

# Record of Proceedings, Including Reasons for Decision

In the Matter of

Subject Licence Amendments to Strengthen Regulatory  
Controls on Radioactive Sealed Sources

Date December 16, 2005

## RECORD OF PROCEEDINGS

Purpose: Licence Amendments to Strengthen Regulatory Controls on  
Radioactive Sealed Sources

Date(s) of hearing: November 16, 2005

Location: Canadian Nuclear Safety Commission (CNSC), 280 Slater St.,  
Ottawa, Ontario

Member present: L.J. Keen  
A. Graham  
C. Barnes

Secretary: M. Leblanc

Recording Secretary: P-D. Bourgeau

General Counsel: J. Lavoie

	<b>Document Number</b>
<b>CNSC staff submissions</b>	CMD 05-H32 CMD 05-H32.A
	<b>Document Number</b>
<b>Submissions by Affected Parties</b>	See Attachment A

**Licences:** Amended  
**Date of Decision:** November 16, 2005

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## 1. Introduction

The Canadian Nuclear Safety Commission (CNSC<sup>1</sup>), as part of its mandate under the *Nuclear Safety and Control Act*<sup>2</sup> (NSCA), regulates the safety and security of radioactive sealed sources<sup>3</sup> in Canada. This includes licensing the possession and use of all such sources in Canada, as well as their import and export to and from Canada.

CNSC staff has recommended that the Commission take measures to further strengthen the regulation of sealed sources in response to recent national and international concerns and improvement initiatives related to the safety and security of sealed sources. Strengthening national programs and harmonizing international controls on sealed sources will lead to greater public safety, reduce the likelihood of accidents where sealed sources could be accessed by unauthorized persons, and lessen the risk of potential use of radiological dispersal devices in acts of terrorism.

CNSC staff therefore recommended that the Commission amend the existing 278 licences that involve high-risk (Category 1 and 2) sealed sources. The proposed modified licences would require the licensees to adhere to stricter reporting requirements and would remove any current general authorizations for the unrestricted export of Category 1 and Category 2 sealed sources. CNSC staff advised the Commission that the amendments would be consistent with strengthened international norms in this area, particularly with respect to the International Atomic Energy Agency's (IAEA) *Code of Conduct on the Safety and Security of Radioactive Sources* (2004).

After taking into consideration CNSC staff's recommendations and the views of the affected licensees, the Commission decided to amend the identified licences on its own motion pursuant to section 25 of the NSCA.

Background:

In considering each of the 278 licences, the Commission was required to decide pursuant to paragraph 8(2)(h) of the *General Nuclear Safety and Control Regulations*<sup>4</sup>,

- a) if failure to amend the licence could pose an unreasonable risk to the environment, the health and safety of persons or national security.

Furthermore, the Commission was required to decide pursuant to subsection 24(4) of the NSCA,

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<sup>1</sup> In this *Record of Proceedings*, the *Canadian Nuclear Safety Commission* is referred to as the "CNSC" when referring to the organization and its staff in general, and as the "Commission" when referring to the tribunal component.

<sup>2</sup> S.C. 1997, c. 9.

<sup>3</sup> A sealed source is defined in Section 1 of the *Nuclear Substances and Radiation Devices Regulations* (SOR/2000-207) as "a radioactive nuclear substance in a sealed capsule or in a cover to which the substance is bonded, where the capsule or cover is strong enough to prevent contact with or the dispersion of the substance under the conditions for which the capsule or cover is designed".

<sup>4</sup> SOR/2000-202.

- b) if the licensee is qualified to carry out the activities under an amended licence, and will make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security measures required to implement international obligations to which Canada has agreed.

#### The Proceedings:

A panel of the Commission, established by the President of the Commission pursuant to subsection 22(1) of the NSCA, considered the matter in accordance with Part 3 of the *Canadian Nuclear Safety Commission Rules of Procedure*<sup>5</sup>.

In accordance with those rules, a Notice of Opportunity to be Heard was issued to the affected parties on August 30, 2005. In that notice, the parties were provided an opportunity to be heard by way of written submissions to the Commission. Information on the specific amendments being considered was attached to the notice. The deadline for filing submissions with the Commission was set for October 4, 2005. Nine of the affected parties made formal submissions in response to the notice.

