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March 9, 2012

Huda Akhavannik
Licensing Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards

Subject: Application for F-431 Transportation Package – Second Request for Additional Information

Dear Ms. Akhavannik

We are submitting a revised Safety Analysis report that addresses the points discussed in a conference call between Best Theratronics and the USNRC on February 29, 2012.

If you any further questions, please don't hesitate to contact me.

Sincerely,

Richard Wassenaar, PhD
RSO
Best Theratronics
Ottawa, ON, Canada
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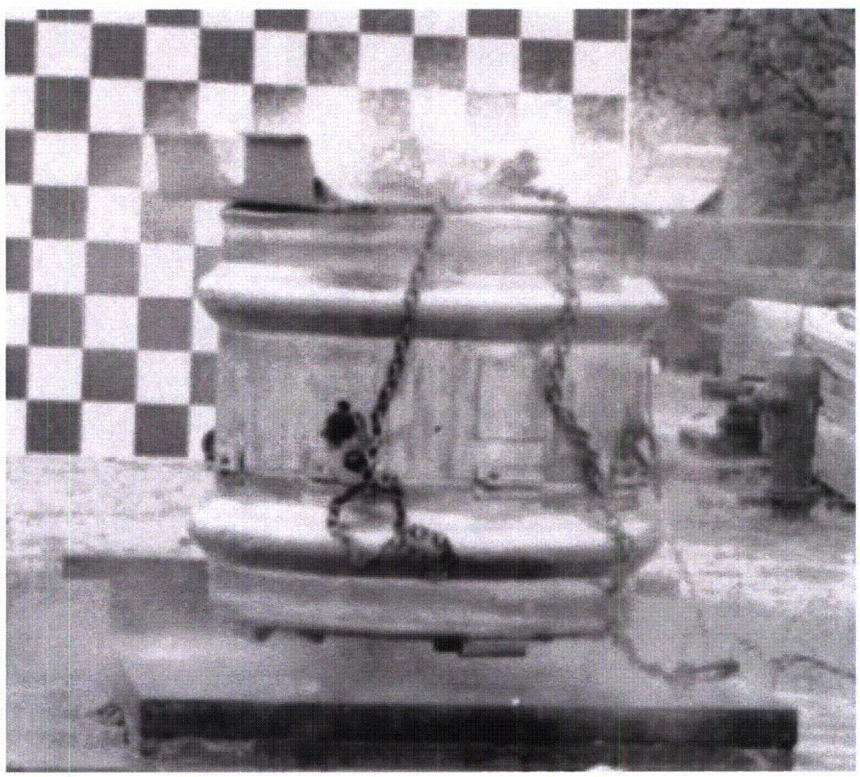
NMSS24

Supplemental Safety Analysis Report for the **F430 Transport Package**

IN/TR 6088 F430 (C)



Non-Proprietary Information

Best® Theratronics

Supplementary Safety Analysis Report for the F-430 Transport Package

Signatures

Prepared by: _____ Date: 6-Mar-12
J. Barroeta Robles, Engineering

Reviewed by: _____ Date: MAR 06/2012
V. Moga, Engineering

Approved by: _____ Date: March 8, 2012
R. Wassenaar, Compliance

Document History

Date	Version	Comments	Prepared by	Reviewed by	Approved by
Oct. 2011	A	DC30761	B. Menna	V. Moga	R. Wassenaar
Feb. 2012	B	DC30806	J. Barroeta Robles	V. Moga	R. Wassenaar
Mar. 2012	C	DC30825			

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CHAPTER 1 – GENERAL INFORMATION

1.1 INTRODUCTION

The Best Theratronics F-430 transport package has been developed as a safe means of transporting self-contained irradiators (SCI). The F-430 was designed principally to transport the Gammacell 40 Irradiator (GC40) (see Figure 1).

The F-430 provides impact and thermal protection for the radioactive contents. Containment is provided by the sealed source and shielding by the SCI.

This report describes some changes to the GC40 design due to the incorporation of additional security features and their affect on the safety analysis of the F-430.

