Deaconess
Medical
Center

April 24, 1992

United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Deaconess Medical Center, Inc.
Ninth Avenue North
P.O. Box 37000
Billings, MT 59107

RE: Quality Management Program for
License Number 25-01051-01

Quality Management Program

1. Objective
A Quality Management Program that meets the five objectives of 10 CFR 35.32.

The five objectives are:

(1) A written directive is prepared before administration;
(2) The patient's identity is verified, by more than one method, as the individual named in the written directive, before each administration;
(3) Final plans of treatment and related calculations for brachytherapy are in accordance with the respective written directives;
(4) Each administration is in accordance with the written directives; and
(5) Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

2. Responsibility, Authority, and Audit

The responsibility and authority to establish and implement Quality Management Program shall be given to the radiation safety officer.

3. Elements for Medical Use - Radiopharmaceutical Therapies and NaI I-125 or I-131>30 uCi

A. Prior to administration, a written directive will be prepared for:
   1. Any therapeutic administration of a radiopharmaceutical and
   2. Any administration of NaI I-125 or I-131 greater than 30 microCuries.

With regard to diagnostic and therapeutic radiopharmaceutical "A written directive" means an order in writing for a specific patient, dated, and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, containing the following information:

Patient name
Patient identification number
Radiopharmaceutical
Dosage
Route of administration

B. Prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive by the person administering the radiopharmaceutical.

1. The patient shall be called by name.
2. The patient shall be asked to spell their name.
3. The patient shall be asked to state their birth date.
4. The patient shall be asked for some identification such as a driver's license.
5. The patient's wrist band shall be checked.

If the information obtained from both of any two of these methods do not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive verification that this procedure is intended for this patient is obtained.

C. Each administration is in accordance with the written directive.

The technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear to the technologist, they shall contact an authorized user for clarification. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the technologist. If the technologist preparing the dose is different from the technologist administering the dose, both technologist shall read and understand the written directive.

The technologist shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the written directive. The actual dose calibrator assay shall be verified with the dosage listed on the written directive.

A procedure manual shall be available and shall contain protocols for all radiopharmaceutical procedures preformed which require written directives. A procedure which requires a written directive shall not be initiated until a written protocol approved by the radiation safety committee is available.

The technologist shall be familiar with the contents of the manual. They shall be instructed to refer to the manual before proceeding with non-routine procedures or in any case where the protocol is not completely familiar to them.

The protocols shall contain the following elements:

- -pharmaceutical
- -radionuclide
- -routine dosage
- -route of administration

Each change in protocol shall be approved by authorized user and/or the radiation safety committee, before the change is implemented and before the change is incorporated into the procedure manual. Each technologist shall be instructed in the change before it is implemented or incorporated into the procedure manual.

D. Any unintended deviation from the written directive is identified and evaluated and appropriate action taken.

Upon identification of an unintended deviation, an investigation of the incident shall be made. The cause of the incident shall be determined and if appropriate, corrective procedures will be implemented. Documenting and reporting of the unintended deviation shall be in according with the reporting rules of Part 35.

4. Elements for Brachytherapy

A. Prior to administration, a written directive will be prepared for:

Any brachytherapy radiation dose.

With regard to brachytherapy: A written directive means an order in writing for a specific patient dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, containing the following information.

1. For high dose rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or
2. For all other brachytherapy:
   a. Prior to administration, the radioisotope, 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, equivalently, the total dose).

B. Prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive.

C. Each administration is in accordance with the written directive.

D. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

E. Final plans of treatment and related calculations for brachytherapy are in accordance with the written directive.

Annual Review

The annual review shall be conducted by a member of management and the radiation safety officer. The review shall be conducted at intervals not to exceed 12 months. The review shall determine the effectiveness of the QM objectives of 35.32(a).

Audit: Records of each review, including the evaluations and findings in an auditable form for three years.

Frequency: An audit of the quality management program shall be conducted at twelve (12) month intervals.

Responsibility: An audit shall be conducted by the radiology administrator and radiation safety officer.

Scope: The audit shall evaluate the following items.

1. The compliance rate of having written directives prior to administration of a radiopharmaceutical or radiation in those cases where written directives are required.

2. The content of the written directive is as required.

3. The instruction of the supervised individual(s) in the licensees's written quality management program and requirement of following the authorized user's instructions.

4. The methods of verifying the patient's identity by more than one method is performed as stated in the QM program.

5. The compliance rate of verifying the patient's identity by more than one method.

6. Radiopharmaceutical or radiation administrations are in accordance with the written directives.

7. The compliance of the staff identifying, evaluating, and taking appropriate corrective actions for unintended deviations from the written directive.

