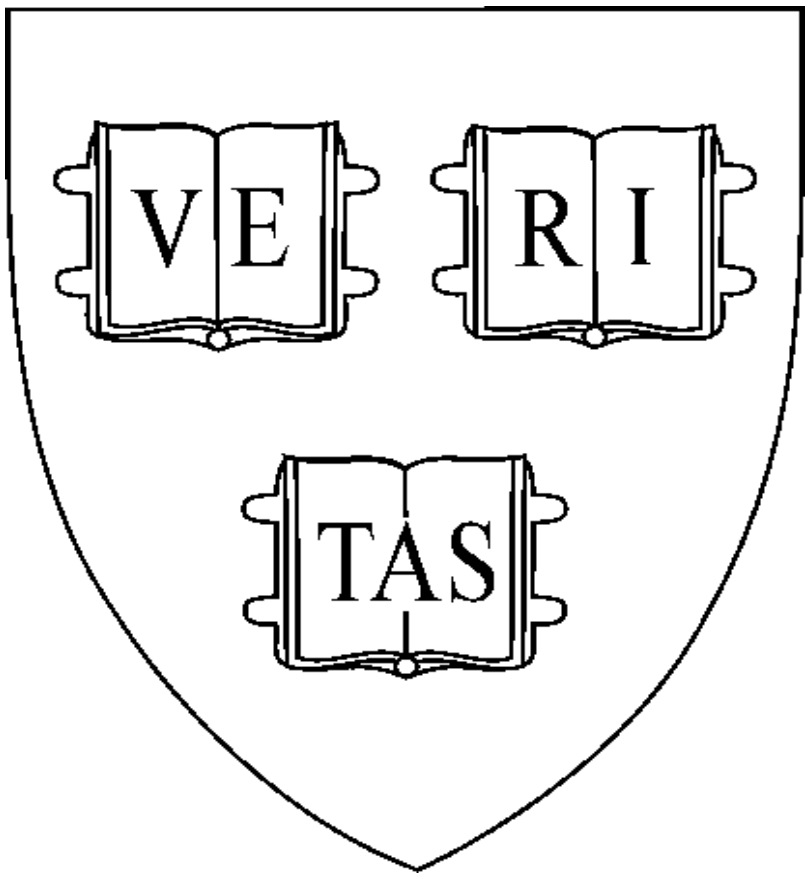
Harvard University
X-ray Safety Manual



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Forward

This manual was approved by the Radiation Safety Committee on December 6, 2017 and supersedes the information contained in the previous revision of the Radiation Safety Manual. This manual states the Policies and Standards for safely working with x-ray generating devices at Harvard University. It does not cover devices containing radioactive material, laser devices, or other non-ionizing radiation generating devices. This manual also provides guidance on compliance with Federal, State and Local governmental agencies.

An electronic copy of this manual is available on the EHS website at http://www.ehs.harvard.edu/services/radiation-protection.

Executive Summary

The X-ray Safety Manual describes the responsibilities and safe work practices of all individuals involved with the use of x-ray generating devices (XGDs) throughout Harvard University. Fulfillment of these responsibilities is done in accordance with the relevant government regulations of 105 CMR 120. Due to the potential hazards associated with x-ray radiation, no individual may use any XGD without the written authorization from the Harvard Environmental Health and Safety (EH&S) Radiation Safety Services (RSS) group.

The role of the Principal Investigator (PI), also known as the Permit Holder, is particularly important as the PI is *ultimately responsible* for the health and safety of his or her laboratory members. The actions of the PI help ensure that radiation exposure to lab users due to x-rays is kept As Low As Reasonably Achievable (ALARA).

PI responsibilities include the following:

- Submit an X-ray Permit Application any time a new XGD will be used in a laboratory
- Submit a Permit Amendment any time there are equipment changes, room changes, or significant changes to the manner of use
- Ensure that laboratory staff follow the Permit conditions, XGD-specific standard operating procedures, and the X-ray Safety Manual
- Maintain an up-to-date list of personnel who may use XGDs and ensure each person has completed the RSS online x-ray safety training
- Control the purchase, use, transfer and/or disposal of XGDs
- Maintain an operating log and any equipment history or maintenance records for the XGD
- Ensure that Dosimetry is used as recommended and that dosimeters are returned for readout on time
- Maintain the availability of a calibrated radiation detector in lab
- Ensure the security of any XGD in lab
- Notify Radiation Safety Services (RSS) if:
    - Any emergency involving the XGD occurs
    - Any changes are made to equipment, location, or manner of use of the XGD
    - Minors under 18 are involved in experiments using XGDs

Radiation Safety Services Mission

The mission of Radiation Safety Services (RSS) is to implement a program committed to the safe and proper use of X-Ray Generating Devices (XGDs) in accordance with the policies set by the Radiation Safety Committee (RSC) in compliance with governmental regulations and in full support of the programs at affiliated institutions. Fulfillment of this mission relies strongly on fostering a spirit of cooperation with personnel working with XGDs and instilling the necessary knowledge of regulations and safety procedures through user training, personal interface with users, and oversight by RSS Staff. RSS strives to maintain high performance standards from participants by placing a strong emphasis on safety, quality, productivity, and cost effectiveness, and by working cooperatively with Principal Investigators (Permit Holders) and other machine operators.

This mission is carried out through the following service model:

- Provide education, training, and guidance for program participants.
- Perform evaluation, risk assessment, and approval of proposals for the specific uses of XGDs at the University.
- Perform regular reviews of laboratory use of XGDs through annual surveys and permit reviews.
- Provide monitoring of individuals in accordance with the potential for radiation exposures and institutional policies.
- Manage device purchases, registration, inventory, transfer, and disposal.
- Calibrate radiation monitoring equipment on site or coordinate offsite calibration services.
- Collect, manage, and report on data compiled in the performance of program operations.
- Provide 24/7 emergency response.
- Act as regulatory liaison for the University.
- Maintain a highly qualified and committed staff.

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I Policy

No one may use or bring into Harvard University ("University") or remove from the University any XGD without obtaining written authorization (i.e. Permit) from RSS in the Harvard Environmental Health and Safety (EH&S) department. This authorization process includes approval by the University's RSC, and as necessary, registration of the devices with the applicable governmental agencies.

All work with XGDs must comply with the conditions of use specified in Federal, State, and University regulations, and the authorization issued by RSS.

No one may activate any XGD unless it has been reviewed and approved by RSS and registered as necessary with the State, and unless all individuals using the device have been instructed in general x-ray safety training and the safe use of the device by a qualified individual.

No one may enter or work in an area designated for use with XGDs except as authorized and under conditions specified by RSS in the user's Permit. Special arrangements may be made with RSS for visitors accompanied by trained personnel.

All persons who work with XGDs must ensure that work-related radiation exposures are kept as far below the limits established by regulatory limits as reasonably achievable (ALARA).

II General Policies and Procedures

1. General Policy Statement

XGDs are potentially hazardous unless used safely. To ensure safety, institutions and governmental agencies have established extensive regulations, rules, and safety practices to minimize the impacts on the user, members of the Harvard University Community, and members of the general public. This Manual sets forth the roles and responsibilities, and safe operating procedures, associated with the use of XGDs at the University as managed by RSS.

2. Access to Program Documents

The Commonwealth of Massachusetts has issued the University registrations to use specifically designated XGDs. Under State regulatory requirements, the University is required to make available documents related to the registrations (e.g. State Regulations), and any notice of violation issued to the University by the Commonwealth's Radiation Control Program (RCP). These documents may be reviewed at the RSS Cambridge Office. Additionally, employees located in buildings that use x-ray radiation also have access to the state Notice to Employees and Harvard Rules and Regulations for more information about the University's x-ray safety program.
Registered radiation users may request a copy of their radiation exposures annually or upon termination of employment. Requests should be made in writing or by email to RSS (radiation_protection@harvard.edu).

3. Regulatory Basis and University License

The Commonwealth requires registration of XGDs under the provisions of 105 CMR 120.020, Registration of Radiation Machines Facilities and Services. These devices include x-ray tubes, clinical x-ray machines, and any other device that can generate voltage-controlled ionizing radiation beam. In addition to the requirements of 105 CMR 120.020, all registrants (i.e. Permit Holders) are subject to the applicable provisions of other parts of 105 CMR 120.000 (e.g. Standards for Protection Against Radiation, Radiation Safety Requirements for Analytical X-ray Equipment, etc.).

4. Program Administration and Responsibilities

4.1 Administration

The Vice President of Campus Services has ultimate responsibility for oversight of the Radiation Safety Program. The Radiation Safety Program is administered by the Harvard EH&S department. To ensure safety, Harvard's Radiation Safety Program is overseen by the **Radiation Safety Committee** (RSC). The RSC is a University standing committee consisting of faculty and administration that sets safety policy, approves program changes, and approves use of XGDs. The members of the RSC are appointed by their School or administrative unit.

Radiation Safety Services (RSS) in the EH&S department provides radiation safety services. EH&S is a department of Harvard Campus Services. The Radiation Safety Officer (RSO) is responsible for managing the day-to-day operations of RSS.

To ensure local management and control of radiation (e.g. XGDs), the RSC issues Permits to those holding University appointments (faculty members and officers) whose training and experience are commensurate with the use of XGDs in their laboratory research. Each member's Permit must specify the Permit Holder, the person responsible for ensuring compliance with the Permit and the X-ray Safety Manual, as well as any and all Registered Users. The Registered Users are the scientists, students, research staff, and others who use the XGD(s) under the direct supervision of the Permit Holder.

4.2 The Radiation Safety Committee

The RSC, a standing committee at the University, is the governing body for all aspects of radiation safety within the University, including all affiliated research, clinical, instructional, and service units using XGDs in facilities owned or controlled by the University. The Committee shall ensure that all use, transfer and disposal of XGDs by University personnel complies with pertinent Federal and State regulations, and that all concomitant radiation exposures are maintained **A**s **L**ow **A**s **R**easonably **A**chievable (ALARA).

As noted in Committee's Charter, the Committee is a "University Standing Committee that is responsible for the management and oversight of the University Radiation Safety Program." In fulfillment of this role, the Committee promulgates policies, rules and procedures for the safe use of XGDs. The Committee has the authority to grant, deny, or withdraw permission for the use of radiation sources within the University.

It is the intent of the University that no use of radiation proceeds without the knowledge and approval of the Committee.

The Committee reports to the University Vice President of Campus Services. In its oversight role of RSS, the Committee is responsible for the following:

- Establishing University policies,
- Establishing training procedures and criteria,
- Review and approval of all proposals for use of XGDs and limiting conditions of their use as identified by RSS,
- Voting to approve, disapprove, or amend proposals,
- Ensuring that only qualified individuals are permitted to use XGDs, or that other users are supervised by qualified individuals

- Conducting audits and assessments of RSS that includes a review of documentation and performance required to comply the Commonwealth of Massachusetts regulations, and RSC Policies. This audit is reviewed, discussed, and recorded at an RSC meeting
- Enforcing compliance with the program, including imposition of sanctions for noncompliance,
- Voting to change service vendors as may be required by license, regulation, or commercial requirements,
- Maintaining a list of the members and their appropriate training and experience,
- Making recommendations to the University Vice President of Campus Services on risk management issues related to radiation safety.

