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DEPARTMENT OF VETERANS AFFAIRS
Medical Center
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In Reply Refer To: 506/50R

United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Subj: Quality Management Program, License #21-00159-04

Modifications have been made to our Quality Management Program (QMP). Enclosed is a complete and current QMP for Radiation Oncology Services.

Please direct any questions or requests for additional information to Ms. Melonie Payne at the above address or telephone (313) 761-7916.

Sincerely,

Edward L. Gamache
Director

Enclosures

cc: Radiation Safety Committee Chairman (115)
Regional Radiation Safety Manager (115HP)
National Health Physics Director (115HP)

PM: 3-21-97

RADIATION ONCOLOGY SERVICE
BRACHYTHERAPY QUALITY MANAGEMENT PROGRAM

I. INTRODUCTION

A written quality management program is required by Federal Regulation 10 CFR 35.32 to "provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user." All of the objectives required by the regulation will be met by the implementation of the program listed here.

II. RESPONSIBILITY AND AUTHORITY OF PROGRAM

The responsibility and authority for maintaining this quality management program is assigned to Radiation Oncology Service Chief, Medical Physicist, and the Radiation Safety Officer.

III. POLICIES AND PROCEDURES

Note: Any task assigned to a dosimetrist may be alternately performed by a physicist, but not vice versa.

A. Written Directive: 10 CFR 35.32(a)(1) requires a written directive for any brachytherapy radiation dose. As defined by 10 CFR 35.2, 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, except as specified in paragraph (6) of this definition, containing the following information:

(6) For all other brachytherapy (other than HDR remote afterloading):

(i) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(ii) 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)."

VAMC Brachytherapy QM Policy/Procedure #1:

For every brachytherapy implant, the following sections of the "Written Directive and Dosimetry Form" must be filled out, dated and signed by the physician before the sources may be implanted:

Patient information (including patient name, physicians' names, and diagnosis/treatment site), source information (radioisotope), implant/source configuration (including number of sources, activity of each source, total activity of implant and total number of sources), staff physician's signature and date. (See Appendix C for a sample form of how information is documented.)

After the sources have been implanted, but prior to completion of the procedure, the following information must be added to the "Written Directive and Dosimetry Form" (same information regardless of type of implant or radioisotope):

Total dose to specific point of interest or isodose line, planned treatment time, actual date and time of implant insertion, and intended date and time of implant removal, staff physician's signature and date.

The radioisotope, treatment site, and total source strength (activity) will already be contained on the written directive sheet. If changes to the written directive need to be made, they must be clearly noted, documented, signed and dated by the authorized user prior to the administration of the brachytherapy dose or the next brachytherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardie the patient's health, an oral directive will be acceptable provided that the information provided in the oral directive is documented in the patient's record and a written directive is prepared within 24 hours of the oral directive. Oral revisions will be documented immediately in the patient's record and a written directive will be signed and dated by an authorized user within 48 hours of the oral revision.

B. Patient Identification: 10 CFR 35.32(a)(2) requires that, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive.

VAMC Brachytherapy QM Policy/Procedure #2

Sources may be implanted in the operating room, as in the case of permanent implants and eye plaques, or afterloaded in the patient's hospital room, as in the case of most other temporary implants.

Before implanting the sources in the operating room, the nurse or physician in the preoperative holding area must check the patient's identity by two methods:

The nurse or physician will ask the patient 1) the patient's name and confirm it and 2) the name on the patient's wrist band with the hospital chart.

Before implanting sources in the patient's hospital room, the physician must check the patient's identity by two methods:

The physician will ask the patient 1) the patient's name and confirm it and 2) the name on the patient's wrist band with the written directive.

On the "Written Directive and Dosimetry Form", the line stating "Patient identity confirmed by 2 means before loading sources" must be initialed or check-marked. Only after positive confirmation of the patient's identity may the sources be loaded.

C. Treatment Plan Checks: 10 CFR 35.32 (a)(3) requires that final plans of treatment and related calculations for brachytherapy are verified to be in accordance with the written directives.

