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

MAR 08 1983

MEMORANDUM FOR: William J. Walker, Jr., Ph. D., Section Leader
Medical and Academic Section
Material Licensing Branch
Division of Fuel Cycle and Material Safety, NMSS

FROM: Joseph DelMedico
Patricia C. Vacca
Material Licensing Branch
Division of Fuel Cycle and Material Safety, NMSS

SUBJECT: MEMORANDA DATED FEBRUARY 28, 1983 AND MARCH 2, 1983 TO BE CONSIDERED AS COMMUNICATIONS OF PERSONAL OPINIONS WITH THE COMMISSIONERS

This is to inform you that our memoranda dated February 28, 1983 and March 2, 1983 addressed to the Commissioners should be considered as direct communications of personal opinions as provided for in the Open Door Policy and in Mr. Davis' memorandum dated November 18, 1981 (copy enclosed).

Copies of our memoranda were provided to you and Mr. Cunningham on March 4, 1983. Most of the attachments to our memoranda are available in our Section secretary's office; however, several of the attachments were personal copies of the document in question and may be obtained from the Commissioners' staff.

Our memoranda were intended to bring certain areas of our concerns to the attention of the Commissioners. At this time we are not formally filing these memoranda in accordance with the procedures in Manual Chapter 4125.

Joseph DelMedico

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Patricia C Vacca

Patricia C. Vacca
Material Licensing Branch
Division of Fuel Cycle and
Material Safety, NMSS

Enclosure: As stated

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

MAR 02 1983

MEMORANDUM FOR: Chairman Palladino
Commissioner Gilinsky
Commissioner Ahearne
Commissioner Roberts
Commissioner Asselstine

FROM: Patricia C. Vacca
Material Licensing Branch
Division of Fuel Cycle and Material Safety, NMSS

SUBJECT: EXPRESSION OF DISSENTING PROFESSIONAL OPINION CONCERNING SECY-83-62 (PROPOSED REVISION OF 10 CFR PART 35)

I am writing to support the views expressed in J. DelMedico's February 28,1983 memorandum. For more than seven years I have been a health physicist assigned to NMSS' Material Licensing Branch's Medical and Academic Section. During that time I have reviewed all types of licenses issued to medical and academic institutions, been involved with various amendments to the current Part 35, been detailed as Acting Section Leader for a seven-month period and acted in the place of our Section Leader during shorter absences.

I am not opposed to the concept of putting all of NRC's requirements into one document, Part 35. However, I am concerned about this proposed revision of Part 35; I am not convinced that this proposed revision will provide the same level of protection of health and safety as do our current procedures.

My principal concerns are two-fold:

1. Lack of NRC review of physicians' qualifications before a license is issued. Experience shows that virtually all physicians believe that their qualifications meet NRC's minimum training and experience criteria as described (principally) in Appendix A of Regulatory Guide 10.8 (Enclosure 1). However, many do not meet the Appendix A criteria. Of those that do meet the Appendix A criteria, it often takes 1-3 rounds of correspondence to elicit the documentation to verify the matter. Under the proposed revision of Part 35, the lack of qualifications of physicians may not become apparent until such time as an inspection is conducted, assuming that the inspector reviews the physicians' qualifications.

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2. Lack of NRC review of various procedures before a license is issued. Our current procedure involves a detailed review of an applicant's or licensee's step-by-step procedures for various aspects of his radiation safety program. The proposed revision simply requires that the licensee have certain procedures (e.g., procedures for contamination control). It does not require that the procedures be followed nor does it specify certain minimum factors that must be contained in the procedures. In this regard I would have fewer objections to the proposed revision of Part 35 if it required licensees (a) to have certain types of procedures, (b) to incorporate in their procedures certain minimum steps and (c) to follow their established procedures.

I am also concerned that the proposed revision of Part 35 does not reflect "lessons learned" from past AEC/NRC experience. For example, approximately 5-6 years ago NRC amended the current Part 35 to clarify the circumstances under which licenses would be issued in the name of a physician vs. the name of a medical institution. This action was taken because there were situations where several physicians and a medical institution held AEC/NRC licenses to cover the same activities. This led to instances in which some safety-related activities "fell through a crack" and no one wanted to take responsibility for problem areas. The requirements of the amendment that clarified the current regulations are not clearly incorporated in the proposed revision of Part 35.

The decrease in review by the NRC material licensing staff might be more acceptable if there were to be a corresponding increase in NRC's inspection activities for these medical licensees. However, I understand that there will be no increased inspection activities; if anything, the materials inspection activities will be reduced. In light of these constraints, I doubt that the inspectors will be able to spend much, if any, time reviewing physicians' qualifications and licensees' procedures.

I would also like to mention a few specific concerns that I have with the proposed revision of Part 35.

1. There is no provision in the proposed revision of Part 35 that is equivalent to the current 35.14(c). Many Group medical licensees are using carbon-14 and iodine-125 for in vitro studies and disposing of their waste from these studies without regard to its radioactivity as permitted by the authorization in the current 35.14(c). In view of the costs of waste disposal, this authorization is very valuable to the licensees. Must each of these licensees now file Form NRC-483 in order to continue this practice? Can NRC cope with a large number of these in vitro general licenses? How much will it cost licensees in terms of time, money and aggravation?

