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| Rad | iation Safety Training Handout for |
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| Cabinet X-R | ay Machine Operations in the United States |

COURSE OBJECTIVES

Lesson 1 – History of X-Rays

- \circ \quad Describe who, when, where and how X-Rays were discovered.
- Describe the characteristics of x-rays.
- What are the three (3) ways x-rays will interact with the material being scanned.
- Discuss how material density and greyscale are used to evaluate an x-ray image.
- What the limitations are of contaminate detection using x-rays?
- What is an atomic Z number?
- List at least 3 uses of X-ay technology today.
 Lesson 2 US FDA and State Radiation Agencies
- State which Federal agency regulates the "manufacturer" of Cabinet x-ray equipment.
- Which federal regulation contains the Performance Standard for Cabinet x-ray equipment?
- Discuss the State radiation machine registration requirements.
- Describe the purpose of the Notice to Employees document
- List several responsibilities of the facility Radiation Safety Officer.
- What plan is required to be implemented at every facility where any source of radiation is located? Lesson 3 – Radiation Fundamentals
- You should be able to list the 3 subatomic particles that make up matter, state their charges and location in the atom.
- Define the Strong Force and discuss what it does.
- Define Binding Energy and what its purpose is.
- Know the difference between stable and unstable atoms.
- Who discovered the energy released from unstable atoms and named it Radiation?
- What is ionization and why is it important?
- State what two factors determine the energy of radiation.
- Describe the difference between Non-Ionizing & Ionizing Radiations.
- Lesson 4 Units of Measure
- Describe the difference between exposure and exposure rate.
- o Determine total exposure by calculating exposure rate x time when given an example.
- $\circ \quad \ \ {\rm Discuss\ how\ ionizing\ radiation\ is\ actually\ measured.}$
- State the three Conventional units of radiation measure.
- State the two Standard International (SI) units of radiation measure.
- Describe the relationship between the conventional units and the SI units of radiation measure.

Lesson 5 – Sources of Radiation

- o Name the two categories of background radiation and the percentage of dose we receive from each category.
- o Be able to list the 4 sources of natural background and 4 sources of man-made background dose.
- Describe the source of background which provides us with the highest annual dose and approximately how much.
- Describe the source of background radiation which is the second most frequent cause of lung cancer after smoking.
- State the total annual dose from the combined sources of both natural and made sources.

Lesson 6 – Biological Effects of Radiation

- \circ \quad Describe the process that can damage the cells of our bodies.
- \circ \quad Name the 2 potential effects of radiation on our cells.
- \circ \quad Define the difference between direct and indirect cell damage.
- \circ \quad List the 4 common effects of radiation on our cells.
- o Define the term Deterministic Effect and state what level of ionizing radiation is necessary to observe this effect.
- Discuss the difference between Acute and Chronic Dose.
- \circ \quad Discuss the difference between Somatic and Genetic Effects.
- Understand the risk associated with exposure to low level dose to ionizing radiation.

Lesson 7 – ALARA Program

- Define the meaning of ALARA and its concept.
- $\circ~$ State the 3 ICRP principles of radiological protection.
- \circ \quad Discuss the key ALARA elements that make up an effective ALARA Program.
- What are the 3 methods of dose reduction an individual can practice to maintain dose ALARA.
- Discuss the bad practices working with Cabinet x-ray machines that should not be allowed.

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Lesson 8 – Regulatory Dose Limits

- o State the federal whole-body dose limits for an occupational worker and for members of the general public.
- Describe when dosimetry monitoring of radiation dose is required.
- o Discuss the strict requirements for the wear and care of a dosimetry device if required to wear.
- o Describe the Declared Pregnant Woman (DPW) requirements and the dose limit to the embryo/fetus during the entire gestation period.

Lesson 9 – Surveys & Monitoring

List the two most common types of radiation detection instruments used to measure the radiation levels on the external surface of a Cabinet xray machine.

- Describe the 4 instrument checks to be performed prior to use.
- State the minimum radiation survey frequency and the recommended survey frequency.
- o Describe the additional reasons when a radiation survey should be performed.
- o Discuss the additional recommended radiation surveys and why these are also important.

Lesson 10 – Production of X-Rays

- List the major components of an x-ray tube.
- State the purpose of the collimator.
- o Describe how x-rays are produced when a high voltage is supplied to the x-ray tube.
- Name the two types of x-rays produced and state which type is the predominate type of x-rays produced.
- o Define kVp and mA and discuss the relationship between these two parameters and the x-rays produced.

Lesson 11 – Cabinet X-Ray Design Requirements

- Discuss the FDA requirements for X-ray ON indication.
- List the 3 warning labels recommended for all Cabinet x-ray systems.
- What is the requirement for Key that allows x-ray initiation?
- Describe the purpose and function of the Emergency Stop.
- What are the main purposes of extension shrouds and lead impregnated curtains or drapes?
- What is the purpose of the operator presence device and when is its use required?
- What is the purpose of safety interlocks, when should they be tested and what precautions and procedures should be followed if a safety interlock needs to be bypassed temporarily?

Lesson 12 - Owner & Operator Responsibilities

- Discuss the main responsibilities of X-Ray Operators.
- Describe the various recommended safety checks to perform prior to operation.
- Discuss the safety rules and the do's and don'ts while operating a Cabinet x-ray system.
- List the Emergency procedures to be followed in the event of a suspected or actual radiation accident associated with a Cabinet x-ray system.
- Describe the ultimate role and responsibilities of both the Owner of the Cabinet x-ray system and the facility RSO.

INTRODUCTION

Welcome to this unique Radiation Safety Training course designed specifically for facilities that own and operate baggage and Cabinet x-ray systems used primarily for security and threat detection inspection purposes and for use in the food processing and packaging industry.

Today there are several thousand baggage and Cabinet x-ray inspection machines installed, in part, in hundreds of airports, courthouses, jails, critical infrastructure, mailrooms and food processing and packaging facilities worldwide as a method of increased security, identifying contraband and for increased quality controls and safety of products distributed by food processing and packaging companies to consumers.





The ultimate objective of this course is to increase your knowledge in radiation fundamentals in order for you to perform your work safely by complying with proper radiation protection practices when working with or around radiation generating devices like the non-medical Cabinet x-ray inspection machine.

This course is divided into twelve short (12) training Lessons which introduce the radiological subject matter required by the regulations.

There is a 50-question exam at the end of the course to test your knowledge and understanding of the materials presented. Upon successful completion of this course you may generate and print a Certificate of Completion using the template provided. Make sure you provide a copy of this certificate to your facility Radiation Safety Officer for record retention and State inspection.

LESSON 1 - HISTORY OF X-RAYS

Throughout history and most notably over the past 200 years, several scientists, inventors, engineers and physicist such as Volta, Faraday, Edison, Westinghouse and Tesla investigated the relationship between electricity and magnetism and then used the results of these investigations to invent the first of many devices such as the electric battery, the electric generator, the incandescent lamp and hydroelectric power using AC generators and transformers. Arguably these were some of the greatest technological advances that catapulted the world into the 20th century.

Volta's Voltaic Pile

Faraday's Electric Generator



The first electric battery invented by Volta in 1800

Original Bulbs Lasted 40 hours

Thomas Edison's Incandescent Lamp



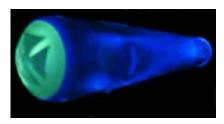
The first electric generator invented by Faraday in 1831.

Nikola Tesla's and George Westinghouse



The first hydroelectric plant in Niagara Falls, NY in 1896.

During this same period in history, particularly near the end of the 19th century, there were other scientists like Hertz, Hittorf, Crookes and Lenard who had developed various types of glass vacuum tubes containing a positive and negative electrode. It was well known that when the cathode of an electric circuit was heated in a vacuum with a large potential difference applied between the cathode and the anode, a beam appeared to travel between the two electrodes.





Originally this beam was thought to be an electromagnetic wave called **cathode rays** however it was discovered years later that cathode rays are actually negatively charged particles called electrons.

It was Wilhelm Conrad Roentgen (27 March 1845 – 10 February 1923), a German physicist at the University of Wurzburg, who hypothesized that cathode rays could likely travel in air at some distance as was reported by Lenard. In the late afternoon of November 8, 1895, Dr. Roentgen constructed a black cardboard covering to place over his Hittorf-Crookes tube. As he passed the Ruhmkorff coil charge through the tube, he determined the cover was light-tight and turned to prepare the next step of his experiment. Dr. Roentgen noticed a faint glow from a bench a few feet away from the tube. He quickly recognized the illumination was originating from a barium platinocyanide photographic screen he had intended to use in his experiment.



Dr. Roentgen speculated that a new kind of ray might be responsible. In the several weeks to follow he ate and slept in his laboratory as he investigated many properties of the new rays he termed **X-rays**, since X represented the mathematical designation for the unknown. Although the new rays would temporarily bear his name in many languages known as Roentgen Rays, he always preferred the term X-rays.

CHARACTERISTICS OF X-RAYS

He continued his experiments and tests with this invisible ray and discovered it travels in straight lines, the ray was not reflected or refracted by electrical or magnetic fields like cathode rays (electrons) and this new ray has the ability to penetrate lower density materials and has less penetrating ability with higher density materials such as lead.





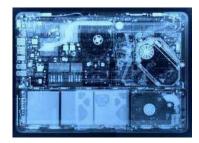
Like radio waves, microwaves, infrared light, visible light, ultraviolet light, gamma and cosmic rays, the X-ray is a form of electromagnetic radiation. All electromagnetic radiation is characterized by the movement of waves of energy called **photons**.

Photons have no mass and no charge and they travel near the speed of light. Photons move with a characteristic wavelength and frequency that defines the specific type of electromagnetic radiation. X-rays which have a relatively short wavelength and high frequency possess a great deal of energy.

Another characteristic of x-rays is they are produced outside the nucleus of the atom as electrons "jump" from energy shell to energy shell. They do not originate from the nucleus of an unstable atom as we will discuss in Lesson 3.

Because of their short wavelength, x-rays can penetrate materials that absorb or reflect visible light. Like light, X-rays can produce a visible image on photographic film. Because of these properties the use of x-rays has found wide applications in the fields of medicine, industry, security and research.









Six weeks later, on the Sunday before Christmas of 1895, he invited his wife Anna Bertha into the laboratory and took a 15-minute shadow-graph of the bones of her hand with her wedding ring clearly visible. When she saw her skeleton she exclaimed "I have seen my death!"

This is one of the most famous images in photographic history. Within weeks he became an international celebrity and would later receive the first Noble Prize in Physics in 1901. While likely inevitable, it was Wilhelm Conrad Roentgen who made the unexpected and monumental discovery that would transform science, industry and the medical community forever.

Today's imaging technology includes X-Ray devices used in the medical industry, automotive industry, the food packaging industry and also for circuit board inspections and materials analysis. One of the common uses of x-ray technology outside the medical industry is the non-medical Cabinet x-ray machine used for security and inspection at federal, State and local facilities. These non-human use x-ray inspection systems are used for the purpose of detecting contraband, to act as a deterrent against terrorist and criminals and to prevent potential catastrophic harm to life and property.

Today there are well over 150,000 non-medical security and inspection x-ray machines located in more than 150 countries.



The advancement in x-ray technology in the past 100 years has been remarkable, unfortunately however, it wasn't long before the harmful effects of this new ray became evident. X-Rays are a form of ionizing radiation and can be harmful to our bodies.

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This course will provide you with a fundamental understanding of what radiation is, where it comes from, what the harmful effects can be and what actions you can take to reduce your exposure to x-ray radiation to as low as reasonably achievable (ALARA).

While in fact radiation can be harmful, sources of radiation are used every day to benefit mankind. The ultimate goal of this course is to provide you the operator with the necessary information to allow you to work safely with the x-ray inspection machine and to provide you with safe radiological practices that will allow you to maintain your radiation exposure ALARA.

LESSON 2 – US FDA & SATE RADIATION CONTROL AGENCIES

Radiation Emitting Devices like the Cabinet x-ray inspection machine have stringent regulatory and design criteria which the manufacturer of these devices must meet and demonstrate to the satisfaction of US FDA before they can be operated in the United States. Manufacturer's compliance with the Cabinet x-ray performance standard 21 CFR 1020.40 regulations and requirements falls under the jurisdiction of the US FDA. Cabinets DO NOT have an FDA performance standard.





There are several manufacturers' who offer non-medical Cabinet x-ray machines for sale, lease and use throughout the world. In the United States, all radiation emitting devices are regulated by the Food and Drug Administration or FDA. All manufacturers of non-medical security and inspection cabinet x-ray machines must comply with the performance standards outlined in FDA regulations 21 CFR 1020.40. CFR stands for Code of Federal Regulations.

