UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 9, 2004

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SUBJECT: REPORT ON TWO OVEREXPOSURES CARDINAL HEALTH, NRC LICENSE Number 04-26507-01MD

Dear Mr. Krueger:

Thank you for your report regarding overexposures to the extremities of two individuals at two of your radiopharmaceutical facilities. We have reviewed the information in the report, as well as the more detailed information from your glove study which you have provided to us informally. Your report also asked for guidance on a number of issues, and this letter provides answers to these questions and also the Nuclear Regulatory Commission's (NRC's) position in this matter.

Before addressing the specific issues you raised, it may be helpful to inform you of steps NRC has taken to address this situation. NRC recognizes that the work now being undertaken by Cardinal Health, specifically the glove studies, is an important contribution towards understanding the problem of extremity monitoring, and will be of significant assistance to the NRC in developing appropriate guidance for the industry in this area. We would like to encourage Cardinal Health to continue this important work, and to keep NRC staff informed of progress and findings. We also recognize that the glove study significantly increases the probability of identifying extremity doses that are in excess of the applicable regulatory limit in cases that would not have been identified had the currently accepted NRC guidance on extremity monitoring been used. In order to avoid imposing penalties on Cardinal Health for work voluntarily undertaken in an effort to assist NRC and the industry in their efforts to resolve a very difficult technical problem, NRC will issue an Enforcement Guidance Memorandum (EGM) to address the glove study being conducted by Cardinal Health. The EGM will provide for enforcement discretion not to cite violations in cases that involve extremity doses that exceed the applicable regulatory limit, and that were (1) identified as a result of the experimental monitoring work that Cardinal Health is conducting under the glove study, and (2) were not detected using regulatory proscribed monitoring devices. The EGM will be in effect until December 31, 2005, which should cover the expected duration of these studies. During that time, NRC will evaluate each overexposure case to determine whether it falls within the

scope of the EGM. The two cases that you reported in your letter will be considered to fall within the scope of this EGM, and therefore no enforcement action will be taken. NRC would like to encourage Cardinal Health to continue the important work it has undertaken in this area, and not to limit the glove study to cases that are anticipated to yield doses below the applicable limit, but to extend it to cases that are deemed high dose potential cases and difficult to monitor cases. Study of such cases will be valuable in bounding the parameters of the problem and in developing appropriate guidance.

The discussion which follows reiterates your questions related to specific guidance issues, followed by our responses:

1. *How should the results of these glove studies be treated? Should the presumed Assigned Shallow Dose Equivalent (ASDE) as reported above be assumed to be "the dose of record" for all individuals so studied?*

   The results of the ring dosimeter monitoring, interpreted as per currently accepted policy, should be used as the dose of record for these cases. However, because the studies indicate at least the possibility that these doses may not be accurate, the results of the glove studies should also be entered in the record as possible doses based on experimental measurements. The practice of entering two doses in the record, one indicating the "regulatory" dose and the other indicating the dose that the licensee believes better reflects the actual dose, is common and widely used, and should be used in these cases as well.

2. *Since exposure reports provided by our dosimetry vendor do not currently report the ASDE, only the Shallow Dose Equivalent (SDE), discrepancies between dosimeter results and Form 5s will be significant. What level of documentation would an inspector expect to see when reviewing such records?*

   Because the ASDE is still an "experimental" result, the SDE reported by the dosimetry vendor should be entered in FORM 5, and the ASDE should also be entered as a note, indicated in Item 1 above, to indicate the possibility that the dose of record may not be accurate. Inspectors who inspect Cardinal Health facilities and records will be aware of the ongoing experimental work and the EGM, and any questions that may arise as a result of records reviews that cannot be satisfactorily resolved during the inspection will be referred to Regional management and to NRC Headquarters.

3. *What type of comments should be placed in a FORM 5 if the ASDE is reported from a unique correction factor?*

   The record should indicate that the ASDE was entered in the record in addition to the formal FORM 5 SDE because ongoing experimental work suggests that the current practice of measuring SDE may not provide a sufficiently accurate indication of extremity dose. The ASDE, as measured in the glove study, results from an experimental methodology that is not yet accepted by the NRC nor the regulated community, therefore it cannot be used in place of the SDE as the dose of record.

4. *The issue of ASDE versus dosimeter results will continue to be a vexing issue until guidance is provided by the Commission. In addition, in the Agreement States there is no uniformity in the skin/extremity dose limit vis-a-vis the new definition of the extremity dose limit. This makes universal application of correction factors across the company problematic. Under the compatibility rules, when would the NRC require all states to adopt the new definition?*

   The revised skin dose rule was assigned compatibility A, which means that the States are required to adopt an identical rule within 3 years of the effective date of the rule, which was June 2003. The States are therefore expected to have completed adoption of this rule by June 2006.

Please call Mark Shaffer in Region IV (817-860-8287) or Sami Sherbini at Headquarters (301-415-7853) if you have any questions regarding the positions stated in this letter or in connection with your ongoing experimental work.

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cc: Mark Shaffer, Region IV
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