SAINTMARY'SHOSPITAL

030-19962

January 17, 1992

Licensing Assistance
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

Re: License No. 29-20597-01

Dear Sir or Madam:

In accordance with the requirements of 10 CFR 35.32, St. Mary's Ambulatory Care Hospital has developed a Quality Management Program for Radiopharmaceutical Therapy procedures. Enclosed is a general description of the program, a specific policy for Iodine - 131 radiopharmaceutical therapy and a sample form for documentation. St. Mary's Ambulatory Care Hospital does not perform any Brachytherapy, Teletherapy, or Gamma Stereotactic Radiosurgery procedures.

If you require any additional information regarding this matter, please contact us at 201-266-3055.

Sincerely,

Michael Teters, M.S.
Health Physicist

Mary Natrella, M.D.
Radiation Safety Officer

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## QUALITY MANAGEMENT PROGRAM

I. Diagnostic Procedures--Compare ordered procedure on request document to prescribed radiopharmaceutical, dosage, and route of administration listed on dose schedule. Dose schedule should be posted in dose preparation area.

II. Verify the identity of the patient (for diagnostic or therapy procedures) by two methods before administration.

Check patient's name orally and on a written document (e.g. ID bracelet, chart, ID card, etc.). If the patient cannot speak, verify the patient orally with a relative or guardian.

III. A "Written Directive" must be received before each therapy or sodium I-131, I-125 (>30$\mu$Ci) procedure. It must contain the patient's name, the date of the order, the authorized user's signature, the radiopharmaceutical, and the dosage. For P-32 therapy, the route of administration must also be included. The administered dose must be reviewed and agree with the written directive. This review should be noted on the written directive. Complete all normally required information contained in the administration log, including assay of the dose.

No one is authorized to administer a dose without a written directive (when required). Also, do not administer a dose when the written directive is unclear or incomplete.

IV. "Recordable events" occur when any deviation from the written directive is identified, and include:

A. A missing or late written directive.
B. When an administered dose is not recorded.
C. When the prescribed dose differs from the administered dose by more than 10% and 15 $\mu$Ci for sodium I-131, I-125 (>30$\mu$Ci).
D. When the prescribed dose differs from the administered dose by more than 10% for P-32.

Recordable events must be evaluated and documentation must include the cause and relevant facts, and the corrective action to prevent future reoccurrence.

V. Misadministrations include:

A. For sodium I-131, I-125 (>30$\mu$Ci):
   1. When an administered dose differs from the prescribed dose by > 20% and 30 $\mu$Ci.
   2. The wrong patient.
   3. The wrong radiopharmaceutical.

B. For P-32:
   1. The wrong patient.
   2. The wrong radiopharmaceutical.
   3. The wrong route of administration.
   4. When the administered dose differs from the prescribed dose by > 20%.

C. For diagnostic procedures:
   1. The wrong patient, or the wrong pharmaceutical, or the wrong route of administration, or the wrong dosage, and
   2. The whole body dose equivalent is > 5 rems, or a organ dose is > 50 rems.

Misadministrations must be reported to the NRC, the referring physician, and the patient within 24 hours, and evaluated within 15 days.

VI. As part of the periodic Radiation Protection Audit, the Quality Management Program will be reviewed by the health physicist. This shall be performed at least annually, and should be performed quarterly when deemed necessary by the Radiation Safety Committee. The review will include:

A. A representative sample of patient administrations.
B. All recordable events.
C. All misadministrations.

The results of the audits will be evaluated to determine the program's effectiveness, and will be presented to the Radiation Safety Committee and documented in the minutes.

VII. Changes to the Quality Management Program may be made as approved by the Radiation Safety Committee. Notification of the changes must be submitted to the NRC.

# IODINE - 131 RADIOPHARMACEUTICAL THERAPY

Written Directive

Patients Name_____ IP/OP

Prescribed Dose_____

Authorized User_____ Date_____

Dose Measurement

Dose_____ Time_____ Date_____

Comments:

Signature_____

Verification Post - Administration

Does written directive agree with administered dose ? YES ____ NO____

# QUALITY MANAGEMENT PROGRAM

## Iodine - 131 Radiopharmaceutical Therapy (35.32)

Purpose: This quality management program is designed in accordance with the objectives of 10 CFR 35.32 to assure Iodine - 131 therapy prescriptions are properly administered.

1. Prior to administration of Iodine - 131, a written directive must be prepared by an authorized user.

2. The patient is refered to by name and asked to read and sign a consent form which contains their name. This assures a double confirmation of patient identification.

3. Prior to administration of the Iodine - 131 capsule(s), the capsules are measured in the dose calibrator and the results compared with the prescribed dosage in the written directive. The measured dosage must be within 10% of the prescribed dosage.

4. Post - administration of the therapy dose, a qualified person (e.g., a Nuclear Medicine Physician, Physicist or Technologist), who was not involved with administration will verify the written record of the patient dosage.

5. During the annual Radiation Protection Audit by the Physicist, a representative portion of the I -131 administrations shall be reviewed for unintended deviation from the written directive, as a means of evaluating the effectiveness of the program. A copy of the results shall be maintained for three years.

# QUALITY MANAGEMENT (QM) PROGRAM CHECKLIST

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1. *NAME OF LICENSEE: SAINT MARY'S HOSPITAL

Date QM Plan submitted to NRC 1/17/92

*License No.: 29-20597-01

*Docket No.: 030-19962

Telephone No.: (201) 266-3055

LLNL Authorization Reviewer# 19

Reviewer#_____ Reviewer Loc (UCSF or other)_____

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

LLNL Reviewer# 19

Reviewer's Notes:

License rd

*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.*

*R.S.O. PABLO P. ROY, M.D. (include title ,e.g. Dr., Mr., Ms., etc.)

*Department NUCLEAR MEDICINE (e.g., Nuclear Med., Radiation Oncology, etc.)

*Street or P.O. Box 135 SOUTH CENTER STREET

*City ORANGE State NJ Zip Code 07051

*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

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 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. <u>prior to administration</u> 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 <u>prior to administration</u>.*

## <u>OBJECTIVE 2 - PATIENT IDENTITY VERIFICATION [10 CFR 35.32 (a)(2)]</u>

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).*

## <u>OBJECTIVE 3 - TREATMENT PLANS VERIFICATION (NOT APPLICABLE TO RADIOPHARMACEUTICAL ADMINISTRATION)</u>

## <u>OBJECTIVE 4 - VERIFICATION PRIOR TO ADMINISTRATION TO WRITTEN DIRECTIVE [10 CFR 35.32(a)(4)]</u>

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

X 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 — _ YES X 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. — _ YES X 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. — _ 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)]

86. Time intervals (intervals not to exceed 12 months) — X YES _ 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. _ YES X 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. X YES _ 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 _ 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: _____

# 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 X 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 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.

96. 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)]

97. Procedure to verify patient's identity by more than one method prior to administration — X 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. — X 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 — X 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 X 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 X 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)(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 — X 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 — 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)]

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. _ 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)]

103. Time intervals (intervals not to exceed 12 months) X YES _ 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 _ YES X 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 X YES _ 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).

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: _____