The changes to the GC40 were implemented to delay the potential unauthorized access to the sealed sources from the outside of the irradiator. There are two versions of the new design. The first version is intended to be installed on existing devices at licensees' sites (field retrofit) and the second version will be incorporated on new devices during manufacturing (in-house). The design is the same for both versions (see Figure 2). This Safety Analysis Report (SAR) demonstrates that the F-430 overpack can safely transport the new GC40 design.

1.2 PACKAGE DESCRIPTION

1.2.1 Packaging

The design of the F-430 is described in the existing SAR [1]. Except for changes to the payload, the design of the F-430 is unchanged.

The F-430 is a stainless steel drum 1.27 m (50 in.) in outside diameter, 1.27 m (50 in.) in height, placed on a removable steel skid 1.27 x 1.27 x 0.20 m (50 in. x 50 in. x 8 in.). It has a cylindrical cavity 0.914 m (36 in.) in diameter, 0.895 m (35.25 in.) in height. The main materials of construction are 304L stainless steel and rigid polyurethane foam.

1.2.2 Contents

The Gammacell 40 (GC40) is a self-contained irradiator used primarily for research. It consists mainly of an upper and a lower shielding head, each containing one Cs-137 sealed source.

The proposed design changes have no affect on the operation of the GC40 when it is installed in the laboratory. However, the new features added to the device make it harder to dismantle and this has an impact on how the device is prepared for shipment. The different designs of the GC40 and the process of preparing the shielding heads for shipment are discussed in the following paragraphs.

When preparing the GC40 for shipment, the device is partially disassembled from the laboratory configuration. The covers, the drive systems and the mechanical interlock are removed and the shielding heads are separated.

During transport, it is important to secure the source drawer from movement within the head. Currently, this is done with two redundant means. First, the Retaining Ring is removed from one end of each head and a Shipping Tube is installed (Refer to Figure 1). The Shipping Tube has the same outside diameter as the Source Drawer and it fills the length of the bore not occupied by the Source Drawer. When the retaining ring is replaced, the Shipping Tube and Source Drawer are blocked in place.

In order to further secure the source drawer, Shipping Plates are fastened to each end of the shielding heads (Refer to Figure 1). The Shipping Plates block the Source Drawer Assembly inside the bore. The Source Drawer Assembly consists of the Source Drawer and the Drawer Interlock Bar. The Drawer Interlock Bar is part of the GC40 mechanical interlock. This steel bar is 1 inch square and passes through the Retaining Ring during operation of the GC40. However, when the Shipping Plates are installed, the Source Drawer Assembly cannot move.

The proposed new design of the GC40 incorporates many additional fasteners with security features. Because of the new features, it is not practicable to remove the mounting plates for transport (Refer to Figure 2). Therefore the Shipping Tube cannot be installed on upgraded units. However, the Source Drawer Assembly is secured from movement with Shipping Plates. The new Shipping Plates are very similar to the existing Shipping Plates. They fasten to the GC40 shielding head using the same fasteners as before (four 3/8-16 socket head cap screws. Additionally, a ½-20 socket head cap screw fastens through one of the Shipping Plates into the Source Drawer. This further secures the source drawer.

An important feature of the existing Shipping Plate is the fact that it is partly recessed in a cournterbore on the GC40 shielding head. In the event of an impact, the force on the shipping plate is borne by the interface with this counterbore, as well as the fasteners. The new Shipping Plates maintain this feature (refer to Figure 2).

Because the Mounting Plates are left in place for transport, the weight of the GC40 shielding heads each increases by approximately 7 kg (15 lb.). The effect of this slight increase in weight is discussed in Chapter 2.

