

DL-111698-04

Naeem A. Qazi, M.D., F.A.C.C., P.C.

89 WESTWOOD MEDICAL PARK
BLUEFIELD, VIRGINIA 24605
TELEPHONE (540) 326-1136

November 16, 1998

U.S. Nuclear Regulatory Commission, Region II
Atlanta Federal Center
Division of Nuclear Materials Safety
61 Forsyth Street South West, Suite 23T85
Atlanta, Georgia 30303-3415

REFERENCE: NRC LICENSE APPLICATION

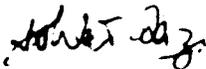
Dear Sir or Madam:

Attached you will find a completed application for a specific nuclear medicine license for Four Seasons Nuclear Medicine, Inc. A check in the amount of \$1800, the fee required for a Category 7C license application, is also enclosed.

We would like to open on January 1, 1999. Any help in expediting the licensing process would be greatly appreciated.

Please contact Roy F. Heltzel, Jr., our consulting physicist, at 757-518-9523, should further information be required.

Very truly yours,



Naeem A. Qazi, MD

Enclosures

258168

(10-84)
10 CFR 30 32 33
34, 35, 36, 38 and 40

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST 8 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-8 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001 AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

APPLICATION FOR MATERIAL LICENSE

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS.

IF YOU ARE LOCATED IN:

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

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

US NRC RB-ATLANTA FEDERAL CENTER
SUITE 23785, ATTN: DNMS
61 FORSYTH STREET
ATLANTA, GA 30303

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

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION REGION II
801 WARRENVILLE RD
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON TX 76011-6084

1. THIS IS AN APPLICATION FOR (Check appropriate box)

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

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

Four Seasons Nuclear Medicine, Inc.
#9-Westwood Medical Park
Bluefield, VA 24605

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

1279 Stadium Drive
Bluefield, WV 24701

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Roy F. Heltzel, Jr.
Consulting Physicist

TELEPHONE NUMBER
757-518-9523

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL a. Isotopes and mass number b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
9. FACILITIES AND EQUIPMENT	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT	12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY 7C AMOUNT ENCLOSED \$1,800.00

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

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT NAMED IN ITEM 2 CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10 CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 38, 39 AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

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

CERTIFYING OFFICER - TYPEPRINTED NAME AND TITLE
Nacem A. Qazi, MD President

SIGNATURE

DATE

11/17/98

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

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Item 5 RADIOACTIVE MATERIAL

Radioactive material will be used as shown in this table:

<u>Byproduct Material</u>	<u>Amount</u>	<u>Purpose</u>
5.a Material in § 31.11	as needed	6.a in vitro testing
5.b Material in § 35.100	as needed	6.b medical use
5.c Material in § 35.200	as needed	6.c medical use
5.d Material in § 35.300	as needed	6.d medical use

Item 6 PURPOSE

31.11	in vitro clinical or laboratory testing
35.100	uptake, dilution, and excretion studies
35.200	imaging and localization studies
35.300	therapeutic administration

**Item 7 INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAMS--
THEIR TRAINING AND EXPERIENCE**

7.1 Authorized Users for Medical Use

Nadeem Gul Qazi, M.D. for material identified in 10 CFR 35.100, 35.200, 35.300, 31.11 and Iodine-131 sodium iodide for treatment of hyperthyroidism and cardiac dysfunction.

NRC Form 313 M, Supplement A "Training and Experience" is attached.

**NRC FORM 313M
SUPPLEMENT A**

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

**TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER**

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER Nadeem Gul Qazi, M.D.	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED Tennessee
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3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Nuclear Medicine		Dr. Qazi took ABNM exam Sept. 1998

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY C	CLOCK HOURS OF SUPERVISED ON-THE-JOB-EXPERIENCE D
a. RADIATION PHYSICS AND INSTRUMENTATION	Univ. Tenn. Med. Ctr., Knoxville 7/96 - 6/98	60	15
b. RADIATION PROTECTION	Univ. Tenn. Med. Ctr., Knoxville 7/96 - 6/98	10	10
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Univ. Tenn. Med. Ctr., Knoxville 7/96 - 6/98	14	5
d. RADIATION BIOLOGY	Univ. Tenn. Med. Ctr., Knoxville 7/96 - 6/98	12	5
e. RADIOPHARMACEUTICAL CHEMISTRY	Univ. Tenn. Med. Ctr., Knoxville 7/96 - 6/98	4	28

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

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
All common, clinically used isotopes in millicurie quantities for a two year period in a busy nuclear medicine laboratory. See Supplement B for details.				

NRC Form 313 M
SUPPLEMENT B

U.S. NUCLEAR REGULATORY COMMISSION

SUPPLEMENT

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 form each.

I. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1. Supervised examination of patients to determine the suitability for radiolotope diagnosis and/or treatment and recommendation for prescribed dosages.
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.

