U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, D.C. 20590

JUL 08 2014

Ms. Christina D. Cahill CNMT, RT(R)
Lead Technologist
Fairview Hospital
29 Lewis Ave.
Great Barrington, MA 01230

Ref. No.: 14-0086

Dear Ms. Cahill:

This is in response to your email dated April 18, 2014, requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) relating to the transportation requirements for radioactive surgical specimens. You state that your radioactive specimens have an activity of 1.0 millicuries or less prior to injection, and after injection there is some residual in the syringe. You state that there will be less than .27 millicuries of Technetium-99m (Tc-99m) by the time the driver would handle any radioactive material. Your questions are paraphrased and answered below:

Q1. You ask if training for personnel and couriers must comply with the training requirements found in Subpart H of Part 172 of the HMR.

A1. Section 173.436 sets activity concentrations for exempt material and activity limits for exempt consignments. The activity limit for exempt consignments of Tc-99m is less than .27 millicuries. If the only radionuclide present is Tc-99m, and the total activity in the consignment is less than either the activity concentration limit or the activity limit for consignments shown in § 173.436, that consignment would not be considered to be a radioactive material under the HMR. Assuming the specimen does not meet the definition of any other hazard class, the material is not regulated as a hazardous material and none of the training requirements of Subpart H of Part 172 of the HMR are applicable.

Q2. Surgical specimens containing Tc-99m can be transported from one RAM licensed facility to another licensed facility as stated in the licenses?

A2. The licensing you mention does not appear to be an HMR requirement. Please direct this question to the appropriate authority.

Q3. Must specimens be labeled with a radioactive material label until the less than .27 millicures activity limit is met for "exemption"?

A3. If offered as a fully regulated radioactive material under the HMR, yes, labeling would be required. Depending on the activity present (see § 173.425), your specimens may qualify to be offered as Radioactive material, excepted package-instruments *or* articles, UN 2910 and further excepted from labeling as a radioactive material.

Q4. Until a specimen reaches the "activity limit for exempt consignment" in accordance with § 173.436, there is no requirement for radioactive labeling?

A4. See A1.

I trust this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,

Shane C. Kelley

Shane C. Kelley
Acting International Standards Coordinator
Standards and Rulemaking Division

Stevens
§173.436
RAM
14-0086

Drakeford, Carolyn (PHMSA)

From: INFOCNTR (PHMSA)
Sent: Monday, April 21, 2014 9:46 AM
To: Drakeford, Carolyn (PHMSA)
Subject: FW: Tc99m Activity limit for exempt consignment.

Hi Carolyn,

This caller requested we submit this e-mail as a formal letter of interpretation.

Thanks,

Victoria

From: Cahill Christina (Debbie) [mailto:ccahill2@bhs1.org]
Sent: Friday, April 18, 2014 1:32 PM
To: INFOCNTR (PHMSA)
Cc: Conroy, Michael (PHMSA); Dillon Bob; Ghani Mazen; HOWIE.GONIA@YAHOO.COM
Subject: FW: Tc99m Activity limit for exempt consignment.

Magdy El-Sibaie
Director of the Office of Hazardous Materials Standards
PHMSA's Office of Hazardous Materials

Dear Mr. El-Sibaie,

I have been in contact with Michael Conroy (Sciences Branch / Division of Engineering and Research / Office of Hazardous Materials Safety)
in regards to an issue which needed expedient clarification, so as to not delay patient care. I realize an official position response can take 6-8 weeks. With his guidance (as shown below with our emails), I believe we do have the clarification necessary and am now requesting the "official position" written interpretation to satisfy administration.

My question to Mr. Conroy and now you, is in regards to the handling, labeling & transport of radioactive surgical specimens. I have done extensive research and been in communication with the MASS DPH/Radiation Control Program, MASS DOT and now the US DOT. If you can confirm the information below, I would appreciate it greatly.

