Quality Assurance Testing of AtomLab® Dose Calibrators
(Manufacturer’s* Instructions)

Introduction

The following procedures are the manufacturer’s instructions for qualifying AtomLab® 100, 100+, 200, 300, 400, and 500 dose calibrators in accordance with NRC regulation 10 CFR 35.60 of 1 January 2003 (or applicable agreement State Regulation). Use of these instructions outside the USA may require modification in order to satisfy local regulations.

Qualification is the determination of errors associated with the following tests at the indicated frequency. Acceptable errors for each test are indicated in parentheses.

- **Constancy:** Starting at installation and at least once each day before measuring patient dosages (±5 percent).
- **Dial Value Setting:** at first receipt of isotope activity in container other than a plastic syringe (±10% from decay corrected calibration activity).
- **Linearity:** at installation and at least quarterly thereafter (±5 percent).
- **Geometry:** at installation (±5 percent).
- **Accuracy:** at installation and at least annually thereafter (±5 percent).

After repair of the dose calibrator, repeat the above tests as a new installation.

NOTE: A plastic well liner and source dipper must be used in all measurements.

NOTE: If possible, leave the dose calibrator powered-on 24 hours a day, 7 days a week. If not, allow 1 hour warm-up after power-on before performing these procedures.

NOTE: We have an acceptance variance percentage listed for each test. These are the default settings. You can use ±10% for acceptability and ±5% for investigation. Call Biodex Service Dept. if readings are outside the acceptable range. The default acceptable range is based on 10CFR35.60 of January 1, 2003 and IEC-61145. You must consider what your state or government regulations require.

NOTE: Assay means to place the source container into the dose calibrator so that the dipper is resting in the well liner.

NOTE: The AtomLab® 500 control module has built-in Constancy, Linearity, Geometry, and Accuracy software functions which provide ease-of-use to the user in performing the functions below.

Constancy

**Constancy** means reproducibility in measuring the same source, over a period of time, with decay correction.

Assay a relatively long-lived source (such as Cs-137) each day before using the calibrator.

Cs-137, 100 μCi minimum activity, is strongly recommended because the 30-year half life will assure use of the same source throughout the life of the calibrator, and it is readily available.

Consider using the following procedure or equivalent:

1. Press the Zero Background (Bkgnd) button. When the display zeroes, the unit has automatically adjusted for Background.
2. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137.)
3. Record the activity reading of the constancy source in a permanent log.
4. Compare the measurement observed to the calculated activity of the source and if the measurement exceeds 5% of predicted, investigate potential sources of error (patients in the area, exposed sources, use of the wrong isotope or setting, etc.)
5. If the constancy result is determined to be greater than 10% of predicted, suspend the use of the instrument and repair or replace the dose calibrator.

NOTE: It is recommended that the Cs-137 and Ba-133 sources be replaced when the activity is below 100 μCi. It is recommended to replace a Co-57 source when the activity is less than 1 mCi.
Dial Value Settings and Source Containers (Glass Vial, Glass Syringe, etc.)

The Atomlab Dial Value (DV) settings enable the software to convert ion chamber current into a displayed activity value for the isotope corresponding to the DV selected. The displayed activity value is directly proportional to the DV. The isotope’s “source container” is either a vial or syringe; the composition of the vial or syringe MAY influence the accuracy of the activity measurement. The DV supplied in the Atomlab User Guide (Instruction Manual), or pre-programmed into the isotope buttons, are calibrated for use with the source material in an un-shielded plastic syringe (nominal 1mm wall), while hanging in the supplied “source dipper” syringe support. For isotopes contained in sealed long lived QA sources (Cs-137, etc.), the DV supplied are calibrated for use with type Vial E epoxy sources or equivalent.

Accurate measurement of unsealed sources in any other configuration must be with a new Container Dial Value “CDV”, determined by the USER with the following procedure.

NOTE: This is important to determine the appropriate Dial Value for Beta and low energy gammas when the container (syringe or vial) changes.

During following steps, set DV to the Atomlab published value.

