AUG 11 1994

CHARLTON MEMORIAL HOSPITAL
363 HIGHLAND AVENUE
FALL RIVER, MA 02720

ATTN: CHARLES MANDELL, M.D.

RE: Docket Number: 030-01875
License Number: 20-05691-01

Dear Dr. Mandell:

This letter acknowledges receipt of your letter dated July 16, 1994, in response to our letter which addressed deficiencies in your Quality Management Program (QMP). Your implementation of the QMP and its adequacy will be reviewed as part of the next NRC inspection. This inspection will include a review of your letter referenced above and any resulting changes to your QMP.

This QMP will not be incorporated into your license by condition. You have the flexibility to make changes to your quality management program without obtaining prior NRC approval. However, modifications to your program must be submitted to this Office within 30 days as required by 10 CFR 35.32(e).

Thank you for your cooperation in this matter; no reply is required in response to this letter.

Sincerely,

Original Signed By:
James P. Dwyer

James P. Dwyer
Quality Management Program Coordinator
Region I

OFFICIAL RECORD COPY - D:\QM-ACK\002112.ACK - 07/25/94

ML 10

NOTE TO DMB:

THE ATTACHED DOCUMENTS ARE TO BE PROCESSED AS ONE QUALITY MANAGEMENT PACKAGE.

LICENSE NUMBER: 20-05691-01

DOCKET NUMBER: 030-01875

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

280042

CHARLTON MEMORIAL HOSPITAL

"Our mission is to serve others"

030-01875
20-05691-01

July 16, 1994

Mr. James P. Dwyer
Quality Management Coordinator
Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Mr. Dwyer,

Enclosed please find the revisions to Charlton Memorial Hospital's Quality Management Program that you have requested. We have expanded our program to correct the weaknesses that were discovered by the NRC contractor and NRC staff. If these revisions are not satisfactory please inform us as soon as possible so that further modifications an be implemented.

Thank you for your help and consideration in this matter. If you need anything further it will be sent to you immediately.

Sincerely yours,

Carl O. Weaver

Carl O. Weaver
Vice-President, Support & Diagnostic Services

COW:pat

enclosures

ML 10

JUL 21 1994

Charlton Memorial Hospital
363 Highland Avenue
Fall River, Massachusetts 02720
Telephone 508 679-3131

CHARLTON MEMORIAL HOSPITAL, INC.
Radiology Imaging Services Policy

Policy: Nuclear Medicine Quality Management Program

Effective: January 27, 1992

Approved: _____
Jagdish R. Shah, M.D.
Chairman

Debra A. Desmarais
Debra A. Desmarais
Director

Purpose: To ensure that the proper guidelines established by the NRC Quality Management Program shall be utilized with all administrations of I-131 greater than 30 uCi and all therapeutic radiopharmaceuticals other than I-131. The Nuclear Medicine Department does not utilize I-125.

Policy: The Nuclear Medicine Quality Management Program established by the NRC for use with I-125 and/or I-131 and all therapeutic radiopharmaceuticals other than I-125 and/or I-131 will be followed for both diagnostic and therapeutic applications. The following procedures will be followed:

1. Prior to administration of I-131 greater than 30 uCi and/or any other therapeutic radiopharmaceutical, a written directive, must be obtained. 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. The written directive must contain the dosage to be administered to the patient.

2. Prior to administration of a radiopharmaceutical dosage, the licensee shall identify the patient by the following two methods:
    1. Name
    2. Date of Birth

3. Prior to the administration of a therapeutic dosage of I-131, P-32 or SR-89 informed consent is obtained.

4. Before administration of the radiopharmaceutical the dosage shall be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive. A copy of the written directive should be attached to the pharmaceutical receipt book.

5. The specific details of the administration must be in accordance with the written directive and confirmed by the individual administering the radiopharmaceutical to verify agreement with the written directive.

6. All workers who do not understand how to carry out the written directive should ask the Nuclear Medicine Department Manager (Chief Technologist) if they have any questions about what to do or how it should be done rather than continuing a procedure where there is any doubt.

7. The Nuclear Medicine Technologist following an administration supervised by an authorized user, will make, date, and sign/initial a written record, that documents the administered dosage in the patient's chart.