The FDA requires every manufacturer to submit an initial product report for all new radiation emitting devices before they can be offered for commerce in the United States. Each year the manufacturer is required to submit an annual report providing manufacturing, distribution and testing data for each product sold. The responsibility for compliance with the federal FDA standards falls on the manufacturer who must demonstrate radiation emitting device compliance based on their submitted test plans, procedures, quality assurance programs and documentation of results.

Each State Radiation Control Agency regulates the use of radiation emitting devices within their boundaries. There are thirty five (35) States who currently require the manufacturer or any other person or company who offers sales and servicing of any radiation emitting device like a non-medical security and inspection x-ray machine, to "register" with each applicable State Radiation Control Agency where sales and servicing are offered.

Find Information about a State Radiation Control Agency and their Regulations at:

https://scp.nrc.gov/asdirectory.html



This is known as "Vendor Registration." States like Alabama, Colorado, Mississippi, North Carolina, Oregon, South Carolina and Tennessee, require the actual individual providing these services to be registered and listed on the applicable State approved list. These Vendors, typically the manufacturer, also have regulatory requirements for *reporting all installations* they perform within the specified time frame listed in each States registration and radiation control regulations.

For all radiation emitting devices like your Cabinet x-ray inspection machine located at **your facility**, the **facility owner** is responsible for "**registering**" any and all radiation generating equipment with their respective State Radiation Control Agency. This "owner registration" requirement is separate from the Vendor registration required for the manufacturer.

Unless your facility is exclusively operated by the federal government, facility registration with the applicable State Radiation Control Agency is required and is the responsibility of the facility owner to register every nonmedical security and inspection Cabinet x-ray machine operated at your facility.

It is not the responsibility of the manufacturer, distributor, installer or sales representative who sold you the machine to register your non-medical industrial Cabinet x-ray machine for the facility owner. This continues to be a misconception in the industry which results in many unauthorized/unregistered x-ray machines operating throughout the United States.

Individual Responsible for Radiation Safety – The Radiation Safety Officer (RSO)

The facility owner is required by law to apply the applicable radiation protection regulations to all work involving sources of radiation and to make available to you a copy of these regulations and the operating procedures which apply to work you are engaged in and to explain their provisions to you. These documents are required to be maintained at your facility and are typically made available to you through your designated individual responsible for radiation safety, typically referred to as the facility Radiation Safety Officer or RSO.



The facility Radiation Safety Officer is the primary contact between your facility and your State Radiation Control Agency. The original state issued" Certificate of Registration", annual registration renewal letters, annual registration fee invoices and any proposed or actual regulation changes will all be mailed to this designated individual.

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When the State inspector arrives at your facility to perform a compliance inspection, the inspector will request to see the Radiation Safety Officer listed on the Application for Registration first.

Your designated facility Radiation Safety Officer is required to ensure compliance with all applicable regulations, which include, but not limited to, posting of the document called the "Notice to Employees." The Notice to Employees is required to be posted in several locations so the employee can view it to and from the restricted area (i.e., area where the x-ray machine(s) are located).



After this course, you should verify you can locate the Notice to Employees document posted at your facility and we strongly encourage you to read it. If you have any questions or cannot find this required posted document, inform your facility Radiation Safety Officer or the facility owner.

The facility Radiation Safety Officer is responsible for developing and implementing a written radiation protection program, for routinely inspecting the radiation emitting device and for performing or have performed, at a minimum, an annual radiation survey of the non-medical security and inspection x-ray machine to verify the radiation levels on the external surfaces of the system and the radiation levels at the Restricted Area surrounding the x-ray machine are in compliance with federal and applicable state radiation control agency limitations and to verify and demonstrate compliance with the radiation dose limits for occupational workers, declared pregnant women and members of the public.

The facility Radiation Safety Officer is responsible for testing of the safety devices such as E-Stops and the safety interlock system on a routine frequency. A Pre-Startup Checklist has been provided with this program.

It is recommended only trained and qualified service providers test safety interlocks located inside the access panels and connected to critical components such as the x-ray collimator assembly or detector array box as inexperienced personnel could potentially be exposed to high levels of radiation.

LESSON 3 – RADIATION FUNDAMENTALS

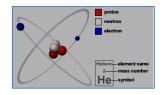
Both Federal and State regulations require that all individuals, who in the course of their employment have duties and responsibilities working with sources of radiation and who may potentially be exposed to ionizing radiation, shall receive training in areas addressing radiation safety including basic radiological fundamentals.

Let's begin by first examining the foundation in which all our future discussions are based on; The Atom.

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Everything is made of what we call matter and the smallest component of matter is the atom. Atoms are extremely small particles which are the fundamental building blocks of nature. It takes about 100 billion billion (this is not a typo) atoms to make up the head of a pin. We cannot see atoms, but we know they exist. It was as early as the 5th Century B.C. when the Greek philosopher Democritus proposed that all matter was composed of invisible particles in motion, he called *atoma* or "invisible units" from which we derive the English word atom.

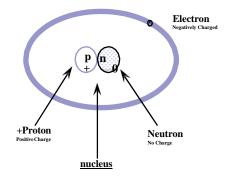
The atom actually consists of even smaller particles called **subatomic particles**. There are three subatomic particles that make up an atom. They are called the proton, the neutron, and the electron.



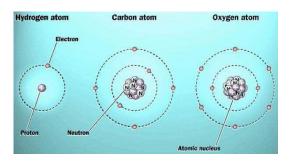
Protons and neutrons are located in the center of the atom which we call the nucleus and are similar in size. Protons have a positive electrical charge and are often represented with the mark of a plus "+" sign. Neutrons have no electrical charge; they are neutral yet very important in helping to bind the protons together.

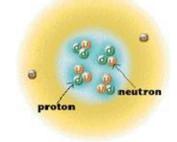
Orbiting around the nucleus are very small particles called electrons. If you can image for just a moment that if the earth represents the size of the nucleus of an atom, then electrons orbiting around the nucleus, would be about the size of an apple.

Electrons have a negative charge and are often represented with the mark of a negative "– "sign. Electrons spin as they circle the nucleus billions of times every second; traveling at about three fourths the speed of light. At this speed an electron could orbit the earth seven and a half times every second. If we could see these electrons, they might appear to look like a cloud around the nucleus.



Electrons are arranged in a maximum of seven (7) energy levels or "shells" around the nucleus and only a certain number of electrons can occupy each energy level or shell at the same time. Each element has a certain number of protons, neutrons and electrons. Hydrogen for example has one electron orbiting its nucleus. The Helium atom has two electrons, oxygen has eight electrons and uranium has ninety-two electrons orbiting around its nucleus. When electrons gain or lose energy, they jump between energy levels as they rotate around the nucleus. While this may not seem that important right now, you will see the significance of this phenomenon later when we discuss how x-ray radiation is produced.





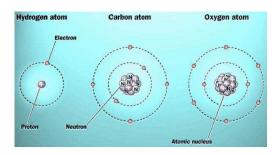
We know that opposite charges attract and like charges repel. So what keeps the atom from breaking apart?

There are forces within the atom that account for the behavior of the protons, neutrons, and electrons. An atom could not stay together without these forces. Remember, protons have a positive charge, electrons have a negative charge, and neutrons are neutral, they have no charge.

Electrons maintain their position around the nucleus because there is an electromagnetic field of attraction between the positive charge of the protons and the negative charge of the electrons because opposite charges attract.

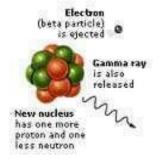
There is also an atomic force if you will, which is called the **strong force** that opposes and overcomes the force of repulsion between the protons which holds the nucleus together. The energy associated with this strong force is called the **binding energy**. It's this binding energy that acts like atomic glue that keeps the nucleus together.

In some atoms, the binding energy is great enough to hold the nucleus together. These atoms are called stable atoms. Stable atoms have just the right number of protons and neutrons in their nucleus so they are content just being a stable atom. There are approximately 270 known stable atoms.



In other atoms however, the binding energy is not strong enough to hold the nucleus together. These atoms are called unstable atoms. Unstable atoms have too many or too few protons or neutrons in their nucleus; therefore they must release these excess particles until they become a stable atom. We will discuss this transformation further in just a moment. There are approximately 900 known unstable atoms.





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RADIATION, RADIOACTIVE MATERIALS AND RADIOACTIVE DECAY

Within just a few months after Dr. Roentgen's discovery of X-rays in November 1895, the French physicist Henri Becquerel decided to investigate the work of Roentgen to determine if there was any connection between X-rays and naturally occurring phosphorescence.

Using uranium salts he inherited from his father which phosphoresce when exposed to light, Henri Becquerel placed these salts near a photographic plate covered with opaque paper and placed them in sunlight. He quickly discovered the photographic plate had fogged lending him to initially believe the uranium salts phosphorescent properties must be the source of x-rays since it was Roentgens phosphorescent plate containing barium salts that created his photographic images; so he thought.







One day it was too cloudy for Becquerel to expose his film to sunlight. He placed the uranium salts and photographic film in a desk drawer and it wasn't until a few days later that Becquerel removed the materials from his desk and discovered an image of the uranium salts on the photographic film without exposing them to sunlight. Becquerel concluded this was a property of the uranium and not from its phosphorescent properties.

Becquerel showed the rays emitted by uranium, which for a long time were called Becquerel Rays, caused gases to ionize and they were different from X-rays because these new rays could be deflected by electric and magnetic fields; x-rays could not.

Becquerel named the energy released from the uranium; **radiation** and any materials which emitted radiation were called **radioactive elements**.

In 1898, Marie and Pierre Curie discovered two new radioactive elements in a material called pitchblende. They named these new radioactive elements Polonium and Radium.



Marie Curie



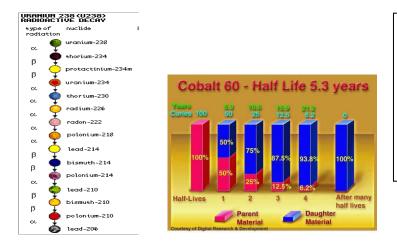
Pitchblende



Pierre Curie

For his discovery of spontaneous radioactivity Becquerel was awarded half of the Nobel Prize for Physics in 1903, the other half being given to Pierre and Marie Curie for their study of the Becquerel radiation.

Unstable atoms will lose neutrons and protons as they attempt to become stable. We call this process radioactive decay. These unstable atoms are constantly changing as a result of the imbalance of energy within the nucleus. When the unstable nucleus changes; it gives off energy. *This energy released from an unstable atom is called radiation* and radioactive decay will continue until the original unstable atom becomes a stable atom. For some radioactive elements, this can take only a few seconds or minutes, but for many radioactive elements this takes days, weeks and in some cases millions and millions of years to reach stability.



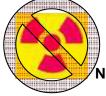
Radioactive Half-Life is the time it takes a radioactive element to decay to one half its original value.

The radioactive element Cobalt-60 has a 5.3 year half-life whereas Uranium-238 has a radioactive half-life 4.47 billion years.

Using and handling radioactive materials safely is very important to understand however; the good news is **Non**medical Cabinet x-ray machines do not contain radioactive materials to produce x-ray radiation therefore this course is not intended to instruct you in the proper methods, controls and safety precautions for using and handling radioactive materials.

What is important for you to understand is that radioactive elements can exist in the form of a solid, liquid or a gas. Radioactive elements like Cobalt 60, Cesium 137, Iodine 131, Uranium 235, Polonium 210 and Radium 226 emit excess energy from their nucleus we call radiation and this radiation emitted from radioactive elements can exist in the form of a particle which has mass like alpha, beta and neutrons or in the form of electromagnetic waves like x-rays and gamma rays which have no mass and no charge.

Because Cabinet x-ray inspection machines do not contain any radioactive materials, it is impossible for you as an operator, your facility or any materials passing through a Cabinet x-ray inspection machine to become radioactive.



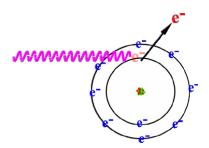
Nothing Can Become Radioactive or Radioactively Contaminated...Nothing !

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IONIZATION AND IONIZING RADIATION

We mentioned earlier that Henri Becquerel discovered the energy released from a radioactive element could ionize gases. Let's examine what ionization is and discuss why it is important.

lonization is the process of "knocking" an electron from the orbit of a neutral atom which creates charged particles we call ions.



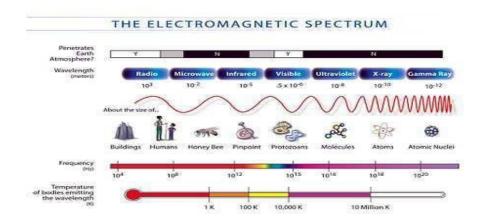
Atoms are held together by a *binding energy*. In order to "knock" an electron from its orbit, the **energy** doing the knocking must be *at least equal to or greater than* the binding energy that holds the electron in orbit.

