

71-9215

NEUTRON PRODUCTS inc

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September 5, 2002

Mr. E. William Brach,
Director
Spent Fuel Project Office
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Two White Flint North
11545 Rockville Pike
Rockville, MD 20555

Re: Renewal of Certificate of Compliance USA/9215/B(U) without any changes to the package

Dear Mr. Brach:

This is to request that Neutron's Certificate of Compliance USA/9215/B(U) be:

- renewed without any changes in the package for the maximum period; and,
- amended to reflect its compliance with the 1985 revision of the IAEA Safety Series No. 6 or Regulations for the Safe Transport of Radioactive Materials, TS-R-1, whichever is the latest applicable regulation.

It is our understanding that the NRC has not made a final determination on establishing harmonization with TS-R-1, and, as a result, it may be inappropriate for us to ask for the Certificate to reference TS-R-1. However, as use of the 9215 package is limited to the shipment of Special Form cobalt-60 sources, there are no significant changes between the 1973 and 1985 revisions of the IAEA Safety Series No. 6 and the Regulations for the Safe Transport of Radioactive Materials, TS-R-1. Accordingly, we submit that the 9215 package meets the requirements specified in all of them. However, if it is not appropriate for the NRC to reference TS-R-1 on the Certificate, we would appreciate if the 1985 standard were referenced on the Certificate, and we will apply for an upgrade to TS-R-1 after the NRC adopts it, if it ultimately decides to do so.

We calculate that there have been more than 3,000 shipments in the 9215 package to and from

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Mr. E. William Brach, USNRC
Renewal of Certificate of Compliance USA/9215/B(U)
September 5, 2002
Page 2 of 6

forty-seven (47) states and four (4) continents without any adverse incidents. We know of no technical reason why our request should not be granted.

The referenced Certificate is Neutron's only type B(U) package for the export of our cobalt-60 teletherapy sources and the return of the expended sources and is essential for our continuing to service the worldwide radiation therapy community for the treatment of cancer. An inability to continue the use of this package would cause potential irreparable harm to our business and would serve to remove an effective competitor from the world market and would predictably increase the cost of cancer treatment and the number of patients who would not be treated at all.

We would appreciate your most timely renewal to allow for the review period required by the Department of Transportation for the issuance of a Certificate of Competent Authority.

To facilitate your review, we have attached:

- corrections that have been made in the previous submittal in ATTACHMENT 1; and,
- the background of Neutron's shipment of cobalt-60 teletherapy sources in ATTACHMENT 2.

We have also attached the following:

1. Drawing 240116, Revision F
2. Drawing 240122, Revision H, Sheet 1 of 2 (hereinafter referred to simply as "SHEET 1") and Sheet 2 of 2 (hereinafter referred to simply as "SHEET 2")
3. Operating Procedures R-2014, Rev 6; and R-2019, Rev 1

Thank you for your attention to this request, and we look forward to your response. If you have any questions or require additional information, please call me.

Sincerely,

Neutron Products inc

Pamela Burda for

Marvin M. Turkanis
Vice President

TAC #'s
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ATTACHMENT 1
List of Corrections

This document lists the corrections and/or minor changes in our prior submittal, and accompanies and is a part of Neutron Products inc's letter to the USNRC dated September 5, 2002, requesting that our Certificate of Compliance USA/9215/B(U) be amended and renewed.

- 1.1 The drawings have been converted to CAD drawings. In the process, they were updated to be consistent with current drafting practices. In addition, they were changed from N size drawings to E size drawings.
- 1.2 The package lifting bale has been added to SHEET 1 of Drawing 240122, Revision H, and the drawing on which it was previously depicted, Drawing A 240012, has been obsoleted and should be withdrawn from the information supporting this Certificate.
- 1.3 Both of the end caps shown on SHEET 1 have the same handle, which is shown as having an opening under the handle of 4 inches. However, the opening under the handle in previous revision appears to be 5 inches, if measured with a scale. SHEET 1 was modified to actually measure 4 inches, which is consistent with the dimension shown.
- 1.4 The weld specification for the 6 inch diameter, threaded plug on the bottom of the teletherapy cask was added to SHEET 1.
- 1.5 A second end view of the square drawer drum was added to Drawing 240122, Revision H (hereinafter referred to as SHEET 2), whereas the previous revision only depicted one end view.
- 1.6 The section views in SHEET 2 were converted to full sections and the hidden lines removed, which is only a stylistic change.
- 1.7 On item 2, SHEET 2, minor dimensional corrections were made. For example, the dimensions for the overall length of the square drawer drum were modified to add tolerances to be consistent with the drawings for the round drawer drums (item 5 on SHEET 1 and item 4, SHEET 2).
- 1.8 Another 5/8 inch nut was added on the top of the threaded rod depicted in View D, Drawing 240116. In the previous revision, the 5/8 inch nut holding the wood together was shown, but the 5/8 inch nut on top of the lid was not.
- 1.9 The Grade 5 specification was added the 1/2 inch nut and cap screw depicted in Partial Section A-A of Drawing 240116.