**Container with no source material**

1. Assay a quantity of isotope source material in a plastic syringe, nominal wall thickness of 1mm, record as (Plastic Syringe Activity)
2. Transfer part or all of the source material from the plastic syringe into the empty Container.
3. Assay the Container with the isotope source material, record as (Container Activity).
4. Assay the partial or “empty” plastic syringe for residual activity, record as (Plastic Syringe Activity)2
5. Calculate the Container Dial Value for use with isotope assayed in that type of container,

$$CDV = DV \cdot \frac{(PSA)_{1} - (PSA)_{2}}{(Container\ Activity)}$$

where $PSA = Plastic\ Syringe\ Activity$.

**Container with source material**

1. Assay Container with the isotope source material, record as (Container Activity)1.
2. Transfer part or all of the source material from the Container into a plastic syringe, nominal wall thickness of 1mm.
3. Assay the plastic syringe with the isotope source material, record as (Plastic Syringe Activity).
4. Assay the partial or “empty” Container for residual activity, record as (Container Activity)2.
5. Calculate the Container Dial Value for use with isotope assayed,

$$CDV = DV \cdot \frac{(PSA)}{(CA)_{1} - (CA)_{2}}$$

where $PSA = Plastic\ Syringe\ Activity$ and $CA = Container\ Activity$.

Typically, for glass wall source Containers, CDV will be higher than DV when the isotope has a significant portion of low energy photons in its emission spectrum.
**Linearity**

Linearity means the proportionality of the measurement result to the activity measured, as determined over the intended range of use for the dose calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radio pharmaceutical kit, in a unit dosage syringe, or in a radio pharmaceutical therapy, whichever is largest.

There are several acceptable methods for preparing linearity testing. The difference in these methods is which reading is used for decay correction of the activities. The following methods are all acceptable for determining the normalized value.

a. Decay correct the test sample from the first reading and compare each reading to the decay corrected reading.

b. For Tc-99 select 30 hours as the normalized reading, and decay correct this reading to calculate the expected activities at the times you took your readings. Compare the readings to the calculated activities. You can change from 30 hours to another time point and perform your normalized calculation from that time point.

The Atomlab 500 automated linearity test uses 30 hours as the default method.

c. The following decay method described in detail decay corrects each reading, then averages these calculated activities, and then divides the average by the time corrected reading to determine a correction factor. If the correction factor is between certain values, the calibrator is linear.

**Decay Method**

1. Zero the Background by pressing the Zero Background (Bkgnd) button.
2. To perform the linearity test, you should have a vial of Tc-99m that is at least as large as the maximum activity that will be measured. If you choose to use a syringe, make sure you have a unit dosage syringe or in a radio pharmaceutical therapy, whichever is largest.
3. To perform the linearity test, you need to have a vial or syringe of Tc-99m that is at least as large as the maximum activity that will be measured. If you choose to use a syringe, make sure you have a unit dosage syringe or in a radio pharmaceutical therapy, whichever is largest.
4. For low activity values, if the readings are acceptable range and if the 1st linearity test passes. The two linearity tests should have overlapping activity values in the acceptable range and if the 1st linearity test passes. The two linearity tests should have overlapping activity values in the acceptable range.

### NOTE:

- Some state regulations allow linearity tests to end at activities greater than 10 μCi. You may discontinue the linearity test at the activity which your state regulations or license permit.

### NOTE: Use of a spreadsheet, such as Microsoft Excel, in steps 4 and 5 will simplify calculations.

**Sleeve Test Method**

If you decide to use a set of “sleeves” of various thicknesses or combination of sleeves to test for linearity, it will be necessary to first use the Decay Method to show the calibrator is linear. Then immediately repeat the test. The directions furnished with your lead sleeves (i.e. Lineator instructions.)

If failure occurs at the low activities, check for Mo-99 contamination by repeating the test with 1 mCi. See NOTE under “Decay Method,” step 4.

**NOTE:** You can perform the Sleeve Test procedure first and immediately perform a traditional Linearity test. This allows the user to perform both tests with one dose.

