

SEP 15 1994

BRIGHAM & WOMEN'S HOSPITAL
75 FRANCIS STREET
BOSTON, MA 02115

ATTN: FRANK P. CASTRONOVO, JR. PH.D.

RE: Docket Number: 030-12239
License Number: 20-17131-01

Dear Dr. Castronovo:

This letter acknowledges receipt of your letter dated August 11, 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

240156

OFFICIAL RECORD COPY - C:\D\QM-ACK\002063.ACK - 08/25/94

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PDR ADOCK 03012239
C PDR

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NOTE TO DMB:

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

LICENSE NUMBER: 20-19131-01

DOCKET NUMBER: 030-12239

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!



BIOLOGICAL
AND
WOMEN'S
DIVISION



FRANK P. CASTRONOVO, JR., PhD
RADIATION SAFETY OFFICER
NRC REGION I
1200 MOUNTAIN VIEW AVENUE
BETHLEHEM, PA 18015
610-395-6100

July 11, 1994

THRU: KIM LEE
TO: JIM DWYER

James P. Dwyer
QMP Coordinator
NRC Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Rec'd QMP
8/11/94, 8/15/94
ACK 8/25/94

RE: Docket # 3012239
Lic. # 20-17131-01
Plan File Date: 28 May 93
Region No. 1

Dear Mr. Dwyer:

I would like to apply for an extension to modify our written QMP to meet the objectives of 10 CFR 35.32 as discussed in your letter received on 23 June 94. The extension period requested is until 31 August 1994.

Sincerely,

Frank P. Castronovo, Jr, PhD
Radiation Safety Officer

FPC/rac

cc: Phil Cobb
NRC QMP file

JUL 14 1994



BRIGHAM
AND
WOMEN'S
HOSPITAL



Harvard Medical School

Associate Professor
of Radiology

Frank P. Castronovo, Jr., Ph.D.
Director, Department of Health Physics
and Radiopharmacology
Radiation Safety Officer

Radiopharmacist/Radiopharmacologist

75 Francis Street
Boston, Massachusetts 02115
617/32-6057
FAX: 617/586-9574

August 11, 1994

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

RE: Docket #: 3012239
License #: 20-17131-01
Plan File Date: 28 May 93
Region Number : 1

Dear Mr. Dwyer:

The following modifications in our Quality Management Program (QMP) are submitted for your review:

1. Regarding Brachytherapy

- a. The Joint Center for Radiation Therapy (JCRT) has modified its QMP to better meet the objectives in 10CFR35.32.
- b. The Brachytherapy modifications, as submitted by the JCRT, are contained in Appendix A.

2. Regarding I-125 and/or I-131 > 30 Microcuries and Other Therapeutic Radiopharmaceuticals

- a. The modified written directive for radiopharmaceutical therapies is contained in Appendix B. Please note that the "patients name", "ID #", "radiopharmaceutical", "Rx dose", "dosage administered", "the route of administration", "Authorized User's Signature", "two means of identification" and the "technologist's signature" are included.

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AUG 15 1994

- b. If, because of the patient's condition or the emergent nature of the patient's condition, an oral revision of the written directive is necessary, it will be documented in the patient's record.
- c. Revisions to written directives, if prescribed by the authorized user, will be made prior to the administration of diagnostic or therapeutic quantities of I-125 and/or I-131 as well as other therapeutic radiopharmaceuticals. Such revisions will be made on the original written directive form, as contained in Appendix B, and initialed by the authorized user. A new written directive may also be completed.
- d. The verification of the written directive is accomplished by having this document present during each administration. The "check-list" and "fill-in the blank" format insures live time documentation of the written directive.
- e. After the discovery of a recordable event we shall evaluate and respond within 30 days the following information:
 - (1). the relevant facts including the cause,
 - (2). identification of, if any, corrective action is required to prevent recurrence, and
 - (3). we will retain a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

3. Representative Sample

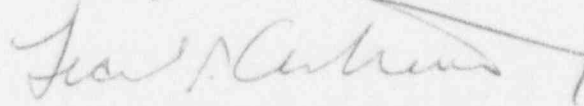
The QMP shall be reviewed by the Brigham and Women's Hospital radiation safety committee at intervals no greater than 12 months. This review shall be required to determine the effectiveness of the QMP and to determine if any modifications will be required. This audit will include all recordable events, all misadministrations, and a sample of patient administrations. The number of patient cases to be sampled shall be based on the principles of statistical, acceptance sampling and will represent each modality performed at the Brigham and Women's Hospital. A representative sample will be selected as follows; 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. If a recordable event or misadministration is uncovered during each review, we will sample an additional number of patients. If necessary, we will implement QMP modifications based on

James P. Dwyer
August 11, 1994
Page Three

any negative findings. All modifications to the QMP shall be reported to the NRC within 30 days after each modification has taken place.

Please contact me if questions arise concerning the above material.

Sincerely,



Frank P. Castronovo, Jr., Ph.D.
Radiation Safety Officer

FPC/fpc

Enclosures

cc: NRC QMP file

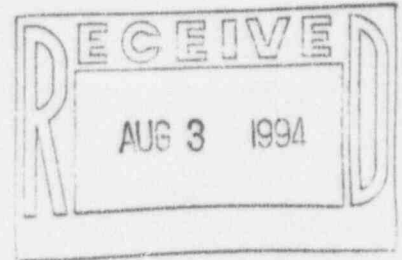
Appendix A

Brachytherapy Modifications

NEDH RADIATION SAFETY MANUAL
August 2, 1994

QUALITY MANAGEMENT PROGRAM
SECTION 35.32

JOINT CENTER FOR RADIATION THERAPY
QUALITY MANAGEMENT PROGRAM (QMP)



Radiation Therapy Departments

New England Deaconess Hospital (NEDH)
Dana-Farber Cancer Center (DFCI)
Brigham-Women's Hospital (BWH)
The Children's Hospital (CHMC)
Beth Israel Hospital (BIH)

The Nuclear Regulatory Commission (NRC) has issued a regulation that requires each licensee to establish a "Quality Management Program" (QMP) for the administration of By-Product Material to Patients. This QMP will be applicable to all JCRT Hospital Radiation Therapy Departments and will become part of the NRC License of each hospital, after approval by each Radiation Safety Committees (RSC). The JCRT has no NRC licensed teletherapy units or gamma stereotactic radiosurgery units.

