Revision 3
4/97

NEN LIFE SCIENCE PRODUCTS QUALITY ASSURANCE PROGRAM FOR TYPE B CONTAINERS

POLICY

1 NEN Life Science Products' policy requires that radioactive materials and their containers shall be handled and prepared for transportation to assure their safety in transportation and ensure compliance with applicable regulatory requirements (1), license conditions and in accordance with written program approvals.

PURPOSE

2 To ensure that appropriate procedures are used to control the quality of safety related functions in the procurement, receipt, handling, storage and shipment of Type B packaging used to contain greater than Type A quantities of radioactive materials (2).

3 To assure site management and applicable regulatory agencies that the use of Type B containers meets satisfactory safety standards and regulatory requirements (1). The Operations Manager requires adherence to the policies, purpose and procedures of the NEN Life Science Products Quality Assurance Program.

SCOPE

4 Quality control (QC) procedures are described to ensure the safe use of purchased or leased Type B containers.

5 Quality assurance (QA) procedures are described to assure that greater than Type A quantities of radioactive materials are prepared for safe shipment in purchased or leased Type B containers.

6 This QA program prohibits the design, fabrication or modification of Type B containers.

DEFINITIONS

7 Quality Assurance Program: All planned and implemented actions necessary to assure the safe transportation of greater than Type A quantities of radioactive materials in type B containers.

8 Quality Control Procedures: All actions necessary to ensure the safe procurement, receiving, handling, storage, shipment and inspection of Type B containers.

9 Quality Assurance Procedures: All actions necessary to assure that QC procedures are implemented effectively to ensure safe transportation of greater than Type A quantities of radioactive materials in Type B containers.

ORGANIZATION

10 All programs and operations on or servicing the NEN Life Science Products facilities are subject to the management of the Operations Manager. Specific functions may be delegated to managers reporting to the Operations Manager and to contractors.

11 All activities necessary for the safe shipment of Type B containers are coordinated or supervised by the QC Administrator (QCA).

12 The NEN Life Science Products licensed Radiation Protection Officer (RPO) provides assurance of compliance with all applicable QA program conditions, safety and regulatory requirements.

13 The QCA and RPO shall be provided with qualified alternates.

14 The QCA and RPO or their respective alternates shall report in separate management lines providing for the independence of QC and QA functions.

15 The NEN Life Science Products licensed Radiation Safety Committee (RSC) approves procedures, facilities, the supervision of radioactive materials and corrective and preventive actions resulting from infractions or site radiation protection requirements.

