3701:1-38-03 Application and renewal of registrations for handlers of radiation-generating equipment.

(A) As used in this rule, "facility" means the state, any political subdivision, person, public or private institution, or group, or any unit of one of those entities, but does not include the federal government agencies, and includes the following:

(1) All buildings, equipment, structures and other stationary items that are located on a single site or on contiguous or adjacent sites and that are operated by the same person and have common corporate or business purposes; and

(2) Portions of a building or structure which are operated by the same person and have common corporate or business purposes.

(B) Notwithstanding the definition of "facility," the director may consider sites that are not contiguous or adjacent as one facility provided that:

(1) The sites are operated by the same person;

(2) The sites are of the same facility type as categorized in paragraph (B) of rule 3701:1-38-04 of the Administrative Code;

(3) The applicant for a registration provides for one individual responsible for radiation protection and implementing quality assurance procedures and policies necessary for effective compliance with Chapter 3748. of the Revised Code and rules adopted thereunder, and if applicable, one quality assurance committee, as responsible for all sites; and

(4) The director is reasonably satisfied from the information provided in the application that the applicant will adequately control the radiation-generating equipment at all sites listed in the application. Unless the director has information of violations of Chapter 3748. of the Revised Code or the rules adopted thereunder at one or more sites, he or she shall presume the applicant will adequately control the radiation-generating equipment at all sites if the sites are located not more than five miles apart.

The director shall continue to renew a registration issued under this paragraph that contains all the sites listed thereon provided the registrant demonstrates continued compliance with this paragraph, Chapter 3748. of the Revised Code, and the rules adopted thereunder.

(C) Except as provided in paragraph (D) of this rule, every facility that proposes to handle radiation-generating equipment shall apply for a registration at least thirty days prior to handling the equipment. Registration is required for dental, medical, therapeutic, and non-medical radiation-generating equipment. Application for a registration or renewal thereof shall be made on a form prescribed and provided by the director and shall be accompanied by a non-refundable registration fee in accordance with section 3748.07 of the Revised Code. The application shall include the name and qualifications of the individual designated as responsible and readily available for radiation protection and implementing quality assurance policy and procedures necessary for assuring compliance with Chapter 3748. of the Revised Code and rules adopted thereunder. Registrations shall expire two years from the date of issuance.
Registration certificates are not transferable. If a facility is sold or otherwise transferred to another person after a certificate of registration has been issued, the new handler is required to apply and receive a new registration certificate for the radiation-generating equipment.

(D) Facilities do not need to register the following types of radiation-generating equipment:

1. Electronic equipment that produces ionizing radiation incidental to its operation for other purposes, if the exposure rate averaged over an area of ten square centimeters does not exceed one-half milliroentgen per hour at a distance of five centimeters from any accessible surface of such equipment; or

2. Radiation-generating equipment that is already registered under Chapter 3748 of the Revised Code by its possessor.

(E) An applicant for a registration shall submit to the director a complete application for registration on a form provided by the director together with the required registration fee. The application shall contain all the information required on the form and accompanying instructions. The applicant for a registration shall provide to the director within thirty days of receipt of the request, all additional requested information. If the director does not receive the requested information within the thirty days, the director may consider the application abandoned. Any further consideration for a new registration shall be pursuant to another application accompanied by another non-refundable registration fee.

(F) The director shall grant a new registration or renewal to any applicant who has submitted a complete application, paid the registration fee, and is in compliance with applicable rules adopted under Chapter 3748 of the Revised Code.

(G) Registrations shall be renewed in accordance with the standard renewal procedure established in Chapter 4745 of the Revised Code. The registrant shall apply for renewal at least thirty days prior to the expiration of the registration.

(H) Any handler that assembles, installs, or disposes of radiation-generating equipment within this state shall notify the director, in writing, at least quarterly of such actions.

Each report shall contain the name and address of the facility that received equipment; the manufacturer, model, and serial number of the x-ray tube or x-ray generator transferred, disposed of, or installed; and the date of transfer, disposal, or installation of the radiation-generating equipment.

The state copy of the United States department of health and human services, food and drug administration "Report of Assembly of a Diagnostic X-ray System" form, used for reporting diagnostic x-ray systems which contain certified components, may be used to meet the notification requirements for this rule.

(I) No handler shall transfer, service, or install radiation-generating equipment or the components used in connection with such equipment unless such components and equipment, when properly placed in operation and used, meet the requirements of this chapter and all applicable requirements of Chapter 3701:1-66 or 3701:1-67 of the Administrative Code.

(J) The registrant shall notify the director, in writing, fifteen days prior to making any
change which would render the information contained in the application for registration or registration certificate no longer accurate.

(K) Notwithstanding any other requirements of this rule, out-of-state owners of radiation-generating equipment who:

(1) Operate the radiation-generating equipment within Ohio are required to:
   (a) Possess a valid Ohio registration;
   (b) Provide written notification three days prior to the dates when the radiation-generating equipment will be used in Ohio; and
   (c) Assure that the operation of the radiation-generating equipment complies with all applicable rules in Chapters 3701:1-38, 3701:1-66, 3701:1-67, and 3701-72 of the Administrative Code.

(2) Solely transport the radiation-generating equipment to an Ohio facility to be operated by the Ohio facility are not required to register. The Ohio facility using the radiation-generating equipment shall:
   (a) Possess a valid Ohio registration;
   (b) Provide written notification three days prior to the dates when the radiation-generating equipment will be used in Ohio; and
   (c) Verify that the operation of the radiation-generating equipment complies with all applicable rules in Chapters 3701:1-38, 3701:1-66, 3701:1-67, and 3701-72 of the Administrative Code.

(L) Any facility found as an unregistered handler shall be notified by the director that registration is required pursuant to the requirements of paragraph (C) of this rule. Any such facility that does not apply for registration within ten business days of receiving a notice to register shall be inspected by the department. The unregistered handler shall pay the fee required by section 3748.13 of the Revised Code.

A facility that handles radiation-generating equipment and engages in activities involving the use of radiation-generating equipment that does not obtain an Ohio registration as required by this rule is subject to the fee for the inspection of an unregistered handler specified in section 3748.13 of the Revised Code.

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