May 15, 2002

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4/5/02
67 FR 16467
(7)

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NRC Staff:

The following comments regard NUREG-1556 Vol. 9 Appendix T "Model Procedures for the Safe Use of Licensed Material." The fourth procedural item advocates the use of *syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed vein, infants). In these exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle).*

The use of syringe shields is certainly a wise precaution to reduce exposure when drawing doses from prepared kits. However, the continued assertion that syringe shields are to be used in all cases (except where contraindicated by recessed veins or age) fails to take into consideration that most modern nuclear medicine departments utilize single unit, pre-prepared doses of radiopharmaceuticals provided by commercial nuclear pharmacies. No distinction is being made between the differences in both time and geometry when cradling a syringe being drawn from a radioactive vial versus holding a syringe pre-prepared for injection.

The continued requirement for syringe shields in almost all situations is also contrary to the NRC's stated goal of *placing added emphasis on conducting its regulatory activities in a risk-informed and performance based manner. This approach is intended to be less prescriptive and allow for the implementation by the licensees that may be specific to their needs while meeting regulatory requirements.* A more performance based approach would be to **require** syringe shields **only** when drawing doses from radioactive kits. For single unit pre-prepared doses of radiopharmaceuticals supplied by a commercial nuclear pharmacy, the RSO should have the discretion to compare extremity exposures to Level I and II ALARA action limits and specify syringe shield use accordingly. Under the current regulations, the RSO has the discretion to eliminate extremity monitoring all together, if the exposures received are less than 10% of the occupational limit. Yet there is little latitude in the use of syringe shields, despite low extremity exposures.

The syringe shield requirements recognize exceptions only for recessed veins or age. There appears to be no consideration given to the increased difficulty in performing an injection with a shield due to:
(1) the increased weight
(2) the additional manipulation time
(3) the change in the angle of injection
(4) the reduced sensitivity for the technologist during the injection
(5) the difficulty using syringe shields with some injection apparatus.

This last item especially can be a source of spills during the injection process. Other facilities have also reported problems with syringe shields and injection apparatus. To illustrate these points, I have attached a review of one facility's syringe shield use with radiopharmaceuticals obtained from commercial nuclear pharmacies in a single unit, pre-packaged form. If you have any questions, or need clarification, you may contact me at 601-856-4750. Thank you for your time and your consideration in this matter.

Sincerely,

Michael J. Smith, Radiation Safety Officer

Template = ADM-013

E-RIDS = ADM-03
Add = R. Broseus (RWB)

1. Facilities that use single unit, pre-prepared radiophamacuetical doses experience lower hand doses during injections due to less manipulation time and differences in geometry. A six-year review of annual cumulative ring badge doses for nuclear medicine technologists at one facility has indicated exceedingly low hand doses despite the fact that a large number of problem patients often make the use of syringe shields impractical.

**Table 1.**
**COMPARISON OF JACKSON VA EXTREMITY DOSES**
**(In mrems)**

| Worker | 2001 | 2000 | 1999 | 1998 | 1997 | 1996 |
|---|---|---|---|---|---|---|
| **No.1** | 1660 | 1270 | 900 | 910 | 1020 | 1390 |
| **No.2** | 1020 | 830 | 930 | 720 | 880 | 990 |
| **No.3** | 1260 | 780 | 750 | 720 | 790 | 900 |

All technologists were on a bi-weekly rotating schedule, which indicates that over an extended period of time all technologists should have performed similar tasks. Technologist exposures were less than the **15,000 mrems** Level II limit requiring an investigation and less than the **5,000** Level I limit that would require no action under NUREG-1556 Vol. 9. In fact, extremity exposures less than 5,000 mrems (10% of the occupational limit for extremities) could justify the elimination of radiation monitoring for the extremities entirely as allowed under 10 CFR Part 20.

