CEDARBROOK CARDIOLOGY
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MS16
Q-2

February 24, 1997

Mr. John D. Kinneman, Chief
Nuclear Material Safety Branch 2
Division Nuclear Materials Safety
Region 1
475 Allendale Road
King of Prussia, Pa. 19406

Dear Mr. Kinneman,

Attached please find the additional information and clarification requested by Mr. Fitar Lodi.

Please expedite the application. We appreciate your help and interest.

Sincerely,

Younus A. Rakla, M. D.

YAR/vcs

124129

FEB 25 1997

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This is in reference to the telephone conversation with Mr. Sitar Lodi on February 24, 1997 and your letter dated February 5, 1997. Following is the additional information clarification requested :

[1]. Item [3]. Please disregard the sealed source(s) requested in the application. Our operation will be limited only to diagnostic procedure and no sealed sources are required for such procedure.

[2]. Item 6(a). Attached is the Unit Dose Log sheet that will be used for logging the dispensed doses.

[3]. Attached is the Dose Calibrator QC procedure with correction. All the measurements are background corrected and we also **confirm** that geometrical dependence verification will also be performed any time the dose calibrator is relocated.

If and when linearity is performed by employing attenuator method manufacturer recommended procedure will be employed and the reference manual will be provided to the individual performing the test. This procedure will be available to every one in the lab at all the time.

[4]. Attached is the updated Waste Disposal Procedure. **Please disregard the mention of the basement storage area in our initial application**. The attached Waste management procedure is the most current and accurate. The waste will be stored in the hot lab in lead lined waste container and will be handled and disposed of as stated in the attached procedure.

Be assured that the procedures established at our facility will meet regulatory guide 10.8, rev.2.

RADIOACTIVE WASTE MANAGEMENT

PURPOSE

The Nuclear Medicine Department uses radionuclides only for Diagnostic procedure. These radionuclides have different half lives (T 1/2). The dose preparations and injections produce waste which is contaminated by the radionuclides and therefore is classified as **Radioactive Waste.** It is the responsibility of the **Nuclear Medicine Department Staff to handle and dispose of this radioactive waste APPROPRIATELY.**

Radioactive Waste if not **handled properly becomes a RADIATION HAZARD** and can cause unnecessary exposure to the members of the general public and can contaminate the Environment. Therefore proper waste management is a very important function of the Nuclear Medicine Department.

Under no circumstances should Radioactive Waste be disposed of through the regular waste WITHOUT PROPER MONITORING.

PROCEDURE

In the Nuclear Medicine Department approximately 75% of the time short half life Radionuclides (99m Tc). Therefore it is very easy to separate the waste by it's half life and store it for decay before disposal.

Short Half Life: Any radionuclide with Half Life of seven (7) hours or less.

Long Half Life: Any radionuclide with Half Life of seven (7) hours or more.

Collection of Short Half Life and Long Half Life Radioactive Waste:

Sine the Nuclear Medicine Department operates from Monday to Friday, it is easy to collect the waste from Monday to Friday. Leave the trash in the lead lined waste container for decay during week end in the Hot Lab.

Collect ALL Short and Long half life waste separately as follows and label them appropriately:

(a.) All 99m Tc waste
(b.) All 201 TI waste
and (e.) All other waste SEPARATELY in the containers provided for these wastes.

DO NOT MIX SHORT AND LONG HALF LIFE MATERIALS.

1. **Syringes/Needles:**

Place all the syringes and needles in the lead container that was received from the local pharmacy. Place all the lead syringe container in the boxes provided by the local pharmacy. Ship this boxes to the pharmacy after wipe tested and when the boxes are found to be contamination free.

Log the wipe test results in the appropriate forms.

All other contaminated trash must be placed in the appropriate lead lined container for storage.

Store this container in the hot lab for decay (**10 half lives**) before disposal. (follow disposal procedure)

Follow the same procedure for **Thallium 201 and other long half life** materials. **These wastes must be collected separately in the containers provided. NO MIXING OF THESE WASTES IS ACCEPTABLE.**

Store this trash for decay (**10 half lives**) before disposal. Follow the disposal procedure.

When the trash is placed in the Hot Lab for Storage and for decay, record the following information on the form provided:

1. **Storage Date:** the day the trash is placed in the Hot Lab in the lead lined trash container.

2. **Half Life:** e.g. 6 hrs for 99m Tc waste.

3. **Isotope.**

4. **Proposed Disposal Date:** e.g. for 99m Tc waste disposal is after 60 hrs (10 half lives). So if the waste was stored on the first of the month, then the proposed disposal date would be the third of the month.

