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MAR 8 1982

MEMORANDUM FOR: Ronald C. Haynes, Regional Administrator, Region I
James P. O'Reilly, Regional Administrator, Region II
James G. Keppler, Regional Administrator, Region III
John T. Collins, Regional Administrator, Region IV
Robert Engelken, Regional Administrator, Region V

FROM: John G. Davis, Director
Office of Nuclear Material Safety and Safeguards

SUBJECT: REGULATORY IMPROVEMENT IN MATERIAL LICENSING

This is to inform you of a major effort underway to make the materials licensing process more efficient through regulatory improvement. Although some members of your staff have already been made aware of this effort, I am bringing it personally to your attention to encourage regional participation in these planning stages. The current effort includes elements I consider essential to successful regionalization of material licensing. A description of the work is attached.

For these efforts to succeed, your full cooperation and participation is essential. As an initial step, I request that each region identify a key individual as a representative to the Task Force. I further suggest that the Chief of the Technical Inspection Branch, or his equivalent in your Region, be designated. A meeting is being arranged in Silver Spring during the week of March 22, or a mutually agreeable day, to brief the regional representatives and to discuss the work of the Task Force. We would also be interested in investigating what more formal role the Regions may play in bringing the program to successful implementation. A memorandum from Leo Higginbotham (dated February 11, 1982) to Technical Inspection Branch Chiefs in Regions I-IV and the Radiation Safety Branch Chief in Region V, gave a general description of the Task Force and enclosed an early draft of the Part 35 revision.

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I have asked the Task Force leader, Dr. William Walker, to schedule trips to each region to personally brief you once a final package has been released for office concurrences. I anticipate this to occur in approximately six weeks.

I am pleased with our progress at this point and would be happy to entertain any questions, suggestions, or comments you may have.

(Signed) John G. Davis
John G. Davis, Director
Office of Nuclear Material
Safety and Safeguards

Enclosure: As stated

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REGULATORY IMPROVEMENT IN MATERIAL LICENSING

The present review and licensing process was appropriate for the stage of technological development when radiation safety issues were not well defined, specific regulatory requirements had not caught up with developing technology and the size of NRC's program was small. The process is now becoming cumbersome and costly in a technology that is fully developed and where the essential requirements for safety are well defined on the basis of experience.

My staff is now in the process of redefining the materials licensing process into a system that has the following key elements:

1. Clear and specific requirements in the regulations for certain types of uses, e.g., medical diagnosis and therapy.

2. A check-list application form which identifies the critical safety issues. By filling the appropriate boxes on the application and signing the form, the applicant would certify that he has the proper facilities, equipment and training for the types of uses proposed.

3. A computerized record management and processing system. It is planned that the application will be processed via an automated Licensing Management System (LMS), the reviewer will review the application through the LMS, the appropriate information will be entered into the LMS for a license. The LMS will print the license and provide a mailing label. With computer terminals also in each of the Regions, the Regions will have ready access to licensee information either for regional licensing or inspection purposes. The computer will also enable the rapid retrieval of statistical data, such as licensee performance based on inspections, to enable analysis of the effectiveness of the combined licensing and inspection program.

Considerable progress has been made in developing the new licensing concepts. Statistical data have been compiled both regarding the relative hazards associated with various categories of byproduct material uses and previously noted deficiencies in applications and inspection findings. These have proved to be valuable tools in developing the simplified regulations and application forms as the objective is to orient the appliciation and its review to the critical elements related to health and safety.

A task force is presently developing appropriate regulations and an application form for medical licensing. This package will be submitted to the Commission as a proposed rule in April. Medical users constitute our largest single class of byproduct material licensees. We anticipate developing similar licensing procedures for other categories based on experience gained with medical.