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Ref: SA/LAB

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Division of Public Health Services
Department of Health and Welfare
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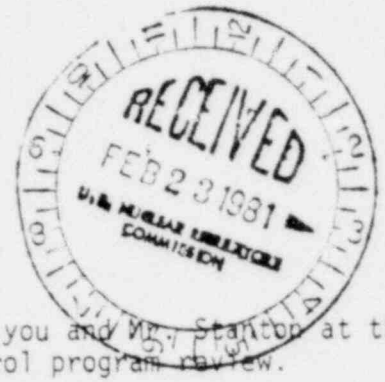


Dear Ms. Tefft:

This is to confirm the comments made to you and Mr. Stanton at the conclusion of the recent radiation control program review.

Based on the results of the review, the staff believes that the New Hampshire program for control of agreement materials is adequate to protect the public health and safety and is compatible with the NRC's program.

While no significant problems were found in any program area during the review, we believe that improvements can be made in the program. Specific comments and recommendations are enclosed. I would appreciate your review of our recommendations and receiving your comments on them.

I appreciate the courtesy and cooperation extended to Mr. Bolling during the meeting.

Sincerely,

Donald A. Nussbaumer

Donald A. Nussbaumer
Assistant Director
for State Agreements Program
Office of State Programs

Enclosure:
As stated

cc: Dr. M. Mires
J. Stanton

COMMENTS AND RECOMMENDATIONS ON THE

NEW HAMPSHIRE RADIATION CONTROL PROGRAM

I. Licensing. Licensing Procedures is a Category II Indicator. The following minor deficiency was noted.

A. Comment

A review of program licensing procedures and discussions with program staff indicate the need for developing supplementary licensing guidance for license reviewers.

Recommendation

We recommend the development of internal licensing guides. These guides will help to assure that uniform and up-to-date licensing practices are followed. New licensing guides will also aid in the training of new staff.

Licensing. Licensing Actions is a Category I Indicator. The following minor deficiency was noted.

B. Comment

A review of selected license files indicates that greater emphasis is needed on the use and performance testing of dose calibrators.

Recommendation

We strongly recommend that each medical applicant whether for initial license or renewal be required to have a dose calibrator. The applicant should have step-by-step procedures for its use and calibration. Each applicant should have a set of appropriate check sources. (See attachment)

Licensing. Licensing Actions is a Category I Indicator. The following minor deficiency was noted.

C. Comment

A review of selected license files indicates that the training and experience of radiation safety committee members is not always adequately documented.

Recommendation

We recommend that applicants be required to submit training and experience data for each radiation safety committee member. This information should be documented in the licensee's folder and updated as new committee members are added by amendment and during license renewals.

II. Compliance. Independent Measurements is a Category II Indicator. The following minor deficiency was noted.

A. Comment

A review of selected compliance files indicated that independent measurements were not performed during all compliance inspections.

Recommendation

We recommend that confirmatory measurements be performed during each inspection and that the results of such measurements be documented in the inspection report.

Compliance. Enforcement Procedures is a Category I Indicator. The following minor deficiency was noted.

B. Comment

A review of selected compliance files showed the need for a more timely review of inspection reports and dispatch of enforcement letters.

Recommendation

We recommend that inspection reports be reviewed and enforcement letters be dispatched within 30 days of the licensee inspection.

Compliance. Inspection Frequency is a Category II Indicator. The following minor deficiency was noted.

C. Comment

The inspection priority schedule indication is that in-plant radiography is assigned to priority B-II. This calls for inspections at 24-month intervals after an initial inspection at 8 months.

Recommendation

We strongly recommend that in-plant radiography be upgraded to inspection priority I. This would require yearly inspections with extensions to 18 months for licensees with favorable compliance histories. This recommendation is based on the fact that in-plant radiography is as potentially hazardous as field radiography and that under NRC practice, industrial radiography would be subject to inspection at a frequency of one per year.

