Updated Version 1/5/06

NRC FORM 7 (5-2003) 10 CFR 110 — U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0027 — EXPIRES: 05/31/2006

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APPLICATION FOR LICENSE TO EXPORT NUCLEAR MATERIAL AND EQUIPMENT

(See Instructions on Reverse)

1. APPLICANT'S USE	a. DATE OF APPLICATION	b. APPLICANT'S REFERENCE	2. NRC USE	a. DOCKET NUMBER	b. LICENSE NUMBER
	12/12/2005	Not Applicable			XBP0018

3. APPLICANT'S NAME AND ADDRESS

a. NAME: Orlando Regional Heathcare Systems, Inc.

b. STREET ADDRESS *(Facility Site)*: 92 W. Miller Street

c. CITY: Orlando — d. STATE: FL — e. ZIP CODE: 32806

f. TELEPHONE NUMBER: (321) 841-1398 — g. FAX: (321) 841-6485 — h. E-MAIL: larrys@orhs.org

4. SUPPLIER'S NAME AND ADDRESS *(Complete if applicant is not supplier)*

a. NAME

b. STREET ADDRESS

c. CITY — d. STATE — e. ZIP CODE

5. FIRST SHIPMENT SCHEDULED	6. FINAL SHIPMENT SCHEDULED	7. APPLICANT'S CONTRACTUAL DELIVERY DATE	8. PROPOSED LICENSE EXPIRATION DATE	9. CONTRACT NO.
[redacted]	[redacted]	[redacted]	[redacted]	Not Applicable

10. ULTIMATE FOREIGN CONSIGNEE

a. NAME: MDS Nordion

b. STREET ADDRESS *(Facility Site)*: 447 March Road

c. CITY: Ottawa — d. COUNTRY: Canada

11. ULTIMATE END USE *(Include plant or facility name)*

MDS Nordion manufacturers and distributes sealed sources and devices and will accept return sources from customers for inspection, disposal, recycling or reuse.

11a. DATE REQUIRED

12. INTERMEDIATE FOREIGN CONSIGNEE

a. NAME: Not Applicable

b. STREET ADDRESS *(Facility Site)*

c. CITY — d. COUNTRY

13. INTERMEDIATE END USE

Not Applicable

13a. DATE REQUIRED

14. INTERMEDIATE FOREIGN CONSIGNEE

a. NAME: Not Applicable

b. STREET ADDRESS *(Facility Site)*

c. CITY — d. COUNTRY

15. INTERMEDIATE END USE

Not Applicable

15a. DATE REQUIRED

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16. COM CODE	17. DESCRIPTION *(Include chemical and physical form of nuclear material; give dollar value of nuclear equipment and components)*	18. MAX. ELEMENT WEIGHT	19. MAX. WT. %	20. MAX. ISOTOPE WEIGHT	21. UNIT
	Return source(model) and device(Gammacell 1000 to 3000) Cesium 137 [redacted] Chemical form: Element Physical form: Solid	N/A	N/A	[redacted]	[redacted]

22. FOREIGN OBLIGATIONS BY COUNTRY AND PERCENTAGE *(Use separate sheet if necessary)*

Not Applicable — This request is for export only.

23. ADDITIONAL INFORMATION ON CONSIGNEES, END USES, AND PRODUCT DESCRIPTION *(Use separate sheet if necessary)*

Please find attached MDS Nordion facility license which is valid until Octobr 31, 2010 and allows the possession of Cesium 137.

24. The applicant certifies that this application is prepared in conformity with Title 10, Code of Federal Regulations; and that all information in this application is correct to the best of his/her knowledge.

25. AUTHORIZED OFFICIAL	a. SIGNATURE	b. TITLE
	Richard Gobbi, Jr	Dept Adm. Director of Nuclear Medicine

NRC FORM 7 (5-2003) — PRINTED ON RECYCLED PAPER

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

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Our file Notre référence

42-1-1-0

NUCLEAR SUBSTANCE PROCESSING FACILITY OPERATING LICENCE

MDS NORDION, A DIVISION OF MDS (CANADA) INC.

