Radiation Protection Guidance For Hospital Staff

Prepared for Stanford Hospital and Clinics, Lucile Packard Children's Hospital And Veterans Affairs Palo Alto Health Care System

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For additional information contact the Health Physics office at 723-3201

Preface

The privilege to use ionizing radiation at Stanford University, Stanford Hospital and Clinics, Lucile Packard Children's Hospital and Veterans Affairs Palo Alto Health Care System requires each individual user to strictly adhere to federal and state regulations and local policy and procedures. All individuals who work with radioactive materials or radiation devices are responsible for knowing and adhering to applicable requirements. Failure of any individual to comply with requirements can jeopardize the investigation, the laboratory, and the institution.

This guidance document provides an orientation on ionizing radiation, and describes radiation safety procedures we have implemented to ensure a safe environment for our patients and students, the public, and ourselves. Our goal is to afford users as much flexibility as is safe and consistent with our policy of as low as reasonably achievable (ALARA) below the limits provided in the regulations.

The Radiation Safety Officer is responsible for managing the radiation safety program subject to the approval of the Administrative Panel on Radiological Safety, and is authorized to take whatever steps are necessary to control and mitigate hazards in emergency situations.

Consult with the Radiation Safety Officer at 723-3201 for specific information.

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Section 1 - Introduction

The purpose of this guidance document is to describe the policies and procedures of the Stanford Hospital and Clinics, Lucile Packard Children's Hospital and Veterans Affairs Palo Alto Health Care System.

The regulatory basis of the Stanford University Radiation Protection Program includes Title 17, California Code of Regulations, Division 1, Chapter 5, 10 CFR 20 (Title 10 Code of Federal Regulations, Part 20) and 10 CFR 35 (Title 10 Code of Federal Regulations, Part 35). In addition, stipulations of the Food and Drug Administration, the United States Department of Transportation, the Occupational Safety and Health Administration (in the case of VAPAHCS), and the Joint Commission contribute to the regulatory environment.

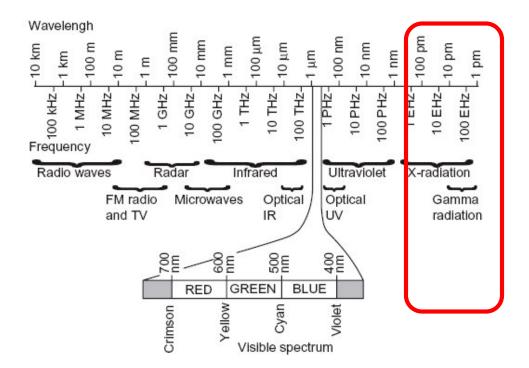
Due to frequent changes in the regulatory climate, and changes in the needs of the users of radioactive material at Stanford University, all policies and procedures outlined in this guidance document shall be considered to be subject to change.

The safe use of lasers and other forms of non-ionizing radiation such as ultra sound or magnetic fields will not be covered in this document.

Section 2 - The Hazards of Radiation Exposure

Since the end of the 19th Century, man has learned to use radiation for many beneficial purposes. Today, many sources of radiation, such as x-ray machines, linear accelerators and radionuclides are used in clinical and research applications. Such beneficial uses may at times create potentially hazardous situations for personnel who work within the hospital.

All uses of ionizing radiation at the Stanford Hospital & Clinics (SHC), the Lucile Packard Children's (LPCH) Hospital and the VA Palo Alto Health Care System (VAPAHCS) are subject to review and approval by the Administrative Panel on Radiological Safety (APRS). The review assures that projects can be conducted safely. The Radiation Safety Officer (RSO) manages the health physics program.



Ionizing versus Nonionizing Not all radiation interacts with matter in the same way. Radiation that has enough energy to move atoms in a molecule around or cause them to vibrate, but not enough to remove electrons, is referred to as "non-ionizing radiation." Examples of this kind of radiation are sound waves, visible light, and microwaves.

Radiation that falls within the ionizing radiation" range has enough energy to remove tightly bound electrons from atoms, thus creating ions. This is the type of radiation that people usually think of as 'radiation.' We take advantage of its properties in diagnostic imaging, to kill cancer cells, and in many manufacturing processes.

Examples of non-ionizing radiation exposures in the clinical setting include, Magnetic resonance imaging (MRI), ultrasound and LASERS.

Natural sources

We live in a radioactive world. There are many natural sources of radiation which have been present since the earth was formed

The three major sources of naturally occurring radiation are:

- Cosmic radiation
- Sources in the earth's crust, also referred to as terrestrial radiation
- Sources in the human body, also referred to as internal sources.

Cosmic radiation

Cosmic radiation comes from the sun and outer space and consists of positively charged particles, as well as gamma radiation. At sea level, the average cosmic radiation dose is about 26 mrem per year. At higher elevations the amount of atmosphere shielding cosmic rays decreases and thus the dose increases. The average dose in the United States is approximately 28 mrem/year.

Terrestrial

There are natural sources of radiation in the ground, rocks, building materials and drinking water supplies. This is called terrestrial radiation. Some of the contributors to terrestrial sources are natural radium, uranium and thorium. Radon gas, which emits alpha radiation, is from the decay of natural uranium in soil and is ubiquitous in the earth's crust and is present in almost all rocks, soil and water. In the USA, the average effective whole body dose from radon is about 200 mrem per year while the lungs receive approximately 2000 mrem per year.

Internal

Our bodies also contain natural radionuclides. Potassium 40 is one example. The total average dose is approximately 40 mrem/year.

Human sources of radiation

The difference between man-made sources of radiation and naturally occurring sources is the place from which the radiation originates. The following information briefly describes some examples of human-made radiation sources.

Consumer products

Examples include TV's, older luminous dial watches, some smoke detectors, and lantern mantles. This dose is relatively small as compared to other naturally occurring sources of radiation and averages 10 mrem in a year.

Atmospheric testing of nuclear weapons

Another man-made source of radiation 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 in a year.

Medical radiation sources

X rays are identical to gamma rays; however, they are produced by a different mechanism. X rays are an ionizing radiation hazard. A typical radiation dose from a chest x ray is about 10 mrem. A typical radiation dose from a whole body CT is about 1500 mrem. In addition to x rays, radioactive

isotopes are used in medicine for diagnosis and therapy.

X-ray machines

Any electronic device that has fast-moving electrons is a potential source of ionizing radiation. One is the diagnostic x-ray machine. First used in 1896, it permitted non-invasive imaging of internal human structures. Today, in the US alone, medical procedures from ionizing radiation accounts for fifty-one percent of our annual dose from radiation (the other 50% is from naturally occurring sources such as cosmic rays, radon, and soils).

X-rays

X-rays are a type of radiation commonly found in the hospital. These radiations are produced mainly by machines when high voltage electrons interact with matter. X-rays are a type of energy similar to light and like gamma rays; pass easily through fairly thick materials. X-ray machines and the rooms they are used in have built-in shielding. The useful beam is restricted by a cone or an adjustable collimator.

High energy x-ray machines and/or accelerators

High energy x-ray machines, also called accelerators, operating in the 4 MV to 25 MV energy range, are therapy machines used to treat many illnesses.

Sealed sources

Many devices use sealed radioactive sources because they provide a convenient, inexpensive source of ionizing radiation. Sealed radioactive sources are often made by encapsulating the salt or metal of a radionuclide in a welded metal container whose size typically ranges from smaller than a pencil lead to the size of a golf ball. The encapsulation ensures that there will be no radioactive contamination of the laboratory. Applications range from low activity alpha sources that are used in home smoke detectors to Brachytherapy which is a form of radiotherapy where a radioactive source is placed inside or next to the area requiring treatment.

Gamma Radiation

Gamma Radiation is similar to light and x-rays. It may penetrate through many inches of iron, concrete, wood, plastic, water, etc. Patients who have received large doses of radioactive materials that emit gamma rays (for example, in undergoing some therapy procedures such as Iodine-131 MIBG used to treat neuroendocrine tumours) may be a source of exposure to nurses and other personnel.

Beta Radiation

Beta radiations are electrons with a range of energies. They are less penetrating than gamma particles, but generally will be stopped by about one-half inch thick wood, plastic, water, tissue...etc, depending on the energy. A patient who has received a radioactive material that gives off only beta radiations does not become an external radiation hazard to nurses or others. Problems may arise, however, due to contamination of bedding, dressings, when such materials are excreted in urine or perspiration.

Applications include Yttrium 90 (⁹⁰Y) for cases where it is not possible to surgically remove hepatic tumors. The ⁹⁰Y can be used to deliver targeted, internal radiation therapy directly to the tumor. The ⁹⁰Y is delivered by loading the yttrium into tiny resin microspheres. The spheres are very small and are injected via microcatheter into the common hepatic artery.

Positron Radiation

Isotopes used in positron emission tomography (PET) scans, such as ¹⁸F, ¹¹C, or ¹³N, decay by positron emission. A positron, the anti-particle of a beta particle, is emitted by a proton-rich nucleus. It has the same mass as an electron, but carries a positive charge. Positrons yield two 0.511 MeV photons. Positron photon radiation is similar to gamma radiation in that it can penetrate through inches of iron, concrete, wood, plastic, water, etc. Patients who have received positron emitters (for example the radiopharmaceutical fluorodeoxyglucose, commonly abbreviated ¹⁸F-FDG, is used in PET) are a source of exposure to nurses and other personnel.

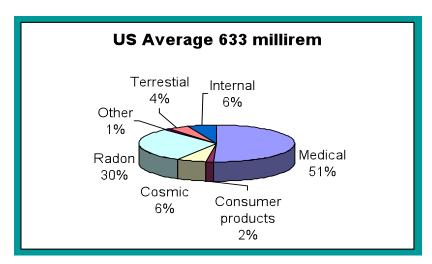
Radioactive Decay

If one starts with a sample of radioactive material, i.e., a specific number of atoms, as that sample undergoes radioactive transformation, over time one will have progressively smaller numbers of the original radioactive atoms present. When half of the original atoms have decayed, the material is said to have gone through a half-life. During the next half-life, half of the remaining atoms will decay; leaving one-fourth of the original and so on. The number of atoms which decay each second is the measure of radioactivity.

Some elements, such as Cesium-137 (¹³⁷Cs) have a very long half-life (30 years), so they essentially maintain a significant level of radioactivity over a human life span. Others, such as Flourine-18 (¹⁸F) and Iodine-131 (¹³¹I), have fairly short half-lives, approximately 2 hours and eight days respectively, and therefore, the level of radioactivity diminishes relatively rapidly. Nuclides which are used for diagnostic purposes, scans, or images have short half-lives. For example, a commonly used nuclide, Technetium-99m (^{99m}Tc) has a half-life of six hours. In 42 hours, 99.3% of ^{99m}Tc's initial activity decays.

