AUG 09 1994

LIFE CARE INSTITUTE
601 NORTH MAIN STREET
GLASSBORO, NJ 08028

ATTN: DOLORES SIEGEL DEPERSIA, M.D.

RE: Docket Number: 030-31418
License Number: 29-28460-01

Dear Dr. Depersia:

This letter acknowledges receipt of your "Quality Management Program" received on July 14, 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

220173

OFFICIAL RECORD COPY - D:\QMP-ACK\002684.ACK - 07/20/94

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NOTE TO DMB:

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

LICENSE NUMBER: 29-28460-01

DOCKET NUMBER: 030-31418

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

030-31412

QUALITY MANAGEMENT PROGRAM
LIFE CARE INSTITUTE
NRC LICENSE NO. 29-28460-01

POLICIES AND PROCEDURES FOR RADIOPHARMACEUTICAL THERAPY AND THE USE OF NaI I-125 AND I-131 > 30 uCi

1. **An authorized user shall date and sign a written directive prior to the administration of any therapeutic dosage of a radiopharmaceutical or any dosages greater than 30 uCi of either NaI I-125 or I-131. The written directive must specify the following:**

   a) The patient's name
   b) The radiopharmaceutical requested
   c) The specific activity requested
   d) The planned date of administration
   e) The route of administration

REVISIONS:

Written

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.

Oral

If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user or a physician under the supervision of an authorized user within **48 hours** of the oral revision.

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JUL 14 1994

Oral Directive

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 allowable, provided that the information contained in the oral directive includes that specified in a - e above and is documented immediately in the patient's record and a written directive is prepared within **24 hours** of the oral directive.

2. **Prior to administration of a radiopharmaceutical dose the patient's identity shall be confirmed by at least two methods and verification established that the patient identified is the patient named in the written directive.**

The procedure used to identify the patient shall be to ask the patient's name and confirm the name and **at least one** of the following by comparison with information contained in the patient's record:

(a) birth date
(b) address
(c) social security number
(d) signature
(e) the name on the patient's ID bracelet or hospital ID card
(f) the name on the patient's medical insurance card.

3. **The individual responsible for administering the radiopharmaceutical shall verify, before administration, that the details of the administration are in accordance with the written directive.**

The following shall be confirmed prior to administration:

(a) The radiopharmaceutical
(b) The dosage as determined by dose calibrator measurement
(c) The route of administration

4. **Any individual involved with the execution of the written directive shall seek guidance if they do not understand the written directive or the procedures to be followed in its execution.**

   Workers are instructed to ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

5. **The authorized user or a qualified person under the supervision of the authorized user (e.g., a nuclear medicine physician, physicist or technologist), after administering a radiopharmaceutical, make, date, and sign or initial a written record that documents the administered dosage in the patient's chart or Quality Management form.**

   The written records shall be kept in auditable form for a period not less than **three years**.

6. **The Quality Management Program shall be reviewed at least every twelve months by the RSO or his designate. The review will include for each patient's case, a comparison between the written directive and that which was executed. All patient cases for the twelve month period will be reviewed. The patient reviews can be ongoing during the twelve month period, (e.g., weekly, monthly, quarterly, etc.), depending upon patient volume. Records of each QMP review will be maintained for three years.**

   The following shall be evaluated for correctness for each patient case:

   (a) Patient
   (b) Radiopharmaceutical
   (c) Route of administration
   (d) Dosage

Deviations from the Written Directive

A deviation from the written directive shall prompt an investigation to determine magnitude, cause, procedures and corrective actions to prevent recurrence. The procedures which will be followed after discovery of a deviation will be determined by the magnitude and are stated below.

Misadministration: The wrong patient or wrong radiopharmaceutical are administered, or the dosage administered differs from that prescribed by more than **20%** and exceeds 30 uCi. The NRC must be notified by **telephone** (301-816-5100) by the **next calendar day**. A **written report** shall be filed within the next **15 days** containing, the information requested in 10 CFR Part 35.33 (2) and all other procedures stated in Part 35.33 must be followed. Records shall be kept **5 years**.

Recordable Event: The administration of a radiopharmaceutical without a written directive where one is required, or inadequate documentation of dosage delivery, or a deviation of delivered dosage from prescribed dosage of greater than **10%** if the deviation exceeds 15 uCi for I-125 or I-131.

