that either: (i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

7. Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph C.6 of this section;

8. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

9. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by 10 CFR parts 30, 40, and 70 of this chapter;

10. For any shipment or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

11. Notify the shipper and the Administrator of the nearest Commission Regional Office listed in appendix D of this part when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of NRC Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by 10 CFR 61.801 until the Commission terminates the license; and

3. Notify the shipper and the Administrator of the nearest Commission Regional Office listed in appendix D of this part when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

E. Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the nearest Commission Regional Office listed in appendix D to this part. Each licensee who conducts a trace investigation shall file a written report with the appropriate NRC Regional Office within 2 weeks of completion of the investigation.

[60 FR 15664, Mar. 27, 1995, as amended at 60 FR 25983, May 16, 1995]
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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.

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

(b) For persons licensed to construct a facility under a construction permit issued under §50.23 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under §50.55(e) of this chapter satisfies each person’s evaluation, notification, and reporting obligation to report defects and failures to comply under this part and the responsibility of individual directors and responsible officers of such licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

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

(d) Nothing in these regulations should be deemed to preclude either an individual, a manufacturer, or a supplier of a commercial grade item (as defined in §21.3) not subject to the regulations in this part, or any other entity doing business within the United States, and which constructs or operates a production or utilization facility, or a geologic repository for the disposal of high-level radioactive waste under part 60 of this chapter, from reporting to the Commission, a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure. NRC regional offices and headquarters will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers of the four regions (answered during regular working hours) are listed in appendix D to part 20 of this chapter. The telephone number of the NRC Operations Center (answered 24 hours a day—including holidays) is (301) 816-5100.

(e) The regulations in this part apply in accordance with 10 CFR 76.60 to each individual, partnership, corporation, or
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other entity required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter.


§ 21.3 Definitions.

As used in this part:

Basic component. (1)(i) When applied to nuclear power plants licensed pursuant to 10 CFR part 50 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

(A) The integrity of the reactor coolant pressure boundary;
(B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
(C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §50.34(a)(1) or §100.11 of this chapter, as applicable.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with 10 CFR part 50, appendix B, or commercial grade items which have successfully completed the dedication process. When applied to other facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, basic component means a structure, system, or component, or part thereof that affects their safety function, that is:

(i) Not subject to design or specification requirements that are unique to those facilities or activities;

(ii) Used in applications other than those facilities or activities; and

(iii) 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).

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

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

Critical characteristics. When applied to nuclear power plants licensed pursuant to 10 CFR part 50, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedicating entity. When applied to nuclear power plants licensed pursuant to 10 CFR part 50, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to §21.21(c) of
this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

Dedication. (1) When applied to nuclear power plants licensed pursuant to 10 CFR part 50, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer’s facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.

(2) When applied to facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

Defect means:
(1) A deviation 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, 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 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.

Deviation means a departure from the technical requirements included in a procurement document.

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.

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

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

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

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

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.

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.

Substantial safety hazard means a loss of safety function to the extent that
§ 21.4 Interpretations.

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

§ 21.5 Communications.

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

§ 21.6 Posting requirements.

(a)(1) Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of—
(i) The regulations in this part;
(ii) Section 206 of the Energy Reorganization Act of 1974; and
(iii) Procedures adopted pursuant to the regulations in this part.

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

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

§ 21.7 Exemptions.

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

§ 21.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0035.

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

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

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

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

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

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

(ii) Contains a defect.

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

(c) A dedicating entity is responsible for—

(1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and

(2) Maintaining auditable records for the dedication process.

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

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

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

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

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

(i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816–5151 or by telephone at (301) 816–5100 within two days following receipt of information by the director or
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responsible corporate officer under paragraph (a)(1) of this section, on the identification of a defect or a failure to comply. Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in § 21.22(a)(2).

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

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

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

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

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

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

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

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

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

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

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

(e) Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply. Commission action to obtain additional information may be based on reports of defects from other reporting entities.


PROCUREMENT DOCUMENTS

§ 21.31 Procurement documents.

Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure 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.

[60 FR 48374, Sept. 19, 1995]

INSPECTIONS, RECORDS

§ 21.41 Inspections.

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

[60 FR 48374, Sept. 19, 1995]

§ 21.51 Maintenance and inspection of records.

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

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

(2) Suppliers of basic components must retain any notifications sent to purchasers and affected licensees for a
(3) Suppliers of basic components must retain a record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.

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

§ 21.61 Failure to notify.

(a) Any director or responsible officer of an entity (including dedicating entity) that is not otherwise subject to the deliberate misconduct provisions of this chapter but is 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.

(b) Any NRC licensee subject to the regulations in this part who fails to provide the notice required by §21.21 or otherwise fails to comply with the applicable requirements of this part shall be subject to a civil penalty equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

(c) The dedicating entity, pursuant to §21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process. NRC enforcement action can be taken for failure to identify and evaluate deviations, failure to report defects and failures to comply, or failure to maintain auditable records.

[60 FR 48374, Sept. 19, 1995]

§ 21.62 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 21 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 21 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§21.1, 21.2, 21.3, 21.4 21.5, 21.7, 21.8, 21.61, and 21.62.

[57 FR 55071, Nov. 24, 1992]