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A. Principles of Design, Operation

1. X-ray Tube

The generation of x-rays for use in analytical x-ray equipment is accomplished by the collision of high energy electrons with a metal target in a vacuum tube. Figure 1 illustrates the basic design of an x-ray tube.

Figure 1

A high voltage is applied between the cathode and anode in the x-ray tube. Electrons are stripped off of the electrically heated cathode by the high voltage between the cathode and anode and are accelerated toward the anode where they collide with a metal target. A variety of metals are used as target material including tungsten, iron, gold, chromium, cobalt, molybdenum and copper. The collision produces heat and also x-rays which are directed out of one side of the tube. When the high voltage to the x-ray tube is turned off x-ray production ceases.

The collision between the accelerated electrons and the anode target produces x-rays by two atomic processes. In the first process known as bremsstrahlung (also called white radiation), x-rays are produced by the rapid deceleration of electrons as they interact with the coulombic field of the nucleus of the atoms of the metal target as shown in Figure 2. The x-rays produced by this process range in energy from zero to the maximum energy of the accelerated electron (e.g. 100 keV).

Figure 2

In the second atomic process, shown in Figure 3, the bombarding electrons ionize the K-shell orbital electrons of the anode target atoms. The vacant orbital in the target atom is then filled by an L-shell or M-shell orbital electron with the release of "characteristic x-rays" whose energy is equal to the difference in energy between the L or M shell and the K-shell of the target atom (e.g.
20 - 30 keV). An L to K shell transition is referred to as a $K_\alpha$ transition and the associated x-ray that is released is referred to as a $K_\alpha$ x-ray. An M to K shell transition is referred to as a $K_\beta$ transition and the characteristic x-ray which is produced is referred to as a $K_\beta$ x-ray. Since the energy difference between the M and K shell is greater than the energy difference between the L and K shell, the $K_\beta$ x-ray has greater energy than the $K_\alpha$ x-ray.

Figure 3

The type of anode material used depends on the photon energies required for the specific application. For example, some applications such as radiography require higher energy photons that will penetrate dense or thick material, while other applications such as x-ray diffraction analysis require low energy photons.

Since x-ray tubes generate heat, a method of heat removal is required to avoid damaging the tube. To prevent heat damage to the anode, the target material generally has a copper base which provides excellent heat conduction away from the anode. The heat that accumulates in the x-ray tube is removed by a water cooling system.

X-ray tubes that are designed to have high radiation output also have rotating anodes which help distribute the heat over the entire anode surface to prevent pitting and damage to the anode. Because of the high radiation output, these systems require less time to radiograph or analyze a sample. However, the advantage of reduced radiography or analysis time is somewhat offset by the increased radiation hazard from this type of equipment and the additional protective measures that are required.

2. X-ray Diffraction Equipment

X-ray diffraction analysis is based on the principle that x-rays can undergo elastic collisions with atoms - known as Thomson and Raleigh scattering - which change the direction of the x-ray photon without changing its energy. The change in the direction of the x-ray photon depends in a complex way on the target atom and its structural relationship to other atoms in the sample. Different compounds produce different x-ray diffraction patterns and by analyzing the type of x-ray diffraction pattern produced, the structure and identity of the material under analysis can be determined. Figure 4 shows a diagram of the typical components of an x-ray diffraction system.
The x-rays which are produced are sent through a device called a goniometer which consists of a shutter, attenuation filters, a sample chamber, and a mechanism for rotating the sample in an arc relative to the x-ray beam. As the x-ray beam strikes the sample it is diffracted at discrete angles characteristic of the material in the sample. The specific angles of diffraction are determined by a detector connected to an arm on the goniometer which rotates the detector in an arc around the sample. The detector sends an electronic signal to a data processor whenever radiation is detected. The data processor in turn, produces a spectrograph of radiation pulses versus angle of rotation and this can be compared to a spectral library to determine the structure and identity of the sample.

X-ray diffraction analysis typically makes use of the mono-energetic $K_{\alpha}$ x-rays. X-rays of other energies such as the $K_{\beta}$ and white radiation (Bremsstrahlung radiation) interfere with the analysis process. Since white radiation increases with the atomic number of the target used, use of a lower atomic number target such as cobalt or chromium will produce less white radiation than would be produced by a higher atomic number target such as tungsten or gold. The white radiation that is produced can be further reduced by the use of filters that selectively attenuate this radiation. Unwanted $K_{\beta}$ x-rays can be eliminated from the diffracted beam by using a monochromator placed between the sample and the detector which splits the $K_{\alpha}$ from the $K_{\beta}$ x-rays based on their different diffraction angles from a crystal within the monochromator. In this manner, only $K_{\alpha}$ x-rays are directed toward the detector.

To reduce radiation exposure to the operator from radiation scattered off the sample and other components in the beam line, the sample chamber and beam line are enclosed within metal covers and conduits which prevents radiation leakage from inside of the goniometer. Another design feature which protects the operator from both scatter and direct radiation are shutters that block the primary x-ray beam from reaching the sample chamber when it is open during sample replacement.

