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United States Nuclear Regulatory Commission
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Dear Ms. Sampson:

J.L. Shepherd and Associates (JLS&A) is considering applying to the US Nuclear Regulatory Commission (NRC) as a registered user for Certificate of Compliance (CoC) USA/9215/B(U), Revision Number 13, issued to Neutron Products (NPI), Inc., 223012 Mt. Ephraim Road, Dickerson, MD for the Package Model NPI-20WC6 Mk II. NPI interprets the CoC to permit shipment of pencil-type Cobalt-60 and Cesium-137 sources used in JLS&A irradiators, as well as the point sources used in the teletherapy devices for which the CoC was initially issued, and has so represented to JLS&A. For reasons stated below, JLS&A has concerns about relying on NPI's interpretation, but cannot say that NPI is incorrect, given potential ambiguities in the terms of the CoC and potential inconsistencies between the CoC and its underlying documentation. Because of its desire to comply with NRC requirements and its desire to avoid noncompliances, JLS&A requests the assistance of the NRC Staff in construing the terms of CoC 9215 as applied to pencil-type sources.

NPI's June 7, 2013 email (attached) represents that this package permits shipment of pencil type sources (seemingly without restriction) in addition to teletherapy sources:

> "As we have discussed previously, the NRC has consistently taken the position that the controlling language was that contained in the "Contents" section of the certificate, which requires the sources to meet the requirements of special form, but does not restrict them to teletherapy. This is consistent with the SER from a previous renewal which described their evaluation of the use of the package with "pencil sources"."

Based upon our ADAMS research of this CoC, JLS&A is concerned that there are configuration and control issues that could make verbatim compliance with the CoC impossible in use of this package for shipments of JLS&A pencil type sources. This concern is based on the CoC's basis documents (both Safety Analysis and Safety Evaluation Reports) that we have found on ADAMS. Historically this CoC appears to have been limited to the shipment of a single

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teletherapy type source in a drawer configuration, with three drawers, maximum, permitted per inner cask. In 2010, with CoC Revision 10, Cesium-137 sources (maximum 600 Curies) were added, provided they were in configurations already specified in the CoC. Revision 12 increased the maximum Curies of Cs-137 from 600 Curies to 20,600 Curies.

This letter presents JLS&A's concerns to the NRC and asks the NRC for a determination concerning specific source types, configurations and numbers of sources permitted for use by CoC 9215 prior to requesting registered user status.

JLS&A Concerns: Can various Cobalt-60 and Cesium-137 pencil type source capsules be shipped in this CoC and can pencil type source capsules be shipped without source holders in this CoC?

JLS&A understands the importance of verbatim compliance with a CoC, both with the language of CoC itself and with information contained within Safety Analysis and Safety Evaluation Reports. JLS&A is concerned that the sealed source types shipped in CoC 9215 (teletherapy point sources versus irradiator pencil sources) could present configuration and control issues. Our ADAMS research of both Safety Analysis (SARs) and Safety Evaluation (SERs) Reports seems to indicate that the safety analysis underlying CoC 9215 is focused on sealed sources configured in shielded drawers that are used in teletherapy device applications, but does not seem to address the multiple configurations of pencil-type sources . This is potentially significant since the differences between teletherapy and pencil type sources are distinctive, including dimensions and uses.

NUREG-1556, Vol. 3, Rev.1, *Consolidated Guidance About Materials Licenses, Applications for Sealed Source and Device Evaluation and Registration*, describes these differences. JLS&A pencil type sources meet the following Principal Use Codes:

> J. Gamma Irradiation, Category I: "An irradiation in which the sealed source is completely contained in a dry container constructed of solid materials, the sealed source is shielded at all times, and human access to the sealed source and the volumes undergoing irradiation is not physically possible because of the design of the irradiator." and
>
> K. Gamma Irradiation, Category II: "A controlled human access irradiation in which the sealed source is contained in a dry container constructed of solid materials, is fully shielded when not in use, and is exposed within a radiation volume that is maintained inaccessible during use by an entry control system."

Teletherapy sources, by contrast, meet the Principal Use Code for AD Photon-emitting Teletherapy Unit, "For use in photon-emitting teletherapy units in accordance with 10CFR35.600, or equivalent Agreement State regulations."

Not only are the principal use codes different; the sealed sources themselves are of different sizes and configurations, designed to meet the intended applications. JLS&A Category I and II Irradiator or pencil type sources may not fit into the source holders referenced in the SARs and SERs that fit into the drum assemblies as referenced in CoC 9215. Medical teletherapy sources

are point sources with generally similar dimensions to fit into an international source holder that is inset into a teletherapy unit shielded drawer. The international teletherapy capsule is typically 1.260" diameter (max.) x 1.65" long (max.), placed in shielded holders or drawers that fit into the inner container drum assemblies referenced in the CoC. Typical sketches from NPI's October 29, 1992 Consolidated Application for renewal of Certificate of Compliance No. 9215, including NPI's Sealed Source and Device Registry MD474A109S for a Medical Teletherapy Source (point sources) are attached for descriptive purposes. JLS&A has also added Sealed Source and Device Registry CA0598S128S for a JLS&A Gamma Source - Medical Teletherapy (point source) and Atomic Energy of Canada Limited (AECL) and MDS Nordion information for collaboration on teletherapy source designs. The CoC itself only references sources contained in drum assemblies. The SARs and SERs are where source holder information that is contained in the drum assembly can be found. JLS&A Category I and II irradiator and calibrator sources are stand-alone line or pencil type sources, of an entirely dissimilar configuration. They are not contained or fixed in a source holder or drawer; i.e., J Gamma Irradiation, Category I sources range from 11/16" (or less) diameter x 1/2" to 15-1/2" long and K Gamma Irradiation, Category II sources range from 11/16" to 1.5" diameter by 1" to 15-1/5" long. Typical sketches from the Sealed Source and Device Registry CA0598S128S are attached for descriptive purposes.

On the face of it, the language of CoC 9215 seems simple. Its contents, as found in ¶ 5.(b) (1) (i) and (ii), permits the shipment of Cobalt-60 and Cesium-137 as sealed sources which meet the requirement of special form radioactive material. There is no restriction to what types of Cobalt-60 or Cesium-137 sources can be shipped within the CoC itself. However, ¶ 5.(b)(2), (i), (ii) and (ii), ¶ 6.(b) and ¶ 7 seem to add restrictions to the contents. The supporting documentation (SARs and SERs) referenced below, seems to restrict the authorized contents of this CoC to Cobalt-60 teletherapy type point sources and to Cesium-137 teletherapy type point sources or small length pencil type sources.

JLS&A is concerned that for Cobalt-60, only teletherapy type point sources may be shipped in this CoC and has found no amendments to the COC or other ADAMS references that would permit a different source and source holder configuration permitted in the inner container drum assembly. Please consider NPI's Consolidated Application for Renewal of COC Number 9215, dated October 29, 1992, Figure 2.1.1 for a descriptive sketch and Figures 3.1 and 4.2 for a typical teletherapy source capsule as described in Chapter 4. Chapter 5, Shielding Evaluation of this consolidated application, only describes a point source analysis. Figure 5.4.2.1. Detail of International Capsule Positioning Within Inner Container Drum was withheld, but referenced Figure 4.3 (attached) shows a point source placed at the center of the inner container. A teletherapy source capsule is 1.260" diameter (max.) x 1.65" long (max.). Chapter 2, Structural Evaluation, 2.8 Special Form, states: "A typical teletherapy source capsule is described in Chapter 4 on containment and shown in Figures 4.1 and 4.2." Chapter 2, Structural Evaluation, 2.10.7 Limiting Loadings, A. Source Capsule Loading, states: "Teletherapy sources, while having generally similar configurations, are made to various component dimensions. Figure 4.1 in Chapter 4 shows the construction of a typical medical therapy source." A JLS&A pencil type source capsule can be as long as 15-1/2" and is not contained in the type of holder described. CoC 9215, Revisions 10, 11, 12 and 13 do not address the addition of Cobalt-60 pencil type sources.