16 The RSC is comprised of qualified members representing operations, service functions and the RPO.

17 The following diagram illustrates the organizational structure relevant to the QA Program for Type B Containers:

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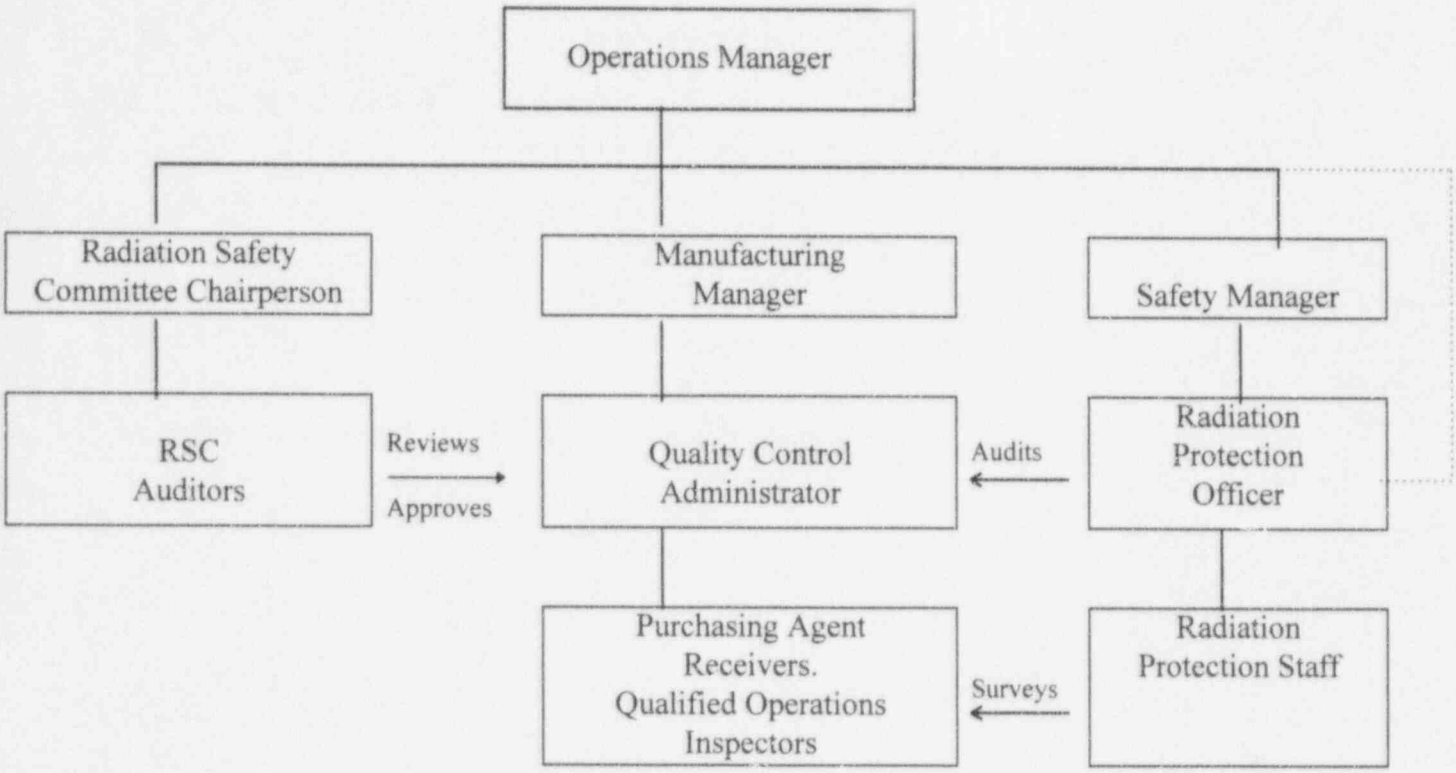

RESPONSIBILITIES

Operations Manger

18 Ultimate responsibility for NEN Life Science Products QA Program and associated operations. Appoints Manger, RSC Chairperson and RPO.

QC Administrator

19 Ensures the completion of all required QC procedures including procurement, receiving, handling, storage, shipping, inspections, qualifications and training of operators, documentation, document control and records.

20 Shall be appropriately qualified and trained in applicable regulations pertaining to the packaging and transportation of radioactive material and the handling and shipping of Type B Containers. Shall have a minimum of three years experience working under a NRC or Agreement State licensed program handling Type B containers.

Qualified Operators

21 Qualified and trained employees or contractors shall be assigned for the following functions: procurement, receiving, handling, storage, shipping and inspection of Type B containers.

22 The individual assigned to prepare a Type B container for shipment must be a different person from the individual who inspects the preparation of the container prior to shipment.

Radiation Protection Officer

23 Ensure that program activities are monitored and audited to assure that all requirements of the QA Program are compiled with. Reports results of audits to the Operations Manager and all other relevant individuals in the QA Program. Maintains posted notices required by regulations (3). Notifies applicable regulatory authorities of defects and items of non-compliance (4).

24 Shall be appropriately qualified and trained as specified in the Materials License (5) and in applicable packaging and transportation regulations (1).

Radiation Protection Staff

25 Qualified and trained employees or contractors shall be assigned to routinely monitor and inspect operations and facilities where Type B containers are handled to assure appropriate contamination, radiation and access control, posting and labeling, and monitoring instrument maintenance.

