

APPENDIX D

Procedures for Calibrating a Dose Calibrator

1. Test for the following at the indicated frequency. Repair, replace, or correct mathematically if the dose calibrator falls outside the stated tolerances.
 - ◆ Constancy at least once each day prior to assay of patient dosages, during an assigned shift for facilities operating continuously, or after re-location of the dose calibrator. Repair or replace if outside plus or minus 10 percent.
 - ◆ Accuracy at installation and at least every 12 months thereafter. Repair or replace if outside plus or minus 10 percent.
 - ◆ Linearity at installation and at least every three months thereafter. Repair, replace or correct mathematically if outside plus or minus 10 percent.
 - ◆ Geometry dependence at installation. Repair, replace or correct mathematically if outside plus or minus 10 percent.
2. After repair or adjustment of the dose calibrator, repeat the above tests as appropriate.
3. Any of the above dose calibrator tests other than daily constancy tests may be performed by an individual licensed by the department, U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform these tests. Nationally recognized standards or the manufacturer's instructions may be used to calibrate instrumentation. The standards or instructions used must be available for inspection by the department.

Constancy Test Procedures

Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, or Co-57 using a reproducible geometry each day before using the calibrator. Use the following procedure:

- A. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
- B. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
- C. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
- D. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
- E. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of a suspected malfunction of the calibrator. These action levels will be written in the log book or posted on the calibrator. The regulation requires repair or replacement if the error exceeds 10 percent.

Accuracy Test Procedures

Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by the NIST. Certified sources are available from the NIST and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) will be used. One source will have a principal photon energy between 100 keV and 500 keV. If a Ra-226 source is used, it will be at least 10 microcuries; other sources will be at least 50 microcuries. Use at least one reference source with an activity in the range of activities normally assayed.

- A. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.
- B. Average the three determinations. The average value should be within 10 percent of the certified activity of the reference source, mathematically corrected for decay.
- C. Repeat the procedure for other calibrated reference sources.
- D. If the average value does not agree, within 10 percent, with the certified value of the reference source, the dose calibrator must be repaired or replaced.

Linearity Test Procedures

Linearity means that the calibrator is able to indicate the correct activity over the entire range of use of that calibrator. This test will be done using a vial or syringe of Tc-99m or F-18 whose initial activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy dose, whichever is largest. The test shall continue until the activity contained in the vial or syringe is smaller than the smallest activity assayed, but greater than 10 microcuries.

Decay Method

- A. Assay the Tc-99m or F-18, syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time, for example, 8:00 a.m.
- B. If starting at 8:00 a.m., repeat the assay at 2:00 p.m. Continue on subsequent days until the assayed activity is less than the minimum activity normally assayed. For dose calibrators with a range switch, select the range normally used for the measurement.
- C. Convert the time and date information recorded for each assay to hours elapsed since the first assay.
- D. On a sheet of semi-log graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Plot the data.
- E. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.

$$\frac{A_{\text{observed}} - A_{\text{line}}}{A_{\text{line}}} = \text{deviation}$$

- F. If the worst deviation is more than plus or minus 0.10, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."
- G. Place a sticker on the dose calibrator or record in log book when next linearity test is due.

Shield Methods

For initial calibration or reinstallation of the dose calibrator the decay method will be used to determine linearity and to establish calibration factors for shield methods.

- A nationally recognized standard or the manufacturer's linearity test kit and instructions will be used for doing linearity tests of the dose calibrator. These standards or instructions must be available for review by the department for inspection. **Submittal of standards or manufacturer's instructions to the department is not required.**
- We will use a set of "sleeves" of various thicknesses' to test for linearity other than the manufacturer's test kit. The sleeves will be calibrated using the following procedure:

Calibration of the sleeves:

- A. Begin the linearity test as described in the above decay method. After making the first assay, the sleeves will be calibrated as follows. Steps B - D below must be completed within six minutes.
- B. Put the base and sleeve one in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- C. Remove sleeve one and put in sleeve two. Record the sleeve number and indicated activity.
- D. Continue for all sleeves.
- E. Complete the decay method linearity test steps B - G above.
- F. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve one in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step B.
- G. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step C.
- H. Continue for all sleeves.
- I. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set. The sleeve set may now be used to test dose calibrators for linearity.

Calibration of the dose calibrator:

- A. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the new activity in millicuries. Record the net activity.
- B. Steps C - E below must be completed within six minutes.
- C. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- D. Remove sleeve one and put it in sleeve two. Record the sleeve number and indicated activity.
- E. Continue for all sleeves.
- F. On a sheet of semi-log graph paper, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.
- G. Plot the data using the equivalent decay time associated with each sleeve.
- H. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.
$$\frac{A_{\text{observed}} - A_{\text{line}}}{A_{\text{line}}} = \text{deviation}$$
- I. If the worst deviation is more than plus or minus 0.10, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow a conversion from activity indicated by the dose calibrator to "true activity."
- G. Place a sticker on the dose calibrator or record in log book when next linearity test is due.

Geometry Test Procedures

Geometry dependence means that the indicated activity does not change with volume or configuration. This test will be done using a syringe that is normally used for injections. When using generators and radiopharmaceutical kits we will also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If volumes of syringes and vials differ from above, then the procedures will be changed so that syringes and vials are tested throughout the range of volumes commonly used.

- A. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline or tap water.
- B. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Document the volume, millicuries and record instrument setting.
- C. Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
- D. Repeat the process until a 2.0-cc volume has been assayed.
- E. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. The data will be graphed with horizontal 10 percent error lines drawn above and below the chosen "standard volume."
- F. If any correction factors are greater than 1.10 or less than 0.90, or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow conversion from "indicated activity" to "true activity." If this is necessary, label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
- G. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
- H. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
- I. Repeat the process until a 19.0-cc volume has been assayed. The entire process must be completed within 10 minutes.
- J. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, the data may be graphed and draw horizontal 10 percent error lines above and below the chosen "standard volume."
- K. If any correction factors are greater than 1.10 or less than 0.90 or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow conversion from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

Calibration Records

1. Constancy check records shall include:
 - (a) The model and serial number of the dose calibrator;
 - (b) The identity and decay corrected activity of the radionuclide contained in the check source;
 - (c) The date of the check;
 - (d) The activity measured;
 - (e) The percent error;
 - (f) The instrument settings; and
 - (g) The initials of the individual who performed the check.

2. Accuracy test records shall include:
 - (a) The model and serial number of the dose calibrator;
 - (b) The model and serial number of each source used and the identity of the radionuclide contained in the source and its activity;
 - (c) The date of the test;
 - (d) The results of the test;
 - (e) The instrument settings; and
 - (f) The name of the individual performing this test.

3. Linearity test records shall include:
 - (a) The model and serial number of the dose calibrator;
 - (b) The calculated activities;
 - (c) The measured activities;
 - (d) The date of the test; and
 - (e) The name of the individual performing this test.

4. Geometry dependence test records shall include:
 - (a) The model and serial number of the dose calibrator;
 - (b) The configuration of source measured;
 - (c) The activity measured and the instrument setting for each volume measured;
 - (d) The date of the test; and
 - (e) The name of the individual performing this test.

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