The $K_{\alpha}$ and $K_{\beta}$ x-rays are relatively low energy photons (< 30 Kev) and are easily attenuated by most metals. Although lead is the best type of material for attenuating photon radiation, lower atomic number material such as steel can be used for lower energy x-rays provided the radiation intensity is not too high such as in areas of scattered radiation. However, if shielding is required to stop or attenuate the high intensity, direct x-ray beam lead will be required.
Another design feature which protects the operator from radiation exposure is a transparent, lead acrylic enclosure around the diffraction equipment which has sliding doors interlocked with the power supply for the x-ray tube to prevent inadvertent access to high radiation areas. If the sliding doors are opened while the x-ray tube is energized or the shutter is open, a magnetic switch on the door is activated which automatically shuts off the x-ray tube. This interlock feature can be defeated using a key switch on the control panel during times when the beam must be left on while the operator is inside of the enclosure such as during beam alignment. However, having a removable key to operate the switch provides a measure of administrative security over this interlock.

3. X-ray Spectrometers

Whereas x-ray diffraction equipment is used to determine the microstructure of matter, x-ray spectrometers are used to determine its elemental composition. This is based on the fact that each element produces a distinct fluorescence spectrum when exposed to x-rays. X-rays are absorbed by electrons in the inner K and L shells of atoms which causes electrons to be ejected from the atom (ionization) and results in vacant inner orbitals. Fluorescence is the emission of photons following electron transitions from high energy to vacant low energy orbitals of the ionized atom. Figure 5 illustrates this principle.

![Figure 5](image_url)

Each element produces a spectrum of fluorescence photons which is characteristic of the element and which can be used to identify the element. The energies of the photons emitted from the sample are determined using a radiation detector connected to a multi-channel analyzer. The radiation detector converts the photons emitted from the sample into pulses of electrical current. The size of each electrical pulse produced is proportional to the energy of the emitted photon and by separating the electrical pulses according to their size the system's digital analyzer determines the energy spectrum of the radiation emitted from the sample undergoing fluorescence.

Unlike x-ray diffraction equipment which requires low energy, mono-energetic x-rays for analysis of the compound, x-ray spectrometers utilize polyenergetic x-rays to excite and ionize atoms in the sample to be analyzed. This allows for a somewhat simpler design in that the elimination of x-rays of certain energies is not required as it is for x-ray diffraction analysis. However, the disadvantage is that any scatter or leakage radiation will also consist of higher energy, more penetrating x-rays that will require lead as the shielding material. The use of other types of material such as iron or aluminum will not be as effective in shielding x-ray spectrometers as it is for shielding the low energy x-rays used in x-ray diffraction equipment.
To reduce the hazard from the high energy x-rays, x-ray spectrometers have a lead shielded, closed design that eliminates the need to gain personal access to the x-ray beam. Overall, this makes x-ray spectrometers somewhat safer than x-ray diffraction equipment, where close access to the beam is possible.

4. Cabinet X-ray Equipment

Cabinet x-ray equipment is used to determine the existence of inhomogeneities in the structure of a sample. This is generally accomplished by taking a radiograph of the sample using x-ray film, although other imaging techniques may also be employed.

When x-ray film is used, the sample is placed between the source of x-rays and the film and an image of the sample is taken on the film. Any inhomogeneities in the sample will appear on the film as light or dark spots depending on the difference in x-ray absorption between the inhomogeneity and the rest of the sample. For example, cracks in the sample will allow more radiation to pass through and this will be seen as a dark spot on the film since the degree of film darkening is proportional to the degree of radiation exposure on the film.

Cabinet x-ray equipment generally have a box-like design consisting of the following components:

- shielded interior cabinet
- x-ray tube
- beam collimator
- imaging element
- shielded access doors and panels
- control panel which includes
  1. key switch to enable energizing the x-ray tube
  2. on/off switch for x-ray production
  3. "power-on" warning light
  4. "x-rays-on" warning light
- safety interlocks on the door and exterior panels

In order to penetrate relatively thick or dense samples such as rock or pieces of metal, intense, high energy x-rays must be used to take the radiograph. This also means that more lead is required to shield the equipment which would otherwise leak radiation to the surroundings. However, cabinet x-ray equipment must be designed to meet minimum standards of radiation leakage and generally this equipment will not pose a radiation hazard to the operator if maintained properly.

The main concern is that access to the interior of the cabinet must be prevented while a specimen is radiographed thereby preventing exposure to the direct beam. This is accomplished by designing the equipment with an electrical interlock which prevents x-rays from being generated while the cabinet door is open - similar to the system used on microwave ovens.
B. Safety Requirements

The primary hazard of analytical x-ray equipment is the ionizing radiation produced by this type of equipment and the potential for biological damage as a result of exposure to x-rays. Therefore, most of the safety requirements that are implemented are related to preventing exposure to x-rays produced by the equipment. There are two types of safety requirements associated with this type of equipment including:

- design safety requirements
- administrative safety requirements

The following paragraphs describe these safety requirements.

1. Design Safety Requirements

The design safety requirements for analytical x-ray equipment are specified in the Radiation Emitting Devices Regulations (Reference 4) and also in Health Canada Safety Code 32 (Reference 5). Table 1 identifies the design safety requirements for all existing x-ray diffraction, x-ray spectrophotometer and cabinet x-ray equipment.