Types of radiation which do not have enough energy to cause ionization to occur are called **Non-ionizing Radiations**. Radio waves, microwaves, infrared light, visible light and ultraviolet light are examples of non-ionizing forms of radiation.

Visible light for example, is energy that travels in waves. There are many different kinds of energy that travel in waves. For example, sound is a wave of vibrating air. Light is a wave of vibrating electric and magnetic fields. The energy of the radiation depends on its wavelength and frequency. Wavelength is the distance between the crests of the waves. Frequency is the number of waves that pass by each second.

The longer the wavelength, the lower the frequency, and therefore the less energy the electromagnetic wave contains. The shorter the wavelength, the higher the frequency, the more energy it contains.

The energy range of these waves can be characterized by what is called the **electromagnetic spectrum**.



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Types of radiations that possess enough energy to cause ionization, or knock electrons from their orbit are called *lonizing Radiations*. X-Ray radiation is just one example of a type of ionizing radiation.

So why is ionization important to understand?

It is this process of *lonization*, caused by ionizing forms of radiation like x-rays, which can cause damage to the atoms in the cells of our body and it is this process which, in part, also allows us to detect the presence of ionizing radiation. How is radiation measured? The human body cannot sense the presence of radiation and for many years after the discovery of x-rays and radioactive material there were no "radiation detection" instruments.

LESSON 4 - UNITS OF RADIATION MEASURE

Radiation is all around us and we are constantly being exposed to both natural and man-made sources. Before we discuss these sources of radiation let's first discuss the units we use to measure radiation.

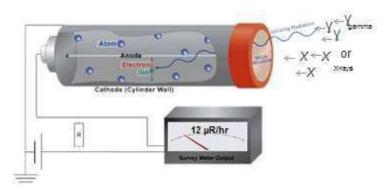
Most scientists in the international community measure radiation using the System Internationale or SI units which is a uniform system of weights and measures that evolved from the metric system. The United States continues to use the conventional system of measurement. For purposes of comparison, both systems will be discussed below.

Exposure is a measure of the ability of photons, like X and gamma radiations only, to produce ionization in air. The unit of exposure is the *Roentgen*.

As x-ray or gamma radiation enters an air-filled chamber, negatively charged electrons are ejected. These negatively charged electrons are then attracted to a positively charged anode located inside the air-filled chamber and the newly formed ions which are positively charged are attracted to the negative charge of the detector wall. As negatively charged electrons collect on the positively charged anode, an electrical potential can be measured.

This unit of measure is called the <u>Roentgen</u> (R). Most instruments used to detect and measure x-ray radiation around the Cabinet x-ray machine and restricted area surrounding the x-ray machine use this principle of detection. There is no

System Internationale (SI) unit defined for exposure. This was done to discourage further use of the Roentgen as a unit of measure, but it's still used in the United States and most radiation detection instrumentation use the Roentgen (R), milli roentgen (mR) and micro Roentgen (μ R) as the unit of measure in air filled detectors like Geiger Mueller (GM) and Ion Chamber detectors.



1 Roentgen (R) = 1000 milli Roentgen (mR)

1 mR = 1000 micro Roentgen (µR)

To make this clearer, standing next to the external surface of a cabinet x-ray machine, radiation measurements are limited by US FDA REDA regulations to less than 0.5 milli roentgens (500 micro roentgens in any one hour) measured 5 centimeters (cm) away from all external surfaces.

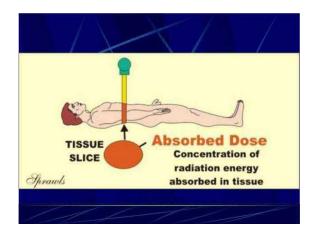


When measuring radiation exposure with common radiation detection equipment like a Geiger Mueller (GM) detector or an Ion Chamber, the detector will provide a radiation measurement unit expressed as an exposure per unit time, typically one hour. We call this an **exposure rate**.

An example of exposure rate is the average exposure rate measurement of natural background radiation near sea level of approximately 10-12 **micro**_roentgen per hour, abbreviated µR/hr on the meter face.



The *RAD or <u>Radiation Absorbed Dose</u>* recognizes different materials that receive the same exposure may not absorb the same amount of energy. A *Rad* measures the amount of radiation energy transferred to some mass of material, typically humans. When a person is exposed to radiation, energy is deposited in the tissues of the body. The amount of energy deposited per unit of weight of human tissue is called the *absorbed dose*. Absorbed dose is measured using the conventional unit called the **Rad** or the **SI unit called the Gray, abbreviated Gy**.



US Conventional Unit

1 Rad (R) = 1000 milli Rad (mRad)

1 mRad = 1000 micro Rad (µRad)

An individual's biological risk, that is, the risk a person will suffer health effects from an exposure to radiation, is measured using the conventional unit called the **Rem** which stands for <u>*Roentgen Equivalent Man*</u> or the **SI unit called the Sievert, abbreviated Sv.**

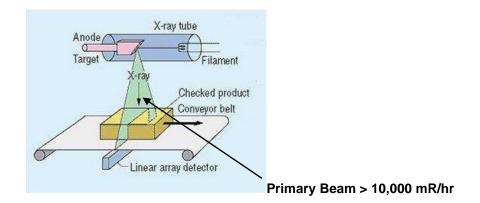


To determine a person's biological risk, scientists have assigned a number to each type of ionizing radiation like alpha and beta particles, gamma rays, neutrons and x-rays depending on the ability of each type of radiation to transfer energy to the cells of the body. This number is known as the **Quality Factor** (Q).

When a person is exposed to radiation, scientists can multiply the dose in Gray (Rad) by the quality factor for the type of radiation present and estimate a person's biological risk in Sieverts (Rem). Thus, risk in Sieverts (Rem) = Gray (Rad) x Q. **The Quality Factor for X-ray radiation is one (1)**. Compare this to the quality factor for alpha particles which is twenty (20). Biological risk therefore is 20 times greater for alpha particles than x-ray radiation.

If you inadvertently reach inside the access port opening of a Cabinet x-ray inspection machine with your hand or arm about six to ten (6 to 10) inches, the radiation levels would be approximately 10 Roentgen per hour or about 10,000,000 times greater than background radiation levels.

This is why it is important for the Cabinet x-ray inspection machine operator to keep their body parts out of the Cabinet.



LESSON 5 - SOURCES OF RADIATION

Radiation is all around us and we are constantly being exposed to both natural and man-made sources. Let's take a few moments now to identify some of the sources of background radiation we are all exposed to whether you operate a non-medical security and inspection x-ray machine or not.

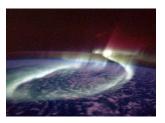
Sources of background radiation are divided into two categories. The first category is referred to as **Natural Sources** of radiation and the second category is **Man Made Sources** of radiation.

About eighty percent (80%) of your annual dose to background radiation comes from natural sources and the remaining twenty percent (20%) comes from man-made sources.

NATURAL SOURCES OF RADIATION

The first source of natural background radiation is the dose we all receive from <u>cosmic radiation from the sun and outer</u> <u>space</u>. The annual dose from this source is about 28 mRem per year (0.28 mSv per year).







If you live in areas of higher elevation, this number is at least double because you are closer to the sun. It would make sense therefore, if you were to fly in an airplane at 30,000 feet; the radiation level should be higher as well. At sea level, the average background exposure rate is approximately ten to twelve (10 -12) microR per hour (μ R/hr). At 30,000 feet, the average background dose rate is approximately 350 - 400 microR per hour (μ R/hr).

If you fly from Toronto to Vancouver and back again, about a 10-hour flight round trip; and during this flight the average dose rate is 400 microR/hr, then after the 10 hour round trip flight, your final equivalent dose will be 4000 μ Rem or 4 mRem. In other words, dose rate times time equals total dose received.

Dose Rate x Time = Dose.

Baggage and Cabinet x-ray inspection machine operators typically receive little if any additional dose above background when the x-ray machine is properly operated under normal operating conditions.

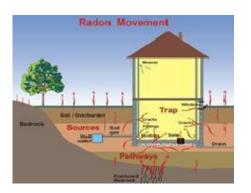
The second source of natural background radiation is the earth itself or what is referred to as "terrestrial sources" of radiation. From terrestrial sources in North America we receive about 28 mRem per year (0.28 mSv per year).

Radioactive elements exist throughout the world naturally in soil, minerals, water and vegetation. The more abundant radioactive elements include uranium and the decay products of uranium, such as thorium, radium, and radon gas. Some of these materials are ingested with food and water, while others, such as radon gas, are inhaled. The dose from terrestrial sources varies in different parts of the world. Locations with higher concentrations of uranium and thorium have higher exposure levels. Some areas in Brazil, China, and the Nile delta in Egypt have high concentrations of monazite sand deposits which contain high levels of thorium. Elevated terrestrial levels can also be found in the areas of Ramsar and Mahallat in Iran which are caused by Radium deposited from waters flowing from their hot springs. The annual dose here is approximately 13,000 mRem per year as compared to approximately 28 mRem per year in North America.

The third and largest source of radiation dose from natural background sources is **Radon**. Radon is a terrestrial source of radiation of particular concern because this radioactive element can be found in high concentrations in many areas of the world where it represents a significant health hazard. Our continuous exposure to radon gas accounts for a little over half of your annual dose from sources of both natural and man-made sources. This dose is approximately 200 mRem per year.

Radon is a decay product of uranium which is relatively common in the earth's crust and generally concentrated in orebearing rocks scattered around the world. Radon is an odorless, colorless gas which seeps out of these ores into the atmosphere or into ground water and can accumulate within dwellings where air circulation is poor and expose humans to high concentrations.

The United States Environmental Protection Agency (EPA) estimates that 1 in 15 homes in the U.S. have radon levels above the recommended guideline of 4 picocuries per liter. Iowa has the highest average radon concentration in the United States and studies performed there have demonstrated a 50 percent increased lung cancer risk with prolonged radon exposure above the EPA's action level.



At the average radon concentrations in the United States there is a 2 percent increase in developing cancer for non-smokers and a 17 percent increase for smokers.

Radiation dose received from the inhalation of Radon gas is the second leading cause of lung cancer after smoking and accounts for 15,000 to 22,000 cancer deaths per year in the US alone.

Cigarettes contain the radioactive elements Polonium-210 and

Lead-210 which add to the total dose received by smokers. Radiation dose received from the inhalation of Radon gas is the second leading cause of lung cancer after smoking and accounts for 15,000 to 22,000 cancer deaths per year in the United States alone. Cigarettes contain the radioactive elements Polonium-210 and Lead-210 which add to the total dose received by smokers.

The fourth source of natural radiation dose to your body which most people are not aware of is YOU or *internal sources*. Some of the essential elements that make up the human body, mainly potassium and carbon, have radioactive isotopes that add to our annual radiation dose. An average human contains about 30 milligrams of potassium-40 (⁴⁰K) and about ten to the minus eight (10⁻⁸) grams of carbon -14 (¹⁴C). The largest component of internal radiation exposure from the human body is from potassium-40.



The dose contribution is about 39 mRem peryear.



MAN-MADE SOURCES OF RADIATION

Twenty percent (20%) of your annual dose is from man-made radiation sources.

The largest source of man-made dose is from *medical procedures* you may undergo during the course of any one year. This dose will be variable depending on whether or not you undergo any medical treatment involving the use of radiation and/or radioactive materials such as radiopharmaceuticals.





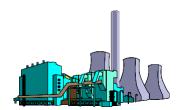
Medical exams and treatments could include a typical chest x-ray, a CT scan, tests involving the use of radiopharmaceuticals, a dental examination or a mammogram, just to name a few examples.

The average person receives an annual dose of approximately 54 mRem per year from medical procedures. For example, the dose from a chest x-ray procedure (two views) is approximately 20-26 mRem. The effective radiation dose from a mammogram is about 70 mRem, which is about the same as the average person receives from background radiation in three months. The average dose for a dental x-ray (one bitewing) is 3.8 mRem per bitewing; however, a full mouth dental x-ray exam which may include 21 views can total approximately 32 mRem. Because these doses are to localized portions of the body, the effective dose equivalent to the whole body is a fraction of these values.

Consumer products_represent a source of man-made radiation dose. Examples include older radium luminous dial watches, fertilizers; thorium impregnated welding rods, some smoke detectors and older lantern mantles. This dose is relatively small as compared to other naturally occurring sources of radiation and averages 10 mRem in a year.



Industrial uses include coal fired plants and nuclear power plants used to produce electricity, x-ray machines and radioactive sources used for radiography to test pipe welds and bore-holes. Most people receive little if any dose from these sources which is estimated at less than less than 3 mRem per year.