Background Radiation

Background radiation dose consists of the radiation doses received from natural and man-made background. For someone residing in the US, the annual background dose is approximately 633 millirem (mrem), but in some locations can be much higher. The highest known level of background radiation affecting a substantial population is in Kerala and Madras States in India where some 140,000 people receive an annual dose rate which averages over 1500 mrem per year from gamma, plus a similar amount from radon, for a total of 3000 mrem.



Properties of Radioactivity And Units Of Measure

How is Radiation Measured?

In the United States, *radiation absorbed dose*, *dose equivalent*, and *exposure* are often measured and stated in the units called *rad*, *rem*, or *roentgen (R)*. This exposure can be from an external source irradiating the whole body, an extremity, or organ resulting in an *external radiation dose*. Alternately, internally deposited radioactive material may cause an *internal radiation dose* to the whole body or other organ or tissue.

Smaller fractions of these measured quantities often have a prefix, e.g., milli (m) means 1/1,000. For example, 1 rad = 1,000 mrad.

The International System of Units (SI) for radiation measurement is now the official system of measurement and uses the "gray" (Gy) and "sievert" (Sv) for absorbed dose and equivalent dose respectively. Conversions are as follows:

- 1 Gy = 100 rad
- 1 mGy = 100 mrad
- 1 Sv = 100 rem
- 1 mSv = 100 mrem

With radiation counting systems, radioactive transformation events can be measured in units of "disintegrations per minute" (dpm) or, "counts per minute" (cpm). Background radiation levels are typically less than 0.02 mrem per hour, but due to differences in detector size and efficiency, the cpm reading on various survey meters will vary considerably.

Half-life

Probably the best known property of radioactivity is the half-life T. After one-half life has elapsed, the number of radioactive decay events in a sample per unit time will be observed to have reduced by one-half. The decay rate or activity at any time t can be described mathematically:

$$A_t = A_0 e^{-[0.693 t/(T)]}$$

Where:

 A_0 = initial activity

 A_t = final activity at time t

t = lapsed time

T = isotope half-life

Alternatively, if n is the number of elapsed half-lives, then:

$$A_t = A_0 (1/2)^n$$

Half-lives range from billionths of a second to billions of years. The half-life is characteristic of the radioisotope at hand, and cannot be inferred. The half-life is included with the description of the decay scheme.

Measures of Activity

The size or weight of a quantity of material does not indicate how much radioactivity is present. A large quantity of material can contain a very small amount of radioactivity, or a very small amount of material can have a lot of radioactivity.

For example, uranium-238, with a 4.5-billion-year half-life, has only 0.00015 curies of activity per pound, while cobalt-60, with a 5.3-year half-life, has nearly 513,000 curies of activity per pound. This "specific activity," or curies per unit mass, of a radioisotope depends on the unique radioactive *half-life* and dictates the time it takes for half the radioactive atoms to decay.

In the United States, the amount of radioactivity present is traditionally determined by estimating the number of *curies* (*Ci*) present. The more curies present, the greater amount of radioactivity and emitted radiation.

Common fractions of the curie are the millicurie (1 mCi = 1/1,000 Ci) and the microcurie (1 μ Ci = 1/1,000,000 Ci). In terms of transformations per unit time, 1 μ Ci = 2,220,000 dpm.

The SI system uses the unit of **becquerel** (**Bq**) as its unit of radioactivity. One curie is 37 billion Bq. Since the Bq represents such a small amount, one is likely to see a prefix noting a large multiplier used with the Bq as follows:

- 37 GBq = 37 billion Bq = 1 curie
- 1 MBq = 1 million Bq = \sim 27 microcuries
- 1 GBq = 1 billion Bq = \sim 27 millicuries
- $1\text{TBq} = 1 \text{ trillion Bq} = \sim 27 \text{ curies}$

Section 3 - Regulations for the Safe Use of Ionizing Radiation

Occupational Exposure Limits to Radiation

The NRC radiation dose limits in 10 CFR Part 20 and adopted by Title 17, California Code of Regulations, Division 1, Chapter 5 were established by the NRC based on the recommendations of the International Commission on Radiological Protection, (ICRP) and the National Council on Radiation Protection and Measurements (NCRP). The limits were recommended by the ICRP and NCRP with the objective of ensuring that working in a radiation-related industry was as safe as working in other comparable industries. The dose limits and the principle of as low as reasonably achievable (ALARA) should ensure that risks to work, are maintained indistinguishable from risks from background radiation.

No level of radiation exposure is free of some associated risk. Thus the principle of radiation safety is to keep the level of exposure ALARA.

Maximum Permissible Occupational Doses

Organ, tissue	Occupational Doses		Non-occupational	
	rem/year	mSv/year	rem/year	mSv/year
Whole body	5	50	0.1	1
Lense of the eye	15	150	NA	NA
Shallow dose (skin				
and extremities)	50	500	NA	NA

The **deep-dose equivalent** is the whole-body dose from an external source of ionizing radiation. This value is the dose equivalent at a tissue depth of 1 cm.

The **lens dose equivalent** is the dose equivalent to the lens of the eye from an external source of ionizing radiation. This value is the dose equivalent at a tissue depth of 0.3 cm.

The **shallow-dose equivalent** is the external dose to the skin of the whole-body or extremities from an external source of ionizing radiation. This value is the dose equivalent at a tissue depth of 0.007 cm averaged over and area of 10 cm².

The dose limit to **non-occupational workers** and **members of the public** are two percent of the annual occupational dose limit. Therefore, a non-radiation worker can receive a whole body dose of no more that 0.1 rem/year from industrial ionizing radiation. This exposure would be in addition to the 0.3 rem/year from natural background radiation and the 0.33 rem/year from manmade sources such as medical x-rays.

Additional limits for pregnant workers

Because of the increased health risks to the rapidly developing embryo and fetus, pregnant women can receive no more than 0.5 rem during the entire gestation period and no more than 0.05 rem each month. This is 10% of the dose limit that normally applies to radiation workers.

Posting Requirements

The use of warning or caution signs is necessary to warn unauthorized or unsuspecting personnel of a hazard <u>and</u> to remind authorized personnel as well.

Radioactive Materials, Radiation Areas, High Radiation Areas, Very High Radiation Areas, Airborne Radioactivity Areas, shipping containers and vehicles shall be marked or posted as required by various regulations. Health Physics will assist in providing the necessary information, signs, and/or labels.

All signs, labels, and signals will be posted in a conspicuous place.

The standard radiation symbol appears with the required trefoil symbol as shown below. The symbol is magenta, purple, or black on a yellow background.



Labeling requirements

Containers with greater than 10 CFR 20 Appendix C quantities must be labeled with the radiation symbol, the words "Caution, Radioactive Material," and appropriate precautionary information such as radionuclide, activity, date, dose rate at a specified distance, and chemical form.

Radioactive Package Receipt Requirements

Most radioactive materials packages found at the SHC, LPCH or VAPAHCS contain radioactive drugs. The radioactive drugs are given to patients for the detection and treatment of disease. Packages of radioactive materials are safe to handle under normal conditions. Studies show that cargo handlers get very little radiation exposure from handling them. If a package is labeled as containing radioactive material, or appears damaged, it must be promptly monitored for dose rate and contamination. If certain thresholds are exceeded, Health Physics must notify the carrier, the Department of Health Services and the Nuclear Regulatory Commission.

Contact Health Physics if any package labeled as containing radioactive material is left unattended in public areas.

Section 4 - Personnel monitoring

The purpose of personnel monitoring is to provide early notice if your exposure is not below the limits and ALARA. The monitoring program also provides a permanent record of your exposure.

Types of dosimeters

Film badges are used to measure the radiation dose that you receive while attending patients undergoing therapeutic or diagnostic procedures with radionuclides or while working with radiation generation devices (e.g., linear accelerator, fluoroscope unit). If the film is exposed to radiation it will darken; the amount of darkening increases with exposure. Most finger rings use a LiF TLD to measure radiation exposure. The crystal stores some of the radiation energy. When it is heated the energy is released as visible light. LiF TLDs are also used as whole body dosimeters in areas which have both radionuclides and x-rays (e.g., nuclear medicine). Both film badges and TLDs are processed by a contractor. They are collected the first of each month. Most monitors can read as low as 10 millirem.

Required Monitoring

The regulations state monitoring is required for any worker who might exceed 10 percent of the occupational limit (500 mrem), and any worker in a high or very high radiation areas. Years of monitoring history demonstrate that most SHC, LPCH and VAPAHCS exposures are nondetectable. Areas where exposures are observed include nuclear medicine and interventional radiology. Each location bears the cost of its dosimetry service and nonreturned dosimeter fees.

Use

Body badges are to be worn at the collar. If lead aprons are used wear the badge outside of the apron at the collar. Finger rings are worn on the hand where the highest exposure is expected underneath gloves to avoid contamination. If you are supplied both types, wear both whenever you are working with radiation. These devices provide legal records of radiation exposure; therefore, it is imperative that they only be used as prescribed.

Precautions

Do not wear for non-work exposures such as a dentist's office.

Store badges in a safe location when not in use, away from sun, heat, sources of radiation or potential damage. Protect badges from impact, puncture, or compression.

Do not store Extremity (finger) rings in lab coat pockets. Storing rings in the lab coat pocket may expose the rings to radiation measured by the whole body badge. Rings are to measure hand exposures only.

A missing or invalid dosimeter reading creates a gap in your radiation dose record and affects the monitoring program's ability to provide accurate exposure readings. For a missing dosimeter a "Lost/Damaged Dosimeter Report" is required.

Dosimetry Requests

Dosimetry requests can be made through the following web link: https://ehsappprd1.stanford.edu/dosimetry/dosimetry/home.jsp

Records of Prior Exposure

Each individual having a previous or on-going radiation exposure history with another institution is required to submit an "Authorization to Obtain Radiation Exposure History" form. The form can be found at the following web link:

http://www.stanford.edu/dept/EHS/prod/researchlab/radlaser/manual/appendices/forms/forms.htm

Lost Dosimetry

A missing or invalid dosimeter reading creates a gap in your radiation dose record and gives the impression of a lackadaisical monitoring program. A lost monitor report is required. The form can be found at the following web link: http://www.stanford.edu/dept/EHS/prod/researchlab/radlaser/manual/appendices/forms/forms.htm

Late Dosimetry

Dosimeters are considered "late" when they have not been returned to the dosimetry location's contact within one week after the end of the wear period (e.g., if issued a monthly dosimeter on the 1st of October, return the worn dosimeter to the contact by the 7th of November). Dosimetry accounts will be charged a late fee in addition to the usual dosimeter costs for dosimeters not returned within 90 days.

