Revised U.S. Nuclear Regulatory Commission 10 CFR 35 Regulations for Medical Use of Byproduct Material in Radiation Oncology

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In 1997, The U.S. Nuclear Regulatory Commission (NRC) began the process of completely rewriting its regulations (10 CFR 35) governing medical use of byproduct material, in response to its own Strategic Assessment Initiative (1995-1997) and the Institute of Medicine's (IOM) highly critical 1995 report, "Radiation Medicine: a Need for Regulatory Reform." The final rule is expected to be approved by the NRC Commissioners in June 1999 and implemented in Fall 1999. The new rule, like its predecessor, addresses only byproduct materials, leaving regulation of naturally occurring and accelerator produced radiation and radioactivity to the states. However, the revised rule is more "risk informed" in that "low risk" modalities (diagnostic nuclear medicine) will enjoy some regulatory relief compared to "high risk" therapeutic modalities. In several areas, the new rule is more "performance based" specifying the regulatory endpoint and leaving the detailed compliance methodology to the licensee's discretion. Technical requirements for HDR brachytherapy and stereotactic radiosurgery are explicitly outlined in Part 35 rather than in Regulatory and Licensing Guides. As of mid-March, some of the more striking changes include:

(a) Retains the requirement for a radiation safety committee for licensees practicing two or more modalities but does not specify its role in executing the licensee's mandated administrative and safety responsibilities.

(b) Eliminates QMP requirements, but retains requirements for written directives, and verifying patient identity, treatment calculations and correct implementation of the treatment. Part 20 ALARA requirements are no longer duplicated in Part 35/

(c) Replaces "teletherapy physicist" with "authorized medical physicist" (AMP) and defines AMP duties for all byproduct modalities.

(d) Minor modifications in Training and Experience Requirements for AMP and for authorized user (including retention of three-year residency requirement) of therapeutic modalities.

(e) Technical requirements for gamma stereotactic, teletherapy, remote afterloading and manual brachytherapy that are more consistent with Task Group 40, 56 and 59 recommendations

(f) Exempts end users from verifying brachytherapy source calibrations if vendors can supply calibrations satisfying "nationally recognized protocols."

(g) To cover emerging treatment modalities, a new category (35.1000) is added for medical uses not elsewhere defined that can be authorized by license amendment without requesting variances from 10 CFR 35. Intravascular irradiation is not explicitly addressed.

(h) Establishes a minimum dose threshold (> 0.5 Sv and 20% deviation from expected dose) for wrong-site misadministration (called "Medical Event").

With respect to technical details, the revised 10 CFR 35 improves upon its predecessor. However, few, if any, of the basic deficiencies of the overall regulatory system identified by IOM and other critics are addressed.