NOTICE OF VIOLATION

Hurley Medical Center
Flint, Michigan

License No. 21-00338-02
Docket No. 030-01993

During an NRC inspection conducted from March 1, through March 14, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

1. 10 CFR 35.32(a)(1) requires, in part that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the specific objectives that: (1) prior to administration, a written directive is prepared for any brachytherapy, or administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, or any therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131; (2) prior to each administration, the patient's identity is verified by more than one method; (3) final plans of treatment and related calculations for brachytherapy are in accordance with the written directive; (4) each administration is in accordance with the written directive; and (5) any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

   Contrary to the above, between January 8, 1992, and March 1, 1994, the licensee did not establish and maintain a written quality management program to provide high confidence that byproduct material would be administered as directed by the authorized user.

   This is a Severity Level IV violation (Supplement VI)

2. 10 CFR 35.32(b) requires, in part, that the licensee develop procedures for and conduct a review to verify compliance with all aspects of the quality management program at intervals no greater than 12 months.

   Contrary to the above, as of January 8, 1992 the licensee had not developed procedures for conducting a review to verify compliance with the licensee's quality management program.

   This is a Severity Level IV violation (Supplement VI)

3. 10 CFR 35.22(b)(6) requires that, to oversee the use of licensed material, the Radiation Safety Committee must review annually, with the assistance of Radiation Safety Officer, the radiation safety program.

   Contrary to the above, from February 27, 1992 until March 1, 1994, the licensee's Radiation Safety Committee did not review, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program.

   This is a Severity Level IV violation (Supplement VI).

4. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

   Contrary to the above, from at least February 27, 1992 to March 2, 1994, the licensee did not survey with a radiation detection survey instrument the radioactive waste storage room, an area where radiopharmaceutical waste is stored.

   This is a Severity Level IV violation (Supplement VI).

5. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

   Contrary to the above, from at least February 27, 1992 to March 2, 1994, the licensee did not survey for removable contamination in the radioactive waste storage room, an area where radiopharmaceuticals were routinely stored.

   This is a Severity Level IV violation (Supplement VI).

6. 35.70(h) requires in part that a record of each survey be made that includes the trigger level established for each area.

   Contrary to the above, no trigger level was indicated on the records of contamination surveys that were made since at least February 27, 1992.

   This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, University of Michigan is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois, 60532, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

APR 13 1994
Dated

Roy J. Caniano, Chief
Nuclear Materials Safety Branch

Enclosure 2

During this inspection, the inspector identified that the quality management program you submitted in January 8, 1992, did not provide the essential elements of policies/procedures that indicate how you will meet the objectives listed in 10 CFR 35.32. Please provide policies and procedures that will meet the requirements for each modality of use.

1. You must have policies and procedures that require the preparation of written directives prior to the administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131 (10 CFR 35.32(a)(1)). The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user. Your QMP must include a written policy that requires that such a written directive be prepared prior to each patient administration.

2. Your written directive for radiopharmaceutical therapy for a radiopharmaceutical other than sodium iodide I-125, or I-131 does not include the radiopharmaceutical, the dosage, and the route of administration as defined in 10 CFR 35.2.

3. 10 CFR 35.32(a)(1) requires that QMPs for brachytherapy include a procedure for the preparation of written directives prior to administration of any brachytherapy dose. The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user. Your QMP must include a written policy that requires that such a written directive be prepared for each patient.

4. Written directives for brachytherapy, other than high-dose-rate remote afterloading brachytherapy, as defined in 10 CFR 35.2, must include:

   a. Prior to implantation: the radioisotope, number of sources, and source strengths; and

   b. 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).

   Your QMP must include a written policy/procedure that requires that any written directives for brachytherapy doses will include all treatment parameters prior to administration.

5. Written directives for high-dose-rate remote afterloading brachytherapy must include the total dose, dose per fraction, treatment site and overall treatment period as defined in 10 CFR 35.2. Your QMP must include a written policy/procedure that requires that all written directives for brachytherapy doses at your facility will include all treatment parameters prior to administration.

6. Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage. Your QMP should include a policy/procedure that requires that revisions to written directives will be made prior to administration.

7. Revisions to written directives for brachytherapy may be made provided that the revision is dated and signed by an authorized user prior to the administration of the brachytherapy dose or the next brachytherapy fractional dose. Your QMP should include a policy/procedure that requires that revisions to written directives will be made prior to administration of the brachytherapy dose, or the next brachytherapy fractional dose.

8. Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2) have not been adequately addressed in your QMP. Your QMP must include a policy/procedure to require that, prior to each brachytherapy or radiopharmaceutical administration, the patient's identity will be verified by more than one method as the individual named in the written directive as required by 10 CFR 35.32(a)(2).

9. Your submittal does not include adequate policies/procedures that ensure that final plans of treatment and related calculations for brachytherapy are in accordance with the written directive as required by 10 CFR 35.32(a)(3). Your procedures should include:

   a. a plan of treatment will be prepared in accordance with the respective written directive.

   b. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations)

   c. verification of the position of dummy sources or fixed geometry applicators prior to inserting sealed sources,

   d. performance of acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations, and checking computer generated dose calculations

10. Your submittal for radiopharmaceutical administration does not include adequate policies/procedures to ensure that each administration is in accordance with the written directive as required by 10 CFR 35.32(a)(4). Describe your policy/procedure to verify, before administering the byproduct material, that the specific details of the administration are in accordance with the written directive. The radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive.

11. Your submittal for brachytherapy does not include adequate policies/procedures to ensure that each administration is in accordance with the written directive. Your procedures should include:

    a. verification, before administering each brachytherapy dose, that the specific details of the administration are in accordance with the written directive and plan of treatment. The prescribed radioisotope, number of sources, source strengths, treatment site, loading sequence, and total dose should be confirmed by the person administering the brachytherapy treatment to verify agreement with the written directive and treatment plan.

    b. procedures for checking the dose calculations before administration of the prescribed brachytherapy dose. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations, should check the dose calculations.

    c. prompt recording, by the authorized user, of the number of sources, the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder) and sign or initial the patient's chart or appropriate record, and the method for verification that the sources have been loaded in the correct position.

12. Your QMP must include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive.

13. A commitment to maintain a written record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d)(2). Describe the procedure for an authorized user or a qualified individual under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist, or technologist), after administering a radiopharmaceutical, to make, date, sign or initial a written record that documents the administered dosage in the patient's chart or other appropriate record.

14. Your QMP must include a commitment to maintain a written record of each administered radiation dose for three years after the date of administration as required in 10 CFR 35.32(d)(2). Your QMP should describe the procedure for a qualified individual under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist), after administering a dose or dose fraction, to make a written record. Your procedure should describe what this record will include.

15. Your QMP for brachytherapy and radiopharmaceutical therapy must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5).

16. Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified.

17. Your submittal for brachytherapy and radiopharmaceutical therapy does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). Your procedure should include the time intervals for your reviews (in months) and describe your representative sample. These reviews should be conducted at intervals no greater than 12 months. Program reviews must include an evaluation of a representative sample of all patient administrations, and should include all recordable events and misadministrations. Your QMP review should include provisions to expand the review in the event that unidentified reportable events or misadministrations are found. Your QMP should describe your procedure for evaluating each of these reviews, and for making modifications to meet the objective of the QMP. Regulatory Guide 8.33, Section 6 (enclosed) may be of help in developing procedures for review of your QMP.

18. Your QMP must include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP.

19. Your QMP must include procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2).

20. Please include a provision to submit modifications to your QMP to the NRC within 30 days after the modification has been made.

21. Your QMP must include assurance that records of each review and evaluation must be maintained for three years.

22. Multiple misadministrations and other errors have occurred due to sources that are inaccurately placed or have moved. In addition, wrong organs have been irradiated as a result of unintentional and undetected movement of the source, once implanted. Each licensee should review their procedures to ensure that source positions are verified and frequently checked.

Your response to Violations 1. and 2. of the attached Notice of Violation must include the information requested above.

U.S. NUCLEAR REGULATORY COMMISSION

October 1991

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.33
(Task DG-8001)

QUALITY MANAGEMENT PROGRAM

USNRC REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience.

Written comments may be submitted to the Regulatory Publications Branch, DFIPS, ARM, U.S. Nuclear Regulatory Commission, Washing-

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A. INTRODUCTION

According to § 35.32, "Quality Management Program," of 10 CFR Part 35, "Medical Use of Byproduct Material," applicants or licensees, as applicable, are required to establish a quality management (QM) program. This regulatory guide provides guidance to licensees and applicants for developing policies and procedures for the QM program. This guide does not restrict or limit the licensee from using other guidance that may be equally useful in developing a QM program, e.g., information available from the Joint Commission on Accreditation of Healthcare Organizations or the American College of Radiology.