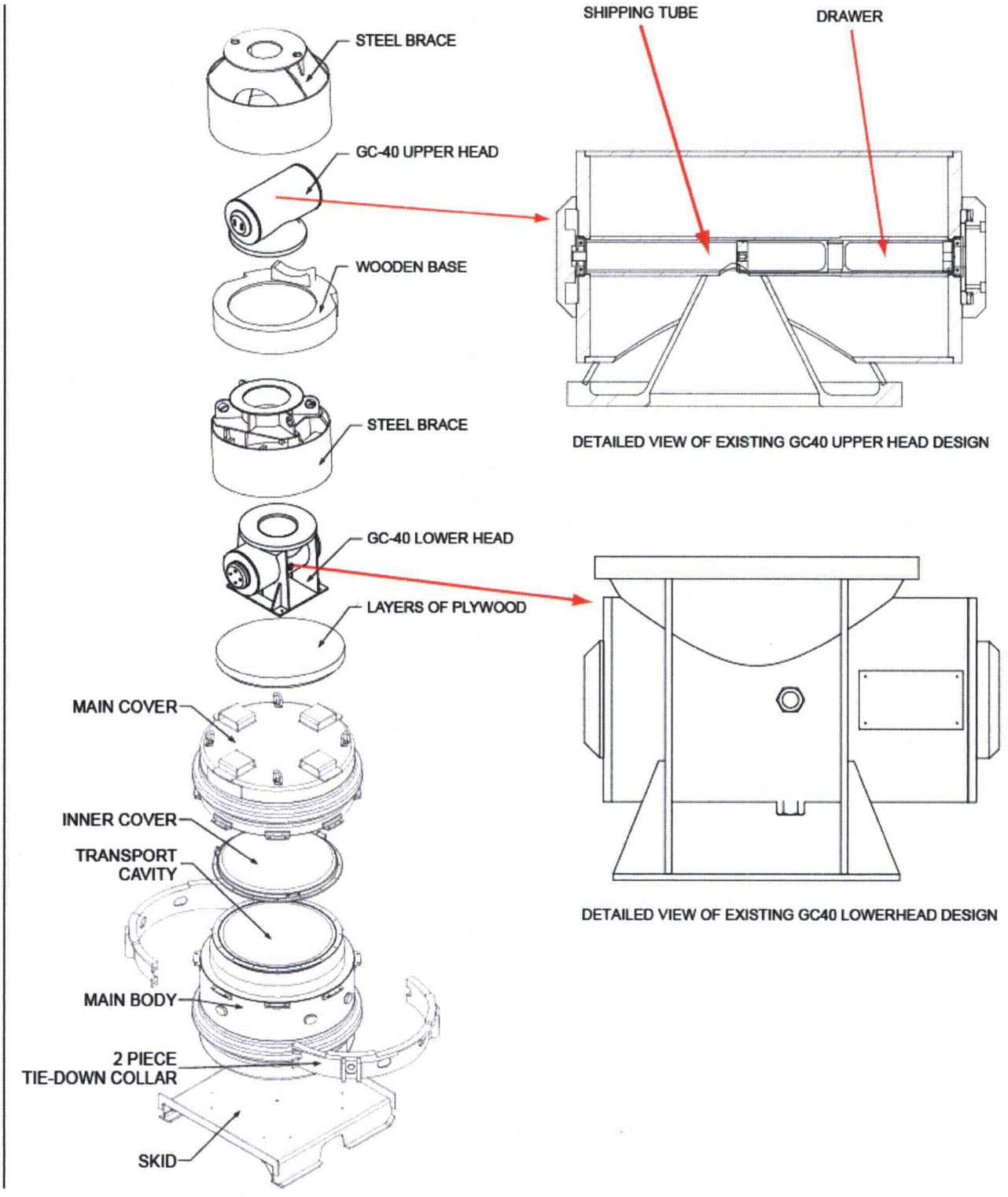


Figure 1: GC40 Existing Design Prepared For Shipment

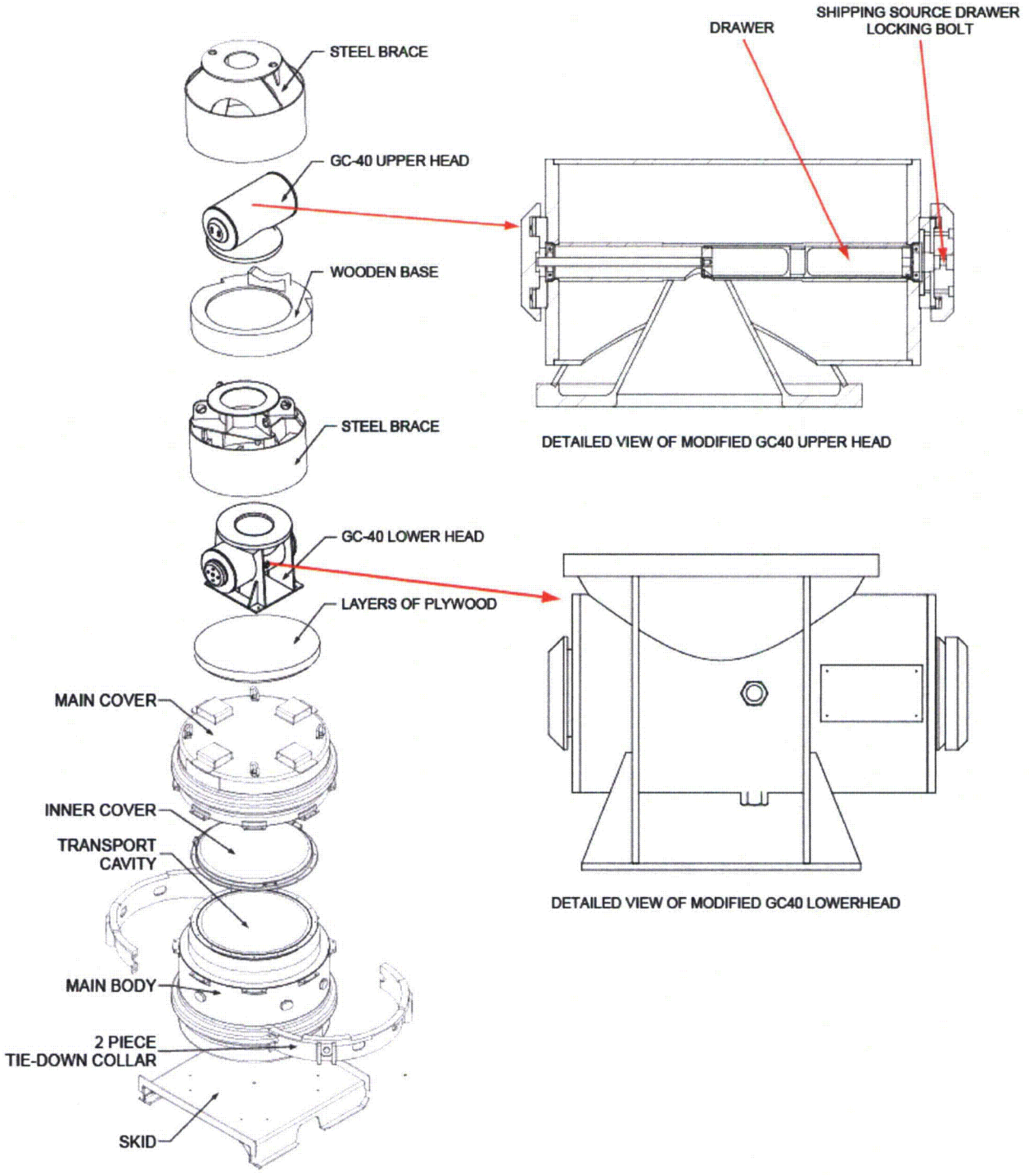


Figure 2: GC40 Modified Design (field retrofit and in-house) Prepared For Shipment

1.2.3 Special Requirements for Plutonium

The F-430 does not contain plutonium, therefore this section is not applicable.

1.2.4 Operational Features

The F-430 is a simple package from an operational perspective. There are no valves or piping. The package consists of a main body, and inner lid and an outer lid. The procedure for preparing the package for shipment is described in Chapter 7.

1.3 REFERENCES

[1] Menna, Blair. Safety Analysis Report for the F-430/GC40 Transport Package, MDS Nordion Technical Report No. IN/TR 1608 F430, March 2010.

