U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No. 030-28902/96-001 Program Code 03211

Docket No. 030-28902

License No. 20-00320-21 Priority 1 Category B

Licensee: E. I. du Pont de Nemours & Co., Inc.
Medical Products/Imaging Systems
NEN Products
549 Albany Street
Boston, Massachusetts 02118

Facility Name: E. I. du Pont de Nemours & Co., Inc.
Medical Products/Imaging Systems
NEN Products

Inspection At: 575 Albany Street, 100 East Canton Street, and 120 and 123 East Dedham Street, Boston, Massachusetts

Inspection Conducted: July 15 -16, 1996

Inspectors: _____ 10-15-96
John R. McFadden, Ph.D. date
Health Physicist

_____ 10/9/96
John D. Jones date
Senior Health Physicist, Region III Office

_____ 10/9/96
Elizabeth Ullrich date
Senior Health Physicist

Approved By: _____ 10-15-96
John D. Kinneman, Chief date
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Inspection Summary: Routine, unannounced safety inspection conducted on July 15 and 16, 1996. Licensee and NRC laboratory analyses of confirmatory samples were not completed at the time of this report, and results of the analyses will be issued in an addendum to this report. (Inspection Report No. 030-28902\96-001)

Areas Inspected: Organization and scope of licensed activities; Radiation Safety Committee; Radiation Protection Office staff; annual program review and audits; facilities and equipment; materials; personnel radiation protection; area surveys; effluent monitoring; waste disposal; transportation; incidents and reported events; and NRC independent and confirmatory measurements.

Results: Two minor violations were identified: failure to maintain a record of the calibration of the thyroid monitoring equipment (Section 6); and failure of records of decay-in-storage to contain all information required by the license condition (Section 11). One concern was identified regarding the level of staff in the Radiation Protection Office (Sections 4 and 9).

DETAILS

1. Persons Contacted

*	T.C. Kung, Ph.D.	Operations Manager
*	Louis R. Todisco	Area Supervisor, Safety and Environmental Affairs
*	Leonard R. Smith	Radiation Protection Consultant/RSO
*	William Thistle	Lead Radiation Protection Specialist
*	Terence Clark	Radiation Protection Specialist
*	Elizabeth Gillis	Environmental Engineering
*	Robert S. Lucas, Jr.	Manager, Materials and Support
	George Anderson	Supervisor, Environmental Engineering
	Jan Anderson	Shipping Supervisor
	John Donovan	Distribution worker
	Greg Foley	Operations Specialist
	B. Gannon	Supervisor, Tritium Precursor
	Philip D. Stewart	Manager, Tritium and Carbon-14 Precursor
	Tony Stokes	Shipping Lead
	Mark Waldig	Lead Dock Distribution
	various laboratory personnel	

* Individuals present at exit meeting

2. Organization and Scope of Licensed Activities

E. I. du Pont de Nemours & Company, Incorporated (E. I. du Pont) is authorized to possess multi-curie quantities of licensed material by License No. 20-00320-21, a Type A specific license of broad scope, for manufacturing, distribution, and research and development. The license currently authorizes activities in Boston, Massachusetts where the principle radionuclides used include kilocuries of tritium, and several hundred curies of carbon-14, phosphorus-32, phosphorus-33, and sulfur-35. Licensed material is used primarily for the production of radiolabelled compounds for distribution to customers who use them in health care and life-sciences research activities. The Boston facility produces more than 1500 radioactive and non-radioactive chemicals. Licensed material is used also to perform research and development of new and existing products, and for custom synthesis of labeled compounds.

The Radiation Protection Officer for this license is Leonard Smith. He is directly responsible for the day-to-day operation of the Radiation Protection staff. The Radiation Protection staff and the Environmental Engineering staff make up the Safety and Environmental Affairs Area. The Area Supervisor for this department is Lou Todisco. The Safety and Environmental Affairs Area is part of Materials and Support group managed by Bob Lucas who reports directly to the Site Manager, Michael Johnson.

E. I. du Pont also conducts activities at the DuPont Merck Pharmaceutical Company (DuPont Merck) facilities in North Billerica, Massachusetts. These facilities in Billerica were formerly owned and operated by E. I. du Pont until 1991 when the DuPont Merck Company was formed and received a separate license for the Billerica site. E. I. du Pont is a parent company of DuPont Merck, and employees of E. I. du Pont continue to work in designated facilities in Billerica under the DuPont Merck license. However, E. I. du

Pont is in the process of divesting the licensed activities to a separate company known as NEN Life Sciences, which will not be related to DuPont Merck or to E. I. du Pont. When the divestiture is completed, NEN Life Sciences will conduct activities in the Billerica facilities formerly used by E. I. du Pont, but under the NEN Life Sciences license. NEN Life Sciences will lease the Billerica facilities from DuPont Merck, and will contract for radiation safety services from DuPont Merck. All licensed activities performed by NEN Life Sciences in Billerica and Boston will be the responsibility of the Radiation Protection staff currently overseeing the activities of the E. I. du Pont license.

