



December 17, 2018

Mr. M. A. Leblanc  
Commission Secretary  
Canadian Nuclear Safety Commission  
P.O. Box 1046, Station B  
280 Slater St., Ottawa, Ontario, K1P 5S9

Dear Mr. Leblanc:

**Subject: Request for Issuance of a Class 1B Licence to BWXT ITG Canada, Inc. for operation of Nordion (Canada) Inc.'s existing Medical Isotopes Facility**

This is a request for issuance of a Class 1B licence to BWXT ITG Canada, Inc. (BWXT ITG) for operation of the existing Nordion (Canada) Inc. (Nordion) medical isotopes facility. On July 30, 2018, BWXT acquired Nordion's medical isotope business which is conducted in the Nordion Class 1B Facility in Ottawa. Approximately 150 Nordion employees associated with the operations of the facility were hired by BWXT. Since that time, Nordion has continued to operate the medical isotope facility under its Class 1B licence NSPFOL-11A.00/2025 and the Nordion Management System for Safety and will do so as BWXT seeks their own licence. The medical isotopes facility is inclusive of the radiochemical and radiopharmaceutical facilities in the Nuclear Medicine Production Facility (NMPF) which is located in the Kanata Operations Building and the radiopharmaceutical facilities in the Kanata Manufacturing Facility (KRMF).

On May 7, 2018 BWXT ITG announced that it had developed an innovative technology for producing molybdenum-99 (Mo99) using a natural molybdenum target, and the corresponding technetium-99m (Tc99m) generator. This initiative was a key driver supporting the acquisition of Nordion's Medical Isotope assets. BWXT ITG has a 24 month transition services agreement with Nordion which ends on July 31, 2020. BWXT ITG would like to be able to commence commercial operation under its own licence by early 2020. We therefore request issuance of a Class 1B licence to BWXT ITG in the first calendar quarter of 2020.

We also respectfully request that the public review of this licence application take place in a 1 day hearing. Although BWXT ITG Canada, Inc. is a new applicant, the facility to be licensed is part of an existing facility currently operating under Nordion's Class 1B licence that has been in operation for the past several decades. The performance of the licensee that includes the operations carried out in the BWXT part of the facility is reviewed by the CNSC through their normal oversight program and includes auditing of the operations, review of the annual compliance report and public review of the performance of the licensee in the annual Regulatory Oversight Meeting. The supporting information for this application includes information that has been presented to the Commission at previous hearings and meetings involving licensing and performance review of Nordion over its long history. We believe that a 1 day hearing would still permit a licensing process that demonstrates openness, transparency and inclusiveness, allowing adequate opportunity for public intervention.

Information required to be contained in a licence application in respect of a Class 1 nuclear facility as required by the Nuclear Safety and Control Act and Regulations is provided in Attachment 1. Additional information is included in Attachments 2 to 6. These are supported by the enclosed standard operating procedures.

The Supplementary Report in Attachment 3 provides information related to BWXT ITG's organizational structure, business plans for the NMPF, and approach to addressing the 14 Safety and Control Areas. We have included performance data achieved during operation of the Class 1B facility by Nordion as we believe it is indicative of the performance anticipated for the operation of the NMPF by BWXT ITG which will:

1. remain within the scope of the licensing basis established for Nordion
2. employ a work force comprised largely of Nordion personnel hired by BWXT ITG at the time of the acquisition
3. adopt the existing Nordion Management System for Safety.

The issuance of a Class 1B licence to BWXT ITG has a neutral impact on designs, operating conditions, policies, programs, methods or other elements that are integral to the existing Nordion licensing basis. The proposed processing and manufacturing of nuclear substances used in medical applications will remain within the existing Nordion licensing basis. BWXT ITG employees currently work under contract to Nordion and are required to adhere to all aspects of the Nordion Management System for Safety which BWXT will adopt upon issuance of the licence. For these reasons, we request a Class 1B licence that allows the same flexibility of operation the current Nordion licence allows and further we request the licence be issued for a period of 10 years.

BWXT ITG will adopt the existing Nordion Management System for Safety upon issuance of the licence, and will subsequently revise this program and underlying procedures to reflect the BWXT ITG organizational structure. The Management System for Safety will be revised within 30 days of receiving the Class 1B licence. The Tier 1 and 2 procedures referenced in the

Management System for Safety document will be revised within 12 months of issuance of the Class 1B licence. Other operational procedures will be revised at the next required operational revision or as part of the regular periodic review process, whichever occurs earlier.

BWXT ITG will require a period of time to assess the following standards and codes. We commit to complete our assessments, and submit the findings, along with any proposed implementation plans by June 30, 2019.

1. CSA B51-14 (2014): *Boiler Pressure Vessel and Pressure Piping Code*
2. NBC-2015 (2015): *National Building Code*
3. NFC-2015 (2015): *National Fire Code*
4. CSA N288.7-15 (2015): *Groundwater Protection Programs at Class I Nuclear Facilities and Uranium Mines and Mills*
5. CSA N288.8-17 (2017): *Establishing and implementing action levels for releases to the environment from nuclear facilities*

Under a landlord-tenant arrangement, BWXT ITG will lease the medical isotope facility from Nordion. BWXT ITG will retain ultimate responsibility for security, fire protection and facility maintenance. Some aspects of these programs will be provided by Nordion as per the lease. Similarly, BWXT ITG will retain ultimate responsibility for management oversight of BWXT licensed activities and for emergency response. In practice, in addition to the BWXT ITG EHS Committee, a joint BWXT ITG-Nordion EHS Committee will be established. A joint BWXT ITG-Nordion emergency response plan will also be established. BWXT ITG must seek Nordion approval for facility modifications. The executed Lease Agreement has been provided under separate cover as it contains certain sensitive and confidential proprietary information.

The proposed licence does not impact the provisions in place for the protection of the environment, the health and safety of persons and the maintenance of national security and measures to implement international obligations to which Canada has agreed.

Should you have any questions, please do not hesitate to contact Jackie Kavanagh at (613) 592-3400 extension 2730, or e-mail at [jkavanagh@bwxt.com](mailto:jkavanagh@bwxt.com).

Respectfully,

BWXT ITG Canada, Inc.



Tom Burnett,  
Vice-President and General Manager

**cc.: Caroline Ducros, Michael Young - CNSC  
Ron McGregor, Jackie Kavanagh - BWXT ITG  
Richard Wassenaar, Shannon Lacasse - Nordion**

**Enclosures:**

- Attachment 1: Information Required for Issuance of a Class 1B Licence**
- Attachment 2: List of Regulations, Permits, Certificates, and Licenses Applicable to BWXT ITG**
- Attachment 3: Supplementary Report to Support Class 1B Licence Application**
- Attachment 4: Certificate of Incorporation for BWXT ITG Canada, Inc.**
- Attachment 5: BWXT ITG Canada, Inc. Organizational Charts**
- Attachment 6: Permission for BWXT ITG Canada, Inc. to Operate a Class 1B Facility on Nordion (Canada) Inc. Site  
Standard Operating Procedures and Other Documents referenced in the application**

**Reference:**

- [1] Tom Burnett, BWXT ITG, letter to M.A. Leblanc, CNSC, "Submission of additional information related to BWXT ITG Canada, Inc. (BWXT ITG) Class 1B licence application", December 17, 2018.**

## Attachment 1: Information Required for Issuance of a Class 1B Licence

	REQUIREMENTS	SCA <sup>1</sup>	Response
<b>General Nuclear Safety and Control Regulations</b>			
3(1)	An application for a licence shall contain the following information:		
3(1)(a)	the applicant's name and business address;		<p>BWXT ITG Canada Inc.                      Corporate No.: 002599290 (Ontario)                      447 March Road                      Ottawa, ON                      K2K 1X8                      Certificate of incorporation is attached.</p> <p>Applicant authority:                      [REDACTED]                      Vice-President and General Manager                      BWXT ITG Canada Inc. [REDACTED]                      [REDACTED]</p>

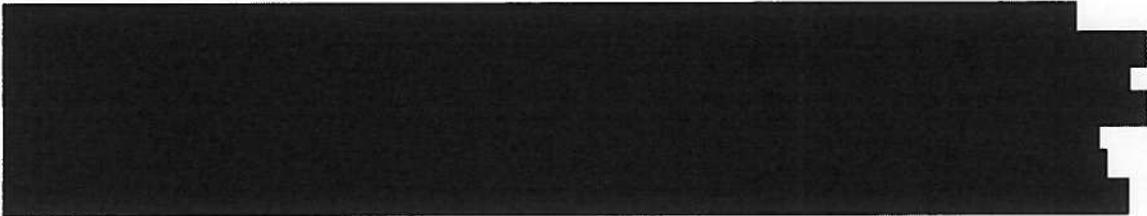
<sup>1</sup> See acronyms at the end of the table.

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(1)(b)	the activity to be licensed and its purpose;		<ul style="list-style-type: none"> <li>• BWXT ITG Canada Inc. is applying for a Class 1B licence for operation of the Nuclear Medicine Production Facility which is currently licensed as part of the Nordion (Canada) Inc. nuclear processing facility situated at the location named in Section 3(1)(a) of this table under the <i>General Nuclear Safety and Control Regulations</i>. A licence is requested for a period of 10 years.</li> <li>• Activities to be licensed: <ul style="list-style-type: none"> <li>▪ Operate a nuclear substance processing facility at the location named in Section 3(1)(a) of this table under the <i>General Nuclear Safety and Control Regulations</i>, encompassing only those areas identified in the facility description (refer to Section 3(1)(d) of this table under the <i>General Nuclear Safety and Control Regulations</i>), and comprising the Nuclear Medicine Production Facility as described in the "Final Safety Analysis Report for the Nuclear Medicine Production Facility", IS/SR 1070 Z000.</li> <li>▪ Possess, transfer, use, process, import, manage, store and dispose the nuclear substances that are required for, associated with or arise from the operation of the facility.</li> <li>▪ Use prescribed equipment that is required for, associated with, or arises from the operation of the facility.</li> <li>▪ Possess and use prescribed information that is required for, associated with, or arises from the operation of the facility.</li> </ul> </li> </ul>
3(1)(c)	the name, maximum quantity and form of any nuclear substance to be encompassed by the licence;	SA	<ul style="list-style-type: none"> <li>• <math>&gt;1 \times 10^{15}</math> Bq per calendar year, Mo-99 in solid form.</li> <li>• Various other radioisotopes atomic numbers 1-89, <math>&lt;1 \times 10^{15}</math> Bq per calendar year in solid, liquid or gaseous form.</li> <li>• The products we will process will have half-lives <math>&lt; 1</math> year. It is not unusual to have trace impurities with half-lives <math>&gt; 1</math> year. We do not expect significant releases associated with these impurities.</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(1)(d)	a description of any nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence;	SA	<ul style="list-style-type: none"> <li>• "Final Safety Analysis Report for the Nuclear Medicine Production Facility", IS/SR 1070 Z000</li> <li>• "KOB GROUND FLOOR LICENSED NUCLEAR FACILITY", PEAE-61266. This drawing contains prescribed information and is submitted under separate cover.</li> <li>• "KOB SECOND FLOOR LICENSED NUCLEAR FACILITY", PEAE-61267. This drawing contains prescribed information and is submitted under separate cover.</li> <li>• "KOB BASEMENT LICENSED NUCLEAR FACILITY", PEAE-61278. This drawing contains prescribed information and is submitted under separate cover.</li> <li>• [REDACTED] Calibrator Serial Number 10279 used for calibrating survey meters, containing a Cs-137 source.</li> <li>• [REDACTED] Calibrator Serial Number 201 used for calibrating survey meters, containing a Cs-137 source.</li> <li>• [REDACTED] CAD Tester Serial Number 118 used for testing charcoal adsorber filters, containing an H-3 source.</li> <li>• Security sensitive information including security response plans and procedures and CNSC security correspondence.</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(1)(e)	the proposed measures to ensure compliance with the <i>Radiation Protection Regulations</i> and the <i>Nuclear Security Regulations</i> ;	RP/NS	<p><i>Radiation Protection Regulations</i>:</p> <ul style="list-style-type: none"> <li>• “Radiation Protection Manual – Ottawa Site”, SE-RP-001 <ul style="list-style-type: none"> <li>▪ organization and administration for RP <ul style="list-style-type: none"> <li>○ Refer to BWXT ITG organizational charts (Refer to Attachment 5a and 5b)</li> </ul> </li> <li>▪ RP training and qualification <ul style="list-style-type: none"> <li>○ Refer to Section 4(a)(ii) of this table under <i>Radiation Protection Regulations</i></li> <li>○ “Radiation Surveyors and Monitors On-the-Job Training Program”, SE-TRN-001 for Radiation Surveyors and Monitors</li> </ul> </li> <li>▪ classification of areas and local rules <ul style="list-style-type: none"> <li>○ “Radiation Protection Manual – Ottawa Site”, SE-RP-001 Section 4.4</li> </ul> </li> <li>▪ radiation exposure and dose control <ul style="list-style-type: none"> <li>○ “Keeping Radiation Exposures and Doses “As Low as Reasonably Achievable (ALARA)”, SE-RP-002</li> </ul> </li> <li>▪ RP equipment and instrumentation <ul style="list-style-type: none"> <li>○ Refer to Section 3(1)(i) of this table under <i>Nuclear Substances and Radiation Devices Regulations</i></li> </ul> </li> <li>▪ radiation monitoring and dose assessment <ul style="list-style-type: none"> <li>○ “Radiation Protection Manual – Ottawa Site”, SE-RP-001 Sections 5.6, 5.7, and 6</li> </ul> </li> <li>▪ contamination control <ul style="list-style-type: none"> <li>○ “Radiation Protection Manual – Ottawa Site”, SE-RP-001 Section 7</li> </ul> </li> <li>▪ planning for unusual situations <ul style="list-style-type: none"> <li>○ Refer to Section 4(a)(iv) of this table under <i>Radiation Protection Regulations</i></li> </ul> </li> </ul> </li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(1)(e), continued			<ul style="list-style-type: none"> <li>• RP program oversight <ul style="list-style-type: none"> <li>○ EHS Committee - "Nordion Environmental, Health &amp; Safety Responsibilities and Committees", CPM-6-19. RP program oversight is provided by the EHS Committee.</li> <li>○ In addition, an EHS regulatory compliance audit will be performed at least once every 3 years by an external 3<sup>rd</sup> party. This audit is conducted to review all aspects of EHS, including Radiation Protection</li> </ul> </li> </ul> <p><i>Nuclear Security Regulations:</i>  BWXT ITG will retain ultimate responsibility for meeting the requirements of the <i>Nuclear Security Regulations</i>. Under the lease agreement, Nordion will provide site security. The lease contains prescribed information and confidential information and is submitted under separate cover.</p> <ul style="list-style-type: none"> <li>• </li> <li>• Nordion "2018 Security Plan", submitted previously to the CNSC on March 31st, 2018. The plan covers all aspects of the security program for the site. This is prescribed information.</li> <li>• Nordion "Physical Security Threat Assessment". Updated annually and available to CNSC Security Division review on site at request, as per normal protocol. (Refer to Section 6(l) of this table under Class I Nuclear Facilities Regulations).</li> </ul>
3(1)(f)	any proposed action levels for the purpose of section 6 of the <i>Radiation Protection Regulations</i> ;	RP	<ul style="list-style-type: none"> <li>• Sections 5.6, 5.7, 9.5 and 10 of the "Radiation Protection Manual – Ottawa Site", SE-RP-001</li> <li>• "Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)""", SE-RP-002</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(1)(g)	the proposed measures to control access to the site of the activity to be licensed and the nuclear substance, prescribed equipment or prescribed information;	NS	<p>BWXT ITG will retain ultimate responsibility to control access to the site of the activity to be licensed and the nuclear substance, prescribed equipment or prescribed information. Under the lease agreement, Nordion will provide site security</p> <ul style="list-style-type: none"> <li>• </li> <li>• Nordion "2018 Security Plan", submitted previously to the CNSC on March 31st, 2018. The plan covers all aspects of the security program for the site. This is prescribed information.</li> <li>• Nordion "Physical Security Threat Assessment". Updated annually and available to CNSC Security Division review on site at request, as per normal protocol. (Refer to Section 6(l) of this table under Class I Nuclear Facilities Regulations).</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(1)(h)	the proposed measures to prevent loss or illegal use, possession or removal of the nuclear substance, prescribed equipment or prescribed information;	NS	<p>BWXT ITG will retain ultimate responsibility to prevent loss or illegal use, possession or removal of the nuclear substance, prescribed equipment or prescribed information. Under the lease agreement, Nordion will provide site security. Nordion will be responsible for conducting facility access security clearances.</p> <ul style="list-style-type: none"> <li>  </li> <li>Nordion "2018 Security Plan", submitted previously to the CNSC on March 31st, 2018. The plan covers all aspects of the security program for the site. This is prescribed information.</li> <li>Nordion "Physical Security Threat Assessment". Updated annually and available to CNSC Security Division review on site at request, as per normal protocol. (Refer to Section 6(l) of this table under Class I Nuclear Facilities Regulations).</li> <li>"Facility Access Security Clearance", SE-SC-005</li> </ul>
3(1)(i)	a description and the results of any test, analysis or calculation performed to substantiate the information included in the application;	SA	"Final Safety Analysis Report for the Nuclear Medicine Production Facility", IS/SR 1070 Z000 Section 8
3(1)(j)	the name, quantity, form, origin and volume of any radioactive waste or hazardous waste that may result from the activity to be licensed, including waste that may be stored, managed, processed, or disposed of at the site of the activity to be licensed, and the proposed method for managing and disposing of that waste;	WM	<ul style="list-style-type: none"> <li>Nordion's historical Annual Compliance and Operational Performance Reports</li> <li>"Final Safety Analysis Report for Nuclear Medicine Waste Management", IS/SR 1052 Z000</li> <li>"Final Safety Analysis Report for the Waste Diversion Program", IN/SR 1859 C000</li> <li>"Radiation Protection Manual – Ottawa Site", SE-RP-001 Section 13</li> <li>"Chemical Handling and Storage", SE-HS-008</li> <li>"Waste Management Program", SE-ENV-022</li> <li>BWXT ITG is developing a new process for Technetium 99m generators. There will be no releases to the sanitary system allowed from this process. Radioactive and hazardous waste associated with the new process will meet the acceptance guidelines of our waste providers. Radioactive waste will be disposed of to licensed waste facilities.</li> </ul>

	<b>REQUIREMENTS</b>	<b>SCA<sup>1</sup></b>	<b>Response</b>
3(1)(k)	the applicant's organizational management structure insofar as it may bear on the applicant's compliance with the Act and the Regulations made under the Act, including the internal allocation of functions, responsibilities and authority;	MS	Organization charts for Regulatory, EHS and Compliance, and Senior Leadership Team (Refer to Attachment 5)
3(1)(l)	a description of any proposed financial guarantee relating to the activity to be licensed; and	OMRI	BWXT ITG will put in place a financial guarantee acceptable to the CNSC to cover the estimated cost of decommissioning the Nuclear Medicine Production Facility. [REDACTED]
3(1)(m)	any other information required by the Act or the Regulations made under the Act for the activity to be licensed and the nuclear substance, nuclear facility, prescribed equipment or prescribed information to be encompassed by the licence.	OMRI	As requested.

	<b>REQUIREMENTS</b>	<b>SCA<sup>1</sup></b>	<b>Response</b>
3(1.1)	<p>The Commission or a designated officer authorized under paragraph 37(2)(c) of the Act, may require any other information that is necessary to enable the Commission or the designated officer to determine whether the applicant</p> <p>(a) is qualified to carry on the activity to be licensed; or</p> <p>(b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed.</p>	OMRI	As requested.

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(2)	Subsection (1) does not apply in respect of an application for a licence to import or export for which the information requirements are prescribed by the <i>Nuclear Non-Proliferation Import and Export Control Regulations</i> , or in respect of an application for a licence to transport while in transit for which the information requirements are prescribed by the <i>Packaging and Transport of Nuclear Substances Regulations</i> .	N/A	Not applicable.

	REQUIREMENTS	SCA <sup>1</sup>	Response
15	<p>Every applicant for a licence and every licensee shall notify the Commission of:</p> <p>(a) the persons who have authority to act for them in their dealings with the Commission;</p> <p>(b) the names and position titles of the persons who are responsible for the management and control of the licensed activity and the nuclear substance, nuclear facility, prescribed equipment or prescribed information encompassed by the licence; and</p> <p>(c) any change in the information referred to in paragraphs (a) and (b), within 15 days after the change occurs.</p>	MS	<p>Applicant authority:</p> <p>[REDACTED]  Vice-President and General Manager  BWXT ITG Canada [REDACTED]  [REDACTED]</p> <p>Signing authorities: [REDACTED]  Senior Manager, Nuclear Regulatory and EHS  [REDACTED]  [REDACTED]</p> <p>[REDACTED]  Vice-President, Regulatory and EHS Compliance  [REDACTED]  [REDACTED]</p>

	REQUIREMENTS	SCA <sup>1</sup>	Response
<b><i>Class I Nuclear Facilities Regulations</i></b>			
3	An application for a licence in respect of a Class I nuclear facility, other than a licence to abandon, shall contain the following information in addition to the information required by section 3 of the <i>General Nuclear Safety and Control Regulations</i> :		
3(a)	a description of the site of the activity to be licensed, including the location of any exclusion zone and any structures within that zone;	SA/PD	<ul style="list-style-type: none"> <li>• Refer to Section 3(1)(d) of this table under the <i>General Nuclear Safety and Control Regulations</i></li> <li>• "Final Safety Analysis Report for the Nuclear Medicine Production Facility", IS/SR 1070 Z000</li> <li>• The province, county or district, and municipality or township in which the facility is located and its address; (IS/SR 1070 Z000 Section 4.3)</li> <li>• A plan of the site that includes the facility, the location of the nearest residences and communities, roads and transportation corridors; (IS/SR 1070 Z000 (5), Section 4.5. The description in IS/SR 1070 Z000 is inclusive of the structures which are owned by Nordion. The Nuclear Medicine Production Facility comprising Medical Isotopes Operations and the KRMF is leased by Nordion to BWXT ITG. The leased spaces are delineated on the drawings listed in Section 3(1)d of this table under <i>General Nuclear Safety and control Regulations</i>).</li> <li>• A plan showing the location of the Nordion facility within the site. (IS/SR 1070 Z000 Section 4.5)</li> <li>• A description of the use of the land near the site. (IS/SR 1070 Z000 Section 4.4)</li> <li>• A description of activities that take place, near to the facility. (IS/SR 1070 Z000 Section 4.4)</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(b)	plans showing the location, perimeter, areas, structures, and systems of the nuclear facility;	PD	<ul style="list-style-type: none"> <li>• Refer to Section 3(1)(d) of this table under the <i>General Nuclear Safety and Control Regulations</i></li> <li>• “Final Safety Analysis Report for the Nuclear Medicine Production Facility”, IS/SR 1070 Z000: <ul style="list-style-type: none"> <li>○ The building name, its principal uses, number of floors and basic construction (e.g., steel frame, reinforced concrete, wood frame, etc.); (Sections 4.5 Nordion Facilities, 4.1 General Description, and 4.6.1 Structure) – Note: The BWXT ITG facility comprises the Medical Isotopes Operations and the Kanata Radiopharmaceutical Manufacturing Facility (KRMF). [REDACTED]</li> <li>○ A description of the facility ventilation, heating and cooling systems, electrical circuits, fire protection features, systems and equipment, emergency lighting and location of emergency exits; (Sections 4.9 Ventilation System, 4.8.2 Electrical, 6.3 Controls, 6.2.4 Fire Detectors, 4.8 Site Services, and 4.7 Internal Layout (for location of emergency exits))</li> <li>○ A description of building and laboratory hazards including such things as natural gas pipes, compressed gas storage, significant combustible inventories and water mains that are a potential flooding hazard. (Section 8 Hazard Analysis and Safety Assessment)</li> </ul> </li> <li>• Identification of the boundaries of the BWXT ITG facility encompassed by the licence; “Facility Description”, SE-LIC-018”</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(c)	evidence that the applicant is the owner of the site or has authority from the owner of the site to carry on the activity to be licensed;		Nordion (Canada) Inc. (Nordion) is the owner of the site (land and buildings) at 447 March Road, and has leased the Nuclear Medicine Production Facility and associated areas to BWXT ITG [REDACTED]. Under the lease agreement, the Ottawa Property is subject to the control and management by Nordion. The leased areas are defined in the lease [REDACTED]. Refer to the letter from Nordion providing authority to BWXT ITG to carry on the activity to be licensed (Attachment 6) and to the lease agreement (sent under separate cover as it contains both prescribed information and confidential information).
3(d)	the proposed quality assurance program for the activity to be licensed;	MS	SE-LIC-001, "Management System for Safety"  Clarification of responsibilities of BWXT ITG and Nordion for safety related activities is described in: <ul style="list-style-type: none"> <li>• "BWXT ITG - Nordion Safety Responsibilities", SE-LIC-XXX (draft)</li> </ul>
3(e)	the name, form, characteristics and quantity of any hazardous substances that may be on the site while the activity to be licensed is carried on;	WM	<ul style="list-style-type: none"> <li>• Chemical inventory available upon request</li> <li>• MSDS sheets for all substances available upon request</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(f)	the proposed worker health and safety policies and procedures;	CHS	<ul style="list-style-type: none"> <li>• "Nordion Environmental, Health and Safety Policy", CPM-6-06</li> <li>• "Occupational Health and Safety Management System Manual", SE-HS-044</li> <li>• "Nordion Environmental, Health &amp; Safety Responsibilities and Committees", CPM-6-19</li> <li>• "Management System for Safety", SE-LIC-001</li> <li>• "External Personal Radiation Monitoring", SE-RP-004</li> <li>• "Protective Clothing and Gloves in Active Area Laboratories", SE-RP-005</li> <li>• "Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)", SE-RP-002</li> </ul> <p>BWXT ITG will retain ultimate responsibility for meeting the requirements for fire protection. Under the lease agreement, Nordion will be responsible for fire protection systems..</p> <p>■ [REDACTED]</p> <ul style="list-style-type: none"> <li>• "Fire Protection Program", SE-EHS-007</li> <li>• "Fire Hazards Analysis Report", SE-EHS-017</li> <li>• "Fire Safety Plan", SE-ERP-001</li> </ul>
3(g)	the proposed environmental protection policies and procedures;	EP	<ul style="list-style-type: none"> <li>• "Nordion Environmental, Health and Safety Policy", CPM-6-06</li> <li>• "Nordion Environmental Protection Program", SE-ENV-015</li> <li>• "Environmental Management System Manual", SE-ENV-001</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(h)	the proposed effluent and environmental monitoring programs;	EP	<ul style="list-style-type: none"> <li>• "Nordion Environmental Protection Program", SE-ENV-015</li> <li>• "Environmental Management System Manual", SE-ENV-001</li> <li>• "Soil Monitoring Program", SE-ENV-017</li> <li>• "Non-Radiological Environmental Monitoring Program", SE-ENV-021</li> <li>• "Radiation Protection Manual - Ottawa Site", SE-RP-001</li> <li>• "Stack Air Sampling", SE-OP-010</li> <li>• "Water Effluent Monitoring", SE-OP-013</li> <li>• "Groundwater and Sanitary Sampling", SE-ENV-028</li> </ul>
3(i)	if the application is in respect of a nuclear facility referred to in paragraph 2(b) of the <i>Nuclear Security Regulations</i> , the information required by section 3 of those Regulations;	N/A	Not applicable.
3(j)	the proposed program to inform persons living in the vicinity of the site of the general nature and characteristics of the anticipated effects on the environment and the health and safety of persons that may result from the activity to be licensed; and	OMRI	"Public Information and Disclosure Program for BWXT ITG", SE-LIC-020
3(k)	the proposed plan for the decommissioning of the nuclear facility or of the site.	WM	<ul style="list-style-type: none"> <li>• "Preliminary Decommissioning Plan for BWXT ITG's Class 1B Facility", SE-LIC-021. This procedure contains prescribed information and is submitted under separate cover.</li> </ul>