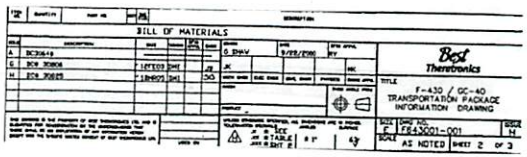
1.4 APPENDICES

Appendix 1.4.1 F-430 Engineering Information Drawing

Appendix 1.4.1:
F-430 Engineering Information Drawing
F643001-001 rev P (sheets 1 & 2)

Figure Withheld Under 10 CFR 2.390

Figure Withheld Under 10 CFR 2.390



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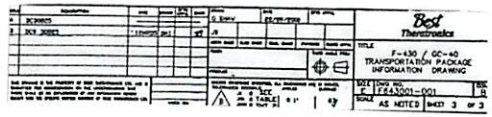

CHAPTER 2 – STRUCTURAL EVALUATION

This chapter presents the structural evaluation that demonstrates that the Best Theratronics F-430/GC40 package design meets all applicable structural criteria. The F-430 SAR [1] presents the overall experimental verification and evaluation of the F-430. This supplementary SAR demonstrates that the proposed design changes for the GC40 also satisfy the regulatory structural requirements.

2.1 DESCRIPTION OF STRUCTURAL DESIGN

The design criteria and the codes and standards for the F-430 package design have not changed.

The principal structural members and components of the F-430 package have not changed. The inner bracing has not changed. Only the means of securing the Source Drawer from movement has changed. The impact of this change is discussed in Section 2.7.

The weight of the new GC40 head design increases by approximately 7 kg (15 lb.). The weights of the various GC40 head configurations are listed in Table 2-1. The F-430 structural analysis in the F-430 SAR was based on a payload weight of 1740 kg (3835 lb.) and a total package weight of 3175 kg (7000 lb.)[1]. Since the weight of the GC40 remains less than that in the original analysis, the existing analysis is still valid.

Table 2.1: GC40 Head Weights

Component	Weight
GC40 Upper Head (Original Design)	1157 kg (2550 lb.)
GC40 Lower Head (Original Design)	1241 kg (2735 lb.)
GC40 Upper Head (New Design)	1164 kg (2565 lb.)
GC40 Lower Head (New Design)	1248 kg (2751 lb.)
GC40 Test Specimen	**1740 kg (3835 lb.)**

2.2 MATERIALS

The mechanical properties of materials are addressed in IN/TR 1608 F430 [1]. The discussion regarding material properties, specification, chemical and galvanic reactions and the effects of radiation are unchanged.

2.3 FABRICATION AND EXAMINATION

The fabrication and examination processes for the F-430 are unchanged from the original SAR [1].

2.4 GENERAL STANDARDS FOR ALL PACKAGES

The proposed design changes to the F-430 contents have no affect on the package's ability to satisfy the general standards for all packages. Therefore the analysis in IN/TR 1608 F430 [1] remains valid.

2.5 LIFTING AND TIE-DOWN STANDARDS FOR ALL PACKAGES

Although the weights of the GC40 Upper and Lower Heads have increased slightly, the original analysis of the F-430 contained a margin for an increase in weight. The existing analysis in IN/TR 1608 F430 [1] is based on a total package weight of 3175 kg (7000 lb.) and a GC40 test specimen weight of 1740 kg (3835 lb). The new maximum weight of GC40 heads is 1248 kg (2751 lb). This is less the weight of the test specimen and therefore the analysis remains valid.

2.6 NORMAL CONDITIONS OF TRANSPORT

The design changes to the GC40 do not affect the performance of the F-430/GC40 under the normal conditions of transport. The original analysis in IN/TR 1608 F430 [1] remains valid and the effectiveness of the package will not be reduced as a result of the normal conditions of transport.

2.7 HYPOTHETICAL ACCIDENT CONDITIONS

The F-430/GC40 was subjected to the hypothetical accident conditions of transport by test and analysis. The test specimen included an additional 500 kg of lead added to the GC40 payload. A single test specimen was subjected to nine drop tests including three drops from 9 meters.

After the drop tests, the GC40 was inspected and found to have suffered very little damage. This is because the F-430 overpack absorbed almost all of the energy and the GC40 is cradled firmly inside the Inner Brace. The Shipping Plates were completely protected during the drop tests. Since these are the only features that have changed as a result of the design change, the new shipping configurations will also survive the drop test without damage.