E. I. du Pont has requested amendment of their license to reflect the divestiture of licensed activities to NEN Life Sciences. The amendment will be issued when the divestiture is completed and all required financial assurance items are submitted and approved. Licensed activities performed currently in Boston and in Billerica by E. I. du Pont employees will be performed under the NEN Life Sciences license after divestiture is completed and the license amended. Separate programs are being established for the NEN Life Sciences company for activities which were formerly conducted jointly by E. I. du Pont and DuPont Merck. Some of these programs are: the customer license verification system; radioactive waste storage, inventory, and disposal; and shipment of customer orders.

No violations or safety concerns were identified.

3. Radiation Safety Committee

The Radiation Safety Committee (RSC) is an independent body comprised of managers, supervisors, experienced radiation workers, and service representatives. Each major functional area in which licensed materials are used is represented on the RSC, as well groups such as Site Services whose employees frequent areas where licensed material is used. The current chairman of the RSC is Philip D. Stewart, Manager, Tritium and Carbon-14 Precursors.

The minutes of Radiation Safety Committee meetings were reviewed for the period of June 27, 1995 through June 25, 1996. The minutes reviewed indicate that the RSC meets once every two weeks to review incidents, survey and monitoring reports, and other information. Incidents include any effluent releases, bioassay, or other monitoring results which exceed internal notification or reporting action levels. For selected incidents, supplementary information, which is provided to committee members with the meeting agenda, was also reviewed. Information in the supplements was detailed, and the minutes indicated the issues were thoroughly reviewed by the committee at the meetings. Corrective actions for incidents were also reviewed at subsequent meetings.

No violations or safety concerns were identified.

4. Radiation Protection Office Staff

The Radiation Protection staff consists of the Radiation Protection Consultant, who is a Certified Health Physicist and who is the Radiation Protection Officer; a Lead Radiation Protection Specialist; a Radiation Protection Specialist; and an Associate Technologist. The staff performs routine and emergency response surveys; analyses of effluent air samples, sewer release samples, and environmental monitoring; analyses of bioassay samples; and audits of radiation worker laboratories and practices, and audits of the Environmental Engineering radioactive waste disposal program. They also ensure that radiation monitoring equipment is operable and calibrated, and maintain all official records for the Radiation Protection program.

The Radiation Protection staff appears to have had some difficulty in completing routine work assignments since the last inspection. For example, several survey records during the week of April 22, 1996, were marked "survey not done, responding to emergency", and many survey records were not in the file and may be missing or not done. The number of training sessions for the Radiation Protection staff is less than that of previous years due to lack of time. In addition, the Radiation Protection Consultant, who is the Radiation Safety Officer for the NRC license, appears to be the only professional-level health physicist available on the staff. There is no back-up health physicist to oversee emergencies, perform dose assessments, or make health physics recommendations for new or unusual procedures. Although there are other individuals available who have had training or experience in the Radiation Protection program, they are not health physicists. The additional individuals' current work assignments are in other areas, and they are available only if needed, usually in emergency situations.

The other members of the Radiation Protection staff do an excellent job of performing routine surveys and analyses, but they are less familiar with health physics theory than the Radiation Protection Consultant, and may not appropriately identify unusual problems. This is especially true with the pre-established computer programs used to analyze samples, such as with liquid scintillation counting, where the technologists use the programs but are unfamiliar with the assumptions and calculations used in the program.

Many improvements in the handling of licensed material have been made in recent years. However, the quantity and types of licensed materials used at this site are still of significant concern because small volumes of material could result in large health physics concerns. This program requires a high level of attention to detail, and an understanding of the way measurements and calculations are used to generate information about the program. The level of staffing and the performance of the staff in carrying out the Radiation Protection program should continue to be reviewed carefully to ensure that sufficient time and attention by appropriate persons are available in the future.

No violations were identified.

5. Annual Program Review and Audits

Audits of the Radiation Protection Program and the Radiation Protection Office are performed throughout the year. Audits may be performed by safety professionals outside of the Radiation Protection Program, members of the RSC, or other specialists familiar with the type of operations in a particular area. The Radiation Protection staff also perform an annual audit of their own program. Audits of the laboratories and other operations which handle radioactive materials are also performed by the Radiation Protection staff.

The 1995 Annual Audit Report was issued September 25, 1995. This report included a summary of the 1994 radiation protection program activities, and worker and public dose estimates. The report also included a summary of the findings of all audits performed in 1995 of the Radiation Protection Program by external reviewers. A memo dated December 7, 1995 responded to the findings with a schedule for corrective actions taken or planned in response to the findings. Audit findings and corrective actions were appropriate.

No violations or safety concerns were identified.