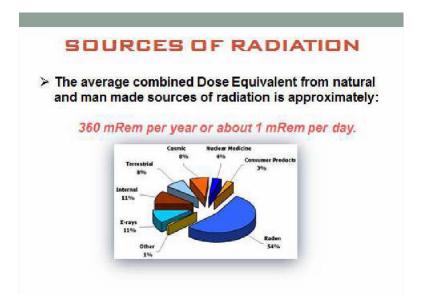




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The last man-made source of radiation we will discuss includes *residual fallout from atmospheric nuclear weapons testing* in the 1950's and early 1960's. Atmospheric testing is now banned by most nations. The average dose from residual fallout is about 2 mRem peryear.

If we now total up all the different sources of both natural and man-made radiation we are ALL exposed to each year, the average individual annual dose is **360 mRem per year or about 1 mRem per day.**



LESSON 6 - BIOLOGICAL EFFECTS OF RADIATION

We know that too much radiation exposure is harmful. The degree of radiation injury depends on the amount of radiation received and the time involved. In general, the higher the dose received, the greater the severity of early effects which can occur within a few weeks and the greater the possibility of late effects in life such as cancer.

The Biological Effects of Ionizing Radiation (BEIR) Committee of the National Research Council estimates that among 100,000 people exposed to a one-time dose of 10 Rem or 10,000 mRem and followed over their life span, about 790 more would die of cancer than the estimated 20,000 cancer deaths that would be expected among a non- exposed group of the same size.

The fact that ionizing radiation produces biological damage has been known for many years. The first case of human injury was reported in literature just a few months following Dr. Wilhelm Roentgen's original paper in 1895 announcing the discovery of X-rays. The first case of radiation-induced cancer was reported seven years later.



Mihran Kassabian (Edison Assistant)



Thomas Edison

Early human evidence of the harmful effects of ionizing radiation as a result of high exposures also became available in the 1920's and 30's through the experience of radiologists, miners exposed to airborne radioactivity and workers in the radium industry. The long-term biological significance of smaller, repeated doses of radiation was not widely appreciated until later.



Edison's Handheld Fluoroscope



Uranium Milling & Mining

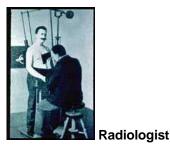


Radium Dial Painters

The biological effects and risks associated with exposure to radiation and radioactive elements have been studied more thoroughly than any other hazardous agent in the laboratory. Billions of dollars have been expended for research.

We have a large body of information available regarding exposures to humans which have been organized into four (4) major groups of people exposed to significant levels of radiation.

The **first group** includes the early workers, such as radiologists, who received large doses of radiation before the biological effects were recognized.





Clarence Dally



Marie Curie

The **second group** was the more than 100,000 Japanese survivors of the atomic bombs dropped on Hiroshima and Nagasaki. These survivors received estimated acute doses in excess of 50,000 mRem.





The **third group** are individuals who have been involved in radiation accidents, the most notable being the Chernobyl accident. The 30 firefighters who perished from overexposure received approximately 800,000 mRem of acute dose.



Chernobyl Nuclear Plant Reactor 4, April 26, 1986

The **fourth and largest group** is patients who have undergone radiation therapy treatment for cancer. These cumulative doses are approximately 100,000 – 200,000 mRem delivered over a period of several weeks.



Whether the source of radiation is natural or man-made, whether it is a small chronic dose of radiation or a large acute dose, there will likely be some effect resulting from exposure to radiation. We could spend weeks and weeks talking about the biological effects of radiation but that is certainly not the intent of this class. Let's discuss what the general effects of radiation have on the body's cells.

Your body is made up of billions and billions of cells. At conception, the germ cell of the male (or sperm cell) unites with the germ cell of the female (or egg cell). All other cells are called somatic cells.

Each of these **germ cells** contains 23 chromosomes which then fuse together to form the normal 23 pairs of chromosomes which allow the offspring to share the characteristics of both parents. This newly formed <u>single cell</u> then splits and divides through a process called **cell mitosis** into two new identical daughter cells.



These cells will also grow and eventually split and divide and so on and so on. Within just a few hours after conception some cells have already decided what they are going to be when they grow up. Some cells will form the brain, some the heart or lungs, while others may become a kidney, a spleen or the skin.

Just like an architect provides the blueprints to the builder to construct a magnificent building, your parents have passed on their blueprint to form you. Within the nucleus of every cell are long strands of **DNA**, the code that holds all the information needed to make and control every cell within a living organism. The DNA segments that carry your genetic information are called **genes**.

DNA is organized into structures called **chromosomes**. These chromosomes are duplicated before cells divide, in a process called **DNA replication**. DNA, which stands for deoxyribonucleic acid, resembles a long, spiraling ladder or double helix. It consists of just a few kinds of atoms: carbon, hydrogen, oxygen, nitrogen, and phosphorus.





We tend to think of biological effects as the effect's radiation has on the whole body. However, ionizing radiation, by definition, interacts only with the **atoms** of living cells through the process we discussed earlier called **ionization**. All biological effects therefore begin with ionizing radiation interactions with the atoms which form the cells of your body.

Radiation causes *ionization* of the atoms which may affect molecules which may affect a cell which could impact tissue which may affect an organ which may ultimately have an impact on your whole body. Ionizing radiation can interact with the **atoms of any part** of a cell. The two mechanisms by which radiation ultimately affects a cell are commonly referred to as *direct and indirect effects*.

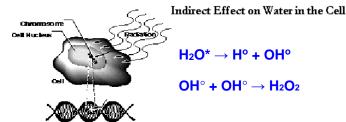
If radiation interacts with the atoms of the **DNA molecule**, or some other cellular component critical to the survival of the cell, it is referred to as a **direct effect**. Such an interaction may affect the ability of the cell **to reproduce**. If enough atoms are affected and the chromosomes do not replicate properly during cell division, or if there is a substantial alteration in the information carried by the DNA molecule, then the cell may be destroyed by "direct" interference.



If a cell is exposed to radiation, the probability of the radiation interacting with the DNA molecule is **very small** since these critical components make up such a small part of the cell.

Each cell, as is the case for *the human body, is mostly water*. Therefore, there is a much higher probability of radiation interacting with the water that makes up most of the cell's volume.

When radiation interacts with water, it may break the bonds that hold the water molecule together, producing free radicals such as hydrogen (H) and hydroxyl (OH) ions. These fragments may recombine or may interact with other ions to form compounds, such as water, which would not harm the cell. However, they could combine to form toxic substances, such as hydrogen peroxide (H₂O₂), which can contribute to the destruction of the cell.



Some cells are more sensitive than others to environmental factors such as viruses, toxins and ionizing radiation. Damage to cells may depend on how sensitive the cells are to radiation. In other words, those cells which undergo rapid cell reproduction like blood cells and the embryo/fetus and are not yet fully mature will be more susceptible to the potential harmful effects from radiation while those cells which reproduce slower and are typically more specialized like brain, muscle and nerve cells are less sensitive.

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When a cell is exposed to ionizing radiation, several things can happen. The following are possible effects of radiation on cells.

- 1. There is no cell damage.
- 2. Cells repair the damage and operate normally.
- 3. Cells are damaged and operate abnormally
- 4. Cells die as a result of the damage.

At any given moment thousands of our cells are dying and being replaced by normal cells nearby. It is only when the dose of radiation is very high or is delivered very rapidly that the cell may not be able to repair itself or be replaced.

Potential biological effects also depend on how much and how fast a radiation dose is received. Radiation exposure can be grouped into two categories, *acute and chronic exposure*.

An **acute effect** is a physical reaction due to massive cell damage. This damage is caused by a *large* radiation dose received in a *short* period of time. The body can't repair or replace cells fast enough from acute dose therefore physical effects such as reduced blood count, fatigue, nausea, dizziness, diarrhea and hair loss may occur.

Slight blood changes may be seen at acute doses of 10-25 Rem or 10,000-25,000 mRem but an individual would not otherwise be affected.

At acute doses greater than 100 Rem or 100,000 mRem, typical effects are mild to moderate nausea (50% probability at 200 Rem), with occasional vomiting, setting in within 3-6 hours after exposure, and lasting several hours to a day.

If the acute dose to the whole body is very large, on the order of 500 Rem or 500,000 mRem or greater, it may cause so much damage the body cannot recover. An example is the **30 firefighters at Chernobyl who received acute doses in excess of 800 Rem or 800,000 mRem**. These individuals succumbed to the effects of the burns they received compounded by their radiation dose.





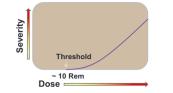


It is possible that radiation exposure may be limited to a part of the body such as the hands. There have been accidents, particularly with diagnostic and analytical type x-ray machines and linear accelerators used for radiation therapy, in which individuals have exposed their fingers to part of the intense radiation beam. In some of these cases individuals have received doses of <u>millions</u> of mRem resulting in finger loss.

After an acute dose, damaged cells can be replaced by new cells and the body does have the ability to repair itself, although this may take a number of months. Only in those extreme cases, such as the Chernobyl firefighters, would the dose be so high as to make recovery unlikely. On the following page you will find acute doses, the immediate symptoms at these acute doses, the latent phase, post-latent symptoms and the prognosis of survival at the acute dose received.

Deterministic Effects of radiation is the dose received which results in the first observable effect. There is a threshold where an effect from a dose of radiation is NOT observable but could occur randomly the more dose you receive over your lifetime. This is called a **Stochastic Effect** based on the Linear No-Threshold Model.

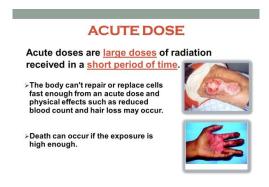
DETERMINISTIC EFFECTS



Severity of the Radiation Effect Increases with Increasing Dose

Threshold Exits for Observable Effects

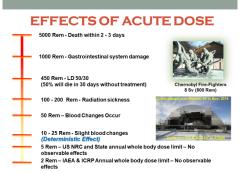
An acute effect is a physical reaction due to massive cell damage. This damage is caused by a large radiation dose received in a short period of time. The body can't repair or replace cells fast enough from acute dose therefore physical effects such as reduced blood count, fatigue, nausea, dizziness, and diarrhea and hair loss may occur. Slight blood changes may be seen at acute doses of 10 to 25 Rem but an individual would not otherwise be affected.



This bar graph represents the deterministic effects from acute exposures to radiation. The greater the dose you receive and the faster you receive this dose, the greater the severity. At acute doses greater than 100 Rem, typical effects are mild to moderate nausea with a 50% probability at 200 Rem, with occasional vomiting, setting in within 3-6 hours after exposure, and lasting several hours to a day.

If the acute dose to the whole body is very large, on the order of 500 Rem or greater, it may cause so much damage the body cannot recover. An example is the 33 firefighters at Chernobyl who received acute doses in excess of 800 Rem. These individuals succumbed to the effects of the burns they received compounded by their radiation dose.