	<b>REQUIREMENTS</b>	<b>SCA<sup>1</sup></b>	<b>Response</b>
5	An application for a licence to construct a Class 1 nuclear facility shall contain the following information in addition to the information required by section 3:		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.
5 (a)	A description of the proposed design of the nuclear facility, including the manner in which the physical and environmental characteristics of the site are taken into account in the design;		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.
5 (b)	a description of the environmental baseline characteristics of the site and the surrounding area;		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.
5 (c)	the proposed construction program, including its schedule;		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.
5 (d)	a description of the structures proposed to be built as part of the nuclear facility, including their design and their design characteristics;		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.
5 (e)	a description of the systems and equipment proposed to be installed at the nuclear facility, including their design and their design operating conditions;		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.

	<b>REQUIREMENTS</b>	<b>SCA<sup>1</sup></b>	<b>Response</b>
5 (f)	a preliminary safety analysis report demonstrating the adequacy of the design of the nuclear facility;		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.
5 (g)	the proposed quality assurance program for the design of the nuclear facility;		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.
5 (h)	the proposed measures to facilitate Canada's compliance with any applicable safeguards agreement;		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.
5 (i)	the effects on the environment and the health and safety of persons that may result from the construction, operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects;		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.
5 (j)	the proposed location of points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of releases of nuclear substances and hazardous substances into the environment, including their physical, chemical and radiological characteristics;		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.

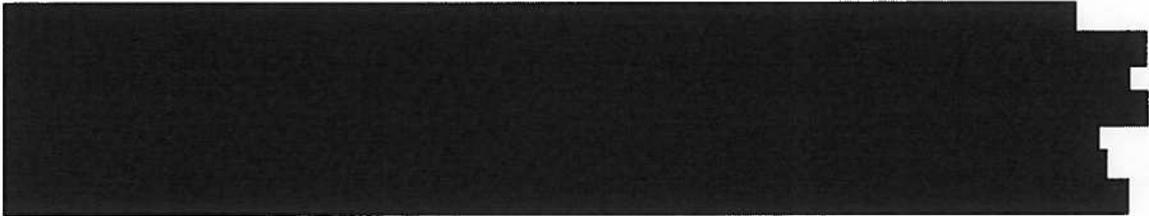
	<b>REQUIREMENTS</b>	<b>SCA<sup>1</sup></b>	<b>Response</b>
5 (k)	the proposed measures to control releases of nuclear substances and hazardous substances into the environment;		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.
5 (l)	the proposed program and schedule for recruiting, training and qualifying workers in respect of the operation and maintenance of the nuclear facility; and		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.
5 (m)	a description of any proposed full-scope training simulator for the nuclear facility.		Not applicable. Application is for a licence to operate an existing Class 1B nuclear facility.
6	An application for a licence to operate a Class I nuclear facility shall contain the following information in addition to the information required by section 3 of the <i>Class I Nuclear Facilities Regulations</i> :		
6(a)	a description of the structures at the nuclear facility, including their design and their design operating conditions;	PD	"Final Safety Analysis Report for the Nuclear Medicine Production Facility", IS/SR 1070 Z000 Section 4.6
6(b)	a description of the systems and equipment at the nuclear facility, including their design and their design operating conditions;	PD	"Final Safety Analysis Report for the Nuclear Medicine Production Facility", IS/SR 1070 Z000 Sections 4.8, 4.9, and 8.8

	REQUIREMENTS	SCA <sup>1</sup>	Response
6(c)	a final safety analysis report demonstrating the adequacy of the design of the nuclear facility;	SA	"Final Safety Analysis Report for Nuclear Medicine", IS/SR 1070 Z000
6(d)	the proposed measures, policies, methods, and procedures for operating and maintaining the nuclear facility;	OP/FS/E M/MS	<ul style="list-style-type: none"> <li>• "Management System for Safety", SE-LIC-001</li> <li>• "EHS Regulatory Reporting and Notifications", SE-EHS-009</li> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001</li> <li>• "Facilities Maintenance Master Plan", R-Master</li> <li>• "Nordion Ottawa Site Instrument Maintenance and Calibration", CP-Master</li> <li>• Schedules for performing all routine maintenance available upon request</li> <li>• "Monitoring and Trending of Alarm Points for the Radiopharmaceutical Manufacturing Facility Using the Metasys System", 100020.SOP</li> <li>• "Change Control Procedure", QAP-AP-45</li> <li>• "Fire Protection Program", SE-EHS-007</li> <li>• "Fire Hazards Analysis Report", SE-EHS-017</li> <li>• "Fire Safety Plan", SE-ERP-001</li> </ul> <p>BWXT ITG will retain ultimate responsibility for fire protection. Under the lease, Nordion will be responsible for fire protection systems. [REDACTED]</p> <ul style="list-style-type: none"> <li>• "Fire Protection Program", SE-EHS-007</li> <li>• "Fire Hazards Analysis Report", SE-EHS-017</li> <li>• "Fire Safety Plan", SE-ERP-001</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
6(e)	the proposed procedures for handling, storing, loading, and transporting nuclear substances and hazardous substances;	WM/PT/ OP	<ul style="list-style-type: none"> <li>• "Management System for Safety", SE-LIC-001</li> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001</li> <li>• "Transport of Radioactive Material", SE-OP-036</li> <li>• "Receiving Radioactive Material", SE-OP-015</li> <li>• Shipping Radioactive Material", SE-OP-014</li> <li>• "Chemical Handling and Storage", SE-HS-008</li> <li>• "Sealed and Unsealed Source Tracking, "SE-OP-079</li> </ul>
6(f)	the proposed measures to facilitate Canada's compliance with any applicable safeguards agreement;	SG	"Safeguards Program", SE-LIC-016
6(g)	the proposed commissioning program for the systems and equipment that will be used at the nuclear facility;	PD	"Management System for Safety" SE-LIC-001 Section 5.18
6(h)	the effects on the environment and the health and safety of persons that may result from the operation and decommissioning of the nuclear facility, and the measures that will be taken to prevent or mitigate those effects;	SA/EP	<ul style="list-style-type: none"> <li>• "Final Safety Analysis Report for the Nuclear Medicine Production Facility", IS/SR 1070 Z000</li> <li>• "Nordion Environmental Protection Program", SE-ENV-015</li> <li>• "Environmental Management System Manual", SE-ENV-001</li> <li>• "Nordion Class 1B Facility Environmental Risk Assessment", REP-EHS-010</li> <li>• "Preliminary Decommissioning Plan for BWXT ITG's Class 1B Facility", SE-LIC-021. This document contains prescribed information and is submitted under separate cover.</li> </ul>

	<b>REQUIREMENTS</b>	<b>SCA<sup>1</sup></b>	<b>Response</b>
6(i)	the proposed location of points of release, the proposed maximum quantities and concentrations, and the anticipated volume and flow rate of releases of nuclear substances and hazardous substances into the environment, including their physical, chemical and radiological characteristics;	EPWM	<ul style="list-style-type: none"> <li>• "Final Safety Analysis Report for the Nuclear Medicine Production Facility", IS/SR 1070 Z000</li> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001 Section 9 for airborne effluent</li> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001 Section 10 for liquid effluent</li> <li>• "Nordion Class 1B Facility Derived Release Limits", REP-EHS-009</li> <li>• Refer to Attachment 3 for quantities released</li> </ul>
6(j)	the proposed measures to control releases of nuclear substances and hazardous substances into the environment;	EPWM	<ul style="list-style-type: none"> <li>• "Nordion Environmental Protection Program", SE-ENV-015</li> <li>• "Environmental Management System Manual", SE-ENV-001</li> <li>• "Soil Monitoring Program", SE-ENV-017</li> <li>• "Non-Radiological Environmental Monitoring Program", SE-ENV-021</li> <li>• "Radiation Protection Manual - Ottawa Site", SE-RP-001</li> <li>• "Chemical Handling and Storage", SE-HS-008</li> <li>• "Stack Air Sampling", SE-OP-010</li> <li>• "Water Effluent Monitoring", SE-OP-013</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
6(k)	<p>the proposed measures to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of national security, including measures to:</p> <p>(i) assist off-site authorities in planning and preparing to limit the effects of an accidental release,</p> <p>(ii) notify off-site authorities of an accidental release or the imminence of an accidental release,</p> <p>(iii) report information to off-site authorities during and after an accidental release,</p> <p>(iv) assist off-site authorities in dealing with the effects of an accidental release, and</p> <p>(v) test the implementation of the measures to prevent or mitigate the effects of an accidental release;</p>	EM	<p>BWXT ITG will retain ultimate responsibility to prevent or mitigate the effects of accidental releases of nuclear substances and hazardous substances on the environment, the health and safety of persons and the maintenance of national security,. Under the lease agreement, there will be a joint emergency response plan established between Nordion and BWXT ITG. [REDACTED]</p> <p>Currently, BWXT ITG employees have been trained on the Nordion emergency response program and make up many of the response team.</p> <ul style="list-style-type: none"> <li>• "Emergency Response Plan (ERP)", SE-ERP-002</li> <li>• "Radiation Emergency Response Plan", SE-ERP-011</li> <li>• "Emergency Response Training and Testing", SE-ERP-010</li> <li>• "Chemical Spill Response Plan", SE-ERP-1-005</li> </ul> <p>BWXT ITG will retain ultimate responsibility for fire protection. Under the lease agreement, Nordion will provide fire protection systems . [REDACTED]</p> <ul style="list-style-type: none"> <li>• "Fire Safety Plan", SE-ERP-001</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
6(l)	the proposed measures to prevent acts of sabotage or attempted sabotage at the nuclear facility, including measures to alert the licensee to such acts;	NS	<p>BWXT ITG will retain ultimate responsibility measures to prevent acts of sabotage or attempted sabotage at the nuclear facility, including measures to alert the licensee to such acts. Under the lease agreement, Nordion will provide site security</p> <ul style="list-style-type: none"> <li>  </li> <li>Nordion "2018 Security Plan", submitted previously to the CNSC on March 31st, 2018. The plan covers all aspects of the security program for the site. This is prescribed information.</li> <li>Nordion "Physical Security Threat Assessment". Updated annually and available to CNSC Security Division review on site at request, as per normal protocol.</li> </ul>
6(m)	the proposed responsibilities of and qualification requirements and training program for workers, including the procedures for the requalification of workers; and	HP	<ul style="list-style-type: none"> <li>Job descriptions are available for all Active Area Operations employees.</li> <li>"EHS Competence Criteria", SE-EHS-024</li> <li>Generally, the minimum education requirement for professionals is a University Degree or a College Diploma. In exceptional circumstances, equivalent work experience in a relevant work field may be acceptable.</li> <li>"Management System for Safety", SE-LIC-001 Section 5.5.2</li> <li>"Systematic Approach to Training", SE-TRN-006</li> <li>"Compliance Environment, Health and Radiation Safety Training", SE-TRN-003 defines the available EHS training, training frequencies and who requires the training.</li> <li>Departmental training programs define the initial and continuing training requirements. These are available upon request.</li> </ul>

	<b>REQUIREMENTS</b>	<b>SCA<sup>1</sup></b>	<b>Response</b>
6(n)	the results that have been achieved in implementing the program for recruiting, training and qualifying workers in respect of the operation and maintenance of the nuclear facility.	HP	<ul style="list-style-type: none"> <li>• There are currently 103 Nuclear Energy Workers (NEWs) employed by BWXT ITG working in the Nordion licensed Nuclear Medicine Production Facility. In the past year, EHS Compliance training has been provided by Nordion to meet the training frequency described in "Compliance Environment, Health and Radiation Safety Training", SE-TRN-003.</li> <li>• Training is assigned and tracked electronically in an Electronic Quality Management System (EQMS) that incorporates training management.</li> </ul>
<b>Radiation Protection Regulations</b>			
4	Every licensee shall implement a radiation protection program and shall, as part of that program,		
4(a)	keep the amount of exposure to radon progeny and the effective dose and equivalent dose received by and committed to persons as low as is reasonably achievable, social and economic factors being taken into account, through the implementation of	RP	Radon progeny is not applicable
4(a)(i)	management control over work practices,	RP	<ul style="list-style-type: none"> <li>• "Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)""", SE-RP-002 Section 4.1</li> <li>• "Nordion Environmental, Health &amp; Safety Responsibilities and Committees", CPM-6-19</li> <li>• "Management System for Safety", SE-LIC-001</li> <li>• "Radiation Protection Manual - Ottawa Site", SE-RP-001</li> <li>• "Work Permit Authorization Program", SE-HS-009</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
4(a)(ii)	personnel qualification and training,	RP	<ul style="list-style-type: none"> <li>• "Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)""", SE-RP-002 Section 4.2</li> <li>• "Management System for Safety", SE-LIC-001 Section 5.5.2</li> <li>• "Compliance Environment, Health and Radiation Safety Training", SE-TRN-003</li> <li>• "Radiation Surveyors and Monitors On-the-Job Training Program", SE-TRN-001 for Radiation Surveyors</li> </ul>
4(a)(iii)	control of occupational and public exposure to radiation, and	RP	<ul style="list-style-type: none"> <li>• "Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)""", SE-RP-002 Section 4.3</li> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001 Sections 5.6 and 5.7</li> <li>• "Nordion Class 1B Facility Derived Release Limits", REP-EHS-009</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
4(a)(iv)	planning for unusual situations; and	RP	<ul style="list-style-type: none"> <li>• "Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)"" , SE-RP-002 Section 4.4</li> <li>• "Safety Analysis Reports", CPM-6-20</li> <li>• "Nordion Environmental, Health &amp; Safety Responsibilities and Committees", CPM-6-19, Section 5.4</li> <li>• "EHS Requirements Checklist", SE-EHS-014</li> <li>• "Change Control Procedure", QAP AP-45</li> <li>• "External Personal Radiation Monitoring", SE-RP-004</li> <li>• "Protective Clothing and Gloves in Active Area Laboratories", SE-RP-005</li> <li>• "Respirator Protection Program", SE-HS-014</li> <li>• "EHS Committee Approved Activity Limits", SE-LIC-007</li> <li>• "Work Permit Authorization Program", SE-HS-009</li> </ul> <p>BWXT ITG will retain ultimate responsibility for planning for unusual situations. Under the lease agreement, there will be a joint emergency response plan established between Nordion and BWXT ITG. [REDACTED]</p> <p>Currently, BWXT ITG employees have been trained on the Nordion emergency response program and make up many of the response team.</p> <p>Reference Nordion procedures:</p> <ul style="list-style-type: none"> <li>• "Emergency Response Plan (ERP)", SE-ERP-002</li> <li>• "Radiation Emergency Response Plan", SE-ERP-011</li> <li>• "Emergency Response Training and Testing", SE-ERP-010</li> <li>• "Chemical Spill Response Plan", SE-ERP-1-005</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
4(b)	ascertain the quantity and concentration of any nuclear substance released as a result of the licensed activity (i) by direct measurement as a result of monitoring, or (ii) if the time and resources required for direct measurement as a result of monitoring outweigh the usefulness of ascertaining the quantity and concentration using that method, by estimating them.	RP	<ul style="list-style-type: none"> <li>• "Nordion Environmental Protection Program", SE-ENV-015</li> <li>• "Environmental Management System Manual", SE-ENV-001</li> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001 Sections 9 and 10</li> <li>• "Monitoring and Decontamination Services Daily, Weekly and Monthly Checks Procedure", 070534.SOP</li> <li>• "Daily Workstation Air Monitoring", SE-OP-007</li> <li>• "Weekly Environmental Equipment Testing", SE-OP-027</li> <li>• "Stack Air Sampling", SE-OP-010</li> <li>• "Water Effluent Monitoring", SE-OP-013</li> </ul>
5(1)	For the purpose of keeping a record of doses of radiation in accordance with section 27 of the Act, every licensee shall ascertain and record the magnitude of exposure to radon progeny of each person referred to in that section, as well as the effective dose and equivalent dose received by and committed to that person.	RP	Radon progeny is not applicable

	<b>REQUIREMENTS</b>	<b>SCA<sup>1</sup></b>	<b>Response</b>
5(2)	A licensee shall ascertain the magnitude of exposure to radon progeny and the effective dose and equivalent dose (a) by direct measurement as a result of monitoring; or (b) if the time and resources required for direct measurement as a result of monitoring outweigh the usefulness of ascertaining the amount of exposure and doses using that method, by estimating them.	RP	Radon progeny is not applicable
7(1)	Every licensee shall inform each nuclear energy worker, in writing,		
7(1)(a)	that he or she is a nuclear energy worker;	RP	<ul style="list-style-type: none"> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001 Sections 5.1 and Acknowledgement of Nuclear Energy Worker Status form Appendix H</li> <li>• NEW acknowledgement forms, available upon request</li> </ul>
7(1)(b)	of the risks associated with radiation to which the worker may be exposed in the course of his or her work, including the risks associated with the exposure of embryos and fetuses to radiation;	RP	<ul style="list-style-type: none"> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001 Sections 5.6 and 5.7, and Appendix B</li> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001 Sections 5.1 and Acknowledgement of Nuclear Energy Worker Status form Appendix H</li> </ul>

	<b>REQUIREMENTS</b>	<b>SCA<sup>1</sup></b>	<b>Response</b>
7(1)(c)	of the applicable effective dose limits and equivalent dose limits prescribed by sections 13, 14 and 15; and	RP	<ul style="list-style-type: none"> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001 Section 5.6</li> <li>• Radiation Protection Manual – Ottawa Site", SE-RP-001 Sections 5.1 and Acknowledgement of Nuclear Energy Worker Status form Appendix H</li> </ul>
13(1)	Every licensee shall ensure that the effective dose received by and committed to a person described in column 1 of an item of the table to this subsection, during the period set out in column 2 of that item, does not exceed the effective dose set out in column 3 of that item.	RP	<ul style="list-style-type: none"> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001 Sections 5.6 and 5.7</li> <li>• "Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)""", SE-RP-002</li> </ul>
14(1)	Every licensee shall ensure that the equivalent dose received by and committed to an organ or tissue set out in column 1 of an item of the table to this subsection, of a person described in column 2 of that item, during the period set out in column 3 of that item, does not exceed the equivalent dose set out in column 4 of that item	RP	"Radiation Protection Manual – Ottawa Site", SE-RP-001 Sections 5.6 and 5.7

	REQUIREMENTS	SCA <sup>1</sup>	Response
20(1)	<p>No person shall possess a container or device that contains a radioactive nuclear substance unless the container or device is labelled with the radiation warning symbol set out in Schedule 3 and the words "RAYONNEMENT – DANGER –RADIATION"; and the name, quantity, date of measurement and form of the nuclear substance in the container or device.</p> <p>(2) Subsection (1) (2) Subsection (1) does not apply in respect of a container or device</p> <p>(a) that is an essential component for the operation of the nuclear facility at which it is located;</p> <p>(b) that is used to hold radioactive nuclear substances for current or immediate use and is under the continuous direct observation of the licensee;</p> <p>(c) in which the quantity of radioactive nuclear substances is less than or equal to the exemption quantity; or</p> <p>(d) that is used exclusively for transporting radioactive nuclear substances and labelled in accordance with the Packaging and Transport of Nuclear Substances Regulations.</p>	RP	<ul style="list-style-type: none"> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001 Section 4.4.5.1</li> <li>• "Procedure for Waste Package Identification and Labeling", 070203.SOP</li> </ul>

	<b>REQUIREMENTS</b>	<b>SCA<sup>1</sup></b>	<b>Response</b>
21(1)	<p>Every licensee shall post and keep posted, at the boundary of and at every point of access to an area, room enclosure or vehicle, a durable and legible sign that bears the radiation warning symbol set out in Schedule 3 and the words "RAYONNEMENT – DANGER – RADIATION"; if</p> <p>(a) there is a radioactive nuclear substance in a quantity greater than 100 times its exemption quantity in the area, room, enclosure or vehicle; or</p> <p>(b) there is a reasonable probability that a person in the area, room, enclosure or vehicle will be exposed to an effective dose rate greater than 25 µSv/hr.</p>	RP	"Radiation Protection Manual – Ottawa Site", SE-RP-001 Section 4.4.5.1
21(2)	<p>Subsection 1 does not apply in respect of a vehicle that is placarded in accordance with the Packaging and Transport of Nuclear Substances Regulations.</p>		

	REQUIREMENTS	SCA <sup>1</sup>	Response
22	<p>22. Whenever the radiation warning symbol set out in Schedule 3 is used,</p> <p>(a) it shall be</p> <p>(i) prominently displayed,</p> <p>(ii) of a size appropriate for the size of the container or device to which it is affixed or attached, or of the area, room, enclosure or vehicle in respect of which it is posted,</p> <p>(iii) in the proportions depicted in Schedule 3, and</p> <p>(iv) oriented with one blade pointed downward and centred on the vertical axis; and</p> <p>(b) no wording shall be superimposed on it.</p>	RP	"Radiation Protection Manual – Ottawa Site", SE-RP-001 Section 4.4.5.1
<b><i>Nuclear Substances and Radiation Devices Regulations</i></b>			
3(1)	<p>An application for a licence in respect of a nuclear substance or a radiation device, other than a licence to service a radiation device, shall contain the following information in addition to the information required by section 3 of the <i>General Nuclear Safety and Control Regulations</i>:</p>		

