



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

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MEMORANDUM FOR: William Olmstead, Director
Regulations Division, OELD

Karl Goller, Director
Division of Radiation Programs and
Earth Sciences, RES

John Philips, Chief
Rules and Procedures Branch, ADM

FROM: Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and Material Safety

SUBJECT: REQUEST FOR COMMENTS ON PROPOSED RULEMAKING TO AUTHORIZE
APPROVED RADIOPHARMACEUTICALS FOR UNAPPROVED USES

Attached for your comment is a proposed rulemaking that would amend 35.14(b)(7) of 10 CFR Part 35, "Human Uses Of Byproduct Material." The proposed rule is in accordance with NRC's policy as described in the Federal Register on February 3, 1983 (48 FR 5217).

This proposed rulemaking would amend the regulations to allow licensees to use the following FDA approved drugs for the indicated unapproved uses: technetium-99m labeled sulfur colloid for gastroesophageal imaging; technetium-99m labeled sulfur colloid, pertechnetate, or macroaggregated human serum albumin for LeVein, ventriculo-atrial, and ventriculo-peritoneal shunt imaging; and technetium-99m labeled pertechnetate for cystography and dacryocystography.

Please review the enclosures and submit your comments to me by 11/8/84.

Vandy L. Miller
Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

- Enclosures:
1. Federal Register Notice Package
2. 48 FR 5217

Technetium-99m labeled sulfur colloid can be administered orally either as a solid or liquid test meal. Following oral administration, technetium-99m sulfur colloid goes from the esophagus to the stomach, small intestine, and the upper large intestine. This clinical procedure permits external imaging which is helpful in assessing gastric emptying, gastroesophageal reflux, and esophageal transit. The gastric emptying procedure is useful in demonstrating the presence and the severity of gastric motor disorder; the gastroesophageal reflux study may demonstrate backward flow in the digestive tract. The esophageal transit study may demonstrate obstructions or abnormal transit time. The radiation dose to an average adult patient from 1 millicurie of orally administered technetium-99m sulfur colloid as a liquid is: 0.1 rad to the stomach wall; 0.3 rad to the small intestine; 0.5 rad to the upper large intestine; 0.3 rad to the lower large intestine; 0.1 rad to the ovaries; 0.01 rad to the testes; and 0.02 rad to the whole body. The estimated absorbed radiation dose to an average adult patient from 1 millicurie of orally administered technetium-99m sulfur colloid as a solid food is: 0.2 rad to the stomach wall; 0.2 rad to the small intestine; 0.4 rad to the upper large intestine; 0.3 rad to the lower large intestine; 0.1 rad to the ovaries, 0.004 rad to the testes; and 0.02 rad to the whole body.

Explain what this means
viv-a-viv (1) other digestive,
(2) therapeutic procedures, &
(3) part 20 limits. A
short paragraph that is clear
to an intelligent person will
serve in radiation dose will
do.