



DEPARTMENT OF THE ARMY
FITZSIMONS ARMY MEDICAL CENTER
AURORA, COLORADO 80045

HSHG-PMH

13 SEP 1983

SUBJECT: Request for License Amendment, BML Number 05-00046-13: Linearity
of Dose Calibrators

7, 20 Sep 83

THRU: Commander
U. S. Army Health Services Command
ATTN: HSPA-P
Ft. Sam Houston, TX 78234

HQDA
ATTN: DASG-PSP-E
Washington, DC 20310

TO: Nuclear Regulatory Commission
Material Licensing Branch
Division of Fuel Cycle & Material Safety
Washington, DC 20555

1. Request that FAMC BML Number 05-00046-13 be amended to allow our dose calibrators to be checked for dose linearity with model 086-508 Lineator.
2. The nature of the amendment is described in the attached Lineator Instructions 086-507 (Incl 1) manual.

FOR THE COMMANDER:

1 Incl
as

Jimmie L. Craft
JIMMIE L. CRAFT
LTC, MSC
Adjutant General

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PDR FOIA
GLADE96-395

PDR

ADDRESS ALL COMMUNICATIONS TO THE COMMANDER
FITZSIMONS ARMY MEDICAL CENTER

9703040199

LINEATOR INSTRUCTIONS

0 8 6 - 5 0 7

Atomic Products Corporation

A T A I A L DIVISION • ESTABLISHED 1943
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516/451-1271
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16C58

Rev. 5/20/83

8607300499XA

LINEATOR INSTRUCTIONS

Introduction- The Lineator is a simple device for testing linearity and dynamic range of isotope calibrator instruments. Its use simplifies compliance with the Nuclear Regulatory Commission Appendix D of Regulatory Guide 10.8, October, 1980 and various state requirements.

The Nuclear Regulatory Commission, and other licensing agencies typically require a license amendment before use of the Lineator is authorized. A sample license amendment form is included in these instructions as Appendix D. This form should be transferred to your stationery, signed by authorized personnel, and sent to the appropriate agencies with any required fees. When the amendment is received use of the Lineator is authorized. Note that the NRC Regulatory Guide 10.8 Appendix D dated October, 1980 requires test of calibrator linearity at installation and quarterly thereafter. State and local requirements may differ. The Lineator may be used for this quarterly calibration. The concentration of Mo 99 should be less than .1 uCi per mCi of Tc99m.

The Lineator consists of four tubes, three of which are lead lined, which can be arranged concentrically. The smallest diameter tube is labeled 0 and is used to contain and position a source of Technetium 99m of the maximum activity to be measured in the dose calibrator in normal service. The lead lined tubes, labeled A, B & C, slide over the central tube, and are used singularly, or in combination. Each of these outer tubes absorbs some of the radiation from the source and reduces the effective source activity seen by the dose calibrator. Use of the Lineator thus allows the operator to simulate a total of eight different source strengths with only one source. The effective reduction increases from tubes A to B to C, and is affected slightly by the shape of the source used, and by the characteristics of the isotope calibrator.

The principle of operation of the Lineator is reproducibility over a wide dynamic range, rather than absolute calibration. Initially the linearity of the dose calibrator must be established by conventional means, such as dilution or decay of a Technetium source. The initial calibration using the Lineator then establishes the effective reductions in activity (ratios of activity with lead tube(s) inserted relative to source in central tubes alone). All subsequent use of the Lineator will show the same effective ratios unless:

1. The dose calibrator becomes defective, at which time it must be repaired, or
2. The Lineator components are damaged or replaced. Care should be taken that the bottom end of the Lineator components are not damaged.

OPERATION

General Instructions-

1- Remove all sources from the region of the calibrator to be tested.

2- Remove the source holder/hanger from the calibrator. Remove the chamber liner, if necessary, to allow insertion of the central Lineator tube.