JLS&A is also concerned that for Cesium-137, only teletherapy point or small length pencil sources in source holders may be shipped. Please consider NRC's SER, dated May 13, 2010, Docket No. 71-9215 Model No. NPI-20WC-6 MkII Package, CoC 9215, Revision No. 10, amended to add 600 Curies Cesium-137, where NRC staff performed dose rate calculations for shielded and unshielded Cesium-137 and Cobalt-60 point sources with additional calculations performed for a 600 Curie Cesium-137 line source to represent a pencil source. The diameter and length of the line or pencil source were not included in the SER. The Shielding Evaluation of this SER permits 600 Curies of Cesium-137 to be shipped, "provided it is in the configurations specified in the CoC Rev. 9, Sections 5(b)(2)(i) and (ii); and provided that the applicant uses at least 2 inches of Lead or Tungsten, or 3 inches of steel as axial shielding material in the drum assembly. ... The shielding material may be part of the plugs and spacers or part of the source drawer, but must be inserted between the source and the S/TC cover." The Cesium-137 source configuration is not shown in the SAR, so it is not possible to determine the permitted configuration.

JLS&A Concern – Can more than one source capsule be shipped per drum assembly cavity insert in this CoC?

CoC 9215 lists the maximum Curies or wattage of Cobalt-60 and Cesium-137 that may be shipped. The CoC itself does not list the maximum number of sources that can be shipped in each hole of the drum assembly chamber. JLS&A is concerned that only one source may be shipped in each hole in the drum assembly, with a maximum of one, two or three sources depending on the drum assembly type per package, as the SARs and SERs referenced below seem to indicate. Please consider NPI's Consolidated Application for Renewal of COC Number 9215, dated October 29, 1992, 2, Structural Evaluation, 2.1 Structural Design, 2.1.1 Discussion which states: "Figure 2.1.2 is a vertical section of the S/TC inner container with the structural components identified. Depending upon the type of teletherapy machine for which the source is being supplied, the source holder either fills an entire Drum Assembly chamber or is centered by the shield plugs as shown in Figure 2.1.2. Drum Assembly chambers not carrying a source are loaded with full length shield plugs." Chapter 5, Shielding Evaluation, 5.1 Discussion and Results, states: "The cobalt-60 source is normally loaded into a holder or drawer, either horizontally or vertically, which is specifically designed to fit a particular model teletherapy unit." Chapter 5, Figure 5.4.2.1, Detail of International Capsule Positioning Within Inner Container Drum, was withheld from ADAMS, so the most likely source of the most specific information is not accessible. NPI's November 17, 1993 request for approval to utilize alternate cask internals states: "Teletherapy sources are shipped in the through-holes of a drum assembly. A shipment utilizing a drum with three holes normally contains one or two sources, and a shipment utilizing a drum with two holes normally contains one source. Each source is loaded into a holder or drawer that positions the source near the axial midpoint of the drum assembly during shipment and that mates with the teletherapy machine at a hospital or clinic to effect the source transfer."

JLS&A references as found on ADAMS follow.

Reference: CoC 9215, Rev. 13,

¶ 5.(b) Contents, (2) Maximum quantity of material per package,

"(i) For contents described in 5(b)(1)(i) and 5(b)(1)(ii):
For sources contained within drum assembly shown as Item 5 on Neutron Products, Inc., Drawing No. 240122, Sheet 1 of 2, Rev. H:
For contents described in 5(b)(1)(i): Maximum activity not to exceed 15,000 curies, maximum decay heat not to exceed 240 watts.
For contents described in 5(b)(1)(ii): Maximum activity not to exceed 20,600 curies, maximum decay heat not to exceed 97 watts."
(ii) For contents described in 5(b)(1)(i) and 5(b)(1)(ii):
For sources contained within drum assembly shown as Item 4 on Neutron Products, Inc., Drawing No. 240122, Sheet 2 of 2, Rev. H:
For contents described in 5(b)(1)(i): Maximum activity not to exceed 9,500 curies, maximum decay heat not to exceed 150 watts.
For contents described in 5(b)(1)(ii): Maximum activity not to exceed 20,600 curies, maximum decay heat not to exceed 97 watts.
(iii) For contents described in 5(b)(1)(i) and 5(b)(1)(ii):
For sources contained within drum assembly shown as Item 2 on Neutron Products, Inc., Drawing No. 240122, Sheet 2 of 2, Rev. H: Maximum activity not to exceed 6,300 curies, maximum decay heat not to exceed 100 watts.
For contents described in 5(b)(1)(ii): Maximum activity not to exceed 20,600 curies, maximum decay heat not to exceed 97 watts.

6. "In addition to the requirements of Subpart G of 10 CFR Part 71:
(b) The package shall be prepared for shipment and operated in accordance with Unloading and Loading Procedure for USA/9215/(B(U) Package Procedure R-2014-G, Revision 2, provided in the supplement dated March 29, 2013. .[1]". R-2014-G, Section 2 Scope, ¶ 2.2 now states "Transferring radioactive sources between transfer cask and a therapy or irradiation unit is within the scope of the licensee's operating license and is not covered under this procedure." [2]

7. "The contents must be secured in the drum assembly so as to restrict movement in any direction to less than 0.25 inch, by lead, steel, or tungsten full diameter plugs and spacers."

Reference: October 29, 1992, NPI Consolidated Application for Renewal of COC Number 9215 for the Model NPI-20WC6 MkII Shipping Package, supplementing the initial application for renewal, dated September 14, 1992, and providing information in the form requested by the NRC's letter of October 9, 1992. Teletherapy Source, Source Holder and Drum assembly references in this consolidated application follow.

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[1] Previous Revisions of this Procedure were titled Teletherapy Shipping/Transfer Cask Unloading and Loading Procedures From R-2014, Revision 5 dated September 15, 1992 through R-2014-G, Revision 1.

[2] R-2014-G, Revision 1, and previous versions of this Procedure, state: "Transferring sources between a TC and a unit that utilizes the teletherapy sources is within the scope of Neutron Products' radioactive materials license MD-31-025-03 and is not within the scope of this procedure." Radioactive Materials license MD-31-025-03 has been terminated, per the November 22, 2002, NRC Information Notice 2002-33: Notification of Permanent Injunction Against Neutron Products Inc. of Dickerson, MD (attached).

1.2 Package Description, 1.2.1 Packaging.

¶ 1 "The inner container serves as a transfer cask to mate with and exchange cobalt-60 sources with teletherapy devices, as well as providing a shielding and containment function during shipment."

¶ 2 "Figure 2.1.1 is a section drawing of the package showing the S/TC inner container in place and the principal structural components."

¶ 3 "The S/TC shielded inner container consists of a 3/8 inch thick spherical shell ...containing a chambered, shielded Drum Assembly, held in place by two Cover Assemblies. ... The cavity within the cylinder houses the chambered source positioning Drum Assembly."

¶ 4 "The Drum Assembly chambers carry the source holders, which may vary from one model of teletherapy machine to another. The Drum Assembly is removable and can be interchanged with another to provide for the different design of source holders. During shipment, the chambers, or section of chambers, that are not filled with source holders, are fitted with full diameter, steel encased lead or tungsten plugs and spacers, which restrict movement to less than 0.25 inches laterally and 0.1 inches radially. The Drum Assembly, source holders, and plugs are secured in the container by shielded Cover Assemblies bolted to the Shell Assembly at both ends of the Drum Assembly containing cylinder."

2. Structural Evaluation. 2.1 Structural Design. 2.1.1 Discussion.

¶ 3 "Figure 2.1.2 is a vertical section of the S/TC inner container with the structural components identified. Depending upon the type of teletherapy machine for which the source is being supplied, the source holder either fills an entire Drum Assembly chamber or is centered by the shield plugs as shown in Figure 2.1.2. Drum Assembly chambers not carrying a source are loaded with full length shield plugs."

2. Structural Evaluation. 2.8 Special Form.

¶ 1. The radioactive sources intended for transport in the present package meet the requirements of special form material as specified in 10 CFR 71.75, as well as corresponding U.S. Department of Transportation and International Atomic Energy Agency documents, as applicable, and are appropriately certified. A typical teletherapy source capsule is described in Chapter 4 on containment and shown in Figures 4.1 and 4.2."

2. Structural Evaluation. 2.10.7 Limiting Loadings.

¶ 1 "A. Source Capsule Loading. "Teletherapy sources, while having generally similar configurations, are made to various component dimensions. Figure 4.1 in Chapter 4 shows the construction of a typical medical therapy source. The following sketch is a

representation selected for calculation as developing a more severe inertial loading than most. The double wall has been combined into one to simplify calculations."

