regional meetings and contains several examples that will provide additional guidance on what constitutes a substantial safety hazard. Copies of NUREG-0302 may be purchased from the National Technical Information Service, Springfield, VA 22161.

Furthermore, licensees are required to have procedures that implement the requirements to report defects. Procedures should assign responsibilities to the appropriate individuals, to identify and report deviations to responsible company officers. The responsibilities of company officers should be described; that is, to evaluate and report deviations to purchasers, and to inform NRC of defects within the required time frames. Licensees should evaluate their own programs and develop procedures appropriate for their activities. Attachment 3 provides a sample procedure for identifying and reporting defects, under Part 21.

Manufacturers or suppliers who provide licensees with basic components that contain, or are used with, radioactive material, would normally need more extensive procedures to ensure proper identification and reporting of defects than customers who do not supply components to others. These procedures should contain, as a minimum, the following:

1. Directions to acquire information sufficient to describe the deviation.
2. Directions to analyze the effect of the deviation, in a basic component, if used by a licensee.
3. Directions to reach a conclusion, based on the analysis as to whether the deviation could create a substantial safety hazard.

Licensees are subject to inspection for compliance with Part 21, as well as other applicable NRC requirements, and may be subject to enforcement action for noncompliance. This information notice does not require any written response. If you have any questions about this matter, please contact the technical contact listed below or the appropriate NRC regional office.



Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety

Technical Contact: Cheryl A. Trottier, NMSS
301-492-3422

Attachments:

1. 10 CFR Part 21
2. Guidelines for Determining Whether a Substantial Safety Hazard Exists
3. Sample Procedure for Identifying and Reporting Defects Under 10 CFR Part 21
4. List of Recently Issued NMSS Information Notices
5. List of Recently Issued NRC Information Notices

**UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS**

Attachment 1
IN 91-39
June 17, 1991
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TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS - ENERGY

21.1

21.3(a)

**PART
21**

REPORTING OF DEFECTS AND NONCOMPLIANCE

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Authority: Sec. 161, 66 Stat. 948, as amended, sec. 234, 63 Stat. 494, as amended (42 U.S.C. 2201, 2202); sec. 203, as amended, 208, 66 Stat. 1242, as amended, 1246 (42 U.S.C. 5841, 5844).

Sec. 21.2 also issued under sec. 133, 141, Pub. L. 87-423, 66 Stat. 2232, 2241 (42 U.S.C. 1015a, 10151).

For the purposes of sec. 221, 66 Stat. 954, as amended (42 U.S.C. 2273); §§ 21.9, 21.11(a) and 21.31 are issued under sec. 161b, 66 Stat. 944, as amended (42 U.S.C. 2201(b)); and §§ 21.21, 21.41 and 21.51 are issued under sec. 161c, 66 Stat. 950, as amended (42 U.S.C. 2201(c)).

GENERAL PROVISIONS

§ 21.1 Purpose.

The regulations in this part establish procedures and requirements for implementation of section 306 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, 39, 40, 60, 61, 70, or 72 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, and/or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high-level radioactive waste, or to construct, manufacture, possess, own, operate and/or transfer within the United States, any production or utilization facility, or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS), and to each director (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 60 of this chapter, an independent spent fuel storage installation (ISFSI) for the storage of spent fuel licensed pursuant to Part 72 of this chapter or a monitored retrievable storage installation (MRS) for the storage of spent fuel or high-level radioactive waste licensed pursuant to Part 72 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, 39, 40, 50, 60, 61, 70, 71, or 72 of this chapter. Nothing in these regulations should be deemed to preclude either an individual or a manufacturer/supplier of a commercial

grade item (see § 21.3(a-1)) not subject to the regulations in this part from reporting to the Commission a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure.¹

§ 21.3 Definitions.

As used in this part:

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

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

(3) In all cases "basic component" includes 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.

¹ 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: 54 FR 42287

Region:		
I	(Philadelphia).....	(215) 237-8000
II	(Atlanta).....	(404) 331-4800
III	(Chicago).....	(708) 780-4300
IV	(Dallas).....	(817) 880-6100
IV	Tri-State Recovery Field Office (Denver).....	(303) 276-2876
V	(San Francisco).....	(415) 943-3700

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

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

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

(c) "Constructing" or "construction" means the 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.

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

(d) "Defect" means:

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

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

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

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

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

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

(g) "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, 60, 61, 70, 71, or 72 of this chapter.

(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 Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, U.S. Nuclear Regulatory Commission, Washington, DC 20553, or to the Administrator of a Regional Office at the address specified in Appendix D of Part 20 of this chapter. Communications and reports may be delivered in person at the Commission's offices at 2120 L Street NW, Washington, DC, or at 11555 Rockville Pike, Rockville, Maryland.