After an acute dose, damaged cells will be replaced by new cells and the body will repair itself, although this may take several months. Only in those extreme cases, such as the Chernobyl firefighters, would the dose be so high as to make recovery unlikely. There is a table in your handout which provides additional information regarding different amounts of acute dose and the effects it can have.



| Dose (Rads) | Immediate symptoms | Latent phase | Post-latent symptoms | Prognosis |
|----------------|---|------------------|---|--|
| 0 - 50 | No obvious effect | None | No obvious effect, except, possibly, minor blood changes and anorexia. | Certain survival |
| 50-100 | Vomiting and nausea for about 1 day in 10 to 20% of exposed personnel. Fatigue, but no serious disability. | days to weeks | In this dose range no obvious sickness occurs. Detectable changes in blood cells begin to occur at 0.25 Sv but occur consistently only above 0.50 Sv. These changes involve fluctuations in the overall white blood cell count <i>(with drops in lymphocytes)</i> , drops in platelet counts, and less severe drops in red blood cell counts. | Almost certain survival |
| 100- 200 | Mild acute symptoms occur in this range. Symptoms begin to appear at 1 Sv and become common at 2 Sv. Typical effects are mild to moderate nausea (50% probability at 2 Sv), with occasional vomiting, setting in within 3-6 hours after exposure, and lasting several hours to a day. This will be followed by other symptoms of radiation sickness in up to 50% of personnel. | 10 - 14 days | Tissues primarily affected are the <i>blood forming</i> tissues; sperm forming tissues are also vulnerable. Blood changes set in and increase steadily during the latency period as blood cells die naturally and are not replaced. There is a 10% chance of temporary hair loss. Mild clinical symptoms return in 10-14 days. These symptoms include loss of appetite (50% probability at 1.5 Sv), malaise, and fatigue (50% probability at 2 Sv), and last up to 4 weeks. | Fatality rate is about 10% |
| 200- 350 | Nausea becomes universal, the incidence of vomiting reaches 50% at 2.8 Sv and 100% at 3 Sv. Nausea and possible vomiting starting 1 to 6 hours after irradiation and lasting up to 2 days. This will be followed by other symptoms of radiation sickness, <i>e.g.</i> , loss of appetite, diarrhea, minor hemorrhage | 7 - 14 days | Illness becomes increasingly severe, and significant mortality sets in. Symptoms may include <i>hair loss</i> , 50% probability at 3 Sv, fatigue, diarrhea (50% prob. at 3.5 Sv), and hemorrhage (<i>uncontrolled bleeding</i>) of the mouth and kidney (50% prob. at 4 Sv). At 3 Sv the mortality rate without medical treatment becomes substantial (<i>about 10%</i>). The possibility of permanent sterility in females begins to appear. Recovery takes 1 to 3 months. | Fatality rate 35% to 40% |
| 350- 550 | Nausea and vomiting within half an hour, lasting up to 2 days. This will be followed by other symptoms of radiation sickness, <i>e.g.</i> , fever, hemorrhage, diarrhea, and emaciation. | 7 - 14 days | Hair loss, internal bleeding, severe bone marrow damage with high risk of bleeding and infection. Mortality rises steeply in this dose range, from around 50% at 4.5 Sv to 90% at 6 Sv Recovery takes several months to a year, blood cell counts may take even longer to return to normal. Female sterility becomes probable. Survivor's convalescent for about 6 months. | Fatality rate 50% within 6 weeks |
| 550- 750 | Severe nausea and vomiting within 15 - 30 minutes, lasting up to 2 days, followed by severe symptoms of radiation sickness, as above. | 5 - 10 days | Hair loss, internal bleeding, severe bone marrow damage leading to complete failure of blood system, high risk of infection, moderate gastrointestinal damage. Gastrointestinal Syndrome. Survival depends on stringent medical intervention. Bone marrow is nearly or completely destroyed, requiring marrow transfusions. Gastrointestinal tissues are increasingly affected. The final phase lasts 1 to 4 weeks, ending in death from infection and internal bleeding. Recovery, if it occurs, takes years and may never be complete. Survivor's convalescent for about 6 months. | Death probable within 3 weeks |
| 750- 1000 | Excruciating nausea and vomiting within 5 - 15 minutes, lasting for several days | 5 - 7 days | Hair loss, internal bleeding, severe bone marrow damage leading to complete failure of blood system, high risk of infection, severe gastrointestinal damage. | Death almost certain within 3 weeks. |
| 1000- 2000 | Immediate nausea occurs due to direct activation of the chemoreceptive nausea center in the brain. The onset time 5 minutes. | 5 - 7 days | Above 10 Sv rapid cell death in the gastrointestinal system causes severe diarrhea, intestinal bleeding, and loss of fluids, and disturbance of electrolyte balance. These effects cancause death within hours of onset from circulatory collapse. Death is certain, often preceded by delirium and coma. Therapy is only to relieve suffering. | Certain death in one week or less. |
| 2000- 8000 | Immediate disorientation and coma will result; onset is within seconds to minutes. | None | Metabolic disruption is severe enough to interfere with the nervous system. Convulsions occur which may be controlled with sedation. Victim may linger for up to 48 hours before dying. | Certain death |
| > 8000 | Coma | None | Military experts assume that 80 Sv of fast neutron radiation (<i>from a neutron bomb</i>) will immediately and permanently incapacitate a soldier. Lethal within 24 hours due to damage to central nervous system. | Certain death |

A chronic radiation dose is small amount of radiation dose received over a long period of time.

An example of a chronic dose is the dose we receive from natural background radiation every day of our lives, standard medical procedures involving radiation dose or the dose we receive from occupational exposure when working with a source of radiation like a Cabinet x-ray machine.

The body is better equipped to handle a chronic dose than an acute dose. The body has time to repair damage because a smaller percentage of the cells need repair at any given time. The body has time to replace dead or non-functioning cells with new healthy cells. It is only when the dose of radiation is high and is received very rapidly that the cellular repair mechanisms are overwhelmed, and the cell can die before repair occurs.

The effect of radiation experienced only by the individual receiving the dose is called a **Somatic Effect**. The abnormality may be a delayed effect manifested only after many generations of cell replication. The delayed somatic effects of ionizing radiation include an increase in the probability of the development of various types of cancers. The probability of this is very low at the occupational dose limit of 5000 mRem per year and for the non-medical security and inspection x-ray machine operator who will likely receive less than one percent (1%) of the allowable occupational dose limit.

A Heritable Effect is a genetic effect inherited or passed on to an offspring. In the case of heritable effects, the individual has experienced damage to some genetic material in the reproductive cells. Heritable effects from radiation have never been observed in humans but are considered possible and have been observed in studies of plants and animals.

While the risks of cancer or genetic damage are very low for an occupational radiation worker, the unborn embryo/fetus is at a higher risk. It is important for women who are pregnant or who are considering pregnancy to be aware of the special needs of their situation.

The embryo/fetus is particularly radiosensitive during the first **three months** after conception; when a woman may not be aware she is pregnant. Women who work with sources of radiation and are considering pregnancy should request additional published information and studies from the facility Radiation SafetyOfficer.



It is strongly recommended women who are pregnant or are considering pregnancy be informed of the potential hazards associated with prenatal radiation dose and they are informed of the regulatory requirements and their options during the term of the pregnancy. Since the health of the unborn can be influenced by the behavior of the mother's co-workers and supervisors, it is essential that every occupational radiation worker, not just the mother, be familiar with the regulatory guidelines and limitations pertaining to pregnancy. We will discuss the regulatory guidelines and limitations are pregnancy.

Exposure to radiation is not a guarantee of harm. However, most agree the more radiation dose received the greater the risk and it is widely accepted there is no dose of ionizing radiation so small it will not have some effect.

In order to reduce this risk to acceptable levels it is a generally accepted practice to limit radiation dose to levels which are *As Low as Reasonably Achievable (ALARA)*.

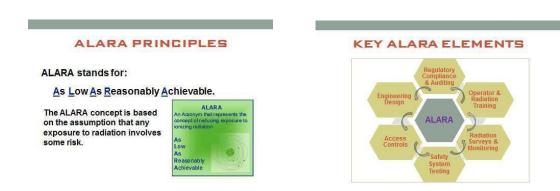
LESSON 7 - ALARA & PROTECTIVE MEASURES

The fundamental objective of radiation safety is to maintain your exposure to ionizing radiation "as low as reasonably achievable". The acronym ALARA is used to define this philosophy which means, in part, making every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits as practical, taking into account the current state of technology, the economics of improvements and the evaluation of the benefits versus risk to public health and safety.

Implementation of ALARA principles is the responsibility of all employees and its success is dependent on management's commitment and support as well as each worker's attitude and actions. ALARA needs to be a routine practice when working with and around a non-medical industrial Cabinet x-ray machine.

The majority of x-ray radiation emitted by a Cabinet x-ray inspection machine is contained and maintained inside the shielded x-ray chamber itself. While in fact radiation dose to Cabinet x-ray inspection machine operators is generally not distinguishable between the doses received from background radiation sources; it is still necessary to understand and apply basic ALARA practices to accomplish the goal of ALARA.

An effective ALARA program must include regulatory compliance, written administrative radiation safety policies and procedures, trained and qualified operators, access controls to prevent unauthorized use of the x-ray inspection machine, routine audits, the testing of safety devices and x-ray machine inspections of not only the machine but also a review of operator use and public interaction and controls during operations.



Routine radiation surveys and inspections of the x-ray inspection machine and radiation surveys of the immediate and adjacent areas surrounding the x-ray machine are required by regulation and they provide the individual responsible for radiation safety with information necessary to evaluate the effectiveness of the Cabinet shielding and identify any potential anomalies that need to be addressed. These can include inspecting for worn or missing curtains, missing warning labels, misaligned access panels or collimator assembly, damaged parts or unlit warning indicator lights. These routine radiation surveys also provide information and documentation to demonstrate compliance with the regulatory dose limits to the x-ray inspection machine operator and all others considered members of the general public.

| | Radiation Safety Training Handout for Cabinet X-Ray Machine Operations in the United States | |
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The most effective actions for any individual to implement during their daily use and operation of the x-ray machine are to apply the three (3) basic methods of dose reduction. These three (3) methods include:

- 1. Minimizing your time around the source of radiation
- 2. Maximize your distance from the source of radiation
- 3. Maintain and utilize all available shielding between you and the source of radiation (Discussed in Lesson 11)

Minimizing Time

Minimizing your time around a Cabinet x-ray inspection machine.

The FDA regulations require X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and at similar facilities, to be provided with a means to insure operator presence at the control panel in a position which permits surveillance of the ports and doors during generation of x-radiation.

During x-ray inspection, when the machine is actually ON and generating x-rays and materials are passing through the machine, x-ray radiation will either be absorbed by the materials, pass right through the materials or scatter off the materials in multiple directions. It is this "scatter radiation" during inspection operations which can escape from the entry and exit access ports. What do most cabinet x-ray inspection machines have attached at each end at these entry and exit access ports? Correct...lead impregnated curtains covering the openings. Cabinets DO NOT typically have shielded curtains, therefore; engineering controls such as covers, extensions, training, warning labels and routine surveys and inspections are necessary to ensure safe operations.

As you increase your distance from the access port openings, exposure rates will decrease quickly to at or near background radiation levels in as little as 1-3 feet (about an arm's length away). Since it is extremely unlikely and certainly NOT recommended the Cabinet x-ray machine operator will be located up close and in front of the access port openings during inspection, the radiation dose from scatter radiation is greater than that of cabinet x-ray equipment.

Be vigilant of other workers loitering near the access port openings during x-ray operations. This location is generally where elevated radiation levels exist as materials pass through the shielded curtains allowing some x-ray radiation to escape the cabinet (i.e., radiation leakage). When there are no curtains, radiation levels will be higher (2-5 mR/hr at 30 cm) so covers, extensions and distance must be used to maintain individual operators' dose ALARA.

Often support staff working with a cabinet x-ray machine at security checkpoints especially, tend to lean directly over the top of the extension shrouds and usually right above the access port openings. Cabinet x-ray operators should ask support personnel to step back from the Cabinet openings during x-ray inspection while x-rays are ON. There is no reason these individuals need to be located that close to the access ports during automated inspection. Non-essential personnel should be asked to move away from the access port openings as good ALARA practice.

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Maximize Distance

The highest exposure rate produced by the baggage and Cabinet x-ray inspection machine is from the **primary x-ray beam located inside the Cabinet at or near centerline INSIDE the inspection tunnel**.

In order to reduce this high exposure rate, manufacturer's provide shielding around the x-ray tube itself, provide shielding (beam stop) for the Cabinet to prevent x-ray radiation from penetrating the Cabinet and some may provide lead impregnated shielded curtains at the entry and exit access port openings to reduce the amount of scatter radiation that may escape the Cabinet.

To ensure individuals reduce and maintain their exposure to radiation to as low as reasonably achievable, manufacturers provide end louvers or access port extensions to prevent people from reaching inside the x-ray machine. These end louvers or extension tunnels provide additional <u>distance</u> away from the primary x-ray beam of radiation within the Cabinet housing.

The general rule of thumb is if you double your distance from a source of radiation, you will reduce your dose by one-fourth. *This is called the inverse square law*.

By maximizing your distance from any source of radiation you will reduce your dose. The dose you could receive from radiation sources like a Cabinet x-ray inspection machine, although very low, can be reduced to at or near background radiation levels by stepping back just one step or keeping an arm's length away from the access port openings. **Never reach inside the Cabinet x-ray inspection machine while x-rays are being produced.**

Engineering Design & Controls

Engineering design and controls are one of the most significant elements of an effective ALARA program. We will discuss these controls in Lesson 11.

LESSON 8 - REGULATORY DOSE LIMITS & MONITORING

Several scientific groups provide information and recommendations concerning radiation safety. These groups include the National Council on Radiation Protection (NCRP), the International Commission on Radiation Protection (ICRP), the International Atomic Energy Agency (IAEA), and the American National Standards Institute (ANSI). These agencies have performed numerous experiments and studies and have determined acceptable dose limits for the occupational radiation worker so no clinical evidence of harm would be expected in an adult working within these limits for an entire lifetime.

The US Nuclear Regulatory Commission (NRC) sets federal radiation dose limits for occupational radiation workers based on the recommendations of the International Commission on Radiation Protection (ICRP Report 103 -2007).

