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

June 13, 1983

MEMORANDUM FOR: Commissioner Roberts

FROM: John E. Zerbe

SUBJECT: SECY-83-62 (10 CFR PART 35)

In your May 5, 1983 memorandum, you requested that OPE provide an analysis of the significance and impact of the changes to the proposed 10 CFR Part 35 as well as additional requirements suggested by Mr. DelMedico and Mrs. Vacca, in light of the requirements presently in the proposed rule. The staff's proposal in SECY-83-62 consists of two major aspects: (a) an amended Part 35 rule which incorporates all safety elements considered essential by the Task Force appointed to develop a revised rule and a consolidation of the general and specific licenses (item A below); and (b) proposed changes in the process of issuing licenses (items B, C, and D below). In the following discussion we have segregated the issues into revision of the rule, pre-licensing review of physicians' qualifications, processing of licensing amendments, and pre-licensing review of operating procedures.

A. Revision of the Rule

The staff paper (SECY-83-62) points out that most medical institutions and physicians operate under a specific license covering a variety of nuclear medicine procedures. The staff currently reviews in detail each application for a specific license prior to issuance. A relatively small number of licensees are authorized by general licenses. General licenses are given to physicians who use small quantities of certain prepackaged radiopharmaceuticals. Under current procedures the NRC staff does not perform a pre-licensing program review of physicians operating under a general license. The staff proposal to replace the general license category with a specific license would result in no practical change in this NRC practice. Consolidation of essential safety elements from the regulations, guides and branch positions into a single Part 35 rule would provide clearer direction for applicants and we believe it would bring about an improvement in regulatory practice covering medical use of byproduct materials.

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B. New Licenses: NRC Pre-Licensing Review of Physicians' Qualifications[1/]

Under current procedures, the physician supplies supporting documentation of his training and experience with his license application. This will typically include two training and experience supplements to the medical application form. The first supplement is completed by the physician (applicant) and lists his radiation safety and radio-isotope training and experience. The second supplement is signed by a fully qualified physician preceptor who has been responsible for guiding the clinical aspects of the applicant's training. The reviewer obtains needed additional information by reference to published documents, telephone calls or written inquiries.

The revised requirements in Part 35, as proposed by the staff in SECY-83-62, would give the physician three options for meeting NRC training and experience requirements. These are (1) appropriate board certification, (2) the physician's statement (by checking box (b) under physician training and experience on the application form) that he meets the requirements of Subpart J of Part 35 or (3) a request for an exemption. If an applicant checks box (b) on the license application, NRC would accept the undocumented statement that the applicant's training and experience conform to requirements in the revised Part 35 and NRC would rely on a post-license site inspection to verify this information. The majority of physicians who apply for isotope user status and are not Board-certified would be expected to indicate that they meet the requirements of Subpart J of Part 35. This would involve the least effort both by the physician-applicant (in terms of supplying

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1/ In performing our analysis, OPE notes for the Commission the views expressed by one of the Agreement State Task Force members reviewing proposed Part 35 changes. These views were identified in the April 22, 1983 letter from Mr. William H. Spell, Nuclear Program Administrator for the State of Louisiana to the Chairman and forwarded to the Commission on June 3, 1983. They cover the two issues regarding the review of physicians' qualifications and the review of operating procedures; these are summarized as follows: A signed statement that the applicant has adequate procedures would not provide the assurance needed for licensing personnel to issue a license. Nor does it assure the license reviewer that a physician has proper training ... the NRC and the Agreement States should issue a license only after reasonable assurance that safety can, in fact, be demonstrated. ... the proposed method of implementation now in the draft revised Part 35 cannot provide the needed assurance ... The strongest support for continuing a procedure/physician qualification review prior to issuing a license is stated in the proposed change -- that roughly 40 percent of current applications are deficient.

documentation) and the NRC staff reviewer (in terms of license application review).

