To: Bryan Parker,
Health Physicist,
Materials Licensing Branch,
NRC

From: Robert M Sweeney, RSO
Midwest Health Professionals

Re: License No. 24-32391

In review of our license in Amendment No. 07, we would like to request the following changes be made.

- Ronald A Weiss, M.D. should be removed as an authorized user.

In review of the 'tie-down' documentation submitted by Stan A. Huber Consultants, Inc. #ML12187A201 dated 7/2/2012, we would like the following changes:

- We would like leak testing to be performed either by qualified consultants or in-house in compliance with NUREG Appendix Q.
- Our dose callbrator is no longer being used for measuring patient doses. Secondary to use solely for purposes of QC, references to yearly calibration of the dose calibrator should not be needed unless the dose calibrator is returned to service for patient administration purposes.
- We do not notice any indication for a requirement of efficiency testing our well counter on an annual basis. This item was added to some licenses handled by Stan A. Huber Consultants, Inc. If such a requirement occurs on our license, we would like to remove the Well Counter Efficiency test. Our well counter has been of stable performance and this test is not required under the guidelines.

We have provided an updated tie-down document in the following pages. Minor formatting and wording changes included.

We believe that this information is sufficient to grant our request for amendment. If you need further information please contact me at (314) 749-4235 or Robert Sweeney at (314) 799-5648.

Sincerely,
Midwest Health Professionals, P.C.

Tshiswaka Kayembe, M.D. 3/28/16
President

Ref. NRC 313 Item 9.2
Calibration of Survey Meters

Radiation Monitoring Instruments

Type	Manufacturer	Model	Range	Use
Survey Meter [1]	Ludlum	14C	0-1500 mr/hr	Measuring
Dose Calibrator [2]	Captintec	CRC-15R	0.005-770 mCi	Quality Control

1 - Our Survey Meter will be calibrated at intervals not to exceed 12 months and after repairs by any firm that is approved by the NRC or Agreement State for such calibrations. Instruments will be calibrated on at least two (2) points on each scale range. For our calibration service we may use Stan A. Huber Consultants, Inc., of New Lenox, IL, whose sources and procedures are on file with the Illinois Department of Nuclear Safety license #IL-01013-01, or another licensed calibration firm.

2 - Our dose calibrator is not being used for patient administration and remains in service for quality control procedures.

Ref. NRC 313 Item 9.3
Procedure for Calibrating Dose Calibrator

Our dose calibrator is currently in use only for purposes of quality control. Patient administration is through unit doses and time-decay activity calculation. Should circumstances change all appropriate testing must be performed again. These details follow:

In the event we need to begin using the dose calibrator for patient administration again, we have developed and will implement written dosage measuring equipment calibration procedures that meet the full requirements in 10 CFR 35.60 and 10 CFR 35.62 as applicable.

We will use unit dose procedures if the dose calibrator is not operational.

All radiopharmaceuticals will be assayed for activity to an accuracy of +/- 10% using an ionization type dose calibrator. The dose calibrator must be checked for accurate operation at the time of installation, reactivation as a means of dose measurement for patient

administration, after repair or adjustment, and periodically thereafter as described in this procedure. The periodic operational tests include the following:

A. Dose Calibrator Constancy

Daily or before each day-of-use of the dose calibrator, measure and record the apparent activity of a long-lived standard radionuclide such as Cs^{137}, at the radionuclide settings to be used that day. Choose a source with a minimum activity of 50 µCi (10 µCi .

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 Ra^{226} using a reproducible geometry each day before using the dose calibrator. Use the following procedure:

a. Assay each reference source using the appropriate dose calibrator setting (i.e., Cs^{137} setting for Cs^{137}.)
b. Measure background level at same dose calibrator setting and subtract or confirm the proper operation of the automatic background subtraction circuit if it is used.
c. Repeat the procedure used for the Cs^{137} source for all of the radionuclide settings to be used that day and record the results.
d. Any dose calibrator instrument setting reading which differs by +/- 10% from the reading recorded at the most recent accuracy test for that setting will require the individual performing the test to immediately notify the RSO of suspected malfunction of the dose calibrator. If the constancy error exceeds +/- 10%, the dose calibrator shall be repaired or replaced.

