U. S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION I

Report Nos. 30-4579/80-01
30-4581/80-02
30-4704/80-01

Docket Nos. 30-4579
30-4581
30-4704

License Nos. 20-00320-09
20-00320-13
20-11868-01 Priority 1 Category B

Licensee: New England Nuclear Corporation

549 Albany Street

Boston, Massachusetts 02118

Facility Name: Labeled Chemical Division, Boston
Nuclides and Sources Division, Billerica
Medical Diagnostic Division, Billerica

Inspection At: Billerica and Boston, Massachusetts

Inspection Conducted: May 27-29, 1980

Inspectors: Phillip C. Jerman, Radiation Specialist — 8-13-80 date

_____ date

Approved by: John D. Kinneman, Chief, Materials Radiological Protection Section, FF&MS Branch — 8-13-80 date

Inspection Summary:
Inspection on May 27-29, 1980 (Combined Report Nos. 30-4579/80-01; 30-4581/80-02 and 30-4704/80-01)
Areas Inspected: Special, announced inspection including a review of circumstances surrounding possible internal exposure reported to IE:I by letter dated May 2, 1980, corrective action, radioactive waste disposal, xenon-133 operations, cesium-137 operations, package monitoring, personnel monitoring, misshipment, release to sewer, activities at 100 Canton Street, Boston, bioassay program and training. The inspection involved 17 inspector-hours onsite.
Results: No items of noncompliance were identified.

Region I Form 12
(Rev. April 1977)

DETAILS

1. Persons Contacted

*C. Killian, Director, Environmental Control
*D. Dumas, Director, Radiation Protection Department
L. Smith, Technical Director, Radiation Protection Department
E. Cumming, Specialist, Health Physics
T. Labenski, Specialist, Health Physics
D. Dole, Specialist, Health Physics
D. Wagner, Supervisor, Production, Medical Diagnostic Division (M.D.D.)
F. Byron, Supervisor, Quality Control, M.D.D.
L. Lessard, Manager, Production, M.D.D.
W. Wonyz, Supervisor, Packaging, M.D.D.
**E. Grurerman, Vice President, Nuclear Medicine Technology
R. Shaw, Supervisor, Nucleotides, Labeled Chemical Division (L.C.D.)
W. Sullivan, Supervisor, Amino Acids, L.C.D.
V. Ahern, Supervisor, Customer Synthesis, L.C.D.
J. Kreiger, Supervisor, Research and Development, L.C.D.
J. Lola, Supervisor, Phosphorus-32 Production, L.C.D.
***L. Geller, Manager, Labeled Chemical Division

Two exit interviews were held.

* denotes presence at both interviews
** denotes presence at exit interview in Billerica on May 28, 1980
*** denotes presence at exit interview in Boston on May 29, 1980

2. Radiation Incident

a. Notification

In a letter dated May 2, 1980, the licensee reported that on April 10, 1980, a laboratory technologist ingested a small particle containing about 2.6 µCi of Americium-241.

b. Review of Circumstances

The inspector reviewed the circumstances surrounding this incident. The technologist was interviewed and stated that she had worked in the americium-241 facility on April 10, 1980 and that when she made her final personal survey before going home, she discovered contamination in the abdominal region. The monitoring device used was a Ludlum Model 177 low energy gamma scintillator with a Model 44-3 probe. The device was located outside the contamination control area of the Nuclides and Sources Building, Billerica.

The Radiation Protection Department was notified and a Health Physics Specialist made surveys. He verified the presence of contamination on the individual. Efforts to decontaminate the skin failed to reduce the level. The individual was whole body counted which verified the presence of radioactivity. Assuming that the contamination was fixed, the worker was allowed to go home. Another whole body count was made the next day, April 11, 1980, which showed the radioactivity had moved. Thus it now appeared that activity was in the GI tract.

The individual had worked on April 10, 1980 in the small room used for final processing of Americium-241 sources. The sources enter this room as ceramic material singly encapsulated and are given final cleaning. A second encapsulation is made on some of the sources. It appears likely that a small particle got on her glove and was some how transferred to her mouth. Her supervisors had noted that she sometimes absent-mindedly scratched her mouth and nose area, although the individual did not think she had done this while she was wearing gloves in the room.

