PUBLIC

21-04109-08
030-00274

MAR 01 1994

Henry Ford Hospital
ATTN: Stephen Velik, Group Vice President
2799 West Grand Boulevard
Detroit MI 48202

SUBJECT: ACCEPTANCE OF QUALITY MANAGEMENT PROGRAM

Dear Mr. Velik:

This refers to the review of your Quality Management Program (QMP) dated January 23, 1992 in accordance with 10 CFR 35.32. A review of the QMP was performed to determine whether policies and procedures have been developed to meet the objectives of the rule. Based on your submission, your QMP appears to meet the requirements of 10 CFR 35.32. We have also determined that Confirmatory Order EA 84-67 should be rescinded. This will be handled as a separate matter.

You are reminded that the training and/or instruction of supervised individuals for implementation of your QMP is required in 10 CFR 35.25. In addition, you are also reminded to retain the records of each review of administrations.

Please be advised that this QMP will not be incorporated into your license's "tie-down" condition. This allows you the flexibility to make changes to your quality management program without obtaining prior NRC approval. When modifications are made to your program, you should submit any changes to your QMP to this Office within 30 days as required by 10 CFR 35.32(e).

No reply is required in response to this letter. We will review implementation of your QMP at the next regular inspection of your facility.

Thank you for your cooperation in this matter. If you have any questions, please contact Patricia Pelke of my staff at (708) 829-9887.

Sincerely,
Original Signed By
John R. Madera, Chief
Materials Licensing Section

RIII	RIII	RIII
Pelke/pjp	Frazier	Madera
02/25/94	02/25/94	02/25/94

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PDR ADOCK 03000274
C PDR

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February 17, 1994

Note to: Patricia Pelke

From: Jay McGurren

SUBJECT: HENRY FORD HOSPITAL

In response to your note to Steve Lewis of February 4, 1994, I have been asked to inform you that we agree that there is basis to rescind the July 17, 1984, Confirmatory Order. This, however, must be accomplished by an order, not by a letter. Since the licensee is agreeing to this rescission, it would be a Confirmatory Order Rescinding the Confirmatory Order of July 17,1984. I would be glad to assist you in the preparation of this order. If you have any questions, please call me.

cc: J. Goldberg
S. Lewis
B. Berson, RIII

REQUEST FOR TECHNICAL ASSISTANCE

DATE: June 7, 1993

TO: John Glenn, Chief, Medical, Academic, and Commercial Use Safety Branch, NMSS

FROM: Roy Caniano, Chief, Nuclear Materials Safety Branch Region III

LICENSEE: Henry Ford Hospital LICENSE NO. 21-04109-08

_____ Control No. _____ (enclosed)

X Letter dated April 8, 1993 (enclosed)

_____ Suggested change in licensing procedure (enclosed)

_____ Other (see remarks)

Problem/Issue: Licensee is requesting that we rescind NRC Confirmatory Order issued July 17, 1984 (copy enclosed).

Action Required: Expedite review of licensee's Quality Management Program dated January 23, 1992 (copy enclosed).

Alternatives Considered:

Recommended Alternative:

Remarks: If rescission is appropriate, please provide recommended/acceptable wording for letter transmitting rescission of Order, and advise if license condition necessary for QM Program.

Regional Reviewer: Patty Pelke

Reviewer Code: R6

Reviewer Phone No. (708) 790-5619

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

DEC 13 1993

MEMORANDUM FOR: Roy J. Caniano, Chief
Nuclear Materials Safety Branch, RIII

FROM: John E. Glenn, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and Medical
Nuclear Safety, NMSS

SUBJECT: REVIEW OF QUALITY MANAGEMENT PLANS FOR
HENRY FORD HOSPITAL, DETROIT, MICHIGAN

As requested in a memorandum dated April 8, 1993 (Enclosure 1), the staff has reviewed the Quality Management program (QMP) submitted by Henry Ford Hospital of Detroit, Michigan. The enclosed draft letter to the licensee (Enclosure 2) will be sent to the region electronically. The letter may be signed by the appropriate license reviewer.

Since Henry Ford Hospital's QMP appears to meet the requirements listed in 10 CFR 35.32, I recommend that you work with the Office of Enforcement to rescind the NRC Confirmatory Order issued July 17, 1984.

This QMP should not be incorporated into the license's "tie-down" condition. This allows the licensee the flexibility to make changes to the QMP without obtaining prior NRC approval.

If you have any questions please contact Sally Merchant at (301) 504-2637.