8. Oral directives and revisions to written directives will be acceptable, only as a result of a patient's condition, or a delay in an order to provide a written revision to an existing directive which would jeopardize the patients 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 written 48 hours of the oral revision. This is in accordance with CFR 35.32 (a)(1)

9. 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. This revision to the written directive must be made prior to the administration of the radiopharmaceutical.

10. A committment is made by the licensee to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration as required in 10 CFR 35.32 (d).

11. An annual review of the Quality Management Program will be conducted by the Radiation Safety Officer at the end of each year.
(See attached sample of the Annual Audit)

12. The annual Quality Management Program audit will include an adequate representative sample of patient administrations that (a) include at least 20% of all cases performed, (b) all recordable events and (c) all misadministrations since the last review as required in 10 CFR 35.32 (b) (1).

13. As required in 10 CFR 35.32 (c) the licensee shall evaluate and respond within 30 days after the discovery of a 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

    The representative sample of patients will be expanded greater than 20% when a misadministration or recordable event is uncovered during the periodic review of the Q.M.P.

14. The Annual Quality Management Program audit and statistical sampling analysis shall be presented to the Radiation Safety Committee to evaluate the effectiveness of the program. The reviews will be conducted at intervals no greater than 12 months and reported in the first quarterly Radiation Safety Committee meeting of the new year. All QMP modications shall be submitted within 30 days after the modification have been made as required by 10 CFR 35.32 (e)

Ref: A:POL-82.pat

Reviewed: April 1993

Date Deleted/Superseded: July 1994

CHARLTON MEMORIAL HOSPITAL
Radiology Imaging Services

NUCLEAR MEDICINE DEPARTMENT QUALITY MANAGEMENT PROGRAM
Annual Audit - January 1993 - December 31, 1993

==========

As part of our annual QMP review, a representative sample of patient administrations, all recordable events and all misadministrations are reviewed.

The following findings are presented for January 1, 1993 through December 31, 1993.

PATIENT ADMINISTRATIONS - (Breakdown I-131 P-32)

Total # of I-131 Patients	77	
Total # of P-32 Patients	4	
Total # of Administrations	81	
Total # of Cases Analyzed	81	- 100%
Total # of Recordable Events	-0-	
Total # of Misadministrations	-0-	

Results	Compliance Rate
1. Written Directive Prior to administration	100%
2. Patient identified by (2) methods	100%
3. Informed Consent Obtained	100%
4. Administration in accordance to written directive	100%
5. Oral directive utilized due to patient's health	-0-
6. Unintended deviation from written directive	-0-

Reported To:
Radiation Safety Committee : _____

Managers Meeting: _____

Radiologists/Managers Meeting: _____

Nuclear Medicine Meeting: _____

CHARLTON MEMORIAL HOSPITAL

QUALITY MANAGEMENT PROGRAM

Annual Audit of Quality Management Program

An annual review of the quality management program will be conducted by the Radiation Safety Officer at the time of the annual ALARA audit.

NRC License No. 20-05691-01

Date of Audit _____

Audit Conducted By _____

Audit Findings

The scope of the audit consisted of a review of the quality management program and supporting documentation, interview with appropriate personnel, and direct observations of certain procedures. The following findings resulted from this audit:

A. Patient Records

1. Prior to administration a written directive was prepared for:
   a. Any administration of radioactive sodium iodide in quantities greater than 30 microcuries (uci)
   yes _____ **no** _____ **N/A** _____
   b. Any therapeutic administration of a radiopharmaceutical other than sodium iodide.
   yes _____ **no** _____ **N/A** _____

2. Each written directive was maintained in an auditable form for three years.
   yes _____ **no** _____

3. A record of each administered radiopharmaceutical dosage where a written directive is required is maintained for three years.
   yes _____ **no** _____

4. Prior to dosing, the patient's identity was verified by more than one method as the individual named on the written directive.
   yes _____ **no** _____

5. Each administration of a radiopharmaceutical was in accordance with the written directive when a written directive was required.
   yes _____ **no** _____

6. any unintended deviation from a written directive was identified and evaluated.
   yes _____ no _____ N/A/ _____