2. User qualifications either do not exist or, if they do, they do not all correspond with previously published NRC documents. In the latter cases, there are no explanations for the changes.

   a. There are no training and experience criteria for individuals wishing to use sealed sources for diagnostic studies (e.g., bone mineral analyzer or other diagnostic tools to be added to the new Group VII in the future).

   b. The qualifications of the qualified expert for teletherapy (new Section 35.961(b)) are not equivalent to the current requirements in 35.24(b), i.e., the proposed revision of Part 35 deletes the need for one year of full-time training in therapeutic radiological physics. Also there is no provision for NRC review of proposed qualified experts who are not Board-certified and who do not hold master's or doctoral degrees in the specified fields of study; specifically, there is no equivalent to Footnote 2 of the current 35.24(b).

   c. The criteria for physicians wishing to use brachytherapy sources (new 35.940) are not equivalent to the recent revision of Appendix A of Regulatory Guide 10.8 published in final form in the Federal Register on December 2, 1982 (Enclosure 2). Specifically, the minimum clinical experience in the proposed Part 35 appears to be 2 years, rather than 3 years.

   d. The criteria for physicians wishing to use teletherapy sources (new 35.960) are not equivalent to the criteria for using brachytherapy sources (as is the current practice), do not reflect all of the acceptable Board certifications and are not equivalent to the criteria published for comment in Appendix B of the draft teletherapy licensing guide identified as Division 10, Task TM 608-4, March 1982 (Enclosure 3). Note that no individual who commented on TM 608-4 expressed concern with the basic training and experience criteria outlined in Appendix B of that document, including the therapy members of NRC's Advisory Committee on the Medical Uses of Isotopes. Note also that the new 35.960 indicates a minimum of 500 hours (i.e, 3 months) clinical experience, rather than 3 years of clinical experience as described in Appendix B of TM 608-4. There is no explanation for this change.

e. There is no rationale for the addition of iridium-192 as wire and of tantalum-182 wire to the sources in Group VI. ELD is insisting that the staff make an independent finding of the safety and effectiveness of a new diagnostic device being considered for addition to the current Part 35 Group VI. Yet, these two sources to be used for therapy have been added to the proposed Part 35 without the staff having made an independent finding of the safety and effectiveness of these sources and without there being an approved distributor for the sources. This latter situation would put licensees in a Catch-22 situation with NRC effectively saying, "You may use these two sources for therapy as long as you obtain the sources from someone authorized to distribute them to you (i.e., someone who holds a license issued pursuant to 10 CFR 32.74). But there are no such distributors in the United States." The staff has taken great care in the past to avoid putting licensees in this kind of Catch-22 situation.

3. Xenon-133 gas is being added to the new Group II/III with the intention of authorizing an "as needed" possession limit. This radionuclide had not been added to Group II in the past because of NRC's belief that each licensee's facility needed to be reviewed on a case-by-case basis to ensure the licensee's ability to handle a radioactive gas safely and in compliance with Part 20 requirements. Experience shows that many licensees who request authorization for xenon-133 have marginal facilities as far as air handling systems are concerned and, in these cases, the staff has carefully limited the authorized possession limits to correspond to anticipated usage and the capabilities of the facility. Also with the increased importance of energy conservation, many licensees' facilities are recirculating air throughout the building making compliance with the Part 20 air concentration requirements even more difficult than in the past.

4. The activity specified in the new 35.50 for the sources to be used for calibration of a dose calibrator are inadequate. ANSI N42.13-1978 (Enclosure 4), prepared in response to the request of our former Section Leader, Dr. Leo Wade, specifies sources of much higher activity; see Sections 4.5.1 and 4.6.1 of the ANSI document.

5. The current 35.14(b)(6) requires that licensees who use an approved drug for an unapproved diagnostic procedure maintain the same chemical and physical form, route of administration and dosage range (except as authorized in 35.14(b)(7)). The new 35.100(b) and 35.200(b) delete the requirement to maintain the same chemical form. With no requirement to maintain the same chemical form, would licensees be permitted to use iodine-131 as sodium iodide (an approved drug) to label a protein and then administer the labelled protein to a patient? I do not believe that it is NRC's intention to authorize such a procedure but, knowing how licensees have understood (or misunderstood) NRC's regulations in the past, I believe that it is important that the regulations clearly require that chemical form not be changed.

6. It is not clear to me to what extent the proposed Part 35 affects broad medical licensees or how the proposed Part 35 will be implemented, assuming it is approved. For example, after the revised Part 35 is approved, will any Group II licensee be permitted to possess and use xenon-133 (that is available in individual patient doses of 10-20 millicuries and in "bulk" containers with a nominal activity of 1.0 Curie), including those whose facilities the staff had previously found to be unacceptable?

I would also respectfully recommend that you take the opportunity to hear the specific concerns of representative(s) of the Agreement States.

Patricia C. Vacca
Material Licensing Branch
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Enclosures:
1. Regulatory Guide 10.8 (Rev. 1), October 1980
2. 47 FR 54376
3. Draft Teletherapy Licensing Guide (Division 10, Task 608-4), March 1982
4. ANSI N42.13-1978