Late dosimeters may not be read as accurately as dosimeters returned on time. A control badge accompanies the badges while in transit to and from the dosimetry vendor. Its purpose is to record background radiation during the use period and to record any radiation received by the badges during shipment. The exposure recorded by the control badge is subtracted from the exposure on the badges worn by the workers. The net exposure is the value found on the exposure reports. When a badge is returned late it cannot be processed with the control badge and a correct exposure may not be reported.

Late dosimeters may also affect the whole location for the dosimeter because the location contact may delay return of the entire group of badges while waiting for individuals who turn badges in late. This delays the processing and reporting of results to other users.

If a significant exposure occurs, an early report is very desirable. If a badge is returned late, higher work exposures can not be investigated in a timely manner. Returning a dosimeter late is the same as not wearing one.

Bioassays

Bioassays determine the quantities, and in some cases, the locations of radioactive material in the human body, whether by direct measurement, called in vivo counting, or by analysis and evaluation of materials excreted from the human body. Individuals who handle large amounts of easily ingested radionuclides may be required to participate in a bioassay monitoring program. Bioassays may also be ordered by the RSO after a spill, an unusual event, or a procedure that might result in an uptake.

Note: Dosimeters cannot detect very low levels of beta particle radiation (average energies below 70 KeV).

Frequently Asked Question

Are dosimeters needed if exposed to ultrasound or MRI radiation?

Answer:

Dosimeters measure ionizing radiation only therefore dosimeters are not responsive to radiation emitted from ultrasound or magnetic resonance imaging equipment.

If there are any questions regarding the wearing of these badges or any questions regarding radiation, please contact the Stanford University Health Physics Department at 723-3203.

Note: Failure of an employee to use required safety apparatus, such as film badges, may result in appropriate disciplinary action. When badges are required, it is both the individual and the supervisor's responsibility to ensure that they are worn.

Declaration of Pregnancy

The National Council on Radiation Protection and Measurements (NCRP) has recommended that, because the unborn are more sensitive to radiation than adults, radiation dose to the fetus that results from occupational exposure of the mother should not exceed 500 millirem during the period of gestation. California and the NRC have incorporated this recommendation in their worker dose limit regulations.

Employees who become pregnant and must work with radioactive material or radiation sources during their pregnancy, may choose to contact Health Physics and complete a confidential Declaration of Pregnancy form. Formal Declaration of Pregnancy is voluntary. After declaring her pregnancy, the employee will then receive:

- 1. An evaluation of the radiation hazard from external and internal sources.
- 2. Counseling from the staff of the Radiation Safety Division regarding modifications of technique that will help minimize exposure to the fetus.
- 3. A fetal monitoring badge, if appropriate.

Note: It is the employee's responsibility to decide whether the exposure she is receiving from penetrating radiation and intake is sufficiently low. Contact Health Physics to determine whether radiation levels in your working areas could cause a fetus to receive 0.5 rem or more before birth. Health Physics makes this determination based on personnel exposure monitor reports, surveys, and the likelihood of an accident in your work setting. Very few work positions would require reassignment during pregnancy.

Section 5 - General workplace safety guidance

Safe use of hazardous materials in the workplace depends on the cooperation of individuals who have been educated in the science and technology of the materials, who have technical training specific to their application, and who follow administrative and technical procedures established to ensure a safe and orderly workplace.

Security

No matter what source of radiation you work with, one way to enhance safety is to allow access only to those with business in the area. If you see unfamiliar individuals in the area, it is important to question them or call security. Regulatory agencies consider a high degree of security to be an important compliance matter.

The Basic Principles of Radiation Protection

External contamination occurs when radioactive material, in the form of dust, powder, or liquid, comes into contact with a person's skin, hair, or clothing. In other words, the contact is external to a person's body. People who are externally contaminated can become internally contaminated if radioactive material gets into their bodies.

Internal contamination occurs when people swallow or breathe in radioactive materials, or when radioactive materials enter the body through an open wound or are absorbed through the skin. Some types of radioactive materials stay in the body and are deposited in different body organs. Other types are eliminated from the body in blood, sweat, urine, and feces.

A person exposed to radiation is not necessarily contaminated with radioactive material. A person who has been exposed to radiation has had radioactive waves or particles penetrate the body, like having an x-ray. For a person to be contaminated, radioactive material must be on or inside of his or her body. A contaminated person is exposed to radiation released by the radioactive material on or inside the body. An uncontaminated person can be exposed by being too close to radioactive material or a contaminated person, place, or thing.

The use of universal precautions when handling human blood, human tissue and body fluids equally protects occupational workers from radioactive material contamination.

In general the basic means of reducing your exposure to radiation and keeping your exposure ALARA regardless of the specific source of radiation are as follows:

- Keep the time of exposure to a minimum
- Maintain distance from source
- Where appropriate, place shielding between yourself and the source
- Protect yourself against radioactive contamination

Protection against Radiation Exposure

The radiation worker can control and limit his/her exposure to penetrating radiation by taking advantage of *time*, *distance*, and *shielding*.

By reducing the *time* of exposure to a radiation source, the dose to the worker is reduced in direct proportion with that time. Time directly influences the dose received: if you minimize the time spent near the source, the dose received is minimized.

The exposure rate from a radiation source drops off by the inverse of the distance squared. If a problem arises during a procedure, don't stand next to the source and discuss your options with others present. Move away from the source or return it to storage, if possible.

The third exposure control is based on radiation shields, automatic interlock devices, and in-place radiation monitoring instruments. Except temporary or portable shields, this type of control is usually built into the particular facility.

Recommended Shielding For Radionuclides

Type of Radiation	Permanent	Temporary
beta radiation (e.g., Y90,	Aluminum, plastics	Aluminum, plastics, wood,
Sm153)		rubber, plastic, cloth
Gamma, Xrays, positrons	Lead, iron, lead glass, heavy	Lead, iron, lead glass, concrete
(e.g., I131, F18)	aggregate concrete, ordinary	blocks, water, lead equivalent
	concrete, water	fabrics such as gloves (for
		diagnostic xray machines
		only)

Lead shielding for fluoroscopic units

Leaded eyewear and thyroid shields are recommended if monthly collar badges readings exceed 400 mrem.

Transparent upper body shields are usually suspended from the ceiling and protect the upper torso, face and neck. The shield is contoured so that it can be positioned between the irradiated patient anatomy and the operator.

Flat panel mobile shields and when used must be placed between personnel and the sources of radiation (i.e., the irradiated area of the patient and the x-ray tube). Mobile shields are recommended for the operator and for ancillary personnel who must be in the room but who are not performing patient-side-work.

X-ray attenuating surgical gloves help to reduce the risk of radiation dermatitis in physician's hands from exposure to scattered radiation. These gloves do NOT adequately shield hands in the primary x-ray field.

Lead Apron Policy:

Lead aprons are used in medical facilities to protect workers and patients from unnecessary x-ray radiation exposure from diagnostic radiology procedures. A lead apron is a protective garment which is designed to shield the body from harmful radiation, usually in the context of medical

imaging. Both patients and medical personnel utilize lead aprons, which are customized for a wide range of usages. As is the case with many protective garments, it is important to remember that a lead apron is <u>only</u> effective when it is worn properly, matched with the appropriate radiation energy and is used in a safe and regularly inspected environment. For example, per California Title 17 (30307 Fluoroscopic Installations) "Protective aprons of at least 0.25 mm lead equivalent shall be worn in the fluoroscopy room by each person, except the patient, whose body is likely to be exposed to 5 mR/hr or more."

Personnel who are required to wear lead aprons or other similar radiation protection devices should visually inspect these devices prior to each use for obvious signs of damage such as tears or sagging of lead.

Examples of when a lead apron is effective and appropriate:

- A lead apron is inadequate for shielding ¹¹¹In or ¹³¹I but is appropriate for an 80 kVp x-ray beam (about 95 percent of the x-rays will be shielded). The lead apron can cause stress and pain in the back muscles; to protect back strain often a skirt style apron covering the lower abdomen is adequate.
- For fluoroscopic procedures a lead apron of at least 0.25 mm lead equivalence (0.5 mm is recommended) will reduce scattered x-rays by 95%. Additionally a thyroid collar is recommended. A lead apron is not necessary if only imaging patients (e.g., chest radiograph).
- All occupation workers exposed to greater than 5 mrem/hr from fluoroscopic units must wear lead. Dose rates of greater than 5 mrem/hr can be measured within 6 feet of the table and includes where the fluoroscopist stands.

Examples of when a lead apron is NOT appropriate:

• A lead apron does not provide much shielding for ¹³⁷Cs or ¹³¹I therapy patients. In the case of therapy patients, heavy portable shields are provided. Radiation Oncology provides shields for brachytherapy patients and Health Physics provides shields for the radioactive iodine therapy patients.

Lead Apron Inspection and Inventory Policy

Due to standards set forth by the Joint Commission, health care organizations must perform annual inspections on medical equipment, including lead aprons. SHC, LPCH and VAPAHCS are responsible for lead apron inspection and inventory.

The recommended apron inspection policy is as follows:

- Annually perform a visual and tactile inspection
- Look for visible damage (wear and tear) and feel for sagging and deformities.
- In cases of questionable condition, one can choose to use fluoroscopy or radiography to look for holes and cracks.
- During fluoroscopic examination, use manual settings and low technique factors (e.g. 80 KVp). Do not use the automatic brightness control, as this will drive the tube current and high voltage up, resulting in unnecessary radiation exposure to personnel and wear on the tube. Lead aprons can also be examined radiographically.

Fluoroscopic lead apron are to be discarded if inspections determine there is:

- A defect greater than 15 square mm found on parts of the apron shielding a critical organ (e.g., chest, pelvic area).
 A defect greater than 670 square mm along the seam, in overlapped areas, or on the back
- of the lead apron.
- Thyroid shields with defects greater than 11 square mm.

Section 6 - Radiation-Producing Machines (X-Ray) in the Healing Arts

Note: PRIOR to installation and during the architectural planning phase: A review of shielding plans or the adequacy of shielding for each room where ionizing radiation-generating equipment is used shall be conducted by Health Physics.

California Code of Regulations (CCR), Title 17, section 30108 states: Every registrant having physical possession or control of a radiation machine capable of producing radiation in the State of California shall complete a separate registration form for each installation within 30 calendar days of acquisition of each radiation machine. A radiation machine is any device capable of producing x-rays when its associated control devices are operated.

Additionally, CCR, Title 17, section 30115 states:

The registrant shall report in writing to the Department, within 30 days, any change in: registrant's name, address, location of the installation or receipt, sale, transfer, disposal or discontinuance of use of any reportable source of radiation.

Machine Acquisition

All machines that generate ionizing radiation, including those for either medical diagnostic or therapeutic purposes, must be registered with the State of California. Their installation and operation must be registered with Health Physics. Departments preparing to purchase or acquire radiation-producing machine(s) must provide Health Physics the following information:

- Name of the primary supervisor/operator.
- Description of the machine and its proposed use.
- Health and safety provisions may require such items as shielding and monitoring devices.