Figure 4.1. Medical Teletherapy Source. Diagram from Registry of Radioactive Sealed Sources and Devices, Safety Evaluation of Sealed Sources, No. MD 474S109S. NPI's NPT T-Series Cobalt-60 Medical Teletherapy source.

Figure 4.2. Teletherapy Source. Shows assembly sketch of a teletherapy source.

FIG. 5.4.2.1. Detail of International Capsule Positioning Within Inner Container Drum. (REF. FIG. 4..3). Drawing withheld.

5. Shielding Evaluation. 5.1 Discussion and Results.

¶ 2 "The shielding can be considered comprising three parts: the source holder, the drum into which the source holder fits, and the lead filled, Steel Shell assembly and covers."

¶ 3 "The cobalt-60 source is normally loaded into a holder or drawer, either horizontally or vertically, which is specifically designed to fit a particular model teletherapy unit. The holder or drawer is fabricated of one or more of the following shielding materials: steel, depleted uranium, tungsten, lead, or brass. The remaining space in the Drum Assembly chambers is filled with shielding fabricated of steel, tungsten, and/or lead of a dimension to provide the specified clearance tolerance during shipment. Thus, the Drum Assembly chambers are filled with shielding that is an inherent part of the source capsule or the shipping packaging. As expected, and verified in Table 5.1.1, the dose rate from the package depends upon the specific shielding arrangement and source orientation, as well as the total activity."

¶ 4 "The drum in which the source holder or drawer is carried is the second shielding barrier. The drum is an 8-3/16 inch diameter cylinder, 21-5/8 inches long, penetrated by 3 tubes, each 2.560 inches in inside diameter, which form the source chambers. The tubes are parallel to the axis of the drum and extend through its entire length. The axis of the tubes are equally spaced circumferentially on a circle of 1-3/4 inch radius concentric with the axis of the drum. The source holder and the teletherapy drawer are slip fits into the source chambers. Frequently only one source is carried per container. The source chambers not containing sources are loaded with lead filled or tungsten shield plugs. The drum fits into the Shell Assembly which, along with the two covers, provides the third shielding barrier. Both the Shell Assembly and covers are lead filled."

5. Shielding Evaluation. 5.4.1 Radial Gamma Attenuation.

¶ 1 " The specific shielding arrangement within the drawer or holder placed in the drum chamber may vary. However, a comparison of radial (in the plane perpendicular to the axis of the drum) attenuation in the original with that of a new inner container can be made from the drum liner outward."

¶ 2. "For both purposes a point source model was used."

FIG. 5.4.2.1. Detail of International Capsule Positioning Within Inner Container Drum. (REF. FIG. 4.3). Drawing withheld.

5. Shielding Evaluation. 5.4.2 Axial Gamma Attenuation.

¶ 1 "Evaluation of the shielding in the direction parallel to the axis of the new inner container drum involves the source loading arrangement. The loading arrangement of a source in an international capsule is shown in Figure 4.3. This is representative and one of the more frequent loading arrangements."

5. Shielding Evaluation. 5.4.3 Package Radiation Measurements.

¶ 1 "The results of a radiation survey of a package incorporating the new inner container are provided in this appendix." ... "The source was fitted into an international capsule and held in the central region of the drum chamber between tungsten alloy and plugs."

7.4 Appendix. 7.4.1 Teletherapy Shipping/Transfer Cask Unloading and Loading Procedure R 2014, Revision 5, September15, 1992. Scope.

¶ 1 "The teletherapy shipping package, NPI-20WC-6, consists of a specially designed inner lead shielded shipping/transfer cask contained within an overpack." ... Background. "Both unloading and loading is covered here in a single procedure because the most frequent circumstance in the shipping and transfer of teletherapy sources is receipt of a package containing a spent source which, after appropriate initial operations and surveys, is removed from the package in the hot cell and placed in interim storage; whereupon the cask is inspected, cleaned, resleeved, as necessary, and loaded with a new source in the hot cell for subsequent shipment off site."

Reference: NPI's November 17, 1993 request for approval to utilize alternate cask internals.

NPI's November 17, 1993 letter

¶ 2 " We are making this request to allow foreign shipments of double-encapsulated, cobalt-60 teletherapy sources for teletherapy units that have source holders that cannot be accommodated in the drum assembly currently authorized by Certificate of Compliance No, 9215."

Technical Assessment of Alternative Configurations of Teletherapy-Source Shipping/Transfer Cask Internals. Background. Prior Licensing Activities.

¶ 1 "Certificate of Compliance No. 9215 is the third generation of authorizations for shipping packages used by Neutron Products to ship teletherapy sources and make source exchanges in the field with various makes and models of teletherapy machines."

¶ 2 " Regarding Certificate of Compliance No. 9215, both the initial application dated August 5, 1986, and the consolidated application for renewal dated October 29, 1992, remark that several alternative configurations of the cask internals, specifically the drum assemblies, are needed to match the range of teletherapy machines with which source transfers are made."

Technical Assessment of Alternative Configurations of Teletherapy-Source Shipping/Transfer Cask Internals. Alternate Drum Assembly Designs.

¶ 1 "(1) One of the alternative drum assembly designs (Item 4 on Sheet 2 of Drawing N240122, Rev. G) has three round holes of 2.810 inch I.D., whereas the currently authorized design (Item 5 on Sheet 1 of Drawing N240122) has three round holes of 2.560 inch I.D. This alternative drum assembly design is identical to the drum assembly design shown in the certification drawing (Neutron Products Drawing D240010, Rev.C) for Certificate of Compliance No. 9102.

(2) The second alternative drum assembly design (Item 2 on Sheet 2 of Drawing N240122, Rev. G) has two square holes of 3 inches by 3 inches. This drum assembly, which is used to ship and transfer sources to some models of Theratron and Siemens teletherapy units, meets the requirements of US DOT Specification 20WC-6 and Competent Authority Certificate USA/5800/B.

Technical Assessment of Alternative Configurations of Teletherapy-Source Shipping/Transfer Cask Internals. Source Holders/Drawers.

¶ 1 "Teletherapy sources are shipped in the through-holes of a drum assembly. A shipment utilizing a drum with three holes normally contains one or two sources, and a shipment utilizing a drum with two holes normally contains one source. Each source is loaded into a holder or drawer that positions the source near the axial midpoint of the drum assembly during shipment and that mates with the teletherapy machine at a hospital or clinic to effect the source transfer."

Technical Assessment of Alternative Configurations of Teletherapy-Source Shipping/Transfer Cask Internals. Proposed Changes to the Certificate of Compliance.

¶ 1 "In order to facilitate authorization to utilize the alternative drum assembly designs with package USA/9215/B( ), Neutron Products proposes that the maximum quantity of material per package would depend on the configuration of drum assembly used and would not exceed the currently authorized limits for packages USA/9102/B( ) and USA/5800/B. Proposed values are:

- For Drawing Item 5 (the currently authorized drum assembly design) the maximum authorized values would remain 15,000 curies of Co-60, or 240 thermal watts.

- For Drawing Item 4 (the drum assembly currently authorized by Certificate of Compliance No. 9102) the maximum authorized values would be 9,500 curies of Co-60, or 150 thermal watts.

- For Drawing Item 2 (a drum assembly design authorized by the U.S Department of Transportation's 20WC-6 specification and USA/5800/B) the maximum authorized values would be 6,300 curies of Co-60 or 100 thermal watts."

Technical Assessment of Alternative Configurations of Teletherapy-Source Shipping/Transfer Cask Internals. Technical Assessment of Alternative Drum Assembly Designs. Shielding Evaluation

¶ 1 "The principal shielding is provided by the shipping/transfer cask. This shielding can be considered as comprising three parts: (1) the source holder or drawer and any sleeves or plugs in the holes of the drum assembly, (2) the drum assembly itself, and (3) the lead-filled steel shell assembly and cover plate assemblies."

¶ 2 "The design guidelines for all of the teletherapy-source shipping packages are the same: that is, maximum dose rates of 100 mr/hr at the accessible surfaces of the package and 10 mr/hr at a distance of one meter from the surface of the package when the package is loaded with the maximum authorized quantities of material per package. As verified by numerous dose rate measurements, these limiting dose rates are met for the three drum assembly designs, when loaded up to the maximum authorized quantities of material per package."