John E. Glenn, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures:
1. TAR frm RIII dtd 6/7/93
2. Draft ltr to Henry Ford Hospital

DEC 20 1993

Henry Ford Hospital
ATTN: Stephen Velik, Group Vice-President
2799 West Grand Boulevard
Detroit, Michigan 48202

Dear Mr. Velik:

This refers to the review of your Quality Management Program (QMP) for brachytherapy, teletherapy and radiopharmaceutical therapy dated January 23, 1992, which describes the medical quality management program implemented by Henry Ford Hospital in accordance with 10 CFR 35.32. A review of the QMP was performed to determine whether policies and procedures have been developed to meet the objectives of the rule. Based on your submission, your QMP appears to meet the requirements of 10 CFR 35.32. You are reminded that the training and/or instruction of supervised individuals for implementation of your QMP is required in 10 CFR 35.25.

You are reminded to retain the records of each review of administrations to be maintained for three years.

No reply is required in response to this letter. We will review implementation of your QMP at the next regular inspection of your facility.

Please be advised that this QMP will not be incorporated into your license's "tie-down" condition. This allows you the flexibility to make changes to your quality management program without obtaining prior NRC approval. When modifications are made to your program, you should submit any changes to you QMP to this Office within 30 days as required by 10 CFR 35.32(e).

Thank you for your cooperation in this matter. If you have any questions, please call me at _____.

Enclosure 2

Rec'd Rec 6/14/93

FROM: Glenn

TO: Camper

CLASSIFICATION: | FILE CODE:

DESCRIPTION: TAR Rule III Review
Qtr Program Submitted

ENCLOSURES: By Henry Ford Hosp.
Determine if Confirmatory

REMARKS: Item can be Removed

DATE OF DOCUMENT	DATE RECEIVED	NO.
		1478

TYPE OF DOCUMENT
- LETTER
- MEMO
- REPORT
- OTHER (Specify)

DATE ANSWER DUE: 7/14/93

DATE ANSWERED:

BY:

- ACTION NECESSARY
- NO ACTION NECESSARY

REFERRED TO	DATE	RECEIVED BY	DATE
SM1	6/14/93		

NRC FORM 326 (5-90)

CORRESPONDENCE CONTROL

U.S. NUCLEAR REGULATORY COMMISSION

Enclosure 1

93-10

REQUEST FOR TECHNICAL ASSISTANCE

DATE: June 7, 1993

TO: John Glenn, Chief, Medical, Academic, and Commercial Use Safety Branch, NMSS

George Roy Caniano for 6/8/93

FROM: Roy Caniano RJC, Chief, Nuclear Materials Safety Branch
Region III

LICENSEE: Henry Ford Hospital LICENSE NO. 21-04109-08

_____ Control No. _____ (enclosed)

X Letter dated April 8, 1993 (enclosed)

_____ Suggested change in licensing procedure (enclosed)

_____ Other (see remarks)

Problem/Issue: Licensee is requesting that we rescind NRC Confirmatory Order issued July 17, 1984 (copy enclosed).

Action Required: Expedite review of licensee's Quality Management Program dated January 23, 1992 (copy enclosed).

Alternatives Considered:

Recommended Alternative:

Remarks: If rescission is appropriate, please provide recommended/acceptable wording for letter transmitting rescission of Order, and advise if license condition necessary for QM Program.

Regional Reviewer: Patty Pelke

Reviewer Code: R6

Reviewer Phone No. (708) 790-5619

93-10

Henry Ford Hospital

2799 West Grand Boulevard
Detroit, Michigan 48202

April 8, 1993

A. Bert Davis
Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Mr. Davis:

Henry Ford Hospital was issued a Confirmatory Order on July 17, 1984 (EA 84-67) as a result of a medical teletherapy misadministration involving one patient. We are requesting that the Confirmatory Order applied to NRC License No. 21-4109-08 be completely rescinded.

We believe that the Confirmatory Order can be withdrawn without any compromise of patient safety for the following reasons:

1. All subsequent NRC inspections have found Henry Ford Hospital to be in compliance with the Confirmatory Order;

2. No therapeutic misadministrations have occurred at Henry Ford Hospital since the Order was issued in 1984; and

3. Regulatory changes in 10 CFR Part 35 pertaining to the Quality Management Program encompass all aspects of the Confirmatory Order. Thus, the Order would appear to be redundant with current regulatory requirements.