6. Facilities and Equipment

The facilities visited during the inspection included the production laboratories for tritium, carbon-14, and sulfur-35 labelled compounds in Building 100 (third floor); the storage, packaging, and shipping operations where customer orders are packaged for distribution in Building 120 (first floor); the phosphorus-32 synthesis and dispensing laboratory in Building 120 (second floor); the radiation protection laboratory and environmental engineering waste handling facility (first floor) and decay-in-storage facility (basement) in Building 575; production laboratories for tritium, carbon-14, and sulfur-35 labelled compounds in Building 575 (second floor); the carbon-14 precursor laboratories in Building 575 (third floor); the tritium precursor and production laboratory in Building 575 (fourth floor); and the custom synthesis laboratory for tritium and carbon-14 labelled compounds in Building 575 (fifth floor). The facilities were as described in the license application, except where renovations and improvements were made. Processes which involve volatile compounds are performed in closed systems or fume hoods. Laboratories are equipped with remote handling equipment and other specialized safety equipment where needed. The licensee uses their in-house developed, specialized gas-flow Geiger-Muller tritium detector for monitoring of wipes and for use by personnel in monitoring themselves and any items leaving the laboratory areas for tritium contamination. Appropriate safety equipment was seen to be in use including: laboratory coats, shoe covers or booties, safety glasses, gloves, shielding, radiation survey instruments, and personal radiation dosimeters. Licensed material was observed stored in laboratory hoods, refrigerator and freezer units, or other appropriate containment. Required and appropriate postings were observed.

The improved tritium handling and recycling facility on the fourth floor of Building 575, which was noted in the past two inspections, continues in operation. Improved systems for handling of tritium gas built into the facility include permanent conduits (housing dual-wall stainless steel tubing) for moving tritium gas from the bulk tritium hood to production hoods and computer-controlled systems which transfer tritium gas, turn on scrubbers, and perform other commands as appropriate. The tritium recycling system is also part of this automated system, allowing recovery of tritium gas for further use, and reducing releases of tritium to the environment. The tritium facility includes a welding station for containment of tritium gas waste, eliminating the need to transfer bulk tritium waste to another facility for packaging for disposal. The tritium facility includes a highly efficient scrubber system designed to minimize effluent releases. Real-time radiation monitors are installed in the exhaust ventilation system. An indicator lights up when action level parameters are exceeded. This indicator is also displayed in the guard building, where an emergency call list is maintained for after-hours notification.

The use of automation and robotics in the phosphorus-32 laboratories for manipulations of large quantities of this radionuclide was noted as evidence of ALARA awareness. Numerous Johnson Air Monitors (real-time monitors) are used in the various laboratories to monitor room air, hood/enclosure air, and exhaust duct air for immediate detection of elevated airborne concentrations of licensed materials. There are also numerous continuous air sampling stations for room air and exhaust duct air. Each of these is equipped with a particulate filter, charcoal filter, water impinger, or sodium hydroxide (NaOH) impinger or a combination of same as appropriate for the radionuclides to be sampled.

Areas that were not attended were observed to be locked for security purposes. Authorized employees accompanied other employees who are not normally assigned to work in an area. The outside doors of all buildings require a key-card for entry. Visitors are required to sign in at the parking lot guard building, where they are issued "Visitor" badges and the person to be visited is contacted to provide escort for the visitor. These procedures were followed during the inspection.

Appropriate survey meters were available in the laboratories. All survey instruments observed in use in the laboratories had current calibration labels. Counting procedures and selected records for the radiation protection laboratory counting instrumentation for contamination wipes, impinger samples, charcoal filters, urine and breath bioassay samples, and thyroid bioassays were reviewed and appeared adequate. However, the calibration record for the thyroid monitoring system was not available in the Boston records, or in the Billerica facilities where it was calibrated.

The failure to maintain a record of the calibration of equipment used for thyroid monitoring is a minor violation.

No safety concerns were identified.

7. Materials

The April 1996 monthly radionuclide inventory was reviewed. The inventory is generated from monthly logs submitted to the Radiation Protection Office by each laboratory, and includes material stored as waste. The inventory listed 23,457 curies of tritium, 155 curies of carbon-14, 242 curies of sulfur-35, 53 curies of phosphorous-32, 2 curies of phosphorous-33, 22.5 millicuries of iodine-125, and 450 grams of depleted uranium. The depleted uranium is the container for the bulk tritium shipments from EG&G Mound Laboratory and is part of the Type B shipping container. No sealed sources requiring leak-testing are possessed at the site. The types and quantities of radioactive material possessed were within the limits of the license.

Currently, all materials used or stored by E. I. du Pont at the DuPont Merck site in Billerica is authorized by the DuPont Merck license. This includes material used in the manufacture of labelled bionuclides as well as waste transferred from the Boston facility to Billerica for storage or preparation for transfer to a burial site. However, when the divestiture is completed of the Boston facility from E. I. du Pont to NEN Life Sciences, this license will authorize the activities in Billerica which are owned and operated by the NEN Life Sciences as well as in Boston. The licensee is planning to revise the monthly inventory procedures to include the Billerica materials used by NEN Life Sciences.

No violations or safety concerns were identified.