3- Set the calibrator to TC-99m, check background reading using most sensitive scales. Zero out the background reading or note the value for later calculations. Check zero on all ranges. Note that background readings which vary widely may indicate a defective machine or a changing radiation environment which will affect the calibration.

4- The Lineator is designed for use ONLY with TC-99m. Load tube B with a vial of 99mTc whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator). The base is formed to center a 10ml or a 20ml vial. Place the tube in the calibrator chamber with the open end up. Use caution to avoid damaging the calibrator or the Lineator. The source and central tube will stay in place until the calibration procedure is complete.

5- Be prepared to work quickly. Arrange Lineator components, data sheets and clock for ease of operation. A complete calibration requires less than 5 minutes. Completion in 7 minutes introduces only a 1% total error due to decay of TC-99m. If linearity test duration exceeds 7 minutes the procedure should be repeated.

6- Set the range switch, as necessary, to read the activity to three significant figures.

CALIBRATION PROCEDURE

Having established the linearity of the calibrator by standard means, an initial calibration provides the factors to be expected for all future linearity checks, so long as the calibrator maintains its linearity and the Lineator components are not damaged.

After performing the steps given in the General Instructions, continue with the following steps, adjusting range switch to obtain 3 significant figures:

7- Record the time and the initial activity with the source in the central tube, and only the central tube inserted in the calibrator. Use a data sheet similar to or a copy of Appendix B.

8- Place tube A over the central tube and lower gently. Record reading A.

9- Remove tube A and place tube B carefully over the central tube, record reading B.

10- Insert tube A between central tube and tube B, record reading AB.

11- Remove tubes A & B, insert tube C, record reading C.

12- Add tube A, record reading AC.

13- Remove tube A, add tube B record reading BC.

14- Add tube A, record reading ABC.

15- Record time.

16- Remove and store Lineator components; store source in shield.

17- Calculate the eight factors as indicated on the work sheet, Appendix A: Divide the value for the central tube only by the value for each reading for each tube combination and enter results in column headed "Present Factors". Be sure all readings are in the same units (e.g. mCi or uCi). If this is an initial calibration the factors should be retained for future reference and transferred to a master work sheet similar to or a copy of Appendix C, in the column labeled "Initial Factors". Copies of this master work sheet will be used for subsequent calibrations.

If not performing an initial calibration continue with the following steps.

18- Divide each entry in "Present Factors" column by corresponding entry in column labeled "Initial Factors". Enter results times 100 in column labeled Percent Ratio. The ratios should have values near 100.

19- Examine entries in Percent Ratio column (3) to be sure that each is within the allowed tolerance limit for the present radioactive material license. For example, if the license allows 5% variation, all the values in the ratio column should be between 95 and 105. If all ratio values are within acceptable range the calibration is complete and the isotope calibrator has been proven to have acceptable linearity.

If any value of the Percent Ratio is outside the acceptable range renormalize by finding an average value for all eight percent ratio values and dividing each ratio by this average, then multiplying each by 100.

If still beyond tolerance, the problem may be due to:

a- Changing background conditions, including activity in nearby patients. stabilize background activity and repeat.

b- Failure to properly subtract background for each reading. check and repeat procedure if appropriate.

c- Damage to lineator components. Inspect and replace as necessary. Each component may be purchased separately but will require a new initial calibration.

d- A defect in the dose calibrator. This requires repair of the calibrator, followed by a demonstration of linearity using conventional methods, and an initial calibration to establish the factors to be expected with future operation with the lineator.

20- Sign data sheet and retain for future proof of calibration and compliance with regulations.

