August 2, 2002

Mr. Marc-André Charette
Regulatory Affairs Senior Associate
MDS Nordion
447 March Road
Ottawa, Ontario
Canada, K2K 1X8

SUBJECT: REQUEST FOR CLARIFICATION OF THE INFORMATION IN THE APPLICATION FOR A CERTIFICATE FOR THE C-168 SOURCE

Dear Mr. Charette:

We have reviewed your request, dated June 8, 2001, to reactivate and update the C-168 sealed source registration certificate and the additional information you provided on December 14, 2001. In reviewing the correspondence, we find that sufficient information is still not available to reach a decision. Therefore, we request that you address the issues outlined in the attached Enclosure.

Please refer to NRC's NUREG-1556, Volume 3, for additional information regarding the type of information that would fully address these items. NUREG-1556, Volume 3, can be found on NRC's website (www.nrc.gov).

Please submit the requested information within thirty days of the date of this letter and be certain to address all the areas of concern cited herein. If you have any questions, please contact me at (301) 415-7038.

Sincerely,

/RA/

William R. Ward, P.E.
Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

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Distribution: SSD case # 02-05 ADAMS case folder NR-0220-S-125-S
Accession number: ML022120659

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Additional questions for the MDS Nordion C-168 source application (SSD case # 02-05)

1 In your summary data page you checked that this source was to be used by both specific and general licensees. However, due to the curie content and single encapsulation design of the source, we will only authorize it for specific licensees. This would not preclude the sale of the source to manufacturers of generally licensed devices for use in those devices since the manufacturers of the devices are specific licensees. Also, this source would not be authorized for use in well-logging or irradiators other than category I. Is this acceptable?

2 The drawings provided in your December 2001 response do not include tolerances on the various parameters. Please provide tolerances.

3 Please provide a copy of your current ISO 9001 certificate for the Quality Assurance program which applies to the production of C-168 sources.

4 How and when do you certify the isotope and activity prior to distribution?

5 For the prototype testing, you stated that you tested two 0.50 inch length prototypes and two 0.91 'extended' length prototypes, which were selected to validate the helium leak testing of the welds. Based on my calculations (see table below), the internal void volume of any of your prototypes is less than 0.10 ml. The requirement in ANSI N43.6-1997, Appendix A, section A.1 is that there should be at least 0.1 ml of free volume to use any of the tests listed in section A2, otherwise you are restricted to the tests of section A2.1 which require active sources. However, you used inactive pellets for your testing, therefore the tests of section A2.1 would not be valid either. Please justify your choices of leak tests used to confirm the validity of the prototype testing.

Table of calculated void volumes for C-168 prototype tests

	inches/in^3	mm/ml	inches/in^3	mm/ml	inches/in^3	mm/ml	inches/in^3	mm/ml
Capsule length	**.50**	12.70	**.50**	12.70	**.50**	12.70	**.91**	23.11
Capsule depth	**.35**	8.89	**.35**	8.89	**.35**	8.89	.76	19.30
Capsule ID	.075	1.91	.061	1.55	.075	1.91	.075	1.91
Capsule volume	1.55e-03	2.53e-02	1.02e-03	1.68e-02	1.55e-03	2.53e-02	3.36e-03	5.50e-02
Plug depth	**.27**	6.86	**.27**	6.86	**.27**	6.86	**.27**	6.86
Plug OD	**.061**	1.55	**.061**	1.55	.075	1.91	.075	1.91
Plug volume	7.89e-04	1.29e-02	7.89e-04	1.29e-02	1.19e-03	1.95e-02	1.19e-03	1.95e-02
Pellet depth	0.0394	**1.00**	0.0394	**1.00**	0.0394	**1.00**	0.0394	**1.00**
Pellet OD	0.0394	**1.00**	0.0394	**1.00**	0.0394	**1.00**	0.0394	**1.00**
Pellet volume (x2)	9.59e-05	7.85e-04	9.59e-05	7.85e-04	9.59e-05	7.85e-04	9.59e-05	7.85e-04
void volume	6.61e-04	1.16e-02	1.38e-04	3.05e-03	2.58e-04	5.01e-03	2.07e-03	3.47e-02
threshold (.10 ml)	6.10e-03	1.00e-01	6.10e-03	1.00e-01	6.10e-03	1.00e-01	6.10e-03	1.00e-01
void volume fraction of threshold	10.8%	11.6%	2.3%	3.0%	4.2%	5.0%	33.9%	34.7%
above .10 ml threshold	No	No	No	No	No	No	No	No

Additional questions for the MDS Nordion C-168 source application
(SSD case # 02-05)

6 Paragraph A.2.2.7 of ANSI/HPS 43.6-1997 states that the liquid nitrogen-alcohol bubble test is only for sources having high decay heat. You used inactive pellets. This was identified in our first set of questions dated November 20, 2001. In your response dated December 14, 2001, you did not adequately explain how this test could be used with an inactive pellet. Since the inactive pellet does not generate heat, it could not be expected to generate the gas the test expects. Please explain how this test can be used with inactive pellets.

7 In the TESTING OF PROTOTYPES section, page 3, you state that one test capsule, number 0007, "had a degraded surface condition that resulted in an inconclusive helium leak test." Additionally, in the CAPSULE TESTING WORK SHEET for the temperature test, you stated that the helium leak test "results were inconclusive see appendix B." In your response dated December 14, 2001, you provided additional information on the degraded surface condition which stated that the condition resulted in inconclusive helium leak test results. As a result, the Liquid Nitrogen-Alcohol Bubble test was used to qualify these capsule. However, per question 6 above, this test is also inconclusive. Please provide test data that clearly establishes the integrity and protective capability of the source containment boundary.