DEC 0 3 1985

License No. 37-21489-01
Docket No. 030-20851
Control No. 104612

Erie Nuclear Cardiology Center
ATTN: R. Philip Canosa, D.O.
2010 West 38th Street
Erie, Pennsylvania 16508

Gentlemen:

Please find enclosed an amendment to your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5239, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

OFFICIAL RECORD COPY ML 37-21489-01/LTR - 0001.0.0
11/21/85

ML18

We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:
Josephine M. Piccone

Josephine M. Piccone, Ph.D.
Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards

Enclosures:
1. Amendment No. 02
2. Requirements for Materials Licensees

RI:DRSS
Piccone/kl
J.M.P
12/ 3 /85

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11/21/85

NRC FORM 218 (4-76) NRCM 0240

U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE OR VERBAL CONVERSATION RECORD

DATE 11/20/85

TIME 12:45 ☐ A.M. ☒ P.M.

☐ INCOMING CALL ☒ OUTGOING CALL ☐ VISIT

PERSON CALLING	OFFICE/ADDRESS	PHONE NUMBER	EXTENSION
Piccone	NRC Region I		5169

PERSON CALLED	OFFICE/ADDRESS	PHONE NUMBER	EXTENSION
Dr. Philip Canosa	Erie Nuclear Cardiology Center, Erie, PA	(814) 868-5481	

CONVERSATION

SUBJECT: amendment request

SUMMARY

Request is just to follow Appendix D as written using a 3-5 mCi Co-57 source for accuracy testing instead of 10 mCi Co-57 (they were cited for not having a 10 mCi Co-57 source for accuracy testing)

ML10

"OFFICIAL RECORD COPY"

REFERRED TO:

☐ ADVISE ME OF ACTION TAKEN.

ACTION REQUESTED

Amendment written as requested

INITIALS

DATE

ACTION TAKEN

INITIALS J.M.P.

DATE 11/20/85

ERIE NUCLEAR CARDIOLOGY CENTER

Plaza Thirty-Eight Medical Arts Building
2010 West 38th Street • Erie, PA 16508
814/868-5481

November 1, 1985

Licensing Branch
Division of Fuel Cycle and Material
Safety
U.S. Nuclear Regulatory Commission
Region I
631 Park Avenue
King of PRussia, Pennsylvania
19406

Re: Amendment of RAM License #37-21489-01

Please amend license #37-21489-01, Erie Nuclear Cardiology Center, to show the following change:

1) Delete the 10 mCi Co-57 source for testing of dose calibrator accuracy. Dose calibrator accuracy will be done annually as per appendix D, section 2 of the USNRC Regulatory Guide 8.20.

Thank you for your time and consideration of this matter.

Sincerely,

R. Philip Canosa D.O.

R. Philip Canosa, D.O.

RPC/sgc

Nov 12 - I

Applicant.....
Check No. 350 #120.00
Amount/Fee Category
Type of Fee Amd
Date Check Rec'd 11/15/85
Received By jacques

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1p.

U.S. NRC REGION I
FEE BRANCH

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U.S. NUCLEAR REGULATORY COMMISSION

September 1979

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 8.20

APPLICATIONS OF BIOASSAY FOR I-125 AND I-131

A. INTRODUCTION

Section 20.108, "Orders Requiring Furnishing of Bioassay Services," of 10 CFR Part 20, "Standards for Protection Against Radiation," indicates that the Nuclear Regulatory Commission (NRC) may incorporate into a license provisions requiring a specific program of bioassay measurements as necessary or desirable to aid in determining the extent of an individual's exposure to concentrations of radioactive material. In certain cases, the requirement of bioassay may also be included in the license by reference to procedures specifying in vivo measurements, measurements of radioactive material in excreta, or both.

This guide provides criteria acceptable to the NRC staff for the development and implementation of a bioassay program for any licensee handling or processing I-125 or I-131. It further provides guidance to such licensees regarding the selection of workers who should participate in a program to detect and measure possible internal radiation exposure. The guide is programmatic in nature and does not deal with measurement techniques and procedures.

B. DISCUSSION

The topics treated in this guide include determinations of (1) whether bioassay should be performed, (2) frequencies of bioassay, (3) who should participate, (4) the actions to take based on bioassay results, and (5) the particular results that should initiate such actions.

