UNIVERSITY OF LETHBRIDGE

X-RAY SAFETY and PROCEDURES MANUAL

CAMPUS SAFETY – SAFETY SERVICES

V.3 2017
V.2 2015
V.1 2009

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1 Introduction

The University of Lethbridge X-Ray Safety Program outlines requirements for compliance with applicable legislation and to ensure the health and safety of research personnel and students who use diffraction, analytical, cabinet and other research based x-ray equipment.

All occupational exposures to both ionizing and non-ionizing radiation shall be limited in accordance with the ALARA principle (As Low As Reasonably Achievable) and within legislated prescribed dose limits. This is achieved through training and implementation of standard operating procedures and protocols to control the storage, use and disposal of X-ray generating and emitting equipment.

2 Scope

All faculty, staff and students working with X-ray generating equipment and devices must comply with the requirements of the University's X-Ray Safety Program which include procedures outlined in this manual, including appropriate training and all regulatory requirements.

X-ray equipment is defined as an electrically powered device with a primary purpose of producing x-rays. These may be used analyze materials or structures or are medical devices that are being used in novel and new applications and are therefore not intended or approved for use in any medical purpose on humans or animal exposure.

X-ray sources are any part of a device that emits x-rays, whether or not the device is part of x-ray equipment. The Alberta Radiation Protection Regulations list the following types of equipment and refers to the equipment as "radiation emitting devices":

- Cabinet x-ray equipment;
- Diffraction and analytical x-ray equipment;
- Industrial x-ray equipment;
- Irradiation x-ray equipment;
- Particle accelerators;
- Diagnostic or therapeutic x-ray equipment;
- Computed tomography equipment;
- Baggage inspection x-ray equipment;
- Security x-ray equipment

The Alberta Radiation Protection Act and Regulation regulates all aspects of radiation emitting devices this includes registration, usage, training, labeling and safety features for all X-ray equipment.

3 Administration

3.1 Legislation

X-ray equipment is regulated in Alberta under the Radiation Protection Act and

Regulation. The regulation requires that x-ray equipment be registered before it is used. The registration process requires a formal compliance inspection to be carried out to ensure that the x-ray equipment meets certain specified safety standards before it can be used.

The safety standard that has been adopted under the Radiation Protection Regulation for x-ray equipment is Health Canada "Safety Requirements and Guidance for Analytical X-ray Equipment" - Safety Code 32.

3.2 Inspection and Registration Procedure

The University Radiation Safety Officer will coordinate application for registration and inspections for owners of University of Lethbridge x-ray equipment.

To register x-ray equipment, the owner of the equipment must apply to register the x-ray equipment with Campus Safety – Safety Services. The application form is available from the Radiation Safety Officer.

Upon receiving the completed application form, the Radiation Safety Officer will submit this to the Alberta Radiation Health Administrative Organization. The Radiation Safety Officer will make arrangements with the owner of the x-ray equipment for a compliance verification of the x-ray equipment and the associated facility. This will include identification of safety design features, the use of personal protective equipment, the implementation of safety procedures, and other items specified in Safety Code 32.

An inspection report will then be sent to the owner of the equipment. Any deficiencies that are identified must be corrected before the x-ray equipment can be registered. The owner of the equipment will be required to provide evidence that corrective action has been taken.

Upon receiving written notification that corrective action has taken place, the Radiation Safety Officer will submit the inspection report and any follow-up correspondence to Alberta Radiation Health Administrative Organization. A registration certificate will then be issued to the owner of the x-ray equipment.

The registration certificate allows the x-ray equipment to be operated and is normally valid for four years. Prior to the expiration of the registration certificate, the owner of the x-ray equipment will receive a notice and an application form for renewing the registration of the x-ray equipment. The inspection and registration process described above must then be repeated to continue use of the equipment.

If x-ray equipment is no longer in used and placed in storage, this must be reported to the Radiation Officer who will advise the Alberta Radiation Health Administrative Organization. Any change in storage location and requests for disposition must also be reported to the Radiation Safety Officer.

3.3 Responsibilities

3.3.1 Radiation Safety Committee

The Radiation Safety Committee is responsible for:

- Providing oversight of the X-Ray Safety Program in compliance with the Alberta Radiation Protection Act and Regulation, and the Alberta Radiation Health Administration Regulation.

