EXHIBIT A

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved GAO R0557

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Montana Heart Institute, P.C.
1145 North 29th Street
Suite 204
Billings, MT 59101
TELEPHONE NO.: AREA CODE (406) 245 6233

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Same as 1.a. (030-28780)
LHL 23189

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Scott Baker
TELEPHONE NO.: AREA CODE (406) 245 6233

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*
- a. ☒ NEW LICENSE
- b. ☐ AMENDMENT TO LICENSE NO. _____
- c. ☐ RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Keith Richard Weeks, M.D.

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Keith Richard Weeks, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

See Page 1a

ADDITIONAL ITEMS	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
99 mTc*	any	200	Medical testing "Cardiology"
201 Tl*	Chloride	100	Medical testing "Cardiology"
57 Co	Sealed Sources	5 mCi 1 mCi	Quality Control Quality Control

FORM NRC-313M (8-78)

* For Nuclear Cardiology procedures only.

License Fee Information on Page 3

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INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. 1 Date: 10/80

7. MEDICAL ISOTOPES COMMITTEE	
	Names and Specialties Attached; and
	Duties as in Appendix B; or *(Check One)*
X	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
X	Supplements A & B Attached for Each Individual User; and
X	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
X	Equivalent Procedures Attached; and
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
	Appendix F Procedures Followed; or
X	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Appendix G Rules Followed; or
X	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
	Appendix H Procedures Followed; or
X	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
	Appendix J Form Attached; or
X	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	N/A
--	Appendix K Procedures Followed; or
--	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	N/A
--	Detailed Information Attached; and
--	Appendix L Procedures Followed; or *(Check One)*
--	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	N/A
--	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	N/A
--	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
--	Detailed Information Attached N/A

FORM NRC-313M
(8-78)

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R. S. Landauer	1 X/ month at 1st
		TLD		of month
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R. S. Landauer	1 X / month at 1st
		OTHER (Specify)		of month
c. WRIST		FILM	not needed	
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

See attached sheet, Item 24, for a more complete description of the use of personnel monitoring devices

July - 2 - IV

Applicant. .....
Check No. 3633 ... $580 - 7C
Amount, Fee Category ...
Type of Fee ...
Date Check Rec'd 7/19/85
Received By Jacquie

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL: St. Vincent Hospital

MAILING ADDRESS: 1233 N. 30th Street

CITY: Billings | STATE: MT | ZIP CODE: 59101

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR. *

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY: 7C

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL (Signature): Keith Weeks

(1) NAME (Type or Print): Keith R. Weeks, M.D.

(2) TITLE: Owner/user/applicant

c. DATE: 6.24.85

FORM NRC-313M (8-78)

* see the last page of this application.

Saint Vincent
HOSPITAL AND HEALTH CENTER

P.O. Box 35200
Billings, Montana 59107-5200
406-657-7000

June 25, 1985

To Whom It May Concern:

This will inform you that Dr. Keith Weeks can admit patients who may have radiopharmaceuticals in their body.

Yours sincerely,

William M. Murray
Administrator

WMM/ge

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FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Keith Richard Weeks, M.D.

STREET ADDRESS

1145 North 29th St., Suite 204

CITY	STATE	ZIP CODE
Billings	MT	59101

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING	60+	see attached sheet
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER			

FORM NRC-313M-SUPPLEMENT B
(8-78)

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PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			
59 Fe	Hematology Studies	500+	estimate 500 + hours
201 Tl	Cardiac studies	60+	see attached sheet

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

1967 - 1971 for 59 Fe 500 + hours ?
1981 (17 Feb. - 10 April) 120 Hours *

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
J. P. Smith

b. NAME OF INSTITUTION
National Naval Medical Center

c. MAILING ADDRESS
Bethesda

d. CITY
Maryland

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE
See attached sheet

7. PRECEPTOR'S NAME *(Please type or print)*
See attached sheet

8. DATE
17 Feb. - 10 Apr. 1981

FORM NRC-313M-SUPPLEMENT B
(8-78)

* see attached sheet

☆U.S. GOVERNMENT PRINTING OFFICE: 1981 - 341 742 1160

FORM NRC-313M-SUPPLEMENT A (8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Keith R. Weeks, M.D.	Montana MEV 004012

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
also Wyoming 3516A. However, use of radioisotopes in Montana Only.		