From the information gathered, I am lead to believe:

1.) Radiation safety training for our personnel and couriers, "for handling & transporting" Tc99 radioactive surgical specimens can be provided in-house by our medical physicist.

Note: (Specimens will have an activity of 1.0millicuries or less, at the time of injection, there is some residual in the syringe that is not fully injected. There will be less than .27millicuries by the time the driver would handle the container.)

2.) for radiation & transportation purposes, radioactive surgical specimens containing Tc99m, can be transported from one RAM licensed facility to another licensed facility as stated in the licenses.

3.) the specimens must be labeled with a radioactive material label UNTIL the less than .27 millicures activity limit is met for "exemption".

4.) when the specimen reaches the "activity limit for exempt consignment" , in this case Tc99m, less than .27millicuries, in accordance with 49 CFR 173.436, there is NO requirement for radioactive labeling,

5.) NOR is there a requirement for DOT HAZMAT training for "exempt consignment" material for personnel handling, packing or transporting.

6.) FYI: Until the "less than .27mCi activity" is confirmed, the specimens will be securely stored in a leaded "transport container" in the Nuclear Medicine hot lab satisfying the UN2910 less than .5mR/hr at the surface of the container.

Please advise and respond by email at your earliest convenience, as time is a concern for us in providing safe & quality patient care.

Thank you for taking your time to assist me in this matter.

Respectfully submitted,

Debbie

Christina **D**. Cahill CNMT, RT(R)
Lead Technologist
Department of Nuclear Medicine
Fairview Hospital
29 Lewis Avenue
Great Barrington, MA 01230

Phone: (413) 854-9757
FAX: (4134) 854-9794

dcahill@bhs1.org

REFERENCE EMAILS WITH MR. CONROY:

From: Cahill Christina (Debbie)
Sent: Friday, April 18, 2014 10:59 AM
To: 'Michael.Conroy@dot.gov'
Cc: Dillon Bob; Ghani Mazen; HOWIE.GONIA@YAHOO.COM
Subject: RE: Tc99m Activity limit for exempt consignment.

Dear Mr. Conroy,

I appreciate your prompt response to this matter and have submitted a "written interpretation" request.

RE: Figure 2: UN2910 is for "transport container" from the OR to NM and storage in the secure hot lab only, until the exempt consignment activity is reached. It will not leave the facility. Nothing but specimens confirmed as "exempt consignment" will be transported via courier, requiring no radioactive labeling or additional HAZMAT training for personnel.

Thank you for your assistance and clarification.

Debbie

From: Michael.Conroy@dot.gov [mailto:Michael.Conroy@dot.gov]
Sent: Thursday, April 17, 2014 5:44 PM
To: Cahill Christina (Debbie)
Subject: RE: Tc99m Activity limit for exempt consignment.

Debbie–

Please note: This is not an official "DOT position." If you wish to obtain an "official position", this should be done by requesting a written interpretation from the Director of the Office of Hazardous Materials Standards, following the directions in 49 CFR 105.20(a)(4).

If I understand your question correctly, you want to know what the DOT requirements are for shipping a specimen that contains less than .27 millicuries of Tc-99m.
You are correct that the "activity limit for exempt consignment" , in this case Tc99m, is less than .27millicuries, in accordance with 49 CFR 173.436.
Please note that the exempt limit is for the "consignment", so if there are multiple specimens in a consignment, you would need to look at your total activity in all of the specimens in the consignment to see if you are still exempt. ("Consignment" means a package or group of packages or load of radioactive material offered by a person for transport in the same shipment.)

If the only radionuclide present is Tc-99m, and if the total activity in the consignment is less than either the activity concentration limit OR the activity limit in the table in 49 CFR 173.436, that consignment would not be considered to be a radioactive material under DOT's Hazardous Materials Regulations (HMR) and no marking, or labeling would be required for transport purposes as radioactive material. (Other non-transportation regulations (e.g., NRC, EPA, OSHA) may apply however.) If that is all you are preparing for shipment, since it is not regulated under the HMR, there would be no training required under the DOT HMR.

