TEMPORARY INSTRUCTION 2800/031

EXTREMITY EXPOSURE MONITORING

PROGRAM APPLICABILITY: 2800

2800/031-01 OBJECTIVE

01.01 To verify licensees are providing shallow dose equivalent (SDE) assessments to the portion of skin of the extremity likely to receive the highest dose [10 CFR 20.1201(c)], by:

a. Properly using individual monitoring devices appropriate for measuring the SDE; or

b. Using appropriate dosimetric modeling and calculational methodologies to estimate the SDE to the portion of skin of the extremity likely to receive the highest dose; and

c. Ensuring timely processing of monitoring devices and prompt review of results, sufficient to ensure that dose limits and As Low As Reasonably Achievable (ALARA) objectives are met [10 CFR 20.1101(a)].

01.02 To verify that licensees are providing:

a. Training that is appropriate and effective for handling radioactive material when extremity exposure is likely to exceed 10% of the applicable limit (10 CFR 19.12);

b. Oversight, by appropriate levels of management, of workers and their performance and techniques [10 CFR 20.1101(c)], sufficient to ensure that work is performed in accordance with approved licensee procedures developed to maintain worker doses ALARA [10 CFR 20.1101(b)];

c. Appropriate special tools and shielding devices, and requiring their use as specified by licensee operating procedures.

2800/031-02 BACKGROUND

A recent Information Notice (IN)(IN-2000-10, dated July 18, 2000), describes several instances in which extremity overexposures have occurred. These overexposures occurred in a manufacturing facility and a radiopharmacy. Reasons for these overexposures include:

improper handling of radiopharmaceuticals, inadequate supervisory oversight for workers, improper dose calculation methodology for dose to finger tips, inadequate shielding, and poor health physics practices. Also, failure to recognize that the extremity dosimeter readings were not representative of the high extremity doses contributed significantly to the overexposure incidents in the manufacturing facility. For more detail about the incident descriptions, see IN 2000-10.

2800/031-03 INSPECTION REQUIREMENTS

During routine inspections of all licensed radiopharmacies, medical licensees that handle radiopharmaceuticals in other than unit doses, manufacturing facilities that have employees who handle unsealed radioactive material or large unshielded sources, and other licensees that have the potential for significant dose to the extremities, inspectors shall:

03.01 Confirm, by observation of work procedures, whether appropriate extremity monitoring is provided for employees likely to receive doses in excess of 10 percent of the limit.

03.02 Confirm that the assigned SDE reflects the dose to the portion of the extremity likely to receive the highest exposure.

03.03 Confirm that extremity monitoring device processing (collection, process, and assessment) is performed in a timely manner, so that this information can be used to prevent noncompliance with occupational limits.

03.04 Confirm that appropriate radiation protection equipment, such as syringe shields and remote handling tools, is used when handling radioactive materials.

03.05 Confirm that approved procedures are available, understood, and are being followed when handling shielded or unshielded sources.

The Regional Offices should attempt to inspect all nuclear pharmacy licensees, and all manufacturing and distribution type A broad licensees, during the effective period of this TI.

2800/031-04 INSPECTION GUIDANCE

04.01 For the extremity, the annual limit is 0.5 Sv (50 rem) to the skin [10 CFR 20.1201(a)]. Therefore, an individual likely to exceed 0.5 Sv (5 rem) to the skin of the extremity is required to use an extremity monitor [10 CFR 20.1502]. Exceeding the limit can occur when working in a non-uniform radiation field or working closely with unshielded, or partially shielded containers of radioactive material. Licensed radiopharmacies, medical licensees that handle radio-pharmaceuticals in other than unit doses, manufacturing facilities at which workers handle unsealed radioactive material or large unshielded sources, and other

licensees have the potential for significant SDE to the extremities.

04.02 Wearing dosimetry does not necessarily assure proper assessment of the highest exposure. The inspector should evaluate the adequacy of the licensee's methods used to assess the SDE to the portion of the skin of the extremity expected to have received the highest dose. Particular attention should be given to the distance between the location that is likely to have received the highest dose when sources are manipulated manually (even when shields are used) and where the extremity monitor is worn. The assigned dose should be based on the best available data, which may include, but are not limited to:

a. Extremity dosimetry (i.e., ring badges or fingertip badges);

b. Whole body dosimetry;

c. Survey data;

d. Correlations with other similarly employed persons for whom similar monitoring is provided;

e. Any combination of the above or other data that are appropriate for such calculations.