- Providing advice and recommendations on the safe use of designated x-ray equipment and implementation of corrective actions, if required.

3.3.2 Radiation Safety Officer

The Radiation Safety Officer is responsible for:

- Ensuring that the necessary records required by applicable government regulations are maintained including registration certificates, compliance verifications reports, training records, lists of analytical x-ray equipment users and exposure reports, etc.
- Accompanying regulatory agency inspectors during inspections of the x-ray equipment and facilities.
- Ensuring corrective action is taken on noted deficiencies.
- Investigating x-ray equipment related incidents and initiating appropriate action including the preparation of reports to regulatory agencies.
- Evaluating x-ray equipment control measures including standard operating procedures, and providing recommendations to the Radiation Safety Committee.

3.3.3 Principal Investigator (Equipment Owner)

The Principal Investigator (PI) is typically named on the Registration Certificate as the equipment owner. The PI must be knowledgeable of the requirements for analytical x-ray equipment safety, potential x-ray hazards, associated control measures, and the policies, practices and procedures pertaining to the x-ray equipment under the PI's control, and must ensure that the equipment meets all applicable radiation safety standards. The PI is responsible for:

- Ensuring that the equipment is installed in accordance with the facility safeguard requirements;
- Ensuring that all users have received training on the proper operation and x-ray hazards appropriate to the analytical x-ray equipment installed;

- Prescribing and posting prominently near the x-ray equipment radiation safety rules, and safe operating and emergency procedures which shall include address information and contact details of a hospital or clinic where medical treatment can be administered;

- Making readily available a copy of this manual for reference by users and maintenance personnel;

- Implementing a system of verification, supervision and periodic review to ensure that all users and maintenance personnel have received adequate training, and have read and understood the relevant parts of this manual, the applicable radiation safety rules, safe operating and emergency procedures before using and servicing the x-ray equipment;

- Establishing a maintenance program, taking into account the age and frequency of use, that ensures all safety devices and components critical to both x-ray production and shielding, are routinely checked and defective parts replaced or repaired;

- Providing an appropriate survey meter, and ensuring that it is in a working and functional condition at all times for use by users and maintenance personnel;

- Conducting prompt investigations of all radiation overexposures and accidents, and submitting appropriate reports to the Radiation Safety Officer as soon as possible but within 5 calendar days;

- Ensuring that personnel who may have receive radiation overexposures obtain appropriate medical attention

- Determining the appropriate corrective measures following radiation overexposures, unsafe events and accidents, and ensuring that such measures are implemented effectively;

- Ensuring that during a radiation protection survey, a copy of the most recent survey report including summaries of corrective measures recommended and instituted on the equipment, is readily available to the radiation inspector (if applicable).

- Ensuring all X-ray equipment when left unattended is in a secure and safe condition.

- Coordinating all acquisitions of X-ray equipment and with the Radiation Safety Officer, prior to the sources arrival.

- Coordinating all disposal activities with the Radiation Safety Officer prior to any equipment leaving the campus.

3.3.4 Authorized X-Ray Workers

Authorized X-Ray Workers may be faculty members, technical support staff, graduate students, or individuals under the direct supervision of the PI with experience in the safe use of X-Ray equipment and who have successfully completed training. Each authorized Radiation Worker is responsible for:

- Following the standard operating procedures as prescribed by the manufacturer of the equipment and any requirements specified by the Principal Investigator or the Radiation Safety Officer.
- Allowing only authorized persons to enter rooms that are specified as restricted areas for reason of radiation protection.
- Supervising students using the x-ray equipment and instructing them in safe and responsible procedures for using these devices or machinery.
- Wearing personal radiation monitors, if required.
- Reporting to the Radiation Safety Officer any incidents involving suspected exposures to ionizing radiation exceeding permissible standards.
- Ensuring all X-ray equipment when left unattended

3.3.5 Maintenance Personnel Responsibilities

Maintenance personnel are individuals who are trained and authorized to perform alignments, maintenance or repairs of analytical and cabinet x-ray equipment. All personnel responsible for the maintenance of x-ray equipment must:

