UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

OCT 11 1994

Department of the Army
ATTN: CPT Regina Russell
HSHG-RP
Fitzsimons Army Medical Center
Aurora, CO 80045-5001

RE: Docket Number: 030-01233
License Number: 05-00046-13
Plan File Date: January 30, 1992
Region Number: 4

Dear CPT Russell:

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:

1. Regarding Brachytherapy:

   A. Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

   B. Written directives for brachytherapy, other than high-dose-rate remote afterloading brachytherapy, as defined in 10 CFR 35.2, 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
      - Prior to implantation:

        -- the radioisotope
        -- number of sources
        -- source strengths

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C. 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.

D. 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.

E. 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:

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

F. Your procedures should include a requirement for 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.

G. 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.

H. Your QMP for brachytherapy 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.

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

J. As required in 10 CFR 35.32(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.

K. 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.

L. 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).

M. 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).

N. 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).

O. 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.

2. Regarding I-125 and/or I-131 >30 microcuries:

A. Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

B. 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.

C. 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.

D. 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.

E. Your submittal for NaI I-125 or I-131 >30 microcuries does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews should be conducted at intervals no greater than 12 months.

F. 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.

G. 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).

H. 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).

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

A. Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

B. 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.

C. 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.

D. 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.

E. Your submittal for therapeutic radiopharmaceutical use other than I-125 or I-131 does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews should be conducted at intervals no greater than 12 months.

F. 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.

G. 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).

H. 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).

I. 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 NRC 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 817-860-8132.

Sincerely yours,

Original Signed By
Jacqueline D. Burks

Jacqueline D. Burks
Health Physicist
Nuclear Materials Licensing Branch

OCT 11 1994

bcc:
LJCallan
SJCollins
RAScarano, DRSS/RIV
WLFisher
LLKasner
FAWenslawski
JDBurks
MIS System
RIV Files (2)
SLMerchant, NMSS/IMAB, MS: T-8 S5
MLanza, LLNL

RIV:NMLB	C:NMLB			
JDBurks	WLFisher			
10/07/94	10/7/94			

QUALITY MANAGEMENT (QM) PROGRAM CHECKLIST

FILE COPY

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NF1:

1. *NAME OF LICENSEE: Department of the Army / Fitzsimons Army Medical (

Date QM Plan submitted to NRC 1/30/92

*License No.: 05-00046-13

*Docket No.: 030-01233

Telephone No.: (303) 361-8411

LLNL Authorization Reviewer# 16

Reviewer# 61 Reviewer Loc (UCSF or other) UCSF

2nd Reviewer# 53 Reviewer Loc (UCSF or other) UCSF

LLNL Reviewer#

Reviewer's Notes:

B plan
Ready for UCSF

license Jd

Reviewers: Cross out comments which are no longer relevant. Date and initial comments. This information will not be stored in database. These are comments to the tracking office.

(1)

*R.S.O. CAPT. Regina L. Russel (include title ,e.g. Dr., Mr., Ms., etc.)

*Department HSHG-RP (e.g., Nuclear Med., Radiation Oncology, etc.)

*Street or P.O. Box 12101 East Colfax Ave

*City Aurora State CO Zip Code 80045-5001

*Reviewer: Take this information from license only.

2a. Authorized user for Teletherapy (35.600)..... ☐ YES ☒ NO ☐ U

2b. Authorized user for Gamma Stereotactic Radiosurgery..... ☐ YES ☒ NO ☐ U

2c. Authorized user for High-Dose-Rate Remote Afterloading Brachytherapy (HDR)..... ☐ YES ☒ NO ☐ U

2d. Authorized user for Brachytherapy (35.400)..... ☐ YES ☒ NO ☐ U

2e. Authorized user for I-125 and/or I-131> 30 uCi ☒ YES ☐ NO ☐ U

Any or all of 35.100, 35.200, 35.300, unless both I-125 and I-131 are excluded or not included in section 6 of license ..... ☒ YES ☐ NO ☐ U

2f. Authorized user for Radiopharmaceutical Therapy other than I-125 and/or I-131 (35.300)..... ☒ YES ☐ NO ☐ U

Reviewer: U means that the licensee is authorized for this modality but has stated in a letter that the facility will not be using this modality in practice.

Quality Management Program for Brachytherapy

57. A written QMP for Brachytherapy was provided. X YES _ NO (3d)

A written QMP must be established and maintained for each Brachytherapy use as required in 10 CFR 35.32(f)(1). Please provide your QMP for your Brachytherapy program

58. Written certification that QM program has been implemented _ YES X NO (4)

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

OBJECTIVE 1 - WRITTEN DIRECTIVE [10 CFR 35.32(a)(1)]

59a. A written directive is prepared for Brachytherapy, other than high-dose-rate: X YES _ NO (11)

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.