7. Have recordable events been evaluated within thirty (30) days after discovery? (10 CFR 35.32 (c)).
   yes _____ no _____ N/A _____

8. Have records of recordable events been retained for three (3) years?
   yes _____ no _____ N/A _____

9. Has the NRC been informed of any misadminstrations?
   yes _____ no _____ N/A _____

10. Have the reporting requirements of 10CFR 35.33 (a) (3) and (a) (4) been completed for each misadministration?
    yes _____ no _____ N/A _____

11. Have records of misadministrations been maintained for ten (10) years? (10 CFR 35.33 (b))
    yes _____ no _____ N/A _____

12. Has the Radiation Safety Committee reviewed previous audits to determine the effectiveness of the quality management program and made modifications as necessary? (10 CFR 35.32 (b) (2))
    yes _____ no _____ N/A _____

13. Has the hospital retained records of the audit for three (3) years? (10 CFR 35.32 (b) (3))
    yes _____ no _____ N/A _____

Reviewed by Radiation Safety Officer

Signature: _____ **Date:** _____

Reviewed by Radiation Safety Committee

Signature: _____ **Date:** _____

JUN 17 1994

CHARLTON MEMORIAL HOSPITAL
363 HIGHLAND AVENUE
FALL RIVER, MA 02720

ATTN: CHARLES MANDELL, M.D.

RE: Docket Number: 3001875
License Number: 20-05691-01
Plan File Date: 24-JAN-92
Region Number: 1

Dear Dr. Mandell:

This refers to the review of your written Quality Management Program (QMP) submitted in accordance with 10 CFR 35.32. A review of the QMP was performed to determine whether policies and procedures have been developed to meet the objectives of the rule. Based on this submission, there appear to be significant weaknesses and potential substantial failure of your QMP to meet the objectives in 10 CFR 35.32 in that:

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

The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user, and, for any administration of quantities greater than 30 microcuries of either I-125 or I-131, the dosage. Your QMP is missing procedures to require that the written directive for I-125 and/or I-131 > 30 microcuries:

- be an order for a specific patient

- is dated and signed by the authorized user

- contains the dosage to be administered

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by

an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a policy in your QMP.

Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage. Your QMP must include a policy/ procedure that requires that revisions to written directives will be made prior to administration.

A commitment to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d). Describe the procedure for an authorized user or a qualified individual under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist or technologist), after administering a radiopharmaceutical, to make, date, sign or initial a written record that documents the administered dosage in an auditable form.

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

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

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

Your 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.

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

Your QMP should include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32 (b)(2).

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

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

The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user, and, for a therapeutic use of a radiopharmaceutical other than I-125 or I-131, the radiopharmaceutical, dosage, and route of administration. Your QMP is missing procedures to require that the written directive include:

- the radiopharmaceutical
- the dosage
- the route of administration
- an order for a specific patient
- the date and signature of an authorized user

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health.

Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive. Please include such a policy in your QMP.

Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage. Your QMP must include a policy/ procedure that requires that revisions to written directives will be made prior to administration.

A commitment to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d). Describe the procedure for an authorized user or a qualified individual under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist or technologist), after administering a radiopharmaceutical, to make, date, sign or initial a written record that documents the administered dosage in an auditable form.

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

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

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

Your 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.

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

Your QMP should include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32 (b)(2).

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

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

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

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

approval. When modifications are made to your program, You should submit any changes to your QMP to this Office within 30 days as required by 10 CFR 35.32(e).

Your QMP was reviewed by an NRC contractor following a standard review plan and related checklist provided by the NRC staff. This letter outlining the findings of that review was prepared by the contractor utilizing standard paragraphs previously reviewed and approved by NRC headquarters and regional management. If you have any questions about this review, you may call me at (610)337-5309. Thank you for your cooperation in this matter.

Sincerely,

Original Signed By:
James P. Dwyer

James P. Dwyer
Quality Management Program Coordinator
Region I

Enclosure: As stated

030-01875

QUALITY MANAGEMENT PROGRAM

For Charlton Memorial Hospital

This Program will be implemented by January 27, 1992.

NRC 20-05691-01

IMLL 10

FAX JAN 24 1992

NUCLEAR MEDICINE QUALITY MANAGEMENT PROGRAM

The Nuclear Medicine Department uses 131I for diagnostic and therapeutic treatment.

