PUBLIC / PDR

Environmental Health & Safety
University of Missouri-Columbia

Research Park Development Building
Columbia, MO 65211-3050
PHONE (573) 882-7018
FAX [573] 882-7940

HAZARDOUS WASTE MANAGEMENT	882-7018
INDUSTRIAL HYGIENE SERVICES	882-7018
RADIATION SAFETY OFFICE	882-7221
WORKERS' COMPENSATION	882-7019

July 14, 1997

U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60632-4351

Attn: Cassandra Frazier

RE: License No. 24-00513-32
Docket No. 030-02278

Subject: Submittal of Revised Quality Management Program for the University of Missouri-Columbia

Dear Ms. Frazier:

Enclosed is Revision 2 of the Quality Management Program (QMP) for the University of Missouri-Columbia. Modification to our Program was made as part of the University's review of its radiation safety program. The modification consists of wording changes and rearrangement of some sections to make the document more understandable.

A copy of this QMP revision is being furnished to you in accordance with 10CFR35.32(e). If you have any questions on the revision you may call me at (573) 882-7221.

Sincerely,

Susan M. Langhorst

Susan M. Langhorst, Ph.D., CHP
Radiation Safety Officer

Enclosure: as described

cc: W.H. Miller
J.K. Jones
J.P. McCormick
J.L. Beckett

Pm: 7-16-97

ML
31 DH

QUALITY MANAGEMENT PROGRAM
Medical Uses of Byproduct Materials

A. Use of Radiopharmaceuticals

The following are policies and procedures to be followed in the administration to patients of therapeutic radiopharmaceuticals, or doses of I-125 or I-131 sodium iodide over 30 microcuries. If the person assigned to do any or all of the preparation and/or administration of radiopharmaceuticals does not understand any portion of a written directive, or a diagnostic procedure as approved by an authorized nuclear medicine physician, they are to stop and ask sufficient questions to adequately clarify the radiopharmaceutical, dose, route of administration, patient identify, and any related details before proceeding with the procedure.

1. Written Directives for Therapeutic Radiopharmaceuticals, and Doses of I-125 or I-131 Sodium Iodide over 30 microcuries

A written directive which identifies the patient, radiopharmaceutical, dose and route of administration shall be signed and dated by an authorized nuclear medicine physician prior to preparation or administration of any therapeutic radiopharmaceutical, or doses of I-125 and I-131 sodium iodide over 30 microcuries. Procedures for emergency oral directives (approved nuclear medicine consult), and revisions to written directives are given in a footnote to 10 CFR 35.32(a)(1).

Records will be retained of written directives and administration of radiopharmaceutical dosage for a period of three years after the date of administration, as set forth in 10 CFR 35.32(d). For each recordable event, the following records shall be kept in an auditable form for a period of three years: (a) facts describing the event and the cause; and (b) description of what, if any, corrective actions were required to prevent recurrence.

2. Patient Identification

Prior to administering the radiopharmaceutical, the person who is to administer the radiopharmaceutical will verify the identity of the patient in the written directive by at least two methods. The patient should be asked what is their name, if possible; other methods of identification that can be used are recorded birth date, social security number, ID bracelet, other hospital identification, address, or personal knowledge of the physician.

3. Verification of Dose Prior to Administration

Prior to administering the radiopharmaceutical, the person who will do the administration is to verify that the details of the administration are in accordance with the written

directive (or approved nuclear medicine consult). In addition to verifying the patient's identity, the radiopharmaceutical, dose (activity), and the route of administration are to be verified to be in agreement with the written directive, or with the oral revision made by the authorized nuclear medicine physician's [written directive or revision of written directive must be obtained in accordance with 10 CFR 35.32(a)(1), footnote 1]. The radiopharmaceutical photon activity is to be measured in a dose calibrator, and the results recorded and compared to the written directive.

4. Documentation of Administered Dose

The authorized physician, or a qualified individual under supervision of an authorized physician (nuclear medicine physician, physicist or technologist), shall make a record of the administration. The record will include the date, patient's name, radiopharmaceutical dose, and signature or initials of the person administering the dose. The administration record is included on the same form with the written directive, and is available for audit. This form will include the following statement, or equivalent: "Retain record for three years following administration, as required by 10 CFR 35.32(d)."

B. Brachytherapy Procedures

The following are policies and procedures to be followed in the use of radiation from brachytherapy sources for patient procedures. The use of sealed radioactive sources for brachytherapy procedures may involve one or more qualified persons (radiation therapy physicist, radiation therapy technologist, dosimetrist, oncology physician) working under the supervision of an authorized physician. Prior to the delivery of radiation from any brachytherapy source to a patient, there must be a written directive, see paragraph below. If at any point a supervised worker does not understand how to carry out the written directive, they are to stop and ask sufficient questions to clarify the procedures described in the written directive.

