California Polytechnic State University
San Luis Obispo

X-Ray Safety Manual

Reviewed, revised April 2019
Original: April 2018

1. ADMINISTRATIVE PROCEDURES AND RESPONSIBILITIES

1.0 Introduction

The purpose of the Radiation Safety Program is to assure the safe use of ionizing radiation through training, consultation, and surveillance consistent with government regulations. The Radiation Safety Program will be reviewed for effectiveness on an annual basis. This Manual pertains to use of machines producing radiation by means of an x-ray tube.

Radiation producing machines have a potential to expose individuals to hazardous amounts of radiation if not operated properly with all required safety features in place. They shall be secured from unauthorized removal or use through the use of locked rooms, or passwords required for use.

The California Polytechnic State University, San Luis Obispo, (hereinafter referred to as "CPSU") X-Ray Safety Manual sets the standards of operations for the Radiation Producing Machine Program.

Requests for records should be directed to:
California Polytechnic State University
Office of Environmental Health & Safety
Building 80
San Luis Obispo, CA 93407

1.1 Radiation Safety Officer (RSO)

The Radiation Safety Officer (RSO) is responsible for the review of campus performance with respect to University and campus policies on radiation and radiation protection, and for informing management of program issues. The RSO is assigned the responsibility for surveillance of departmental activities and for providing services in radiation safety in conformity with policies and standards set forth in this manual. The RSO is part of the Department of Environmental Health and Safety.

The RSO is responsible for all aspects of radiation control on the campus. Each use of radiation is reviewed and approved by the RSO.

1.2 Authorized User

The Authorized user is responsible for safe use of radiation producing machines under their purview. They must ensure that such use complies with all applicable State of California and University regulations. This shall include:

A. Instructing all personnel using the machines, in good radiation safety practices as

follows:

i. Operating and emergency procedures specific to their tasks.
ii. Proper maintenance of records
iii. ALARA considerations and goals.

B. Ensuring that operations involving radiation-producing machines are performed by properly trained and authorized personnel.

C. Ensuring that machines under their purview have all the required safety features and are properly shielded to prevent excessive radiation leakage.

D. Posting warning labels, guidelines, and other appropriate postings as requested by the Environmental Health and Safety Office.

E. Notifying the Environmental Health and Safety Office of all new radiation producing machines when they are acquired, including the location.

F. Notifying the Environmental Health and Safety Office immediately in the case of an accident involving radiation or potential excessive exposure.

G. Ensuring the use of personnel dosimetry and survey instruments as applicable.

1.3 Audits

An audit of the program must be performed annually.

1.4 Records

The records maintained by the Environmental Health and Safety Office are classified as First Class Records and are considered vital as stated in the CPSU Vital Records Protection Plan.

1.5 Procurement Policy

All purchases of radiation producing machines shall be accomplished through established campus purchasing channels and with the approval of the Environmental Health and Safety Office.

2. EXPOSURE STANDARDS AND DOSIMETRY

21 Radiation Exposure Goals

The California Polytechnic State University goal is to maintain human radiation exposure levels to as low as reasonably achievable (ALARA). The annual exposure limits for personnel over the age of 18 years are shown in table 5.1.

Table 5.1 - Annual Limits

Total Effective Dose Equivalent (TEDE)	5 rem (0.05 Sv)
Lens of the Eye (LDE)	15 rem (0.15 Sv)
Skin (Shallow Dose, H_s)	50 rem (0.5 Sv)
Extremities	50 rem (0.5 Sv)

The administrative goals for annual exposure are shown in table 5.2.

Table 5.2 - Administrative ALARA Goals for Annual Exposure

Total Effective Dose Equivalent (TEDE)	2 rem (0.03 Sv)
Lens of the Eye (LDE)	5 rem (0.05 Sv)
Skin (Shallow Dose, H_s)	10 rem (0.1 Sv)
Extremities	10 rem (0.1 Sv)

The annual exposure limits and administrative goals for a person under the age of 18 years (a minor) are shown in table 5.3.

