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United States Nuclear Regulatory Commission
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DUPONT
MERCK

L. Coblenz
59FR49215
9/27/94

Reference: Proposed Rule, Request for Public Comment, Federal Register Vol 59,
Page 43298, Date: August 23, 1994.

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Subject: Reexamination of the NRC Enforcement Policy

Dear Mr. Meyer:

As the holder of an NRC Type A manufacturing license of broad scope we wish to provide general comments to you concerning the issues raised in the above-referenced notice in the Federal Register.

The Radiopharmaceutical Division of the DuPont Merck Pharmaceutical Company is a member of the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) and endorses the comments they have previously sent to your office on this topic. The following information is based on our experiences over many years as a major NRC licensee of Region I.

1. The balance between providing deterrence and incentive (both positive and negative) for the identification and correction of violations should be pushed more towards positive incentives.

Carried over from the days of the Atomic Energy Commission, the Nuclear Regulatory Commission appears to be constantly utilizing the psychological concept of negative reinforcement in order to ensure all licensees comply with the regulations. When an apparent violation of the regulatory requirements of any magnitude is identified by representatives of the Commission the enforcement process and the accompanying negative messages to the licensee begin.

While it may be necessary to identify and potentially penalize a licensee for items of non-compliance it is more important to establish positive incentives for those licensees with a proactive program. For example, it would be more motivational if each time a licensee was found to be in full compliance with the regulatory requirements the various licensing fees were reduced. A point system could be set up where licensees could redeem their points for free license renewals or getting a reduction in the annual license fee.

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A Partnership of Du Pont and Merck & Co., Inc.

2. The appropriateness of NRC sanctions should only be an issue for those licensees that have consistently demonstrated poor performance in regulatory compliance.

Obviously there are situations where licensed operations are so out of control sanctions against the licensee are needed in order to ensure public health and safety is maintained at the highest levels. The trick is to set up a system of sanctions that only are applicable to those licensees with the poorest of regulatory records. Sanctions should not be imposed until investigations show the licensee's program is out of control and could imminently impact the safety and health of workers and the general public.

It appears that in the existing enforcement program there is an adequate process in place for the determination of appropriateness and implementation of sanctions for those licensed programs that are out of control. The problem is that for the remaining 99+% of the licensees that are conscientious about the regulatory requirements, this issue of sanctions hangs over them like a heavy weight. The majority of these licensees operate in fear of the NRC wondering if "sanctions" are going to be imposed for such relatively minor safety issues such as if a survey meter is out of calibration or a radiation worker was not trained properly. We do not believe this image is in the best interests of the Commission.

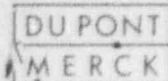
3. The Commission should not seek statutory authority to increase the amount of civil penalties.

It has been seen in the Federal Register and other publications describing repeat enforcement actions that civil penalties have little impact on all but the smallest of licensees. Please note our company does not subscribe to such tactics, but many licensees as commercial enterprises can actually absorb or anticipate monetary penalties and actually accept the risk of non-compliances being identified and just pay the penalty. For this reason higher civil penalties may be warranted, but it is more prudent to provide monetary rewards/incentives to licensees with high levels of performance as described previously, while at the same time encouraging a program of self-assessment for all licensees.

4. There should be different enforcement policies and practices for each of the categories of materials licensees, in contrast to power reactors or large fuel facilities.

The enforcement program should develop and implement policies that are unique to each category of material licensees and that would have a completely different emphasis than the program for fuel facilities and power reactors. The licensed program for each category of licensee varies with regard to what aspects are more important to the safety of the workers and the general public. An example of this could be the internal and external monitoring program for certain licensees. External dosimetry is vital to gamma radiography operations. The lack of such dosimetry is cause for severe enforcement action, where-as a university researcher found without a dosimeter represents more of a minor safety infraction. On the other hand, lack of a bioassay assessment may be a critical violation for the researcher and a minor consideration for the radiographer. The enforcement policies need to be flexible enough to account for the differences in the various materials license programs and not react to items of non-compliance using a rigid policy of enforcement for all.

5. The Commission should not continue the program of open enforcement conferences as the normal practice.



With regard to open enforcement conferences it has been shown in testimony to the Commissioners that this process is not working. In fact it appears to be a detriment to the process. Once an enforcement conference is declared open to the general public, both sides, the NRC representatives and the licensee representatives, feel obligated to prepare statements beforehand and discuss the issue in very formal terms in front of this public audience. Several years ago we had an "opportunity" to experience an enforcement conference. Overall it was an experience which our management does not wish to repeat, thus the process was apparently effective. On the other hand, there was valuable insight gained by our management with regards to the NRC philosophy of regulatory compliance. This insight would have been difficult to attain if the two parties were reading from prepared statements. In any case, there appears to be little to no interest from the public in attending these conferences, as evidenced by the poor attendance record to date, so the program should be discontinued.

We hope our comments are of value to the Review Team in their efforts to evaluate the existing enforcement policies of the Nuclear Regulatory Commission.

Please feel free to contact me if we could provide any additional input.

Sincerely,

A handwritten signature in cursive script that reads "Dennis Dumas".

Dennis Dumas
Assoc. Director
Safety and Environmental Engineering

Telephone: 508-671-8669