Henry Ford Hospital is committed to providing quality patient care with the highest degree of safety to patients and staff. Your expeditious response to this request would be gratefully appreciated because we are submitting for timely renewal of this NRC license, which expires May 31, 1993.

Sincerely,

Stephen Velick
Group Vice President
Chief Operating Officer

/kmm
cc: Radiation Safety Committee
J.H. Kim, M.D.
C. Martin

21-04109-08

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

JUL 17 1984

cense No. 21-04109-08
84-67

Henry Ford Hospital
ATTN: Mr. Douglas Peters
Vice President and
Executive Director
2799 W. Grand Boulevard
Detroit, MI 48202

Gentlemen:

SUBJECT: CONFIRMATORY ORDER

This letter is to advise you of the issuance of the enclosed Confirmatory Order. This Order is being issued as a result of a medical teletherapy misadministration in which a patient at Henry Ford Hospital received a therapy dose of 8,700 rads although the prescribed dose was only 6,000 rads. This matter was discussed between members of your staff and the NRC staff at the NRC Region III office in Glen Ellyn, Illinois during an enforcement conference on April 3, 1984. As a result of that conference your staff prepared a teletherapy treatment Quality Assurance Program Outline and submitted it for NRC review and approval.

In the interest of public health and safety the NRC staff has determined that this quality assurance program should be implemented as required in Section III of the enclosed Order. The program is required to be implemented effective immediately upon issuance of this Order if it has not already been implemented. We will review the effectiveness of this program during subsequent inspections.

Sincerely,

Richard C. DeYoung, Director
Office of Inspection and Enforcement

Enclosure:
Confirmatory Order

AUG 3 1984

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of)
)
HENRY FORD HOSPITAL) License No. 21-04109-08
2799 West Grand Boulevard) EA 84-67
Detroit, MI 48202)

CONFIRMATORY ORDER

I

The Henry Ford Hospital ("the licensee") holds Byproduct Material License No. 21-04109-08, which authorizes the licensee to possess and use cobalt-60 sealed teletherapy sources in teletherapy units for treatment of humans. The license was renewed on March 22, 1983 and will expire on March 31, 1988.

II

A patient was scheduled to receive a prescribed therapy dose of 6,000 rads over a total of 30 treatments. However, the dosimetrists who performed the calculations that were necessary before initiating the treatments made an error in the calculations and the error was not discovered until the patient had received a total of 8,700 rads in the course of treatments during the period January 30 through March 5, 1984. The licensee reported the misadministration to the NRC on March 6, 1984.

The misadministration was reviewed during a special safety inspection that was conducted by the NRC Region III staff on March 12 and 13, 1984. It was determined that the misadministration resulted from an error in a dose

calculation and the licensee's failure to have the calculations verified independently by a second dosimetrist.

Although the misadministration did not constitute a violation of NRC regulatory requirements, the NRC is concerned that the circumstances surrounding the misadministration reflect inadequate control over the safe use of licensed material. The licensee met with the NRC staff during an enforcement conference at the NRC Region III office in Glen Ellyn, Illinois on April 3, 1984, to review the circumstances that led to this event. During the enforcement conference, the licensee proposed various corrective actions that could be taken to reduce the possibility of another teletherapy misadministration. The licensee agreed to submit these proposals to the NRC in writing for review and approval.

By letter dated April 17, 1984, the licensee submitted a teletherapy treatment Quality Assurance Program Outline. Based on this submittal and further conversations with licensee representatives, the licensee has agreed that:

1. Treatment dose calculations, performed by dosimetrists, are to be checked by a physicist prior to the third treatment. In those cases where a modification in the treatment plan is made, this check will also be performed. Technologists will verify that this check has been performed before administration of the third treatment.

2. Weekly chart checks will be performed by the technical supervisor(s). This weekly check is designed to verify that the treatment is being administered according to the prescription and the treatment plan, and that any changes recommended by the therapist have been implemented.

3. If the technologists have questions or require clarification regarding a treatment plan, patient set up, or dose calculation, those questions are to be brought to the attention of a dosimetrist and/or physicist.

4. The technologists will not make changes in the treatment plans. Any proposed changes are to be brought to the attention of a dosimetrist or physicist. If a proposed change involves a modification in the dose calculations, the modification dose calculations will be checked by a physicist.

5. The technologists may perform calculations on an emergency basis (e.g., for an emergency case on a Saturday, Sunday, or a holiday). These calculations will be later checked by a dosimetrist or a physicist.