- Be adequately trained and competent in the proper maintenance and repair of the various x-ray equipment for which they are responsible, with emphasis on maintenance operations that may require x-ray production.
- Have read, understood and follow all radiation safety rules, requirements and emergency procedures applicable to the x-ray equipment and the facility, including the guidelines on operational safety and personal exposure monitoring.
- Wear personal radiation dosimeters recommended by the Radiation Safety Officer to monitor separately whole body and extremity doses as deemed appropriate for the operation(s) being undertaken and x-ray system design.
- Use a properly functioning radiation survey meter to identify and monitor the radiation levels at critical areas (tube housing, beam ports, shutters, analysis accessories, etc.) of the equipment during set up, beam alignment and maintenance procedures, and following modifications and alterations to the device or its accessories.

- Undertake precautionary measures to eliminate or reduce radiation levels (measured according to the preceding clause) to ensure that the regulatory limit (5 uSv (0.5 mR) per hr at 5 cm from any external surface of the equipment) is met, and that guidance levels including the permissible dose limits would not be exceeded during routine operational conditions of the equipment.

- If alignment of analysis accessories requires use of an open x-ray beam, use remote handling devices, low x-ray tube current, and fluorescent beam definers of higher radiation sensitivity to reduce or eliminate radiation exposure to extremities and other parts of the body.

- Perform regular reviews of their own personal dosimetry data and identify unexpected radiation exposures, investigate them as to root cause(s) and implement appropriate corrective action(s) as may be necessary.

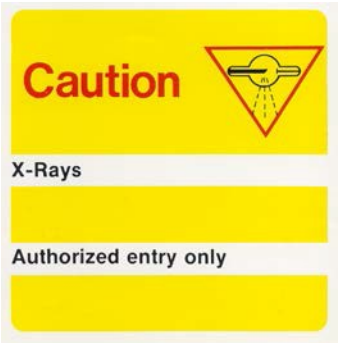
- Provide the user and the equipment owner or designee with a written report that specifies explicitly any user procedure or action that could lead to an x-ray hazard, as soon as such a procedure or action is identified.

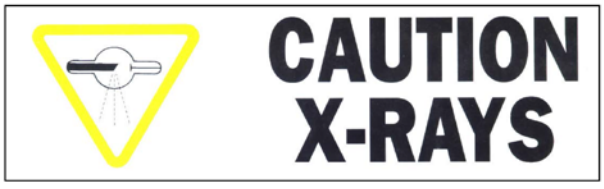
- Prevent the operation of the analytical x-ray equipment if any unsafe operational conditions arise, and immediately notify the equipment owner or designee of such conditions.

4 Security and Area Control

4.1 Signage and Equipment Control

- X-ray warning signs must be posted on the entrance doors to the controlled area. The sign must be clearly legible and visible at a distance of 2 meters. Examples are provided below:





- Doors must be kept locked when the room is unoccupied and the master key to the x-ray control unit should be kept stored in a secure location when the equipment is not in use.

- Access to the room housing the x-ray equipment must be restricted to equipment users and authorized personnel whenever the x-ray equipment is in use.

- For operations not requiring constant user supervision or surveillance, the analytical equipment must be adequately secured to prevent access by unauthorized individuals.

4.2 Visitors

Visitors that are granted permission to enter an area where x-ray equipment is operated must be accompanied by an authorized staff member and must be provided with the following:

- Information on potential radiation exposure
- Information on safety precautions
- Radiation dosimeters if required by the Radiation Safety Officer

4.3 Staff (Non-lab Personnel)

Admission of staff members (e.g. Facilities Building Maintenance, Utilities, and Caretakers) is subject to the following restrictions:

- Only authorized staff members are permitted entry into the controlled area during x-ray operations. All other staff are considered to be visitors to the controlled area.
- Non-lab personnel such as Facilities workers may not conduct maintenance or repair work in the facility unless the *Laboratory Clearance to Work procedure* has been completed.
- Persons requiring access to the controlled area must be provided with x-ray radiation hazard awareness training and radiation dosimeters prior to entry, if required by the Radiation Safety Officer.

