RECEIVED

VOID SHEET 90 DEC 26 A7:47

TO: License Fee Management Branch

FROM: Bob Hattons

SUBJECT: VOIDED APPLICATION

Control Number: 90262

Applicant: Rajesh Dalati, M.D, P.C.

Date Voided: 12-17-90

Reason for Void: Licensee unable to meet timeliness goal.

Robert M. Hattons Jr 12-17-90
Signature Date

Attachment:
Official Record Copy of "Voided" Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

☐ Refund Authorized and processed

☑ No Refund Due

☐ Fee Exempt or Fee Not Required

Comments: after the

Log completed 5

Processed by: [signature]

ML30
1/1

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: _____
STATUS CODE: 3
FEE CATEGORY: _____
EXP. DATE: 0
FEE COMMENTS: _____

LICENSE FEE TRANSMITTAL

A. REGION III

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: RAJESH GULATI, M.D.
RECEIVED DATE: 900924
DOCKET NO: 3031914
CONTROL NO.: 390262
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
AMOUNT: $580.00
CHECK NO.: 13293

9/21/90

3. COMMENTS

$100 ✓

SIGNED T P Lovett
DATE 9-26-90

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /__/)

1. FEE CATEGORY AND AMOUNT: K - $370

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL _____
LICENSE ✓

3. OTHER _____

SIGNED _____
DATE 10/1/90

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

10/10/90

Rajesh C. Gulati, M.D., P.C.
975 Merriman Road
Westland, MI 48185

REFUND OF APPLICATION FEE

1. BACKGROUND:

Check Received September 28, 1990

Application Dated September 21, 1990

Check Number 12992

Check Amount $580

2. REFUND:

Amount $10

This refund is now being processed and will be sent as soon as possible.

3. REASON FOR REFUND:

Overpayment of application fee for application dated September 21, 1990, for a Materials License as specified in fee Category 7C ($570) of Section 170.31, 10 CFR 170.

NOTE: ENCLOSED IS A COPY OF THE MAY 23, 1990 FEDERAL REGISTER NOTICE CONTAINING THE COMMISSION'S REVISED FEE REGULATIO CH WENT INTO EFFECT JULY 2, 1990. IF YOU HAVE ANY QUEST! NCERNING THE FEES TO BE SUBMITTED WITH FUTURE APPLICATIONS, ASE CONTACT US AT 301-492-4650.

Maurice Messier

Maurice Messier
License Fee and Debt Collection Branch
Division of Accounting and Finance
Office of the Controller

Enclosure: May 23, 1990
Federal Register notice

DEC 18 1990

Rajesh Gulati, M.D., P.C
975 Merriman
Westland, MI 48185

SUBJECT: ABANDONMENT OF YOUR REQUEST FOR NRC LICENSE
DATED SEPTEMBER 21, 1990

Gentlemen:

This refers to your request for an NRC License dated September 21, 1990 and our teleconference with Jim Mikowski on November 6, 1990 in which we requested additional information and notified you that unless a response was received by December 1, 1990 we would void your request.

We have not received a response to date.

You are hereby notified that we consider that you have abandoned your application and we have voided the request. This action is without prejudice to resubmission.

If you resubmit the same request within one year of the date of this letter, we will reactivate our review. Information submitted in response to this letter should refer to VOIDED CONTROL NUMBER 90262.

Sincerely,

Robert G. Gattone, Jr.
Materials Licensing Section

RIII
(RG)
Gattone/rr
12/18/90

CONVERSATION RECORD

TIME: 11:45 | DATE: 11-6-90

TYPE: ☐ VISIT ☐ CONFERENCE ☑ TELEPHONE ☑ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Jim Mikowski	Rajesh Gulati	708 365-3658

SUBJECT: C/N 90262

ROUTING	
NAME/SYMBOL	INT

SUMMARY

Wider extension to respond time
Granted
Now due 12-1-90

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE

ACTION TAKEN

SIGNATURE	TITLE	DATE
Robert G. Hatton Jr	Reviewer	11-6-90

F

NOV 01 1990

Rajesh Gulati, M.D., P.C.
975 Merriman
Westland, MI 48185

Gentlemen:

We have reviewed your application dated September 21, 1990 requesting an NRC License and find that we will need additional information as follows:

1. Clarify whether or not you wish authorization for Xenon-133 use. If you wish to use Xenon-133, you will need to respond to Items 10.13.1, 10.13.3, and 10.13.4 of Regulatory Guide 10.8, Revision 2.