On October 25, 2005, CNSC staff filed a supplementary document that included the staff's disposition of the comments made by the nine respondents. The nine participants were provided the relevant sections of the CNSC staff's supplementary document and were notified of a further opportunity to make supplementary submissions to the Commission in writing by November 9, 2005. No supplementary submissions were received in response to the second notice.

## 2. Decision

Based on its consideration of the matter, as described in more detail in the following sections of this *Record of Proceedings*, the Commission concludes that, for each of the 278 licences, failure to amend the licence could pose an unreasonable risk to the environment, the health and safety of persons or national security. Furthermore, the Commission is of the opinion that, for each of the 278 licence amendments, the licensee is qualified to carry out the activities under the amended licence, and will 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.

Therefore,

the Canadian Nuclear Safety Commission, pursuant to section 25 of the NSCA and paragraph 8(2)(h) of the *General Nuclear Safety and Control Regulations*, amends the 278 licences listed in Attachment B of CMD 05-H32.

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<sup>5</sup> SOR/2000-211.

The Commission amends the licences in accordance with the recommendations of CNSC staff as set out in Appendices B and C of CMD 05-H32 with the following changes:

- The reporting requirement set out in paragraph a) of the proposed licence conditions for sealed source tracking (identified as proposed licence conditions 1 and 2 in Appendix C of CMD 05-H32) is changed to read as follows:

*“a) at least 7 days before any transfer or export.”*

This change removes reference to “calendar days” so to avoid any confusion with how such time frames are defined in the *Interpretation Act*<sup>6</sup>.

A new condition in each of the 278 licences requires the licensees to report the transfer, receipt, import and export of high risk sealed sources in a specified manner beginning January 1, 2006. Another licence condition that will be added to 159 of the licences later in 2006 by a CNSC staff Designated Officer will introduce enhanced export controls.

### **3. Issues and Commission Findings**

In making each of its licensing decisions, the Commission considered a number of issues to determine if failure to amend the licence could pose an unreasonable risk to the environment, the health and safety of persons or national security, and to assess the adequacy of the licensee’s qualifications and provisions for protecting the environment, the health and safety of persons, and for maintaining national security and international obligations to which Canada has agreed. The Commission’s findings on these issues are summarized below.

#### **3.1 Tracking Sealed Sources**

##### **3.1.1 Risk to Environment, Persons and National Security**

CNSC staff explained that sealed sources used in or exported from Canada could result in exposures to persons or the environment through lost or orphaned sources that have not been adequately tracked. CNSC staff also explained the risks to national security by the potential diversion of Canadian-supplied sealed sources to unauthorized uses or malicious or terrorist actions (such as in the fabrication and use of a radiological dispersal device or “dirty bomb”).

CNSC staff noted that the CNSC currently maintains data in its licensing administration database system on several thousand sealed sources. However, limitations in the source inventory and tracking tools have been identified, which include infrequent updating of the inventory and incomplete information on exports. The database system is being modified to include an upgraded National Sealed Source Registry, which will maintain an accurate national inventory of high-risk sealed sources and prescribed equipment (Sealed Source Tracking System).

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<sup>6</sup> R.S.C. 1985, c. I-21.

CNSC staff expressed the view that measures are needed to further strengthen regulatory controls and licensee accountability for the management of sealed sources. Specifically, CNSC staff recommended that licensees be required to notify CNSC of the transfer, receipt, export or import of Category 1 or 2 sealed sources, at least seven days before such transfer or export, and within 48 hours of any receipt or import.

In cases where Section IV of the existing licence identifies the nuclear substances that the licensee may possess, CNSC staff recommended that the proposed “Condition 1” in Appendix C to CMD 05-H32 be added to the licence. Conversely, where the existing licence does not specify the substances permitted, the more generic “Condition 2” is recommended (i.e., to achieve the desired result, either Condition 1 or Condition 2, but not both, would be added depending on the type of licence). CNSC staff’s recommendations on which licences should receive Condition 1 and which should receive Condition 2 are presented in Appendix B to CMD 05-H32.

One licensee, in its submission, raised specific questions concerning how the security of the information in the Sealed Source Tracking System will be maintained and protected. In response to these questions, CNSC staff indicated that appropriate security precautions have been designed into the system and that the data will be managed appropriately as “Protected B”. The Commission accepted this response and is satisfied that adequate security measures will be taken in management of the information system.