Unless otherwise provided for in this licence, words and expressions used in this licence have the same meaning as in the *Nuclear Safety and Control Act* and its associated Regulations.

I) LICENCE NUMBER: **NSPFOL-11A.00/2015**

II) LICENSEE: Pursuant to section 24 of the *Nuclear Safety and Control Act*, this licence is issued to:

MDS Nordion, a Division of MDS (Canada) Inc.
447 March Road
Ottawa, ON
K2K 1X8

III) LICENCE PERIOD: This licence is valid from **November 1, 2005** to **October 31, 2015**, unless sooner suspended, amended, revoked or replaced.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

(a) operate a nuclear substance processing facility (hereinafter the "facility") at the location named in part II of this licence, encompassing only those areas identified in the facility description described in Appendix "A", and comprising the Nuclear Medicine Production Facility and the Cobalt Operations Facility (hereinafter "KOB") as described in the documents listed in Appendix "B";

(b) possess, transfer, use, process, import, manage and store the nuclear substances that are required for, associated with or arise from the operation of the facility described in (a).

Canada

V) CONDITIONS:

1. GENERAL

1.1 The appendices attached to this licence and the contents of the documents cited in those appendices form part of this licence.

1.2 Unless otherwise indicated in this licence, the licensee shall not make any change to any of the documents listed in Appendices "A", "B", and "D" without the prior written approval of the Canadian Nuclear Safety Commission (hereinafter "the Commission"), or a person authorized by the Commission.

Amendment of this licence is not required prior to the implementation by the licensee of a proposed change that has been approved in writing by the Commission, or by a person authorized by the Commission. An approved change is deemed to be part of this licence.

1.3 Unless otherwise indicated in this licence, the licensee may make changes to the documents listed in Appendix "C" provided the changes are made in accordance with the following requirements:

(a) before a change can be made, the licensee must justify and subject the change to the same level of internal review and approval as was originally obtained;

(b) persons reviewing and approving a proposed change must understand the original intent and the associated requirements, and must be able to assess the effect the proposed change will have on both; and

(c) when a change is proposed, its effect on existing operating conditions must be determined and be shown to be acceptable.

1.4 The licensee shall establish and continuously maintain a register that lists all current documentation relevant to the licensing of the facility.

2. OPERATIONS

2.1 Without limiting the applicability of the Nuclear Safety and Control Act, its regulations or any other condition of this licence to the operation of the facility, the operation of the facility shall be governed by and be in accordance with the documents listed in Appendices "A", "B", "C", and "D".

2.2 The licensee shall control, monitor and record releases of nuclear substances from the nuclear facility, and such releases shall not exceed the applicable limits as specified in Appendix "D" to this licence.

2.3 The licensee shall control, monitor and record releases of hazardous substances from the facility.

2.4 For the purpose of limiting, during the lifetime of the facility, the risks related to the failure or unavailability of any structure, system or component whose performance may affect the safe operation or security of the facility, the licensee shall establish, document and implement a maintenance program.

2.5 The maintenance program shall include testing and inspection and shall be of such quality and be performed in such a manner that the availability, reliability and effectiveness of any structure, system or component remain consistent with the documents *Final Safety Analysis Report for the Nuclear Medicine Production Facility* and *Safety Analysis Report for Cobalt Operations*, listed in Appendix "B", (hereinafter "the Safety Reports") and the documents listed in Appendix "C".

2.6 In emergency situations, the licensee shall respond to the emergency in accordance with the document *Emergency Response Plan - MDS Nordion Ottawa Site* listed in Appendix "C", (hereinafter "the Emergency Response Plan").

2.7 The licensee shall have in place for the facility radiation emergency procedures in accordance with the Emergency Response Plan.

3. MODIFICATIONS

3.1 The licensee shall not modify any building, structure, component or equipment at the facility as described in the documents in Appendices "A" and "B", or modify the operating conditions, methods or procedures, without prior written approval of the Commission or a person authorized by the Commission, except as allowed by condition 3.2.