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION	See Attached Sheets		
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
99 mTc	200 mCi	National Naval Medical Center Bethesda, MD	Feb. 17 - Apr. 10, 1981 See Attached Sheets	Human
201 Tl	100 mCi			Human
133 Xe	75 mCi			Human
57 Co	5 mCi			Quality Control
195 Au	1 mCi			Human
59 Fe	2 mCi	University of Oregon	1967 - 1971 500+ Hours	Human

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NRC 313M
Supplement A
Item 4.

BUREAU OF MEDICINE AND SURGERY
DEPARTMENT OF THE NAVY

This is to certify that

KEITH RICHARD WEEKS, M.D.

has attended the

NUCLEAR MEDICINE IMAGING AND RADIOISOTOPE TECHNIQUES--COURSE #8102
(BASIC SCIENCE AND CLINICAL MODULES)

given by the

National Naval Medical Center
Bethesda, Maryland

17 FEBRUARY 1981 *to* 10 APRIL 1981

John P. Smith
COURSE DIRECTOR

William Cox
UNITED STATES NAVY

J. T. Hagan

NRC 313M
Supplement A
Item 4.

NATIONAL NAVAL MEDICAL CENTER

BETHESDA, MARYLAND - 20014

IN REPLY REFER TO
NNMC:C95:MAT:sb
Course #8102
10 April 1981

Keith Richard Weeks, M.D.
625 O'Malley
Billings, Montana 59102

Dear Dr. Weeks:

The following information is enclosed for your records and for use when applying for a NRC By-Products Materials License.

Part 4 to Form NRC-313M-Supplement A (7-77) 10 CFR 30

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES			
		TYPE AND LENGTH OF TRAINING	
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	NATIONAL NAVAL MEDICAL CENTER, BETHESDA, MD 20014 COURSE #8102 17 Feb 81 to 10 April 1981	84	20
b. RADIATION PROTECTION	SAME AS ABOVE	26	04
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	SAME AS ABOVE	28	—
d. RADIATION BIOLOGY	SAME AS ABOVE	25	—
e. RADIOPHARMACEUTICAL CHEMISTRY	SAME AS ABOVE	53 216	— 24

The training and experience indicated above was obtained under the supervision of: F. G. Mannarino, CAPT, MC, USN
NRC License #19-02891-05
The student attended and successfully completed an additional 120 hours of Clinical Nuclear Medicine Imaging.

J. P. Smith
CAPT, MC, USN
Chief, Radiology Service

INSTRUMENTATION
FOR
KEITH RICHARD WEEKS, M.D.

1. Survey meters

   Manufacturer's name: Atomic Products

   Manufacturer's model number: Beta Gamma Survey Meter * 069-701

   Number of instruments available: 1

   Minimum range: 0 mR/hr to 0.5 mR/hr

   Maximum range: 0 mR/hr to 50 mR/hr

2. Diagnostic instruments

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Picker	DynaCamera
Computer	Picker	PSC 512

3. Dose Calibrator

   Manufacturer's name: Atomic Products

   Manufacturer's model number: 086 061 or 086 307

CALIBRATION OF SURVEY INSTRUMENTS AT KEITH RICHARD WEEKS, M.D.

Survey instruments will be calibrated

a. By the manufacturer or

b. By a manufacturer/supplier licensed to calibrate survey meters and using the following procedure:

Calibration will be performed at two points on each scale.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within +/- 10% of the calculated or known values for each point checked. Readings within +/- 20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

c. The outside firm will be Victoreen, Tracerlab, ICN or other manufacturer to be selected and whose procedures and sources have been approved by the Department and are on file with the Department.

CALIBRATION OF SURVEY INSTRUMENTS FOR KEITH RICHARD WEEKS, M.D.