1.1 All administrations of 131I (diagnostic or therapeutic) shall have an authorized user, date, and signed written directive, prior to administration of any therapeutic dose or any dose of quantities greater than 30 microcuries of sodium iodide 131. The Nuclear Medicine Department does not use 125I.

1.2 Before administering a radiopharmaceutical dosage, the licensee shall verify the patient's identity by asking the patient what their name is and their date of birth. Patients receiving 131I therapy doses are also required to sign an informed consent form.

1.3 Before administering the by-product material, the specific details of the administration must be in accordance with the written directive. The radiopharmaceuticals must 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.

1.4 All workers who do not understand how to carry out the written directive should ask the Chief Technologist, Mary Jensen, if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

1.5 The Chief Nuclear Medicine Technologist, after administering a radiopharmaceutical, will make, date and sign, or initial a written record that documents the administered dosage in the patient's chart.

1.6 See attached QMP review form.

1.7 P32 is administered under the guidelines 1.1 to 1.5.

mst

5. Each administration of a radiopharmaceutical was in accordance with the written directive when a written directive was required.

Yes_____ No_____

6. Any unintended deviation from a written directive was identified and evaluated.

Yes_____ No_____ N/A_____

7. Have recordable events been evaluated within thirty (30) days after discovery? (10 CFR 35.32 (c)).

Yes_____ No_____ N/A_____

8. Have records of recordable events been retained for three (3) years? (10 CFR 35.32 (c) (3)).

Yes_____ No_____ N/A_____

9. Has the NCR been informed of any misadministrations?

Yes_____ No_____ N/A_____

10. Have the reporting requirements of 10 CFR 35.33 (a) (3) and (a) (4) been completed for each misadministration?

Yes_____ No_____ N/A_____

11. Have records of misadministrations been maintained for ten (10) years? (10 CFR 35.33 (b))

Yes_____ No_____ N/A_____

12. Has the Radiation Safety Committee reviewed previous audits to determine the effectiveness of the quality management program and made modifications as necessary? (10 CFR 35.32 (b) (2))

Yes_____ No_____ N/A_____

13. Has the Hospital retained records of the audit for three (3) years? (10 CFR 35.32 (b) (3))

Yes_____ No_____ N/A_____

Reviewed by Radiation Safety Officer

Signature: Charles Wendell MD DABNM Date: 1/23/92

Review by Radiation Safety Committee

Signature of Chairman: Charles Wendell MD DABNM Date: 1/23/92

P32

CHARLTON MEMORIAL HOSPITAL

HIGHLAND AVENUE AT NEW BOSTON ROAD
FALL RIVER, MASSACHUSETTS 02720
(617) 679-3131

CONSENT UPON ADMISSION TO REPORT FOR TREATMENT AND/OR SURGERY

PATIENT:_____ TIME:_____ a.m. p.m. DATE:_____

1. I hereby authorize Dr._____and/or such assistants as may be selected by him to treat the condition or conditions which appear indicated by the diagnostic studies already performed.

_____
(Explain the nature of the condition)

2. The procedure(s) necessary to treat my condition (has, have) been explained to me by Dr._____ and I understand the nature of the procedure(s) to be: (a description of the procedure in the language of laymen.)

_____

_____

3. I recognize that, during the course of the operation, unforeseen conditions may necessitate additional or different procedure(s) than those set forth in paragraph 2. I, therefore, authorize and request that the above-named surgeon, his assistants, or his designees perform such procedures as are in the exercise of professional judgment necessary and desirable, including but not limited to, procedures involving surgery. The authority granted under this paragraph 3 shall extend to treating all conditions that require treatment and are not known to Dr._____ at the time the operation is commence

4. I have been made aware to my complete understanding and satisfaction by Dr._____the nature and purpose of the operation, possible alternatives, methods of treatment and the risks and consequences that are associated with the procedure(s) described in paragraph 2.

5. I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees have been made to me concerning the results of the operation or procedure. I have been informed there are other risks such as severe loss of blood, infection, cardiac arrest, etc., that are attendant to the performance of any surgical procedure.