For the user's convenience, the following terms are presented with their definitions as used in this guide:

Bioassay–The determination of the kind, quantity or concentration, and location of radioactive material in the human body by direct (in vivo) measurement or by analysis in vitro of materials excreted or removed from the body

Intake–The total quantity of radioactive material entering the body.

In vivo measurements–Measurement of gamma- or x-radiation emitted from radioactive material located within the body for the purpose of detecting or estimating the quantity of radioactive material present.

In vitro measurements–Measurement of radioactivity in samples of material excreted from the human body.

C. REGULATORY POSITION

1. Conditions Under Which Bioassay Is Necessary

a. Routine[1] bioassay is necessary when an individual handles in open form unsealed[2] quantities of radioactive iodine that exceed those shown in Table 1 of this guide. The quantities shown in Table 1 apply to both the quantity handled at any one time or integrated as the total amount of activity introduced into a process by an employee over any 3-month period.

b. When quantities handled in unsealed form are greater than 10% of Table 1 values,

*Lines indicate substantive changes from previous issue.

[1] Routine means here that an individual is assigned on a scheduled and repeatable basis to submit specimens for bioassay or to report for in vivo measurements. Either radiochemical bioassay of urine or in vivo counting is acceptable to the NRC staff for estimating internal radioactivity burdens or intakes. In some cases, however, a licensee may wish to corroborate estimates from urinalysis data with in vivo determinations. Since there are adequate references in the literature to help devise bioassay measurements, this guide does not include recommended analytical procedures. Each installation should adopt procedures or obtain services best suited to its own needs.

[2] See discussion in the footnote to Table 1 of this guide.

routine bioassay may still be necessary under certain circumstances. A written justification for not performing such measurements should be prepared and recorded for subsequent review during NRC inspections whenever bioassay is not performed and the quantities handled exceed 10% of the levels in Table 1.

c. Except as stated in regulatory position 1.e, bioassay is not required when process quantities handled by a worker are less than 10% of those in Table 1.

d. In nuclear reactor installations, employees should be bioassayed by an in vivo count within 30 days after the end of exposure in work locations where concentrations exceeded, or might have exceeded, 9×10^{-9} μCi/ml averaged over any 40-hour period. Table 1 and regulatory position 4 regarding frequency of bioassays are not applicable to reactor licensees.

e. Special bioassay measurements should be performed to verify the effectiveness of respiratory protection devices and protective clothing. If an individual wearing a respiratory protective device or protective clothing is subjected to a concentration of I-125 or I-131 (in any form) in air such that his or her intake with no protection would have exceeded the limits specified in paragraph 20.103(a)(1) of 10 CFR Part 20,[3] bioassays should be performed to determine the resulting actual I-125 or I-131 intake. These special bioassay procedures should also be conducted for personnel wearing respirators if for any reason the I-125 or I-131 concentration in air and the duration of exposure are unknown or cannot be conservatively estimated by calculation.

2. Participation

All workers handling radioactive iodine or sufficiently close to the process so that intake is possible (e.g., within a few meters and in the same room as the worker handling the material) should participate in bioassay programs described in regulatory position 1.

[3]Multiplying the concentrations given in Appendix B to 10 CFR Part 20, Table 1, Column 1, 5×10^{-9} μCi/ml for I-125 (soluble) and 9×10^{-9} μCi/ml for I-131 (soluble), by 6.3×10^{8} ml gives the corresponding quarterly intake of the respective iodines by inhalation. These quarterly intakes would be about 3.2 μCi for I-125 and 5.7 μCi for I-131, which would give a thyroid dose commitment of about 7.5 rems to a 20-gram thyroid integrated over all future time using effective half-lives of 41.8 days for I-125 and 7.6 days for I-131 and using a quality factor (*QF*) of 1.7 to calculate effective disintegration energy in the case of I-125. (This QF of 1.7 is used for conservatism, even though the International Commission on Radiological Protection (1969) and the National Council on Radiation Protection (1971) have published a QF of 1, because some calculations in more recent scientific literature have suggested the use of QF values higher than 1 for electron or beta energies of 0.03 MeV or less.)