Reference: NPI's September 5, 2002 Renewal of Certificate of Compliance USA/9215/B(U) without any changes to the package.

¶ 4 "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."

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-Bames, 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 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. ...

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."

Reference: NPI's April 15, 2010 email to Christopher Staab, NRC, regarding adding Cesium-137 to COC 9215.

"In response to our discussion earlier today, if we receive authorization to ship the Cs-137 source in our 9215 package, we are planning to configure the package either as shown in item 5 on our drawing no. 240122, Sheet 1 of 2, Rev. H, or as shown in item 4 on our drawing no. 240122, Sheet 2 of 2, Rev. H.

The item 5 configuration is good for 15,000 Ci of cobalt-60 with a maximum decay heat not to exceed 240 watts, while the item 4 configuration is good for 9,500 Ci of cobalt-60, with a maximum decay heat not to exceed 150 watts. Either configuration is more than sufficient for the cesium-137 source with an activity less than 600 Ci and a decay heat of approximately 3.1 watts."

Reference: NRC's May 13, 2010 Safety Evaluation Report, Docket No. 71-9215 Model No. NPI-20WC-6 MkII Package, Certificate of Compliance No. 9215, Revision No. 10.

SUMMARY

"By application dated April 8, 2010, Neutron Products, Inc., requested an amendment to Certificate of Compliance (CoC) No. 9215 for the Model No. NPI-20WC-6 MkII package. The applicant specifically requested allowance to add Cesium-137 as a new content to the CoC as a sealed source which meets the requirements of a special form radioactive material."

EVALUATION

Thermal Evaluation

"The staff reviewed the request for the CoC No. 9215 to transport a special form Cesium-137 source with an activity not to exceed 22.2 Tbq (600 Curies), which corresponds to 3.1 watts. The package was originally designed for special form sources with higher activity, including Cobalt-60 with an activity not to exceed 15,000 Curies, which corresponds to 231 watts. Therefore, the proposed content is bounded by the approved original heat source.

Based on staff review, the staff finds reasonable assurance that the USA/9215/B(U) package design meets the thermal performance requirements set forth in 10 CFR Part 71."

Shielding Evaluation

"NRC staff reviewed the applicant's submittal, the applicant's SAR (ML092180416), the above referenced drawings, the current CoC (ML080970006), and the Rev. 10 Safety Analysis Report (SER) (ML030100087). NRC staff reviewed the configurations shown in item 5 of Drawing No. 240122, sheet 1 of 2, Rev. H (ML022800515), and item 4 of Drawing No. 240122, sheet 2 of 2, Rev. H (ML022800529). NRC staff finds that these package configurations are already approved for 15,000 and 9,500 Curies of Cobalt-60 (60Co), respectively. During radioactive decay of 60Co two gamma rays are emitted with energies of 1.17 and 1.33 MeV. During radioactive decay of 137Cs one gamma ray is emitted with an energy of 0.6617 MeV. So 60Co emits two gamma rays that each has roughly twice the energy as the single gamma ray emitted by 137Cs. This strongly suggests that 137Cs is bounded by 60Co. To confirm this staff performed dose rate calculations for shielded and unshielded 137Cs and 60Co point sources. Additional calculations were performed for a 600 Ci 137Cs line source to represent a pencil source. The results of these calculations confirmed the applicant's argument that 137Cs is bounded by 60Co; and that a 600 Ci 137Cs source does not violate the limits under normal conditions of transport or hypothetical accident conditions.

Based on a review of the representation within the application and independent calculations, staff finds reasonable assurance that a package with 600 Ci of 137Cs meets the radiation limits of Part 71, provided it is in the configurations specified in the CoC Rev. 9, Sections 5(b)(2)(i) and (ii); and provided that the applicant uses at least 2 inches of Lead or Tungsten, or 3 inches of steel as axial shielding material in the drum assembly. This is in addition to the shielding that is already part of the shipping/transfer cask (S/TC) and S/TC cover. The shielding material may be part of the plugs and spacers or part of the source drawer, but must be inserted between the source and the S/TC cover."

CONCLUSION

"Condition No. 5(b) of the certificate was revised to add Cesium-137 as a new content – a sealed sources which meet the requirements of special form radioactive material, with a maximum activity not to exceed 600 curies and a maximum decay heat not to exceed 3.1 watts. Condition No. 10 was added to ensure Cesium-137 and Cobalt-60 sources are not shipped together in the same package."

Reference: NPI's March 12, 2008 request for renewal of Certificate of Compliance USA/9215/B(U)

NPI's NPI's March 12, 2008 letter

¶ 1 " 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 of time of five (5) years.

¶ 2 "We have updated the applicable loading and unloading, and maintenance procedures referenced in the Certificate of Compliance to reflect:
- changes in the references in the applicable regulations;
- changes in responsibilities at Neutron; and,
- editorial clarifications
Attached are copies of the referenced procedures:
- R-2014-G, Teletherapy Shipping/Transfer Cask Unloading and Loading Procedure, Revision 1; and,
- R-2019-G, Teletherapy Shipping Packaging Maintenance Procedure, Revision 1

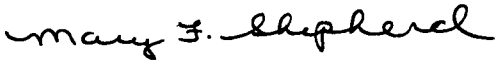
¶ 5 "We calculate that there have been more than 3,050 shipments in the 9215 package to and from forty-seven (47) states within the United States and five (5) continents without any adverse incidents. The referenced Certificate is for Neutron's only type B(U) package authorized for the export of cobalt-60 teletherapy sources and the return of the expended sources. It is essential for our continuing participation to serve the worldwide radiation therapy community for the treatment of cancer. The 9215 Certificate package is capable of unloading and loading essentially all of the models of teletherapy units that we know of that have been manufactured to date and can continue to be useful in unloading and transporting "orphan" sources for their safe disposal from all domestic and foreign locations. We believe that there is no technical reason why this request should not be granted."

For these reasons, JLS&A requests the NRC Staff's help in resolving the following specific issues:

1. The COC does not prohibit shipment of Cs-137 sources, and appears to permit shipment of such sources in pencil-type configuration as long as radiation limits, physical configuration limits (including length and diameter) and other criteria (e.g., shielding) stated in the CoC and underlying safety analyses are not exceeded. Is this the case?
2. Does the CoC permit shipment of Cs-137 pencil-type sources if physical dimensions (e.g., length) exceed those stated in the CoC and underlying safety analyses?
3. Does the CoC permit shipment of Cobalt-60 pencil-type sources if physical dimensions (e.g., length) exceed those stated in the CoC and underlying safety analyses?
4. The CoC and underlying safety analyses do not address the issue of source holders. May otherwise compliant pencil-type Cs-137 or Co-60 sources not having source holders be shipped under the CoC?
5. The CoC and underlying safety analyses discuss and evaluate circumstances under which one, or one or two, sources might be shipped simultaneously in the package. Does this mean that more than one pencil-type source may not be shipped each hole of the drum assembly chamber simultaneously under the CoC, even if all other criteria (isotopes, radioactivity, size, shielding, etc.) are met?

JLS&A much appreciates the Staff's willingness to review these issues. Compliance with a CoC, whether our own or as a registered user, is an essential and integral element of JLS&A's organization ethic. Our corporate goal is verbatim compliance.