Following the discovery of a recordable event we shall respond within **30 days** by :

(a) Assembling the relevant facts including the cause;
(b) Identifying what, if any, corrective action is required to prevent recurrence;
(c) Implementation of corrective actions as necessary to meet QMP objectives;
(d) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

Modifications in the Quality Management Program

Modifications in the QMP to better meet the objectives of the program shall be submitted to the NRC within **30 days** following there implementation.

REVIEW OF QUALITY MANAGEMENT PROGRAM

THE QUALITY MANAGEMENT PROGRAM IS REVIEWED FOR ADEQUACY IN ACHIEVING THE OBJECTIVES OF 10 CFR PART 35.32 AND FOR COMPLIANCE WITH OUR INTERNAL QUALITY MANAGEMENT PROGRAM.

The review involves a comparison between the written directive and that which was executed and whether a written directive was given when required.
All patients requiring a written directive under the QMP are reviewed.

The following are evaluated for correctness for each radiopharmaceutical therapy and I-125 and I-131 administration involving > 30 uCi:

(a) Patient
(b) Radiopharmaceutical
(c) Route of administration
(d) Dosage

RESULTS:
Number of Misadministrations: 0
Number of Recordable Events: 0
Were proper procedures followed upon discovery of misadministrations and or recordable events: Yes No (NA)
Recommended modifications to the QMP (must submit to the NRC within 30 days of implementation): None (See Attached)

D A Petersen
RADIATION SAFETY OFFICER

7-11-94
DATE

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

LIFE CARE INSTITUTE
601 NORTH MAIN STREET
GLASSBORO, NJ 08028

JUN 23 1994

ATTN: DOLORES SIEGEL DEPERSIA, M.D.

Response enclosed

RE: Docket Number: 030-31418
License Number: 29-28460-01
Plan File Date: 21-MAY-93
Region Number: 1

Dear Dr. Depersia:

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

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

1 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.

2 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

3 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

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JUN 23 1994

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License Number: 29-28460-01
Plan File Date: 21-MAY-93
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2 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

3 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.

4 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.

5 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.

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

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

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

9 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.

10 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.

11 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.

12 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).

13 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).

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

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

1 A written QMP must be established and maintained for use of Radiopharmaceuticals for therapy other than I-125 and I-131 as required in 10 CFR35.32(f)(1). Please submit your QMP for your Radiopharmaceutical therapy.

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:
Francis M. Costello

James P. Dwyer
Quality Management Program Coordinator
Region I

Enclosure: As stated

LIFE CARE MEDICAL CENTER

Complete Outpatient Services

601 N. MAIN STREET • P. O. BOX 188 • GLASSBORO, NJ 08028 • 609-881-5800 • FAX 609-881-3511

May 21, 1993

030-31418

David Everheart, NRC
475 Allendale Road
King of Prussia, PA 19406

Dear Mr. Everheart:

Regarding NRC license #29-28460-01, please find enclosed a copy of our Quality Management Program.

Please feel free to contact me should you have any questions.

Yours truly,

D.A. DePersia, M.D.
Radiation Safety Officer
Life Care Medical Center

ENC.
DAD/gm

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MAY 24 1993

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601 N. MAIN STREET • P. O. BOX 188 • GLASSBORO, NJ 08028 • 609-881-5800 • FAX 609-881-3511

QUALITY MANAGEMENT PROGRAM FOR DOSAGE GREATER THAN 30 uCi 131 I AND 125 I

1. The authorized user shall date and sign a written directive for the administration of the radiopharmaceutical prior to administration.

2. The worker or authorized user, prior to administration, shall identify the patient by more than one method.

   The patient's name should be asked and confirmed by at least one of the following in the patient's record: birth date, address, social security number, signature, name or ID bracelet or card, or name on medical insurance card.

3. The worker or authorized user, prior to administration, shall verify that the specific details of the administration are in accordance with the written directive.

   The radiopharmaceutical, dosage and route of administration shall be confirmed by direct reference to the written directive by the person administering the radiopharmaceutical to verify agreement. The dosage shall be confirmed by direct measurement in a disc calibrator.

4. Any worker or authorized user who does not totally understand the written directive shall contact the authorized user who signed the directive for guidance prior to administration.

5. The worker or authorized user who administers the radiopharmaceutical shall sign and date the appropriate record form documenting the dosage administered.

6. The above procedures shall be reviewed whenever necessary but no less frequently than annually by the radiation safety officer.

   The review shall consist of a comparison between the written directive and that which was administered and shall involve all cases for the year.