

A Brief Overview of State Radiation Regulatory Requirements

Introduction

Disclaimer: This document introduces some general concepts regarding radiation safety and state regulatory requirements. You should consult a radiation safety expert who can help you navigate requirements in your state or contact your state radiation regulatory agency.

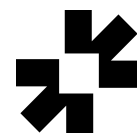
The use of radioactive materials and radiation-generating machines is monitored and controlled by many agencies globally to protect people and the environment. In the United States, the FDA regulates the manufacture of radiation-generating devices and the use of these products is typically regulated by agencies in each state.

Lumafield CT Scanners are cabinet X-ray systems certified to meet requirements in [21 CFR 1020.40](#). They do not use or generate radioactive materials.

To meet this certification, the radiation emissions must be less than **5 $\mu\text{Sv/h}$ at 5 cm** from all exterior surfaces of the device. The device must have additional safety features, including interlocks that disconnect the X-ray source power while the door is open.

Lumafield CT Scanners are certified to emit **less than 1 $\mu\text{Sv/h}$ at 5 cm**, significantly less than the federal limit. The following table gives a sense of how these figures compare to other everyday sources of radiation:

| Exposure source | Typical dose/rate |
|---|--|
| Background dose (terrestrial, cosmic, inhalation and ingestion) | 920 $\mu\text{Sv/year}$ - Atlantic Coast 1,860 $\mu\text{Sv/year}$ - Colorado |
| Mammography screening | 3000 μSv |
| Diagnostic chest X-ray | 100 μSv |
| Diagnostic dental X-ray | 10 μSv |
| Commercial airline flight | 3-5 $\mu\text{Sv/h}$ |
| Cabinet X-ray (federal limit) | 5 $\mu\text{Sv/h}$ at 5 cm from surface |
| Lumafield CT scanner | <1 $\mu\text{Sv/h}$ at 5 cm from surface |



Regulations overview

The general outline and content of radiation safety regulations in each state are quite similar. Each state adapts their own requirements from the same core guidelines, the [Suggested State Regulations for Control of Radiation](#), published by the Conference of Radiation Control Program Directors. The content of these regulations covers a broad range of topics and while much of the language reads similarly from state to state some specifics may differ, please refer to your own state's regulatory code for more details.

The regulatory requirements for these topics are proportional to the size and likelihood of radiation hazards. The spectrum of hazard and exposure ranges from the low end, TV receivers and cabinet X-ray systems, to intermediary risk, medical X-ray like CT scanners or industrial radiographic devices with radionuclides, and high risk, nuclear reactors.

Standard regulations that apply to facilities with a Lumafield CT Scanner usually include but are not limited to the following topics:

- Registering the machine and/or facility with the appropriate regulators
- Radiation safety program and training
- Personnel monitoring (dosimetry)
- Routine maintenance
- Recordkeeping for the above

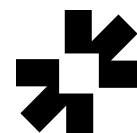
Other regulations like radioactive materials, financial assurances, healing arts, etc. are not usually applicable to our machine. Always consult the state agency responsible for the control of radiation or a radiation safety expert for guidance.

Cabinet X-ray device exemption

Cabinet X-ray systems are purposefully designed to exclude people and protect them from X-rays generated during use. Due to the high level of integrated safety features required to meet cabinet X-ray standards, some States will exempt cabinet X-ray systems from portions of the more rigorous requirements other radiation-generating devices may be subject to.

For example, in New York State, 10 NYCRR Part 16 discusses the requirements for ionizing radiation. The regulations state the following in *Appendix 16A Table 1-B Radiation Equipment*:

Item (a) Radiation equipment constructed so that it cannot emit radiation at a level greater than 0.5 milliroentgens per hour, measured two inches or five centimeters from the surface, and averaged over an area of 1.55 square inches or 10 square centimeters is exempt from the requirements of this Part; provided, however, that



such exemption shall not apply to the testing or servicing of such equipment during its production. (As of February 2023)

Lumafield CT Scanners meet the requirements of Item (a) in *Table 1-B Radiation Equipment* and are therefore exempt from the requirements established in 10 NYCRR Part 16.

Machine and/or facility registration with the appropriate regulators

Regardless of device type, most states require the registration of the facility and/or notification to the appropriate regulatory authority when installing a device. In some states, registration is required before Lumafield may install the machine. Other states allow registration after installation, usually within 30 days. Refer to your state code for details of the registration requirement.

Registration paperwork often requires technical information for the specific machine you are receiving. Lumafield can assist in providing this information.

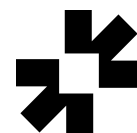
Radiation safety requirements: radiation safety program, designating a radiation safety officer (RSO), and radiation safety training

As mentioned before, radiation safety requirements generally scale with the radiation hazard. Each state sets different minimums for safety programs based on the sources of radiation (e.g. cabinet X-ray vs. radionucleotides).

Radiation safety programs generally involve appointing a Radiation Safety Officer (RSO), personnel training, safety precautions, postings and emergency procedures, personnel monitoring, proper documentation and reporting of all aspects of the radiation safety program, and any other administrative requirements mandated by the state.

The Radiation Safety Officer is responsible for overseeing and supervising the radiation safety program implemented at the facility. This person is responsible for compliance with local, state, and federal regulations. The RSO must meet certain education and training requirements to be considered knowledgeable enough by the state. The duties of the RSO may include but are not limited to implementing a radiation safety plan, overseeing personnel training and monitoring, and incident reporting.

Some states will accept credentials and training requirements for an RSO that scales with the radiation hazard, which means that your state may accept someone who has received



general radiation safety training and training on the Lumafield CT Scanner, and forgo a requirement needing 2,000 hours of training, for example. Contact your state's regulatory agency for what is acceptable.