1. Prior to administration of radioactive material for a brachytherapy or radiopharmaceutical therapeutic procedure, a written directive must be submitted via FAX (632-0578) to the JCRT Radiation Safety Office (RSO). This written directive must be signed by a JCRT staff physician.

a. **NEDH ONLY: THERAPY RADIOPHARMACEUTICAL ADMINISTRATIONS:** The written directive will be the "Implant Schedule Form". This form is already in existence and is currently sent via FAX to the RSO. Any administration of sodium iodide I-125 or I-131 in quantities greater than 30 microcurie must have a written directive.

b. **BRACHYTHERAPY REQUIRING A FORMAL PLAN:** The plan completed immediately prior to the implant loading and/or the written directive must be sent via FAX to the staff physician from the JCRT Planning Center for his/her signature. The signed plan is then sent via FAX to the JCRT RSO.

c. **BRACHYTHERAPY NOT REQUIRING A FORMAL PLAN PRIOR TO IMPLANT LOADING OR THERAPY RADIOPHARMACEUTICAL ADMINISTRATIONS:** The staff physician must complete and sign the JCRT WRITTEN DIRECTIVE FORM and sent via FAX to the RSO.

NOTE: Therapeutic radiopharmaceutical administrations of sodium iodide I-131 are not administered by the JCRT Radiation Therapy Departments at DFCI, BWH, CHMC, or BIH.

THE SIGNED WRITTEN DIRECTIVE MUST BE RECEIVED IN THE JCRT RADIATION SAFETY OFFICE BEFORE THE BRACHYTHERAPY PROCEDURE CAN BE COMPLETED.

2. The written directive for a specific brachytherapy patient must include:
- a. Prior to Implantation: radioisotope, number of sources, and source strengths;
 - b. After Implantation and prior to treatment completion: radioisotope, treatment site, total dose

****NEDH RADIATION SAFETY MANUAL****

August 2, 1994

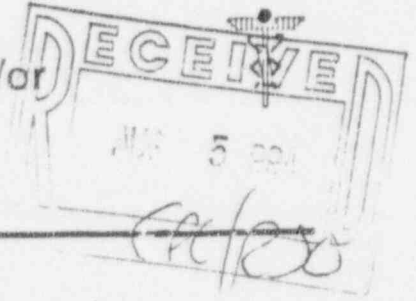
3. Oral revisions to the written directive are acceptable because of the patient's condition would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and the revision noted under "Directive Modification" on the written directive within 48 hours of the oral revision. In addition, if the patient's condition is critical and the delay to provide a written direction would jeopardize the patient's health, than an oral directive is acceptable provided that the oral directive is documented in the patient's record and the written directive is prepared within 24 hours of the oral directive. All other revisions to the written directive must be documented at the time of the revision.
4. Prior to each administration, the patient's identity shall be verified by wrist band identification and by statement of the name to the patient, as the individual named in the directive.
5. The final plans of treatment and related calculations shall be in accordance with the written directive.
 - a. Brachytherapy calculations must be check by a person who did not originally perform the calculations.
 - b. The position of the sources must be verified with dummy sources or fixed geometry applicators prior to inserting the sealed sources. (IF VERIFICATION IS SPECIFIED BY THE PHYSICIAN)
 - c. The computer program used to calculated dose rates must be "acceptance tested" to determine that the correct dose rates are being calculated.
6. The administration shall be in accordance with the written directive. Prior to administration, the person administering the treatment, must verify that all the details specified in the written directive and the treatment plan. (CHECKING THE TREATMENT PLAN IS NECESSARY IF A TREATMENT PLAN IS REQUIRED BY THE PHYSICIAN) All details of the treatment must be recorded promptly in the patient's record.
7. Any unintended deviation from the written directive shall be identified and evaluated, and appropriate action taken. Any intended deviation will be documented on the written directive and in the patient's chart with the signature of the staff physician.
8. Recordable events will be evaluated and recorded within 30 days of the event.
9. The QMP shall be reviewed by the JCRT Quality Assurance Committee, and the RSC at the specific hospital where the procedures are performed. The review shall be at intervals no greater than 12 months. This review shall be required to determine the effectiveness of the QMP and to determine if any modifications are required in the QMP. This audit will included all recordable events, all misadministration, and a sample of patient administrations. (>100 patients, sample 20% of treatments; 20-100 patients, sample 20 treatments; <20 patient, sample all treatments). If a recordable event or misadministration is uncovered during the quarterly review, it will be required to sample an additional number of patients. All modification to the QMP must be reported to the NRC within 30 day after the modifications have taken place.
10. Any deviations from the QMP shall be reported to the hospital Radiation Safety Committee on a quarterly basis.

Appendix B

Written Directive for Radiopharmaceutical



Brigham and Women's Hospital
Radiopharmaceutical Therapies and/or
Uses of Iodine-131 > 30µCi



Patient's Name: 131 I Patient's I.D. Number: 29.9 mCi

Radiopharmaceutical: control of hyperthyroid Prescribed Dose: 29.9 mCi Administered Dose: 29.9 mCi

Procedure Desired: control of hyperthyroid Route of Administration: oral

Authorized Users Signature: [Signature] Date: 7/29/94
(Permit # 702)

▼ ▼ ▼ COMPLETE TWO MEANS OF IDENTIFICATION ▼ ▼ ▼

- Patient was called by name. (required)
- Patient was asked to state their date of birth.
- Patient was asked to present identification. (i.e. Driver's License) hospital card
- Patient was an in-patient and wrist band I.D. was confirmed.
- Patient was asked to spell name.
- Patient was asked to state their S.S.N.

