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Faculty of Medicine
Department for BioMedical Research

Internal directive for radiation safety

Use of the X-RAD-225 Biological Irradiator

By François Achermann and Dr. Aurélie Quintin

François Achermann
Radiation Safety Officer DBMR
Murtenstrasse 28, Office 412
CH-3008 Bern
Tel.: +41 31 684 04 45
safe@dbmr.unibe.ch
www.safety.dbmr.unibe.ch

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A.1 Scope

This directive applies to all users of the X-RAD-225 Biological Irradiator, the X-RAD coordinator and the radiation safety officer (RSO) DBMR.

A.1.1 Authorization requirement

Non-medical systems for the generation of photon beams of an energy over 5 kV must be reported to the Federal Office for Public Health (FOPH) for approval.

A.1.2 Approved system

The operation of the X-RAD-225 Biological Irradiator from the company Precision X-Ray Inc. is approved until November 15, 2031 (License-no. A-195141-70).

A.1.2.1 Location

Murtenstrasse 35, Room B810, 3008 Bern. Because the X-RAD system is equipped with full protection, it is not set up in a controlled area. The key to enter the room is stored in the key box at the entry of the room. The pin of the key box is provided to the users by the coordinator of the X-RAD system. The pin is regularly changed to avoid that former users have access to the X-RAD system. If the system is installed at a different location, it may only be operated with a new license for handling ionizing radiation.

A.2 Legal provisions and documents

A.2.1 Radiological Protection Act and Ordinances

- Radiological Protection Act (RPA) of March 22, 1991 (Status as of May 1, 2017)
- Radiological Protection Ordinance (RPO) of 26 April 2017 (Status as of January 1, 2021)
- Verordnung des EDI über den Strahlenschutz bei nichtmedizinischen Anlagen zur Erzeugung ionisierender Strahlung (SnAV) vom 26. April 20017 (Stand am 1. Januar 2018)
- Verordnung des EDI über die Personen- und Umgebungsdosimetrie (Dosimetrieverordnung) vom 26. April 20017 (Stand am 1. Januar 2018)
- Verordnung des EDI über die Aus- und Fortbildungen und die erlaubten Tätigkeiten im Strahlenschutz (Strahlenschutz-Ausbildungsverordnung) vom 26. April 2017 (Stand am 1. Oktober 2021)

A.2.2 Further applicable directives and documents

- BAG Wegleitung «SV Aufgaben» vom 1.6.2019
- BAG Wegleitung «Betriebsinterne Weisungen» vom 14.6.2021
- DBMR safety guidelines of 1 June 2015 (Status as of 5 December 2019)
- DBMR safety concept – biological safety of 8 June 2016 (Status as of 10 September 2018)
- X-RAD Biological Irradiator user manual, version 2.1

B. Responsibilities

The license holder and the radiation safety officer (RSO) are responsible for the safe operation of the X-RAD-225 Biological Irradiator. The X-RAD coordinator is obliged to ensure the compliance with the regulations. All users must follow the instructions of the X-RAD coordinator and the RSO.

- **License holder**
  Universität Bern
  Department for BioMedical Research
  Murtenstrasse 35
  3008 Bern

- **RSO DBMR**
  François Achermann
  Murtenstrasse 28, Office 412
  3008 Bern
  Tel.: 031 684 04 45
  Francois.achermann@dbmr.unibe.ch

- **Deputy RSO DBMR**
  Martin Hungerbühler
  Murtenstrasse 35, G816
  3008 Bern
  Tel.: 031 632 86 85
  Martin.hungerbuehler@dbmr.unibe.ch

- **Coordinator X-RAD**
  Dr. Aurélie Quintin
  Murtenstrasse 35, E816
  3008 Bern
  Tel.: 031 632 09 36
  Aurelie.quintin@dbmr.unibe.ch

- **Deputy Coordinator X-RAD**
  Rahel Riedo
  Murtenstrasse 35, E811
  3008 Bern
  Tel.: 031 632 8710
  Rahel.riedo@dbmr.unibe.ch

C. Occupationally exposed persons

The users of the X-RAD Biological Irradiator are not designated as occupationally exposed to radiation and don't need to wear a personal dosimeter. The maximal ambient dose rate is 0.2 µSv/hr.

D. Education in radiation safety

D.1 Persons bearing radiation safety responsibility towards others

The RSO must attend the appropriate training courses (annex 4, Strahlenschutz-Ausbildungsverordnung). The RSO ensures, that the coordinator has sufficient knowledge to coordinate the use of the X-RAD Biological Irradiator.