Subpart J in the revised Part 35 states that the physician should either be Board-certified or meet certain training and experience requirements (e.g., classroom and laboratory training and experience of 100 hours in radiation physics and instrumentation, 30 hours in radiation protection, etc.) within 5 years prior to the license application. The staff proposal states that the pre-licensing review of the physicians' documentation can be eliminated without compromising safety. A primary benefit would be a reduction of regulatory and administrative burden on medical licensees and a decrease in license process time. However, in the professional opinion of Mrs. Vacca and Mr. DelMedico, elimination of the review of physicians' qualifications would reduce the assurance, albeit unquantifiably, that the physician is, in fact, qualified. They consider it important that this determination should be made prior to the time of licensing. Moreover in their view, the first site inspection--perhaps six months after licensing--is not an adequate substitute for the pre-licensing documentation review of physicians' qualifications.

Based upon our discussion with NRC staff we understand that they have no objection to continuing the requirement that physicians submit evidence of their training and experience for pre-licensing review by the licensing staff. This would continue to provide the assurance that the licensee has proper personnel to administer the byproduct material and this pre-licensing review should not impede the licensing process. We support this continuation of NRC pre-licensing review of physician's qualifications.

C. Processing of Part 35 License Amendments

Under current practice, a licensee must apply for an amendment to the license whenever changes are made in any of the following: in adding or deleting staff, in operational procedures, and in the radioactive material to be handled. Approximately 1,300 license amendments are applied for annually. Staff estimates that processing each Part 35 license amendment requires approximately one-half professional staff day for the NRC reviewer and about the same for the physician. In addition, staff estimates that preparation of the license amendment requires one day secretarial time by the licensee.

The proposed Part 35 rule requires that licensees would only apply for amendments in those safety-related cases which might increase the potential for radiation exposure to either workers or the public. These include (a) changes in type of human use or types and quantities of byproduct material; (b) use of byproduct material at an address not identified on the license and (c) a change in either the individual listed as the Radiation Safety Officer or as the qualified teletherapy calibration expert. The NRC staff has proposed to limit the instances where an amendment would be required in view of the fact that most of the amendments now received which are subject to NRC

staff review do not involve increased risk of radiation exposure. Mr. DelMedico and Mrs. Vacca have not expressed a different opinion on the subject of processing of amendments. We believe that the NRC staff proposal to restrict amendments to safety significant areas of potential increased risk is worthy of consideration since it contributes to the reduction of regulatory burden not justified by safety concerns. However, we believe it would be useful for the staff to clarify how this can be implemented effectively while ensuring safety. For example, if the licensee alone makes the judgment that a specific change does not require a license amendment, then NRC may desire to receive at least a notification of the change in order to confirm the continuing safety of the licensee's operations.

D. NRC Pre-Licensing Review of Operating Procedures

In our review we have learned that this is the most important issue to be decided by the Commission. Currently, an applicant for a specific Part 35 license must submit the proposed operating procedures for NRC staff review. As indicated in SECY-83-62, elimination of the staff review of operating procedures would save NRC reviewers time but not reduce the administrative burden on the licensee since he must prepare his operating procedures in any case. These procedures are attached to the prospective licensee's application. Regulatory Guide 10.8 describes the type and extent of information on operating procedures needed by the NRC to evaluate an application. For instance, in calibrating dose calibrators, an applicant may either choose to follow the procedures specified in the Reg. Guide 10.8 Appendix D or prepare equivalent procedures. In this area the Appendix D procedures call for tests of the instrument's constancy, accuracy, linearity, and geometrical variation. Similarly, in other areas of the operating procedures (e.g., instrumentation, emergency and area survey, waste disposal, etc.) the applicant may elect to follow procedures provided in the guide or develop equivalent procedures. In some areas (e.g., personnel training program, procedures for ordering and receiving radioisotopes, etc.), the applicant must provide detailed information on his specific procedures.