Sincerely yours,



Mary F. Shepherd
Vice President, Licensing and Special Projects

CONSOLIDATED APPLICATION FOR RENEWAL OF

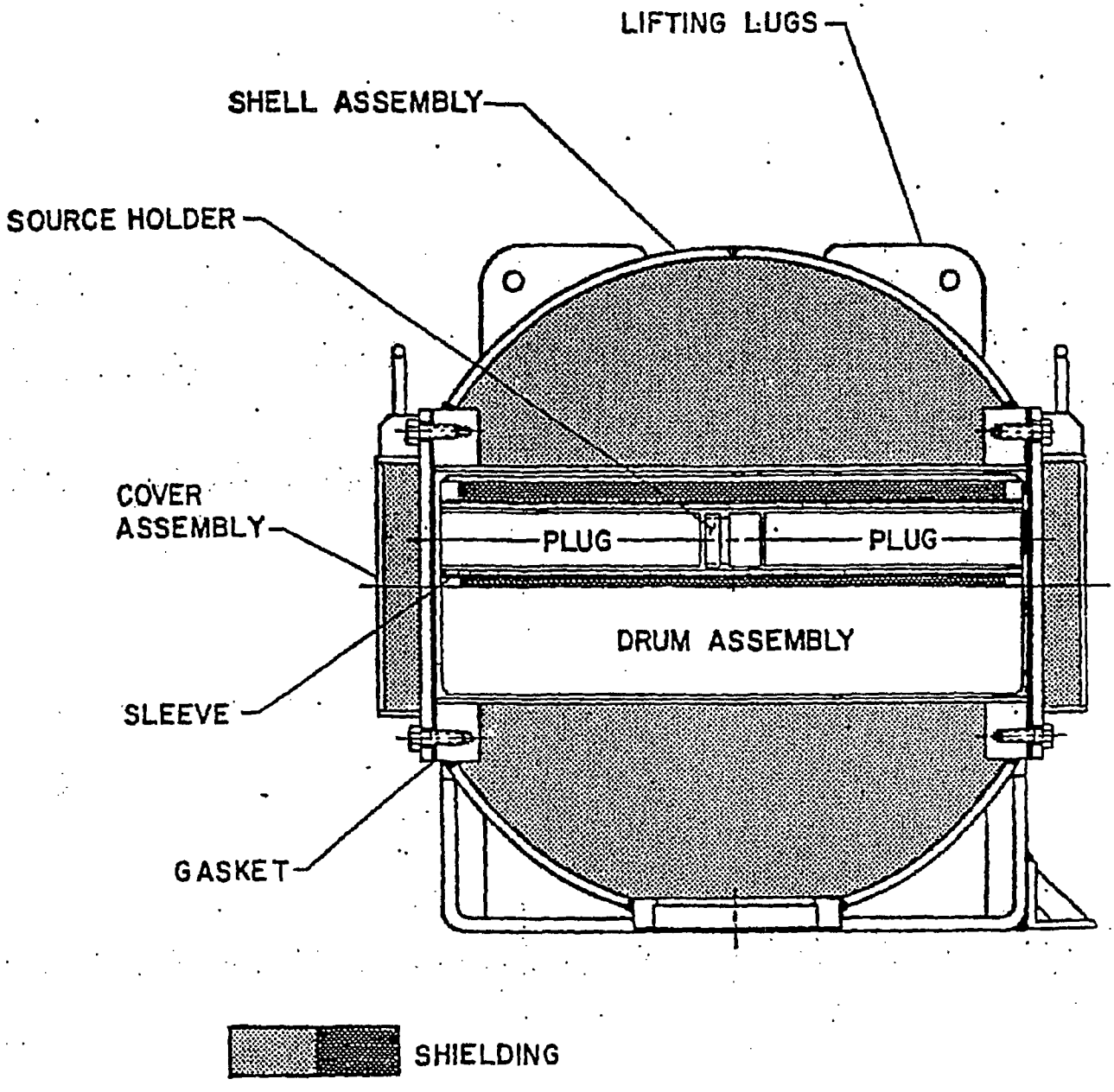
CERTIFICATE OF COMPLIANCE NO. 9215 FOR A TYPE B(U)

RADIOACTIVE MATERIAL TRANSPORTATION PACKAGING

MODEL NUMBER NPI-20WC-6 MkII

neutron products inc

22301 Mt. Ephraim Road • P.O. Box 68 • Dickerson, Maryland 20842 USA • 301/349-5001
TWX: 710-828-0542 • FAX: 301/349-2433



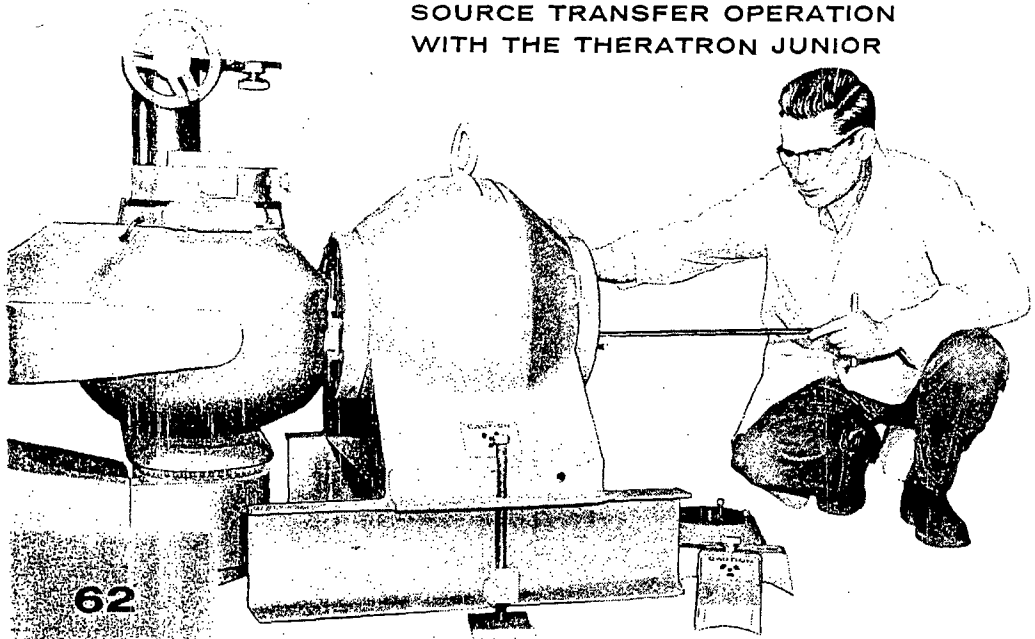
S/TC INNER CONTAINER - VERTICAL SECTION

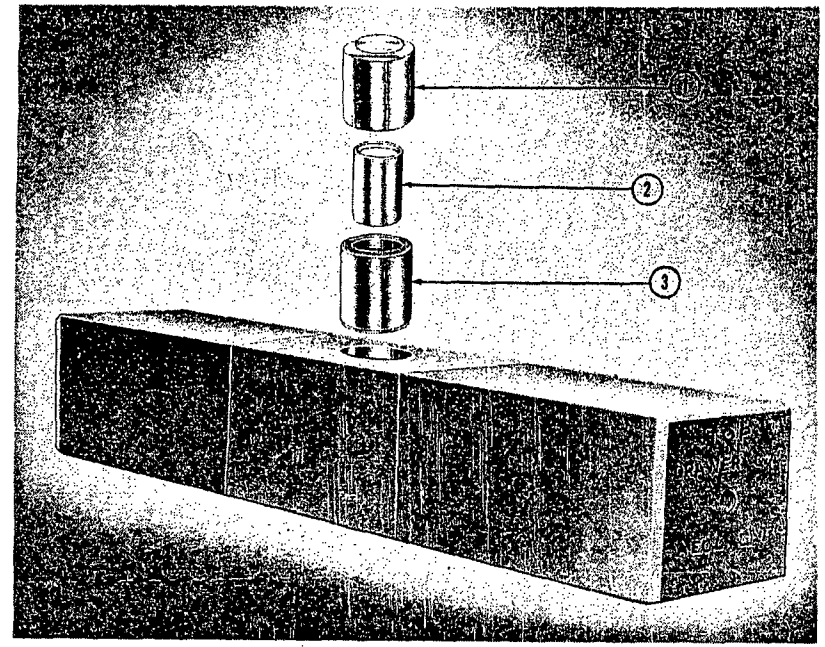
FIGURE 1.2.3

LOADING, SHIPPING AND REPLACING SOURCES

By means of the unique Atomic Energy of Canada Limited "drawer" system, all phases of source handling are made simple and safe. After preparation, the source is loaded into the "drawer" which is, in turn, inserted into the shipping container. Subsequently, hot-cell facilities are not required and the source may be routinely transferred into and out of any AECL teletherapy sourcehead.

FIG. 49
SOURCE TRANSFER OPERATION WITH THE THERATRON JUNIOR





1. Filler Cap *2. Source Capsule* *3. Liner*

FIG. 48 - SOURCE DRAWER AND COBALT 60 TELETHERAPY SOURCE. Cylindrical tungsten "liners" are used to fit small diameter sources in the standard drawer.