The changes to the GC40 have no affect on the performance of the F-430/GC40 with respect to thermal or water immersion. Therefore, the original analysis for the Hypothetical Accident Conditions remains valid.

2.8 ACCIDENT CONDITIONS FOR AIR TRANSPORT OF PLUTONIUM

The F-430 does not contain plutonium, therefore these requirement are not applicable.

2.9 ACCCIDENT CONDITIONS FOR FISSILE MATERIAL PACKAGES FOR AIR TRANSPORT

The F-430 does not contain fissile material, therefore these requirement are not applicable.

2.10 SPECIAL FORM

The special form sources inside the F-430 are not changing and therefore the analysis in IN/TR 1608 F430 [1] remains applicable

2.11 FUEL RODS

This requirement is not applicable since the F-430 does not transport fuel rods.

2.12 REFERENCES

[1] Menna, Blair. Safety Analysis Report for the F-430/GC40 Transport Package, MDS Nordion Technical Report No. IN/TR 1608 F430, March 2010.

CHAPTER 3 – THERMAL EVALUATION

This chapter presents a thermal evaluation demonstrating that the Best Theratronics F-430/GC40 package design meets all applicable thermal criteria. The original F-430 SAR [1] presents the overall analysis and evaluation of the F-430.

3.1 DISCUSSION

The proposed changes to the GC40 will have no impact on the thermal evaluation of the F-430.

3.2 SUMMARY OF THERMAL PROPERTIES OF MATERIALS

A summary of the thermal properties of materials is presented in IN/TR 1608 F430 [1] and remains valid.

3.3 TECHNICAL SPECIFICATIONS OF COMPONENTS

Technical specifications of components is addressed in IN/TR 1608 F430 [1] and are unchanged.

3.4 THERMAL EVALUATION FOR NORMAL CONDITIONS OF TRANSPORT

The thermal analysis of the F-430 under the Normal Conditions of Transport is presented in IN/TR 1608 F430 [1]. The original analysis conservatively assumed that the internal heat generation was 100W. The heat generated by the GC40 is unchanged.

Two analyses were performed for the Normal Conditions of Transport; a steady state analysis and a 12 hour transient analysis. Both analyses assumed an ambient temperature of 38°C and solar heat fluxes as defined by the Regulations.

The steady state analysis was conservative and overstated the temperatures inside the F-430. On the top of the F-430, where the solar heat flux was greatest (800 W/m^2), the temperature reached 126°C. On the sides of the F-430, the temperatures were lower (typically around 89 °C), since the solar heat flux was lower (400 W/m^2). Moving from the outside toward the center of the package, the temperatures dropped across the outer layer of low-density foam to around 125°C. Due to the heat generated internally by the Gammacell, the temperature increases across the inner layer of high-density foam, typically to about 133°C. The highest temperature (143°C) occurred inside the GC40 shield. Since the Gammacell shield is made of highly conductive materials (steel and lead), it has a relatively uniform temperature of around 142°C. The new features added to the Gammacells (also steel) will have no impact on the temperatures of the Gammacell shield.

The transient thermal analysis was more realistic. The solar heat fluxes were applied for a duration of 12 hours. The highest temperature (124°C) occurred on the outside top surface of the F-430. On the sides of the F-430, the temperatures were lower (typically around (86°C). The temperature gradients were most significant across the thickness of the top of the F-430 overpack. Across the outer layer of polyurethane foam, the temperature drops to about 80°C. Moving closer to the center of the package, the temperatures start to increase again due to the heat generated by the sealed source. However, temperatures inside the F-430 overpack are relative stable, ranging from 80°C to 96°C. Because the temperatures across the GC40 are very uniform, the new steel components will have no affect on the transient thermal analysis.