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(1)(a)	the methods, procedures and equipment that will be used to carry on the activity to be licensed;	OP	<ul style="list-style-type: none"> <li>• "Management System for Safety", SE-LIC-001</li> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001</li> <li>• Procedures associated with the licensed activity fall into the following categories: <ul style="list-style-type: none"> <li>- EHS procedures which cover radiation protection, chemical handling, calibration, environmental protection, emergency response</li> <li>- Operating procedures for production of Medical Isotopes products</li> <li>- Packaging of nuclear substances</li> <li>- Shipping</li> <li>- Waste handling</li> <li>- Maintenance</li> <li>- Security</li> </ul> </li> </ul> <p>Environmental, health, and safety procedures are submitted with this application. Other procedures are available upon request.</p>
3(1)(b)	the methods, procedures and equipment that will be used while carrying on the activity to be licensed, or during and following an accident, to		
3(1)(b)(i)	monitor the release of any radioactive nuclear substance from the site of the activity to be licensed,	EP	"Radiation Protection Manual – Ottawa Site", SE-RP-001 Section 9 and 10
3(1)(b)(ii)	detect the presence of and record the radiation dose rate and quantity in becquerels of radioactive nuclear substances at the site of the activity to be licensed,	RP/EP	"Radiation Protection Manual – Ottawa Site", SE-RP-001 Section 12

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(1)(b)(iii)	limit the spread of radioactive contamination within and from the site of the activity to be licensed, and	EP	"Radiation Protection Manual – Ottawa Site", SE-RP-001 Section 14
3(1)(b)(iv)	decontaminate any person, site or equipment contaminated as a result of the activity to be licensed;	RP/EP	<ul style="list-style-type: none"> <li>• "Radiation Protection Manual – Ottawa Site", SE-RP-001 Section 14</li> <li>• "Investigations", SE-RP-003 Section 5.2.1 and Appendix A</li> </ul>
3(1)(c)	a description of the circumstances in which the decontamination referred to in subparagraph (b)(iv) of the <i>Nuclear Substances and Radiation Devices Regulations</i> will be carried out;	RP/EP	"Radiation Protection Manual – Ottawa Site", SE-RP-001 Section 14
3(1)(d)	the proposed location of the activity to be licensed, including a description of the site;	PD	"Final Safety Analysis Report for the Nuclear Medicine Production Facility", IS/SR 1070 Z000
3(1)(e)	the roles, responsibilities, duties, qualifications, and experience of workers;	HP	"Management System for Safety", SE-LIC-001 Sections 4 and 5.5.2
3(1)(f)	the proposed training program for workers;	HP	<ul style="list-style-type: none"> <li>• "Management System for Safety", SE-LIC-001 Section 5.5.2</li> <li>• "Systematic Approach to Training Program", SE-TRN-006</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(1)(g)	the proposed instructions for dealing with accidents, including fires and spills, in which the nuclear substance may be involved;	EM	<p>BWXT ITG will retain ultimate responsibility for instructions for dealing with accidents, including fires and spills, in which the nuclear substance may be involved;. Under the lease agreement, there will be a joint emergency response plan established between Nordion and BWXT ITG. [REDACTED]</p> <p>Currently, BWXT ITG employees have been trained on the Nordion emergency response program and make up many of the response team.</p> <ul style="list-style-type: none"> <li>• "Emergency Response Plan (ERP)", SE-ERP-002</li> <li>• "Radiation Emergency Response Plan", SE-ERP-011</li> <li>• "Emergency Response Training and Testing", SE-ERP-010</li> <li>• "Chemical Spill Response Plan", SE-ERP-1-005</li> </ul> <p>BWXT ITG will retain ultimate responsibility for fire protection. Under the lease agreement, Nordion will be responsible for fire protection systems. [REDACTED]</p> <ul style="list-style-type: none"> <li>• "Fire Protection Program", SE-EHS-007</li> <li>• "Fire Hazards Analysis Report", SE-EHS-017</li> <li>• "Fire Safety Plan", SE-ERP-001</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(1)(h)	the proposed inspection program for the equipment and systems that will be used to carry on the activity to be licensed;	FS	<p>BWXT ITG will retain ultimate responsibility for the inspection program for the equipment and systems that will be used to carry on the activity to be licensed.</p> <p>Nordion will be responsible for facilities infrastructure ("Base Building Systems") as the landlord under the lease agreement. [REDACTED]</p> <p>BWXT ITG will be responsible for inspection of equipment within the leased premises specifically related to the processing of medical isotopes, including hot cells, fume hoods and gloveboxes.</p> <ul style="list-style-type: none"> <li>• "Facilities Maintenance Master Plan", R-Master</li> <li>• "Nordion Ottawa Site Instrument Maintenance and Calibration", CP-Master</li> </ul>
3(1)(i)	the methods, procedures and equipment that will be used to calibrate radiation survey meters in accordance with these Regulations;	FS	<ul style="list-style-type: none"> <li>• "Calibration of Survey Meters", SE-CA-002</li> <li>• "Source Activity Decay Correction", SE-CA-003</li> <li>• "General Procedure for the Calibration of Contamination Meters", SE-CA-005</li> <li>• "Testing of Direct Reading Dosimeters", SE-CA-008</li> </ul>
3(1)(j)	the methods, procedures and equipment that will be used to calibrate and verify the calibration of dosimeters referred to in paragraphs 30(3)(d) and (e) of the <i>Nuclear Substances and Radiation Devices Regulations</i> ;	FS	<ul style="list-style-type: none"> <li>• "Testing of Direct Reading Dosimeters", SE-CA-008</li> <li>• "External Personal Radiation Monitoring", SE-RP-004</li> </ul>
3(1)(k)	the methods, procedures and equipment that will be used to conduct the leak tests and surveys required by these Regulations;	FS	"Radioactive Material Inventory", SE-LIC-015 Section 13

	<b>REQUIREMENTS</b>	<b>SCA<sup>1</sup></b>	<b>Response</b>
3(1)(l)	where the application is in respect of a nuclear substance that is an unsealed source and that is to be used in a room, the proposed design of the room;	PD	"Final Safety Analysis Report for the Nuclear Medicine Production Facility", IS/SR 1070 Z000
3(1)(m)	if the application is in respect of a nuclear substance that is contained in a radiation device, the brand name and model number of the radiation device, and the quantity of the devices;	PD	Not applicable
3(1)(n)	where the application is in respect of Category I, II or III nuclear material, as defined in section 1 of the <i>Nuclear Security Regulations</i> ,	N/A	Not applicable
3(1)(n)(i)	the measures that will be taken to prevent nuclear criticality, and	N/A	Not applicable
3(1)(n)(ii)	the information required by section 3 or 4 of the <i>Nuclear Security Regulations</i> , as applicable;	N/A	Not applicable

	REQUIREMENTS	SCA <sup>1</sup>	Response
3(1)(o)	<p>if the applicant will be manufacturing or distributing radiation devices referred to in paragraph 5(1)(c) of the <i>Nuclear Substances and Radiation Devices Regulations</i> or section 6 or 7 of the <i>Nuclear Substances and Radiation Devices Regulations</i>, or check sources mentioned in section 8.1 of the <i>Nuclear Substances and Radiation Devices Regulations</i>, the proposed procedure for the disposal of each radiation device or check source or for its return to the manufacturer.</p>	WM	Not applicable

	REQUIREMENTS	SCA <sup>1</sup>	Response
<b><i>Nuclear Security Regulations</i></b>			
41	An application for a licence in respect of a nuclear facility shall contain, in addition to the information required by sections 3 to 8 of the <i>Class I Nuclear Facilities Regulations</i> , a description of the physical protection measures to be taken to ensure compliance with sections 42 to 48.	NS	<p>BWXT ITG will retain ultimate responsibility for the physical protection measures to be taken to ensure compliance with sections 42 to 48. Under the lease agreement, Nordion will provide site security. Nordion will be responsible for conducting facility access security clearances.</p> <ul style="list-style-type: none"> <li>  </li> <li>Nordion "2018 Security Plan", submitted previously to the CNSC on March 31st, 2018. The plan covers all aspects of the security program for the site. This is prescribed information.</li> <li>Nordion "Physical Security Threat Assessment". Updated annually and available to CNSC Security Division review on site at request, as per normal protocol. (Refer to Section 6(l) of this table under Class I Nuclear Facilities Regulations).</li> <li>"Facility Access Security Clearance" SE-SC-005</li> <li>"Security Guard Vehicle Inspection Post Orders" SE-SC-014. This is prescribed information and available to CNSC Security Division review on site at request, as per normal protocol.</li> <li>"Written Arrangements between Nordion (Canada) Inc. and the Ottawa Police Service pursuant to Section 47 of the Canadian Nuclear Security Regulations". This is prescribed information and available to CNSC Security Division review on site at request, as per normal protocol</li> </ul>
<b><i>Packaging and Transport of Nuclear Substances Regulations – 2015</i></b>			

	REQUIREMENTS	SCA <sup>1</sup>	Response
	Compliance of the licensee programs and procedures to these regulations	PT	<ul style="list-style-type: none"> <li>• "Transport of Radioactive Material", SE-OP-036 <ul style="list-style-type: none"> <li>• roles and responsibilities of personnel - "Transport of Radioactive Material", SE-OP-036 Section 3</li> <li>• package preparation and shipment - "Transport of Radioactive Material", SE-OP-036 Section 6.6</li> <li>• marking, labeling and placarding - "Transport of Radioactive Material", SE-OP-036 Section 6.6</li> <li>• transport documents - "Transport of Radioactive Material", SE-OP-036 Section 6.7</li> <li>• instructions for carriers - "Transport of Radioactive Material", SE-OP-036 Section 6.7</li> <li>• measures to be employed in controlling radiation exposures during transport and packaging operations - "Transport of Radioactive Material", SE-OP-036 Section 6.14</li> </ul> </li> <li>• shipment notifications and confirmations - "Transport of Radioactive Material", SE-OP-036 Sections 6.7.1, 6.12, 6.13</li> <li>• receipt of packages - "Transport of Radioactive Material", SE-OP-036 Section 6.9</li> <li>• opening of packages - "Transport of Radioactive Material", SE-OP-036 Section 6.9</li> <li>• undeliverable consignments – "Requirements for the Transport of Radioactive Materials", 000079.SOP Section 4.3</li> <li>• packaging inspection and maintenance - "Transport of Radioactive Material", SE-OP-036 Section 6.5</li> <li>• training and certification of workers - SE-TRN-003 "Compliance Environment, Health and Radiation Safety Training"</li> <li>• documentation records for all types of packages – SE-OP-036 Section 6 – embedded throughout</li> <li>• registration for use - "Transport of Radioactive Material", SE-OP-036 Section 6.6</li> <li>• dangerous occurrences reporting - "Transport of Radioactive Material", SE-OP-036 Section 6.16</li> </ul>

	REQUIREMENTS	SCA <sup>1</sup>	Response
<b><i>Nuclear Non-Proliferation Import and Export Controls Regulations</i></b>			
	Compliance of the licensee programs and procedures to these regulations	SG	<ul style="list-style-type: none"> <li>• SE-LIC-016 Safeguards Program</li> <li>• SE-EHS-013 Export/Import Controls and Sanctions Program</li> <li>• CPM-7-06 Export/Import Controls and Sanctions Policy</li> </ul>
<b><i>Other Matters of Regulatory Interest</i></b>			
	Financial guarantees	OMRI	• Refer to 3 (1) (l) <i>General Nuclear Safety and Control Regulations</i>
	Improvement plans and significant future activities	OMRI	• Refer to Attachment 3
	Licensee public information program	OMRI	• Refer to 3 (j) <i>Class I Nuclear Facilities Regulations</i>

## ACRONYMS

SCA	Safety and Control Area	EP	Environmental Protection
MS	Management System	EM	Emergency Management and Fire Protection
HP	Human Performance Management	WM	Waste Management
OP	Operating Performance	NS	Security
SA	Safety Analysis	SG	Safeguards
PD	Physical Design	PT	Packaging and Transport
FS	Fitness for Service	OMRI	Other Matters of Regulatory Interest
RP	Radiation Protection	N/A	Not Applicable
CHS	Conventional Health and Safety		

## Attachment 2: List of Regulations, Permits, Certificates, and Licenses Applicable to BWXT ITG

A list of codes and regulations applicable to BWXT ITG, other than those pursuant to the *Nuclear Safety and Control Act* is provided in Table 2.1.

**Table 2.1: List of Codes and Regulations Applicable to BWXT ITG**

Regulatory Authority	Code, Act, or Regulation
Employment and Social Development Canada (ESDC)	Canada Labour Code II
Environment Canada	Canadian Environmental Assessment Act
	Canadian Environmental Protection Act
	New Substance Notification Regulations (Chemicals and Polymers), SOR/2005-247
	New Substance Notification Regulations (Organisms), SOR/2005-248
	Prohibition of Certain Toxic Substances Regulations
	Ozone Depleting Substances Regulations
	Federal Halocarbon Regulations
	Migratory Birds Convention Act and Regulations
Transport	Transportation of Dangerous Goods Act
	Transportation of Dangerous Goods Regulations
Canada Food Agency	D-98-08: Entry Requirements for Wood Packaging Materials Produced in All Areas Other than the Continental United States
Department of Fisheries & Oceans	Fisheries Act
National	National Building Code, 2015
	National Fire Code, 2015
	National Fire Protection Association, NFPA-801, 2003 edition
Federal	Hazardous Products Act
	Canadian Biosafety Standard – 2 <sup>nd</sup> Edition 2015
Provincial	Ontario Regulation 347 - General Waste Management
	Ontario Regulation 102/94 - Waste Audits and Waste Reduction Work Plans
	Environmental Protection Act
	Ontario Regulation 419/05 - Air Pollution Regulation - Local Air Quality
	Technical Standards & Safety Act
	Ontario Regulation 213/01 - Fuel Oil

**Table 2.1 (Cont'd)**

<b>Regulatory Authority</b>	<b>Code, Act, or Regulation</b>
Provincial	Ontario Regulation 220/01 - Boilers and Pressure Vessels
	Ontario Regulation 127 - Airborne Contaminant Discharge Monitoring and Reporting
	Ontario Regulation 455 - Toxic Reduction Act
	Ontario Water Resources Act
	Ontario Regulation 360 - Spills
	Workplace Safety and Insurance Act
City of Ottawa	Water Use By-law No 2003-500 (Backflow Prevention)
	Sewer Use By-law No. 2003-514
National Research Council of Canada	2005 National Fire Code

A list of permits, certificates and licences that have been issued to BWXT ITG by authorities other than CNSC is provided in Table 2.2.

**Table 2.2: List of Permits, Certificates, and Licenses**

<b>Permit, Certificate, or License</b>
1 licence from the USA that authorizes radioactive material distribution.
1 sealed source and device registration from the USA
BWXT is a CNSC registered user for all transport package certificates used in Canada
Hazardous Waste Disposal Generator Registration (Ministry of Environment)
Permit To Import Human Pathogens
Permit to Import Animal Pathogens



## Attachment 3

# Supplementary Report to Support Class 1B Licence Application

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**Supplementary Report to Support Class 1B Licence Application**


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**TABLE OF CONTENTS**

<b>1. INTRODUCTION</b>		<b>5</b>
1.1	Background	5
1.2	Lease Arrangements	5
1.3	Scope of the Supplementary Report	6
<b>2. BUSINESS PLAN</b>		<b>6</b>
<b>3. SAFETY AND CONTROL AREAS</b>		<b>7</b>
3.1	Management System	7
3.1.1	Relevance and Management	7
3.1.2	Past Performance - Nordion	9
3.1.3	Improvements to the Management System	9
3.1.4	Future Plans	9
3.1.5	Challenges	9
3.2	Human Performance Management	9
3.2.1	Relevance and Management	9
3.2.2	Past Performance - Nordion	11
3.2.3	Improvements to Human Performance Management	13
3.2.4	Future Plans	14
3.2.5	Challenges	14
3.3	Operating Performance	14
3.3.1	Relevance and Management	14
3.3.2	Past Performance - Nordion	16
3.3.3	Improvements to Operating Performance	16
3.3.4	Future Plans	16
3.3.5	Challenges	16
3.4	Safety Analysis	16
3.4.1	Relevance and Management	16
3.4.2	Past Performance - Nordion	17
3.4.3	Improvements to Safety Analysis	19
3.4.4	Future Plans	19
3.4.5	Challenges	19
3.5	Physical Design	19
3.5.1	Relevance and Management	19
3.5.2	Past Performance – Nordion	20
3.5.3	Improvements to Physical Design	20

---

**Supplementary Report to Support Class 1B Licence Application**


---

3.5.4	Future Plans.....	20
3.5.5	Challenges.....	20
3.6	Fitness for Service	21
3.6.1	Relevance and Management.....	21
3.6.2	Past Performance - Nordion.....	21
3.6.3	Improvement to Fitness for Service.....	22
3.6.4	Future Plans.....	22
3.6.5	Challenges.....	22
3.7	3.7 Radiation Protection	22
3.7.1	Relevance and Management.....	22
3.7.2	Past Performance - Nordion.....	25
3.7.3	Improvements to Radiation Protection Program.....	31
3.7.4	Future Plans.....	31
3.7.5	Challenges.....	31
3.8	Conventional Health and Safety	31
3.8.1	Relevance and Management.....	31
3.8.2	Past Performance – Nordion.....	32
3.8.3	Improvements to Conventional Health and Safety.....	33
3.8.4	Future Plans.....	34
3.8.5	Challenges.....	34
3.9	Environmental Protection	34
3.9.1	Relevance and Management.....	34
3.9.2	Past Performance - Nordion.....	36
3.9.3	Improvements to the Environmental Protection Program.....	41
3.9.4	Future Plans.....	41
3.9.5	Challenges.....	41
3.10	Emergency Management and Fire Protection	41
3.10.1	Relevance and Management.....	42
3.10.2	Past Performance – Nordion.....	43
3.10.3	Improvements to the Emergency Management and Fire Protection Programs.....	45
3.10.4	Future Plans.....	45
3.10.5	Challenges.....	45
3.11	Waste Management	45
3.11.1	Relevance and Management.....	45

---

**Supplementary Report to Support Class 1B Licence Application**


---

3.11.2	Past Performance – Nordion .....	47
3.11.3	Improvements to the Waste Management Program .....	47
3.11.4	Future Plans.....	48
3.11.5	Challenges.....	48
3.12	Security	48
3.13	Safeguards and Non-Proliferation	48
3.13.1	Relevance and Management.....	48
3.13.2	Past Performance – Nordion .....	48
3.13.3	Improvements to the Safeguards Program .....	49
3.13.4	Future Plans.....	49
3.13.5	Challenges.....	49
3.14	Packaging and Transport	49
3.14.1	Relevance and Management.....	49
3.14.2	Past Performance - Nordion .....	50
3.14.3	Improvements to Packaging and Transport .....	51
3.14.4	Future Plans.....	51
3.14.5	Challenges.....	51
<b>GLOSSARY</b>		52
<b>APPENDIX A: ORGANIZATIONAL CHARTS</b>		54

## 1. INTRODUCTION

This Supplementary Report was prepared to support BWXT ITG Canada, Inc.'s (BWXT ITG) application for a Class 1B operating licence for the existing Nordion (Canada) Inc. (Nordion) medical isotopes facility. The medical isotopes facility is currently included in the scope of Nordion's current Class 1B licence. The medical isotopes facility is inclusive of the radiochemical and radiopharmaceutical facilities in the Nuclear Medicine Production Facility which is located in the Kanata Operations Building and the radiopharmaceutical facilities in the Kanata Manufacturing Facility (KRMF). Unless otherwise indicated, reference to NMPF throughout this document is inclusive of the KRMF. This report was prepared using the document REGDOC-3.4.1, "Guide for Applicants and Intervenors Writing CNSC Commission Member Documents".

### 1.1 Background

BWXT ITG acquired Nordion's medical isotope business assets (staff, commercial ownership of facilities, contracts) effective July 30, 2018. The terms of the acquisition also provided for a long term lease to BWXT ITG of the portions of the Ottawa operations dedicated to the Medical Isotopes business. Products encompassed by the medical isotopes business are manufactured in the existing medical isotopes facility which is included in the scope of Nordion's Class 1B licence. BWXT ITG found the acquisition to be an attractive alternative to a greenfield approach, it allowed for acquisition of a facility with an operating history, staff trained and skilled in working with radioisotopes intended for human use, and developed systems that support a licence that allowed for flexibility in the type of business BWXT ITG intends to carry out at the site.

Due to the short half-life of the product being manufactured by the acquired part of Nordion's business, it was critical at the time of the acquisition to maintain the uninterrupted ability to operate. Nordion sought approval from the CNSC to allow BWXT ITG work as contractors within the medical isotopes facility under its Class 1B licence and the Nordion Management System for Safety. BWXT ITG was contracted to provide operational and support personnel. In practice, BWXT ITG staff continues to act as Nordion staff utilizing the systems and procedures that were in place prior to the acquisition. This arrangement will continue until such time as BWXT ITG secures its own Class 1B licence, and at that point, although responsibility will shift from Nordion to BWXT ITG, the BWXT ITG staff will continue to use the same systems and procedures that were used prior to the acquisition and through the period post acquisition where Nordion remained responsible.

The Nordion Class 1B facility has been in operation for over 30 years and is comprised of two major production areas. One involves the processing a variety of radioisotopes used in nuclear medicine (the NMPF and the KRMF) and the other involves high activity sealed sources used in cancer therapy and irradiation technologies (the Cobalt Operations Facility (COF)). The BWXT ITG premises comprise an administrative area known as the "Non-Active Area" and a controlled access production area known as the "Active Area". The Active Area encompasses the Kanata Radiopharmaceutical Manufacturing Facilities (KRMF) and the radiochemical and radiopharmaceutical facilities in the Nuclear Medicine Production Facility. Products produced are used for diagnosis and treatment of disease, benefiting the lives of millions of people around the world.

BWXT ITG acquired both the facility and roughly half of the Nordion personnel present at Nordion at the time of the acquisition. The average length of service for the transferred employees who have been operating within the Nordion Medical Isotope facility is 19 years. The average length of service for the management team of the BWXT ITG entity on site is 29 years of service working at Nordion predominantly supporting the Medical Isotopes business.

Upon issuance of a Class 1B licence to BWXT ITG, Nordion plans to continue operations of the Cobalt Operations Facility and will be requesting amendment to their existing licence to remove the medical isotopes facility from the scope of licensed activities.

### 1.2 Lease Arrangements

Nordion (Canada) Inc. is the owner of the site and has leased the medical isotopes portion of the building and associated areas to BWXT ITG [REDACTED]. Under the lease, the Kanata Property is subject to the control and management by Nordion. Although BWXT ITG

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## Supplementary Report to Support Class 1B Licence Application

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will remain ultimately responsible for security, fire protection and facility maintenance requirements under its Class 1B licence, Nordion will be subcontracted to provide those services. BWXT ITG must seek Nordion approval for building modifications and introduction of processes that were not carried out previously at Nordion. A joint EHS Committee has been established with representation by BWXT on Nordion's EHS Committee. Coordinated joint emergency response plans will be developed.

### 1.3 Scope of the Supplementary Report

This Supplementary Report provides information related to BWXT ITG's business plans for the NMPF and BWXT ITG's organizational structure. In addition, it provides information on the 14 Safety and Control Areas, including performance data achieved during operation of the Class 1B facility by Nordion.

We have included the Nordion performance data as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will:

1. remain within the scope of the licensing basis established for Nordion
2. employ a work force comprised largely of Nordion personnel hired by BWXT ITG at the time of the acquisition
3. adopt the Nordion Management System for Safety.

Nordion's past performance data is also available in Nordion's Annual Compliance and Operational Performance Reports submitted to the Canadian Nuclear Safety Commission.

## 2. BUSINESS PLAN

Today the BWXT ITG Ottawa-based business is comprised solely of yttrium-90 (Y90) [REDACTED], a sterile, active implantable Class III medical device used to treat liver cancer, manufactured by Nordion for BWXT ITG by BWXT ITG employees. BWXT ITG is under contract for a third party. In the next year, BWXT ITG plans to bring a new diagnostic radiopharmaceutical to market in the United States that was recently approved by the US Food and Drug Administration. The product is based on an indium-111 (In111) radioisotope. On commercial launch in late 2019, one batch per week will be produced in the NMPF using In111 obtained from BWXT ITG's Medical Isotope Vancouver Operation.

The production of molybdenum-99 (Mo-99) has a long history at Nordion. Fission Mo-99 from the NRU reactor at Chalk River had been produced at the Nordion facility since the mid-1980's and prior to that at AECL Tunney's Pasture. This process was associated with long lived waste, including highly enriched uranium, noble gases, and radioiodines. Production of fission Mo-99 ceased in late 2016 with the shutdown of the NRU reactor.

On May 7, 2018 BWXT ITG announced that it had developed an innovative technology for producing Mo-99 using a natural molybdenum target, and the corresponding technetium-99m (Tc-99m) generator. This initiative was a key driver supporting the acquisition of Nordion's Medical Isotope assets as they provide a significant jump forward operationally and de-risk the overall program. The Tc-99m generator program will be the next new product for Ottawa after the In-111-based product, with the aim for a commercial launch in early to mid-2021. The new Tc-99m generator program will draw upon much of the established infrastructure, expertise and quality systems that are in place. Establishing the manufacturing and testing capability will involve the modification to some existing processing hot cell facilities and the construction of new ones; all of which is planned to be within the existing NMPF and KRMF building perimeter. These facility modifications will proceed within the licensing basis established by Nordion's existing Class 1B licence and adopted by BWXT ITG. The facility modifications may be completed under Nordion's Class 1B licence depending on the timing of issuance of a Class 1B licence to BWXT ITG. Facility modifications require Nordion's approval.