Dose limits are established for external dose and for internal dose. Since baggage and Cabinet x-ray inspection machines contain NO radioactive material, internal dose limits are not applicable and no internal monitoring is necessary or required.

In its 1990 Publication 103 (formally ICRP 60), the International Commission on Radiological Protection (ICRP) **Recommended** dose limits for ionizing radiation.

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The dose limits do not include medical and natural background ionizing radiation exposures and are indicated below.

| | NRC Federal Limits | Recommended Administrative Limits |
|-------------------------------|--------------------|-----------------------------------|
| Whole Body (DDE) | 5 Rem/year | 500 mRem/year |
| Skin (SDE, WB) | 50 Rem/year | 5000 mRem/year |
| Extremities | 50 Rem/year | 5000 mRem/year |
| Lens of the Eye (LDE) | 15 Rem/year | 1500 mRem/year |
| Declared Pregnant Woma | n 500 mRem/term | 100 mRem/term |
| General Public | 100 mRem/year | 100 mRem/year |

Most State regulations for dose limits are the same as the Nuclear Regulatory Commission however, there are still a few that use different dose limits for occupational workers like the pre-1994, and current OSHA limit of 1.25 Rem per quarter limit for the whole body and some States use a 25 milli Rem per week limit. It is very unlikely that any Cabinet x-ray machine operator can exceed any of these dose limits whether it is a weekly limit, guarterly limit or the annual limit provided the x-ray machine is properly operated and maintained.

The facility Radiation Safety Officer is responsible for ensuring no occupational radiation worker, a pregnant occupational radiation worker or any member of the general public exceeds the applicable dose limits for his or her State.

It is recommended the facility Radiation Safety Officer consult with the applicable State regulations or contact the State Radiation Control Agency to determine which dose limits apply. It is also recommended the facility Radiation Safety Officer establish lower administrative dose limits below the regulatory requirements as part of an effective ALARA policy and to ensure no individual exceeds any regulatory dose limits.

The NRC established revised dose limitations to the embryo/fetus of a pregnant occupational radiation worker which went into effect January 1, 1994. The 500 mRem dose limit for the entire gestation period has been a guideline for many years. Now that it is a regulatory limit, in order for a female occupational radiation worker who becomes pregnant to be placed on the 500 mRem limit for the entire term of the pregnancy, the female must voluntarily "declare" her pregnancy in writing. If she does not voluntarily declare her pregnancy in writing, then no additional actions are required by the facility Radiation Safety Officer and there will be no limitations placed on the female occupational radiation worker other than those in place for all occupational radiation workers.

It is recommended that all pregnant occupational workers who routinely work with the industrial Cabinet x-ray machine to inform the facility Radiation Safety Officer so they may, at a minimum, receive additional information and materials published by the Nuclear Regulatory Commission, specifically NRC Regulatory Guides 8.13, NRC Regulatory Guide 8.29 and NRC Regulatory Guide 8.36. These documents may be printed from the following internet link http://www.reirs.com/reg_gds.htm or provided to you by your RSO.

Personal Dosimetry Monitoring Badges

The Nuclear Regulatory Commission's (NRC) federal regulations for the "Standards for Protection Against Radiation" found in 10 CFR 20 (see www.nrc.gov) were revised entirely and each license or registrant was required to fully implement these revisions on or before January 1, 1994. The regulations only require individual monitoring if an occupational worker is likely to receive an occupational dose in excess of 500 mRem in a year. Based on years of historical data, it is unlikely that any occupational worker operating a Cabinet x-ray machine will receive in excess of 500 mRem in a year (average Cabinet x-ray operator annual dose is less than 10 mRem in a year).

Cabinet X-Ray operators typically do not wear nor are they required to wear the personal dosimetry badge since it is very unlikely that any "Cabinet" x-ray operator would meet the regulatory requirements for monitoring (i.e. > 500 mRem/yr).

It is recommended that each facility RSO verify with their State Radiation Control Agency what additional policies they may have regarding dosimetry badging of personnel or possible badging of the immediate and/or adjacent areas around the Cabinet x-ray machine (e.g., Area Monitors) as there are still a few States that require personal dosimetry monitoring which include Kansas, Maryland, Nevada (area monitoring only), New Jersey, North Carolina and South Carolina.



Copper filter Open window Tin filter Imaging filter

Landauer OSL Dosimetry Device

When the Cabinet x-ray machine is operated and maintained properly, it is unlikely a Cabinet x-ray operator could receive a dose in excess of any regulatory limits. If required to be worn, dosimeter badges shall be worn in a location that will record a dose representative of the whole body or *trunk of the body*. Standard practice is to wear the dosimetry device between the neck and the waist in the front of the body or in the area of highest expected dose. *Should you lose your assigned dosimetry badge, you are required to immediately report this loss to your facility RSO.*

If you are issued a dosimetry device for purposes of monitoring and recording your individual occupational radiation dose please note your employer must maintain records of doses received by all individuals for whom monitoring is required. Your employer must furnish to you, upon your written request, an annual written report of your exposure to radiation; and your employer must give you a written report, upon termination of your employment if you request the information in writing.

LESSON 9 – SURVEYS & MONITORING

Federal and State radiation control agency regulations require radiation surveys be performed to evaluate the radiation hazards. They state that each registrant shall make or cause to be made, surveys that--

- (1) May be necessary for the registrant to comply with the regulations; and
- (2) Are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels.

While this regulation provides general guidance, what it means is the registrant needs to perform radiation surveys routinely and as necessary to evaluate the source of radiation to ensure the radiation levels are known and actions are taken as necessary to maintain dose to individuals ALARA. These surveys can also be used to demonstrate compliance with the dose limits for occupational workers and members of the public in lieu of individual dosimetry monitoring badges. It is recommended a *quarterly* radiation leakage emission survey; however, the minimum survey frequency in most States is **ANNUALLY** but *there are a handful of States that require quarterly surveys and safety device testing*.

In order to demonstrate compliance with regulatory dose limits, a general area radiation survey should be performed and documented routinely in the "restricted area" immediately surrounding the Cabinet x-ray inspection machine and a general area radiation survey should be performed in the "unrestricted area" located outside and adjacent to the restricted area.

It is recommended the end user perform, at a minimum, a quarterly radiation leakage emission survey of all external surfaces of the Cabinet x-ray inspection machine and a quarterly general area radiation survey of the restricted area and unrestricted area. These documented surveys meet the intent of both the survey requirements stated above and can be used to demonstrate compliance with all regulatory dose limits in lieu of individual and/or area monitoring using a dosimetry badge.

While the frequency of radiation surveys depends on the conditions of use, performance history and type of x-ray system, the appropriate State Radiation Control Agency defines the required survey frequency.

A radiation survey must be performed when:

- 1. upon installation of the equipment;
- 2. following any change in the initial arrangement, number, or type of local components in the system;
- 3. following any maintenance requiring the disassembly or removal of a local component in the system;
- 4. during the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;
- 5. any time a visual inspection of the local components in the system reveals an abnormal condition; or
- 6. whenever individual monitoring devices show a significant increase over the previous monitoring period, the readings are approaching the radiation dose limits, or a radiation incident has occurred.

Surveys shall be performed by the facility Radiation Safety Officer or authorized designee or by the appropriate radiation protection regulatory authority. Authorized designee's may be permitted to perform radiation surveys provided they are properly trained and approved, in writing, by the facility Radiation Safety Officer.

A radiation survey should include:

- 1. An inspection of all safety devices and radiation shields.
- 2. Radiation measurements over the entire x-ray inspection system that are carried out under simulated worst-case conditions, to ensure compliance with the applicable regulatory limit
- 3. An assessment of occupational and public exposures when stray radiation has exceeded the regulatory limit; and
- 4. A safety and performance assessment of the x-ray inspection system between survey periods by reviewing:
 - a. the most recent survey report specific to the system being surveyed, together with any corrective measures
 - b. recommended and/or instituted on that system or at the facility since the last survey,
 - c. maintenance records that identify which components critical to safety were replaced or repaired, and the
 - d. tests carried out and their results, and
 - e. Reports of radiation exposure incidents or unsafe events or accidents, including the corrective actions implemented.

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| 5. | Survey reports must include the following: |

- Survey reports must include the following:
- a. an identification of the Cabinet x-ray inspection system revealing the system manufacturer, brand name, model number, and date of manufacture
- b. an assessment of the safety devices, radiation shields and the occupational exposure levels to personnel and the general public; and
- specific corrective actions, if any, that are required for compliance, including the completion date.
- 6. After a Cabinet x-ray machine has been decommissioned, all reports of surveys, accidents, radiation exposure incidents and x-ray system misuse must be retained for a period of at least three (3) years by the system owner or designee at the facility at which the x-ray inspection system was lastoperated.

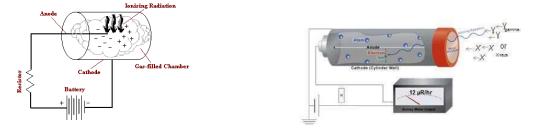
Radiation Detection Instrumentation

Radiation exposure controls used to minimize dose to workers are based on routine inspections of the x-ray inspection machine and from routine measurements obtained with portable radiation-detection instruments. An understanding of these instruments is important to ensure the data obtained is accurate and appropriate for the source and energy of radiation being measured.

The most widely used radiation detectors are devices that respond to ionizing radiation by producing electrical pulses. In gas-filled detectors, the detector is provided with a positively (+) charged anode positioned in the center of the detector internals. The cylinder acts as the cathode and it possesses a negative (-) charge.

Since we know that opposite charges attract and we know ionizing radiation has sufficient energy to cause ionization, negatively charged electrons liberated by the incoming ionizing radiation will migrate towards and be collected on the positively charged anode which results in an electrical charge or current which can be measured.

This unit of measurement is called the **Roentgen** as discussed in Lesson 4.



Ionization chambers are designed to provide a *quantitative measurement* of exposure rate. Baggage and Cabinet xray machine manufacturers typically use an ion chamber to accurately measure the x-ray radiation leakage emissions.

While in fact the ion chamber is the preferred radiation detection instrument to obtain an accurate measurement, one disadvantage of using this type of large volume detector is that for small size beams emanating from the Cabinet x-ray inspection machine, it has been found this type of radiation detection instrument can under respond by as much as 50 percent.

Ion chambers must be calibrated, at a minimum, on an Annual frequency. Calibration should be performed for an appropriate energy range for your x-ray machine which is likely to be approximately 30 keV to 120 keV photon energies. Calibration with higher energy sources like Cesium 137 or Cobalt 60 will likely lead to errors that may be significant.

Most ion chambers are pressurized. In order to ship and/or transport this radiation detection instrument into the United States for calibration, the shipper must be qualified as a "Hazmat Employee" in accordance with Dangerous Goods regulations and the instrument must be properly packaged, marked and labeled.



Ion Chamber – Fluke Model 451P

An alternative to the ion chamber is the energy-compensated Geiger Mueller or **GM detector**. Thin walled Geiger-Mueller (GM) instruments are very useful in making a *qualitative measurement* to identify the location of the largest amount of radiation emission on the external surface. GM meters cannot be adequately calibrated for making *quantitative measurements* of x-ray emission since X-ray produce radiation in a range of different energies.

GM detectors can be most useful in **detecting** x-ray radiation the larger ion chamber could miss. The GM detector readings compare relatively close to the ion chamber readings in uniform radiation fields and can provide a relatively reliable method for detecting x-ray radiation levels. There are no shipping restrictions for the GM detection instrument.



ThermoElectron RadEye Model G20-ER10



Thermo Electron Model FH40GL

Each portable survey instrument should be checked for proper operation *before it is used*.



1. Check the calibration sticker

Radiation detection instruments are required to be calibrated to national standards at least **annually**. Provided with each calibrated instrument is a "calibration certificate". The facility RSO shall retain all calibration certificates for inspection and should ensure a calibration label is affixed to the instrument so the individual performing the radiation survey can verify the instrument has not exceeded the calibration due date. If the date of calibration is more than **twelve** (12) months do not use the survey instrument and turn it in to the facility RSO.

2. Check battery

Turn the instrument ON. Check the battery indicator or verify the Low BAT indicator is not illuminated. Batteries should be changed whether they need it or not twice a year to prevent corrosion and to maintain the instrument in "ready to use" condition at any time. Once the instrument is ON, allow the instrument electronics to "warm up" for 5-10 minutes.

3. Check speaker

If there is an audio switch or speaker button on the detector, turn it to "ON." Although most work environments are noisy, you can hear an increase in radiation levels much quicker than you could observe the increase. If you are looking away from the detector read out and came across an elevated reading, your trained ear would hear the increase and prompt you to look down. It is very easy to miss a small stream of x-ray photons if you aren't watching and/or listening carefully.