3.5 HYPOTHETICAL ACCIDENT THERMAL EVALUATION

The analysis of the F-430 during the hypothetical accident thermal conditions showed that the thick outer layer of polyurethane foam was very effective in insulating the Gammacell inside. At the end of the 30 minute fire, the outside surface of the F-430 overpack was near 800°C, but the temperature dropped to 200°C over the first few inches of the polyurethane foam. Inside the overpack cavity and throughout the Gammacell shield, temperatures were relatively uniform at around 100°C. Since the temperature gradients inside the overpack were very small, the changes to the Gammacell would have very little effect on the temperatures at the end of the 30 minute fire.

Immediately after the fire was extinguished, the outside surfaces of the F-430 began to cool. However the heat absorbed in the outer layers of the overpack continued to flow inward toward the payload. This heat transfer was slow and temperatures inside the Gammacell shield peaked 18 hours after the fire. During this period, the temperature gradient from the inside of the F-430 overpack cavity wall to the inside of the Gammacell shield was only about 10°C. Since the temperature gradient inside the overpack cavity was very low, the small changes to the Gammacell would have no effect on the heat transfer.

3.6 REFERENCES

[1] Menna, Blair. Safety Analysis Report for the F-430/GC40 Transport Package, MDS Nordion Technical Report No. IN/TR 1608 F430, March 2010.

CHAPTER 4 – CONTAINMENT

The containment system for the F-430 is defined as the sealed sources which are located inside the GC40 shielding heads. Since the sealed sources have not changed, the containment analysis presented in IN/TR 1608 F430 remains valid.

CHAPTER 5 – SHIELDING EVALUATION

The F-430 overpack is not intended to serve a shielding function. Shielding is provided by the GC40 shielding heads. The modifications to the GC40 design affect the exterior of the radiation shields and have no affect on the shielding performance. Therefore the shielding analysis presented in IN/TR 1608 F430 remains valid.

CHAPTER 6 – CRITICALITY EVALUATION

The requirements of this chapter are not applicable since the F-430 package does not transport fissile materials.

CHAPTER 7 – PACKAGE OPERATIONS

This chapter describes the procedure for preparing the F-430/GC40 for shipment. The intention is to ship heads without the additional security features (existing design) and with the additional security features (modified design).

7.1 OPERATING PROCEDURE

The original F-430 SAR [1] presents the complete procedure for preparing the F-430/GC40 for shipment.

The process of preparing the GC40/F430 for shipment consists of three main steps:

1. Dismantling the GC40 device
2. Securing the GC40 shielding heads for shipment
3. Loading the GC40 inside the F-430 and preparing the F-430 for shipment.

Only the process for securing the GC40 shielding heads for shipment has changed. The changes are minimal and are described below. The specific changes to the work instructions are listed in Table 7.1.

Because it is not practical to remove the extra security hardware, it is not possible to install the Shipping Tube (or "Tube Spacer") inside the bore of the GC40 heads. On devices that have the new security hardware, the step for installing the Shipping Tube is omitted.

The upgraded GC40 devices will use the new shipping plate. The procedure for installing the new shipping plates is unchanged, except that one additional ½-20 UNF screw is installed.

The process of loading the GC40 into the F-430 and preparing the F-430 for shipment is unchanged.

Table 7.1: Changes to Operating Procedures

Applicable Section of IN/TR 1608 F430	Existing Operation	New Operation
Section 7.2.1, Step 8 Section 7.2.2, Step 9 Section 7.2.3, Step 9	"Install the end Shipping Plate to the source head using the four 3/8-16 UNC x 45 mm long socket head screws provided"	To the current instructions, add "If the GC40 has the upgraded security hardware, install the ½-20 UNF socket head screw provided. Torque to 85 ft-lb."
Section 7.2.1, Step 12 Section 7.2.2, Step 13 Section 7.2.3, Step 13	"Unscrew the upper Source Drawer retaining ring and insert the Tube Spacer over the interlock bar into Source Drawer bore. This tube retains the source in the Safe position during shipment."	To the current instructions, add "If the GC40 has the upgraded security hardware installed, this step is omitted."
Section 7.3.1, Step 2, a)	a) "Insert the drawer shipping spacer in the source tube."	To the current instructions, add "If the GC40 has the upgraded security hardware installed, this step is omitted."
Section 7.3.1, Step 2, b)	b) "Screw the locking rings into the source tube at both ends of the respective heads."	To the current instructions, add "If the GC40 has the upgraded security hardware installed, this step is omitted."
Section 7.3.1, Step 2,c)	c) "Install the drawer shipping plate at both ends using four 3/8-16 UNC x 1.75 in. long ASTM A490 socket head screws or the approved equivalent. Torque each screw to 20 to 22 Nm (180 to 200 in-lb.)"	To the current instructions, add "If the GC40 has the upgraded security hardware, install the ½-20 UNF socket head screw provided. Torque to 85 ft-lb."