4.3 Radiation Safety Services

Under the direction of the Radiation Safety Officer (RSO), RSS is responsible for:

- Ensuring compliance with Commonwealth of Massachusetts Department of Public Health (DPH);
- Maintaining a registry of all devices, persons and facilities subject to the Radiation Safety Program;
- Developing and evaluating training programs in the safe use of XGDs;
- Advising on implementation of all aspects of the Radiation Safety Program, including safety and cost-effectiveness;
- Assisting in use at the laboratory level;
- Calibrating radiation detection instruments;
- Auditing approved permits and programs biannually, through meetings with authorized users and inspection of operations;
- Reviewing laboratory operations to determine compliance with the ALARA principle;
- Providing personnel monitoring services;
- Responding to emergencies;
- Investigating incidents involving XGDs and violations of regulations;
- In cases of noncompliance, suspending authorizations in accordance with guidelines established by the RSC;
- Conducting an annual inventory of all XGDs;
- Conducting annual surveys of XGDs
- Performing commissioning/decommissioning activities
- Assisting with users who have lower dose limitations (declared pregnant workers, minors)
- Maintaining complete records of program operations that are in a form suitable for inspection by regulatory agencies and can be readily retrieved and distributed.

4.4 Radiation Safety Officer

The duties, responsibilities, and authority of the Radiation Safety Officer consist of:

- Day-to-day coordination and management of the Radiation Safety Program;
- Establishing action levels for personnel exposure, and radiation limits;
- Executing the established policies of radiation safety and ensuring compliance with Federal, State and Local regulations;

- Supervising radiation control activities as required by the Radiation Safety Program and the RSC;
- Investigating all proposals for XGD use, use conditions, and the transmittal of proposals to the RSC, with recommendations for approval or disapproval;
- Providing provisional approval to satisfactory proposals in accordance with guidelines of the RSC;
- Halting operations involving XGDs if unsafe or unacceptable conditions exist (operations may resume only when authorized by the RSC);
- Reviewing laboratory operations to determine compliance with the ALARA principle;
- In certain cases of noncompliance, suspending authorizations to use XGDs in accordance with guidelines established by the RSC, and authorizing provisional reinstatement following achievement of compliance pending review and final action by the RSC;
- Maintaining records of program operations that are suitable for inspection by regulatory agencies and can be retrieved and distributed.

4.5 Permit Holder Responsibilities

The Permit Holder is an individual authorized by the RSC to use and supervise the use of XGDs and is directly responsible for:

- Maintaining an up-to-date listing with RSS of XGDs, rooms where the XGDs are used or stored, and names of personnel who may use these devices;
- Ensuring that laboratory staff follow the Permit conditions, standard operating procedures, and the X-ray Safety Manual;
- Allowing only personnel who are identified on the Permit and properly trained to use XGDs;
- Developing standard operating procedures for device use
- Contacting the Radiation Safety Services before:
    - starting a new procedure that varies from the authorized protocols;
    - renovating, altering, repairing or vacating any laboratory space that could affect the use and safety of the XGD(s);
    - changing laboratory locations;
    - leaving the University;
    - repair, transfer or disposal of any XGD;
    - allowing students under 18 to be involved in experiments using XGDs.
- Ensuring those working under his/her Permit satisfactorily complete x-ray safety training;
- Minimizing radiation exposures to the user, the University Community, and general public;
- Ensuring that dosimetry is used and dosimeters are returned on time.
- Maintaining the availability of a calibrated radiation detector in lab for users
- Maintaining a written inventory and security over XGDs;
- Controlling the purchase, use, transfer and/or disposal of XGDs in his or her possession;
- Maintaining records of operating procedures, equipment history, and specific training on use of the equipment;
- Complying with the University's Policy governing the use of XGDs to ensure compliance with governmental regulation;
- Complying with any special conditions listed on his or her Permit;
- Implementing the policies of the X-ray Safety Manual.
- For Permit termination, please notify RSS 30 days in advance.
- Ensuring that XGDs are transferred to other authorized users before leaving the premises. This transfer may require prior notification to the Commonwealth of Massachusetts RCP.

4.6 Registered User Responsibilities

Persons who use XGDs must follow all applicable regulations pertaining to the use of radioactive materials as presented in the Harvard University X-ray Safety Manual, in the permit issued to the Permit Holder, and in notices issued by RSS. XGDs must be handled in a manner that also ensures the health and safety of others. Anyone who must enter a laboratory for work with XGDs, but who is not authorized to work with these devices, must do so under the direct supervision of a user from that laboratory.
In addition, all authorized users must:

- Registered/identified with and receive training and authorization from RSS prior to using any radiation generating source;
- Comply with the conditions on the laboratory's Permit;
- Complying with standard operating procedures for device use
- Receive appropriate dosimetry from RSS before working with XGDs;
- Complete biannual x-ray safety refresher training;
- Wear assigned radiation dosimetry as directed;
- Use XGDs to minimize radiation exposures;
- Maintain records as required by RSS or the X-ray Safety Manual;

5. Ensuring Compliance with Radiation Safety Policy

The University has promulgated a strong enforcement policy to maintain high standards for radiation safety. The State of Massachusetts DPH, which regularly inspects University laboratories for compliance, emphasizes the need for "meticulous attention to detail and a high standard of compliance with regulations." Adverse findings by the State DPH can result in fines, and in extreme cases, suspension of the University registration to use XGDs, even if no significant harm results to an individual. Accordingly, the RSC takes the necessary measures to achieve compliance with governmental regulations.

The RSC has promulgated a schedule of mandatory suspensions of authorizations, with the penalties dependent on the severity and frequency of observed violations. The RSC will suspend the use of XGDs for any of the actions listed below, to ensure personnel safety, to correct regulatory compliance issues, and at the discretion of the RSC. Under the terms of this suspension all XGD work covered by the Permit must stop.

The RSO has the authority to reinstate an authorization for an interim period until the next meeting of the RSC with the satisfactory completion of an audit by a staff health physicist. This audit will review laboratory compliance with the conditions of the Permit and implementation of measures to prevent recurrence of violations. The Permit may not be reinstated until the Permit Holder ensures effective resolution and documents the incident and corrective actions in writing to the RSC.

A suspended authorization will not be fully reinstated until the incident is reviewed by the RSC and the Committee is assured that reasonable measures have been instituted to prevent recurrence. This review may be a corrective action summary report presented by the RSO or an appearance of the Permit Holder and, at the discretion of the RSC, a dean of the school involved before the RSC.

Enforcement Actions are ranked as follows:

A. Those for which a single occurrence will result in a suspension of the authorization:

- Misuse of XGD that has or could result in unintended radiation exposure in excess of ALARA Investigation Level I;
- Intentionally disabling or removing X-ray warning or safety devices;
- Operating a XGD without state authorization;

B. Incidents that occur twice in a twelve-month period:

- Use of a XGD in a space not approved on the Permit;
- Not wearing assigned dosimetry when using XGDs;

C. Three occurrences of any particular incident in any twelve-month period:

- Working with XGDs before successfully completing x-ray safety training;

In addition to the conditions for mandatory suspensions noted above, the RSO may halt operations involving XGDs whenever unsafe or unacceptable conditions exist.

6. Obtaining a Permit

Any purchase, receipt, use or work with XGDs requires prior written authorization, referred to as a Permit, from the RSC. Such authorization requires notification with RSS, an agreement in writing to become familiar with and comply with the requirements of RSS and conformance with specified training and experience criteria. The Permit Holder is responsible for controlling all XGDs covered by the Permit from the time of receipt until transfer or disposal.

6.1 Ordering X-ray Equipment

All XGDs shall be procured through either through the HCOM marketplace or approved commercial vendors. RSS helps to provide points of contact for major commercial vendors such as Bruker, Ludlum, and GE, which are able to provide service specific to the University's registration needs.

6.2 Applying for an Permit

For an individual to become a Permit Holder, the person must have acceptable training and experience before the RSC will authorize his or her use of XGDs.

6.2.1 Submitting an X-ray Permit Application

The Permit Holder must file an X-ray Permit Application (Appendix B) that meets the requirements of this section, as well as a Standard Operating Procedure (SOP) describing the general method of use for the XGD and associated safety guidelines specific to the device. The application process includes a technical review of qualifications by RSS staff that will make a recommendation to the RSO. This position will be reviewed by the RSO and if deemed appropriate forwarded to the RSC for consideration and approval. Authorizations approved by RSC are valid for 2 years, after which the Permit Holder must file a renewal application with the RSC/RSS.

The evaluation of the X-ray Permit Application to hold Permit Holder status includes the following:

- Identification and review of the model and proposed uses of all x-ray sources in the application form. This review and subsequent Permit approval is based on the design parameters of the XGD. The applicant must agree to abide by all policies and procedures for safely using XGDs.
- The applicant must meet the requirements of a Qualified User (see below), by demonstrating the appropriate education, training, and practical experience commensurate with the radiation sources to be used. If the applicant does not meet these requirements, (s)he may, with the approval of the RSC, delegate responsibility for all uses of radiation under the authorization to a Qualified User under his or her direct supervision.

A Qualified User is an individual who has:

- A college degree at the bachelor level, or equivalent training and experience, in the physical, biological, or engineering sciences;
- Satisfactorily completed x-ray safety training and is qualified to work independently with radiation sources and to supervise such use by others;
- Provided evidence of adequate training and experience commensurate with the proposed use of XGDs. This training may be accomplished either within the institution or on the basis of documented prior training or by testing to document adequate knowledge.

The applicant is interviewed by a health physicist to assess adequacy of training, experience, and understanding of the University's radiation safety Policies commensurate with the hazards. The laboratory facilities/use locations are reviewed against the design criteria; expected laboratory experimental use of XGDs; and access to appropriate instrumentation is verified. Additionally, RSS will submit an X-ray registration application to the State for approval by the DPH.

6.2.2 Initial workspace evaluation and survey

Once the X-ray Permit Application and associated SOP have been reviewed, the health physics staff will audit the facilities to verify that the applicant satisfactorily complies with the requirements of the X-ray Safety Manual. The RPO will classify the equipment at the time of permitting to determine the regulatory and safety requirements. The health physicist will evaluate the intended workspace to ensure that adequate engineering and administrative controls are in place to protect laboratory workers and the general public from radiation hazards. The requirements of this workplace evaluation include proper personnel training, dosimetry, signs and warning indicators, equipment labels and indicators, interlocks, and emergency procedures. Further guidelines based on equipment type are also provided in the Appendices below.

After DPH approval to activate the x-ray machine has been given, the health physicist also conducts an initial x-ray survey of the intended workspace to measure dose rates and calculate total potential exposure to lab users. This survey ensure that radiation exposure will be limited to be within the University ALARA investigation levels, taking into account the frequency of usage of the XGD. Additional modifications to usage time, distance, and shielding may be made as a result of the survey if these limits cannot met based on the initial design. A finalized standard operating procedure (SOP) detailing the instructions for safe use of the device will be developed in conjunction with RSS that must be acknowledged and available to all x-ray device users.