2. The extremely low hand exposures listed in item no. 1 above can be attributed to the almost exclusive use of single unit pre-prepared doses of radiopharmaceuticals at the facility. The nuclear pharmacy generally fills the syringes with small quantities of liquid near the needle end of the syringe and away from the plunger end of the syringe where the technologist's fingers are placed. With pre-prepared doses, there is no cradling of the hand around the syringe as when the dose is drawn from a vial, and there is significantly less time involved. With pre-prepared doses, time and distance from the source together may well be as important as shielding in reducing hand doses.

**Table 2.**
**SURVEY OF RADIOPHARMACEUTICAL DOSES AT ISOTOPE AND FINGER LOCATIONS**

Surveys made by placing the GM tube probe as close as possible to the surface of the syringe perpendicular to the long axis of the syringe and centered over the liquid mass in the syringe.

| | | |
|---|---|---|
| **5.946 mCi Tc-99m Source** | Unshielded syringe | >500 mR/hr (internal tube) |
| **20.024 mCi Tc-99m Source** (larger volume in syringe) | Unshielded syringe | >500 mR/hr (internal tube) |

Survey made by placing the GM tube probe as close as possible to the surface of the syringe perpendicular to the long axis of the syringe at plunger end approximately where the fingers would be placed to depress the syringe plunger.

| | | |
|---|---|---|
| **5.946 mCi Tc-99m Source** | Unshielded syringe | 170 mR/hr |
| **20.024 mCi Tc-99m Source** | Unshielded syringe | 145 mR/hr |

**Meter used was Picker Model 655-186 no. 449 calibrated 10/06/00 using Cs-137 and a pulse analyzer. The meter was fitted with a sidewall GM probe in the closed position. Both meter and probe are similar to Eberline Model E520 survey meters used by medical facilities and other licensees in conjunction with an HP-270 sidewall GM**

**tube. The HP-270 style probe has a reading to field ratio of approximately 90% at 140 KeV according to Eberline literature.**

**Two Tc-99m sources were used: (1) Tc-99m rest perfusion study 10 mCi as of 8:30 a.m. 12/19/00; 0.67 ml of liquid filling the syringe to the 0.6 ml mark near the needle; corrected to 1:00 p.m. 12/19/00 – 5.946 mCi (2) Tc-99m stress perfusion study 30 mCi as of 9:30 a.m. 12/19/00; 1.13 ml of liquid filling the syringe to the 1.0 ml mark near the needle – corrected to 1:00 p.m. 12/19/00 – 20.024 mCi.**

The above table of survey results (while not compensating for different liquid volumes, absorption by the syringe wall, and shielding by the probe wall) did indicate a considerable reduction in dose rates depending on the proximity to the radiopharmaceutical in the syringe. An 18-second injection time of a pre-prepared syringe would yield, based on Table 2, a hand dose of 0.725 to 0.85 mrems unshielded. [The average time measured by stopwatch to administer a dose through the IV port was 18 seconds - a longer handling time than a simple injection]. Given 10 injections per day for 5 days per week for 52 weeks per year, an estimated workload of 2,600 annual injections was calculated. Using the 18 second injection time, the hand dose for this estimated workload was estimated to be 1,885 to 2,210 mrems yearly when measured near the plunger end of an unshielded syringe pre-prepared by a commercial nuclear pharmacy.

By comparison, the **combined extremity exposure** for the facility technologists during 2000, as monitored by ring badges, was found to be 2,880 mrems. This combined extremity exposure was less than the 5,000 mrem Level I action limit for extremities, only 19% of the Level II action limit for extremities, and less than the 5,000 mrems threshold that would ordinarily require monitoring (10% of the occupational limit). However, the facility technologists administered on average 161 doses monthly during October and November 2000 or 1,932 injections during the year 2000 – less than the previous estimated workload mentioned above. Using the previously calculated hand dose of 0.75 to 0.85 mrems unshielded per 18-second injection, the combined technologists' year 2000 extremity dose was calculated to be 1,642 mrems. This calculated combined extremity exposure for 2000 is 43% less than the actual combined extremity exposures as monitored by ring badges.

