

JOSEPH R. PEACOCK, M.D.

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WEST CHESTER, PA 19382

July 25, 1996

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Docket No. 030-28798
License No. 07-20884-01
Inspection No. 030-28798/96-001

Subject: Letter dated July 18, 1996

Gentlemen:

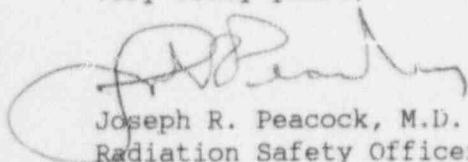
Items B and C of the Notice of Violation:

We have already implemented the action stated in our letter dated May 28, 1996. In addition to requiring that source inventory and sealed source leak test results be faxed to my office, I am requiring that these documents also be faxed to consulting medical physicist. If for some reason a nuclear medicine technologist will not be available to perform these functions at the stated time interval, either my consulting medical physicist or I will perform these functions. Sealed source inventories will be performed quarterly and sealed source leak tests will be performed at six-month intervals.

Item E:

I have reviewed the training programs contained in our license application and contained in our amendments to our license for both of our facilities. The training programs will be implemented as stated in license and amendments to the Nuclear Regulatory Commission. I and my consulting medical physicist will be involved in monitoring the training programs at both facilities.

Very truly yours,



Joseph R. Peacock, M.D.
Radiation Safety Officer

JRP/pml

cc: Dr. W. Maguire
Dr. A. Lombardi
Dr. E. Torvik

RADIATION TRAINING FOR **ANCILLARY PERSONNEL**

I. Introduction:

Ionizing radiation (radionuclides, x-rays, gamma rays) is potentially hazardous unless used with strict adherence to safety rules and procedures. It is not only hazardous to you but also can do damage to future generations by altering the DNA molecule. Thus, the safety rules which govern all uses of ionizing radiation are as concerned with preventing genetic damage as with protecting the health of the exposed individual. When followed faithfully, these rules limit exposures of workers, members of the general public, and patients to levels far below those which could cause any adverse effect to you or produce genetic changes in the DNA molecule.

II. Radiation Safety Officer:

The Radiation Safety Officer (RSO) has primary responsibility for radiation safety of all individuals within this facility. The RSO is responsible for assuring that radiation safety activities are being performed in accordance with approved procedures and federal and state regulatory requirements. If You have any concerns about your radiation safety, contact the Radiation Safety Officer.

III. Radiation Dosimeter Procedure:

It is the policy of this facility to provide radiation dosimeters to all individuals who work directly with radioactive material or work in an area classified as a controlled area. Ancillary personnel are not issued radiation dosimeters because their exposure to ionizing radiation is less than 10 percent of the maximum annual limit. In fact, our nuclear medicine technologist usually receives less than 10 percent of the maximum annual limit. Therefore, ancillary personnel's radiation dose would be less.

Although exposure to naturally occurring radiation cannot be avoided (for example, the radiation dose due to natural background may vary from 100 to 200 mrem/year depending on geographical location), all occupational exposure is considered to carry some risk, and unnecessary exposure should be avoided.

Radiation Safety Precautions:

- a. Minimize unnecessary time near patients containing radioactive material. Patients who have completed their imaging studies could contain as much as 40 millicuries of Tc-99m.
- b. Have patients who have completed their imaging studies sit so their distance from you is maximized. Increasing their distance from your location will minimize your exposure to radiation being emitted from the radioactive material in their body.

IV. Regulations:

This facility operates under federal and state licenses, and is required to comply with conditions attached to our license, and appropriate federal and state regulations. The regulations and licenses are available for inspection by workers at this facility and are located in the nuclear medicine section of this facility.

Any questions with regard to radiation safety may be addressed to the Radiation Safety officer of the Nuclear Regulatory Commission, King of Prussia, Penn.

V. Bio-Effects of Radiation:

Biological Considerations:

The basic assumption behind all rules and regulations governing the exposure of individuals to ionizing radiation is that all ionizing radiation will produce biological damage at the cellular level and that this damage is non-repairable, i.e., the radiation damage is additive in its effect

on the organism. The risk of long term radiation damage to the individual is directly associated with the total absorbed dose.

The types of biological damage induced by ionizing radiation can be divided into two categories.

Somatic Effects:

Effects which may become evident in the irradiated individual at the tissue and cellular level are called somatic. These effects may manifest themselves in the irradiated individual 20 to 30 years post irradiation. There are many examples of carcinogenesis and leukemogenesis in humans exposed to ionizing radiation. Marie Curie and daughter are both thought to have died of radiation induced leukemia.

Genetic Effects:

Effects which become evident in the descendants of the individual exposed to ionizing radiation are called genetic. Such effects result from alterations in the reproductive cells which can lead to defects in the offspring. Genetic mutations are always recessive in nature, i.e., they do not improve the functional efficiency of the organism so mutated. The genetic damage may not be manifest in the descendants of the exposed individual, but may lie dormant for several generations. Information on the genetic effects of radiation comes almost entirely from animal experiments.