In other submissions received from the affected parties during the hearing, some licensees expressed concern that the proposed requirement to report to the Commission any transfer, receipt, import or export of a sealed source at least 7 calendar days prior to the transaction taking place could significantly disrupt their business operations and thus their ability to meet client needs in a timely manner. In response to this concern, CNSC staff, in its supplementary information, explained that the 7 calendar day notice requirement was identified as a common starting point for all of the licences and that different reporting time frames could be authorized by the CNSC staff Designated Officer upon receipt of a properly supported application. Such authorizations could be done on a case-by-case basis, or by way of a further amendment of a specific licence. CNSC staff noted that it is prepared to proceed with such applications on a risk-informed and expedited manner. The Commission is satisfied that this approach will provide an appropriate level of flexibility in the reporting requirements.

Further with respect to the reporting time frames, the Commission notes that, to remain consistent with how these types of limited time periods are defined in the *Interpretation Act*<sup>7</sup>, the Commission is of the view that the time limits should be expressed in terms of “days”, rather than “calendar days”.

The Commission also noted a variety of other questions and comments on the proposed Sealed Source Tracking System from the affected parties that, while not related to matters of risk or security, appeared to indicate a need for more information on how to use the system efficiently and effectively, and in a way that will not add a costly administrative burden to their operations. While the Commission is satisfied with the CNSC staff’s responses to the specific questions raised, the Commission considers that the comments may be indicative of a lack of

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<sup>7</sup> *Supra* note 6.

understanding of the system by the licensees in general, and that this should be addressed through an intensive and focussed information program by the CNSC.

Based on the information received, the Commission is satisfied that, for each of the 278 licences, failure to amend the licence as recommended by CNSC staff could pose an unreasonable risk to the environment, the health and safety of persons or national security.

### 3.1.2 Licensee Qualifications and Adequacy of Provisions

The Commission notes that the proposed new licence conditions for the tracking of sealed sources would not change the type, amount or form of the nuclear substances that the licensees are currently authorized to possess and use, nor would the amendment allow for those substances to be used in a different manner or for a different purpose. Furthermore, the Commission did not receive any information during the hearing that would suggest that any of the licensees affected are not qualified to continue the currently licensed activities and, in doing so, make adequate provision to protect the environment, the health and safety of persons and to maintain national security and international obligations to which Canada has agreed.

Therefore, based on the information received, the Commission is satisfied that, for each of the 278 licences identified for this amendment, the licensees are qualified to carry out the activities that the amended licence would authorize. The Commission is also satisfied that the licensees will make adequate provisions to protect the environment, the health and safety of persons and to maintain national security and international obligations to which Canada has agreed.

## 3.2 Export Controls

### 3.2.1 Risk to Environment, Persons and National Security

Under the CNSC's current export and import authorization process, there are 159 of the 278 licences that have general regulatory approval to export and import Category 1 and 2 high-risk sealed sources.

CNSC staff noted that export controls are needed in order to assure Canadians and the international community that Canadian exports of high-risk sealed sources do not contribute to radiological security threats and are used only for beneficial and peaceful purposes. CNSC staff added that current controls involve the use of certain classes of licences that typically provide general, unrestricted, export and import authorizations for high-risk sealed sources. This process of general export and import licensing does not allow a case-by-case assessment by the CNSC of international transfers, and thus makes it difficult for the CNSC to assess any related safety and security risks. CNSC staff therefore recommended that Condition 3 in Appendix C of CMD 05-H32 be added to the applicable 159 licences as identified in Appendix B of CMD 05-H32.



In their submissions for the purpose of the hearing, some licensees expressed the view that the export control measures being proposed would negatively impact industry by causing delays and additional costs in the export of high-risk sealed sources. Some of the affected parties recommended that there be assurances for uniform international implementation of controls through coordination and common practices, thereby assuring that a level competitive “playing field” is maintained. In this respect, CNSC staff indicated that it intends to implement the export and import licensing and control program in a manner that respects the provisions of the International Atomic Energy Agency’s *Code of Conduct on the Safety and Security of Radioactive Sources*. That Code will harmonize, to the greatest extent possible, CNSC export and import control practices with bilateral trading partners and will ensure the other jurisdictions with whom Canada trades in these materials is implementing similar controls. The Commission accepts these statements of CNSC staff and is satisfied that these multilateral and bilateral arrangements will address this concern. Furthermore, and similar to the above discussion of the sealed source tracking requirements, the Commission is of the view that many of the concerns of the participants about program efficiencies and cost can be addressed through a comprehensive and responsive CNSC information program.

