Attachment 1

Cost Comparison Between the Current and Proposed Revision to 10 CFR Part 35

Cost Comparison and Differences Between the Current and Proposed Revision to 10 CFR Part 35

Summarized in the table appearing below are data extracted from the Regulatory Analysis that accompanies the proposed revision to 10 CFR Part 35[1]. The extracted data are for sections that may affect diagnostic nuclear medicine; they show the estimated values and impacts of the revisions to 10 CFR Part 35. For each regulatory change described in the Regulatory Analysis, the table lists estimated total annual costs avoided (-) or total costs added (+), i.e., the change in costs from the current rule, for a particular section of the rule. Added to the table, for the convenience of the reader, is a column giving the titles of the relevant sections.

Sections Affecting Diagnostic NM and Estimated Costs (Savings)				
Section	Section Title	Change in Licensee Costs (nominal $/yr.)	Change in NRC and Agreement States Costs (nominal $/yr.)	Total Change in Costs[2] (nominal $/yr.)
35.6	Provisions for the protection of human research subjects	0	0	0
35.11	License required	0	0	0
35.12	Application for license, amendment, or renewal	-1,000	0	-1,000
35.13	License amendments	-85,000	-81,000	-166,000
35.14	Notifications	10,000	12,000	22,000
35.24	Authority and responsibilities for the radiation protection program	-2,167,000	0	-2,167,000
35.26	Radiation protection program changes	-14,000	0	-14,000
35.27	Supervision	-1,158,000	0	-1,158,000
35.32	Quality management program[3]	-4,436,000	-1,899,000	-6,335,000
35.40	Written directives	0	0	0
35.50	Training for Radiation Safety Officer	5,000	2,000	7,000
35.55	Training for an authorized nuclear pharmacist	2,000	1,000	3,000
35.60	Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material	-521,000	0	-521,000
35.61	Calibration of survey instruments	-136,000	0	-136,000
35.63	Determination of dosages of unsealed byproduct material for medical use	0	0	0
35.69	Labeling of vials and syringes	0	0	0

Sections Affecting Diagnostic NM and Estimated Costs (Savings)				
Section	Section Title	Change in Licensee Costs (nominal $/yr.)	Change in NRC and Agreement States Costs (nominal $/yr.)	Total Change in Costs[2] (nominal $/yr.)
35.80	Provision of mobile medical service	0	0	0
35.92	Decay-in-storage	-1,000	-1,000	-2,000
35.190	Training for uptake, dilution, and excretion studies	5,000	2,000	7,000
35.204	Permissible molybdenum-99 concentration	-993,000	0	-993,000
35.290	Training for imaging and localization studies	-238,000	0	-238,000
35.2024	Records of authority and responsibilities for radiation protection programs	-9,000	0	-9,000
35.2026	Records of radiation protection program changes	-17,000	0	-17,000
35.2060	Records of calibrations of instruments used to measure the activity of unsealed byproduct materials	0	0	0
35.2061	Records of radiation survey instrument calibrations	0	0	0
35.2063	Records of dosages of unsealed byproduct material for medical use	0	0	0
35.2080	Records of mobile medical services	0	0	0
35.2092	Records of decay-in-storage	0	0	0
35.2204	Records of molybdenum-99 concentrations	-12,000	0	-12,000
35.3047	Report and notification of a dose to an embryo/fetus or a nursing child	4,000	0	4,000
	TOTALS	9,762,000	1,964,000	11,726,000

1. Data extracted from Regulatory Analysis, Table 6-1, Summary of Rule's Cost Effects.

2. The total cost saving related to diagnostic nuclear medicine is approximately $11.7M per year.

3. The quality management program was deleted from the revised rule; retained elements were moved to 35.40.