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**Supplementary Report to Support Class 1B Licence Application**

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There are a number of other potential products under consideration in Ottawa, all of which will fall within Nordion's Class 1B licensing basis and BWXT ITG's anticipated Class 1B licence. Several candidates under consideration are radioisotopes that have been safely produced by Nordion in Ottawa in the past. Management will make the decision on whether to proceed with the specific radioisotopes once the business cases have been prepared. The overall intent is to better leverage the Medical Isotope assets in Ottawa by increasing the portfolio of radiochemical and radiopharmaceutical products.

BWXT ITG will manufacture nuclear substances in excess of  $1 \times 10^{15}$  Bq / year. Isotopes with > 1 year half-life will not be manufactured, although some impurities will be present that have longer half-lives, all well below  $1 \times 10^{15}$  Bq / year. Production will remain below historical capacity (total radioactive material processed) for the foreseeable future.

### **3. SAFETY AND CONTROL AREAS**

#### **3.1 Management System**

The Management System SCA covers the framework that establishes the processes and programs required to ensure an organization achieves its safety objectives, continuously monitors its performance against these objectives, and fosters a healthy safety culture.

##### **3.1.1 Relevance and Management**

###### **3.1.1.1 Environmental, Health and Safety Policy**

BWXT ITG will adopt the principles of Nordion's Environmental, Health and Safety Policy (CPM-6-06) which describes the company's commitment to operate in a safe, responsible manner that respects the environment and the health of employees, customers, and the communities where it operates. The EHS Policy will be the foundation of BWXT ITG's environmental, health and safety systems.

###### **3.1.1.2 Organization**

The BWXT ITG senior management organizational structure is provided in Appendix A. The organizational chart for the BWXT ITG Regulatory and EHS Compliance department is also included in Appendix A.

BWXT ITG will establish an Environmental, Health and Safety Committee (EHS) similar to that established at Nordion. The BWXT ITG EHS Committee will be chaired by the Vice-President, Regulatory and EHS Compliance, or designate. The EHS Committee will review the operations and approves changes to the facility. The EHS Committee will oversee all CNSC related activities, as per licence conditions, ensuring review of design and safety of operations. Sub-committees will be appointed as necessary, to conduct detailed technical reviews and report back to the EHS Committee. The EHS Committee will regularly review occupational health and safety, radiation safety, and environmental management performance metrics. The EHS Committee will report to the Vice-President and General Manager.

Under the lease arrangements with Nordion, a joint BWXT ITG - Nordion EHS Committee has been established. A BWXT ITG Workplace Health and Safety Committee will be established in 2019. Currently key BWXT ITG personnel continue to participate in the Nordion EHS Committee that is chaired by Nordion under Nordion's Class 1B licence.

###### **3.1.1.3 Management System for Safety and Environmental Management System**

BWXT ITG will adopt Nordion's Management System for Safety (SE-LIC-001) which has provided the means of controlling those activities that affect safety of CNSC licensed activities in the Nordion licensed facility. This program applies to all CNSC licensed activities that will be conducted under the Class 1B nuclear substance and processing facility operating licence.

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**Supplementary Report to Support Class 1B Licence Application**

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The Management System for Safety controls work carried out to perform, or in support of, licensed activities from the planning stages to completion, and covers the control of activities both at the working level, and at the corporate level. The latter ensures the oversight needed to provide corporate direction and maintain overall accountability, and to ensure that communication between individuals and organizations is effective and in the interest of safety. Performance reviews and annual management reviews of the Management System for Safety will be conducted (refer to Section 3.1.1.4.).

**3.1.1.4 Performance Reviews**

Performance reviews of the Management System for Safety will be conducted on a routine basis by the BWXT ITG EHS Committee. At each BWXT ITG EHS Committee meeting, the Committee will review EHS performance, including the status of environmental, health and safety corrective actions and preventive actions (CAPAs), results of EHS incidents or investigations, status of EHS objectives and targets, internal EHS audit findings, and the status of actions from previous meetings. The EHS Committee will review this information and documents any actions resulting from the review in the meeting minutes.

In addition, the Committee will conduct an annual management review of the Management System for Safety to ensure this program remains suitable and effective. Results from the annual EHS Performance Report will be reviewed (refer to Section 3.3.1.3). The management review will involve the evaluation of:

- Actions from the previous meeting
- The Environment Health & Safety Policy (CPM-6-06)
- Adequacy of resources
- Environmental health and safety objectives and targets
- Changing circumstances
- Recommendations for improvement

Actions and decisions resulting from the EHS Committee review of the Management System for Safety performance and environmental performance will be documented in the EHS Committee meeting minutes.

**3.1.1.5 Change Management**

BWXT ITG will adopt the existing Nordion change control process which is part of the Management System for Safety. This process ensures any changes are justified, reviewed and approved by appropriate personnel, and to ensure their effect on existing conditions is assessed. The EHS Committee will approve all significant changes to facilities. The BWXT ITG EHS and Quality Assurance departments will use the same efficient, robust system for change management.

Design control is applicable to all process equipment and facilities' buildings, systems and equipment in support of licensed activities. BWXT ITG will adopt Nordion's established design control program to ensure that design meets established codes and standards and all applicable requirements.

**3.1.1.6 Operating Experience**

The EHS Committee will have responsibility for conducting reviews of Operating Experience (OPEX). The OPEX process is an information gathering and review process to identify, obtain and evaluate in-house and external experience related to the operations conducted under BWXT ITG's facility operating licence. The analysis of this information will be used, and action taken to improve safety and the management processes.

**3.1.1.7 Records Management**

BWXT ITG will adopt the existing Nordion process for the identification, storage, protection, retrieval, retention, and disposition of licensing records.

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**Supplementary Report to Support Class 1B Licence Application**

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**3.1.1.8 EHS Program Objectives and Target**

BWXT ITG's EHS Committee will conduct an annual performance review of the Management System for Safety. The performance of the Management System for Safety will be judged by how well the EHS objectives and targets are met and the effectiveness of the program as determined by the overall review. The results of the performance review will drive continuous improvements to the program.

**3.1.1.9 Safety Culture**

BWXT ITG will adopt Nordion's current safety culture practices. A strong safety culture has been instilled in the BWXT ITG employees who work in the NMPF. Safety is at the forefront of all of the work that is done. BWXT ITG employees will have performance objectives to work safety at all times, report the occurrences of workplace injuries, unsafe conditions, near-misses, and to correct or coach co-workers who are working unsafely. Safety culture is embedded in the Nordion programs, standards and procedures which will be adopted by BWXT ITG.

**3.1.2 Past Performance - Nordion**

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion, using a work force for BWXT ITG comprised largely of Nordion personnel hired at the time of the acquisition and adopting the Nordion Management System for Safety. The internal performance indicators for the management system SCA used by Nordion are:

- Overall performance against the EHS program objectives and targets
- Safety culture survey results

The performance of the Management System for Safety has been judged by how well the EHS objectives and targets are met and the effectiveness of the program is determined by the overall review. Refer to Section 3.3.2.

**3.1.3 Improvements to the Management System**

BWXT ITG commits to continuous improvement of the existing Nordion Management System for Safety, including safety culture. No specific improvements have been identified.

**3.1.4 Future Plans**

BWXT ITG will adopt the existing Nordion Management System for Safety.. Safety Culture is an important part of the overall culture at BWXT ITG. BWXT ITG will continue to ensure safety culture remains a strong component of the Management System for Safety.

**3.1.5 Challenges**

BWXT ITG does not anticipate any specific challenges under the Management System SCA.

**3.2 Human Performance Management**

The Human Performance Management SCA covers activities that enable effective human performance through the development and implementation of processes that ensure a sufficient number of licensee personnel are in all relevant job areas and have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.

**3.2.1 Relevance and Management**

BWXT ITG will adopt the existing Nordion Environment, Health and Radiation Safety Training Program which consists of courses designed to train applicable employees to meet requirements of regulations, legislation or certification and minimize potential impacts to the environment, health and safety.

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**Supplementary Report to Support Class 1B Licence Application**


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A variety of radiation safety training courses have been designed and maintained.. Employees who are not classified as Nuclear Energy Workers (NEWs) receive a basic course on Health, Safety and Environment, which provides information on the facilities, emergency response procedures and alarms, and basic procedures to follow for safety in the workplace. Nuclear Energy Workers receive a NEW Indoctrination Course. To be authorized to enter the Active Area unescorted, the employee must complete and pass a written test, as evidence of understanding the principles of radiation protection and safe work practices. NEW retraining and retesting are conducted on a three year frequency. In addition, NEWs are provided with a half day Radiation Instrumentation Workshop, dealing specifically with the selection and use of radiation survey and contamination meters for the Active Area.

Supplementary EHS training programs are provided to all personnel depending on the nature of the job and the requirements specified by their Manager. These programs include such topics as:

- Working with Radioiodines
- Emergency Response Awareness
- Care and Use of Respirators
- Material Handling Training
- Working Safely With Fume-hoods

Management identifies qualifications and training requirements. Personnel are given appropriate training and instruction, and tasks are assigned to personnel who have been properly trained. Training programs are monitored and assessed regularly, and the competency of personnel is reviewed to maintain their effectiveness and skill levels. Records of training, qualifications, and experience are maintained.

Initial selection of qualified personnel is performed through the Human Resources hiring process. Personnel who are assigned responsibilities are competent on the basis of applicable education, training, skills, and experience. Established training programs ensure personnel have the required training to perform their job functions. The employee training programs support the Management System for Safety and ensure that it is understood, implemented and maintained.

The Director and Manager of each department is responsible for ensuring that the employees are competent and qualified to perform their required job functions and for determining and documenting the training needs of each employee in their department. Departmental Directors and Managers are responsible for ensuring the effectiveness of the training provided to the employee, managing the completion of employee training, and maintaining paper records as required.

#### 3.2.1.1 Number of Qualified Staff

BWXT ITG will ensure the availability of the minimum number of personnel required to provide safety oversight during overnight operations and during emergency situations.

BWXT ITG will retain ultimate responsibility for security for the NMPF. Under the lease, Nordion will provide site security. Nordion Security is on site at all times. Radiation Surveyors are always on site when production involving radioactive materials is occurring.

BWXT ITG will retain ultimate responsibility for emergency response for the NMPF. Under the lease, there will be a joint emergency response plan established between Nordion and BWXT ITG. Currently, BWXT ITG employees have been trained on the Nordion emergency response program and make up many of the response team. Nordion has key emergency response, Facilities and Production Managers on-call at all times. The Incident Manager, or the person in charge of the response, can initiate a call-in of both on-call and regular emergency response personnel. Currently there are approximately 70 Fire Wardens and Marshalls and over 80 other emergency response personnel.

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**Supplementary Report to Support Class 1B Licence Application**

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Nordion routinely assesses the availability of qualified staff as part of the Emergency Response Program and through drills and exercises. Nordion tests its emergency call list annually and the results have demonstrated year over year that within one hour of the onset of an emergency, adequate emergency response personnel and at least one representative from each of the key emergency response groups would be available on-site.

There is a minimum of one and normally two Health Physicists on call who are qualified to establish and direct radiation safety activities to protect personnel, the public, and the environment from radiation hazards, and to develop safe work methods and procedures.

Nordion maintains a formal on-call roster that includes the Manager, Corporate Security (or designate) and the Senior Manager Radiation Safety & Compliance (or designate), who is also a qualified Health Physicist.

### 3.2.2 Past Performance - Nordion

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion, using a work force for BWXT ITG comprised largely of Nordion personnel hired at the time of the acquisition and adopting the Nordion Management System for Safety.

Internal performance indicators for the human performance SCA used by Nordion include:

- Attendance rate
- Trainee reaction
- Trainee learning
- Training results

#### 3.2.2.1 Attendance Rate

Nordion designed and maintains a variety of radiation safety training courses. New employees who are not classified as NEWs receive a basic course on Health, Safety and Environment, Level I, which provides information on the facilities, emergency response procedures and alarms, and basic procedures to follow for safety in the workplace. Nuclear Energy Workers receive a NEW Indoctrination Course. To be authorized to enter the Active Area unescorted, the employee must complete and pass a written test, as evidence of understanding the principles of radiation protection and Nordion safe work practices. NEW retraining and retesting are conducted on a three year frequency. In addition, NEWs are provided with a half day Radiation Instrumentation Workshop, dealing specifically with the selection and use of radiation survey and contamination meters for the Active Area. In 2017, there were no radiation safety incidents nor were there any anomalous Thermo-luminescent Dosimeter (TLD) readings attributed to employee radiation safety practices. This indicates that the radiation safety training was effective.

Supplementary training programs are provided to all personnel working on behalf of Nordion depending on the nature of the job and the requirements specified by their manager. These programs include, but are not limited to, such topics as "Working with Radioiodines", emergency response awareness, care and use of respirators, material handling training, and working safely with fume-hoods.

Employees who transport, handle, or offer dangerous goods for transport are trained in the TDG requirements. The training program includes a one day classroom training course that is required once on employment or upon job change. Retraining is conducted on a 2-year frequency and is accomplished through self-study. The self-study program is separated into three levels.

Employees are required to complete the self-study refresher training level that is appropriate for their job function. For each training course, participants must complete and pass a written test, as evidence of understanding the course contents.

A summary of the key training programs is provided in Table 1.

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**Supplementary Report to Support Class 1B Licence Application**


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In 2017, the number of scheduled participants that required safety training was 520, and by the end of the year, 510 of the scheduled participants completed the training, which included refresher training. Therefore, the attendance completion rate in 2017 was 98%. The 10 course not completed represent two employees; one who could not complete 9 courses due to being on extended leave during 2017 and another who completed the required training course in January 2018.

**Table 1  
2017 Safety Training Programs**

<b>Program</b>	<b>Duration</b>	<b># of Participants Requiring Training in 2017</b>	<b># of Participants who Completed Training in 2017</b>	<b># Participants with Overdue Refresher Training at the End of 2017</b>
Nuclear Energy Worker (NEW) Indoctrination <sup>3</sup>	6 Hours	11	11	0
NEW Refresher <sup>3</sup>	Self Study	96	94	1 <sup>1</sup> and 1 <sup>2</sup>
Radiation Instrumentation Workshop <sup>3</sup>	3 Hours	48	47	1 <sup>1</sup>
Radiation Safety Review for Operators <sup>3</sup>	Half Day	18	18	0
Radioiodine Handling <sup>3</sup>	2 Hours	20	19	1 <sup>1</sup>
Transport of Dangerous Goods Level I <sup>3</sup>	Self Study	5	5	0
Transport of Dangerous Goods Level II <sup>3</sup>	Self Study	13	13	0
Transport of Dangerous Goods Level III <sup>3</sup>	All Day In-Class	40	39	1 <sup>1</sup>
TDG for Contractors <sup>3</sup>	Full Day	23	23	0
Working with BETA <sup>3</sup>	1 Hour	34	33	1 <sup>1</sup>
Crane	Half Day	18	18	0
Pallet	Half Day	24	24	0
Forklift	Half Day	12	12	0
Contractor Radiation Safety Protection Training <sup>3</sup>	Half Day	14	14	0
Contractor Radiation Safety Protection Refresher <sup>3</sup>	2 Hours	10	9	1 <sup>1</sup>
Contractor EHS Training Level I <sup>3</sup>	2 Hours	40	40	0
HEGS Safety Training	2 Hours	0	0	0
In-Depth Security Awareness <sup>3</sup>	2 Hours	31	31	0
Emergency Response Part 1 <sup>3</sup>	2 Hours	18	17	1 <sup>1</sup>
Emergency Response Part 2 <sup>3</sup>	2 Hours	13	12	1 <sup>1</sup>
Emergency Response Part 3 <sup>3</sup>	2 Hours	8	8	0
Emergency Response: Security <sup>3</sup>	1 Hour	18	18	0
Emergency Response: Site Security Volunteer <sup>3</sup>	1 Hour	0	0	0
Emergency Response: Monitors <sup>3</sup>	1 Hour	1	1	0
SCBA Part 1 <sup>3</sup> & 2 <sup>3</sup>	1 Hour	5	4	1 <sup>1</sup>
<b>TOTAL</b>		<b>520</b>	<b>510</b>	<b>10</b>

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**Supplementary Report to Support Class 1B Licence Application**

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<sup>1</sup> On extended leave

<sup>2</sup> Refresher training completed in January 2018

<sup>3</sup> Key EHS course

### 3.2.2.2 Evaluation of Training Effectiveness

#### Trainee Reaction

Trainee reaction is the degree to which participants find the training favourable, engaging and relevant to their jobs. These three components are evaluated by analyzing data collected through the completion of training evaluation forms for all internally developed key EHS training courses and delivered by EHS classroom instructors. The data is analyzed so that corrective actions can be taken, if necessary, to improve content and delivery. The degree to which trainees find the training favourable is evaluated by analyzing the overall training assessment rating for each course. Overall training is assessed as one of five options: Excellent, Very Good, Good, Poor or Very Poor. The training evaluation form allows the trainee to select which aspects related to training engagement and relevance they perceived as strengths or weaknesses. In addition, a review of the optional comments section is completed to identify any issues that would contribute to trainees discomfort and distraction that could have impacted employee engagement (such as room temperature, catering, lighting etc.).

For 2017:

- 100% of courses had an overall rating of good, very good or excellent. 0% of courses had an overall rating of poor or very poor. Therefore, overall trainee satisfaction is high.
- Training courses were perceived by trainees as engaging and relevant and trainees felt participation was encouraged.

#### Trainee Learning

Trainee learning is the degree to which trainees acquire the intended knowledge and skills based on their participation in the training. Learning is evaluated by the pass rate of tests written for key EHS training courses.

For 2017, 100% of trainees passed the assessment test for all key EHS training courses and there were no rescheduled tests due to failed attempts.

#### Training Results

Training results is the degree to which targeted outcomes occur as a result of the training. The effectiveness of training results are measured by the EHS significance (high, medium, low) and the frequency of unplanned events documented through processes such as the deviation process, the non-conformance process, investigations, and customer complaints where the root cause was determined to be related to human error or training. The targeted outcome is zero high risk unplanned events related to human error or training as well as no trend for recurrence (three or more) of the same unplanned event with the same human error or training root cause.

There were 11 unplanned events in 2017 for which the root cause was determined to be related to human error or training (9 low and 2 medium significance).

There was no trend for recurrence (three or more) of the same unplanned event with the same human error or training root cause.

### 3.2.3 Improvements to Human Performance Management

BWXT ITG is committed to continuous improvement of human performance management. No specific improvements have been identified.

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**Supplementary Report to Support Class 1B Licence Application**

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**3.2.4 Future Plans**

BWXT ITG will continue to provide training and support to employees to carry out duties related to the licensed activities. This will be achieved through adoption of the existing Nordion systems. BWXT ITG will ensure a sufficient number of licensee personnel in all relevant job areas.

**3.2.5 Challenges**

BWXT ITG does not anticipate any specific challenges with human performance management. The experienced employee base hired from the acquisition from Nordion are trained and highly qualified.

**3.3 Operating Performance**

The Operating Performance SCA includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.

**3.3.1 Relevance and Management****3.3.1.1 Conduct of Licensed Activities**

BWXT ITG will adopt existing Nordion procedures to ensure work undertaken will be planned and controlled. Work activities will be identified, sequenced, and defined in approved plans, procedures, instructions, and drawings. Work activities include design control, procurement, operations, shipping, receiving, handling and maintenance. The department and, where appropriate, the identity of the person performing the work will also be specified. Supervisor acceptance will be scheduled as required.

Requirements will be identified for avoiding damage, contamination, and foreign material ingress, for maintaining clean and protective conditions, and for proper handling, storing, shipping and preservation. Independent verifications are identified and scheduled to verify that specific requirements are met. Procedures, instructions, drawings, programs, and tools will be identified, prepared and approved for use.

The safety analysis report for medical isotope manufacturing (IS/SR 1070 Z000, "Final Safety Analysis Report for the Nuclear Medicine Production Facility") describes the following:

- Operations within the Nuclear Medicine Production Facility
- The potential radiation safety and occupational safety hazards that exist
- The worst case accident scenarios
- The measures in place to mitigate the consequences of the hazards

Each processing area also has a secondary level safety analysis report that provides analysis of the safety hazards unique to that area. Currently, there are fourteen FSARs that support the primary Nuclear Medicine Production Facility (NMPF) FSAR.

**3.3.1.2 Environment, Health and Safety Committee**

BWXT ITG will establish a BWXT ITG Environment, Health and Safety (EHS) Committee whose role is to review and approve, from a safety perspective, the design, construction, commissioning, operation, and decommissioning of BWXT ITG nuclear facilities and operations. The review takes into consideration the potential impact of facility hazards on the public and employees and ensures measures are taken to minimize the risk.

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**Supplementary Report to Support Class 1B Licence Application**

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The BWXT ITG EHS Committee will be comprised of senior management and technical professionals and will be chaired by the Vice- President, Regulatory and EHS Compliance or designate. The BWXT ITG EHS Committee will review new and amended processes which might have an impact on health, safety, and environment. Activities that relate specifically to CNSC licensing and the radiation protection of workers, the public and the environment, will be addressed in the BWXT ITG EHS Committee meetings typically held on a bi-monthly basis with ad hoc meetings arranged as required. Typical agendas will include Safety Analysis Reports, significant changes (repairs or modifications) to existing facilities, Radiation Incident Report reviews, safety procedures, and review of CNSC licensing requirements (radiation monitoring, as low as reasonably achievable (ALARA) program, emissions, dosimetry, project approval, etc.).

Final Safety Analysis Reports (FSARs) are prepared by project leaders or by EHS Compliance to encompass risk analysis and safety and environment reviews. Safety assessments are performed for new facilities or processes, or when significant changes are made to existing processes. FSARs must be approved by the BWXT ITG EHS Committee before a new process goes into full production. Revisions to the Nuclear Medicine Production Facility FSAR the main document covering the production operations, will be reviewed and approved internally, and submitted to the CNSC for approval. Secondary FSARs (for each individual production process) will be reviewed and approved internally as per an established review schedule.

In addition to the BWXT ITG EHS Committee, a joint BWXT ITG - Nordion EHS Committee has been established. The joint BWXT ITG - Nordion EHS Committee at minimum reviews and approves changes that could impact the facility and changes to the types or quantities of processing that take place within the BWXT ITG leased space.

### 3.3.1.3 Reporting and Trending

BWXT ITG will adopt Nordion procedures for reporting and trending. When EHS-related non-conformances (i.e. deficiencies in equipment, systems or management processes which are used to carry out, or in support of, licensed activities) are found, they will be identified, recorded and reported as required.

Incidents and non-conformances will be identified through the non-conformance procedures, investigations, and internal audits. As part of the Management System for Safety, internal audits will be conducted annually to verify compliance with applicable procedures and requirements. These audits will ensure that BWXT ITG's programs and systems are compliant to applicable standards and regulatory requirements, conform to internal policies and procedures, and are properly implemented and maintained.

A process will be in place for reviewing and analyzing EHS related non-conformances and corrective and preventive actions. Annually, an EHS Performance Report will be prepared to document the analysis of data from the previous year. The data will be analyzed to determine the presence of any undesirable trends, the effectiveness of corrective action taken and whether additional corrective action is needed. The EHS Performance Report will be distributed to and reviewed by the BWXT ITG EHS Committee in the annual Performance Review of the Management System for Safety and the EMS (refer to Section 3.1.1.4).

Corrective Action and Preventive Actions (CAPAs) will be issued as required to address the incidents and non-conformances. There will be a CAPA process to investigate and identify the root cause of environmental and safety issues and to implement and track corrective actions needed to prevent recurrence. It will also be used to initiate preventive actions to deal with potential problems.

Regulatory reporting will take place as required. Events will be investigated, as applicable, for operational deficiencies, radiation, ALARA, device, transport, or contamination incidents, environmental incidents, fires, occupational injuries, hazardous occurrences, and near-miss situations.

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## Supplementary Report to Support Class 1B Licence Application

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### 3.3.2 Past Performance - Nordion

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion, using a work force for BWXT ITG comprised largely of Nordion personnel hired at the time of the acquisition and adopting the Nordion Management System for Safety. The internal performance indicators for the operating performance SCA used by Nordion are:

- The number of significant unplanned events and major occurrences (reportable events)
- The results of the trend analysis

There were no high risk unplanned events and no major facility or transport non-conformances within the last eight years. Nordion's programs in place for auditing and capturing non-conformances identified issues in areas that required corrective actions.

