Since 1997 the U.S. Nuclear Regulatory Commission (NRC) has been engaged in a major revisions of its regulations governing medical use of byproduct material, 10CFR35. The final rule is expected to be published in July 2001 and is expected to be fully implemented by licensees following a 6 month transitional period. 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, stereotactic radiosurgery, and $^{60}$Co teletherapy 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 requires written directives and verification of patient identity, treatment calculations and correctness of the treatment implementation. Part 20 ALARA requirements are no longer duplicated in Part 35.

(c) Replaces “teletherapy physicist” with “authorized medical physicist” (AMP) and defines AMP in terms of required teletherapy, brachytherapy and stereotactic radiosurgery duties.

(d) The radiation oncology authorized user (AU) and AMP retain the same academic degree and years of experience requirements, including the 3 year residency for therapy AUs. However, only Commission-approved board certification mechanisms will automatically qualify physicians and physicists as AUs or AMPs. Boards will be approved only if they certify that their diplomates comply with the “alternative pathway” requirements, including having hands-on supervised experience with HDR and LDR remote Co-60 teletherapy and gamma stereotactic. As of April 2001, it appears likely that ABR and ABMP certification in Radiation Oncology Physics will cease to be either necessary or sufficient to qualify for AMP status. Similar problems exist for Radiation Oncologist and RSO.

(e) Technical requirements for gamma stereotactic, teletherapy, remote afterloading and manual brachytherapy that are more consistent with Task Group 40, 56 and 59 recommendations. End-users are exempted from verifying brachytherapy source calibrations if vendors can supply calibrations satisfying “nationally recognized protocols.”

(f) For nuclear medicine imaging, AU training and experience requirements are reduced from 1200 to 700 hours. Also, dose-calibrator activity assays are no longer required when unit doses are administered.

(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 (now called “Medical Event”).

While the basic deficiencies of the overall regulatory system have not been addressed, the revised 10 CFR 35 improves upon its predecessor with respect to technical details and recognition of the importance of the medical physicist in patient and public safety. A major new problem is the possible irrelevance of board certification in the regulatory arena.