FULL NAME

Nadeem Gul Qazi, M.D.

STREET ADDRESS

706 Tanager Drive

CITY

Bluefield

STATE

VA

ZIP CODE

24605

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION	COMMENTS <i>(Additional information or comments may be submitted in duplicate on separate sheets.)</i>
	Thyroid imaging	354	This document supercedes the previously submitted report dated March 5, 1998, which included information for the period July 1, 1996 through February 28, 1998. This document includes information for Dr. Qazi's entire residency period--July 1, 1996 through June 30, 1998.
	Thyroid uptake	341	
	Lung perfusion scan	1637	
	Lung ventilation study (Xenon)	1511	
	Renal scanning/Renograms	552	
	Brain imaging	4	
	Liver / spleen imaging	154	
	Skeletal imaging	2282	
	Gastric emptying/Reflux	192	
	Shunt patency (incl. LeVeon)	5	
	Cystography	69	
	Myocardial perfusion imaging	3313	
	Exercise ventriculography	7	
	Ventriculography	525	

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NRC Form 313 M
SUPPLEMENT B

PROPOSED PHYSICIAN USER Nadeem Gul Qazi, M.D.

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	COMMENTS <i>(Additional information or comments may be submitted in duplicate on separate sheets.)</i>
	Gallium scan: whole body tumor/soft tissue	102	<p>This document supercedes the previously submitted report dated March 5, 1998, which included information for the period July 1, 1996 through February 28, 1998.</p> <p>This document includes information for Dr. Qazi's entire residency period--July 1, 1996 through June 30, 1998.</p>
Tc-99m	Gastrointestinal bleeding	116	
In-111	Cisternography	11	
In-111	WBC/Platelet imaging	142	
Tl-201	Parathyroid imaging	85	
Tc-99m	RBC hemangioma	24	
Co-57	Schillings tests	217	
Cr-51	I-125 RBC, Plasma in Vivo test (In-vivo, non-imaging)	71	
Tc-99m	Vascular flow	0	
Tc-99m	Testicular scan flow	1	
Tc-99m	Lymphatic imaging	38	
	GFR (quantitative renal)	16	
	DISIDA (hepatobiliary imaging)	504	
	DEXA (bone mineral densitometry)	1949	
	Sr-89 Therapy	4	
	I-131 MIBG (adrenal imaging)	6	
In-111	Octreoscan (peptide/octreotide imaging)	16	
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	2	
P-32 (Colloidal)	INTRACAVITARY TREATMENT	0	
I-131	TREATMENT OF THYROID CARCINOMA	46	
I-131	TREATMENT OF HYPERTHYROIDS	226	

NRC Form 313 M
SUPPLEMENT B

PROPOSED PHYSICIAN USER Nadeem Gul Qazi, M.D.

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	COMMENTS <i>(Additional information or comments may be submitted in duplicate on separate sheets.)</i>
Au-198	INTRACAVITARY TREATMENT	0	This document supercedes the previously submitted report dated March 5, 1998, which included information for the period July 1, 1996 through February 28, 1998. This document includes information for Dr. Qazi's entire residency period--July 1, 1996 through June 30, 1998
Co-60 or Cs-137	INTERSTITIAL TREATMENT	0	
	INTRACAVITARY TREATMENT	0	
I-125 or Ir-192	INTERSTITIAL TREATMENT	0	
Co-60 or Cs-137	TELE THERAPY TREATMENT	0	
Sr-90	TREATMENT OF EYE DISEASE	0	
	RADIOPHARMACEUTICAL PREPARATION		
MO-99/Tc-99m	GENERATOR	6	
Sn-113/In-113m	GENERATOR	0	
Tc-99m	REAGENT KITS	11	
OTHER			
I-131	Whole body metastatic survey	70	
Tc-99m	Venography	0	
N-13, C-11 & F-18	VARIOUS PET STUDIES	25	

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

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
The University of Tennessee Medical Center at Knoxville	7/1/96 - 6/30/98	-4000

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

A. NAME OF SUPERVISOR
Gary T. Smith, M.D. *Gary T. Smith MD*

B. NAME OF INSTITUTION
University of Tennessee Medical Center/ Radiology

C. MAILING ADDRESS
1924 Alcoa Highway

D. CITY
Knoxville, Tennessee 37920

E. MATERIALS LICENSE NUMBER(S)
R-47011 (State of Tennessee)

6. PRECEPTOR'S SIGNATURE
Karl F. Hubner, M.D.

7. PRECEPTOR'S NAME (Please type or print)
Karl F. Hubner, M.D.
Director, Nuclear Medicine Residency
and Fellowship Programs

8. DATE
10-08-98

7.2 Authorized Users for Nonmedical Use - Not applicable

7.3 Radiation Safety Officer

Nadeem Gul Qazi, M.D.