VAMC Brachytherapy QM Policy/Procedure #3

All brachytherapy implant calculations and treatment plans must be submitted to a physicist for evaluation before the implant is removed. The computer generated treatment plan will be checked by examining the computer printout to ensure that the correct inputs for the patient were used in the calculations, specifically the correct number and type of sources. For Iridium-192 and Iodine-125 implants, whose source strengths must be entered by the user, the source strengths should be checked to ensure that the decay from the calibration date to the treatment date was calculated correctly. (An inventory of Cesium sources is kept in the treatment planning system and source strengths are decayed automatically by the program. When new versions of the program are installed, checks are done by the physicists to ensure that the decay is calculated correctly.) Manual dose calculations (such as the determination of the treatment time and the total dose to each point of interest) will be checked for arithmetic errors, correct transfer of data from the written directive, and correct use of all pertinent data

in the calculations. When these checks are completed, the physicist will sign and date the "Written Directive and Dosimetry Form".

D. Other Verification Checks: 10 CFR 35.32 (a)(4) requires that each administration be verified to be in accordance with the written directive.

VAMC Brachytherapy QM Policy/Procedure #4

Verifying that the administration is in accordance with the written directive requires three separate steps:

1) The dosimetrist or physician must verify and document that the radioisotope, number of sources, source strengths, and if applicable, loading sequence of the sources to be used are in agreement with the written directive and plan of treatment before implanting the sources.

For Cesium-137 Implants: Cesium sources are stored in clearly marked storage spaces for each type of source. The inventory form for each implant illustrates this configuration and the spaces from which the sources are removed are marked directly on the form by the dosimetrist at the time the sources are prepared. Paint marks reflecting the universal color coding of these sources are visible on one end of each source so that it is easy to identify each source type and place it back in the correct spot. Once a year the entire Cesium patient inventory is assayed in a cylindrical well ionization chamber to confirm the source strength of each source and the serial numbers of the sources are checked as well. To verify the information listed above, a second person (dosimetrist or physician) must watch the sources being placed into the applicator and confirm that the source strengths and configuration match the written directive and plan of treatment. On the "Written Directive and Dosimetry Form", the line stating "Sources prepared as described above" must be signed or initialed by both personnel preparing the sources.

For Iridium-192 Implants: Iridium sources are not kept as part of a permanent inventory. Usually a single shipment from the manufacturer is used for a single patient. Extra sources from one shipment may be used for another patient but sources are never reused from patient to patient. The manufacturer color codes ribbons with seeds of different source strengths. When the sources are taken up to the patient's room for loading, as each ribbon is pulled from the lead pig, the dosimetrist will count the sources, check the color, and hand the ribbon to the physician to double check this information before loading the ribbon into the patient. Alternatively, the dosimetrist could prepare the sources in the source room with a physician or second dosimetrist in attendance and properly label each ribbon with its number of sources. When the dosimetrist then pulls the ribbon from the lead pig up in the patient's room, the dosimetrist can double check the ribbon number and color before handing the ribbon to the physician to place into the patient. This second procedure probably leads to better personnel safety since it will reduce the patient loading time where shielding is more difficult to set up for personnel. Once the sources have been prepared, whether in the source room or up in the patient's room, the appropriate line on the "Written Directive and Dosimetry Form" must be signed or initialed.

For Iodine-125 Implants: Iodine-125 sources are usually ordered as single shipments but sometimes can be kept as part of a semi-permanent inventory. In either case, the sources will be kept in clearly marked storage vials. For I-125 eye plaques, the physicist or dosimetrist preparing the plaque must have another physicist, physician, or dosimetrist watch to confirm the placement of sources in the plaque. For I-125 brain implants, two people (physicists, physicians, or dosimetrists) must watch when the sources are placed in the catheters and when the catheters are loaded into the patient. Once the sources have been prepared, whether in the source room or up in the patient's room, the appropriate line on the "Written Directive and Dosimetry Form" must be signed or initialed.

2. For all implants, radiographs or other imaging studies must be taken of either non radioactive "dummy" sources, the fixed-geometry template (if used), or the actual radioactive sources themselves to verify the position of the sources for use in or verification of the treatment plan.

3. After insertion of the sources, the physician attending the insertion must sign and date beneath the line stating "Sources loaded as per planned configuration". If the loading was accomplished per the implant/source configuration information already listed on the "Written Directive and Dosimetry Form", no further remarks need be made. If the loading is changed, the physician must note any changes on the "Written Directive and Dosimetry Form" and/or in the patient's chart. The final treatment plan must reflect the actual loading of sources in the patient.

E. Unintended Deviations From the Written Directive: 10 CFR 35.32 (a)(5) requires the licensee to identify and evaluate any unintended deviations from the written directive, and take appropriate action. 10 CFR 35.32 (c) discusses steps that need to be taken to deal with "recordable events" and 10 CFR 35. 33 (a) and (b) discuss steps that need to be taken to deal with "misadministrations". The definitions of both of these terms (located in 10 CFR 35.2) are listed below.