Survey instruments will be calibrated at least annually and following repair by the instrument manufacturer, supplier or consultant/firm and a. through c. below:

a. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

   The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within +/- 10 percent of the calculated or known values for each point checked. Readings within +/- 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within +/- 10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

b. The manufacturer, supplier or consultant/firm will document that they followed a. above and followed either the attached "Methods for Calibration" or procedures approved by the NRC or by an Agreement State and furnish a copy of their NRC or Agreement State License authorizing them to calibrate survey instruments.

c. The calibration organization furnishes a certificate of calibration containing at least the information as contained on the enclosed "Certificate of Calibration".

METHODS FOR CALIBRATION OF (X- AND GAMMA-RAY) SURVEY METERS, INCLUDING PROCEDURES, STANDARDS, AND FREQUENCY FOR KEITH RICHARD WEEKS, M.D.

A. Calibration of survey meters shall be performed with radionuclide sources by a company licensed to calibrate survey meters and will follow their procedures.

1. The sources shall be approximate point sources.

2. The source activities shall be traceable within 5% accuracy to the U.S. National Bureau of Standards (NBS) calibrations.

3. The frequency shall be at least annually and after servicing.

4. Each scale of the instrument shall be calibrated at least at two points such that (a) one point is in each half of the scale and (b) the two points are separated by 35-50% of full scale.

5. The exposure rate measured by the instrument shall differ from the true exposure rate by less than 10% of full scale (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings within +/- 20% will be considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

NOTE: Sources of Cs-137, Ra-226, or Co-60 are appropriate for use in calibrations. The activity of the calibration standard should be sufficient to calibrate the survey meters on all ranges, or at least up to 1 R/hr on the higher-range instruments. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation.

B. A reference check source of long half-life, e.g., Cs-137 or Ra D and E, shall also be read at the time of the above calibration. The readings shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source should be taken:

1. Before each use and also after each survey to ensure that the instrument was operational during the survey.

2. After each maintenance and/or battery change.

3. At least quarterly.

   If any reading with the same geometry is not within +/- 20% of the reading measured immediately after calibration, the instrument should be recalibrated (see item A).

C. The instrument must be calibrated at lower energies if its response is energy dependent and it is to be used to measure the Xe-133 or Tc-99m energy ranges.

   This calibration may be done either

   1. As in item A above with calibrated standards of radionuclides at or near the desired energies or

   2. As a relative intercomparison with an energy-independent instrument and uncalibrated radionuclides.

D. Records of the above items A, B-2, B-3, and C will be maintained.

GAMMA CAMERA CALIBRATION AND QUALITY CONTROL PROCEDURES FOR KEITH RICHARD WEEKS, M.D.

The manufacturers' directions will be followed for calibration and maintenance of the gamma camera. The Quality Assurance procedures will follow the recommendations of the FDA as published in FDA 76-804 6 "Quality Control for Gamma Cameras" as follows:

1. Photo peak adjustment - daily, per manufacturer's recommendations.

2. Oscilloscope and imager adjustment - daily, per manufacturer's recommendations.

3. Uniformity Flood - daily or weekly if no uniformity problems are anticipated, per manufacturer's recommended instructions using a 57Co flood source from NEN Source NES-297 5 mCi

4. Resolution - Distortion - daily, using a bar phantom and the source as indicated above per the manufacturer's recommendations.

5. Sensitivity - daily, using the above source, by comparison of each day's count rate with the same source position, phantom position and % PHA window. These readings will be compared to the manufacturer's sensitivity readings as performed by the service representative.

6. Linearity - will be performed according to the manufacturer's recommendations and will daily be evaluated from the bar phantom images as seen in item 4.

CALIBRATION OF DOSE CALIBRATOR
FOR
KEITH RICHARD WEEKS, M.D.

A. Sources Used for Linearity Test:

I will use a 50 mCi dose from the radiopharmacy.

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Activity (mCi)	Accuracy
Co-57*	1.0	+/- 5%

This should be sufficient in so much as the authorization request is for 99mTc and 201 Tl only.

C. The Procedures described in the attached will be used for calibration of the dose calibrator.

* source to be obtained from New England Nuclear Catalog number NES 206.

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NOTE ON DOSE CALIBRATOR
FOR KEITH RICHARD WEEKS, M.D.