2. As referenced in Item 7. of your application, NRC License Number 21-16450 does not exist. The Harper Grace Hospital license number 21-04127-02 is a Broad Medical License. The Radiation Safety Committee named in this type of license is authorized to appoint authorized users without amending the license. Therefore, your reference to that license for the purpose of satisfying the description of the physician's training and experience is inadequate.

   In order for us to authorize Dr. Dua as a user on your license, you will need to submit a copy of her board certification or documentation of her training and experience pursuant to 10 CFR 35.920. This training and experience must have been obtained within five years preceding the date of the application or Dr. Dua must have had related continuing education and experience since the required training and experience was completed (see 10 CFR 35.972).

3. Confirm that you will document all personnel training to minimally include date, topics discussed, and attendees.

4. Clarify whether or not you wish to be authorized for generator use.

5. On a detailed version of your facility diagram, please indicate the type, dimensions, position and thickness of shielding that you will use for:

   a. Use and storage of Tc-99m generators.

   b. Storage of radiopharmaceuticals.

   c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste.

   d. Preparation and dispensing of 35.200 kit radiopharmaceuticals.

   Identify adjacent areas across the walls from use and storage locations.

6. Submit the names and qualifications of all individuals responsible for doing survey meter calibrations. Include the isotope name, activity, and serial number of all sources to be used for survey instrument calibration. Describe the safety equipment to be used during the calibrations.

7. Your procedure for dose calibrator calibration is not equivalent to the model procedure in Appendix C of Regulatory Guide 10.8, Revision 2. Please implement the model procedure or resubmit equivalent procedures to include:

   a. Commitment to repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

   b. Confirmation that manufacturer's certified data will not be used in lieu of computed geometrical variation correction factors.

   c. Step-by-step procedures for assessing syringe geometrical variation.

8. Submit the names, qualifications, and experience of all individuals responsible for performing leak tests.

9. Clarify whether or not you wish to be authorized for material in 35.300.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 10 days, and refer to Control Number 90262.

Upon failure to file a response within the specified time, we will consider that you have abandoned your request and will void this action. This is without prejudice to resubmission of the application.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 790-5625.

Sincerely,

Original Signed By
Robert G. Gattone, Jr.
Materials Licensing Section

Enclosures:
1. Regulatory Guide 10.8, Revision 2
2. 10 CFR Part 35

RIII
BB
Gattone/dsv
~~10/ /90~~
11-1-90

NRC FORM 313
(9-89)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 5-31-92

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUIRIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [XX] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Rajesh Gulati, M.D., P.C.
975 Merriman
Westland, MI 48185

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

Rajesh Gulati, M.D., P.C.
975 Merriman
Westland, MI 48185

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION | TELEPHONE NUMBER

Stan Buhr or Jim Mikowski, Standard Nuclear Consultants, Ltd. | (708) 365-5858

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL. a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM.
11. WASTE MANAGEMENT.	12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY | AMOUNT ENCLOSED $

13. CERTIFICATION *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE - CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Rajesh Gulati	Rajesh Gulati, M.D.		9/21/90

14. ANNUAL RECEIPTS

- [ ] less than $250K
- [ ] $250K - $500K
- [ ] $500K - 750K
- [ ] $750K - 1M
- [ ] $1M - $3M
- [ ] $3M - 7M
- [ ] $7M - 10M
- [ ] > $10M

15. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

16. VOLUNTARY ECONOMIC DATA

a. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial - proprietary - information furnished to the agency in confidence.)*

- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
QNNP	003	7C		
AMOUNT RECEIVED	**CHECK NUMBER**			**DATE**
$580	12998	Refund 9/24/90		

RECEIVED
SEP 24 1990
REGION III

PRIVACY ACT STATEMENT ON THE REVERSE

CONTROL NO. 90262
SEP 24 1990

Items 5 and 6: Radioactive Material

Byproduct Material	Amount	Purpose of Use
5.a. Material in 10 CFR 35.100	As needed	Medical Use (diagnosis)
5.b. Material in 10 CFR 35.200	2.0 Curies	Medical Use (diagnosis)

Item 7: Authorized Users

Name	Authorized Users
Veena Dua, M.D.	All & Radiation Safety Officer

For Dr. Dua's nuclear medicine credentials, please reference NRC license no. 21-16450 and the Harper Grace Hospital, Detroit, MI NRC materials license.

