UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

April 16, 2002

NRC REGULATORY ISSUE SUMMARY 2002-06 EVALUATING OCCUPATIONAL DOSE FOR INDIVIDUALS EXPOSED TO NRC-LICENSED MATERIAL AND MEDICAL X-RAYS

Addressees:

All medical licensees.

Intent:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to inform addressees of a personnel radiation monitoring compliance issue identified during recent inspections of medical licensees. In addition, this RIS provides specific guidance for determining doses to individuals who receive exposures from medical x-ray radiation, while wearing protective apparel (i.e., protective apron, or protective apron and thyroid shield). No specific action nor written response is required.

Background:

The NRC staff has observed that some medical licensees assigned whole body doses to occupationally exposed employees in a manner that did not conform with the requirements, in10 CFR Part 20, for calculating occupational doses. These employees were subject to NRC dose limits because they were exposed to NRC-licensed material. The individuals also received occupational exposure from medical x-ray equipment, which is not regulated by NRC. The licensees had used fluoroscopy-specific dose methodologies approved by their States to demonstrate compliance with NRC dose limits. These methodologies differed from the methodology specified in Part 20. The licensees had not requested prior NRC approval for the use of these methodologies in demonstrating compliance with NRC dose limits.

This RIS provides specific guidance for appropriate methodologies when licensees receive occupational exposures from medical x-ray radiation, while wearing protective apparel.

Summary of Issue:

The NRC regulations [10 CFR 20.1201(a)] require that occupational doses from radiation shall not exceed annual limits of 0.05 sievert (Sv) (5 rem) total effective dose equivalent (TEDE), or 0.5 Sv (50 rem) to any one organ. In accordance with Section 20.1001(b), the limits apply to the total dose from both licensed and unlicensed sources. Section 20.1201(c) also

requires that the assigned deep dose equivalent (DDE) be for the part of the body that receives the highest exposure. In addition, Footnote 2 to the "Organ Dose Weighting Factors" table in 10 CFR 20.1003 states that "For purposes of weighting the external dose (for adding to the internal dose), a single weighting factor $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued."

The use of weighting factors for organs or tissues is defined in 10 CFR 20.1003 only in the context of calculating an effective dose equivalent. However, the definition of TEDE in Section 20.1003 [i.e., the sum of the DDE (external) and the committed effective dose equivalent (internal)] does not use the effective dose equivalent for external exposures. Footnote 2 in the "Organ Dose Weighting Factors" table in 10 CFR 20.1003 does permit approval of the use of organ and tissue weighting factors for external exposures on a case-by-case basis. NRC, reading Part 20 as a whole, to give meaning to the footnote concerning external exposure, concludes that the footnote provides the staff with the discretion to permit the use of effective dose equivalent for external exposures in place of DDE, in the definition of TEDE. In accordance with the discretion provided by the footnote, TEDE may be redefined, for purposes of applying the footnote, as the sum of the effective dose equivalent for external exposure and the committed effective dose equivalent for internal exposure. When this redefinition of TEDE is used, 10 CFR 20.1201(c) does not apply, because the DDE is no longer used in the definition of TEDE.

NRC will allow licensees to implement radiation protection programs that redefine TEDE in particular situations when reliable, accurate, and predictable estimates of the effective dose equivalent are possible, given the conditions of exposure, and are based on methods that are acceptable to NRC. The proposed methods should be appropriate for the exposure conditions. NRC will accept methods approved by appropriate State regulatory agencies with jurisdiction over the radiation source. For the specific case of occupational exposure to medical x-ray radiation while wearing protective apparel, the guidance that follows may be used to demonstrate compliance with the Part 20 occupational dose limits. This guidance does not apply to any other exposure scenarios.

A licensee will be considered to be in compliance with Part 20 for the determination of occupational dose when occupational exposures result in part from medical x-ray radiation, while wearing protective apparel, under the following conditions:

1) A licensee uses a method approved by a State that has regulatory jurisdiction governing the use of its medical x-ray generating equipment.