The dose calibrator will be calibrated following the procedures outlined in the attached documents, (see Methods for Calibration of Dose Calibrator) however, only 57 Co will be used for accuracy and consistancy because only low energy, 201 Tl and 99 mTc radioisotopes are being requested. If, at a later time, authorization is received for other radioisotopes of higher energies, then authorization will also be requested for 137 Cs and/or 226 Ra calibration sources to be used as indicated in the attached procedure.

METHODS FOR CALIBRATION OF DOSE CALIBRATOR
FOR KEITH RICHARD WEEKS, M.D.

All radioharmaceuticals 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 uCi of Cs-127 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:

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 the 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.

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

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 behave 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 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 calbration 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-127, 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.

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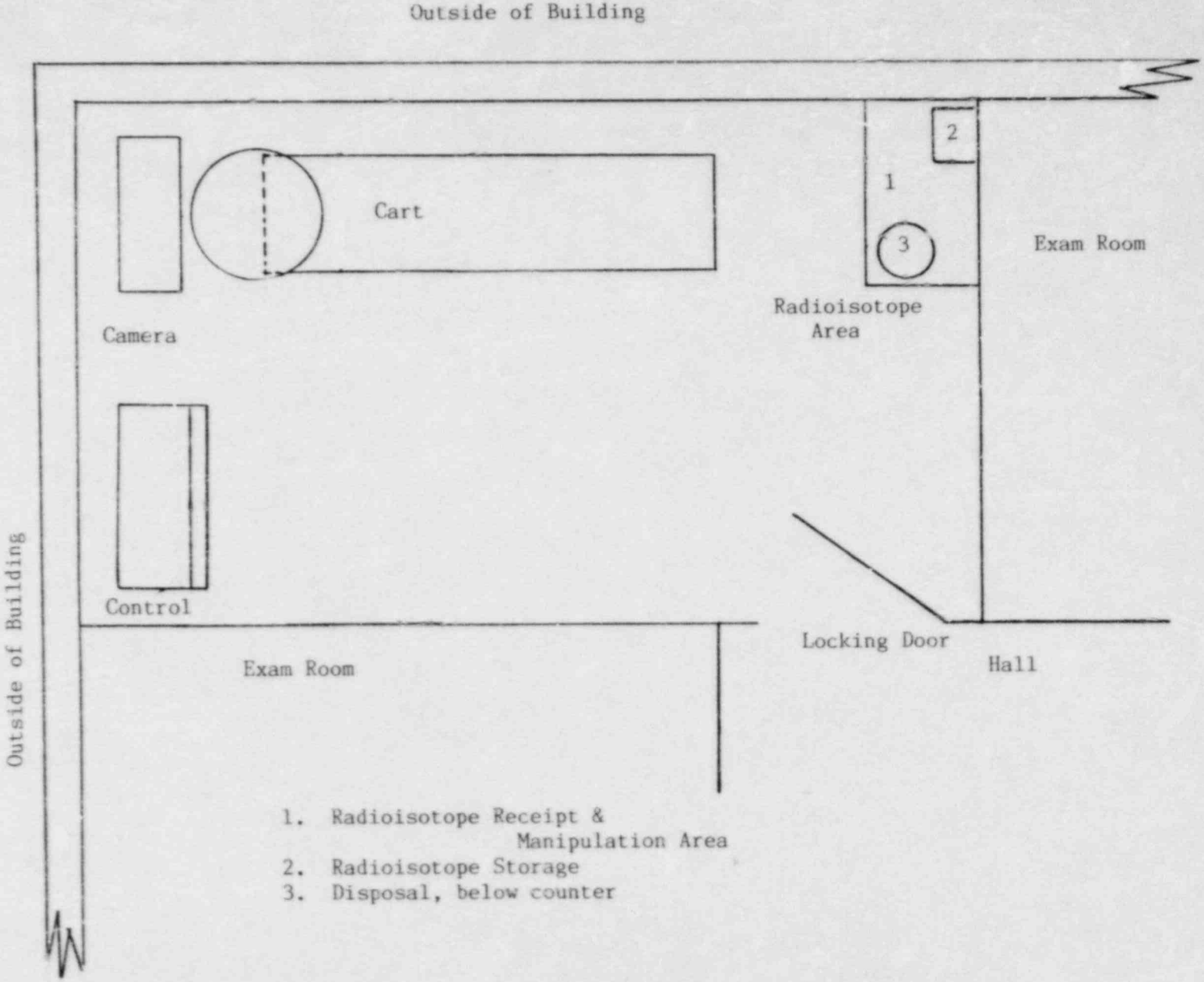
NRC - 313M
Item 11



