The University of Texas Medical Branch at Galveston 77550

Medical School
Graduate School of Biomedical Sciences
School of Allied Health Sciences
School of Nursing
Marine Biomedical Institute
Institute for the Medical Humanities
UTMB Hospitals at Galveston

ANTHONY R. BENEDETTO, PH.D.
ASSOCIATE PROFESSOR

NUCLEAR MEDICINE DIVISION
RADIOLOGY DEPARTMENT
(409) 761-2921

June 25, 1985

Secretary of the Commission
US Nuclear Regulatory Commission
ATTN: Docketing and Service Branch
Washington, DC 20555

SUBJECT: ANPRM, 50 FR 23960

This letter is being written in response to the subject ANPRM dealing with the assurance of financial capability to adequately decontaminate subsequent to a major radiation accident. My specific comments will be restricted to the medical uses of radionuclides, but I will also make general comments related to all licensed users as outlined in the ANPRM.

General

1. A discussion of the potential cleanup problems for the medical use of radionuclides is included in subsequent paragraphs of this letter. I have not had sufficient experience in other areas of radioactive material use to comment in detail on problems encountered in these other areas. As a general observation, however, I agree with the philosophy of assuring that a licensee can clean up any contamination his licensed operations cause, both technically and financially. The old saw that "He who messes up, cleans up" is equally true at the licensee level as it is at the level of the individual laboratory worker.

2a. Each licensee should propose the maximum credible accident (MCA) for each radionuclide requested in a license application. The expense of cleaning up after each MCA should be estimated by the licensee in broad, general categories, such as difficulty, time, radiation hazard to workers, radiation hazard to public and environment, and expense. All of the factors listed in the ANPRM (half-life, encapsulation, activity, physical form) would be taken into account in categorization of the MCA's. There appears to be an infinite number of combinations of these factors, so there will not be a definite cutoff value which is obvious. For example,

a few hundred millicuries of sealed Cs-137 sources is clearly of minimal concern compared to kilocurie sealed Cs-137 sources, but it is not at all clear where the dividing line should be. For long-lived nuclides (half-life greater than 3-6 months) the cutoff might be set arbitrarily at an aggregrate of one curie, since most sources seem to be either much less or much more than this amount.

2b. It is difficult to intelligently discuss the effect on licensees of requiring assurance of financial ability to decontaminate a major accident at this point, since mechanisms and associated costs have not been set out. Clearly, though, a 100% cash deposit or reserve would have a major impact on small licensees. My preference for provision of this assurance is discussed more fully in para 2g below, but it would seem to be the least expensive alternative on a collective basis. Briefly, I propose a Federal Contamination Cleanup Insurance Corporation (FCCIC), similar in concept to FDIC and FSLIC. Each licensee would pay a fee based on the categories of hazard discussed in para 2a above. Since every licensee would share this burden, the financial impact on any individual licensee should be minimized but still proportionate to the risk they pose. The FCCIC fund would be used only after a licensee has exhausted all other forms of financial support for the cleanup. NRC should investigate legislative changes to the bankruptcy laws to insure that a licensee can't capriciously declare bankruptcy and thereby escape financial liability. NRC should be able to place itself ahead of all other creditors until the cleanup is completed.

2c. There should be a "sliding scale" financial responsibility requirement. Licensees capable of causing very serious contamination hazards should be financially responsible for a major cleanup effort. Licensees posing only a small potential contamination threat should only have to be financially responsible for a small cleanup effort. Perhaps the "sliding scale" should be rather coarse, with categories for minimal risk ($250,000 or less), moderate risk, ($250,000-500,000), severe risk ($500,000-1,000,000), and extraordinary risk (more than $1,000,000). Since the likelihood of needing to use FCCIC funds would be low, the fees should be very small until there is a track record for more accurate calibration of the fees.

2d. As indicated in both earlier and subsequent paragraphs, some users should be exempted. For example, all unsealed radioactive material use in nuclear medicine and most brachytherapy use in radiation oncology should be exempted (see para 2a).

