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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

March 6, 2006

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Attention: Rulemaking and Adjudication Staff

RE: (PRM-35-18) Peter G. Crane; Receipt of Petition for Rulemaking. Federal Register Vol. 70, No 244, December 21, 2005.

These comments concerning the Petition for Rulemaking filed by Peter G. Crane are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include manufacturers and shippers of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medical applications. While CORAR has an interest in ensuring that these products can be made available as needed for the delivery of quality patient treatment and care, we also have concern for the health and safety of patients, those who provide treatment and care for them, the public and patient family members.

At face value it appears that the scope of applicability of the petitioner's amendment would be limited to therapeutic I-131 administered orally. CORAR membership includes companies that manufacture and prepare doses of I-131 for therapeutic administration. It has been reported[1] that in 2004, approximately 122,000 procedures were performed in the U.S. to treat hyperthyroidism, Grave's Disease and thyroid cancer using therapeutic I-131. Treatment of hyperthyroidism involved the administration of, on average, 2 to 30 mCi, whereas 30 to 300 mCi were administered for thyroid cancer therapy. Most (85%) hyperthyroid procedures were performed on an outpatient basis as were the majority (62%) of the procedures for thyroid cancer. If a three day hospitalization would have been required for each of the approximate 20,000 cancer treatments conducted on an outpatient basis, the financial impact in 2004 would have been approximately 60 million dollars, assuming an average cost of $1,000 per day for a hospital stay.

The petitioner does not discuss issues that would be relevant to I-131 administered by perfusion or in other forms, including sealed sources, introduced into the body. CORAR assumes that the petition does not intend to address these other applications. Regardless, CORAR opposes the petitioner's request to amend 10 CFR 35.75 to prohibit the release of patients from radioactive isolation with more than the equivalent of 30 mCi of I-131 in their systems. The basis of our position is that the petition does not provide adequate justification for amending the current release criteria and that the existing regulatory framework provides adequate protection

[1]The U.S. Imaging Market Guide, January – December 2004 by AMR/Arlington Medical Resources, Inc.

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SECY-02

in accordance with recommendations of national and international standards-setting organizations. We provide a response to each of the key issues raised by the petitioner on the following pages.

CORAR appreciates the opportunity to express comments on this Petition for Rulemaking. Please contact us if there should be any questions or if any additional information is needed concerning these comments.

Sincerely,

Henry Kramer / MD

Henry H. Kramer, Ph.D.
Executive Director
Council on Radionuclides and Radiopharmaceuticals

COMMENTS – Council on Radionuclides and Radiopharmaceuticals
NRC Docket No. PRM-35-18
Peter G. Crane; Receipt of Petition for Rulemaking
Federal Register, Vol. 70, No. 244. December 21, 2005

CORAR objects to the petitioner's request and this position is based on the view that the current regulation with supplementary guidance is adequate in terms of overall risk and benefit to all concerned. The basis of our disagreement with the petitioner and our recommendation to reject the petition is explained by the following responses to the individual points raised in the petition.

1. Patients treated for thyroid cancer with I-131 are being sent home under conditions that guarantee that family members will receive larger and potentially harmful doses of radiation under uncontrolled conditions.

CORAR disagrees with the position expressed by the petitioner. The current release criteria for release of these patients are dose-based and consistent with the recommendations of Report 37 from the National Council on Radiation Protection and Measurements (NCRP), as well as the recommendations of the International Commission on Radiation Protection (ICRP) in 1991 and 1996. NRC NUREG-1556, Volume 9, Appendix U, provides licensees with calculations, also consistent with NCRP Report 37, that enable a determination to be made of the potential dose to family members as well as members of the public. Model calculations are provided for a variety of scenarios, including administration of 150 mCi of I-131, that take into account patient-specific factors such as activity administered and occupancy times in various locations. For the most part there is an element of conservatism maintained within the methodology. The results of the calculations provide licensees with the ability to determine whether or not the release criteria in 10 CFR 35.75 can be satisfied. The regulations and associated NUREG-1556 instruction are quite clear in establishing that a patient cannot be released by the licensee if the dose to any other individual is likely to exceed 5 mSv (1 mSv to a child) and conditionally in a situation where the dose is likely to exceed 1 mSv.

If the licensee fulfills the obligation to comply with these requirements, then neither family members nor other members of the public will receive doses that NCRP would consider to be potentially harmful. ICRP Publication 94 states that the typical doses to adults from radioiodine therapy patients have a very low risk of cancer induction and that "actual measurements from relatives or caregivers who followed radiation protection precautions show that doses rarely approach or exceed the ICRP recommended dose constraint of a few mSv/episode." ICRP Publication 94 also recommends that doses to children be constrained to less than 1 mSv and that doses to children from patient contamination have the potential to be far greater than from external exposure. In light of this, there may be a need for NRC to consider adding instruction NUREG-1556, Volume 9, regarding the avoidance of exposure of children to patient contamination.