Radiation Safety Committee

26 Approves operations, facilities, programs and all written policies, procedures and rules involving radiation safety requirements. Approves individuals to supervise operations affecting the handling of radioactive materials. Reviews incident investigations and corrective and preventive actions resulting from any incident where RSC approved radiological limits are exceeded.

27 The Chairperson of the RSC shall be appropriately qualified and trained as specified in the Materials License (5). RSC members shall also be appropriately qualified by training and experience.

QUALITY CONTROL PROCEDURES

Procurement

28 The procurement of radioactive material in a Type B container is accomplished with a written purchase order.

29 Purchase order documents are controlled by a limited number of individuals in Purchasing authorized to expedite them.

30 The following procedures are required to allow the purchase or lease of a particular model of Type B container:

a. A vendor is proposed.

b. The proposed vendor is evaluated to verify that they have a NRC QA program or equivalent, to verify their historical performance in quality and delivery, to verify that they permit inspection or audit of their QA program and to ensure that they provide inspectable technical specifications.

c. The QC Administrator reviews and approves the vendor evaluation by signing procurement documents.

d. Copies of written vendor evaluations and subsequent purchase orders are maintained as inspectable records by Purchasing and the QC Administrator.

Receiving

31 Type B containers are inspected promptly following receipt.

32 Materials received are identified and conformance to receiving documentation verified.

33 Materials received are inspected for conformance with specifications prior to use.

34 Containers are identified and marked or tagged to indicate their inspection status prior to transfer to storage or use.

35 The results of the inspection are documented on inspection form indicating:

a. the activities inspected

b. the individuals conducting the inspection

c. acceptance criteria

d. inspection method

e. results of the inspection

Storage

36 When not in use or transit, Type B containers shall be stored in designated areas with appropriate access control and conducive environmental conditions.

37 The indication of the status of containers shall be maintained during storage.

Handling

38 Type B containers shall be handled to prevent damage that could compromise the safety of the container.

Shipping

39 Type B container shall be correctly assembled, marked and labeled, prior to shipment, according to vendor provided instructions.

40 Prior to shipment the container and contents shall be properly described on the transport document.

41 On completion of all preparations for shipment, another individual, not involved in the preparation, shall inspect the container and transport document and record the results of this inspection in a similar manner to the inspection when receiving a container.

Measurement Control

42 All equipment used to make measurements relevant to the safety of the container shall be maintained to ensure the validity of the measurements.

No-Conformance

43 Any non-conforming aspect of the Type B container shall be documented, the container isolated and secured and the QC Administrator promptly notified.

44 The disposition of non-conforming items shall be determined by the QC Administrator.

45 Non-conforming components shall be identified and separated from acceptable components to preclude their inadvertent use.

46 The Radiation Protection Officer shall be promptly notified of any radiological conditions that are suspected to exceed or threaten to exceed applicable regulatory limits (1) (6).

Corrective and Preventive Actions

47 In the event of determining defects, non-conformance or other conditions or practice with potential for adverse consequence to the safety of the container, the QC Administrator shall promptly:

a. investigate the event

b. determine the cause

c. determine the implement corrective action

d. determine and implement preventive action

e. report applicable investigation for RSC review and approval

f. evaluate corrective and preventive actions

Notifications

48 In addition to the notifications indicated above:

a. The RPO shall provide for the maintenance of posted notices in the workplace to comply with regulatory requirements (3).

b. The QC Administrator shall make appropriate routing notifications prior to offering greater than Type A quantities of radioactive material in a Type B container for transportation and shall document these notifications in compliance with regulatory requirements (1).

c. The QC Administrator shall promptly notify the supplier of the Type B container of any defects or non-conformance items.

d. The RPO shall notify appropriate regulatory authorities of defects and non-conformance items that have significant safety implications (4).

Documentation and Records

49 The QA program and implementation procedures (SOPs) shall be detailed in written documents.

50 The QC Administrator shall maintain and control the distribution of SOPs to ensure that current SOPs are available to authorized individuals in the workplace.

51 The QC Administrator shall maintain records on personnel qualifications and training, program amendments, procurement, inspection and non-conformance. These records shall be available for regulatory inspection in conformance with regulatory requirements.