Item 8: Training for Individuals Working in or Frequenting Restricted Areas

8.1: We will follow the model training program outlined in Appendix A of Regulatory Guide 10.8 Revision 2, (8/87). This training will be given to radiation workers as well as ancillary personnel such as clerical, nursing, housekeeping and security employees working in or frequenting areas where radioactive materials are used or stored.

Instructions will be delivered orally, by videotape, or in writing as appropriate, and will follow the frequency stated in the above model training program.

8.2: Not applicable.

Item 9: Facilities and Equipment

9.1: Annotated Drawing

Please refer to the attached diagram of our nuclear medicine department.

9.2: Survey Instrument Calibration

We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2 (8/87).

9.3: Dose Calibrator Calibration

We have attached a dose calibrator calibration procedure for your review that is appended as ATT 9.3.

9.4: Personnel Monitoring Program

We will establish and implement the model personnel external monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2 (8/87).

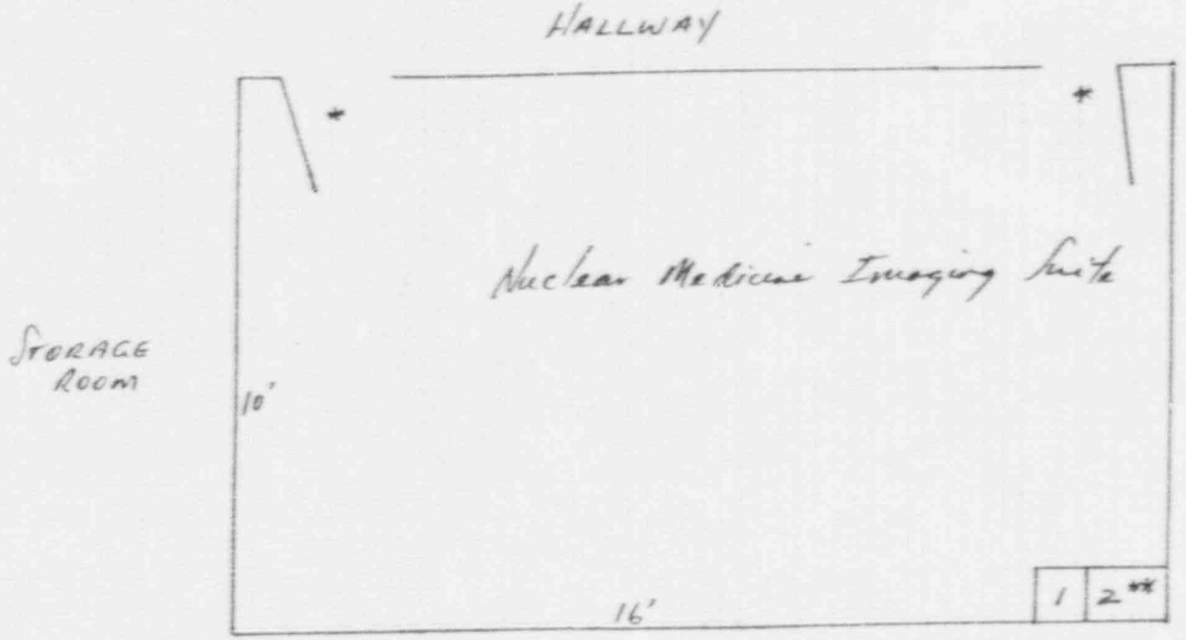
9.5:& 9.6: Not applicable.