Based on the information received, the Commission is satisfied that failure to amend the identified 159 licences to strengthen sealed source export and import control measures would pose an unreasonable risk to the environment, the health and safety of persons or national security.

### 3.2.2 Licensee Qualifications and Adequacy of Provisions

The Commission notes that the proposed new licence condition for export control would not change the type, amount or form of the nuclear substance that the licensees are currently authorized to possess and use, nor would the amendment allow for those substances to be used in a different manner or for a different purpose. Furthermore, the Commission did not receive any information during the hearing that would suggest that any of the licensees affected are not qualified to continue the currently licensed activities and, in doing so, make adequate provision to protect the environment, the health and safety of persons and to maintain national security and international obligations to which Canada has agreed.

Therefore, based on the information received, the Commission is satisfied that, for each of the 159 licences identified for this export control amendment, the licensees are qualified to carry out the activities that the amended licence would authorize. The Commission is also satisfied that the licensees will make adequate provisions to protect the environment, the health and safety of persons and to maintain national security and international obligations to which Canada has agreed.

### 3.3 Environmental Assessment

Prior to making any licensing decisions, the Commission must be satisfied that all requirements of the *Canadian Environmental Assessment Act*<sup>8</sup> (CEAA) have been fulfilled. In this respect, the Commission examined the application of the CEAA to the proposed licence amendments. CNSC staff stated that the amendments are deemed to be administrative in nature and are not related to an authorization allowing for the construction, operation, modification or decommissioning of a physical work.

Based on the information received, the Commission concludes that, for each of the proposed amendments, an environmental assessment in accordance with the CEAA is not required as there is no project as defined in section 2 of the CEAA. Furthermore, there is no trigger for an assessment pursuant to paragraph 5(1)(d) of the CEAA.

### 4. Conclusions

The Commission has considered the information and submissions of the affected parties and CNSC staff as presented in the material available for reference on the record.

The Commission concludes that failure to amend the 278 licences on its own motion could pose an unreasonable risk to the environment, the health and safety of persons or national security. The Commission also concludes pursuant to section 24 of the NSCA that the affected licensees are qualified to carry out the activities under the amended licences, and will make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security measures required to implement international obligations to which Canada has agreed.

The Commission therefore amends on its own motion, pursuant to section 25 of the NSCA and paragraph 8(2)(h) of the *General Nuclear Safety and Control Regulations*<sup>9</sup>, the licences identified in Appendices B and C of the staff CMD 05-H32. The first amendment (to take effect on January 1, 2006) is to place requirements on the licensees who manage and use sealed sources to report transactions involving sealed sources to the CNSC, including through use of the CNSC's sealed source tracking system. The second amendment, to be added by the CNSC staff Designated Officer on or before December 31, 2006, will remove any general authorization that is provided in the licences for the unrestricted export of Category 1 and Category 2 sealed sources.

The Commission notes that the amendments affect a large number of licensees that are involved in a wide variety of industrial, research and medical activities across various regions in Canada. Furthermore, as noted above, it is apparent that some licensees may lack information on how to comply with the new requirements and do so without incurring undue administrative costs. For these reasons, the Commission is of the view that CNSC staff will need to engage in a highly focused, proactive and sustained information program to assure licensee understanding of, and

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<sup>8</sup> S.C. 1992, c. 37

<sup>9</sup> *Supra* note 4.

compliance with, the new requirements. The Commission notes from the CNSC staff submission that a variety of related outreach activities are planned. The Commission also notes that the circumstances will demand the development and strict adherence to quality management systems for assured success.

The Commission therefore requests that CNSC staff present to the Commission a progress report on the success of the new controls and information programs in early 2007.

Marc Leblanc  
Secretary,  
Canadian Nuclear Safety Commission

Date of decision: November 16, 2005

Date of release of Reasons for Decision: December 16, 2005

## Appendix A – Written Submissions

Written Submissions	Document Number
TowerScan	CMD 05-H32.1
AITEC Inc.	CMD 05-H32.2
Quality NDE	CMD 05-H32.3
X-PER-X Inc.	CMD 05-H32.4
IRSS	CMD 05-H32.5
MDS Nordion	CMD 05-H32.6
Atomic Energy of Canada Limited	CMD 05-H32.7
Canadian Blood Services	CMD 05-H32.8
IRISNDT Corp.	CMD 05-H32.9