<table>
<thead>
<tr>
<th>Item</th>
<th>Engineering Control</th>
<th>X-ray Diffraction</th>
<th>X-ray Spectrometer</th>
<th>Cabinet X-ray</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A label exists on the control panel with the x-ray warning symbol and the words: “Caution x-rays. This equipment produces high intensity x-rays when energized. To be used and serviced by qualified personnel only.”</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>2</td>
<td>A label exists on the external surface of any enclosure door or access panel with the x-ray warning symbol and the words: “Caution, X-rays - Attention, Rayons X”</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>3</td>
<td>Controls, meters, lights and other indicators are readily discernable and clearly labelled as to function.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>4</td>
<td>There are separate fail-safe lights to indicate when the x-ray tube is energized and when x-rays are being produced.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>5</td>
<td>Warning lights exist to indicate the open/shut status of radiation aperture shutters.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>A beam limiting device exists for cabinet x-ray equipment to align the beam with the detector.</td>
<td>-</td>
<td>-</td>
<td>x</td>
</tr>
<tr>
<td>7</td>
<td>A control panel exists that regulates the x-ray tube.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Item</td>
<td>Engineering Control</td>
<td>X-ray Diffraction</td>
<td>X-ray Spectrometer</td>
<td>Cabinet X-ray</td>
</tr>
<tr>
<td>------</td>
<td>------------------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>--------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>8</td>
<td>An &quot;on/off&quot; switch to energize the control panel exists with warning lights to indicate when the control panel is energized.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>9</td>
<td>A key actuated switch exists that prevents x-ray production when the key is removed.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>10</td>
<td>An &quot;on/off&quot; x-ray switch exists for each x-ray tube.</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>X-ray tubes not in use are either disconnected or removed.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>12</td>
<td>Unused beam ports are permanently blocked-off with lead.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>13</td>
<td>Unused shutters are secured to prevent casual opening.</td>
<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Radiation aperture shutters remain closed when not in use.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>15</td>
<td>Positive operator action is required to open a radiation aperture shutter.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>16</td>
<td>Radiation aperture shutters are equipped with an interlock in the operating mechanism.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>17</td>
<td>For equipment operating under an open beam configuration access to the radiation field must be restricted by some means such as a physical enclosure.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>18</td>
<td>Enclosures surrounding equipment with open beams have sliding doors or similar access openings.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>19</td>
<td>Enclosures surrounding equipment with open beams have an automatic shut-off or audible alarm when any sliding door or access opening is not in the closed positions.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>20</td>
<td>An enclosure surrounding equipment with open beams attenuates the radiation level to 0.5 mR per hour or less at 5 cm from its external surface.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

x required  - not applicable

In addition to the requirements specified in Table 1 which are applicable to all x-ray equipment, any x-ray equipment which was manufactured after 1981 when the Radiation Emitting Devices Regulations came into effect, must also comply with the requirements specified in Table 2.
Table 2. **Required Safety Features - equipment manufactured after 1981**

<table>
<thead>
<tr>
<th>Item</th>
<th>Engineering Control</th>
<th>X-ray Diffraction</th>
<th>X-ray Spectrometer</th>
<th>Cabinet X-ray</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The make, model, serial number, date and country are indicated on the control panel and accessories.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>2</td>
<td>Where a radiation aperture must be opened in order to set up or align the equipment, a visual and audible indicator warns the operator that the radiation aperture is open for the duration that it is open.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>Indicators and meters of tube voltage and current exist for each x-ray tube.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>A timing device exists for each x-ray tube.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>The radiation beam is contained within protective shielding that is equipped with an interlock.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>6</td>
<td>Radiation aperture shutters can be removed only with special tools.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>7</td>
<td>Radiation aperture shutters are designed with protective shielding.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>There are labyrinth-type joints, couplings or interfaces between radiation apertures, shutters, protective shielding, beam limiting devices and accessories.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>9</td>
<td>Interchangeable filters have interlocks or other means to ensure that insertion or removal of those filters is possible only when x-rays are not being produced.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>10</td>
<td>Interchangeable filters have filter slots that are covered by protective shielding when they are not in use.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>11</td>
<td>Accessories supplied by the manufacturer contain information that sets out the specific analytical x-ray equipment for which the accessory is designed.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>12</td>
<td>Accessories supplied by the manufacturer have information that indicates the design and specification of couplings, fittings, interfaces and parts necessary for the installation and functioning of that accessory.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>Item</td>
<td>Engineering Control</td>
<td>X-ray Diffraction</td>
<td>X-ray Spectrometer</td>
<td>Cabinet X-ray</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>--------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>13</td>
<td>Accessories associated with the production, collimation, transmission or detection of x-rays shall be contained within protective shielding that prevents the radiation beam from touching any part of the operator's body.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>14</td>
<td>Accessories associated with the production, collimation, transmission or detection of x-rays shall be equipped with an interlock.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>15</td>
<td>Radiation does not exceed 0.5 mR per hour at a distance of 5 cm from any accessible external surface of any x-ray tube housing, beam-limiting device, protective shielding or accessory. (For cabinet x-ray equipment this may be averaged over 10 cm²).</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>16</td>
<td>X-radiation does not exceed 0.5 mR per hour at a distance of 5 cm from any radiation aperture, shutter or filter slot that is in the closed position.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>17</td>
<td>X-radiation does not exceed 0.5 mR per hour at a distance of 5 cm from any point on the housing of the high-voltage generator.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
<tr>
<td>18</td>
<td>Instructions from the manufacturer as to the installation, interconnection, testing, operation and maintenance of the equipment and its accessories or replacement components are available.</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>19</td>
<td>Information from the manufacturer on the recommended accessories and replacement components is available.</td>
<td>x</td>
<td>x</td>
<td>-</td>
</tr>
</tbody>
</table>