Technologist's Signature: Christopher W. Farrell Date: _____

RETURN A COMPLETED COPY OF THIS FORM TO:



Frank P. Castronovo, Ph.D.
Director, Department of Health Physics
& Radiopharmacology
Carrie M. Hall Building, 4th floor



BRIGHAM
AND
WOMEN'S



Harvard Medical School

Frank P. Cantorino, M.D.
Medical Director
Quality Management
Department

August 11, 1994

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

RE: Docket #: 3012239
License #: 20-17131-01
Plan File Date: 28 May 93
Region Number : 1

Dear Mr. Dwyer:

The following modifications in our Quality Management Program (QMP) are submitted for your review:

1. Regarding Brachytherapy
 - a. The Joint Center for Radiation Therapy (JCRT) has modified its QMP to better meet the objectives in 10CFR35.32.
 - b. The Brachytherapy modifications, as submitted by the JCRT, are contained in Appendix A.
2. Regarding I-125 and/or I-131 > 30 Microcuries and Other Therapeutic Radiopharmaceuticals
 - a. The modified written directive for radiopharmaceutical therapies is contained in Appendix B. Please note that the "patients name", "ID #", "radiopharmaceutical", "Rx dose", "dosage administered", "the route of administration", "Authorized User's Signature", "two means of identification" and the "technologist's signature" are included.

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AUG 15 1994

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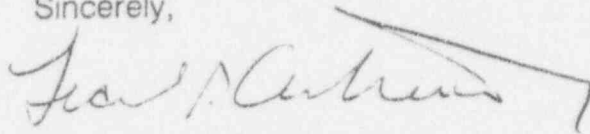
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James P. Dwyer
August 11, 1994
Page Three

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Please contact me if questions arise concerning the above material.

Sincerely,

A handwritten signature in black ink, appearing to read "Frank P. Castronovo, Jr.", with a long horizontal stroke extending to the right.

Frank P. Castronovo, Jr., Ph.D.
Radiation Safety Officer

FPC/fpc

Enclosures

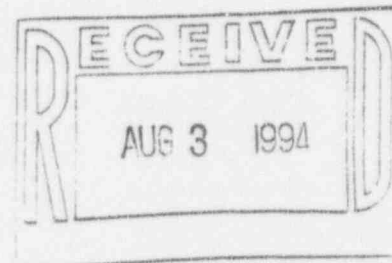
cc: NRC QMP file

Appendix A

Brachytherapy Modifications

****NEDH RADIATION SAFETY MANUAL****

August 2, 1994

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SECTION 35.32JOINT CENTER FOR RADIATION THERAPY
QUALITY MANAGEMENT PROGRAM (QMP)

Radiation Therapy Departments

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****NEDH RADIATION SAFETY MANUAL****

August 2, 1994

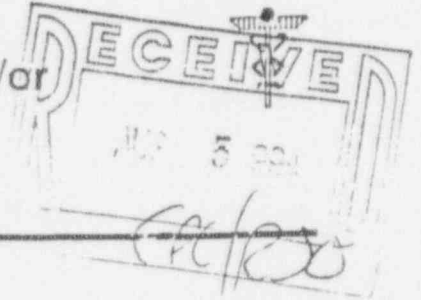
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 - a. Brachytherapy calculations must be check by a person who did not originally perform the calculations.
 - b. The position of the sources must be verified with dummy sources or fixed geometry applicators prior to inserting the sealed sources. (IF VERIFICATION IS SPECIFIED BY THE PHYSICIAN)
 - c. The computer program used to calculated dose rates must be "acceptance tested" to determine that the correct dose rates are being calculated.
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Appendix B

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 Radiopharmaceutical Therapies and/or
 Uses of Iodine-131 > 30 μ Ci



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Radiopharmaceutical: control of hyperthyroid Prescribed Dose: 29.9 mCi Administered Dose: 29.9 mCi

Procedure Desired: control of hyperthyroid Route of Administration: oral

Authorized Users Signature: [Signature] Date: 7/29/94
 (Permit # 702)

▼ ▼ ▼ COMPLETE TWO MEANS OF IDENTIFICATION ▼ ▼ ▼

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Technologist's Signature: Christopher W. Farrell Date: _____

RETURN A COMPLETED COPY OF THIS FORM TO:



Frank P. Castronovo, Ph.D.
 Director, Department of Health Physics
 & Radiopharmacology
 Carrie M. Hall Building, 4th floor

BRIGHAM & WOMEN'S HOSPITAL
75 FRANCIS STREET
BOSTON, MA 02115

JUN 17 1994

ATTN: FRANK P. CASTRONOVO, JR. PH.D.

RE: Docket Number: 3012239
License Number: 20-17131-01
Plan File Date: 28-MAY-93
Region Number: 1

Dear Dr. Castronovo:

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

Regarding Brachytherapy

Written directives for brachytherapy, other than high-dose-rate remote afterloading brachytherapy, as defined in 10 CFR 35.2, must include: the radioisotope, number of sources, and source strengths; and after implantation, but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose). Your QMP must include a written policy/procedure which requires that written directives for brachytherapy doses will include all treatment parameters prior to administration. Your QMP is missing procedures to require that the written directive include:

- An order for a specific patient

Prior to implantation:

- the radioisotope

- number of sources
- source strengths

After implantation, but prior to completion of the procedure:

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

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

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 for brachytherapy may be made provided that the revision is dated and signed by an authorized user prior to the administration of the brachytherapy dose or the next brachytherapy fractional dose. Your QMP must include a policy /procedure that requires that revisions to written directives will be made prior to administration of the brachytherapy dose or next fractional brachytherapy dose.

Your submittal does not include policies/procedures that ensure that final plans of treatment and related calculations for brachytherapy are in accordance with the written directive as required by 10 CFR 35.32(a)(3). Your procedures should require that:

- procedures for performing a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations). Procedures for checking the dose calculations before administration of the prescribed brachytherapy dose. An authorized user or a qualified person under the supervision of an authorized user (e.g., a radia-

tion therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible did not make the original calculations, should check the dose calculations

- verification of the position of dummy sources or fixed geometry applicators prior to inserting sealed sources, is accomplished
- acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations, and checking computer generated dose calculations is performed

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

Your procedures should include a requirement for verification, before administering each brachytherapy dose, that the specific details of the administration are in accordance with the written directive and plan of treatment. The prescribed radioisotope, number of sources, source strengths, treatment site, loading sequence, and total dose should be confirmed by the person administering the brachytherapy treatment to verify agreement with the written directive and treatment plan.

Your procedures should include a requirement for prompt recording, by the authorized user, of the number of sources and the actual loading sequence of the radioactive sources implanted (e.g., location of each sealed source in a tube, tandem, or cylinder) and sign or initial the patient's chart or appropriate record.