For the majority of the years, there have been no significant trends identified as a result of the trend analyses performed and documented in the EHS Performance Reports.

### 3.3.3 Improvements to Operating Performance

BWXT ITG is committed to continuous improvement of processes and systems that contribute to operating performance. No specific improvements have been identified.

### 3.3.4 Future Plans

BWXT ITG is committed to continuous improvement in areas that affect operating performance and the conduct of licensed activities. Actions will be taken as required to improve safety performance and the management process.

### 3.3.5 Challenges

BWXT ITG does not anticipate any specific challenges with maintaining an acceptable level of operating performance. Operational performance will be maintained and improved with ongoing monitoring and consideration of issues and problems as they arise.

## 3.4 Safety Analysis

The Safety Analysis SCA covers maintenance of the safety analysis that supports the overall safety case for the facility. Safety analysis is a systematic evaluation of the potential hazards associated with the conduct of a proposed activity or facility and considers the effectiveness of preventative measures and strategies in reducing the effects of such hazards.

### 3.4.1 Relevance and Management

#### 3.4.1.1 Facility Safety Analysis

BWXT ITG will adopt the Nordion process for safety analysis established in CPM-6-20, "Safety Analysis Reports". Safety assessments will be performed for new Active Area facilities or processes, or when changes are to be performed on a facility, ventilation system, safety system, equipment, operation or process which will significantly affect the worst case scenario as outlined in an existing safety analysis. The assessment will include a description of the safety-related systems, features, and administrative controls (i.e. operating procedures, training, etc.) in place to detect, prevent and control hazards to protect the environment and assure adequate safety of employees and the public. Safety analysis of facilities and processes will be documented in Final Safety Analysis Reports (FSARs). FSARs will be prepared by project leaders or EHS Compliance and approved by the EHS Committee. The FSAR provides the evidence that safety requirements have been met and that the facility, equipment, or operation is safe.

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**Supplementary Report to Support Class 1B Licence Application**

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The BWXT ITG EHS Committee will be responsible for reviewing and approving significant changes to facilities which could alter any conclusions reached regarding the safety of the facility as established in the approved safety analysis. FSARs must be approved by the EHS Committee prior to a new process going into full production or prior to unrestricted production start-up following modifications.

The safety case for the overall facility will be maintained in the Nuclear Medicine Production Facility FSAR. This FSAR describes the operations within the facility, the potential radiation safety and occupational safety hazards that exist, the worst case accident scenarios and the measures in place to mitigate the consequences of the hazards. Revisions to this document will be reviewed and approved internally, and submitted to the CNSC for approval. Secondary FSARs (for each individual production process) have been prepared to provide analysis of the safety hazards unique to those areas. These FSARs will be reviewed and approved internally as per an established review schedule. When modifications are made to secondary FSARs, an assessment will be performed and details will be captured in the primary FSARs, as required. The overall safety case for the facility will be reviewed and approved by the EHS Committee.

#### 3.4.1.2 Fire Hazard Analysis

BWXT ITG will retain ultimate responsibility for fire protection for the NMPF. Under the landlord-tenant agreement, Nordion will provide fire protection within the NMPF and other spaces leased by BWXT ITG. A Fire Hazard Analysis compliant with the National Fire Protection Association, NFPA 801:2003 has been accepted by the CNSC. The Fire Hazard Analysis was conducted by a qualified third party and assessed potential risks from a fire to personnel safety, property and operations, and the environment to ensure these risks are managed in a manner that minimizes potential impacts.

Any changes to the facility that potentially impact fire protection systems will be reviewed by a qualified third party to ensure that these changes do not pose a risk to life, safety or the environment. These reviews will be submitted to the CNSC. Annually a third party will conduct a compliance review regarding inspection, testing and maintenance of the Fire Protection System. These reviews will be submitted to the CNSC.

#### 3.4.2 Past Performance - Nordion

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion, using a work force for BWXT ITG comprised largely of Nordion personnel hired at the time of the acquisition and adopting the Nordion Management System for Safety.

The Final Safety Analysis Reports (FSARs) are prepared by EHS and/or project leaders to encompass risk analysis, safety and environmental reviews and are performed every five years.

The performance indicators are:

- Number of additional hazards identified
- Number of actions resulting from review
- Number of actions completed
- Whether FSAR review met target due date
- Number of modifications and changes to the Facility that may affect the safety analysis

#### 3.4.2.1 Additional Hazards and Actions

Nordion implemented a Systematic Approach to Hazards Evaluation (SAHE) in 2016. A SAHE ensures that the hazard assessment process is performed thoroughly and properly documented. The information gathered during the SAHE is used for the revision of any Safety Analysis Reports (SARs) due for review.

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**Supplementary Report to Support Class 1B Licence Application**


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In 2017, there were five FSARs reviewed and approved by the EHS Committee. The details are shown below:

FSAR	# Additional hazards identified	# Actions resulting from review	# Actions completed	Approved by Committee by target date? <sup>1</sup>
IS/SR 1058 Y90 ██████████ Production Facility in Room 1224	11	11	11	No <sup>2</sup>
IN/SR 1859 C000 Waste Diversion Program	1	0	n/a	No
IS/SR 1816 Z000 KRMF Manual Packaging Facility	6	2	2	No <sup>3</sup>
IS/SR 1849 Y90 Multi-Purpose Packaging Facility	11	3	3	Yes
IS/SR 2020 Z000 Radiochemical Quality Control Facility and Processes	0	0	n/a	Yes <sup>4</sup>
<b>Totals</b>	<b>29</b>	<b>16</b>	<b>16</b>	

<sup>1</sup> FSARs are due on the five year anniversary date of their last approval by the Committee.

<sup>2</sup> Delay in completion of review was due to the Facility being in refurbishment for a period from 2015 – 2017.

<sup>3</sup> Review was completed by the target date, but presentation to EHS Committee was one month past due intentionally to present both packaging FSARs to the Committee at the same time.

<sup>4</sup> Target date extended from Aug. 9 to Dec. 31, 2017 as per V.P. QA, Regulatory and EHS Compliance.

**NOTE:** Where the number of actions resulting from the review is less than the number of additional hazards identified, existing mitigations were already in place.

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**Supplementary Report to Support Class 1B Licence Application**


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<b>Year</b>	<b># Additional hazards identified</b>	<b># Actions resulting from review</b>	<b># Actions completed</b>	<b>Approved by Committee by target date?</b>
2015	6	26	24	6/7
2016	7	16	16	4/6
2017	29	16	16	2/5

**3.4.3 Improvements to Safety Analysis**

BWXT ITG is committed to continuous improvement of the safety analysis process, including fire hazards analysis. No specific improvements have been identified.

**3.4.4 Future Plans**

The BWXT ITG EHS Committee will review and approve new facilities, equipment, or operations and significant changes, as they arise. BWXT ITG is developing a new process for Molybdenum-99.

**3.4.5 Challenges**

BWXT ITG does not anticipate any challenges with maintaining and continuously improving the established Nordion safety analysis process.

**3.5 Physical Design**

The Physical Design SCA relates to activities that impact the ability of structures, systems and components to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.

**3.5.1 Relevance and Management**

BWXT ITG will adopt Nordion's design control program that ensures that designs meet established codes and standards and all applicable requirements. Design requirements will be identified, documented and controlled. Design control is applicable to all process equipment and facilities' buildings, systems and equipment in support of licensed activities.

BWXT ITG will retain ultimate responsibility for facilities' buildings, systems and equipment required for operation of the NMPF. Under the lease, Nordion will maintain the facilities infrastructure (Base Building Systems). BWXT ITG will be responsible for maintenance and inspection of equipment within the leased premises specifically related to the processing of medical isotopes, including hot cells, fume hoods and gloveboxes.

Design control is the responsibility of the Design Authority. The Design Authority is responsible to ensure all design activities related to the licensed activities are controlled and meet all applicable licences, regulations, codes and standards. In practice, the Design Authority may delegate responsibility to Technical Design Authorities who have been assigned based on specific product lines and facility requirements.

Changes to designs of existing processing facilities will be controlled in accordance with the change control process. The Design Authority ensures that these changes do not impinge on the established safety margin for the protection of health, safety and the environment.

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**Supplementary Report to Support Class 1B Licence Application**

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The BWXT ITG EHS Committee will be responsible for approving significant changes to facilities which could alter any conclusions reached regarding the safety of the facility as established in the approved safety analysis. Any facility modifications require Nordion's approval. The BWXT ITG EHS Committee will be responsible for approving any safety systems that are intended to protect the operator, other employees and the public from a radiation hazard. As stated previously, changes to nuclear processing facilities and associated activities are documented in safety analysis reports. EHS Compliance will work through the BWXT ITG EHS Committee to review and approve the safe design of new and modified facilities.

BWXT ITG Procurement will be responsible for ensuring that outside firms used to carry out work on equipment specifically related to medical isotopes processing are qualified. Under the lease arrangement, Nordion will identify any newly purchased equipment or instrument (Base Building System as per the lease) to the Nordion Facilities Department. Nordion Procurement and Facilities will be responsible for ensuring all outside maintenance or calibration firms being used by Nordion are qualified to carry out work in the NMPF.

BWXT ITG will adopt the Nordion process for conceptual, ergonomic, and final design reviews, and control of design. Subject matter experts will be engaged to ensure a good design based on their knowledge and subject matter expertise that aligns to existing specifications, regulations, and quality requirements.

The EHS Requirements Checklist will ensure that changes within BWXT ITG that may have environment, health, and safety impacts are appropriately evaluated by qualified EHS personnel. This will apply to acquisitions of capital equipment, new products, materials, or chemicals that are being brought on site for the first time, and for projects that could have a significant impact on the environment, health and safety (e.g. the installation of new facilities, the design of new production processes, modifications to existing facilities or processes, and changes to the Nuclear Ventilation System (NVS)). -

### 3.5.2 Past Performance – Nordion

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion, using a work force for BWXT ITG comprised largely of Nordion personnel hired at the time of the acquisition and adopting the Nordion Management System for Safety.

In 2017, Nordion did not make any modifications to the physical design of the facility. The FSAR review process identifies areas of continuous improvement to ensure that the overall design basis for the facility is both validated and maintained. In 2017, there were no significant design issues identified through these reviews. Overall, Nordion's facility design has been maintained.

### 3.5.3 Improvements to Physical Design

BWXT ITG is committed to continuous improvement to the physical design process that is in place to assess the impact to the ability of structures, systems and components to continue to meet and maintain their design basis, given new information arising over time and taking changes in the external environment into account. No specific improvements have been identified.

### 3.5.4 Future Plans

BWXT ITG will continue to assess the ability of structures, systems and components specific to meet and maintain their design basis.

### 3.5.5 Challenges

BWXT ITG does not anticipate any challenges with ensuring the physical design is maintained for structures, systems and components specific to medical isotope processing, including hot cells, fume hoods and gloveboxes.

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**Supplementary Report to Support Class 1B Licence Application**


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**3.6 Fitness for Service**

The Fitness for Service SCA covers activities that impact the physical condition of structures, systems and components to ensure that they remain effective over time. This area includes programs that ensure all equipment is available to perform its intended design function when called upon to do so.

**3.6.1 Relevance and Management**

BWXT ITG will retain ultimate responsibility for facilities' buildings, systems and equipment required for operation of the NMPF. Under the lease, Nordion will maintain the facilities infrastructure (Base Building Systems).

BWXT ITG will be responsible for maintenance and inspection of equipment within the leased premises specifically related to the processing of medical isotopes, including hot cells, fume hoods and gloveboxes, including radiation meters.

There is a system in place for the maintenance and control of equipment that supports the facility. The program provides guidelines for the documentation and maintenance of the system to ensure responsibilities are identified, filing systems are maintained, and all necessary controls are in place for facility calibration and maintenance.

The Advanced Maintenance Management System (AMMS) is used to control calibration and maintenance activities. The AMMS is used to catalogue all equipment requiring calibration or maintenance, record equipment information, schedule maintenance, and issue work orders.

Detailed processes and rules governing the preventative maintenance program are available in R-Master, "Facilities Maintenance Master Plan" and CP-Master "Nordion Ottawa Site Instrument Maintenance and Calibration".

The AMMS provides the necessary oversight to ensure equipment integrity. All equipment inspections and preventative maintenance schedules are dictated by the use of the AMMS. New software upgrades keep the AMMS system up-to-date. The latest update was in September of 2011.

BWXT ITG will retain ultimate responsibility for aging management of facilities' buildings, systems and equipment required for the operations of the NMPF. Under the lease, Nordion provides aging management for facilities infrastructure (Base Building Systems). Under the lease, BWXT ITG is responsible for aging management of equipment specifically related to medical stopes processing, including hot cells, fume hoods and gloveboxes.

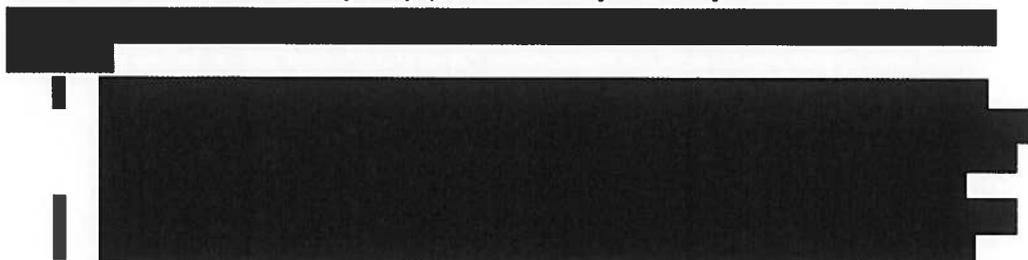
**3.6.2 Past Performance - Nordion**

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion, using a work force for BWXT ITG comprised largely of Nordion personnel hired at the time of the acquisition and adopting the Nordion Management System for Safety.

The Nordion performance indicators for the fitness for service SCA are:

- The availability of equipment to perform its intended use
- The results of facility equipment trend analysis (the number of equipment failures)

The management structure of Nordion's Preventative Maintenance Program has not altered greatly over the years. The Preventative Maintenance Program continues to prove effective as there were no major equipment failures year over year.



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**Supplementary Report to Support Class 1B Licence Application**

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[REDACTED]

**3.6.3 Improvement to Fitness for Service**

BWXT ITG is committed to continuous improvement to fitness for service to ensure the physical condition of structures, systems and components remain effective over time and all equipment is available to perform its intended design function when called upon to do so. No specific improvements have been identified.

**3.6.4 Future Plans**

BWXT ITG will adopt the AMMS to control BWXT ITG's maintenance activities and to replace critical equipment that are required for the safety of the NMPF and business continuity.

**3.6.5 Challenges**

BWXT ITG does not anticipate any challenges with ensuring continued fitness for service.

**3.7 3.7 Radiation Protection**

The Radiation Protection SCA covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations*. This program must ensure that contamination and radiation doses received are monitored and controlled, and maintained as low as reasonably achievable (ALARA).

**3.7.1 Relevance and Management**

BWXT ITG will adopt the measures and systems Nordion has in place to ensure that radiation exposure to employees and the public are kept ALARA, social and economic factors being taken into consideration. This reflects the corporate commitment to provide employees with a safe and healthy work environment and to protect the public and the natural environment as described in CPM-6-06, "Nordion Environmental, Health and Safety Policy", and CPM-6-19, "MDS Nordion Environmental, Health and Safety Responsibilities and Committees".

**3.7.1.1 Radiation Monitoring Program**

BWXT ITG will adopt Nordion's program to keep radiation doses received by workers and members of the public ALARA. This program defines requirements for management control over work practices, personnel qualification and training, control of occupational and public exposure to radiation, planning for unusual situations, and review of radiation doses and trends by the EHS Committee. A personnel monitoring program to control radiation exposure is in place. To ensure that the external exposure of NEWs to ionizing radiation from all routine work is kept to a minimum and within safe limits, an intensive program of routine radiation surveys is carried out in all Active Areas.

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**Supplementary Report to Support Class 1B Licence Application**

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All employees who regularly work in the Active Area are classified as NEWs and are assigned monthly dosimeters from a dosimetry service company licensed by the CNSC. Nordion refers to personnel dosimeters as Thermo-luminescent Dosimeters ("TLDs") regardless of the technology used. Nordion has historically used TLDs for ring dosimeters, but switched from TLDs to Optically Stimulated Luminescent Dosimeters (OSLD's) for body dosimeters in 2006.

Production Technicians are trained to work in various production processes and move from one production area to another during the year. In the NMPF, personnel may receive exposure from working with more than one radionuclide. Other employees who normally work outside the Active Area and visit the Active Area on a regular basis are also classified as NEWs, but are assigned quarterly TLDs. Contractors who are given access to the Active Area are called "Contractor NEWs". They are trained as NEWs, tested and have security clearance, but are subject to the regulatory dose limit and internal levels of non-NEWs. Contractor NEWs are not permitted to handle radioactive material.

Radiation doses to employees are reviewed and assessed in accordance with the ALARA principle. Nordion has also developed approved activity limits for hot cells, glove-boxes, and fume-hoods to control employees' external radiation exposure. Use of activity in excess of these limits is only allowed under approved Work Permit.

#### 3.7.1.2 Internal Occupational Radiation Doses

Personnel who work in the Active Areas have the potential to be exposed to radioactive materials. Workplace air sampling and monitoring programs help to identify any release of contamination into the air or onto surfaces. Process controls are present throughout the facility to help prevent employee exposures to radioactive materials. Although personal dosimetry by use of TLDs provides a satisfactory estimate of exposure to external sources of ionizing radiation, bioassay techniques are necessary to detect and quantify the potential internal deposition of radioactive materials for Active Area personnel. Routine thyroid measurements were conducted by Nordion when radioiodines were processed as assurance that the air sampling and monitoring program is effective in determining low-level exposure. Should work with radioiodines recommence, BWXT ITG would implement the routine thyroid measurements as Nordion had performed before. In the event that internal dose to radioiodines or other radionuclides is determined to be possible for work conducted under BWXT ITG's Class 1B licence, special bioassay would be performed.

#### 3.7.1.3 Dosimetry Review

BWXT ITG will adopt Nordion's established Administrative and Action Levels that are well below the regulatory radiation exposure limits. Routine and timely review of dosimetry collected from TLD badges and thyroid bioassay data ensures that Administrative Levels are observed. The Administrative Levels trigger investigation and, where warranted, initiate changes to work practices to lower the risk of exposure. These events are documented as ALARA incidents. Action Levels are set at a higher level than Administrative Levels and may indicate a loss of control of a part of the radiation protection program. Investigations at this level are documented in a Radiation Incident Report (RIR).

Following review by BWXT ITG EHS Compliance staff, the dosimetry data will be reviewed by management. In addition, an electronic database will be maintained to permit generation of radiation exposure reports for communication of dose to employees as well as the preparation of performance metrics. This data will be presented at each EHS Committee meeting to permit the radiation safety programs performance to be evaluated continuously throughout the year. Radiation safety performance metrics will also be presented to senior management on a monthly basis. The metrics will be presented alongside targets that constitute BWXT ITG's commitment to ALARA and environmental protection.

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**Supplementary Report to Support Class 1B Licence Application**

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**3.7.1.4 Contamination Control**

BWXT ITG will adopt Nordion's processes for contamination control. The contamination control program for the Active Area includes routine sampling and monitoring on a daily basis of the floors, benches, fume-hoods, glove-boxes, support and service areas, and on a weekly basis, change-rooms and inactive floors. Regular sampling, by wipe testing, of the corridors and office areas is conducted several times daily to ensure areas are maintained contamination free and, should contamination be found, to decontaminate immediately to the levels specified in the decontamination procedure.

In addition, equipment leaving the Active Area is monitored by wipe test and/or direct measurement to provide assurance that equipment leaving the Active Area meets administrative and regulatory requirements.

Air sampling and monitoring is also conducted to:

- Monitor the adequacy of radioactive dust or gas containment systems
- Assess employee exposure and likelihood of intake, which assists in selection and frequency of bioassay techniques
- Promptly identify abnormal situations that require immediate attention to limit exposure
- Assist in determining any sources of exposure
- Demonstrate compliance with the CNSC Regulations and licence conditions

Contamination incidents, defined as the uncontrolled movement of radionuclides indicating a potential loss of process and/or engineering controls will be investigated and documented as contamination incidents in a database that will be maintained by EHS Compliance.

**3.7.1.5 Application of ALARA Principle**

BWXT ITG will adopt Nordion measures to keep radiation doses received by workers and members of the public ALARA. These include:

- Management control over work practices
- Personnel qualification and training
- Control of occupational and public exposure to radiation
- Planning for unusual situations

The ALARA concept takes into consideration relevant social and economic factors.

BWXT ITG is committed to a policy of safety and good radiation protection to keep all doses ALARA. This commitment is expressed in the Environmental, Health and Safety Policy (CPM-6-06).

The EHS Committee will provide oversight of the radiation protection program.

The commitment of workers to radiation safety is an important element of the ALARA program. Demonstration of this commitment through adherence to radiation protection practices and procedures derived from the written policy statements will be assessed through internal audits.

BWXT ITG is committed to ensuring personnel qualification and training in accordance with the Management System for Safety. Workers are provided with specific working procedures that take into account existing and potential radiological hazards.

Routine and timely review of dosimetry collected from TLD badges and thyroid bioassay data will ensure that the Administrative Levels are observed. These levels are designed to trigger an investigation and, where warranted, initiate changes to work practices to lower the risk of exposure.

## Supplementary Report to Support Class 1B Licence Application

Planning for unusual situations, such as a spill of radioactive material, loss of containment, or loss of shielding for processes, is a requirement of the safety analysis report process (refer to Section 3.4). This planning is completed before routine production of new processes can begin. Engineering and procedural controls are put in place, and deemed acceptable for all processing at Nordion.

Major projects will be reviewed and approved by the EHS Committee. Work Permits or Change Forms (CFs) will be required for lower level unusual situations (e.g. maintenance or repair activities). Work Permits and CF's will receive appropriate review by EHS Compliance to ensure the potential exposures resulting from the work are ALARA.

### 3.7.2 Past Performance - Nordion

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion, using a work force for BWXT ITG comprised largely of Nordion personnel hired at the time of the acquisition and adopting the Nordion Management System for Safety.

The internal performance indicators for the radiation protection SCA used by Nordion are:

- Radiation doses against EHS targets, internal levels, and regulatory limits
- The number of instances of, and the nature of internal occupational radiation doses
- The number and nature of radiation exposure events
- The number and nature of contamination incidents

#### 3.7.2.1 Worker Doses - Nordion

The worker dose data for Nordion employees in the NMPF and the COF is provided in Tables 2-4. Year-over-year, Nordion met the established EHS targets for dose rate.

#### Worker Effective Doses

The annual average and maximum worker effective doses for Active Area NEWs (those who work routinely in the Active Area) and Non-Active Area NEWS from 2005-2017 are shown in Table 2.

**Table 2**  
**Average and Maximum Worker Effective Doses (mSv)**

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
<b>Active Area Personnel</b>													
<b>Average</b>	1.11	1.03	0.76	0.80	0.62	0.65	0.64	0.56	0.59	0.44	0.39	0.49	0.42
<b>Maximum</b>	7.8	7.5	5.4	6.1	4.6	4.9	5.1	5.2	6.4	6.0	5.2	4.9	5.5
<b>Non- Active Area Personnel</b>													
<b>Average</b>	0.27	0.13	0.09	0.53	0.14	0.12	0.06	0.13	0.12	0.14	0.16	0.20	0.13
<b>Maximum</b>	1.1	1.7	1.9	2.1	2.0	1.5	0.8	1.4	1.5	1.7	1.9	2.1	1.5
<b>Total Monitored (Active and Non-Active Areas)</b>	372	343	368	345	335	332	325	293	284	269	264	267	263

### Supplementary Report to Support Class 1B Licence Application

The worker effective doses for Nordion Active Area NEWs have been consistent with Nordion's ALARA program and well below the regulatory dose limit of 50 mSv/year for NEWs.

Average doses to Nordion Active Area NEWs have steadily declined. This is due to decreased production of Medical Isotopes. In recent years, (from 2009 to 2017) the average doses were relatively stable at or below 0.2 mSv/year.

#### Extremity Doses

The annual average and maximum extremity doses to Nordion NEWs from 2005-2017 are shown in Table 3. The Active Area and Non-Active Area NEWs were grouped together as there are very few Non-Active Area NEWs with extremity dosimeters.

**Table 3**  
**Average, and Maximum Extremity Doses from 2005-2017 (mSv)**

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
<b>Average</b>	1.9	1.6	1.1	1.1	0.8	0.9	0.7	0.5	0.5	0.7	0.5	0.8	0.5
<b>Maximum</b>	14.6	15.3	16.3	11.9	9.8	18.0	12.3	10.3	7.4	9.5	9.3	8.3	16.4

The extremity doses for Nordion Active Area NEWs have been consistent with Nordion's ALARA program and well below the regulatory dose limit of 500 mSv/year for NEWs.