Urine sampling was started. Consecutive 24 hour urine samples were collected beginning at 9:00 p.m. on April 10, 1980. Following April 18, 1980, a 24 hour urine sample was collected weekly until May 25, 1980 when sampling was done on a monthly frequency. Urinalysis concentrations were as follows:

Date of Sample		DPM/Liter
4/10 - 4/11		5.9
4/11 - 4/12		1.8
4/12 - 4/13		0.13
4/13 - 4/14		0.2
4/14 - 4/15		0.13
4/15		0.13
4/16		0.13
4/16 - 4/17		0.1
4/17 - 4/18	less than	0.08
4/24 - 4/25	less than	0.08

The urinary excretion rate was 1.1 liters per day

The individual was sent to a contractor on April 14, 1980 for a whole body count which determined that the radioactivity had moved further down the GI tract. Fecal sampling was started on April 14. Subsequent sampling followed on April 15 and 16. The results of analyses of these samples were as follows:

Sample voided on April 14 contained 1.6 nCi
Sample voided on April 15 contained 2.4 nCi after a ceramic particle containing 2.85 µCi had been removed.
Sample voided on April 16 contained 3.1 nCi

c. Dosimetry

The inspector reviewed the licensee's evolution of the individual's exposure uptake (ATTACHMENT 1). The licensee calculated that, based on the ICRP Publication 19 recommendation that systematic body burden equals 1×10^{4} times the nontransportable activity, the invididual's uptake was 0.285 nCi. In addition, the feces voided by the individual for three successive days beginning one day before and ending one day after the ceramic particle was voided, contained 7.1 nCi excluding the particle. It is assumed that the Americium-241 in fecal material passed through the GI tract at the same time as the larger ceramic particle.

Assuming the effective half-life is 2×10^{4} days, the 0.285 nCi systematic body burden results in following dose equivalents:

Initial dose rate to bone - 5 mrem/week
Initial dose rate to whole body - 0.1 mrem/week

Therefore, the lifetime dose equivalent to bone is 9.3 rems and to the whole body, 0.26 rems.

The inspector agreed with the results of the licensee's evaluation. This uptake is much less than that which would result from inhaling insoluble Americium-241 for 40 hours per week for 13 weeks at the uniform concentration specified in Appendix B, Table I, Column I of 10 CFR 20.

No items of noncompliance were identified.

3. Corrective Action by Licensee

The inspector reviewed the action taken by the licensee to prevent recurrence of the item of noncompliance listed in Combined Inspection Report Nos. 30-4579/79-03; 30-4581/79-03 and 30-4704/79-03. The item involved the licensee shipping a vial of phosphorus-32 labeled phosphorus-33 to a customer. The licensee added an additional check to the system which requires checking the packing slip after the orders are printed on a computer system. This verifies that the customer is getting the material that was ordered. In addition, the packaging technologists have been retrained in the importance of assaying packages with the appropriate detector.

4. Radioactive Waste Disposal

Packaging of radioactive waste is performed by the Radiation Protection Department. At Billerica, three operators under the supervision of a Health Physics Specialist, handle and package all waste. Waste is collected and packaged daily. Short lived waste is placed in plastic drums and allowed to decay at least 10 half lives before the contents is removed, monitored and if background, disposed to normal trash. Long lived solid waste is compacted in 55 gallon steel drums in a room in the Nuclides and Sources Facility. The solidification of aqueous waste in concrete has been initiated. Packaged waste is stored in a 10,000 square foot building. It was noted that several drums of cesium-137 solid waste were stored in the center of stacked drums, such that the radiation level outside the stack was 2 mrem/hr.

At the Boston facility, waste is processed by 3 operators guided by a Lead Technical Specialist. Users are provided 55 gallon steel drums into which to place radioactive solid waste. This waste is brought into a compactor room in which the material in the drums is removed and sorted, and that which is acceptable is compacted. Aqueous waste is solidified in concrete in 55 gallon drums. Liquid organic waste is mixed 1 part to 2.5 parts adsorbing material in 30 gallon drums. Each 30 gallon drum so packaged is placed in a 55 gallon drum which is packed with adsorbing material. All waste packaged in Boston is transported to Billerica for storage before loaded onto semi-trailers for shipment to disposal sites.

No items of noncompliance were identified.

5. Xenon-133 Operations

The inspector observed the production of Xenon-133 at Billerica. The gas was metered into sealed glass vials which were placed in lead cylinders with a plastic cap on the end containing a lead plug.

The Quality Control Operation was observed. The quantity of xenon-133 in each vial was assayed and then the loaded lead cylinders are fitted on the top with an elongated plastic cap and placed in a rack for an overnight leak test. The next morning the caps are surveyed to detect any gas which may have leaked from the glass vials.