Using the previously estimated workload for a department [10 doses/day X 5 days/week X 52 weeks/year = 2,600 injections], the maximum 18 second extremity exposure of 0.85 mrems unshielded, and adjusting the estimate upward by 43% [to compensate for observed increased ring badge measurements], the estimated combined extremity exposure for such a workload was be calculated to be 3,877 mrems. This would be the exposure received by using an unshielded syringe pre-prepared by a commercial nuclear pharmacy with the technologist's hand near the plunger end of the syringe. This estimated hand exposure was less than the 5,000 mrems Level I action limit for extremities, only 26% of the Level II action limit for extremities, and less than the 5,000 mrems threshold that would ordinarily require monitoring (10% of the occupational limit). Based on these observations and calculations, a nuclear medicine department could inject 38 doses per day or 9,880 doses per year of pre-prepared syringes without syringe shields. The resulting extremity exposure would not exceeding the Level II action limit of 15,000 mrems that would require an investigation by the RSO – even if only one technologist performed the injections. Since this would be an unrealistic workload for a single technologist, the exposure would have to be distributed among multiple technologists further reducing the extremity doses per individual. In short, there is very little chance that a large scale nuclear medicine department [employing multiple technologist performing injections without syringe shields] can exceed the Level II action limits [or possibly even the Level I action limits] when using pre-prepared single unit doses of radiopharmaceuticals due to the significant reduction in the exposure levels at opposite ends of the syringe and brief handling times.

3. While employing a syringe shield would reduce the radiation readings measured in Table 2 above, the insertion of the syringe in the shield adds an additional step in handling the pre-prepared syringe and presents a problem with the dose identification tag attached to the syringe. After observing and interviewing the facility technologists, the tag was found in many cases to be too loosely wrapped around the syringe to fit into the shields without either wrapping the tag more tightly around the syringe or removing the tag altogether. Wrapping the tag obviously increases the hand dose during this process, and removing the tag creates dose identification problems if not reattached to the shield. After observing this situation, the Radiation Safety Officer attempted to load into syringe shields the two syringes listed in Table 2 above. With both syringes and using two different types of shields, the attached tag made shielding the syringes more difficult to accomplish.

In one instance, the tag almost jammed the syringe inside the shield. The RSO concluded that an additional delay would be required to remove the syringe label, attach the label to the syringe shield, and reattach the label to the syringe after the injection

4. In reviewing the nuclear medicine department case load for November and December 2000, it was noted that three of the four most common studies performed used apparatus that made syringe shields more difficult or nearly impossible to use. Myocardial studies (26 % of all studies in October and 20 % in November) involve administration of the radiopharmaceutical through the IV port (Alaris Latex-Free Infusion Set No. 20). In the case of the metal syringe shield, once the needle was removed the nipple of the shielded syringe was just long enough to allow the technologist to twist and lock the shielded syringe into place on the IV line. In the case of the leaded glass syringe shield, the nipple of the shielded syringe was actually recessed in the end of the shield requiring slight pressure to twist and lock the syringe onto the IV line. The technologist was unable to observe the syringe locking into place and had to feel the syringe lock as it is twisted.

   For three phase bone, 1st pass GHS, and renal studies (3% of all studies in October and 7 % in November), a 3-way stopcock (Medix MX531-1L) was used to attach the syringe. In the case of the metal syringe shield, the stopcock could operate only if the shielded syringe leaded glass window was turned away from the stopcock valve control making it very difficult to observe the liquid being injected while operating the stopcock. In the case of the leaded glass shield, the stopcock valve control could not be used at all with the shielded syringe attached.

