Draft Model Procedures for Evaluating and Reporting Extravasation Medical Events

This draft model provides acceptable procedures for administrations in which an extravasation could occur. Applicants may either adopt this model procedure or develop their own procedure to meet the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 35.42.

Procedures for Evaluating and Reporting Extravasations

This model provides guidance to license and applicants for developing, maintaining, and implementing written procedures for evaluating and reporting extravasation medical events. This model does not restrict use of other guidance in developing, maintaining, and implementing written procedures for evaluating and reporting extravasation medical events. These procedures are to provide high confidence that the objectives specified in 10 CFR 35.42 will be met.

The written procedures must contain the information described in 10 CFR 35.42 and be retained in accordance with 10 CFR 35.2042, “Records for procedures for evaluating and reporting extravasations.”

Discussion

Before an administration of radioactive materials for diagnostic or therapeutic purposes, the authorized user (AU) should inform the patient about what the procedure will involve, including any possible complications, feelings, or sensations arising from an extravasation. The AU should inform the patient of what steps to take if they feel a symptom that could indicate a possible extravasation (e.g., unexpected burning sensations near the injection site).

During the administration, the licensee should monitor the patient to detect an extravasation as soon as it happens. Examples of monitoring include frequent contact with the patient during longer administrations, consideration of patient feedback, observation of symptoms such as swelling, and use of monitoring technologies. If the licensee identifies that an extravasation has occurred, the licensee must determine whether it has resulted in, or could potentially result in, a radiation injury in accordance with 10 CFR 35.42(b). If a physician determines that the extravasation has resulted in, or has the potential to result in, a radiation injury, the licensee should report the extravasation to the NRC in accordance with 10 CFR 35.3045.

To ensure that a radiation injury from a delayed reaction will be detected in a timely manner, the licensee should inform the patient about the potential complications of the treatment and let the patient know how to contact the licensee if a potential radiation injury occurs. The licensee should give the patient an information card to minimize the burden to the patient of having to remember the information. The information card should include the name of the physician, the radiopharmaceutical or treatment given, the location of the treatment, the date of the treatment, and a way of contacting the clinic providing the treatment.

Because radiation effects may be delayed, a patient may go to another healthcare provider if effects occur. The licensee should use any information provided by other healthcare providers as necessary to determine whether a radiation injury has resulted from an extravasation. If a physician later determines that an extravasation resulted in, or has the potential to result in, a radiation injury, the licensee should report the extravasation to the NRC in accordance with 10 CFR 35.3045.

Figure AA.1 Patient Information Card. Licensees should provide information to patients after their treatment to assist patients if they develop symptoms posttreatment and seek medical care for a potential radiation injury.