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Mr. John D. Kinneman, Chief
Nuclear Materials Section A
Nuclear Materials Safety and Safeguard Branch
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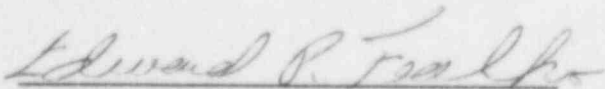
October 21, 1985

Gentleman,

Attached are the policies, guidelines and other information necessary to correct the deficiencies described in your letter dated October 2, 1985.

This information is forwarded to you so that our amendment application to license No. 37-07284-01 may be complete.

Sincerely Yours,



Edward P. Fealko
Administrative Director
Nuclear Medicine

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CALIBRATION OF INSTRUMENTS

- A. Survey meters will be checked for operability prior to each use. This will be accomplished by holding the detector against an instrument check source or the dose calibrator sealed constancy source depending on the instrument or range to be tested. If any reading with the same geometry is not within $\pm 20\%$ of the reading displayed after calibration, the instrument will be recalibrated. The reading obtained will be included on all recorded surveys.

The units will be calibrated after servicing and at least annually by the manufacturer or by UNIVERSAL CONSULTANTS, INC. N. RIDGEVILLE, OH in accordance with the procedure outlined in application for NRC license #34-20327-01. Records of these calibrations will be maintained and recommendations for repair will be followed. A survey meter will not be used beyond the anniversary of its last successful calibration.

Arrangements will be made for the availability of at least one survey meter while a unit is away for calibration or repair.

- B. The dose calibrator will be calibrated as follows:

1. Sealed sources will be used to establish accuracy. They will consist of:

<u>Nuclide</u>	<u>Suggested Activity</u>	<u>Activity (mCi)</u>	<u>Accuracy</u>
Co-57	3-5 mCi	1 mCi or more	Within $\pm 5\%$
Ba-133	0.1-0.5 mCi	100 uCi or more	Within $\pm 5\%$
Cs-137	0.1-0.3 mCi	100 uCi or more	Within $\pm 5\%$

2. The accuracy of the assay of the above standards will be at least $\pm 5\%$ and traceable to National Bureau of Standard sources.

3. The calibration procedure will be as follows:

a. The dose calibrator will be checked for accuracy at annual intervals and following repair using sealed sources having energies which encompass that portion of the spectrum of energies for which the dose calibrator is used. Nuclides that will be used are listed in Item 1 above.

Item #10
1 of 4 pages
Prepared:

The activity displayed by the dose calibrator must agree with the stated assay within $\pm 5\%$ of the limits of the standard's calibration accuracy. If the unit displays readings with an error greater than $\pm 5\%$, arrangements will be made for immediate repair or adjustment.

b. The dose calibrator will be checked for constancy each day of use. This will be accomplished using a Cs-137 standard. The sealed source will be placed in the chamber and the unit set to measure that nuclide. The activity displayed with background and decay considered, must fall within $\pm 5\%$ of the predicted activity based on the value obtained at the time of the original accuracy test.

The daily constancy check will be extended to include verification of displayed activities using the same standard but with the dose calibrator set to measure each of the different nuclides to be assayed on that day. With background and decay considered, variation in displayed activities must fall within $\pm 5\%$ of the activity shown at the time of the most recent accuracy check. If variations greater than $\pm 5\%$ are noted, arrangements will be made for immediate repair or adjustment.

c. The dose calibrator will be checked for activity linearity at quarterly intervals and following repair. This test will be performed using the maximum dose received from a Radiopharmacy or the first elution from a new Mo/Tc generator. In the latter case, after assaying the entire elution vial, an aliquot will be drawn calculated to contain 200 mCi. The aliquot will be assayed for agreement with the calculated activity to within $\pm 5\%$. If 200 mCi cannot be spared for performance of linearity testing, an aliquot less than 200 mCi will be drawn and used. The reduced amount will then be established as the maximum activity to be employed for patient doses or kit preparation for the remainder of the quarter or until linearity testing can be repeated utilizing a greater activity. In this way, the accuracy of the unit will be assured in the measurement of activity from the maximum on hand to a quantity approximately the maximum amount drawn and assayed for kit preparation.