8. Personnel Radiation Protection

For external dosimetry, the licensee monitors worker whole body and extremity exposure using personnel badges from a NVLAP-approved supplier. Most individuals are on a quarterly exchange wear period for whole body badges and on a monthly exchange wear period for ring badges. The whole body exposure badge data for the 1995 calendar year indicated annual doses less than ten percent of the limits in 10 CFR 20.20.1201(a) for the total effective dose equivalent, the lens of the eye, and the skin of the whole body, except for one individual with an assigned shallow dose approaching 50 percent of the annual limit. This assigned shallow dose is discussed in Section 13. The ring badge results for the 1995 calendar year also indicated annual doses less than ten percent of the extremity limits. The 1996 first quarter whole body results and the 1996 ring badge results through the end of May indicated a trend which would yield average annual results less than ten percent of the limits. One individual did have a cumulative ring badge result (for 01-01-96 through 05-31-96) of approximately ten percent of the annual extremity limit.

For internal dosimetry, the licensee performs routine urine, breath, and thyroid bioassay analyses for their potentially exposed workers. Licensee procedures for collection and analysis of bioassay samples were reviewed and observed. Appropriate bioassays were performed, and the analyses appeared to be in accordance with standard industry practices. The results of these analyses for 1995 and 1996 did not indicate any intakes in excess of ten percent of the applicable Annual Limit on Intake (ALI) values in

Table 1, Columns 1 and 2, of Appendix B to 10 CFR Part 20. Room air samplers are also utilized to monitor airborne radioactivity in work areas.

Records of exposures, surveys, monitoring, and evaluations were maintained. There were no worker-declared pregnancies or planned special exposures since the last inspection.

No violations or safety concerns were identified.

9. Area Surveys

Radiation workers who use licensed materials have the primary responsibility for performing surveys of their work area to identify potentially contaminated areas. If corrective action is required, it is performed by the worker. Records of worker surveys were not reviewed during this inspection. The Radiation Protection staff survey areas where radioactive materials are used, stored, and transported such as change areas, production areas, waste storage areas, and the unrestricted areas including the perimeter of the buildings. The Radiation Protection staff maintain the survey records for compliance with the conditions of the license.

The Radiation Protection staff uses a table of acceptable contamination levels to determine if corrective action is needed. The allowable contamination levels vary according to the radionuclide, the type of area (restricted, controlled, or unrestricted), and the location (floor, bench top, inside of a hood, etcetera). If the Radiation Protection technologist identifies radioactive contamination above the allowable limits, he notifies his supervisor and the Area Supervisor of the laboratory being surveyed. Area Supervisors have until the following day to correct the deficiency, when the technologist returns to the same laboratory to verify that the item has been corrected. If contamination in a laboratory exists which is greater than 30 times the licensee's contamination action levels, the laboratory supervisor is also required to perform an investigation, determine the cause of the contamination, implement corrective actions and submit a report with the results of the investigation to the Radiation Safety Committee.

Records were reviewed of surveys performed by the Radiation Protection staff during the period of January through June 1996. Results of radiation level surveys appeared satisfactory, and the records indicated that corrective actions took place when appropriate. Areas where contamination was identified as exceeding the licensee's action levels were decontaminated appropriately, re-surveyed and recorded by the Radiation Protection staff. The Radiation Protection staff also recorded recommendations made to improve laboratory safety conditions where potential problems were identified.

Wipes for removable contamination are counted on a liquid scintillation counter using a pre-programmed procedure. Results are reported for counts detected in the low energy window (tritium), a medium energy range window (carbon-14 and sulfur-35) and higher energy range window (anything greater

than the carbon-14 energy). Results are given in gross disintegrations per minute (dpm) as calculated by the pre-established program using the most recent efficiency for those energy ranges, and an external source measurement to correct for quenching.

Surveys are performed by the Radiation Protection staff weekly, monthly, or quarterly according to the areas and the radioactive material in use, as determined by the Radiation Safety Committee and the Radiation Protection staff. A master schedule is maintained to track which facilities are due for surveys, and which Radiation Protection staff member will perform the survey. All of the Radiation Protection staff members interviewed believe that all surveys have been performed as required by their internal procedures. However, records of some of the surveys were not available in the files during the inspection. For example, Laboratory 070, the Tritium Precursor Laboratory, is required to be surveyed by the Radiation Protection staff weekly. However, the survey file for this laboratory contained records of surveys performed only on January 2, 15, 22, and 30; February 12 and 27; March 26; April 9, 16, and 26 (although the record noted that the 4/26 survey was not done due to staff responding to an emergency); and May 6 and 13. Similar examples of missing records were noted in the files for Laboratories 080 (monthly, May missing), 120 (monthly, February and June missing), 130 (weekly, three missing in May), 140 (monthly, January and May missing), and 230 (monthly, February and April missing). The staff believe the records to be among the staff paperwork that has not yet been filed, and stated that they would review their records to be certain that all surveys have been performed and recorded, and that the survey records will be filed where they can be easily retrieved.

No additional safety concerns were identified. No violations were identified.