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Part 35, which provides the regulatory basis for this guide. The information collection requirements in 10 CFR Part 35 have been cleared under OMB Clearance No. 3150–0010.

B. DISCUSSION

The administration of byproduct material can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department when the authorized user prescribes a teletherapy treatment, the delivery process may involve a team of medical professionals such as a radiation therapy physicist, dosimetrist, and radiation therapy technologist. Conducting the plan of treatment may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam-modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures.

The administration of byproduct material or radiation from byproduct material can involve a number of treatment modalities, e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, or gamma stereotactic radiosurgery. For each modality, this regulatory guide recommends specific policies or procedures to ensure that the objectives of 10 CFR 35.32 are met. In general, this guide recommends that licensees have:

- Policies to have an authorized user date and sign a written directive prior to the administration,
- Procedures to identify the patient by more than one method,
- Procedures to be sure the plans of treatment are in accordance with the written directive,
- Procedures to confirm that, prior to administration, the person responsible for the treatment modality will check the specific details of the written directive (e.g., in radiopharmaceutical therapy, verify the radiopharmaceutical, dosage, and route of administration; or in oncology, verify the treatment site, total dose, dose per fraction, and overall treatment period),
- Procedures to record the radiopharmaceutical dosage or radiation dose actually administered.

C. REGULATORY POSITION

This regulatory guide provides guidance to licensees and applicants for developing a quality management program acceptable to the NRC staff for complying with 10 CFR 35.32. However, a licensee or applicant may use other sources of guidance and experience in addition to or in lieu of this regulatory guide. The NRC staff would review such a program on a case-by-case basis.

The licensee's QM program should contain the essential elements of the policies and procedures listed in the following sections.

1. SUGGESTED POLICIES AND PROCEDURES FOR CERTAIN RADIOPHARMACEUTICAL USES

1.1. The licensee should establish a policy to have an authorized user date and sign a written directive 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. A written directive is required by 10 CFR 35.32(a)(1). Procedures for oral directives and revisions to written directives are contained in Regulatory Position 5.

1.2. Before administering a radiopharmaceutical dosage, the licensee should establish a procedure to verify by more than one method the identity of the patient as the individual named in the written directive. Identifying the patient by more than one method is required by 10 CFR 35.32(a)(2). The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, or the name on the patient's medical insurance card.

1.3. The licensee should establish a procedure to verify, before administering the byproduct material, that the specific details of the administration are in accordance with the written directive. The radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical to verify agreement with the writ-

ten directive, that is, the dosage should be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive.

1.4. The licensee should establish a policy for all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

1.5. The licensee should establish a procedure to have an authorized user or a qualified person under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist, or technologist), after administering a radiopharmaceutical, make, date, and sign or initial a written record that documents the administered dosage in the patient's chart or other appropriate record. The responsibilities and conditions of supervision are contained in 10 CFR 35.25. A record of the administered dosage is required by 10 CFR 35.32(d)(2).

1.6. The licensee should establish procedures to perform periodic reviews of the radiopharmaceutical QM program. Guidance on periodic reviews is provided in Regulatory Position 6. A QM program review is required by 10 CFR 35.32(b).

2. SUGGESTED POLICIES AND PROCEDURES FOR TELETHERAPY

2.1. The licensee should establish a policy to have an authorized user date and sign a written directive prior to the administration of any teletherapy dose. A written directive is required by 10 CFR 35.32(a)(1). Procedures for oral directives and revisions to written directives are contained in Regulatory Position 5.

2.2. Before administering a teletherapy dose, the licensee should establish a procedure to verify by more than one method the identity of the patient as the individual named in the written directive. Identifying the patient by more than one method is required by 10 CFR 35.32(a)(2). The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, or the photograph of the patient's face.

2.3. The licensee should establish a policy to have an authorized user approve a plan of treatment that provides sufficient information and direction to meet the objectives of the written directive. Suggested guidelines for information to be included in the plan of treatment may be obtained from the American College of Radiology.