Item 8 **TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING
RESTRICTED AREAS**

8.1 Training Program

We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2.

TABLE 8.1

<u>GROUPS OF WORKERS</u>	<u>TYPE OF TRAINING</u>
Nuclear Medicine Technologist	Lecture and/or Demonstration
Ancillary Personnel	Lecture and/or Demonstration

8.2 Other Training Program - Not applicable

Item 9 **FACILITIES AND EQUIPMENT**

9.1 Annotated Drawing

The layout of the facilities is as shown in the attached floor plan.

9.2 Survey Instrument Calibration

We will:

Establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2; or

Use the services of a consultant licensed by the NRC to perform survey instrument calibrations.

9.3 Dose Calibrator Calibration

We will:

Establish and implement the model procedure for calibrating dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2; or

Use the services of a consultant licensed by the NRC to perform dose calibrator calibrations.

9.4 Personnel Monitor Program

We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2. We will use a badge supplier approved by NAVLAP.

9.5 Imaging Equipment

We will not be transporting imaging equipment.

9.6 Other Equipment and Facilities

The gamma camera will be a ADAC Genesis single-head or equivalent.

The portable survey meter will be sufficiently sensitive to cover the range from background to greater than 1,000 mR/hr.

The Hot Laboratory will be equipped with a sink, a work bench, a shadow shielded "L" shield and lead which will be available for extra shielding.

A dose calibrator will be provided which meets the regulatory requirements of the nuclear medicine facility.

A well counter will be provided which meets the regulatory requirements of the nuclear medicine facility.

A thyroid uptake probe will be provided which meets the regulatory requirements of the nuclear medicine facility.

Item 10 RADIATION SAFETY PROGRAM

10.1 Radiation Safety Committee/Radiation Safety Officer

We will not have a Radiation Safety Committee.
Nadeem Gul Qazi, M.D. will be the Radiation Safety Officer.

10.2 ALARA Program

We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2.

10.3 Leak Test

We will:

Establish and implement the model procedure for leak testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, Revision 2; or

Use the services of a consultant licensed by the NRC to perform leak testing.

10.4 Safe Use of Radiopharmaceuticals

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

For restricted area radiation dose rate, trigger level will be 5 mR/hr or less. For unrestricted area radiation dose rate, trigger level will be 0.5 mR/hr or less. For removable Technetium-99m gamma contamination, trigger level will be 2,000 dpm/100 cm². For removable Iodine-131 beta contamination, trigger level will be 200 dpm/100 cm².

10.5 Spill Procedures

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

10.6 Ordering and Receiving

We will establish and implement the model guidance for ordering and receiving radioactive materials that was published in Appendix K to Regulatory Guide 10.8, Revision 2.

10.7 Opening Packages

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

10.8 Unit Dosage Records

We will establish and implement the model procedure for a unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2.

10.9 Multidose Vial Records

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

10.10 Molybdenum Concentration Records

We will use a nuclear pharmacy and will not use a generator.

Should we begin using a generator, we will establish and implement the model procedure for measuring and recording molybdenum that was published in Appendix M.3 to Regulatory Guide 10.8, Revision 2.

10.11 Implant Source Use Records - Not applicable

10.12 Area Survey Procedures

We will establish and implement the model procedure for area surveys as was published in Appendix N to Regulatory Guide 10.8, Revision 2.

10.13 Air Concentration Control

We will establish and implement the model procedure for calculating worker dose from aerosols that was published in Appendix O.1 to Regulatory Guide 10.8, Revision 2.

We will not directly vent spent aerosols and gases to the atmosphere; therefore, no effluent estimate is necessary.

We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions.

We will calculate spilled gas clearance times according to the procedure published in Appendix O.4 to Regulatory Guide 10.8, Revision 2.

10.14 Radiopharmaceutical Therapy

We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix P to Regulatory Guide 10.8, Revision 2.

We will perform thyroid monitoring on the person administering to patients an Iodine-131 therapy dose equal to or greater than 30 mCi. This monitoring will occur one to three days after administering the dose to the patient. We will possess an Iodine uptake probe having the sensitivity to detect the 0.04 microcurie action point noted in Regulatory Guide 8.26 "Applications of Bioassay for I-125 and I-131".

Should the above action point be exceeded, we will immediately contact the Radiation Safety Officer and will perform a repeat bioassay measurement within two weeks to confirm the presence of Iodine-131 and to obtain its effective half life for use in establishing dose commitment.

Only outpatient iodine therapy will be performed. We do not have the facilities nor the intent to perform inpatient iodine therapy.