Average extremity doses are less than 1% of the dose limit and have steadily declined. This is due to decreased production of Medical Isotopes.

The maximum extremity doses are typically, though not exclusively, received by [REDACTED]. Doses are below the 500 mSv/yr annual limit, [REDACTED].

[REDACTED] The low maximum doses demonstrate adequacy of design and control of the production, quality control, and decontamination facilities as well as the diligence of employees following procedures and safe practices.

#### Doses to Contractor NEWs

The annual average and maximum doses to Contractor NEWs from 2005-2017 are shown in Table 4.

**Table 4**  
**Average, and Maximum Doses to Contractors from 2005-2017 (mSv)**

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
<b>Average</b>	0.23	0.05	0.04	0.14	0.06	0.05	0.05	0.03	0.03	0.09	0.03	0.07	0.02
<b>Maximum</b>	1.20	1.46	0.88	0.38	0.55	0.36	0.45	0.21	0.27	0.31	0.13	0.36	0.2

### Supplementary Report to Support Class 1B Licence Application

Prior to 2008 there were instances involving worker effective doses to Contractors above the Nordion Action Level of 0.75 mSv/year and the regulatory dose limit of 1 mSv/year. However, these instances were found to be non-personal as they were principally due to TLDs being returned late and being processed without a control dosimeter. When this happens, background radiation is not subtracted and a higher dose is recorded than occurred. For the 1.46 mSv recorded dose in 2006, it was determined that 1.36 mSv of this dose was attributable to the dosimeters being processed without a control. In recent years, Contractor dosimeters have only been processed with a control dosimeter. This improvement is reflected in the overall downward trend in maximum and average dose to Contractor NEWs. For the remaining years, the contractor doses have been consistent with Nordion's ALARA program and have been below the regulatory dose limit.

In both of the above instances where the dose was above the regulatory limit, the recorded doses were determined in later years. To resolve this, in fourth quarter 2006, Nordion created a separate dosimetry group for Contractor NEWs. This change improved the speed and accuracy of dosimetry data review for this group against the lower dose limit.

In 2005, there was a fourth quarter processing anomaly which artificially increased doses; therefore, the average dose for 2005 is higher than the averages in subsequent years.

#### 3.7.2.2 Internal Occupational Radiation Doses

Nordion's bioassay program includes thyroid monitoring on a scheduled routine basis and whole body counting or urine analysis if air or contamination monitoring indicates it is needed. A summary of the instances of internal occupational radiation doses for 2005-2017 are shown in Table 5.

**Table 5**  
**Summary of Instances of Internal Occupational Radiation Doses for 2005 to 2017**

Year	Number of Employees		
	Exceeding Nordion's Administrative Level (1000 Bq)	Requiring whole body counting or urinalysis	With recorded internal doses exceeding dose limits in Sections 13 and 14 of the <i>RP Regulations</i>
2005	0	4	0
2006	1	0	0
2007	1	1	0
2008	0	0	0
2009	0	0	0
2010	0	0	0
2011	0	0	0
2012	0	0	0
2013	0	0	0
2014	0	0	0
2015	0	7	0
2016	0	1	0
2017	0	1	0

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**Supplementary Report to Support Class 1B Licence Application**

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In 2005, four employees had measurable committed whole body dose of up to 0.08 mSv as a result of an ALARA incident [REDACTED]

In 2006, there was one case of an employee exceeding Nordion's Administrative Level of 1000 Bq I-125 or I-131, causing an effective dose of 0.2 mSv. A second employee had a measurable thyroid burden of I-131, which was below the 1000 Bq investigation level. In both cases, the employees were Radiation Monitors. The first wore an improperly fitting respirator. The second wore no respirator when one should normally have been worn. Respirator fit testing and training was performed and re-enforced with the employees.

In 2007, there was one case of an employee exceeding Nordion's Administrative Level of 1000 Bq I-131, causing an effective dose of 0.3 mSv. A second employee had a measurable thyroid burden of I-131 on two occasions, although both were below the 1000 Bq level. Precautionary measures required when handling radioiodines were reviewed with personnel and expanded continuous air monitoring was conducted. There was one employee who received a cut to the tip of his index finger, through his glove from in-cell equipment contaminated with Sr-82. Urinalysis indicated an effective dose of 0.2 mSv.

Whole body counting was performed once in 2015 on seven Nordion employees as Special Bioassay. This was as a result of the investigation into an ALARA incident (ALR 15-17) where airborne Co-60 creation was deemed possible though intake was unlikely. No internal contamination was detected.

No urinalysis was required in 2015.

During 2016, whole body counting was performed once in 2016. No urinalysis was required in 2016. Whole body counting was performed once in 2017. No urinalysis was required in 2017.

From 2008 to 2017, there were no cases of employees exceeding Nordion's Administrative Level of 1000 Bq I-125 or I-131. There were no employees who recorded internal doses exceeding any of the dose limits in Sections 13 and 14 of the *Radiation Protection Regulations*.

### 3.7.2.3 Radiation Exposure Events - Nordion

Nordion conducts internal investigations if established Administrative and Action Levels are exceeded. Administrative Levels have been developed as internal indicators in keeping with the ALARA principle. Action Levels are set at a higher level than Administrative levels and may indicate a loss of control of a part of the Radiation Protection Program.

An event is considered a Radiation Incident if it involves radiation exposure or environmental release which has, or is likely to exceed an Action Level. These events are documented as Radiation Incident Reports (RIRs).

An event is considered an ALARA incident if it involves radiation exposure or environmental release which has or it likely to exceed an Administrative Level. These events are documented as ALARA Reports.

A summary of the radiation exposure events for 2005-2017 are shown in Table 6.

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**Supplementary Report to Support Class 1B Licence Application**


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**Table 6**  
**Summary of Radiation Exposure Events for 2005 to 2017**

<b>Year</b>	<b>Radiation Incidents</b>	<b>ALARA Reports</b>
<u>2005</u>	<u>4</u>	<u>3</u>
<u>2006</u>	<u>4</u>	<u>5</u>
<u>2007</u>	<u>2</u>	<u>14</u>
<u>2008</u>	<u>0</u>	<u>5</u>
<u>2009</u>	<u>1</u>	<u>2</u>
<u>2010</u>	<u>0</u>	<u>3</u>
<u>2011</u>	<u>0</u>	<u>3</u>
<u>2012</u>	<u>0</u>	<u>1</u>
<u>2013</u>	<u>0</u>	<u>1</u>
<u>2014</u>	<u>0</u>	<u>0</u>
<u>2015</u>	<u>0</u>	<u>3</u>
<u>2016</u>	<u>1</u>	<u>1</u>
<u>2017</u>	<u>0</u>	<u>0</u>

From 2005-2017 there have been 12 RIRs, and a number of ALARA Reports. The radiation incidents were due mainly to TLDs being returned late and processed without control dosimeters as detailed in Section 3.7.2.2. In addition to the incidents described in Section 3.7.2.3, the ALARA events were mainly due to administrative issues or issues within the HEGS Facility. As a result, improved procedural and engineering controls were put in place in the HEGS Facility as well as the development of a new safety training program specifically for personnel processing Ir-192.

Year-over-year, Nordion has met the established EHS targets for radiation incidents.

#### 3.7.2.4 Contamination Control - Nordion

A summary of the contamination incidents by contamination level and by radionuclide for 2005-2017 are shown in Table 7 and 8 respectively.

## Supplementary Report to Support Class 1B Licence Application

**Table 7**  
**Contamination Incidents by Contamination Level**

Year	Not recorded**	<500 cpm	>500 cpm, <2,000 cpm	>2,000 cpm, <10,000 cpm	> 10,000 cpm, < 50,000 cpm	>50,000 cpm	Annual Total
2005	2	12	14	24	16	6	74
2006	0	10	17	16	8	15	66
2007	1	10	22	15	6	10	64
2008	0	16	35	22	5	5	83
2009	4	5	35	23	7	5	79
2010	1	2	18	15	4	3	43
2011	0	11	11	9	3	3	37
2012	1	1	7	13	6	4	32
2013	0	1	12	8	6	5	32
2014	1	2	16	12	12	4	47
2015	1	2	15	12	6	7	43
2016	0	2	10	8	4	2	26
2017	0	1	4	6	1	2	14

**Table 8**  
**Contamination Incidents by Radionuclide**

Year	Not recorded**	C-14	Co-60	I-125	I-131	Mo-99	Y-90	Decayed Mo-99
2005	1	*	12	10	22	12	13	*
2006	2	*	4	4	24	15	7	*
2007	1	*	15	6	19	14	1	*
2008	1	2	15	2	21	29	3	*
2009	1	0	21	1	20	10	9	*
2010	0	0	3	1	13	3	8	5
2011	1	0	7	3	6	12	3	0
2012	1	0	5	2	7	10	5	0
2013	1	0	9	1	10	5	4	0
2014	1	2	12	3	4	13	7	*
2015	0	1	12	1	5	11	5	*
2016	0	0	6	2	6	6	0	*
2017	2	0	4	0	0	0	2	*
Year	Ir-192	In-111	Lu-177	Xe-133	Sr-82	I-123	Eu-152	Annual Total
2005	0	1	3	0	0	0	*	74
2006	4	0	3	1	1	1	*	66
2007	3	0	0	1	3	1	*	64
2008	5	0	0	3	0	1	8	82
2009	10	1	0	0	4	0	1	78
2010	2	0	0	1	7	1	0	43



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**Supplementary Report to Support Class 1B Licence Application**

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- Accident Prevention
- Occupational Health
- Safety Communication and Reporting
- Emergency Response
- Safety Training

The Vice-President, Regulatory and EHS Compliance will have overall responsibility for the Occupational Health and Safety Program.

The Workplace Health and Safety Committee provides oversight of conventional safety and conducts regular safety inspections. The EHS Committee and the Senior Leadership Team sets targets each fiscal year in the areas of Medical Treatment Incidents, Lost Time Incidents and Severity Rates, and annually reviews the overall performance of the Occupational Health and Safety Program. Conventional Health and Safety performance is reviewed monthly by senior management and by the applicable health and safety committees.

The Workplace Health and Safety Committee is represented by union and management and typically meets on a monthly basis.

A program is in place to capture potential accidents through near-miss reporting. Employees are encouraged to report near misses, thus allowing prevention or mitigation of potential incidents.

### 3.8.2 Past Performance – Nordion

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion, using a work force for BWXT ITG comprised largely of Nordion personnel hired at the time of the acquisition and adopting the Nordion Management System for Safety.

The internal performance indicators for the conventional health and safety SCA used by Nordion are:

- The number of lost-time injuries
- The number medical treatment injuries
- Incident, and severity rates against EHS targets
- Incident rate as compared to the average incident rate for all Schedule 1 Ontario employers
- The results of 3<sup>rd</sup> party safety compliance audits
- The results of internal Workplace Health and Safety Committee inspections

The reportable incidents for 2005-2017 are shown in Table 9. This data shows an approximate 44% downward trend during this time. All corrective action taken as a result of these incidents have been completed.

## Supplementary Report to Support Class 1B Licence Application

**Table 9**  
**Reportable Conventional Health and Safety Incidents 2005 - 2017**

Year	No. of Lost Time Injuries	No. Minor Injuries	Kanata Site Incident Rate	Average Schedule 1 Ontario Employer Incident Rate
2005	3	7	1.77	5.92
2006	1	10	2.03	5.38
2007	4	5	1.68	5.22
2008	1	10	2.44	5.02
2009	1	4	1.51	4.21
2010	2	4	0.93	3.86
2011	1	4	1.05	3.69
2012	0	5	1.27	3.59
2013	1	3	0.96	N/A*
2014	3	5	2.36	3.41
2015	0	4	1.83	3.21
2016	3	3	2.20	3.25
2017	1	5	1.79	3.31

\*Average Schedule 1 Ontario Employer Incident Rate results not compiled for 2013.

The average Incident Rate for all Schedule 1 Ontario employers is compiled by the Workplace Safety & Insurance Board (WSIB). Nordion's Incident Rate remains considerably lower than the average Ontario rate.

In 2006 to 2008, incident rate, the number of incidents per 200,000 hours worked, was above the EHS targets ( $\leq 1.7$  per 200,000 hrs worked for 2006 and  $\leq 1.5$  per 200,000 hrs worked for 2007 and 2008). This was due to the number of incidents occurring in those years. As a result, improvements were made to ergonomics, handling of materials, and training. For all other years, Nordion has met the established EHS targets for conventional health and safety.

Nordion was in compliance with Part II of the Canadian Labour Code during this timeframe. All reportable occupational injuries or illnesses were reported to Human Resources & Skills Development Canada (HRSDC) and the Ontario WSIB.

There was one high risk finding from the 3<sup>rd</sup> party compliance audits in the area of conventional health and safety regarding machine guarding. The remainder of the findings from the audits over the years were medium and low risk. In all cases, corrective actions were implemented to address the observations.

There were no significant findings from the routine internal safety inspections.

### 3.8.3 Improvements to Conventional Health and Safety

BWXT ITG is committed to continuous improvement to the Conventional Health and Safety Program to continue to prevent, manage and respond to potential or actual hazards or emergencies in the workplace. No specific improvements have been identified.

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**Supplementary Report to Support Class 1B Licence Application**

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**3.8.4 Future Plans**

BWXT ITG will adopt the existing Nordion Conventional Health and Safety programs and procedures. BWXT ITG management will strive to ensure the scheduling of known strenuous tasks has adequate resources and continue to encourage regular rest breaks for manipulator users. Ergonomics issues related to processing and handling of radioactive materials will continue to be assessed as part of the design review process for new and existing facilities.

**3.8.5 Challenges**

Ergonomics related to manipulator use will continue to be a challenge. Ergonomic issues have included wrist injuries due to gripping action, elbow injuries due to rotation, and shoulder injuries due to lifting or over-reaching.

**3.9 Environmental Protection**

The Environmental Protection SCA covers programs that identify, control and monitor all releases of radioactive and hazardous substances and effects on the environment from facilities or as the result of licensed activities.

**3.9.1 Relevance and Management**

BWXT ITG will adopt the Nordion Environmental Protection Program to manage actual and potential environmental aspects resulting from activities, products and services.

The Environmental Protection Program outlines Nordion's programs and processes to ensure safety and the application of the ALARA principal specifically related to:

- Airborne effluent
- Liquid effluent
- Environmental dosimetry
- Environmental contamination
- Hazardous chemical storage and handling
- Waste management and disposal

Each of these areas is discussed in more detail below. The Vice-President, Regulatory and EHS Compliance will have overall responsibility for the Environmental Protection Program.

The production facilities have been designed and will be operated in a manner to ensure that releases to the environment via air or water emissions are within the limits approved by the CNSC and to prevent radioactive waste or hazardous chemicals being released to municipal garbage or sewer systems.

The environmental monitoring program will monitor and measure effluent releases and environmental contamination. Limits for radioactive emissions will be determined by the Derived Release Limit (DRL). The DRL was determined by Nordion for each of the major radioisotopes processed in the facility and then approved by the CNSC. The DRL takes into account the critical pathway analyses and the most probable location of highest radiation exposure. The DRL uses the 1.0 mSv annual public dose limit as the limiting factor.

**3.9.1.1 Airborne Effluent**

BWXT ITG will adopt Nordion's program for monitoring airborne effluent. All production operations are contained within cells, glove-boxes and/or fume-hoods. Ventilated air from these containment systems is filtered through roughing and HEPA filters and, where appropriate, activated charcoal adsorbers. These systems are designed with redundant fan/motor and filtration units that include pre-filters, primary and secondary filtration units to filter particulates and gaseous airborne effluent. The NVS has been designed and is maintained to prevent the unnecessary release of radioisotopes and other hazardous materials to the atmosphere.

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**Supplementary Report to Support Class 1B Licence Application**

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The program for monitoring airborne effluent will include qualitative continuous monitoring of process ventilation and stack emissions. This will be performed with the use of in-situ detectors and computerized recording.

Quantitative analysis of effluent will be performed by weekly air sampling of stack emissions using stack cartridges for radioiodines and particulates. Radio-xenons will be quantified by in-situ detectors.

Ventilation and stack sampling will be conducted by using particulate and/or activated charcoal filters, depending on the physical and chemical nature of the radionuclide. Radioiodine sampling will involve the use of activated charcoal filter cartridges, and analyses by gamma measurement. Particulates will be sampled by use of cellulose filter papers and analyzed by gamma measurement. Noble gases will be monitored in real time via detector/Multi-Channel Analyzer (MCA) sampling lines on the ventilation duct of both the Xe-133 and Mo-99 processes.

**3.9.1.2 Liquid Effluent**

BWXT ITG will adopt Nordion's process for radioactive liquid effluent. Radioactive liquid waste will be collected and transported to a licensed radioactive waste management facility. Other waste water which might potentially contain small amounts of radioactive contamination (from emergency showers, personnel wash sinks, water used for routine floor cleaning, etc.) will be collected in holding tanks and then sampled and analyzed against derived release limits to ensure that it is in compliance with licence conditions prior to being released to the municipal sanitary sewer.

**3.9.1.3 Environmental Dosimetry**

BWXT ITG will adopt Nordion's process for environmental monitoring. Environmental TLD's have been installed at predetermined locations outside of the facility to monitor radiation levels on an ongoing basis. The dosimeters are placed to generally cover the points of a compass and preferentially to the east of the facility, which is the direction of the prevailing winds.

Year over year data for the monitoring points will be compared with environmental effluent, or other operational data to see if a correlation can be determined.

Environmental monitoring data is expected to vary independently of operations at Nordion.

**3.9.1.4 Environmental Contamination**

BWXT ITG will adopt Nordion's program for monitoring environmental contamination. Soil samples will be regularly taken and analyzed from various locations on the Nordion property to test for the presence of radioisotopes and to detect potential soil contamination. Soil sampling is conducted at least every two years.

Groundwater will be monitored at least once a year for non-radioactive contaminants. This monitoring will be done to ensure there are no significant changes in results since the Limited Phase I and Phase II Environmental Site Assessment which was conducted by an environmental engineering company for Nordion in August 2005. Monitoring is also done for potential radiological contaminants.

At least once every two years, sanitary sampling will be conducted to analyze for non-radiological contaminants. Results of the analysis will be compared against municipal by-law limits.

**3.9.1.5 Hazardous Chemical Storage and Handling**

BWXT ITG will adopt Nordion's process for hazardous chemical storage and handling. Non-radioactive hazardous chemicals used for processing, analytical testing, decontamination, and cleaning purposes are typically used in small quantities and will be handled and disposed of in accordance with company operating procedures and relevant legislation. Any hazardous chemicals that come in contact with radioactive products will be segregated for approved disposal, rather than being disposed of as hazardous chemical waste.

### Supplementary Report to Support Class 1B Licence Application

#### 3.9.1.6 Waste Disposal Program

BWXT ITG will adopt Nordion's radioactive waste management program, which complies with applicable laws, regulations and licence conditions. Waste diversion programs have been designed and implemented to divert waste below CNSC accepted clearance levels for release through conventional waste methods. Refer to Section 3.11.

#### 3.9.2 Past Performance - Nordion

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion. The internal performance indicators for the environmental protection SCA used by Nordion are:

- Effluent and emission releases against EHS targets, internal levels, and regulatory limits
- The results of environmental dosimetry
- The results of environmental monitoring and assessments
- The number and nature of environmental incidents

##### 3.9.2.1 Airborne Effluent - Nordion

A summary of airborne effluent releases is provided in Tables 10 and 11. All airborne effluent releases have been below the Nordion Action Level of 50% and well below regulatory limits. Year-over-year, Nordion has met the established EHS targets for airborne releases. The airborne emissions were less than 2.0% of the DRL. The airborne effluent releases for each year are shown in Table 10 and the emissions expressed as a percentage of the DRL in Table 11.

**Table 10**  
**Airborne Effluent Releases 2005-2017**

Year	C-14* (GBq/ yr)	Co-60 (GBq/y r)	I-125 (GBq /yr)	I-131 (GBq/yr)	Xe-133 (GBq/yr )	Xe-135* (GBq/yr )	Xe- 135m* (GBq/yr )	Total %DRL
2005	*	0.0057	0.99	1.20	129981	*	*	0.67%
2006	*	0.0052	0.76	1.29	102083	*	*	0.57%
2007	960.9	0.0048	1.09	2.41	43559	41038	57240	0.49%
2008	635.4	0.0050	0.26	1.98	67193	48677	60845	0.37%
2009	37.8	0.006	0.47	1.05	26,407	14,439	20,444	0.24%
2010	43.1	0.006	0.37	0.99	9,066	6,407	9,366	0.17%
2011	67.9	0.006	0.38	0.29	34,967	17,239	27,688	0.20%
2012	15.7	0.006	0.46	0.40	36,153	23,943	39,498	0.22%
2013	N/A**	0.005	0.23	0.39	30,735	28,193	43,383	0.18%
2014	N/A**	0.005	0.14	0.46	15,018	13,075	18,170	0.96%
2015	N/A**	0.005	0.12	0.15	11,916	8,237	10,758	0.07%
2016	N/A**	0.006	0.21	0.35	7,277	4,299	5,421	0.12%
2017	N/A**	0.0034	0.001 2	0.0008	0	0	0	0.005%
Nordion Action Level	n/a	50%	50%	50%	50%	n/a	n/a	50%
Regulatory Limit	n/a	100%	100 %	100%	100%	n/a	n/a	100%



## Supplementary Report to Support Class 1B Licence Application

**Table 12**  
**Liquid Effluent Releases (GBq/yr) 2005-2017**

Year	Litres	$\beta < 1\text{MeV}$	$\beta > 1\text{MeV}$	I-125	I-131	Mo-99	Co-60	Nb-95	Zr-95	Cs-137
2005	919,940	0.289	0.067	0.007	0.019	0.110	0.023	0.0004	0.0004	0.0002
2006	1,264,516	0.497	0.126	0.010	0.035	0.170	0.034	0.0004	0.0007	0.0002
2007	986,058	0.373	0.083	0.008	0.015	0.122	0.028	0.0006	0.0005	0.0002
2008	1,087,471	0.481	0.086	0.007	0.014	0.127	0.029	0.0005	0.0005	0.0005
2009	1,130,670	0.424	0.096	0.008	0.016	0.144	0.034	0.0006	0.0004	0.0007
2010	1,510,764	0.569	0.129	0.011	0.021	0.180	0.044	0.001	0.001	0.001
2011	1,024,391	0.395	0.088	0.007	0.013	0.116	0.027	0.001	0.001	0.0004
2012	720,821	0.261	0.060	0.005	0.009	0.075	0.017	0.0002	0.0003	0.0004
2013	782848	0.288	0.065	0.005	0.009	0.077	0.022	0.0006	0.0006	0.0005
2014	600162	0.209	0.05	0.051	0.006	0.055	0.018	0.0007	0.0005	0.0004
2015	590570	0.191	0.044	0.111	0.006	0.06	0.019	0.001	0.001	0.0004
2016	680559	0.222	0.051	0.144	0.006	0.052	0.026	0.001	0.0015	0.0007
2017	661376	0.212	0.048	0.145	0.006	0.049	0.022	0.001	0.002	0.0007

The following table provides a summary of the liquid effluent releases expressed as a total percentage of the Derived Release Limit (DRL) per year from 2005 to 2017. All liquid effluent releases have been below the Nordion Action Level of 50% and well below regulatory limits. Year-over-year, Nordion has met the established EHS targets for liquid releases. The liquid effluent releases were less than 0.007% of the DRL.