x required - not applicable

2. Administrative Control Measures

In addition to design safety features, administrative control measures (operational and maintenance) are important for establishing a safe work environment around x-ray equipment. For equipment manufactured prior to the establishment of the Radiation Emitting Devices Regulations (1981) some of the design safety features that are found in newer equipment may not exist in the older equipment and it is imperative in that case that administrative control measures be implemented to establish an equivalent level of safety with the older equipment.

In general, the three ways that radiation exposure can be reduced include; minimizing the exposure time, increasing the exposure distance and the use of shielding. The following paragraphs provide some specific information on how these principles can be applied in the use of analytical x-ray equipment.
(a) General safeguards

In order to achieve an acceptable level of protection, x-ray facilities must include the following safeguards:

- Allocate a room, or portion thereof, in order to isolate the x-ray equipment.

- Permanently affix on the entrance door either of the x-ray warning signs shown below:

![X-ray Room Sign](image1)

- Access to the room housing the x-ray equipment must be restricted to equipment users and authorized personnel whenever the x-ray equipment is in use.

- For operations not requiring constant user supervision or surveillance, the analytical equipment must be adequately secured to prevent access by unauthorized individuals.

- Personnel must not expose any part of the body to the primary beam. If and when alignment of analysis accessories requires the use of an open x-ray beam, specific precautions must be exercised to reduce or eliminate radiation exposures to the extremities and other parts of the body. Long-handle forceps or remote handling devices, low x-ray tube current and fluorescent beam-definers of higher radiation sensitivity should be employed.

- While it may be necessary under some circumstances for maintenance operations to be performed with stray radiation fields above the regulatory limit (0.5 mR per hr), every effort must be made to minimize exposures to organs or parts of the body that could be affected, so as to minimize the likelihood of long-term risks. The maximum permissible dose limits must not be exceeded by any maintenance personnel and in general the radiation exposure should be kept as low as reasonably achievable.

- All protective apparel and safeguards, including the radiation survey meter(s), must be tested regularly to ensure that they are in proper working and functional condition and are not defective. Proper documentation that such tests were carried out should be maintained.
(b) Pre-operational Safeguards

Pre-operational safety checks must be carried out after installing x-ray equipment or accessory components and after conducting maintenance on the equipment. The safety checks should ensure:

- the proper functioning of all protective and safety devices;
- the proper assembly and functioning of all radiation shields, beam ports, accessories and fittings;
- that ambient radiation levels are within the permissible regulatory limit (0.5 mR per hr at 5 cm from all external surfaces of the equipment) by using an appropriate survey meter;
- any safety by-pass procedures are of the one time actuation type and revert back to a fail-safe situation at start-up time of the x-ray generator.

(c) Maintenance Safeguards

The greatest risk of radiation exposure from analytical x-ray equipment occurs during maintenance procedures in which personnel are potentially exposed to the primary beam or intense scatter radiation. Therefore, it is imperative that manufacturer's guidelines be followed and that unauthorized individuals are not near the x-ray equipment. The following procedures must be followed during maintenance of the x-ray equipment:

- Test all safety devices and features and ensure their proper functioning. If by-passing a safety device is deemed essential to facilitate a specific maintenance task perform the following:
  - Install a flashing red light or intermittent sound signal that is clearly visible or audible to a person with normal or corrected vision and hearing near that part of the equipment where the safety device was altered;
  - Attach, near the flashing red light or intermittent sound signal, a written notice that indicates explicitly what safety device was altered;
  - Use an appropriate survey meter if radiation emissions are potentially associated with the intended task, and ensure that the permissible limits are not exceeded.
  - Ensure that the safety device is re-established and that any shielding that was removed or modified to facilitate the intended task is replaced after the task is completed.
- Examine all radiation shields, beam ports, shutters, accessories and fittings for proper installation and function;
• Monitor the radiation levels nearest that part of the equipment where maintenance functions will be carried out, before and after the maintenance functions(s). Use an appropriate survey meter and observe the guidance reference limits for body organs and the permissible levels established for the performance of the equipment.

(d) Radiation Protection Surveys

A radiation protection survey of analytical and cabinet x-ray equipment is intended to determine whether the equipment functions according to applicable design and performance standards and is used and maintained in a way that provides maximum radiation safety to all persons. In order to achieve these objectives, the following requirements apply to all facilities:

• Analytical x-ray equipment must be surveyed when it is initially installed, and when maintenance, modifications, damage or overexposure accidents have occurred.

• Surveys must be performed by the Radiation Protection Officer during compliance inspections as part of the process for registering the equipment.

• Routine surveys of x-ray equipment should be conducted at a frequency that depends on the particular equipment design, conditions of use, and performance history. The survey frequency may be based on consultation with the Radiation Protection Officer.

