

Limited Scope X-Ray Technician Course

Module 6: Rules & Regulations

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Outline

- Overview of Federal and State Regulations
- X-Ray Licensing and Registration
- Radiation Dose Limits
 - ALARA (As Low As Reasonably Achievable)
 - Radiation Dosimetry
- Regulatory Requirements
- Radiation Safety Review



Standard & Regulatory Agencies



International Standards Committees



National Standards Committees



Standards Committee

- Publishes consensus documents regarding the health effects of radiation exposure.
- Provides recommendations to limit the public health impact from exposure to radiation.
- Provides guidance with regards to best practices.
- Are not regulations. Do not have the enforcement of law.



Regulatory Agencies



Regulatory Agencies

- Publishes regulations governing the use of ionizing radiation.
- Establishes limits for radiation exposure.
- Establishes minimum professional requirements (licensure).
- Establishes minimum facility requirements (workplace safety).
- Are the rule of law.
- Criminal and civil penalties for non-compliance.
- Fines for non-compliance.



US Nuclear Regulatory Commission (1971)

- Successor to the AEC (Atomic Energy Commission, 1954) which was principally responsible for regulating the civilian nuclear power industry.
- When reorganized as the NRC, was granted authority to regulate by-product radioactive materials (i.e. stuff from nuclear reactors).
- Does not regulate X-Ray machines or devices that generate non-ionizing radiation



Environmental Protection Agency (1970)

- Tasked with the development of various radiation protection guidelines (i.e. recommended standards). These guidelines are not regulatory but simply represent recommended practices.
- Develop environmental regulatory standards for radiation exposure of the public.
- Maintain surveillance of air, food and water (with respect to environmental radiation releases). This would mostly focus on radioactivity.
- NRC must meet EPA requirements in their regulations.



Occupational Safety and Health Administration (1971)

- Regulate and establish standards for all non-mining sources of occupational radiation that is not regulated by the NRC.
- Establish occupation exposure limits to radiofrequency radiation from 10Mhz to 100 Ghz and laser radiation.
- Does have regulatory standards for occupational exposure to ionizing radiation (dose limits) but those are out of date.
- Can become involved when there is a workplace injury.



Food and Drug Administration (1906)

- Responsible for established radiation standards for source of radiation not already regulated by the NRC.
- X-Ray machines fall under this category.
- FDA does not regulate the use of X-Ray machines but instead regulates the manufacturing of X-Ray system through regulatory performance standards.
- X-Ray use is the responsibility of state agencies.



X-Ray Regulatory History



Radiation Control for Health and Safety Act -1968



- Established the Bureau of Radiological Health within the FDA, later combined with the Bureau of Medical Devices renamed the Center Devices and Radiological Health (CDRH).
- Established to protect the public from the hazards of unnecessary radiation exposure (both ionizing and non-ionizing) resulting from electronic products (such as TVs), but X-Ray equipment was also included.
- First attempt in the US to limit public as opposed to personnel exposure to radiation.

FDA X-Ray Standards - 1974

- Established basic operational standards for x-rays machines.
- This was the first attempt in the US to essentially limit the radiation dose to patients from x-ray machines.
- The standard established system performance requirements for manufacturers of x-ray systems.
- Note that this is approximately 80 years after the discovery of x-rays.

Medical Devices Act - 1976

- Permitted the FDA to regulate the manufacturing and performance requirements for medical devices.
- Further expanded the FDA's authority to govern the performance requirements for X-Ray producing devices.
- This was followed up with the Safe Medical Devices Act - 1990 that granted additional authority for premarket approval of devices.



Consumer-Patient Radiation Health and Safety Act - 1981

- Established minimal standards for accreditation of educational programs for persons who administer radiation and the certification of such persons.
- This is essentially to insure that persons administering radiation are trained properly (again to limit radiation doses and effects).
- Directed states to develop rules and regulations for the licensing of individuals performing X-Ray imaging.



States Licensing Rules

- 43 states have rules that requires individuals performing X-Rays to be licensed.
- 7 states (Alabama, Georgia, Idaho, Missouri, Nevada, North Carolina, and South Dakota) and the District of Columbia do not require licensure for personnel performing X-Rays.
- 28 states have some sort of limited scope licensing for X-Ray imaging.



Idaho Department of Health and Welfare

- Idaho Statutes designate the Department of Health and Welfare as the state agency responsible for the administration of the regulatory, licensing, and radiation control provisions associated with X-ray producing machines.
- The Idaho Radiation Control Rules are the specific ways in which IBL will ensure the licensing and safe use of X-ray producing machines in the State of Idaho. These rules apply to all persons who possess, use, transfer, own, or acquire any X-ray producing machine.
- The Idaho Radiation Control Program is under the Division of Public Health and operated out of the Idaho Bureau of Laboratories (IBL).
- Over 1,400 facilities using X-ray producing machines in Idaho are regulated by IBL under the Idaho Radiation Control Program.
- The Occupational Safety and Health Administration (OSHA) is a regulatory agency of the United States Department of Labor that ensures safe and healthful working conditions by setting and enforcing standards. OSHA standards regarding ionizing radiation are found in 29 CFR 1910.



X-Ray Usage

Idaho Regulations



X-Ray Licensure (Registration)

- All facilities in Idaho utilizing X-Ray radiation (medical, industrial, research, etc.) must be licensed with ID DHW (Department of Health and Welfare).
- Licensure / Registration is site/address specific.
 - Each facility with imaging has its own x-ray registration.