Section 2

## METHODS FOR CALIBRATION OF DOSE CALIBRATOR*

All radiopharmaceuticals must be assayed for activity to an accuracy of 10 percent. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument constancy (daily)
2. Instrument accuracy (at installation and annually thereafter)
3. Instrument linearity (at installation and quarterly thereafter)
4. Geometrical variation (at installation)

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. Test for Instrument Constancy

*Instrument constancy* means that there is reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Assay at least one relatively long-lived reference source such as Cs-137, Co-57,** or Ra-226** using a reproducible geometry before each day's use of the instrument. Preferably, at least two reference sources (for example, 3-5 mCi of Co-57 and 100-200 μCi of Cs-137 or 1-2 mg Ra-226 (with appropriate decay corrections) will be alternated each day of use to test the instrument's performance over a range of photon energies and source activities.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).
2. Measure background level at same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.
3. Calculate net activity of each source subtracting out background level.
4. For each source, plot net activity versus the day of the year on semilog graph paper.
5. Log the background levels.
6. Indicate the predicted activity of each source based on decay calculations and the ±5 percent limits on the graph.
7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
8. Variations greater than ±5 percent from the predicted activity indicate the need for instrument repair or adjustment.
9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

E. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will use a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator).

1. Assay the Tc-99m vial in the dose calibrator, and subtract background level to obtain net activity in millicuries.
2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.
3. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

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* See ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides" (American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 100.8).

** Co-57 and Ra-226 are not subject to NRC licensing; the respective State agency should be consulted to determine its requirements for possessing this material.

| *Assay Time* (hr)* | *Correction Factor* |
|---|---|
| 0 | 31.633 |
| 6 | 15.853 |
| 24 | 1.995 |
| 30 | 1 |
| 48 | 0.126 |

*Example*: If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be 15.625 mCi x 15.853 = 247.7 mCi and 15.625 mCi x 0.126 = 1.97 mCi, respectively.

4. On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval).

5. The activities plotted should be within ±5 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ±5 percent indicate the need for repair or adjustment of the instrument.

6. If instrument linearity cannot be corrected, it will be necessary in routine assays to use either (a) an aliquot of the eluate that can be accurately measured or (b) the graph constructed in step 4 to relate measured activities to calculated activities.

F. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than ±2 percent. (Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.) When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

To measure variation with volume of liquid, a 30-cc vial containing 2 mCi of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

1. Assay vial at the appropriate instrument setting, and subtract background level to obtain net activity.

2. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1. (Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

3. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy), and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

*Example*: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected,

$$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows:

True Activity = Measured Activity x Correction Factor

where the correction factor used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial, and a correction factor may be calculated.

7. It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established.

An alternative to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

G. Test for Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides, including Cs-137, Co-57, and Ba-133, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS and documented.

* Assay times should be measured in whole hours and correction factors should be used to the third decimal place as indicated. The more recent half-life of $T_{1/2}$ = 6.02 hours has been used in calculating these correction factors.

The activity levels of the reference sources used should approximate those levels normally encountered in clinical use (e.g., Co-57, 3-5 millicuries) giving adequate attention to source configuration. Identify in your application the three sources that you will use. State nuclide, activity, and calibration accuracy. The lower-energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. Assay the reference standard in the dose calibrator at the appropriate setting, and subtract the background level to obtain the net activity.

2. Repeat step 1 for a total of 3 determinations, and average results.

3. The average activity determined in step 2 should agree with the certified activity of the reference source within ± 5 percent after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

6. Calibration checks that do not agree within ± 5 percent indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.

7. At the same time the instrument is being initially calibrated at the licensee's facility with the reference standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more reference standards. Keep a log of these initial and subsequent readings.

## CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

_____ First elution from new Mo-99/Tc-99m generator

or

_____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

| Radionuclide | Suggested Activity (mCi) | Activity (mCi) | Accuracy |
|---|---|---|---|
| Co-57 | 3-5 | _____ | _____ |
| Ba-133 | 0.1-0.5 | _____ | _____ |
| Cs-137 | 0.1-0.2 | _____ | _____ |
| Ra-226 | 1-2 | _____ | _____ |
| _____ | | _____ | _____ |

C. _____ The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator.

or

_____ Equivalent procedures are attached.

*For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalent to the highest activity used.