APR 0 3 1985

MEMORANDUM FOR: Samuel J. Chilk
Secretary of the Commission

FROM: William J. Dircks
Executive Director for Operations

SUBJECT: AMENDMENTS TO 10 CFR PART 35 LICENSES

At the March 20, 1985 Commission meeting on the proposed revision of 10 CFR Part 35, "Medical Use of Byproduct Material," the staff was asked to characterize licensees' requests for license amendments. The staff has analyzed 100 recent medical license amendments, selected in order of receipt (this represents a sample of 5 percent of 10 CFR Part 35 license amendment requests for a calendar year). The results follow:

Number of Completed Actions that were Analyzed: 100*

Number of Requests that Included a Major Change which would require an amendment under the proposed revision of 10 CFR Part 35: 69

- Users - 51
- Type of Use - 15
- Location - 5
- Inventory - 2

Number of Requests for an Administrative Change, e.g.. name change, change of address but not location, short-term extension, etc.: 6

Number of Requests that Included a Minor Change which would not require an amendment under the proposed revision of 10 CFR Part 35: 37

- Area of Use - 21
- Replacement Equipment - 5

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- Equipment Quality Assurance Procedures - 11
- Service Contractor - 8
- Handling Procedure - 6

*Some requests contained both Major and Minor changes and therefore were tallied twice; thus the division by Major, Administrative and Minor does not add up to 100.

The average time to complete action on these 100 amendments was 62 calendar days; about 40 percent of both hospital and private practice requests were deficient. There were no submissions that had major safety deficiences. All the minor safety deficiencies were in areas where requirements are not clear or are scattered. Some minor deficiencies were administrative in nature, e.g., wrong fee, Chief Executive Officer did not sign the application.

It was also suggested during the meeting that perhaps large hospitals should be allowed to make minor changes in their radiation safety programs, but that small hospitals and private practice physicians should be required to submit their minor changes for regulatory review. The measure of hospital size could be the number of beds in the hospital; a demarcation line of 200 beds was suggested. The staff has analyzed this proposal by measuring whether large hospitals submit fewer deficient amendment requests than small hospitals.

For the sample of 100 recent medical license amendment requests, the staff was able to determine the number of beds for 64 of the 88 hospitals that submitted such requests; the other 12 requests were submitted by private practice physicians. A table that shows the fraction of amendment requests that were deficient for different hospital sizes appears below:

Bed Size	Number of Amendment Requests	Fraction that was Deficient
Information Not Available	24	.42
Private Practitioners	12	.42
1-199	20	.40
200-399	25	.44
400-	19	.53

Based on this analysis, the staff has concluded that the number of beds in a hospital does not provide a valid basis for distinguishing in the regulatory treatment of medical licensees.

(Signed) William J. Dircks

William J. Dircks
Executive Director
for Operations

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