3. Types of Bioassays That Should Be Performed

a. Baseline (preemployment or preoperational). Prior to beginning work with radioactive iodine in sufficient quantity that bioassay is specified in regulatory position 1.

b. Routine. At the frequency specified in regulatory position 4.

c. Emergency. As soon as possible after any incident that might cause thyroid uptakes to exceed burdens given in regulatory position 5.a(2), so that actions recommended in regulatory position 5.a(2)(b) can be most effective.

d. Postoperational and with Separation Physical. A bioassay should be performed within 2 weeks of the last possible exposure to I-125 or I-131 when operations are being discontinued or when the worker is terminating activities with potential exposure to these radionuclides.

e. Diagnostic. Followup bioassay should be performed within 2 weeks of any measurements exceeding levels given as action points in regulatory position 5 in order to confirm the initial results and, in the case of a single intake, to allow an estimate of the effective half-life of radioiodine in the thyroid.

4. Frequency

a. Initial Routine. Except in situations where thyroid burdens may exceed quantities specified in regulatory position 5.a(2), a bioassay sample or measurement should be obtained within 72 hours following entry of an individual into an area where bioassay is performed in accordance with regulatory positions 1 and 2 (but waiting at least 6 hours for distribution of a major part of the iodine to the thyroid[4]) and every 2 weeks or more frequently thereafter as long as the conditions described in regulatory positions 1 and 2 exist. When work with radioactive iodine is on an infrequent basis (less frequently than every 2 weeks), bioassay should be performed within 10 days of the end of the work period during which radioactive iodine was handled (but not sooner than 6 hours unless emergency actions to obtain an early prognosis and thyroid blocking treatment are appropriate[4]).

b. After 3 Months. When a periodic measurement frequency has been selected in accordance with regulatory position 4.a, it may be changed to quarterly if, after 3 months, all the following conditions are met:

(1) The average thyroid burden for each individual working in a given area was

[4]NCRP Report No. 55, "Protection of the Thyroid Gland in the Event of Releases of Radioiodine," National Council on Radiation Protection and Measurements, Washington, D.C., August 1, 1977, p. 21.

less than 0.12 μCi of I-125, less than 0.04 μCi of I-131, and less than the corresponding proportionate amount[5] of a mixture of these nuclides during the initial 3-month period:

(2) The quarterly average radioiodine concentration (μCi/ml) in air breathed by any worker (as obtained when measurements of radioiodine concentrations in air are required) does not exceed 25% of the concentration values for "soluble"(s) iodine given in Appendix B to 10 CFR Part 20, Table 1, Column 1, (5×10^{-9} μCi/ml for I-125 and 9×10^{-9} μCi/ml for I-131), i.e., 25% of these concentrations multiplied by the total air breathed by an employee at work during one calendar quarter, 6.3×10^{8} ml, does not exceed 0.8 μCi of I-125 or 1.4 μCi of I-131. The appropriate proportionate amount[5] of a mixture of these nuclides should be used as a guide when both I-125 and I-131 are present; and

(3) The working conditions during the 3-month period with respect to the potential for exposure are representative of working conditions during the period in which the quarterly bioassay frequency will be employed, and there is no reasonable expectation that the criteria in regulatory positions 4.b(1) and 4.b(2) above will be exceeded.

c. After Use of Respiratory Protection Devices. Between 6 and 72 hours after respiratory protective devices, suits, hoods, or gloves are used to limit exposure as stated in regulatory position 1.e.

For individuals placed on a quarterly schedule, sampling should be randomly distributed over the quarter but should be done within one week after a procedure involving the handling of I-125 or I-131. This will provide a more representative assessment of exposure conditions.

5. Action Points and Corresponding Actions

a. Biweekly or More Frequent Measurements

(1) Whenever the thyroid burden at the time of measurement exceeds 0.12 μCi of I-125 or 0.04 μCi of I-131, the following actions should be taken:

(a) An investigation of the operations involved, including air and other in-plant surveys, should be carried out to determine the causes of exposure and to evaluate the potential for further exposures.

(b) If the investigation indicates that further work in the area might result in exposure of a worker to concentrations that would cause the limiting intakes established in § 20.103 of 10 CFR Part 20 to be exceeded, the licensee should restrict the worker from further exposure until the source of exposure is discovered and corrected.

(c) Corrective actions that will eliminate or lower the potential for further exposures should be implemented.

(d) A repeat bioassay should be taken within 2 weeks of the previous measurement and should be evaluated within 24 hours after measurement in order to confirm the presence of internal radioiodine and to obtain an estimate of its effective half-life for use in estimating dose commitment.