One cap and end lead plug is installed on all lead cylinders before the filled xenon vials are placed in them. Each cap is tested for presence of a properly fitted lead end plug by visual examination. After the xenon is loaded and the second end cap with lead plug is installed, the shielded cylinders are placed in a rack and both ends surveyed with a meter to determine that there is no radiation leakage.

The inspector observed a monitoring device on a package conveyor system which surveys four sides of packages as they pass. A licensee representative stated that device is used to spot check about 20 percent of packages processed by the Medical Diagnostics Division. The same packages which are monitored are wipe tested.

No items of noncompliance were identified.

6. Cesium-137 Operations

The inspector observed that the two laboratory rooms which were used for fabricating cesium-137 sources were in the process of decontamination. All material had been removed from the cells themselves, but much material remained in the rooms. The doors had been sealed with tape to prevent movement of air outside the rooms. Dose rates as high a 9.5 mR/hr at 3 feet were posted on the doors to the rooms. The inspector verified these dose rates. The licensee has discontinued the fabrication of cesium-137 sealed sources.

No items of noncompliance were identified.

7. Package Monitor, Nuclides and Source Division

The inspector observed a monitoring device which was placed in operation about May 1, 1980 in the Nuclides and Sources Division. The device is associated with a package conveyor system with radiation detectors placed such that each package is monitored at 3 feet from each of its six sides simultaneously. All packaged products of the Nuclides and Sources Division are monitored with the device to determine the Transport Index.

No items of noncompliance were identified.

8. Personnel Monitoring, Billerica

The records of personnel monitoring for the period from January 1, 1979 through April 30, 1980 at Billerica were reviewed. No individual received an exposure in excess of 10 CFR 20.201 limits. It was noted that no individual at Billerica received a whole body exposure exceeding 7 rems during 1979. Among the five individuals who received the highest exposures was an individual who worked in the cesium-137 source fabrication facility. The other four were assigned to the cyclotron operation.

No items of noncompliance were identified.

9. Misshipment

On March 31, 1980, Region I received notification from a non-licensee that a package had been received from New England Nuclear which contained radioactive material. This matter was reviewed during the inspection.

New England Nuclear on March 31, 1980 shipped in one of its trucks a package of computer parts to a computer company. The individual who packaged the material used packing material from an incoming package. This package had been opened and contained some returned xenon-133 vials from an NEN Distribution Center. One of the vials was included with the packing material in the package. NEN retrieved this vial and assayed it to find that it contained 65 microcuries of xenon-133. This is an exempt quantity and no safety hazard existed for the receiver of the material. NEN promptly retrieved the material.

No items of noncompliance were identified.

10. Release to Sewer, Boston

The inspector reviewed the records of releases of radioactivity to the sewer. Each Boston facility which disposes radioactive waste to the sewer has one or more drain devices which continuously sample the liquid released to the sewer. Each sample collected is a known fraction of the total released based on monthly calibrations performed.

Records examined showed the breakdown of radioactive material discharged to the sewer each month. The following tables show the radioactivity released to sewer during calendar year 1979 and during the period from May 1, 1979 through April 30, 1980.

Isotope	1979	5/1/79 - 4/30/80
Hydrogen-3	6956.32 mCi	7672.8 mCi
Carbon-14	179.94	97.04
Other	55.57	46.02
Total	7191.83 mCi	7815.86 mCi

The releases are within the limits of 10 CFR 20.303 and the conditions of the license.

No items of noncompliance were identified.

11. Activities at the 100 Canton Street Facility, Boston

The inspector toured this facility. The facility housed laboratories which had been transferred within the past twelve months from other locations in the Boston complex. The following lab groups were visited: Nucleotides, Amino Acids, Custom Synthesis, Research and Development, and Phosphorus-32 Production. Supervisors of these groups were interviewed to determine the isotopes used and the radiation control programs. The inspector observed the licensee's operations and noted procedures for handling licensed materials.

No items of noncompliance were identified.

12. Bioassay Program, Boston

The records of bioassay data since January 1, 1980 were examined. It was noted that urinalyses for tritium were performed weekly for some individuals and monthly for others based on the nature of their work assignments. Breath analyses for carbon-14 were performed weekly. It was noted that an investigation was made for all cases that exceeded the licensee's action limits. The airborne concentrations to which personnel were exposed did not exceed the limits of 10 CFR 20 Appendix B, Table 1, Column 1.