It may also be permissible to appoint someone external to your organization, who is a radiation safety expert and contracted with your company, as your RSO.

Radiation safety training is required before using a radiation-generating device or radioactive materials to educate individuals about their rights and responsibilities at your facility. The programs and training provided may vary based on previous experience, education, training, and exposure to potential radiation hazards. The following topics are standard for working with any level of radiation:

- Risk of exposure to radiation (or radioactive materials)
- Fundamentals of radiation protection concepts
- Routine and emergency controls, policies, or procedures implemented at a facility to limit risk and dose As Low As Reasonably Achievable (ALARA)

Personnel monitoring (dosimetry)

Each state has a section that discusses personnel monitoring and indicates an occupational dose limit for adults, a stricter limit for pregnant women, and/or a threshold at which a monitoring device is required. Typically, the occupational limit is **0.05 Sv** and a dosimeter is required if personnel are expected to meet **10%** of that limit. Please check your state guidelines for the exact limits.

By meeting 21 CFR 1020.40, the scanner must meet the following emissions limit: radiation emission must be less than 0.5 milliroentgens per hour (5 microsieverts per hour, 5 $\mu\text{Sv/h}$). Our Lumafield CT scanners are certified to emit **< 1 $\mu\text{Sv/h}$** . With this figure in mind, we can perform a sample worst-case annual dose calculation:

FTE Annual Use Calculation at 5cm from Lumafield CT Scanner:

$$[1 \mu\text{Sv/h}] * [40 \text{ hours/week}] * [52 \text{ weeks/year}] = 2,080 \mu\text{Sv/year}$$

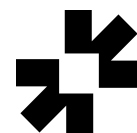
Annual Exposure Limit

$$0.05 \text{ Sv per year} = 50 \text{ mSv/year} = 50,000 \mu\text{Sv/year}$$

10% of Annual Exposure Limit for Monitoring

$$10\% * 50,000 \mu\text{Sv/year} = 5,000 \mu\text{Sv/year}$$

Under normal operating conditions, standing next to the machine for 40/hr per week still puts you under annual exposure limits.



The above calculation represents someone standing 5 cm from the surface of the scanner for 40 hours a week every week. Radiation intensity reduces by a factor of distance squared. Someone standing several feet from the source will experience orders of magnitude less radiation, which should be near background radiation.

Ultimately, the monitoring policy your organization determines is entirely up to you, as long as the state limits are adhered to. The above calculation is to demonstrate that under normal operating conditions, the scanner can be considered safe from radiation exposure.

Routine maintenance

Periodic maintenance and safety checks are required to ensure the machine is operating in a safe manner. At a minimum, annual surveying of the machine is required to ensure that the machine is within the radiation emissions limit. Some states will require safety feature testing in a more frequent capacity, for example, ensuring interlocks are working appropriately.

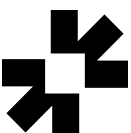
All machine maintenance, including annual surveying, is to be performed by Lumafield or a third party authorized by Lumafield. Lumafield will provide a copy of the survey results for facility recordkeeping and reporting purposes.

Recordkeeping & Posting Requirements

Many states require conspicuously posting some, if not all, of the following documents to ensure worker safety:

- Registration certificate (if applicable)
- "Notice to employees"
- Operating procedures
- Emergency procedures
- State regulations

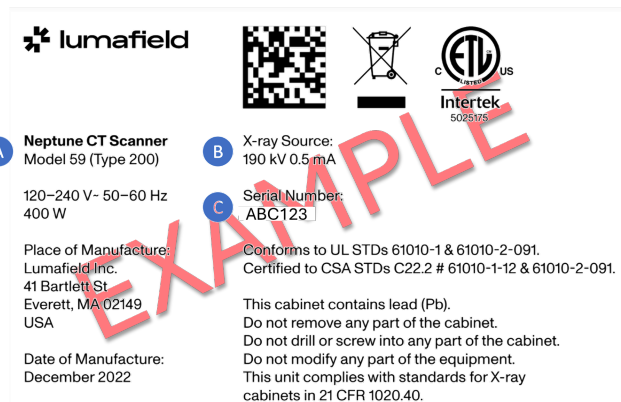
In addition to posting requirements, most states also mandate some form of recordkeeping with retention limits. Standard requirements include maintenance records, personnel training logs, registrations, personnel monitoring records, etc. This information will likely have a minimum retention period of 3 years. Records must be easily accessible for state inspection.



State Registration Information

The Lumafield CT Scanner is an X-ray machine used for non-destructive testing (non-medical/healing arts).

Machine specific information can be found on the **back of your scanner**, look for the following label:



- **Manufacturer:** Lumafield Inc.
- **Model (A):** Model ## (Type ####)
- **Max kV (B):** ### kV
- **Current at max kV (B):** 0.# mA (or #### μ A)
 - If the form asks for "current at max power", this is the same thing
- **Serial number (C):** #####

The registration form may also ask for some of these additional pieces of information:

- **Cabinet type:** not walk in, certified cabinet x-ray system
- **Number of X-ray tubes:** 1
- **Type of X-ray source:** Sealed monoblock
- **Type of X-ray tube:** Closed
- **Waveguide:** None
- **Electron tubes:** None
- **Max power:**
 - If Type 120 (120 kV) device, max power 36 W
 - If Type 130 (130 kV) device, max power 39 W
 - If Type 200 (190 kV) device, max power 95 W

Please contact Lumafield for advice if you require any additional registration information.