The QMP provides procedures to require that the written directive include: (12)

59b. Order for a specific patient..... _ YES X NO (12a)
59c. Dated and signed by authorized user ..... _ YES X NO (12b)

Prior to implantation: (12c)

59d. the radioisotope, ... _ YES X NO (12d)
59e. number of sources,..... _ YES X NO (12e)
59f. source strengths;..... _ YES X NO (12f)

After implantation, but prior to completion of the procedure: (12g)

59g. the radioisotope, ... X YES _ NO (12h)
59h. treatment site, ... X YES _ NO (12i)
59i. total source strength and exposure time (or, equivalently, the total dose)..... X YES _ NO (12j)

Written directives for brachytherapy, other than high-dose-rate remote afterloading brachytherapy, as defined in 10CFR35.2, 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 any 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:

(a)Order for a specific patient.
(b)Dated and signature of authorized user
(c)Prior to implantation:
(d) the radioisotope,
(e) number of sources,
(f) source strengths;.
(g)After implantation, but prior to completion of the procedure:
(h) the radioisotope,
(i) treatment site,
(j) total source strength and exposure time (or, equivalently, the total dose)

60. Documentation of oral revisions and oral directives: X YES _ NO (18a)

a. Policies/Procedures for documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. within 48 hours of the oral revision

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.

b. If, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that information 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 provision in your QMP _ YES X NO (18b)

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients 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.

61. Revisions to written directives dated and signed by a.u. prior to administration of brachytherapy dose or next fraction of brachytherapy dose _ YES X NO (22)

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.

OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]

62. Procedure to verify patient's identity by more than one method prior to administration X YES _ NO (23d)

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 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).

OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL THERAPY)

63. For brachytherapy other than high-dose-rate remote afterloaders:

a. a plan of treatment will be prepared in accordance with the respective written directive. _ YES X NO (24a)

b. procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations). Dose calculations checked by 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 technologis who whenever possible did not make the original calculations. X YES _ NO (24b)

c. verification of the position of dummy sources or fixed geometry applicators prior to inserting sealed sources X YES _ NO (24c)

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 X YES _ NO (24d)

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:

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) are prepared. 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. verification of the position of dummy sources or fixed geometry applicators prior to inserting sealed sources, is accomplished

d. 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.

OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE [10 CFR 35.32(a)(4)]

64a. Procedures to ensure, before administration, that each administration is in accordance with the written directive. X YES __ NO (29d)

Your submittal for brachytherapy does not include policies/procedures that ensure that each administration is in accordance with the written directive as required by 10CFR35.32(a)(4). Please include such a provision in your QMP.

64b. The person administering the brachytherapy treatment should confirm the prescribed radioisotope, number of sources, source strengths, treatment site, loading sequence, total dose. **(*Reviewer, if any one item is missing, mark "no")** _ YES X NO (29e)

Your procedures should include a requirement for 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.

64c. Prompt recording, by the authorized user, of the number of sources and 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. X YES _ NO (29f)

Your procedures should include a requirement for prompt recording, by the authorized user, of the number of sources and 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.

65. Commitment for all workers to seek guidance if they do not understand how to carry out the written directive X YES _ NO (31)

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. Please include such a provision in your QMP.

66. A written directive and records of each administered Brachytherapy must be maintained for three years. _ YES X NO (33)

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, date, and sign or initial a written record. Your procedure should describe what this record will include.

OBJECTIVE 5 - UNINTENDED DEVIATIONS [10 CFR 35.32(a)(5)]

67. Policies/Procedures for identification and evaluation of unintended deviations from the written directive _ YES X NO (34d)

Your QMP for Brachytherapy 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). Please include such a provision in your QMP.

68a. Institution of corrective actions to be taken after the deviation has been identified _ YES X NO (35)

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

EVALUATION AND RESPONSE TO RECORDABLE EVENTS [10 CFR 35.32(c)]

68b. Commitment for evaluation and response to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. _ YES X NO (1)

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:(i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

PERIODIC REVIEWS OF THE QM PROGRAM [10 CFR 35.32(b)]

69. Time intervals (intervals not to exceed 12 months) X YES _ NO (36d)

Your submittal for Brachytherapy does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews These reviews should be conducted at intervals no greater than 12 months.

70. Review includes an evaluation of acceptable representative sample of all patient administrations, all recordable events, and misadministrations X YES _ NO (37)

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) 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.

71. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP. _ YES X NO (38)

According to guidance provided by Regulatory Guide 8.33, 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 this provision in your QMP.

72. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program _ YES X NO (39)

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).

73. Modifications to QM program submitted to NRC within 30 days after modification has been made — _ YES X NO (40)

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).

74. Records of each review and evaluation to be maintained for 3 years — _ YES X NO (41)

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

COMMENTS: _____

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Quality Management Program for I-125 and/or I-131 > 30uCi

75. A written QMP for I-125 and/or I-131>30 uCi was provided. X YES _ NO (3e)

A written QMP must be established and maintained for each I-125 and/or I-131>uCi use as required in 10 CFR 35.32(f)(1). Please provide your QMP for your NaI I-125 or I-131 >30 microCi.

76. Written certification that QM program has been implemented _ YES X NO (4)

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

OBJECTIVE 1 - WRITTEN DIRECTIVE [10 CFR 35.32(a)(1)]

77a. A written directive is prepared for administration of greater than 30 uCi of I-125 and/or I-131 X YES _ NO (7)

The preparation of written directives prior to the administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131 is required by 10 CFR 35.32(a)(1). Your QMP must include a written policy that requires that such a written directive be prepared prior to each patient administration.

The QMP provides procedures to require that the written directive include:

77b. an order for a specific patient..... X YES _ NO (8a)
77c. date and signature of authorized user..... X YES _ NO (8b)
77d. dosage to be administered..... X YES _ NO (8c)

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 uCi:

(a) be an order for a specific patient
(b) is dated and signed by the authorized user
(c) contains the dosage to be administered.

78. Documentation of oral revisions and oral directives: _ YES X NO (18a)

a. Documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. <u>within 48 hours of the oral revision</u>

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 <u>within 48 hours of the oral revision</u>. Please include such a policy in your QMP.

b. If, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that information 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 provision in your QMP _ YES X NO (18b)

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients 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.

79. Revisions to written directives dated and signed by a.u. prior to administration of a radiopharmaceutical dosage _ YES X NO (19)

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.

OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]

80. Procedure to verify patient's identity by more than one method prior to administration X YES _ NO (23e)

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 NaI I-125 or I-131 >30 microCi 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).

OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL ADMINISTRATION)

OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE [10 CFR 35.32(a)(4)]

81a. Procedures to ensure, before administration, that each administration is in accordance with the written directive. X YES _ NO (27a)

Your submittal for I-125 and/or I-131 > 30uCi administration does not include policies/procedures that 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.

81b. For I-125 and/or I-131 > 30uCi:

Dosage measured in dose calibrator and results compared with the prescribed dosage in the written directive _ YES _ NO (27b)

According to guidance provided by Regulatory Guide 8.33, 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.

82. Commitment for all workers to seek guidance if they do not understand how to carry out the written directive — X YES _ NO (31)

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. Please include such a provision in your QMP.

83. A written directive and records of each administered I-125 and/or I-131>30 uCi must be maintained for three years. — X YES _ NO (32)

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.

OBJECTIVE 5 - UNINTENDED DEVIATIONS [10 CFR 35.32(a)(5)]

84. Policies/Procedures for identification and evaluation of unintended deviations from the written directive — X YES _ NO (34e)

Your QMP for **NaI I-125 or I-131 >30 microCi** 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). Please include such a provision in your QMP.

85a. Institution of corrective actions to be taken after the deviation has been identified — X YES _ NO (35)

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

EVALUATION AND RESPONSE TO RECORDABLE EVENTS [10 CFR 35.32(c)]

85b. Commitment for evaluation and response to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. — X YES _ NO (1)

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:(i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

PERIODIC REVIEWS OF THE QM PROGRAM [10 CFR 35.32(b)]

86. Time intervals (intervals not to exceed 12 months) — _ YES X NO (36e)

Your submittal for **NaI I-125 or I-131 >30 microCi** does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews should be conducted at intervals no greater than 12 months.

87. Review includes an evaluation of acceptable representative sample of all patient administrations, all recordable events, and misadministrations. X YES _ NO (37)

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) 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.

88. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP. _ YES X NO (38)

According to guidance provided by Regulatory Guide 8.33, 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. Please include such a provision in your QMP.

89. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program. _ YES X NO (39)

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).

90. Modifications to QM program submitted to NRC within 30 days after modification has been made _ YES X NO (40)

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).

91. Records of each review and evaluation to be maintained for 3 years X YES _ NO (41)

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

COMMENTS: _____

_____

_____

Quality Management Program for Therapeutic Radiopharmaceutical other than I-125 or I-131

92. A written QMP for Therapeutic Radiopharmaceutical other than I-125 or I-131 was provided. _X_ YES _ NO (3f)

A written QMP must be established and maintained for Radiopharmaceutical use as required in 10 CFR 35.32(f)(1). Please submit your QMP for your Radiopharmaceutical therapy.