D.2 Persons without radiation safety responsibility towards others

The X-RAD coordinator make sure new users are instructed adequately before they operate the instrument.

E. Operational radiation safety

E.1 Radiation safety information

The X-RAD Biological Irradiator produces dangerous levels of X-ray radiation that can cause serious injury or death if used improperly. This equipment must be used by qualified personnel only.

A key is required to operate the system. When the system is not being used, the key must be removed.

Although the equipment is delivered with safety functions required by federal regulations, the following additional measures must be taken to assure safe operation and continued protection for users of this equipment:

1. Carefully read all user manuals provided for this equipment before operating the equipment.
2. Never defeat the installed protection mechanisms. This includes safety door switches, warning lights, lead shielding, and equipment connections.
3. Never open any of the covers or side panels on this unit. Failure to comply could result in elevated radiation leakage and personal injury.
4. Warning: there are no user serviceable parts in this unit. Service and maintenance of the equipment must be performed by qualified service technicians.

E.2 Operational Safety

The X-RAD Biological Irradiator features safety interlocks to prevent accidental radiation exposure to the users. If one or more of the interlocks are disabled, X-Rays will not be permitted. If X-Rays are on and an interlock is disabled, i.e. emergency stop, X-Rays will immediately shut off. The system is equipped with an CDRH Switch, Center for Devices and Radiological Health Switch, located on the cabinet door which physically inhibits X-Rays from being produced while the door is open.
The X-RAD Biological Irradiator is considered a cabinet X-ray system because all of the radiation is confined to the inside of the metal structure. This is accomplished by using steel of a sufficient thickness to block X-rays of the energies produced by the X-ray source tube. Some cabinet parts incorporate additional shielding to prevent leakage. There are no ports, apertures, or other openings through which any part of the human body can be placed when X-rays are being generated.

E.3 TouchRAD Panel

E.3.1 System Key-Switch

The System Key-Switch puts the X-RAD Biological Irradiator in one of three modes: *Off*, *Standby* and *On*. When the System is in the *OFF* state, X-Rays cannot be produced and the TouchRAD User Interface is inoperable. When the system is in *STANDBY* mode, the TouchRAD User Interface is operable but X-Rays cannot be produced. When the System is in the *ON* state, the whole system is operable. By switching the System Key Switch to the *ON* position, the safety circuit for the X-Ray system is closed allowing X-Rays to be produced.

E.3.2 Warning Lamp

The Warning Lamp is a steady yellow light that is on while X-Rays are being produced. The TouchRAD warning lamp is not included in the safety circuit as it is a secondary indicator. If the TouchRAD warning lamp bulb fails, X-Rays CAN be produced.

E.3.3 Emergency Stop

The Emergency Stop is hardwired into the X-Ray Power Supply via the safety circuit and will instantly stop X-Rays when activated. To activate the Emergency Stop, simply push the button inward toward the panel. To deactivate the Emergency Stop, twist the button counterclockwise and it will pop out to its inactivated state.

E.4 Function test

Each day before use, the operator should perform these quick visual inspections to verify system integrity:

1. Inspect the cabinet and all visible components and cables for signs of recent damage or misuse.
2. Verify that there are no gross cooling system leaks or fluids on the floor.
3. Verify that the cabinet door closes properly and that there are no loose screws or hardware on the latching mechanism.

E.5 Leak test

The X-RAD coordinator performs monthly a radiation leak test, by verifying that X-ray cannot be produced, while the cabinet door is open. The result of the monthly leak test must be documented.

E.6 General rules of conduct

1. All users must be registered in the user logbook (date, name, operating time)
2. All users must read all documentation supplied with the instrument.
3. Frequently verify that all safety procedures are followed, the X-RAD Biological Irradiator has not been modified, and no safety interlocks have been disabled.
4. Follow all guidance supplied by the coordinator and the RSO.
5. Keep records of X-ray surveys, instrument repairs, or other data required by the RSO. Keep registration certificates, compliance or safety audit reports, instrument inspections, training records, and the list of authorized users.
6. Keep records of any accident or investigation reports, or user complaints. Inform the coordinator X-RAD and the RSO.
7. Do not relocate manuals and safety instructions positioned on the machine.

E.7 Maintenance

The X-RAD Biological Irradiator requires system maintenance be performed by an authorized Precision X-Ray engineer on an annual basis to assure proper system performance and longevity. The following services are performed during annual maintenance: high voltage interface maintenance, cooling system inspection, cabinet radiation survey, safety systems verification and operational performance testing. The X-RAD coordinator organizes the annual maintenance and provides a copy of the service report to the responsible RSO. The license holder bears the costs for maintenance and any repairs.