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

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

Your QMP review procedure does not provide an evaluation of:(a) an adequate representative sample of patient administrations, (b) all recordable events, and (c) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient

cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

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

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

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

Please be advised that multiple misadministrations and other errors have occurred due to sources that are inaccurately placed or have moved. In addition, wrong organs have been irradiated as a result of unintentional and undetected movement of the source, once implanted. Each licensee should review their procedures to ensure that source positions are verified and frequently checked.

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

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

- be an order for a specific patient
- contains the dosage to be administered

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

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

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

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

Your submittal for I-125 and/or I-131 > 30 microcuries administration does not include policies/procedures that ensure before administration that each administration is in accordance with the written directive as required by 10 CFR 35.32(a)(4). Describe your policy/procedure to verify, before administering the by-product material, that the specific details of the administration are in accordance with the written directive.

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

As required in 10 CFR 35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (a) assembling the relevant facts including the cause, (b) identifying what, if any, corrective action is required to prevent recurrence, and (c) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. Please include such a provision in your QMP.

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

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is

prepared within 24 hours of the oral directive. Please include such a policy in your QMP.

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

Your submittal for 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 by-product material, that the specific details of the administration are in accordance with the written directive.

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

As required in 10 CFR 35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (a) assembling the relevant facts including the cause, (b) identifying what, if any, corrective action is required to prevent recurrence, and (c) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. Please include such a provision in your QMP.

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



BRIGHAM
AND
WOMEN'S
HOSPITAL



Harvard Medical School

Associate Professor
of Radiation

Frank P. Castronovo, Jr., Ph.D.
Director, Health Physics Department
Radiation Safety Officer

Radiopharmaceuticals Division

77 Avenue Louis Pasteur
Boston, Massachusetts 02115
Tel: 617-355-6057
FAX: 617-355-6054

070-12239

May 28, 1993

Quality Management Program
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

To Whom It May Concern:

Enclosed is the Quality Management Program which
has been implemented at the Brigham and Women's
Hospital under Broad License # 20-17131-01.

Sincerely,

Frank P. Castronovo, Jr., Ph.D.
Radiation Safety Officer

FPC/rac

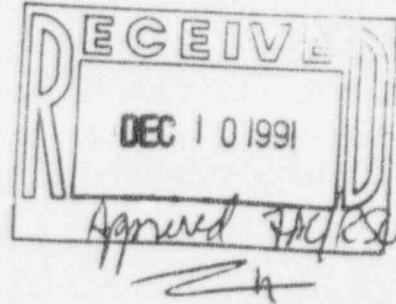
Enclosure

cc: NRC QM file

JUN 03 1993

(FAX REC'D 5/28/93)

PAGE 10



MEMORANDUM

TO: Dr. Frank Castronovo, Radiation Safety Officer
FROM: Beverly Potter, Laboratory Manager Endo-Hyper
DATE: December 5, 1991
SUBJECT: NRC Policies and Procedures

=====

In response to your request for our policies and procedures for Thyroid uptakes and therapy:

1. Authorized user date and sign a written directive prior to the administration of any therapeutic: see attachment nos.1-2.
2. Verify by more than one method the identity of the patient as the individual named in the written directive: see attachment no.3, section D, Patient procedure.
3. Dose should be measured in dose calibrator and the results compared with the prescribed dosage in the written directive: see attachment no.4.
4. Workers to seek guidance rather than continuing a procedure when there is any doubt: see attachment no.5.
5. Make, date, and sign or initial a written record that documents the administered dosage in the patient's chart: see attachment no. 6. When ¹³¹I is administered the form is sent to the patient's physician for the patient chart. When ¹²³I is administered, the form is kept in the Thyroid Uptake Patient Record Book.
6. Perform periodic review of radiopharmaceutical Quality Management/Quality Control program: see attachment no.5.



BRIGHAM
AND
WOMEN'S
HOSPITAL

75 Francis Street
Boston, Massachusetts 02115

Phone: ext. 7501

TO: All Physicians ordering radiiodine administration
to patients

FROM: Richard Underwood, Ph.D., Laboratory Director Atty.
Beverly Potter, Laboratory Manager

DATE: September 2, 1987

RE: Radioactive Iodine Patient Administration
(Uptake and/or Therapy)

In order to comply fully with NRC regulations we would like all physicians ordering an uptake and/or therapy to adhere to the following revised procedure.

A written requisition must first be completed, using the hospital clinical laboratory test requisition for all in/out patients and using the green Endocrine-Hypertension (253) slip for patients in the ACC and Endocrine Clinic. Telephone call should be made to ext. 7501 (Endocrine-Hypertension Clinical Assays Laboratory, attn. Ms. Betty Bent) to arrange a date and time for the particular test, which will be entered into a treatment log book. It is essential that the completed requisition slip be immediately put in the hospital mail system in an envelope addressed for Endocrine-Hypertension, Lab building +3, attn. Beverly Potter. Please note that a radiiodine administration cannot be carried out until the written requisition is received and checked with the verbal request entered in the treatment log book. An adhesive label stamped with the patient's hospital identification plate will be fixed to the appropriate page of the treatment log book on which the verbal request has been entered. A copy of the written request slip will be kept on file in the laboratory.

cc: Richard Underwood
Reed Larsen
Beverly Potter



A Teaching Affiliate of Harvard Medical School

AMBULATORY CLINICAL CENTER
221 LONGWOOD AVENUE
BOSTON, MASSACHUSETTS 02115

No 2
TELEPHONE
732-5666

example

NAME Greedy Fildard AGE _____
ADDRESS _____ DATE 9/22/89

Rx

131 I

7.4 mCi

P. R. Larsen M.D.

REFILL 0 1 2 3 4 5 PRN
LABEL

DEA NO.

P. R. Larsen, M.D. M.D.
AL 8306-08 TYPE NAME
(MASSACHUSETTS LAW REQUIREMENT)
(617) 732-6761

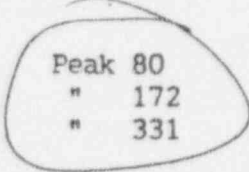
Interchange mandated unless the
practitioner writes words "no
substitution" in this space.