6.2.3 Permit approval by the RSC

Following successful conclusion of the audit, the RSO will make a recommendation to the RSC requesting approval of the Permit. At the meeting, the RSC reviews the application and votes by majority rule, to accept, modify, or deny the application. Alternatively, RSS may seek RSC approval by paper or electronic mail ballot. Approval by the RSC is finalized by a signature of a designated representative of the RSC (usually the Chair or his/her alternate).
This authorization is valid for two years. If at the end of the two year period, a renewal application has been submitted before the expiration date, the permit will remain in effect until the completion of the renewal process. Following the permit authorization, XGDs will be registered by applying a Harvard University X-ray Survey Record label.

6.3 Permit Amendments

All requests for amendments must be submitted in writing or email to RSS by filling out the X-ray Permit Application as an Amendment (Appendix B). Amendments include changes to experimental protocols, identified laboratories, equipment changes and radiation users. RSS will review the requested amendment with the Permit Holder or his/her designee. RSS staff can approve simple changes in experimental protocol, equipment/devices, laboratories and users upon completion of the appropriate paperwork. Any change of a Permit condition, additional XGDs or complex experimental protocols must be approved by the RSC. New devices and change of location require registration with the State RCP.

6.4 Permit Renewals

Each Permit will be subject to renewal every two years. At the discretion of RSS, the Permit may be renewed earlier. The Permit Holder will sign and return a Permit Renewal Application at least two weeks before the Permit's expiration date. A Health Physicist will meet with the Permit Holder to review the current and expected activities. This renewal will include a review of user initial training, retraining, laboratory compliance history, instrument calibrations, radiation exposure data and records, and review of annual x-ray surveys. Based on this review, RSS will make a recommendation on renewal to the RSC. The RSC will consider renewal at the next scheduled quarterly meeting.

6.5 Permit Termination

Authorization to use XGDs terminates when the Permit Holder leaves the University or at the Permit expiration date. The Permit Holder must notify RSS by submitting an X-ray Termination Form (Appendix E) and associated documentation at least 30 days before leaving the University or terminating a Permit. The Permit Holder must ensure the proper transfer of devices before leaving the University or terminating the Permit.

7. Minors in Lab

The Youth Protection Office oversees all lab work conducted by minors under the age of 18. Any minor that plans to conduct work in a laboratory that contains XGDs must first register their work through the Youth Protection website at https://youthprotection.harvard.edu/. Their registration and work description will be reviewing by the EHS department, including RSS.
In general, no person under 18 years of age is allowed to be in a laboratory that uses XGDs unless the person is first be approved by RSS and the Youth Protection Office. Such persons must be in compliance with the Policy for the Safety & Protection of Minors (https://youthprotection.harvard.edu/policy).

No person under the age of 16 is allowed to be in a laboratory that is actively using a XGD.

8. Pregnant or Potentially Pregnant Radiation Users

The Massachusetts RCP has established a 500 mrem radiation dose limit to the embryo/fetus during the nine-month gestation period for those who declare their pregnancy in writing to RSS. As described in the Declared Pregnant Radiation User Policy (see Appendix K), this declaration may be made in confidence. When a person notifies RSS of participation in this program, RSS will provide a monitoring program that meets the requirements of the Policy. At the University, this Policy applies to persons of any gender who are either pregnant or trying to become pregnant.

III X-ray Producing Equipment

1. General X-ray Considerations

Research and clinical uses of many types of x-ray equipment include analytical, medical, dental, cabinet systems, and electron microscopes. All XGDs must be authorized by RSS. In addition, XGDs are required to be registered with the State in accordance the Commonwealth of Massachusetts regulations 105 CMR 120.020. The State registration of an XGD begins by first obtaining a Permit issued by RSS. This Permit specifies the Permit Holder, use restrictions, and approved machine operators. All operators, unless specified by RSS, must be identified on the Permit with RSS and receive safety training before using any x-ray equipment. Once this is completed, RSS will assist with submitting the state x-ray registration form on behalf of the Permit Holder. Training and permitting is required to ensure that the user is aware of the hazards of x-ray beams.

XGDs produce a large amount of radiation in a small diameter beam and it is therefore very important to proper shielding is used to protect humans from deterministic effects. It is the absorption of a high quantity of radiation dose in a short period of time that overwhelms the biological systems and poses safety concerns. See Section III.2 Biological Effects of Acute Radiation Exposures below for more information.

Regulations vary according to the type of x-ray equipment. As a result, guidance is given by machine type (e.g. analytical, open beam, radiography, dental, etc.). RSS will classify the equipment at the time of permitting to determine the regulatory and safety requirements. See additional information on X-Ray Safety Policies and Procedures.

2. Biological Effects of Acute Radiation Exposures as Related to x-ray Systems

With a properly functioning machine and proper safety precautions, there is very little risk of significant radiation exposure. However, one should know the signs of an acute exposure to a localized area of the human body to understand the importance of the safety interlocks and following proper procedures. These symptoms are shown below in Table 1. These effects can be caused by contact with the beam for only a fraction of a second.

Table 1 Acute Local Radiation Exposure Symptoms	
Received Dose	**Symptoms**
200 - 300 rad to the skin	Erythema (redness of the skin). The area may turn red within two to three weeks after the exposure depending upon dose. Epilation (hair loss) is possible within two to three weeks.
1,000 to 5,000 rad to the skin	Wet or dry blisters within one to two weeks of exposure that usually break open and are subject to infection. Epilation may be permanent.
Over 5,000 rad to the skin	Severe transepidermal injury that resembles intense scalding or chemical burn with the immediate onset of pain. Epilation is permanent.
Above 200 rad to the eye	There may be conjunctivitis (inflammation of the eye). It is possible that chronic exposures may lead to cataract formation.

The most common effect from a large radiation exposure from an x-ray device is reddening of the skin (erythema). With a dose of a few hundred rem the superficial layers of the skin are damaged and the skin will redden in a fashion similar to but more complex than a sunburn. The erythema effect will most often reverse itself within a few weeks. It is also possible that doses on this level could damage cell division and temporarily stop hair growth and possibly cause the hair to fall out. With a low enough dose, hair growth should return. There could also be damage to the sebaceous glands that produce the skin oil, which could cause a temporary decrease in the amount of oil produced.

There are other less common and less transitory responses. If a large area is exposure to a large amount of radiation, there could be changes in the skin pigmentation. This effect may not be reversible and could result in permanent skin changes. If the exposure is large the transitory damage to the skin, skin hair, or sebaceous glands could cause skin scarring or lead to Radiation Dermatitis, Chronic Radiation Dermatitis, or radiation induced skin cancer.

To protect yourself from the radiation consider the following potential sources of radiation exposure:

1. The primary beam.
2. Primary beam leakage from poor shielding or guide tube replacement.
3. Beam penetration through stops and shutters.
4. Secondary radiations from beam interaction of the primary beam with the sample or shielding.
5. Radiation released from the diffraction of the beam.
6. Radiation produced from support equipment such as power supplies.

3. Analytical and Cabinet X-ray Systems

The predominant x-ray-producing equipment used in research is analytical x-ray machine. It produces intense beams of x-rays. Exposure to the direct beam can cause severe injury. To prevent exposures, newer instruments are designed with hood enclosures, interlocks, and beam shielding to minimize the risk of inadvertent exposures. With high exposure rates, the hazard is not limited to the primary beam, but can also be related to leakage or scatter radiation. As result, x-ray machines should not be modified without

the authorization of RSS. A radiation survey should be done whenever a new type of sample is placed in the beam, the beam is diffracted, experimental setup changed, or when equipment is replaced.

The local components of an analytical x-ray system shall be located, arranged, shielded, and access controlled such that no radiation levels exist in any area surrounding the device use location which could result in a dose to an individual present in excess of the dose limits per 105 CMR 120.221 (Dose Limits to Individual Members of the Public) at any tube rating (Ref. 105 CMR 120.604(A)).

3.6 Shielding and Keep Out Zones

Low-energy analytical x-ray machines usually can be readily shielded with about 1 mm of lead or by creating a keep out zone outside which the exposure level while the XGD is activated is below 2 mrem per hour and below ALARA investigation levels. These keep out zones must be delineated from the rest of the label, with appropriate signage, and specified in the SOP and training for all lab users. Plastic finger guards are also recommended for shielding handheld low-energy devices.

High-energy x-ray machines may require thicker lead shielding as well as shielding embedded in room walls. Due to the intensity of the primary beam, leakage and scatter may create a significant source of unwanted radiation. RSS must consult with the XGD vendor in order to develop sufficient shielding for the extended use of high-energy XGDs. RSS may additionally consult with outside contractors specializing in x-ray shielding design in the event that high energy XGDs are used. Use shutters, collimators, and shielded door skirts, secure unused ports, reduce the beam cross-section by collimation, and whenever appropriate enclose the entire beam path or use a sufficient beam stop. Also to consider are additional sources of x-rays from miscellaneous support equipment such as high-voltage supplies. In the case of high-energy x-ray machines, room shielding design must be submitted for review by the state.

3.7 Interlocks and Safety/Warning Devices

Operational interlocks and safety devices shall be provided to ensure that the primary x-ray beam cannot be interrupted by any portion of an individual's body or extremities or by machine equipment under any operating condition. If the beam is interrupted, this interlock will shut off the primary beam. These interlocks and safety devices may not be altered without the written authorization of the RSO. Approved temporary modifications must be terminated as soon as possible, specified in writing and posted near the x-ray machine tube and operators console.

Open-beam configurations shall be provided with a readily discernible indication of the x-ray tube “ON-OFF” status located near the radiation source housing. In addition, there must be a shutter status indicator that unambiguously reports if the shutter is “OPEN-CLOSED” if the primary beam is controlled in this manner. These warning devices shall be labeled so that their purpose is easily identified.

Any unused tube ports or beam ports shall be secured to prevent accidental opening, and with indicators available to give open/closed status or interlocks such that the x-ray may not be turned one while a beam port is still open.

3.8 Warning Light

All x-ray machines will contain an operational and clearly visible light labeled with the words “X-RAY ON” or words of similar intent near any switch that energizes the X-ray tube and shall be illuminated only when the tube is

energized. This should be a failsafe indicator. This can also be in the form of an on-screen indicator within the software user interface.

3.9 Postings

The following documents should be placed near the controls of each analytical x-ray unit and readily accessible to the operator in either paper or electronic form:

- X-ray Safety manual
- Device user manual
- Specific written instructions/Operating Procedure (SOP) (See example in Appendix O)
- Analytical X-ray emergency contact information (included in Emergency Response Guide)
- Safe Working Practices for Analytical X-ray Checklist (See Appendix G).
- X-ray machine Operating Log (Appendix J).

Each area or room containing analytical X-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION – X-RAY EQUIPMENT" or words having a similar intent in accordance with 105 CMR 120.238 (ref. 105 CMR 120.604(c)). This may be included in the lab's main door placard. Laboratories will also have their lab Personal Protective Equipment (PPE) Assessment and Emergency Response Guide posted in an accessible area within the lab.

