Prime Heart
for Complete Heart Care

www.primeheart.com

Sunil M. Patel, MD
Diplomate
ABIM - Cardiovascular Diseases
Board of Nuclear Cardiology
National Board of Echo Cardiography

August 3, 2006

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RECEIVED
REGION 1
2006 AUG 11 PM 1:03

Bryan A. Parker
Health Physicist
Division of Nuclear Materials Safety
USNRC Region I
475 Allendate Road
King of Prussia, PA 19406-1415

Dear Mr. Parker

03037104

Re: License No. 29-31112-01

We would like to apply to amend our radioactive material license no. 29-31112-01 to use a dose calibrator to measure radioactive dosages of radiophahrmaceuticals This equipment will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions. Attached is a copy of a protocol of quality assurance tests to be performed on the dose calibrator.

Thank you very much again for your immediate attention to this request.

Sincerely,

Sunil M Patel, M.D.
Owner

Attachment

139273
NMSS/RGN1 MATERIALS-002

Irvington Office: 40 Union Ave., Suite 101 • Irvington, New Jersey 07111 • Tel: 973-371-3166 • Fax: 973-371-3266

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ATTACHMENT

DOSE CALIBRATOR CALIBRATION

A. Constancy

Frequency: 1. At installation and at the beginning of each day of use.
2. After repair, adjustment, or relocation of the dose calibrator.
Sources: 100-200 uCi of Cs-137
0.500-5 mCi of Co-57

1. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
2. For each source used, log in a book the net activity of each constancy source.
3. Using the Cs-137 source, repeat the above procedure for all commonly used radionuclide settings. Log the results.
4. If the error exceeds 5%, the dose calibrator requires repair or replacement.

B. Linearity:

Frequency: 1. At installation and at least quarterly thereafter.
2. After repair, adjustment, or relocation of the dose calibrator.
Source: Tc-99m in a syringe with an activity greater than the activity administered to patients.

Decay Method

1. Assay the Tc-99m syringe 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 on the Linearity Test form. The first assay should be done in the morning at regular time, for example 8.a.m.
2. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 30 microcuries.
3. Convert the time and date information you recorded to hours elapsed since the first assay.
4. On a sheet of semilog graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the tope of the graph, note the date and the manufacturer, model number, and serial number of the dose brator. Then plot the data.
5. 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 (A-observed-A-line)/(A-line) = deviation.

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6. If the worst deviation is more than +/-0.05, 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".

Shield Method

Equipment Kit: Calicheck

Kit Calibration:

1. Remove any syringe hanger or chamber liner, if necessary, from the dose calibrator.
2. Set dose calibrator to measure Tc-99m.
3. Adjust zero, background, etc., if applicable. Check zero on each range. If background is not "zero" on all ranges, zero on one range and record values on all other ranges, to add or subtract from fine results when those ranges are used.
4. Place calibration source into black tube and insert black tube into dose calibrator carefully with the open end in the upward position. Observe displayed activity.
5. Record reading in appropriate positions on the Literacy Check form.
6. Place red tube in the dose calibrator over the black tube. Record reading as the appropriate denominator on the form.
7. Replace red tube with orange tube. Record.
8. Replace orange tube with yellow tube. Record.
9. Replace yellow tube with green tube. Record.
10. Replace green tube with blue tube. Record.
11. Replace blue tube with purple tube. Purple tube must go down over the base pedestal. Record.
12. Leaving the purple tube in place, install the red tube over the black central
13. Remove the red tube (only) and replace with the orange tube. Record. Continue inserting colored tubes into the purple tube in the same sequence (yellow, green, blue) as directed above but only until the dose calibrator display is 30 uCi. Record each display as you proceed.
14. Divide the numerator by the denominator in Column B to determine the Calibration factor, and record in Column C. These factors will be used for all future activity linearity tests provided all conditions of the tests are met.

Linearity Procedure:

1. Repeat steps 1-14 above recording data in Column B on another Linearity Check form.
2. Enter the calibration factors in Column C of the form.
3. Multiply the value in Column B by the corresponding value in Column C to determine the product of each entry for Column D. Record values. (Ideally, these values will all be the same.

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4. Add all products in Column D and divide by the number of entries on Column D to determine the mean value. Multiply the mean by 1.05 and 0.95 as indicated. These define the upper and lower limits of +/-5% variation.
5. If all the values in Column D fall between these two limits, your dose calibrator has acceptable activity linearity.
6. If any values in Column D fall outside the limits, repeat the study to rule out possible variations in the initial data. Consistent results that are outside the limits that the instrument is exhibiting non-linearity. Corrective action is indicated.

C. Accuracy

Frequency: 1. At installation and at least annually thereafter.
2. After repair, adjustment, or relocation of the dose calibrator.
Source: 100-200 uCi of Cs-137
0.5-5.0 mCi of Co-57

1. Assay a calibrated reference source at the appropriate setting (i.e. use the Co-57 setting to assay Co-57), and record this measurement on a form. Repeat for a total of three determinations.
2. Calculate the mean of the three determinations. The mean value should be within 5% of the certified activity of the reference source, mathematically corrected for decay.
3. Repeat the procedure for other calibrated reference source.
4. If the mean value does not agree within 5% with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. If the error exceeds 10%, the dose calibrator requires repair or replacement.

D. Geometry

Frequency: 1. At installation.
2. After repair, adjustment, or relocation of the dose calibrator.
Sources: A. 10 mCi of Tc-99m
B. 30 mCi of Tc-99m

1. Draw 0.5 cc of source A into a 3 cc syringe and assay it. Record the volume and millicuries indicated.
2. Remove the syringe from the calibrator, draw additional 0.5 cc of non-radioactive saline or tap water and assay again. Record the volume and millicuries indicated.
3. Repeat the process until one has assayed a 3 cc volume. Use 1 cc as the standard volume and divide the millicurie reading for the standard volume by the millicuries indicated in each volume. The quotient is a volume corrector factor.
4. Use 1 cc as the standard volume and divide the millicurie reading for the standard volume and divide the millicuries indicated in each volume. The quotient is a volume corrector factor.

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5. Graph the data and draw horizontal 5% error lines above and below the standard volume.
6. If any data points lie outside the 5% error lines, make a correction table or graph that will convert from "indicated activity" to true activity".
7. Draw 1.0 cc of source B in a 5-cc vial and assay it. Record the volume and millicuries indicated.
8. Remove the vial from the calibrator and, using a clean syringe, inject 0.5 cc of nonradioactive saline or tap water and assay again. Record the volume and millicuries indicated.
9. Repeat the process until you have assayed a 5 cc volume. The entire process must be completed within 10 minutes.
10. Use 1 cc as the standard volume and divide the millicuries reading for each volume. The quotient is a volume correction factor.
11. Graph the data and draw horizontal 5% error lines above and below the standard volume.
12. If any data points lie outside the 5% error lines, make a correction table or graph that will convert from "indicated activity" to "true activity".

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This is to acknowledge the receipt of your letter/application dated

8/31/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 29-31112-01

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 139273.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader