

May 12, 2006

MEMORANDUM TO: George Pangburn, Director
Division of Nuclear Materials Safety, RI

FROM: Thoms H. Essig, Chief */RA/*
Material Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST DATED
APRIL 5, 2006: BAYHEALTH MEDICAL CENTER

I am responding to your technical assistance request (TAR), dated April 5, 2006, (enclosed) concerning a skin exposure at Bayhealth Medical Center

Issue: A member of the public received a substantial skin dose as a result of handling radioactive material, but the dose does not appear to be subject to any regulatory limit. Region I requests guidance on whether this exposure is subject to enforcement action, and also on the necessity for developing guidance and rulemaking to address this situation.

Background: The event occurred in a hospital outpatient setting when the member of the public was assisting her mother, and in the process came in contact with a capsule containing the radioactive material that had been administered orally to the patient in the form of a capsule. The capsule contained sodium iodide, tagged with 10.2 millicuries of iodine-131. The dose to the thumb, which was estimated by RI to be 9.7 mSv (970 mrem) averaged over 10 cm², arose as a result of contamination that was quickly removed by the licensee. Enforcement action was considered but the U.S. Nuclear Regulatory Commission's (NRC) regulations, specifically 10 CFR Part 20, do not appear to impose any limits on this type of exposure. This indicates a regulatory deficiency, and suggests that revision of the regulation, or at least guidance, may be appropriate. As indicated in the TAR, exposure of members of the public to skin doses that do not appear to be subject to a regulatory limit occur in other settings, such as during the care of patients released under 10 CFR 35.75, caregivers in hospitals who are engaged in caring for patients undergoing treatment, and exposure to some generally-licensed devices.

Discussion: The dose limit for members of the public is specified in 10 CFR Part 20.1301(a)(1) as 1 mSv (0.1 rem) per year total effective dose equivalent (TEDE). No other limit on public exposure is specified. TEDE is defined in §20.1003 as the sum of deep dose equivalent (DDE) for external exposures and the committed effective dose equivalent for internal exposures. Because this case, as in most such cases, did not involve internal exposures, the TEDE is equal to the DDE. DDE is defined in §20.1003 as the dose equivalent at a tissue depth of 1 cm applied to external exposure of the whole body. Whole body means, for purposes of external

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exposure, head, trunk, arms above the elbow, or legs above the knee. The parts of the body excluded from the definition of the whole body are referred to as the extremities. The dose limit for the extremities, as well as for the skin of the whole body, is limited in occupational exposures by a limit on the shallow dose equivalent (SDE), but there is no corresponding SDE limit for members of the public.

For external exposure of the whole body to penetrating radiation, the DDE and SDE are numerically nearly equal, and therefore limitation of DDE will also limit the SDE to about the same level. This is usually the most common mode of exposure to external radiation for members of the public, and in such cases the current regulations are adequate. For external exposure to non-penetrating radiation, the SDE can be much higher than the DDE in some circumstances, particularly in cases of exposures to beta radiation. The limitations placed on the DDE will therefore not necessarily be protective against high a SDE. The DDE is also not defined for the extremities, and therefore these parts of the body for members of the public are not subject to any regulatory limit. In summary, therefore, there is no regulatory limit on the SDE, whether for the whole body or for the extremities, for members of the public.

It should be noted that the dose limit on extremity and skin doses for occupational exposures is a limit on the SDE, and is specified in Part 20 as 0.5 Sv (50 rem) per year. This limit is based on the avoidance of long-term deterministic skin effects. The lifetime dose implied in this limit, that ensures that no threshold for skin effects is exceeded, and is about 25 Sv (2500 rem). The 0.5 Sv per year limit also ensures that the threshold for any prompt deterministic effects, such as erythema, is not exceeded. The stochastic risks arising from skin exposures are very small in comparison with the stochastic risks arising from exposure of other parts of the body. No health effects are therefore expected to result from the exposure in the current case of less than 10 mSv (1 rem).

Conclusions: Based on the above discussion, the following conclusions may be reached:

- (a) The occurrences of cases of members of the public who receive SDEs not subject to a regulatory dose limit should be corrected by changes to the regulations, but they do not constitute an immediate public health and safety concern. Using the recommendations of the International Commission on Radiological Protection (ICRP) as provided in ICRP Publication 60, the recommended dose limit for the skin for members of the public is 50 mSv (5 rem). Therefore, should the NRC's rules be changed to include a limit on the SDE for members of the public, it would most likely be 50 mSv. This dose limit would be higher than the dose received in this case, and also the doses received by most caregivers in hospital settings. Therefore, these cases would be in compliance with such a possible limit, and the exposures, though they should be subject to a limit, do not constitute an immediate, unregulated hazard.
- (b) Revision of 10 CFR Part 20 to include a limit on SDE for members of the public should not be attempted ad hoc, but should be made in the context of a more general revision of the regulation. The reason is that a revision of Part 20 is likely to include revisions of the definitions of the dosimetric quantities used in specifying limits, and therefore the change needed to include limitation of shallow dose equivalent is most likely to be

affected by such changes.

- (c) The extent of occurrence of unregulated SDE dose to members of the public is unclear, but it appears to be limited to specific and narrow circumstances. Most exposures to members of the public are due to uniform penetrating radiation, and in such cases the limit on the TEDE is adequate to protect against high SDE levels. SDE doses that are not constrained by the limit of TEDE tend to occur in special settings, such as in hospitals. This makes them amenable to direct control by the licensee, such as by better assessments of sources of exposure to members of the public, and better control and monitoring of these exposures.
- (d) The relative rarity of unregulated SDE exposures of members of the public, coupled with the relatively low doses compared with any potential limit, may not warrant issuance of a generic communication. However, regional inspectors can play a direct and important role in alerting individual licensees engaged in activities for which there is a potential for such exposures. To this end, it may be appropriate to issue a temporary instruction (TI) to direct inspectors to identify facilities with a potential for such exposures, and when identified, to discuss with licensees the nature of the hazards, the regulatory shortfalls, and the preventive actions that may be undertaken to minimize or eliminate the potential for exposure and to minimize the dose if an exposure is unavoidable.

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