To ensure that building occupants are properly notified of their rights and responsibilities associated with XGDs, the safety bulletin board or common area bulletin board on each floor that has labs with these materials will contain the Harvard University Rules and Regulations (Appendix N) posting as well as the Massachusetts Radiation Control Program "Notice to Employees" (see Appendix M).

3.10 Labels

Analytical x-ray equipment will be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

- "CAUTION – HIGH INTENSITY X-RAY BEAM" or words having similar intent on the x-ray source housing, and

- "CAUTION RADIATION – THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or words of similar intent near any switch that energizes an x-ray tube.

The Harvard University X-ray Survey Record Label (Appendix D) also includes the relevant Caution wording, and also includes the following information:

- Latest survey date and inspector
- Permit Holder
- Permit series code
- Asset code
- Manufacturer
- Model
- Max operating voltage
- Max operating current
- Emergency phone number

3.11 Emergency Response

If there is a case of suspected or actual accidental exposure, turn off the system power, and notify RSS immediately. If required, exposed personnel should seek Urgent Care medical attention.
Emergency phone contact names and numbers should be available at the x-ray use location and on the Emergency Response Guide available in every Harvard lab.

3.12 Surveys

Radiological surveys of X-ray devices are conducted by RSS staff in conjunction with the Permit Holder upon initial equipment setup and at least once a year. Additional surveys may be required after and modification, alignment activities, or repair that could significantly affect the x-ray system operational parameters, or when visual inspection finds a defect in the x-ray system. A visual inspection, survey, or risk assessment may also be conducted by RSS at the request of the Permit Holder or system operator.
X-ray surveys are conducted using the Harvard Assessment & Inspection Management System (AIMS). A sample survey form may be found in Appendix C. Surveys include an inspection of all x-ray lab safety devices and protocols, including administrative controls, equipment safety devices, and training and documentation. Following the inspection, an x-ray survey is conducted with a lab member operating the XGD. This survey serves to ensure that the x-ray does not generate dose rates to personnel exceeding the University ALARA investigation levels or general public dose rate limits given in 105 CMR 120.221 at areas accessible to the general public, and to fulfill the dose requirements as specified in 105 CMR 120.603:

- Each radioactive source housing or port cover or each x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of five centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing x-ray tubes, this limit shall be met at any specified tube rating.
- Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 μSv) in one hour.

3.13 Dosimetry

State and Federal regulators set low-risk annual exposure limits. Additionally, the RSC has voluntarily set lower exposure goals based on the principle of "As Low As Reasonably Achievable" (ALARA). The RSC has established a conservative exposure limit of 10% of the regulatory limit. The University has a goal of keeping radiation exposures below this limit and to investigate and implement corrective action if exposures exceed the ALARA conservative limits. Refer to Appendix F. The annual occupational exposure limits and goals are shown in Table 1G.
Most users' radiation exposures are well below Harvard's exposure limits. In addition, the RSC has set Investigation Levels, which would initiate an investigation by RSS even before reaching exposure limits. Based on a review of the exposure(s), RSS will recommend appropriate safety measures to maintain exposures ALARA.
All equipment operators are required to wear whole body dosimeters unless a risk assessment of the device is performed by a Health Physicist and an area badge is issued instead. While equipment is designed to keep exposures to a minimum, it is possible that unusual events could lead to inadvertent exposures. These operations should never be attempted without appropriate safety precautions.
A Register User is assigned a temporary dosimeter at the successful completion of the required safety training. Each dosimeter is assigned to an individual and an individual may not wear the dosimeter assigned to another person. The dosimeter must be worn whenever in the laboratory, working with or

around x-ray sources. Whole body dosimeters are to be worn on the torso, positioned so that it is closest to the source of x-rays. Wearing it on the chest or at bench level are two suitable locations. It should be worn outside the lab coat.
In addition, a TLD ring dosimeter is assigned for open-beam applications (i.e. with no Safety Device or enclosure) or where RSS has determined there is a potential for hand exposures to the x-ray beam (i.e. beam alignment activities). The ring TLD should be worn on the hand used most often used.

3.14 Dosimetry Records

Radiation dosimetry results are first reviewed by the vendor and then RSS when the dosimeter is processed. A report is available online at Landauer's Individual Dose Report (IDR) feature at https://www.myldr.com/WebSelfService/ using Harvard's username and password ("**harvard_ird**" for both).

To ensure that doses follow the ALARA principle, any routine dosimeter with an exposure in excess of 100 millirem will be investigated by RSS. Other types of dosimeters have review criteria appropriate to the dosimeter use.

On an annual basis, dose reports will be mailed to individual Permit Holders. Personnel can also request individual dose information in writing or by email as needed.

3.15 Security

XGDs and/or their operating keys must be either locked within an access-controlled room, cabinet, or equipment case, or otherwise secured in a way that reasonably prevents the use and removal of the XGD by unauthorized personnel.

3.16 Safe Working Practices for Analytical X-ray Equipment

Equipment-specific SOPs shall be written and available to all x-ray equipment operators. No deviation from written operating procedures is allowed without written authorization from the RSO.
No person shall bypass a safety device or interlock unless permission is obtained in writing from the RSO. A time limit for the approval is required, and a sign bearing the words "SAFETY DEVICE NOT WORKING" must be placed on the X-ray tube housing. If possible the device should be locked out (voltage source disconnected) prior to the bypass.
Any repair of modification of the X-ray device shall not be done without determining that the tube is off and will remain off until save conditions have been restored.

3.17 Beam Alignment Activities

RSS highly recommends that any beam alignment procedures be conducted by the machine manufacturer, if possible, or by trained maintenance personnel. In the event that beam alignment must take place, laboratories should request assistance from RSS and follow these steps:

1. Wear a finger dosimeter.
2. Whenever available, use electronic alignment.
3. Use long handles on the fluorescent alignment screens.
4. Only a trained and qualified user should do an alignment.

5. If safety locks must be bypassed, first gain RSS approval and then post a sign indicating the safety switch status. Reinstate the safety switch as soon as possible.
6. Use the lowest power settings possible for beam alignment procedures.

3.18 Sample Changing

For safe sample changing, ensure the x-ray beam is inactive by using a radiation detector.
Use the shutter to stop x-rays. Verify shutter activation and that the shutter indicator is properly reporting shutter status prior to operating the XGD.

4. Cabinet X-Ray Systems

Cabinet x-ray systems consist of the x-ray tube installed in an enclosure which is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during x-ray production. Machines that may generate x-ray radiation as a secondary interaction (ie. electron microscopes, sputterers, or lithographs) may also fall under the category of Cabinet x-ray system. The protective cabinet limits the leakage of radiation measured at a distance of five (5) centimeters from its external surface such that it is not capable of producing dose in excess of 0.25 mrem (2.5 μSv) in any one hour.
An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding is not generally considered a cabinet x-ray system.

Dosimetry is not typically required for this application unless assessment by RSS indicates use condition warrant personnel monitoring devices. Operators have the option to request dosimetry, if desired.
Most other requirements of Analytical X-ray Systems identified above apply to use of this equipment including Permits, labeling, posting, operating procedures, emergency procedures, surveys, training, operating log, and warning lights.
Refer to cabinet (See Appendix H) or electron microscope (See Appendix I) checklists for specific additional guidance.
These instructions are not applicable to Cabinet x-ray systems constructed in accordance with 21 CFR 1020.40, and that are used for macroscopic examination of sample material. Refer to 21 CFR 1020.40 for equipment and labeling requirements, and State of Massachusetts 105 CMR 120.303 for annual inspection requirements for this equipment.

5. Clinical X-ray Systems

Clinical x-ray systems for human use have some exemptions from personnel monitoring requirements according to State regulations, as detailed below. Only users at the following schools are authorized to use x-ray machines for human use: University Health Services, Harvard School of Dental Medicine, Harvard Medical School, and Harvard Athletics. These clinical machines include, but are not limited to, dental intraoral, panoral, and handheld x-ray machines, radiography, and mammography machines.
New clinical x-ray systems or x-ray machines being moved to a new location require registration with the State DPH as well as submission of room shielding designs. RSS coordinates with clinical facilities and their architects for the design and construction of shielded rooms for medical x-ray use where necessary. This may include lead shielded walls and doors, and consultation services on the placement of patient chairs/standing areas during x-ray use and on/off switches in compliance with all state regulations.

The facility must have their x-ray registration certificate as provided by the State posted in a conspicuous location on the main floor of the building (usually in a patient lobby).
The registrant shall ensure that the equipment is in safe working order. Preventative maintenance shall be performed at least every three years by a registered provider per 105 CMR 120.026. These records must be reviewed and signed by a licensed dentist within 30 days of completion. Any corrective actions must be implemented within 30 days. Records of the last two calibrations must be kept at the facility. The University recommends conducting annual x-ray surveys, which are conducted by third-party vendors including but not limited to, PCI, Benco, and Massachusetts General Hospital. RSS coordinates these inspections with the x-ray owners.
The operator shall stand at least six feet away from the useful beam or behind a protective barrier in view of the patient. Film holding devices are required unless specific exemptions are being taken per 105 CMR 120.407(E)(1).
Protective equipment (e.g. aprons and shields shall be checked annually for defects such as holes, cracks, and tears to assure reliability and integrity. Documentation of these inspections shall be kept for at least five years. When gonadal shielding is provided to patients it should be at least 0.5 mm of lead equivalents. Aprons should be stored when on in use on a flat surface to prevent defects from developing.
Dental and medical x-ray units that are not used on humans are considered and registered as analytical x-ray devices.
Individuals who operate only Dental radiographic systems are exempt from the personnel monitoring requirements per 105 CMR 120.407(E)(4).

6. Training

All users must complete the online x-ray device safety training course (RSS102) and must also be provided specific written instructions by the Permit Holder before using the equipment. These instructions include notice of radiation hazards; machine specific safe work practices; and symptoms of acute, localized exposure to radiation. Users must also complete the online x-ray device safety refresher every two years.
All individuals who wish to independently operate, modify, or maintain diagnostic, veterinary, analytical, industrial, or analytical cabinet x-ray systems, or who will be used as patient or film holders, shall receive instruction in and demonstrate ability in:

- Identification of x-ray hazards associated with the use of the equipment and levels of radiation expected;
- Significance of the various x-ray warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;
- Facilities proper operating procedures and control (i.e. locking and securing of x-ray machines) requirements for the equipment;
- Characteristics of x-ray radiation;
- General information on use of radiation survey instruments: operation, calibration, limitations, and survey techniques if required for use of the x-ray equipment (e.g. specifically required for Industrial Radiographic x-ray use per RHB 8.12.2);
- Units of radiation dose and methods for controlling radiation dose (i.e. time, distance, shielding);
- Personnel monitoring and the use of personnel monitoring equipment (e.g. pocket dosimeters when applicable, use with lead aprons, etc.);
- Symptoms of an acute localized exposure;
- Proper notification procedures for reporting an actual emergency or suspected overexposure
- Procedures to minimize exposure in the event of an accident;
- Emergency procedures;

- Requirements of pertinent state regulations;
- Procedures of record control and documentation;
- Ability shall be demonstrated by completing the online x-ray safety training located at the Harvard Training Portal (HTP) at http://trainingportal.harvard.edu/;
- Having the Permit Holder verifying a user's competence with machine operations (i.e. SOP specific operating procedure) by signing approval of the user for the specific equipment,
- When used, ability shall be demonstrated on the use of survey instruments, pre-experiment response checks, and limitations by observation of RSS and documentation of satisfactory performance.

