RADIATION PROTECTION OFFICE
FITZSIMONS ARMY MEDICAL CENTER
AURORA, CO 80045-5001

STANDING OPERATING PROCEDURE 15 January 1992

QUALITATIVE MANAGEMENT PROGRAM

1. PURPOSE. To prescribe policies and procedures to be followed for compliance with the Qualitative Management Program by consolidating all applicable policies from existing SOP's into one central location.

2. SCOPE. This SOP applies to Nuclear Medicine Service, Therapeutic Radiology Service, Radiation Protection Office, and other services that administer byproduct material or radiation from byproduct material for diagnostic or therapeutic procedures.

3. REFERENCES.

a. 10 CFR Part 35 - "Medical Use of Byproduct Material".

b. Nuclear Regulatory Guide 8.33 - "Qualitative Management Program", October 1991.

4. RESPONSIBILITIES.

Radiopharmaceutical Uses:

a. The Nuclear Medicine Service will:

(1) Have an authorized user or co-worker date and sign a written prescription prior to the administration of any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131. (NMS SOP #: 401, 402, 403, 412)

(2) Before administering a radiopharmaceutical dosage, verify by more than one method the identity of the patient as the individual named in the written prescription. The procedure used to identify the patient should be to: (NMS SOP #: 401, 403, 412, 418, proposed SOP dtd 7 Jan 92, Memo dtd 6 Jan 92)

(a) Ask the patient's name, and

(b) Confirm the name and at least one of the following by comparison with corresponding information in the patient's record:

(1) Birth Date,

(2) Address,

(3) Social Security Number,

(4) Signature,

(5) Name on patient's ID bracelet or hospital ID card, or

(6) Name on the patient's medical insurance card.

(3) Before administering the byproduct material, verify that the specific details of the administration are in accordance with the written prescription. The following should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written prescription: (NMS SOP #: 401, 403, 412, 418, proposed SOP dtd 7 Jan 92)

(a) Radiopharmaceutical,

(b) Dosage, and

(c) Route of administration.

(4) Have workers seek guidance if they do not fully understand how to carry out the written prescription. Workers should ask questions about what to do or how it should be done rather than continuing a procedure when there is any doubt. (NMS SOP #: 401, 403, 412, 418)

(5) After administering a radiopharmaceutical, have an authorized user or a qualified person under the supervision of an authorized user make, date, and sign or initial a written record that documents the administered dosage in the patient's chart or other appropriate record. (NMS SOP #: 401, 403, 412, 418, Memo dtd 6 Jan 92, proposed SOP dtd 7 Jan 92, FAMC Form 40-7105)

(6) Perform periodic reviews of the radiopharmaceutical Qualitative Management program. (NMS SOP #: 405, 408)

Teletherapy

b. The Therapeutic Radiology Service (TRS) will:

(1) Have an authorized user date and sign a written prescription prior to the administration of any teletherapy dose. (TRS SOP #: 500, para 3.C.8)

(2) Before administering a teletherapy dose, verify by more than one method the identity of the patient as the individual named in the written prescription. The procedure used to identify the patient should be to: (TRS SOP #: 500, para 3.C.11)

(a) Ask the patient's name, and

(b) Confirm the name and at least one of the following by comparison with the corresponding information in the patient's record:

(1) Birth date,

(2) Address,

(3) Social Security Number,

(4) Signature,

(5) Name on the patient's ID bracelet or hospital ID card,

(6) Name on the patient's medical insurance card, or

(7) Photograph of the patient's face.

(3) Have an authorized user or co-worker approve a plan of treatment that provides sufficient information and direction to meet the objectives of the written prescription. (TRS SOP #: 500, para 3.C.1, 3.C.3, 3.C.10)

(4) Before administering each teletherapy dose, verify that the specific details of the administration are in accordance with the written prescription and plan of treatment. In particular, the treatment site and the dose per fraction should be confirmed by the person administering the teletherapy treatment to verify agreement with the written prescription and plan of treatment. (TRS SOP #: 500, para 3.C.2, 3.C.10)

(5) Have workers seek guidance if they do not fully understand how to carry out the written prescription. (TRS SOP #: 500, para 3.C.13)

(6) Have a qualified person under the supervision of an authorized user, after administering a teletherapy dose fraction, make, date, and sign or initial a written record in the patient's chart or in another appropriate record that contains for each treatment field, the treatment time, dose administered, and the cumulative dose administered. (TRS SOP #: 500, para 3.C.19, 3.C.20, 3.C.23)

(7) Have a weekly chart check performed by a qualified person under the supervision of an authorized user to detect mistakes that may have occurred in the daily and cumulative teletherapy dose administrations from all treatment fields or in connection with any changes in the written directive or plan of treatment. (TRS SOP #: 500, para 3.C.21)

(8) If the prescribed dose is to be administered in more than three fractions, have the dose calculations checked within three working days after administering the first teletherapy fractional dose. An authorized user or a qualified person under the supervision of an authorized user, who whenever possible did not make the original calculations, should check the dose calculations. If the prescribed dose is to be administered in three fractions or less, the dose calculations should be checked before administering the first teletherapy fractional dose. (TRS SOP #: 500, para 3.C.4, 3.C.8, 3.C.20)

(9) After full calibration measurements have been done, have an independent check performed on some of the full calibration measurements. This independent check should be performed within 30 days following such full calibration measurements. (TRS SOP #: 501, para 4.E)

(10) Have full calibration measurements include the determination of transmission factors of trays and wedges. Transmission factors for other beam-modifying devices should be determined before the first medical use of the beam-modifying device and after replacement of the source. (TRS SOP #: 501, para 4.D)