123I - THYROID UPTAKE PROCEDURE

I. Memory Usage	#1 (1/8)	Room background	Day 1 and Day 2
	#2 (2/8)	Control capsule	Day 1 and Day 2
Function 1	#3 (3/8)	Patient No.1	Day 1
	#4 (4/8)	"	Day 2
Function 2	#5 (5/8)	Patient No.2	Day 1
	#6 (6/8)	"	Day 2
Function 3	#7 (7/8)	Patient No.3	Day 1
	#8 (8/8)	"	Day 2

II. Range of Interest - R.O.I.

123-I	Channels	65-95	Peak 80
131-I	"	142-202	" 172
137-Cs	"	306-354	" 331



III. Procedure

- A. Quality Control - Place the 137-Cs bar in the probe to check for any drift in the system.
 Set: Memory/Eighth/ 4 /Clear/Data/Collect
 If the peak appears in the highlighted area (Ch 306-354), the system passes Q.C. If not, the system must be recalibrated as explained in the Set-Up section (notify the Lab Manager first).
 Record the Q.C. Intg on the Patient(s) data sheet.
- B. Room Background - Place the probe approx where the patient will sit. Check the probe distance marker for correct position length.
 Set: Memory/Eighth/ 1 /Clear/Data/Collect
 Record the Intg on the Patient(s) data sheet.
- C. Control Capsule - Place the capsule at the center of the probe
 Set: Memory/Eighth/ 2 /Clear/Data/Collect
 Record the Intg on the Patient(s) data sheet.
- D. Patient procedure
 Greet the patient(s) briefly and tell them what you are going to do.
Record the patient's hospital I.D. information from their card
 onto a label and place on the patient data sheet, an Endo-Hyper requisition and the yellow radioisotope form and the consent form.
 - Have the patient sign the consent form (a spanish form is available). There should be no doubt about the possibility of pregnancy in females. If the patient is unsure, a pregnancy test must be performed before the uptake capsule is given.
 - Conduct the patient to the chair provided and position the probe so that the bar is centered at the top of the sternal notch. Press bar firmly against patient, face squarely into probe and instruct patient not to move during counting

Pre-set bin = 60

move cursor to 331 peak

move cursor to peak

No. 3

123I Capsules for Thyroid Uptakes

1. Order the number of capsules required through Radiopharmacy, ext. 7171, by 11 a.m. of the weekday preceeding administration ^{set} to the patient. Order enough capsules for the patients plus one for control.
2. Pick up the capsules in Radiopharmacy at 8:30 a.m.. Dose ^{200 μ Ci} calibrate with the Dose calibrator located in Radiopharmacy. ^{123I}
3. Record dose in the 123I log book located in the Thyroid Treatment room. Date and initial. Place the descriptive sticker (see below) in the log book next to the recorded dose.
4. Discard the unused capsules and lead pigs in Radiopharmacy on a weekly basis. Monitor the trash container for disposal with either radioactive waste or regular trash.

131I-Na Capsules For Thyroid Therapy

1. Oder capsules on an as needed, amount requested basis only, by 1p.m. of the weekday preceeding the scheduled therapy. Capsules can be ordered as one or multiple capsules.
RS00712-
2. Ordering information: S.O.: AA04625 (expires 11/30/99)
Squibb: 1-800-447-6883
cust. no. 01190800233
specify: date of delivery and calibration
deliver to: Radiopharmacy, L-2, attn:
Endocrine, ext. 7501
3. Capsules are dose calibrated in Radiopharmacy directly before administration to the patient.
To operate the Capintec Radioisotope Calibrator, CRC-5R:
 - a. Press the 131I button, set '0' with the dial, set the range to either 20 or 200 as required.
 - b. Remove the capsule (keep in plastic vial) from the lead container with tweezers and place in the well of 5R container. Wear gloves and work behind the shield provided.
 - c. Record the dose in the 131I log book along with the calibration sticker from the lead pig. Initial and date.
4. Bring the capsule(s) to the treatment room when the physician is ready to administer to the patient.
5. Any unused capsules must be brought back to Radiopharmacy for disposal directly after administration.

Note: Always keep the isotope in the lead container until administration to the patient.

Never leave the isotopes unattended, Keep door locked unless the technician is in the room.

Record by the value on the patient data sheet.

Patient #2

Set: Memory/Eighth/ 6 /Clear/Data/Collect

Record the INTG on the patient data sheet

Compute Function 2 (F2): Compute/Func/F2

- continue as above

Patient #3

Set: Memory/Eighth/ 8 /Clear/Data/Collect

Record the INTG on the patient data sheet

Compute Function 3 (F3): Compute/Func/F3

- continue as above.

G. QM Program: All records are reviewed and signed by the Laboratory Supervisor on a monthly basis. All record books are reviewed and signed on a biannual basis by the Medical Director of the Thyroid Division.

H. Problems and/or questions regarding should be directed to the appropriate person in charge:

Instrument problems: Lab Manager, ext. 7501

Patient problems: The physician in charge
(i.e. Dr. Larsen, ext. 6762 or Dr. Williams, x5661)

Do not continue a procedure if there are any doubts concerning the equipment, the patient, or complying with any procedure or policy.

RADIOACTIVE ISOTOPE FORM



DIAGNOSTIC

THERAPEUTIC

6. 6

RADIOACTIVE ISOTOPE FORM

The above named patient has been given the following radioactive isotope

at _____ M on _____ 19 _____.

Isotope: _____ Dose: _____ Route of Administration: _____

Effective Half-Life: _____ Organ of Maximal Concentration: _____

The following checked precautions are to be observed:

None (Xe-133, etc.)

Short-lived isotope (Tc-99m, etc)
Use gloves when handling any body fluids within 24 hours.

Long-lived isotope (Ga-67, I-131, Co-57, In-111, Tl-201, etc)
During the next seven days,
(1) Use gloves when handling blood, urine, feces or drainage.
(2) Dispose these into a flushing commode, discard gloves into the trash.
(3) Label as radioactive any samples stored or sent to the laboratories.

Written instructions are attached.

All personnel responsible for the medical or nursing care of this patient must review and be familiar with the special procedures and requirements outlined in the Radiation Safety Manual, Brigham and Women's Hospital.

In the event of spillage or isotopic contamination notify at once the undersigned and the Radiation Safety Office. (2-6056). Make no attempt to clean the area or to remove any item touched by the isotope.

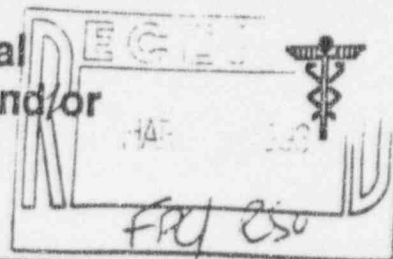
Signed _____ M.D.

Licensed Isotope Administrator





Brigham and Women's Hospital
 Radiopharmaceutical Therapies and/or
 Uses of Iodine-131 > 30 μ CI



Desmond, Daniel
 Patient's Name

112-99-06-2
 Patient's I.D. Number

131I
 Radiopharmaceutical

5.0 mCi
 Prescribed Dose

5.1 mCi
 Administered Dose

Iodine Body Scan
 Procedure Desired

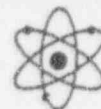
[Signature] 3/29/93
 Authorized Users Signature Date

▼ ▼ ▼ COMPLETE TWO MEANS OF IDENTIFICATION ▼ ▼ ▼

- Patient was called by name. (required)
- Patient was asked to state their date of birth.
- Patient was asked to present identification. (i.e. Driver's License) Hospital Card
- Patient was an in-patient and wrist band I.D. was confirmed.
- Patient was asked to spell name.
- Patient was asked to state their S.S.N. 019-68-1524

Christopher M Farrell 3/29/93
 Technologist's Signature Date

RETURN A COMPLETED COPY
 OF THIS FORM TO:



Frank P. Castronovo, Ph.D.
 Director, Health Physics Department
 Carrie M. Hall Building, 4th floor



**Brigham and Women's Hospital
Radiopharmaceutical Therapies and/or
Uses of Iodine-131 > 30 μ Cl**



Kelleher, Susan Patient's Name	<div style="border: 1px solid black; padding: 2px; display: inline-block;"> RECEIVED MAY 9 1993 053-76-93-3 F.P./ESU 12.0mCi </div>	Patient's I.D. Number
I ¹³¹ Radiopharmaceutical	12.0mCi Prescribed Dose	12.03mCi Administered Dose
Treat hyperthyroidism Procedure Desired		

M. A. Brent Authorized Users Signature	5/7/93 Date
---	----------------

▼ ▼ ▼ COMPLETE TWO MEANS OF IDENTIFICATION ▼ ▼ ▼

- | | | | |
|--|---|---|---|
| <input type="checkbox"/> Patient was called by name. (required)

<input type="checkbox"/> Patient was asked to spell name. | 11/16/61
<input checked="" type="checkbox"/> Patient was asked to state their date of birth.

<input type="checkbox"/> Patient was asked to state their S.S.N. | <input type="checkbox"/> Patient was asked to present identification. (i.e. Driver's License) | <input type="checkbox"/> Patient was an in-patient and wrist band I.D. was confirmed. |
|--|---|---|---|

Christopher M. Farrell Technologist's Signature	5/7/93 Date
--	----------------

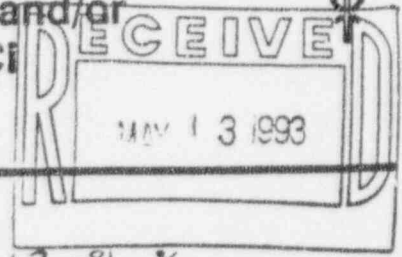
RETURN A COMPLETED COPY OF THIS FORM TO:



Frank P. Castronovo, Ph.D.
 Director, Health Physics Department
 Carrie M. Hall Building, 4th floor



Brigham and Women's Hospital
Radiopharmaceutical Therapies and/or
Uses of Iodine-131 > 30µCi



Cook, William
Patient's Name

053-62-86-8
Patient's I.D. Number

I131
Radiopharmaceutical

150mCi
Prescribed Dose

148.9 mCi
Administered Dose

Ablation of residual thyroid post thyroidectomy for papillary thyroid cancer
Procedure Desired

MA Brent MD
Authorized Users Signature

4/16/93
Date

▼ ▼ ▼ COMPLETE TWO MEANS OF IDENTIFICATION ▼ ▼ ▼

- Patient was called by name. (required)
- Patient was asked to state their date of birth.
- Patient was asked to present identification. (i.e. Driver's License)
- Patient was an in-patient and wrist band I.D. was confirmed.
- Patient was asked to spell name.
- Patient was asked to state their S.S.N.

Christopher M Farrell
Technologist's Signature

4/16/93
Date

RETURN A COMPLETED COPY OF THIS FORM TO:



Frank P. Castronovo, Ph.D.
Director, Health Physics Department
Carrie M. Hall Building, 4th floor

20.6.13 QUALITY MANAGEMENT PROGRAM
SECTION 35.32

JOINT CENTER FOR RADIATION THERAPY
QUALITY MANAGEMENT PROGRAM (QMP)

Radiation Therapy Departments

New England Deaconess Hospital (NEDH)
Dana-Farber Cancer Center (DFCI)
Brigham-Women's Hospital (BWH)
The Children's Hospital (CHMC)
Beth Israel Hospital (BIH)

The Nuclear Regulatory Commission (NRC) has issued a regulation that requires each licensee to establish a "Quality Management Program" (QMP) for the administration of By-Product Material to Patients. This QMP will be applicable to all JCRT Hospital Radiation Therapy Departments and will become part of the NRC License of each hospital, after approval by each Radiation Safety Committees (RSC). The JCRT has no NRC licensed teletherapy units or gamma stereotactic radiosurgery units

1. Prior to administration of radioactive material for a brachytherapy or radiopharmaceutical therapeutic procedure, a written directive must be submitted via FAX (731-3903) to the JCRT Radiation Safety Office (RSO). This written directive must be signed by a JCRT staff or resident physician.
 - a. **NEDH ONLY: THERAPY RADIOPHARMACEUTICAL ADMINISTRATIONS:** The written directive will be the "Implant Schedule Form". This form is already in existence and is currently sent via FAX to the RSO. Any administration of sodium iodide I-125 or I-131 in quantities greater than 30 microcurie must have a written directive.
 - b. **BRACHYTHERAPY REQUIRING A FORMAL PLAN:** The plan completed immediately prior to the implant loading must be sent via FAX to the staff or resident physician from the JCRT Planning Center for his/her signature. The signed plan is then sent via FAX to the JCRT RSO.