1. Radioisotope Receipt & Manipulation Area
2. Radioisotope Storage
3. Disposal, below counter

PERSONNEL TRAINING PROGRAM
FOR
KEITH RICHARD WEEKS, M.D.

Only Dr. Weeks and the technologist will be allowed to manipulate the radioactive materials. The technologist will be informed of the following information prior to assuming duties and will receive annual refresher training as well as immediate instruction whenever there is a significant change in duties, regulations, or terms of the license.

a. Areas where radioactive material is used or stored

b. Potential hazards associated with radioactive material

c. Radiological safety procedures appropriate to their respective duties

d. Pertinent regulations

e. Rules and regulations of the licensee

f. Pertinent terms of the license

g. Their obligation to report unsafe conditions

h. Appropriate response to emergencies or unsafe conditions

i. Their right to be informed of their radiation exposure and bioassay results

j. Locations where the licensee has posted or made available notices, copies of pertinent regulations and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required.

The technologist will receive a refresher review of the above information on not less than an annual basis.

Other workers, i.e., nurses, clerical, etc., will be instructed in items a, b, g, and h above. They will not be allowed to handle radioactive materials.

Housekeeping personnel will be instructed in a, above and will not be allowed to clean the areas without the supervision of the technologist.

TECHNOLOGIST QUALIFICATIONS FOR EMPLOYMENT
BY KEITH RICHARD WEEKS, M.D., P.A.

1. Technologists will be registered/certified in nuclear medicine by the ARRT, ASCP or NMTCB or

2. Will have equivalent training and experience to that required by the ARRT, ASCP or NMTCB or

3. Have not less than the following formal documented classroom training in nuclear cardiology with completion by written examination

Radiation Physics and Instrumentation	78 hrs
Radiation Protection	26 hrs
Mathematics of the Use and Measurements of Radioactivity	17 hrs
Radiation Biology	17 hrs

and clinical certification in nursing, medical laboratory, medical x-ray or other related medical technologies.

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PROCEDURES FOR ORDERING AND RECEIVING

RADIOACTIVE MATERIAL

FOR KEITH RICHARD WEEKS, M.D.

1. The Physician or Nuclear Medicine Technologist will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Cardiology Department.

3. During off-duty hours, no radioactive material will be received.

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL FROM THE RADIOPHARMACY FOR KEITH RICHARD WEEKS, M.D.

1. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

2. Put on gloves.

3. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip, and label on bottle), and check integrity of final source container (inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material). Check also that shipment does not exceed possession limits.

4. Monitor the packing material and packages for contamination before discarding.

   a. If contaminated, treat as radioactive waste.

   b. If not contaminated, obliterate radiation labels before discarding in regular trash.

In all the above procedures, take wipe tests with a paper towel, check wipes with a thin-end-window G-M survey meter, and take precaution against the spread of contamination as necessary.

*NOTE: If radionuclides are received from other than the radiopharmacy, then the procedures for safely opening the packages will be as follows:

1. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

2. Measure exposure rate at 3 feet from package surface and record. If >10 mR/hr, stop procedure and notify Radiation Safety officer.

3. Measure surface exposure rate and record. If >200 mR/hr, stop procedure and notify Radiation Safety Officer.

4. Put on gloves.

PROCEDURES FOR SAFELY OPENING PACKAGES
CONTAINING RADIOACTIVE MATERIAL
FROM THE RADIOPHARMACY
FOR KEITH RICHARD WEEKS, M.D.
(CONTINUED)

5. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents (compare requisition, packing slip, and label on bottle), and check integrity of final source container (inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material). Check also that shipment does not exceed possession limits.

6. Wipe external surface of final source container with moistened cotton swab or filter paper held with forceps; assay and record.

