International Isotopes Inc.

November 6, 2009

Mr. Rick Boyle

U.S. Department of Transportation
Office of Hazardous Materials Technology
PHH-23 Radioactive Materials
1200 New Jersey Ave., SE East Building, 2nd Floor
Washington, D.C. 20590-0001

Subject: Revalidation of AUS/2007-13/B(U)-96

Dear Mr. Boyle,

International Isotopes, Inc. (INIS) submitted a request to revalidate the Analogue & Digital Measurements (A&DM) P/L Model 1860A Type B(U) package, certificate number AUS/2007-13/B(U)-96 in March 2008. The application to revalidate the package was subsequently pulled in March 2009 so that actions needed to correct unresolved safety questions could be completed. The US Nuclear Regulatory Commission (NRC) acknowledged the withdrawal of the application in a letter dated April 10, 2009 Docket No. 71-3082. This letter included a six page enclosure detailing the package deficiencies which were categorized as (1) Shielding Deficiencies and (2) Thermal Deficiencies.

The thermal deficiency resulted from a lack of clarity in the model provided to the NRC. To address this deficiency A&DM conducted a thermal test using a source drawer with a 250W heating element at its center and obtaining temperature measurements on the package itself. The test description and conclusions are included in the *Model 1860A Type B(U) Supplementary Safety Analysis Version 1.03*.

The NRC provided a detailed summary of the shielding deficiencies along with six recommended actions. These deficiencies can be categorized as those associated with hypothetical accident conditions and normal conditions of transport.

The deficiency associated with the hypothetical accident condition stems from NRC staff's concern that the source and end cap will not remain in place following an accidental condition, as simulated by the 1-meter drop test onto a steel bar (reference TS-R-1 727(b)) due to shearing of the end cap bolts. A&DM modified the package design by including bolt-on cover plates that cover the 156 mm openings at either end of the crumple shield, thereby preventing a steel bar of sufficient length from impinging onto the end plate if the drop test were conducted at an angle that would allow the steel bar to pass through the crumple shield opening. A&DM has also modified the end caps for configurations B through F by adding a shoulder to the end cap flange such that any side loading is directed onto the flange shoulder thereby minimizing the amount of shear force directed onto the retaining bolts. Further detail is provided in *Model 1860A Type B(U) Supplementary Safety Analysis Version 1.03* and Appendices 9 and 11.

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Deficiencies associated with normal condition of transport were based on maximum Transport Index (T.I.) calculations conducted by NRC staff. The NRC staff concluded that maximum T.I.s calculated using the proposed maximum activity contents for the various package configurations would require exclusive use transport. NRC staff provided a table with revised Co-60 quantity limits for package configurations A through F as well as source drawer specifications that coincided with the NRC modeling assumptions. A&DM has incorporated the lower activity limits and included detailed source drawer configuration drawings into the *Model 1860A Type B(U) Supplementary Safety Analysis Version 1.03* and Appendix 10. Of equal importance is the addition of the cover plate that has been introduced to prevent the steel bar from impinging the end plate should it pass through the 156 mm opening on either end of the crumple shield. Considering this modification along with A&DM's acceptance of reduced activity limits, the actual T.I.s associated with the maximum Co-60 quantity limits prescribed by the NRC are expected to be far below 10.0. If this is demonstrated to be true based on the first use surveys of the various configurations then A&DM and INIS may desire to increase the authorized maximum quantity through a revision of the certificate after it has been revalidated, consistent with the NRC's statement on Page 3 of their previously referenced enclosure. A&DM has also addressed the NRC recommendations regarding the first use procedure and pre-transport operations.

The items addressed in the Supplementary Safety Analysis are summarized in the table below.

Item	Description
1.	Security of the drawer retention in the event of a force applied to the side of the end cap (drop test 727b)
2.	Model1860 Isotope quantity limits
3.	Design & specifications on the compatible source drawers for use with the Model1860
4.	Addition of end cap shield to eliminate possible damage to the end attenuator end cap from (drop test 727b)
5.	Measurement of the transport index from the end cap
6.	Addition of pre and post transport inspection instructions
7.	Perform temperature rise test to confirm calculations

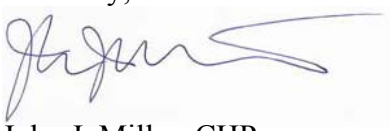
While A&DM has been in discussions the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) regarding the package enhancements necessary to obtain revalidation of the Model 1860 by the US Competent Authority, the Australian Certificates of Competent Authority have not yet been revised to reflect these modifications. We do recognize that US revalidation will not be issued unless the Australian Certificates of Competent Authority reflect the design changes that address the unresolved safety questions. However it is our desire to proceed with the US review for revalidation in parallel with ARPANSA's review to revise the certificates.

To support the re-submittal of the Model 1860 Type B(U) package the following documents are included in electronic format with this letter.

File Name	Description
Model1860_SSAR1.03.pdf	Model 1860A Type B(U) Supplementary Safety Analysis Version 1.03
A1_ Model1860.pdf	Appendix 1 – Maintenance and Inspection Manual
A2_ Model1860.pdf	Appendix 2 – Engineering Training Manual
A3_ Model1860.pdf	Appendix 3 – Emergency Response Plan
A4_5_6 Model1860.pdf	Appendices 4, 5, & 6 – Use checklists and survey form
A7_ Model1860.pdf	Appendix 7 – Drop Test Schematics
A8_ Model1860.pdf	Appendix 8 – Competent Authority Certificates (AU & RUS)
A9_ Model1860.pdf	Appendix 9 – Drawings - End Cap Configurations
A10_ Model1860.pdf	Appendix 10 – Drawings – Source Drawer Configurations
A11_ Model1860.pdf	Appendix 11 – Drawings – Crumple Shield & Cover Plate
A12_ 14_Model1860.pdf	Appendix 12_14 – Thermal test heater sketch, photos, and temperature charts. (Note there is no Appendix 13)
A15_ Model1860.pdf	Appendix 15 – Welding qualifications and certificates
A16_ Model1860.pdf	Appendix 16 – Updated drawings with US weld protocols
A17_ Model1860.pdf	Appendix 17 – Updated Construction Manual, Configuration C
A18_ Model1860.pdf	Appendix 18 – Updated Drawings, general layout all configurations
A19_ Model1860.pdf	Appendix 19 – Source transfer procedures, upload and download
A20_ Model1860.pdf	Appendix 20 – NRC letter Docket No. 71-3082, April 10, 2009
ADM _ARPANSA_Ltr.pdf	A&DM Cover Letter requesting revision of AUS/2007-13B(U)-96

We are looking forward to the completion of the revalidation effort so that we may include the A&DM Model 1860 Type B(U) package. Should you have any questions, please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com

Sincerely,



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cc

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