The proposed revision to Part 35 (SECY-83-62) would eliminate a pre-licensing review of operating procedures, relying instead on the applicant's statement that he has developed and implemented the procedures set forth in the rule and that these procedures contain the essential safety elements specified by the rule. If the Commission adopts the proposed method of implementing the revisions to Part 35, as stated in SECY 83-62, applicants would continue to have Reg. Guide 10.8 available for use in preparation of their operating procedures.

At issue before the Commission is a judgment regarding the extent to which the review of the applicant's operating procedures is actually needed in order to support the licensing standard of reasonable assurance of protection of public health and safety. The staff indicates that the total professional

review time for a new license is approximately 8 hours--most of which is associated with the review of operating procedures. (Note: There are approximately 100 new license applications annually.) The staff believes that this review contributes little assurance that an applicant has the capability to carry out operating procedures. In the case where an outside consultant is hired by the applicant to prepare the application, sometimes the licensee doesn't even know the content of the procedure submitted to NRC for review. For the pre-licensing determination, staff would rather rely on the proven capability of the isotope user and Radiation Safety Officer, demonstrated by the comprehensive training a physician undergoes to qualify for nuclear medicine practice. Much of that training is specifically in the areas of radiation safety and the biological effects of radiation. In the staff's opinion, the best method of determining an applicant's capability to comply with the regulations and to conduct a safe program is an on-site visit by NRC (either a representative of licensing or an inspector) a few months after licensing by which time the licensee will have put his program into operation and brought in the necessary staff to run the program.

On the other hand, Mr. DelMedico and Mrs. Vacca believe that NRC pre-licensing review of the applicant's operating procedures is essential in order to provide assurance of safety. They feel that without such a pre-licensing review of procedures, the NRC cannot be sure that the applicant has, in fact, developed (any) procedures or that they will be found adequate. They do not feel that a post-licensing inspection visit (in lieu of the pre-licensing review) will satisfactorily assure protection of health and safety in the medical use of byproduct materials. They further believe that the applicant's commitments regarding his procedures must be inspectable by NRC. They are concerned that, if SECY-83-62 were approved, a licensee could be cited only if he did not have the required procedures and could not be cited if his procedures were technically incorrect or inadequate.

On balance, we believe that the Commission should continue the pre-licensing review of applicants' operating procedures. We believe that post-licensing site visits, although useful, are not a substitute for an NRC staff review of an applicant's operating procedures prior to licensing. Even with the current practice of reviewing operating procedures, we have learned from IE that there are a significant number of deficiency citations found on the staff's first inspection. In the event the Commission decides to continue NRC review of operating procedures the staff will require some resources to continue to conduct these reviews (approximately one-half professional staff-years).

If the Commission adopts our recommendation, we suggest the staff be instructed to make the appropriate changes to the draft Part 35. A draft staff requirement memorandum is attached.

Attachment:
As Stated

cc: Chairman Palladino
Commissioner Gilinsky
Commissioner Ahearne
Commissioner Asselstine
Herzel Plaine
Samuel Chilk

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

MEMORANDUM FOR: William J. Dircks
Executive Director for Operations

FROM: Samuel J. Chilk
Secretary

SUBJECT: SECY-83-62 (10 CFR PART 35)

With respect to the staff's proposed changes to 10 CFR Part 35 (SECY-83-62), the Commission has made the following decisions:

(1) The Commission approves the consolidation of the essential safety elements from regulations, guides and branch positions into a Part 35 rule.

(2) The Commission has decided to continue the pre-licensing review of physicians' qualifications in processing applications for human use of byproduct material in nuclear medicine and instructs the staff to amend the draft Part 35 accordingly.

(3) The Commission has decided to continue the pre-licensing review of applicants' operating procedures by NRC licensing staff. The Commission instructs the staff to make the changes as needed to reflect its decision that operating procedures are to be reviewed prior to licensing.

(4) The staff should clarify how it will implement the proposed requirements regarding license amendments, while continuing to ensure safety in the licensee's operations.

(5) The staff should provide the Commission with a proposed Part 35, revised as directed above, by July 30, 1983, for Commission action.