8. The compliance with the requirement to respond to each recordable event.

9. The compliance with the requirement to notify and report a misadministration.

10. The compliance with the requirements to keep the appropriate records, including:
    - -the annual reviews
    - -the written directives
    - -the radiopharmaceutical dosages
    - -the recordable events
    - -the misadministration

Brachytherapy Only

11. The final treatment plans and related calculations are in accordance with the written directive.

Method:

Items 1, 2, 3, 4, 5, and 6. Spot checks of the administration records for the previous twelve months shall be made at numerous intervals. A minimum of twenty (or if volume is less than this, all) administrations records where written directives were required shall be reviewed for compliance.

Items 7,8, and 9. Any unintended deviations discovered in the above review shall be tracked to determine if they were identified by staff. Records made by the staff shall be reviewed for thoroughness.

Item 10. Records made by the staff shall be reviewed for appropriateness. Current practices shall be reviewed with the staff to determine if the actions taken to address the unintended deviations are being followed.

Item 11. (brachytherapy only) The final treatment plans shall be reviewed by the Radiation Oncology Quality Management Physician and Radiation Safety Officer. They must be in accordance with the respective written directive.

We have enclosed our Quality Management Program developed inaccordance with 10CFR35.32. We will implement this program on or before May 1, 1992.

Sincerely,

Jerry D. Wolf, MD
Radiation Safety Officer

Lynne Mattison
Vice President of Professional Services

Deaconess Medical Center
Department of Nuclear Medicine

Brachytherapy order form to be completed by the Radiation Ocologist.

Patient Name_____

Birthdate_____

Date of implant_____

Isotope: Iridium-192 Gold-198 Iodine-125 Palladium-103

# of Ribbons	Seeds/ Ribbon	Act/ Seed	Spacing (cm)	Leader (cm)

Hardware/Misc. Goods

_____
_____
_____
_____

Verification of Source Activity Before Implantation

_____

Below information to be completed by the technologist.

Sources returned to manufacture_____ _____
date initials

Please FAX or mail this form to the DMC Nuclear Medicine Department.

DEACONESS MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
Nuclear Medicine

131 I WHOLE BODY SCAN

WRITTEN DIRECTIVE

PATIENT NAME: _____

DATE OF BIRTH: _____ SOCIAL SECURITY NUMBER: _____

REFERRING PHYSICIAN: _____

CLINICAL INDICATIONS: _____

RADIOPHARMACEUTICAL: _____ DOSE: _____

ROUTE OF ADMINISTRATION: _____

AUTHORIZED USER: _____ DATE: _____

VERIFICATION	YES	NO
PATIENT IDENTIFIED BY TWO METHODS	___	___
NEGATIVE PREGNANCY TEST VERIFICATION (Child Bearing Age)	___	___
CORRECT PHARMACEUTICAL	___	___
CORRECT ROUTE OF ADMINISTRATION	___	___
APPROPRIATE CLINICAL INDICATORS	___	___

DOSE PRESCRIBED: _____

DOSE ASSAYED: _____ INITIALS: _____

DOSE ASSAY CHECK: _____ INITIALS: _____

TREATMENT IN ACCORDANCE WITH WRITTEN DIRECTIVE: ___YES ___NO

TECHNOLOGIST ADMINISTERING THERAPY: _____

PATIENT CONSENT

I autherize the Department of Nuclear Medicine of Deaconess Medical Center to perform I-131 whole body scan. The procedure with radioactive iodine has been thoroughly explained to me, and I understand the indications for the procedure. The risks of radiation have been explained to me, and I have a good understanding of the procedure.

_____ _____
(Signature of Patient) (Date)

_____ _____
(Signature of Witness) (Date)

DEACONESS MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
Nuclear Medicine

131 I THYROID FOR HYPERTHYROIDISM

WRITTEN DIRECTIVE

PATIENT NAME: _____

DATE OF BIRTH: _____ SOCIAL SECURITY NUMBER: _____

REFERRING PHYSICIAN: _____

CLINICAL INDICATIONS: _____

RADIOPHARMACEUTICAL: _____ DOSE: _____

ROUTE OF ADMINISTRATION: _____

AUTHORIZED USER: _____ DATE: _____

VERIFICATION	YES	NO
PATIENT IDENTIFIED BY TWO METHODS	___	___
NEGATIVE PREGNANCY TEST VERIFICATION (Child Bearing Age)	___	___
CORRECT RADIOPHARMACEUTICAL	___	___
CORRECT ROUTE OF ADMINISTRATION	___	___
APPROPRIATE CLINICAL INDICATORS	___	___