2e. I am very much in favor of strong action against licensees with poor safety or inspection histories. A licensee's FCCIC fee should be increased for a period of two years after an adverse inspection report or major accident due to management negligence, after which it would revert to its usual level if performance had improved to acceptable levels.

2f. As discussed in 2g below, I favor a FCCIC mechanism to which every non-exempt licensee would be required to contribute. For other types of arrangements, there must be a mechanism for alerting NRC to any changes requested by the licensee prior to the changes being effected. If specific mechanisms are not listed by NRC, each licensee will come up with his own scheme, making it difficult for NRC to provide a priori guidelines for acceptability.

2g. I propose the creation of a Federal Contamination Cleanup Insurance Corporation (FCCIC), membership in which would be required of all nonexempt licensees. A fee would be assessed against each licensee, at application and at each subsequent renewal, with all funds invested for financial safety and growth. NRC would order disbursement of funds from FCCIC after a licensee has exhausted all of its financial resources in the course of recovering from a major contamination (whether acute or chronic).

2h. Not applicable.

2i. Not applicable.

2j. I do not know if there are satisfactory mechanisms available at the present time.

2k. If a FCCIC were created, it would disburse funds promptly and only after direction from NRC. For other mechanisms, payout should be contingent on receipt by the guarantor of a letter from NRC describing the circumstances and directing payout. A licensee should not be able singlehandedly to request payout. Payout should be to the licensee only if there is reasonable assurance that the money will be properly handled. Otherwise, an

agent of FCCIC should oversee the financial aspects of the cleanup, in conjunction with NRC technical personnel. Additionally, a licensee should not be able to block the disbursement of funds.

21. NRC does not and should not have authority or responsibility to regulate the cleanup of nonradiological components of a radiation accident. A related aspect is the frequent co-location of non-NRC licensed radioactive materials with NRC-licensed materials. An accident involving NRC-licensed materials may also involve non-NRC licensed materials. What authority does NRC have in this instance? The general public won't care whose responsibility each type of material is, but only that the mess be cleaned up.

2m. If the FCCIC concept is adopted, NRC won't need to be so concerned about the financial health of licensees. For other mechanisms, NRC probably can only require that a licensee inform NRC if his financial condition becomes perilous. Inquiring into and assessing a licensee's financial status is a "privacy" can of worms that NRC doesn't want to open.

2n. The purpose of the ANPRM is to address the cleanup of contamination. The pathway by which the contamination occurred would seem to be of no consequence in this current proceeding. Since any contamination serious enough to be of concern would surely be in violation of existing NRC rules and regulations, punitive measures could be taken without any necessity to worry about the cleanup; the cleanup must be accomplished irrespective of whether the release was intentional or accidental.

2o. I see no reason to restrict the upper limit of liability to $2,000,000. Under my FCCIC proposal, these licensees would simply pay a higher fee. Even under alternate mechanisms, a higher limit than $2,000,000 seems reasonable. The public will want the mess cleaned up and will care little about the cost since radiation is involved.

The remainder of my comments will address medical radionuclide use in diagnostic nuclear medicine, therapeutic nuclear medicine, and radiation therapy. The comments will address the "Specific Considerations" listed in the ANPRM.

Diagnostic Nuclear Medicine

The radionculides used in diagnostic nuclear medicine fall into two broad categories: short-lived, which are generally used in millicurie quantities, and long-lived, which are used in microcurie and nanocurie quantities. Approximately 90% of all in vivo nuclear medicine studies use Tc-99m, which has a relatively soft gamma ray and a half-life of 6 hours. The remainder of the short-lived nuclides have half-lives on the order of 2-8 days. If a large spill of Tc-99m occurred, we would simply quarantine the area for several days and let decay perform our decontamination after our initial cleanup. The remainder of the short-lived nuclides and all of the long-lived nuclides are used in such small activities that they would present no significant public health concern. The area could either be quarantined or could be established as a restricted access area, taking the necessary minimal precautions to guard against removable contamination. The Mo-99 generator is a special case of a very e activity and a short half-life. A generator accide uldn't be expected to cause a contamination problem, nough, since the Mo-99 probably wouldn't escape from the alumina column and all of the surrounding lead and plastic containment.

