Dose Calibrator Operation & Quality Control

A dose calibrators is an integral part of any nuclear medicine department. This tutorial focuses on the main principles of operation and all of the issues related to quality control testing of this equipment; in addition, it describes a dose calibrator and discusses the principles and the parameters within which it works as well as patient related and NRC issues. Included is a detailed description of the required quality control tests and the testing frequency required to keep this equipment operational.

PRINCIPLES OF OPERATION

The typical radioisotope calibrator contains an ionization chamber, a high voltage power supply, an electronic amplifier, and a display unit on which one can select the radioisotope to be calibrated. The ionization chamber is cylindrical in shape (see photos below) and is used to measure the total amount of ionization produced by the sample to be calibrated. The ionization chamber contains Argon gas under high pressure, often 20-30 atm) and the hermetically sealed chamber contains two electrodes having an electric potential between them. When the vial or syringe containing the radionuclide is placed into the chamber, the Argon gas is ionized, the ion pairs migrate toward the anode and cathode and an electrical current flows between them. This current is proportional to the activity of the measured radioisotope. The magnitude of this current is usually very small (on the microampere level), even if large amounts of activity are present. A device called an electrometer, designed for quantifying very small electric currents, is used and its output is displayed in either mCi or MBq.

Dose calibrator function is based on a number of parameters. Most important are the activity, the energy level of the photons, and whether particulate emitters (e.g., beta particles) are being calibrated. The chamber's response is different for pure gamma emitters like Tc-99m than for a beta/gamma emitter like I-131. This means that the dose calibrator requires a different internal setting for each individual radioisotope. It is particularly difficult to calibrate a pure beta emitter such as Y-90. The readings are very geometry dependent, aside from other issues such as self-absorption in the sample being measured and X-ray production when the beta particles interact with the lead shielding

surrounding the ionization chamber. The use of custom-designed lightweight plastic sample holders and deep-well detectors has virtually eliminated poor results caused by variations in sample positioning in the well.

PATIENT RELATED ISSUES

- Every dose administered to a patient must be assayed in a properly functioning radioisotope dose calibrator.
- This device must be capable of reliably calibrating doses as small as 10 μCi as well as on the multi-Ci range. Central Radiopharmacies routinely handle activities in the range of 5-15 Ci of Tc-99m.
- According to current NRC Regulations, administered doses must be within ±20% of the prescribed dose.

It is the obligation of the person calibrating the dose, typically the Nuclear Medicine Technologist, to assay the dose and to insure that it meets the specification set down in the 20% rule (**all administered doses must be within 20% of the prescribed dose**). Some Agreement States require that administered doses must be within ±10% of the prescribed dose. The prescribed dose may be modified only by a physician and a note must be made on the requisition and initialed by the physician indicating the change in prescribed dose.

Dose Calibrator Operation and Quality Control Testing

One is required to evaluate calibrator performance on-site at specified intervals. The current NRC Regulations displayed below were taken from the Code of Federal Regulations, Title 10, Part 35.60:

- § 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material. (a) For direct measurements performed in accordance with § 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject. (b) A licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions. (c) A licensee shall retain a record of each instrument calibration required by this section in accordance with § 35.2060.

- The nationally recognized standards mentioned in (b) above are published by the NIST (National Institute for Standard and Technology) and are downloadable (for a fee) from their website. The condition of reliability exists when both accuracy and precision are maintained. To insure that the dose calibrator is reliable, there are certain mandatory quality control tests that must be performed on a routine basis.

Required Dose Calibrator Tests and Frequency of Performance

The required dose calibrator tests and the frequency of their performance are listed in the following chart.

TEST REQUIRED	FREQUENCY
Accuracy	at installation, then annually thereafter
Constancy	at installation, then daily thereafter
Linearity	at installation, then quarterly thereafter
Geometry	at Installation; after repair or moving instrument

It is essential to perform these test procedures correctly since patient safety is highly dependent upon the reliability of this instrument. All too often, procedural errors are made in performing QC testing of dose calibrators, even by experienced operators. It is critical to perform steps in the proper order to insure correct readings. The following paragraphs describe the recommended procedure for performance of mandatory dose calibrator quality control testing and are in compliance with guidelines set forth in the most recent NIST publication regulating dose calibrator quality control test procedures.

