Successful Device Approvals

U.S. PRODUCT REGISTRATION OF NON-MEDICAL X-RAY EQUIPMENT FEBRUARY 5, 2019

X-ray systems in which the beam is full enclosed and shielded are referred to as cabinet x-ray systems. They are primarily used in security industry, and for the examination of components such as electronics, plastic molding, or food safety.

Some companies are under the misconception that there are no U.S. federal regulations regarding the manufacture and distribution of non-medical x-ray equipment.

Cabinet x-ray systems are required to be registered with the U.S. Food and Drug Administration, Center for Devices as Radiological Health (US FDA CDRH). An "Abbreviated" product report is required to be filed. The product report must contain information regarding the radiation dose rate outside the unit, shielding, interlocks, warning lights, fail-safes, access control, labeling, instructions to users, etc.

The requirements for cabinet x-ray systems are listed in 21 CFR 1020.40, Cabinet X-ray Systems, posted at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.40

Reports may be filed electronically by using the FDA's "e-submission" software or by mail. Unlike the U.S. Nuclear Regulatory Commission, which regulates devices containing radioactive sources, the CDRH does not actually approve devices. The product report is merely received and acknowledged. An "Accession Letter" is issued, assigning an accession number to the product, which confirms registration.

After receipt of the accession letter, the manufacturer may be contacted by the CDRH regarding certain content of the report. For example, if the CDRH does not believe that the interlock system is satisfactory they may require that you revise the system.

The CDRH does take products out of commerce and test them for compliance with their regulations. They also perform field inspections of manufacturers and distributors of x-ray equipment.

The state Radiation Control Programs establish regulatory requirements for installers and service providers, as well as users of x-ray equipment. In general states follow the Suggested State Regulations of the Conference of Radiation Control Program Directors (CRCPD), www.crcpd.org, but there are many exceptions. States may impose their own individual requirements depending upon the product. States have their own reporting regulations, reciprocity requirements, etc.

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If you have any questions or if we can assist you in registering your product please call me at 781.767.2176 or e-mail at schapel@irsc-inc.com.

Sincerely,

Sean C. Chapel
President

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