3.2 The licensee may make modifications to the layout or physical arrangement of the building, structure, component or equipment, or the operating conditions, provided that the modifications do not:

(a) result in an adverse impact on health, safety or the environment that is different in nature or greater in magnitude or probability than that described in the Safety Reports; or

(b) result in a non-compliance with the Safety Reports.

4. NUCLEAR SUBSTANCES

4.1 The licensee's employees shall handle nuclear substances, including sealed sources, in accordance with written work procedures.

4.2 The licensee shall ensure that its personnel who are allowed or required to handle nuclear substances have been instructed in the safe handling of such substances, in accordance with the documentation listed in Appendix "C".

4.3 This licence does not authorize the licensee to import in a calendar year more than:

(a) 37 TBq of tritium;
(b) 1 GBq of plutonium;
(c) 2 MBq of thorium 228 or 232;
(d) 200 MBq of enriched uranium 233;
(e) 37 kBq of enriched uranium 235;
(f) 6 MBq of natural uranium; or
(g) 6 MBq of depleted uranium except when incorporated as shielding in a radiation device.

5. DISPOSAL

5.1 The licensee shall dispose of all solid waste containing nuclear substances to a CNSC licensed waste facility, except:

(a) the licensee may dispose of solid waste from Cobalt Operations to a landfill site provided that the nuclear substances are in solid form and the activity concentrations of the individual radionuclide are less than the derived unconditional clearance levels defined in the International Atomic Energy Agency Document IAEA-TECDOC-855 *Clearance Levels for Radionuclides in Solid Materials;*

(b) the licensee may dispose of solid waste from Cobalt Operations by an option and criteria other than given in condition 5.1(a), if the disposal option and criteria is approved in writing by the Commission, or by a person authorized by the Commission.

6. REPORTING

6.1 The licensee shall make reports to the Commission as specified in condition 6.3, of any:

(a) failure of equipment or procedures which led to or which, in the absence of safety systems provided, could have led to any release of nuclear substance from the facility exceeding the release limits referred to in condition 2.2;

(b) failure of equipment or procedures which led to or which, in the absence of safety systems provided, could have led to a significant release of a hazardous substance from the facility;

(c) failure of a protective system which did prevent or could have prevented the system from performing in accordance with the documents referred to in condition 2.1;

(d) degradation, weakening, incipient failure or failure of components or systems whose degradation, weakening or failure would create or significantly increase the risk to the health or safety of any person or to the environment;

(e) inaccuracy or incompleteness in the documents referred to in condition 2.1 that could affect the results of the safety assessment in these documents;

(f) hazard different in nature or greater in probability or magnitude than that described in the documents referred to in condition 2.1; and

(g) event that constitutes or reveals a violation of any conditions of this licence, the *Nuclear Safety and Control Act* or its regulations.

6.2 The licensee shall prepare and submit to the Commission as specified in condition 6.4 reports that cover:

(a) the operation and maintenance of the facility, summarizing facility and equipment performance and changes, changes to operating policies, changes in organization, occurrences described in condition 6.1, personnel radiation exposures and releases of nuclear substances and releases of hazardous substances from the facility;

(b) changes to the emergency procedures referred to in condition 2.7, other changes that affected or may affect the facility's emergency response arrangements, training activities, drill and exercise activities and unplanned events in which the facility's emergency response organization has been tested;

(c) the results of the effluent monitoring referred to in condition 2.2, and personnel radiation exposures for the facility;

(d) the results of environmental monitoring; and

(e) a summary of non-radiological health and safety activities, including information on minor incidents and lost-time incidents.

6.3 Except as otherwise directed or approved in writing by the Commission or a person authorized by the Commission, the reports described in condition 6.1, shall be made to the Commission as follows:

a) verbally and no later than twenty-four hours after discovery of the events referred to in condition 6.1 (a), (b), (c), (f) and (g); and

b) the licensee shall file a full written report of the situations referred to in condition 6.1, including any corrective actions taken, with the Commission within 21 working days after becoming aware of the matter.

6.4 Except as otherwise directed or approved in writing by the Commission or a person authorized by the Commission, the report described in condition 6.2 covering the preceding calendar year shall be submitted to the Commission by March 31 of each year.

