

CSULA RADIATION SAFETY MANUAL

SECTION 3

UNIVERSITY REGULATIONS, POLICIES AND SAFETY GUIDELINES FOR RADIATION PRODUCING MACHINES

This section of the CSULA Radiation Safety Manual is specifically directed to the possession and use of machines that produce ionizing radiation. Other general information related to radiation safety and the possession of machines may be found elsewhere in the Radiation Safety Manual. Issues that may be addressed elsewhere in the Radiation Safety Manual will be referenced and machine users are encouraged to visit referenced sections for more complete information so as to ensure compliance with all State, Federal and local regulations.

Campus radiation machines are divided into six categories based upon the hazards involved. The six categories are:

Electron Microscopes
Medical Machines
Cabinet X-Ray Machines
X-Ray Diffraction and Fluorescence Analysis Machines
Accelerators
Miscellaneous machines

All machine users must be familiar with the general regulations pertaining to the use of ionizing radiation as well as those regulations and policies specific to the use of machines that produce ionizing radiation. General regulations and policies for the use of ionizing radiation and unsealed sources may be found in Section 1 of the Radiation Safety Manual. Section 2 of the Radiation Safety Manual is directed towards ionizing radiation contained as a "sealed source". Policies and regulations related to the used of non-ionizing radiation, such as lasers, UV light, and EMF sources are addressed in separate publications, and may be obtained by contacting the Environmental Health and Safety Office or the Radiation Safety Office.

3.0 General Requirements

3.1 Acquisition of Radiation Producing Machines:

To acquire a radiation-producing machine the Principle Investigator must complete an "Application for Radiation Producing Machine" (Appendix 3.1) and submit the completed application with all required attachments to the Radiation Safety Office. Required information shall include, but is not limited to the following:

- (a) Responsible contact person.

- (b) Evidence of Training of all users of the machine.
- (c) Completed "Training and Experience" forms (Appendix 3.2) for all users of the machine.
- (d) A complete description of the machine including, type of unit, manufacturer, model, year of manufacture, maximum energy, typical or anticipated operating energies, and beam current.
- (e) A complete profile of any sealed sources that may be used for detector calibrations. (Please refer to Section 2: Sealed Sources for additional information).
- (f) A scaled floor plan of the facility where the unit is located indicating the location of the unit and the direction of the beam. (Appendix 3.3)
- (g) A listing of all safety features and interlocks on the unit, such as warning lights, "beam on" lights, shutter interlocks, power shut-off interlocks.
- (h) A copy of Operating Procedures. (Appendix 3.4)
- (i) Radiation Survey/ monitoring procedures.
- (j) A complete description (make, model, serial number) of all detectors and meters utilized to survey for exposures or to detect the presence of ionizing radiation, such as Geiger Counters, Sodium-Iodide (NaI) Scintillation detectors and ion chambers and a copy of the most recent calibration certificate for each unit.

3.2 Review and Inspection of Facility and Equipment:

The application and plans for facilities that include radiation-producing machines shall be reviewed by the Radiation Safety Office and selected members of the Radiation Safety Committee prior to the machine being used. The machine is not to be used until such time as the review and inspection is completed and the Radiation Safety Committee membership has approved the "Authorization to Use Radiation Producing Machines". Upon review and approval by the Radiation Safety Committee the Principal Investigator may begin using the machine. The Radiation Safety Officer will deliver to the Principal Investigator a copy of the approved "Authorization" which shall be maintained with all other records related to radiation safety.

3.3 Initial Review and Inspection:

The purpose of the review and inspection is to ensure that the facility is appropriate for the machine and that the machine is safe for the intended use and in compliance with appropriate Federal, State and Local regulations.

3.4 Routine Annual Review and Inspection:

Periodically, but not less than annually, the Radiation Safety Office shall conduct reviews and inspections of machines and facilities housing machines so as to ensure guidelines and regulations related to the use of the machine are being followed. Such inspections shall include, but not be limited to the following items:

- (a) Review of "Use Logs" (Appendix 3.5).

- (b) Review of maintenance records.
- (c) Review of "Safe Operating Procedures" (Appendix 3.6).
- (d) Confirmation of all required postings, notices and labels.
- (e) Verification of performance of all safety interlocks.
- (f) Surveys for radiation leaks or potential exposure from secondary or "scattered" radiation.
- (g) Inspection for calibration and operational status of detectors, survey meters and ion chambers.
- (h) Verification of operational status of all warning lights.
- (i) Confirmation of "Training and Experience" records of all machine users.
- (j) Verification of the appropriate use and handling of all dosimetry issued to users of the machine.

