

November 24, 2003

MEMORANDUM TO: Thomas Essig, Chief
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety, NMSS

FROM: Joseph DeCicco, Senior Health Physicist */RA/*
Section A
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety, NMSS

SUBJECT: SUMMARY OF NOVEMBER 20, 2003, PUBLIC MEETING
REGARDING ISSUES OF MONITORING EXTREMITY DOSES

On November 20, 2003, the Division of Industrial and Medical Nuclear Safety (IMNS) arranged for a public meeting at the request of the Nuclear Energy Institute (NEI) and the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) This was a follow-on to a public meeting held on January 16, 2003 where extremity dosimetry issues were discussed. The agenda for this meeting is contained in Attachment 1. Attendees are listed in Attachment 2; participants included members of CORAR, a representative from NEI, a representative from the Alpine Group, and staff and management from NRC headquarters and three Regions. The meeting was conducted as a round table discussion among participants to discuss the issues in a draft white paper (see ADAMS accession number ML033090012), prepared by CORAR, on issues related to monitoring extremity doses.

The meeting began with brief introductions of participants, followed by an overview by NRC of the purpose and agenda of the meeting. The recent Information Notice (IN) 2003-12, "Problems Involved in Monitoring Dose to the Hands Resulting from the Handling of Radiopharmaceuticals," was briefly discussed before the agenda was addressed. This IN provided information to licensees, and a starting point for NRC and industry to address the issue in more detail. The efforts of the industry groups are focused on the categorization of licensees and methodologies in an effort to find uniformity that may be used in extremity dose monitoring within the categories. NRC expressed its hope that industry can help in developing methods to determine effective monitoring procedures.

The CORAR representative then proceeded to address each of the nine issues that are listed in the draft white paper. CORAR emphasized that efforts should seek to arrive at an effective way to characterize radiopharmaceutical procedures and methods, provide a procedure to demonstrate compliance, and standardize dosimetry. The group exchanged ideas on the level of complexity to show compliance with the regulation by a licensee; it was noted that there is no regulation or procedure that specifies how to show compliance, and that licensees would use a graded approach, increasing dosimetry efforts and accuracy as the hazard and dose increases toward a limit.

NRC emphasized that it did not agree with a statement in the draft white paper that “there is considerable conservatism already incorporated in the extremity dose limit . . . ,” and that the agency approaches limit establishment and dose determinations by realistic avenues rather than conservative treatment.

NRC summarized the initiatives it is taking to address the issue of extremity monitoring in the radiopharmaceutical arena. NRC is approaching the issue with an analytical focus, and has contracted to develop a modeling methodology to calculate doses to different parts of the extremity from different isotopes in different geometries. The efforts are expected to take six to twelve months.

The meeting was concluded with the focus on next steps to be taken by NRC and stakeholders. NEI indicated that there was no intention to do more specific data collection, or to develop a recommendation on appropriate correction factors for extremity dosimetry. CORAR suggested that a procedure to standardize an approach to show compliance should be developed. With NRC’s efforts to develop a mathematical model expected to take six months to a year, NRC asked NEI and CORAR to develop recommendations for standardized procedures to show compliance in this same time frame.

Attachments: (1) Public Meeting Agenda
(2) Public Meeting Attendees

Pubic Meeting Agenda
Issues on Monitoring of Extremity Dose
November 20, 2003 1-4 pm
Room: O-4B6

Opening remarks by NRC

Presentation of Draft White Paper Issues by NEI/CORAR

Questions and Comments by NRC

NRC Action Initiatives

Discuss Next Step - Path Forward

Open for Public Comments

**Public Meeting Attendees
November 20, 2003, 1 - 4 pm
O-04B6
Issues on Monitoring Extremity Dose**

Name	Organization
Bailey, Marissa	NRC/NMSS
Coffey, Jack	CORAR-Cardinal Health
DeCicco, Joe	NRC/NMSS
Essig, Thomas	NRC/NMSS
Johnson, Courtney	Alpine Group
Karagiannis, Harriet	NRC/NMSS
Killar Jr., Felix M.	NEI
Krueger, David	CORAR-Cardinal Health
Lanzisera, Penny	NRC/RI (via teleconference)
Seifert, Katherine	CORAR-Cardinal Health
Shaffer, Mark	NRC/RIV (via teleconference)
Sherbini, Sami	NRC/NMSS
Smith, Leonard R.	CORAR - PKI
Wiedeman, Darrel	NRC/RIII (via teleconference)
Yoder, Kay	CORAR - Mallinckrodt

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DATE	11/24/03		11/25/03	