JUN 2 6 1990

Woodland Medical Group
ATTN: Harold Daitch, M.D.
Radiation Safety Officer
22341 West Eight Mile Road
Detroit, MI 48219

Gentlemen:

Enclosed is Amendment No. 26 renewing your NRC License No. 21-13255-01 in accordance with your request.

After review of your license we have determined that the type, form, and quantity of material authorized does not warrant the development and submittal of a decommissioning funding plan, or certification of financial assurance as described in 10 CFR 30.35 (enclosed). However, this does not relieve you of record keeping requirements relative to information which the Commission considers important to decommissioning. Therefore, we have added License Condition 14. requiring that you maintain such records as set forth in Section 30.35(g).

Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Possess radioactive material only in the quantity and form indicated in your license.

3. Use radioactive material only for the purpose(s) indicated in your license.

4. Notify NRC in writing of any change in mailing address.

5. Request and obtain appropriate amendment if you plan to change ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. Any amendment request should be accompanied by the appropriate fee specified in 10 CFR Part 170.

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6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations in your license application will result in enforcement action against you in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

If you have any questions or require clarification of any of the above stated information, contact us at (708) 790-5625.

Sincerely,

Original Signed By
Robert G. Gattone, Jr.
Materials Licensing Section

Enclosures:
1. Amendment No. 26
2. 10 CFR Part 30

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BD.
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06/21/90

NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE _____ OF _____ PAGES

Amendment No. 26

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Woodland Medical Group	In accordance with application dated March 15, 1990 3. License number 21-13255-01 is renewed in its entirety to read as follows:
2. 22341 W. Eight Mile Road Detroit, MI 48219	4. Expiration date August 31, 1995
	5. Docket or Reference No 030-02149

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300 (excluding iodine-131 for thyroid carcinoma)	C. As needed
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits	D. As needed

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

C. Medical use described in 10 CFR 35.300 (excluding iodine-131 for thyroid carcinoma).

D. In vitro studies.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 21-13255-01
Docket or Reference number: 030-02149
Amendment No. 26

CONDITIONS

10. Location of Use: 22341 W. Eight Mile Road, Detroit, Michigan and 41935 W. Twelve Mile Road, Novi, Michigan.

11. Radiation Safety Officer: Harold Daitch, M.D.

12. Authorized Users:

A. Harold Daitch, M.D., for material in 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma) and 31.11.

B. Richard Small, M.D., for material in 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma) and 31.11.

C. Seymour Mirkes, M.D., for material in 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma) and 31.11.

13. The licensee is not required to have a Radiation Safety Committee described in 10 CFR 35.22. The Radiation Safety Officer may make radiation safety program changes permitted by 10 CFR 35.31 with the advise and consent of the licensee's management.

14. The licensee shall maintain records of information important to safe and effective decommissioning at the addresses in Condition 10. per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

15. This license is based on the licensee's statements and representations listed below:

A. Application dated March 15, 1990; and

B. Letter dated June 8, 1990 (with attachments).

For the U.S. Nuclear Regulatory Commission

Original Signed
By Robert G. Gattone, Jr.
Materials Licensing Section, Region III

Date: June 26, 1990

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QUALITY MANAGEMENT (QM) PROGRAM CHECKLIST

1. NAME OF LICENSEE: Woodland Medical Group

Date QM Plan submitted to NRC: 1/2/92

License No.: 21-13255-01

Docket No.: 030-02149

Telephone No.: ( ) 538-4700

LLNL Authorization Reviewer# 9

Reviewer#_____ Reviewer Location (UCSF or other)_____

Second Reviewer#_____ Reviewer Location (UCSF or other)_____

LLNL Reviewer# 9

Response letter should be sent to:

Contact: Harold J. Daitch (include title, e.g. (Dr.), Mr., Ms., etc.)

Department: RSO (e.g., Nuclear Med., Radiation Oncology, etc.)

Street (or P.O. Box): 22341 W. Eight Mile Road

City: Detroit State MI Zip Code 48219

2a. **Authorized user for Teletherapy (35.600)**..... _ YES X NO (pg. 2)

2b. **Authorized user for Gamma Stereotactic Radiosurgery.** _ YES X NO (pg. 9)

2c. **Authorized user for High-Dose-Rate Remote Afterloading Brachytherapy (HDR)**..... _ YES X NO (pg. 14)

2d. **Authorized user for Brachytherapy (35.400)**..... _ YES X NO (pg. 22)

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) ..... X YES _ NO (pg. 29)

2f. **Authorized user for Radiopharmaceutical Therapy other than I-125 and/or I-131** (35.300)..... X YES _ NO (pg. 34)

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 X YES _ 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. 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.

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 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 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. _ 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. — 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. _ 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. _ 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 _ 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 X YES _ 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)
(*Reviewer, either item is missing, mark "no")

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 — 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.

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. — 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 — _ 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 — _ 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).

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:_____