Medical Center

1601 SW Archer Road
Gainesville, FL 32608-1197

Department of Veterans Affairs

November 30, 1998

In Reply Refer To

US Nuclear Regulatory Commission
Region II,
Atlanta Federal Center
61 Forsyth Street, SW, Suite 23T85
Atlanta, Georgia 30303-3415

SUBJ: MODIFICATION TO QUALITY MANAGEMENT PROGRAMS (License No. 09-12467-02)

Gentlemen:

In addition to the seven Quality Management Programs previously submitted to NRC by us, we have developed a new program (QMP-8) for intravascular brachytherapy procedures. A copy of this program is enclosed.

Please note that the only modification in our quality management programs is the addition of this QMP-8, the rest of the QM programs have not changed.

If there are any questions concerning this request for amendment of our license, please contact me at (352)-374-6059.

Sincerely,

Shailendra Shukla, Ph.D.
Radiation Safety Officer

Phone: (352)-374-6059
FAX: (352)-374-6113

enc: QMP-8

VA Medical Center

Gainesville, FL

QUALITY MANGEMENT PROGRAM 8 (QMP-8)

SUBJECT: Quality Management Program for Intravascular Brachytherapy

PURPOSE: To provide high confidence that radiation from intravascular brachytherapy sources will be administered as directed by the authorized user and to eliminate potential misadministrations and recordable events.

BACKGROUND:

The Gainesville Veterans Administration Medical Center (VA) does not have an in-house radiation oncology service. The Radiation Oncology Department of the Shands Clinic of the University of Florida (State of Florida Radioactive Materials License No, 31-3) conducts the radiation implant procedures on VA patients at the VA facility. We have thus established the Quality Management Program for intravascular brachytherapy, which delineates responsibilities of both the UF and the VA so that the objectives of this program as well as the regulatory requirements of the Nuclear Regulatory Commission are met. The UF Radiation Oncology department as well as Gainesville Veterans Administration Medical Center shall make all the applicable records available for inspection by the regulating agencies.

PROCEDURE:

I. Policy regarding elements for intravascular brachytherapy:

A. Written Directive: Prior to administration, a written directive issued by an authorized user (attending physician) shall be prepared for any intravascular brachytherapy dose. With regard to intravascular brachytherapy doses, a written directive is defined as an order, written in ink, for a specific patient, dated and signed by an authorized user (attending physician) prior to the administration of a intravascular brachytherapy dose, containing the following information:

1. Patient's name.
2. Patient medical record identification number.
3. Implant Site.
4. Radionuclide sources and the number of sources.
5. Target Dose (written as "either *n* cGy or 0 cGy", where *n* is the intended prescription dose).
6. Treatment Date(s).
7. Dose Prescription Point(s).

Except in emergent situations as defined in subsection I., no intravascular brachytherapy dose shall be administered in the absence of a signed directive with the above elements.

Responsibility for verification: The responsibility for verifying that a written directive exists lies with UF Radiation Oncology personnel. A copy of the written directive shall be given to the VA Radiation Safety Office. The original written directive shall be

kept in the UF Radiation Oncology patient file.

B. Identity of the Patient: Prior to administration, the patient's identity shall be verified by more than one method as the patient named in the written directive. UF Radiation Oncology personnel do the verification of the patient. Verification of identity must include at least two of the following methods:

1. The patient shall be asked to state his/her name.
2. The patient shall be asked to state his/her Social Security Number (SS#).
3. The in-patient's wrist identification band shall be checked for name and patient SS#.
4. For patients unable to respond, an accompanying relative/friend may attest to the identity. Record of the attesting person's name and relationship with the patient shall be kept in the UF Radiation Oncology patient file.

Responsibility for verification: UF Radiation Oncology personnel are required to verify the identity of the patient on the first day of treatment.

C. Pre-Treatment Radiation Survey: Prior to administration, UF Radiation Oncology personnel will perform radiation survey to determine the presence, if any, of preexisting radiation levels in the patient (e.g., from a previous nuclear medicine scan).

Responsibility for verification: UF Radiation Oncology personnel shall verify that a pre-treatment radiation survey has been performed in the UF Radiation Oncology patient file.

D. Treatment Plan Verification: Before administering the intravascular brachytherapy dose, the specific details of the brachytherapy administration shall be in accordance with the written directive and plan of treatment. An authorized user or a qualified person under the supervision of an authorized user shall do the verification of the treatment plan. In particular, the implant site, applicators used, target doses, number of fractions, dose per fraction, treatment date(s) and dose prescription point(s), shall be verified to concur with the written directive and plan of treatment. If any portion of the written directive is unclear to the person responsible for the dose administration, he/she must contact the specific authorized user (attending physician) who provided the directive for clarification before administering the brachytherapy dose.

If an authorized user who is physically present during a procedure decides to deviate from the original written directive at the time of dose administration, such deviation will be documented on the UF Radiation Oncology patient file prior to the procedure and signed by the authorized user (attending physician).

