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May 9, 1991

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

DU PONT
MERCK

Attention: Docketing and Service Branch

Reference: Docket No. RIN 3150-AD87

Gentlemen:

This is written to comment on the Proposed Rule published in the Federal Register on 4/12/91, page no. 56 FR 14870, concerning the Revision of the Fee Schedules established by the regulations of Title 10 CFR Part 170 and Title 10 CFR Part 171.

Our company, the Du Pont Merck Pharmaceutical Company, Radiopharmaceuticals Division in Billerica Massachusetts, is a major manufacturer and distributor of radiopharmaceuticals for authorized recipients worldwide.

We support your need to collect fees for services rendered as provided under the Independent Offices Appropriation Act of 1952 (31 U.S.C. 9701) and understand the need for the fee increases proposed in the regulations of Title 10 CFR Part 170. We do not agree however that the proposed regulatory change regarding annual fees in Title 10 CFR Part 171 complies with Public Law 101-508 Section 6101, subtitle B and the Conference Report to the Legislation Subsection (c) (3) on October 26, 1990.

Fees should be promulgated based on the services rendered to the recipient. Part 170 fees are designed to recover the costs to the NRC of providing individually identifiable services to applicants and holders of NRC licenses. Part 171 annual fees are designed to recover generic costs attributable to classes of licensees. We believe the intent of the new annual fee requirements in Part 171 do not represent a fair and equitable allocation of the total amount of the charges to be recovered among licensees.

Just as each class of licensee has its own regulatory requirements, each licensee within each class has differing needs for the services of the NRC. Our operations encompass 7 fee categories or classes of licensees. The license category we occupy with regards to distribution type licenses (Fee Category 3D) involves the services of the NRC during the approval and amending process which occurs infrequently. In the interim the license sits in effect without the need for intervention or servicing by the NRC unless a need arises through the enforcement process. The financial mechanisms are firmly in place for the enforcement process. The same is true of the Type B QA program approvals and sealed source registrations. The costs associated with these license categories should be recovered when services are provided and furthermore these charges should recover the complete cost of the service rendered. An annual fee on such a license class appears to provide excess revenue that the NRC will be able to allocate to any other NRC budget item which will not necessarily serve the needs of Materials Licensees.

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The promulgation of the proposed rule-change for Part 171 of imposing annual fees to all Materials licensees will drastically increase the costs of doing business for the majority of licensees (both NRC and Agreement State) in the United States.

As an example, licensed medical users will have to pay the annual fees at least twice. They will have to pay the newly promulgated annual fees from the NRC and they will also have to pay an increase in the cost of the medical product to the manufacturer and/or distributor of the material in price increases. Over time the increase in price of the medical product is passed from the manufacturer to the distributor, such as a nuclear pharmacy, and to the final user, the hospital or clinic. As you know these costs will be passed on to the patients and the health care insurance providers resulting in further increases in the cost of health care in the United States.

Another side effect of this type of legislation will be a drastic reduction in the use of radioactive material for research purposes. It is becoming our experience that more and more researchers are using alternative methods to the use of radioactive materials in research. In our opinion this is occurring due to the political issues pertaining to the disposal of radioactive waste and the proposed promulgation of redundant environmental regulations. The proposed annual fees for materials licensees will further enhance the trend towards a decrease in the use of radioactive research products. This will eventually affect the commercial suppliers of such products based in the U.S. and the availability of this material for the scientific community. Projecting into the future the scientific community may only be able to obtain radioactive research products from foreign suppliers outside the jurisdiction of the NRC.

We also question the equitable nature of these proposed regulations since the content of the ruling emphasizes the acquisition of additional funds to pay for the Commission's budget. This Public Law does not establish any requirements for the NRC to optimize its budget authority and setup internal mechanisms for reducing costs. It is not fair for Materials Licensees to have to pay for services the NRC provides to some other class of licensee, that may or may not be necessary, and have no direct influence on the NRC's budget process.

In summary, we support the NRC's need to review and modify where necessary the regulations of Part 170 with regards to the fees charged for direct services rendered. We do not support the proposed rule changes for the regulations of Part 171 pertaining to the requirements for annual fees for Materials Licensees, Holders of Certificates of Compliance, Holders of Sealed Sources and Device Registrations, and Holders of Quality Assurance Program Approvals.

We request the NRC consider the following actions:

- Reevaluate the allocation of FY1991 Budget to Material Users Base Fees and provide more detailed information to all Materials Licensees on how the $30.2 million base amount was determined, including the justification for the proposed annual fees based on the specific classes of licensee determined by the Commission.

- Revise the proposed regulation of Part 171 to promulgate annual fees based on the actual services provided to Materials Licensees, considering that certain types of licenses are strictly administrative distribution approvals, as well as established sealed source and device registrations, which do not require any on-going services from the NRC. The Commission should also revise the Part 171 proposed rule to ensure that licenses and sealed source and device registrations filed by the NRC as officially "inactive" are not assigned an annual fee.

- In order to recover 100 percent of the NRC budget authority for FYs 1991 through 1995, the Commission should actively pursue cutting their budget rather than passing on the existing operating costs to Materials Licensees that must operate in a recession economy.

One final comment, these new regulations may eventually put our medical products business at a disadvantage compared to our competitors overseas, such as located in Europe. Manufacturers and distributors of radioactive material outside the U.S. will not have the same costs of doing business and may become more attractive to our customers in the U.S.

As a major NRC Materials Licensee in the U.S. we request your consideration of our comments.

Sincerely,

Dennis Dumas

Dennis O. Dumas
Radiation Safety Officer

Reference: Materials License 20-00320-21
Materials License 20-00320-19
Distribution Approval 20-00320-17MA
Materials License 20-00320-16MD
Materials License 20-00320-18MD
Materials License 20-00320-14E
Materials License 20-00320-15G
Materials License 20-00320-22G
QA Program Approval 0711
QA Program Approval 0384