5 Training

All workers who are likely to be exposed to radiation from x-ray equipment at the University of Lethbridge must be informed of the potential hazards of the x-ray equipment and the precautions to be taken to protect themselves and other persons from those hazards. To comply with this requirement the following must be brought to the attention of each worker:

- The worker's responsibilities and duties under the Act and Regulation
- The type of x-ray equipment the worker will be using
- Radiation protection principles and maximum exposure limits for radiation
- The uses and limitations of the facility, x-ray equipment and radiation sources the worker will use
- Known or suspected health hazards associated with the radiation exposure

For more information on radiation safety training, contact the University of Lethbridge Radiation Safety Officer at safety.services@uleth.ca

6 Exposure Limits

For the purpose of radiation protection, individuals may be classified in one of two groups: radiation worker or member of the general public. Radiation workers are persons who are exposed to ionizing radiation in the course of their work. Students are classified as members of the general public for the purpose of dose limitation even if they are using x-ray equipment as part of their studies. Table 3 lists the maximum permissible dose limits for radiation workers and members of the general public for various body organs and tissues.

Table 3 Maximum Permissible Dose Limits

Body organ or tissue	Radiation Worker (mSv)	Member of General Public (mSv)
Whole body[a]	50[b]	1
Lens of the eye	50[b]	15
Skin	500	50
Extremities (hands, feet)	500	50

a. Pregnant radiation workers may not exceed 4 mSv to the abdomen for the remainder of pregnancy after pregnancy has been declared.
b. Up to 50 mSv may be received in any single year provided that the average dose over any consecutive five year period does not exceed 20 mSv.

6.1 Personal Exposure Monitoring

Individuals who work with analytical and cabinet x-ray equipment are potentially exposed to ionizing radiation and must not exceed the maximum permissible dose limits listed in Table 3.

Individuals who work with analytical and cabinet x-ray equipment may be required to wear whole-body dosimeters that measure both whole-body (deep dose) and skin dose, as per regulatory requirements. The whole-body dosimeter should be worn either at chest or waist level depending on the location of the x-ray source relative to the person's body.

In addition to this, persons who perform beam alignments or otherwise work in close proximity to open, primary x-ray beams are required to wear two extremity (ring) dosimeters on the hand closest to the x-ray source. One extremity dosimeter should be worn on the dorsal surface of the finger and the other extremity dosimeter worn on the palmar surface in order to detect exposures from narrow beams.

Dosimeters are normally worn for a three month period and then exchanged for a new one. The dosimeters are issued and read by a dosimeter service provider (Health Canada – National Dosimetry Service) who send the exposure reports to the Radiation Safety Officer for review.

Dosimetry records should be maintained for at least five years after a user has terminated working with the x-ray equipment.

Whenever the annual cumulative dose exceeds 50 percent of the dose limit, the person will be notified by the Radiation Safety Officer and will be requested to advise the Radiation Safety Officer on how the exposure might have been received.

7 Records

The following records shall be maintained for all x-ray equipment:

- Registration Certificates (current and previous)
- Compliance verification reports (current and previous)
- Internal audits and inspection reports (indefinite period)
- Maintenance and service records (indefinite period)
- Accident and investigation reports (indefinite period)
- List of x-ray equipment users (current)
- Training records (indefinite)

8 Compliance and Enforcement

The University of Lethbridge will ensure compliance with the Act and Regulation for x-ray equipment under its jurisdiction. Compliance will be enforced by:

- requiring the owner of the x-ray equipment to implement the regulatory standard for analytical x-ray equipment, Health Canada Safety Code 32
- requiring the owner of the x-ray equipment to take remedial action to correct any condition which contravenes the Act or Regulation, or which is inconsistent with safe operating practices
- Prohibiting the use of x-ray equipment that;

  (a) is in such a condition or at such a location that it cannot be used without risk of unnecessary exposure to personnel,

  (b) is used in such a manner that it causes risk of unnecessary exposure to personnel or,

  (c) exposes persons to x-ray equipment radiation beyond the maximum permissible exposure limit.

Owners of x-ray equipment shall comply with all written directives issued to them by the University of Lethbridge and the Alberta Radiation Health Administrative Organization.