2.4. The licensee should establish a procedure to verify, before administering each teletherapy dose, that the specific details of the administration are in accordance with the written directive 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 directive and plan of treatment.

2.5. The licensee should establish a policy for all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

2.6. The licensee should establish a procedure to have a qualified person under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist), 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. The responsibilities and conditions of supervision are contained in 10 CFR 35.25. A record of the administered dose is required by 10 CFR 35.32(d)(2).

2.7. The licensee should establish a procedure to have a weekly chart check performed by a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, dosimetrist, oncology physician, or radiation therapy technologist) to detect mistakes (e.g., arithmetic errors, miscalculations, or incorrect transfer of data) 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. The responsibilities and conditions of supervision are contained in 10 CFR 35.25.

2.8. If the prescribed dose is to be administered in more than three fractions, the licensee should establish a procedure to check the dose calculations 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 (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), 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, a procedure for checking dose calculations as described in this paragraph should be performed before administering the first teletherapy

fractional dose. The responsibilities and conditions of supervision are contained in 10 CFR 35.32.

Manual dose calculations should be checked for:

(1) Arithmetic errors,

(2) Appropriate transfer of data from the written directive, plan of treatment, tables, and graphs,

(3) Appropriate use of nomograms (when applicable), and

(4) Appropriate use of all pertinent data in the calculations.

Computer-generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations (e.g., patient contour, patient thickness at the central ray, depth of target, depth dose factors, treatment distance, portal arrangement, field sizes, or beam-modifying factors). Alternatively, the dose should be manually calculated to a single key point and the results compared to the computer-generated dose calculations.

If the manual dose calculations are performed using computer-generated outputs or vice versa, particular emphasis should be placed on verifying the correct output from one type of dose calculation (e.g., computer) to be used as an input in another type of dose calculation (e.g., manual). Parameters such as the transmission factors for wedges and the source strength of the sealed source used in the dose calculations should be checked.

2.9. The licensee should establish a procedure for independently checking certain full calibration measurements as follows:

After full calibration measurements that resulted from replacement of the source, or whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay, an independent check of the output for a single specified set of exposure conditions should be performed. The independent check should be performed within 30 days following such full calibration measurements.

The independent check should be performed by either:

(1) An individual who did not perform the full calibration (the individual should meet the requirements specified in 10 CFR 35.961) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system should meet the requirements specified in 10 CFR 35.630(a)), or

(2) A teletherapy physicist (or an oncology physician, dosimetrist, or radiation therapy technologist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming teletherapy doses and that is accurate within 5 percent.

2.10. The licensee should establish a procedure to have full calibration measurements (required by 10 CFR 35.632) include the determination of transmission factors for trays and wedges. Transmission factors for other beam-modifying devices (e.g., nonrecastable blocks, recastable block material, bolus and compensator materials, and split-beam blocking devices) should be determined before the first medical use of the beam-modifying device and after replacement of the source.

2.11. The licensee should establish a procedure to 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 (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.

2.12. 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 (see Regulatory Position 2.8) or (2) teletherapy output (see Regulatory Position 2.11) 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 completion of the treatment.

2.13. The licensee should establish a procedure for performing acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program that could be used for teletherapy dose calculations. Acceptance testing should be performed before the first use of a treatment planning or dose calculating computer program for teletherapy dose calculations. Acceptance testing should also be performed after full calibration measurements when the calibration was performed (1) before the first medical use of the teletherapy unit, (2) after replacement of the source, or (3) when spot-check measurements indicated that the output differed by more than 5 percent from the output obtained at the last full calibration corrected

mathematically for radioactive decay. Computer-generated beam data should be compared to measured beam data from the teletherapy unit. The licensee should assess each treatment planning or dose calculating computer program based on the licensee's specific needs and applications.

2.14 The licensee should establish procedures to perform periodic reviews of the teletherapy QM program. Guidance on periodic reviews is provided in Regulatory Position 6. A QM program review is required by 10 CFR 35.32(b).

3. SUGGESTED POLICIES AND PROCEDURES FOR BRACHYTHERAPY

3.1 High-Dose-Rate Remote Afterloading Devices

Similar licensee policies and procedures for low- and medium-dose-rate remote afterloading devices would be equally helpful.

3.1.1. The licensee should establish a policy to have an authorized user date and sign a written directive prior to the administration of any brachytherapy dose from a high-dose-rate remote afterloading device. A written directive is required by 10 CFR 35.32(a)(1). Procedures for oral directives and revisions to written directives are contained in Regulatory Position 5.