Accuracy Test

This test is designed to show that the calibrator is giving correct readings throughout the entire energy scale one is likely to encounter. Low, medium, and high energy standards (usually Co^{57}, Ba^{133} or Cs^{137}, and Co^{60}, respectively), are measured in the dose calibrator using appropriate settings. The value on the label indicating the activity at a specific calibration time and date is mathematically decay-corrected to the testing date. The standard is then assayed in the dose calibrator and standard and measured values are compared. All values are recorded in the appropriate logbook. Measured values should be within ± 10% of the standard value. The following table displays the data collected during an annual Accuracy Test. The dose calibrator has passed the test.

Standard	Energy (keV)	expected value (mCi)	measured value (mCi)
Co-57	122	2.48	2.48
Cs-137	662	3.38	3.29
Co-60	1,332	1.55	1.52

Constancy Test

This test, performed at installation and daily, measures instrument precision and is designed to show that reproducible readings are obtained day after day on all the various isotope settings likely to be used. A long-lived source, usually 30 yr Cs-137, is placed in the dose calibrator. Activity is then measured on the Cs-137 setting (this actually represents a "mini" accuracy test) and on all other settings used on a daily basis. Values are recorded in the appropriate logbook and are compared with recent values to determine if the instrument is performing consistently on a day-to-day basis. Measured values must be within ± 10% of the standard value. It should be noted that, since we are reading the activity of a Cs^{137}source on settings for Tc^{99m}, Tl^{201}, I^{123}, Xe^{133}, and other isotopes, incorrect readings will be obtained. Our expectation is to obtain the same incorrect reading day after day. The following table displays the data collected during a daily constancy test over a one-week time period. The dose calibrator has passed the test.

ISOTOPE	**READING (mCi)**				
SETTING	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
Cs^{137}	123	124	122	126	124
Ga^{67}	223	224	222	224	226
Tl^{201}	163	164	162	166	164
Tc^{99m}	243	242	244	246	244
I^{131}	313	314	312	316	314
I^{123}	193	192	194	196	194
In^{111}	283	284	282	286	284
Xe^{133}	433	434	432	436	434

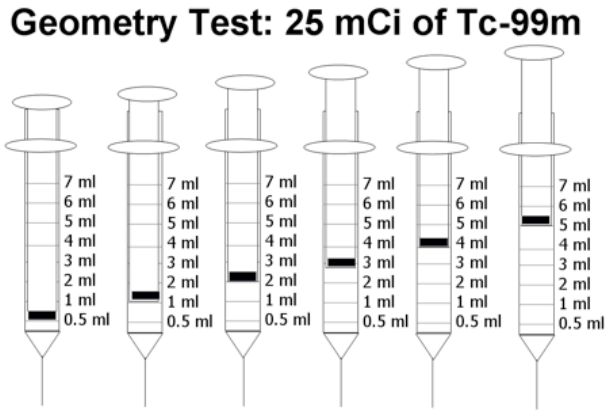
Linearity Test

This test is designed to prove that the dose calibrator readout is linear for sources varying from the μCi range through the mCi range. A high activity Tc^{99m} source (50-300 mCi) is measured at T_0 and at predetermined time intervals until activity reaches approximately 30 μCi. This can take as long as 96 hours, depending upon initial activity. Using decay factors for Tc^{99m}, one can take the activity at T_0 and decay-correct it to predict what the activity should be at the predetermined times. Expected and actual measurements are recorded in the appropriate logbook (and may be analyzed graphically), and then are compared to determine if the instrument is linear throughout the usable activity range of the dose calibrator. The following table displays the data collected during a quarterly Linearity Test. The dose calibrator has passed the test.