3.5 Non-Routine Inspections:

The Radiation Safety Office shall perform non-routine inspections of facilities and radiation producing machines in certain circumstances including but not limited to the following situations:

- (a) High or unexpected exposures recorded by a personnel dosimetry device.
- (b) In response to complaints or concerns conveyed to the Radiation Safety Office regarding the performance of the machine or the practices of individuals using the machine.
- (c) After notification of any change, modification, repair, or maintenance to the machine or the housing enclosure for the machine.
- (d) Upon any notification of injury or safety-related problems associated with the machine as distributed by the manufacturer or any agency charged with publishing, monitoring or reporting injuries associated with radiation producing machines or the malfunctioning of medical devices, or upon the publication of accidents or injuries associated with the same type of machine in any publication.

3.6 Registration of Machines:

The EH&S Radiation Safety Office shall register all radiation producing machines with the State of California, Radiologic Health Branch within 30 days after initial operation and as required thereafter and shall assure the prompt payment of any fees associated with the registration of machines in accordance with the fee schedule as delineated in Title 17.

3.7 Annual Authorization Renewal:

Each year the individual who is responsible for a radiation-producing machine shall receive from the Radiation Safety Office an "Authorization Renewal" form. All authorizations shall expire on December 31st of each year regardless of when the initial Authorization was submitted or approved. If the researcher desires to maintain an authorization for continuing the use of the radiation machine the "Authorization Renewal" form shall be completed by the researcher and submitted the Radiation Safety Office. The "Authorization Renewal" shall include an update on the following items:

- (a) Any facility changes that are planned or not currently reflected on the floor plan on file in the Radiation Safety Office.
- (b) Any changes in the roster of users.
- (c) Any changes in research procedures or protocols.

3.8 Maximum Allowed Exposures:

Radiation producing machines shall be used according to the instructions of the manufacturer and in such a way that the radiation exposure to operators and other individuals in the surrounding areas shall be maintained as low as reasonably achievable and does not exceed the limits specified elsewhere in the CSLA Radiation Safety Manual. (Appendix 3.7)

3.9 Radiation Exposure Monitoring:

To assure that radiation exposures to personnel are as low as reasonably achievable and that maximum limits are not exceeded as specified elsewhere in the CSULA Radiation Safety Manual. Individuals using machines that produce ionizing radiation are strongly advised to not become reliant upon exposure reports from their film badges or other dosimetry devices as being evidence or verification of non-exposure. Many machines that produce ionizing radiation emit the radiation in the form of a very concise and focused beam that could cause severe tissue damage, but is not likely to register on the dosimetry device as the beam may strike tissue without ever striking the dosimeter.

(a) *Personnel Monitoring:*

Radiation exposure monitors shall be worn by all individuals working in areas where the potential for exposure to radiation meets the criteria specified in the CSULA Radiation Safety Manual. Typically, personnel monitors should be worn by all individuals working with any radiation producing machine. Exceptions from personnel monitoring shall include users of standard electron microscopes, x-ray fluorescence units and other self-contained low kV/mA machines.

(b) *Obtaining Personnel Exposure Monitors:*

Exposure monitors shall be ordered for all machine users that have meet the following criteria:

- i. A completed "Training and Experience" form has been submitted to the Radiation Safety Office.
- ii. Initial Safety Awareness Training, consisting of viewing one video and a meeting with the Radiation Safety Officer, must be completed.
- iii. Demonstrated an understanding of the operational aspects of the machine, included emergency power shutoff switches, warning lights, and safety interlock devices.

(c) *Area Surveys:*

Radiation area surveys shall be performed prior to initial operation, following modifications and periodically thereafter. Appropriate survey methods and the frequency of these surveys shall be determined by EH&S Radiation Safety Office

during the initial review and reevaluated periodically during the process of routine inspections conducted thereafter. The determination of methods and frequencies at which the area surveys occur shall be based upon generally accepted practices and relevant conditions associated with the operational conditions specific to each machine. However, in no event shall documented inspections and surveys occur less frequently than once per year (annually), with such reviews typically scheduled to occur in the last month of the calendar year.

3.10 Personnel Protective Equipment:

Generally, personnel protective equipment such as leaded aprons, gloves and safety glasses are useful only for low energy (less than 100 kVp) x-ray sources. Recognizing this limitation, personnel protective equipment should be used to protect any part of the body that may be exposed to a primary beam or whenever an exposure could be reduced by the use of personal protective equipment. However, personal protective equipment should not be used in place of engineering controls for minimizing exposure.

3.11 Engineering Controls and Safety Devices:

Safety devices or features that are “engineered” into the machine are always preferable to reliance upon personal protective equipment or “administrative controls”. Certain safety features installed as engineering controls are required by either Federal, State or local regulations for each radiation producing machine. Required safety devices include:

- (a) Fail safe warning lights
- (b) Fail safe interlocks (power and beam exit port shutter)
- (c) Beam enclosures
- (d) Shielding
- (e) Radiation survey meters

3.12 Prior approval for modifications of safety devices:

All safety devices shall be maintained in working order and shall not be replaced or modified without prior notification and specific approval of the Radiation Safety Office. No safety device is absolutely fail-safe or foolproof and such devices should not act as a back-up or replacement for proper operational procedures and protocols.

3.13 Defeat Or Modification of Safety Devices and Interlocks:

Safety devices must never be purposely defeated. If the design of a safety device makes a desired or necessary operation inconvenient or impossible, an alternate safety device or method shall be developed that provides the same degree of protection. Modified or defeated safety devices discovered upon any radiation producing machine shall be considered sufficient cause for the Radiation Safety Office to cause such machines to be subjected to “Lock-Out/Tag-Out” procedures which shall be effected without a requirement of prior notice to users and shall

remove the use of the machine by means of either restricting access to the machine or restricting operational capacity of the machines.

3.14 Operating Procedures:

Operating procedures approved by the Radiation Safety Office must be available in the work area to all users of radiation producing machines and a copy of the operating procedures must be on file in the Radiation Safety Office.

3.15 Use Logs:

“Use Logs” must be maintained and utilized each time a radiation producing machine is used. Required information on the use log shall include the date of use, the name of user, operational status of machine, operating parameters and nature of use. Information contained in the Use Logs may be useful when investigating accidents or determining the operational reliability of a machine. Therefore, the Use Log is most important for those machines that have the capacity to potential exposure the users to ionizing radiation.

Based on the above considerations, a Use Log should be maintained for all radiation producing machines but shall be maintained for all radiation producing machines with open beams or those not equipped with fail-safe engineering controls (safety interlocks) that will effectively contain the radiation.

Information required on the Use Log shall be:

- (a) Name of User
- (b) Description of Use
- (c) Date of Use
- (d) Malfunctions/problems and corrective actions
- (e) Information related to repairs, service or maintenance.

3.16 Records Related to Maintenance, Repairs and Service:

A copy of all records related to maintenance, repairs and service on any radiation producing machine must be maintained in the facility with the machine and a copy forwarded to the Radiation Safety Office.

3.17 Inspection Records for Medical X-Ray Machines:

Medical X-Ray machines shall be inspected by a properly trained and certified firm or individual no less than once each year (annually) and the results of all such inspections shall be maintained and available for review at any time by representatives of the Department of Health Services, Radiologic Branch or the Radiation Safety Officer. A copy of all inspection findings, service or maintenance work or calibration reports shall be forwarded to the Radiation Safety Office within seven (7) days of the receipt of any report or finding by the Principal Investigator or Responsible Party for any medical x-ray machine as provided by the firm or individual that performed the services on the machine.

3.18 Required Postings (Signs, Notices, and Instructions):

Radiation producing machines and the facility in which such machines are located shall be prominently identified by signs, notices, instructions or labels in accordance with the requirements in 17, CCR, Section 30278.

Posting requirements include the following:

- (a) Notice To Employees.
- (b) Operating and Safety Instructions.
- (c) Warning signs as appropriate in the area of the machine and at the entrance to any room where a radiation producing machine is located.

3.19 Training Requirements:

All users of radiation producing machines must have documented training that is adequate for the work being performed. Training shall be documented by the presence of a "Training and Experience" form signed and dated by the trainee and distributed for completion at the time of training. Training typically consists of a video presentation followed by a meeting with the Radiation Safety Officer during which the trainee shall be expected to demonstrate an understanding of the operational parameters of the machine, be conversant in the research procedures and protocols, and be familiar with and demonstrate the location and significant of all engineered safety controls on the machine which is to be used by the trainee.

Training shall be considered having met minimum standards for adequate training providing the following topics have been addressed:

- (a) A description of ionizing radiation.
- (b) Effects of ionizing radiation.
- (c) Radiation exposure limits.
- (d) Potential exposures relevant to the work to be performed.
- (e) Methods or techniques for minimizing exposure.
- (f) Methods or techniques for detecting ionizing radiation.
- (g) An overview of relevant Federal, State and local regulations.
- (h) Required notices, labels, signs and postings.
- (i) Review of "Operating Procedures".
- (j) Procedures related to high exposures on monitoring devices.
- (k) Suspected exposures occurring during "work-in-progress".
- (l) Required notifications to the Radiation Safety Office.
- (m) Completed, signed and dated "Training and Experience" form.
- (n) Proper care and handling of personnel exposure monitors.