QUALITY ASSURANCE PROCEDURES

52 Radiation Protection staff shall include Type B containers practices and conditions in their routine surveillance program.

53 The RPO shall provide for independent comprehensive audit of the Type B Container QA Program to include:

a. the use of an audit check list

b. evaluation and verification of procedures and practices

c. review of documentation and document currency and control

d. review of records quality and maintenance

e. the results of the audit

54 RPO audits shall be scheduled no later than one year following a shipment from the Boston Site exceeding Type A quantities of radioactive material or more frequently as necessary.

55 The RSC shall conduct independent audits of the program as necessary.

56 The results of all surveys and audits shall be documented and maintained by Radiation Protection.

57 All items of non-compliance determined in surveys and audits shall be promptly communicated to the QC Administrator and follow-up action scheduled to confirm that corrective actions have been implemented.

REFERENCES

1. Nuclear Regulatory Commission 10 CFR 71, Packaging and Transportation of Radioactive Material.

2. Nuclear Regulatory Commission 10 CFR 71 Subpart H Quality Assurance.

3. Nuclear Regulatory Commission 10 CFR 19.11 and 10 CFR 21.6(a) and (b).

4. Nuclear Regulatory Commission 10 CFR 21.

5. Massachusetts Department of Public Health Materials License 20-00320-21.

6. Massachusetts Department of Public Health 105 CMR 120.

DUPONT

E.I. DU PONT DE NEMOURS & CO. (INC.)
~~MEDICAL PRODUCTS DEPARTMENT~~
NEW Life Science Products

~~May 22, 1996~~
April 24, 1997

U. S. Nuclear Regulatory Commission
Containment and Storage Inspection Section
Office of Nuclear Material Safety and Safeguards
Washington, DC 20555-0001

Attention: John P. Jankovich, Section Leader

Subject: Amendment of Quality Assurance Program Approval

Reference: Quality Assurance Program Approval No. 0711, Rev. 1
Docket Number 71-0711
Application for Amendment of Material License 20-00320-21, submitted to ~~NRC on 4/10/96~~. the Massachusetts Department of Public Health on 4/11/97.

Dear Mr. Jankovich:

The enclosed application is submitted to amend the Quality Assurance Program Approval No. 0711 in its entirety to accommodate a change of ownership and name of licensee.

DuPont has negotiated sale of substantially all its NEN Products business assets to NEN Life Sciences ~~Company~~. Closing is scheduled for ~~July this year~~. We request continued approval of our Quality Assurance Program for using Type B containers provided by vendors.

Products, Inc. about May 30, 1997.

There are no substantive changes to this Quality Assurance Program except the change of ownership and name.

NEN Life Sciences ~~Company~~ is a radiochemical manufacturer licensed by the ~~Nuclear Regulatory Commission (NRC)~~ Massachusetts Department of Public Health (MDPH) to receive, acquire, possess, transfer and deliver radioactive material according to conditions specified in Materials License 20-00320-21.

Products, Inc.

Products are shipped for biomedical and industrial research applications predominantly in small quantities in excepted or Type A packages. On rare occasions radioactive materials may

NEW Life Science Products
~~MEDICAL PRODUCTS DEPARTMENT~~
549 Albany Street, Boston, Massachusetts 02118 Telephone 617-482-9595 Fax (617) 542-8468

be shipped to or from license facilities in a Type B container. In the unlikely event that a damaged package should require design, fabrication, assembly testing or modification these activities shall only be allowed when certifications are obtained from package suppliers to indicate that the activities are conducted in accordance with a NRC approved QA program.

To facilitate the divestiture of the NEN ~~Products~~ business we would appreciate if the NRC sends us written confirmation of the approval of this application to indicate that the amendment will be effective on the day of Closing. ~~We would appreciate if you could send this to us in early June to enable us to meet other regulatory timelines~~. we intend to inform you of the actual day of Closing when we have that information. We have enclosed a marked-up copy of our previous pending amendment application to assist you to identify the changes.