NEUTRON PRODUCTS inc

Mr. E. William Brach, USNRC
Renewal of Certificate of Compliance USA/9215/B(U)
September 5, 2002
Page 4 of 6

- 1.10 The number of vent holes in the steel sheet (Item 2, Drawing 240116) was corrected to show 3 holes, which is the number specified for the DOT 20WC package and the number in Neutron's steel shell.
- 1.11 The description of the permanent label described in Drawing 240116 was changed to refer to Proper Shipping Names and UN numbers instead of specifying the specific applicable Proper Shipping Names and UN numbers to allow the package permanent marking to be in compliance with the current and future IAEA, IATA and IMDG requirements without an amendment to the CoC per note 1.

The above corrections do not involve changes to the package and have been reviewed before this submission, in accordance with our Quality Assurance requirements.

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ATTACHMENT 2
Background of Neutron's Teletherapy Shipping Packages

Prior Licensing Activities

CoC USA/9215/B(U) is the third generation of shipping packages used by Neutron to ship teletherapy sources and to exchange, install and remove teletherapy sources involving teletherapy units manufactured by Atomic Energy of Canada, Ltd./ Theratronics/MDS Nordion, Picker/AMS/ATC, Keleket-Barnes, Westinghouse, TEM Instruments, Ltd., Philips, Siemens, Toshiba and CIS-bio.

1. Initially, Neutron shipped its teletherapy sources in packages which conformed to the USDOT 20WC-6 specification and subsequently shipped them internationally in packages authorized by Certificate of Competent Authority USA/5800/B. Although these authorizations limited the activity per package to 100 thermal watts (approximately 6300 curies), they did not limit Neutron's use since many of the teletherapy units of the era had maximum capacities of less than 6300 curies, as did most of the teletherapy sources purchased.
2. In 1977, Neutron applied for and was granted authorization for our CoC 9102 shipping package with an activity limit of 9,500 curies of cobalt-60, or a maximum decay heat of 150 watts, in response to the growing number of teletherapy units having a maximum capacity of 9000 curies.
3. In 1986, Neutron applied for and was granted authorization for our CoC and CoCA 9215 package with an authorized limit of 15,000 curies of cobalt-60 or a maximum decay heat of 240 watts for the round drawer drum, in response to many teletherapy units having a maximum capacity of 15,000 curies that would utilize this drum.

Regarding CoC 9215, the initial application, dated August 5, 1986, the consolidated application for renewal, dated October 29, 1992 and our request dated November 17, 1993, provided for several alternative configurations of the cask internals, specifically the drum assemblies, which are needed to match the range of source holders for the teletherapy units in which the sources are to be exchanged, installed and removed.

Source Holder/Drawers

Teletherapy sources are shipped in the through-holes of the drum assemblies. An outgoing shipment utilizing a drum with three holes (round drum drawer) normally contains one or two sources, whereas an incoming shipment may contain sources in all three holes. Each source is loaded into a holder or drawer that is positioned in the cask so that the source is near the axial

NEUTRON PRODUCTS inc

Mr. E. William Brach, USNRC
Renewal of Certificate of Compliance USA/9215/B(U)
September 5, 2002
Page 6 of 6

midpoint of the drum assembly during shipment.

At a hospital or clinic, the cask is mated with the teletherapy machine to effect the source transfer.

The source holders are specific to and are an inherent part of the teletherapy unit, and, as such, are evaluated and approved as part of the authorization for the sale of the unit. They are fabricated from one or more of the following materials: steel, depleted uranium, tungsten, brass and/or lead which is encapsulated by welding in steel. After loading the source holder(s) and drawer(s), the remaining lateral space in the through-holes, including holes that do not contain sources, is filled with full diameter spacers and/or plugs fabricated from steel, tungsten, or lead in welded steel capsules to restrict the lateral movement to less than 0.25 inches.

Containment of the Sources During Transport

The primary containment of the cobalt-60 source is the source capsule, which meets the requirements for Special Form radioactive material, and consists of two concentric stainless steel capsules with welded closures. For containment, the source capsule design has been tested under conditions specified by ANSI N43.6-1996 "Sealed Radiation Sources, Classification 96E53524," which are more stringent than those required by Special Form requirements. The specific requirements of this classification are:

Temperature: - 40°C (20 min), + 600°C (1hr) and thermal shock 600°C to 20°C.
External Pressure: 25 kn/m² to 2 MN/m²
Impact: 5 kg (11 lbs) from 1 m.
Vibration: 30 min. 25 to 500 HZ at 5g peak amp.
Puncture: 50 g (1.76 oz.) from 1 meter

Secondary containment of the source(s) is provided by the following components of the shipping/transfer cask: the cylindrical shell of the through-cavity, the spherical shell of the cask, the flanges at the ends of the cask cavity, and the two bolted-on cover plate assemblies. As long as this secondary containment remains intact, the source(s) in the cask are surrounded by solid metal and cannot move any significant distance.

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