

From: William Ward
To: WARBICK CERONE, Ann (Kanata)
Date: 9/7/01 2:01PM
Subject: GammaMed 212 source registration questions

Ms. Cerone,
Mr. Charette,

We are nearing completion of our review of your application for registration of the GammaMed 212 source. As part of the review, we have developed several questions or requests. They are listed below. Please respond to these question via letter, email or fax. Our fax number is (301) 415-5369. If you have any questions concerning these, you may phone me at the number provided below. Thank you very much.

1. In section 7.1, BAM Testing, you stated that BAM tested models in configurations per drawings GM212.03-004, GM212.13-002 and GM212.13-001. However, reading the test results in Appendix G, it appears that both source assemblies tested were only of the configuration per drawing GM212.03-004. Drawings of the GM212.13 series are not mentioned in the BAM testing. Please confirm that BAM tested only models constructed per drawing GM212.03-004 or provide additional information showing the results of testing on other designs. Also, please describe any effect to the design due to raising the maximum source capacity from 10 Ci as stated on GM212.03-004 (tested version) to the 15 Ci stated on GM212.13-010 (application version).
2. In Appendix G, the certificate provided from BAM expired on June 6, 1991. Please provide a copy of the current certificate demonstrating compliance with Special Form requirements.
3. In Appendix G, the temperature test appears to have been to 800 degrees C for 10 minutes. ISO 2919 requires holding the maximum temperature for 1 hour, and a thermal shock test down to 20 degrees C. Additionally, if the 800 degree requirement were met, the source would have rated a '6' for the temperature requirement versus the '5' stated in the certificate. Please describe how the BAM testing demonstrates that the source can be classified as a '5' for the temperature test.
4. In Appendix G, there is no mention of any external pressure testing. However, BAM stated that the source satisfied the rating for a '3' for ISO 2919 classification purposes. Please describe how the BAM testing demonstrates that the source can be classified as a '3' for the external pressure test.
5. In the German version of Appendix G, it appears to state that the minimum detectability of the Helium testing equipment is 10E-4 mbar/sec. In the English translation, it says 10E-10 mbar/sec. Please clarify this apparent transcription error.
6. In section 7.2, you describe tests performed by the French Laboratoire National D'Essais to demonstrate the source assembly's compliance with the ISO 2919 classification of 53211. Copies of the documents provided to you by the French laboratory are provided in Appendix F. In Appendix F, test report file 2080231 - document DEMB/2 references file 2080231-document DEMB/1 as the test report for the ISO 2919 testing. However, you did not provide a copy of the test report DEMB/1. DEMB/2 appears to only be a certification that the source meets the ISO

2919 classification of 53211, whereas DEMB/1 is apparently the test descriptions and results.
Please provide a copy of DEMB/1.

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CC: CHARETTE, Marc-Andre (Kanata)

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