



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D. C. 20555

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MEMORANDUM FOR: Ronald M. Scroggins, Director  
Office of the Controller

FROM: Robert M. Bernero, Director  
Office of Nuclear Material Safety  
and Safeguards

SUBJECT: LICENSE FEES

This memorandum responds to your request for NMSS reexamination of several licensee fee areas and a final office position on proposed changes to the licensee fee schedule.

As a general rule, NMSS believes that staff hours from RITS should be the bases for estimating licensee fees, with management judgment applied when the RITS data are not adequate. In this regard, a hierarchy exists in the time required to perform licensing reviews of new applications, renewals and amendments. That hierarchy is: new license application reviews take more time than renewals and license renewal reviews take more time than licensing amendment reviews. On the average, the manpower reporting data, staff experience and management judgment support this general finding. However, there are a limited number of cases where this general rule does not apply. Specifically, NMSS believes that the following classes of licensees require a different expenditure of staff time to complete the various licensing reviews.

1. LICENSE FEE CATEGORY 3B:

This class of licensees includes manufacturing and distribution operations utilizing a small number of radioisotopes, power source/SNM heat generation manufacturing and heart pacemaker manufacturing and distribution. The average of two years of recorded staff time to perform licensing reviews of this class of licensees indicate that new application reviews require about 11 hours, amendments require about 5 hours and renewals require about 20 hours. We attribute this situation to two factors. First, this type of licensee often has frequent amendments to add new products or to change existing descriptions of products or processes. The renewal process often requires a review of many documents to determine which descriptions are current and which have been superceded; a situation which does not occur with a new application. Second, companies applying for new licenses will on the average operate simpler programs using both smaller activities and varieties of radioisotopes than are utilized by the existing companies.

2. LICENSE FEE CATEGORY 7C:

This class of licensees included hospitals, medical centers, clinics, private physicians and mobile nuclear medicine services. The recorded staff time over a two year period indicates that on an average it requires

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about six hours to review a new application, four hours for an amendment and nine hours for a renewal. Please note that review time has decreased from the common time factor which was used to calculate the current fee schedule. Renewals require more time because the average new applicant for a medical use license is a small clinic or private physician who is requesting authorization to perform one or only a few medical procedures. The average medical use licensee renewing a license is an institution offering a full variety of diagnostic services and often some therapy services. Because of the total revision of 10 CFR Part 35 in 1987, new applicants and licensees renewing medical use licenses must submit complete applications and descriptions for all activities to be authorized. Thus the simplifications in the licensing process due to revision of 10 CFR Part 35 have helped reduce review time for the simpler programs being initiated more than for the existing programs with more activities to describe.

3. For several other classes of licensees (3E, 3M, 3P, and 6A) the recorded staff time indicated that the review time for renewals was greater than for new applications. However, further analysis and application of management judgment determined that the data were not representative of the usual situation or were based on small sample size. Therefore, we recommend that the time necessary to perform the review of a new or a renewal application should be approximately the same for these classes of licensees.

The NMSS inspection staff time rates included in 10 CFR Part 170 were developed based on recorded staff time, regional management estimates and management judgment. With this additional evaluation, NMSS now recommends that the hours charged for inspecting one class of licensee be reduced. License category 2B routine inspections require approximately 4 hours not 10, and non-routine inspections require 8 hours, not 14. With this change, NMSS has selected the more conservative manpower estimate in all cases. The proposed rates include all time necessary to complete a licensee inspection. That is, preparation for the inspection by going through the docket, file and other historical data to become familiar with the individual licensee's operation, travel to the site, conducting the actual on-site inspection, return travel to the Regional or Headquarters Office and finally the preparation and approval of the inspection report describing and documenting the inspection. The NMSS experience with inspections of material licensees has shown a significant increase in the time required to perform these services.

This increase is due in large part to the NRC's response to the increasing number of incidents or events involving materials licensees, particularly medical use misadministrations. The Commission has demanded that greater regulatory oversight be provided to the nuclear material licensees and users. Therefore, the increase in inspection time is appropriate due to the more thorough inspections now being performed.

The foregoing information represents the NMSS position concerning the hours charged to service our various materials licensees.

Finally, I understand that during the meeting on license fees an option was discussed by OGC which would result in licensees being charged a single, fixed fee for services, but they would be billed over multi-years. We support that option, if it passes legal review. It would greatly reduce the administrative burden associated with license fee collection from material licensees.



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Office of Nuclear Material Safety  
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cc: H. L. Thompson, Jr., DECS