



U.S. Department of Transportation
**Pipeline and Hazardous Materials
Safety Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

SEP 07 2011

Mr. Sean Chapel
President
International Radiation Safety Consulting, Inc.
17 Norfolk Road
Holbrook, MA 02343

Ref. No.: 11-0163

Dear Mr. Chapel:

This responds to your July 12, 2011 letter requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171–180) applicable to the transportation of excepted packages for radioactive instruments and articles. Your questions are paraphrased and answered below.

Q1: You ask whether, under the requirements for excepted packages for radioactive instruments and articles and contamination control (see §§ 173.424(g) and 173.443(a)), a shipper may perform a wipe test on the instrument itself instead of the actual external surface of the package?

A1: Provided certain conditions are met, the answer is yes. As required by § 173.424(g), the non-fixed (removable) radioactive surface contamination on the external surface of the package must meet the requirements specified in § 173.443(a), which has both a quantitative upper limit, and an as-low-as reasonably achievable component. Section 173.443(a) requires that the level of non-fixed radioactive contamination may not exceed the limits set forth in Table 9 of § 173.443.

The shipper must either make one or more package wipe measurements and compare the results against the limits in Table 9, or use another method of equal or greater efficiency. If a shipper utilizes a method which relies on a wipe test on the instrument itself instead of the actual external surface of the package, it is acceptable provided it is of equal or greater efficiency than the methodology in § 173.443(a)(1) and meets compliance.

Q2: You ask whether it would be necessary to wipe test every device to demonstrate compliance, or if a representative sample of devices per lot shipped could be wipe tested? Further, you ask what minimum criteria would constitute a representative sample?

A2: A physical contamination survey on the outside of every package, or a wipe test on every device, is not mandated prior to each shipment. Furthermore, there is no minimum criterion of what would constitute a sample. The contamination limits must be met, and it is the shipper's responsibility to determine the methodology, as permitted by § 173.443(a)(2), to be utilized by its operations while maintaining compliance with the requirements of the HMR. It should be noted that many shippers survey every package because they do not want to assume the increased perceived risk of using an alternate method that might allow a contamination non-compliance issue.

I hope this satisfies your inquiry. Please contact us if we can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "T. Glenn Foster". The signature is written in a cursive style with a long horizontal flourish extending to the right.

T. Glenn Foster
Chief, Regulatory Review and Reinvention Branch
Standards and Rulemaking Division

Nickels
§173.424(g)
§173.443(a)
RAM
11-0163



Successful Device Approvals

July 12, 2011

Jim Williams
Radioactive Materials Branch, PHH-23
Office of Hazardous Materials Technology
Pipeline and Hazardous Materials Safety Administration
U.S. Department of Transportation
1200 New Jersey Ave. SE
East Building, 2nd Floor (PH)
Washington D.C. 20590-0001

Dear Mr. Williams:

This letter is a request for a formal regulatory interpretation of the requirements listed in 49 CFR 173.424(g), which state:

(g) The nonfixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in §173.443(a);

Is it acceptable for the shipper of an instrument containing a radioactive source to perform a wipe test on the instrument itself, as opposed to wiping the actual external surface of the package it is being shipped in, in order to demonstrate compliance with this requirement?

In addition, please confirm if it would be necessary to wipe test every device to demonstrate compliance, or if a representative sample of devices per lot shipped could be wipe tested. If so please confirm what minimum criteria would constitute a representative sample.

17 Norfolk Rd., Holbrook, MA 02343 USA Ph. 877.266.0794 (U.S.)
781.767.2176 (outside U.S.) Fax: 781.207.0453 www.irsc-inc.com

If you have any questions please call me at 781.767.2176 or email me at schapel@irsc-inc.com.

Sincerely,

A handwritten signature in cursive script that reads "Sean C. Chapel". The signature is written in black ink and is positioned below the word "Sincerely,".

Sean C. Chapel
President