3.1.2. Before administering a brachytherapy treatment, the licensee should establish a procedure to verify by more than one method the identity of the patient as the individual named in the written directive. Identifying the patient by more than one method is required by 10 CFR 35.32(a)(2). The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, or the photograph of the patient's face.

3.1.3. The licensee should establish a procedure to verify, before administering the brachytherapy dose, that the specific details of the brachytherapy administration are in accordance with the written directive and plan of treatment. The prescribed radioisotope, treatment site, and total dose should be confirmed by the person administering the brachytherapy treatment to verify agreement with the written directive and plan of treatment.

3.1.4. The licensee should establish a policy for all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

3.1.5. The licensee should establish a procedure for using radiographs or other comparable images (e.g., computerized tomography) as the basis for verifying the position of the nonradioactive "dummy" sources and calculating the administered brachytherapy dose before inserting the sealed sources.*

3.1.6. The licensee should establish a procedure to check the dose calculations before administering the prescribed brachytherapy dose. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations, should check the dose calculations. The responsibilities and conditions of "supervision" are contained in 10 CFR 35.25. Suggested methods for checking the calculations include the following:

- Computer-generated dose calculations should be checked by examining the computer printout to verify that correct input data for the patient were used in the calculations (e.g., source strength and positions).
- The computer-generated dose calculations for input into the brachytherapy afterloading device should be checked to verify correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).

3.1.7. The licensee should establish a procedure to have an authorized user, after administering the brachytherapy treatment, date and sign or initial a written record of the calculated administered dose in the patient's chart or in another appropriate record. A record of the administered dose is required by 10 CFR 35.32(d)(2).

3.1.8. If the authorized user determines that delaying treatment in order to perform the checks of dose calculations (see Regulatory Position 3.1.6) 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 the treatment.

3.1.9. The licensee should establish a procedure for performing acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program that could be used for brachytherapy dose calculations when using high-dose-rate remote afterloading devices. Acceptance testing should be performed before the first use of a treatment planning or dose calculat-

*The term sealed sources includes wires and encapsulated sources.

ing computer program for brachytherapy dose calculations when using high-dose-rate remote afterloading devices. The licensee should assess each treatment planning or dose calculating computer program based on the licensee's specific needs and applications.

3.1.10. The licensee should establish procedures to perform periodic reviews of the brachytherapy QM program for using the high-dose-rate remote afterloading device. Guidance on periodic reviews is provided in Regulatory Position 6. A QM program review is required by 10 CFR 35.32(b).

3.2. All Other Brachytherapy Applications

3.2.1. The licensee should establish a policy to have an authorized user date and sign a written directive prior to the administration of any brachytherapy dose. A written directive is required by 10 CFR 35.32(a)(1). Procedures for oral directives and revisions to written directives are contained in Regulatory Position 5.

3.2.2. Before administering a brachytherapy dose, the licensee should establish a procedure to verify by more than one method the identity of the patient as the individual named in the written directive. Identifying the patient by more than one method is required by 10 CFR 35.32(a)(2). The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, or the photograph of the patient's face.

3.2.3. The licensee should establish a procedure to verify, before administering the brachytherapy dose, that the specific details of the brachytherapy administration are in accordance with the written directive and plan of treatment. In particular, the radioisotope, number of sources, and source strengths should be confirmed to verify agreement with the written directive and plan of treatment.

3.2.4. The licensee should establish a policy for all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

3.2.5. The licensee should establish a procedure to have an authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist) 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 directive and plan of treatment before implanting the radioactive sealed sources.* The licensee may use any appropriate verification method, such as checking the serial number of the sealed sources behind an appropriate shield, using a radiation detector, using a dose calibrator, using color-coded sealed sources, or using clearly marked storage locations, i.e., one location for each source strength. The responsibilities and conditions of supervision are contained in 10 CFR 35.25.

3.2.6. For temporary brachytherapy implants, the licensee should establish a procedure for using radiographs or other comparable images (e.g., computerized tomography) 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). Whenever possible, nonradioactive "dummy" sources should be used before inserting the radioactive sources (e.g., cesium-137 sealed sources used for intracavitary applications). However, some brachytherapy procedures may require the use of various fixed geometry applicators (e.g., appliances or templates) to establish the location of the temporary sources and calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary provided the position of the sources is known prior to inserting the radioactive sources and calculating the exposure time (or, equivalently, the total dose).