2) Federal licensees, where a State regulatory entity does not have jurisdiction, may use one of the alternative methods outlined in Attachment 1.

3) If a State has not approved a specific alternative method, then one of the alternative methods in Attachment 1 is acceptable to NRC. Nothing in this RIS relieves a licensee from the need to comply with applicable State regulatory requirements or laws.

4) Any alternative method that is used must have been incorporated into the licensee's procedures and radiation safety program before the exposure for which the alternative method is to be applied.

5) The effective date of the guidance in this RIS is April 16, 2002. Licensees may not apply this guidance to exposures received before the effective date of the RIS.

Licensees who receive occupational exposures from medical x-ray radiation, while wearing protective apparel, are not required to submit an exemption or amendment request if they adhere to the above conditions of this RIS.

In addition, NRC is issuing an Enforcement Guidance Memorandum (EGM) 02-002 on this issue. This EGM provides that enforcement discretion should be exercised for violations of Sections 1201(a) and (c) involving x-ray exposures that have already occurred. This policy of exercising enforcement discretion is being made effective for 60 days following issuance of this RIS to allow for receipt of the RIS, and implementation of its guidance. Violations of Sections 1201(a) and (c) involving x-ray exposures after the 60 day grace period will be considered for enforcement action in accordance with the NRC Enforcement Policy.

For all licensees, all other occupational exposures should continue to be evaluated using the DDE provisions of 10 CFR 20.1201(c), unless specific application has been made and approved. Licensees are reminded that Section 20.1201 also contains annual occupational dose limits for individual organs, the lens of the eye, extremities, and the skin. The guidance in this RIS does not affect the determination of occupational dose for those parts of the body.

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the technical contact listed below or the appropriate regional office.

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Attachments:
1. Acceptable Alternative Methods for Compliance with 10 CFR Part 20 with Occupational Exposure to Medical X-ray Radiation When Protective Apparel is Used
2. List of recently issued NRC Regulatory Issue Summaries

Acceptable Alternative Methods for Compliance with 10 CFR Part 20 with Occupational Exposure to Medical X-ray Radiation When Protective Apparel is Used

1. From the Conference of Radiation Control Program Directors, Inc., "Suggested State Regulations for Control of Radiation, Volume 1 (Ionizing)", 1995, Frankfort, Kentucky

   When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in D.502a.iv., the effective dose equivalent for external radiation shall be determined as follows:

   (1) When only one individual monitoring device is used and it is located at the neck outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation; or

   (2) When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in D.201.a., the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

   (3) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported by the individual monitoring device located at the waist under the apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

2. From the National Council on Radiation Protection and Measurement, NRCP Report 122, "Use of Personal Monitors to Estimate Effective Dose Equivalent and Effective Dose to Workers for External Exposure to Low-LET Radiation," 1995, Bethesda, Maryland.

   When two personal monitors are used, one worn under a protective apron at the waist or on the chest [where H_W is the $H_p(10)$ value for this personal monitor] and the other worn outside and above the apron at the neck, it is recommended that the value of H_E be estimated from the formula:

   $$H_E(\text{estimate}) = 1.5H_W + 0.04H_N .$$

   [NRC Note: $H_p(10)$ is the personal dose equivalent for strongly-penetrating radiation determined at a depth of 10 mm, and is synonymous with deep dose equivalent. H_N denotes the monitor located at the neck]

3. From an American National Standard Institute / Health Physics Society, ANSI/HPS N13.41 - 1997, “Criteria for Performing Multiple Dosimetry,” Health Physics Society, McLean, Virginia

   The resultant effective dose equivalent estimate is the under-apron dosimeter providing an estimated dose equivalent for the thorax, abdomen, right and left thigh, multiplied by 0.89, plus the unshielded dosimeter providing a dose equivalent estimate for the head/neck and upper arms, multiplied by 0.11.

   [NRC Note: This method uses two dosimeters, worn similarly as in 2.]

4. Updated versions of methods listed in 1, 2, or 3.