7. Monitor the packing material and packages for contamination before discarding.

   a. If contaminated, treat as radioactive waste.

   b. If not contaminated, obliterate radiation labels before discarding in regular trash.

In all the above procedures, take wipe tests with a paper towel, check wipes with the thin-end-window G-M survey meter, and take precaution against the spread of contamination as necessary.

SAMPLE
RADIOACTIVE SHIPMENT RECEIPT REPORT
FROM RADIOPHARMACY
FOR KEITH RICHARD WEEKS, M.D.

1. P.O. # _____ Survey Date _____ Time _____

Surveyor _____

2. CONDITION OF PACKAGE:

_____ O.K. _____ Punctured _____ Status _____ Wet

_____ Crushed _____ Other

3. DO PACKING SLIP AND VIAL CONTENTS AGREE?

a. Radionuclide ____ yes ____ no, difference _____

b. Amount ____ yes ____ no, difference _____

c. Chem Form ____ yes ____ no, difference _____

4. IF NRC/CRHS/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSONS NOTIFIED.

_____ _____
Signature Date

* NOTE: if radionuclides are to be received from other than the radiopharmacy, then the package will also be surveyed for the following conditions:

1. RADIATION UNITS OF LABEL: _____ Units (mRem/hr)

2. MEASURED RADIATION LEVELS:

a. Package surface _____ mRem/hr

b. 3 feet or 1 meter from surface _____mRem/hr

3. WIPE RESULTS FROM:

a. Outer _____ CPM = _____ DPM
eff = ( )

b. Final source container _____ CPM = _____ DPM
eff = ( )

4. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____ mRem/hr, CPM

5. DISPOSITION OF PACKAGE AFTER INSPECTION _____

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GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL FOR KEITH RICHARD WEEKS, M.D.

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances such as pediatric cases when their use would compromise the patient's well-being.

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

6. Unless unit dose from radiopharmacy, assay each patient dose in the dose calibrator which will be obtained prior to purchase of any radiopharmaceuticals from suppliers other than the radiopharmacy, prior to administration. Do not use any doses that differ from the prescribed dose by more than 10%.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in the specially designated receptacle.

10. Never pipette by mouth.

11. Survey all preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always transport radioactive material in shielding containers.

PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AS LOW AS REASONABLY ACHIEVABLE (ALARA) FOR KEITH RICHARD WEEKS, M.D.

1. Management Commitment

   a. I, the management of this facility, am committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, I hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution.

   b. I will perform a formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

   c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgement, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Officer (RSO)

   a. Review of Proposed Users and Uses

      (1) The RSO will thoroughly review the qualifications of each employee with respect to the types and quantities of materials and uses for which he/she will use to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSO will review efforts to maintain exposure ALARA. The employee will have systematized procedures to ensure ALARA and shall incorporate them through the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

(3) The RSO will ensure that the user employee uses the procedure and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSO authority is essential to the enforcement of an ALARA program.)

(1) The RSO may delegate authority to the employee or consultant for enforcement of the ALARA concept.

(2) The RSO will support the designate in those instances where it is necessary for the designate to assert his/her authority.

c. Review of ALARA Program

(1) The RSO will encourage all employees to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSO will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table C-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).

(3) The RSO will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the designate, authorized users, and workers as well as those of management.

3. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provision of Section 6 of this program.

(3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

(1) The authorized user will determine that ALARA will be achieved before initiating new procedures.

(2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsiblity of Authorized User to Persons Under His/Her Supervision

(1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.

(2) The authorized user will ensure that persons under his/her supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Persons Who Receive Occupational Radiation Exposure

a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.

b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels In Order To Monitor Individual Occupational External Radiation Exposures

This facility hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table 0-1 below. These levels apply to the exposure of individual workers.

TABLE 0-1

Investigational Levels
(mrems per calendar quarter)

		Level I	Level II
1.	Whole body, [illegible] and trunk; act[illegible]d-forming org[illegible]ens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625

The Radiation Safety Officer will review and record current occupational external radiation exposure, results of personnel monitoring not less than once in any calendar quarter. The following action will be taken at the Investigational Levels as stated in Table 0-1 above.

a. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's expsoure is less than TABLE 0-1 values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, a copy of the individual exposure record maintained will be presented. Committee minutes will be sent to the management. The reports containing details of the investigation, will be made available to inspectors for review at the time of the next inspection.

d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in TABLE 0-1.