6. An internal administrative audit will be conducted on a quarterly basis for the first 12 months and annually thereafter. The audit is to be made by a member or members of the Radioisotope Committee and the findings will be reported to the hospital administration in writing and retained.

7. Periodic departmental meetings will be held to discuss any relevant issues regarding the administration of therapeutic treatment modalities and quality assurance activities. Minutes of these meeting will be maintained.

The NRC staff has reviewed the licensee's submittal. Implementation of the licensee's program should provide enhanced assurance that all calculations for treatment with the cobalt-60 teletherapy unit are accurately made and verified by an independent dosimetrist and that licensed material is safely used. Accordingly, to ensure continued implementation of the licensee's commitments, I have determined that the public health, safety, and interest require confirmation of the licensee's commitments by an immediately effective Order.

III

Accordingly, pursuant to Sections 81 and 161b. of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR Parts 2, 30 and 35, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, that:

The licensee shall implement the Teletherapy Treatment Quality Assurance Program described in numbered paragraphs 1 through 7 of Section II of this Order.

IV

The licensee may request a hearing on this Order. Any request for hearing shall be sent within 25 days of the date of issuance of this Order to the Director, Office of Inspection and Enforcement, U. S. Nuclear Regulatory Commission, Washington, D.C. 20555. A copy of any hearing request shall also be sent to the Executive Legal Director at the same address. A REQUEST FOR HEARING SHALL NOT STAY THE EFFECTIVENESS OF THIS ORDER.

If a hearing is to be held, the Commission will issue an Order designating the time and place of hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Richard C. DeYoung, Director
Office of Inspection and Enforcement

Dated at Bethesda, Maryland
this 17 day of July 1984

Henry Ford Hospital

Distribution
PDR
SECY
CA
RCDeYoung, IE
JTaylor, IE
JAAxelrad, IE
EFlack, IE
JKeppler, RIII
JLieberman, ELD
VStello, DED/ROGR
LCobb, IE
FIngram, PA
VMiller, NMSS
RCunningham, NMSS
JCrooks, AEOD
GMessenger, OIA
BHayes, OI
DNussbaumer, OSP
Enforcement Coordinators
RI, RII, RIII, RIV, RV
IE:ES File
IE:EA File
EDO Rdg File
DCS

Telephone

RIII	RIII	RIII	RIII	RIII	RIII	RIII	RIII	RIII
Slawinski	Simmons	Sreniawski	Axelson	Hind	Lewis	Schultz	Davis	Keppler
7/ /84	7/ /84	7/ /84	7/ /84	7/ /84	7/ /84	7/13/84	7/ /84	7/ /84

IE:ES	ELD	IE:DD	IE:D
EFlack	JLieberman	JAAxelrad	JTaylor RCDeYoung
7/13/84	7/13/84	7/16/84	7/ /84 7/ /84

Cc: Resident Inspector
Headquarters w/ NMSS (V. Miller)

FILE COPY

Henry Ford Hospital

2799 West Grand Boulevard
Detroit, Michigan 48202

January 23, 1992

U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Attn: Chief, Materials Licensing Section

Gentlemen:

Please find enclosed the Quality Management Program for Henry Ford Hospital, which is being submitted in compliance with 10 CFR 35.32. This program affects our NRC License Nos. 21-04109-08 and 21-04109-16. This program generally follows the suggested policies in Regulatory Guide 8.33, dated October, 1991. The program will be implemented within 30 days following notice that these policies are found acceptable by the Nuclear Regulatory Commission.

If you should require further information, please contact Ralph P. Lieto, Radiation Safety Officer, at (313) 876-7042.

Sincerely,

M Tomlanovich

Michael C. Tomlanovich, M.D.
Medical Director
Professional Practice Review Group

/kmm
Enc.
cc: J.H. Kim, M.D.
K.C. Karvelis, M.D.
HFH Radiation Safety Committee

JAN 27 '92

HENRY FORD HOSPITAL

QUALITY MANAGEMENT PROGRAM

The administration to humans of unsealed byproduct material (dosage) or radiations from byproduct material (dose) involves the following modalities: radiopharmaceuticals from the Division of Nuclear Medicine and teletherapy or brachytherapy from the Department of Radiation Oncology. The following policies and procedures are intended to provide a program that will deliver the prescribed dosage from certain radiopharmaceuticals or the prescribed therapeutic dose from sealed sources to patients. The certain radiopharmaceutical involved as those administered in a therapeutic dosage or greater than 30 microcuries of I-125 or I-131 as sodium iodide.