10. Effluent Monitoring

The effluent monitoring program includes continuous stack air sampling stations, and continuous environmental air sampling stations. Inspectors accompanied a licensee radiation protection specialist during collection of air monitoring samples. Stack monitoring stations were equipped with collection systems having a particulate filter, charcoal filter, water impinger, or sodium hydroxide (NaOH) impinger, or a combination of same as appropriate for the radionuclides to be sampled. Environmental air sampling stations were equipped with particulate filter and water impinger collection systems. Effluent release records for 1995 and for the first quarter of 1996 were reviewed and appeared adequate and in compliance with regulatory limits. The licensee used impinger data to demonstrate compliance with NRC public dose limits and the limits of the Environmental Protection Agency (EPA) National Emission Standards for Hazardous Air Pollutants (NESHAP) criteria for 1995. Impinger data was used with the EPA computer code, COMPLY, to calculate the dose to the nearest critical receptor, a resident of 99 East Canton Street. The critical receptor was

estimated to have received 23 microrem from airborne radioactive materials released during 1995. This estimated dose was less than the 39 microrem estimated for 1994. The licensee also performed a calculation of public dose due to releases from the facility using their own dispersion model, and the dose was in agreement with that calculated by COMPLY.

No safety concerns or violations were identified.

11. Waste Disposal

The Environmental Engineering Department is comprised of a supervisor and two technicians who package and ship all radioactive waste at the site. The site generates four main categories of radioactive waste: dry solid waste, liquid scintillation vials, liquid aqueous waste, and mixed waste. The licensee has two compactors for volume reduction of dry solid waste, which is transferred first to Billerica for consolidation, then to an authorized radioactive waste broker for supercompaction prior to final disposal by burial at a licensed low-level waste disposal site. Liquid scintillation vials containing tritium or carbon-14 in quantities less than 0.05 microcuries per milliliter of cocktail are no longer crushed on site, but disposed of directly to an authorized broker. Liquid scintillation vials containing other radionuclides, or concentrations of tritium or carbon-14 greater than specified above, are held as mixed waste.

Most liquid waste is disposed of to the sanitary sewerage system in accordance with 10 CFR 20.2003. Drain samples are collected using a continuous liquid sampling system to monitor liquid releases to the sanitary sewer. Records of sewer disposals indicate that releases were within the regulatory limits. Other liquid waste, principally tritium, is solidified for transfer for burial. Such waste is typically Class B, containing 60-70 curies of tritium in polyvinyl high integrity containers. Tritium gas is also packaged in cylinders welded shut in Boston, and transferred to Billerica in 55-gallon drums containing not more than 1080 curies of tritium, for storage and re-packaging.

Phosphorus-32 waste is the primary material held for decay-in-storage in Boston. Most phosphorus-33, sulfur-35 and iodine-125 waste material is shipped to the DuPont Merck site in Billerica for decay-in-storage. Mixed wastes are stored in special designated cabinets in the Environmental Engineering area, and in Billerica.

The Boston waste processing and storage areas were inspected and found to be clean and orderly. Waste was properly stored and clearly labelled. Waste cards used to track the types and quantities of materials by the generators at the site were properly filled out, and appeared to be appropriately tracked through the disposal process. Drums ready for shipment to Billerica were appropriately marked in accordance with Department of Transportation regulations. Records of final disposal to the low-level burial site are maintained at this time by DuPont Merck, who is the shipper of the waste at that time. When the divestiture of licensed activities from E. I. du Pont to NEN Life Sciences is completed, NEN Life Sciences will be performing activities and maintaining records related to

shipment of radioactive wastes for disposal from both the Boston site and the facilities in Billerica leased by NEN Life Sciences.

Procedures and records for disposal by decay-in-storage at the Boston site were reviewed. The decay-in-storage area is located in a fenced basement facility, adjacent to other fenced storage facilities to which only the Environmental Engineering staff have keys. Radiation levels are monitored for each drum that is brought to the storage area. Regular surveys of the storage areas are performed, as well as TLD monitoring of the perimeter walls. Radioactive waste is organized in the decay-in-storage area by release date, which is based on holding for a minimum of ten half-lives and also on the total quantity of material in a given container. Phosphorus-32 is generally held for a period of 5 months (ten half-lives), 8 months, or 12 months depending on the total activity. A special area is provided for storage of very high activity phosphorus-32 waste which requires holding for a period which exceeds ten half-lives, and may be a year or more. Records of the decay-in-storage waste are maintained using the "Waste Container - IDR Form", which is stamped with a grid that requires the technicians to fill out the date the material is received, the radiation levels on receipt, and the initials of the technician performing the incoming survey, the date the material is removed from storage for disposal, the instrument used for monitoring, the date the instrument was calibrated, and the initials of the technician performing the outgoing survey. There is no place on the card for technicians to record the background radiation level measured by the survey instrument, or the radiation level measured at the surface of the waste container when disposed of, as is required by Condition 19.C. of the license.

The finding that the records of decay-in-storage do not contain all the information required by Condition 19.C. of the license is a minor violation.

No safety concerns were identified.

12. Transportation

Transfer of licensed material consists of two main activities: shipment of customer orders, and disposal of waste. All customer orders are packaged, surveyed, labelled, and shipped from Building 120. Approximately 21,000 packages of licensed material are shipped to customers each month, containing about 42,000 individual vials of material. The process of filling customer orders requires duplicate verification of vial container labels, package contents, and the customer order. Shipping papers are generated for each customer order. The shipping papers include the information about the customer, the requested material and activity, and the type of package and labeling to be used. This information is based on operational studies performed by the licensee in which actual measurements of radioactive materials packages were used to establish tables of appropriate labeling for a range of typical packages. Workers in Shipping use the information provided on the shipping papers to fill the customer order and label the packages. Shipping employees interviewed were able to describe and demonstrate their work procedures.

