

<p>Volume IV Orientation and Training</p>	<p style="text-align: center;">ORA LABORATORY MANUAL</p> <p style="text-align: center;">FDA Office of Regulatory Affairs Office of Regulatory Science</p>	<p>DOCUMENT NO.: IV-12 VERSION NO.: 1.3 FINAL EFFECTIVE DATE: 10-01-03 Revised: 02-14-13</p>
<p>Section 12</p>	<p style="text-align: center;">RADIOACTIVITY</p>	<p>Section 12</p>

12.6 Answer Key

12.2 Radiation Safety

1. **Define the term “atom.”** An atom is the smallest component of an element having the properties of that element. An atom consists of a central nucleus, comprised of positively charged protons and uncharged neutrons, surrounded by negatively charged electrons. The number of protons in the nucleus of the atom determines the identity of the element. The atomic mass number, **A**, is equal to the sum of the number of protons, **Z**, plus the number of neutrons, **N**, in the nucleus.
2. **Discuss the characteristics of alpha-particle decay, beta-particle decay, and gamma-ray and x-ray emission. Which types of radiation have an electrical charge? Discuss the difference between x-ray and gamma-ray emission.** Alpha-particle decay is characterized by the emission of a highly energetic helium nucleus, or alpha particle, from the nucleus of a radioactive isotope, resulting in the transformation of the isotope to one whose nucleus contains two fewer protons and two fewer neutrons. Beta-particle decay is characterized by the ejection of an ordinary electron from the nucleus of a radioactive isotope, resulting in the transformation of a neutron into a proton in the nucleus. Positron decay, sometimes called beta-plus decay, is characterized by the ejection of a positively charged electron from the nucleus, resulting in the transformation of a proton into a neutron in the nucleus. Gamma rays and x-rays are electromagnetic radiation emitted by atoms following radioactive transformation. Alpha and beta particles and positrons carry charge; gamma and x-rays are uncharged. X-rays and gamma rays are electromagnetic radiation; x-rays originate in the extra nuclear structure of atoms and gamma rays originate in the nuclei of atoms.

3. **Define “ionization.”** Ionization is the process of removing an atomic electron from the electric field of the nucleus, resulting in an ion pair consisting of the remaining positively charged atom and the negatively charged electron.
4. **Describe the three ways in which photons interact with atoms.** Photons interact with matter primarily via the following mechanisms: photoelectric effect, Compton Effect, and pair production. In the photoelectric effect, a photon interacts with an atomic electron, resulting in the emission of an electron having energy equal to that of the incident photon minus the binding energy of the electron. The incident photon disappears. In the Compton Effect, a photon collides with an electron resulting in a scattered photon and a scattered electron. The scattered photon has less energy than that of the incident photon, and the difference between the incident and scattered energy of the photon is transferred to the scattered electron. In pair production, a photon of energy greater than 1.02 MeV spontaneously disappears as it passes near a nucleus, resulting in the production of an electron and a positron (an electron-positron pair).
5. **What is the difference between genetic and somatic effects of ionizing radiation?** Genetic effects are those that occur in the descendants of a parent whose DNA molecules are modified due to exposure to ionizing radiation. Somatic effects are those which occur in the exposed individual. Genetic effects may affect subsequent unexposed generations; somatic effects are limited to the exposed individual.
6. **Define the threshold theory and the linear non-threshold theory.** The threshold theory of dose response is used to describe radiation effects that occur only after a minimum, or threshold, dose has been received. The magnitude of the effect increases with the dose received, and there is a clear causal relationship between radiation exposure and the observed effect. The linear non-threshold theory is used to describe the frequency of occurrence of a defined radiation effect as a function of dose received by an exposed population. The plot of frequency of response vs. dose is linear and passes through the origin of the plot.
7. **Describe three types of personal dosimeters worn by individuals for personnel monitoring; discuss the use of control badges.** Personal dosimeters are devices worn by individuals to measure radiation exposure. Three types of personal dosimeters are: pocket meters, film badges, and thermoluminescent dosimeter (TLD) badges. Pocket meters are generally based on an air wall ionization chamber and can either be of the “direct reading” type, where the dose may be read from a scale or other indicator on the device, or the “indirect reading” type, where an instrument is needed to read the dose. Film badges consist of one or more small sheets of photographic film enclosed in a light-tight container that may be affixed to clothing. The exposed film is developed to obtain the radiation dose. TLD badges contain thermoluminescent crystals that absorb and store energy when exposed to radiation, and emit light when heated. The light output is proportional to the radiation dose. The dose is read by heating the TLD crystal in a device equipped to detect the emitted light.

Control badge readings are used to correct personal dosimeter readings to more accurately reflect the exposure received by individuals working with radiation. Control badges are generally maintained in an area remote from radiation areas but under similar environmental conditions as those where personal dosimeters are worn. See ORA Radiation SOP – TLD Program for information about the ORA TLD program.