6.5 If any action level set out in the *Radiation Protection Manual-Ottawa Site*, listed in Appendix "C", is reached or exceeded, the licensee shall notify the Commission within 7 days of becoming aware of the matter and shall file a final written report with the Commission within 45 working days of becoming aware of the matter.

7. RECORDS

7.1 In addition to any records required to be maintained pursuant to the regulations, and by other conditions of this licence, the licensee shall maintain the records specified in the Final Safety Analysis Reports.

7.2 The licensee shall keep records that describe fully and accurately any nuclear substance in its possession including:

(a) the name, form, quantity and location of the nuclear substances;
(b) where the nuclear substance is a sealed source, the model and serial number of the source;
(c) where the nuclear substance is contained in a radiation device, the model number and serial number of the device;
(d) the quantity of the nuclear substance used; and
(e) the manner in which the nuclear substance was used.

7.3 The licensee shall keep records that describe fully and accurately:

(a) the quantity and type of nuclear substances released from the facility into the environment;
(b) the quantity, type and location of nuclear substance sent from the facility to a radioactive waste management site;
(c) the quantity of solid waste released from the facility to a landfill site or by other option; and
(d) the production of nuclear substances other than those referred to in (a), (b) and (c).

8. SAFEGUARDS

8.1 The licensee shall take all necessary measures to facilitate Canada's compliance with any applicable safeguards agreement.

8.2 The licensee shall provide the International Atomic Energy Agency, an International Atomic Energy Agency inspector, or a person acting on behalf of the International Atomic Energy Agency with such reasonable services and assistance as are required to enable the International Atomic Energy Agency to carry out its duties and functions pursuant to a safeguards agreement.

8.3 The licensee shall grant prompt access at all reasonable times to all locations at the facility to an International Atomic Energy Agency inspector, or to a person acting on behalf of the International Atomic Energy Agency, where such access is required for the purposes of carrying

on an activity pursuant to a safeguards agreement. In granting access, the licensee shall provide health and safety services and escorts as required in order to facilitate activities pursuant to a safeguards agreement.

8.4 The licensee shall disclose to the Commission, to the International Atomic Energy Agency or to an International Atomic Energy Agency inspector, any records that are required to be kept or any reports that are required to be made under a safeguards agreement.

8.5 The licensee shall provide such reasonable assistance to an International Atomic Energy Agency inspector or to a person acting on behalf of the International Atomic Energy Agency, as is required to enable sampling and removal or shipment of samples required pursuant to a safeguards agreement.

8.6 The licensee shall provide such reasonable assistance to an International Atomic Energy Agency inspector or to a person acting on behalf of the International Atomic Energy Agency, as is required to enable measurements, tests and removal or shipment of equipment required pursuant to a safeguards agreement.

8.7 The licensee shall not alter, deface or break a safeguards seal, except pursuant to a safeguards agreement.

8.8 The licensee shall implement measures to prevent damage to or the theft, loss or sabotage of samples collected pursuant to a safeguards agreement or the illegal use, possession or removal of such samples.

8.9 The licensee shall make such reports and provide such information to the Commission as are required to facilitate Canada's compliance with any applicable safeguards agreement.

8.10 The licensee shall make and submit reports to the Commission in accordance with the document AECB-1049, *Reporting Requirements for Fissionable and Fertile Substances*, on the inventory and transfer of fissionable and fertile substances.

9. SECURITY

9.1 The licensee shall maintain the measures for facility security as specified in the document entitled *Annual Physical Security Report*, listed in Appendix "C".

9.2 The licensee shall annually update the document *Annual Physical Security Report*, and submit the document by March 31, of the following calendar year.

9.3 The licensee shall update its Vulnerability Threat Risk Assessment, established to meet the requirements of subsection 6.(l) of the *Class I Nuclear Facilities Regulations*, and paragraphs 3.(1)(g) and (h) of the *General Nuclear Safety and Control Regulations*, when any significant changes are made to the security of the facility or if the threat to the facility increases. Once an update has been completed, it shall be submitted to the Commission or a person authorized by the Commission for review and comment.