Please call the undersigned at 617-350-9111 if you need clarification or further information. We appreciate your assistance.

Sincerely yours,

Leonard R. Smith, CHP
Radiation Protection Officer

Enclosures: Application for Amendment
Duplicate Copy of Application
~~Check for Amendment Application~~
Marked-up copy of previous pending amendment application.

~~cc: K. Brown, NRC Region 1~~

NRC FORM 313 (6-93)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD
LISLE, IL 60532-4351

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 0711
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

See attached

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

See attached

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Leonard R.Smith

TELEPHONE NUMBER
(616) 350-9111

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5.	RADIOACTIVE MATERIAL. a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6.	PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7.	INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.	8.	TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9.	FACILITIES AND EQUIPMENT.	10.	RADIATION SAFETY PROGRAM.
11.	WASTE MANAGEMENT.	12.	LICENSEE FEES *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY 10B AMOUNT ENCLOSED $ ~~240~~ N/A

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Leonard R. Smith, Radiation Protection Officer	L R Smith	~~4/24/96~~ 5/22/96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

PROGRAM APPROVAL AMENDMENT

ITEM 2: NAME AND MAILING ADDRESS OF APPLICANT

1. The name and mailing address of the present licensee and applicant is E. I. DuPont de Nemours and Company (Inc.), ~~Medical Products~~, Life Science NEN Products, 549 Albany Street, Boston, Massachusetts 02118.

2. Following completion of the transfer of ownership, subject to NRC approval, the name of the licensee will be NEN Life Sciences ~~Company~~ Products, Inc. at the same mailing address.

ITEM 3: ADDRESSES WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Licensed material will be used or possessed in compliance with conditions specified in Materials License 20-00320-21, as amended at:

a. the Boston site at 100 E. Canton Street, 120 and 123 E. Dedham Street and 575 Albany Street, Boston, Massachusetts 02118,

b. the Billerica site at parts of building numbers 250 and 325 leased from DuPont Merck Pharmaceutical Company located at 331 Treble Cove Road, North Billerica, Massachusetts 01862.

Revision ~~2~~ 3
~~5/96~~
4/97

NEN LIFE SCIENCES ~~QUALITY~~ PRODUCTS QUALITY ASSURANCE PROGRAM FOR TYPE B CONTAINERS

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C1682798

PAYMENT QUESTIONS SHOULD BE DIRECTED TO THE PURCHASING SITE

E.I. DU PONT DE NEMOURS AND COMPANY

FINANCE - VENDOR PAYMENT
WILMINGTON, DELAWARE 19898

ALWAYS REFER TO OUR P.O. NUMBER IN YOUR CORRESPONDENCE

006199110

52600066 05/17/96

VOUCHER NO.	INVOICE NO.	P.O. NO.	DATE	GROSS	DISCOUNT	NET
EM0362	15MAY1996	YNEN4395	05-16-96	240.00	.00	240.00
TOTALS				240.00	.00	240.00

CR-12 3/92

DU PONT

E.I. DU PONT DE NEMOURS AND COMPANY

Not negotiable

FINANCE - VENDOR PAYMENT
WILMINGTON, DELAWARE 19898

62-20
311

DATE	CHECK NUMBER	AMOUNT
05/17/96	52600066	**********240.00

NOT VALID AFTER 90 DAYS

PAY TO THE ORDER OF
US GOVT
US NUCLEAR REGULATORY COMM
REGION I NUCLEAR MAT
475 ALLENDALE RD
KING OF PRUSSIA PA 19406-1415

TO:
CITIBANK DELAWARE
A Subsidiary of Citicorp
One Penn's Way
New Castle, DE 19720

D006

⑈52600066⑈ ⑆031100209⑆ 38788577⑈

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SEE REVERSE SIDE FOR OPENING INSTRUCTIONS

Sent with initial application dated May 22, 1996.

AFTER FIVE DAYS RETURN TO
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BMP-19-2212
WILMINGTON, DELAWARE 19880-0019

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