"Misadministration" means the administration of:

A brachytherapy radiation dose:

(i) Involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(ii) Involving a sealed source that is leaking;

(iii) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(iv) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

"Recordable event" means the administration of:

(i) A radiopharmaceutical or radiation without a written directive where a written directive is required;

(ii) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

F. Questions Regarding Written Directives:

Each administration must in accordance with the written directive.

Staff shall read the written directive before preparing or administering the treatment or procedure. If any portion of the written directive is unclear, he/she shall contact the specific authorized user who provided the directive for clarification. The procedure or treatment shall not be performed until the intent of the written directive is thoroughly understood.

VAMC Brachytherapy QM Policy/Procedure #5

Procedures to identify and evaluate any unintended deviations from the written directive will include the following:

1. A record separate from the patient's chart will be kept (called the "Implant List") for each implant. It will contain the following information specific to each implant: patient name, isotope, activity, implant duration, dates/times of implant insertions and removal, and a space to confirm (by initials or check mark) that the physicist has checked the treatment plan and dosimetry calculations and verified that the written directive was filled out and signed properly. The dosimetrist in charge of the implant will be responsible for filling out all of the information in the list except the physics checks and it should aid in the detection of recordable events and misadministrations.

2. When the sources are removed, the date and time of removal will be noted on the "Written Directive and Dosimetry Form" and the total treatment time will be calculated. If the total treatment time is not within 1 hour of the planned treatment time, the "Patient Dose Summary" section of the "Written Directive and Dosimetry Form" will be updated to reflect the actual total treatment time. The reasons for the deviation from the plan will also be addressed and will be reviewed by the physicist and the physician. If the change in total dose from the prescribed dose is large enough to qualify the implant as a recordable event or misadministration, of if at this time, any other problem with the implant is discovered that would qualify the implant as a recordable event or misadministration, the steps outlined below will be followed.

3. When deviations from the written directive are found to be recordable events:

a. The physics staff will assemble the relevant facts including the cause for the recordable event.

b. Corrective action to prevent recurrence will identified, if required.

c. A report will be written and retained for a period of three (3) years of the relevant facts and what corrective action, if any, was taken. The incident will be discussed with the departmental chairman and all other personnel involved.

4. When deviations from the written directive are found to be misadministrations:

a. The physics staff will notify by telephone the VAMC Radiation Safety Officer and the NRC Operations Center no later than the next calendar day after discovery of the misadministration.

b. The physics staff will assemble the relevant facts including the cause for the misadministration.

c. Corrective action to prevent recurrence will be identified, if required.

d. A report will be written and submitted to the appropriate NRC Regional Office within 15 days after discovery of the misadministration. The report will contain all items listed in 10 CFR 35.33 (a)(2).

e. The requirements of 10CFR35.33(a)(3) and (4) will be followed with respect to notifying the referring physician and the patient.

f. The record of the misadministration will be maintained for five (5) years as outlined in 10 CFR 35.33 (b).

F. Maintaining Written Directives in Auditable Form: 10 CFR 35.32 (d) requires that the licensee retain each written directive and a record of each administered radiation dose in an auditable form for three (3) years after the date of administration.

VAMC Brachytherapy QM Policy/Procedure #6

Each written directive and record of administered dose will be kept for 3 years following the date of administration.

IV. AUDIT PROGRAM

10 CFR 35.32 (b) requires that each licensee shall:

1. "Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

   (i) A representative sample of patient administrations

   (ii) All recordable events

   (iii) All misadministrations

   to verify compliance with all aspects of the quality management program. These reviews must be conducted at intervals no greater than twelve (12) months.

2. Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to the objectives of paragraph (a) of this section, and

3. Retain records of each review, including the evaluations and findings of the review, in an auditable form for three (3) years.

A. Brachytherapy Administration Audit Sampling Policy:

1. Following completion of every brachytherapy implant there will be a complete audit by a physicist, of patient, implant and source information as described in the policies and procedures section of the Brachytherapy Quality Management Program.

2. Results of brachytherapy implant audits will also be reviewed at least once a year by the faculty physicist, consulting physicist, or the Radiation Safety Officer as part of a yearly review of the QM Program. Evaluations of the effectiveness of the QM Program will be made and, if required, modifications will be made to meet the objectives of 10 CFR 35.32 (a).

