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## 1.0 SCOPE

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This procedure has been established to indicate the practice which will be used by any individual director or responsible officer of AMS who obtains information reasonably indicating:

- a. That the AMS facility, an 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 NRC relating to substantial safety hazards or,
- b. that the AMS facility, an activity, or basic component supplied to such facility or activity, contains defects which could create a substantial safety hazard. To immediately notify the NRC of such failure to comply or such defect, unless he has actual knowledge that the NRC has been adequately informed of such defect or failure to comply.

### 2.0 DEFINITIONS

- 1. "Basic Component", 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 10 C.F.R. § 21.3(d)) or failure to comply with any applicable regulation in Chapter 1, order, license issued by the Commission could create a substantial safety hazard (see 10 C.F.R. § 21.3(k)).
- 2. In all cases "basic components" 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 10 C.F.R. § 21.3(c-1)).
- (a-1) "Commerical 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 Chapter 1 and, (2) used in applications other than facilities or activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of Chapter 1 and,

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- (a-1) (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:
  - A deviation (see 10 C.F.R. § 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 10 C.F.R. § 21.3(g)), the deviation could create a substantial safety hazard; or
  - 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 Chapter 1 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 Chapter 1.
- (e) "Deviation" means a departure from the technical requirements included in a procurement document (see 10 C.F.R. § 21.3(i)).

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(f) "Director" means an individual authorized to manage and direct the affairs of AMS.

- (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 Engineering Manager, Director of Regulatory Affairs or another individual in AMS who is vested with authority over activities subject to this procedure.
- (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 Chapter 1.
- (1) "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 10 C.F.R. Part 21.

#### 3.0 WHOM TO NOTIFY

All communications and reports concerning the regulations in this part should be addressed to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or to the Administrator of a Regional Office at the address specified in Appendix D of Part 20 of Chapter 1. Communications and reports may be delivered in person at the Commissioner's offices at 2120 L Street, N.W., Washington, DC, or at 11555 Rockville Pike, Rockville, Maryland.

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### 4.0 POSTING REQUIREMENTS

a. AMS shall keep 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 10 C.F.R. Part 21, (2) section 206 of the Energy Reorganization Act of 1974, and (3) procedures adopted pursuant to the regulations in 10 C.F.R. Part 21.

### 5.0 NOTIFICATION OF FAILURE TO COMPLY OR EXISTENCE OF A DEFECT

- A director or responsible officer, subject to the regulations of Chapter 1, Part 21, or a designated person shall notify the NRC 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 Chapter 1 and that is within his organization's responsibility or,
  - (ii) a basic component that is within AMS' 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 Chapter 1. The above notification is not required if such individual has actual knowledge that the NRC has been adequately informed of such defect or such failure to comply.
- 2. Initial notification required by this paragraph must be made within two (2) days following receipt of the information. Notification must be made to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or to the Administrator of Regional Office. If initial notification is by means other than written communication, a written report must be submitted to the appropriate office within five (5) days after the information is obtained. Three copies of each report must be submitted to the Director, Office of Nuclear Material Safety and Safeguards.
- 3. The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

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- (i) Name and address of the individual informing the NRC.
- (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 10 C.F.R. Part 21.
- (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.

# 6.0 PROCUREMENT DOCUMENTS

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AMS 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 C.F.R. Part 21 apply.

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## 7.0 INSPECTIONS

AMS shall permit duly authorized representatives of the NRC to inspect its records, premises, activities, and basic components as necessary to effectuate the purposes of 10 C.F.R. Part 21.

### 8.0 MAINTENANCE OF RECORDS

- a. AMS shall maintain such records in connection with the licensed facility or activity as may be required to assure compliance with the regulations in 10 C.F.R. Part 21.
- b. AMS 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 10 C.F.R. § 21.3(g)) or notifications to the Commission (see 10 C.F.R. § 21.2) such records shall be offered to the purchase 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 10 C.F.R. Part 21 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 10 C.F.R. Part 21, until, if necessary, the licensee shall make the determination.

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c. Records that are prepared only for the purpose of assuring compliance with the regulations in 10 C.F.R. Part 21 and are not related to evaluations or notifications to the Commission may be destroyed after delivery of the facility or component.

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