Appendix A - Definitions

Definitions and Terms

Agreement State - Any state with which the U.S. Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended. Under the agreement, the state regulates the use of by-product, source, and small quantities of special nuclear material within said state.

ALARA - Acronym for "As Low As Reasonably Achievable". Making every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits as practical, consistent with the purpose for which the licensed activity is undertaken. It takes into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, societal and socioeconomic considerations, and in relation to utilization of radioactive materials and licensed materials in the public interest.

Analytical x-ray equipment - any machine utilizing x-rays for examination of the microscopic structure, or elemental or chemical composition of materials. This includes x-ray equipment used for x-ray diffraction, fluorescence analysis, or spectroscopy.

Ancillary Worker - Any individual who works in support of the laboratory operations and does not work with radioactive materials directly.

Attenuation - The process by which radiation is reduced in intensity when passing through some material. It is the combination of absorption and scattering processes.

Authorization - The approval issued to an individual by the Radiation Safety Committee to use and supervise the use of radioactive materials.

Authorized User - The individual authorized by the Radiation Safety Committee to use and supervise the use of radioactive materials. Typically, the Authorized User is a senior investigator or faculty member who has the primary scientific, financial, and legal responsibility for a research program. The Authorized User may use the authorized radiation sources directly or, with the approval of the Radiation Safety Committee, may delegate the operational responsibilities to a Qualified User. The Authorized User has primary responsibility for radiation safety in facilities under his or her control.

Background Radiation - Radiation from cosmic sources; naturally occurring radioactive materials, including radon and fallout from nuclear weapons tests.

Beam Axis -a line from the source through the centers of the x-ray fields.

Beam-limiting device - a device which provides a means to restrict the dimensions of the x-ray field.

Bremsstrahlung - X-rays produced when a charged particle loses energy in interactions with heavy nuclei when moving through matter.

Cabinet x-ray system - an x-ray system with the x-ray tube installed in an enclosure which is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during x-ray production. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

Calibration - The check or correction of the accuracy of a measuring instrument to assure proper operational characteristics.

Charged Particle - An elementary particle or ion which carries a positive or negative electric charge.

Committed Effective Dose Equivalent - The dose equivalent to organs or tissues of reference that will be received from an intake of radioactive material by an individual during the 50 year period following intake.

Collimator - a device or mechanism by which the x-ray beam is restricted in size.

Counter - A general term used for a radiation detection instrument, survey meter, or a liquid scintillation counter (LSC) that detects and measures radiation. The signals (needle blip and audio beep) show ionization events called counts.

Cumulative Dose - The total dose resulting from repeated exposures of radiation to the same region, or to the whole body, over a period of time.

Declared Pregnant Worker - A woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

Deep Dose Equivalent - A term that applies to external whole-body exposure, and is the dose equivalent at a tissue depth of 1 cm.

Detector - A material or device that is sensitive to radiation and can produce a signal suitable for measurement or analysis. A radiation detection instrument.

Dose - A generic term referring to the amount of radiation received by a biological organism.

Dose Equivalent - The product of the absorbed dose in tissue, quality factor, and other modifying factors at the location of interest. The units are mrem.

Dose Rate - The ionizing radiation dose delivered per unit time, such as mrem/hour.

Dosimeter - A portable instrument for measuring the total accumulated exposure to ionizing radiation.

Effective Dose Equivalent - The sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated.

Embryo/Fetus - The developing human organism from conception until the time of birth. More specifically; embryo: 2 weeks (implantation) - 8 weeks; fetus : 8 weeks - term.

Exposure - 1) A measure of the ionization produced in air by x or gamma radiation. The unit of exposure is the Roentgen (R). 2) Being exposed to ionizing radiation or to radioactive material.

Exposure Rate - The amount of ionization in air caused by X-ray or gamma ray radiation per unit time; unit of measurement is the Roentgen per unit time (R/hr)

External Dose - The portion of the dose equivalent received from radiation sources outside the body.

Extremity - Arm below the elbow and the leg below the knee.

Eye Dose Equivalent - Applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 cm.

Geiger-Mueller Counter (GM) - A radiation detection instrument that can detect alpha, beta and gamma radiation; response is not energy dependent.

Gonadal shield - a protective barrier for the testes or ovaries.

Half Value Layer - The thickness of any given absorber (shield) that will reduce the intensity of incident radiation to one half of its initial value.

Health Physics - The science concerned with recognition, evaluation, and control of health hazards from non-ionizing and ionizing radiation.

High Radiation Area - An area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 mrem in 1 hour at 30 cm from the radiation source or from any surface that the radiation penetrates.

Ionization - The process of adding or removing one or more electrons from atoms or molecules. High temperatures, electrical discharges, or radiation can cause ionization.

Ionization Chamber - An instrument that detects and measures ionizing radiation by measuring the electrical current that flows when radiation ionizes gas in a chamber, making the gas a conductor of electricity.

Ionizing Radiation - Any radiation capable of displacing electrons from atoms or molecules, producing ions. Examples: alpha, beta, gamma, X-rays, neutrons, and ultraviolet light. High doses may produce severe skin or tissue damage.

Irradiation - Exposure to radiation.

Kilovolts peak - (See "Peak tube potential"). kV - kilovolts.

Leakage radiation (non-diagnostic) - **all** radiation from within the tube housing complex except the useful beam(s).

Limits - The permissible upper bounds of radiation doses.

NaI (Sodium Iodide) Detector - A detector which combines a scintillation crystal (produces light when struck by ionizing radiation), a photomultiplier tube, and associated electronic circuits for counting light emissions produced in the crystal (NaI) by ionizing radiation. A NaI scintillation probe with a ratemeter can be used for detection of gamma and X-rays.

Occupational Dose - The dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation and to radioactive material. This does not include dose received from background radiation, as a patient from medical procedures, from voluntary participation in medical research programs, or as a member of the general public.

Open beam configuration - an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

Operating procedures- detailed written instructions including, but not limited to, use of the x-ray equipment, use of shielding and barriers, quality assurance methods, occasions and methods for conducting area surveys, use of personnel monitoring devices, and alignment, calibration, or preventative maintenance of x-ray equipment. Routine and emergency radiation safety considerations are part of these procedures. Emergency procedures shall include methods of notifying proper persons in the event of an emergency, to include the listing of names, addresses and phone numbers.

OSLD (Optically Stimulated Luminescent Dosimeter) - A crystalline material (usually Al_2O_3:C) which when exposed to light dexcites by the emission of another wavelength of light; used in dosimetry.

Permit - Official document issued by the Radiation Safety Committee to the authorized user stating scope of the authorization to use radioactive materials and conditions of use.

Permit Holder - The individual to whom the Permit is issued by the Radiation Safety Committee.

Personnel Monitoring - The determination of the degree of radioactive contamination on individuals using survey meters, or the determination of radiation dosage received by means of dosimetry devices.

Primary beam - ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube located in the radiation source housing.

Protective apron - an apron made of radiation absorbing material used to reduce radiation exposure.

Protective barrier - a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(1) "Primary protective barrier" the material, excluding filters, placed in the useful beam, to protect anyone other than the patient from radiation exposure.
(2) "Secondary protective barrier" a barrier sufficient to attenuate the stray radiation to the required degree.

Quality Factor - The modifying factor that is used to derive dose equivalent from the absorbed dose. They vary for different radiation types and reflect the degree of biological effect.

Qualified User - An individual who through appropriate training and experience is qualified and authorized to work independently with radiation sources and to supervise such use by others. A Qualified User works under the direction and authority of an Authorized User, but does not necessarily have his or her own Authorization.

Quarter - A period of time equal to one-fourth of the year observed by the licensee (approx. 13 consecutive weeks). Providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

Rad - The special unit of absorbed dose. One rad is equivalent to 100 ergs/gram or 0.01 J/kg.

Radiation - Alpha particles, beta particles, gamma rays, X-rays, neutrons, high speed electrons, high speed protons, and other charged particles capable of producing ions. Radiation, as used in this context, does not include non-ionizing radiation, such as radio waves, microwaves, or visible, infrared, or ultraviolet light.

Radiation Area - An area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 5 mrem in 1 hour at 30 cm from the radiation source or from any surface that the radiation penetrates.

Radiation Detection Instrument - A device that detects and records the characteristics of ionizing radiation.

XGD or Machine (RGD) - Any device capable of producing radiation except those which produce radiation only from radioactive material.

Radiation Safety Committee - The University Committee that is responsible for the oversight of and for setting the policies of the Radiation Safety Program.

Radiation Safety Officer - The individual responsible for implementing the policies and procedures of the Radiation Safety Committee and for the day-to-day operation of the Radiation Safety Program.

Radiation Shielding - Reduction of radiation by placing a shield of absorbing material between any radioactive source and a person, work area, or radiation sensitive device.

Radiation Source - Usually a manmade sealed source of radiation used in teletherapy, radiography, as a power

source for batteries, calibration, or in various industrial gauges. Machines such as accelerators, radioisotope generators, and natural radionuclides may be considered sources.

Radiation Standards - Exposure standards, permissible concentrations, rules for safe handling, regulations for transportation, regulations for industrial control of radiation and control of radioactive material by legislative means.

Radiation Warning Symbol - An officially prescribed symbol (a magenta trefoil) on a yellow background that must be displayed where certain quantities of radioactive materials are present or where certain doses of radiation could be received.

Registered Worker – An individual whose official duties and responsibilities involve the use of radioactive materials or XGDs under the supervision of an Authorized User. Registered workers include authorized user, personnel listed in the permit issued to the authorized users, and other individuals, such as maintenance personnel, who may come in contact with radioactive material.

Rem - The special unit for dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rads, multiplied by the quality factor.

Roentgen (R) - A unit of exposure to ionizing radiation. It is that amount of gamma or X-rays required to produce ions carrying 1 electrostatic unit of electrical charge in 1 cubic centimeter of dry air under standard conditions. Named after Wilhelm Roentgen, German scientist who discovered X-rays in 1895.

Restricted Area - An area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation or radioactive materials. Restricted area does not include areas used as residential quarters, offices, etc.

Safety device - a device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path.

Scattered radiation - radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation).

Scintillation Detector - A radiation detection instrument comprised of a phosphor, photomultiplier tube(s), and associated electronic circuits for counting light emissions produced in the phosphor by ionizing radiation.

Shallow Dose Equivalent - Applies to the external exposure of the skin or an extremity. This is the dose equivalent at a tissue depth 0.007 cm averaged over an area of 1 square centimeter.