8. **Define the three methods used for minimizing radiation exposure.** Radiation exposure may be limited by minimizing the time or duration of exposure, by maximizing the distance between the radiation source and the exposed individual, and by maximizing the shielding between the source and the exposed individual.
9. **Define “survey.”** A survey is an evaluation of radiological conditions to determine the presence of surface or airborne contamination, unknown sources, or dose rate in the area. See WEAC Radiation Safety Manual for information describing WEAC survey program.
10. See WEAC Radiation Safety Manual for the procedure for purchasing standards.
11. See WEAC Radiation Safety Manual the procedure for screening packages for radioactivity.

12.3 WEAC Laboratory Radiation Detection Instrumentation

1. **Describe the theory of operation and its application in the laboratory for the following: a proportional counter, a scintillation counter, and a solid state detector coupled to a multichannel analyzer.** A proportional counter consists of a gas-filled chamber containing two electrodes across which an electrical potential is applied. Under the influence of the electric field, ions generated by radiation in the gas are collected, producing an output signal proportional to the energy deposited in the counter by the radiation. Therefore particle identification and energy measurement are possible for any charged particle. A scintillation counter consists of a medium that produces light when ionizing radiation passes through it, and a detector, usually a photomultiplier tube, which amplifies the light and produces an output signal. The scintillator may be solid, liquid, or gas. Photons, neutrons, and charged particles may be detected using scintillation counters. A solid state detector consists of a semiconductor crystal across which a bias voltage is applied. Charges generated in the crystal by radiation are collected and produce a voltage pulse proportional to the energy deposited in the crystal. The pulse-height distribution or spectrum may displayed using a multichannel analyzer (MCA) and consists of a plot of counts versus energy.

12.4 Radionuclides in Foods Program

- 1. What is the purpose for using the 400-mL fill line in the analysis of gamma-emitting radionuclides?** The 400-mL fill line is the level to which a plastic sample container is filled in order to maintain a constant geometry for all samples counted on the detector. The detector is also calibrated using a radioactive source in an identical plastic container filled to the 400-mL line.
- 2. Describe the separation methods utilized for Sr-90 in the Market Basket Strontium 90 method.** In this method the activity of Y-90, the decay product of Sr-90 present in radioactive secular equilibrium with Sr-90 in the sample, is measured. A known quantity of food homogenate is dried and charred at high temperature, and the ash is dissolved in nitric acid. The acid solution is shaken in a separatory funnel with tributylphosphate and strontium and yttrium carrier solutions. Y-90 is differentially dissolved (or separated from Sr-90) in the organic phase. After a series of procedures, Y-90 as oxalate is deposited onto a paper filter, and assayed using a beta particle counter. The Y-90 activity is then used to calculate the Sr-90 activity in the original food sample.
- 3. Describe the sample preparation for the analysis of tritium by liquid scintillation analysis.** A weighed, edible portion of sample is transferred to a special glass distillation tube. An identical tube, used as a water trap, is joined to this tube and to a vacuum pump via an adapter. The sample tube is sealed and mildly heated, and the water trap is evacuated using the pump, and chilled. The two tubes are then joined together via the adapter and water vapor from the sample is gradually collected in the cold trap. The collected water is then mixed with liquid scintillator solution (sometimes referred to as a “cocktail”) which produces visible light when ionizing radiation (emitted by tritium) passes through it. The light pulses are detected and counted in the liquid scintillation counter.

12.5 Radiopharmaceutical Program

- 1. Define radiochemical purity and radionuclidic purity.** Radiochemical purity is the degree to which a radioactive compound is free of chemical contaminants. Radionuclidic purity is the degree to which a radioactive substance is free of radionuclides other than those declared.
- 2. Define the term “cold kit.” What precautions are to be taken when preparing a cold kit with Tc-99m? What happens when air is inadvertently introduced into the cold kit? A “cold kit” is a compound or complex that is combined, or reconstituted, with Tc-99m**

resulting in a radioactive pharmaceutical. The compound is usually contained in a septum-sealed vial into which sodium pertechnetate solution may be injected by syringe. The vial may also be under vacuum or contain an inert gas. Procedures for reconstituting the kit are specified in the labeling. Precautions to prevent the accidental introduction of air while adding the pertechnetate solution may be needed. Air inadvertently introduced into the vial may react with reducing agents or other chemicals in the vial resulting in the production of radiochemical impurities in the drug.

3. **Discuss the theory of operation and use of a Tc-99m/Mo-99 generator.** A Tc-99m/Mo-99 generator contains Mo-99 fixed on an alumina column. Tc-99m, the decay product of Mo-99, is removed, or eluted, from the generator by passing a saline solution through the column, resulting in a sodium pertechnetate solution. The pertechnetate solution may be used to reconstitute cold kits.