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

Canadian Certificate No.	Issue Date	Expiry Date	CNSC File
CDN/0004/S-96 (Rev.9)	**Dec-13-2006**	**Sep-30-2010**	**30-A2-190-0**

Certificate
for
Special Form

The special form radioactive material identified below is certified by the Canadian Nuclear Safety Commission pursuant to paragraph 21(1)(h) of the *Nuclear Safety and Control Act* and Section 7 of the *Packaging and Transport of Nuclear Substances Regulations*, and to the 1996 Edition (Revised) of the IAEA *Regulations for the Safe Transport of Radioactive Material.*

CAPSULE IDENTIFICATION

Designer : **MDS Nordion**
Make/Model : **C-146; C-151 and XC-325 Teletherapy Source Capsules**

CAPSULE DESCRIPTION

The C-146 Teletherapy Source Capsule (Types 0.50 to 3.0), as shown on MDS Nordion Drawing No. A03038, (Issue M), consists of a doubly encapsulated, stainless steel welded capsule assembly with dimensions 8.55 mm to 32.9 mm diameter (dependent on type) by 36.7 mm long.

An illustration of the C-146 capsule is shown on attached Drawing No. C-146, (Rev.21).

The configuration of the C-146 capsule is as follows:

Shape :	**Cylinder**	Shielding :	**n/a**
Mass :	**n/a**	Outer Casing :	**n/a**
Length :	**n/a**	Height :	**36.7 mm**
Width :	**n/a**	Diameter :	**32.9 mm**

The C-151 Teletherapy Source Capsule (Types 1.0 to 3.0), as shown on MDS Nordion Drawing No. A03049, (Issue N), consists of a doubly encapsulated, stainless steel welded capsule assembly with dimensions 13.5 mm to 32.9 mm diameter (dependent on type) by 36.7 mm long.

An illustation of the C-151 capsule is shown on attached Drawing No. C-151 (Rev.24).

The configuration of the C-151 capsule is as follows:

Shape :	**Cylinder**	Shielding :	**n/a**
Mass :	**n/a**	Outer Casing :	**n/a**
Length :	**n/a**	Height :	**36.7 mm**
Width :	**n/a**	Diameter :	**32.9 mm**

Canada

Canadian Certificate No.	Issue Date	Expiry Date	CNSC File
CDN/0004/S-96 (Rev.9)	**Dec-13-2006**	**Sep-30-2010**	**30-A2-190-0**

The XC-325 Teletherapy Source Capsule, as shown on MDS Nordion Drawing No. G132520-101, (Issue P), consists of a doubly encapsulated, stainless steel capsule assembly with dimensions 23.4 mm diameter by 36.7 mm long.

An illustration of the XC-325 capsule is shown on attached Drawing No. XC-325, (Rev.9).

The configuration of the XC-325 capsule is as follows:

Shape :	**Cylinder**	Shielding :	**n/a**
Mass :	**n/a**	Outer Casing :	**n/a**
Length :	**n/a**	Height :	**36.7 mm**
Width :	**n/a**	Diameter :	**23.4 mm**

AUTHORIZED RADIOACTIVE CONTENTS

The capsules are authorized to contain not more than the following limits of cobalt-60 metal:

a) C-146 and C-151: 560 TBq (15,000 Ci); or

b) XC-325: 450 TBq (12,000 Ci).

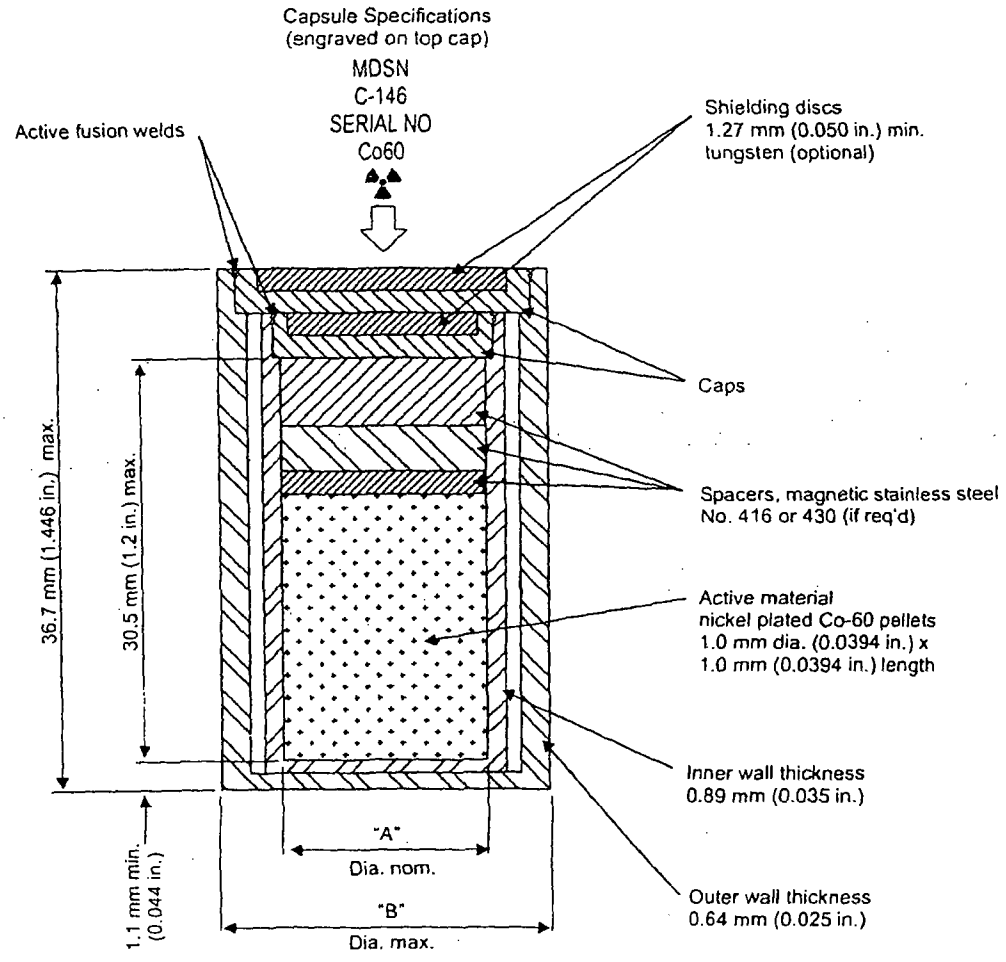
QUALITY ASSURANCE

Quality assurance for the design, manufacture, testing, documentation, use, maintenance and inspection of the capsule shall be in accordance with :

- MDS Nordion Document No. IN/QA 0562 A000 (3), "Sealed Source Quality Plan"
- Canadian Packaging and Transport of Nuclear Substances Regulations
- IAEA Regulations

A. Régimbald
Designated Officer pursuant to paragraph 37(2)(a)
of the Nuclear Safety and Control Act

Canada



Type	"A" dia. (source) nominal		"B" dia. O.D. max.	
	(cm)	(in.)	(cm)	(in.)
1.50	1.50	0.591	1.83	0.722
2.0	2.0	0.787	2.34	0.922

Notes:

1. Capsule material No. 316L stainless steel unless otherwise specified.
2. Dimensions shown are at 20°C (68°F).
3. Nominal packing density of radioactive pellets 5.78 g/cm^3.
4. "A" dia. (source) nominal and "B" dia. O.D. max. shown only for two capsule types. For other capsule types refer to dwg. A03038

30 AUG 2006

MDS Nordion
447 March Road
Ottawa, Ontario
Canada, K2K 1X8
Tel: (613) 592-2790
Fax. (613) 592-6937

