

(A) As used in this rule:

- (1) "Basic component" means:
  - (a) A structure, system, or component, or part thereof that affects their safety function, that is directly procured by the licensee or registrant of facility or activity subject to the rules promulgated pursuant to Chapter 3748. of the Revised Code and in which a defect or failure to comply with any rule promulgated pursuant to Chapter 3748. of the Revised Code, order issued by the director, or license issued by the department could create a substantial safety hazard; and
  - (b) Safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.
- (2) "Commercial grade item" means an item that is:
  - (a) Not subject to design or specification requirements that are unique to those facilities or activities;
  - (b) Used in applications other than those facilities or activities; and
  - (c) To be ordered from the manufacturer or supplier on the basis of specifications set forth in the manufacturer's published product description, such as a catalog.
- (3) "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 this rule and consulting services related to the facility or activity that are safety related.
- (4) "Dedication" means an item has been received and designated for use as a basic component.
- (5) "Defect" means:
  - (a) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to this rule, if, on the basis of an evaluation, the deviation could create a substantial safety hazard; or
  - (b) The installation, use, or operation of a basic component containing a defect as defined in this paragraph.
- (6) "Deviation" means a departure from the manufacturer's specification's or technical specifications as part of a license or registration issued by the department for a given safety device or safety system associated with that device.

- (7) "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 paragraph (G) of this rule.
  - (8) "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.
  - (9) "Failure to comply" means a failure to meet the requirements of any of the following that could create a substantial safety hazard:
    - (a) A rule promulgated pursuant to Chapter 3748. of the Revised Code;
    - (b) An order issued by the director; or
    - (c) License issued by the department.
  - (10) "Operating" or "operation" means the operation of a facility or the conduct of a licensed or registered activity which is subject to this rule and consulting services related to operations that are safety related.
  - (11) "Responsible officer" means:
    - (a) 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 rule, or
    - (b) An individual who is 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, responsible officer means the individual.
  - (12) "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 either public health and safety or the environment, for any facility or activity licensed or registered pursuant to Chapter 3748. of the Revised Code.
  - (13) "Supplying" or "supplies" means contractually responsible for a basic component used or to be used in a facility or activity which is subject to this rule.
- (B) This rule establishes procedures and requirements for implementation of section 3748.04 of the Revised Code, which applies to reporting of defects in equipment used for licensed or registered activities. Any responsible corporate officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed, registered, or otherwise regulated pursuant to Chapter 3748. of the Revised Code, obtaining information reasonably indicating either of the following, shall notify the director within twenty-four hours:
- (1) That the facility, activity or basic component supplied to such facility or activity fails to comply with any applicable rule, regulation, order,

registration, or license of the department relating to substantial safety hazards; or

- (2) That the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard.
- (C) This rule applies, except as specifically provided otherwise in Chapter 3748. of the Revised Code, to each individual, partnership, corporation, or other entity licensed or registered pursuant to Chapter 3748. of the Revised Code to possess, use, or transfer within the state of Ohio source material, radioactive material, special nuclear material, or to construct, manufacture, possess, own, operate or transfer within the state of Ohio any radiation-generating equipment and to each responsible officer of such a licensee or registrant. This rule applies also to each individual, corporation, partnership or other entity doing business within the state of Ohio, that supplies basic components for a facility or activity licensed, under Chapter 3748. of the Revised Code.
- (D) Nothing in this rule should be deemed to preclude either an individual, a manufacturer, or a supplier of a commercial grade item not subject to this rule from reporting to the director, 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. The department will accept collect telephone calls from individuals who wish to speak to department representatives concerning radiation safety-related problems.
- (E) Each individual, partnership, corporation, dedicating entity, or other entity subject to this rule shall post current copies of this rule and procedures adopted pursuant to this rule. These documents must be posted in a conspicuous position on any premises within the state of Ohio where the activities subject to this rule are conducted. If posting of this rule or the procedures adopted pursuant to this rule is not practicable, the licensee, registrant, or firm subject to this rule may post a notice which describes the rules and procedures, including the name of the individual to whom reports may be made, and where the rules and procedures may be examined.
- (F) The director may, upon application of any interested person or upon the director's own initiative, grant such exemptions from the requirements of this rule as the director determines to be authorized by law and will not endanger public health and safety or the environment, and are otherwise in the public interest. Suppliers of commercial grade items are exempt from the provisions of this rule to the extent that they supply commercial grade items.
- (G) Each individual, corporation, partnership, dedicating entity, or other entity subject to this rule shall adopt appropriate procedures to:
- (1) Initiate evaluations of deviations and failures to comply that are associated with substantial safety hazards as soon as practicable, but no later than ten days from the date of discovery of the deviation or failure to comply. The director shall be notified of any such deviation or failure to comply in accordance with paragraph (B) of this rule.

- (2) Evaluate a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, within thirty days of its discovery, except as provided by paragraph (G)(3) of this rule.
  - (3) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within thirty days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the director through a responsible corporate officer. 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 thirty days of discovery of the deviation or failure to comply; and
  - (4) Ensure that a responsible corporate officer subject to this rule is informed as soon as practicable, and, in all cases, within five working days after completion of the evaluation described in this paragraph if the construction or operation of a facility or activity, or a basic component supplied for such facility or activity either fails to comply with any applicable rule, regulation, order, or license or registration of the department relating to a substantial safety hazard, or contains a defect.
- (H) 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 or registrants within five working days of this determination so that the purchasers or affected licensees or registrants may evaluate the deviation or failure to comply, pursuant to paragraph (G) of this rule. Nothing in this rule shall be deemed to require manufacturers or suppliers to adopt or maintain procedures for defect identification and evaluation, where the item or service is not dedicated for purposes of licensed or registered activities or equipment. Instead, such is the responsibility of the registrant or licensee, in accordance with paragraph (B) of this rule.
- (I) A responsible corporate officer subject to this rule must notify the director within thirty days when he or she obtains information reasonably indicating a failure to comply or a defect affecting:
- (1) The construction or operation of a facility or any activity within the state of Ohio that is subject to the licensing or registration requirements under Chapter 3748. of the Revised Code and that is within the facility's responsibility; or
  - (2) A basic component that is within the facility's responsibility and is supplied for a facility or an activity within the state of Ohio that is subject to the licensing requirements of Chapter 3748. of the Revised Code.
- (J) The notification required by paragraphs (B) and (I) of this rule shall include the following information, to the extent known:
- (1) Name and address of the individual or individuals informing the director.

- (2) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the state of Ohio which fails to comply or contains a defect.
  - (3) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.
  - (4) 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.
  - (5) The date on which the information of such defect or failure to comply was obtained.
  - (6) 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 this rule.
  - (7) 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.
  - (8) 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.
- (K) The responsible corporate officer may authorize an individual to provide the notification required by paragraph (J) of this rule, provided that, this shall not relieve the responsible corporate officer of his or her responsibility under this paragraph. Individuals subject to this rule may be required by the director to supply additional information related to a defect or failure to comply. Department action to obtain additional information may be based on reports of defects from other reporting entities.
- (L) Each individual, corporation, partnership, or other entity subject to this rule shall prepare and maintain records necessary to accomplish the requirements of this rule, including retaining evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation. Each individual, corporation, partnership, dedicating entity, or other entity subject to this rule shall permit the department 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.
- (M) Suppliers of basic components must retain any notifications sent to purchasers and affected licenses for a minimum of five years after the date of the notification. Suppliers of basic components must retain a record of the purchasers of basic components for ten years after delivery of the basic component or service associated with a basic component.

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Certification

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Date

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