Shielding - Any material or obstruction that absorbs radiation and thus tends to protect personnel or materials from the effects of ionizing radiation.

Shutter- a device attached to the tube housing assembly which can totally intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

Source of radiation - any device or equipment emitting or capable of producing x-ray radiation.

Stray radiation - . the sum of leakage and scattered radiation.

Survey Meter - Any portable radiation detection instrument especially adapted for inspecting an area to establish the existence and amount of radioactive material or contamination present.

Target - that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

Tube - an x-ray tube, unless otherwise specified.

Tube housing-apparatus complex- those parts of an analytical x-ray device in which x-rays are produced and utilized for a useful purpose. This includes the x-ray tube housing, shutter or port assemblies, collimators, cameras, goniometers, and electronic radiation detectors.

TLD (ThermoLuminescent Dosimeter) - A crystalline material which emits light when heated after radiation exposure; used in dosimetry.

Vendor - a person who is engaged in the business of selling, leasing, installing, or offering to sell, lease, or install x-ray machines or machine components or is engaged in the business of furnishing or offering to furnish x-ray machine services, which includes, but is not limited to, reinstalling, reassembling, leasing, servicing, maintenance, calibration, and repair of x-ray equipment, facility and shielding design, radiation surveys, instrument calibration, personnel dosimetry, processor cleaning and maintenance, and health physics consultations.

Whole Body - Refers to the head, trunk (including gonads), arms above the elbow, and legs above the knee.

X-rays - Penetrating electromagnetic radiation (photon) having a wavelength that is much shorter than that of visible light. They can be produced by excitation of the electrons around certain nuclei (characteristic X-rays) or by the interaction of high speed electrons with the electric fields around nuclei.

X-ray system - an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high voltage generator, an x-ray control, a tube housing assembly, a beam limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

Appendix B – X-ray Permit Application Form

Form can also be found on the EHS website at: http://ehs.harvard.edu/programs/x-rays

☐ New ☐ Amendment ☐ Renewal ☐ Transfer	**Harvard University** **Application for a Permit to use X-Ray Devices** Return to: Harvard University Radiation Protection Office 46 Blackstone Street; Cambridge, MA 02139 Facsimile: (617) 496-5509

Authorized User: (Permit Holder)	(Last)	(First)	(M.I.)	Degree(s):
Appointment:	School:			Dept:
Office Address: (Bldg.)	(Room)	(Street Address)	(City)	Telephone:
E-mail address:				Facsimile:
Alternate Permit Holder:	(Last)	(First)	(M.I.)	Alternate's Telephone:
Alternate's e-mail address:				Alternate's Facsimile:
Preferred Contact: (M.I.) Contact's Title (Laboratory Safety Officer, Admin, etc.):	(Last)	(First)		Contact's Telephone:
Contact's e-mail address:				Contact's Facsimile:

SECTION 1: LABORATORY SPACES

SECTION 1	Building(s):	Laboratory Room Numbers:

SECTION 2: X-RAY PRODUCING EQUIPMENT

SECTIO	Manufacturer	Model No.	Serial No.	Operating Parameters (KVp/Ma)	Type of Use (Analytical/Medical)

SECTION 3: RADIATION DETECTION INSTRUMENTATION AVAILABLE TO THE LABORATORY

SECTION 3	*Liquid Scintillation Counters*			*Gamma Counters*			*Survey Meters*		
	Manufacturer	Model Number	Quantity	Manufacturer	Model Number	Manufacturer	Model Number	Probe Type	Quantity

SECTION 4: AUTHORIZED USER'S FORMAL TRAINING

Application for a Permit to Use X-Ray Devices *(Form Rev. July 2016)* Page 1 of 2

Appendix C – X-ray Survey Form Sample

HARVARD
Assessment & Inspection Management System (AIMS)

AIMS Inspection Report
Full Report

Description			
Type:	X-ray	**Date:**	Oct 31, 2016
Space :	EHS Test Lab	**School/Organization:**	Campus Services
Inspector:	Tiffany Lee	**Department:**	Environmental Health and Safety
		Inspection Scope:	Blackstone S: EHS Test Lab

Roster	
Tiffany Lee	EHS, Lab Safety Officer,

Question Responses
1. Xray-Admin Controls
1.1 Are the Harvard Rules and Regulations and MA State Regulations posted? **Selection:** Yes
1.2 Is the x-ray located in a dedicated location with access control? **Selection:** Yes
1.3 Is "Caution X-ray Equipment" sign bearing the radiation symbol present? **Selection:** Yes
1.4 Are emergency response procedures posted? **Selection:** Yes
1.5 Is an x-ray operating log present? **Selection:** Yes
1.6 Are interlocks never bypassed, except with approval of the RSO? **Selection:** Yes
1.7 Are x-rays never modified or unshielded, except with approval from the RSO? **Selection:** Yes
2. Xray-Documentation
2.1 Is the x-ray permit up to date? **Selection:** Yes
2.2 Are standard operating procedures (SOPs) written? **Selection:** Yes
2.3 Are all operators listed on the x-ray permit? **Selection:** Yes
2.4 Have all operators completed the online X-ray Device Safety Training? **Selection:** Yes
2.5 Are all operators specifically trained for the x-ray machine? **Selection:** Yes
2.6 Are operators aware of the Declared Pregnancy Policy and Minors Policy? **Selection:** Yes
2.7 For open-beam configurations, are operators issued chest/finger dosimeters? **Selection:** Yes
2.8 Is the x-ray registered with the state? **Selection:** Yes

3. Xray-Equipment	
3.1 Is an illuminated, fail-safe "X-ray On" warning light present near the tube switch?	
Selection:	Yes
3.2 Is a tube switch label "Caution Radiation- This Equipment Produces Radiation When Energized" present?	
Selection:	Yes
3.3 Is a source housing label "Caution- High Intensity X-ray Beam" present?	
Selection:	Yes
3.4 If the source is a radionuclide, is a source housing label "Caution- Radioactive Material" present?	
Selection:	Yes
3.5 For open-beam configurations, is a tube "on-off" or shutter "open-closed" status indicator present?	
Selection:	Yes
3.6 Are warning devices labeled and fail-safe?	
Selection:	Yes
3.7 Is x-ray tube housing equipped with an interlock?	
Selection:	Yes
3.8 For open-beam configurations, are safety devices (interlock, finger shield, shutter) present and checked periodically?	
Selection:	Yes
3.9 Are unused ports on radiation source housing securely closed when unused?	
Selection:	Yes
3.10 For open-beam configurations, are beam shutters collimated?	
Selection:	Yes
3.11 For medical fluoroscopic equipment, are lead aprons utilized and checked periodically?	
Selection:	Yes
4. Xray-Survey	
4.1 Survey instrument	
Response:	1
4.2 Machine operator	
Response:	1
4.3 Estimated x-ray workload	
Response:	1
4.4 Survey locations	
Response:	1
4.5 Test voltage (kVp)	
Response:	1
4.6 Test current (mA)	
Response:	1
4.7 Exposure rate 5cm from generator cabinet (mrem/hr)	
Response:	1
4.8 Exposure rate 5cm from tube head with shutter closed (mrem/hr)	
Response:	1
4.9 Maximum exposure rate to whole body (mrem/hr)	
Response:	1
4.10 Maximum exposure rate to fingers/hands (mrem/hr)	
Response:	1
4.11 Maximum exposure rate to adjacent areas accessible to the public (mrem/hr)	
Response: 1	
4.12 Record interlock tests	
Response: 1	

Appendix D – X-ray Survey Record Label

CAUTION RADIATION -
THIS EQUIPMENT PRODUCES
RADIATION WHEN ENERGIZED

X-ray Survey Record
Harvard University | Campus Services
Environmental Health & Safety

Survey Date: _____
Permit Holder: _____
Manufacturer: _____
Max Voltage: _____
Inspected By: _____

Asset Code: _____
Series Code: _____
Model: _____
Max Current: _____
For Assistance, Call (617) 496-3797

Appendix E – X-ray Termination Form

Form can also be found on the EHS website at: http://ehs.harvard.edu/programs/x-rays

Permit Holder: _____

Facility Name: _____

Address: _____

_____

Room Number: _____

Telephone Number: _____

X-ray Manufacturer: _____

X-ray Model: _____

X-ray Serial Number: _____

The following information is provided in accordance with 105 CMR 120.030: "Report of Changes". Please check off the items below which are applicable to your registered unit.

☐ The x-ray referenced above has been disposed of by an authorized service provider. Attached is a copy of the receipt from the service provider that removed the unit.

☐ The x-ray unit was disposed of at the town's hazardous waste site with its power cord cut.
Specify town hazardous waste site: _____

☐ The x-ray unit was transferred to:
Name: _____
Address: _____
Telephone: _____

I, the X-ray Permit Holder, hereby certify that the x-ray unit is no longer in my possession and request that the above referenced registration be terminated.

Date: _____

Signature: _____

Title: _____

Appendix F – ALARA Plan

Radiation Safety Services
ALARA Plan

Harvard University follows the policy of minimizing radiation exposures to individuals or releases of radioactivity to the environment resulting from work with radioactive materials. This policy is known as ALARA, an acronym for As Low As Reasonably Achievable. This document sets forth the University's operational plan for implementing ALARA. The plan is based on the Nuclear Regulatory Commission's definition of ALARA, which is maintaining exposures as far below the regulatory limits as practical with consideration of economics, state of technology, and other societal and socioeconomic considerations. To be effective, the plan seeks to establish goals which are accepted by all levels of management and those involved in the use of radioactive material.

Responsibilities

The Radiation Safety Committee (RSC) is responsible for maintaining oversight of activities under the plan. It reviews measures to achieve ALARA. It examines individual and collective doses and releases to the environment for conformance with ALARA. It conducts a comprehensive annual audit of the radiation safety Radiation Safety Program including the effectiveness of adherence to ALARA concepts. This audit includes review of operational procedures, authorization approvals, radiation incidents, radiation dose records and environmental release data. Table 1 sets the ALARA goals and the standards for achieving these goals.

The Radiation Safety Services (RSS) is responsible for executing the plan through the following measures:

(a) Follow ALARA guidelines in reviewing and approving proposed uses of radioactive materials and recommend modifications to experiments where indicated.

(b) Identify measures to achieve ALARA, such as use of protective devices, operational controls, and consideration of ALARA in designing experiments.

(c) Formulate written procedures where applicable in specific instances.

(d) Monitor and track all activities affecting potential exposures of workers and the public.

(e) Provide the training and guidance necessary to University management, the RSC, Authorized Users and University staff to meet the goals of the ALARA plan.

(f) Review records of radiation surveys, occupational exposures, and environmental releases at least quarterly to determine compliance with ALARA and good practice principles.

(g) On an annual basis, RSS will conduct a comprehensive review of the radiation safety Radiation Safety Program for adherence to ALARA concepts and for general program functionality.

Standards

Standards for achievement of ALARA goals are given in Table 1. The table gives measurement levels at which prescribed actions are to be taken by the Radiation Safety Services. If a measurement point is below Level I for a calendar quarter, no additional action will be required. Should the value be between Level I and Level II, RSS will review the circumstances and, at its discretion, take additional steps to investigate and/or take action to reduce the value. Any value which exceeds Investigation Level II requires investigation and efforts to reduce the exposure with consideration of total cost and scientific impact. Reports of all investigations shall be presented, along with an exposure/release history, to the RSC.

Table 1G ALARA Plan Goals and Investigation Levels				
	Regulatory Limit	Harvard Annual ALARA Limit	Investigation Level I (mrem per calendar quarter)	Investigation Level II (mrem per calendar quarter)
Whole Body Exposures	5,000 mrem/y	500 mrem/y	125	375
Lens of the Eye	15,000 mrem/y	1,500 mrem/y	375	1125
Skin and/or Extremity	50,000 mrem/y	5,000 mrem/y	1250	3750
Minors (whole body)	100 mrem/y	50 mrem/y	10	30
Embryo/Fetus	500 mrem in the 9 month gestation period	50 mrem in the 9 month gestation period	20	60
Member of Public on site (NRC)	100 mrem/y whole body exposure	20 mrem/year	5a	15[a]
Member of Public offsite (EPA)[b]	10 mrem/y with less than 3 mrem due to radioiodine from airborne releases	3 mrem/year	1[a]	3[a]
Environmental Releases[c]	10 CFR 20 Appendix B averaged over one year at the unrestricted area boundary.	10 % of 10 CFR 20 Appendix B averaged over one year at the boundary; or listed value at the stack.	10 % of 10 CFR 20 Appendix B averaged over the calendar quarter at the boundary; or listed value at the stack.	30 % of 10 CFR 20 Appendix B averaged over the calendar quarter at the boundary; or listed value at the stack.

a Mathematical models are used to calculate dose based on releases to the environment.

b EPA regulations apply to airborne exposure to a member of the public while NRC regulations apply to all sources of radiation from the institution to the highest exposed member of the public.

c Values based on a total effective dose equivalent of 50 mrem per year.

Appendix G – Analytical X-ray Checklist

Checklist can also be found on the EHS website at: http://ehs.harvard.edu/programs/x-rays

HARVARD
Campus Services
ENVIRONMENTAL HEALTH & SAFETY

X-Ray Diffraction / Fluorescence General Safety Checklist

Machine Identification:

Manufacturer:_____ Model:_____

Principal Investigator:_____ Telephone:_____

General Safety Regulations:

1. Diffraction/fluorescence units may only be operated by Radiation Protection Office (RPO) authorized personnel. All authorized personnel must receive instruction in and demonstrate an understanding of the operation of the machine before starting unsupervised work.
2. An operational fail-safe light is visible to the operator indicating when x-rays are being produced.
3. Use interlocks, barriers or administrative controls to ensure no one can gain access to the primary beam or high scatter radiation areas.
4. Use a calibrated thin-window GM survey meter to verify shielding effectiveness and monitor radiation levels.
5. If the machine is modified, obtain RPO authorization before using the equipment.
6. Whole body and finger ring dosimetry is required for all personnel working with diffraction/fluorescence units.
7. Do not use the safety interlock to turn the machine off; use the main switch.
8. Do not override the safety interlock unless there is a Radiation Protection Office approved written procedure.
9. Make sure the machine is OFF before changing samples or the primary tube safety shutter is closed and verify there is not active beam present; always check the current and voltage meters and/or use a survey meter to detect x-rays.
10. Do not operate with removed covers, shielding materials, or tube housings; or with modified shutters, collimators or beam-stops. Verify that the tube is off and remains off until the machine is completely reassembled and any modifications have been approved. Use the main switch to shut the machine off; do not rely on the safety interlock.
11. Check radiation scatter with a survey meter after each realignment. Notify the Radiation Protection Office immediately if there are unusually high readings.
12. Secure unused ports to prevent accidental exposures.
13. Secure diffraction/fluorescence against unauthorized use by using a unit key control or the room lock. Stop the primary beam by secured shielding that cannot be readily displaced.
14. Maintain an operating log that includes date, operator, beam voltage and current, and time on and off (or total exposure time) for each unit use.
15. Notify the RPO immediately if there is a real or perceived abnormal personnel radiation exposure.
16. Obtain approval for any location changes, purchase or removal of diffraction/fluorescence units from the RPO. Notify the RPO prior to the acquisition, disposal, or transfer of any diffraction/fluorescence unit.
17. Contact the RPO for information regarding radiation safety or radiation survey instrumentation. A copy of the Massachusetts Radiation Control Regulations is available at the RPO.

Appendix H – Cabinet X-ray Checklist

Checklist can also be found on the EHS website at: http://ehs.harvard.edu/programs/x-rays

HARVARD
Campus Services
ENVIRONMENTAL HEALTH & SAFETY

X-Ray Cabinet General Safety Checklist

Machine Identification:

Manufacturer:_____Model:_____

Principal
Investigator:_____Telephone:_____

General Safety Regulations:

1. Only individuals authorized on the permit may operate the machine. All authorized users must receive instruction in and demonstrate an understanding of the operation of the machine before starting unsupervised work.
2. An operational fail-safe light is visible to the operator indicating when x-rays are being produced.
3. Use interlocks, barriers or administrative controls to ensure no one can gain access to the primary beam or high scatter radiation areas.
4. Use a calibrated thin-window GM survey meter to verify shielding effectiveness and monitor radiation levels.
5. Whole body and finger ring dosimetry is required for all personnel working with cabinet units.
6. Do not use the safety interlock to turn the machine off; use the main switch.
7. Do not override the safety interlock unless there is a Radiation Protection Office (RPO) approved written procedure.
8. Make sure the machine is OFF before changing samples or the primary tube safety shutter is closed and verify there is not active beam present; always check the current and voltage meters and/or use a survey meter to detect x-rays.
9. Do not modify the built-in shielding. If modifications must be made, contact the RPO for approval to restart instrument.
10. Secure unused ports, if any, to prevent accidental exposures.
11. Secure cabinet units through a unit key control or room lock.
12. Maintain an operating log that includes date, operator, beam voltage and current, and time on and off (or total exposure time) for each unit use.
13. Notify the RPO immediately if there is a concern for or any abnormal personnel radiation exposure.
14. Obtain approval for any location changes, purchase or removal of diffraction/fluorescence units by the RPO. Notify the RPO prior to the acquisition, disposal, or transfer of any diffraction/fluorescence unit.
15. Contact the RPO for information regarding radiation safety or radiation survey instrumentation. A copy of the Massachusetts Radiation Control Regulations is available at the RPO.

Email **radiation_protection@harvard.edu** to send comments and suggestions to the Radiation Protection Office

Appendix I – Electron Microscope Checklist

Checklist can also be found on the EHS website at: http://ehs.harvard.edu/programs/x-rays

HARVARD
Campus Services
ENVIRONMENTAL HEALTH & SAFETY

Electron Microscope General Safety Checklist

Machine Identification:

Manufacturer:_____Model:_____

Principal
Investigator:_____Telephone:_____

General Safety Regulations:

1. Only personnel trained and approved by the responsible Principal Investigator may operate an electron microscope.
2. An operational fail-safe light is visible to the operator indicating when x-rays are being produced.
3. Use interlocks, barriers or administrative controls to ensure no one can gain access to the primary beam or high scatter radiation areas.
4. Use a calibrated thin-window GM survey meter to verify shielding effectiveness and monitor radiation levels.
5. Secure electron microscopes against unauthorized use by using a unit key control or the room lock. Stop the primary beam by secured shielding that cannot be readily displaced.
6. Secure unused ports to prevent accidental exposures.
7. Maintain an operating log that includes the date, operator, beam voltage, and current time on and off (or total exposure time).
8. Do not modify the built-in shielding and viewing ports. If modifications must be made, contact the Radiation Protection Office (RPO) for a safety survey of the unit.
9. Notify the RPO immediately in the event of any abnormal personnel radiation exposure.
10. Changes in the location or disposition of electron microscopes must have the approval of the RPO. Notify the RPO prior to the acquisition, disposal, or transfer of any electron microscope.
11. Contact the RPO for information regarding radiation safety or radiation survey instrumentation. A copy of the Massachusetts Radiation Control Regulations is available at the RPO.

Email **radiation_protection@harvard.edu** to send comments and suggestions to the Radiation Protection Office

Appendix J – Operating Log

HARVARD
Campus Services
ENVIRONMENTAL HEALTH & SAFETY

Checklist can also be found on the EHS website at: http://ehs.harvard.edu/programs/x-rays

Sample X-ray Machine Operating Log

Date	Operator	Beam Voltage	Current on-time/ off-time	Total beam on-time

Appendix K – Declared Pregnancy Policy

Harvard University

Radiation Safety

Committee

Radiation Work – Declared Pregnancy Policy

As part of a revision of regulations in January, 1994, the Nuclear Regulatory Commission (NRC) issued a rule limiting fetal radiation dose received as a result of a pregnant worker's occupational exposure to 500 mrem in the gestation period[1]. For this limit to apply, the regulation requires the woman to voluntarily declare pregnancy in writing and give the estimated date of conception. If a woman chooses not to declare her pregnancy, the normal occupational dose limit of 5,000 mrem per year would be in effect with the provision to maintain occupational radiation exposure "as low as reasonably achievable" (ALARA)[2].

A radiation worker who decides to declare a pregnancy would do so by informing the EH&S Radiation Safety Services and, at the woman's discretion, her supervisor. As required by law[3], the University maintains this declaration and any dose records to the embryo/fetus with those of the declared pregnant worker which are protected from public disclosure. This notification will initiate a process by which RSS will assess potential doses, evaluate potential exposures from ionizing radiation, and review the individual's radiation exposure history. If this process identifies exposure potential to the embryo/fetus that is not in concert with the ALARA, the individual will be contacted (even if the Declaration Form did not request consultation with a Health Physicist). Recommendations on minimizing radiation exposure may be made on an individual basis after this review.

It has always been Harvard University's Policy to keep radiation doses to potentially exposed individuals ALARA. While the radiation dose limit for occupationally exposed individuals is 5,000 mrem per year, greater than ninety percent of all users of all radioactive material at Harvard have had an annual dose less than 100 mrem.

Anyone with questions relating to radiation safety measures for the embryo/fetus, the Radiation Protection Program or procedures on the declaration of a pregnancy is encouraged to contact the Radiation Safety Services (495-2060) or the local safety office for information.

1 - The Code of Federal Regulations, Standard for Protection Against Radiation 10 CFR 20.1208

2 - ibid 10 CFR 20.1003

3 - ibid 10 CFR 20.2106

Email **radiation_protection@harvard.edu** to send comments and suggestions to the Radiation Safety Services.

Harvard University

Radiation Safety

Committee

Pregnancy Declaration Form

Date: _____

To: Corinne Mitchell, M.S., Radiation Safety Officer

From: _____

Signature: _____

University Telephone:_____

Harvard ID#:_____

Working Under Permit Holder: _____

University Address: _____

With this notice I inform you that I am pregnant or trying to become pregnant with an estimated conception date of_____ and an expected delivery date of_____ . I understand the radiation exposure limit set by the Nuclear Regulatory Commission for embryo/fetus of the declared pregnant worker* is 500 mrem for the entire gestation period. In line with Harvard's policy of minimizing radiation exposure, I will continue to minimize my exposure and participate in a monitoring program for pregnant workers.