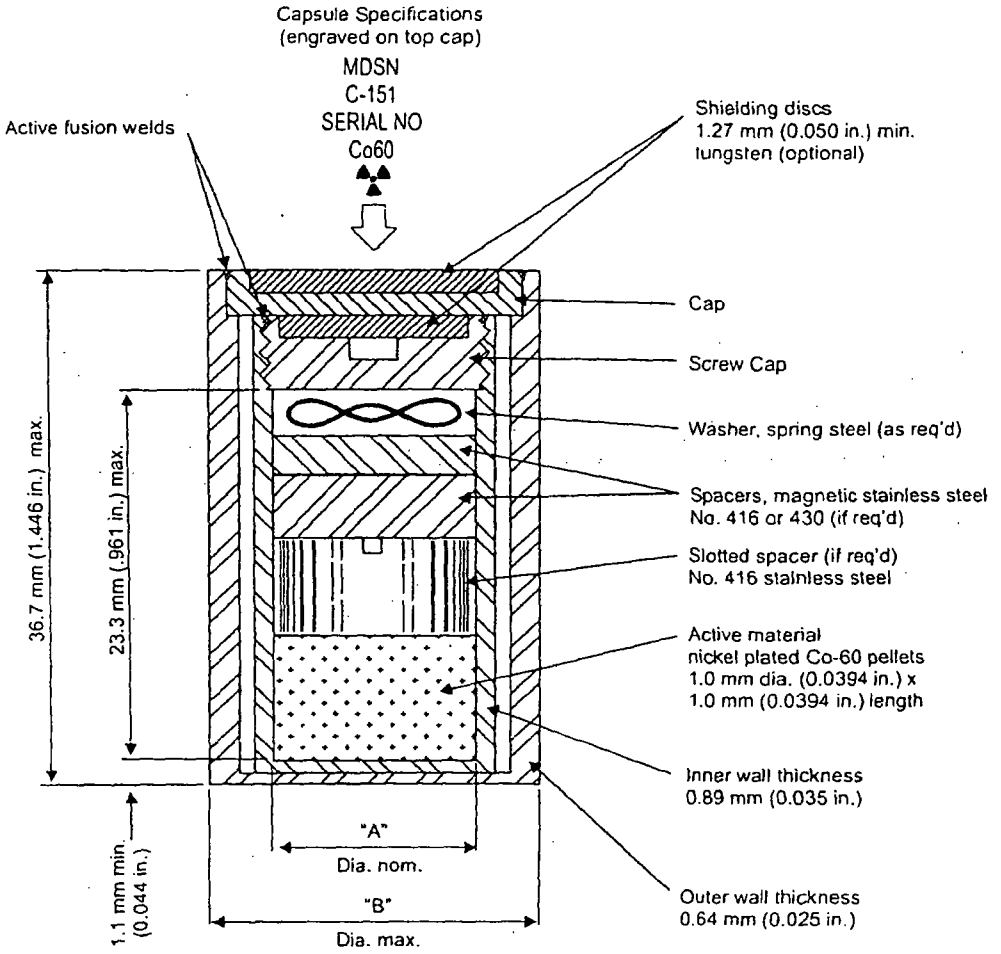
TITLE

Teletherapy Source Capsule

REF. IN/SS 6014 C146 A03038 | REVISED Aug 06 | DC 20019

DATE Jun/4, 1992 | No. C-146 | ISSUE 21

DRAWN BW | CHECKED BM | APPROVED JR | SHEET 1 OF 1



Type	"A" dia. (source) nominal		"B" dia. O.D. max.	
	(cm)	(in.)	(cm)	(in.)
1.50	1.50	0.591	1.83	0.722
2.0	2.0	0.787	2.34	0.922

Notes:

1. Capsule material No. 316L stainless steel unless otherwise specified.
2. Dimensions shown are at 20°C (68°F).
3. Nominal packing density of radioactive pellets:
   5.34 g/cm^3 when pellet height below 0.7 cm.
   5.78 g/cm^3 when pellet height 0.7 cm and above.
4. "A" dia. (source) nominal and "B" dia. O.D. max. shown only for two capsule types. For other capsule types refer to dwg. A03049

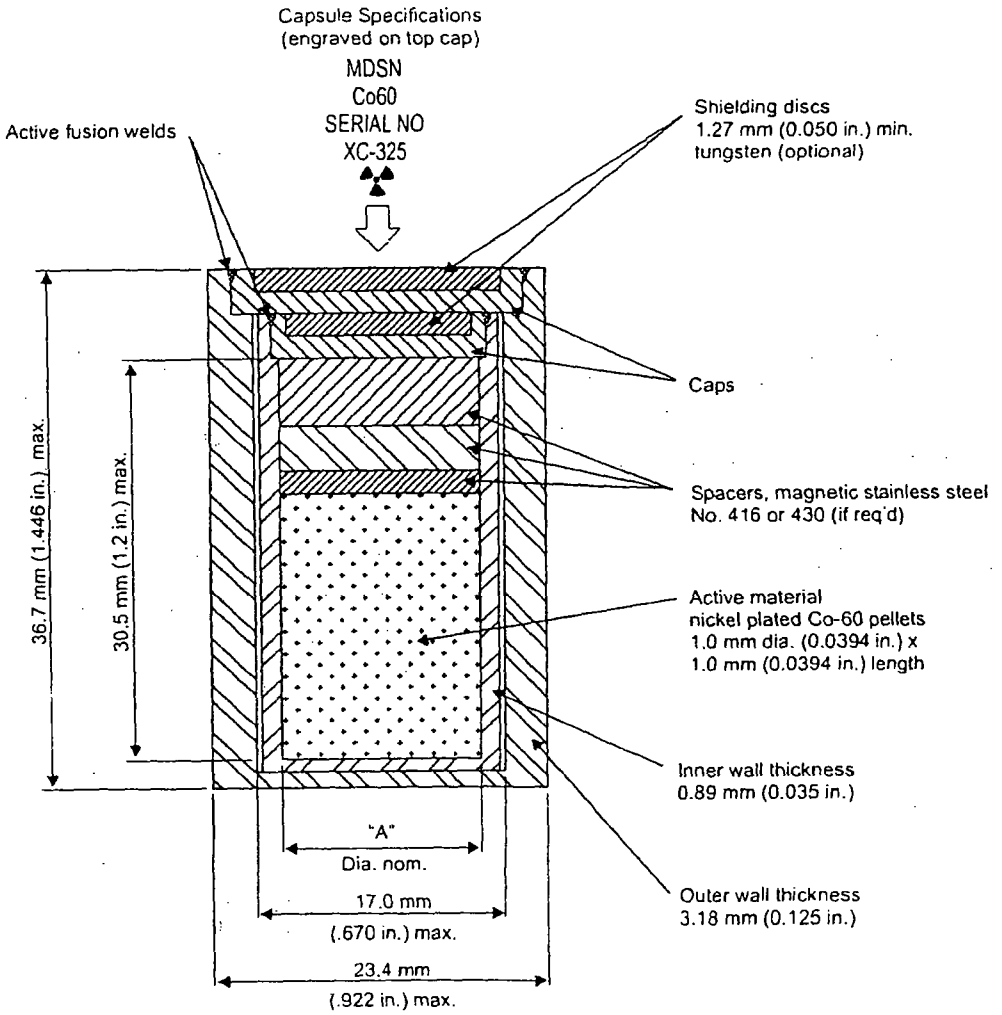
30 AUG 20...

MDS Nordion
447 March Road
Ottawa, Ontario
Canada, K2K 1X8
Tel: (613) 592-2790
Fax. (613) 592-6937

TITLE

Teletherapy Source Capsule

REF. IN/SS 6015 C151 A03049			REVISED Aug 06	DC 20019
DATE Jun 4, 1992			No C-151	ISSUE 24
DRAWN BW	CHECKED BM	APPROVED JR	SHEET 1 OF 1	



Type	"A" dia. (source) nominal	
	(cm)	(In.)
1.50	1.50	0.590

Notes:

1. Capsule material No. 316L stainless steel unless otherwise specified.
2. Dimensions shown are at 20°C (68°F).
3. Nominal packing density of radioactive pellets 5.78 g/cm³.
4. Capsule not for MDS Nordion therapy units.
5. "A" dia. (source) nominal shown for 1.5 type capsule only.
   For other capsule types refer to dwg. G132520-101

30 AUG 2006

MDS Nordion
447 March Road
Ottawa, Ontario
Canada, K2K 1X8
Tel: (613) 592-2790
Fax. (613) 592-6937