Responsibility for verification: The responsibility for verification of the plan of treatment lies with UF Radiation Oncology personnel on the first day of treatment. The final treatment plan will be kept in the UF Radiation Oncology patient file.

E. Verification of Position of Catheter Placement: A radiograph or comparable image must be made prior to a brachytherapy administration to verify the position of catheter placement.

Responsibility for verification: The responsibility for verifying the position of catheter placement lies with UF Radiation Oncology personnel. The verification image will be kept in the UF Radiation Oncology patient file.

F. Dose Calculations: Before the brachytherapy dose has been administered, the dose calculations must be checked, except as described in subsection G. below. The person performing this verification should be an authorized user or a qualified person under the supervision of an authorized user. Computer generated treatment plan dose calculations shall be checked to verify source activity and other treatment parameter as well as dose prescription per the written directive.

Responsibility: The responsibility for performing this requirement lies with UF Radiation Oncology personnel. UF Radiation Oncology personnel shall record the dose calculations in the UF Radiation Oncology patient file.

G. Delayed Check of Dose Calculation: 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 shall be performed within two working days of completion of the brachytherapy implant.

Responsibility: The responsibility for performing this requirement lies with UF Radiation Oncology personnel. The details of the dose calculations shall be kept in the UF Radiation Oncology patient file.

H. Unintended Deviations from the Written Directive: Any unintended deviation from the written directive shall be promptly reported to the UF Chief of Physics, who will relay the information as necessary to the VA Radiation Safety Officer (394-6059 or VA extension 6514, or VA Pager 1322). Upon identification of an unintended deviation, whether a recordable event or a misadministration, an investigation of the incident shall be made. The cause of the incident shall be determined and, if appropriate, corrective procedures shall be implemented. Documentation of the unintended deviation shall be in accordance with the reporting rules of NRC.

Responsibility: The responsibility of informing the VA Radiation Safety Officer of any unintended deviation lies with UF Radiation Oncology personnel. The subsequent evaluation of the deviation is a joint responsibility of both VA Radiation Safety Office and University of Florida Radiation Oncology Department. The Radiation Safety Officer will make any reporting necessary to the NRC.

I. Oral Directives: Oral directives are permissible when a patient's medical condition is such that his/her health would be jeopardized by the delay needed for originating or revising a written directive. When oral directives are employed, the information contained in the oral directive shall be immediately documented in the UF Radiation Oncology patient file and the original written directive shall be prepared within 24 hours of the oral issue. In the situation of an oral revision of an existing written directive, the directive must be revised, dated and signed by the authorized user (attending physician) within 48 hours of the oral revision.

Responsibility: The responsibility for keeping records of the content of oral directives and the subsequent written directives lies with UF Radiation Oncology personnel.

J. Record of Dosage: UF Radiation Oncology personnel must promptly record the calculated administered dose of the radioactive sources implanted and sign the UF Radiation Oncology patient file.

Responsibility for verification: The responsibility for verifying that a record of the dosage administered from the radioactive sources implanted was made in the UF Radiation Oncology patient file lies with UF Radiation Oncology personnel.

K. Patient Discharge Survey:. A radiation survey shall be performed immediately by UF Radiation Oncology personnel after the completion of a treatment to ensure that no radioactive sources are left in the patient. The Discharge Survey will also be compared to the pre-treatment radiation survey to verify there is no residual radioactivity in excess of that found during the pre-treatment radiation survey.

Responsibility for verification: The responsibility of conducting the discharge survey lies with UF Radiation Oncology personnel and shall be kept in the UF Radiation Oncology patient file.

L. Acceptance Testing of Treatment Planning Computer System: Acceptance testing shall be performed on each treatment planning or dose calculating computer program that could be used for brachytherapy dose calculations. Acceptance testing shall be performed before the first use of a treatment planning or dose calculating computer program and after changes in computer hardware or software.

Responsibility: The responsibility for performing this requirement lies with UF Radiation Oncology physicists. UF Radiation Oncology physicists shall record the acceptance test results in the UF Radiation Oncology Acceptance Tests for Treatment Planning Computer Systems File.

M. Locations of Documents: The locations of the documents mentioned in this Quality Management program shall be as follows:

1. Radiation Oncology Patient File:
   Radiation Oncology Department, Shands Cancer Center.
2. Radiation Oncology Acceptance Tests for Treatment Planning Computer Systems: Physics Workroom, Radiation Oncology Department, Shands Cancer Center.

N. Annual Review: The VA Radiation Safety Officer shall conduct the annual review at intervals not exceeding 12 months. Using criteria described in the above sections, the review shall determine the effectiveness of this Quality Management program. Areas identified as inadequate as determined by failure to meet 100% threshold values shall be modified to meet the objectives of 35.32(a). Records of each review, including the evaluations and findings in an auditable form, are to be saved for three years. These records may be reviewed by the appropriate regulatory agencies.

Approved By: _____ Date: 11-30-98

Chairman, Radiation Safety Committee

Approved By: _____ Date: 11/30/98

Radiation Safety Officer