5. **Date Waste was Disposed:** Actual date when the waste is removed from the Hot storage area for disposal after 10 half lives.

6. **Survey.**
   a. BKG: background reading taken outside of the hot lab room in the hallway.

b. Waste: reading of the trash bag surveyed.

7 **Remarks:** Any unusual findings such as high readings after 10 half lives or if the trash was placed for further decay.

DISPOSAL PROCEDURE:

Short Half Life waste stored for decay will be disposed as follows:

1. Whenever handling radioactive trash always use gloves , lab coat, film badge, and ring badge.

2. Every Monday remove the 99m Tc waste from the previous week from the Lead lined waste container.

3. Check the battery on the survey instrument. Take a background radiation reading outside the Hot Lab area in the hallway.

4. Make sure that the survey instrument is operating at the lowest scale (0.05-0.1 mR/hr).

5. Record the background radiation level on the disposal form. (see attached)

6. Place the trash on absorbent pads and place in the front room or hallway and survey the trash thoroughly from all sides,

7. If the survey readings are **NOT ABOVE THE BACKGROUND RADIATION LEVEL READINGS THEN DISPOSE OF THE TRASH IN THE REGULAR TRASH.** Follow the facility guidelines for the regular trash.

8. **IF THE SURVEY READINGS ARE ABOVE THE BACKGROUND RADIATION LEVEL: DO NOT DISPOSE THE TRASH. STORE THE TRASH FOR ANOTHER 24 HOURS.**

9. Survey the trash after 24 hours. If the reading is **NOT ABOVE THE BACKGROUND RADIATION LEVEL THEN DISPOSE OF THE TRASH AS REGULAR TRASH.** Follow the facility guidelines for the trash. **If the survey readings are still above BACKGROUND RADIATION LEVEL: DO NOT DISPOSE OF THE TRASH. NOTIFY THE RADIATION SAFETY OFFICER.**

10. After the completion of the disposal procedure the Technologist must **monitor** his/her :
    a. Hands
    b. Clothes
    c. Bottoms of the shoes.
    d. Record the readings in the appropriate forms.

Long Half Life waste stored for decay will be disposed of as follows:

1. Whenever handling radioactive trash always use gloves, lab coats film badge and ring badge.

2. **Long half life material** will be removed after it has been stored for **10 HALF LIVES.** Follow the disposal procedure.

3. Take the background radiation reading outside the Hot Lab in the hallway.

4. Make sure that he survey instrument is operating at the lowest scale (0.05-0.1 mR/hr)

5. Record the background radiation level on the disposal form. (see attached)

6. Place the trash on the absorbent pads and place in the front room or hallway and survey the trash thoroughly from all sides.

7. If the readings of the survey are **NOT ABOVE THE BACKGROUND RADIATION LEVEL READINGS THEN DISPOSE OF THE TRASH IN THE REGULAR TRASH.**
   Follow the facility guidelines for the regular trash.

8. **IF THE SURVEY READINGS ARE ABOVE THE BACKGROUND RADIATION LEVEL: DO NOT DISPOSE OF THE TRASH. STORE THE TRASH FOR ANOTHER WEEK.**

9. Survey the trash again after one more week. If the reading is NOT **ABOVE THE BACKGROUND RADIATION LEVEL THEN THE DISPOSE OF THE TRASH AS REGULAR TRASH.** Follow the facility guidelines for the trash. If the survey readings are still above **BACKGROUND RADIATION LEVELS: DO NOT DISPOSE OF THE TRASH. NOTIFY THE RADIATION SAFETY OFFICER.**

10. After completion of the disposal procedure the Technologist must **monitor** his/her:

    a. Hands
    b. Clothes
    c. Bottoms of shoes
    d. Record the readings on the appropriate forms.

QUALITY CONTROL FOR DOSE CALIBRATOR

PURPOSE

The accuracy of the dose of the Radiopharmaceutical given to the patients depends on the performance of the Dose Calibrator. Therefore it is very important to have an acceptable QA program for the radionuclide dose calibrator. The QA program for the dose calibrator consists of tests to check the following:

1. Accuracy
2. Consistency/Precision
3. Linearity
4. Geometry dependence

PROCEDURE

1. ACCURACY

This test is normally performed by measuring the reference standards whose activity is traceable to NBS (National Bureau of Standards). Since the radionuclides used in Nuclear Medicine have short half lives, it is not possible to get a standard for such a radionuclide. Therefore a radionuclide standard with a long half life and similar photon energy to the nuclide used in Nuclear Medicine should be used with appropriate correction factors.