93. Written certification that QM program has been implemented _ YES _X_ NO (4)

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32.f)(2). Please provide written certification that your QMP has been implemented.

OBJECTIVE 1 - WRITTEN DIRECTIVE [10 CFR 35.32(a)(1)]

94a. A written directive is prepared for administration of therapeutic radiopharmaceutical other than I-125 and/or I-131 _X_ YES _ NO (9)

10 CFR 35.32(a)(1) requires a QMP to include policies and procedures for the preparation of a written directive, prior to the administration of any therapeutic radiopharmaceutical, other than sodium iodide I-125 or I-131. Please provide such a policy in your QMP.

The QMP provides procedures to require that the written directive include:

94b. Radiopharmaceutical..... _X_ YES _ NO (10a)
94c. Dosage..... _X_ YES _ NO (10b)
94d. Route of administration..... _X_ YES _ NO (10c)
94e. Order for a specific patient..... _X_ YES _ NO (10d)
94f. Dated and signed by authorized user..... _X_ YES _ NO (10e)

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 for therapeutic radiopharmaceutical other than I-125 and/or I-131 include:

(a) Radiopharmaceutical
(b) Dosage
(c) Route of administration
(d) Order for a specific patient
(e) Date and signed by authorized user

95. Documentation of oral revisions and oral directives:

a. Policies/Procedures for documentation of oral revisions to existing written directive signed and dated by an a.u. or physician under the supervision of an a.u. within 48 hours of the oral revision — _ YES ✓ NO (18a)

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.

b. If, a delay in order to provide a written directive would jeopardize the patients health, an oral directive will be acceptable, provided that information 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 provision in your QMP. — _ YES ✓ NO (18b)

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients 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.

96. Revisions to written directives dated and signed by a.u. prior to administration of a radiopharmaceutical dosage — _ YES ✓ NO (19)

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.

OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]

97. Procedure to verify patient's identity by more than one method prior to administration — ✓ YES _ NO (23f)

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 Therapeutic Radiopharmaceutical other than I-125 or I-131 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).

OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL THERAPY)

OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE [10 CFR 35.32(a)(4)]

98a. Procedures to ensure, before administration, that each administration is in accordance with the written directive. ☒ YES _ NO (27c)

Your submittal for administration of therapeutic radiopharmaceutical other than I-125 or I-131 does not include policies/procedures that 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.

98b. Confirm the radiopharmaceutical, dosage and route of administration

Dosage measured in dose calibrator and results compared with the prescribed dosage in the written directive ☒ YES _ NO (27d)

According to guidance provided by Regulatory Guide 8.33, 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.

99. Commitment for all workers to seek guidance if they do not understand how to carry out the written directive ☒ YES _ NO (31)

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. Please include such a provision in your QMP.

100. A written directive and records of each administered Therapeutic Radiopharmaceutical other than I-125 or I-131 must be maintained for three years. ☒ YES _ NO (32)

A comunitment 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)(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 an auditable form.

OBJECTIVE 5 - UNINTENDED DEVIATIONS [10 CFR 35.32(a)(5)]

101. Policies/Procedures for identification and evaluation of unintended deviations from the written directive ☒ YES _ NO (34f)

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 and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

102a. Institution of corrective actions to be taken after the deviation has been identified ☒ YES _ NO (35)

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

EVALUATION AND RESPONSE TO RECORDABLE EVENTS [10 CFR 35.32(c)]

102b. Commitment for evaluation and response to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. _X YES _ NO (1)

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:(i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

PERIODIC REVIEWS OF THE QM PROGRAM [10 CFR 35.32(b)]

103. Time intervals (intervals not to exceed 12 months) _ YES _X NO (36f)

Your submittal for **Therapeutic Radiopharmaceutical other than I-125 or I-131** does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews should be conducted at intervals no greater than 12 months.

104. Review includes an evaluation of acceptable representative sample of all patient administrations, all recordable events, and misadministrations _X YES _ NO (37)

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) 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.

105. Includes procedure to expand review if recordable events or misadministration is uncovered during the periodic review of your QMP. _ YES _X NO (38)

According to guidance provided by Regulatory Guide 8.33, 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.

106. Procedures for determining the effectiveness of the QM program and, if necessary, making modifications to meet the objectives of the program _ YES _X NO (39)

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).

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107. Modifications to QM program submitted to NRC within 30 days after modification has been made — _ YES X NO (40)

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)

108. Records of each review and evaluation to be maintained for 3 years — _ YES X NO (41)

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

COMMENTS: _____