Please check the following as appropriate:

☐ I have questions related to the radiation safety of the embryo/fetus and would like to have a health physicist from the Radiation Safety Services contact me at .

☐ I do not wish to inform the Principal Investigator at this time.

☐ I have informed or will inform the Principle Investigator.

☐ I have questions related to the radiation safety of the embryo/fetus and will contact the Radiation Safety Services at 496-3797.

☐ I do not have questions related to the radiation safety at this time. I understand that I may contact the Radiation Safety Services if I have any questions in the future concerning this pregnancy.

Appendix L – MA DPH Notice to Employees

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM

NOTICE TO EMPLOYEES
STANDARDS FOR PROTECTION AGAINST RADIATION;
NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

The Radiation Control Program (Agency) of Massachusetts Department of Public Health has adopted regulations in 105 CMR 120.200 which establish standards for your protection against radiation hazards. In 105 CMR 120.750, the Agency has also established certain provisions for the options of workers engaged in work under the Department license or registration.

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to—

1. Apply these regulations to work involving sources of radiation.
2. Post or otherwise make available to you a copy of the Massachusetts Department of Public Health regulations for control of radiation, and the operating procedures which apply to work you are engaged in, and explain their provisions to you.
3. Post Notice of Violation involving radiological working conditions, proposed imposition of civil penalties and orders.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the department regulations, and the operating procedures which apply to the work you are engaged in. You should observe their provisions for your own protection and protection of your co- workers.

WHAT IS COVERED BY THESE REGULATIONS

1. Limits on occupational exposure to radiation and radioactive material;
2. measures to be taken after accidental exposure;
3. personnel monitoring, surveys, and equipment;
4. caution signs, labels, and safety interlock equipment;
5. exposure records and reports;
6. options for workers regarding Agency inspections; and
7. related matters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The Department of Public Health regulations require that your employer give you a written report if you receive an exposure in excess of any applicable limit as set forth in the regulations or in the license. The basic limits for exposure to employees are set forth in 105 CMR 120.211 through 120.218 of the regulations. These sections specify limits on exposure to radiation and exposure to concentrations of radioactive material in air.
2. If you work where personnel monitoring is required:
   (a) your employer must advise you of your occupational radiation dose each year, and
   (b) upon termination of employment, your employer must give you a written report of your dose if you request it .

INSPECTIONS

All licensed or registered activities are subject to inspection by representatives of the Department of Public Health, Radiation Control Program. In addition, any worker or representative of workers who believes that there is a violation of the M.G.L.c.111, the regulations issued thereunder, or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Department of Public Health, Radiation Control Program. The request must set forth the specific grounds for the notice, and must be signed by the worker as the representative of the workers. During inspections, Department inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which he believes contributed to or caused any violation as described above

INQUIRIES

Direct all inquiries on the matters outlined herein to:

Massachusetts Department of Public Health
Radiation Control Program
Schrafft Center, Suite 1M2A
529 Main Street
Charlestown, MA 02129
Telephone: (617) 242-3035
Fax: (617) 242-3457
Emergency Phone: (617) 242-3453

POSTING REQUIREMENT

COPIES OF THIS NOTICE MUST BE POSTED IN A SUFFICIENT NUMBER OF PLACES IN EVERY ESTABLISHMENT WHERE EMPLOYEES ARE EMPLOYED IN ACTIVITIES LICENSED OR REGISTERED, PURSUANT TO 105 CMR 120.750, BY THE DEPARTMENT OF PUBLIC HEALTH, RADIATION CONTROL PROGRAM, TO PERMIT EMPLOYEES WORKING IN OR FREQUENTING ANY PORTION OF A RESTRICTED AREA TO OBSERVE A COPY ON THE WAY TO OR FROM THEIR PLACE OF EMPLOYMENT.

MRCP 120.750-1 June 2006

Appendix M – Harvard University Rules and Regulations for Radiation

Harvard University

Regulations Governing the Use of Sources of Ionizing Radiation

AUTHORIZATION

No one may use, bring into or remove from the University any radioactive material or radiation generating device without authorization from Environmental Health & Safety. Individuals working with radioisotopes or in radiation controlled areas must be registered with Environmental Health & Safety.

Training

No individual may work with radioactive material or radiation generating devices without training and indoctrination necessary to ensure safe working habits, to prevent the exposure of others, and to avoid contamination of the surroundings.

Responsibilities

Work with radioactive material or radiation generating devices must be done in accordance with Environmental Health & Safety Policies and MA Department of Public Health Radiation Control Regulations.

These requirements cover maximum exposure limits, area postings, monitoring procedures, procurement, delivery, storage, disposal, records, transportation, protective clothing, contamination, work habits and procedures, accidents, and termination of work.

Notification Requirements

Promptly notify Environmental Health & Safety of all accidents involving possible personnel or area contamination, overexposure to radiation, spread of contamination, difficulty in cleaning up a contaminated area, of any violations or unsafe practices or modifications to radiation generating devices.

Environmental Health & Safety must also be notified in the event of loss or misplacement of radioactive material or radiation generating devices.

In accordance with the provisions of the Code of Massachusetts Regulations, 105 CMR 120, employees are notified that copies of the By-product Materials License and amendments issued to Harvard University, the Commonwealth's regulations in 105 CMR 120 and the Harvard Radiation Safety Manual are available for examination at Environmental Health and Safety, 46 Blackstone Street Avenue Cambridge, MA.

Rules for Effective Radiation Protection

1. Avoid all unnecessary exposure to ionizing radiation.
2. Keep external radiation exposure to a minimum by planning your work habits with minimum exposure in mind. *Use remote handling tools and shielding for significant sources.*
3. Minimize the chances of ingestion or skin contamination and penetration by using appropriate protective clothing, including *gloves.*
4. Do *not pipette by* mouth.
5. *Do not store or eat food or smoke* in rooms where work with any radioactive materials is stored or used.
6. Wash hands when finished working with materials. Monitor face and hands, clothing, and work area. If you used a bottle containing 1 mCi or more record the results, even if they are negative. We recommend that you record all results even if you use less than 1 mCi.
7. Keep yourself informed of all safety measures pertaining to your work, including the appropriate corrective action in the event of an accident.
8. In the event of a significant (more than 10 μCi) spill or accidental release:
    - Restrict access to contaminated area.
    - Prevent spread of contamination.
    - Notify Environmental Health & Safety at (617)-495-2060.
9. **Call Environmental Health and Safety with questions about a radiation hazard or about proper work practices for working with radioactive material orradiation producing machines.**

Environmental Health and Safety
46 Blackstone Street, Cambridge MA 02139
Telephone (24 hours): (617)-495-2060
http://www.uos.harvard.edu/ehs
email to: Radiation_Protection@Harvard.edu

Appendix N –Standard Operating Procedure Template

System Description & Special Safety Concerns	
Provide a brief summary of the purpose and application of the x-ray system.	
X-ray Permit Holder	**Date**
Department/Division	**Location (Building & Room)**

X-Ray Standard Operating Procedure

1. Safety Contacts

Principal Investigator or Lab Manager	
Name	
Phone #	
Safety Officer	
Name	
Phone #	
Emergency Response Phone Numbers	
Fire/Medical Emergency	**911**
Harvard University Police	**(617-49) 5-1212**
University Operations Center	**(617-49) 5-5560**
Environmental Health and Safety (EHS)	**(617-49) 5-2060**

2. Device Identification

Manufacturer	
Model No.	
Serial No.	
Open or Closed Beam?	
Fixed or Mobile?	
Max Operating Voltage (kVp)	
Max Operating Current (mA)	
Estimated Workload (hours per year)	

3. Authorized Personnel Requirements

1. Only individuals authorized on the permit may operate the machine. All authorized users must receive instruction in and demonstrate an understanding of the operation of the machine before starting unsupervised work.
2. To be an authorized user, one must:
    a. Complete the online X-ray Device Safety Training; refer to www.ehs.harvard.edu/training
    b. Complete Refresher X-ray Device Safety Training every year
    c. Complete device-specific training from the Permit Holder or designee on the proper and safety operation of the x-ray machine
    d. Read and fully understand this X-Ray Standard Operating Procedure, including signing the Authorized User Review page at the end of this document
3. Follow all written standard operating procedures and safe work practices.
4. Notify the Permit Holder and RSS (Radiation Safety Services) when anyone is accidentally exposed to x-ray radiation or non-beam hazards.
5. Inform visitors and untrained personnel of proper safety protocol for the lab and provide supervision by authorized personnel.

4. Dosimetry

The following dosimetry is required for users of this x-ray device (check all that apply):

- ☐ Chest Dosimeter
- ☐ Finger Dosimeter
- ☐ None (Area Dosimeter only)
- ☐ Other: _____

5. Personal Protective Equipment

Utilize appropriate personal protective equipment for any hazardous materials that are used in conjunction with x-rays. This includes a lab coat and nitrile gloves for general chemical or biological hazards. If additional shielding is required for the attenuation of x-rays, RSS will provide recommendations on the appropriate shielding material and thickness.

6. Normal Operating Procedures

This section shall include at minimum the following 5 parts:

1. *Initial preparation of laboratory environment for normal operation (key position, status indictor on, interlock activated, etc.)*
2. *Sample preparation*
3. *Special procedures (safety checks, maintenance tests, etc.)*
4. *Operation procedures (power settings, working mode, other parameters setup, etc.)*
5. *Shutdown procedures*

Example:

1. Obtain the interlock key
2. Inform all unauthorized users to leave the room
3. Note the date, operator, beam voltage and current in the Operating Log
4. 2. Power on the device and allow for warm-up time
5. Ensure that "X-ray On" light is illuminated and that the beam shutter is closed
6. Set up the test components as necessary for the experiment
7. Secure test chamber and all beam ports
8. Set the laser power control to the lowest power possible. Or if the laser has one power setting, attenuate the beam to achieve a low power output
9. Insert the interlock key into the interlock switch and unlock the x-ray
10. Turn the x-ray machine on (open beam shutter)
11. Adjust camera settings as necessary
12. Verify that the x-ray beam is off/beam shutter closed prior to changing samples
13. Turn off the laser
14. Complete total exposure time in the Operating Log
15. In case of emergency, shut off the x-ray and remove the interlock key (if possible)

7. Emergency Procedures

X-ray Accidents

1. Bring the x-ray to a safe shutdown condition (if possible) while minimizing any system or configuration changes.
2. Immediately call **911** for help. Do not drive yourself to the hospital.
3. If skin burns are present, cover with a clean, dry dressing to prevent infection.
4. Notify coworkers and ask for assistance.
5. Contact the Permit Holder and Radiation Safety Services to report the accident.

Authorized Personnel Review

I have read and understand this X-Ray Standard Operating Procedure (XSOP) and its contents, and agree to follow this XSOP each time I use the XGD system.

Name	Signature	Date	PI/PI Designee Initial