3.2.7. For permanent brachytherapy implants, the licensee should establish a procedure for using radiographs or other comparable images (e.g., computerized tomography) 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 (e.g., iodine-125 sealed sources used for interstitial applications). However, some brachytherapy procedures may require the use of various fixed geometry applicators (e.g., templates) to establish the location of the sources and calculate the total dose, if applicable. In these cases, radiographs or other comparable images may not be necessary.

3.2.8. After insertion of the temporary implant brachytherapy sources (see Regulatory Position 3.2.6), the licensee should establish a procedure to have an authorized user promptly record the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder) and sign or initial the patient's chart or other appropriate record.

3.2.9. After insertion of the permanent implant brachytherapy sources (see Regulatory Position

*The term sealed sources includes wires and encapsulated sources.

3.2.7), the licensee should establish a procedure to 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.

3.2.10. The licensee should establish a procedure to check the dose calculations before the total prescribed brachytherapy dose has been administered. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations, should check the dose calculations. The responsibilities and conditions of supervision are contained in 10 CFR 35.25. Manual dose calculations should be checked for:

- Arithmetic errors,
- Appropriate transfer of data from the written directive, plan of treatment, tables, and graphs,
- Appropriate use of nomograms (when applicable), and
- Appropriate use of all pertinent data in the calculations.

Computer-generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations (e.g., position of the applicator or sealed sources, number of sources, total source strength, or source loading sequence). Alternatively, the brachytherapy dose should be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), particular emphasis should be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual).

3.2.11. The licensee should establish a procedure to 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). A record of the administered dose (or, equivalently, the total source strength and exposure time) is required by 10 CFR 35.32(d)(2).

3.2.12. If the authorized user determines that delaying treatment in order to perform the checks of dose calculations (see Regulatory Position 3.2.10) 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.

3.2.13. The licensee should establish a procedure for performing acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program that could be used for brachytherapy dose calculations. Acceptance testing should be performed before the first use of a treatment planning or dose calculating computer program for brachytherapy dose calculations. The licensee should assess each treatment planning or dose calculating computer program based on the licensee's specific needs and applications.

3.2.14. The licensee should establish procedures to perform periodic reviews of the brachytherapy QM program. Guidance on periodic reviews is provided in Regulatory Position 6. A QM program review is required by 10 CFR 35.32(b).

4. SUGGESTED POLICIES AND PROCEDURES FOR GAMMA STEREOTACTIC RADIOSURGERY

4.1. The licensee should establish a policy to have an authorized user date and sign a written directive before administering treatment. A written directive is required by 10 CFR 35.32(a)(1). Procedures for oral directives and revisions to written directives are contained in Regulatory Position 5.

4.2. Before administering treatment, the licensee should establish a procedure to verify by more than one method the identity of the patient as the individual named in the written directive. Identifying the patient by more than one method is required by 10 CFR 35.32(a)(2). The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, the name on the patient's medical insurance card, or the photograph of the patient's face.

4.3. The licensee should establish a procedure to have the neurosurgeon, the oncology physician, and the radiation therapy physicist date and sign a plan of treatment that includes, for each target point, the coordinates, the plug pattern, the collimator size, the exposure time, the target dose, and the total dose before administering treatment.

4.4. The licensee should establish a policy for all workers to seek guidance if they do not understand how to carry out the written directive. That is, workers should ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

4.5. The licensee should establish a procedure to verify, before administering each treatment, that the specific details of the administration are in accordance with the written directive and plan of treatment. The verification should be performed by at least one qualified person (e.g., an oncology physician, radiation therapy physicist, or radiation therapy technologist) other than the individuals who dated and signed the written directive and plan of treatment. Particular emphasis should be directed toward verifying that the stereotactic frame coordinates on the patient's skull match those of the plan of treatment.

4.6. The licensee should establish a procedure to check computer-generated dose calculations by examining the computer printout to verify that correct data for the patient were used in the calculations.

4.7. The licensee should establish a procedure to check that the computer-generated dose calculations were correctly input to the gamma stereotactic radiosurgery unit.