Item # 1

R. GULAT, M.D.
975 MERRIMAN
WESTLAND, MI 48185

The entrance doors to the imaging room will remain locked at all times when radioactive materials are present and the area is unattended by authorized personnel.

The entrance doors will be posted with "Caution Radioactive Material" signs.



1 - DOSE CALIBRATOR

2 - DOSAGE PREPARATION

** Only prepared radiopharmaceutical dosages, received from a commercial radiopharmacy will be used. $^{99}Mo/^{99m}Tc$ generators will not be used. Xe-133 will not be used.

September 1990

INSTRUMENTATION

Survey Meters:

Ludlum, Model 14C

Minimum range: 0 - 0.2 mr/hr
Maximum range: 0 - 2000 mr/hr

Dose Calibrator:

Nuclear Associates Rad/Cal II or equivalent

Diagnostic Instruments:

One (1) Gamma Camera, Siemens 2LC, or equivalent

Item 9

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

_____ First elution from new Mo-99/TC-99m generator

or

__X__ Other* (specify) A source of Tc-99m equivalent to the maximum activity administered to patients will be used.**

B. Sources Used for Instrument Accuracy and Constancy Tests.***

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	One millicurie or more	within ±5%
Ba-133	0.1-0.5	100 microcuries or more	within ±5%
Cs-137	0.1-0.2	100 microcuries or more	within ±5%
Ra-226	1-2	N/A	N/A
N/A		N/A	N/A

C. _____ The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator.

or

_____ Equivalent procedures are attached.

---

* For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalant to the highest activity used.

** We also request authorization to use an alternate method of performing dose calibrator <u>linearity</u> checks using a "Lineator" device (Atomic Products Corp., Center Moriches, NY) or a "Calicheck" system (Calcorp). We confirm the manufacturer's product literature will be followed with respect to use, calculations, and replacement of damaged parts.

*** For <u>constancy</u> tests, we will use a Cs-137 source of 100 uCi or more to check the Cs-137 setting as well as the other commonly used radionuclide settings. The shorter half-lives of Ba-133 and Co-57 make frequent decay corrections necessary, and we, therefore, do not feel they are practical for this use.

APPENDIX D (Continued)

Section 2

METHODS FOR CALIBRATION OF DOSE CALBIRATOR*

A'l radiopharmaceuticals must be assayed for activity to an accuracy of 10 percent. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument constancy (daily)

2. Instrument accuracy (at installation and annually thereafter)

3. Instrument linearity (at installation and quarterly thereafter)

4. Geometrical variation (at installation)

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. Test vor Instrument Constancy

Instrument constancy means that there is reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Assay at least one relatively long-lived reference source such as Cs-137, Co-57, or Ra-226 using a reproducible geometry before each day's use of the instrument. Preferably, at least two reference sources (for example, 3-5 mCi of Co-57 and 100-200 uCi of Cs-137 or 1-2 mg Ra-226 (with appropriate decay corrections) will be alternated each day of use to test the instrument's performance over a range of photon energies and source activities.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).

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* See ANSI N42.13-1978, "Calbiration and Usage of Dose Calibrator ionization Chambers for the Assay of Radionuclides" (American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018).

** Co-57 and Ra-226 are not subject to NRC licensing; the respective State agency should be consulted to determine its requirements for possessing this material.

2. Measure background level at same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.

3. Calculate net activity of each source subtracting out background level.

4. For each source, plot net activity versus the day of the year on semilog graph paper.

5. Log the background levels.

6. Indicate the predicted activity of each source based on decay calculations and the ± 10 percent limits on the graph.

7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.

8. Variations greater than ± 10 percent from the predicted activity indicate the need for instrument repair or adjustment.

9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocations, etc.

D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

E. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will use a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator).

1. Assay the Tc-99m vial in the dose calibrator, and subtract background level to obtain net activity in millicuries.

2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.

3. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time* (hr)	Correction Factor
0	31.673
6	15.853
24	1.991
30	1
48	0.126

Example: If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be 15.625 mCi x 15.853 = 247.7 mCi and 15.625 mCi x 0.126 = 1.97 mCi, respectively.