### NOTE: Other isotopes can be used to perform linearity, such as F-18. The sleeves can only be used with Tc-99.

Accept if $0.95 < c_{fM} < 1.05$. Consider correcting the displayed activity measurement (M) of radio pharmaceuticals if a linearity error is greater than ±5% and less than ±10%, i.e., $0.90 < c_{fM} < 0.95$ or $1.05 < c_{fM} < 1.10$. Corrected $M = M_0 \cdot c_{fM}$ where subscript M is closest in value to M in most recent linearity form. For low activity values, if $c_{fM} < 0.95$ see the following note about Mo-99 contamination.

**NOTE:** If there is any Mo-99 contaminant in the Tc-99m sample, then long decay times (>48h) will compromise the decay linearity test. This will be apparent with decreasing $c_{fM}$ values for the lowest displayed activity measurements (M). In order to test for this, prepare another linearity test sample with an activity of about 1 mCi. Repeat the linearity test. If the $c_{fM}$ values are within an acceptable range and if the 1st linearity test by decay produced acceptable $c_{fM}$ values at higher M values, then the dose calibrator passes. The two linearity tests should have overlapping activity values in the acceptable range.¹ *Hint: Recalculate first test ($M_0$) without including failing values from low (M) Mo-99 contamination.

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AtomLab Dose Calibrator Linearity Test, Model: _______________ Serial Number: _______________

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Activity Measured, ( M )</th>
<th>Hours elapsed, ( t )</th>
<th>( M_{0,t} )</th>
<th>( cf_M = \text{Avg} / M_{0,t} )</th>
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**Avg:**

Accept if \( 0.95 < \text{Avg} / M_{0,t} < 1.05 \)

Figure 1. Sample dose calibrator linearity test data collection form
Geometry

Geometry Independence means that the indicated activity does not change with volume or configuration of the source material. This test should be done using a syringe that is normally used for injections. The following test assumes injections are done with 3 ml plastic syringes and that radio pharmaceutical kits are made in 30 ml glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used. If a significant volume correction results from these procedures, the tests should be repeated to verify. AtomLab dose calibrators have been tested for volume dependence in beta measurements which are expected to be worst case and the results were 0.13 %/ml. 2

Syringe Test (example)

1. In a small vial, mix 2.0 ml of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml.

2. Set out a second small vial containing non-radioactive saline solution.

3. Draw 0.5 ml of the Tc-99m solution into the syringe and assay it.

4. Record the volume and activity of the first assayed sample (Figure 2).

5. Remove the syringe from the calibrator, draw an additional 0.5 ml of non-radioactive saline into the same syringe (total volume 1.0 ml), and assay again. Record the volume and measured activity on the form.

6. Repeat step 5 twice more until you have assayed 1.5 ml and 2.0 ml volumes and recorded them.

7. Assay the vial used to draw saline into the syringe. If the measured activity is greater than 1% of the 0.5 ml syringe assay, Tc99m was lost during filling. Repeat the procedure.

8. Divide the average activity by the activity indicated for each volume. The quotient is a volume correction factor.

9. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table "syringe geometry dependence", and note the date of the test as well as the model number and serial number of the dose calibrator.

Vial Test (10 ml) (example)

1. To test the geometry dependence for a 10 ml glass vial, draw 1.0 ml of Tc-99m solution (between 1 and 10 mCi/ml) into a syringe and inject it into the vial. Assay the vial. Record the volume and activity indicated.

2. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 or 3.0 ml of non-radioactive saline, and assay again. Record the volume and activity indicated on the form (Figure 2). Repeat the process until you have assayed a 8.0 ml volume. The entire process must be completed within ten (10) minutes, or, if not, decay-correct the activity.

3. Divide the average activity by the activity indicated for each volume. The quotient is a volume correction factor.

4. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table "vial geometry dependence", and note the date of the test and the model number and serial number of the calibrator.

NOTE: Perform the vial test with the vial size you commonly use.

NOTE: Other isotopes can be used for performing Geometry testing.

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Accuracy

Accuracy means a determination of the dose calibrator’s absolute error resulting from a measurement of a suitable NIST-traceable radionuclide activity. Traceable sources are available from NIST and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60 Cs-137 or Ba-133) should be used. One should have a principal photon energy between 100 keV and 500 keV.