Different radionuclide standards such as Co-57, and Cs-137 are normally used in Nuclear Medicine.

a. Measure the background level at the appropriate instrument setting for the radionuclide standard that is being measured. (Co-57 setting for CO-57). If the instrument is equipped with the automatic background subtraction, make sure it is functioning properly. (see operating manual).

b. Take several measurements of the standards at appropriate instrument settings and correct for background

c. Compare the average of these measurements with the decay corrected standard activity. The measured activity of the standard should be within + or - 5% of the decay corrected standard activity.

This test is normally performed at the Installation of the dose calibrator and quarterly thereafter (See form No A, Dose Calibrator Accuracy Test).

2. PRECISION/CONSTANCY CHECKS:

This test will be performed daily on the dose calibrator. The instrument should be accurate and reproducible within an acceptable degree of precision in measuring the constant activity over time.

The standards are chosen such that their activity is constant over a long period of time. Thus Cs-137 (100-200-uCi & $T_{½}$ = 30y) and
Co-57 (3-5 mCi & $T_{½}$ = 271 d) are used.

a. Measure the background level at the appropriate instrument setting for the radionuclide standard that is being measured. (Co-57 setting for CO-57). If the instrument is equipped with the automatic background subtraction, make sure it is functioning properly. (see operating manual).

b. Measure the activity of each standard and log the net readings on the appropriate forms. (Form B)

c. For Co-57 standard, make sure that the measured activity falls within + or - 5% of the decay corrected, expected activity. (Column: Cal Act, Form B).

d. Repeat the procedure for the Cs-137 standard and log the measurements on Form B.

e. Repeat the measurements using Cs-137 standard at the instrument settings for the various radionuclides used in the department and log the readings on Form B.

f. This test for consistency MUST be performed daily prior to the use of the dose calibrator for patient doses and the measured activity of the standard should fall within + or -5% of the calculated activity. If the measurements DO NOT fall within the set limits then:

   i. DO NOT USE THE DOSE CALIBRATOR.
   ii. Notify:

      (1) RSO

3. LINEARITY.

The Dose Calibrator should be linear over a wide ranger of activities. This means that hc Dose Calibrator should be accurate in measuring a few microcuries to maximum activity normally used by the facility. There are several methods that may be used to determine the linearity of the dose calibrator. (see attached example C & D)

[a]. A Unit Dose of the maximum activity normally used should be used for the Radiopharmacy to perform this test.

[b]. A Tc-99m vial or syringe with the maximum activity is measured at various time intervals until it decays down to 30 uCi, or one can measure the activity using the commercially available kit with various attenuators. (CAL CHECK) Refer to the manual provided with the kit. Reading must include the clinically used dose range.

[c]. Plot the measured activity versus time on the semilog graph paper and draw a best fit straight line through the points.

[d]. The activities plotted should be within + or - 5%, of the calculated activity, if the instrument is linear and functioning properly.

[e]. If the errors found are greater that + or - 5%:

i. DO NOT USE THE DOSE CALIBRATOR
ii. Notify:
(1) RSO
(2) Medical Physicist

4. GEOMETRICAL DEENDANCE

Check for Geometrical Dependence is normally done when the instrument is first installed, after major repair, whenever a change is made in the type of vial or the syringe used in the Radiopharmaceutical dose preparations, and when the dose calibrator is relocated at different location. New generation dose calibrators are normally geometrically independent. However, it should be verified initially and the manufacturer's data should also be checked.

a. Take a 20 to 30 ml vial with 1-2 mCi in 1 to 2 ml.

b. Assay the vial.

c. Increase the volume in the vial with water in steps of 2,4,8,10,15,20,25,ml. Assay the vial after each addition of water. Net activity is obtained by subtracting the background.

d. Select one of the volume as the Standard and calculate the Correction Factor (CF) for each of the volumes.

$$CF = \frac{\text{Standard volume activity}}{\text{Volume Activity}}$$

e. Plot the CF versus Volume on the linear graph paper. Use this graph to select the proper Volume Correction for routine assay of that radionuclide.

f. The true activity of the sample is given by:

True Activity = Measured Activity X CF

g. Similarly the CF for the syringes can be obtained.
Note: CF for plastic syringes cannot be used for glass syringes.
Geometrical Variation should be no more than + or - 2%

See the Example E attached.

Unit Dose Dispensing Records

Shipment Survey

Shipment #	In Coming wipe	Out Going wipe	Survey Surface	1 meter
Bkg				
1				
2				
3				
4				

Dispensed: Time/Date: _____

Activity Dispensed: _____

Affix Customer Copy of RX Label Here

Dispensed: Time/Date: _____

Activity Dispensed: _____

Affix Customer Copy of RX Label Here

Dispensed: Time/Date: _____

Activity Dispensed: _____

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