Shielding For Machines

To ensure that shielding calculations and other recommendations are adequate and the radiation dose to the public is below regulatory limits, the proposed floor plans and shielding shall be submitted to Health Physics for review and approval as early in the design process as possible to reduce the possible necessity of required design changes.

During construction and/or renovations, a shielding evaluation review shall be performed by Health Physics for the area covered in the shielding calculation report.

Machine Purchase and Registration with the State of California

All purchases of radiation-producing machines shall be made through the normal Purchasing Department procedures.

In most cases Health Physics performs all required machine registration functions with mammography machines and Lucile Packard Children's Hospital being notable exceptions. After

the machine is purchased and becomes operable, biennial inspection fees are paid by Health Physics to the State of California. Machine registration fees are recharged to departments that operate x-ray machines.

Survey of Machine Installation

Unless otherwise specified, Health Physics must survey the installation of radiation-producing machine(s), whether newly acquired, relocated, modified, or repaired to determine the effectiveness of health and safety hazard controls.

Warning Signs

All devices and equipment capable of producing radiation when operated shall be appropriately labeled to caution individuals that such devices or equipment produce radiation. Rooms or areas that contain permanently installed x-ray machines as the only source of radiation shall be posted with a sign or signs that bear the words, "CAUTION X-RAY."

Operation Signals

Any radiation-producing machine that is located in an area accessible to occupational workers and is capable of producing a dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source, shall be provided with conspicuous visible or audible alarm signal so that any individual near or approaching the tube head or radiation port is aware that the machine is producing radiation.

Changes in Machine Location and Disposition

- Health Physics shall be notified of changes in the location or disposition of radiationproducing machines.
- Health Physics shall be given notice of intent to dispose or transfer the radiation-producing machine to another user in order to notify the State of the transfer or disposal of the radiation-producing machine.
- If the radiation-producing machine is to be disposed of, all radiation-producing parts (e.g., x-ray tube) must be destroyed.

X-RAY Machine compliance Tests and Calibrations

The following information is provided as guidance:

Medical Diagnostic Machines

Health Physics annually performs x-ray machine compliance tests on medical diagnostic machines to assure compliance with applicable rules and regulations. Records of these compliance tests and any findings are kept at Health Physics. Compliance test copies are also forwarded to Radiology.

Weekly fluoroscopy phantom checks to confirm tube current and potential shall be performed by the department responsible for the unit as required by CCR Title 17.

Note: Mammography machine annual tests are performed by an outside contractor. Health Physics acts as a point of contact for this contractor. Records of these compliance tests are provided to the mammography supervisor/department.

Medical Therapy Machines

Beam calibrations are performed by a Radiation Oncology Medical Physicist before initial operation and at intervals not to exceed twenty-four months. A radiation protection survey must be performed on all new and existing installations not previously surveyed, and spot checks must be performed at least once each week for therapy systems. Annual safety compliance tests are performed by Health Physics. Records of these calibrations, spot checks, and surveys are maintained by Radiation Oncology - Radiation Physics and audited annually by Health Physics.

State Approval Process for New Therapy Machines

The typical flow of information to the State of California Radiological Health Branch (RHB) and ultimate RHB approval for the use of therapy machines is as follows:

- Radiation Oncology Medical Physics and Health Physics will jointly prepare information for submittal and review by RHB (submit to RHB >60 days prior to installation or upgrade) including:
 - Shielding calculations or supported reasoning for why shielding is not required
 - o Safety feature description such as interlocks, audible/visual beam-on indicators
- RHB returns their comments and concerns or approves shielding
- Machine is installed and registered
- RHB approves energization of the beam for the purposes of obtaining applicable TG report/calibration and the environmental survey
- Submit Physicist's Report of Safety Inspection and Comprehensive Environmental Survey
- RHB gives final approval (approval may take up to 60 days)
- Patients treatments can begin

Certificates and Permits

Under the Radiologic Technology Act, the Radiologic Health Branch (RHB):

- Certifies physicians, technologists, and permits technicians who use x-ray machines
 and radioactive materials on human beings, approves radiologic technology schools,
 and annually administers exams to physicians, technologists, and technicians for x-ray
 certification.
- Certifies individuals to use and administer radiopharmaceuticals for medical and therapeutic purposes.

The following certificates and permits are applicable for licentiates:

Licentiate Certificate:

• Radiology Supervisor and Operator (Radiologists only)

Licentiate Permits:

- Fluoroscopy Supervisor and Operator
- Radiography Supervisor and Operator
- Dermatology Supervisor and Operator

A Fluoroscopy Supervisor and Operator permit allows the individual to do any of the following: (1) Actuate or energize fluoroscopy equipment. (2) Directly control radiation exposure to the patient during fluoroscopy procedures. (3) Supervise one or more persons who hold a Radiologic Technologist Fluoroscopy Permit.

Note: Only persons authorized by the individual in charge of the installation shall operate fluoroscopic equipment. All physicians using or supervising use of fluoroscopic equipment are required to be certified by the state of California. Additionally, the Clinical Radiation Safety Committee requires that Veterans Affairs Palo Alto Health Care System comply with the State of California certificate requirements or its equivalent

A Radiography Supervisor and Operator permits allows the individual to do any of the following: (1) Actuate or energize radiography x-ray equipment. (2) Supervise one or more persons who hold a Radiologic Technologist Certificate. (3) Supervise one or more persons who hold a limited permit. (4) Certificates/Permits for Diagnostic Machines

Frequently Asked Questions

Does a resident or fellow need a fluoroscopy permit?

Answer:

No. A resident or fellow <u>working under the supervision</u> of a Certified Fluoroscopy Supervisor physician does not need to be themselves certified.

When is a fluoroscopy certificate NOT required by the State of California?

Answer:

A physician is not required to obtain a certificate or permit from the State if that physician:

- a. Requests an x-ray examination through a certified supervisor and operator.
- b. Performs radiology only in the course of employment by an agency of the Federal Government and only at a Federal facility (Note: As a best management practice the Clinical Radiation Safety Committee requires that Veterans Affairs Palo Alto Health Care System comply with the State of California certificate requirements or its equivalent).

Certificates/Permits for Radiologic Technologists and Limited Permit x-ray Technicians

- Diagnostic Radiologic Technology Certificate
- Mammographic Radiologic Technology Certificate
- Radiologic Technologist Fluoroscopy Permit (Additionally, this individual must be supervised by a licentiate who possesses a valid Fluoroscopy Supervisor and Operator Permit.)
- Therapeutic Radiologic Technology Certificate

• Permits for Limited Permit x-ray Technicians

Restraint/Manipulation of Patients during Examinations

No occupational worker shall regularly/routinely be assigned to hold or support humans during radiation exposures. Personnel shall not perform this service except infrequently and then only in cases where no other method is available. A non-occupational worker, such as a mother or father, can hold the patient. Any individual holding or supporting a person during radiation exposure should wear protective gloves and apron with a lead equivalent of not less than 0.25 millimeters. Under no circumstances shall individuals holding or supporting a person place part of their body directly in the primary beam.

Sources of Incidental X-Rays

Some electrical equipment operating at potentials of 20 kVp and above is capable of producing x-rays. Generally, only equipment operating at potentials of 30 kVp and above is capable of producing x-rays of biological significance. Anyone acquiring or constructing equipment operating at or above 30 kVp, or employing cathode-ray tubes, rectifier tubes, klystrons or magnetrons must contact Health Physics so that the machine may be checked under operating conditions to insure that no significant exposures will occur to operating personnel.

Section 8 - Radioactive Materials in Medicine and Human Research

Clinical Radiation Safety Committee (CRSCo)

At Stanford the oversight of human subject research involving radiology devices and radioactive materials is a function of the Clinical Radiation Safety Committee (CRSCo) which is chartered by the Food and Drug Administration. At SHS, LPCH and VAPAHCS, all uses of radionuclides in humans regardless of quantity or purpose must be approved by CRSCo. Research protocols involving human subjects must also be approved by Stanford's Institutional Review Board (IRB). Reviews may be conducted concurrently. In most cases, according to IRB procedures, only medical faculty and VA staff physicians may apply.

Safety policies and instructions for clinical use of radiation sources at SHS, LPCH and VAPAHCS are available from Health Physics. Additionally, *Guidance for Preparing Research Proposals Involving Ionizing Radiation in Human Use Research* (see Appendix V) provides information on administrative procedures and informed consent language. Health Physics is available to assist protocol directors designing studies with radiation. Early consultation will help assure that the proposal will be approved on the first review.

The Committee meets at least once during each calendar quarter, or more frequently, at the discretion of the Chair. A quorum consists of more than fifty percent of its then current membership, and must include the Chair, the RSO, and the Management representative.

Approval of Human Research with Ionizing Radiation

Application Process

All protocols involving both "research" or "clinical investigations" and "human subjects" must be submitted by the electronic Human Subjects "eProtocol" system and are reviewed and approved by the IRB before recruitment and data collection may start. Applications for Human Subjects which include the use of radiation are forwarded to Health Physics for review. Human subject protocols are then approved by the Stanford Clinical Radiation Safety Committee (CRSCo). If the research requires Radioactive Drug Research Committee (RDRC) review as specified by FDA RDRC regulations 21 CFR 361.1 an additional application from Health Physics must be completed.

Application Review and Approval

Your application must be reviewed by Health Physics and may need to be circulated to individual members of the CRSCO/RDRC committee for evaluation. Consult with Health Physics if you have a time-sensitive need.

Human use research approvals are contingent on contemporaneous approval by the Stanford University Research Compliance Office on Human Subject Research.

Radioactive Drug Research Committee (RDRC)

The purpose of the Radioactive Drug Research Committee (RDRC) is to guarantee patients who take part in either research protocols or clinical trials the highest degree of both radiation and pharmacological safety. It is also the RDRC's responsibility to determine the intrinsic value of the research and weigh risk versus benefit considerations before approving such studies. Federal law defines this committee, and the FDA must individually approve its members. The FDA also specifies its composition.

RDRC Organization and Operation

By law the committee must be composed of:

- A person qualified by both training and experience to formulate radioactive drugs
- A person with special competence in radiation safety and radiation dosimetry
- The remaining members of the committee shall be selected from the pertinent disciplines that may be required to carry out the provisions of the law

The chairman of this committee shall sign all applications, minutes, and reports of the committee. The committee must meet at least four times per year with a quorum (Section 361.1(c)(2)) consisting of more than 50 percent of the RDRC members present at each quarterly meeting, with appropriate representation of the required fields of specialization. Its minutes and records shall include the numerical results of the votes on protocols involving using radioactive drugs in human subjects. No member of this committee may vote on a protocol with which he is associated as an investigator.