In cases where a worker's or a group of workers exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph 6. c. above will be followed.

7. Signature of Certifying Official

I, the applicant for licensure, certify that this facility has implemented the ALARA Program set forth above.

EMERGENCY PROCEDURES
FOR KEITH RICHARD WEEKS, M.D.

Minor Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. EAN UP: Use disposable gloves and remote handling tongs. refully fold the absorbent paper and pad. Insert into a plastic ag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. SURVEY: With the low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: Keith Richard Weeks, M.D.
OFFICE PHONE*:

*NOTE: This is a 24 hour number and page service. This is the number to reach Dr. Weeks day or night.

AREA SURVEY PROCEDURES
FOR
KEITH RICHARD WEEKS, M.D.

1. All preparation, and injection areas will be surveyed daily with a low-range thin-window G-M survey meter and decontaminated if necessary.

2. Areas where only small quantities of radioactive material are used (less than 100 uCi) will be surveyed monthly.

3. All other areas will be surveyed weekly.

4. The weekly and monthly survey will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mRem/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 dpm per 100 cm^2 for the contaminant involved.

5. A permanent record will be kept of all survey results, including negative results. The record will include:

   a. Location, date, and type of equipment used.

   b. Name of person conducting the survey.

   c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc. (see facility drawing).

   d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

   e. Detected contamination levels, keyed to locations on drawing.

   f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

6. Area will be cleaned if the contamination level exceeds 100 dpm/100 cm^2.

NOTE: For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey reports will be recorded.

WASTE DISPOSAL FOR
KEITH RICHARD WEEKS, M.D.

1. Liquid waste will be disposed by containment and by decay as in solid waste (below).

2. Solid waste will be disposed by being held for decay until radiation levels, as measured with the low-level survey meter and with all shielding removed, have reached levels not statistically significant as compared with background levels*. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

*With a GM survey meter having a wall thickness not exceeding 35 mg/cm^2. This is normally taken as twice the background count rate.

PROCEDURES REQUESTED
KEITH RICHARD WEEKS, M.D.

Because I am not interested in applying for all of Group I or Group II, I have applied only for cardiology and only for 99mTc and 201Tl. I have also applied for 57 Cobalt as sealed sources for quality control and equipment calibration.

PERSONNEL MONITORING PROCEDURES FOR KEITH RICHARD WEEKS, M.D.

All persons frequenting the areas where radiopharmaceuticals are stored, manipulated or used, will be required to wear a personnel dosimeter, a film-badge. All persons manipulating and/or injecting radiopharmaceuticals, radioisotope handling, will also wear ring dosimeters, TLD dosimeters.

1. The R.S.O. will be responsible for ordering and distributing dosimeters and maintaining all records.

2. Body dosimeters, film badges, will be worn at the mid-trunk.

3. Extremity dosimeters, TLD ring dosimeters, will be worn on the index finger of the dominant hand.

4. Body and extremity dosimeters will be changed on a monthly basis.

5. Personnel dosimetry records, reports, will be posted in the nuclear cardiology department for one month then maintained in an accessible log book.

LMS WORKSHEET

DOCKET NO: 03028780 LICENSE NO: _____

MAIL CONTROL NO: 460699 RECEIPT DATE: 850708 ACTION TYPE: 2

FED GOVT: N INST CODE: 23189 LICENSING REGION: 4

STATUS: 3 PRIORITY FLAG: N

NAME: MONTANA HEART INSTITUTE, P.C.