2. The ability to determine the dose received by persons exposed to patients in the mode of public transportation and as family members is in question.

CORAR disagrees with this assertion on the grounds that the calculations and assumptions provided in NUREG-1556, Volume 9, Appendix U, enable licensees to conservatively estimate the dose that a person would receive in the mode of public transportation based on the known patient source term and fundamental health physics principles. In the event that a patient was released contrary to the criteria in 10 CFR 35.75, there are methods of dose reconstruction that could be employed to determine the dose likely to have been received by individuals in proximity to the patient. Values of dose rates at various distances at different times following administration of I-131 in different applications are available[2] that can be used to perform these

[2] International Commission on Radiation Protection. (2004). Publication 94. *Release of patients after therapy with unsealed radionuclides.* Tables 6.2 – 6.5.

assessments.

3. Keeping patients in isolation would allow the level of radioactivity in the body to drop to "acceptably safe levels."

While it is true that the level of radioactivity within a patient and the commensurate risk associated with direct exposure to the patient decreases over time, CORAR disagrees with the use of the term "acceptably safe" in the context of promoting the practice of patient isolation. This use of the term "safe" is arbitrary as "safe" has different meanings to different people and it is difficult to characterize safety or the absence of risk posed in any situation as being absolute. The petitioner himself states his support of the linear, no-threshold model and his interpretation that no exposure is safe. At the same time, the acceptability of risk again depends on how it is compared against others, but it is really in the best interests of everyone concerned to have the appropriate standards-setting entities such as NCRP and ICRP make recommendations on the levels of radiation dose that would be acceptable. The universal approach recommended by ICRP is that that the magnitude of individual dose, the number of people exposed, and the likelihood of exposure should be kept as low as reasonably achievable, with economic and social values taken into account. The number of people exposed in the hospitalized patient scenario increases as does the collective dose due to the increased number of source terms (therapy patients), the relatively higher concentration of people (hospital employees, other patients and visitors) around them compared to individual homes, and relatively high occupancy rates of care providers in this environment. Ironically, patient family members may receive a higher dose from visits to a hospitalized patient's bedside than that received at home.

Applying this approach to the issue of isolation of therapy patients, ICRP in Publication 94 states that "the decision to hospitalize or release a patient should be determined on an individual basis. In addition to residual activity in the patient, the decision should take many other factors into account including the patient's wishes, occupational and public exposures, family considerations, the presence of children, cost and environmental factors" and that "isolation of patients after radioiodine therapy can result in significant psychological burden for patients and families." It is therefore unacceptable for the petitioner to dismiss any option other than patient isolation as unacceptably unsafe.

4. The scenario of a patient vomiting at home and subsequent excessive exposure to family members during clean-up would be prevented by administration of anti-nausea drugs as occurs in the hospitalization scenario. As a result of a patient vomiting, the intended dose to the patient may be reduced and a portion of radioactive material may be released, resulting in contamination and dose to family members. The petitioner also questions the frequency or post-treatment vomiting and wonders if data on this exist.

CORAR believes that all of these factors have been adequately addressed by 10 CFR 35.75, as supplemented by the information in NUREG-1556, Volume 9, and as supported by NRC Report 37 and ICRP recommendations.

While the petitioner believes that patient release in accordance with the existing 10 CFR 35.75 contributes to the occurrence of patient vomiting at home because anti-nausea drugs are administered as part of patient hospitalization, it has been reported to CORAR by representatives of the medical community via our liaison with the Society of Nuclear Medicine that often times the same medications are administered to patients prior to release in accordance with the NRC release criteria. Since the option to administer anti-nausea medication is available in both the release and hospitalization scenarios, the petitioner's concern over the potential reduction of the patient's therapeutic dose as a result of vomiting cannot be exclusively attributable to the 10 CFR 35.75 release criteria.

CORAR was not able to obtain data on the frequency at which a patient vomits, either after release or during

confinement, following administration of therapeutic radioiodine. However, based on information obtained from members of the nuclear medicine community, the occurrence of vomiting is relatively uncommon and even when patients are released in accordance with 10 CFR 35.75, this occurs hours after administration when most of the activity has been absorbed into the system. ICRP[3] in a description of the biokinetic model for iodide assumes the mean residence time in the stomach for orally administered iodide is 0.5 hours.

5. "Highly radioactive" patients are being sent out the door where they may or may not come into contact with the public and family members.