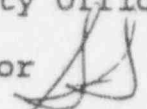
- c. BRACHYTHERAPY NOT REQUIRING A FORMAL PLAN PRIOR TO IMPLANT LOADING OR THERAPY
RADIOPHARMACEUTICAL ADMINISTRATIONS: The staff or resident physician must complete and sign the JCRT WRITTEN DIRECTIVE FORM and sent via FAX to the RSO and to the JCRT Treatment Planning Center.

NOTE: Therapeutic radiopharmaceutical administrations of sodium iodide I-131 are not administered by the JCRT Radiation Therapy Departments at DFCI, BWH, CHMC, or BIH.

THE SIGNED WRITTEN DIRECTIVE MUST BE RECEIVED IN THE JCRT RADIATION SAFETY OFFICE BEFORE THE BRACHYTHERAPY PROCEDURE CAN BE COMPLETED.

2. Prior to each administration, the patient's identity shall be verified by wrist band identification and by statement of the name to the patient, as the individual named in the directive.
3. The final plans of treatment and related calculations shall be in accordance with the written directive.
4. The administration shall be in accordance with the written directive.
5. Any unintended deviation from the written directive shall be identified and evaluated, and appropriate action taken. Any intended deviation will be documented on the written directive and in the patient's chart with the signature of the staff or resident physician.
6. The QMP shall be reviewed by the JCRT Quality Assurance Committee, and the RSC at the specific hospital where the brachytherapy procedures are performed. The review shall be at intervals no greater than 12 months. This review shall be required to determine the effectiveness of the QMP and to determine if any modifications are required in the QMP.
7. Any deviations from the QMP shall be reported to the hospital Radiation Safety Committee on a quarterly basis.

MEMORANDUM

TO: Dr. Frank Castronovo, Radiation Safety Officer
FROM: Sonya Shortkroff, Research Coordinator 
DATE: May 20, 1993
SUBJECT: NRC Policies and Procedures

=====

In response to your request for our polices and procedures for Dysprosium-165 therapy:

1. Authorized user shall date and sign a written directive in the physician order section of the medical record at the time of the administration of the Dysprosium-165 therapy.
2. The identity of the patient as the individual named in the written directive shall be verified by more than one method:see attachment No. 1.
3. The dose shall be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive:see attachment No. 2
5. A yellow radionuclide form, dated, and signed will serve as the written record that documents the administered dosage in the patient's chart:see attachment No. 3
6. Periodic review of the radiopharmaceutical Quality Management/Quality Control program will be performed according to IND #24594.



**Brigham and Women's Hospital
Radiopharmaceutical Therapies and/or
Uses of Iodine-131 > 30 μ Cl**



Patient's Name

Patient's I.D. Number

Radiopharmaceutical

Prescribed Dose

Administered Dose

Procedure Desired

Authorized Users Signature

Date

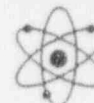
▼ ▼ ▼ COMPLETE TWO MEANS OF IDENTIFICATION ▼ ▼ ▼

- | | | | |
|--|--|---|--|
| <input type="checkbox"/> Patient was called by name.(required) | <input type="checkbox"/> Patient was asked to state their date of birth. | <input type="checkbox"/> Patient was asked to present identification. (i.e. Driver's License) | <input type="checkbox"/> Patient was an in-patient and wrist band I.D. was confirmed |
| <input type="checkbox"/> Patient was asked to spell name. | <input type="checkbox"/> Patient was asked to state their S.S.N. | | |

Technologist's Signature

Date

**RETURN A COMPLETED COPY
OF THIS FORM TO:**



**Frank P. Castronovo, Ph.D.
Director, Health Physics Department
Carrie M. Hall Building, 4th floor**

Procedure for Dose Calibration
for
¹⁶⁵Dy-FHMA Radiation Synovectomy

For each dose to be calibrated:

1. The security seal is removed from the pail, an interior wipe test is done (using geiger counter placed distant from radiation sources) and the dose vial is transported inside the innermost and intermediate lead "pigs" into the Capintec Cabinet.
2. Using 12" long forceps, the vial is lifted by the neck into the Capintec well. (prior to this, the Capintec was set at the scale for up to 2000mCi and the background on this channel has been checked and zeroed if necessary.

The vial is placed upright in the bottom of the Capintec lifter for every calibration. The channel is set on "other" and positioned at 075 for counting Dy¹⁶⁵.
3. The millicurie reading obtained and the time are noted on the patient data sheet.
4. The vial is returned to the lead Pig, after snapping the plastic cap off the vial and wiping the septum/seal with a sterile alcohol sponge.
5. The multiplying factor of 2.8 is used for all millicurie measurement of Dy¹⁶⁵ in glass vials (and the factor 2.2 for all measurement of Dy¹⁶⁵ in plastic syringes).
6. After multiplying the dose (vial) reading by the factor, the number is recorded on the patient data sheet (also recording the original reading and the factor used). The total "vial before" reading is divided by the volume present in the vial as listed on the MIT packing slip to obtain the millicuries per ml at the calibration time. The decay chart and a calculator are used to determine the volume for a 300mCi dose at the time of injection.
7. The "vial after" is measured and the activity left in the vial is calculated.
8. After injection, the syringe and stop cock are calibrated in the same Capintec. All numbers are decay corrected to the time of injection to calculate the exact dose administered.

20-17131-01
030-12239



Children's Hospital

RADIATION SAFETY COMMITTEE

QUALITY MANAGEMENT PROGRAM (QMP)

The Nuclear Regulatory Commission (NRC) has issued regulations (10 CFR 35.32) that require each Licensee to establish a "Quality Management Program" (QMP) for the administration of byproduct material to patients.

The QMP plan for Children's Hospital is based on the program used by the JCRT at participating institutions; New England Deaconess Hospital, Dana-Farber Cancer Institution, Brigham & Women's Hospital, and Beth Israel Hospital.

At Children's Hospital, byproduct materials are administered to patients for diagnosis and treatment of disease. The QMP covers primarily those procedures employing byproduct materials in radiation therapy, although some diagnostic tests using I-125 or I-131 may be included.