6. I consent to the administration of anesthesia under the direction and supervision of members of the Anesthesia Dept., Charlton Memorial Hospital.

7. I consent to the disposal by hospital authorities of any tissues or body parts which may be removed.

_____ _____
Witness Signature of Patient

(If patient is unable to sign or is a minor, complete the following.) Patient (is a minor_____years of age) is unable to sign because _____

_____

_____
Witness

_____ _____
Witness Closest Relative or Legal Guardian

CHARLTON MEMORIAL HOSPITAL,

QUALITY MANAGEMENT PROGRAM

Annual Audit of Quality Management Program

An annual review of the quality management program will be conducted by the Radiation Safety Officer at the time of the annual ALARA audit.

NCR License No. 20-05691-01

Date of Audit: _____

Audit Conducted by: _____

Audit Findings:

The scope of the audit consisted of a review of the quality management program and supporting documentation, interview with appropriate personnel, and direct observations of certain procedures. The following findings resulted from this audit:

A. Patient Records

1. Prior to administration a written directive was prepared for:

   a. Any administration of radioactive sodium iodide in quantities greater than 30 microcuries (uCi).

      Yes_____ No_____ N/A_____

   b. Any therapeutic administration of a radiopharmaceutical other than sodium iodide.

      Yes_____ No_____ N/A_____

2. Each written directive was maintained in an auditable form for three years.

   Yes_____ No_____

3. A record of each administered radiopharmaceutical dosage where a written directive is required is maintained for three years.

   Yes_____ No_____

4. Prior to dosing, the patient's identity was verified by more than one method as the individual named on the written directive.

   Yes_____ No_____

Patients Name: _____

Date: _____

DISCHARGE RECOMMENDATIONS FOLLOWING I-131 TREATMENT

INSTRUCTIONS: Following treatment of I-131

After administered dosage of less than 15mCi:

1. Avoid pregnant females for two (2) days
2. Avoid children under the age of 5 for one (1) to two (2) days. For older children, avoid continued contact, such as prolonged hugging, cuddling or sitting in the lap for two (2) to three (3) days.
3. Be sure to flush toilet twice, particularly if multiple people are using the facility, for two (2) days.

After administered dosage of more than 15mCi but less than 30mCi:

Follow directions above but be more cautious in dealing with young children for three (3) days

If possible, avoid close contact with them completely for two (2) to three (3) days

Further Instructions: _____

_____

_____

_____

_____

_____

Physician

_____

Date

CONSENT TO RADIATION THYROID THERAPY FOR HYPERTHYROIDISM

Patient _____ Age _____

Date _____ Time _____ Place _____

1. I hereby authorize Dr. _____ and whomever he may designate as his assistants, to perform upon _____ (state name or myself) the following therapy procedure decreasing size and/or function of the thyroid gland by giving radioactive iodine to destroy some thyroid tissue.

2. I _____ (state name or myself) am/am not pregnant or lactating.

3. The procedure (s) necessary to aid in treating my condition has/have been explained to me by Dr. _____ and I understand the nature of this procedure (s) to be: A pill or liquid form of Radioactive Iodine is given by mouth. This Radioactivity enters thyroid by the bloodstream and remains there for many weeks, destroying small amounts of thyroid tissue.

4. I have been aware of risk (s) and consequences that are associated with the procedure (s) described in Clause #3. These are:

   a.) Need for retreatment because not enough Radioactivity was given to reduce size/function of thyroid gland.

   b.) Need for replacement hormone therapy because of too much reduction of the gland function resulting in hypothyroidism.

5. The uncertainties and nature of this therapeutic procedure and the risks of injury despite precautions, have been explained to me. I voluntarily assume and accept the risks involved and agree that the above named physician, his assistants and the Charlton Memorial Hospital in Fall River and its personnel shall assume no responsibility for any ill effects or unforeseen result arising from this diagnostic procedure.

6. I know that no guarantee or assurance has been given by anyone concerning injuries, fetal or otherwise, resulting from this radiation diagnostic procedure. I know that radiation is powerful in destroying tissue.

7. I voluntarily consent to this radiation therapy procedure and release the attending physician, his assistants, and the Charlton Memorial Hospital in Fall River and its personnel from liability for any results that may occur.

(Continued)