Elapsed time	**Expected reading**	**Measured reading**
(hr)	(mCi)	(mCi)
0	300	300
1	267	272
2	238	241
3	212	209
6	150	148
12	75	72.4
24	18.75	19.1
48	1.17	1.19
72	0.073	0.074
78	0.036	0.037

Geometry Test

This test is designed to show that correct readings can be obtained regardless of the sample size or geometry. It therefore is necessary to perform this test on every different vial used (e.g., 10 ml, 30 ml)as well as every different syringe used (e.g., 1 ml, 3 ml, 5 ml, 10 ml). For example, to test a 10 ml syringe for linearity, one first places 1.0 ml of Tc^{99m} in a 10 ml syringe (activity 25 mCi). The activity is then measured in the dose calibrator and the value obtained is recorded. The activity is then diluted with water to 2.0 ml, 3.0 ml, 4.0 ml, 5.0 m, etc, up to 10 ml. At each of these points a reading is taken and the value recorded. Data are then evaluated to determine the effect of sample geometry on the dose calibrator reading. If the instrument is geometry-dependent, ideally one should notify the manufacturer that the calibrator has failed acceptance testing and a new calibrator should be requested. If the decision is made to keep the instrument, it may be necessary to routinely correct readings obtained when using calibrator.



The following table displays the data collected during a Geometry Test. The dose calibrator has passed the test.

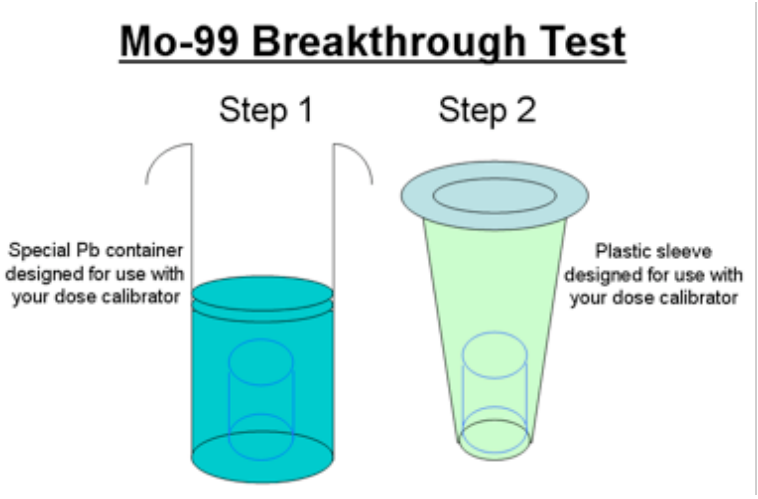
Sample Volume	Activity (mCi)
0.5	25.5
1.0	25.3
2.0	25.0
3.0	24.8
4.0	24.7
5.0	24.5
6.0	24.4

Specifications for All Dose Calibrator QC Tests

NRC and State Regulations require that, for all dose calibrator tests, deviation between standard and expected values must be within ±10%. If the deviation is greater than 10%, then one's obligation is to record the value, note that it is a test failure, repair or recalibrate the instrument, retest to insure that the equipment is now functioning properly, and record new values. In addition to the above steps, every dose must be mathematically corrected until the instrument is repaired. There is no longer a reporting requirement.

QC Test For Mo^{99} Breakthrough Using A Dose Calibrator

Mo^{99} is assayed FIRST directly in the special lead pig supplied by the manufacturer of the dose calibrator using the Mo^{99} setting. Tc^{99m} is THEN assayed directly in the plastic sleeve using the Tc^{99m} setting. Activity (µCi) of Mo^{99} is divided by activity (mCi) of Tc-99m to obtain a ratio. If this ratio is <0.15 µCi Mo^{99} per mCi of Tc^{99m} at time of administration, the generator eluate has passed the Mo^{99} Breakthrough Test.



As a rule of thumb, if the ratio is <0.038 at time of elution, the material will be suitable for injection for at least 12 hours. If test is performed in reverse order, failure is extremely likely due to residual charge on ionization chamber that takes a few minutes to dissipate.

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