Table 5.3 - Annual Exposure Limits and Administrative Goals for Minors

	Limit	**Goal**
Total Effective Dose Equivalent (TEDE)	0.5 rem	0.4 rem
Lens of the Eye (LDE)	1.5 rem	1 rem
Skin (Shallow Dose, H_s)	5 rem	4 rem
Extremities	5 rem	4 rem

Special Requirements for Pregnant Women

The exposure limit for an embryo / fetus, due to tasks or activities performed by a declared pregnant woman shall not exceed 0.5 rem (500 milli-rem) during the entire pregnancy.
The Radiation Safety Officer or Authorized User shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman to satisfy the limit of 500 milli-rem. If the dose to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with paragraph (a) of this section if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy. *The declaration of pregnancy by a female employee to the radiation safety officer is an individual choice of the employee.* For more information, see NRC guidance in Appendix A: Instruction Concerning Prenatal Radiation Exposure.

2.2 Compliance with Exposure Limits and Goals

Each adult receiving occupational exposure shall be provided with an individual monitoring device, and shall be required to use that device, if it is likely that the individual will exceed 10% of the applicable annual exposure limit listed in Table 5.1. Individual monitoring devices include film badges, TLDs, electronic or other self-reading dosimeters, air samplers and similar devices.

The exposure determined from the processing of film badges or TLDs, or recorded by electronic or other self-reading dosimetry will be considered as deep and / or shallow dose. Deep and shallow dose components of exposure will be specified on dosimetry processor documentation as applicable or as requested.

2.3 Dosimetry

The Environmental Health and Safety Office will distribute dosimetry in the form of film badges, TLDs, and self-reading Dosimeters to personnel to aid in the assessment of radiation exposure. Dosimetry shall be issued only when careful evaluation establishes a need for the use of this monitoring technique.

These devices provide legal records of radiation exposure; therefore, it is imperative that they only be used as prescribed. When prescribed, they must be worn at all times while working with radionuclide or radiation producing machines. They must be stored away from radiation sources and protected against heat, moisture, or contamination.

Film badges and TLDs are returned to Environmental Health and Safety and are processed at predetermined intervals. The California Code of Regulations requires that personnel be supplied with and use film badges or other approved personnel monitoring devices, if they enter a radiation controlled area under such circumstances that they are likely to receive more than 10 percent of the appropriate annual exposure limit as specified previously. For persons 18 years of age or older, 10 percent of the external, deep dose limit for the whole body is 500 milli-rem per year, and for persons under 18, 50 milli-rem per year.

Film badge dosimeters, issued when monitoring is required, should normally be changed at quarterly intervals in cases where radiation exposure is likely to be nominal.

2.4 Personnel Exposure Records

Personnel exposure data shall be part of the permanent records of Environmental Health and Safety Office. Upon written request, by any employee or student, Environmental Health and Safety will provide a copy of the individual's exposure history. In addition, in any case where exposures of an individual to radiation must be reported to the NRC and/or the State Department of Health Services pursuant to regulations, such individuals will be notified in writing of the nature and extent of their exposure. The form or record must show each period in which the

individual received occupational exposure to radiation and must be signed by the individual who received the exposure.

3. SPECIFIC REQUIREMENTS FOR RADIATION PRODUCING MACHINES

3.1 Proposal for Use

Departments desiring to purchase or acquire radiation-producing machines shall submit the following information to EH&S:

A. Name of the Authorized User and extent of experience with the particular radiation-producing machine requested.

B. Names of personnel who will use the machine.

C. Description of the machine and its proposed use.

D. Safety provisions that will be provided, such as shielding, equipment safety devices, and monitoring.

E. A use authorization specifically (RUA) designed for the particular radiation-producing machine shall be on file with the Environmental Health and Safety Office. Each individual assigned responsibility for operating the machine shall be thoroughly familiar with the safety protocol prior to assuming his/her duties as an operator.

