CITY OF PHILADELPHIA

DEPARTMENT OF PUBLIC HEALTH
OFFICE OF THE MEDICAL EXAMINER
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ROBERT K. ROSS, M.D.
Health Commissioner

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Medical Examiner

030-06186

November 9, 1993

Mr. Charles W. Hehl, Director
Division of Radiation Safety and Safeguards
Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1416

RE: NRC CONFIRMATORY ACTION
LETTER NO. 1-93-019

Dear Mr. Hehl:

In response to item 3 of the above letter, please find enclosed for your review a copy of our Radiation Safety Program protocol.

Please feel free to contact directly Mr. Guy Purnell, Radiation Safety Officer, (215-823-7463) if you have any questions.

Thank you for your assistance in this matter.

Sincerely,

Barry Dickman

110092

Barry Dickman
Executive Assistant

cc: Pat DiPilla
Haresh G. Mirchandani, M.D.
Ian Hood, M.D.
Dr. Mohamed Shanbaky, (NRC)
Susan Pingree
Guy Purnell

Enclosure

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RADIATION SAFETY PROTOCOL FOR RADIOIMMUNOASSAY

DEPARTMENT OF PUBLIC HEALTH
PHILADELPHIA MEDICAL EXAMINER'S OFFICE
TOXICOLOGY LABORATORY
321 UNIVERSITY AVENUE
PHILADELPHIA, PENN. 19104

11/93

RADIATION SAFETY PROTOCOL FOR RADIOIMMUNOASSAY

INTRODUCTION:

The level of radiation present in substances utilized in the Medical Examiner's Toxicology laboratory is minute. Adherence to the following safety procedures will ensure a safe and pleasant working environment, as well as satisfy Federal, State and local regulations.

WORKING WITH RADIOACTIVE MATERIALS

1. All direct contact with radioactive materials must be avoided.

2. Never pipette radioactive solutions by mouth.

3. Any action which may inadvertently bring radioactive materials in contact with the body, such as eating, drinking, smoking or applying cosmetics is prohibited in areas where radioactive material is present.

4. Gloves must be worn at all times when radioactive materials of any type are unpacked, prepared for use and during the actual pipetting step. The gloves must be worn during all subsequent handling of the assay (e.g. centrifugation, decantation, and addition of tubes to the gamma counter). The gloves must be removed when performing such functions as answering the telephone, using the computer terminals, the rolodex, etc. The potential contamination of these surfaces with radioactive material must be prevented.

5. A properly vented hood must be use whenever the escape of volatile radioactive compounds is possible. Most RIA kits do not require this precaution.

6. A buttoned lab coat must be worn at all times to minimize potential contamination of personal apparel. All spills of radioactive materials onto lab coats must be brought to the attention of the manager or supervisor and Radiation Safety Officer (RSO) as quickly as possible. Attempts will then be made to decontaminate the lab coat with an appropriate detergent. Contaminated lab coats must not be taken out of the RIA laboratory. If the lab coat cannot be decontaminated, it will be discarded along with other radioactive wastes.

7. A person dositermy badge must be worn at all times when one is working in RIA or involved with the disposal of

radioactive materials. Blank badges should be available to ensure compliance for new employees and for lost badges.

8. Waste receptacles should be available in adequate quantity and appropriately labelled for the various isotopes (I125, Co57, H3). Counting vials must be handled as a separate hazardous waste until they have been shown to be free of radioactivity. Only solid radioactive waste is to be added to the specifically labelled receptacles.

9. All spills of radioactive materials must be brought to the attention of the Radiation Safety Officer or Manager, or supervisor, as quickly as possible. The contaminated area must be outlined with tape and the radioactive material must be absorbed with paper towels and the towels discarded in the proper radioactive waste container. The area must then be cleaned with an appropriate detergent until the survey meter indicates satisfactory results. All spills together with the action taken to clean and monitor the spill must be documented. All efforts must be made to keep the water in the water bath free of radioactive materials. If radioactivity is splashed on a test tube rack, the rack must be replaced and the contaminated rack must be decontaminated. Do not place contaminated racks in the water bath.