To reduce personnel exposure from a whole vial measurement of activity, an alternate method of obtaining a source for the activity linearity check may be used. An aliquot such as 0.5 to 1.0 ml will be withdrawn from the elution vial and assayed in a syringe. The concentration of the eluent can be determined by dividing the displayed activity by the volume in the syringe. A 200 mCi aliquot contained in the

proper volume can then be withdrawn from the elution vial and used for the linearity test. If 200 mCi cannot be used, the amount used may be less but the same restrictions as cited in the paragraph immediately preceding will apply. In this way, the accuracy of the dose calibrator will also be assured in the measurement of activities approximating the maximum quantities used for kit preparation.

The linearity test will be continued by repeating the assay of the test aliquot several times a day over a two to three day period until a measurement is made in which the activity displayed is approximately the minimum dose likely to be used in a patient study and also less than the activity displayed during the annual accuracy check utilizing the standard with the energy similar to that of Tc-99m. In this way, the accuracy of the dose calibrator will be assured in the measurement of individual doses throughout the entire ranges of doses drawn for kit preparation and patient studies.

The above linearity test data will be plotted as a function of activity vs. time and compared to predicted activities vs. the same time. The acceptable range of error will be $\pm 5\%$. If test result error exceeds $\pm 5\%$, arrangements will be made for immediate repair or adjustment. The unit may be used in the interim using predetermined correction factors.

As an alternative procedure, the linearity test can be performed with the use of the Calicheck kit from Calcorp, Inc. The manufacturer's instructions for use will be followed. The source used shall be the first elution of a new generator or the activity of the largest dose obtained from a Radiopharmacy if a Radiopharmacy is used. Limits of acceptability and corrective actions will be as described above.

d. The dose calibrator will be tested for geometrical variation at the time of installation and following chamber or liner repair or replacement. This test will be performed using approximately 2 mCi of Tc-99m in a geometrical configuration approximating that of a point source. The source geometry will then be changed by dilution with assays performed at each step. A comparison will also be made to quantify the reduction in displayed activity caused by assaying sources in plastic versus glass containers.

The data will be analyzed relating the various readings to the reading acquired while the test source was in the geometry of the Co-57 accuracy standard. Correction factors will be used in clinical assays when geometry induced errors exceed $\pm 2\%$.

In the event the dose calibrator should fail or if it is away for repairs, the nuclear medicine program will be continued through the implementation of the following procedure:

1. A substitute dose calibrator will be acquired.
2. Eluents and/or doses will be assayed in a dose calibrator located at the nearest cooperating institutions having a functional and properly calibrated unit. If activities must be transported for this purpose, they will be shielded with sufficient lead to reduce levels to 2.0 mR/hr or less on contact with the shield, wrapped in sufficient absorbant toweling to absorb ten times the liquid volume contained in the vial or syringe, marked with labels indicating the presence of radioactivity, and carried by one occupational person assigned to this task throughout the entire trip. This same person will perform the assay, record the data, and return the activity to the location of authorized use.

Method #2 will be depended upon only in cases of medical emergency and until a functional dose calibrator can again be acquired. If only the activity of the eluent is known, mathematical calculations will be used to determine activity needed for patient doses.

The above assay techniques will enable the measurement of Technetium-99m and its Molybdenum-99 contaminant to within $\pm 10\%$ of the true assay. Every effort will be made to expedite repair and return of the dose calibrator.

Diagnostic instrumentation will be calibrated as follows:

1. The camera pulse height analyzer will be calibrated using Tc-99m and a uniform flood check will be performed each day of use.

Item #10
4 of 4 pages
Prepared: