AUG 2 2 1994

Cooley Dickinson Hospital, Inc.
Attn.: Elisabeth Weissbach
30 Locust Street
Northhampton, MA 01060

RE: License Number: 20-03502-01
Docket Number: 030-01863

Dear Ms. Weissbach:

This letter acknowledges receipt of your letter dated July 18, 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

240106

OFFICIAL RECORD COPY - D:\QM-ACK\COOLDICK.ACK - 08/09/94

ML 10

NOTE TO DMB:

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

LICENSE NUMBER: 20-03502-01

DOCKET NUMBER: 030-01863

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

The Cooley Dickinson Hospital Inc.
30 Locust Street
P.O. Box 5001
Northampton, MA 01061-5001
(413) 582-2000

July 18, 1994

Mr. James P. Dwyer
Quality Management Program Coordinator
United States Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

License Number: 20-03502-01
Docket Number: 030-01863
Plan File Date: June 8, 1993

Dear Mr. Dwyer:

Please find enclosed the information you requested concerning our Quality Management Program.

Respectfully submitted,

Elisabeth Weissbach
Vice President, Operations/COO

EMW/bt

Enclosure

ML 10

JUL 25 1994

The Cooley Dickinson Hospital Inc.
30 Locust Street
P.O. Box 5001
Northampton, MA 01061-5001
(413) 582-2000

NUCLEAR MEDICINE DEPARTMENT

QUALITY MANAGEMENT PLAN

June 8, 1993

PURPOSE: To assure clear communication, proper identification and effective treatment of patients within the Nuclear Medicine Department.

*In accordance with policy #35, an authorized user will date and sign the written order prior to the administration of any therapeutic dose or any dose greater than 30 microcuries of I-125 or I-131, or any treatment utilizing the Sr-90 opthalmic applicator.

*In accordance with policy #36, prior to administration of a radiopharmaceutical, the patient will be identified by more than one method. This will be accomplished by asking the patient's name and to confirm the name on the written order. Secondly, confirm by one of the following methods:

Birth date
Address
Social Security number
ID bracelet
Medical Insurance card

*In accordance with policy #37, prior to administration of radiopharmaceutical, the following will be verified:

the radiopharmaceutical
the dosage
the route of administration

NOTE: the dosage will be measured in the dose calibrator

*In accordance with policy #38, if there is any question regarding the written order for a procedure, the individual will consult a senior staff employee or an authorized user before the procedure is performed.

*In accordance with policy #39 an authorized user or a qualified technologist will date and sign or initial the written order that documents the administered dose. This written order is maintained as a permanent record.

*In accordance with policy #40, reviews of the quality management program will be done as part of the quarterly Radiation Safety Committee meeting.

MODIFICATIONS TO QMP PROGRAM

We do certify that our QMP plan has been implemented for the use of I-125 and/or I-131 > 30 micro curies.

It is our policy that 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 quantites greater than 30 micro curies 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 > 30uCi:

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

It is our policy 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.

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

It is our policy that 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 radio pharmaceutical dosage.

It is our policy that we shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

It is our policy to provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b).

It is our policy that our QMP will expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of our QMP we will evaluate the effectiveness of the QMP, and, if necessary, make modifications to meet the objectives of the program as required by 10 CFR 35.32 (b)(2).

It is our policy that modifications to our QMP will be submitted to the NRC within 30 days after the modification has been made.

It is our policy that records of each review and evaluation will be maintained for three years.

We do certify that our QMP plan has been implemented for the therapeutic use of radiopharmaceuticals other than I-125 or I-131.

It is our policy that 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.

It is our policy 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.

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It is our policy that 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.

It is our policy that we shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (i)assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

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The Cooley Dickinson Hospital Inc.
30 Locust Street
P.O. Box 5001
Northampton, MA 01061-5001

STRONTIUM – 89 THERAPEUTIC PRESCRIPTION

This form is to be completed in compliance with the Quality Management policy

1. Prescription *(written directive)*

Patient's Name:_____ RT #:_____

Age:_____ Sex: ☐ M ☐ F ☐ Outpatient ☐ Inpatient (Room # _____)

Referring Physician:_____ Diagnosis:_____

Is this patient pregnant? ☐ **Yes** ☐ **No**

Radionuclide: **Strontium – 89 Chloride Injection**

Decay: Pure Beta (–) Half Life: 50.5 days Energy: 1.463 MeV (max) 100 percent

Typical Dosage: 4mCi **or** 40–60 hCi / kg body weight

Prescribed dose in mCi:_____

Signature of Physician Authorized User:_____

2. Radionuclide Assay

Date:_____

Radionuclide Received:_____ Activity (mCi):_____

Verified by:_____ (RSO)

3. Pre-Injection Verification

Patient I.D. Verified:_____ Radionuclide Verified:_____ Dose Verified:_____
(2 methods)

Signature of Physician Authorized User:_____

4. Post-Procedure Radiation Survey

Check Source:_____ (mR/hr) Background:_____ (mR/hr)

Post-Radiation Monitoring Yielded:_____ (mR/hr)

Performed by:_____ (RSO)

I-131 Therapeutic Prescription

The form is to be completed in accordance with the Quality Management Policy

1. Prescription (written directive)

Patient Name: _____ MR#: _____

Age _____ Sex M or F Outpatient _____ Inpatient Room # _____

Referring Physician _____ Diagnosis _____

Is the patient pregnant ? Yes or **No**

Radionuclide: I-131 Iodide Capsule

Decay γ, β Half Life 8.08 Days Energy γ 364 KeV Typical Dosage 4 - 29 mCi

Prescribed Dose in Mci: _____

Signature of Authorized User: _____

2. Radionuclide Assay

Date: _____

Radionuclide Received: _____ Activity (mCi): _____

Verified by: _____

3. Pre-injection Verification

Patient ID Verified *(2 methods)*: _____ Radionuclide Verified: _____ Dose Verified: _____

Signature of Authorized User: _____

4. Post Procedure Radiation Survey

Check Source: _____(mR/hr) Background: _____(mR/hr)

Post Radiation Monitoring Yielded : _____ (mR/hr)

Performed by: _____ (RSO)

The Cooley Dickinson Hospital Inc.
30 Locust Street
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(413) 582-2000

NUCLEAR MEDICINE DEPARTMENT

QUALITY MANAGEMENT PLAN

June 8, 1993

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Medical Insurance card

*In accordance with policy #37, prior to administration of radiopharmaceutical, the following will be verified:

the radiopharmaceutical
the dosage
the route of administration

NOTE: the dosage will be measured in the dose calibrator

*In accordance with policy #38, if there is any question regarding the written order for a procedure, the individual will consult a senior staff employee or an authorized user before the procedure is performed.

*In accordance with policy #39 an authorized user or a qualified technologist will date and sign or initial the written order that documents the administered dose. This written order is maintained as a permanent record.

*In accordance with policy #40, reviews of the quality management program will be done as part of the quarterly Radiation Safety Committee meeting.

MODIFICATIONS TO QMP PROGRAM

We do certify that our QMP plan has been implemented for the use of I-125 and/or I-131 > 30 micro curies.

It is our policy that 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 quantites greater than 30 micro curies 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 > 30uCi:

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

It is our policy 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.

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

It is our policy that 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 radio pharmaceutical dosage.

It is our policy that we shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

It is our policy to provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b).

It is our policy that our QMP will expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of our QMP we will evaluate the effectiveness of the QMP, and, if necessary, make modifications to meet the objectives of the program as required by 10 CFR 35.32 (b)(2).

It is our policy that modifications to our QMP will be submitted to the NRC within 30 days after the modification has been made.

It is our policy that records of each review and evaluation will be maintained for three years.

We do certify that our QMP plan has been implemented for the therapeutic use of radiopharmaceuticals other than I-125 or I-131.

It is our policy that 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.

It is our policy 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.

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30 Locust Street
P.O. Box 5001
Northampton, MA 01061-5001

STRONTIUM – 89 THERAPEUTIC PRESCRIPTION

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1. Prescription *(written directive)*

Patient's Name: _____ RT #: _____

Age: _____ Sex: ☐ M ☐ F ☐ Outpatient ☐ Inpatient (Room # _____)

Referring Physician: _____ Diagnosis: _____

Is this patient pregnant? ☐ **Yes** ☐ **No**

Radionuclide: **Strontium – 89 Chloride Injection**

Decay: Pure Beta (–) Half Life: 50.5 days Energy: 1.463 MeV (max) 100 percent

Typical Dosage: 4mCi **or** 40–60 hCi / kg body weight

Prescribed dose in mCi: _____

Signature of Physician Authorized User: _____

2. Radionuclide Assay

Date: _____

Radionuclide Received: _____ Activity (mCi): _____

Verified by: _____ (RSO)