The following are instructions and procedures for the Quality Management Plan:

1. WRITTEN DIRECTIVE: Signed by JCRT staff or physician
 - A signed, written directive must be prepared for:
 - Any brachytherapy radiation dose.
 - Any administration of quantities greater than 30 microcuries or either sodium iodide I-125 or I-131.
2. Prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive.
3. The final plans of treatment and related calculations for brachytherapy must be in accordance with the written directive.
4. Each administration is to be in accordance with the written directive.
5. Any unintended deviation from the written directive must be identified and evaluated, and appropriate action taken. Any intended deviation from the written directive will be documented on the written directive and in the patient's chart with the signature of the staff or resident physician.

ALL 10 FAX REC'D MAY 25 1993

RADIATION SAFETY COMMITTEE RESPONSIBILITIES CONCERNING THE
QUALITY MANAGEMENT PLAN

1. Review the QMP at intervals of no greater than 12 months by evaluating:
 - A representative sample of patient administrations including misadministrations.
 - The effectiveness of the QMP. If required, make modifications to meet the plan criteria.
2. Retain records of each review of the QMP in an auditable form for three years.
3. Follow steps outlined in 10 CFR 35.32c for responding to/correcting misadministrations/recordable events (defined in 10 CFR 35.33).
4. Any deviations from the QMP shall be reported to the RSC on a quarterly basis.



BRIGHAM
AND
WOMEN'S
HOSPITAL



Harvard Medical School

Associate Professor
of Radiation

Frank P. Castronovo, Jr., Ph.D.
Director, Health Physics Department
Radiation Safety Officer

Radiopharmacist Radiopharmacologist

75 Francis Street
Boston, Massachusetts 02115
617-732-6057

030-12239

20 July 1992

USNRC
475 Allendale Road
King of Prussia, PA 19406

To whom it may concern:

The purpose of this note is to inform the NRC that Broad License # 20-17131-01 will use Regulatory Guide 8.33 as a model for our Quality Management Program.

Sincerely,

Frank P. Castronovo, Jr., PhD
Radiation Safety Officer

REC'D IN LAS JUN 27 1993



Children's Hospital

RADIATION SAFETY COMMITTEE QUALITY MANAGEMENT PROGRAM

WRITTEN DIRECTIVE

To be completed and signed by the physician administering byproduct materials to patients in the following cases:
All brachytherapy and radiopharmaceutical therapy, and any administration of sodium iodide I-125 or I-131 in excess of 30 microcuries.

PATIENT NAME: _____

PATIENT ID: _____ DATE: _____

RADIOISOTOPE: _____ FORM: _____

PRESCRIBED DOSE: _____ mCi

DURATION OF IMPLANT: _____

ADMINISTERED DOSE: _____ mCi

SIGNATURE OF PHYSICIAN: _____

DOES ADMINISTERED DOSE DEVIATE FROM THE PRESCRIBED DOSE? Y ___ N ___
(If yes, please indicate whether the deviation was intended or unintended.)

___ INTENDED DEVIATION FROM PRESCRIBED DOSE - describe below why the deviation was necessary

___ UNINTENDED DEVIATION FROM PRESCRIBED DOSE - describe below what action will be taken to prevent future unintended deviations from the prescribed dose

Explanation of deviation from prescribed dose:

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20.6.13 QUALITY MANAGEMENT PROGRAM
SECTION 35.32

JOINT CENTER FOR RADIATION THERAPY
QUALITY MANAGEMENT PROGRAM (QMP)

Radiation Therapy Departments

New England Deaconess Hospital (NEDH)
Dana-Farber Cancer Center (DFCI)
Brigham-Women's Hospital (BWH)
The Children's Hospital (CHMC)
Beth Israel Hospital (BIH)

The Nuclear Regulatory Commission (NRC) has issued a regulation that requires each licensee to establish a "Quality Management Program" (QMP) for the administration of By-Product Material to Patients. This QMP will be applicable to all JCRT Hospital Radiation Therapy Departments and will become part of the NRC License of each hospital, after approval by each Radiation Safety Committees (RSC). The JCRT has no NRC licensed teletherapy units or gamma stereotactic radiosurgery units

1. Prior to administration of radioactive material for a brachytherapy or radiopharmaceutical therapeutic procedure, a written directive must be submitted via FAX (731-3903) to the JCRT Radiation Safety Office (RSO). This written directive must be signed by a JCRT staff physician.
 - a. NEDH ONLY:THERAPY RADIOPHARMACEUTICAL ADMINISTRATIONS: The written directive will be the "Implant Schedule Form". This form is already in existence and is currently sent via FAX to the RSO. Any administration of sodium iodide I-125 or I-131 in quantities greater than 30 microcurie must have a written directive.
 - b. BRACHYTHERAPY REQUIRING A FORMAL PLAN: The plan completed immediately prior to the implant loading and/or the written directive must be sent via FAX to the staff physician from the JCRT Planning Center for his/her signature. The signed plan is then sent via FAX to the JCRT RSO.

- c. BRACHYTHERAPY NOT REQUIRING A FORMAL PLAN PRIOR TO IMPLANT LOADING OR THERAPY
RADIOPHARMACEUTICAL ADMINISTRATIONS: The staff physician must complete and sign the JCRT WRITTEN DIRECTIVE FORM and sent via FAX to the RSO and to the JCRT Treatment Planning Center.

NOTE: Therapeutic radiopharmaceutical administrations of sodium iodide I-131 are not administered by the JCRT Radiation Therapy Departments at DFCI, BWH, CHMC, or BIH.

THE SIGNED WRITTEN DIRECTIVE MUST BE RECEIVED IN THE JCRT RADIATION SAFETY OFFICE BEFORE THE BRACHYTHERAPY PROCEDURE CAN BE COMPLETED.

2. Prior to each administration, the patient's identity shall be verified by wrist band identification and by statement of the name to the patient, as the individual named in the directive.
3. The final plans of treatment and related calculations shall be in accordance with the written directive.
4. The administration shall be in accordance with the written directive.
5. Any unintended deviation from the written directive shall be identified and evaluated, and appropriate action taken. Any intended deviation will be documented on the written directive and in the patient's chart with the signature of the staff physician.
6. The QMP shall be reviewed by the JCRT Quality Assurance Committee, and the RSC at the specific hospital where the procedures are performed. The review shall be at intervals no greater than 12 months. This review shall be required to determine the effectiveness of the QMP and to determine if any modifications are required in the QMP.
7. Any deviations from the QMP shall be reported to the hospital Radiation Safety Committee on a quarterly basis.