(e) Reports or notification must be provided as required by §§ 20.405, 20.408, and 20.409 of 10 CFR Part 20 or as required by conditions of the license pursuant to § 20.108 of 10 CFR Part 20.

(2) If the thyroid burden at any time exceeds 0.5 μCi of I-125 or 0.14 μCi of I-131, the following actions should be taken:

(a) Carry out all steps described in regulatory position 5.a(1).

(b) As soon as possible, refer the case to appropriate medical consultation for recommendations regarding therapeutic procedures that may be carried out to accelerate removal of radioactive iodine from the body. This should be done within 2-3 hours after exposure when the time of exposure is known so that any prescribed thyroid blocking agent would be effective.[4]

(c) Carry out repeated measurements at approximately 1-week intervals at least until the thyroid burden is less than 0.12 μCi of I-125 or 0.04 μCi of I-131. If there is a possibility of longer-term compartments containing I-125 or I-131 that require evaluation, continue measurements as long as necessary to ensure that appreciable exposures to these other compartments do not go undetected.

b. Quarterly Measurements. Carry out actions at levels as indicated under regulatory position 5.a(1) and (2). If measurements and surveys indicate an appreciable likelihood that a worker will receive further exposures exceeding the criteria of regulatory positions 4.b(1) and 4.b(2), reinstitute biweekly or more frequent bioassays.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding

[5] See Appendix B to this guide for a description and example of using this condition for mixtures.

ie NRC staff's plans for using this regulatory ıide.

Except in those cases in which the applicant licensee proposes an acceptable alternative the staff will use the methods ıs4 d herein after December 15, 1979, in 'aluating the radiation protection programs of ensees who have bioassay requirements incorporated in their licenses in accordance with § 20.108 of 10 CFR Part 20.

If an applicant or licensee wishes to use the method described in this regulatory guide on or before December 15, 1979, the pertinent portions of the application or the licensee's performance will be evaluated on the basis of this guide.

Table 1

ACTIVITY LEVELS ABOVE WHICH BIOASSAY FOR I-125 OR I-131 IS NECESSARY

Types of Operation	Activity Handled in Unsealed Form Making Bioassay Necessary*	
	Volatile or Dispersible*	Bound to Nonvolatile Agent*
Processes in open room or bench, with possible escape of iodine from process vessels	1 mCi	10 mCi
Processes with possible escape of iodine carried out within a fume hood of adequate design, face velocity, performance reliability	10 mCi	100 mCi
Processes carried out within gloveboxes, ordinarily closed, but with possible release of iodine from process and occasional exposure to contaminated box and box leakage	100 mCi	1000 mCi

*Quantities may be considered the cumulative amount in process handled by a worker during a 3-month period; e.g., the total quantity introduced into a chemical or physical process over a 3-month period, or on one or more occasions in that period, by opening stock reagent containers from which radioactive iodine may escape. Quantities in the right-hand column may be used when it can be shown that activity in process is always chemically bound and processed in such a manner that I-125 or I-131 will remain in nonvolatile form and diluted to concentrations less than 0.1 mCi/mg of nonvolatile agent. Capsules (such as gelatin capsules given to patients for diagnostic tests) may be considered to contain the radioiodine in nonfree form, and bioassay would not be necessary unless a capsule were inadvertently opened (e.g., dropped and crushed). However, certain compounds where radioiodine is normally bound are known to release radioiodine when the material is in process, and the left-hand column may then be applicable. In those laboratories working only with I-125 in radioimmunoassay (RIA) kits, the quantities of I-125 are very small and in less volatile forms; thus, bioassay requirements may be judged from the right-hand column. In field operations, where reagent containers are opened outdoors for simple operations such as pouring liquid solutions, the above table does not apply; bioassay should be performed whenever an individual employee handles in open form (e.g., an open bottle or container) more than 50 mCi at any one time.

Operations involving the routine use of I-125 or I-131 in an open room or bench should be discouraged. Whenever practicable, sealed bottles or containers holding more than 0.1 mCi of I-125 or I-131 should be opened at least initially within hoods having adequate face velocities of 0.5 m/sec or more.