B. Dose Calibrator Linearity

Linearity means that the dose calibrator is able to indicate the correct activity over the range of use of that dose calibrator. This test is done using a vial or syringe of Tc^{99m} which has an activity at least as large as the largest dose to be administered.

a. Decay Method
    i. Assay the Tc^{99m} syringe or vial in the dose calibrator and subtract background level to obtain net activity in millicuries. Record date, time to the nearest minute, and net activity. This assay should be done in the morning, for example 8:00 am.

    ii. Repeat Item (i) at time intervals of 6, 24, 30, and 48 hours after the initial assay. Continue until the assayed activity is less than 30 µCi.

iii. Using the 30 hour activity measurement as a starting point, calculated the predicted activities at 0, 6, 24, 30, and 48 hours using the following table (Note: You must use the decay equation instead of the correction factors if the 30 hour assay is not performed on time.):

Assay Time	Correction Factor
0	32
6	16
24	2
30	1
48	.0125

Example: If the net activity measured at 30 hours was 15.625 µCi, then the predicted activity for 6 and 48 hours would be 15.625 µCi x 16 = 250 mCi and 15.625 µCi x 0.125 mCi, respectively.

iv. Calculate the variance between the measured net activity for each time interval versus the predicted activity.

v. The activities should be within +/- 10% of the calculated activity if the dose calibrator is linear and functioning properly. If the errors exceed +/- 10% for doses greater than 10 µCi, the dosage readings shall be mathematically corrected.

vi. If the need for correction of measured activity must be clearly indicated on or near the dose calibrator.

b. Shield or Sleeve Method

If we decide to use a set of "sleeves" of various thickness to test for linearity, it will first be necessary to calibrate them. The calibration procedure will follow the manufacturer's recommendations.

The sleeve set may now be used to test dose calibrators for linearity in accordance with the manufacturer's specifications. Note, when performing future linearity checks using the shield or sleeve method, be sure to use the same type of container (vial or syringe) as was used when establishing the initial factors for the shields or sleeves.

If the worst deviation is more than +/- 10%, 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." The need for correction of measured activity must be clearly indicated on or near the dose calibrator.

C. Dose Calibrator Accuracy

Accuracy means that, for a given calibrated reference source, the indicated mCi value is equal to the mCi value determined by the National Institute of Standards and Technology (NIST), formerly National Bureau of Standards (NBS), or by the supplier who has compared that source to a source that was calibrated by NIST. The sources are available from the NIST and from many radioisotope suppliers. At least (2) sources must be used, one of which must have a principle photon energy between 10 µCi for Ra^{226} and 50 µCi for any other photon emitting nuclide.

a. Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain the net activity.
b. Repeat Step C (1) for a total of 3 determinations and average the results.
c. The average activity determined in Step C (2) should agree with the certified activity of the reference source within +/- 10% after decay corrections.
d. Repeat the above steps for the other radionuclide reference standards and record these measurements.
e. Calibration checks that do not agree within +/- 10% indicate that the dose calibrator should be repaired or replaced.
f. At the same time the dose calibrator is being initially calibrated with the NIST traceable standards, place a long-lived source in the dose calibrator, set the dose calibrator, 1 turn, at the various radionuclide settings used (e.g. Cs^{137}, Tc^{99m}) and record readings. These values will later be used to check dose calibrator calibration at each setting (after correcting for decay of the long lived source), without requiring more certified standards. A log of these initial and subsequent readings will be maintained.
g. Put a sticker on the dose calibrator which indicates when the next accuracy test is due.

