January 28, 2003

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

FROM: Anita Turner, Health Physicist **/RA/**
Materials Safety and Inspection Branch
Division of Industrial and Medical
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SUBJECT: SUMMARY OF JANUARY 16, 2003 PUBLIC MEETING WITH CARDINAL HEALTH (FORMERLY SYNCOR INTERNATIONAL CORPORATION) REGARDING EXTREMITY MONITORING

On January 16, 2002, the Division of Industrial and Medical Nuclear Safety (IMNS) held a public meeting to discuss policy-related issues relative to extremity monitoring and dosimetry with the regulated radiopharmaceutical industry. The meeting was conducted as a roundtable discussion among participants to address policy and guidance-related issues regarding shallow dose equivalent (SDE) assessments to the portion of the skin of the extremity likely to receive the highest dose. Meeting participants included Cardinal Health, representatives from other radiopharmaceutical companies, a representative from the Organization of Agreement States, and NRC Headquarters and Regional staff. The industry raised many concerns regarding the issue of monitoring dose to the extremities. NRC caucused after the meeting to address these concerns. The meeting agenda, attendance list, and presentation slides are attached.

The meeting began with brief introductions by participants followed by an overview of the purpose of the meeting by NRC staff. Thereafter, Cardinal Health presented extremity monitoring issues which led to their request of the public meeting. Cardinal Health concluded that there was no risk-based reason to change from the current state of the art monitoring of routine occupational extremity overexposures. They also concluded that there is no risk-based reason to apply factors to state of the art measurements.

NRC staff presented information on the revised skin dose limit in 10 CFR Part 20 to clarify the use of the skin dose averaging area in assessing the shallow-dose equivalent. NRC noted that compliance requires assessment of the dose to the highest exposed 10 square centimeters of skin for the entire monitoring year, and not for single operations. Therefore, the need for a correction factor depends on the mix of activities engaged by the worker. The onus is on the licensee to demonstrate compliance.

January 28, 2003

During the roundtable discussion, the representatives of the radiopharmaceutical industry expressed many concerns regarding monitoring dose to the extremities. The industry suggested that there were too many geometries in nuclear pharmacy practices to obtain a correction factor to assess the dose at the highest point of exposure. Guidance was requested by members of the industry in assessing the dose to exposure areas which are less than 10 square centimeters of skin as well as a practical way of assigning dose to the extremities. Additionally, the industry noted that ergonomic considerations such as the sterility of product and needle sticks are important in monitoring dose as handling tools are used.

The meeting was concluded with an agreement that the radiopharmaceutical industry would consider developing a consensus industry standard on extremity monitoring. This development will likely be an iterative process between the NRC staff and the industry.

Attachments:

1. Meeting Agenda
2. Attendance List
3. Presentation Slides (Cardinal Health and NRC staff)

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