In general, ring badges, when used in conjunction with appropriate shielding, are sufficient to estimate the dose at the finger tips. Without shielding, radiation field gradients are large close to the source, and therefore, a calculational correction to a ring badge result may be needed to adequately assess dose to the fingertips. Syringe shields will also flatten the dose rate gradient to a point where a ring badge will represent the highest exposure to the extremity. However, the dosimeter reading depends on many factors when handling shielded and unshielded sources, such as where the dosimeters are worn, what procedures are being performed, how often the procedures are performed, characteristics of the emitted radiation, and which are the dominant hands of the workers. Therefore, the licensee should take the above variables into consideration when assigning the extremity dose to the worker.

04.03 One extremity overexposure occurred because dosimetry information was not reviewed and evaluated in a timely manner, in conjunction with miscommunication between a licensee and the dosimetry processor. The collecting and processing of dosimetry, and evaluating the results as quickly as possible after a monitoring period, are vital to a good dosimetry program. Also, more frequent exchanges (shorter monitoring periods) might be a consideration for procedures involving the potential for higher exposures. For new procedures or workers new to a job, more frequent exchange of dosimetry or multibadging may provide an earlier indication of poor work habits and evaluation of exposure conditions in the work environment.

04.04 ALARA considerations include procedures and engineering controls to reduce exposures. Workers should not be handling unshielded sources directly. Shields should always be used, and

when they cannot (such as when using a dose calibrator in a nuclear pharmacy), remote handling tools (tongs or forceps) should be used. The licensee should provide the necessary equipment to the worker to preclude the need to directly handle radioactive sources.

04.05 Inspectors should determine if procedures are available, and reflect actual work practices. Work procedures should have been documented and reviewed by management and the radiation safety staff. The procedures should be readily available to workers for reference and review. Inspectors should attempt to determine if the managers, supervisors, or senior employees periodically observe actual work practices to ensure that procedures are sufficient for their purpose, understood by the workers, and being followed.

2800/031-05 REPORTING REQUIREMENTS

05.01 Each region shall document its findings in the inspection records.

05.02 Within 60 (sixty) calender days of the expiration of this temporary instruction (TI), each region shall send the Office of Nuclear Material Safety and Safeguards (NMSS) a list of names and license numbers of all facilities that have been inspected according to this TI. For licensees inspected, each region shall send the information listed below. The requested information may be formatted in a manner that is most effective and efficient from the standpoint of regional staff effort.

a. Whether appropriate extremity monitoring was provided;

b. Whether assigned SDE reflected the expected highest extremity exposure;

c. Whether processing (collection, process, and assessment) of extremity monitoring devices was being performed in a timely manner;

d. Whether appropriate radiation protection equipment, such as syringe shields and remote handling tools, was being used;

e. Whether approved procedures were available, understood, and were being followed when handling shielded or unshielded sources.

2800/031-06 COMPLETION SCHEDULE

No change in inspection scheduling will be required to use this TI except to attempt to schedule all nuclear pharmacies, and all manufacturing and distribution type A broad, during the TI’s effective period.

2800/031-07 EXPIRATION

This TI shall remain in effect until December 14, 2001.

2800/031-08 CONTACT

Questions about this TI should be addressed to the Chief, Section B, Materials Safety and Inspection Branch, Division of Industrial and Medical Nuclear Safety (MSIB-B/IMNS),NMSS, at 301-415-7231.

2800/031-09 STATISTICAL DATA REPORTING

All direct inspection effort expended as a result of this TI should be charged against the inspection procedure used during the routine inspection.

2800/031-10 ORIGINATING ORGANIZATION INFORMATION

10.01 The MSIB/IMNS/NMSS initiated this TI.

10.02 The estimated onsite inspection time necessary to complete this TI should be 1 hour. Actual inspections at a specific site may require more or less time, depending on the circumstances.

10.03 There is no specialized training that is required to perform the inspection requirements defined in this TI.

END