10. Accurate records must be kept of all radioactive materials received(date and quantity). Likewise, a log must be kept to document the use of the radioactive materials. This log must be readily available for review by supervisor and by the Nuclear Regulatory Commission.

11. Radioactive warning labels "CAUTION RADIOACTIVE MATERIAL" must be posted in all areas where radioactive materials are used and stored. This means that all freezers and refrigerators and separate vessels which contain radioactive materials must be labelled properly.

12. Routine survey meter and wipe tests must be performed at least once per week in the following areas: RIA laboratory, reagent cold room, radioactive waste storage area and in other strategic areas as determined by the Radiation Safety Officer. Active records of all surveys must be kept for review by the supervisor and the Nuclear Regulatory Commission.

13. All spills of any type together with problems noted during the routine surveys must be brought as quickly as possible to the attention of the Radiation Safety Officer and the Laboratory Safety Officer.

14. All shipments of radioactive materials should be inspected for leakage prior to opening . After a gross examination go over the package with the survey meter to assure that there is no detectable radioactivity indicating leakage. Gloves should be used when opening the packages containing radioactive substances. Report all leakage of improper shipments to the supervisor or manager.

PROPER LABORATORY ORGANIZATION

1. All radiological work must be done in the designated area, away from traffic where danger of contamination is high.

2. Care must be taken to maintain the separation of quantitatively non-compatible radioisotopes.

3. All radioactive substances should be properly labelled by isotope and specific activity. In addition, any volatile substance should be kept tightly sealed.

4. Laboratory equipment and glassware which are subject to contamination must be segregated to prevent cross contamination of different radioisotopes.

5. Laboratory work surfaces should be monitored in accordance with the prevailing regulations of the federal and state or local authorities.

6. All environmental safety surveys should be approved by a supervisor.

SPILL CONTROL

1. Contain the spill. This may be accomplished either by wiping it up with towels for small spills or by absorbing it with sponges, towels, or a spill pillow for more extensive accidents.

2. Isolate the spill area. In order to prevent the inadvertent spread of radioactive material, the spill area should be declared off-limits until decontamination has been accomplished.

3. Determine the type of radioactive material which has been spilled, and prepare for decontamination accordingly.

4. Decontaminate the spill area: Detergent-soak towels should be used and the area wiped dry. Repeat the process until monitoring reveals acceptable levels of contamination.

5. Dispose of materials used for decontamination in accordance with the disposal guidelines mentioned below.

6. All areas of contamination should be monitored during and after decontamination procedures with a wipe test or Survey Meter to determine the efficiency of the cleaning procedure. All counts should be entered in the environment survey log.

7. Any surface that shows radioactive contamination exceeding background counts by a factor of two should be considered a candidate for immediate decontamination procedure.

8. All radioactive materials must be disposed of in accordance with the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory.

9. Liquid or solid items with a short half-life may be allowed to decay to acceptable radiation levels (equivalent to background on a survey meter) and then disposed of in a routine manner, if permitted by the laboratory's radiation license.

10. Disposal of radioactive materials in excess of the maximum described above and/or in water insoluble form (toluene base scintillation cocktails and various solid wastes) should be made by a licensed disposal service. Special receptacles and/or absorption material should be available for the wastes at all times.

STORAGE AND HANDLING OF RADIOACTIVE WASTE

1. Radioactive waste is to be stored in plastic bags, plastic syringe boxes, or metal drums and labelled appropriately with the universal radioactive symbol. Radioactive waste storage locations shall be clearly demarcated by signs. The radioactive waste storage location shall be secured by lock and with access restricted to authorized personnel. All persons required to handle radioactive waste materials will be provided with a radiological safety orientation, protective garments, and equipment recommended for the type of material being handled. A radiation monitoring program shall also be in effect for all employees exposed to radiological materials.

