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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV

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

June 16, 1994

Department of the Army
Madigan Army Medical Center
Radiation Protection Office
Box 2458
Tacoma, Washington 98431-5000

ATTENTION: CAPTAIN R.J. KAMMERER

SUBJECT: Docket Number: 3003368
License Number: 46-02645-03
Plan File Date: 13-JAN-92
Region Number: 4

Dear Captain Kammerer:

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 this submission, there appear to be significant weaknesses and potential substantial failure of your QMP to meet the objectives in 10 CFR 35.32 in that:

Regarding Brachytherapy

Written directives for brachytherapy, other than high-dose-rate remote afterloading brachytherapy, as defined in 10 CFR35.2, must include: the radioisotope, number of sources, and source strengths; and 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 which requires that written directives for brachytherapy doses will include all treatment parameters prior to administration. Your QMP is missing procedures to require that the written directive include:

- An order for a specific patient

- The date and signature of an authorized user

After implantation, but prior to completion of the procedure:

- the radioisotope





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After implantation, but prior to completion of the procedure:

- the radioisotope
- treatment site
- total source strength and exposure time (or, equivalently, the total dose)

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.

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 must include a policy /procedure that requires that revisions to written directives will be made prior to administration of the brachytherapy dose or next fractional brachytherapy dose.

Your submittal does not include 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 require that:

- acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations, and checking computer generated dose calculations is performed

Your QMP must include a commitment to retain each written directive and a record of each administered radiation dose for three years after the date of administration as required in 10 CFR 35.32(d). 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.

Your QMP for Brachytherapy must include policies/procedures to identify and evaluate any unintended deviations from a written directive as required by 10CFR 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.

As required in 10 CFR35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (a) assembling the relevant facts including the cause, (b) identifying what, if any, corrective action is required to prevent recurrence, and (c) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. Please include such a provision in your QMP.

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 10CFR 35.32(e).

Please be advised that 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.

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

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, and, for any administration of quantities greater than 30 microcuries of either I-125 or I-131, the dosage. Your QMP is missing procedures to require that the written directive for I-125 and/or I-131 > 30 microcuries:

- be an order for a specific patient

- contains the dosage to be administered

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 submittal for I-125 and/or I-131 > 30 microcuries administration does not include policies/procedures that ensure before administration 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 by-product material, that the specific details of the administration are in accordance with the written directive.

The dosage should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive; that is, the dosage should be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive. Please provide such (or similar) procedures 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.

As required in 10 CFR35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (a) assembling the relevant facts including the cause, (b) identifying what, if any, corrective action is required to prevent recurrence, and (c) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. Please include such a provision in your QMP.

Your QMP review procedure does not provide an evaluation of:(a) an adequate representative sample of patient administrations, (b) all recordable events, and (c) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110(assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

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 10CFR 35.32(e).

Please provide assurance that records of each QMP review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

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

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, and, for a therapeutic use of a radiopharmaceutical other than I-125 or I-131, the radiopharmaceutical, dosage, and route of administration. Your QMP is missing procedures to require that the written directive include:

- the radiopharmaceutical

- the dosage

- the route of administration

- an order for a specific patient

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.

The radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive; that is, the dosage should be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive. Please provide such (or similar) procedures 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.

As required in 10 CFR35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (a) assembling the relevant facts including the cause, (b) identifying what, if any, corrective action is required to prevent recurrence, and (c) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. Please include such a provision in your QMP.

Your QMP review procedure does not provide an evaluation of:(a) an adequate representative sample of patient administrations, (b) all recordable events, and (c) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You

may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110(assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

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.

Describe your 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).

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 10CFR 35.32(e).

Please provide assurance that records of each QMP review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

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.

Due to the apparent failure of your written QMP to meet the objectives in 10 CFR 35.32, you must immediately modify your written QMP to address the items listed above, and provide those modifications to your NRC regional office within 30 days of the date of this letter. NRC will review these matters during your next routine NRC inspection to determine whether violations of NRC requirements have occurred. Enforcement action may be taken at that time for failure to meet the requirements of 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).

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.

Thank you for your cooperation in this matter. If you have any questions, please call me at 510-975-0249.

Sincerely,

James L. Montgomery

James L. Montgomery
Senior Materials Specialist
Materials Branch
Region IV, WCFO
Walnut Creek, California 94596

Enclosure: Regulatory Guide 8.33

Madigan Army Medical Center

bcc w/o enclosure:
S. Merchant/NMSS
M. Witte, LLNL
M. Smith, WCFO
Docket File
Inspection File

| JMontgomery JM | SEND TO PDR | SEND TO DCS |
|---|---|---|
| REQUEST COPY<br>YES ___ NO X | YES X NO ___ | YES X NO ___ |
| 6/16/94 | | |