3. Pre-Injection Verification

Patient I.D. Verified: _____ Radionuclide Verified: _____ Dose Verified: _____
(2 methods)

Signature of Physician Authorized User: _____

4. Post-Procedure Radiation Survey

Check Source: _____ (mR/hr) Background: _____ (mR/hr)

Post-Radiation Monitoring Yielded: _____ (mR/hr)

Performed by: _____ (RSO)

I-131 Therapeutic Prescription

The form is to be completed in accordance with the Quality Management Policy

1. Pres. .ption (written directive)

Patient Name: _____ MR#: _____

Age _____ Sex M or F Outpatient _____ Inpatient Room # _____

Referring Physician _____ Diagnosis _____

the patient pregnant ? Yes or **No**

Radionuclide: I-131 Iodide Capsule

Decay γ, β Half Life 8.08 Days Energy γ 364 KeV Typical Dosage 4 - 29 mCi

Prescribed Dose in Mci: _____

Signature of Authorized User: _____

---

2. Radionuclide Assay

Date: _ _____

Radionuclide Received: _____ Activity (mCi): _____

Verified by: _____

---

3. Pre-injection Verification

Patient ID Verified *(2 methods)*: _____ Radionuclide Verified: _____ Dose Verified: _____

Signature of Authorized User: _____

---

4. Post Procedure Radiation Survey

Check Source: _____(mR/hr) Background: _____(mR/hr)

Post Radiation Monitoring Yielded : _____ (mR/hr)

Performed by: _____ _____ (RSO)

Cooley Dickinson Hospital, Inc.
Attn.: Elisabeth Weissbach
30 Locust Street
Northhampton, MA 01060

JUN 17 1994

RE: License Number: 20-03502-01
Docket Number: 030-01863
Plan File Date: June 8, 1993
NRC Region: I

Dear Ms. Weissbach:

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 the Quality Management plan for I-125 and/or I-131 > 30 uCi,

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

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 micro curies of either I-125 or I-131, the dosage. Your QMP is missing procedures to require that the written directive for I-125 and/or I-131 > 30 uCi:

- 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 patients health, an oral directive will be acceptable, provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

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 radio pharmaceutical dosage. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration.

Your QMP for NaI I-125 or I-131 >30 microCi must include policies/procedures to identify and evaluate any unintended deviations from a written directive 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 CFR 35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:(i) assembling the relevant facts including the cause; (ii) identifying what, if any, corrective action is required to prevent recurrence; and (iii) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. Please include such a provision in your QMP.

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radio pharmaceutical, 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.

According to guidance provided by Regulatory Guide 8.33, your QMP must include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

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

Regarding the QM plan for Therapeutic Radiopharmaceutical other than I-125 or I-131,

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

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

- Radiopharmaceutical
- Dosage
- Route of administration
- 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 patients health, an oral directive will be acceptable, provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

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

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample

may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

According to guidance provided by Regulatory Guide 8.33, your QMP should include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

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

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

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

OFFICIAL RECORD COPY - D:\QM\COOLDICK.WP - 06/14/94

Enclosure: As stated

The Cooley Dickinson Hospital Inc.
30 Locust Street
P.O. Box 5001
Northampton, MA 01061-5001
(413) 582-2000

June 8, 1993

030-01863

U.S. Nuclear Regulatory Commission
Region I
Nuclear Materials Safety
Section B
475 Allendale Road
King of Prussia, PA 19406

License #20-03502-01

Dear Sirs:

Please find enclosed the documentation of our Quality Management Plan that you requested.

Respectfully submitted,

Elisabeth Weissbach
Vice President/Operations

ML 10

FAX RECD JUL 14 1993

The Cooley Dickinson Hospital Inc.
30 Locust Street
P.O. Box 5001
Northampton, MA 01061-5001
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QUALITY MANAGEMENT PLAN

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ID bracelet
Medical Insurance card

*In accordance with policy #37, prior to administration of radiopharmaceutical, the following will be verified:

the radiopharmaceutical
the dosage
the route of administration

NOTE: the dosage will be measured in the dose calibrator

*In accordance with policy #38, if there is any question regarding the written order for a procedure, the individual will consult a senior staff employee or an authorized user before the procedure is performed.

*In accordance with policy #39 an authorized user or a qualified technologist will date and sign or initial the written order that documents the administered dose. This written order is maintained as a permanent record.

*In accordance with policy #40, reviews of the quality management program will be done as part of the quarterly Radiation Safety Committee meeting.