UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV

Walnut Creek Field Office
1450 Maria Lane
Walnut Creek, California 94596-5368

JUN 7 1994

DBA Pacific Nuclear Laboratory
1319 Punahou St., Suite 1190
Honolulu, HI 96826

Attn: Peter S. Robbins, M.D.

SUBJECT: Docket Number: 3003559
License Number: 53-13061-01
Plan File Date: 20-DEC-91

This refers to the review of your written Quality Management Program (QMP) submitted in accordance with 10 CFR 35.32. A review of the QMP was performed to determine whether policies and procedures have been developed to meet the objectives of the rule. Based on your submission, it appears your written QMP, may not fully meet all objectives in 10 CFR 35.32. You should review the following comments to determine if your program requires additional modification.

Regarding I-125 and /or I-131 > 30 Microcuries

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record, and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

If, because of the emergent nature of the patient's 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 provided 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. Please include such a policy in your QMP.

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 must include a policy/ procedure that requires that revisions to written directives will be made prior to administration.

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Your QMP should include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP.

A commitment to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d). 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 an auditable form.

Your QMP for NaI I-125 or I-131 >30 microcuries must include policies/procedures to identify and evaluate any unintended deviations from a written directive as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

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

Your QMP should 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. Please include such a provision in your QMP.

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10 CFR 35.32(e).

Regarding Therapeutic Radiopharmaceutical other than I-125 and/or I-131

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record, and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

If, because of the emergent nature of the patient's 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 provided 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. Please include such a policy in your QMP.

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 must include a policy/ procedure that requires that revisions to written directives will be made prior to administration.

Your QMP should include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP.

A commitment to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d). 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 an auditable form.

Your QMP for Therapeutic Radiopharmaceutical other than I-125 or I-131 must include policies/procedures to identify and evaluate any unintended deviations from a written directive as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

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

Your QMP should 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. Please include such a provision in your QMP.

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10 CFR 35.32(e).

To meet the requirements in 10 CFR 35.32, you may choose to utilize the procedures described in Regulatory Guide 8.33 (enclosed), or submit procedures that are equivalent. If you choose to use Regulatory Guide 8.33, be certain that the procedures you select are adjusted to meet the specific needs of your program as necessary. Additionally, you are reminded that training and/or instruction of supervised individuals in your QMP is required by 10 CFR 35.25.

NRC will review these matters during your next routine NRC inspection to determine whether violations of NRC regulatory requirements are involved. Enforcement action may be taken at that time. Therefore, you should take prompt corrective action to address any deficiency to ensure your QMP and how it is implemented meet the objectives in 10 CFR 35.32.

Please be advised that this QMP will not be incorporated into your license by condition. This allows you the flexibility to make changes to your quality management program without obtaining prior NRC approval. When modifications

are made to your program, you should submit any changes to your QMP to this Office within 30 days as required by 10 CFR 35.32(e). The NRC will review implementation of your QMP at the next regular inspection of your facility.

Thank you for your cooperation in this matter. Your QMP was reviewed by an NRC contractor following a standard review plan and related checklist provided by the NRC staff. This letter outlining the findings of that review was prepared by the contractor utilizing standard paragraphs previously reviewed and approved by NRC headquarters and regional management. If you have questions about this review, you may call me at 510-975-0249.

Sincerely,

/s/ by

James L. Montgomery
Senior Materials Specialist
Materials Branch

Enclosure as stated

bcc w/enclosure:
Docket File
Inspection File

bcc w/o enclosure:
S. Merchant/NMSS
M. Lanza, LLNL
M. Smith

RV/gmd

JMontgomery JLM	FWenslawski	SEND TO PDR	SEND TO DCS
YES/NO	YES/NO	YES/NO	YES/NO
6/7/94	6/ /94	6/7 /94	6/7/94

U.S. NUCLEAR REGULATORY COMMISSION

October 1991

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.33
(Task DG-8001)

QUALITY MANAGEMENT PROGRAM

TABLE OF CONTENTS

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 32.110 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.