(11) Have a physical measurement of the teletherapy output made under applicable conditions prior to administration of the first teletherapy fractional dose if the patient's plan of treatment includes (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration or (2) transmission factors for beam-modifying devices not measured in the most recent full calibration. (TRS SOP #: 501, para 4.A, 4.B, 4.C)

(12) If the authorized user determines that delaying treatment to perform the checks of (1) dose calculations for a prescribed dose that is administered in three fractions or less or (2) teletherapy output would jeopardize the patient's health because of the emergent nature of 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 should make a notation of this determination in the records of the calculated administered dose. The checks of the calculations should be performed within two working days of treatment completion. (TRS SOP #: 500, 2.B.6.^ 2.B.6.B, 2.C.15)

(13) Have acceptance testing performed by a qualified person on each treatment planning or dose calculating computer program that could be used for teletherapy dose calculations. (TRS SOP # 500, para 3.C.8, 3.C.10)

(14) Perform periodic reviews of the teletherapy Qualitative Management program. (TRS SOP #: 500, para 2.B.1, 2.B.2, 2.B.7, 2.B.8)

Brachytherapy Applications

c. The Therapeutic Radiology Service (TRS) will:

(1) Have an authorized user date and sign a written prescription prior to the administration of any brachytherapy dose. (TRS SOP #: 500, para 3.C.8)

(2) Before administering a brachytherapy dose, verify by more than one method the identity of the patient as the individual named in the written prescription. The procedure used to identify the patient should be to: (TRS SOP #: 500, para 3.C.11)

(a) Ask the patient's name, and

(b) Confirm the name and at least one of the following by comparison with the corresponding information in the patient's records:

(1) Birth date,

(2) Address,

(3) Social Security Number,

(4) Signature,

(5) Name on the patient's ID bracelet or hospital ID card,

(6) Name on the patient's medical insurance card, or

(7) Photograph of the patient's face.

(3) Before administering the brachytherapy dose, verify that the specific details of the brachytherapy administration are in accordance with the written prescription and plan of treatment. In particular, the radioisotope, number of sources, and source strengths should be confirmed to verify agreement with the written prescription and plan of treatment. (TRS SOP #: 500, para 3.D.1, 3.D.2)

(4) Have workers seek guidance if they do not fully understand how to carry out the written prescription. (TRS SOP #: 500, para 3.C.13)

(5) Have an authorized user or a qualified person under the supervision of an authorized user verify 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 prescription and plan of treatment before implanting the radioactive sealed sources. (TRS SOP #: 500, para 3.D.12)

(6) For temporary brachytherapy implants, use radiographs or other comparable images of brachytherapy radioactive sources or nonradioactive 'dummy' sources in place as the basis for verifying the position of the sources and calculating the exposure time (or, equivalently, the total dose). (TRS SOP #: 500, para 3.D.10, 3.E.8)

(7) For permanent brachytherapy implants, use radiographs or other comparable images of brachytherapy radioactive sources in place as the basis for verifying the position of the sources and calculating the total dose, if applicable, after inserting the sources. (TRS SOP #: 500, para 3.F.10, 3.F.11)

(8) After insertion of the temporary implant brachytherapy sources, have an authorized user promptly record the actual loading sequence of the radioactive sources implanted and sign or initial the patient's chart or other appropriate record. (TRS SOP #: 500, para 3.D.11, 3.D.12, 3.D.13, 3.E.14)

(9) After insertion of the permanent implant brachytherapy sources, have an authorized user promptly record the actual number of radioactive sources implanted, and sign or initial the patient's chart or other appropriate record. (TRS SOP #: 500, para 3.E.14, 3.F.9)

(10) Have the dose calculations checked before the total prescribed brachytherapy dose has been administered. An authorized user or a qualified person under the supervision of an authorized user, who whenever possible did not make the original calculations, should check the dose calculations. (TRS SOP #: 500, para 3.C.4, 3.C.8, 3.C.20)

(11) Have an authorized user date and sign or initial a written record in the patient's chart or in another appropriate record after insertion of the brachytherapy sources but prior to completion of the procedure. The written record should include the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose). (TRS SOP #: 500, para 2.C.15, 3.D.13, 3.E.14, 3.F.9)

(12) If the authorized user determines that delaying treatment in order to perform check 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 completion of the brachytherapy treatment. (TRS SOP #: 500, para 2.B.6.A, 2.B.6.B, 2.C.15)

(13) Have acceptance testing by a qualified person on each treatment planning or dose calculating computer program that could be used for brachytherapy dose calculations. (TRS SOP #: 500, para 3.C.8)

(14) Perform periodic reviews of the brachytherapy Qualitative Management program. (TRS SOP #: 500, para 2.B.1, 2.B.2, 2.B.7, 2.B.8)

Radiation Protection Activities

d. The Radiation Protection Office (RPO) will:

(1) Ensure that the requirements listed FAMC Regulation 40-504, Chapter 16, are complied with.

(2) Regularly review the findings of the periodic reviews to ensure that the Qualitative Management program is effective and present the findings to the members of the Radiation Protection Committee.

(3) Reevaluate the Qualitative Management program's policies and procedures after each annual review during the scheduled Radiation Protection Committee meeting in the 1st Quarter of the calendar year.

JOHN P. PETERSEN
MAJ, MC
C, Therapeutic Radiology Service

PETER W. BLUE
COL, MC
C, Nuclear Medicine Service

CHRISTOPHER J. CLAYTON
1LT, MS
Radiation Protection Officer

EDWIN M. HEALEY
COL, MC
Deputy Commander for Clinical Services

MARVIN E. HILL
COL, MC
C, Department of Radiology