I. Radiopharmaceuticals, Teletherapy, and Brachytherapy

1. Before the administration of any dosage or dose, there must be a signed and dated written directive from a physician who is a user properly authorized by the Henry Ford Hospital Radiation Safety Committee. Procedures for oral directions and revisions to written directives are given 10 CFR 35.32.

2. Before the administration of any dose or dosage, the identity of the patient will be verified by two (2) of the following methods:

   a) By asking the patient;
   b) Compare the photo in the patient's record to the patient;
   c) Check the name on the wrist band if an in-patient;
   d) Check that the patient's birthdate matches the one in the patient's record;
   e) Check that the patient's address matches the one in the patient's record;
   f) Check that the patient's social security number matches the one in the patient's record;
   g) Confirm against any other data listed in the patient's record;
   h) Confirmation by a relative or a friend accompanying patient, if the patient cannot speak for himself or herself;
   i) Check the patient's driver's license.

3. All workers should seek guidance if they do not understand how to carry out the written directive. Administration of the dose or dosage should not continue until all questions are resolved.

4. Each modality, i.e. radiopharmaceutical, teletherapy, brachytherapy, will conduct a quarterly review of a statistically representative sample of patient administrations. The review is to determine whether the dosage or dose was in accordance with the written directive or plan off treatment. The review will include all recordable events and misadministrations since the last review. For each patient case reviewed, deviations from the written directive and their cause will be identified. Remedial actions, if any, will be stated. The quarterly review will be reported to the quality assurance committee of the respective Department and the Radiation Safety Office.

II. Cobalt-60 Teletherapy - Department of Radiation Oncology

1. An authorized user must approve a plan of treatment that provides sufficient information and direction to meet the objectives of the written directive.

2. The person administering the Cobalt-60 teletherapy treatment will verify that the treatment site and the dose per fraction are in agreement with the written directive before administering the treatment.

3. The person administering the Cobalt-60 teletherapy treatment will make, date, and sign or initial a written record in the patient's permanent Department of Radiation Oncology chart after administering the treatment.

4. A weekly chart check will be performed by one of the clinical supervisory staff. This check will include, but is not limited to, detecting mistakes in the daily and the cumulative dose administrations and changes in the written directive.

5. Dose calculations will be checked before the third treatment. If the prescribed dose is to be administered in two or less fractions, the check will be performed before the first treatment is administered.

   The calculation will be checked by a person who did not make the original calculation. The check will be performed by a radiation therapy physicist.

   Manual dose calculations should be checked for the following, if applicable:

a) arithmetic errors;
b) appropriate transfer of data from the written directive, plan of treatment, tables, and graphs;
c) appropriate use of nomograms; and
d) appropriate use of all pertinent data in the calculations.

Computer-generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient was used in the calculations.

6. Independent checking of the output of the teletherapy units will be done biannually or within 30 days whenever spot checks indicate that the output differs by more than 5 percent from the output obtained at the last calibration corrected mathematically for radioactive decay.

The independent check will be performed by either:

a) A teletherapy physicist who did not perform the original output check. This individual must use a dosimetry system meeting the requirements specified in 10 CFR 35.630(a), or

b) A teletherapy physicist using a thermoluminescence dosimetry service available by mail that is designed for confirming teletherapy doses and that is accurate within five percent.

7. Transmission factors for beam modifying devices will be determined before the first medical use of the device.

Full calibration measurements as required by 10 CFR 35.622 will also now include the determination of transmission factors for trays and wedges.

8. Physical measurements of the teletherapy output under applicable conditions will be made prior to the first teletherapy fractional dose if the patient's plan of treatment includes field sizes or treatment distances that are outside the ranges measured in the most recent full calibration. Also, any beam modifying devices being used for the first time must have transmission factors measured.

9. If the authorized user determines that delaying treatment to perform the checks of (1) dose calculations for a prescribed dose that is administered in two fractions or less, or (2) teletherapy output, as required by item 8 above, would jeopardize the patient's medical condition, the prescribed treatment may be provided without first performing the checks of dose calculations or physical measurements. The authorized user must make a notation of this determination in the records of the calculated administered dose. The checks of the calculations should be performed within two workdays of completion of the treatment.

10. Acceptance testing will be done by a teletherapy physicist or someone under his supervision on any treatment planning computer before its first use for Cobalt-60 teletherapy dose calculations.

    Additional testing of the computer will be done, if deemed necessary by the teletherapy physicist, when a new Cobalt-60 teletherapy unit is installed or when a new source is installed.