DOSE PRESCRIBED: _____

DOSE ASSAYED: _____ INITIALS: _____

DOSE ASSAY CHECK: _____ INITIALS: _____

TREATMENT IN ACCORDANCE WITH WRITTEN DIRECTIVE: ___YES ___NO

TECHNOLOGIST ADMINISTERING THERAPY: _____

PATIENT CONSENT

I autherize the Department of Nuclear Medicine of Deaconess Medical Center to perform I-131 therapy. The procedure of treatment with radioactive iodine has been thoroughly explained to me, and I understand that various alternative methods which are available for treatment. The long term risks of radiation have been explained to me, and I have a good understanding of the procedure. The need for close follow up by my own physician has been stressed to me and the need for replacement therapy of thyroid hormone in the future has also been explained.

_____ _____
(Signature of Patient) (Date)

_____ _____
(Signature of Witness) (Date)

DEACONESS MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
Nuclear Medicine

131 I THYROID CARCINOMA

WRITTEN DIRECTIVE

PATIENT NAME: _____

DATE OF BIRTH: _____ SOCIAL SECURITY NUMBER: _____

REFERRING PHYSICIAN: _____

CLINICAL INDICATIONS: _____

RADIOPHARMACEUTICAL: _____ DOSE: _____

ROUTE OF ADMINISTRATION: _____

AUTHORIZED USER: _____ DATE: _____

VERIFICATION	YES	NO
PATIENT IDENTIFIED BY TWO METHODS	___	___
NEGATIVE PREGNANCY TEST VERIFICATION (Child Bearing Age)	___	___
CORRECT RADIOPHARMACEUTICAL	___	___
CORRECT ROUTE OF ADMINISTRATION	___	___
APPROPRIATE CLINICAL INDICATORS	___	___

DOSE PRESCRIBED: _____

DOSE ASSAYED: _____ INITIALS: _____

DOSE ASSAY CHECK: _____ INITIALS: _____

TREATMENT IN ACCORDANCE WITH WRITTEN DIRECTIVE: ___YES ___NO

TECHNOLOGIST ADMINISTERING THERAPY: _____

PATIENT CONSENT

I autherize the Department of Nuclear Medicine at Deaconess Medical Center to perform I-131 therapy. The procedure of treatment with radioactive iodine has been thoroughly explained to me, and I understand the various alternative methods which are available for treatment. The long term risks of radiation have been explained to me, and I have a good understanding of the precedure. The need for close follow up by my own physician has been stressed to me and the need for replacement therapy of thyroid hormone in the future has also been explained.

_____ _____
(Signature of Patient) (Date)

_____ _____
(signature of Witness) (Date)

WRITTEN DIRECTIVE

TEMPORARY IMPLANT **DATE:** _____

Verified Treatment Site: _____

Patient: _____ _____

Hosp. ID: _____ _____

Birthdate: _____ _____

Source type (circle): Cs-137 Ir-192

Number/Strength: _____

_____

Estimated Implant Time: _____

LOADING: Fletcher Ovoids Other

Initial prescription: _____ Time "In" _____

Final prescription: _____ Time "Out" _____

Post Brachy Therapy

Cs-137 - Upon returning these sources the Cs-137 vault has all sources in inventory. _____ (Initial)

Ir-192 - The seeds removed from the patient plus the seeds remaining in the pig equal the total number of seeds ordered for use. _____ (Initial)

The number of Ir-192 sources have been verified and returned to the manufacturer. _____ (Initial)

Authorized User: _____

	Yes	No	Initials
Patient verified by two methods	___	___	_____
Treatment in accordance with written directive	___	___	_____

WRITTEN DIRECTIVE

PERMANENT IMPLANT

Verified

Patient: _____ _____ Birthdate: _____

SS # : _____ _____ Hosp. ID: _____

IMPLANT DATE: _____

Source Type (circle) I125 seeds Pd103 seeds Other_____

Number/Strength: _____

_____

Leading (circle) Needle template Other _____

Planned Prescription: _____

Final Prescription: _____

Number of sources not used: _____ _____
Number Initials

Authorized User: _____

Number of sources returned to the manufacturer: _____ _____
Number Initials

	Yes	No	Initials
Patient verified by two methods	___	___	_____
Treatment in accordance with written directive	___	___	_____