F. The RUA will be valid for a period of 5 years as long as the operator or the instrument parameters do not change.

3.2 Purchases

All purchases of radiation producing machines shall be made through the normal procedures of the Purchasing Department upon appropriate approval by the RSO.

3.3 Survey of Installation

Prior to use, installations of radiation producing machines, whether newly acquired, relocated, modified or repaired, shall be surveyed by Environmental Health & Safety in order to determine effectiveness of radiation hazard controls.

3.4 Warning Signs and Labels

All devices and equipment capable of producing radiation when operated shall be appropriately labeled so as to caution individuals that use such devices or equipment. "Caution, produces radiation when energized" shall be posted on the machine. The entry to the use area must be posted "Caution X-Ray"

3.5 Changes in Location and Disposition

Changes in the location or disposition of radiation producing machines must have prior approval of the RSO. Environmental Health & Safety shall be given notice of intent to dispose or transfer a radiation-producing machine.

3.6 State Department of Public Health Registration

The RSO is responsible for notifying the State Department of Public Health (CDPH) of the total number of machines including their type and location. All radiation producing machines shall be registered with CDPH. Departments must notify the RSO as newly acquired radiation producing machines arrive on campus. The RSO will register the machine on the license.

3.7 Training

A. All persons authorized to use a radiation-producing machine shall be trained in the safe use of x-ray machines. Exceptions to this training requirement shall be given to certified x-ray technologists, and those who operate incidental sources of x-rays (Section 3.8) if it is demonstrated that there is no x-ray hazard.

B. Persons operating x-ray machines for the purpose of examination of human beings must be certified by the State of California in Diagnostic Radiologic Technology or equivalent to operate the diagnostic machine they will be using, such as x-ray bone densitometry.

Exemptions: A physician shall not be required to obtain a certificate from the State if that physician meets certain criteria.

Training is on-line or in-person by EH&S, followed up by practical training by the Authorized User. Training will consist of instruction in general radiation concepts, x-ray machine safety requirements, methods of minimizing radiation exposure, health effects of radiation, and operational procedures.

3.8 Sources of Incidental X-Rays

Some electrical equipment operating at potentials of 20 kV and above are capable of producing x-rays. Anyone acquiring or constructing equipment operating at 30kV and higher and employing cathode-ray tubes, rectifier tubes, klystrons, or magnetrons should contact the RSO so that the machine may be checked under operating conditions to insure that no significant exposures may occur to operating personnel. A common example is electron microscopes. Registration is generally required and annual testing for radiation leakage should be performed.

3.9 Analytical X-Ray Equipment

This includes any x-ray equipment where the x-ray beam is used for a specific purpose, except medical or veterinary units. Contact the RSO if there is a question about applicability.

A. Equipment Requirements:

1. 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 shall be provided. Preferable configuration is that the x-ray beam is enclosed in an interlocked cabinet.

2. Warning Devices**.**
   a. X-ray tube status indicator located near the radiation source housing, if the primary beam is controlled in this manner; and/or
   b. Shutter status indicator located near each port on the radiation source housing, if the primary beam is controlled in this manner.
   c. Warning devices shall be labeled so that their purpose is easily identified.

3. Ports**.** Unused ports on radiation source housings shall be secured in the closed position in a manner that will prevent casual opening.

4. Radiation shielding requirements: The external radiation emission shall not exceed 0.5 mR in 1 hour at 5 centimeters from the beam containment at maximum power.

B. Operating Requirements

1. Procedures: Operating procedures shall be written and available to all analytical x-ray equipment workers. They should be posted by the machine. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures.

2. Bypassing: No person shall bypass a safety device unless such person has obtained the written approval of the RSO.

3. Use Log: Each user shall maintain current utilization logs which shall be kept available for inspection, containing the following information for each radiation machine:
   a. The identity of the machine.
   b. The location, date, and the identity of the individual operator for each use.
   c. The voltages current, and exposure time for each use

C. Annual Inspection

Annually EH&S or a qualified expert must evaluate each machine for radiation leakage and interlock function.