8.1 Investigations

If an overexposure or an incident that has the potential of causing overexposure of a person occurs, the PI/Equipment Owner shall immediately notify the Radiation Safety Officer of the time, place and nature of the overexposure or incident.

The Radiation Safety Officer, together with the PI/Equipment Owner will carry out an investigation into the circumstances surrounding any complaint, incident or suspected overexposure, and prepare a report outlining the circumstances and the corrective action required to prevent a recurrence of the overexposure or incident.

8.2 Penalties

Failure to respond to a compliance directive issued by the Alberta Radiation Health Administrative Organization may result in suspension or revocation of the Registration Certificate of the x-ray equipment, prohibition of equipment use, seizure of equipment or referral for disciplinary action.

A person who intentionally contravenes the Alberta Radiation Protection Act/Regulation or who fails to comply with a directive made by an Authorized Radiation Health Administrative Organization under the Act/Regulation may also be subject to fines and/or prosecution under the Radiation Protection Act by the Director of Radiation Health for the Province of Alberta.

9 Portable Hand-Held XRF Devices

Portable hand-held, x-ray tube based open-beam x-ray fluorescence (XRF) devices are a specific type of analytical x-ray device that have been used to examine the microstructure and elemental or chemical analyses of materials, components, or systems in non-destructive testing (NDT) applications. These devices provide a high intensity primary beam that irradiates the test material at very close range. X-ray tube that provides source of ionizing radiation is capable of operating at up to 50 kV, 4W and a few hundreds of microamperes (µA).

The XRF devices are regulated under the Radiation Emitting Devices (RED) Act and Regulations administered by Health Canada. Specific safety requirements applicable for hand- held, x-ray tube based open-beam XRF devices are described in the Addendum to Safety Code 32. The Addendum describes responsibilities of the owner, user, and servicing personnel as well as the requirement for the operator of an XRF device to have a Level 1 Natural Resources Canada (NRCan) certification. The Addendum must be used in conjunction with Safety Code 32.

For further details on hand-held x-ray tube based open-beam XRF devices refer to the Addendum (Reference 8) and Safety Code 32.

10 References

1. University of Alberta, X-ray Safety Manual, 2017. https://cloudfront.ualberta.ca/-/media/ualberta/vice-president-finance/environment-health-saftey/documents/radiation/analytical-xray-equipment-safety-manual-nov-2017.pdf

2. University of Calgary, Radiation Emitting Devices, Research X-ray Safety Program 2016. http://www.ucalgary.ca/safety/system/files/researchxraysafetyprogramtrainingmanual.pdf

Alberta Human Resources and Employment. Radiation Health Administration Regulation, *49/96*. Alberta Queen's Printer, Alberta, 1998. http://www.qp.alberta.ca/1266.cfm?page=1996_049.cfm&leg_type=Regs&isbncln=9780779731_480

4. Alberta Human Resources and Employment. *Radiation Protection Act, 162/90*. Alberta Queen's Printer, Alberta, 2010. http://www.qp.alberta.ca/1266.cfm?page=R02.cfm&leg_type=Acts&isbncln=9780779724376

5. Alberta Human Resources and Employment. *Radiation Protection Regulation, 162/90*. Alberta Queen's Printer, Alberta, 2003. http://www.qp.alberta.ca/1266.cfm?page=2003_182.cfm&leg_type=Regs&isbncln=0779731042

6. Department of National Health and Welfare. *Radiation Emitting Devices Regulations*. Ottawa: Queen's Printer: Canada Gazette: Schedule 1 and 11; 1981. http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1370/FullText.html

7. Health Canada. *Safety Requirements and Guidance for Analytical X-ray Equipment - Safety Code 32*, 94-EHD-186. Health Canada,1994. http://www.hc-sc.gc.ca/ewh-semt/pubs/radiation/index-eng.php#codes

8. Health Canada. Addendum to Safety Code 32: Portable, hand-held, x-ray tube based open- beam XRF devices. Health Canada, 2014 https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/radiation/addendum-safety-code-32-portable-hand-held-tube-based-open-beam-devices.html

11 RELATED FORMS

Registration of Designated Radiation Equipment Procedure.docx

UofL Application for Registration of Designated Equipment.pdf.