1. Press the Zero Background (Bkgnd) button which zeroes the dose calibrator.
2. Assay a calibrated reference source of appropriate activity at the appropriate setting (i.e., use the Co-57 setting to assay Co-57). Record the displayed activity measurement, M, the date, and the reference source identification (nuclide, activity, date of calibration, serial number, model number, and manufacturer.)
3. Take 3 readings for the reference source. Remove and reinsert the reference source between readings.
4. Repeat the procedure for the other calibrated reference source.
5. For both sources, decay-correct the reference source activity value and record as “true activity.”
6. Calculate the average for the 3 measurements and compare the average to the calculated activity.
7. Calculate activity measurement % error from:
   \[
   \% \text{Error} = \left( \frac{M - \text{True}}{\text{True}} \right) \times 100
   \]
8. Evaluate the calculated % errors according to the approximate location of the dots in Figure 3 and take the recommended action corresponding to your error condition.

<table>
<thead>
<tr>
<th>Error Condition</th>
<th>Percent Error*</th>
<th>Recommended Action</th>
</tr>
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<tbody>
<tr>
<td>Between 0 and -5%</td>
<td>-10 -5 0 +5 +10</td>
<td>None.</td>
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<tr>
<td>Between 0 and +5%</td>
<td></td>
<td>Probable source calibration activity error.</td>
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<td>Examine sources with error &gt; 5%, &lt; 10%.</td>
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<tr>
<td>Less than ±5%</td>
<td></td>
<td>Probable source calibration activity error.</td>
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<tr>
<td></td>
<td></td>
<td>Examine sources with error &gt; 5%, &lt; 10%.</td>
</tr>
<tr>
<td>Large difference, skewed low</td>
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<td>Probable dose calibrator error. If average error ≤ 5%, continue use.</td>
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<tr>
<td>Large difference, skewed high</td>
<td></td>
<td>If average error ≥ 5% contact manufacturer. Continue use under advisement.</td>
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<tr>
<td>Both skewed low</td>
<td></td>
<td>Contact manufacturer. Continue to use under advisement.</td>
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<tr>
<td>Both skewed high</td>
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<td>Contact manufacturer to return for repair.</td>
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<tr>
<td>Both high within tolerance</td>
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<tr>
<td>Both low within tolerance</td>
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<td>Both high, straddling 10%</td>
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<td>Both low, straddling 10%</td>
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<td>Both high, outside tolerance</td>
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<tr>
<td>Both low, outside tolerance</td>
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</tbody>
</table>

* A dot represents a source accuracy error. Dot location represents any value between the error bars. For example, in the 3rd row, the left dot indicates a source error of any value between -5% and 0% and the right dot any value between 0% and +5%.

Figure 3. Recommended action for Accuracy test error conditions
Records and Maintenance

Records
Article 10 CFR 35.2060 requires that a NRC licensee maintain instrument qualification records for 3 years. The records must include the model and serial number of the instrument, the date of the qualification, the results of the qualification, and the name of the individual who performed the qualification.

Dipper and Well Liner
Inspect the instrument on a quarterly basis to ascertain that the well liner is in place and is not damaged. Check for contamination of the liner and dipper as follows:

1. Remove the plastic dipper and liner from the well chamber.
2. Press the Zero Background (Bkgnd) button to zero the calibrator.
3. Put the liner back in. If the display reading increases, the liner may be contaminated.
4. If the liner is OK, put the dipper back in and check for contamination.
5. If any part is contaminated, you must decontaminate or replace the item and then recheck for contamination.

Dial Value Checks—Monthly
Each isotope button is programmed with a specific dial value (DV). The user can adjust the DV for a particular need. Each isotope button should be checked periodically to verify if it is set to the correct dial value for that isotope. The method of displaying the dial values varies by model; consult the operation manual for your dose calibrator to see how to display the dial values.

NOTE: The Dial Value check is to verify that no one has accidentally changed the Dial Value from the factory settings or the appropriately determined facility settings.

Repair or Replacement
Consider repair or replacement, if the dose calibrator falls outside the suggested tolerances.

If repair or replacement is required, contact Biodex Medical Systems for instructions.