Packages ready for shipment are placed on a conveyer belt for final verification. Ten percent (about 250 packages) of all packages are tested each day to confirm radiation and contamination levels are in accordance with the licensee's tables for transportation of radioactive materials. Tested packages are measured using an energy-compensated GM detector to verify that the transport index is correct. One wipe is taken per 25 packages, and assayed for removable contamination. If any contamination is identified, all packages are individually checked to identify the source of contamination. Selected records of wipes of packages and transportation indexes for the month of July 1996 were reviewed. No removable contamination had been detected on outgoing packages and no unexpected radiation levels were measured. Radiation levels measured of several packages selected at random during the inspection were in agreement with the labelled transport index. Packages ready for shipment were properly labelled and marked in accordance with Department of Transportation regulations.

The most recent update of the licensee's transportation tables for labelling of packages occurred in 1994, when the Department of Transportation regulations were revised. No significant changes were identified by the licensee in implementing the new regulations, except for the increased quantity of tritium that may be shipped without a label. Certification records of the testing of packages used by the licensee for shipping customer orders were also reviewed during the inspection. Testing information appeared to be current and in accordance with the applicable regulations.

Radioactive waste shipments are made about once a month to DuPont Merck in Billerica by the Environmental Engineering staff. Records of the required Department of Transportation training for individuals in 1995 were reviewed. The 1996 training and test was performed in July, but test results were not yet available. Testing certificates for the drums used for shipment of waste were on file in the Environmental Engineering office. The records of the most recent shipment to Billerica, performed June 19, 1996, were reviewed. Most of the radioactive waste was shipped as "LSA-II" in an exclusive-use vehicle. Records of the vehicle survey and drum surveys indicate that radiation and contamination levels were in accordance with the regulatory limits.

No violations or safety concerns were identified.

13. Incidents and Reported Events

The licensee reported 3 events to the Region I office since the last inspection. These events were reviewed for any additional information during the inspection. An additional incident reported to the Radiation Safety Committee was reviewed during the inspection.

A. MLER-RI-95-62: In a letter dated December 27, 1995, the licensee reported an event in which phosphorus-32 contamination of a laboratory coat worn by a chemist resulted in a skin dose to the individual. The

report involved a third quarter radiation badge result indicating a shallow dose of 22.48 rem. The licensee investigated and concluded that occurred and the individual's laboratory coat and lead vest were contaminated during transfer of bulk quantities of phosphorus-32 in and out of high pressure liquid chromatography (HPLC) units in a shielded and enclosed automated-reaction containment on September 21, 1995. The inside of a containment access door had apparently been contaminated due to inattention to proper handling procedures for transfers of bulk quantities of phosphorus-32 and for proper close-down and start-up for robot operation. The licensee reconstructed the events and evaluated the individual's exposure. The licensee's evaluation included the following parameters:

1) The direct exposure time to elevated dose rate from bulk phosphorus-32 was approximately fifteen seconds.

2) The subject's badge results were reported to be minimal millirem (mrem) for deep dose, minimal mrem for eye dose, and 22,480 mrem for shallow dose.

3) There were no detectable radiation level readings on the front of contaminated laboratory coat when it was surveyed after the activity with the HPLC unit.

4) Surveys of the laboratory coat identified contamination on the right rear shoulder area, believed to be the result of contacting the contaminated inside of the containment access door.

5) The contaminated laboratory coat was worn for 20 minutes.

and 6) The Radiation Protection staff determined that 100 microcuries of phosphorus-32 was present on the maximally contaminated area of laboratory coat.

Based on experimentally derived dose rate information obtained by placing the maximally contaminated area of the laboratory coat and one layer of T-shirt between two whole body radiation badges for a measured time period, the licensee determined the dose to the skin beneath the contamination location to be 20 mrem. In a letter to the NRC dated August 27, 1996, the licensee provided a dose estimate of 40 mrem based on a calculation using the contamination activity estimate, a skin dose conversion factor, a time factor, and a clothing attenuation factor. Since this is much less than the 22.48 rem recorded by the film badge and the licensee's evaluation is that this is an appropriate estimate of the exposure from the bulk P-32, the licensee assigned the 22.48 rem as the whole body shallow dose to the individual. Based on the facts that the shallow dose received during the manipulation of the bulk material was incident on the front of the body and that the shallow dose received during the wearing of the contaminated laboratory coat was incident on the back of the body and thus not additive, the assignment of 22.48 rem to shallow dose appears appropriate.