QUALITY MANAGEMENT PROGRAM

It is the intent of this quality management (QM) program to be in accordance with §35.32 "Quality Management Program" of 10 CFR Part 35 and the Regulatory Guide 8.33 dated October 1991. If clarification is needed, please refer to these two referenced documents. It is also the intent of this QM program that it will lessen the probability of a misadministration of a diagnostic or therapy radioactive isotope that is covered under this QM program.

This QM program applies to the administering of any brachytherapy dose, radiopharmaceutical dose other than sodium iodide I-125 or I-131 and any diagnostic dosage greater than 30 microcuries of either sodium iodide, Iodine-125 or Iodine-131, with exceptions as noted.

Item 1) Before the administration of a dose to which this QM program applies, an authorized physician user will date and sign a written directive.* This written directive is an order for a specific patient, dated and signed by an authorized user prior to the administration of the radiopharmaceutical or radiation containing at least the following information:

1. For any dosage greater than 30 μ Ci of sodium iodide I-125 or I-131: the dosage
2. For therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical dosage and route of administration
3. For brachytherapy:
 - a. Prior to implantation: the radioisotope, the number of sources, and source strengths; and
 - b. After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or the total dose)

This written directive will be retained for a period of at least three years after the date of administration.

Item 2) Before the administration of a dose to which this QM program applies, identity of the individual named shall be verified by more than one method. The procedure used to identify the patient should be ask the patient's name, then confirm the name and at least one of the following by comparison with corresponding information in the patient's record; birth date, address, social security number, signature, the name on patient's ID bracelet or hospital ID card, or the name on the patient's medical insurance card or picture of the patient in the medical record if one is there.

* See 10 CFR 35.32(a)(1) which is copied in Item 7 at the end of the document.

- Item 3) The technologist or person administering the radiopharmaceutical or radiation shall verify that the specific details of administration are in accordance with the written directive. The radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive; that is, the dosage should be measured in a dose calibrator and the results compared with the prescribed dosage in the written directive.

This confirmation through measurement in a dose calibrator does not apply to any therapeutic radionuclide other than I-131. The confirmation of dosage for these therapy radionuclides will be done by using the manufacturer's stated activity of the unit dose. This manufacturer's stated activity will be assumed to be the true activity of the patient dosage and no dose calibrator measurement need be made.

For brachytherapy, prior to administering the dose, the radioisotope, the number of sources, and source strengths shall be confirmed to verify agreement with the written directive and plan of treatment.

If a deviation from a written directive is identified, evaluation of this deviation will be done to determine if it is a Recordable Event or a Misadministration as defined by 10 CFR 35.2. Appropriate notification, reports and records will be generated as required by 10 CFR 35.32(c) and 10 CFR 35.33.

After evaluation of the deviation, action will be taken to prevent recurrence, if possible. This action may include but is not limited to: the addition of new or revision of current policies, the addition of new or revision of current procedures, the addition of training or the increase of supervisory review of work..

- Item 4) Any worker or technologist who does not understand how to carry out the written directive shall ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.
- Item 5) The technologist, authorized user or qualified individual under the supervision of the authorized user shall make a written record of the administered dosage, the date administered and sign or initial the record.
- Item 6) The licensee shall perform a periodic review of the radiopharmaceutical QM program. Periodic means at least once a year. However, for scheduling and compliance purposes, one year is defined as 12 months + 30 days. For example, should January 1 be the due date of the review, then a review of the QM program by January 31 would be acceptable. The target date for the review the next year would remain January 1. It would not advance to 12 months from the date of the review should the review happen to occur in the 30 day grace period.

These periodic reviews will evaluate the effectiveness of the QM program and if recordable events or misadministrations are seen then the actions taken may include but are not limited to: the addition of new or revision of current policies, the addition of new or revision of current procedures, the addition of training or the increase of supervisory review of work. The results of periodic reviews will be compared from year to year to determine if the program is meeting the objectives as stated in 10 CFR 35.32. If the QM program is not meeting these objectives, the actions described above may be repeated or modified and implemented until the stated objectives are being met.

All modifications which serve to increase the QM programs efficiency will be submitted to the NRC within 30 days after the modification has been made.

Item 7) ORAL DIRECTIVES AND REVISIONS TO WRITTEN DIRECTIVES

A footnote to 10 CFR 35.32(a)(1) reads as follows:

"If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is dated and is signed by the authorized user within 48 hours of the oral revision."

"Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose."

"If, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive."

10.15 Implant Therapy

We will not perform any implant therapy.

10.16 Other Safety Procedures - Not applicable

Item 11 WASTE MANAGEMENT

11.1 Waste Disposal

We will establish and implement the general guidance and model procedures for waste disposal that was published in Appendix R to Regulatory Guide 10.8, Revision 2.

Should we use a Mo-99 generator, we may return spent generators as a radioactive material to the original supplier after performing the surveys as required by 49 CFR and using the proper shipping papers furnished by the supplier.

11.2 Other Waste Disposal

See item 11.1.