APPENDIX A

SUGGESTED REFERENCES TO ASSIST IN ESTABLISHING A BIOASSAY PROGRAM

In response to public comments, this list of publications is provided to assist the licensee in establishing measurements and administrative procedures for a bioassay program appropriate to his operations. This list is not intended to be exhaustive and does not replace the need for professional assistance in establishing analytical procedures or services.

1. American National Standard, ANSI N44.3-1973, "Thyroid Radioiodine Uptake Measurements Using a Neck Phantom," American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018, approved August 24, 1973.

2. R. C. Brown, "^{125}I Ingestions in Research Personnel," Operational Health Physics, pp. 276-278, 1976, proceedings of the Ninth Midyear Topical Symposium of the Health Physics Society, Denver, Colorado, February 1976 (P. L. Carson, W. R. Hendee, and D. C. Hunt, Eds., Central Rocky Mountain Chapter, Health Physics Society, P.O. Box 3229, Boulder, Colorado 80303, $15).

3. E. J. Browning, K. Banerjee, and W. E. Reisinger, Jr., "Airborne Concentration of I-131 in a Nuclear Medicine Laboratory," J. Nucl. Med., vol. 19, pp. 1078-1081, 1978.

4. J. G. Dare and A. H. Deutchman, "The Decay Scheme of Iodine-125 and Its Relationship to Iodine Bioassay," op. cit., Ref. 2, pp. 250-254.

5. B. C. Fasiska, "Radiation Safety Procedures and Contamination Control Practices Involved in High Level I-131 Thyroid Therapy Cases," op. cit., Ref. 2, pp. 287-291.

6. A. Gavron and Y. Feige, "Dose Distribution and Maximum Permissible Burden of ^{125}I in the Thyroid Gland," Health Physics, vol. 23, pp. 491-499, 1972.

7. B. Y. Howard, "Safe Handling of Radioiodinated Solutions," op. cit., Ref. 2, pp. 247-249.

8. ICRP Publication 10, "Report of Committee IV on Evaluation of Radiation Doses to Body Tissues from Internal Contamination Due to Occupational Exposure," Recommendations of the International Commission on Radiological Protection, Pergamon Press, Oxford, p. 17, 1968.

9. ICRP Publication 10A, "The Assessment of Internal Contamination Resulting from Recurrent or Prolonged Uptakes," Recommendations of the International Commission on Radiological Protection, Pergamon Press, Oxford, 1969.

10. A. L. Orvis, "What Is a 'Reportable' Thyroid Burden?" op. cit., Ref. 2., pp. 263-271.

11. P. Plato, A. P. Jacobson, and S. Homan, "In Vivo Thyroid Monitoring for Iodine-131 in the Environment," Int. J. Applied Radiat. and Isotopes, vol. 27, pp. 539-545, 1976.

12. Radiological Protection Bulletin 25, "Safe Working with Iodine-125," National Radiological Protection Board, Harwell, Didcot, Oxon, England, pp. 19-20, 1978.

13. R. P. Rossi, J. Ovadia, K. Renk, A. S. Johnston, and S. Pinsky, "Radiation Safety Considerations in the Management of Patients Receiving Therapeutic Doses of ^{131}I," op. cit., Ref. 2, pp. 279-286.

14. C. T. Schmidt, "Thyroid Dosimetry of ^{125}I and an Instrumental Bioassay Procedure," Program and Abstracts: Twenty-Third Annual Conf. on Bioassay, Environmental, and Analytical Chemistry, [illegible], Sept. 15, 16, 1977.

15. A. Taylor, J. W. Verba, N. P. Alazraki, and W. C. McCutchen, "Monitoring of I-125 Contamination Using a Portable Scintillation Camera," J. Nucl. Med., vol. 19, pp. 431-432, 1978.

16. Technical Reports Series No. 148, "Control of Iodine in the Nuclear Industry," International Atomic Energy Agency, Vienna, 1973.