The committee must submit an annual report to the FDA on or before January 31 of each year. This report shall include the names and qualifications of the committee members and of any consultants used by the committee. This report shall also incorporate the reports from the individual institutional users and supply statistical information showing the number of applications, the number of investigators, and pertinent information on any applications not approved for investigational study.

The committee is also obligated to report immediately the approval of any study that will involve the exposure of more than 30 research subjects or if any subjects were expected to be under the age of 18. The FDA will conduct periodic reviews of the approved committee by reviewing the annual reports, reviewing the minutes, and by examination of the full protocols for pertinent studies that have been approved by the committee. They may also institute on-site inspections.

Selection of Physicians to Use Radioactive Material for Human Treatment and Diagnosis

Physicians named as Authorized Users to a Controlled Radiation Authorization (CRA) approved for human treatment and/or diagnosis with radioactive materials should be board certified in their area of specialty practice and must be approved as an Authorized User by the Clinical Radiation Safety Committee prior to radiopharmaceuticals administrations or medical use of byproduct material.. Board certification with the American Board of Nuclear Medicine, American Board of Radiology, American Board of Osteopathic Radiology, British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology", or Canadian Royal College of

Physicians and Surgeons are considered acceptable certification organizations. The physician must also be authorized to practice medicine in the state of California.

Physicians without the above board certifications may be named as users for human treatment and diagnosis with radioactive materials on Radiation Use Authorizations provided that they meet the appropriate training and experience requirements described in 10 CFR 35.

Physicians who are in specialty training (i.e., residents and fellows) may work on Controlled Radiation Authorization (CRA) for human treatment and diagnosis provided that they are under the general supervision of a physician who is board certified in the specialty area that the resident physician is being trained in. Residents and fellows performing therapy must be under the direct supervision of a board certified physician.

Direct Supervision

Residents and fellows performing therapy must be under the direct supervision of a board certified physician. Direct supervision means that the supervisor must be able to assure that the individual being supervised is following directions and performing the task correctly. The supervisor must be able to immediately apply proper instruction and corrective actions.

Radiopharmaceuticals and Radionuclides for Human Use - Authorized User

Physicians who are authorized users may select radiopharmaceuticals in accordance with their professional judgment for the treatment and diagnosis of human beings provided that the radiopharmaceutical is approved for human use by the FDA.

Authorized Users must be approved by the Clinical Radiation Safety Committee prior to radiopharmaceuticals administrations.

Physicians who are authorized users meet the requirements in NRC regulations 10 CFR PART 35--Medical Use of Byproduct Material.

Section 9 - Individuals or Groups Requiring Training

Individuals employed by SHC, LPCH, and VAPAHCS fall into three general categories with respect to their exposure to radiation:

Radiation Workers

Workers whose major responsibilities involve working with sources of ionizing radiation or radioactive material. Examples could include:

- Radiologists
- Nuclear medicine physicians and technologists
- Radiation therapy technologists
- Cardiology technologists working with fluoroscopy equipment
- Authorized Users
- Nurses regularly caring for radionuclide therapy patients

Ancillary Worker

All personnel who may come in contact with or enter an area that contains radioactive material or sources of ionizing radiation. Ancillary Worker examples include:

- Housekeeping
- Waste processors
- Nursing staff occasionally caring for radionuclide therapy patients

Non-Radiation Workers

Personnel who would not normally be expected to encounter radioactive material or radiation sources in the course of their employment. Non-Radiation Workers examples include:

- Administrators and administrative assistants
- Food service employees
- Clerical staff.

Training Frequency for Those Working With or Near Radioactive Material or Radiation Producing Machines

- 1. Radiation workers (including all new nuclear medicine technicians or residents): initial "hands on" orientation is provided by Health Physics including instruction in the proper use and handling of radioactive material and other sources of ionizing radiation. The content of the initial training may be modified for the specific job responsibilities.
- 2. Radiation workers and ancillary workers whose exposure is frequent (waste processors): periodic refresher training.
- 3. Ancillary workers whose exposure to radioactive material and other sources is infrequent (e.g., nursing staff) or who request additional radiation safety training: training occurs on an as needed basis (e.g., for infrequent in-house iodine therapy patient, portable CT machine)
- 4. Non-Radiation workers: General information is available on demand through the webbased course "Working Safely Near Radioactive Materials EHS-5275-WEB."

Section 10 - Emergency Actions

Lifesaving emergency Actions for Patients Administered with Radiopharmaceuticals or for Patients Contaminated with Radioactive Material

If a SHC, LPCH or VAPAHCS patient is in a condition that requires immediate medical treatment, which if not given will result in death or serious medical harm to the patient, that treatment shall take precedence over radiation safety measures designed to prevent infractions of State or Federal law.

Health Physics shall provide medical personnel support as necessary (call 723-3201). Support will be provided in the area of contamination control, advice on radiation safety, and related matters.

If an emergency procedure must be performed that requires transporting the patient to another area (e.g., from the Emergency Department to Surgery), then the patient shall immediately be transported to the necessary location. Health Physics shall be notified immediately. Health Physics shall then assure that appropriate health physics support is provided.

In The Event Of an Injured Contaminated Stanford Researcher

Most radioactive materials used for research at Stanford and VA Palo Alto are low energy beta emitters, low energy photon emitters, or radionuclides that are used in nuclear medicine. These radionuclides on a contaminated patient will cause minimal to zero harm or cancer risk to medical responders. Keep the following in mind:

- Perform lifesaving measures.
- Protect yourself from radioactive contamination by observing standard universal precautions, including protective clothing, gloves, and a mask.
- Call Health Physics 723-3201.

In The Event of A Large Scale Major Radiological Event

If a large local event such as a terrorist act has occurred involving radioactive materials medical providers must be prepared to adequately treat injuries complicated by ionizing radiation exposure and radioactive contamination. Nuclear detonation and other high-dose radiation situations are the most critical (but less likely) events as they result in acute high-dose radiation.

If you are informed that radiation accident victims will be sent to the hospital, immediately notify the nuclear medicine department, health physicist, radiation safety officer and others who have expertise in radiation emergencies.

The following scenarios are adapted from *Medical Management of Radiological Casualties Handbook* (Jarrett, 1999). Acute high-dose radiation occurs in three principal situations:

• A nuclear detonation which produces extremely high dose rates from radiation during the initial 60 seconds and then from fission fallout products in the area near ground zero.

- A nuclear reaction which results if high-grade nuclear material were allowed to form a critical mass ("criticality") and release large amounts of gamma and neutron radiation without a nuclear explosion.
- A radioactive release from a radiation dispersal device (RDD)* made from highly radioactive material such as cobalt-60.

Ionizing Radiation and Terrorist Incidents: Important Points for the Patient and You

(Reprinted from Department of Homeland Security Working Group on Radiological Dispersal Device (RDD) Preparedness: Medical Preparedness and Response Sub-Group (5/1/03 Version))

- 1. All patients should be medically stabilized from their traumatic injuries before radiation injuries are considered. Patients are then evaluated for either *external radiation exposure* or radioactive *contamination*.
- 2. An external radiation source with enough intensity and energy can cause tissue damage (eg, skin burns or marrow depression). This exposure from a source outside the person **does not** make the person radioactive. Even such lethally exposed patients are no hazard to medical staff.
- 3. Nausea, vomiting, diarrhea, and skin erythema within four hours may indicate very high (but treatable) external radiation exposures. Such patients will show obvious lymphopenia within 8-24 hours. Evaluate with serial CBCs. Primary systems involved will be skin, intestinal tract, and bone marrow. Treatment is supportive with fluids, antibiotics, and transfusions stimulating factors. If there are early CNS findings of unexplained hypotension, survival is unlikely.
- 4. Radioactive material may have been deposited on or in the person (contamination). More than 90% of surface radioactive contamination is removed by removal of the clothing. Most remaining contamination will be on exposed skin and is effectively removed with soap, warm water, and a washcloth. Do not damage skin by scrubbing.
- 5. Protect yourself from radioactive contamination by observing standard universal precautions, including protective clothing, gloves, and a mask.
- 6. Radioactive contamination in wound or burns should be handled as if it were simple dirt. If an unknown metallic object is encountered, it should only be handled with instruments such as forceps and should be placed in a protected or shielded area.
- 7. In a terrorist incident, there may be continuing exposure of the public that is essential to evaluate. Evacuation may be necessary. Administration of potassium iodine (KI) is only indicated when there has been release of radioiodine.
- 8. When there is any type of radiation incident many persons will want to know whether they have been exposed or are contaminated. Provisions need to be made to potentially deal with thousands of such persons.
- 9. The principle of *time/distance/shielding* is key. Even in treatment of Chernobyl workers, doses to the medical staff were about 10 milligray or 10 millisievert [20% annual occupational limit]. Doses to first responders at the scene, however, can be much higher and appropriate dose rate meters must be available for evaluation. Radiation dose is reduced by reducing time spent in the

radiation area (moderately effective), increasing distance from a radiation source (very effective), or using metal or concrete shielding (less practical).

Additional resources:

The Radiation Emergency Assistance Center/Training Site

REAC/TS maintains a 24/7 national and international radiation emergency response capability that includes a staff of physicians, nurses, and health physicists experienced in treatment of radiation injuries/illnesses, radiation dose evaluations, and decontamination. **Call (865) 576-3131**

Radiation Emergency Medical Management

Provides evidence-based data for healthcare professionals about radiation emergencies. http://www.remm.nlm.gov/index.html

Acute Radiation Syndrome: A Fact Sheet for Physicians http://www.bt.cdc.gov/radiation/arsphysicianfactsheet.asp

Section 11 – Patient's Receiving Radioisotope Administrations

General Radiation Precautions Regarding Patients Receiving Radioiodine Therapies

Prior to any administration of radioiodine, an Authorized User physician shall date and sign a written directive and a treatment plan for the procedure. The written directive shall include the patient's name, treatment site, radiopharmaceutical, and prescribed dose.

