MAY 13 1986

Docket No. 030-22303 License No. 29-11732-02

Charles E. Dooley, Jr., M.D.
261 Orchard Street
Westfield, New Jersey 07090

Gentlemen:

Subject: Inquiry No. 86-01

This refers to a telephone inquiry by Steven Courtemanche of this office with Dr. Charles Dooley, Jr. on April 17, 1986. This inquiry concerned activities authorized by License No. 29-11732-02, as they relate to the initiation of activities involving licensed materials and the anticipated workload of your program.

From this discussion, it is our understanding that you have never used licensed material under the authorization of this license, but that you plan to initiate use of licensed material in the near future. Please be advised that, as your license is presently written, you are authorized only for storage of licensed materials. We will modify this authorization for use of licensed material upon receipt of the information we requested in our letter dated May 17, 1985 (enclosed).

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter will be placed in the Public Document Room. No reply to this letter is required; however, should you have any questions concerning this inquiry, we will be pleased to discuss them with you.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:
Francis M. Costello

John D. Kinneman, Chief
Nuclear Materials Safety Section A
Division of Radiation Safety and
Safeguards

Enclosure: NRC letter dated May 17, 1985

OFFICIAL RECORD COPY ML 509 COURTEMANCHE - 0001.0.0
05/06/86

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey

bcc:
Region I Docket Room (w/concurrences)
Steven Courtemanche

FMC

RI:DRSS
Courtemanche/bc
5/6/86

RI:DRSS
Kinneman
5/7/86

OFFICIAL RECORD COPY ML 509 COURTEMANCHE - 0001.1.0
05/06/86

MAY 17 1985

DOCKET NO. 030-22303
CONTROL NO. 18790

Charles E. Dooley, Jr., M.D.
261 Orchard Street
Westfield, NJ 07090

Dear Dr. Dooley:

This is in reference to your application dated February 11, 1985, for a Byproduct Material License. In order to continue our review, we need the following additional information:

1. In reviewing the material that you were authorized for in your previous (expired) License No. 29-11732-01, we believe that you require the following byproduct material: Any byproduct material listed in Section 31.11 of 10 CFR Part 31 (enclosed), 1 millicurie; Group I of Section 35.100 of 10 CFR Part 35 (enclosed); iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction, 10 millicuries; phosphorous-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases, 5 millicuries. Please verify that this authorization will satisfy your need for byproduct material.

2. We note that you intend to receive only precalibrated doses of radioactive iodine. However, you should develop and submit procedures for confirming that the manufacturer's assay is correct. You may wish to use instrumentation already available to you (such as the Picker well counter) to assay patient doses prior to administration. If you decide to use your picker well counter you should state how the instrument will be calibrated. Such calibrations should include:

   a) Method of calibrating the well counter.

   b) Types of isotopes, activity and percent accuracy (traceable to NBS) of the calibration standards used.

   c) Frequency of calibration (at least quarterly).

   d) The types of isotopes and activity of the long-lived radioactive sources used to determine daily constancy.

   If you intend to use only a well counter to assay patient doses, then you will need to recalibrate the counter for each patient dose that uses an isotope different from radioactive iodine (as in Group I isotopes), with a calibration standard of the same energy as the isotope being assayed. Correspondingly, Subitem

~~8511210425~~ 850927
REG1 LIC30
29-11732-02 PDR

"OFFICIAL RECORD COPY"

ML10

b) above will need to be answered for the calibration standards used in these cases.

If you intend to assay these patient doses in a dose calibrator, then submit the name of the manufacturer and model number of the dose calibrator you will use to accomplish this as well as all pertinent information requested under Item 10 of Regulatory Guide 10.8 (enclosed). Please submit this information.

3. Regarding your facility diagram, you failed to specify the dimensions, location, thickness and type of shielding used to contain radioactive waste being held for decay. Please submit this information.

4. We note that your response to Item No. 12 of Form NRC-313M (personnel training program) indicated "not applicable". Accordingly, please confirm that you will not delegate duties involving licensed activities to employees (for example, nurses, technicians, etc.).

   Employees who may have occasion to enter the areas where licensed material is used or stored will still need to be informed concerning radiation hazards and appropriate precautions. Please confirm that this instruction will be given both initially and annnually thereafter.

5. We note that your receipt procedures outline steps to be taken for the proper receipt of incoming packages between the hours of 8:30 am and 6:00 pm. We believe you actually meant the off-duty hours between 6:00 pm to 8:30 am the next working day. Please clarify. If you ordered the deliverer never to deliver packages during off-duty hours, then please specify this.

6. Concerning your package opening procedures:

   a) Please confirm that you will wipe the external surface of the final source container, assay the wipe in a low background area, and record the amount of removable radioactivity.

   b) Confirm that these wipes will be assayed in a low background area with a thin-end-window G-M survey meter or equivalent.

   c) Please submit your procedures for surveying the outside of each incoming package. These procedures must encompass the requirements given in Section 20.205 of 10 CFR Part 20.

   d) You should maintain records of the results of checking each package. Appendix F (enclosed) includes a suggested

"Radioactive Shipment Receipt Record."Please submit a copy of the record form you will use.

7. Regarding your laboratory procedures, please confirm that hands and clothing will be monitored for contamination prior to leaving the area where radioactive material is used and prepared. Also confirm that mouth pipetting of radioactive solutions in your facility is prohibited.

8. We note your response to Item No. 17 of Form NRC-313M (area survey procedures was marked "not applicable". Please be advised that Section 20.201(b) of 10 CFR Part 20 states that "each licensee shall make or cause to be made such surveys as may be necessary for him to comply with the regulations to this part." Accordingly, you are required to develop and submit a routine area survey program. Appendix I of Regulatory Guide 10.8 contains a model program we find acceptable. You may also want to consult the enclosed Regulatory Guide 8.23.

9. Please specify the type (whole body or ring) and the exchange frequency for your ICN Tracerlab film badges employed.

We will continue our review of your application upon receipt of the above information. Please reply in duplicate, referencing Control No. 18790.

Sincerely,

Original Signed By
John E. Glenn
John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards

Enclosures:
1. 10 CFR 19, 20, 31, 35
2. Regulatory Guide 8.23
3. Regulatory Guide 10.8