D. Dose Calibrator Geometrical Variation

Geometrical Variation is a measure of the change in the indicated activity with change in volume or configuration of the sample. This test shall be done using a syringe that is normally used for injections. If the specified license authorizes the use of generators and radiopharmaceutical kits, the tests will also be done using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used under the license. The following test assumes injections are done

with 3 cc plastic syringes and that radiopharmaceutical kits are made in 30 cc glass vials. If these are not used, the procedure will be changed so that syringes and vials are tested throughout the range of volumes commonly used under the license. To measure variation with volume of liquid, a 30 cc vial containing 2 mCi of Co^{57} or other appropriate radionuclide, gently mixed, in a volume of 1 ml will be used.

a. Assay the vial at the appropriate dose calibrator setting and subtract background level to obtain net activity.

b. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake the vial to mix the contents and assay as in Step a.

c. Select one volume as a standard (such as the volume or the reference standard used in performing the test for dose calibrator accuracy) and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes respectively, and 10 ml is the reference volume selected, then

4 ml Volume CF = 2.04 / 2.00 = 1.02

d. Either calculate or plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

e. The true activity of a sample is calculated as follows: True Activity = Measured Activity (x) Correction Factor where correction factor used is for the same volume and geometrical configuration as the sample measured.

f. Similarly, the same activity of Co^{57} in a syringe may be compared with that of 10 ml in a 30 cc vial and a correction factor may be calculated.

g. It should be noted that differences of 200% in dose calibrator readings between glass and plastic syringes have been observed for lower energy radionuclides such as I^{125}. Hence, adequate correction factors shall be calculated and used for syringes made of such different materials.

An alternative to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is

then the difference in the two readings (with a volume correction if significant.)

If any correction factors are greater than 1.1 or less than .90 or if any data points lie outside the 10% error lines, it will be necessary to make a correction table or graph that will allow you to convert 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 and serial number of the dose calibrator.

The RSO shall review and sign the records for all dose calibrator geometry, linearity, and accuracy test results.

Ref. NRC 313 Item 10
Occupational Dose

We will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20, or we will provide dosimetry that meets the requirements limit under 'Criteria' in NUREG-1556 Vol 9, Revision 2, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Materials Licenses.'

However, the quarterly investigational levels for exposures will be as follows:

	Level I	Level II
Deep Dose Equivalent (whole body)	125 mRem	375 mRem
Lens of the Eye Dose Equivalent	375 mRem	1125 mRem
Shallow / Extremity Dose Equivalent	1250 mRem	3750 mRem

Our Nuclear Medicine Technologist will be issued a whole body and extremity dosimeter. This monitor will be exchanged on a quarterly basis. We will utilize the services of a NVLAP approved dosimeter provider.

Ref. NRC 313 Item 10
Area Surveys

We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

Ref. NRC 313 Item 10
Spill Contamination Procedures

We have developed and will implement and maintain written procedures for safe response to spills of licensed materials in accordance with 10 CFR 20.1101.

Ref. NRC 313 Item 10.3
Leak Test Procedures

Leak testing of sealed sources not in storage will be performed on intervals not to exceed 6 months. We will perform the leak tests in-house in compliance with NUREG Appendix Q. We may also use the leak test services of Stan A.Huber Consultants, Inc., New Lenox, IL (Illinois Department of Nuclear Safety License #IL 01013-01), using their Model LT-2 (or Model LT-3 if applicable) Leak Test Kit for sealed sources, or other firm specifically authorized by the U.S. Nuclear Regulatory Commission or Agreement State to perform these tests.

Ref. NRC 313 Item 10.4
Safe Use of Radioactive Pharmaceuticals

We will establish and implement the model safety rules published in Appendix T to NUREG 1556 VOl 9, rev 2, "Consolidated Guidance about Materials Licenses." When radiopharmaceuticals are transported between the hot lab and a remote injection or imaging room, they will be shielded in a lead syringe holder or pig.

Ref. NRC 313 Item 11
Waste Management

We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and of 10 CFR 35.92. Our primary disposal method is decay in storage.

Robert M Sweeney, CNMT / RSO