- 1. Patients requiring hospitalization for treatment with radiopharmaceuticals who cannot be released under the conditions of 10 CFR 35.75 shall be provided with a private room with private bathroom facilities.
- 2. Radioactive iodine (¹³¹I) is usually administered orally to the patient. The iodine concentrates in the patient's thyroid. However, iodine will also be eliminated from the patient via the urine, perspiration and other body excreta within the first 48 hours. Radioactivity remaining in the body after 48 hours is located primarily in the patient's thyroid.
 - Fluids from the patient's body will contaminate linen, bed clothes, and much of what the patient touches. The major routes of potential intake are passage through skin and ingestion. For example, if you were to touch a surface contaminated with radioactivity, your fingers could transfer radioactivity to your mouth. Because of the potential for contamination universal precautions are required and effective for attending personnel (for example, a gown, shoe covers, and gloves must be worn).
- 3. Patients receiving the ¹³¹I therapy must be assigned to a room designed with shielding in the walls and a private toilet (e.g., F040, C319). The floor and any objects the patient is likely to touch must be covered with plastic or other protective material to prevent contamination. The Environmental Health and Safety hazardous waste technician will prepare the room prior to the administration of the radioiodine.
- 4. The patients will receive the following instructions:
 - a) You are restricted to your room.
 - b) You must use disposable eating utensils. These utensils should be placed in the special waste container after use.
 - c) You should flush the toilet two or three times after each use. This will insure that all radioactive urine is washed from the toilet bowl.
 - d) Both male and female patients must sit down on the toilet to prevent urine splatter.
 - e) Adult family visitors are encouraged but avoid physical contact with visitors.
- 5. Before the patient's room can be reassigned to another patient, the hazardous waste technician shall survey the room for contamination and remove all radioactive waste. The room will be decontaminated if necessary.

Nursing Care Specific Instructions for Therapy Patients Treated with Radiopharmaceuticals

- 1. Nursing and other hospital staff should minimize time spent in the room and near the patient, consistent with the provision of all necessary care. Specific "stay times" will be provided on the patient's door.
- 2. Attending personnel must wear disposable gloves when handling or touching items in the room. Remove gloves and place in designated waste container before leaving the room.
- 3. Gowns should be worn if significant time will be spent in the room or whenever necessary to protect clothes from contact with the patient or items in the room.
- 4. Shoe covers should be worn when in the patient's room. They must be removed when leaving the room to avoid tracking contamination from the room.
- 5. Disposal items such as plates and eating utensils should be used whenever possible. These items must be placed in the designated waste container.
- 6. Bedclothes, towels, and bed linen used by the patient should be placed in the laundry bag provided and left in the patient's room until monitored by the hazardous waste technician. If contaminated, they will be collected by the hazardous waste technician.
- 7. All items within the room should be checked for contamination by the hazardous waste technician before being removed.
- 8. Excess food may be flushed down the toilet.
- 9. The patient is to be encouraged to take responsibility for his/her own urine collection, if possible. Urine and stool may be disposed of via the sanitary sewer.
- 10. Nursing staff should not provide assistance in bathing the patient for the first 48 hours unless specifically approved by the physician. However, the patient should be encouraged to bathe/shower daily.
- 11. Items such as bedpans, urinals, and basins, if disposable, may be disposed of as radioactive waste. If these items are not disposable, they shall be thoroughly washed with soap and running water. The same items should be used for the individual patient until his/her treatment is terminated and shall be monitored before being returned to general stock. Protective gloves shall be worn while cleaning possibly contaminated equipment.
- 12. Any vomitus, gastric contents collected during the first 24 hours by nasogastric aspiration, or excessive sputum should be collected in a waterproof container and held for disposal by the hazardous waste technician if disposal down the sanitary sewer is not possible. If there has been a large spill of urine, Health Physics (723-3201) or Nuclear Medicine Laboratory personnel shall be notified immediately.
- 13. Before the patient's room can be reassigned to another patient, the hazardous waste technician must survey the room for contamination and remove all radioactive waste. The room will be decontaminated if necessary.

General Radiation Precautions Regarding Patients with Implants of Sealed Radioactive Sources

Prior to any administration of radiation from sealed sources, an Authorized User physician will date and sign a written directive and a treatment plan for the procedure. The written directive shall include the patient's name, treatment site, radionuclide, number and sequence of sources, source strength, and total radiation dose to be delivered to the target area.

Nursing Care Specific Instructions for Patients with Implants of Sealed Radioactive Sources:

- 1. Do not spend any more time in patient's room than is necessary to care for patient. In particular, time at patient's bedside should be kept to a minimum. Specific "stay times" will be provided on the patient's door.
- 2. Place laundry in linen bag and save until surveyed and released by Radiation Oncology or Health Physics.
- 3. Housekeeping staff may not enter the room unless escorted by a nurse. Only essential cleaning should be done.
- 4. Visitors shall be 18 years or older.
- 5. Patient shall not have pregnant visitors.
- 6. Visitors should remain at least 6 feet from the patients and should not stay more than 2 hours per day (unless other information is provided).
- 7. A radiation survey must be performed before patient is discharged and the room is cleaned

General Radiation Precautions Regarding Patients Receiving Doses of Radioactive Material For Diagnostic Studies Or Minor Therapies

The most commonly used radioactive material in Nuclear Medicine studies is technetium-99m (^{99m}Tc), a gamma emitter with a half-life of 6 hours. In many of the studies, especially bone and renal studies, the radioactive compounds are removed from the body in the urine and occasionally in the stool. Most of the radioactivity is gone after 24 hours.

The objective in diagnostic procedures involving radionuclides is to determine something about an organ's shape or function. The administered dose must be small so as not to produce any radiation effect, which might result in a change in the status quo of the patient.

With minor therapies, such as radioiodine for treatment of hyperthyroidism, the amount of radioactivity administered is sufficiently small to permit outpatient treatment of these patients.

Relatively little radiation exposure or contamination hazard to hospital is associated with patients receiving radionuclides for minor therapies or diagnostic studies. Radiation warning signs are not posted for these patients.

General Radiation Precautions Regarding Patients Treated With Yttrium-90 (⁹⁰Y) Glass Microspheres

Yttrium-90 microspheres are tiny spheres loaded with ⁹⁰Y, a radioisotope that emits pure beta radiation. ⁹⁰Y has a "half life" of about 64 hours. The radiation from ⁹⁰Y is largely confined to a tissue depth of 2 - 3 mm. After injection into the artery supplying blood to the tumors, the spheres are trapped in the tumor's vascular bed, where they destroy the tumor cells by delivering the beta radiation. The radiation emissions from the tumor are contained within the patient's body and after 14 days the majority of the radiation effect has occurred.

Because the spheres may have trace amounts of free ⁹⁰Y on their surface, very small amounts of ⁹⁰Y can be excreted in the urine. No special precautions are required except universal precautions.

Nursing Care Specific Instructions for Patients Treated With Yttrium-90 (⁹⁰Y) Glass Microspheres

No special precautions are required when working with patients treated with ⁹⁰Y except using universal precautions. Nursing personnel are not required to wear radiation monitoring badges. No special precautions are needed for dishes, instruments, or linen. The radiation emissions from the tumor are contained within the patient's body.

Release of individuals containing unsealed byproduct material or implants containing byproduct material

10 CFR 35.75 requires that the released individual is provided with instructions, including written instructions, on actions recommended to maintain doses to other individuals ALARA if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). If the dose to a breast-feeding infant or a child could exceed 1 mSv (0.1 rem), assuming there was no interruption of breast-feeding, the instructions shall also include:

- Guidance on the interruption or discontinuation of breast-feeding; and
- Information on the potential consequences of failure to follow the guidance. This implies that the licensee will confirm whether a patient is breast-feeding prior to release of the patient.
- The record is required to be maintained for 3 years after the date of release if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 5 mSv (0.5 rem).

In addition, 10 CFR 35.75 (c) requires that the licensee maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the TEDE is calculated by:

- Using the retained activity rather than the activity administered:
- Using an occupancy factor less than 0.25 at 1 meter;
- Using the biological or effective half-life; or
- Considering the shielding by tissue.

Transportation Service - General Radiation Precautions

Occasionally patients who have received therapeutic levels of radioactivity must be transported within the Stanford Medical Center. The risks associated with transportation of such patients are small, and results in a very insignificant exposure if the following procedures are followed:

- a. Transport the patient by the most direct route.
- b. The patient shall not be left in public waiting areas or corridors. If necessary the transporter shall remain in the area to keep other people at least 6 feet from the patient.
- c. When transporting the patient, do not share elevators with other staff or patients.

Actions In Case of Death for Patients Administered With Therapeutic Radioactive Sources

If a patient dies with internally deposited radioactive material from a therapeutic treatment:

- a. If the radioactivity in the patient is a temporary sealed source implant, the sources shall be removed prior to the decedent being transported to the hospital morgue. A survey by the medical physicist or Health physicist shall be done to assure that no sources remain in the body or in the room.
- b. If the radioactive material is in an unsealed form or a permanent sealed source implant, the attending physician shall tag the body with a radioactive materials tag stating the estimated amount and type of radionuclide in the body. Health Physics shall provide the necessary radiation safety consultation.
- c. An autopsy or other invasive procedure shall not be performed until the Health Physics Radiation Safety Officer or designated representative has met with the appropriate physician(s) and determined the best radiation safety procedures and contamination control measures.

Appendix I - Frequently Asked Questions:

What is the policy on holding patients during diagnostic imaging procedures?

The regulations (California Code of Regulations Title 17) state:

"No individual occupationally exposed to radiation shall be permitted to hold patients during exposures except during emergencies, nor shall any individual be regularly used for this service. If the patient must be held by an individual, that individual shall be protected with appropriate shielding devices such as protective gloves and apron and he shall be so positioned that no part of his body will be struck by the useful beam."

The interpretation of this regulation is that occupational workers shall not routinely hold a patient, but can, in unusual cases, provided that they are protected with appropriate shielding. A non-occupational worker, such as a mother or father, can hold the patient. There is some flexibility in the regulations on how an emergency would be defined.

What are the lead apron requirements when using and fluoroscopes?

- Persons closest to the unit (generally those with "hands on" the patient) should wear a lead equivalent apron when operating the unit.
- Because radiation exposure drops off very quickly, other personnel in the room do not need to wear lead aprons but should also maintain as much distance from an operating unit as feasible. Radiation exposures 6 feet away are near natural background radiation levels.
- Only necessary personnel should be in the room when the unit is operating. However, for ALARA purposes (i.e., to keep exposures As Low As Reasonably Achievable) keep a portable lead shield between the unit and other personnel in that room performing procedures unrelated to the fluoroscopes unit.

What are the criteria for patient gonadal shielding for radiation protection purposes?

For patients, the gonads may or may not need to be in the primary x-ray field. If the gonads are not in the primary field, the radiation exposure drops off rapidly. In practice, the patient may be provided with a leaded apron anyway, because the staff has been trained to do that or it provides reassurance to the patient.

For situations where the gonads are in the primary radiation field, shielding should be employed as long as the areas of interest are not blocked by the shielding. An example might be to image the pelvis to evaluate the heads of the femur bones. For males, the testes are easily shielded by special shields that are in contact with the body. Alternately, shadow shields can be used. These are typically triangular pieces of lead that are suspended by flexible arms (like those for desk lamps) from the x-ray tube housing. Since the collimator light field is aligned to the x-ray field, the shadow cast by the suspended piece of lead will show what area is being shielded from the x rays produced. For females, the gonads are not visible or generally localized in the abdomen. As such, shielding is seldom employed for females, but the x-ray field collimators may be used to shield the center of the abdomen.

How effective are thyroid shields in protecting the radiation worker from unnecessary exposure? At what dose level do you recommend using a thyroid shield?

Typically, when a lead apron is worn during a fluoroscopy procedure, where close-in work is needed, thyroid shields are also used by physicians, and perhaps other support staff, to keep the thyroid dose as low as reasonably achievable (ALARA). Often lead glasses are used too during fluoroscopy x-ray procedures to reduce the dose to the lens of the eye. A typical 0.5-mm lead-equivalent apron or thyroid shield will provide 85% to 95% attenuation of scattered fluoroscopy x-rays. Thyroid shields are designed for fluoroscopy x-rays and can not shield radioisotopes such as ¹³¹I or ¹⁸F.

A patient treated with radioiodine (¹³¹I) has renal failure and is on dialysis. What radiation safety points should I be aware of?

There is some potential for contamination with these procedures, although it is not excessive and it depends on the administered activity and the length of time from the administration to the dialysis procedure. Administering the radioiodine immediately after dialysis will maximize the time for elimination of the excess radioiodine from the body prior to the next dialysis. The dialysis staff will already be using universal precautions to protect themselves from the patient's blood and other body fluids. These are the same precautions that are used to protect against contamination from radioactivity. Flushing of the waste from the dialysis tubing directly to the sanitary sewer line and collecting the dialysis tubing as radioactive waste is appropriate.

What are hospital attending staff radiation safety precautions for patients receiving Samarium (153Sm) palliative therapy?

Because ¹⁵³Sm is mostly a beta particle-emitting radionuclide and beta particles are effectively shielded by the human body ¹⁵³Sm does not present an external radiation hazard. However, ¹⁵³Sm is excreted through the urine for up to three days. Use universal precautions when handling collected urine or urine soiled linens. Urine can be disposed of in the sewer.

When are dosimeters not needed?

Dosimeters measure ionizing radiation only; therefore, dosimeters are not responsive to radiation emitted from ultrasound or magnetic resonance imaging equipment.

Does a resident or fellow need a fluoroscopy permit?

No. A resident or fellow <u>working under the supervision</u> of a Certified Fluoroscopy Supervisor physician does not need to be themselves certified.

When is a Fluoroscopy Supervisor certificate/permit not required?

A physician is not required to obtain a certificate or permit from the State if that physician:

- a. Requests an x-ray examination through a certified supervisor and operator.
- b. Performs radiology only in the course of employment by an agency of the Federal Government and only at a Federal facility (Note: As a best management practice the Veterans Affairs Palo Alto Health Care System complies with the State of California certificate requirements).

Appendix II - Receiving Radioactive Material Packages

Radioactive material packages delivered directly to Nuclear Medicine contain radionuclides that will be administered to patients for diagnostic and therapeutic procedures. Direct deliveries may arrive on any day and at any time of the day.

- Nuclear Medicine may receive packages that are specific to the Nuclear Medicine CRA, including ^{99m}Tc, ¹⁸F from the cyclotron, exempt quantity sources for calibration, and other special calibration sources.
- All packages that are received with a White I, Yellow II, or Yellow III label shall be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours, or within 3 hours of the start of the next business day if received after working hours.
- All packages shall be visually inspected for any sign of external damage (e.g., wet or crushed). If damage is noted, processing of the package shall be halted and Health Physics shall be notified immediately.

Processing Nuclear Medicine Radioactive Packages

Upon receipt, all radioactive material packages will be entered into the Pinestar database or other Nuclear Medicine database.

Nuclear Medicine Package Radiological Receipt Swipe Surveys

The exterior surface of the package shall be surveyed (swiped over an average of 300 cm²) for removable contamination.

- If wipe test results indicate no radioactive contamination is present on the exterior of the package (e.g., less than 22 dpm/cm²), process the package as usual.
- If wipe test results indicate that removable contamination levels are > 22 dpm/cm² and < 220 dpm/cm², the package should be decontaminated prior to further handling (inform Health Physics of this occurrence).
- If wipe test results indicate that removable contamination levels exceed 220 dpm/cm², Health Physics shall be notified immediately.

Nuclear Medicine Package Radiation Surveys

The dose rate from the package at 1 meter from each of the package surfaces shall be measured.

- The Transportation Index (TI) noted on the packages with "Yellow II" or "Yellow III" labels is the dose rate, in mrem/hour, at 1 meter from the package surface. The surface dose rate for such packages shall not exceed 200 mrem/hour.
- The dose rate from packages with "White I" labels shall be less than 0.5 mrem/hour on the package surface. (See 49 CFR 172.403) If dose rates exceed any of the dose rates discussed above, stop and notify the RSO or his/her designee immediately.

Procedure for Empty Packages (i.e., packages that will be returned to the vendor)

- Prior to returning the empty package (usually an ammo box), swipe and monitor the package for contamination.
- If contamination is present, decontaminate.
- If the package is not contaminated remove or switch the radiation label to the "empty" notice
- Receipt and return of all radioactive packages is documented by entering the required data in to the Pinestar Database or other Nuclear Medicine Database.

Appendix III - Use of Inert Gases in Nuclear Medicine

Inert gases (¹³³Xe) in nuclear medicine should be used in such a manner that no individual, other than the patient, is likely to receive a submersion dose greater than 2500 mrem over the course of one year. Inert gases shall be used in such a manner that the instantaneous levels of airborne radioactivity shall not exceed 5 times the inhalation derived air concentration (DAC) listed in 10 CFR 20, appendix B (1E-4 uCi/ml for ¹³³Xe).

Health Physics will assure that appropriate technical assistance and guidance is provided for achieving compliance with the above.

The room where the inert radioactive gas is used must be under negative pressure. The exhaust from the room where the inert gas is used shall be directly vented to the environment. Fresh air may be mixed with the exhaust stream so as to reduce the concentration of radioactive inert gas.

Health Physics shall approve machines used for the administration of radioactive inert gases to patients. The machines must feature:

- a. A rebreathing system.
- b. A charcoal filtered exhaust trap which will trap or hold most of the radioactive gases such that airborne radioactivity levels are not likely to exceed one DAC fraction at 1 meter from the machine's exhaust.
- c. A radiation monitor or other alarm system which indicates that the trap has failed or reached its maximum loading.

In the event the patient experiences breathing difficulties or other medical problems, the patient will be immediately disconnected from the machine. Appropriate first aid measures shall be conducted. As soon as practicable, the machine shall be shut off with the priority directed towards the well-being of the patient.

Appendix IV - Proper Operating Procedures for Fluoroscopic Units

- 1. As in a radiographic procedure, use the smallest possible beam area to reduce patient exposure and scatter radiation.
- 2. Perform visual observation of the alignment of the image intensifier, x-ray tube, and the patient prior to the initiation of a fluoroscopy procedure.
- 3. Minimize fluoroscopic doses by reducing the fluoroscopic time used. Fluoroscopic time, of course, varies with different patients, the type of the examination, and the complexity of the clinical study. Perform quarterly outputs for Entrance Skin Exposure (ESE) rates for all fluoroscopes. Post the ESE rates in the fluoroscopy room for reference by physician/radiologist.
- 4. Operators should use the timing device to indicate a preset time, which will serve as a reminder to keep it as short as possible.
- 5. Use the shortest possible distance from the image intensifier to the patient. For fluoroscopes that are equipped with AEC; AEC operations provide for automatic compensation so that when longer distances are used, a higher radiation dose is given to the patient.
- 6. The fluoroscopist should wear a thyroid shield, leaded gloves, and glasses to reduce exposure to the thyroid, extremities, and eyes.

Appendix V - Guidance for Preparing Research Proposals

Guidance for Preparing Research Proposals Involving Diagnostic Use of Ionizing Radiation in Human Use Research

Introduction

This guidance has been prepared by the Clinical Radiation Safety Committee (CRSCo) to help ensure a careful, complete, and timely review of research projects that include human use of ionizing radiation. CRSCo serves under California Department of Health Services regulations and Nuclear Regulatory Commission regulations as the Radiation Safety Committee for Stanford and Veterans Affairs Palo Alto Health Care System, and is also chartered by the Food and Drug Administration as a Radioactive Drug Research Committee. It meets quarterly.

Review and Approval

Health Physics reviews the application for completeness and accuracy. If the effective dose is less than or equal to 5000 millirem and the organ equivalent dose is less than or equal to the value derived by dividing 5 rad by the associated weighting factor (see table below), Health Physics can approve the application. If the effective dose is greater than 5000 millirem or the organ equivalent dose is greater than the value derived by dividing 5 rad by the associated weighting factor (see table below), it may be approved before the next CRSCo meeting by the Chairman or his designee, the Radiation Safety Officer (RSO) or his designee, and one physician faculty member, or be approved at the next CRSCo meeting. The approval levels listed are for adults. For minors, approval levels are 10% of those listed above and in the table.

All of these approvals are reported to CRSCo at its next meeting; it can re-open and revise the approvals. If the proposal requires the approval of the Radioactive Drug Research Committee, CRSCo must review and approve the application at the next meeting. There are also organ dose limits associated with each category.

Category	Effective Dose in millirem	Organ Equivalent Dose in rad	Approval Authority ²
I	$H \le 5000$ and	$H_T \le 5/W_T$	RSO or designee
		$HSkin \leq 500$	
II	H > 5000 or	$H_T > 5/W_T$	RSO, + Chairman + one
		HSkin > 500	physician faculty or CRSCo

 W_T values are from ICRP Report 60, Table 2: gonads 0.20; red bone marrow 0.12; colon 0.12; lung 0.12; stomach 0.12; bladder 0.05; breast 0.05; liver 0.05; esophagus 0.05; thyroid 0.05; skin 0.01, bone surface 0.01; remainder 0.05.

Radioactive Drug Research Committee proposals require full CRSCo approval. Dose limits: whole body, active blood-forming organs, lens and gonads 3 rem per study and 5 rem total; other organs 5 rem per study and 15 rem total. See 29 CFR 361.1.

Draft "Informed Consent Form" Language

To estimate risk associated with a specific procedure, CRSCo uses the dose calculation methodology established by the International Commission on Radiological Protection in Report 60, "1990 Recommendations of the International Commission on Radiological Protection." Based on the whole body effective dose H and organ equivalent dose H_T, CRSCo has prepared different statements you may want to consider when developing your "Informed Consent Form."

<u>Suggested language for Category I effective dose proposals</u>. You will be exposed to radiation during this research. Your total effective dose will be about X millirems. If there is any risk from this exposure, it is too small to be measured. The risk is low compared to other everyday risks. You receive about 300 millirems each year from natural sources. Radiation workers can receive 5000 millirems each year.