APPENDIX: SAM WORK SHEET

Date: Jan. 2, 1982
 Calibrator Serial No.: _____
 Operator: JR
 Sample: Tc-99m

ZERO (Background) Reading: 0.00
 Range: 0.20 mci (200 mci)
 Start Time: 1610

TUBE(S)	Reading - Background	Present Factor (1)	Initial Factor (2)	Percent Ratio (3)
0 only	<u>8.64 mci</u>	<u>1</u>	<u>1</u>	<u>100</u>
0 + A	<u>2.38</u>	<u>363</u>	<u>3.64</u>	<u>99.7</u>
0 + B	<u>1.65</u>	<u>5.24</u>	<u>5.28</u>	<u>99.2</u>
0 + AB	<u>0.450</u>	<u>19.20</u>	<u>19.39</u>	<u>99.0</u>
0 + C	<u>0.216</u>	<u>40.0</u>	<u>40.2</u>	<u>99.5</u>
0 + AC	<u>.0615</u>	<u>140.5</u>	<u>141.6</u>	<u>99.2</u>
0 + BC	<u>.0430</u>	<u>201.0</u>	<u>202.5</u>	<u>99.3</u>
0 + ABC	<u>.0123</u>	<u>702</u>	<u>716</u>	<u>98.0</u>

Completion Time: 1615

- NOTES: (1) Each factor is the ratio of the reading-background for tube 0 only to the reading-background for that entry.
- (2) Values determined from the initial calibration.
- (3) * Ratio of entries: $100 \times \text{Col. (1)}/\text{Col. (2)}$ If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.

APPENDIX B: INITIAL CALIBRATION WORK SHEET

Date: _____

Calibrator Serial No: _____

Operator: _____

Source: _____

ZERO (Background Reading): _____

Range: _____

Start Time: _____

TUBE(S)	Reading-Background	Present Factor (1)	Initial Factor (2)	Percent Ratio (3)
0 only	_____	1	1	100
0 + A	_____	_____	_____	_____
0 + B	_____	_____	_____	_____
0 + AB	_____	_____	_____	_____
0 + C	_____	_____	_____	_____
0 + AC	_____	_____	_____	_____
0 + BC	_____	_____	_____	_____
0 + ABC	_____	_____	_____	_____

Completion Time: _____

NOTES: (1) Each factor is the ratio of the reading-background for tube 0 only to the reading-background for that entry.

(2) Values determined from the initial calibration.

(3) % Ratios of entries: $100 \times \text{col. (1)} / \text{Col. (2)}$ if any ratio in this column differs from 100 by an amount greater than the license allowance see instructions.

APPENDIX C: WORK SHEET

Date: _____

Calibrator Serial No: _____

Operator: _____

Source: _____

ZERO (Background) Reading: _____

Range: _____

Start Time: _____

TIME(S)	Reading-Background	Present Factor (1)	Initial Factor (2)	Percent Ratio (3)
0 only	_____	<u>1</u>	<u>1</u>	<u>100</u>
0 + A	_____	_____	_____	_____
0 + B	_____	_____	_____	_____
0 + AB	_____	_____	_____	_____
0 + C	_____	_____	_____	_____
0 + AC	_____	_____	_____	_____
0 + BC	_____	_____	_____	_____
0 + ABC	_____	_____	_____	_____

Completion Time: _____

- NOTES:
- (1) Each factor is the ratio of the reading-background for tube 0 only to the reading-background for that entry.
 - (2) Values determined from initial calibration.
 - (3) % Ratio of entries: $100 \times \text{Col. (1)} / \text{Col. (2)}$ If any entry in this column differs from 100 by an amount greater than the license allowance see instructions.

APPENDIX D:

AMENDMENT REQUEST

In order to be in compliance please send the following to your license authority (state or NRC). Remember to use your facility stationary and reference the license number.

NRC or State License #: _____

Facility: _____

Address: _____

City: _____ State: _____ Zip: _____

Contact: _____
(Technologist, Consultant, Doctor, Administrator or RSO)

Phone: _____

Gentlemen:

Please amend our license to allow our dose calibrator to be checked for dose linearity with the model 086-507 Lineator manufactured by Atomic Products Corporation. Test results will be maintained in forms similar to those provided in the manufacturers instruction manual. The test will be performed as per the instruction manual. All corrective actions indicated will be made.