   In the myocardial studies, the technologist would spend additional seconds physically testing the seal of the shielded syringe to the IV line port. For longer periods of time, their fingertips would be closer to the end of the syringe bearing the radioactive material where surveys demonstrate that the radiation levels are higher. The shield would reduce radiation levels around the circumference of the syringe but act like a collimator by releasing the radiation energy through the exposed needless port of the syringe. In all of these studies, the use of a syringe shield may actually increase the possibility of a spill, if shielded syringe connections are uncertain.

   **Two types of syringe shields used: (1) metal barrel type approximately 2.5 inches in length, 7/16 inch in diameter, and 1/16 inch thick possessing a screw tab to lock the syringe in place and a leaded glass window 3/8 inch thick, ¼ inch in width, and 1 11/16 inches in length (2) a leaded glass barrel type approximately 2 ½ inches in length including the chrome rings on each end - one designed to hold the needle end of the syringe and the other fitted with a rubber seal used to lock the syringe in place. The metal barrel of type no. 1 tapers toward the needle end with the metal becoming progressively thinner.**

5. 10 CFR 25.60 (c) states that *the licensee ... shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient.* Nuclear medicine personnel have traditionally considered children with small veins and elderly patients with difficult to locate veins two prime examples of such *contraindications*. Some facilities serve specific populations with a high percentage of older patients. For example, VA hospitals do not typically serve children; however, these facilities do serve an exceedingly high number of elderly patients. WWII, Korean, and Vietnam conflict veterans who served at age 18 are now approximately 75, 66, and 50 respectively. Many of these older patients suffer from circulatory problems that make veins even more difficult to locate during injections. Technologists have indicated in interviews that, in difficult injection situations, they feel when they have seated the needle properly into the vein. One technologist described the sensation as feeling a plastic bubble wrap compartment pop. That same technologist also stated that it was very difficult to feel that response with a shielded syringe. The Radiation Safety Officer made a comparison of syringe weights both shielded and unshielded with the results listed in Table 3 below.

**Table 3.**
**SYRINGE SHIELD WEIGHTS**

| | | |
|---|---|---|
| A | = | 72.808 grams |
| B | = | 76.906 grams |
| C | = | 83.018 grams |
| D | = | 83.983 grams |

Empty Syringe Weight = 3.334 grams
Syringe filled with 2 cc of water = 5.505 grams

**A & B were metal cylinder syringe shields. C & D were leaded glass syringe shields. Both were described in item no. 3 above.**

**Mettler Toledo Model PB303 analytical balance serviced September 2000.**

Even a syringe loaded with 2 cc of liquid weighed on average 14.4 times more when fitted with a syringe shield. Despite the old adage that practice makes perfect, this variation in weight, along with the insulating affect of the shield, would have to affect dexterity and sense of touch during even relatively simple injections. The effect would be even more pronounced during difficult injections such as those encountered with elderly patients. To compound the injection problems, the newer leaded glass syringe shields make it more difficult to place the syringe in a position lying close against the arm at the injection site, because the diameter of the shield raised the angle of the needle on entry. The technologists stated that reducing the angle of injection by placing the syringe closer against the arm improves the injection procedure.

6. The NRC has maintained a policy of not becoming involved in the practice of medicine to avoid the hazards of second guessing physicians who are charged with providing patient care. Health care providers have been left to determine advisability or inadvisability with regard to a patient treatment and wisely so. When using single unit pre-prepared doses of radiopharmaceuticals administered without syringe shields, the extremity exposures for nuclear medicine technologists can be demonstrated to be very low. The exposures at the above facility have been less than the Level I and Level II action limits specified in NUREG-1556 Volume 9 and even less than the 10 CFR Part 20 threshold dose that requires a ring badge - 10% of the occupational limit. As with the case of physicians and the practice of medicine, the facility RSO and the nuclear medicine technologist should have the discretion to determine what practices best strike a balance between serving the patient population and realistically limiting radiation exposures. Given the low extremity exposures from single unit pre-prepared doses of radiopharmaceuticals, the Level I and II action limits for extremities should be the yard stick used to determine the need for syringe shields rather a blanket policy requiring shield use.