11. A sample based on the sampling tables of 10 CFR 32.110 will be randomly created from all the Cobalt-60 teletherapy patients treated during that quarter. Each case in the sample will be checked to determine that the total dose, dose per fraction, the treatment site, and the overall treatment period are in agreement with the written directive. A report of the results will be made quarterly.

III. High Dose Rate Remote Afterloading Devices - Department of Radiation Oncology

1. Before administering the brachytherapy treatment, the person administering the treatment will verify that the radioisotope, treatment site, and the intended total dose are in agreement with the written directive.

2. Before inserting the sealed sources from a high dose rate remote afterloading device, the intended position will be verified by (1) using radiographs of the patient containing dummy sources, or (2) visual confirmation of the position of the applicator will be made. Note that the source positioning of the device is checked first on any treatment day.

3. Before administering the brachytherapy dose, the dose calculations will be checked by a person who did not make the original calculations. Examples of people who can do the check are (1) a radiation therapy physicist, or (2) a dosimetrist.

   Checks should include reviewing the computer printout to verify the radioisotope, the number of source stops used, and the dose rate at the point of written directive. The calculation determining the stopping time for each source position should be redone. The form containing the number of tubes, and the location, number, and stopping time for the source positions should be checked for correct transfer of data.

   Repeat applications for the same patient that are identical to the application checked do not have to be checked again.

4. After administering the brachytherapy treatment, the authorized user will date and also sign or initial the written record of the calculated administered dose in the patient's chart.

5. If the authorized user determines that delaying treatment in order to perform the checks of dose calculations would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations should be performed within two working days of the treatment.

6. Acceptance testing shall be done before the first use of a new treatment planning or dose calculating computer program used for high dose remote afterloading brachytherapy applications. This testing shall be done by or supervised by a teletherapy physicist.

7. A sample based on the sampling tables of 10 CFR 32.110 will be randomly created from all the high dose rate afterloading brachytherapy patients treated during that quarter. Each case in the sample will be checked to determine that the radioisotope, the treatment site, and the total dose are in agreement with the written directive. A report of the results will be made quarterly.

IV. Non-Remote Brachytherapy Applications - Department of Radiation Oncology

1. Before administering the brachytherapy treatment, the person administering the treatment will verify that the radioisotope, number of sources, and the source strengths are in agreement with the written directive.

2. Before administering the brachytherapy treatment, the person preparing the sources for implant will verify that the radioisotope, number of sources, the source strengths, and if applicable, the loading sequence are in agreement with the written directive and the plan of treatment. Verification will include checking the serial numbers of the sealed sources or using clearly marked storage locations. The signature of the person making the entry concerning the removal of radioactive material is indication that this verification occurred. These entries are made in bound books kept in the radioactive storage room.

3. All temporary brachytherapy implants will have some basis for the determination of source position and exposure time. This basis may be computerized tomography of the patient, radiographs of the application, or some other method approved by the authorized user. When possible, nonradioactive "dummy" sources should be used in establishing this basis.

4. All permanent brachytherapy implants will have some basis for the determination of source position and exposure time. This basis may be computerized tomography of the patient, radiographs of the application, or some other method approved by the authorized user.

5. After insertion of the temporary implant brachytherapy sources, the authorized user will promptly record the actual loading sequence of the radioactive sources implanted and sign or initial the patient's chart or other appropriate record.

6. After insertion of the permanent implant brachytherapy sources, the authorized user will promptly record the actual number of radioactive sources implanted and sign or initial the patient's chart or other appropriate record.

V. Radiopharmaceuticals - Division of Nuclear Medicine

1. All therapeutic administrations of radiopharmaceuticals and dosages of I-125 and I-131 greater than 30 microcuries will be dispensed only after receipt of a written directive from an authorized user specifying the radiopharmaceutical, dosage, and route of administration.

2. Therapeutic dosages must be assayed in a dose calibrator with two (2) qualified persons (authorized user, physicist, nuclear medicine technologist, nuclear medicine physician) present. The assay will be compared to the prescribed dosage.

3. The authorized user and a medical physicist, or their designates, shall be present or available in the hospital during the administration of therapeutic dosages.

4. After administration of the radiopharmaceutical, the dosage will be assayed by a qualified person and the administered dosage properly documented.

5. A sample based on the sampling tables of 10 CFR 32.110 will be randomly created from all radiopharmaceutical therapy patients treated during that quarter. Each case will be checked to determine that the radiopharmaceutical, dosage, and route of administration are in agreement with the written directive.