10. PRESSURE BOUNDARIES

For the purposes of the conditions of this section, "registered", "accepted", "approval" and "approved" means either by the Commission, by a person authorized by the Commission, or by an authority identified by the Commission for that purpose.

For the purposes of the conditions of this section, "active areas" are those areas as defined in the *Radiation Protection Manual Ottawa site* listed in Appendix "C". "Non-active Areas" are all other areas of the facility.

10.1 For non-active areas, the licensee shall design, manufacture, fabricate, procure, install, modify, repair, test, examine, inspect or otherwise perform work related to pressure vessels, boilers, systems, piping, fittings, parts, components and supports according to the specifications in the Ontario *Technical Standards and Safety Act, 2000* and its *Regulation 220/01 for Boilers and Pressure Vessels*.

10.2 For active areas, the licensee shall design, manufacture, fabricate, procure, install, modify, repair, test, examine, inspect or otherwise perform work related to pressure vessels, boilers, systems, piping, fittings, parts, components and supports according to the (untitled) code classification logic diagram, found in the attachment to the June 23, 2005 letter titled *Pressure Retaining Components (PRCs)*, from J. Kavanagh to A. Erdman, using nuclear and/or conventional code and standard classifications approved by the Commission or a person authorized by the Commission.

10.3 For both licence conditions 10.1 and 10.2 where indicated by the applicable standards, the licensee shall obtain and maintain current the following regulatory approvals for this work:

(a) registered designs;
(b) accepted overpressure protection reports;
(c) approval of applicable standards and code classifications;
(d) registered welding and brazing procedures;
(e) qualified welders, welding operators, brazers, and examination personnel;
(f) accepted quality control and quality assurance programs; and
(g) accepted plans and procedures.

10.4 The licensee may employ the services of a contractor with valid and current Certificate of Authorization(s) from the Ontario Technical Safety and Standards Authority. The contractor may carry out the activities listed in condition 10.1 in accordance with Ontario *Technical Standards and Safety Act, 2000* and its *Regulation 220/01 for Boilers and Pressure Vessels*, for pressure boundary systems and components that do not contain nuclear substances, do not adversely impact a nuclear safety system or do not cause an unreasonable risk involving nuclear substances at the facility.

10.5 Where the licensee employs the services of a contractor with valid and current Certificate of Authorization(s) from the Ontario Technical Safety and Standards Authority and with prior approval of the CNSC staff, the contractor may carry out the activities listed in condition 10.2 pressure boundary systems and components that contain nuclear substances, that could adversely impact on a nuclear safety system or could cause risk(s) involving nuclear substances at the facility.

10.6 The licensee shall operate vessels, boilers, systems, piping, fittings, parts, components, and their supports safely and keep them in a safe condition. The licensee shall:

(a) follow accepted plans and procedures to test, maintain, or alter overpressure protection devices;

(b) comply with operating limits specified in certificates, orders, designs, overpressure protection reports, and applicable codes and standards;

(c) inspect and perform material surveillance according to accepted schedules, plans and procedures;

(d) have any certified boiler or pressure vessel that is in operation or use inspected and certified by an authorized inspector according to an accepted schedule; and

(e) ensure that vessels, boilers, systems, piping, fittings, parts, components and supports have markings as specified in the applicable standards.

10.7 The licensee shall keep records of regulatory approvals and other documents required under conditions 10.1 to 10.6 of this licence and the standards applicable to the work or equipment.

10.8 In addition to any reporting requirements set out in the conditions in section 6 of this licence or in the *Nuclear Safety and Control Act* and its associated regulations, the licensee shall report promptly, to the Commission and to the Ontario Technical Standards and Safety Authority, when the licensee becomes aware of any failure of a pressure boundary that has caused injury, death or property damage.

