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ACNP/SNM

American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE

June 27, 1997

The Honorable Shirley Ann Jackson
Chairman
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Dear Chairman Jackson:

On behalf of the Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP), we wish to thank NRC for supporting the attendance of Dr. Donald Cool at our meeting in San Antonio on June 4, 1997. Dr. Cool discussed the process envisioned at present for the complete rewrite of 10 CFR Part 35.

Much of what Dr. Cool described sounded promising, and we look forward to participating with the NRC so that the process will produce a consensus regulatory scheme. We wanted to share with you some of our thoughts about the meeting, and our interpretation of the discussions with Dr. Cool.

1) We would like the NRC to consider utilizing the recently-completed report of the Presidential / Congressional Commission on Risk Assessment and Risk Management (enclosed) as the methodology described would be an excellent model for guiding the revision of Part 35. The report highlights the following: the participation of appropriate stakeholders at all levels of decision-making, the critical importance of peer-review consensus throughout the process, the search for alternatives to "command and control regulation", and the need for a widely-based risk assessment as opposed to a very narrow one, which is traditionally used by NRC. We favor the methodology described by the Presidential / Congressional Commission and believe that it can improve our communication and regulatory participation with NRC. We hope that you will agree that a partnership between the NRC and stakeholders to begin the regulatory revision process requires a level playing field. The NRC, by adopting the referenced risk management document, could be providing the pivotal shift in the paradigm that lays the groundwork for the successful rewrite of part 35.

2) Dr. Cool assured us that as far as the new 10 CFR Part 35 is concerned, he is starting with " a clean sheet of paper". During our discussions with Dr. Cool, the ACNP and SNM emphasized the importance of providing comments to the agency during the entire process, and allowing for an interactive forum where stakeholders and staff can review and comment on regulatory language.. Part of Dr. Cool's response indicated opportunities for public meetings with staff where ACNP and SNM can bring forward comments and proposals, as well as roundtable meetings that would provide a forum to review and revise language as it is being created. We strongly encourage the Commission to provide the NRC staff with enough flexibility to incorporate such public meetings into the final plan. We also believe that this open process, if followed, will remove many of our concerns about the medical program staff working in isolation, and making decisions independent of the appropriate stakeholders. We strongly encourage NRC to increase the participation of the Medical Fellows program and reinstate a member into the position vacated by Mr. Mark Rotman

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3) We feel strongly about the supervision of the regulatory revision process. It is clear that although the NRC, the regulated community, and the NAS/IOM do not agree on the exact details, we all do agree that part 35 needs to be rewritten. Starting with a "clean sheet of paper" implies that the existing part 35 will be left behind, thus shifting the regulatory paradigm to create a new part 35. We believe it would be a show of good faith for the Commission to develop a regulatory revision plan to prevent the existing paradigm from unduly influencing the revision process. During our meeting with Dr. Cool, we proposed that the NRC group to lead this process to rewrite Part 35, include certain mid-level staff of the Office of State Programs with extensive medical and medical/academic backgrounds. As most medical, pharmacy, and medical/academic licensees are Agreement State Licensees, we believe that the NRC staff dealing with Agreement States have valuable expertise to lend to the process.

4) As far as appropriate stakeholders are concerned, in addition to the professional societies dealing with byproduct medicine, pharmacy, and technology, we recommend ample representation by CRCPD (the present two members are insufficient, we recommend 3-4), medical physics and health physics groups, a physician representing DOE's medical research program, and a representative of those who pay for health care services (private / public insurers and/or managed care organizations). Those who fund medical research, including the National Institutes of Health, are also legitimate stakeholders.

Thank you for your attention and consideration, We eagerly await your decision regarding the rulemaking process. If you have any additional questions feel free to contact us through Mr. David Nichols, Associate Director - Government Relations at (703) 708-9773.

Sincerely,

Martin Nusynowitz, M.D.
President
American College of Nuclear Physicians

H. William Strauss, M.D.
President
Society of Nuclear Medicine

cc: Commissioner Greta Dicus (letter only)
Commissioner Kenneth Rogers (letter only)
Commissioner Edward McGaffigan (letter only)
Commissioner Nils Diaz (letter only)