3.20 Machine Location and Security:

As a general safety precaution and to ensure the security of the unit and unauthorized personnel, the Radiation Safety Office highly recommends that an entire room or securable area be dedicated for the location of any radiation producing machine. When this is not possible the machine should be located in an

area away from the main traffic flow and away from high occupancy areas. Unless confined or secured by some other means, primary beams shall be intercepted by a primary barrier and limited such that personnel cannot be irradiated with "beam stops" and engineered beam line housing as the primary safety controls. Scatter, or secondary, radiation shall be controlled such that the radiation exposures are as low as reasonably achievable, but in no case greater than the limits specified in the CSULA Radiation Safety Manual. With the exception of mobile x-ray units related to medical use, any change in location of a radiation producing machine must be approved by the Radiation Safety Office prior to relocation.

3.21 Summary of Requirements for Specific Machine Categories:

The following summaries may not be suitable for all circumstances. Modifications may be necessary to accommodate specific research projects to conform to constraints imposed by the facility or room in which the machine is located. Actual requirements for specific machines may be different from the general requirements delineated below.

A. *X-Ray Diffraction:*

Open beam x-ray diffraction units present a high risk of potential overexposure. Open beam units typically are capable of exposure rates of several 100,000 R/minute at the beam exit port. Serious injury is probable if any part of an individual is exposed to this high radiation exposure rate, even for a short period of time. Exposure prevention efforts with open beam units are frequently compromised due to the fact that the beam diameters are extremely small and thus are difficult to find or measure. The already hazardous conditions are heightened by the fact that most open beam units are older models that often are deficient in engineering controls such as safety interlocks and warning lights. Many users of such older open beam units tend to have extensive experience with the unit. Such experience may actually prove to be detrimental as there is some evidence to indicate that as experience increases so does a casual or complacent attitude with respect to safety. A combination of the above conditions associated with open beam units often is responsible for exposures leading to extreme tissue damage and necrosis leading to loss of extremities.

General Requirements for X-Ray Diffraction Units:

1. All individuals using a unit must have documented training to use the specific type of equipment.
2. Written operating procedures must be approved and followed.
3. Use Logs are mandatory, must be utilized and must be available for inspection.

4. Monitor radiation exposures at the time of initial operation and anytime after modifications occur and use appropriate instrumentation.
5. Personnel exposure monitors (dosimetry) must be worn when operating any x-ray diffraction unit.
6. Required and appropriate warning lights and other safety devices shall be in place and operational.
7. Required and appropriate radiation shielding shall be installed on each x-ray diffraction unit.
8. Required shields should be interlocked to prevent radiation exposure to personnel in the event the shield is removed or otherwise displaced.
9. All beam shutter mechanisms shall be interlocked so as to prevent operation if the shutter is not properly closed.
10. All required notices, radiation warning signs and labels shall be posted.

B. Electron Microscopes and X-Ray Fluorescence Units:

Generally, electron microscopes and x-ray fluorescence units pose little risk of significant radiation exposure provided the units are not modified, damaged or altered and the manufacturer's operating instructions are followed.

Specific requirements for electron microscopes and x-ray fluorescence units:

1. Follow the manufacturer's operating instructions.
2. Stop operation and notify your supervisor if equipment is damaged (e.g., cracked windows).
3. The radiation exposure limits for electron microscopes shall not exceed 0.5 mR/hr at 2cm from any point on the surface of the unit.
4. Unless specified otherwise by the Radiation Safety Office, radiation exposure monitors are not required for personnel working with electron microscopes.

C. Medical Radiographic Machines:

For the general population, the predominant non-occupational exposure to ionizing radiation occurs during routine medical radiographic procedures. To satisfy the regulatory requirements related to medical radiography and to minimize the radiation exposure received by patients and workers during medical procedures, it is essential to comply with all of the following requirements and safety practices.

