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

October 18, 2001

Docket No. 03020681 License No. 07-13441-02
Control No. 130368

Joseph Montovino
Manager, Facilities
E. I. duPont de Nemours and Co., Inc.
Stine-Haskell Research Center
P.O. Box 30, Elkton Road (Rt. 2)
Newark, DE 19714-0030

SUBJECT: E. I. DUPONT DE NEMOURS AND CO., INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 130368

Dear Mr. Montovino:

This is in reference to your application dated September 26, 2001 requesting to renew Nuclear Regulatory Commission License No. 07-13441-02. In order to continue our review, we need the following additional information:

1. Your current license, amendment No. 11, authorizes you to possess 200 curies of Hydrogen-3. Your renewal application requests 20 curies of Hydrogen-3. Is this your intention or is this a typographical error?

2. Your current license, amendment No. 11, authorizes you to possess Americium-241 as a check source in a Packard liquid scintillation counter. Your renewal application does not request Americium-241. Please provide documentation demonstrating that the source was properly disposed and that it was not leaking at the time of disposal (leak test).

3. In item No. 6.2 (Field Studies) of your application, you request to spray or treat crops or soil. 10 CFR 51.22(c)(14)(v) identifies as a categorical exclusion (from the requirement to prepare an environmental impact statement) the use of radioactive material for research and development and for educational purposes. However, this categorical exclusion does not encompass, among other things, performance of field studies in which licensed material is deliberately released directly into the environment for purposes of the study. This type of request requires that you file an environmental report and that the NRC conduct an environmental assessment, pursuant to 10 CFR Part 51.

   If you want to continue to conduct field studies in which licensed material is deliberately released to the environment for the purpose of studies, please provide the following information, in addition to that provided in item No. 6.2 of your application:

a. Describe the field studies that have been conducted thus far. Include in the description the number of studies and the activities of radionuclides involved.

b. Describe the training and experience of the individuals who will be using the material.

c. Provide a complete experimental protocol.

d. Provide your criteria for releasing the plots at the conclusion of the studies, including the soil concentration limits you will utilize.

e. Provide your calculation of the expected radiation dose to humans. Use of the decontamination and decommissioning (DandD) computer screening code may be helpful to you in developing your response. The DandD code can be installed by downloading the self-extracting program file, setup.exe, accessed through the Web site <http://techconf.llnl.gov/radcri/java.html> clicking on "dose assessment" and then on "decontamination and decommissioning software." The installation instruction file "readme.txt" can also be downloaded using the above Web site, to help users installing the code.

f. Provide a letter from Executive Management of E. I. duPont de Nemours and Co., Inc. or, if duPont is not the property owner, a letter from Executive Management of the property owner, that authorizes use of radioactive materials at the proposed site.

g. Provide a letter from the appropriate state health authorities indicating that they have reviewed your application and do not object to your request.

4. Your current license, amendment No. 11, authorizes locations of use at the Glasgow Site Building 300, Glasgow, Delaware; and Delaware Technology Park, Newark, Delaware. Your renewal application does not request these locations of use. We cannot remove these facilities from your license until you provide provide one of the following: evidence that the facilities have been properly decommissioned; a statement that licensed material was never received, used or stored at the facilities; or a statement that the facilities are listed as locations of use on another active NRC license (provide license number). Please explain the radiological status of these two locations.

5. In item 7 of your application, you state that, "NRC approval will be obtained when replacing the Committee Chairperson and RSO(s)" The name of the chairman of the Radiation Safety Committee (RSC) is no longer explicitly listed on broad scope licenses. NUREG-1556, Volume 11 guidance permits licensees to provide criteria for selecting a chairman which will allow you change chairmen without submitting an amendment request to the NRC. Please provide your criteria for selecting a chair for the RSC. Section 8.7.2 of NUREG-1556, Volume 11 concerns the RSC and may be helpful in developing your response.