B. Brachytherapy Administration Audit Documentation:

1. The physicist performing the brachytherapy audit will evaluate the implant for all recordable events and misadministrations. The auditor will be responsible for ensuring that proper recording and reporting of such events has or will occur as defined in the QM Program and 10 CFR Part 35.

2. The auditor will also be responsible for documenting all significant nonrecordable and nonmisadministration deviations discovered during the audit on the "Implant List". This information will be useful in determining the effectiveness of the QM Program during the yearly QM Program review.

3. The auditor will sign and date the "Implant List" to document that all brachytherapy implant information has been entered as described in the QM Program.

4. The person performing the yearly review will document such review and any modifications made in the QM Program. (See Appendix D for a sample yearly audit report.)

5. The department and/or the RSO will retain records of each review, including the evaluations and findings of the review, in auditable form for three (3) years.

V. IMPLEMENTATION:

Procedures specified in this document will be implemented as of 8/1/94. Renewal or reissue will be evaluated annually in conjunction with recommendations of the Annual Report. Any modifications to the QMP will be submitted to the NRC within 30 days after modification has been made as required by 10 CFR 35.32 (e).

J. FRED LITTLES, M.D.
CHIEF, RADIATION ONCOLOGY (114B)

Concur/Nonconcur Date 5/10/97

APPENDIX C

INTRACAVITARY BRACHYTHERAPY TREATMENT FOR CS-137
"WRITTEN DIRECTIVE AND DOSIMETRY FORM"

PATIENT INFORMATION:

Patient Name:_____SS# _____

Physicians' Names (Attending/Resident: _____

Diagnosis/Treatment Site: _____

SOURCE INFORMATION:

Cs-137 Half-life = 30 years Γ = 3.28 R-cm^2/mCi-hr mCi/mgRa eq = 2.52

APPLICATOR INFORMATION:

Applicator Type: _____Tandem No. _____

Ovoid Description: _____

IMPLANT/SOURCE CONFIGURATION:

Source Number	Nominal Strength (mg Ra eq)	Actual Strength (mg Ra eq)
1	_____	_____
2	_____	_____
3	_____	_____
4	_____	_____
5	_____	_____
6	_____	_____
7-16	_____	_____

DIAGRAM:

Total # of sources: _____Total Activity (in mg Ra eq): _____

Dosimetrist (Initials & Date):_____

Staff Physician (Signature & Date): _____

Sources prepared as described above:_____

Deviations:_____

PREVIOUS EXTERNAL TREATMENT:

Total dose: _____(cGy) to _____

Total treatment time: _____(days) # of fractions: _____

Date of last treatment: _____

NOTE: **Save this record for at least 3 years post the last day of treatment.**

APPENDIX D

ANNUAL SUMMARY OF QUALITY MANAGEMENT PROGRAM
RADIATION ONCOLOGY SERVICE

Administration of Brachytherapy Radiation Doses

Period of audit Feb 19 to 19

Date(s) of audit _____

Auditor's name _____

Auditor an authorized user (check one) Y____ N_____

Total number of therapies under QMP: _____

Number of implant therapies administered:

I-125_____ Cs-137 Ir-192_____ Other _____

I. Criteria	**Yes**	**No**	**% Compliance**
1. Written directive prior to administration			
2. Oral directive only if patient's health jeopardized. _____ occurred. number			
3. Written directive includes: (score each item) Prior to treatment: patient's name patient's identification number physician's name (authorized user) diagnosis and treatment site radioisotope implant/source configuration number of sources activity of each source total activity of implant total number of sources signature and date of authorized user After implantation, but prior to completions of procedure: radioisotope treatment site total source strength total exposure time or total dose signature and date of authorized user			
4. All individuals involved in brachytherapy preparation/administration instructed in this QM program.			
5. Employed more than one method of verifying patient's identity before administration			

6. Brachytherapy administrations in accordance with written directives			
7. Unintended deviations (total _____ number annually) from written directives, identified evaluated corrective actions taken			
8. Each recordable event, (total number annually) evoked proper response			
9. Misadministration(s) (total number _____) & Recordable event(s) (total number _____) reported as required to: NRC attending physician Quality Management			
10. Maintain adequate records including: annual review written directives doses recordable events misadministrations			

II. Recommendations:

_____

_____

_____

_____

_____

_____

_____

_____

_____

III. Signature of Reviewer:_____Date _____

IV. Summary Report reviewed by:

_____

J. FRED LITTLES, M.D. Concur/Nonconcur Date_____
CHIEF, RADIATION ONCOLOGY SERVICE (114B)