DEPT/BUREAU: _____

BUILDING: _____

STREET: 1145 N. 29TH ST., STE. 204

CITY: BILLINGS STATE: MT ZIP: 59101

CONTACT PERSON: _____ CONTACT PHONE: ___-___-____

PROGRAM CODES: _____ _____ _____ _____ _____

LICENSE ISSUE DATE: _____ (YYMMDD) EXPIRATION DATE: _____ (YYYYMMDD)

RSO: _____

STATES WHERE USE AUTHORIZED: _

0 - ALL LISTED STATES
1 - SAME AS STATE IN ADDRESS
2 - ALL STATES
3 - NON-AGREEMENT STATES

INDIVIDUAL STATES: __ __ __ __ __ __ __ __ __ __

RIS CODES: ___ ___ ___

APPROVED FOR:

REDISTRIBUTION:	_	INCINERATION:	_
STORAGE ONLY:	_	BURIAL:	_
TEMP JOB SITES:	_		

EXEMPTIONS

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

MC40

POSSESSION LIMIT INFORMATION

MATERIAL TYPE:	----------	FORM CODE:	---
SS/MFG MODEL NO:	------------------------------		

ISOTOPE QUANTITY:	---------------	UNIT:	
ITEM QUANTITY:	---------------	UNIT:	---
TOTAL QUANTITY:	---------------	UNIT:	---
OTHER:	-	SOURCES:	---
MATERIAL TYPE:	----------	FORM CODE:	---
SS/MFG MODEL NO:	------------------------------		

ISOTOPE QUANTITY:	---------------	UNIT:	---
ITEM QUANTITY:	---------------	UNIT:	---
TOTAL QUANTITY:	---------------	UNIT:	---
OTHER:	-	SOURCES:	---
MATERIAL TYPE:	----------	FORM CODE:	---
SS/MFG MODEL NO:	------------------------------		

ISOTOPE QUANTITY:	---------------	UNIT:	
ITEM QUANTITY:	---------------	UNIT:	---
TOTAL QUANTITY:	---------------	UNIT:	---
OTHER:	-	SOURCES:	---
MATERIAL TYPE:	----------	FORM CODE:	---
SS/MFG MODEL NO:	------------------------------		

ISOTOPE QUANTITY:	---------------	UNIT:	---
ITEM QUANTITY:	---------------	UNIT:	---
TOTAL QUANTITY:	---------------	UNIT:	---
OTHER:	-	SOURCES:	---
MATERIAL TYPE:	----------	FORM CODE:	---
SS/MFG MODEL NO:	------------------------------		

ISOTOPE QUANTITY:	---------------	UNIT:	---
ITEM QUANTITY:	---------------	UNIT:	---
TOTAL QUANTITY:	---------------	UNIT:	---
OTHER:	-	SOURCES:	---
MATERIAL TYPE:	----------	FORM CODE:	---
SS/MFG MODEL NO:	------------------------------		

ISOTOPE QUANTITY:	---------------	UNIT:	---
ITEM QUANTITY:	---------------	UNIT:	---
TOTAL QUANTITY:	---------------	UNIT:	---
OTHER:	-	SOURCES:	---

INDIVIDUAL USERS

NAME	AUTHORIZATION
______________________________	____
______________________________	____
______________________________	____
______________________________	____

ADDRESS WHERE MATERIAL IS USED OR POSSESSED

BUILDING:	______________________________	______________________________
ROOM:	__________	__________
STREET:	______________________________	______________________________
CITY:	____________________	____________________
STATE:	__ ZIP_________	__ ZIP_________
BUILDING:	______________________________	______________________________
ROOM:	__________	__________
STREET:	______________________________	______________________________
CITY:	____________________	____________________
STATE:	__ ZIP_________	__ ZIP_________
BUILDING:	______________________________	______________________________
ROOM:	__________	__________
STREET:	______________________________	______________________________
CITY:	____________________	____________________
STATE:	__ ZIP_________	__ ZIP_________
BUILDING:	______________________________	______________________________
ROOM:	__________	__________
STREET:	______________________________	______________________________
CITY:	____________________	____________________
STATE:	__ ZIP_________	__ ZIP_________
BUILDING:	______________________________	______________________________
ROOM:	__________	__________
STREET:	______________________________	______________________________
CITY:	____________________	____________________
STATE:	__ ZIP_________	__ ZIP_________
BUILDING:	______________________________	______________________________
ROOM:	__________	__________
STREET:	______________________________	______________________________
CITY:	____________________	____________________
STATE:	__ ZIP_________	__ ZIP_________