

DSI-21
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December 2, 1996

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Attn: Chief of Docketing Service Branch
Washington, DC 20555-0001

**RE: U.S. Nuclear Regulatory Commission Strategic Assessment and Rebaselining Initiative:
Direction Setting Issue No. 21 - Fees**

These comments are submitted on behalf of SENTINEL, Amersham Corporation. Amersham Corporation manufactures industrial radiography sealed sources and device for both national and international distribution. We are particularly concerned about NRC's current and future activities and the level of service provided with respect to the fees paid by licensees.

Amersham supports the NRC initiative to determine which strategy and direction the agency should take to meet current and future challenges. As an affected licensee, we appreciate having the opportunity to submit these written comments.

1. What, if any, important considerations may have been omitted from the issue paper?

Our most serious concern is over the fact that NRC seems to be constantly expanding the scope of its regulation and increasing the amount of information and interaction required in the process of review and approval of licensing applications while its available resources are being reduced. This may explain the fact that the level of service provided to licensees who are paying fees has become increasingly unsatisfactory.

We appreciate some recent steps taken by the NRC to reduce the burden on the agency and licensee resources, such as the extension of expiration dates on some materials licenses. We have suggested alternatives to reduce review times based on the licensee's Quality Assurance program. The use of a comprehensive QA program should result in a more expeditious review as the licensee has already performed a thorough assessment prior to the request for an amendment. The use of a QA program could also reduce the number of amendment requests that need to be submitted, if the request has no safety significance. The

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NRC is auditing these QA programs and can ensure the appropriate review is performed.

In addition, substantial annual fees are required for the having an NRC approved QA program with no net benefit to the licensee. By allowing credit for the QA program the NRC could reduce the need for detailed reviews thereby saving NRC resources for higher risk activities or reviews. NRC should consider the impact these changes could have on its resources and assess the need to address resource needs solely through funding mechanisms.

2. How accurate are the NRC's assumptions and projections for internal and external factors discussed in the issues paper?

It is stated in DSI 21 that NRC activities serve a need broader than service to a licensee or applicant and this broader need includes building and maintaining public confidence in the use of materials which is of benefit to the entire U. S. nuclear industry. In making this statement, it is apparent that NRC has lost sight of the fact that is the "public" and not just the "nuclear industry" that benefits from the use of these materials. It is the public who undergoes diagnostic tests using radiopharmaceuticals rather than invasive surgery, who travels on commercial airlines whose jet engines are inspected using nondestructive radiographs, and who benefits from drugs that treat numerous illnesses that were developed using radiochemical tracers.

As licensees, our industry has paid its share of fees to support mandated activities of the NRC. While we pay the specified fees for licenses, registrations, amendments, and certifications, the inability to have applications reviewed and approved in a timely fashion affects the public when products can not be manufactured and distributed because an application for a license, amendment or container approval takes several months or years. The direct result on industry is that it often cannot meet the needs of customers or improve its products on a timely basis. This may ultimately lead to a further reduction in the number of licensees funding the NRC.

3. Do the Commissioner's preliminary views associated with the issue paper respond to the current environment and challenge?

While the NRC is focussed on the mission to perform functions to ensure public health and safety, whether or not there are fees, it must recognize that the broader need involves much more than building and maintaining public confidence is the use of materials. Just as licensees have an obligation to maintain compliance with NRC requirements, NRC also has an obligation to effectively conduct the activities funded by licensees to ensure the continued availability of the products provided by industry and needed by the public. As suggested by

other DSI's as part of the strategic assessment, the challenge may be more effective utilization of NRC resources rather than the way NRC is funded.

4. Which option do you endorse?

We do not endorse option 1 as the existing approach has resulted in a situation where licensee fees appear to be supporting activities not related to the activities for which the fees were paid. The services for which fees have been paid are not being effectively provided.

Certain features of the other three options are preferred. The NRC should seek to have Congress and the Administration address funding when new statutory responsibilities are given to NRC. Fees should only be applied to specific activities that are mandated and have a direct impact on the licensees paying the fees. With the fee structure, there needs to be a schedule of time frames for completion of review and approval of various applications. If resources are an issue with regard to the turnaround time expected for review and approval, then the NRC should address this by evaluating the efficiency and management of its programs. NRC should consider the impact any changes, possibly as part of this strategic assessment initiative, have on the ability to provide services that are funded directly by fees.

5. What funding mechanism should NRC pursue to recover the cost of its operations?

We prefer funding mechanism 1, which would recover the cost of providing requested services from the requestor, using fees and reimbursable agreements. The cost of activities that serve the collective interest of the public would be recovered from general revenues raised from taxes.

Amersham appreciates the opportunity to provide comments on this important direction setting issue. Please contact me at 617-272-2000, extension 210 if you have any questions concerning these comments or if additional information is required.

Sincerely,



Cathleen Roughan
Regulatory Affairs Manager