No items of noncompliance were identified.

13. Training

The licensee's training programs were reviewed. New employees spend their first week in orientation at the location to which assigned. One day is spent in radiation safety training and in touring the facility. Handouts are given which the new employees are expected to read. On Friday the new employees are given a test covering radiation safety and must receive a passing grade to be assigned to work in a restricted area.

One method of retraining used is the lunch time session. Groups are made up of individuals who have common needs and the discussions that ensue are tailored to fit the group's interest.

No items of noncompliance were identified.

14. Exit Interviews

The inspector met with licensee representatives as denoted in paragraph 1. In both instances, the inspector described the scope of the inspection and stated that no items of noncompliance or deviations were identified.

The situation described in paragraph 9 was discussed during the first meeting on May 28, 1980. The licensee stated that a written instruction was issued which prohibits the reuse of packing material contained in in-coming shipments for out-going shipments.

ATTACHMENT 1.

New England Nuclear

To: P. Jerman, N.R.C. Region I

From: L. R. Smith

Date: June 30, 1980

Subject: Americium-241 Intake Dosimetry Results

Uptake and Transportation Data

Subject whole body weight:		53 kg.
Time particle traversed:	stomach	1 h
	small intestine	4 h
	cecum	6 h
	ascending colon	8 h
	transverse colon	13 h
	descending colon	19 h
	sigmoid colon and rectum	31 h
Estimated time of intake:		4/10/80 a.m.
Mode of intake:		Ingestion
Chemical and physical form:		^{241}Am Oxide incorporated in ceramic matrix

Assay Data

Voided 10.5 g fecal sample on 4/14/80, 18.30 h, containing 1.6 nCi

Voided 17.5 g fecal sample on 4/15/80, 14.30 h, containing 2.4 nCi plus 2.85 μCi ceramic particle

Voided 80 g fecal sample on 4/16/80, 21.30 h, containing 3.1 nCi

Urinalysis concentrations:

4/10 - 4/11	5.9 dpm l^{-1}
4/11 - 4/12	1.8 dpm l^{-1}
4/12 - 4/13	0.13 dpm l^{-1}
4/13 - 4/14	0.2 dpm l^{-1}
4/14 - 4/15	0.13 dpm l^{-1}
4/15	0.13 dpm l^{-1}
4/16	0.13 dpm l^{-1}
4/16 - 4/17	0.1 dpm l^{-1}
4/17 - 4/18	< 0.08 dpm l^{-1}
4/24 - 4/25	< 0.08 dpm l^{-1}

Urinary excretion rate: 1.1 l d^{-1}

601 Treble Cove Road, North Billerica, Massachusetts 01862 Telephone (617) 667-9531 Telex 94-7488

G.I. Tract Dosimetry

Using New ICRP dosimetry model for the G.I. tract and adjusting for real transfer times and body weight, dose correction factor for transfer of activity compared with ICRP 59 assumptions are:

S	1.32
SI	1.34
ULI	6.45
LLI	4.38

$\therefore$ LLI is the critical organ.

Calculations assume all the Americium-241 in fecal material passes through the G.I. tract at the same time as the ceramic particle. Self-absorption in large particle reduces dose rates to G.I. tract by a factor of 0.153 (determined by self-absorption studies applied to MIRD data). Critical dose equivalent is 132 mRem to LLI. *

Urinalysis indicates a maximum systemic body burden of 1.1 nCi transportable ^{241}Am. This assumes an effective half-life of 2×10^4 d (as recommended in ICRP 59) from the time when concentration falls to 0.08 dpm l^{-1} (the MDA of urinalysis system employed at the 7th day). However, the elimination curve at the 7th day appears to have a half-life $\approx$ 7 days. It is advisable to use the ICRP recommendation that systemic body burden = 10^{-4} times non-transportable activity in the G.I. tract, i.e. 0.287 nCi.

Assuming 2×10^4 d effective half-life, 0.287 nCi systemic body burden results in the following dose equivalent commitments:

Initial dose rate to bone	= 5 m rem wk^{-1}	
Initial dose rate to whole body	= 0.1 m rem wk^{-1}	
Lifetime dose equivalent to bone	= 9.3 Rems	*
Lifetime dose equivalent to whole body	= 0.26 Rems	*

L. R. Smith
Technical Director, Radiation Protection

*These doses have been assigned to the subject's dose records