1. Written Directives

Prior to any administration of radiation from brachytherapy sources, an authorized physician will date and sign a written directive and a treatment plan for the procedure. The written directive will include the patient's name, treatment site, radionuclide, number and sequence of sources, source strength, and total radiation to be delivered to the target area, and for temporary implants, the date and time for removal of the sources. Procedures for emergency oral directives and revisions to written directives are given in a footnote to 10 CFR 35.32(a)(1).

Records of written directives and administration of each administered dose will be retained for a period of three years after the date of administration, as set forth in 10 CFR 35.32(d). For each recordable event, the following records shall be kept in an auditable form for

a period of three years: (a) facts describing the event and the cause; and (b) description of what, if any, corrective actions were required to prevent recurrence.

2. Patient Identification

Before administering a brachytherapy dose, at least two methods will be used to verify that the patient is the individual named in the written directive. The patient should be asked their name if possible. Other identification methods that may be used include birth date, address, social security number, name on patient's ID bracelet or hospital card, name on the patient's medical insurance card, or the photograph of the patient's face made during the examination and planning portion of the patient's radiation therapy care.

3. Verification of Brachytherapy Plan of Administration

Before brachytherapy radioactive sources are administered, a qualified person such as a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist, working under the supervision of an authorized physician will verify that the radioisotope, number of sources, and source strengths of the brachytherapy sources described in the plan of treatment are in agreement with the written directive. The person verifying agreement between the plan of treatment and the written directive will sign or initial and date the plan of treatment.

4. Checking Brachytherapy Dose Calculations

a. Before the total prescribed brachytherapy dose has been administered, an authorized physician or a qualified person such as a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist, under the supervision of an authorized physician, will check the dose calculations for the brachytherapy procedure. Whenever possible, this will not be the same person who made the original calculations. Manual dose calculations will be checked for:

i. arithmetic errors;
ii. appropriate transfer of data from the written directive, plan of treatment, tables, and graphs;
iii. appropriate use of nomograms;
iv. appropriate use of all pertinent data in the calculations.

b. If available, printouts from computer-generated dose calculations will be checked to verify the correct data were used in the calculations, including position of the applicator or sealed sources, isotope, number of sources, total source strength, or source loading sequence. Checking may also use manual calculation of a radiation dose to a single key point,

with comparison to the computer generated dose calculations. In the cases where radiation doses are calculated during a combination of computer generated output and manual calculation, verifying will include checking that the correct output from one type of calculation is properly used as the input for the other type of calculation.

5. Verification of Brachytherapy Source Administration

Prior to administering brachytherapy sources, a qualified person, such as a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist, under the supervision of an authorized physician will verify that the radioisotopes, 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. The verification method will be appropriate to the sources used, and may include checking the serial number of sealed sources behind an appropriate shield, using a dose calibrator, observing color codes on the sources, monitoring radiation output of the sources with a radiation detector, or using clearly marked storage locations where separate storage areas are used for different source strengths.

6. Temporary Brachytherapy Source Position and Exposure Time Verification

For temporary brachytherapy implants, the position of the sources will be verified using x-ray imaging procedures. When possible, the x-ray imaging will be done with "dummy" sources before the radioactive sources are inserted. These x-ray images of source position will be used to calculate the exposure time needed to achieve the prescribed radiation doses, or to calculate the total dose. In the cases where fixed geometry applicators, appliances or templates are used to calculate an exposure time or total dose, x-ray imaging of the source positions is not mandatory. Immediately after implanting sources in the patient, survey of the patient and the surrounding area will be made to confirm no sources are unintentionally misplaced outside of the patient. Daily surveys of the patient and the surrounding area will be made to confirm that no sources have subsequently become misplaced outside of the patient.

7. Recording Application of Temporary Brachytherapy Implant Sources

After insertion of temporary implant brachytherapy sources, an authorized physician will promptly record the actual loading sequence of the radioactive sources implanted, including the location of each sealed source in the tube, tandem, or cylinder. This record will be in the patient's chart or other appropriate record, and will be signed or initialed by the authorized physician.

After insertion of the brachytherapy sources, but prior to completion of the procedure, an authorized physician will date and sign or initial a written record. This written record will include the radioisotope, treatment site, and total source strength and exposure time

(or total dose). The administration record is included on the same form with the written directive, and is available for audit. This form will include the following statement, or equivalent: "Retain record for three years following administration, as required by 10 CFR 35.32(d)."