6. In item 7 of your application you state that, “Official meetings will require a quorum consisting of four members, including at least one of the Radiation Safety Officers.” With regard to this statement, please address the following:

   a. Please note that the NRC recognizes only one RSO for a given radiation safety program. The use of back-up or alternate RSOs may be a part of your administrative procedures. However, while some of the duties of the RSO may be assigned to other qualified individuals, the responsibilities of the RSO cannot be transferred. Please confirm that the RSO for your license is Norman W. Henry, III and that a quorum of the Radiation Safety Committee will include Mr. Henry’s presence and not that of an alternate or back-up RSO.

   b. The minimum members considered acceptable for a quorum by the NRC are: Chairperson, RSO, management representative, and committee member(s) representing the department/area from which radiation safety issues/request, to be discussed at a given meeting originated, and any other committee member whose field of expertise is necessary to assure all safety aspects of the issue/request have been addressed. Please note that it is generally not acceptable to have an alternate attend in place of the RSO. The RSO should be present for each meeting. Please confirm that your RSC will meet these quorum requirements.

7. In item 7 of your application, under “RSC Duties and Responsibilities,” you state that, “The Committee may revise procedures and programs after indicating: 1. The reason for the change; 2. The radiation safety issues evaluated; and 3. How the change will be implemented/communicated.” You may make some program changes and revise some procedures previously approved by the NRC without amendment of the license. Flexibility to revise certain programs and procedures without prior NRC approval is discussed in Sections 1 and 8.7.2 of NUREG-1556, Volume 11 (enclosed). If you would like to request this flexibility, please provide the following information:

   a. Specify the programs and procedures that you want flexibility to change without prior NRC approval. Please note that as stated in Section 1 of NUREG-1556, Volume 11, flexibility will only be granted in the following programmatic areas: training, audits, radiation monitoring instruments, material receipt and accountability, occupational dose, safe use of radionuclides and emergency procedures, and surveys. As such, you are <u>not</u> permitted to make changes in other areas of your program without prior NRC approval.

   b. Confirm that the duties and responsibilities of the RSC will include:

      i. review and approval of program and procedural changes prior to implementation;

      ii implementation of program and procedure changes;

      iii. audit of licensed operations to determine compliance; and

iv. taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.

c. Describe the process for procedure and program review and approval, including the documentation of the specific change. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.

8. In item 7 of your application, under “RSC Duties and Responsibilities,” you provide the criteria for approving radioactive material users (authorized users = principle investigator?). In addition to the criteria provided in your application, your RSC must assure that authorized users candidates have certain basic training and experience before the committee will consider authorizing them. Please review the requirements in 10 CFR 33.15(b) (e.g., a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering and 40 hours of additional training and experience related to radioactive materials). These requirements should be considered as you address the basic training and experience your RSC will require for qualification of authorized user candidates. In your response to this letter, provide the basic training and experience that your RSC will require of a candidate authorized user.

9. Item 9 of your application, under “Special Use Facilities,” discusses tritium gas labeling, and loose material generating alpha particles. You must specify the locations of these special application facilities. Please provide buildings and room numbers for these facilities.

10. Item 9 of your application "Facilities and Equipment," discusses radioactive materials use by DuPont Pharmaceuticals Company (soon to be Bristol-Myers Squibb) within the Stine-Haskell Research Center. We received a letter from Frieda Fisher-Tyler, Director, Environmental Health and Safety, DuPont Pharamceuticals Company, Experimental Station dated September 12, 2001, regarding the use of Building H-1 at the Stine-Haskell Research Center site. In the letter, she requested that two licensees, E. I. du Pont de Nemours and Co., Inc. (07-13441-02); and DuPont Pharmaceuticals Company (07-00455-40), be authorized to perform licensed activities in the same building. The NRC does not usually issue licenses to multiple entities at the same address. Usually only a single licensee is authorized to perform activities at a single address. However, because the Stine-Haskell site and the Experimental Station site were locations where licensed activities were authorized to the same licensee in the past, we have continued to allow the sites to be shared by the subsidiary companies. Because of the past relationship and the continuing radiation safety responsibility for the sites by the same individuals, we could accept having the formerly related licenses at the same address, provided responsibility for specific facilities and the relationship between the facility owner and the lessee are clear. However, we believe that it is not appropriate to allow separate licenses to authorize activities in the same building.

