



Compliance Counts: Nuclear Medicine Gastric Emptying Studies

The Nuclear Medicine Department of the hospital is regulated through the rules of several agencies including (but not limited to):

- Joint Commission
- Nuclear Regulatory Agency (CFR Title 10, Chapter I:Energy)
- Centers for Medicare and Medicaid (CMS) Conditions of Participation (CFR Title 42: §482.53)
- Occupational Safety and Health Administration (OSHA)

To remain clear of findings in all areas, it is recommended that regulatory specialists review the practices within the department to detect the potential for violations in any of the standards as they apply to a specific patient situation. For instance, any test that includes a contrast agent will be subject to several Joint Commission Medication Management standards for the ordering, review, dispensing, and administration of the contrast agent. Organizations who manage compliance with Medication Management out of the main Pharmacy may discover opportunities for findings during survey unless the entire organization is examined.

As it relates specifically to gastric emptying studies, the *Consensus Recommendations for Gastric Emptying Scintigraphy: A Joint Report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine*, it outlines recommendations for patients undergoing the procedure.

This consensus statement recommends the following:

- Use of 4 oz. of liquid egg white (Egg Beaters® or generic equivalent) radiolabeled with 0.5–1 mCi 99mTc, two slices of white bread, strawberry jam, water (120 mL).
- The eggs can be cooked either scrambled on a hot skillet (nonstick frying pan) or microwaved in an appropriately shielded container.
- The egg mixture should be stirred once or twice during cooking and is cooked until it has the consistency of an omelet (3–5 min). The bread is toasted. Jelly is spread on the bread, and a sandwich is made of the jellied bread and cooked egg mixture.
- The patient ingests the sandwich meal within 10 min.
- If the patient vomits part of the meal at any time during the test, this should be indicated on the report as it may affect the test interpretation.

All relevant regulatory agencies should be considered for impact on this complex procedure. Three key steps of this procedure include preparation of the meal, conducting the test, and post-procedure follow-up.

Storage and preparation of the Technetium for inoculation of the test meal

The relevant regulatory standards in this step will be the most familiar to the nuclear medicine department. Standard procedures for receipt, preparation, and use of nuclear medicine tracers are well documented in most organizations. “Cradle to grave” documents log the use and disposition of all nuclear materials received by the organization.



Compliance Counts: Nuclear Medicine Gastric Emptying Studies

Preparation of the food component of the test meal (in compliance with the FDA Food Code)

This is the area that is most susceptible to variance from regulatory requirements. The 2005 FDA Food Code has clear guidelines for the storage and preparation of raw eggs. This may not be able to be accomplished in the confines of the hot lab or nuclear medicine department in part, because refrigerators may not be able to properly maintain raw eggs. Further, staff members are required to demonstrate the knowledge and competency for correctly preparing foods for consumption by patients. The use of the pasteurized egg white product (Egg Beaters®) eliminates some of the requirements of the Food Code but must be maintained in a refrigerator at the appropriate temperature according to manufacturer's recommendations. Proper cooking temperatures of the initial product may be attained according to the Food Code. Use of microwaves and the food served from them is specifically outlined in the Food Code at 3-401.12 and include a need to cook to a consistent temperature of 165°F following holding. Proper serving asepsis must also be followed.

Policies, procedures, and protocols for administering the test and contrast agent.

Policies and procedures should outline the steps to be taken for each step in the test, including the preparation of the test meal. Staff must show competency in preparing the test meal according to approved policies and procedures established by the Medical Staff. Orders for the test and the corresponding contrast agent are subject to appropriate standards regarding review by pharmacy and appropriate administration. Additional policies may apply to special consideration for managing waste generated through the preparation and administration of the radiopharmaceutical.

Post-test care of the patient and relevant precautions.

One of the common findings during the informal survey was the discovery of a lack of procedures to follow for patients undergoing a gastric emptying study. It is assumed that the majority of patients undergoing the study are having problems with slow gastric emptying, commonly manifested by nausea and vomiting. The ingestion of a meal may cause the return of such symptoms. While the guidelines speak to the effects of vomiting on the sensitivity of the test, it does not speak to precautions to be taken for the biological waste generated by the patient that is tagged by the nuclear material. Policies and procedures should take this into account.

The gastric emptying study commonly lasts about 4 hours, with pictures taken at 0.5,1,2,3,4 hours. Depending on organizational procedures, patients may return to their room between scans to rest. Technetium, the most common tracer used for this study, has a short 6 hour half-life. This means that the emesis generated by the patients undergoing the gastric emptying study may contain radioactive material considered to be carcinogenic (see Technetium MSDS for further information). In light of this, the hospital should consider precautions to be taken for staff caring for study patient if vomiting should occur post-study. Isolation and clean-up of the material should only be done by competently trained individuals. Outpatients at higher risk may also require post-study instructions.