4.8. The licensee should establish a procedure to have the neurosurgeon or the oncology physician, after administering the treatment, date and sign or initial a written record of the calculated administered dose in the patient's chart or in another appropriate record. A record of the administered dose is required by 10 CFR 35.32(d)(2).

4.9. If the authorized user determines that delaying treatment in order to perform the checks of the dose calculations (see Regulatory Positions 4.6 and 4.7) 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 the treatment.

4.10. The licensee should establish a procedure for performing acceptance testing by a qualified person (e.g., a teletherapy physicist) on each treatment planning or dose calculating computer program that could be used for gamma stereotactic radiosurgery dose calculations. Acceptance testing should be performed before the first use of a treatment planning or dose calculating computer program for gamma stereotactic radiosurgery dose calculations. The licensee should assess each treatment planning or dose calculating computer program based on the licensee's specific needs and applications.

4.11. The licensee should establish procedures to perform periodic reviews of the gamma stereotactic radiosurgery QM program. Guidance on periodic reviews is provided in Regulatory Position 6. A QM program review is required by 10 CFR 35.32(b).

5. ORAL DIRECTIVES AND REVISIONS TO WRITTEN DIRECTIVES

A footnote to 10 CFR 35.32(a)(1) reads as follows:

> "If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.
>
> "Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.
>
> "If, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive."

6. PERIODIC REVIEWS

The licensee should establish written procedures to conduct periodic reviews of each applicable program area, e.g., radiopharmaceuticals, teletherapy, brachytherapy, and gamma stereotactic radiosurgery. The review should include, from the previous 12 months (or since the last review), a representative sample of patient administrations, all recordable events, and all misadministrations. The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each treatment modality performed in the institution, e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery. For example, using the acceptance sampling tables of 10 CFR 32.[illegible]0 and assuming an error rate (or lot tolerance percent defective) of 2 percent, the number of patient cases to be reviewed (e.g., 115) based on 1000 patients treated would be larger than the number of patient cases to be reviewed (e.g., 85) based on 200 patients treated. In order to eliminate any bias in the sample, the patient cases to be reviewed should be selected randomly. For each patient's case, a comparison should be made between what was administered versus what was prescribed in the written directive. If the difference between what

was administered and what was prescribed exceeds the criteria for either a recordable event or a misadministration, that comparison is unacceptable. The number of "unacceptable comparisons" that is allowed for each sample size and lot tolerance percent defective is provided in the acceptance sampling tables of 10 CFR 32.110.

These periodic reviews could be conducted weekly, monthly, or quarterly if one of these periods is more compatible with the licensee's operations.

If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. The licensee or designee should regularly review the findings of the periodic reviews to ensure that the QM program is effective.

For each patient case reviewed, the licensee should determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the written directive or plan of treatment, as applicable. For example, were the following correct:

- For radiopharmaceutical therapy: the radiopharmaceutical, dosage, and route of administration;
- For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;
- For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose;
- For all other brachytherapy prior to implantation: the radioisotope, number of sources, and source strengths; after implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, total dose);
- For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose.

For each patient case reviewed, the licensee should identify deviations from the written directive, the cause of each deviation, and the action required to prevent recurrence. The actions may include new or revised policies, new or revised procedures, additional training, or increased supervisory review of work.

The licensee should reevaluate the QM program's policies and procedures after each annual review to determine whether the program is still effective or to identify actions required to make the program more effective.

Program review results should be documented and should be available for NRC inspectors. To obtain the maximum results from the lessons learned from each review, the program review reports should be distributed within the institution to appropriate management and departments. Corrective actions for deficient conditions should be implemented within a reasonable time after identification of the deficiency.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees and applicants regarding the use of this regulatory guide by the NRC staff.

This guide was published for public comment to encourage public participation in its development. The public comments were used in the development of this final regulatory guide. Except in those cases in which a licensee or an applicant proposes an acceptable alternative method for complying with specified portions of the NRC's regulations, this regulatory guide will be used by the NRC staff in evaluating quality management programs for the administration of byproduct material or radiation from byproduct material.

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REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this regulatory guide. The regulatory analysis prepared for the amendment, "Quality Management Program and Misadministrations," to 10 CFR Part 35 provides the regulatory basis for this guide and examines the cost and benefits of the rule as implemented using the guide. A copy of the regulatory analysis is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street, NW., Washington, DC.