§ 21.6 Posting requirements.

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

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

(c) The effective date of this section has been deferred until January 8, 1978.

21.7

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21.51(b)

§ 21.7 Exemptions.

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

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

§ 21.8 Information collection requirements: OMB approval.

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

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

NOTIFICATION

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

(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) Falls to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order or license of the Commission relating to 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, 60, 61, 70, 71, or 72 of this chapter 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, 60, 61, 70, 71, or 72 of this chapter. 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 must be made within 2 days following receipt of the information. Notification must be made to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or to the Administrator of a Regional Office. If initial notification is by means other than written communication, a written report must be submitted to the appropriate Office within 5 days after the information is obtained. Three copies of each report must be submitted to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate.

(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 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 (b) of this section 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 designs, 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 § 21.31), 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

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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, partnership, 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 equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

[Note removed 49 FR 19623]

**GUIDELINES FOR DETERMINING WHETHER
A SUBSTANTIAL SAFETY HAZARD EXISTS**

1. A 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 ensure public health and safety. Note that the term "public health and safety" includes both members of the public and licensee workers/employees.
2. From a radiological perspective, a substantial safety hazard exists if there is a potential for moderate exposure to, or release of, licensed material.
 - a. Guidelines for determining moderate exposure:
 - o Greater than 25 rem (whole body or its equivalent to other body parts) to occupationally exposed workers in a period of a year or less.
 - o Exposure of 0.5 rem (whole body or its equivalent to other body parts) to an individual in an unrestricted area in a period of a year or less.
 - b. Guideline for determining potential for release of licensed material:
 - o Release of materials in amounts reportable under the provisions of 10 CFR 20.403(b)(2).

For additional discussion, see NUREG-0302, Revision 1 (page 21.3(k)-1), which may be purchased from the National Technical Information Service, Springfield, VA 22161.

**SAMPLE PROCEDURE FOR
IDENTIFYING AND REPORTING DEFECTS
UNDER 10 CFR PART 21**

Employees shall:

1. Identify deviations in a basic component (insert appropriate part or component nomenclature).
2. Promptly report the deviations to the responsible company officer or director (insert appropriate position).

Company official (insert appropriate position) shall:

1. Cause deviation to be evaluated or reported to purchaser.
2. If determined to be a defect, promptly (within two days of receipt of information) inform the Nuclear Regulatory Commission (NRC).
 - By telephone, facsimile, or in writing to the Director, Office of Nuclear Material Safety and Safeguards, USNRC, Washington, DC 20555, or to the Regional Administrator.
3. If initial notification was by telephone or facsimile, a written report must be sent to NRC within 5 days of receipt of the information. Submit three copies.
 - Identify the basic component with the defect or activity that failed to comply.
 - Include the nature of the defect or failure and the safety hazard created or that could be created by the defect or failure.
 - Identify the date the information was obtained and the name of the individual informing NRC.
 - List all locations where the basic component may be in use.
 - Describe corrective actions taken or being taken.
 - Advice related to the defect that has been, or will be given to customers.

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
91-35	Labeling Requirements for Transporting Multi-Hazard Radioactive Materials	06/07/91	All U.S. Nuclear Regulatory Commission (NRC) licensees
91-30	Inadequate Calibration of Thermoluminescent Dosimeters Utilized to Monitor Extremity Dose at Uranium Processing and Fabrication Facilities	04/23/91	All fuel cycle licensees routinely handling unshielded uranium materials.
91-26	Potential Nonconservative Errors in the Working Format Hansen-Roach Cross-Section Set Provided with The Keno and Scale Codes	04/02/91	All fuel cycle licensees and other licensees, including all holders of operating licenses for nuclear power reactors, who use physics codes to support criticality safety in the use of fissile material.
91-23	Accidental Radiation Overexposures to Personnel due to Industrial Radiography Accessory Equipment Malfunctions	03/26/91	All Nuclear Regulatory Commission (NRC) licensees authorized to use sealed sources for industrial radiography.
91-16	Unmonitored Release Pathways from Slightly Contaminated Recycle and Recirculation Water Systems At A Fuel Facility	03/06/91	All fuel cycle facilities.
91-14	Recent Safety-Related Incidents at Large Irradiators	03/05/91	All Nuclear Regulatory Commission (NRC) licensees authorized to possess and use sealed sources at large irradiators.
91-03	Management of Wastes Contaminated with Radioactive Materials ("Red Bag" Waste and Ordinary Trash)	01/07/91	All medical licensees.

