



Nuclear Medicine Groups Submit Testimony to NRC

The Society of Nuclear Medicine and the American College of Nuclear Physicians (ACNP) have submitted written testimony to the Nuclear Regulatory Commission (NRC) concerning the regulation of nuclear medicine. The NRC is currently conducting a strategic assessment initiative designed to allow the NRC Commissioners to gauge the direction of many of the main programs at NRC. The SNM and ACNP used this opportunity to request that three issues be addressed within this initiative.

The first issue applies to diagnostic nuclear medicine. SNM and ACNP believe that diagnostic nuclear medicine should be generally licensed to remove prescriptive regulations and recognize the low risk involved with these procedures. A general license, as proposed, would recognize the use of material and require annual reporting of the continued use of that material and nothing more. The testimony mentions the exemplary safety record for the tracers involved in these procedures and urges that the NRC re-evaluate its current attitude toward their regulation. Testimony cites the absence of deaths or significant injuries attributed to radiation safety issues in at least the last 20 years. Another argument for revision of NRC regulations, the testimony also noted, was the now widespread use of diagnostic tracers. Specific items pertaining to physician, dentist, podiatrist and veterinarian training and experience requirements are included in the testimony.

The second issue applies to therapeutic nuclear medicine. The groups' testimony stresses that therapeutic nuclear medicine regulation needs to be discussed in an open forum and dealt with through a process such as an enhanced participatory workshop. SNM and ACNP concur with the National Academy of Science-Institute of Medicine (NAS-IOM) report, which expresses doubt as to whether or not adverse events in radiation medicine are sufficiently widespread or serious to warrant the current burdens of regulation now directed at the field. The testimony also addresses the fear that potential growth in the field of therapeutic nuclear medicine could be stifled by excessive regulation. One example used to illustrate the point of overregulation compares the relatively flexible regulation of the Drug Enforcement Agency over controlled substances to the NRC's regulation of byproduct material.

The third and final issue applies to nuclear pharmacies. It is SNM and ACNP's contention that nuclear pharmacies should not be regulated in the same manner as radiopharmaceutical manufacturers, but rather that NRC should develop regulations similar to those applying to a nuclear medicine physician. SNM and ACNP understand the need for radioactive drugs to be dispensed by a pharmacist to authorized practitioners who, in turn, apply these drugs to patients, but make the point that the nuclear pharmacist's credentials and practice

skills, and not necessarily the process itself, make a pharmacy practice safe. Specific language for pharmacist training and experience requirements are included in the testimony.

The Commission is now reviewing the testimony and is expected to issue a report on direction-setting some time in late January.

—David Nichols is the associate director of the ACNP/SNM government relations office

FDA Commissioner Kessler Set to Resign

On November 25 Commissioner David Kessler announced his intention to resign, citing a desire to return to private life as soon as his successor is chosen. Kessler served as Commissioner for the Food and Drug Administration (FDA) for more than six years, a longer term than any previous appointee. Kessler highlighted what he considered to be several key accomplishments of his administration, including the promulgation of rules for food labels and tobacco, mammography standards, increased food safety and fraud enforcement, and improvements in drug approval times. The White House is now considering candidates for the Commission job, including several deputy commissioners now at the FDA.

Presidents of SNM and ACNP Meet with NRC Commissioners

Michael Devous, Sr., PhD, David Brill, MD, and Robert Carretta, MD, met on November 22 with NRC Commissioners Nils Diaz and Edward McGaffigan, Jr, both recently appointed to the NRC. The leadership of SNM and ACNP met with the commissioners to present a briefing on what nuclear medicine is, to offer the support of the professional organizations and to discuss issues involving the medical program. Much of the discussion focused around the agency's strategic assessment initiative, which could have a significant impact on the regulation of nuclear medicine. The issue of risk involved with nuclear medicine also came up and will be one of the topics that the NRC considers during its strategic assessment. For background information refer to the October issue of *JNM*, p. 34N.