## Supplementary Report to Support Class 1B Licence Application

**Table 13**  
**Liquid Releases (% DRL/year), 2005 – 2017**

DRL (GBq/yr)	$\beta < 1\text{MeV}^*$	$\beta > 1\text{MeV}^*$	I-125	I-131	Mo-99	Co-60	Nb-95*	Zr-95*	Cs-137*	Total %DRL
2005	3.7E-03	6.4E-05	4.9E-05	1.7E-04	2.4E-05	3.5E-05	5.5E-07	5.9E-07	3.57E-07	4.04e-3
2006	6.4E-03	1.2E-04	7.0E-05	3.0E-04	3.6E-05	5.0E-05	6.0E-07	1.0E-06	4.0E-07	6.98e-3
2007	4.8E-03	7.9E-04	5.2E-05	1.4E-04	2.6E-05	4.4E-05	8.8E-07	8.5E-07	3.9E-07	5.85e-3
2008	6.19E-03	8.18E-05	4.81E-05	1.32E-04	2.73E-05	4.50E-05	8.13E-07	7.25E-07	7.39E-07	6.53e-3
2009	5.45E-03	9.18E-05	5.49E-05	1.50E-04	3.08E-05	5.29E-05	8.97E-07	6.14E-07	1.07E-06	5.83e-3
2010	7.32E-03	1.23E-04	7.15E-05	1.91E-04	3.86E-05	6.81E-05	2.19E-06	1.41E-06	1.82E-06	7.82e-3
2011	5.07E-03	8.36E-05	4.79E-05	1.23E-04	2.49E-05	4.26E-05	1.73E-06	1.07E-06	6.81E-07	5.40e-3
2012	3.35E-03	5.76E-05	3.59E-05	7.92E-05	1.62E-05	2.63E-05	3.58E-07	4.97E-07	6.63E-07	3.57e-3
2013	3.70E-03	6.18E-05	3.45E-05	8.19E-05	1.64E-05	3.49E-05	9.12E-07	9.36E-07	7.74E-07	3.93e-3
2014	2.69E-03	4.76E-05	3.47E-04	5.56E-05	1.18E-05	2.81E-05	1.09E-06	7.80E-07	6.24E-07	3.18e-3
2015	2.46E-03	4.19E-05	7.55E-04	5.56E-05	1.28E-05	2.96E-05	1.56E-06	1.56E-06	6.24E-07	3.35e-3
2016	2.78E-02	1.38E-04	1.22E-02	1.53E-03	4.79E-04	6.31E-02	4.37E-05	9.13E-05	2.72E-03	5.11e-7
2017	3.21E-04	2.29E-05	1.97E-04	2.56E-05	4.36E-06	1.44E-05	2.54E-07	2.51E-07	4.92E-07	5.86e-4
Nordion Action Level	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Reg. Limit	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

\* The DRL for Sr-90 is used for  $\beta < 1\text{MeV}$  and the DRL for Y-90 is used for  $\beta > 1\text{MeV}$ . Nb-95, Zr-95 and Cs-137 are contaminants which are expected to be present in small quantities or non-detectable. Although Nordion does not formally monitor for these contaminants, their presence was detected by the analysis method used to check the liquid effluent samples for the major isotopes. DRLs are required for only the major isotopes. The majority of the recorded releases are the minimum detectable activities being conservatively reported as real values instead of using zero. As a result, this number is proportional to volumes released.

Liquid effluent releases measured at the Medical Isotopes delay tanks (before release) closely follow the number of litres dumped to the sanitary sewer. This is due to Nordion's conservative practice of using the limit of detection value instead of a "zero" when the measurement assay detects nothing. Increased volumes of water were released via the KRMF facility in 2010 due to a leak of fresh water from an autoclave in the Component Preparation Area of the KRMF. Water effluent in the KRMF is associated with non-active component preparation to meet pharmaceutical requirements. No radioactivity was detected in KRMF liquid effluent in 2010. Nordion's practice of assuming releases equivalent to the Minimum Detectable Activity (MDA) has resulted in larger reported releases although it is possible that no radioactivity was released from the KRMF delay tanks in 2010. Nordion employs a conservative practice of assuming the minimum detectable activity is always released.

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**Supplementary Report to Support Class 1B Licence Application**

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**3.9.2.3 Environmental Dosimetry - Nordion**

There have been no significant changes in the recorded doses for the environmental TLDs from year-to-year. Soil samples at the locations representative of critical receptors for air effluent from the facility have not shown any radionuclides attributable to Nordion's licensed activities. Variation in the recorded doses between locations has been observed; however, this has been attributed to variations in natural background radiation.

**3.9.2.4 Environmental Contamination - Nordion**

Soil sampling was performed in 2006, 2008, 2010, 2012, 2014, 2016 and 2017. In 2006, small quantities of I-131 were detected in some locations. As a result, 11 additional locations at the perimeter of the facility were sampled. No artificial radionuclides were detected in soil samples at the perimeter of the facility. In 2010, Co-60 was detected in samples; however, the levels found were much less than the exemption levels outlined in IAEA RS-G-1.7, "Application of the Concepts of Exclusion, Exemption and Clearance". For 2008, 2012, 2014, 2016 and 2017 no radionuclides attributable to licensed activities were detected in the soil samples.

Each year, groundwater samples were taken from four wells and analyzed for non-radiological contaminants. The results of these assessments have demonstrated that there have been no significant changes in the groundwater since the Limited Phase I and Phase II Environmental Site Assessment which was conducted by an environmental engineering company in August 2005.

In 2013, five groundwater wells surrounding the operations building were sampled for radiological contaminants. The results of this sampling determined that only naturally occurring radionuclides which are not processed at this site were detected.

The results of the sanitary sampling demonstrated compliance with City of Ottawa Sewer Use By-law limits with the exception of the following instances:

- In 2006 and 2008, the samples were found to have Total Suspended Solids (TSS) above by-law limits. For 2006, it was determined that the high levels were due to the samples being taken during the annual cleaning of the cooling tower. For 2008, it was determined that the high levels were due to facility vehicles cleaning activities.
- In 2011, the sample was found to have total phosphorous above the by-law limit. It was determined that this was the result of vial washing validation activities. Phosphorous based detergent concentrated in the KRMF delay tank was released at the time the sample was taken.

Each instance and the cause were reported to the City of Ottawa.

In 2010, an Emissions Summary and Dispersion Modeling report was completed to assess non-radiological air emissions from the site. This was again updated in 2013 as required by Nordion's Certificate of Approval (Air) from the Ontario Ministry of the Environment. Nordion remained in compliance with the Certificate of Approval requirements at all times.

**3.9.2.5 Non-radiological Environmental Incidents**

The non-radiological environmental incidents for 2005-2017 are shown in Table 14.

**Table 14**  
**Non-radiological Environmental Incidents 2005 - 2017**

Year	No. of Environmental Incidents
2005	1
2006	0
2007	0
2008	2
2009	0
2010	2
2011	2
2012	2
2013	2
2014	0
2015	1
2016	3
2017	2

There were seventeen environmental incidents within this timeframe. A number of these incidents were related to the use of halocarbons in facility HVAC units, fire suppression systems and City of Ottawa Sewer Use By-law exceedances; however, there were no trends identified in these incidents. Environmental incidents were reported to the appropriate regulatory authorities as applicable and corrective actions were taken to address the causes of the incidents.

#### 3.9.3 Improvements to the Environmental Protection Program

BWXT ITG is committed to continuous improvement to the Environmental Protection Program. No specific improvements have been identified.

#### 3.9.4 Future Plans

BWXT ITG will continue to assess potential environmental releases as production increases and new radioisotopes are processed. As Nordion stopped production of fission Mo-99 where the Xe-135m impurity was the most significant contributor to the DRL, measures to mitigate Xe air release are no longer required. Should BWXT ITG begin processing radioisotopes of or those that contain Xe, measures to mitigate Xe release will again be considered.

#### 3.9.5 Challenges

BWXT ITG does not anticipate any challenges related to the management of environmental releases.

### 3.10 Emergency Management and Fire Protection

The Emergency Management and Fire Protection SCA covers emergency plans and emergency preparedness programs that exist for emergencies and for non-routine conditions. This area also includes any results of participation in exercises.

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**Supplementary Report to Support Class 1B Licence Application**

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**3.10.1 Relevance and Management****3.10.1.1 Emergency Preparedness Program**

BWXT ITG will retain ultimate responsibility for emergency preparedness for the NMPF. Under the lease agreement, there will be a joint emergency response plan established between Nordion and BWXT ITG.

Currently, BWXT ITG employees have been trained on the Nordion emergency response program and make up many of the response team. At this time, only a Nordion employee can fulfil the role of Incident Manager.

Emergency response planning is required to reduce or mitigate operational impacts and potential environmental, health and safety impacts that may occur in the event of an emergency. There is an extensive emergency preparedness program to respond to various types of emergency situations, including on-site and off-site emergencies. There are a number of Emergency Response Plans (ERPs) to address various emergency situations. These plans outline response actions to be taken to minimize potential environmental, health and safety impacts. Depending on the nature and scale of an emergency, the appropriate ERP is activated. The ERPs will be routinely reviewed, updated, and tested in the form of drills, desk top training exercises and full-scale evacuation exercises. A schedule to test each of these plans will be established with a target of testing each plan within a five year period.

An Emergency Response Planning Committee will be established and meet on a regular basis to discuss and assess the Company's emergency planning needs, to plan emergency response exercises and drills to test existing Emergency Response Plans and as necessary, to review the emergency response plans for suitability and effectiveness. In addition, emergency response procedures will be regularly reviewed and revised, as necessary, in particular immediately following the occurrence of an incident, accident or emergency situation.

Testing of the Emergency Response Contact List will be performed annually to ensure accuracy of off-hour contact information listed, to determine availability of personnel, and to estimate response times.

BWXT ITG will work in partnership with Nordion and the local Fire and Police Departments to ensure safe and appropriate response to potential emergency situations. BWXT ITG will ensure there are regular orientation sessions to the local Fire and Police Departments to familiarize them with the facility and to discuss how to work together in an emergency situation. BWXT ITG will ensure local emergency response organizations are invited to participate in emergency response drills at the site to test how these types of emergencies would be managed. Where possible, emergency response drills will be attended by the local Fire Department, HAZMAT and Paramedics who will participate as exercise players, allowing them and BWXT ITG to improve interoperability of response.

Meetings with hospitals will be conducted to strengthen BWXT ITG's relationship with the local hospitals and to optimize rapid, safe care of casualties.

The emergency response plans outline steps to be taken to notify surrounding community and businesses in the event of an emergency which could impact the local community. Checks of emergency response equipment will generally be managed through the AMMS and/or by Radiation Surveyors. A schedule of drills and exercises will be maintained to ensure testing and exercises are conducted regularly.

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**Supplementary Report to Support Class 1B Licence Application**

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**3.10.1.2 Fire Protection Program**

BWXT ITG will retain ultimate responsibility for fire protection for the NMPF. Under the lease, Nordion will be responsible for providing fire protection systems in the NMPF.

BWXT ITG will adopt Nordion's Fire Protection Program which has been established to minimize the probability and consequences of a fire. The objective of this program is to promote life safety, the conservation of property and essential equipment, the protection of the environment, and the continuity of operations through provisions of fire prevention and fire protection measures.

This program outlines the commitment to:

- Maintain a Fire Hazard Analysis
- Ensure the design, analysis, and operation of Nordion facilities are planned and controlled
- Manage changes that could impact fire protection to minimize potential impacts
- Ensure Nordion operates, maintains, tests, and inspects the facility in accordance with applicable codes and requirements
- Ensure impairments to fire protection systems are managed in a manner to minimize the duration of equipment outages and that they are pre-planned wherever feasible
- Ensure impaired equipment is identified, tagged, and tracked and appropriate personnel are notified
- Ensure areas are kept clear of debris and the movement and storage of flammable and combustible materials is controlled
- Establish and regularly test Fire Safety Plans

**3.10.2 Past Performance – Nordion**

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion, using a work force for BWXT ITG comprised largely of Nordion personnel hired at the time of the acquisition and adopting the Nordion Management System for Safety.

The internal performance indicator for the emergency management and fire protection SCA are the results of ERP exercises and, as applicable, of actual unplanned events that require activation of emergency procedures. The significance of findings identified from these drills and any actual events helps Nordion to assess program performance. Another performance indicator is whether commitments to scheduled activities, such as planned exercises, have been met.

Nordion has conducted a number of emergency response exercises, including, but not limited to:

- Desktop and full-scale emergency response exercises to test elements of the plan and to provide ongoing training to participants
- In class training to all Emergency Response (ER) Personnel which is required training every two years
- A test of Nordion's Communicable Disease and Bio-Terrorism Emergency Response Plan
- A test of Nordion's Emergency Response Procedure for Industrial Irradiation Equipment
- Regular tests of the Fire Safety Plan
- Regular tests of the Emergency Response Contact List
- A test of Nordion's Chemical Spill Plan
- A test of Nordion's Transportation Emergency Response Assistance Plan

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**Supplementary Report to Support Class 1B Licence Application**

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From 2005 to 2018 Nordion worked closely with external agencies hosting tours and meetings. This included, but was not limited to meetings and tours with:

- Ottawa Carleton Regional Police
- Kanata Fire Department
- Ottawa Police Duty Inspectors
- City of Ottawa Emergency and Protective Services
- City of Ottawa Fire Services
- Hospital Emergency Planning Committee of Ottawa (HEPCO)
- The Ottawa Hospital and the Queensway Carleton Hospital

A test of the emergency response contact list is conducted annually to ensure Nordion has sufficient resources available in the event of an emergency at the site on off-hours. These tests demonstrated that within one hour of the onset of an emergency, adequate emergency response personnel and at least one representative from each of the key emergency response groups would be available on-site.

Full scale Emergency Response Exercises were conducted in 2006, 2011 and 2016 with the involvement of external agencies (Ottawa Fire Services, HAZMAT and Paramedics) and typically under the observation of the CNSC. The objectives of the exercises were to test multiple elements of Nordion's emergency response plans, including:

- Building evacuation
- Activation of the Site Emergency Response Plan
- Set-up of the Emergency Operations Centre (EOC)
- First-aid response
- Contamination identification and control
- Radiation emergency response procedures
- Media and community relations
- Building and site security

Actions arising from these exercises were addressed and tracked. These drills were successful tests of the multiple elements of Nordion's emergency response plans. Smaller scale exercises were conducted in 2017 and 2018.

Familiarization tours of the site have been conducted for city first responders, including all platoons of the two potential responding fire stations, HAZMAT, Ottawa Police Duty Inspectors and key Paramedic service representatives. In 2013, Nordion also hosted a meeting and familiarization tour for the Hospital Emergency Planning Committee of Ottawa, which included representatives from Ottawa area hospitals.

An unplanned event in which the facility emergency response plan was tested took place during a 5.0 magnitude earthquake on June 23, 2010. All of the Nordion buildings were evacuated as a precaution. There were no injuries or damage as a result. This was a successful test of the Site Emergency Response Plan.

An unplanned event in August 2015 in which there was a roof fire also tested the emergency response plan. The roof fire occurred while repair work was being performed by a contracted roofing company and resulted in a full evacuation of the KOB building. The fire resulted in a number of corrective actions including; creation of a procedure for formal review of future roof work plans, improvements to the Work Permit Authorization procedure, implementation of annual Fire Watch Training for Nordion employees and measures to eliminate the potential for uncontrolled release of run-off water into the storm drain in the event of another fire.

Each year, overall compliance with the Emergency Management Program was proven satisfactory. There were no events (planned or actual) demonstrating non-compliance with the existing Emergency Management Program.

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**Supplementary Report to Support Class 1B Licence Application**

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The Fire Safety Plan is tested annually. This test involves evacuation of the three on-site buildings (KOB, RE Building and Heating Plant) by activation of the building fire alarm system.

Each year, overall compliance with the Fire Protection Program was proven satisfactory.

**3.10.3 Improvements to the Emergency Management and Fire Protection Programs**

BWXT ITG is committed to continuous improvement to the Emergency Management Program and the Fire Protection Program. No specific improvements have been identified.

**3.10.4 Future Plans**

BWXT ITG will participate with Nordion in the development of a joint emergency response plan for the Nordion site, inclusive of the BWXT ITG and Nordion Class 1B facilities.

**3.10.5 Challenges**

BWXT ITG does not anticipate any challenges with regard to emergency management and fire protection. Development of a comprehensive joint emergency response plan for the Nordion site, inclusive of the BWXT ITG and Nordion Class 1B facilities will require close cooperation of both parties to ensure CNSC requirements are met for both Class 1B licences.

**3.11 Waste Management**

The Waste Management SCA covers internal waste-related programs that form part of the facility's operations up to the point where the waste is removed from the facility to a separate waste management facility. This area also covers the planning for decommissioning.

**3.11.1 Relevance and Management**

BWXT ITG will adopt the Nordion comprehensive waste management programs for managing radioactive, hazardous and non-hazardous waste.

**3.11.1.1 Waste from the Active Area**

Waste from the Active Area is categorized into four main waste types: routine waste, liquid waste, non-routine waste, and divertible waste. Routine waste is waste generated from production processes that is routinely shipped to approved external radioactive waste management facilities. This waste has been characterized into repositories, or "Waste Blocks". Included in the routine waste is high-level liquid waste which is typically solidified. Low-level liquid waste is collected separately and routinely shipped to an approved radioactive liquid waste receptor. Radioactive waste that has not been characterized into a waste block or is not low-level liquid waste is considered non-routine radioactive waste. Non-routine radioactive waste is evaluated for conventional waste disposal or packaged for shipment to a licensed radioactive waste management facility. Waste generated within the Active Area that meets the CNSC unconditional clearance levels is diverted from the solid active waste stream being sent to licensed radioactive waste facilities and is disposed of by conventional waste disposal methods, such as landfill.

Waste from other radioisotope licensees will not be transferred to BWXT ITG for subsequent disposal.

**3.11.1.2 Waste Management**

BWXT ITG will manage its radioactive wastes in a manner that ensures conformance with the regulatory objectives, requirements, and guidelines of the CNSC, as well as the waste acceptance requirements of radioactive waste receivers.

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**Supplementary Report to Support Class 1B Licence Application**

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The production facilities have been designed and will be operated in a manner to prevent radioactive waste from being released to municipal garbage or sewer systems and to ensure that releases to the environment via air or water emissions are within limits approved by the CNSC. All radioactive waste that is generated through production operations will be collected and sent to an approved radioactive waste management facility.

There are designated space and processes to store and segregate radioactive waste that is generated in production operations. Primary long term decay storage areas are located in the KOB active shipping and receiving facility. Additional space for long term storage of divertible waste, if needed, exists in the KRMF facility. Space is also designated for storage of containers and management of waste being prepared for shipment to external waste management facilities.

**3.11.1.3 Waste Minimization**

To continuously improve performance and to meet the spirit of ISO 14001, BWXT ITG will regularly monitor waste and establishes objectives and targets for continuous improvement.

BWXT ITG will encourage and promote techniques that reduce waste, in all areas of operation. BWXT ITG will adopt the Active Area waste diversion program implemented by Nordion within the NMPF. The waste diversion program has successfully diverted waste from disposal at a licensed radioactive waste facility to regular landfill through segregation at source and the use of sensitive monitoring equipment for verification that the segregated waste is below the unconditional clearance levels prescribed in CNSC regulations.

Waste that does not meet the unconditional clearance levels may be stored for decay and subsequently re-monitored or sent to a separate licensed radioactive waste management facility. Hazardous and biological materials will be diverted to separate waste streams prior to segregation at source of the solid waste.

**3.11.1.4 Non-radioactive Chemical Waste**

BWXT ITG will adopt Nordion's process for non-radioactive chemical waste disposal. Non-radioactive chemical waste is consolidated in designated cabinets in the shipping areas. Non-radioactive chemicals are primarily used in the quality control labs for analyses and testing, in the Radiopharmaceutical wing for decontaminating and disinfecting laboratories, and as carrier solutions for radioactive product. Non-radioactive chemical waste is inventoried on log-sheets. Waste chemicals are then picked up by a licensed waste disposal company for treatment and/or disposal.

**3.11.1.5 Non-Hazardous Waste**

BWXT ITG will adopt the Nordion programs for managing non-hazardous waste in the Non-Active Areas of the facility to divert waste such as plastics, metals, paper, cardboard, and organics from landfill. Annually BWXT ITG will conduct a waste audit of non-hazardous waste to determine diversion program performance.

BWXT ITG will establish targets to reduce non-hazardous waste sent to landfill. Initiatives to meet these targets include reducing waste, raising awareness of existing recycling programs and looking for further opportunities to divert waste as feasible.

**3.11.1.6 Decommissioning Plan**

BWXT ITG's Decommissioning Plan is described in SE-LIC-021, "Preliminary Decommissioning Plan for BWXT's Class 1B Facility". BWXT ITG is responsible for the decommissioning of the NMPF.

## Supplementary Report to Support Class 1B Licence Application

### 3.11.2 Past Performance – Nordion

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion, using a work force for BWXT ITG comprised largely of Nordion personnel hired at the time of the acquisition and adopting the Nordion Management System for Safety.

The internal performance indicators for the waste management SCA used by Nordion are:

- Performance relative to EHS objectives and targets for waste minimization
- The amount of non-hazardous waste diverted from landfill
- The amount of waste diverted from licensed radioactive waste facilities

In recent years, Nordion has met the established EHS objectives and targets for waste minimization.

In the 2017 audit of Nordion's non-hazardous waste, it was concluded that out of a total of [REDACTED]

The amount of waste diverted from licensed radioactive waste facilities for 2014 to 2017 are shown in Table 15.

**Table 15**  
**Waste Diverted To Landfill In Kilograms (kg) 2014-2017**

	2014	2015	2016	2017
<b>Amount Diverted (kg)</b>	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Since 2005, the trends that are of note are the increase in diverted waste as the program grew from one production area (Cobalt established since 2002) to three production areas (Radiopharmaceutical Manufacturing in 2008 and Medical Isotope Operations in 2011); and the impact of the radiopharmaceutical business.

From 2005 to 2007, the diverted waste was below [REDACTED]. When the program expanded in 2008 to include the Kanata Radiopharmaceutical Manufacturing Facility (KRMF) Active Area, the diverted waste averaged [REDACTED] with a peak of over [REDACTED] in 2010. The KRMF involves special gowning in Active Areas so the amount of divertible waste from this area contributes largely to this. During this period there were three main products in KRMF. A fourth product was added in KRMF from 2009 to 2011. When the diversion program expanded again to include the Medical isotope Operations in 2011, the KRMF had reduced to two products, so the average diverted waste stayed at approximately [REDACTED] into 2012 and the percent diverted remained relatively strong.

In 2013, diverted waste reduced slightly, to just over [REDACTED] as there was less processing in KRMF, and both Cobalt and the Medical Isotopes Operations areas diverted relatively less than previous years.

In October 2016, [REDACTED]. Leading up to this was a decrease in the amount of radioactive waste produced.

### 3.11.3 Improvements to the Waste Management Program

BWXT ITG is committed to continuous improvement to the Waste Management Program. No specific improvements have been identified.

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**Supplementary Report to Support Class 1B Licence Application**

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**3.11.4 Future Plans**

BWXT ITG will work with partners who provide radioactive waste management services and facilities to manage waste shipments as safely and efficiently as possible.

BWXT ITG is developing a new process for Molybdenum-99. The way waste has been handled in the NMPF in the past under Nordion will not change. There will be no intentional releases from the process to the sanitary sewer system. Radioactive and hazardous waste associated with the new process will meet the acceptance guidelines of our waste providers. Radioactive waste will be disposed of to licensed waste facilities.

**3.11.5 Challenges**

The limitations as to what the waste service providers will and will not accept will limit BWXT ITG's potential waste diversion activities. BWXT ITG will work with the waste service providers to achieve waste diversion objectives.

**3.12 Security**

The security SCA covers the programs required to implement and support the security requirements stipulated in the regulations, the licence, orders, or expectations for the facility or activity.

BWXT ITG will retain ultimate responsibility for security for the NMPF. Under the lease, Nordion will provide site security.

Information regarding the Security safety and control area is considered confidential-prescribed information and will be provided under separate cover upon request.

**3.13 Safeguards and Non-Proliferation**

The safeguards and non-proliferation SCA covers the programs and activities required for the successful implementation of the obligations arising from the Canada/International Atomic Energy Agency (IAEA) safeguards agreements, as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.

**3.13.1 Relevance and Management**

BWXT ITG will adopt Nordion's program for the management of safeguarded material at the Nordion Ottawa site, SE-LIC-016, "Management of Safeguarded Material".

**3.13.2 Past Performance – Nordion**

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion, using a work force for BWXT ITG comprised largely of Nordion personnel hired at the time of the acquisition and adopting the Nordion Management System for Safety.

The internal performance indicators for the safeguards and non-proliferation SCA are:

- The results of PITs
- The number of times reporting was not completed in accordance with RD-336

Each year there were no significant findings or observations from the PITs with the exception of 2010 in which there were two findings. These two findings documented the results of an initiative to identify historical material that needed to be removed or added to the accounting records.

Nordion has performed accounting and reporting of nuclear material as required by RD-336. Nordion volunteered to participate in the testing of the new Nuclear Materials Accountancy Reporting (NMAR) e-business system. Nordion has been submitting reports electronically since the official launch of the new NMAR e-business system in November 2013.

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**Supplementary Report to Support Class 1B Licence Application**

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Each year conducted, the PIT-Es were successful. All material was accounted for and the required documentation was in order with the exception of 2010 in which a number of forms required revision and re-submission. There were no follow-up items or comments received from the IAEA as a result of the Complimentary Access Inspection in November of 2006. There was one minor comment received from the CNSC that was subsequently addressed.

**3.13.3 Improvements to the Safeguards Program**

BWXT ITG is committed to continuous improvement to the Safeguards Program. No specific improvements have been identified.

**3.13.4 Future Plans**

BWXT ITG will implement a safeguards program to meet CNSC requirements. Timing will be as directed by the Safeguards Division of the CNSC as it will first require establishment of BWXT ITG as a separate Material Balance Area (MBA).

**3.13.5 Challenges**

BWXT ITG does not anticipate any challenges with regard to implementation of the program for management of safeguarded material.