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
91-38	Thermal Stratification in Feedwater System Piping	06/13/91	All holders of OLs or CPs for nuclear power reactors.
91-37	Compressed Gas Cylinder Missile Hazards	06/10/91	All holders of OLs or CPs for nuclear power reactors.
91-36	Nuclear Plant Staff Working Hours	06/10/91	All holders of OLs or CPs for nuclear power reactors.
91-35	Labeling Requirements for Transporting Multi-Hazard Radioactive Materials	06/07/91	All U.S. Nuclear Regulatory Commission (NRC) licensees.
91-34	Potential Problems in Identifying Causes of Emergency Diesel Generator Malfunctions	06/03/91	All holders of OLs or CPs for nuclear power reactors.
91-33	Reactor Safety Information for States During Exercises and Emergencies	05/31/91	All holders of OLs or CPs for nuclear power reactors.
91-32	Possible Flaws in Certain Piping Systems Fabricated by Associated Piping and Engineering	05/15/91	All holders of OLs or CPs for nuclear power reactors.
91-31	Nonconforming Magnaflux Magnetic Particle (14AM) Prepared Bath	05/09/91	All holders of OLs or CPs for nuclear power reactors.
91-30	Inadequate Calibration of Thermoluminescent Dosimeters Utilized to Monitor Extremity Dose at Uranium Processing and Fabrication Facilities	04/23/91	All fuel cycle licensees and other licensees routinely handling unshielded uranium materials.

OL = Operating License
CP = Construction Permit

Manufacturers or suppliers who provide licensees with basic components that contain, or are used with, radioactive material, would normally need more extensive procedures to ensure proper identification and reporting of defects than customers who do not supply components to others. These procedures should contain, as a minimum, the following:

1. Directions to acquire information sufficient to describe the deviation.
2. Directions to analyze the effect of the deviation, in a basic component, if used by a licensee.
3. Directions to reach a conclusion, based on the analysis as to whether the deviation could create a substantial safety hazard.

Licensees are subject to inspection for compliance with Part 21, as well as other applicable NRC requirements, and may be subject to enforcement action for noncompliance. This information notice does not require any written response. If you have any questions about this matter, please contact the technical contact listed below or the appropriate NRC regional office.

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety

Technical Contact: Cheryl A. Trottier, NMSS
301-492-3422

Attachments:

1. 10 CFR Part 21
2. Guidelines for Determining Whether a Substantial Safety Hazard Exists
3. Sample Procedure for Identifying and Reporting Defects Under 10 CFR Part 21
4. List of Recently Issued NMSS Information Notices
5. List of Recently Issued NRC Information Notices

*See previous concurrence

OFFC: IMOB* : IMOB : IMAB* : IMSB* : NMSS* : IMNS* : IMNS / 5 /

NAME: CTrottier/11:JHickey : JGlenn : CHaughney : EKraus : GSjoblom:RECunningham

DATE: 5/01/91 : 5/ /91 : 05/01/91 : 5/02/91 : 5/16/91 : 5/23/91 : 6/13/91

the appropriate individuals, to identify and report deviations to responsible company officers. The responsibilities of company officers should be described; that is, to evaluate and report deviations to purchasers, and to inform NRC of defects within the required time frames. Licensees should evaluate their own programs and develop procedures appropriate for their activities. Attachment 3 provides a sample procedure for identifying and reporting defects, under Part 21.

Manufacturers or suppliers who provide licensees with basic components that contain, or are used with, radioactive material, would normally need more extensive procedures to ensure proper identification and reporting of defects than customers who do not supply components to others. These procedures should contain, as a minimum, the following:

1. Directions to acquire information sufficient to describe the deviation.
2. Directions to analyze the effect of the deviation, in a basic component, if used by a licensee.
3. Directions to reach a conclusion, based on the analysis as to whether the deviation could create a substantial safety hazard.

Licensees are subject to inspection for compliance with Part 21, as well as other applicable NRC requirements, and may be subject to enforcement action for noncompliance. This information notice does not require any written response to NRC. If you have any questions about this matter, please contact Cheryl A. Trottier at 301-492-3422.

Richard E. Cunningham, Director
 Division of Industrial and
 Medical Nuclear Safety

Technical Contact: Cheryl A. Trottier, NMSS
 301-492-3422

Attachments:

1. 10 CFR Part 21
2. Guidelines for Determining Whether a Substantial Safety Hazard Exists
3. Sample Procedure for Identifying and Reporting Defects Under 10 CFR Part 21
4. List of Recently Issued NMSS Information Notices
5. List of Recently Issued NRC Information Notices

*See previous concurrence

*C2J
6/6/91*

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NAME: CTrottier/11:JHickey	: JGlenn	: CHaughney	: EKraus	: GSjoblom	: RECunningham	
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Re: previous, CC-C comments incorporated 5/31

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