3.10 Radiation Safety Requirements for Medical, Dental, and Veterinary X-Ray Equipment

This equipment must be designed, used, and maintained according to California State Regulations. New installations and modifications must be approved by EH&S. California Code of Regulations Title 17 Sections 30305 through 30314 will apply. X-ray protection shielding for patients, operators, and the public must be designed according to standards. Medical equipment should be evaluated by the manufacturer or other qualified individual annually. Dosimetry will be assigned to operators.

3.11 Radiation Safety Requirements for Industrial Radiography

Industrial radiography means the examination of the physical structure, but not the microscopic structure, or elemental or chemical composition, of materials, other than human beings or animals, by nondestructive testing, utilizing radiation. At CPSU any industrial radiography must be done in an interlocked cabinet, unless specific permission is given by the RSO. Cabinet radiography operators are required to have additional written and practical training. An example of cabinet radiography is a pass-through package inspection system. Requirements for analytic x-ray equipment apply (see section 3.9).

4. EMERGENCIES

In the event of an overexposure or excessive levels of radiation delivered to the whole body, skin or extremities:

A. Notify the RSO weekdays, 0800-1700, extension 66628; other times call the University Police, extension 62281, who will contact the RSO.

B. If necessary, in accordance with CCR Title 17, 30295 and 30297, notification and reporting to the State Department Health Services, Radiological Health Branch, will be carried out by the RSO.

C. Do not delay in arranging prompt medical attention should an exposure in excess of the limits in table 5.1 be suspected or if skin erythema or any other non- stochastic injury should appear.

An Incident Report must be filled out and submitted to the RSO within 24 hours.

APPENDIX A: INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

Adapted from: U.S. NUCLEAR REGULATORY COMMISSION REGULATORY GUIDE 8.13 (Draft was issued as DG-8014)

A. INTRODUCTION

The Code of Federal Regulations in 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," in Section 19.12, "Instructions to Workers," requires instruction in "the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed." The instructions must be "commensurate with potential radiological health protection problems present in the work place."

The Nuclear Regulatory Commission's (NRC's) regulations on radiation protection are specified in 10 CFR Part 20, "Standards for Protection Against Radiation"; and 10 CFR 20.1208, "Dose to an Embryo/ Fetus," requires licensees to "ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv)." Section 20.1208 also requires licensees to "make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman." A declared pregnant woman is defined in 10 CFR 20.1003 as a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

This regulatory guide is intended to provide information to pregnant women, and other personnel, to help them make decisions regarding radiation exposure during pregnancy. This Regulatory Guide 8.13 supplements Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure" (Ref. 1), which contains a broad discussion of the risks from exposure to ionizing radiation.

Other sections of the NRC's regulations also specify requirements for monitoring external and internal occupational dose to a declared pregnant woman. In 10 CFR 20.1502, "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," licensees are required to monitor the occupational dose to a declared pregnant woman, using an individual monitoring device, if it is likely that the declared pregnant woman will receive, from external sources, a deep dose equivalent in excess of 0.1 rem (1 mSv). According to Paragraph (e) of 10 CFR 20.2106, "Records of Individual Monitoring Results," the licensee must maintain records of dose to an embryo/fetus if monitoring was required, and the records of dose to the embryo/ fetus must be kept with the records of dose to the declared pregnant woman. The declaration of pregnancy must be kept on file, but may be maintained separately from the dose records. The licensee must retain the required form or record until the Commission terminates each pertinent license requiring the record.