An NRC estimate of the skin dose from the contamination (Attachment 1), based on items 5 and 6 above and the estimated equivalent thickness of a typical laboratory coat and T-shirt and using a computer program, VARSKIN Mod 2, yielded values closer to, but less than, the 22.48 rem which was assigned to the individual as whole body shallow dose than to the skin dose of 20 to 40 millirem estimated by the licensee. It appears that the different assumptions made by the licensee concerning the beta attentuatuion due to the laboratory coat and T-shirt account for the difference in the NRC estimate. However, the licensee should provide a justification for the appropriateness of their estimate for beta attenuation due to clothing that accounts for the difference between the licensee's dose estimate of 20 to 40 mrem and the dose range of 1.2 to 11.3 rem estimated by NRC calculation.

The licensee's actions to prevent recurrence of this type of incident were reviewed and appeared adequate. The actions included a review of all pertinent Standard Operating Procedures (SOPs) and pertinent operations for adequacy and the retraining of personnel in these SOPs. This item is closed.

B. On January 11, 1996, the licensee contacted the Region I office by telephone to report that radioactive material was missing from a damaged package received by a customer at Mt. Sinai Hospital in New York City. The package arrived at Mt. Sinai missing the container of 1 millicurie of sulfur-35 that had been shipped. At the time of the report, the licensee was informed by the courier that the package was crushed in transit, and a temporary employee taped the box closed and continued its shipment. This was not in accordance with the courier's normal procedure, which is to return damaged shipments to the licensee. As of July 1996, the vial of sulfur-35 had not been recovered. The licensee plans no further actions. This item is closed.

C. On April 2, 1996, the licensee reported by telephone that a customer at the Miami University of Ohio was missing a vial containing 500 microcuries of phosphorus-32. The customer had received the material and logged the information about the shipment into their records. Later, the customer could not locate the material and believed that the vial and its shipping container may have been returned to E. I. du Pont's styrofoam recycling center. However, as of October 1996, the recycling center did not receive the styrofoam container or the vial of phosphorus-32. The customer did not report locating the material. No additional actions are planned by the licensee. This item is closed.

D. On August 24, 1995, a customer who ordered 100 microcuries of phosphorus-32 was incorrectly shipped 1.0 millicurie of phosphorus-32. Because the customer had a license limit of 1.0 millicurie of phosphorus-32, this error could have caused the customer to be in non-compliance with the conditions of their license if any other phosphorus-32 was possessed at the time. This incident was not required to be reported to the NRC; however, it was investigated and reported to the Radiation Safety Committee. The cause of the incident was determined to be mis-matching of the activity listed on the shipping papers (generated from the customer order) to the activity listed on the container when the order was filled. Re-training was provided on September 1, 1995 to

the employee involved in the error. Also, the container labels were modified to be in the same units shown on the shipping papers. Customer order processing procedures and activities were reviewed during the inspection. Corrective actions were implemented. This item is closed.

No violations were identified.

14. NRC Independent and Confirmatory Measurements

Independent measurements were made with an Eberline Model E-120 survey meter with thin end window GM probe, NRC Serial No. 1088, calibrated on March 14, 1996 and a Ludlum Model 3 survey meter with a Model 44-38 side-window GM probe, NRC Serial No. 45625, calibrated August 14, 1995.

Measurements were made in all areas visited (see Section 6, Facilities and Equipment), radiation workers's use locations during work evolutions, and the in the vicinities of storage of stock and waste licensed materials. The inspectors's measurements were compared to those of the licensee where possible and were in agreement.

Samples were split with the licensee for confirmatory analysis. The basic purpose of the confirmatory measurements was to verify the licensee's capability for analyzing radioactive effluents and to achieve and maintain comparable methods of analyses between the licensee and the NRC. Another purpose of these measurements was to investigate possible explanations (such as low activity of sample, short count time, etc.) for the lack of agreement between several analytical results compared in 1994. These current samples include four impinger samples, one drain sample, and one charcoal filter. When the sample analyses are available and have been evaluated and compared, the results will be issued as an addendum to this report.

No violations or safety concerns were identified.

15. Exit Interview

The findings of the inspection were discussed with the individuals indicated in Section 1 of this report. The inspectors stated that this inspection did not include interviews with Radiation Safety Committee members or reviews of the implementation of the Emergency Response Plan, receipt of licensed materials, internal transfer of licensed materials, records of package receipt surveys, records of authorized users' surveys and inventories, or records of portable survey instrument calibration.

Three items were discussed which required additional action by the licensee and the NRC after the site inspection:

1) The procedure for analyses of the samples for confirmatory measurement was reviewed. The licensee agreed to perform the requested analyses and then send the samples to the NRC Region I office for analysis by the

Region I laboratory. If sample analyses are not available at the time the inspection report is issued, an addendum to the report will be issued with the results of the confirmatory measurements.

2) A comparative skin dose assessment of the phosphorus-32 contaminated laboratory coat incident will be done by the Region I staff. Any differences in the comparison of the licensee's evaluation to the NRC evaluation will be discussed by telephone with the Radiation Protection staff.

3) The licensee agreed to inform the Region I office of the date of the next exercise of the Emergency Response Plan, which is expected to take place in September or October, so that the NRC can participate in or observe the exercise.

The inspectors also discussed their concern regarding the level of staffing in the Radiation Protection office.

