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(Sec. 201, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C. 5841))  
 (40 FR 42558, Sept. 15, 1975, as amended at 41 FR 55251, Dec. 23, 1976; 42 FR 26721, May 19, 1977; 43 FR 32741, July 28, 1978; 43 FR 52202, Nov. 9, 1978; 44 FR 63515, Nov. 5, 1979)

**PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE**

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**AUTHORITY:** Sec. 161, Pub. L. 83-703, 68 Stat. 948; sec. 234, Pub. L. 91-161, 83 Stat. 444; sec. 206, Pub. L. 93-438, 88 Stat. 1246 (42 U.S.C. 2201, 2202, 5846), unless otherwise noted.

**SOURCE:** 42 FR 26693, June 6, 1977, unless otherwise noted.

**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

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tion 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 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.<sup>1</sup>

(Sec. 181, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); sec. 201, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C. 5841))

(42 FR 28393, June 6, 1977, as amended at 42 FR 48221, Oct. 19, 1978; 43 FR 52202, Nov. 9, 1978; 44 FR 63515, Nov. 3, 1979)

§ 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 shut down 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

<sup>1</sup>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:

Report		
I (Philadelphia)	_____	(215) 337-5000
II (Atlanta)	_____	(404) 221-5000
III (Chicago)	_____	(312) 932-2500
IV (Dallas)	_____	(817) 334-2841
V (San Francisco)	_____	(415) 943-3700

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

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

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

(d) "Defect" means:

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

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

(3) A deviation in a portion of a facility subject to the construction

permit or manufacturing requirements of Part 50 provided the deviation basis of an evaluation of the facility contained has been offered to the acceptance; or

(4) A condition involving a basic component contribute to the exceed limit, as defined in the specifications of a license issued pursuant to this chapter.

(e) "Deviation" means from the technical included in a procedure (see § 21.3(i)).

(f) "Director" means appointed or elected who is authorized to direct the affairs of a partnership or other case of an individual "director" means the

(g) "Evaluation" means accomplished by or determine whether action could create a hazard.

(h) "Operating" means the operation the conduct of which is subject to this part and considered to operations to safety.

(i) "Procurement" a contract that elements which facilities must meet to be accepted by

(j) "Responsible" president, vice-president, or other individual in the organization, partnership, or other activity who is vested with over activities subject

(k) "Substantial" means a loss of extent that there in the degree of public health and safety or activity licensed pursuant to Parts 30, 40, 50, 70, and 71.

(l) "Supplying" contractually for

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(k)).

(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.

[42 FR 28893, June 6, 1977; 42 FR 36803, July 18, 1977, as amended at 43 FR 48622, Oct. 19, 1978]

#### § 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.

(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

## § 21.7

reports may be made, and states where they may be examined.

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

## § 21.7 Exemptions.

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

(42 FR 28293, June 5, 1977, as amended at 43 FR 49622, Oct. 19, 1978)

## 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 requirement 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 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 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 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 correct been, is being, or name of the individual responsible for the length of time that taken to complete.

(viii) Any advice defect or failure to facility, activity, that has been, is being, or taken to purchasers or licensee.

(4) The director may authorize provide the notification this paragraph; shall not relieve responsible officer of liability under this part.

(c) Individuals subject to (b) of this section, the Commission may provide information relating to failure to comply.

## PROCUREMENT

## § 21.31 Procurement

Each individual, partnership or other entity subject to the regulations in this part shall assure that each procurer of a facility, or a basic component, by him, her or it, on or after January 6, 1978 specifies, in the provisions of this part, the provisions of this part apply.

## INSPECTION

## § 21.41 Inspections.

Each individual, partnership or other entity subject to the regulations in this part shall assure that each procurer of a facility, or a basic component, by him, her or it, on or after January 6, 1978 specifies, in the provisions of this part, the provisions of this part apply.

## § 21.51 Maintenance

(a) Each licensee or activity subject to the regulations in this part shall maintain a connection with the Commission, to assure compliance with the provisions of this part.

(b) Each individual, partnership, or other entity subject to the regulations in this part shall assure that each procurer of a facility, or a basic component, by him, her or it, on or after January 6, 1978 specifies, in the provisions of this part, the provisions of this part apply.

(vi) 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.

(vii) 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

##### § 21.51 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 § 21.21), 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, 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 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 (RO 446).

**PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL**

**GENERAL PROVISIONS**

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  - 30.2 Resolution of conflict.
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- 30.53 Tests.
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**AUTHORITY:** Secs. 81, 82, 171, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2112, 2701, 2232, 2233), sec. 202, 206, 38 Stat. 1244, 1246 (42 U.S.C. 5842 and 5846), unless otherwise noted.

Section 30.24(b) also issued under sec. 184 68 Stat. 954, as amended (42 U.S.C. 2204). For the purposes of sec. 223, 68 Stat. 958, as amended, 42 U.S.C. 2273, § 30.24(c) issued under sec. 151b, 68 Stat. 948 (42 U.S.C. 2201(b)) and §§ 30.51 and 30.52 issued under sec. 161, 68 Stat. 950, as amended (42 U.S.C. 2201(c)).

**SOURCE:** 30 FR 8185, June 25, 1955, unless otherwise noted.

**NOMENCLATURE CHANGES:** 40 FR 8784-8785, Mar. 3, 1975.

**GENERAL PROVISIONS**

**§ 30.1 Purpose and scope.**

This part prescribes rules applicable to all persons in the United States governing domestic licensing of byproduct material under the Atomic Energy Act of 1954, as amended (68 Stat. 919), and under Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242), and exemptions from the domestic licensing requirements permitted by section 81 of the Act.

140 FR 8784, Mar. 3, 1975, as amended at 43 FR 6921, Feb. 17, 1978

**§ 30.2 Resolution of conflict.**

The requirements in addition to, and in addition to, other requirements in this chapter. In any conflict of requirements in this chapter in another requirement in this chapter governs.

**§ 30.3 Activities requiring license.**

Except for persons provided in this part a chapter, no person produce, transfer, own, possess, or use material except as authorized general license issued regulations in this chapter.

(Sec. 161, as amended Stat. 948 (42 U.S.C. amended, Pub. L. 93-58417))

(30 FR 8185, June 25 43 FR 6921, Feb. 17, 1978)

**§ 30.4 Definitions.**

As used in this part of this chapter.

(a) "Act" means the Act of 1954 (68 Stat. any amendments).

(a-1) "Administrator" means the Energy Research Administration or representative.

(b) Terms defined in the Act shall have the same meaning when used in this part and Parts 30 such terms are not defined in this part.

(c) "Agreement" means an agreement with which the Commission or the Regulatory Commission, effective agreement 274b. of the Atomic Energy Act of 1954 means any agreement.

(d) "Byproduct material" means radioactive material nuclear material produced by a nuclear reactor or other nuclear process, or radioactive material produced by a nuclear reactor or other nuclear process, or radioactive material produced by a nuclear reactor or other nuclear process, or radioactive material produced by a nuclear reactor or other nuclear process.