Documentation Testimonial

Six months after implementing this documentation, our hospital attorney requested a meeting with me to discuss possible litigation. Patient A contended that "the technician used a big needle and put a large amount of dye in my arm. My arm was swollen and hurt a lot; and now I cannot use my left arm anymore." Our documentation stated "Unsuccessful attempt to inject with a 25-G needle on 1st attempt into a left antecubital vein with poor blood return. No redness, edema or pallor at site. 20 mCi, 0.3 ml, ^{99m}Tc-MDP injected with 25-G needle into right antecubital vein on 1st attempt with good blood return."

The attorney and I spent several hours going over and over every aspect of my actions in the case. This is a simple procedure, performed in any nuclear medicine laboratory every day. Why was I feeling like an insect

PHOTOCHEMICAL CONSIDERATIONS OF LIGHT-SENSITIVE COLD KITS AND RADIOPHARMACEUTICALS

To the Editor: Photolytic degradation is a critical factor in the stability of pharmaceuticals that are sensitive to light. Some of these light-sensitive drugs are rapidly affected either by natural light (especially ultraviolet radiation) or artificial light (e.g., fluorescent lighting) and become discolored or develop precipitates, while others may undergo photodegradation slowly, which may not be visually apparent. Colored-glass containers (e.g., amber vials or ampules) are commonly used to prevent or to delay the photodecomposition process of light-sensitive pharmaceutical formulations.

Currently, there are three cold kits and one kit component for the production of technetium-99m (^{99m}Tc) labeled radiopharmaceuticals, which are susceptible to photolytic degradation. These light-sensitive radiopharmaceutical formulations are the MICROLITE kit (E. I. du Pont de Nemours & Co., Billerica, MA) for the preparation of ^{99m}Tc albumin colloid, the MPI DMSA Kidney Reagent kit (Medi-Physics, Inc., Arlington Heights, IL) for the preparation of ^{99m}Tc-DMSA, and the TechneScan MAG3 kit (Mallinckrodt Medical, Inc., St. Louis, MO) for the preparation of ^{99m}Tc-MAG_3. It is interesting to note that there is no indication in the official drug monograph that the European TechneScan MAG3 kit (Mallinckrodt Medical B.V., Petten, Netherlands) is sensitive to light (*1*). The light-sensitive kit component is the sodium hypochlorite (NaOCl) syringe in the UltraTag RBC kit (Mallinckrodt Medical, St. Louis, MO) for radiolabeling red blood cells (RBC) with ^{99m}Tc.

The labels on the containers and package inserts (*2–5*) for these products state that the contents of the kits should be protected from light; however, these light-sensitive drug products are packaged in clear and colorless glass containers. This is contrary to the standard practice of protecting light-sensitive drugs in light-resistant (e.g., amber, yellow-green, or blue) containers.

A clear and colorless (translucent) container does offer some advantages over a colored container. Colored-glass or colored-plastic containers cost an average of ~25% more than colorless containers. This may be due to the more costly materials necessary in the manufacture of the colored containers and to the light transmission testing that is required by the United States Pharmacopeia (USP) XXII (*6*). The colored containers must pass these tests in order to qualify for use as light-resistant containers.

In addition, use of a colored container makes it virtually impossible to

inspect for any color change or precipitate which may be directly attributed to photodegradation of the pharmaceutical. Although the contents of light-sensitive drugs can be transferred to a clear and colorless container (e.g., vial or syringe), to examine the clarity and particulate matter, this approach is not suitable for cold kit formulations and radiopharmaceuticals due to the possible oxidation effects on these drugs and the additional radiation exposure to personnel.

There is no information available regarding the time period for which MICROLITE, DMSA, MAG_3, and NaOCl may be exposed to light without causing any deterioration, and it is unclear whether the radiopharmaceuticals (i.e., ^{99m}Tc-albumin colloid, ^{99m}Tc-DMSA, ^{99m}Tc-MAG_3, and ^{99m}Tc-labeled RBC) prepared from these cold kits are also prone to photolytic degradation. Thus, it may be necessary to minimize any direct light exposure to both the cold kit formulations and the radiopharmaceuticals that may be sensitive to light.

The user must take special care to store light-sensitive cold kits and kit components in the original kit box to ensure proper protection from light exposure until dispensed. If the reagent kit formulation is discolored or contains particulate matter during its shelf life, this decomposed drug should be discarded.

The use of vial or syringe lead shields for radioactive drugs not only reduces radiation exposure to personnel, but also provides excellent protection from light exposure for light-sensitive radiopharmaceuticals. However, it remains unknown whether the lead glass or acrylic that is used in the syringe and vial shields (most notably the 360° clear view syringe/vial shields that are usually light yellow in color) would meet USP light transmission testing requirements (*6*) for providing adequate protection of light-sensitive pharmaceuticals from light-exposure degradation.

As a final note, since the preparation of ^{99m}Tc-MAG_3 requires 10-min of heating time in a boiling water bath (*4*), appropriate protection of the ^{99m}Tc-MAG_3 vial from ambient light exposure during the heating period is also advisable.

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