

The speaker has the privilege of representing the Radiation Oncology community on the U.S. Nuclear Regulatory Commission's (U.S. NRC) Advisory Committee on Medical Use of Isotopes (ACMUI). The ACMUI, consisting of representatives of radiation medicine specialties and other groups affected by medical use regulation, is expected to develop critiques and achieve consensus positions on NRC regulatory initiatives, enforcement problems, draft guidance documents, emerging technologies and many other issues. Over the last three years, ACMUI has primarily focused on revision proposed alternatives to the National Academy of Science/Institute of Medicine Regulatory Reform proposals, has articulated its view on underlying regulatory philosophy, achieved consensus on cross-cutting issues such as radiation safety committee role, NRC medical policy statement, prescriptive vs performance based regulations, and training/experience requirements, as well as critiquing two Part 35 drafts. ACMUI lost-causes include a) rational, risk-based regulation should be independent of source of radiation; b) since risks of patient injury in radiation medicine is less than risks from surgery or anesthesia, Patient safety and QA regulation unwarranted and NRC should confine itself to public/staff safety; c) the medical use regulatory program is intrusive, excessively burdensome, and not justified by level of risk; and d) radiation medicine should be regulated by a health-oriented agency. In response, NRC declared that its role was limited to ensuring is correct implementation of the physician's prescription and, accordingly, regulations should address technical and safety, but not clinical, practices and competence. Thus, NRC proposed reducing the three year residency requirements to 7 months of training plus case experience. Other major changes include (i) eliminating most requirements for diagnostic nuclear medicine, adding "authorized medical physicist" with teletherapy training and experience requirements, eliminating ALARA, improving "reportable medical event" definition, and replacing the QM rule with technical requirements compatible with TG40, TG56, and TG59. The latter includes checking all treatment time calculations, and calibrating all brachytherapy sources.

These views are the speaker's personal opinions and do not represent the views of NRC or its ACMUI.