A new technology being introduced is dual photon bone absorptiometry, which utilizes a one curie sealed source of gadolinium-153. Gd-153 has a half-life of about 8 months and decays by electron capture, emitting electrons up to 101 keV and 99 keV gamma rays (55%). If the Gd-153 source were ruptured, the contamination would be a major problem due to the long half-life and large activity. Therefore, users of Gd-153 sealed sources should probably be required to assure their financial ability to conduct a decontamination. The overall cost of decontaminating a room after a fire or other incident which could disperse the Gd-153 should be modest, since the radioactive material is likely to remain relatively contained and should not be of environmental concern.

In summary, there are generally negligible financial implications of a diagnostic nuclear medicine accident due to the short half-lives and small activities used. "Diagnostic nuclear medicine" should not be included in any Proposed Rule resulting from this ANPRM, but users of Gd-153 sealed sources should be considered.

Therapeutic Nuclear Medicine

At the present time the only two important therapeutic nuclear medicine radionuclides are I-131 and P-32. Astatine-211 is being developed, but its widespread use is not imminent. I-131 is used in activities ranging from a few millicuries for hyperthyroidism to a few hundreds of millicuries for thyroid carcinoma, while P-32 doses are usually 1-10 mCi. I-131 emits beta particles and fairly penetrating gamma rays and has a half-life of 8 days; P-32 emits only a high energy beta particle and has a half-life of 14 days. Most of the procedures performed with these radionuclides involve inpatients and hospitals; it would seem unlikely that a practitioner could conduct a nuclear medicine practice that would seriously contaminate an entire hospital. Because of the relatively short half-lives of I-131 and P-32, quarantine and restricted access should be adequate. No facility should be permanently put out of commission because of contamination with these radiopharmaceuticals.

In summary, there are no large financial implications of a therapeutic nuclear medicine accident due to the relatively short half-lives used. "Therapeutic nuclear medicine" should not be included in any Proposed Rule resulting from this ANPRM.

Radiation Oncology

The radioactive materials used in radiation oncology departments are usually moderate- to long-lived and are exclusively in the form of sealed sources. These sources are used either for teletherapy or for brachytherapy. The primary teletherapy radionuclide is Co-60, with a 5.2 year half-life and gamma rays of 1.17 MeV and 1.33 MeV; some institutions may have Cs-137 sources (half-life of 30 years, gamma ray of 662 keV). Teletherapy machines are always located in heavily shielded, isolated rooms, to which access is stringently restricted. The sources (about 10,000 curies) are mounted in heavy lead-tungsten shielding and are very well protected against physical trauma. The only credible accident which could cause dispersal of the source contents in the teletherapy room is a major fire. Cleanup would be extended, but it should be straightforward and uncomplicated.

Brachytherapy sources on the other hand, are small, of varying half-lives, and of relatively modest activity. The major brachytherapy nuclides of NRC concern are Cs-137, I-125, and Ir-192; Ra-226 is still occasionally found in smaller departments. The sources are usually a few tens of millicuries or less on an individual source basis, with an aggregate of a few hundreds of millicuries total activity. Because of their small size and their use in hospital wards, they represent a small potential hazard of causing a contamination problem external to the radiation oncology department. The more serious accident scenario for these sources would be a fire in the source storage area. In this instance the problem would be similar to that encountered for teletherapy sources except for the activity levels involved. Cleanup should be fairly rapid and relatively inexpensive. Institutional licensees probably don't need to demonstrate financial assurance for cleanup of brachytherapy sources, but individual physicians probably should be required to do so.

In summary, teletherapy machine users probably should be required to demonstrate the financial capability for cleanup of a major source disruption because of the expense and hazard of performing the cleanup. Individual physician users of brachytherapy sources also should probably be required to assure the necessary financial resources for a major cleanup, but institutional licensees probably would not need to do so.

Anthony R Benedetto

Anthony R. Benedetto, Ph.D.