TITLE

Teletherapy O.E.M. Source Capsule

REF. IN/SS 6013 XC325
G132520-101

REVISED Aug 06 | DC 20019

DATE Jun 4, 1992

DRAWN | CHECKED BM | APPROVED JR

No. XC-325

ISSUE 9

SHEET 1 OF 1

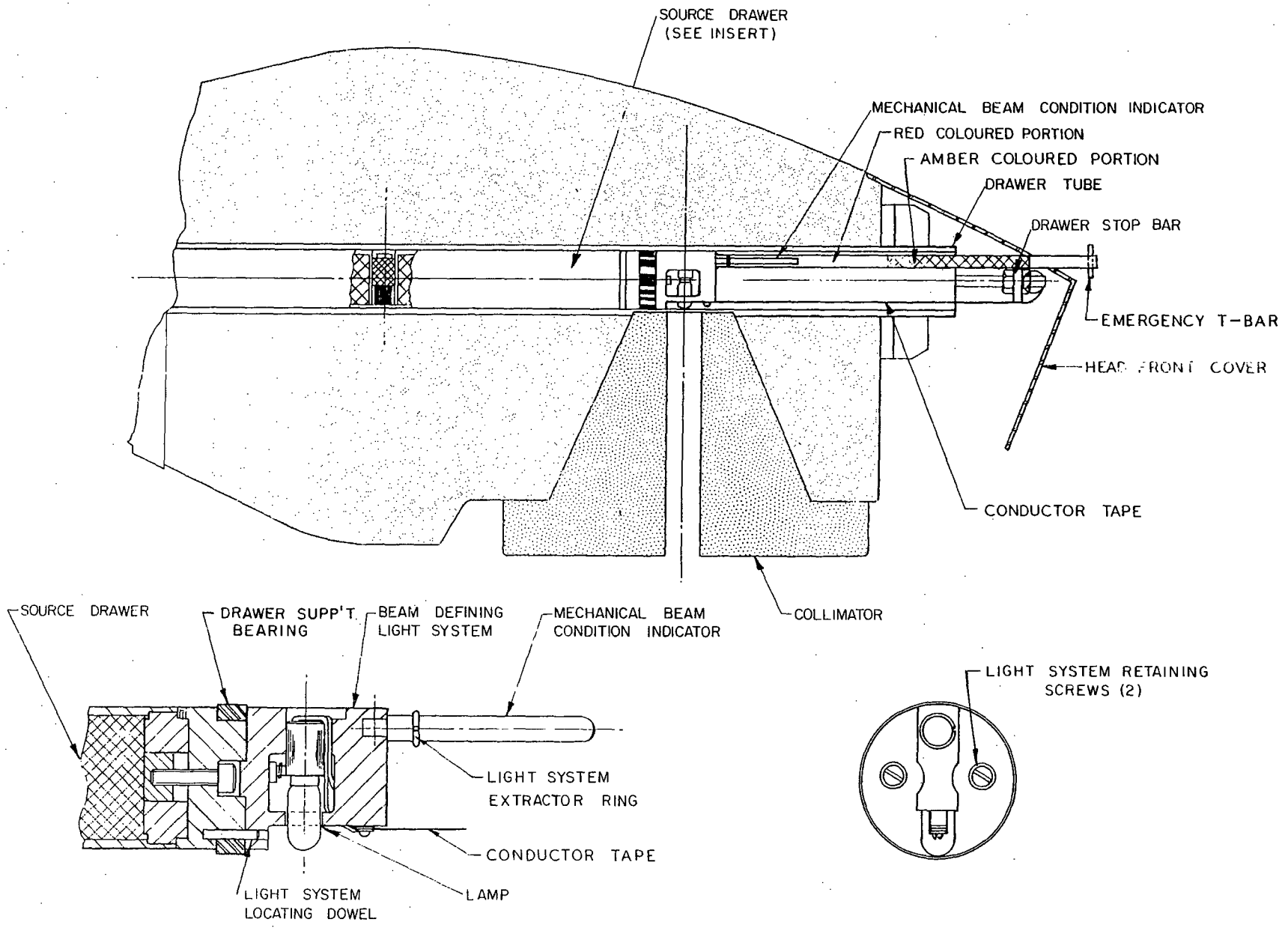
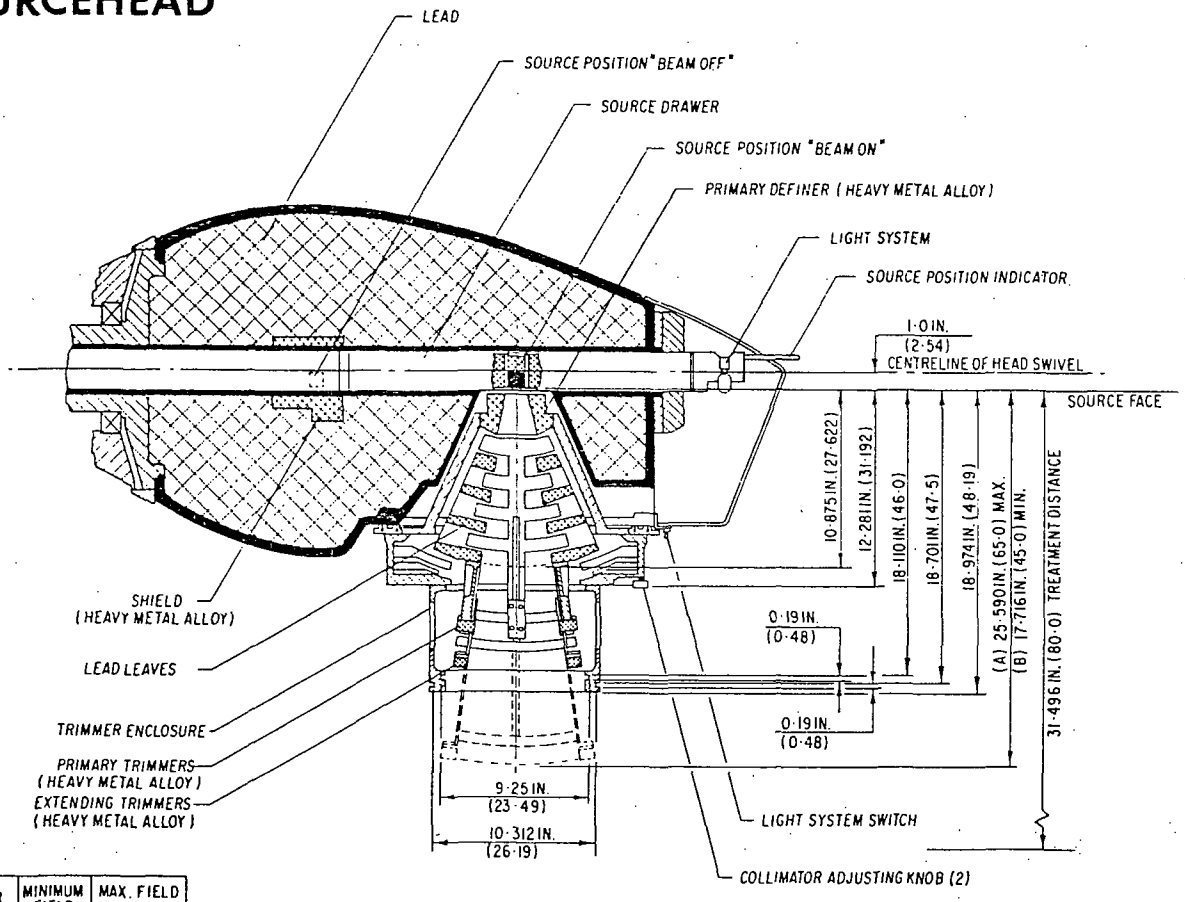


Figure 3. Source Drawer Emergency Closure

SOURCEHEAD



TRIMMER CONDITION	MINIMUM FIELD (CM.SQ.)	MAX. FIELD (CM.SQ.)
(A) EXTENDED	3·5	32·0
(B) RETRACTED	5·0	33·0

FIELD SCALES ARE CALIBRATED FROM –
3·5 CM. TO 25·0 CM. FOR 65·0 CM. TRIMMER DISTANCE
5·0 CM. TO 33·0 CM. FOR 45·0 CM. TRIMMER DISTANCE

NOTES –

1. BRACKETED DIMENSIONS REPRESENT CENTIMETRES
2. FIELD SIZE INDICATORS AND BEAM DEFINING LIGHT SYSTEM ARE AS DEFINED BY 50% GEOMETRIC LINE

Figure 2. Eldorado 8 - General Dimensions