ITEM #7

DEPT OF VETERANS AFFAIRS MEDICAL CENTER
ALBANY, NY 12208

L/N 31-02755-05
D/N 030-10026

Enclosure to letter dated February 25, 1994 update of QMP

QUALITY MANAGEMENT PROGRAM
FOR

Administration of any Brachytherapy Source or a High Dose Remote Afterloading Device, such as Sr-90, I-125, Cs-137, Ir-192, etc.

1. Objectives

To comply with regulatory requirements in regard to administration of only brachytherapy dose from a high dose remote afterloading device for therapy.

To ensure administration of dose is in the prescribed method of the "authorized user."

Eliminate the possibility of misadministration events.

2. Authority, Responsibility, and Audit:

The authority and responsibility to establish and implement the quality management (QM) program should be shared by the "authorized user" and the Radiation Safety Officer. The auditing responsibilities shall be conducted by the Radiation Safety Officer.

This procedure will be incorporated into the Procedure and Quality Assurance Manuals and remains responsive to the VACO, JCAHO, NRC directives, standards, and guidelines.

3. Policy Regarding Elements for Medical Use - Administration of any Brachytherapy Source or a High Dose Remote Afterloading Device, such as Sr-90, I-125, Cs-137, Ir-192, etc.

A. Prior to administration a written directive issued by an authorized user will be prepared for:

i. Any brachytherapy device.
ii. Any HIGH dose remote afterloading device.

With regard to any brachytherapy, a written directive is defined as an order, in writing, for a specific patient, dated and signed by an authorized user prior to the administration. The written directive containing the following information:

1. patient's name
2. patient identification number, if available
3. brachytherapy source
4. total dose
5. treatment site
6. the type of procedure desired

NO brachytherapy source shall be administered by any personnel in the absence of a signed directive with the above elements.

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B. Prior to administration the patient's identity is verified by more than one method as the patient named in the written directive. The person responsible for the administration of the brachytherapy treatment will complete the verification. Verification of identity must include at least two of the following methods:

1. The patient shall be asked to state and spell his/her name.
2. The patient shall be asked to state his/her birth date.
3. The patient shall be asked to state his/her Social Security Number.
4. The patient shall be asked to state his/her address.
5. The patient shall be asked for identification, i.e. driver's license.
6. The inpatient's wrist identification band shall be checked for name and patient number (SS#).
7. For patients unable to respond an accompanying relative/friend may attest to the identity. Record name and relationship of same.

If the information obtained from any two of these methods does not correspond to the information on the written directive, the brachytherapy treatment shall not be administered until conclusive verification is obtained.

A. Following brachytherapy treatment, a dated and signed written note is entered into the patient's record documenting the administration and dosage. Therapeutic administration, including dosimetric estimates, must be recorded into the patient's permanent medical record.

B. If any unintended deviation from the written directive is identified, it is evaluated, and appropriate action taken. Upon identification of an unintended deviation, an investigation of the incident shall be determined and, if appropriate, corrective procedures will be implemented. Documenting and reporting of the unintended deviation shall be in accordance with the reporting rules of 10 CFR, Part 35.

C. **Annual Review:**

The annual review shall be conducted by individuals other than authorized users (in our institution Radiation Safety Officer or consulting medical physicist as needed). The review shall be conducted at intervals not to exceed 12 months. Using pre-established criteria, the review shall determine the effectiveness of this QM 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.

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Audit Protocol:

Frequency: An audit of the quality management program shall be conducted at twelve (12) month intervals with the written summary report filed annually. Appendix B (Audit Form) is a prototype summary report.

Responsibility: The audit shall be conducted by other than authorized users (Radiation Safety Officer). If the audit is performed by the consulting physicist alone, management shall be briefed of the findings in writing.

Scope: The audit shall evaluate 100% compliance with the following criteria:

1. Having written directives prior to administration of brachytherapy dose.

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

3. All individuals involved in the therapy have received instruction in the requirements of the Quality Management Program and documentation of this fact available.

4. More than one method of verifying the patient's identity is performed prior to administration of the radioiodide.

5. Any brachytherapy dose administrations are in accordance with the specific information contained in the written directive.

6. Unintended deviations from the written directive are identified, evaluated, and appropriate corrective actions instituted.

7. Each recordable event must evoke the proper response.

8. Notify proper individuals (e.g. QA, referring M.D.) and report a misadministration.

9. Keep the appropriate records, including the annual reviews, written directives, treatment dosages, recordable events, and misadministrations.

Date: _____

From:

Subject: Annual Summary Quality Management Program

To: Director (00)

Annual Summary of Quality Management Program

Administration of any Brachytherapy Source or a High Dose Remote Afterloading Device, such as Sr-90, I-125, Cs-137, Ir-192, etc.
Period of audit January, 199 to January, 199

Date(s) of audit _____
Auditor's name _____

Auditor an authorized user (check one) Y ____ N ____
Number of Brachytherapy Treatment:
Sr-90_____
I-125_____
Cs-137_____
Ir-192_____

YES	NO	% COMPLIANCE

I. Criteria

1. Written directive prior to admission.

2. Written directive included for each patient.
   - Patient's name
   - Patient's identification number
   - Brachytherapy source
   - Total dose
   - Treatment Site
   - Type of procedure desired
   - Signed by authorized user
   - Date

3. All individuals involved in the brachytherapy have been instructed in this QM program.

5. Employed more than one method of verifying patient's identity before administration.

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YES	NO	% COMPLIANCE

6. Any brachytherapy dose administrations in accordance with written directives.

7. Unintended deviations (total _____ annually) evoked from number

   Written directives
   Identified
   Evaluated
   Corrective actions taken

8. Each recordable event (total # _____ annually) evoked proper response.

9. Therapeutic misadministration(s) (total # _____) reported as required to:

   NRC
   Attending physician
   Quality Management

10. Maintain adequate records including:

    Annual review
    Written directives
    Treatment dosages
    Recordable events
    Misadministrations

II. Recommendations:

III. Summary reviews by:

Concur/non-concur

Concur/non-concur

_____ _____
Chairman, RSC

_____

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