** 4. On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval).

** 5. The activities plotted should be within ± 10 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ± 10 percent indicate the need for repair or adjustment of the instrument.

6. If instrument linearity cannot be corrected, it will be necessary in routine assays to use either (a) an aliquot of the eluate that can be accurately measured or (b) the graph constructed in step 4 to relate measured activities to calculated activities.

F. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than ±10 percent. (Even though correction factors may be provided by the manufacturer, the accurancy of these should be checked.) When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

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* Assay times should be mesured in whole hours and correction factors should be used to the third decimal place as indicated. The more recent half-life of $T_{1/2}$ = 6.02 hours has been used in calculating these correction factors.

** As an alternative to graphing these results, we find we can more accurately determine the % error by the following equation: (Calculated Activity - Measured Activity / Calculated Activity = % Error

To measure variation with volume of liquid, a 30-cc vial containing 2 mCi of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

1. Assay vial at the appropriate instrument setting, and subtract background level to obtain net activity.

2. 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 vial to mix contents and assay as in step 1. (Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

3. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument 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 and 10 ml is the reference volume selected,

   4 ml Volume CF = 2.00/2.04 = 0.98

4. 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.

5. The true activity of a sample is calculated as follows:

   True Activity = Measured Activity x Correction Factor

   where the correction factor used is for the same volume and geometrical configuration as the sample measured.

6. 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.

7. Is should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established.

   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).

G. Test for Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides, including Cs-137, Co-57, and Ba-133, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS and documented.

The activity levels of the reference sources used should approximate those levels normally encountered in clincial use (e.g., Co-57, 3-5 millicuries) giving adequate attention to source configuration. Identify in your application the three sources that you will use. State nuclide, activity, and calibration accuracy. The lower-energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. Assay the reference standard in the dose calibrator at the appropriate setting, and subtract the background level to obtain the net activity.

2. Repeat step 1 for a total of 3 determinations, and average results.

3. The average activity determined in step 2 should agree with the certified activity of the reference source within ±10 percent after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

6. Calibration checks that do not agree within ±10 percent indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.

7. At the same time the instrument is being initially calibrated at the licensee's facility with the reference standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more reference standards. Keep a log of these initial and subsequent readings.

Item 10: Radiation Safety Program

10.1: Radiation Safety Committee/Radiation Safety Officer

We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of authority that was published in Appendix F of Regulatory Guide 10.8 Revision 2, (8/87).

10.2: ALARA Program

We will establish and implement the model ALARA Program that was published in Appendix G to Regulatory Guide 10.8, Revision 2 (8/87).

10.3: Leak Test

We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2 (8/87).

10.4: Safe Use of Radiopharmaceuticals

We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2 (8/87).

10.5: Spill Procedures

We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2 (8/87).

10.6: Procedures for Ordering and Receiving Radioactive Material

We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2 (8/87).

10.7: Procedures for Opening Packages Containing Radioactive Material

We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2 (8/87).

Records of Byproduct Material Use

10.8: Records of Unit Dosage Use

We will establish and implement the model procedure for a unit dose record that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2 (8/87).

10.9: Records of Multidose Vial Use

We will establish and implement the model procedure for a multidose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2 (8/87).

10.10: Molybdenum Concentration Records

We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published in Appendix M.3 to Regulatory Guide 10.8, Revision 2 (8/87).

10.11: Not Applicable.

10.12: Area Survey Procedures

We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2 (8/87).

10.13: Air Concentration Control

Appended as ATT 10.13.1 is our procedure for monitoring, calculating, and controlling air concentrations from noble gases.

For aerosols, we will follow the requirements of 10 CFR 35.14 (b)(8). We will collect spent aerosol in a shielded trap, and, if reusable traps are used, will monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions. For single-use devices, monitoring of the effluent will not be necessary.

10.14: Radiopharmaceutical Therapy

We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix P to Regulatory Guide 10.8, Revision 2 (8/87). Also attached are our "Nursing Instructions for Patients Treated with I-131 Therapy Doses Less than 30 mCi."

10.15:-10.16: Not applicable.

Item 11: Waste Management

11.1. Waste Disposal

We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2 (8/87).