The information collections in this regulatory guide are covered by the requirements of 10 CFR Parts 19 or 20, which were approved by the Office of Management and Budget, approval numbers 3150-0044 and 3150-0014, respectively

B. DISCUSSION

As discussed in Regulatory Guide 8.29 (Ref. 1), exposure to any level of radiation is assumed to carry with it a certain amount of risk. In the absence of scientific certainty regarding the

relationship between low dose exposure and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any expo- sure to ionizing radiation may cause undesirable bio- logical effects and that the likelihood of these effects in- creases as the dose increases. At the occupational dose limit for the whole body of 5 rem (50 mSv) per year, the risk is believed to be very low.

The magnitude of risk of childhood cancer following in utero exposure is uncertain in that both negative and positive studies have been reported. The data from these studies "are consistent with a lifetime cancer risk resulting from exposure during gestation which is two to three times that for the adult" (NCRP Report No. 116, Ref. 2). The NRC has reviewed the available scientific literature and has concluded that the 0.5 rem (5 mSv) limit specified in 10 CFR 20.1208 provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total life- time risk of leukemia and other cancers associated with radiation exposure during pregnancy.

In order for a pregnant worker to take advantage of the lower exposure limit and dose monitoring provisions specified in 10 CFR Part 20, the woman must declare her pregnancy in writing to the licensee. A form letter for declaring pregnancy is provided in this appendix or the licensee may use its own form letter for declaring pregnancy. A separate written declaration should be submitted for each pregnancy. The declination of pregnancy must be sent to the department chair/head with the radiation safety officer copied.

C. REGULATORY POSITION

1. Who Should Receive Instruction

Female workers who require training under 10 CFR 19.12 will be provided with the information contained in this guide. In addition to the information contained in Regulatory Guide 8.29 (Ref. 1), this information may be included, as part of the training required under 10 CFR 19.12.

2. Providing Instruction

The occupational worker will be given a copy of this guide with Appendix C: Question and Answers Concerning Prenatal Radiation Exposure, an explanation of the contents of the guide, and an opportunity to ask questions and request additional information. The information in this guide and Appendix C will also be provided to any worker or supervisor who may be affected by a declaration of pregnancy or who may have to take some action in response to such a declaration. Any questions regarding this material or concerns regarding prenatal radiation exposure can be submitted to the Radiation Safety Officer or they may call the EH&S office at 805-756-6628.

3. Licensee's Policy on Declared Pregnant Women

The instruction provided should describe the licensee's specific policy on declared pregnant women, including how those policies may affect a woman's work situation. In particular, the instruction should include a description of the licensee's policies, if any, that may affect the declared pregnant woman's work situation after she has filed a written declaration of pregnancy consistent with 10 CFR 20.1208.

4. Duration of Lower Dose Limits for the Embryo/ Fetus

The lower dose limit for the embryo/fetus will remain in effect until the woman withdraws the declaration in writing or the woman is no longer pregnant. If a declaration of pregnancy is

withdrawn, the dose limit for the embryo/fetus would apply only to the time from the estimated date of conception until the time the declaration is withdrawn. If the declaration is not withdrawn, the written declaration may be considered expired one year after submission.

5. Substantial Variations Above a Uniform Monthly Dose Rate

According to 10 CFR 20.1208(b), "Cal Poly shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this section," that is, 0.5 rem (5 mSv) to the embryo/fetus. The National Council on Radiation Protection and Measurements (NCRP) recommends a monthly equivalent dose limit of 0.05 rem (0.5 mSv) to the embryo/ fetus once the pregnancy is known (Ref.2). In view of the NCRP recommendation, any monthly dose of less than 0.1 rem (1 mSv) may be considered as not a substantial variation above a uniform monthly dose rate and as such will not require licensee justification. However, a monthly dose greater than 0.1 rem (1 mSv) should be justified by the licensee.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees and applicants regarding the NRC staff's plans for using this regulatory guide.

Unless a licensee or an applicant proposes an acceptable alternative method for complying with the specified portions of the **NRC's** regulations, the methods described in this guide will be used by the **NRC** staff in the evaluation of instructions to workers on the radiation exposure of pregnant women.