<u>Suggested language for Category II effective dose proposals</u>. You will be exposed to radiation during this research. Your total effective dose will be about X rems. This dose has an estimated risk of fatal cancer of about X percent (assume 5 E-2/Sv)₁. This is in addition to the natural fatal cancer risk of about 25 percent.

If individual organ doses are in the Category II levels then a statement regarding the acute risks should be added to the draft language for the effective dose proposals listed above as appropriate.

1- ICRP, 1991:7 0.05 fatal cancers per person-sievert for the entire population

<u>Suggested language for Category II organ equivalent dose proposals</u>. You will be exposed to radiation during this research. The dose to your skin will be about X rads. This dose may result in temporary or permanent hair loss and possible skin changes or damage.

For more information

If you would like a copy of the documents that form the foundation for this guidance, or if you have questions specific to your project, please contact Health Physics at 723-3201.

Appendix VI - Definitions

Absorbed DoseThe energy imparted by ionizing radiation per unit mass

of irradiated material. The units of absorbed dose are the

international unit, gray (Gy) or the rad.

Activation The process of making a material radioactive by

bombardment with neutrons, protons, or other nuclear

radiation

Activity The rate of disintegration per (second = dps, minute =

dpm) or decay of radioactive material. The original unit for measuring the amount of radioactivity was the Curie (Ci). In the International System of Units (SI) the curie

has been replaced by the becquerel (Bq).

Administrative Panel on Radiological Safety

(APRS)

The Administrative Panel on Radiological Safety (APRS) oversees the entire institutional radiation safety program for both Stanford, LPCH and VAPAHCS. It also reviews applications that are outside the jurisdiction of the local control committees (NHRSC, CRSCO, RDRC see below).

ALARA (acronym for As Low As Reasonably Achievable) Make

every reasonable effort to maintain exposures to radiation as far below the dose limits as practical and consistent with the purpose for which the licensed activity is undertaken. ALARA also adheres to the principle of keeping radiation doses of patients As Low As

Reasonably Achievable.

Authorized User Authorized user has two definitions: 1) Authorized user is

a person who has fulfilled the training requirements and has been added to a Controlled Radiation Authorization 2) Authorized User means a physician who meets the requirements in 10 CFR 35.57. Authorized Users must be approved by the Clinical Radiation Safety Committee prior to radiopharmaceuticals administrations or medical

use of byproduct material.

Bioassay The determination of kinds, quantities, or concentrations,

and in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials

excreted or removed from the human body.

Brachytherapy A method of radiation therapy that uses sealed sources to

deliver a therapeutic dose at a distance up to a few

centimeters from the source.

California Code of Regulations (CCR),

Title 17

California State Code of Regulations, also known as Title 17, govern the use of ionizing radiation and radioactive materials at locations where the State of California has jurisdiction.

CFR

Code of Federal Regulations

Clinical Radiation Safety Committee (CRSCo)

At Stanford the oversight of human subject research and standard of care procedures involving radiology devices and radioactive materials is a function of the Clinical Radiation Safety Committee (CRSCo) which is chartered by the Food and Drug Administration. At SH&C and VAPAHCS, all uses of radiation in humans regardless of quantity or purpose must be approved by CRSCo. Research protocols involving human subjects must also be approved by Stanford's Institutional Review Board (IRB). Reviews may be conducted concurrently. In most cases, according to IRB procedures, only medical faculty and VA staff physicians may apply. (For additional information review Radioactive Drug Research Committee below).

Contamination

Deposition of radioactive material such as a liquid or powder in any place where it is not desired.

Controlled Radiation Authorization (CRA)

Controlled Radiation Authorization. The permit issued by the APRS or RSO that allows the use of ionizing radiation.

Curie

See "Activity."

Declared Pregnant Worker

A woman who is occupationally exposed to ionizing radiation and who has voluntarily contacted Health Physics, in writing, of her pregnancy and the estimated date of conception for the purpose of monitoring the radiation dose to the fetus.

Deep dose

The dose from external whole body exposure at a tissue depth of 1 cm.

Deep Dose Equivalent

External whole body exposure that is the dose equivalent at a tissue depth of 1 centimeter (1,000 mg/cm2).

Deterministic Effect

A deterministic effect, also known as Nonstochastic effect, is a health effect who's severity varies with the dose and for which a threshold is believed to exist. Radiation-induced skin burns from fluoroscopic procedures (for skin exposures greater than 1 Gy) and cataract formation (for eye exposures greater than 2 Gy)

are examples.

Diagnostic x-ray System

An x-ray system designed for irradiation of any part of the human or animal body for diagnostic purposes.

Dose Equivalent

The product of the absorbed dose in tissue, quality factor (i.e., rad x Q = rem) or organ dose weighting factors (i.e., Gy x $w_T = Sv$), and all the necessary modifying factors at the location of interest. The units of dose equivalent are the international unit, Sievert (Sv) or the rem.

Dosimetry

Devices that measure the cumulative occupational dose of radiation to an individual or area. Types of dosimetry include film badges, thermoluminescence dosimeters (TLDs), finger rings, and albedo type dosimetry (CR39) for neutron measurements.

Exposure

A measure of the ionization produced in air by x- or gamma radiation. The sum of electric charges on all ions of one sign produced in air when all electrons liberated by photons in a volume of air are completely stopped in air, divided by the mass of the air in the volume. The units of exposure in air are the international unit, coulomb per kilogram or the Roentgen.

Extremity

Hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

Eye Dose Equivalent

External exposure of the lens of the eye that is the dose equivalent at a tissue depth of 0.3 centimeters (300 mg/cm2).

Health Physics

Under contract to the SHC, LPCH and VAPAHCS, Health Physics manages the radiation safety program in the hospital environment. All Health Physics staff report to the Radiation Safety Officer.

High Radiation Area

High radiation area means any area accessible to individuals, in which radiation exists at such levels that an individual could receive in any one hour, a dose equivalent in excess of 100 millirem (1.0 millisievert) at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Ionizing Radiation

Any electromagnetic or particulate radiation capable of producing ions directly or indirectly in its passage through matter. In general, it will refer to gamma rays and x-rays, alpha and beta particles, neutrons, protons, high speed electrons, and other nuclear particles. Ionizing radiation does not include radio waves, visible, infrared, or ultraviolet light (i.e., non-ionizing radiation).

IRB

Institutional Review Board (National Institutes of Health). A committee that reviews and approves research projects that involve human subjects. The Stanford University Administrative Panel on Human Subjects performs this function

LPCH

Lucile Packard Children's Hospital

Monitoring

The measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

Non-Human Use Radiation Safety Committee (NHRSC)

The Non-Human Use Radiation Safety Committee is responsible for reviewing applications under its jurisdiction to provide assurance that the work can be done safely and in accordance with the requirements in the *Radiation Safety Manual* and the *Hazards Evaluation*.

Nonstochastic effect

Nonstochastic effect means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

Nuclear Regulatory Commission (NRC)

The Nuclear Regulatory Commission (NRC) is the primary federal agency charged with regulating the use of byproduct radioactive and special nuclear materials. The NRC replaced regulatory functions of the Atomic Energy Commission (AEC). The NRC was established by the Energy Reorganization Act of 1974. This act abolished the Atomic Energy Commission and transferred to the NRC all the licensing and related regulatory functions

Occupational Dose

The dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation and to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the general public.

Public dose

Dose received by a member of the public from exposure to radiation and to radioactive material released by a licensee. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

Rad

Special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram. 100 rads equal 1 gray.

Radiation Area

An area accessible to individuals, in which radiation exists at such levels that an individual could receive, in any one hour, a dose equivalent to the whole body in excess of 5 mrem (.05 millisievert), at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Radiation Safety Officer (RSO)

The Radiation Safety Officer (RSO), who is identified on the radioactive materials licenses, is the manager of Health Physics, which manages the institutional radiation safety program.

Radiation-producing machine

Any device capable of producing ionizing radiation when the associated control devices are operated, excluding devices that produce radiation only by the use of radioactive materials (e.g., high dose rate (HDR) temporary brachytherapy).

Radioactive Drug Research Committee (RDRC)

The Radioactive Drug Research Committee (RDRC) is chartered by the Food and Drug Administration to review and approve basic research involving the administration of radioactive drugs to human subjects generally recognized as safe and effective when administered under the conditions specified in the RDRC regulations (21 CFR 361.1). The RDRC is a subset of CRSCo.

Radioactive Drug Research Committee (RDRC)

Radioactive Drug Research Committee (RDRC). The RDRC is chartered by the Food and Drug Administration to review and approve basic research projects involving the administration of radioactive drugs to human subjects. CRSCo provides this service.

Radioactive Materials

Any material, solid, liquid, or gas that emits ionizing radiation.

rem

The special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor. For most forms of radiation, one rem is numerically equal to one roentgen or one rad. One sievert equals 100 rems.

Restricted Area

An area, access to which is limited by the licensee for purpose of protecting individuals against undue risk from exposure to radiation and radioactive material. Roentgen (R)

The special unit of radiation exposure. The amount of exposure that liberates one esu of charge per cc of air. For most forms of radiation, one roentgen is numerically equal to one rem or one rad. Although considered obsolete, this term and its abbreviation are still commonly used.

Shall

Used in laws, regulations, or directives to express what is mandatory.

Shallow Dose Equivalent

External exposure of the skin or an extremity that is the dose equivalent at a tissue depth of 0.007 centimeters (7 mg/cm2) averaged over an area of 1 square centimeter.

Should

Used in laws, regulations, or directives to express what is best practice.

sievert (Sv)

SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in greys multiplied by the quality factor. 1 sievert equals 100 rems.

Stanford Medical Machine Use Authorization (SMM)

An authorization issued by Health Physics to operate an ionizing radiation-producing machines.

Stochastic Effect

A stochastic effect is a health effect where the probability of occurrence increases with increasing dose (e.g. cancer)

Survey Meter

Any portable radiation detection instrument designed to determine the presence of radioactive materials and/or ionizing radiation fields. Commonly used survey meters are of the types: a. Count rate meters (GM counters) that detect only the presence of radioactive material. Under certain conditions the survey meter's reading may be used to determine the exposure rate from a source of radioactive material. b. Dose rate meters (ion chambers) that are used to evaluate the intensity of radiation fields in units such as rem per hour, millirem per hour or Sievert

University License

A broad scope license issued to Stanford University and specific off-site locations such as SHC for the use of radioactive materials.

Unrestricted Area

Any area for which access is not limited by Health Physics for the purpose of protecting individuals from exposure to radiation and radioactive materials.

per hour.

Wipe Test (Sample)

A test (sample) made for the purpose of determining the presence of removable radioactive contamination on a surface. A piece of soft filter paper is wiped over 100 square centimeters of the area to be surveyed and counted for radioactivity with an appropriate instrument.