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5 December 1997

Mr. Chip Cameron
United States Nuclear Regulatory Commission
Washington, DC 20555

Dear Chip:

I would like to express to you my most sincere appreciation for the opportunity of being a participant in the Medical Rulemaking Workshop held in Philadelphia on 28, 29, 30 October 1997. It was a most enlightening experience and one which I found very stimulating.

I was delighted to have been able to participate in the program and apologize to you for the delay to you in my comments since I've only just now returned from Europe.

I think that you did an excellent job as the facilitator for the workshops directed toward revision of the Commission's regulations on the medical use of byproduct material. Certainly, the comments have a wide variety of significance in terms of desired changes in the regulations, and it was interesting to see so many individuals who stayed throughout the meetings to participate in the discussions.

The United States Nuclear Regulatory Commission has, in my opinion, done an incredibly good job in overseeing the development of regulations for the medical use of byproduct materials. The Commission itself as well as its advisors from medicine, physics, biologists, etc., have evolved a set of policies that are appropriate and proper to protect the patient, to protect the physician, to protect the public in general, and to insure that those individuals involved in the utilization of the materials for medical purposes are properly and appropriately trained and experienced in doing so.

The Commission is to be congratulated for having set the standards in the appropriate and proper way for the safety of all of those involved directly and indirectly in the use of byproduct material.

With that in mind, I would be in favor, without question, of keeping the present policy intact and to evolve changes carefully and gradually over time and not dramatically.

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I have always been impressed with the fact that the Commission through its various advisory bodies has come to grips appropriately and properly with policy statements.

With regards to the various recommendations for revisions to the Nuclear Regulatory Commission's 1979 medical policy statement, I would make the following comments.

- The current status of general policy to guide regulation of medical uses of radioisotope states is appropriate and the NRC should continue to regulate the medical uses of radioisotopes as necessary to provide the radiation safety of workers, patients and the general public. I see no need for change in this particular statement relative to general policy. The NRC has stated the need for oversight with regards to patient safety but, also, worker safety, physician safety, physicist safety, and the general public safety.

- With regards to patient notification of reportable events, it is my opinion that the status quo should be kept in force requiring the licensee to notify the NRC, referring physician and the patient or responsible relative unless the referring physician personally informs the licensee that he or she will inform the patient or that based on medical judgment telling the patient or the responsible relative would be harmful. In my opinion, the environment in which we live at the moment requires that this be kept intact, and I can see major medical malpractice issues if indeed these guidelines were not pursued. There is no way that the licensee can avoid the responsibility of making the appropriate proper report to the various individuals and agency concerned. Failing to do so, would put the licensee in serious jeopardy with regards to proper and appropriate practice. Such a position is consistent with other NRC requirements, consistent with other Federal legislation relative to the Privacy Act, enables the patient to make timely decisions regarding remedial and prospective medical care in consultation with his personal physician, enables the NRC to identify the causes of misadministrations and how best to correct them in prospect, enables the NRC to fulfill its statutory obligations and is consistent with the present NRC guidelines regarding medical events.

- With regards to alternatives to a quality management program, it would seem to me that one would be far more wise to maintain the current requirements as stated in Sections 35.32. It would require no additional regulatory burden to the licensee, no additional NRC resources for modifications to licensing or inspection procedures, would continue to require licensee to establish and maintain a written quality management program, would have continued to require that licensee's audit their Q & P's, would continue the concept of recordable events, and would continue to require licensees to retain each written directive and record for each administered dose or dosage requiring a written directive. Not only is this good practice, but it also fits with requirements to other issues relative to medical malpractice. With the growing emphasis on quality control and quality

management, any short circuiting of these requirements would ultimately be to the detriment of all concerned and would seriously infringe upon the medical/ legal requirements for the best possible care in patient management in patient protection, radiation worker's protection as well as the public.

- A Radiation Safety Committee is an absolute necessity in my mind for all modalities in a medical institution. The committee is formed from those individuals who are familiar with radiation safety programs and would allow for continuation of an established radiation safety program. The committee provides for communication among the various disciplines and departments in a single committee all of whom have some impact on radiation safety. The requirements for approvals via multidisciplinary point of view represent the contemporary practice of a multidiscipline team in medical management. It allows for review of users, the matters in which they use the radionuclides and offers a personnel and peer review with accountability. Such a committee allows for direct involvement of the executive management of the institution so important to insure that they are monies available for the committee's activities. Therefore, the committee with a varied representation has a wide latitude and authority to develop and implement appropria adiation safety programs within the institution. This has been a well-established procedure in many institutions and works well to the benefit of all the individuals and the institutions involved in such programs.

- With regards to the threshold for reportable events (misadministrations) and recordable events, it remains as listed in current Section 35.2 with the addition of a statement in the reportable definition to address precursor events that are outside the area defined by the term "misadministration." This is an ever-evolving situation and needs to allow the Commission to oversee and recommend changes as more short-term and long-term information is available relative to such reportable events. The regulatory requirement for licensees to identify and/or report or record is appropriate, and is helpful in assessing the overall effectiveness of the radiation safety program. It does provide the licensee with tiered approach to event reporting or recording depending on the nature of the event but, also, enables the NRC to identify the causes of events and help identify precursor events leading to correction and prevention measures. It obviously allows the NRC to fulfill its statutory obligation in reporting abnormal occurrences to Congress. The current definition is well-known by licensees and, therefore, maintaining it in place is appropriate and proper evolving over time as new information becomes available.

- With regards to training and experience, the Nuclear Regulatory Commission, through its advisory groups, has developed an appropriate proper set of guidelines for authorized users. These guidelines are directed toward basic requirements such as being an M.D., with board certification, as well as the specified numbers of hours of training and experience.

As an example, the American Board of Radiology requires designated courses in radiation safety, the medical uses of radionuclides and other byproduct material, and does examine and certify specifically in radiation oncology with all of these requirements as well as in nuclear medicine with all these requirements.

It allows more than one means to meet the authorized users' criteria for use and is modality specific. It depends upon established criteria developed by experts in the field as to appropriate training, and it also assures that the user has radiation safety training prior to embarking upon clinical experience.

The guidelines as set forth are specific, appropriate, proper and do not compromise in any way the necessity to have individuals working with byproduct material who are appropriately properly trained in physics, instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology as well as experience gained under authorized users.

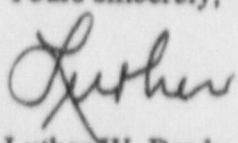
There are many specialists who are involved in the use of radiations in medicine, and it's interesting to note that many of them are poorly trained and over-expose not only the patient but, also, themselves to uncontrolled radiations by prolonged use of fluoroscopes, repetitive utilization of radionuclides, etc. Any change in the basic requirements for training and background would allow for a major breakdown in this very significant and important area for control of safety not only to the patient but to all radiation workers and to the public. The requirements for a radiation safety officer are set forth in a very clear manner and assures that an individual in the position as radiation safety officer is appropriately and properly trained.

I'm deeply grateful to you for the opportunity of being a part of the panel. In large measure, one might assume by my comments that I am in favor of the status quo with slow gradual evolution over time to improve the document but not to make dramatic and major changes that would cause a complete disruption of the well-organized gradual evolution of the medical policy. In Pennsylvania, we have a statement which I think is appropriate--"If it ain't broke, don't fix it."

Again, many thanks for the opportunity of being a part of the panel.

With very best personal regards.

Yours sincerely,



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