4. Check background

Once the instrument has warmed up for a period of 5-10 minutes, note the reading on the instrument. This reading represents the background radiation levels at your facility. With few exceptions, background radiation levels should measure between 4 to 20 microR/hr (μ R/hr).

REGULATORY COMPLIANCE SOLUTIONS TODAY

Buildings constructed of concrete, brick and/or ceramic tiles on the floors and walls could cause a slight elevation in background radiation levels due to the natural occurring radioactive materials within these materials. Always investigate unusual high background readings. Always contact the facility RSO when abnormally low or high background readings are noted.

5. Check physical condition of detector

Radiation detection instrumentation consists of gas filled chambers, soldered wires and electronic parts which are vulnerable to damage. Care must be taken not to drop or knock the radiation detector on hard surfaces. If you see damage like missing screws, cracked meter covers, or missing parts; do not use the instrument. Report the damage to your facility RSO and send the instrument off site for repair. As a general rule, you should always believe elevated radiation measurements until proven unreliable. If you observe unexpected, abnormal or unusually high or low radiation readings or the instrument or unstable or wide fluctuations in the background or other survey readings, do not use the instrument. Send it to the manufacturer or licensed facility for repair and calibration.

6. Test and Measurement

The FDA Radiation Emission Limit contained in 21 CFR 1020.40 states the "Radiation emitted from the Cabinet x-ray system shall not exceed an exposure of 0.5 milli Roentgen in one hour at any point five centimeters outside the external surface". This requirement does not limit the rate of x-ray emission. It limits the total emission possible in any one hour. There are NO FDA radiation emission limits for Cabinets. The manufacturer has provided a radiation profile of the Cabinet. You should contact your facility RSO to review this data.

Consider the factors that will result in the maximum x-ray emission from the external surface of your product when establishing your test program. The system shall be tested at the settings and normal operating conditions resulting in the highest output to assure that this limit cannot be exceeded.

The amount of time x-rays can be on in any one-hour period is called the "duty cycle". The duty cycle is a factor which may be used when determining compliance with the FDA radiation leakage emission limit. X-ray on time can be limited by physical system properties, internal sensors, timers or interlocks.

Total radiation leakage emissions must not exceed an exposure of 0.5 milli roentgen (mR) in one hour even when x-ray on time is at its maximum. However, this gets complicated so we recommend just simply limiting radiation leakage emissions to less than 0.5 mR per hour (< 500 μ R/hr) exposure rate and not worry about how long the unit may or may not operate in one hour.

If the exposure rate is maintained below 500 μ R/hr at 5 cm from all external surfaces then in 1 hour the radiation leakage emission will be below 500 μ R in one hour.

Cabinet x-ray systems with ports often use lead impregnated shielded curtains to reduce radiation leakage emissions. Most shielded curtains are composed of multiple strips of rubber impregnated with leaded material. These strips of shielded material are deflected as items pass through creating intermittent gaps. A cabinet x-ray system with ports covered by shielded curtains must meet the emission limit at the plane of any access port even during an hour when items are being loaded into the system as fast as the system allows. A check of the condition of shielded curtains should be included on the maintenance schedule to assure the system remains compliant with the performance standard.

The facility Radiation Safety Officer should set the rejection limit for the radiation leakage emission test to determine compliance with the emission limit conservatively to account for the inherent error from measurement methods and instrument accuracy.

As a general rule of thumb, move the radiation detection instrument approximately 1-2 inches per second while watching for increases in radiation levels as indicated on the meter face and by the audible response feature, if applicable. When elevated radiation levels are discovered, hold the instrument in place for approximately 15-30 seconds to obtain the largest stable radiation level and then record this level on a radiation survey form. Continue surveying all external surfaces on the front side of the machine, the back, top, bottom and both sides until the unit has been completely surveyed. Record several readings on the radiation survey form noting all elevated radiation leakage emission values above the rejection limit established by the facility Radiation SafetyOfficer.

The facility Radiation Safety Officer or a qualified service provider shall perform all radiation surveys or only those individuals at the facility who have been adequately trained and have demonstrated competence to perform radiation surveys. All facility trained and qualified radiation survey personnel shall be approved in writing by the facility Radiation Safety Officer. These training records shall be retained for State inspection.

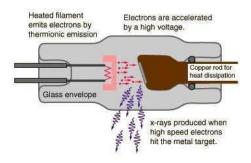
LESSON 10 – PRODUCTION OF X-RAYS

An x-ray generating system requires a source of electrons, a high voltage supply, a means to accelerate the electrons, and a target to stop the high-speed electrons. In 1913, Dr. William Coolidge developed and replaced the cold cathode tube with the hot cathode tube that is still in use today.





A standard hot cathode x-ray tube consists of a cathode with a tungsten filament for generating electrons and a tungsten target embedded in a copper anode that stops the electrons. The filament is located in a concave cup that focuses the electron beam onto a small area of the target called the focal spot. X-rays are directed out of the tube through a small window in the housing called a port. The dimension of the x-ray beam is then limited by a thin collimator which restricts the primary beam size to approximately two to three milli meters (2-3 mm) which is about the thickness of 6-8 sheets of paper.



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HOW X-RAYS ARE PRODUCED

Remember from previous discussions we learned there are NO radioactive materials contained inside an x-ray tube. We also discovered one of the characteristics of x-rays is they are produced outside the nucleus of the atom as electrons "jump" from energy shell to energy shell. Let's now look at how x-rays are produced.

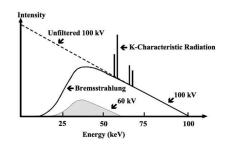
X-rays are produced by two different mechanisms when high speed electrons collide with a metal target in a high vacuum. The x-rays emitted consist of a spectrum of multiple energy photons known as **Bremsstrahlung X-Rays**, which is German for braking radiation.

Bremsstrahlung X-Rays are produced when a *high-speed electron is deflected* from its original course by the nucleus of the metal target, usually tungsten, losing part of its original energy as it slows down or brakes. This loss of energy results in an x-ray photon being produced in order to maintain conservation of energy. The energy of the x-ray photon is dependent on the angle of deflection of the incoming electron and the amount of kinetic energy converted to x-rays, thus producing a continuous distribution of energies.

Bremsstrahlung represents the predominant method of x-ray production in your Cabinet x-ray inspection machine and in medical diagnostic x-ray tubes.

The second type of x-ray produced is called the **K-Shell or characteristic x-ray**. Characteristic x-ray radiation is produced when a *high-speed electron collides* with an orbital electron of the target material. The orbital electron is ejected from the atom creating a vacancy in the electron shell. An electron from a higher energy level falls into this vacancy releasing the excess energy in the form of a characteristic x-ray photon.

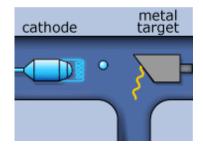
Characteristic x-ray radiation is important in research because each element produces a characteristic spectrum that can be used to identify unknown samples. This forms the basis of x-ray florescence analysis.

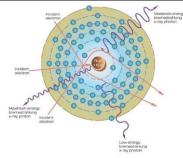


Electrons are produced at the cathode by applying a high voltage to the x-ray tube and *heating the tungsten filament to incandescence* much like when you turn the power on to a common household light bulb. The number of electrons is controlled by adjusting the temperature of the filament. The amount of charge flowing per second to the cathode is the **current**, expressed in milli amps (mA). If you increase the current of the x-ray tube, you will increase the **number** of x-ray photons produced.



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The liberated electrons from the cathode are accelerated towards the positive anode by a high voltage potential. This potential difference is expressed in kilo voltage (kV). Since the voltage across the tube may fluctuate it is usually expressed as peak kilo voltage (kVp).

If you increase the voltage of the x-ray tube you will increase the **energy** of the x-ray photon produced. This also increases the penetrating power of the x-ray photon through a material. The maximum peak kilo voltage represents the maximum energy of any x-ray emitted from the x-ray tube.

The average energy of the photons in the beam is approximately one-third the peak kilo voltage. Adjusting the kVp to 60 for example, will produce an x-ray beam having a maximum energy of 60 keV with an average energy of approximately 20 keV. Typically greater than 99 percent of the energy carried by the electrons will be converted to heat and absorbed by the target with the remaining 1 percent producing x-rays. The target is cooled with water or oil to prevent melting.

If no power is supplied to the x-ray generator, NO x-ray photons can be produced. Just like a light bulb, when you flip the switch ON, visible light is produced. When you flip the switch to OFF, you secure the power source thereby immediately securing the visible light.

Baggage and Cabinet x-ray inspection machines produce x-ray photons only when power is ON and supplied to the x-ray tube. When the power to the x-ray tube is OFF, there can be no x-ray production and therefore it is safe to access the inside of the Cabinet x-ray inspection machine when the power is OFF and all X-RAY ON indicators are not illuminated. There is NO residual x-ray radiation present in the Cabinet tunnel and there is NO waiting time before you can access the Cabinet or Cabinet tunnel, the X-Rays are non-existent without power to the x-ray tube.

LESSON 11 - X-RAY INSPECTION MACHINE DESIGN FEATURES

A Cabinet x-ray inspection system is a machine that is specifically designed to generate x-rays in the low- to-medium keV energy region for use in inspection screening operations.

To reduce the possibility of unsafe acts, the following minimum guidelines apply to all facilities utilizing Cabinet x-ray inspection systems:

- No person must commit any acts that cause unsafe events on an x-ray system when it is in operation. Lifting the lead drapes for any reason when the x-ray beam is on or exposing any part of the body to the x-ray beam or covering the x-ray ON lights or x-ray warning signs are examples of unsafe events.
- Although an x-ray inspection system may be specifically installed or arranged to prevent lifting the lead curtains or to prevent access to the entrance and exit openings of the irradiation chamber, appropriate safety warnings must be legible and in clear view at the point where items are initially presented for x-ray screening.

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- No person must create physical or mechanical conditions that ultimately make the x-ray inspection system unsafe to operate. Defeating safety devices, placing liquid-filled containers on an x-ray inspection system, positioning x-ray inspection systems in confined spaces for carrying out routine maintenance and operational test functions, and positioning x-ray inspection systems for use in areas exposed to rain or snow are examples of hazardous conditions.
- Operators and maintenance personnel must forbid unauthorized individuals from remaining near an x-ray inspection system longer than is warranted.

Warning Lights & Labels

The FDA requires two (2) independent means which indicate when and only when x-rays are being generated and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. All other indicators shall be legibly labeled "X-RAY ON". At least one indicator must be visible from each door, access panel, and port.





Manufacturers shall place identification information on their Cabinet x-ray system which is either permanently affixed as a tag or a label or inscribed on the product. This information must be legible, should be written in English, and It is recommended that radiation warning labels and manufacturer labels be placed on the front of the control panel in direct view of the operator. The identification information must include:

- 1. The full name and address of the manufacturer.
- 2. The place of manufacture.
- 3. The month and year of manufacture. The month and year must not be abbreviated.

| | R'SIDENTIFICATION & ATION LABELS |
|-------------------------------------|---|
| 21 CFR 1010.3 Identification | FULL NAME AND ADDRESS |
| 1. The full name and address of the | he manufacturer. |
| 2. The place of manufacture. | Senial No. Fuse 🕀 AT |
| 3. The month and year of manufa | icture. Mig. Dute MONTH & YEAR |
| The month and year must no | ot be abbreviated. |
| | EXAMPLES |
| 21 CFR 1010.2 Certification | This product has been tested and hereby certified to comply with the U.S. FDA Cabinet X-Ray Performance Standard contained in 21 CFR 1020.40. |
| all applicable standards. The cer | a certification that such product conforms to tification shall be in the form of a label or scribed on such product so as to be legible |
| | nen the product is fully assembled for use. All |

21 CFR 1010.2 Certification

Every manufacturer shall furnish a certification that such product conforms to all applicable standards. The certification shall also be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use. All such labels or tags shall be in the English language.

The remaining required two labels include a permanently affixed or inscribed on the Cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement:

Caution: X- Rays Produced When Energized

| CAUTION X-RAYS PRODUCED WHEN ENERGIZED | |
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| | |

A permanently affixed or inscribed on the Cabinet x-ray system adjacent to each access port a clearly legible and visible label bearing the statement:

Caution: Do Not Insert Any Part of the Body When System is Energized X- RayHazard



Key Control to Prevent Unauthorized Use

A key actuated control is recommended to ensure that x-ray generation is not possible with the key removed. When the Cabinet x-ray inspection machine is not in use it is required the key be removed and maintained by the facility Radiation Safety Officer or designee to prevent unauthorized use.