**3.14 Packaging and Transport**

The Packaging and Transport SCA covers programs for the safe packaging and transport of nuclear substances to and from the licensed facility.

**3.14.1 Relevance and Management**

BWXT ITG will routinely ship unsealed sources of nuclear substances in Type B, Type A and Excepted packages. BWXT ITG will also routinely ship radioactive waste materials (unsealed) in these same package types. Shipments of BWXT ITG's products are made via road and air. Shipments of waste are routinely made via road transport.

BWXT ITG will adopt the Nordion program SE-OP-036, "Transportation of Radioactive Materials Program". This procedure provides a high level overview of Nordion's transportation of radioactive materials program. The program applies to employees involved in design, production, use, inspection, maintenance and repair of packages, and the preparation, consigning, handling, loading, carriage, storage during transport, receipt at final destination, and unloading of packages. It applies to various types of packages including Type A, Type B, and Excepted packages. The content of the program was modeled on regulatory requirements listed in the CNSC *Packaging and Transportation of Nuclear Substances Regulations*, Transport Canada *Transportation of Dangerous Goods Regulations*, IAEA *TS-R-1 Regulations for the Safe Transport of Radioactive Material* (1996 Revised Edition), US DOT 49 CFR, and US NRC 10 CFR part 71.

The Packaging and Transportation Program outlines the various processes that are used to monitor and maintain the health of this program.

Some of the elements discussed include:

- Design
- Testing/Assessment/Documentation
- Regulatory Approvals
- Manufacturing/Procurement
- Inspection/Maintenance
- Loading/Packaging
- Shipment
- Customer Use of Packages
- Return Shipment
- Decommissioning of Transport Packages
- Security
- Safety

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**Supplementary Report to Support Class 1B Licence Application**


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- Package Quality
- Regulatory Oversight

BWXT ITG will also have a Transport Package Quality Plan to describe how the quality assurance requirements for the design, fabrication, assembly, testing, maintenance, repair, modification, and use of BWXT ITG Radioactive Material (RAM) transport packages are achieved. It identifies the activities, responsibilities, and actions necessary to ensure that all regulatory, customer, and internal QA program requirements are met. This plan will be based on the Nordion version.

This plan is applicable to all Radioactive Material Type A and Type B Transport Packages. RAM transport packaging falls within the scope of Nordion's Quality Management System (QMS). The policies, responsibilities, and procedures comprising the QMS are described in the Quality Manual (QSF-00). This Quality Plan supplements the Quality Manual where requirements are specific to transport packages.

Compliance with the program document, the quality plan, and any referenced procedures is tracked through BWXT ITG's Quality Systems (Deviations, Non-Conforming Materials Reports and Customer Complaints). As required, events will be investigated and corrective actions assigned.

#### 3.14.2 Past Performance - Nordion

Nordion past performance is presented as we believe it is indicative of the performance expected for the operation of the NMPF by BWXT ITG which will remain within the licensing basis established for Nordion, using a work force for BWXT ITG comprised largely of Nordion personnel hired at the time of the acquisition and adopting the Nordion Management System for Safety.

The internal performance indicators for the packaging and transport SCA are:

- The results from internal audits
- The number and nature of reportable events related to CNSC, Transport Canada, and International Regulations

There have been no significant findings or observations from internal audits of Nordion's Packaging and Transport Program.

A summary of the number of non-compliances related to packaging and transport of nuclear substances is shown in Table 16.

**Table 16  
Number of Reportable Events Related to  
Packaging and Transport of Nuclear Substances**

Year	No. Reportable Events Related to CNSC Regulations	No. of Reportable Events Related to Transport Canada and International Regulations
2005	1	0
2006	1	0
2007	9	0
2008	12	0
2009	14	0
2010	13	0
2011	18	0

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**Supplementary Report to Support Class 1B Licence Application**


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Year	No. Reportable Events Related to CNSC Regulations	No. of Reportable Events Related to Transport Canada and International Regulations
2012	18	0
2013	18	1
2014	11	0
2015	16	0
2016	7	0
2017	9	0

The one non-compliance with the TDG regulations in 2013 was a situation where a Nordion driver misplaced a shipping document and returned to Nordion to pick up another copy. TDG regulations require that a transport document accompany all dangerous goods transports.

Of the 104 reported events, 29% were the result of carrier actions and 21% were the result of other parties (i.e. consignors, consignees). Many of the reportable events were the result of low risk regulatory non-conformances. Since 2010, 77% of the events were assessed as having a low risk rating. Examples of low risk non-conformances include incorrect shipping documents, errors in labelling, and incorrect activity listed on labels or documents. In addition, the number of reportable events represented approximately 0.2% of the total shipments each year from 2010 to 2013.

There are two increases in the number of reportable events, one between 2006 and 2007 and another between 2010 and 2011. The first change is attributed to an increased number of incidents involving radiography devices and sealed sources. Nordion has since divested that line of business. The increase in 2011 is attributed to clarification by the CNSC that as per Nordion's site licence, NSPFOL-11A.05/2015, Nordion must report all non-compliances with CNSC regulations, not just dangerous occurrences under Section 16.1 of the *Packaging and Transportation of Nuclear Substances Regulations*.

#### 3.14.3 Improvements to Packaging and Transport

BWXT ITG is committed to continuous improvement to the Packaging and Transport of Radioactive Materials Program. No specific improvements have been identified.

#### 3.14.4 Future Plans

BWXT ITG plans to prepare and submit for CNSC approval its own Transport Package Quality Plan. BWXT ITG is already a registered user of the transport packages required for shipments associated with the medical isotopes business.

#### 3.14.5 Challenges

BWXT ITG does not anticipate any challenges related to packaging and transport of radioactive material associated with the NMPF.

## GLOSSARY

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ALARA	As Low As Reasonably Achievable
AMMS	Advanced Maintenance Monitoring System
ASCE/SEI	American Society of Civil Engineers/Structural Engineering Institute
CAPA	Corrective Action Preventative Action
CF	Change Form
CNSC	Canadian Nuclear Safety Commission
COF	Cobalt Operations Facility
CSA	Canadian Standards Association
CTBTO	Comprehensive Test Ban Treaty Organization
DOT	Department of Transport
DRL	Derived Release Limit
EHS	Environment, Health and Safety
EMS	Environmental Management System
EOC	Emergency On Call
EQMS	Electronic Quality Management System
ER	Emergency Response
ERP	Emergency Response Plans
FSAR	Final Safety Analysis Report
HAZMAT	Hazardous Materials
HEGS	High Energy Gamma Source
HEPA	High Efficiency Particulate Air
HEPCO	Hospital Emergency Planning Committee of Ottawa
HRSDC	Human Resource Skills Development Centre
HVAC	Heating, Ventilation and Air Conditioning
IAEA	International Atomic Energy Agency
IMS	Incident Management System
ISO	International Organization for Standardization
JTA	Job Task Analysis
KRMF	Kanata Radiopharmaceutical Manufacturing Facility
KOB	Kanata Operations Building
LLLW	Low Level Liquid Waste
MCA	Multi Channel Analyzer
MDA	Minimum Detectable Activity
NEW	Nuclear Energy Worker
NFPA	National Fire Protection Association
NMAR	Nuclear Material Accountancy Reporting
NMPF	Nuclear Medicine Production Facility
NVS	Nuclear Ventilation System
OHSAS	Occupational Health and Safety Management Systems
OPEX	Operating Experience
OSLD	Optically Stimulated Luminescent Dosimeter
PIT	Physical Inventory Taking
PIT-E	Physical Inventory Taking – Evaluation
PVC	Polyvinyl Chloride
QA	Quality Assurance
QMS	Quality Management System
RAM	Radioactive Material
RE	Roy Errington
RP	Radiation Protection
SAT	Systematic Approach to Training
SOP	Standard Operating Procedures

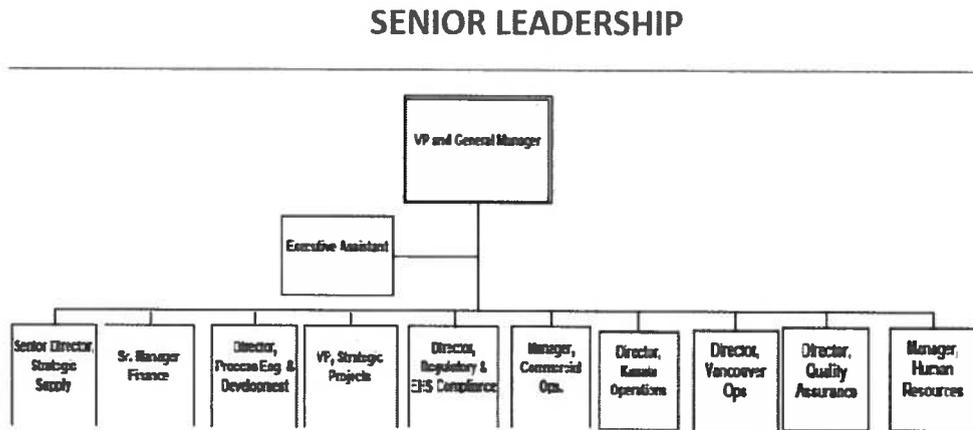
**Supplementary Report to Support Class 1B Licence Application**

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TDG	Transportation of Dangerous Goods
TLD	Thermo-luminescent Dosimeter
TSS	Total Suspended Solids
UPS	Uninterruptible Power Supply
WSIB	Workplace Safety Insurance Board

## APPENDIX A: ORGANIZATIONAL CHART

Figure A.1: BWXT ITG Canada, Inc.  
Senior Management Organizational Chart



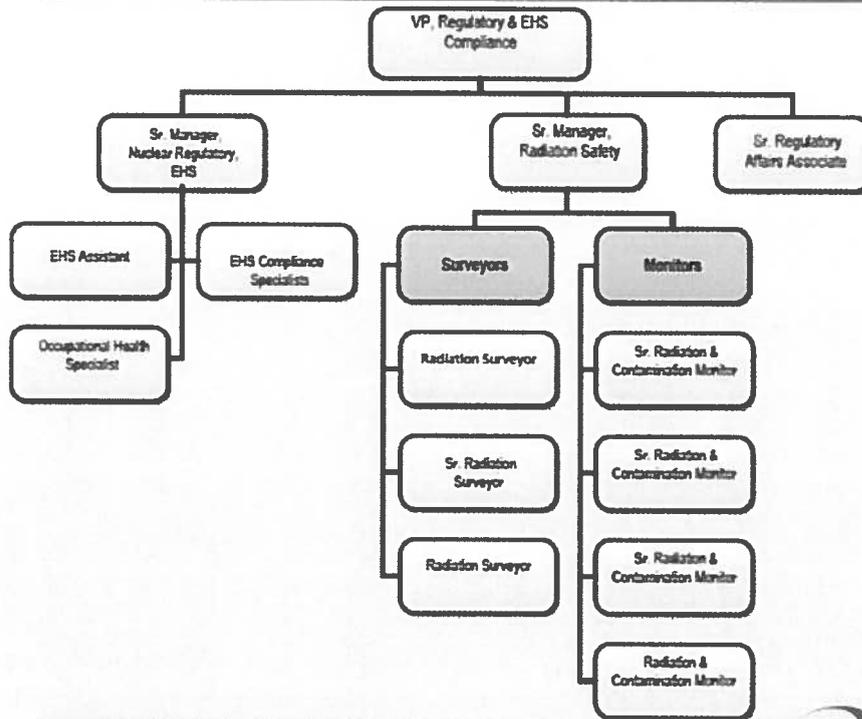
December 2018

BWXT 2000 St. Lawrence  
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Figure A.2: BWXT ITG Canada, Inc.  
Regulatory, EH&S and Compliance Organizational Chart

## Regulatory, EH&S and Compliance



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Request ID: 020769105  
Demande n°:  
Transaction ID: 065795392  
Transaction n°:  
Category ID: CT  
Catégorie:

Province of Ontario  
Province de l'Ontario  
Ministry of Government Services  
Ministère des Services gouvernementaux

Date Report Produced: 2017/09/29  
Document produit le:  
Time Report Produced: 13:58:01  
Imprimé à:

# Certificate of Incorporation Certificat de constitution

This is to certify that

Ceci certifie que

**BWXT ITG CANADA, INC.**

Ontario Corporation No.

Numéro matricule de la personne morale en  
Ontario

**002599290**

is a corporation incorporated,  
under the laws of the Province of Ontario.

est une société constituée aux termes  
des lois de la province de l'Ontario.

These articles of incorporation  
are effective on

Les présents statuts constitutifs  
entrent en vigueur le

**SEPTEMBER 29 SEPTEMBRE, 2017**



Director/Directeur  
Business Corporations Act/Loi sur les sociétés par actions

Request ID / Demande n°

20769105

Ontario Corporation Number  
Numéro de la compagnie en Ontario

2599290

FORM 1

BUSINESS CORPORATIONS ACT

FORMULE NUMÉRO 1

LOI SUR LES SOCIÉTÉS PAR ACTIONS

ARTICLES OF INCORPORATION  
STATUTS CONSTITUTIFS

1. The name of the corporation is: *Dénomination sociale de la compagnie:*  
BWXT ITG CANADA, INC.

2. The address of the registered office is: *Adresse du siège social:*

581 CORONATION BOULEVARD

(Street & Number, or R.R. Number & if Multi-Office Building give Room No.)  
(Rue et numéro, ou numéro de la R.R. et, s'il s'agit d'édifice à bureau, numéro du bureau)

CAMBRIDGE  
CANADA

(Name of Municipality or Post Office)  
(Nom de la municipalité ou du bureau de poste)

ONTARIO  
N1R 5V3

(Postal Code/Code postal)

3. Number (or minimum and maximum number) of directors is: *Nombre (ou nombres minimal et maximal) d'administrateurs:*  
Minimum 1 Maximum 10

4. The first director(s) is/are:

*Premier(s) administrateur(s):*

First name, initials and surname  
*Prénom, initiales et nom de famille*

Resident Canadian State Yes or No  
*Résident Canadien Oui/Non*

Address for service, giving Street & No.  
or R.R. No., Municipality and Postal Code

*Domicile élu, y compris la rue et le numéro, le numéro de la R.R., ou le nom de la municipalité et le code postal*

\* JOHN  
MACQUARRIE

YES

581 CORONATION BOULEVARD

CAMBRIDGE ONTARIO  
CANADA N1R 5V3

Request ID / Demande n°

20769105

Ontario Corporation Number  
Numéro de la compagnie en Ontario

2599290

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5. Restrictions, if any, on business the corporation may carry on or on powers the corporation may exercise.  
*Limites, s'il y a lieu, imposées aux activités commerciales ou aux pouvoirs de la compagnie.*

None.

6. The classes and any maximum number of shares that the corporation is authorized to issue:  
*Catégories et nombre maximal, s'il y a lieu, d'actions que la compagnie est autorisée à émettre:*

An unlimited number of common shares.

Request ID / Demande n°

20769105

Ontario Corporation Number  
Numéro de la compagnie en Ontario

2599290

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7. Rights, privileges, restrictions and conditions (if any) attaching to each class of shares and directors authority with respect to any class of shares which may be issued in series:  
*Droits, privilèges, restrictions et conditions, s'il y a lieu, rattachés à chaque catégorie d'actions et pouvoirs des administrateurs relatifs à chaque catégorie d'actions que peut être émise en série:*

Not applicable.

Request ID / Demande n°

20769105

Ontario Corporation Number  
Numéro de la compagnie en Ontario

2599290

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8. The issue, transfer or ownership of shares is/is not restricted and the restrictions (if any) are as follows:

*L'émission, le transfert ou la propriété d'actions est/n'est pas restreints. Les restrictions, s'il y a lieu, sont les suivantes:*

Shares of the Corporation may not be transferred unless the restrictions on the transfer of securities of the Corporation contained in section 9 of these Articles (entitled "Other provisions, if any") are complied with.

Request ID / Demande n°

20769105

Ontario Corporation Number  
Numéro de la compagnie en Ontario

2599290

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9. Other provisions, (if any, are):

*Autres dispositions, s'il y a lieu:*

Securities of the Corporation, other than non-convertible debt securities, may not be transferred unless:

(a) (i) the consent of the directors of the Corporation is obtained; or (ii) the consent of shareholders holding more than 50% of the shares entitled to vote at such time is obtained; or

(b) in the case of securities, other than shares, which are subject to restrictions on transfer contained in a security holders' agreement, such restrictions on transfer are complied with.

The consent of the directors or the shareholders for the purposes of this section is evidenced by a resolution of the directors or shareholders, as the case may be, or by an instrument or instruments in writing signed by a majority of the directors, or shareholders holding more than 50% of the shares entitled to vote at such time, as the case may be.

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Ontario Corporation Number  
Numéro de la compagnie en Ontario

2599290

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10. The names and addresses of the incorporators are  
*Nom et adresse des fondateurs*

First name, initials and last name  
or corporate name

*Prénom, initiale et nom de  
famille ou dénomination sociale*

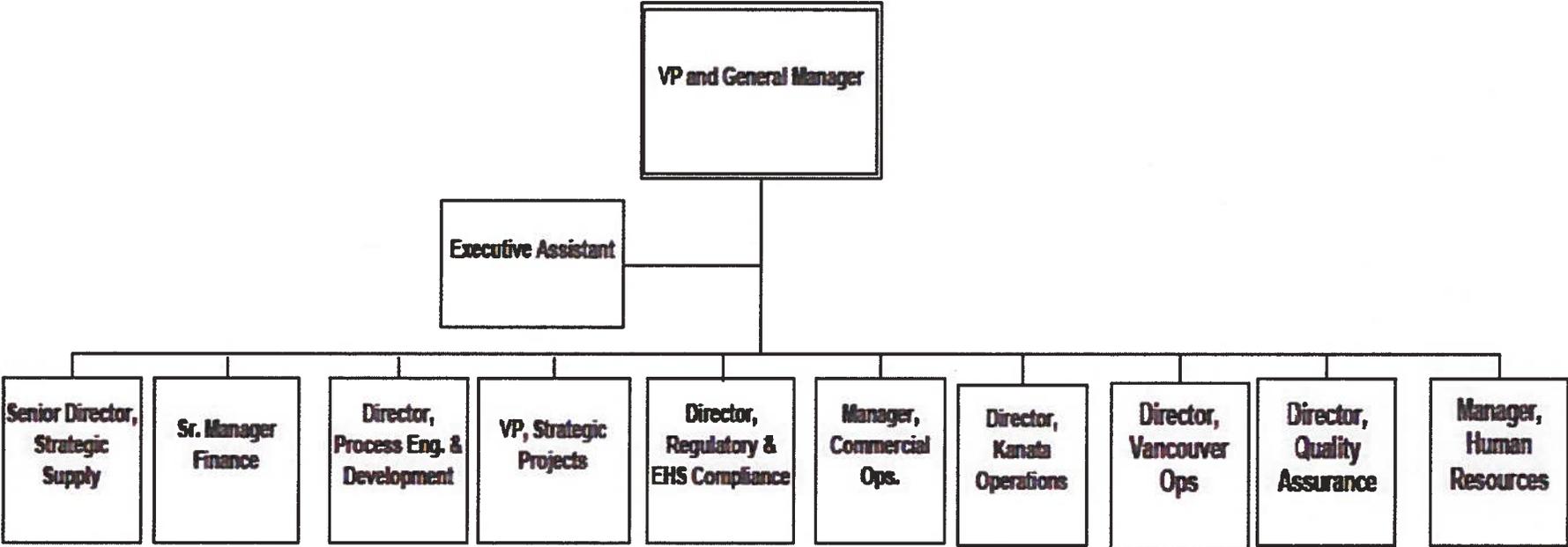
Full address for service or address of registered office or of principal place of business  
giving street & No. or R.R. No., municipality and postal code  
*Domicile élu, adresse du siège social ou adresse de l'établissement principal, y compris  
la rue et le numéro, le numéro de la R.R., le nom de la municipalité et le code postal*

\* JOHN MACQUARRIE

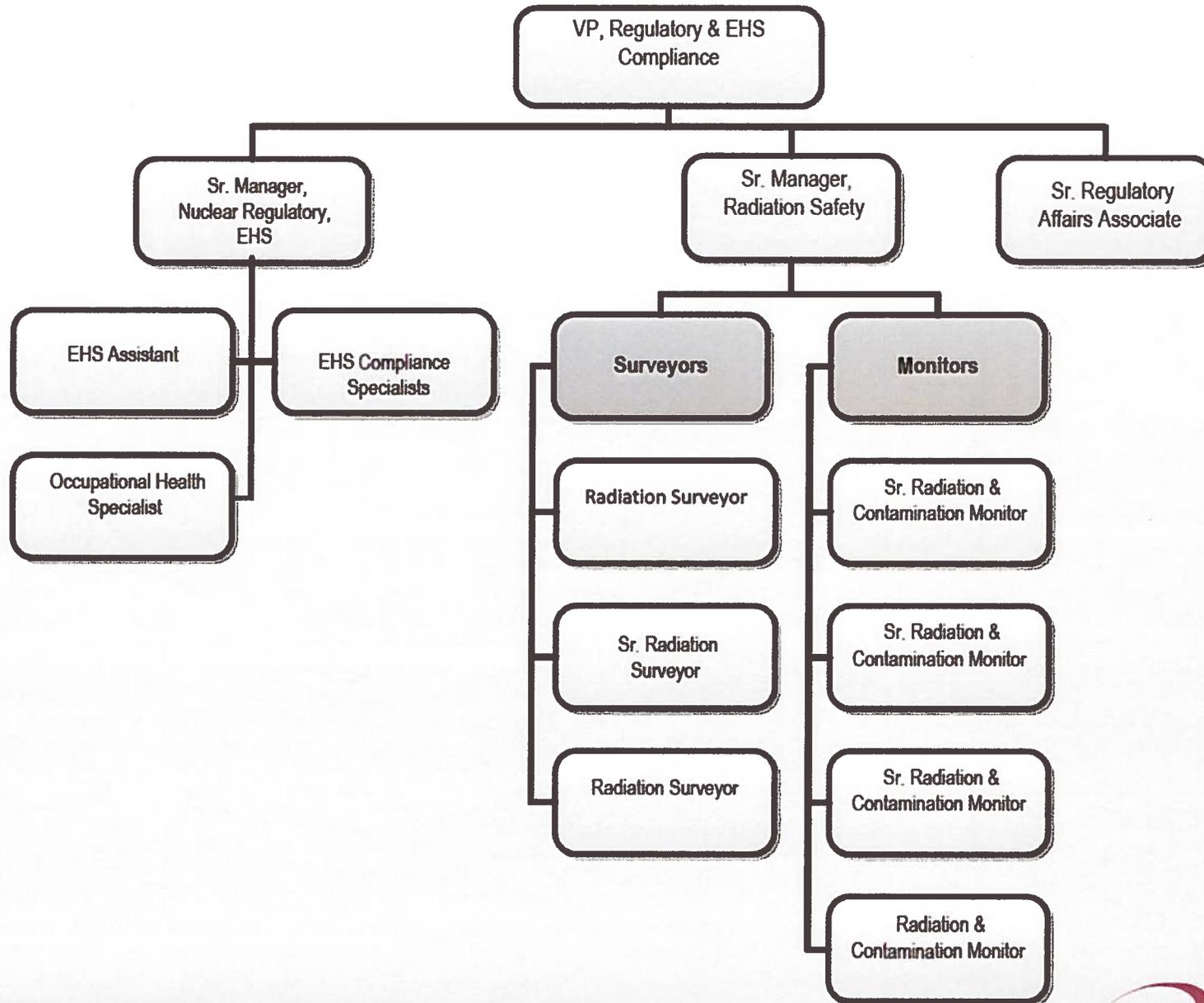
581 CORONATION BOULEVARD

CAMBRIDGE ONTARIO  
CANADA N1R 5V3

# SENIOR LEADERSHIP



# Regulatory, EH&S and Compliance





**Nordion.**

A Sotera Health company

December 11, 2018

Mr. M. A. Leblanc  
Commission Secretary  
Canadian Nuclear Safety Commission  
P.O. Box 1046, Station B  
280 Slater St., Ottawa, Ontario, K1P 5S9

**Subject: Permission for BWXT ITG Canada Inc. to Operate a Class 1B Facility on  
Nordion (Canada) Inc. Site**

Dear Mr. Leblanc,

This is to inform you that Nordion (Canada) Inc. (Nordion) as owner of the 447 March Road, Ottawa site has given BWXT ITG Canada Inc. (BWXT ITG) the authority to carry on the activities associated with the Class 1B licence BWXT ITG is seeking from the CNSC. This authority is described in the lease agreement between Nordion and BWXT ITG which BWXT ITG is submitting as part of their licence application for a Class 1B licence for operation of the medical isotopes facility.

Should you have any questions, please do not hesitate to contact me at [REDACTED]  
[REDACTED] or e-mail at [REDACTED]

Sincerely,

[REDACTED]

President, Nordion (Canada) Inc.