• Surveys of x-ray equipment must include:
  (i) a thorough inspection of all safety devices and radiation shields;
  (ii) stray radiation measurements carried out under worst-case (if feasible) user conditions around the system;
  (iii) proper quantification of stray radiation levels above the regulatory limit and specification of the area or location on the x-ray equipment where they were found;
  (iv) an assessment of occupational and public exposures when radiation levels have exceeded the regulatory limit;
  (v) audits on:
      (a) the availability of a copy of this manual
      (b) the maintenance program established and followed by the equipment owner or designee
      (c) reports of unsafe operational conditions, overexposures incidents and accidents
  (vi) review and assessment of unsafe operational conditions, overexposure incidents and accidents

• Survey reports must state the following:
  (i) an identification of the x-ray equipment that sets out the manufacturer, brand name, model number, serial number and the date of manufacturer,
(ii) an assessment of the safety devices, radiation shields, occupational exposures, and personal dosimetry records and the deficiencies observed,

(iii) specific corrective actions necessary for compliance with this manual, Safety Code 32 and the Radiation Emitting Devices Regulations, including completion deadlines,

(iv) safety recommendations (if any),

(v) after x-ray equipment has been decommissioned, all survey reports pertaining to that equipment must be retained for a period of five years by the last responsible user.

C. Biological Effects of X-rays

1. Ionization Process

X-rays are electromagnetic radiation that have high enough energy to ionize atoms. Ionization occurs when an x-ray photon collides with an orbital electron and transfers some or all of its energy to the electron. The ejected electron moves through space with high kinetic energy and directly ionizes other atoms by coulombic interaction with orbital electrons on other atoms.

To ionize an atom requires a transfer of about 32 eV therefore complete absorption of a 64 keV x-ray photon can result in a many as 2,000 ionizations. Some of the ionizations may result in disruption of important cellular macromolecules such as DNA which can result in deleterious effects within the cell. There are two types of deleterious effects from radiation exposure - deterministic effects and stochastic effects.

2. Deterministic Effects

Deterministic effects are related to cell killing and subsequent tissue damage. Since a critical number of cells must be killed or damaged before tissue function is compromised, deterministic effects will not occur unless a threshold radiation dose is received which is large enough to kill or damage a critical number of cells in the tissue. Furthermore, for most deterministic effects the radiation dose must be received over a short enough period of time that the tissue is unable to regenerate itself before its function is compromised. Once the threshold dose is exceeded, the severity of the deterministic effect increases with an increase in dose. As an example consider the effect of x-ray exposure to skin. At a dose below 3 Sv not enough skin cells are killed or damaged to result in any clinically observable effects. At a dose slightly above the threshold of 3 Sv, skin erythema occurs and as the dose is increased the severity of the skin burn increases. Other types of deterministic effects include the formation of cataracts (3.5 Sv threshold), acute radiation syndrome (1 Sv threshold) and fetal abnormalities (0.1 Sv threshold).

3. Stochastic Effects

Stochastic effects are biological effects that have a probability of occurrence which is a function of dose. Unlike deterministic effects, there is generally no clear threshold below which a stochastic effect will not occur. Even at a very low dose there is assumed to be a small probability of a stochastic effect occurring. Although the severity of a stochastic effect is unrelated to the magnitude of the dose, the probability of the stochastic effect occurring increases with increasing dose.
Two examples of stochastic effects are cancer and hereditary defects in the human genome. In the case of cancer the probability of a cancer occurring as a result of radiation exposure is a function of the magnitude of the dose received and for most types of cancers the probability of occurrence is a linear function of dose. It has been found through studies of populations exposed to ionizing radiation that the probability of a fatal cancer occurring from radiation exposure is approximately 5 percent per Sv. In other words if 100 persons received 1 Sv of whole-body radiation exposure, 5 persons would be expected to develop a fatal cancer from this exposure.

The above risk estimate is based on studies of persons who received high doses (> 0.5 Sv) of radiation and it is uncertain whether the risk estimate is valid at low dose. There is evidence both for and against the existence of a threshold dose for stochastic effects, but in light of the scientific controversy surrounding this hypothesis, the safest approach is to assume that there is some risk even at very low dose. Therefore, the conservative approach is to keep radiation exposure as low as reasonably achievable.

4. Risk Management

Maximum permissible dose limits are established at levels which will prevent deterministic effects from occurring. The current annual whole-body dose limit for radiation workers is 50 mSv per year which is well below the threshold dose for acute radiation syndrome. For pregnant radiation workers the dose limit of 2 mSv to the abdomen ensures that the threshold for fetal abnormalities (100 mSv) will not be exceeded. For extremity exposure the dose limit of 0.5 Sv ensures that the threshold for effects on the skin (3 Sv) will not be exceeded.

The maximum permissible dose limits are also set at a low enough value to minimize if not eliminate the risk of cancer and hereditary defects in the human population. Assuming a linear no-threshold model for radiation carcinogenesis a person receiving 20 mSv per year will have a cumulative dose of 1,000 mSv after 50 years of work which will equate to an increased risk of fatal cancer of 5 percent. This would still be a small risk compared to the background risk of cancer for a person of that age and if the annual dose is kept well below the dose limit the increase risk of cancer from radiation exposure can be kept insignificantly low over the persons life.