For the Stine-Haskell site, provide the following information. License amendments, if required, should be submitted by all licensees involved, including the new owner, Bristol-Myer Squibb.

a. Describe the management controls you will implement ensure that the conditions of all licenses are met, and that licensed materials are controlled by the respective licensees and not intermingled.

b. Describe how licensed material, including waste, assigned to each licensee will be controlled and secured so that it does not inadvertently become mixed with material under the control of the lessee.

c. Submit the procedures that will be required if a lessee must transfer material through areas of the facility which are controlled by another licensee (facility owner), for activities such as receiving and shipping materials from a common loading dock or moving waste to a storage area, which ensure that licensed material is controlled by the appropriate licensee.

d. If any areas are to be shared (such as hallways, Cold Rooms, Counting Rooms, or waste storage facilities), specify who will be responsible for control of licensed materials in these areas, performance of surveys, and other related activities including incidents such as spills.

e. If systems such as ventilation ducts and sewer lines will receive effluent materials from both the owner and a lessee, specify who will be responsible for monitoring these systems, accounting for material released, and maintaining compliance with NRC regulations. Describe any changes in your procedures that may be required if a lessee shares such systems.

11. In item 10 of your application, under “Material Control, Accounting and Security,” you state that, “All transfer of radioisotopes within the facility must be to approved users only.” This appears to imply that transfer of radioactive material between authorized users is permitted without prior notification or approval of the RSO. Please describe how you can maintain an accurate inventory if users are not required to notify the RSO of transfers of materials. Include in your description, your method of timely assessment of lost/missing/stolen materials if users do not have to notify the RSO of in-house transfers.

12. Your request, in item 11.5.2, of your application to dispose of waste meeting certain criteria without regard to radioactive content is receiving additional review. There may be further questions on this matter at a later date.

13. With regard to item 11.6, of your application, “Interim Storage,” if presently available waste disposal facilities close, you may be required to store radioactive waste at your facility until the disposal site planned for your State and/or compact becomes available. However, since waste disposal facilities are available, interim waste storage is not necessary nor permitted at this time. If you want to be authorized at this time for interim storage of radioactive waste, should waste disposal facilities become unavailable in the future, you must waste submit an interim waste storage plan. Please submit a plan which contains all the information in the enclosed Information Notice 90-09 (Please do not refer to any previously submitted material). Otherwise you may apply for an amendment and submit an interim waste storage plan at such time as radioactive waste disposal facilities become unavailable.

14. Regarding your Decommissioning Funding Plan (DFP), please address the following:

    a. Your most recent DFP was submitted as an addendum to the letter dated July 25, 1997, signed by Norman W. Henry, III, Radiation Safety Officer. Using the current status of your program, reevaluate and resubmit your cost estimates for decommissioning (DFP). In general, cost estimates adjustments should be made to account for inflation, for other changes in the prices of goods and services (e.g., disposal cost increases), for changes in facility conditions or operations, and for changes in expected decommissioning procedures. The appropriate level of detail for the cost estimates is discussed on pages F22 through F39 in Appendix F to NUREG-1727, "Standard Format and Content of Financial Assurance Mechanisms for Decommissioning" (enclosed). The results of your evaluation must demonstrate that your current financial assurance for $10,200,000.00 is sufficient to cover the costs of decommissioning your current facilities, and must provide the basis for the cost estimates. If you determine that the amount of financial assurance has increased, you must also resubmit your self-guarantee.

    b. Licensees who use DFPs must specify the means (i.e., the method and frequency) by which they will periodically adjust their cost estimates and associated funding levels over the life of the their facilities. In general, cost estimates should be updated with the current prices of goods and services at least every five years or when the amounts or types of material at the facility change. Please confirm that you will evaluate your cost estimates at least once every five years or when the amounts or types of material at the facility change.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at http://www.nrc.gov/NRC/ADAMS/index.html.

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 130368. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-6952.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson
Senior Health Physicist
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Enclosures:
1. NUREG-1556, Volume 11
2. Information Notice 90-09
3. Appendix F to NUREG-1727

cc w/enclosures:
Norman W. Henry, Radiation Safety Officer

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