CORAR would agree that radioiodine therapy patients may or may not come into contact with the public and family members following release in accordance with 10 CFR 35.75. The release criteria are dose-based and the methods for demonstrating that the exposure to the public and family members will not exceed the constraints recommended by the experts of radiation protection standards-setting organizations take into account factors that include the quantity of I-131 administered, as well as the resulting dose rates at specific distances from the patient, and conservative occupancy factors determined on a patient-specific basis. Relative to background levels, a patient could be considered "highly radioactive," but in the context of the framework established to ensure the released patient does not expose anyone beyond levels of constraint recommended by NCRP and ICRP, it is inappropriate to imply that this level of radioactive material is harmful or negligent.

6. Hyperthyroid patients are not able to fully comprehend or remember instruction provided at the time of release. The patient's memory and conscience have "become the safety radiological safety net for the American people."

CORAR does not have the experience to be able to judge whether hyperthyroid patients can comprehend instruction or are unable to abide by them. However, we do know that it is not the patient's memory or conscience but the regulatory framework that allows for the patient's release that ensures that exposures to family members and the public are within the levels recommended by the standards-setting organizations. The instruction provided to licensees in NRC NUREG-1556, Volume 9, to facilitate compliance with 10 CFR 35.75 enables the determination to be made, on a patient-specific basis and with appropriate conservatism, that the permissible level of exposure to the public will not be exceeded.

7. NRC without regard for the need to "conduct a balancing of harms" has allowed for reduction of exposure to hospital employees and (with added emphasis on) clergy members at the expense of elevated exposure to family members, and particularly, children. As a result of the current patient release criteria, patients are not getting appropriate care and the public and family members are not being adequately protected.

CORAR again disagrees with the petitioner's position. In 1997 when NRC responded in the Final Rule[4] to the comment concerning the ability of I-131 contamination to be adequately controlled at patient's homes, it was conceded that control can be more effective in a hospital. NRC did address other relevant factors such as the likelihood of recurring therapy administrations, increased exposure of hospital employees and visitors, and a reference to NUREG-1492 that doses to household members from contamination were low. The petitioner has taken the NRC's mention of clergy members as a simple example of an individual who may frequent a hospital out of context and has needlessly added emphasis in his remarks to the extent that he has characterized the amended 10 CFR 35.75 as the "Clergy Protection Rule."

NRC discussion concerning comparison of relevant benefits and risks associated with the options of patient

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[3] International Commission on Radiation Protection. (1987). Publication 53. Radiation Dose to Patients from Radiopharmaceuticals.

[4] Federal Register, Volume 62, No. 19. January 29, 1997.

release and hospitalization (or the "balance of harms" as termed by the petitioner) occurs throughout section III of the Notice of Final Rule. In this discussion the NRC considered the results of studies and recommendations current at that time and in some cases references were cited. The conclusions drawn by NRC during the rulemaking process were generally consistent with the recommendations of NCRP and ICRP. Since then, the ICRP[5] has published additional recommendations concerning the decision to hospitalize or release patients and these include:

- The decision to hospitalize or release a patient should be determined on an individual basis. It should not be linked solely to residual activity in the patient but should take many factors into account, including the patient's pattern of contact with other people, the patient's wishes, occupational and public exposures, family considerations, cost and environmental factors.
- ICRP recommendations do not explicitly state that patients should be hospitalized after therapy with high activities of radiopharmaceuticals, but recommend that public dose limits and dose constraints for other should be observed. This should be followed by optimization.
- Recent publications have indicated that assumptions used by some authorities to hospitalize patients may overestimate potential doses to the public and care givers.
- Hospitalization of patients for several days will reduce exposure to the public and relatives, but will increase occupational exposure.
- Hospitalization of patients after radioiodine therapy can result in significant monetary and other costs that should be analyzed and justified.
- Actual measurements from relatives or caregivers who followed radiation protection precautions show that doses rarely approach or exceed the ICRP recommended dose constraint of a few mSv/episode.

It is CORAR's view that compliance with the existing regulatory framework is consistent with this approach and any consideration to rescind it is unwarranted.

[5]International Commission on Radiation Protection. (2004). Publication 94. *Release of patients after therapy with unsealed radionuclides.*

From: Carol Gallagher
To: Evangeline Ngbea
Date: Mon, Mar 6, 2006 11:48 AM
Subject: Comment letter on PRM-35-18

Attached for docketing is a comment letter on the above noted PRM from Henry H. Kramer, Council on Radionuclides and Radiopharmaceuticals, that I received via the rulemaking website on 3/6/06.

Carol

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Subject:	Comment letter on PRM-35-18
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