D. Administrative Procedures

1. Regulations

Analytical x-ray equipment is regulated in Alberta under the Radiation Protection Regulation. This regulation requires that analytical x-ray equipment be registered before it is used. The registration process requires a formal compliance inspection to be carried out to ensure that the x-ray equipment meets certain specified safety standards before it can be used. The safety standard that has been adopted under the Radiation Protection Regulation for analytical x-ray equipment is Health Canada "Safety Requirements and Guidance for Analytical X-ray Equipment" - Safety Code 32 " (Reference 5).
In 1998, the Radiation Health Administration Regulation came into existence which permitted the Government of Alberta to enter into a legal agreement with various professional organizations for the purpose of delegating its authority to the professional organizations for registration of analytical x-ray equipment owned by their members. Under this plan, the University of Alberta became an Authorized Radiation Health Administrative Organization on December 16, 2000 giving it the authority to register all analytical x-ray equipment in its possession.

The Radiation Health Administration Regulation also permits the Government of Alberta to enter into a legal agreement with qualified companies for the purpose of delegating its authority for inspection of analytical x-ray equipment throughout the province. Under this plan, the University of Alberta, Department of Environment, Health and Safety (EHS) became an Authorized Radiation Protection Agency (ARPA) giving it authority to inspect analytical x-ray equipment owned by the University of Alberta. Although EHS provides this service, owners of University of Alberta x-ray equipment may also engage the services of other ARPAs if they so desire, although most will prefer to take advantage of the free service offered by EHS.

2. Inspection and Registration

To register analytical x-ray equipment, the owner of the equipment must apply to register the x-ray equipment with the Department of Environment, Health and Safety (EHS). The application form is available from the Radiation Safety Division in EHS.

Upon receiving the application form, the Radiation Protection Officer will make arrangements with the owner of the x-ray equipment to perform a compliance verification of the x-ray equipment and the associated facility. Items checked will include the existence of safety features designed into the x-ray equipment, the use of personal protective equipment, the implementation of safety procedures and other items specified in Safety Code 32. An inspection report will then be sent to the owner of the equipment. Any deficiencies that are identified must be corrected before the x-ray equipment can be registered, and the owner of the equipment will be required to provide evidence that corrective action has been taken.

Upon receiving written notification that corrective action has taken place, the Radiation Protection Officer will submit the inspection report and any follow-up correspondence to the University of Alberta signing authority for Analytical X-ray Equipment Registration Certificates. The Registration Certificate will then be issued to the owner of the x-ray equipment.

The Registration Certificate allows the x-ray equipment to be operated and is normally valid for two years. Prior to the expiration of the Registration Certificate, the owner of the x-ray equipment will receive a notice and an application form for renewing the registration of the x-ray equipment. The inspection and registration process described above must then be repeated if the x-ray equipment is to continue to be used. There is no requirement to register analytical x-ray equipment that is simply kept in storage however the status of the x-ray equipment in storage must be reported to the Radiation Protection Officer following any changes in storage location or disposition.
3. Responsibilities

a) General Responsibilities

Every person owning, installing, supplying, operating or servicing analytical x-ray equipment shall take all reasonable precautions to protect persons from x-ray exposure. All persons involved in the daily operation of analytical x-ray equipment shall:

- Take all reasonable precautions to ensure the worker's own safety and the safety of fellow workers.
- Use the personal protective equipment and other safety devices provided by the employer.
- Report incidents and exposures to the Equipment Supervisor.

b) Radiation Protection Officer Responsibilities

The Radiation Protection Officer at the University of Alberta is responsible for the evaluation and control of analytical x-ray equipment and for monitoring and enforcing compliance with the requirements given in this manual. The Radiation Protection Officer is required to:

- Ensure that the necessary records required by applicable government regulations are maintained including registration certificates, compliance verifications reports, training records, lists of analytical x-ray equipment users and exposure reports, etc.
- Perform inspections of the x-ray equipment facility and accompany regulatory agency inspectors during their visits.
- Ensure corrective action is taken on noted deficiencies.
- Investigate x-ray equipment related accidents and initiate appropriate action including the preparation of reports to regulatory agencies.
- Determine the adequacy of x-ray equipment control measures including standard operating procedures, maintenance and service procedures, and modifications to the x-ray equipment system or procedures.

c) Equipment Supervisor Responsibilities

The Equipment Supervisor is usually the person listed on the Registration Certificate. The Equipment Supervisor must be knowledgeable of the requirements for analytical x-ray equipment safety, potential x-ray hazards, associated control measures, and the policies, practices and procedures pertaining to the x-ray equipment under the Equipment Supervisor's control. The Equipment Supervisor is responsible for:

- ensuring that the equipment is installed in accordance with the facility safeguard requirements;
- ensuring that all users have received training on the proper operation and x-ray hazards appropriate to the analytical x-ray equipment installed;
• prescribing and posting prominently near the x-ray equipment radiation safety rules, and safe operating and emergency procedures which shall include address information and contact details of a hospital or clinic where medical treatment can be administered;

• making readily available a copy of this manual for reference by users and maintenance personnel;