8. Permanent Brachytherapy Source Position and Total Dose Verification

For permanent brachytherapy implants, x-ray imaging of the sources in place will be performed as a basis for verifying the position of the source and calculating the total dose. If applicable, this x-ray imaging will be done after inserting the sources into the patient. In cases where fixed geometry applicators or templates are used, x-ray imaging of the source positions in the patient is not mandatory. Immediately after implanting sources in the patient, survey of the patient and the surrounding area will be made to confirm no sources are unintentionally located outside of the patient.

9. Recording Application of Permanent Brachytherapy Implant Sources

After insertion of permanent implant brachytherapy sources, an authorized physician will record in the patient's chart or other appropriate record the actual number of radioactive sources implanted. This will be signed or initialed by the authorized physician.

After insertion of the brachytherapy sources, but prior to completion of the procedure, an authorized physician will date and sign or initial a written record. This written record will include the radioisotope, treatment site, and total source strength and exposure time (or total dose). The administration record is included on the same form with the written directive, and is available for audit. This form will include the following statement, or equivalent: "Retain record for three years following administration, as required by 10 CFR 35.32(d)."

10. Brachytherapy for Emergency Medical Conditions

If an authorized physician determines that delaying brachytherapy 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 will be performed within two working days of completion of the brachytherapy treatment.

11. Acceptance Testing of Brachytherapy Dose Planning Computer Programs

Before the first use of treatment planning or dose calculating computer programs for brachytherapy dose calculations, acceptance testing of the programs will be performed by a qualified person. The functions of the computer programs evaluated during acceptance testing

will include the dose and spatial accuracy of calculations in tissue for at least those brachytherapy procedures clinically performed by authorized physicians under this license.

C. Periodic Review of Medical Uses of Byproduct Materials

Any modification to the Quality Management Program will be submitted to the NRC within 30 days after the modification has been made, as set forth in 10 CFR 35.32(e).

1. Radiopharmaceuticals

a. For therapeutic doses of radiopharmaceuticals, or doses of I-125 or I-131 sodium iodide over 30 microcuries, a minimum of 75% of the total number of administrations will be reviewed on at least a 12-month interval to determine accordance with the written directive for a patient. The review will include the radiopharmaceutical use, dose administered, and route of administration. This review will be performed by a health physicist, medical physicist, or other qualified person.

b. For each patient radiopharmaceutical administration reviewed, deviations from the written directive will be identified which are recordable events, or misadministrations. If these deviations have not previously been identified and acted upon, the actions required in 10 CFR 35.32(c) and 10 CFR 35.33 will be taken. This will include assembling the factors surrounding each deviation, organizing and retaining required records, and determining and initiating corrective action to prevent recurrence. In the case of misadministration, the NRC will be notified as required.

c. The results of these reviews will be reported at the meetings of the Medical Use Quorum of the Radiation Safety Committee for discussion and evaluation.

d. The function and effectiveness of the Radiopharmaceutical Quality Management program will be reviewed annually by the Medical Use Quorum of the Radiation Safety Committee (10 CFR 35.22). The Quorum will evaluate the program for changes or additions that would make the program more effective or more efficient. Documentation of reviews and annual evaluations of the Radiopharmaceutical Quality Management Program will be maintained for three years as required in 10 CFR 35.32 (b)(3).

2. Brachytherapy

a. A minimum of 75% of the total number of brachytherapy administrations will be reviewed on at least a 12-month interval to determine accordance with the written directive for each patient. The review will include the radioisotope, number of sources, and

source strengths as documented prior to implantation. The review will verify that proper documentation was performed after implantation prior to completion of the procedure. Documentation must properly record: the radioisotope; a treatment site; and total source strength and exposure time, or the equivalent total dose. This review will be performed by a health physicist, medical physicist, or other qualified person.

b. For each patient brachytherapy administration reviewed, deviations from the written directive will be identified which are recordable events, or misadministrations. If these deviations have not previously been identified, and acted upon, then the actions required in 10 CFR 35.32(c) and 10 CFR 35.33 will be taken. This will include assembling the factors surrounding each deviation, organizing and retaining required records, and determining and initiating corrective action to prevent recurrence. In the case of misadministrations, the NRC will be notified as required,

c. The results of these reviews will be forwarded to the Radiation Safety Office and reported at the meetings of the Medical Use Quorum of the Radiation Safety Committee for discussion and evaluation.

d. The function and effectiveness of the Brachytherapy Quality Management Program will be reviewed annually by the Medical Use Quorum of the Radiation Safety Committee (10 CFR 35.22). The Committee will evaluate the program for changes or additions that would make the program more effective or more efficient. Documentation of reviews and annual evaluations of the Brachytherapy Quality Management Program will be maintained for three years as required in 10 CFR 35.32 (b)(3).