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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D. C. 20555  
AUG 24 1983

MEMORANDUM FOR: Bill Walker, Section Leader  
Medical Licensing Section  
Material Licensing Branch  
Division of Fuel Cycle and  
Material Safety, NMSS

FROM: Bernard Singer, Chief  
Material Certification and  
Procedures Branch  
Division of Fuel Cycle and  
Material Safety, NMSS

SUBJECT: REVISION OF 10 CFR PART 35

As you requested on August 23, 1983, the following are my comments on the Radiological Safety Plan and the Area Survey Procedures.

Some time ago, I concluded that it was not necessary nor desirable to obtain detailed procedures from applicants. All that is needed is a commitment by an applicant that he will have procedures which will contain certain elements which we would specify in guides. Your example of an acceptable Radiological Safety Plan for area surveys is generally in accord with the path we have taken in writing application guides for the Phase II decentralization program. In the formulation of the particular elements for which an applicant should make a commitment for inclusion in procedures, we have tried to consider the regulatory requirements and the least burdensome commitments needed to assure compliance with the regulations.

The daily survey of an area to determine if there is contamination present does not need to be quantitative. If the goal is to keep work areas reasonably clean, the performance of a survey with an appropriate instrument, and cleanup of any contamination found, is all that is needed. If licensees want to make quantitative measurements, that is their prerogative. However, we should not impose quantitative measurements which is not needed to meet regulatory requirements such as the survey requirement in Section 35.70. Therefore, for purposes of simplification, I suggest the example given, Area Survey Plan, be revised as follows:

\*Item 17: Area Survey Plan

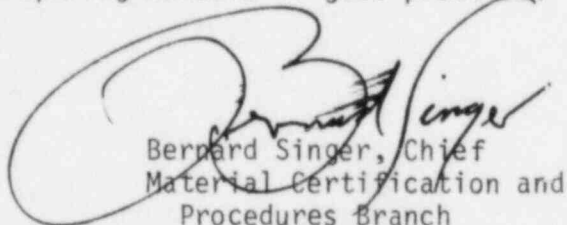
It is not necessary for you to submit the detailed written procedure for the surveys required by Section 35.70 of 10 CFR Part 35. All that is necessary for you to do is make a written commitment that you will have and implement written procedures which contain the following:

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- (1) All areas used for elution, preparation, assay, or dispensing of radioactive material will be surveyed at the end of the work day.
- (2) If any contamination is found, immediate steps will be taken to decontaminate the area.
- (3) The survey meter used will be sufficiently sensitive to detect 0.1 mR/hr.
- (4) At least once a week a survey will be performed where radiopharmaceuticals or radiopharmaceutical waste is stored. If the radiation level exceeds 2 mR/hr at 18 inches from the storage area, immediate steps will be taken to reduce the radiation level to 2 mR/hr at 18 inches from the storage area."

As I have discussed with you on many occasions, I strongly object to including a manual of good practice as part of an application guide. In fact, we did not support RES in its efforts to let contracts for establishing manuals of good practice on the grounds that: (1) it was not the role of the NRC, and (2) the particular segment of the licensee population should be more actively engaged in such endeavors. For the nuclear medical industry, we suggest that a group such as the AAPM should be preparing manuals of good practice.



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cc: R. E. Cunningham  
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