APPENDIX B

CALCULATION OF ACTION LEVELS FOR MIXTURES OF I-125 AND I-131

B.1 Controlling Instantaneous Thyroid Burdens

Regulatory position 4.b(1) is based on controlling the instantaneous amount in the thyroid and is taken as 25% of the maximum permissible organ burden (MPOB) of I-125 or I-131 that would give a dose rate of 0.6 rem/week if continuously present in the thyroid. If a mixture of both nuclides is present in the thyroid and X is the fractional activity that is I-125, a 3-month interval may be resumed when the total activity of I-125 and I-131 is below

$$0.12X + 0.04(1 - X)$$

Example

If the measurements of I-125 and I-131 in a worker's thyroid are 0.10 μCi of I-125 and 0.05 μCi of I-131, the fractional I-125 activity is

$$X = 0.10/(0.10 + 0.05)$$
$$= 0.667$$

$$0.12X + 0.04(1 - X) = 0.12(0.667) + 0.04(0.33)$$
$$= 0.0932$$

$$\text{Total} = 0.10 + 0.05 = 0.15\ \mu\text{Ci}$$

Thus, in this case, the worker involved should remain on the biweekly (or more frequent) schedule and should not be put on the quarterly frequency.

B.2 Controlling Total Intakes

Regulatory position 4.b(2) is based on controlling total intakes[6] during a quarterly period when air concentration data are available to assess the potential exposure of the worker either to random single intakes or to variable or constant continuous exposures. The quantities of 0.8 μCi of I-125 and 1.4 μCi of I-131 were obtained by calculating 25% of the total quarterly intakes of 3.2 μCi of I-125 or 5.7 μCi of I-131 (see footnote 3) that would be inhaled when breathing a total of 6.3×10^8 ml per quarter working at the standard man breathing rate for 40 hours per week for 13 weeks.

Example

If the average quarterly concentrations estimated from air sampled in a worker's breathing zone are 3×10^{-9} μCi/ml for I-125 and 5×10^{-9} μCi/ml for I-131, the total quarterly intakes are:

$$3 \times 10^{-9} \times 6.3 \times 10^8 = 1.89\ \mu\text{Ci I-125}$$

$$5 \times 10^{-9} \times 6.3 \times 10^8 = 3.15\ \mu\text{Ci I-131}$$

$$\text{Total} = 5.04\ \mu\text{Ci}$$

Also, X, the proportion of I-125, is 1.89/5.04 = 0.375

Thus the control level for maintaining biweekly or more frequent bioassay checks is:

$$0.8X + 1.4(1 - X) = 0.8(0.375) + 1.4(1 - 0.375)$$
$$\text{Total} = 1.18\ \mu\text{Ci for this mixture.}$$

Since the intake of 5.04 μCi is greater than 1.18, this employee should stay on the more frequent bioassay schedule.

Note: The numbers of significant digits carried in the above calculations do not imply any given degree of accuracy of measurement. Enough digits are carried to allow following the arithmetic for purposes of the examples.

[6] The limiting total quarterly intakes are in different proportions for I-125 and I-131 than are the MPOBs. This difference is a result of the fact that permissible concentrations are inversely proportional to effective half-lives whereas an MPOB is calculated assuming a constant burden in the organ of concern that is maintained by continuous intake of activity balanced by an equal rate of elimination from the organ.

APPENDIX D (Continued)

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR*

All 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 for 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 μCi 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).

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 ±5 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 ±5 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, relocation, 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:

* See ANSI N42.13-1978, "Calibration 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.

Assay Time* (hr)	Correction Factor
0	31.633
6	15.853
24	1.995
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 ± 5 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ± 5 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 ± 2 percent. (Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.) When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

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.

$$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

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. It 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.

*Assay times should be measured 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.

The activity levels of the reference sources used should approximate those levels normally encountered in clinical 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 ± 5 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 ± 5 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.

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: Erie Nuclear Cardiology Center

Application Dated: 11/1/85

Control No.: 104612

License No.: 37-21489-01

2. FEE ATTACHED

Amount: $120.00

Check No.: 350

3. COMMENTS

02200
11/88

Signed Brenda Platchek

Date 11/5/85

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 7C ($120)

2. Correct Fee Paid. Application may be processed for:

Amendment ✓

Renewal

License

Signed G Jackson

Date 11/20/85

REGION I FORM 213
(MARCH 1983)

"SECTION COPY"

350

ENCC

ERIE NUCLEAR CARDIOLOGY CENTER

Plaza Thirty-Eight Medical Arts Building
2010 West 38th Street • Erie, PA 16508

MARINE BANK
MEMBER FDIC

60-73/433

PAY One Hundred Twenty DOLLARS

DATE	CHECK NO.	AMOUNT DOLLARS	AMOUNT CENTS
11/4/85	350	120	00

TO THE ORDER OF

Erie Nuclear Cardiology Center

Dennis M Stys

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