ATTACHMENT 1

LICENSE NO. 20-00320-21 08-27-96
DOCKET NO. 030-28902 J. MCFADDEN
MLER-RI NO. 95-62

E.I. DU PONT DE NEMOURS & CO., INC., BOSTON, MASSACHUSETTS

POTENTIAL SKIN DOSE EXCEEDING REGULATORY LIMITS

EVENT DATE: 09-21-95

SKIN DOSE CALCULATIONS USING VARSKIN MOD 2 TO COMPARE TO LICENSEE'S DOSE ESTIMATE

GENERAL ASSUMPTIONS:

1. 100 MICROCURIES OF P-32 ON THE MAXIMALLY CONTAMINATED OUTSIDE AREA OF THE LABCOAT.
2. CONTAMINATED LABCOAT WAS WORN FOR 20 MINUTES.
3. SKIN THICKNESS = 7 MG./SQ.CM.
4. CONTAMINATION SOURCE IS TWO DIMENSIONAL.
5. AIR GAP = 0 MM.

VARSKIN RUNS

	**********	RADS	**********	
ASSUMPTIONS	100 UCI/ 1 SQ.CM.	100 UCI/ 10 SQ.CM.		100 UCI/ 100 SQ.CM.
MAT'L = 0 MM.	247	27.1/ 1 SQ.CM.**		3.1
DENSITY = 0.1 G./CC.		25.6/ 10 SQ.CM.		2.8
0 MG./SQ.CM.		02.6/100 SQ.CM.		2.8
MAT'L = 2 MM.	68.6	16.5		1.8
DENSITY = 0.1 G./CC.		13.1		1.8
20 MG./SQ.CM.		1.9		1.6
MAT'L = 4 MM.	35.5	11.3		1.4
DENSITY = 0.1 G./CC.		8.8	*	1.4
40 MG./SQ.CM.		1.4		1.2
MAT'L = 8 MM.	13.9	6.3		0.9
DENSITY = 0.1 G./CC.		4.9		0.9
80 MG./SQ.CM.		0.9		0.8

NOTES:

1. A LICENSEE STUDY INDICATED THAT THE INDIVIDUAL WORE A T-SHIRT UNDER THE LABCOAT.
2. A DRAWING IN A LICENSEE STUDY INDICATED THAT THE MAXIMALLY CONTAMINATED AREA WAS APPROXIMATELY 30 TO 50 SQ.CM.
3. AN ASTERISK (*) MARKS THE MOST PROBABLE SKIN DOSE RANGE BASED ON THE ABOVE DATA.
4. A DOUBLE ASTERISK (**) MARKS A TYPICAL ENTRY WHICH IS TO BE INTERPRETED AS THE AREA OVER WHICH TOTAL BETA DOSE IS AVERAGED.
5. A RELATIVE ERROR OF 0.01 WAS USED.
6. DOSES WERE CALCULATED TWICE AND THE SECOND RESULT WAS USED.
7. THE VARSKIN NUREG (CR-4418) PROVIDES A DOSE FACTOR FOR P-32 OF 9.17 RAD/HOUR AT 7 MG./SQ.CM. FOR 1 MICROCURIE/SQ.CM. WHICH EQUATES TO APPROXIMATELY 30.6 RAD FOR 20 MINUTES ASSUMING 10 MICROCURIES/ SQ.CM. AND NO PROTECTIVE COVERING; THIS VALUE IS CLOSE TO THE COMPARABLE SITUATION AND VALUE OF 25.6 IN THE TABLE ABOVE.
8. THE TABLE ABOVE INDICATES RATIOS OF 7, 2.4, AND 2.2 FOR DOSE WITH NO PROTECTIVE COVERING VS. DOSE WITH 40 MG./SQ.CM. OF PROTECTIVE COVERING.
9. A LICENSEE STUDY USING THE CONTAMINATED LABCOAT AND TLDS YIELDED A RATIO OF 151 FOR DOSE TO A TLD IN DIRECT CONTACT WITH THE CONTAMINATION ON THE LABCOAT VS. DOSE TO A TLD SEPARATED FROM THE CONTAMINATION BY THE THICKNESSES OF THE LABCOAT AND A T-SHIRT.
10. ADJUSTMENT OF THE RESULT OF THE STUDY TLD BADGE EXPOSED IN DIRECT CONTACT WITH THE CONTAMINATION FOR STUDY DURATION AND DECAY YIELDS A VALUE OF 3.1 RAD WHICH IS ROUGHLY THE SAME ORDER OF MAGNITUDE AS THE COMPARABLE SITUATION AND VALUE OF 25.6 IN THE TABLE ABOVE.
11. THE LICENSEE ESTMATED THE DOSE TO SKIN BENEATH THE CONTAMINATION LOCATION TO BE 20 MILLIREM (0.02 RAD).
12. USING AN AVERAGE BETA ENERGY OF 0.7 MEV AND THE RHHB (JAN 1970; PG. 123), THE RANGE FOR 0.7 MEV BETAS APPEARS TO BE APPROXIMATELY 250 MG./SQ.CM.