I am confused by Figure 2 in one of your attachments that shows a UN2910 label. If you are shipping the exempt quantities you describe, that label would not be proper to use. In addition, that is not a DOT label, but is an ICAO label and would only be needed if you were shipping a non-exempt, excepted package by air (as evidenced by reference to "Captain" at the bottom of the label). If your consignment quantities exceed both the exempt limits cited above, but were less than that required to be shipped in a Type A package, they would only need to be marked with UN 2910 (see 49 CFR 173.422) with no label – you'd add the candy-stripe label for shipping such excepted packages by air.

IF there are other materials in the shipment that are considered hazardous materials under the HMR, you would need to consider how to properly comply with the HMR for those substances, including training. The information you provided indicates that your specimens would be shipped with formalin. Please note, I am NOT the right individual to answer questions on classes other than Class 7, radioactive. If you go to the Hazardous Materials Table in 49 CFR 172.101, you will see an entry for Formalin which will direct you to the entry for Formaldehyde. I am attaching a recent rulemaking that addressed shipping formalin. Also, here is a link to a non-DOT article (I cannot vouch for its accuracy!) that addresses shipments of formalin that you might find useful:
http://www2.mlo-online.com/features/201204/education-and-training/formaldehyde-shipments-avoid-potential-pitfalls-lab-safety.aspx
It indicates that depending on the particulars of your shipments, you might be subject to the HMR, including training requirements.

Additional information on DOT's requirements for radioactive materials transportation may be found at:
http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/RAM_Regulations_Review_12-2008.pdf

Information on DOT training requirements may be found here: http://www.phmsa.dot.gov/hazmat/training/requirements

Let me know if you need any additional information.

Michael Conroy
Sciences Branch / Division of Engineering and Research / Office of Hazardous Materials Safety
Pipeline and Hazardous Materials Safety Administration
U.S. Department of Transportation
East Building, PHH-21
1200 New Jersey Avenue, S.E.
Washington, D.C. 20590-0001
Michael.Conroy@dot.gov
(202) 366-3597

From: Cahill Christina (Debbie) [mailto:ccahill2@bhs1.org]
Sent: Thursday, April 17, 2014 1:07 PM
To: Conroy, Michael (PHMSA)
Cc: HOWIE.GONIA@YAHOO.COM; Dillon Bob
Subject: Tc99m Activity limit for exempt consignment.

Mr. Michael Conroy
US DOT: Radiation Safety

Good afternoon Mr. Conroy,

Per our conversation this morning, I am sending the information in regards to the handling, labeling & transport of radioactive surgical specimens. I have done extensive research and been in communication with the MASS DPH/Radiation Control Program, MASS DOT and now the US DOT. If you can confirm the information below, I would appreciate it greatly. I will additionally inquire with a "Letter of Interpretation" to follow.

From the information gathered, I am lead to believe:

1.) Radiation safety training for our personnel and couriers, "for handling & transporting" Tc99 radioactive surgical specimens can be provided in-house by our medical physicist.

Note: (Specimens will have an activity of 1.0millicuries or less, at the time of injection, there is some residual in the syringe that is not fully injected. There will be less than .27millicuries by the time the driver would handle the container.)

2.) for radiation & transportation purposes, radioactive surgical specimens containing Tc99m, can be transported from one RAM licensed facility to another licensed facility as stated in the licenses.

3.) the specimens must be labeled with a radioactive material label UNTIL the less than .27 millicures activity limit is met for "exemption".

4.) when the specimen reaches the "activity limit for exempt consignment" , in this case Tc99m, less than .27millicuries, in accordance with 49 CFR 173.436, there is NO requirement for radioactive labeling,

5.) NOR is there a requirement for DOT HAZMAT training for "exempt consignment" material for personnel handling, packing or transporting.

Please advise and respond by email at your earliest convenience, as time is a concern for us.

Thank you for taking your time to assist me in this matter of providing quality patient care.