Radiation in Early Pregnancy:

Since the Law of Bergonie and Tribondeau was published in 1906 it has been known that the sensitivity of cells to radiation damage is related to their reproductive activity and inversely related to their degree of differentiation. It follows that children could be expected to be more radiosensitive than adults, fetuses more radiosensitive than children, and embryos even more radiosensitive.

A special situation arises when an occupationally exposed woman is pregnant. Exposure of the abdomen of such a worker to penetrating x or gamma radiation would also involve exposure of the embryo or fetus. Because a number of studies have indicated that the embryo or fetus is more sensitive than an adult, particularly during the first three months after conception, when a woman may not be aware that she

is pregnant, the National Council on Radiation Protection and Measurements recommended in its Report No. 39, that special precautions be taken to limit the exposure when an occupationally exposed woman could be pregnant so that the dose to the fetus shall not exceed 0.5 rads.

The principal effects of radiation on the developing embryo and fetus are:

- a. Growth retardation;
- b. Fetal death;
- c. Gross congenital malformations.

A dose of 10 rads to the embryo during the first 6 weeks after conception is often regarded as the cutoff point above which a therapeutic abortion should be considered to avoid the possibility of an anomalous child.

ALARA Program:

This facility has a program in place called ALARA. These letters stand for "As Low As Reasonably Achievable". This means that where it is economically realistic to do so, it will implement changes that will reduce the radiation dose to all individuals within its jurisdiction below regulatory limits. The administrative control of this program has been given to the Radiation Safety Officer.

VII. Unsafe Radiation Conditions:

If conditions exist in your area that could lead to unwarranted radiation exposure to any individual, either employee, patient, or visitor, notify the Radiation Safety officer and your office supervisor.

END

February 22, 1994

8.1

Training Program for Personnel Working With Radioactive Material

The only individuals covered by this program are the Nuclear Medicine Technologist and the Cardiologist. Both individuals are in the imaging room while clinical studies are being performed.

All personnel starting to work in the imaging room or with patients containing radioactive material will attend an orientation session conducted by the Radiation Safety Officer or his designated representative prior to being permitted to perform any functions with radioactive material. This initial orientation session and annual refresher will cover the following topics.

- a. A review of the license and the license application.
- b. A review of the conditions attached to license.
- c. A review of the documents contained in the procedure manual.
- d. ALARA program.
- e. Appropriate NRC regulations contained in Parts 19,20,35.
- f. Biological effects of ionizing radiation.
- g. General principles for controlling radiation exposures:
 - a. Shielding
 - b. distance
 - c. Time
- h. Obligation to report "unsafe " radiation conditions or items of non-compliance to the Radiation Safety Officer.

Personnel will be instructed:

- a. Before assuming duties with, or in the vicinity of radioactive materials.
- b. During annual refresher training.
- c. Whenever there is a significant change in duties, regulations, or conditions attached to license.

Training program for Personnel Working at
Southern Chester County Medical Building
Suite 301
West Grove, Pennsylvania 19390

All personnel starting to work in the imaging room or with patients containing radioactive material will attend an orientation session conducted by the Radiation Safety Officer or his designated representative prior to being permitted to perform any functions with radioactive material. This initial orientation session and annual refresher will cover the following topics.

- a. A review of the license and the license application.
- b. A review of the documents contained in the procedures manual.
- c. ALARA procedure.
- d. Appropriate NRC regulations contained in Parts 19, 20, and 35.
- e. General principles for controlling radiation exposures.
- f. Biological effects of ionizing radiation.
- g. Obligation to report unsafe radiation conditions or items of non-compliance to the Radiation Safety officer

Personnel will be instructed:

- a. Before assuming duties with, or in the vicinity of radioactive materials.
- b. During annual refresher training.
- c. Whenever there is a significant change in duties, regulations, or conditions attached to license.

Ancillary personnel will receive a training booklet when first starting to work at this facility and will attend the annual review session conducted by the Radiation Safety Officer.

Equipment at Suite 301:

- a. L-block
- b. Lead lined storage container for radioactive waste
- c. Lead bricks for shielding
- d. Wipe test counter for surface contamination swipes, Model 05-578 by Nuclear Associates
- e. Syringe shields
- f. Dose Calibrator by Nuclear Associates, Model 34-061
- g. A Baird Atomic imaging camera, Model 77
- h. Survey meters from the Silverside facility will be taken to Suite 301 on days imaging studies are performed.

EMPLOYEE'S RADIATION TRAINING

Employee's Name: _____

Date: _____

Instructor's Name: _____

The following topics were discussed on the above date with this employee.

1. Film Badge Procedure
2. 10CFR Part 19, 20, 35
3. Radiobiological Effects of Radiation
4. License and license application
5. Conditions attached to license
6. Documents contained in the procedure manual
7. ALARA program

If any of the above listed items were not discussed during this instruction session, mark an "X" through that item on this sheet.

Employee's Signature: _____