1. "X-Ray On" warning lights at room entrance must be in place and operational.
2. Operating Instructions must be posted near the equipment console.
3. Patient radiography shall not be performed except by prescription of licentiate of the healing arts recognized by the State of California as a "certified Supervisor / Operator".
4. Patient radiography shall only be performed by a radiologic technologist certified by the State of California.
5. Equipment shall be checked according to the requirements of the State of California Radiation Control Regulations.
6. All personnel shall wear the required personnel monitors assigned to them.
7. Only essential individuals shall be present in the room during the performance of radiography procedures.
8. Any individual required in the room during the production of x-rays shall wear a leaded apron of at least 0.25mm lead equivalent, or stand behind a protective barrier.
9. If a patient must be held the best choice is a non-pregnant parent or relative. Occupationally exposed individuals should not hold patients during x-ray exams, except in an emergency.
10. Any individual who holds a patient during an x-ray examination shall wear a leaded apron and, if the hands are likely to be in the primary beam, leaded gloves.
11. Lead aprons, gloves and other protective devices should be inspected frequently, but not less than once every six months, to detect cracks and breaks in the shielding and should be replaced immediately upon detection of any defects.
12. Collimate x-ray beams to film size or area of interest.
13. Exposure of pregnant females should be avoided particularly if the beam is likely to intercept the uterus.
14. The technologist shall inquire if a female patient is pregnant if the primary beam is likely to intercept the uterus.
15. Use gonadal shielding if the reproductive organs are in the primary beam and if the shield will not interfere with the diagnostic information needed.
16. Fluoroscopists should never place their hands in the primary beam and shall wear shielded gloves when hands are positioned near the primary beam.

17. Because of the high radiation exposure to the patient during fluoroscopy, and especially during cineradiography, special care shall be taken to minimize the duration of beam production.
18. All fluoroscopic units shall be equipped with a manual reset timer that will sound a warning after a preset fluoro time not to exceed five minutes.
19. A technologist operating portable x-ray machines shall wear a lead apron and stay out of the primary beam and at least six feet from the beam during exposure and shall ensure that all other individuals in the area shall not be capable of intercepting the primary beam and shall maintain a distance from the patient as far as possible.

D. *Cabinet Radiography Units:*

By nature, cabinet radiography units present little risk of significant exposure providing that shielding is not modified, interlocks and warning lights operate properly, and if users follow approved operating procedures.

Specific considerations that apply to cabinet units include:

1. Unless approved by the Radiation Safety Committee, the radiation exposure at a distance of 2 cm from the surface of any location on the exterior of the cabinet shall not exceed 0.5 mR/hr.
2. The necessity and desirability for radiation dosimetry at each cabinet radiography unit shall be determined by the EH&S Radiation Safety Office.

E. *Van De Graaff Accelerator:*

The Van De Graaff Accelerator is operated by the CSULA Physics department. This accelerator is capable of an energy output of 4 MeV and requires a high degree of mindfulness when in operation so as to minimize the potential for exposure to personnel and prevent possible damage to the accelerator.

The safety hazards associated with a large Van De Graaff unit are numerous and include electrical hazards, magnetic fields, primary beam hazards, secondary beam hazards, and induced radioactivity. Because of the presence of numerous hazards and the high level of familiarity required to safely operate this specific unit, it is imperative that tight controls and oversight be maintained with respect to the use of the accelerator. In order to ensure the tightest controls as possible, the Radiation Safety Office shall only recognize one Authorized User

for this accelerator. This Authorized User is the primary responsible party for this unit. The Authorized User shall also be the only operator of the accelerator. All other individuals that wish to use the accelerator shall be considered Designated Users, and shall utilize the accelerator under the authority and supervision of the Principal Investigator. In no event shall any Designated User operate the accelerator in the absence of the Authorized User.

Specific procedures associated with the use of the accelerator are as follows:

1. The Authorized User/Operator shall follow the Safety Procedures (posted at the operating console) at all times when then unit is energized.
2. The Authorized User / Operator shall ensure that the Safety Procedures are posted at the operating console and at other locations in the console room so as to ensure the accessibility of these procedures to any visitors and Designated Users that may be present when the accelerator is energized.
3. The Authorized User / Operator shall be responsible for registering every new use of the unit, in advance, with the Radiation Safety Office, by ensuring the accurate completion of the "Application to Use Radiation Producing Machines" and the submission of the application to the Radiation Safety Office. Submission of all applications must allow for sufficient time for review by the Radiation Safety Office and members of the Radiation Safety Committee.
4. The Authorized User shall be responsible for maintaining the "Use Logs" associated with the accelerator.
5. Visiting researchers and projects originating outside of this university, must complete the "Application to Use Radiation Machines". The "Training and Experience Form" must be completed, signed and dated by each individual that will be present at the time the accelerator is utilized.
6. Suspected exposures or any evidence of tampering with this device shall be promptly reported to the Radiation Safety Office.
7. Under no circumstances shall use of the unit be permitted if warning systems and interlocks are in disrepair or malfunctioning.