11. FIRE PROTECTION

11.1 The licensee shall design, build, modify and otherwise carry out work related to the facility with potential to impact protection from fire in accordance with the *National Building Code, 1995, the National Fire Code, 1995* and *National Fire Protection Association, NFPA-801, 2003 edition: Standard for Fire Protection for Facilities Handling Radioactive Materials.*

11.2 The licensee shall operate, maintain, test and inspect the facility in accordance with the *National Fire Code, 1995* and *National Fire Protection Association, NFPA- 801, 2003 edition.*

11.3 The licensee shall, prior to implementing any proposed modification of the facility with potential to impact protection from fire:

(a) submit the proposed modification for third – party review of compliance with Condition no. 11.1 and the standards listed therein;

(b) have the review carried out by one or more independent external agencies having specific expertise with such reviews; and

(c) submit the results of the review in writing to the Commission or a person authorized by the Commission.

11.4 The licensee shall:

(a) arrange for annual third-party reviews of compliance with the requirements of the *National Fire Code*, 1995 and *National Fire Protection Association, NFPA-801, 2003 edition*;

(b) have the review carried out by one or more independent external agencies having specific expertise with such reviews; and

(c) submit the results of the review in writing to the Commission or a person authorized by the Commission.

11.5 In the event of any conflict or inconsistency between a nuclear safety requirement and the *National Building Code, 1995*, *the National Fire Code, 1995*, or *National Fire Protection Association, NFPA-801, 2003 edition*, the licensee shall direct the conflict or inconsistency to the Commission or a person authorized by the Commission for resolution.

12. DECOMMISSIONING FINANCIAL GUARANTEE

12.1 The licensee shall provide, no later than June 1, 2006, a financial guarantee for the future decommissioning of the facility that is acceptable to the Commission or a person authorized by the Commission.

SIGNED at OTTAWA, this 20 day of October, 2005

Linda J. Keen
President
Canadian Nuclear Safety Commission

APPENDIX "A"

THE NUCLEAR SUBSTANCE PROCESSING FACILITY DESCRIPTION

The facility is described in the following document:

1. The letter from L. R. Hillier of MDS Nordion to A. Erdman of the CNSC, *Facility Description*, dated April 14, 2005, as amended May 13, 2005, with the attached drawings.

APPENDIX "B"

THE KANATA OPERATIONS BUILDING (KOB)

The description of the Kanata Operations Building that includes the Nuclear Medicine Production Facility and the Cobalt Operations Facility as described in:

1. *Final Safety Analysis Report for the Nuclear Medicine Production Facility*, MDS Nordion Document No. IS/IR 1070 Z000 (4), dated November 12, 2002.

2. *Safety Analysis Report for Cobalt Operations*, MDS Nordion Document No. IS/SR 1057 Z000 (8), dated August 18, 2003.

3. Section 8. Nuclear Ventilation System, and Section 9. Nuclear Exhaust Monitoring Systems, except for 9.5, of the *MDS Nordion Radiation Protection Manual- Ottawa Site*, MDS Nordion Document No. SE-RP-001.

And illustrated in Drawings PEAE-61266 and PEAE-61267, attached to the letter, *Facility Description* from L. Hillier to A. Erdman, dated April 14, 2005.

APPENDIX "C"

DOCUMENTS PERTAINING TO OVERALL OPERATION

The facility operations are governed by the following documents as amended in accordance with this licence:

1. *Radiation Protection Manual-Ottawa Site*, MDS Nordion Document No. SE-RP-001.

2. *MDS Nordion Environmental Management System Manual- Ottawa Site*, MDS Nordion Document No. SE-ENV-001.

3. *MDS Nordion Environmental Protection Program*, MDS Nordion Document No. SE-ENV-015.

4. *Annual Physical Security Report*, (to be updated annually).

5. *Quality Assurance Program for Safety*, MDS Nordion Document No. CPM-6-26.

6. *Emergency Response Plan - MDS Nordion Ottawa Site*, MDS Nordion Document No. SE-ERP-002.

7. *Health, Safety and Environment Training*, MDS Nordion Document No. SE-TRN-003.

APPENDIX "D"

RADIOACTIVE RELEASES (Condition 2.2)

1 The derived release limit values in the document *Derived Release Limits*, MDS Nordion Document No. SE-OP-29 (4), dated February 4, 2003.