• implementing a system of verification, supervision and periodic review to ensure that all users and maintenance personnel have received adequate training, and have read and understood the relevant parts of this manual, the applicable radiation safety rules, safe operating and emergency procedures before using and servicing the x-ray equipment;

• establishing a maintenance program, taking into account the age and frequency of use, that ensures all safety devices and components critical to both x-ray production and shielding, are routinely checked and defective parts replaced or repaired;

• providing an appropriate survey meter, and ensuring that it is in a working and functional condition at all times for use by users and maintenance personnel;

• conducting prompt investigations of all radiation overexposures and accidents, and submitting appropriate reports to the Radiation Protection Officer as soon as possible;

• ensuring that victims of radiation overexposures receive specialized medical attention (e.g. consultation with a radiation oncologist or physician knowledgeable in human biological effects of ionizing radiation);

• determining the appropriate corrective measures following radiation overexposures, unsafe events and accidents, and ensuring that such measures are implemented effectively;

• ensuring that during a radiation protection survey, a copy of the most recent survey report including summaries of corrective measures recommended and instituted on the equipment, is readily available to the radiation inspector.

d) User Responsibilities

X-ray equipment users are employees who are authorized by the Equipment Supervisor to energize or work with or near x-ray equipment. X-ray equipment users must:

• receive training authorized or approved by Radiation Protection Officer on the operation and radiation hazards relevant to the particular type of x-ray equipment intended for use;

• have read, understood and follow all applicable radiation safety rules and emergency procedures that are prescribed by the equipment supervisors and by the Radiation Protection Officer;
• wear personal radiation monitors consistent with the equipment design and operation and as recommended by the Radiation Protection Officer;

• use an appropriate survey meter to identify and monitor radiation levels at critical areas (tube housing, beam ports, shutters, analysis accessories, etc.) of the equipment during set up and beam alignment procedures, and following modifications and alterations to the device or its accessories, and to ensure that compliance with the regulatory limit (0.5 mR per hr at 5 cm from any external surface of the equipment) is maintained, and that the guidance levels including the permissible dose limits would not be exceeded under routine operational conditions of the equipment;

• conduct the pre-operational safety checks indicated in part B section 2(b) of this manual;

• stop the operation of the x-ray equipment if any unsafe operational conditions arise, and immediately notify the Equipment Supervisor of such conditions.

e) Maintenance Personnel Responsibilities

Maintenance personnel are individuals who are trained and authorized to perform alignments, upkeep, maintenance or repairs of analytical and cabinet x-ray equipment. All personnel responsible for the maintenance of x-ray equipment must:

• be adequately trained in the proper maintenance and repair of the various x-ray equipment for which they are responsible, with emphasis on maintenance operations that may require x-ray production;

• have read, understood and follow all radiation safety rules, requirements and emergency procedures applicable to the x-ray equipment and the facility, including the guidelines on operational safety and personal exposure monitoring;

• wear personal radiation dosimeters to monitor separately whole body and extremity doses as deemed appropriate for the operation(s) being undertaken;

• use a properly functioning radiation survey meter to identify and monitor the radiation levels at critical areas (tube housing, beam ports, shutters, analysis accessories, etc.) of the equipment during set up, beam alignment and maintenance procedures, and following modifications and alterations to the device or its accessories;

• undertake precautionary measures to eliminate or reduce radiation levels (measured according to the preceding clause) to ensure that the regulatory limit (0.5 mR per hr at 5 cm from any external surface of the equipment) is met, and that guidance levels including the permissible dose limits would not be exceeded during routine operational conditions of the equipment;
• perform regular reviews of their own personal dosimetry data and identify unexpected radiation exposures, investigate them as to root cause(s) and implement appropriate corrective action(s) as may be necessary;

• provide the user and the equipment owner or designee with a written report that specifies explicitly any user procedure or action that could lead to an x-ray hazard, as soon as such a procedure or action is identified;

• consult and adhere to the maintenance procedures indicated in section B.2.C of this manual;

• supervise the work of maintenance personnel in training;

• prevent the operation of the analytical x-ray equipment if any unsafe operational conditions arise, and immediately notify the equipment owner or designee of such conditions.

4. Security and Area Control

Signage and Equipment Control
X-ray warning signs must be posted on the entrance doors to the controlled area. See section B.2.a for details on the type of signs which are acceptable. Doors should be kept locked when the room is unoccupied and the master key to the x-ray control unit should be kept stored in a secure location when the equipment is not in use.

Visitors
Visitors that are granted permission to enter an area where x-ray equipment is operated must be accompanied by an approved staff member and must be provided with the following:

• Information on potential radiation exposure

• Information on safety precautions

• Radiation dosimeters if required by the Radiation Protection Officer

Staff
Admission of staff members is subject to the following restrictions:

• Only authorized staff members are permitted entry into the controlled area during x-ray operations. All other staff are considered to be visitors to the controlled area.

• Persons requiring access to the controlled area must be provided with radiation hazard awareness training and radiation dosimeters before hand if required by the Radiation Protection Officer.