7.2 REFERENCES

[1] Menna, Blair. Safety Analysis Report for the F-430/GC40 Transport Package, MDS Nordion Technical Report No. IN/TR 1608 F430, March 2010.

CHAPTER 8 – ACCEPTANCE TESTS AND MAINTENANCE PROGRAM

The Acceptance Tests and Maintenance Program for the F-430 are described in IN/TR 1608 F430 and are unchanged.

CHAPTER 9 – QUALITY ASSURANCE

On May 1, 2008, MDS Nordion sold its teletherapy and self-contained irradiator businesses to Best Medical. The former MDS Nordion operations are now known as Best Theratronics Ltd. At the time of the sale, MDS Nordion transferred to Best Theratronics the F-430 Transport Packages and all of the associated designs and procedures.

9.1 BEST THERATRONICS QUALITY ASSURANCE PROGRAM

Best Theratronics continues to operate and maintain the F-430 transport packages in accordance with the original procedures and drawings that were transferred from MDS Nordion.

Best Theratronics' Quality Assurance has been approved by the USNRC. The approval certificate is attached in Appendix 9.2.1.

9.2 APPENDICES

Appendix 9.2.1 USNRC Quality Assurance Program Approval

APPENDIX 9.2.1:
USNRC Quality Assurance Program Approval For Radioactive Material Packages

NRC FORM 311 (10-2006) 10 CFR 71

U.S. NUCLEAR REGULATORY COMMISSION

QUALITY ASSURANCE PROGRAM APPROVAL
FOR RADIOACTIVE MATERIAL PACKAGES

1. APPROVAL NUMBER: 943
REVISION NUMBER: 0

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Title 10, Code of Federal Regulations, Chapter 1, Part 71, and in reliance on statements and representations heretofore made in Item 5 by the organization named in Item 2, the Quality Assurance Program identified in Item 5 is hereby approved. This approval is issued to satisfy the requirements of Section 71.101 of 10 CFR Part 71. This approval is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

2. NAME
Best Theratronics

STREET ADDRESS
413 March Road

CITY	STATE	ZIP CODE
Ottawa, Ontario	CAN	K2K 0E4

3. EXPIRATION DATE: April 30, 2019

4. DOCKET NUMBER: 71-0943

5. QUALITY ASSURANCE PROGRAM APPLICATION DATE(S)
February 27, 2009

6. CONDITIONS

1. Activities conducted regarding transportation packagings are to be executed under applicable criteria of 10 CFR Part 71, Subpart H. Authorized activities include: design, procurement, fabrication, assembly, testing, modification, maintenance, repair, and use of transportation packagings.

2. Records shall be maintained in accordance with the provisions of 10 CFR Part 71. Specifically:

   a. Records of each shipment of licensed material shall be maintained for 3 years after that shipment [10 CFR 71.91(a)].

   b. Records providing evidence of packaging quality shall be maintained for 3 years after the life of the packaging [10 CFR 71.91(d)].

   c. Records describing activities affecting packaging quality shall be maintained for 3 years after this Quality Assurance Program Approval is terminated [10 CFR 71.135].

3. Planned and periodic audits of all aspects of the Quality Assurance Program shall be conducted in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibility in the areas being audited, in accordance with 10 CFR 71.137.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

SIGNATURE: David W. Pstrak

DATE: 6/4/2009

DAVID W. PSTRAK, CHIEF
RULES, INSPECTIONS, AND OPERATIONS BRANCH
DIVISION OF SPENT FUEL STORAGE AND TRANSPORTATION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

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