DISPOSAL OF RADIOACTIVE WASTE

1. Radioactive waste is to be disposed by one of the following methods as required by NRC and the local state agency responsible for environmental regulation:

a. Disposal through regular trash or sewage after the waste has been stored long enough to have attained radioactive decay to safe levels---as permitted by licensure.

b. The storage for radioactive decay purposes is generally recommended only for materials whose half-life is less than sixty days.

c. Dispatching for burial by a licensed contractor utilizing the NRC approved manifesting system.

d. Dilution and dispersion---Liquid radioactive waste may be disposed of via the sanitary sewer system if the following conditions are met:

1. The quantity of the diluted radioactive material will result in a concentration equal to or below the recommended safe values as established by the NRC.

2. Ten times the quantity specified in appendix "C" of 10 CFR, part 20 .

3. Permitted by local sewer authority.

4. The instantaneous concentration of the effluent should not exceed the safe values.

5. Each sink used for disposal of radioactive waste must display the radioactive caution sign.

6. Federal regulations require documentation of the disposition of all radioactive waste.

7. The record retention period for these records is three years from the date issued. See state regulations for other record keeping requirements.

SPECIAL PROBLEMS OF COUNTING TUBES

1. The counting tubes will be rinsed with water until they are negative for radioactivity as determined by wipe testing. They will then be disposed of with the biohazard waste in the normal way.

PERSONAL MONITORING

1. Radiation dose is monitored by film badge and/or bioassay. The type of monitoring depends on the type, quantity and concentration of radioisotope being used.

2. All employees working in areas where high energy beta and gamma emitters are used must wear either film badges or TLD's which must be processed on a routine (monthly or quarterly) basis.

AREA MONITORING

1. Area monitoring must be carried out weekly to ensure that contamination does not spread outside the restricted area.

2. Several methods can be used for area monitoring:

   a. Smear(or wipe) tests for surface contamination.

   b. Geiger-Meuller tubes for high energy beta and gamma radiation.

   c. Ionization meters to measure fields caused by gamma emitters or X-radiation.

   d. Proportional counters for low energy beta emitters.

3. All monitoring equipment must be calibrated against standards traceable to a certified reference standard source (e.g. National Bureau of Standards in the U.S.A.). The monitoring equipment should be calibrated yearly, and calibrations records maintained on site for 5 years.

RADIATION SAFETY COMMITTEE RESPONSIBILITY

1. A radiation safety committee should be in place in each laboratory and is responsible for:

   a. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with Federal and local guidelines.

   b. The committee shall be composed of the laboratory RSO, Safety Officer, or alternate, a member of the management staff and two(2) RIA department personnel.

RADIATION SAFETY COMMITTEE DUTIES

1. The Committee shall:

   a. Be familiar with all pertinent radiological safety regulations.

b. Review the training and experience of all individuals who use radioactive material and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with local Health Department regulations.

c. Be responsible for monitoring the institution's program to maintain individual and collective doses as low as reasonably achievable.

d. Review semi-annually, with the assistance of the RSO, occupational radiation exposure records of all personnel working with radioactive materials.

e. Establish a table of investigational levels for occupational radiation exposure, which when exceeded, will initiate an investigation and consideration of action by the RSO.

f. Review and approve all request for use of radioactive material within the institution.

g. Prescribe special conditions that may be required during the proposed use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

h. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with Health Department Protocol. The review shall include an examination of all records reports from the RSO , results of local Health Department inspection, written safety procedures, and the adequacy of the institutions management control system.

i. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

j. Maintain written records of all Committee meetings , actions, recommendations, and decisions.

RADIATION SAFETY COMMITTEE MEETINGS

1. The radiation Safety Committee shall meet as often as necessary to conduct its business, but not less than once in each calendar quarter.

2. A quorum shall consist of at least one-half of the

Committee's membership, including the RSO and the management representative.

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