Do not change the key tumbler to allow removal of the key or change to a toggle switch. Do not snap the key off to leave it in the ON position or glue the key in place. These actions have actually taken place at installations where cabinet x-ray inspection machines are operated and likely the same holds true for Cabinets unfortunately.

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Emergency Stop Buttons

A control or controls to initiate and terminate the generation of x-rays other than a safety interlock or the main control panel is required. This is typically accomplished by adding Emergency Stop buttons to the machine and which are accessible to the operator in the event an individual intentionally or unintentionally reaches inside the access port openings or someone doesn't remove their baby from a car seat before passing both through the x-ray machine. Yes, this has happened several times as well.



Ports and Apertures

The insertion of any part of the human body through any port or aperture into the primary beam shall not be possible.



This requirement is intended to prevent accidental and routine operator exposure to the primary x-ray beam. Insertion of any body part into a port must not be a standard operating procedure. Contorting to reach into, crawling into, or riding through the port into the system are *strictly prohibited*.



This is an actual cabinet x-ray image of a Flight Attendant intentionally passing through an x-ray inspection machine. This is NOT a safe practice. A trained x-ray operator assisted her during this scan. Without the assistance of the x-ray operator this image could not have been obtained due to the safety features and controls of the cabinet x-ray machine. The dose to this person was likely between 3 - 5 mRem for this single scan. This is NOT ALARA.

There are numerous means to meet this requirement. A system with a straight tunnel that is at least 36 inches from any port to the primary beam complies with this requirement. A system with a straight tunnel less than 36 inches from any port to the primary beam should have some means other than distance to make the primary beam difficult to reach.

One example includes incorporating photoelectric sensors placed so they are unlikely to be triggered by someone in a normal posture reaching into the Cabinet. Another example is locating system ports lower (near the floor) or higher (at head height) than is conventional. Integrating the system into a production line where the products being examined move fast enough to limit access to the access port itself is also an acceptable method of meeting the requirement.





Shielding Materials

Shielding materials like stainless steel, carbon steel, lead sheet and lead impregnated curtains are used throughout a Cabinet x-ray inspection machine with the primary purpose of reducing the radiation levels on all external surfaces of the Cabinet x-ray device to as low as reasonably achievable which is usually at or near background radiation levels.





Most Cabinet x-ray machines are manufactured for throughput and are equipped with an entry and exit access port. The areas likely to have increased radiation levels above background levels will be at the *access port openings*.

Access Port Opening



IF YOUR CABINET X-RAY INSPECTION MACHINE IS EQUIPPED WITH LEAD IMPREGNATED CURTAINS, DO NOT REMOVE THEM, DO NOT TRIM THEM, DO NOT CUT THE SHAPE OF THE PRODUCT OUT, AND DO NOT TAPE THEM OFF TO THE SIDE OR OVER THE TOP. YOU MUST MAINTAIN THESE CURTAINS IN GOOD CONDITION WITH NO MISSING CURTAIN STRIPS OR GAPS ALLOWED. X-RAY RADIATION WILL EXIT THROUGH THESE GAPS.

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This actually happens frequently, and this is why individuals can receive higher radiation doses. Removing or altering shielding materials provided by the manufacturer is a serious safety violation and a regulatory offense. Always report potential radiation safety violations or issues to your facility RSO. If he/she does not correct the problem immediately, you have the right to contact your State Radiation Control Agency.

Safety Interlocks

Safety Interlocks are an extremely important part of any Cabinet x-ray machine. These interlocks prevent individuals from reaching into or being exposed to the primary beam of x-ray radiation. The primary beam can emit high radiation exposure rates orders of magnitude higher than what is allowed on the external surfaces of the machine.

Following interruption of x-ray generation by the functioning of any safety interlock, the use of a control shall be necessary for resumption of x-ray generation. In other words, if you opened an access panel or a door during x-ray generation, the x-ray generator will shut down. When you close the access panel or door, the Cabinet x-ray inspection machine cannot start automatically. There must be a control which requires operator action to reset and/or resume x-ray generation.

I have personally witnessed several end users who intentionally operate their Cabinet x-ray inspection machines with the safety interlocks bypassed or disabled allowing individuals access to the internals of the machine while x-rays are ON. Those individuals who are not trained or who are unaware of the safety interlocks and other warnings could potentially access the internals of the machine for clearing a jam, maintenance or cleaning and could indeed receive a large dose in a short period of time since the bypassed interlock would not secure x-ray generation.

Maintenance department personnel particularly need to understand the importance of maintaining the safety interlocks in full working condition at all times. The facility RSO should test the safety interlock system and **perform a full x-ray machine safety inspection, at a minimum, once per quarter** and document the results of this inspection. Each State specifies how often safety interlocks must be tested.

Massachusetts is Monthly, other States require Quarterly safety interlock testing like Florida, Idaho, Iowa, Kansas, Louisiana, Maine and Ohio. Alabama, Arizona, Colorado, Connecticut, Kentucky, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, and Virginia are every 6 months for each radiation emitting device. All other States have an annual testing requirement.

If there is a need to override or temporarily bypass a safety interlock for maintenance or repair, written authorization from your facility RSO should be obtained prior to. At the end of the maintenance or repair, the facility RSO shall be notified and the system tested again. If the x-ray machine malfunctions, for whatever reason, you should always contact the manufacturer.



SAFETY DEVICE OR INTERLOCK IS CURRENTLY BYPASSED AND NOT WORKING

LESSON 12 – X-RAY OWNER & OPERATOR RESPONSIBILITIES

X-ray Inspection System Operators

All operators of Cabinet x-ray inspection systems are required to:

- 1. Receive training, authorized by the system owner or designee, on the operation and x-ray safety relevant to the x-ray inspection system(s) intended for use;
- 2. Demonstrate their competence in the operation and general maintenance of the system;
- 3. Read and understand the proper operating and maintenance procedures prescribed by the system manufacturer before operating the inspection system;
- 4. Stop the operation of the x-ray inspection system, if any radiation accidents and/or unsafe events occur, and immediately notify the facility RSO of such conditions; and
- 5. Acknowledge that persons who operate an x-ray inspection system are responsible for carrying out the work in a safe manner to ensure their own protection and that of others.

X-Ray Inspection Machine Operator Safety Features, Controls and Indicator Checklist

The following recommended safety features inspection consists of visual and physical checks of the x-ray machine to ensure safe operation. These checks should be performed on a routine frequency at startup.

- Check the Inside of the Tunnel to ensure it is free of materials.
- Check all Service Panels are closed and locked.
- Check the Service Panels have not been tampered with.
- Check that no lead curtains are torn or missing, and they are hanging straight down.
- Check the outside of the machine for loose, cut or hanging wires.
- Check all video monitor connections are tight and power cord is plugged in.
- Check the circuit breaker switch is set to the ON position.
- Check all Emergency Stops are released and in the normal out position.
- Verify the Power ON capture key is placed in the ON position and lightly pull on the Key to ensure it cannot be removed in the ON position.
- Verify the POWER ON indicator lights are illuminated.
- Check the conveyor belt for alignment, tears and/or sharp protrusions at the sides of the belt and joint connections.
- Scan a Test Bag or Product and Verify all X-RAY ON indicator lights are illuminated.
- Scan a Test Bag or Product and Depress the E-Stop buttons and verify the X-RAY ON lights deenergize AND the conveyor belt stops.
- If the x-ray system is equipped with an Operator Presence device like a foot mat, Scan a Test Bag or Product and Step OFF the foot mat or whatever means required to deactivate the operator presence device. Verify the X-RAY ON lights de-energize AND the conveyor belt stops. (The operator presence device is generally required when x-ray machines are operated and accessible to the general public, such as an airport security check point).

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Emergency Response for Unintentional Radiation Exposures

- 1. Unintentional exposure to radiation may be caused by equipment failure or human error or a combination of both. Radiation accident victims must receive prompt medical attention by a physician. In addition, the root cause of the incident must be investigated, and remedial measures taken to prevent recurrence at the facility.
- 2. To address such situations, the facility is responsible for developing an emergency response plan and having the capabilities to implement the plan.
- 3. Personnel must be trained to handle emergency equipment and to follow written procedures.
- 4. The plan should be tested and validated, and deficiencies identified and corrected.
- 5. The facility needs to liaise with the various personnel identified in the emergency procedures.
- 6. As a guide, the generic emergency response plan should include:
 - **Response Initiator**: A person who initiates the response and performs actions to mitigate the accident at the scene. Usually this is the attendant x-ray operator or the first responder on the scene.
 - **Emergency Response Manager**: A person, who is in charge of the overall plan, manages the priorities and ensures protection of other workers, emergency workers and the public. This person could be a safety officer or manager or senior staff member in the facility.
 - **Radiological Assessor**: A person who is responsible for conducting radiation surveys and dose assessment, and for providing radiation protection support to emergency workers and advice to the facility. This person is usually the RSO or a hired consultant with relevant expertise.

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Emergency Procedures

Accidental exposure: Accidental exposure is considered to be unintentional x-ray exposure to any part of the human body. This can occur if safety and operational procedures are not followed or if the equipment is not properly installed or serviced.

Measures to be taken in the event of accidental or suspected exposure to x-rays:

1. The X-RAY MACHINE OPERATOR shall:

- a. Turn off the x-ray machine and disconnect the power;
- b. Record names of all personnel that might have been exposed;
- c. Contact the Supervisor/Chief Security Officer immediately and report the incident, and the Supervisor/Chief Security Officer will ensure that staff exposed will be immediately dispatched to the emergency room of the hospital indicated below to be seen by the radiation oncologist on duty.

Name of hospital or health care facility: ______ Telephone number:_____

It is the duty of the individual(s) accompanying the exposure victim(s) to the hospital /health care facility to advise the attendant medical staff that accidental exposure to X-rays has occurred. The hospital/health care facility emergency staff should then undertake the protocol for post exposure to ionizing radiation.

- 2. The Supervisor/Chief Security Officer will immediately initiate an accident investigation, file a preliminary report with the regulatory authority that has jurisdiction of the facility in which the x-ray machine is located as soon as sufficient details about the accident become available and prepare a final report.
- 3. The contracted maintenance service provider, ______, shall be contacted and requested to check the machine, participate in the investigation and, if necessary, service the machine accordingly.
- 4. The x-ray machine owner shall:
 - a. Ensure a complete investigation is carried out and appropriate corrective measures are immediately implemented; and
 - b. Ensure a copy of the completed investigation report which shall incorporate the corrective measures is sent within 5 calendar days of the incident to the State Radiation Control Agency.

Note: The user should complete the blanks in the preceding emergency procedures specific to the facility, hospital/health care facility, and contracted maintenance provider. In addition, the information about the personnel named therein must be current. It is the responsibility of the equipment owner to ensure all operators and operators' Supervisor adhere to the emergency procedures.

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Cabinet X-Ray System and X-Ray Generator Disposal

Prior to disposition, the facility Radiation Safety Officer is required to contact the State informing them of the intent to dispose of the registered Cabinet x-ray machine. Until this notification is made, the regulatory authority shall consider the Cabinet x-ray machine to be operational and all regulatory requirements remain applicable.

Prior to disposal, the Cabinet x-ray system must be rendered inoperable, which means disabling the equipment so ionizing radiation cannot be produced. This can be accomplished by removal of the x-ray generator, severing the power cord to the x-ray generator, removal of the control unit and power supply, etc.

Cabinet x-ray machines consist of hazardous materials such as lead, x-ray tube cooling oil, and computer monitors (eWaste). The x-ray tube may contain beryllium metals incorporated in the x-ray tube itself. All of these hazardous materials must be properly recycled or disposed of through a licensed or registered waste management company, licensed land disposal facility and/or certified electronic product recycler.

The x-ray generator, computer, monitor, cables and all printed circuit boards should be removed, leaving the metalwork and drapes. The x-ray tube window shall be investigated to determine whether or not it contains beryllium and if it does, special disposal procedures must apply since beryllium presents a toxic ingestion or inhalation hazard; the vacuum in the x-ray tube must be breached. Care MUST be taken to prevent inhalation, ingest and skin contact with the x-ray tube internals. Gloves shall be worn, and the x-ray tube contained and packaged when breaching the vacuum tube to prevent inhalation, ingestion and skin contact.

The transformer oil contained inside the x-ray generator "tank" contains non-PCB bearing oil used to cool the x-ray tube during operation. If the x-ray generator contains oil, this oil must be drained, collected and disposed of in accordance with pertinent environmental legislation; and/or recycled at a local oil recycling facility. The cooling oil is NOT radioactive.

All materials that contain lead bearing materials such as lead impregnated drapes, leaded components within electronic components; lead sheet used for shielding and in some cases leaded materials sandwiched between stainless steel panels. All lead and leaded materials and components which contain lead shall be recycled by a licensed local recycling or land disposal facility.