5. Training
All workers who are likely to be exposed to radiation from x-ray equipment owned by the University of Alberta must be well informed of the potential hazards of the x-ray equipment and the precautions to be taken to protect themselves and other persons from those hazards.
To comply with this requirement the following must be brought to the attention of each worker:

- The workers responsibilities and duties under the Act and Regulation
- The type of x-ray equipment with which the worker will be working
- Radiation protection principles and maximum exposure limits for radiation
- The uses and limitations of the facility, x-ray equipment and radiation sources the worker will use
- Known or suspected health hazards associated with the radiation exposure

For more information on radiation safety training, contact the University of Alberta Radiation Protection Officer at 492-5655.

6. Exposure Limits

For the purpose of radiation protection, individuals may be classified in one of two groups - radiation worker or member of the general public. Radiation workers are persons who are exposed to ionizing radiation in the course of their work. Students are classified as members of the general public for the purpose of dose limitation even if they are using x-ray equipment as part of their studies.

Table 3 lists the maximum permissible dose limits for radiation workers and members of the general public for various body organs and tissues.

Table 3 Maximum Permissible Dose Limits

<table>
<thead>
<tr>
<th>Body organ or tissue</th>
<th>Radiation Worker (mSv)</th>
<th>Member of General Public (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole body(^a)</td>
<td>50(^b)</td>
<td>1</td>
</tr>
<tr>
<td>Lens of the eye</td>
<td>150</td>
<td>15</td>
</tr>
<tr>
<td>Skin</td>
<td>500</td>
<td>50</td>
</tr>
<tr>
<td>Extremities (hands, feet)</td>
<td>500</td>
<td>50</td>
</tr>
</tbody>
</table>

a. Pregnant radiation workers may not exceed 2 mSv to the abdomen during the duration of pregnancy.

b. Up to 50 mSv may be received in any single year provided that the average dose over any consecutive five year period does not exceed 20 mSv.

7. Personal Exposure Monitoring

Persons who work with analytical and cabinet x-ray equipment are potentially exposed to ionizing radiation and must not exceed the maximum permissible dose limits listed in Table 3.

As a minimum requirement, all persons who work with analytical and cabinet x-ray equipment are required to wear whole-body dosimeters that measure both whole-body (deep dose) and skin dose. The whole-body dosimeter should be worn either at chest or waist level depending on the location of the x-ray source relative to the person's body.
In addition to this, persons who perform beam alignments or otherwise work in close proximity to open, primary x-ray beams are required to wear two extremity (ring) dosimeters on the hand closest to the x-ray source. One extremity dosimeter should be worn on the dorsal surface of the finger and the other extremity dosimeter worn on the palmar surface in order to detect exposures from narrow beams.

Dosimeters are normally worn for a three month period and then exchanged for a new one. The dosimeters are issued and read by a dosimeter service provider (either Health Canada, Landauer Inc. or Mirion Technologies) who send the exposure reports to the Radiation Protection Officer for review.

Whenever the annual cumulative dose exceeds 50 percent of the dose limit, the person will be notified by the Radiation Protection Officer as to this fact and will be requested to advise the Radiation Protection Officer on how the exposure might have been received.

8. Records

The following records shall be maintained with respect to the x-ray equipment:

- Registration Certificates (current and previous)
- Compliance verification reports (current and previous)
- Internal audits and inspection reports (indefinite period)
- Maintenance and service records (indefinite period)
- Accident and investigation reports (indefinite period)
- List of x-ray equipment users (current)
- Training records (indefinite)

9. Compliance and Enforcement

The University of Alberta will ensure compliance with the Act and Regulation for x-ray equipment under its jurisdiction. Compliance will be enforced by:

- requiring the owner of the x-ray equipment to implement the regulatory standard for analytical x-ray equipment, Health Canada Safety Code 32
- requiring the owner of the x-ray equipment to take remedial action to correct any condition which contravenes the Act or Regulation, or which is inconsistent with safe operating practices
- Prohibiting the use of x-ray equipment that:
  (a) is in such a condition or at such a location that it cannot be used without risk of unnecessary exposure to personnel,
  (b) is used in such a manner that it causes risk of unnecessary exposure to personnel or,
  (c) is exposing persons to x-ray equipment radiation beyond the maximum permissible
exposure limit.

Owners of x-ray equipment shall comply with all written directives issued to them by the University of Alberta in its capacity as an Authorized Radiation Health Administrative Organization.

10. Investigations

If an overexposure or an incident that has the potential of causing overexposure of a person occurs, the Equipment Supervisor shall forthwith notify the Radiation Protection Officer as to the time, place and nature of the overexposure or incident. The Radiation Protection Officer, together with the Equipment Supervisor will carry out an investigation into the circumstances surrounding any complaint, incident or suspected overexposure, and prepare a report outlining the circumstances and the corrective action required to prevent a recurrence of the overexposure or incident.

11. Penalties

Failure to respond to a compliance directive issued by the University of Alberta in its capacity as an Authorized Radiation Health Administrative Organization may result in suspension or revocation of the Registration Certificate of the x-ray equipment, prohibition of equipment use, seizure of equipment or referral for disciplinary action.

A person who intentionally contravenes the Alberta Radiation Protection Act/Regulation or who fails to comply with a directive made by an Authorized Radiation Health Administrative Organization under the Act/Regulation may also be subject to fines and/or prosecution under the Radiation Protection Act by the Director of Radiation Health for the Province of Alberta.
E. References