Inspections

- All registered sites are inspected periodically
 - For hospital X-Ray locations – Annually
 - For other Medical – Every 2 Years
 - Chiropractic, Podiatric, Dental, and Veterinary – Every 4 Years
- Inspections are focused on X-Ray machine performance and staff (radiation) safety.
 - Personnel Training Documentation
 - Personnel Credentials
 - Reports from Personnel Monitoring Devices
 - Proper Signage, including display of X-Ray License and Technique Charts
 - Patient and Employee Shielding
 - Instrumentation Inspection
 - Beam Collimator
 - Beam Stop Accuracy
 - Beam Quality
 - Half Value Layer Measurements
 - Linearity
 - Reproducibility
 - Scatter Radiation Surveys
 - Shielding Evaluations



IDAPA 16 – 16.02.27 Radiation Control Rules

- IDAPA regulations provides the rules governing the use of X-Ray machines.
- Administrative and Construction requirements (what you can't do with x-ray machines and radiation shielding requirements).
- Functional performance requirements (for the x-ray machine similar to FDA rules).
- The chapter also includes a section regarding the competency of individuals operating x-ray machines.
 - Section 053
 - 04 "Operator Qualification"
 - 05 "Minimum Safety Requirements"
 - 06 "Subjects to be Covered During the Instruction to Radiographer"



Who Can Take Medical X-Rays

- A Health Care Practitioner
 - Physician
 - Chiropractor
 - Under the direction of a physician (Nurse, PA, optometrist, naturopath)
- X-Ray Technologists
- X-Ray Technicians
 - Anyone who has completed the requisite training modules
 - Records of training and written tests must be retained during the course of employment and 3 years after



X-Ray Technician Limitations

- Take only X-Rays of anatomy you have been trained for



Pregnancy and Radiation

- Radiation Induced Malformations
 - Threshold of 100 - 200 mGy
 - Fetal doses of 100 mGy are not reached even with 20 diagnostic X-Rays
- Pre-conception radiation has never been shown to increase risk of cancer or malformations in children
- Prenatal doses from most properly performed diagnostic procedures present no measurably increased risk of prenatal death or malformation.



Dose Limits & Dosimetry

Annual Limit		
Whole Body (TEDE)	5,000 mrem	50 mSv
Extremities & Skin (SDE)	50,000 mrem	500 mSv
Lens of Eye	15,000 mrem	150 mSv
Gestational Limit		
Declared Pregnant Workers	500 mrem	5 mSv
Limits		
Members of the Public	100 mrem	2 mrem in any 1 hour

This is for occupationally exposed staff only. This does not apply to patients!!



Dosimeters



- May be issued monthly or quarterly
- Dosimetry should be worn at the torso (when no radiation shielding, lead aprons, are utilized)
- If lead aprons are used (i.e. when holding a patient) the dosimeter should be positioned on the torso (or collar) on the outside of the lead (do not place under the lead apron).
- If assigned a fetal badge, that dosimeter should be positioned at the waist and under lead aprons, when worn.
- Practical Tips
 - Store in a low background area
 - Wear outside of your lead, if applicable
 - Only wear your badge!



Dates of the Radiation Exposure

REPORTING PERIOD:	01/01/2018 - 03/31/2018
PAGE:	1 OF 1
LICENSE NO.	

DOSIMETER & EXPOSURE HISTORY											
DOSE EQUIVALENT IN REM (FOR RADIATION INDICATED BELOW)											
QUARTER TO DATE			MAY 1 TO DATE			JUN 1 TO DATE			JULY 1 TO DATE		
HEAD	NECK	THORAX	HEAD	NECK	THORAX	HEAD	NECK	THORAX	HEAD	NECK	THORAX
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0
0	0	0	0	0	0	0	0	0	0	0	0

Dose in mrem



Standards of Practice

Reminders



Stay Behind Control Wall



Protected by 2# Lead Shielding



No radiation protection



X-Ray Signage

- X-Ray rooms typically have an "X-Ray in use" or "X-Ray on" sign.
- Sign should be lit when X-Ray are activated.
- Do not enter the X-Ray procedure room when X-Ray in use light is on.



X-Ray Room Door



X-Ray examinations should not be performed with the door open. The door is part of the radiation shielding for an X-Ray room.



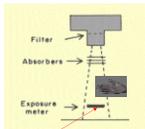
Patient Notifications

**IF YOU ARE PREGNANT
OR THINK YOU ARE PREGNANT
NOTIFY THE TECHNOLOGIST
BEFORE THE EXAM**



Patient Holding During X-Rays

- Patient holding is allowed for situation where patients are having difficulty with self-positioning.
- Holding is allowed when assistive devices cannot be used or will interfere with imaging.
- No staff can be assigned the duty of "holding" patient.
- If holding be aware of the X-Ray field.



X-ray beam 1000x more intense than scatter radiation





Holder's hand in X-Ray field



Staff hand in X-Ray field



Lead Aprons

- No one should be in the X-Ray room other than patient and individuals required to help complete the examination.
- All individuals in the X-Ray room during a procedure must be protected by radiation shielding.



Patient Considerations

- Collimate the useful radiation beam to the anatomy.
- Radiation Dose to the patient is proportional to the area of exposure (double the area double the dose).
- Imaging outside the relevant anatomy does not gain useful diagnostic information and simply results in more dose to the patient.
- Scatter radiation is also proportional to the imaging area



Improper Patient Safety



7 mR entrance exposure to patient's leg

1/4 mR entrance exposure



Proper Patient Safety



Minimize Retakes

- Retaking X-Ray images doubles the radiation exposure to the patient with no additional benefit.
- Before imaging:
 - Insure proper positioning
 - Insure proper collimation
 - Insure patient compliance
 - Double check radiographic technique



Summary

- Idaho Radiation Control Program regulates the use of medical X-Rays
- Individuals performing X-Ray examinations are required to have sufficient training to operate radiographic devices
- Be aware of and insure the implementation of radiation safety requirements for staff, patients and ancillary personnel.