Protocol for
the Medical Isotope Project

Canadian Light Source Inc.
Canadian Nuclear Safety Commission

February 2011

Canadian Light Source / Centre canadien de rayonnement synchrotron

Canadian Nuclear Safety Commission / Commission canadienne de sûreté nucléaire

CNSC FILE # 2.03
E-Docs #3645315

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Summary of Changes

Revision	Change	Date
1	Original draft version	December 20, 2010
2	Draft incorporating comments by Canadian Nuclear Safety Commission staff and Canadian Light Source Inc.	December 22, 2010
3	Initial version for approval	January 7, 2011

Extent of the Protocol

This protocol is essentially administrative in nature. Nothing in this protocol is to be construed or interpreted as affecting the authority, jurisdiction and discretion of the Commission or the Designated Officer in any assessment of any application for licensing purposes under the *Nuclear Safety and Control Act* (NSCA).

Nothing in this protocol fetters the powers of the Commission, Designated Officers or Inspectors who are respecting regulatory decisions or taking regulatory action for the purposes of the NSCA, transparently and independent of any undue influence.

Protocol for the Medical Isotope Project

1. Introduction

On October 15, 2010, the Government of Canada announced further efforts to diversify Canada's supply sources of the medical isotope technetium-99 (Tc-99m) through its Non-reactor-based Isotope Supply Contribution Program (NISP). The program committed $35 million over two years to invest in research, development and demonstration of non-reactor-based technologies for producing this isotope. Natural Resources Canada (NRCan) selected four proposals to participate, one of which was from Canadian Light Source Incorporated (CLSI).

The CLSI proposal involves the production of molybdenum-99 (Mo-99) from a photo-neutron process on 95%-enriched molybdenum-100, using the nuclear reaction Mo-100 (γ, n) Mo-99. The photon beam would be produced using an electron linear accelerator, and the activated Mo-99 target would be processed to yield the daughter product Tc-99m. CLSI proposes to install a Class II 35-MeV linear accelerator within its existing Class IB nuclear facility perimeter, adjacent to the 250-MeV linear accelerator used as an injector for its synchrotron operations. The hot cells for processing the medical isotopes would be installed adjacent to the 35-MeV accelerator, also on the Class IB site.

The Canadian Nuclear Safety Commission (CNSC) would have direct regulatory oversight of the proposed activities. A series of licensing steps is required to allow operation of the 35-MeV linear accelerator and the production and processing of the Mo-99. This document formally outlines the requirements for each of these steps.

2. Objective

The protocol's objective is to provide a framework within which CLSI and CNSC staff will prepare the information needed by the Commission or the Designated Officer (DO) to assess the Medical Isotope Project for licensing purposes. It also establishes the administrative framework, milestones and service standards for licensing activities related to the project.

3. Approach to Licensing

To fully understand the responsibilities for safety and accountability, and to serve the Canadian public, both the CNSC and CLSI recognize the importance of well-planned and coordinated work. Both organizations recognize the complexities of the matter and agree to cooperate in ensuring that timelines and commitments are met.

4. Schedule

The schedule set out in this protocol aligns with the timeline set out under the terms and conditions established by NRCan for the delivery of the medical isotope Tc-99m under the NISP (i.e., an end date of March 31, 2012).

The Medical Isotope Project includes the following licensing phases:

- amendment of the CLSI Class I particle accelerator operating licence PA1OL-02.03/2012, to allow for the necessary modifications to the CLSI Class I facility
- issuance of a construction licence for the proposed Class II nuclear facility, which would comprise the new 35 MeV accelerator and associated processing hot cells
- issuance of an operating licence to commission the Class II facility
- issuance of a routine Class II facility operating licence, which would include authorization to process medical isotopes.

The project schedule considers the time required by CNSC staff to review the technical information submitted by CLSI in support of these steps, as well as the lead-time notices required by the *Canadian Nuclear Safety Commission Rules of Procedure*.

All milestones were established based on several assumptions, some of which relate to activities of project participants who are not signatories to this protocol. Should events unfold differently from what is assumed in this protocol, milestones will be revised according to the processes outlined in this document.

5. Parties and Organizational Representatives

The parties to the protocol are as follows:

CLSI: Owned by the University of Saskatchewan, CLSI is a non-profit corporation that operates Canada's national synchrotron facility. CLSI is the CNSC licensee for this facility and has appointed its Executive Director, Josef Hormes, as the signatory to this protocol, on its behalf.

The CNSC: The CNSC has regulatory and statutory responsibilities under the NSCA and its regulations, and is the responsible authority for the regulatory oversight of CLSI. On its behalf, the CNSC has appointed Ramzi Jammal, Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch, as the signatory to this protocol.

Each party will identify alternate representatives if primary representatives are unavailable.

For the purposes of this protocol, CLSI will be represented by its:

- **Director of Accelerators** (position held by Mark de Jong), for matters of governance Telephone: 306-657-3532
  Email: Mark.deJong@lightsource.ca

- **Manager of Health and Safety & Environment** (position held by Mohamed Benmerrouche), for matters related to implementation.
  Telephone: 306-657-3514
  Email: Mohamed.Benmerrouche@lightsource.ca

For the purposes of this protocol, the CNSC will be represented by its:

- **Director, Accelerators and Class II Facilities Division**, (position held by Kavita Murthy), for matters of governance
  Telephone: 613-993-7853
  Email: Kavita.Murthy@cnsc-ccsn.gc.ca

- **CLSI Project Manager** (position held by Jacinthe Plante, Physics Specialist, Accelerators and Class II Facilities Division), for matters related to implementation
  Telephone: 613-993-7876
  Email: Jacinthe.Plante@cnsc-ccsn.gc.ca

6. Statement of Work

Project requirements

The project requires the installation of a 35-MeV linear accelerator and hot cells for isotope processing. Both the accelerator and the processing facilities will be installed in the basement of the CLSI facility (previously the Saskatchewan Accelerator Laboratory), in an area designated as EA2 in current facility layout drawings.

Under section 1 of the *Class II Nuclear Facilities and Prescribed Equipment Regulations* (CNFPER), the linear accelerator is defined as Class II prescribed equipment and therefore requires a Class II facility licence. The processing hot cells can also be operated under this licence because CLSI expects to process less than 1 petabecquerel (PBq) of Mo/Tc-99 per calendar year.

Project licensing steps and the information that CLSI must submit to CSNC staff for each step are as follows:

(a) Project description for determination of Environmental Assessment requirement

The Medical Isotope Project requires an amendment of CLSI's Class IB nuclear facility operating licence. The amendment of a Class I licence is listed as a "trigger" under the *Law List Regulations* of the *Canadian Environmental Assessment Act* (CEAA).

Therefore, an Environmental Assessment (EA) determination for this project is mandatory.

CLSI must submit a project description in order for CNSC staff to determine if an EA is required for the medical isotope project. **The remainder of this document is based on the presumption that this project will not require an EA.** If it is determined that an EA is required, a new protocol will be written.

(b) Amendment of Class IB licence

The EA2 area is adjacent to the 250-MeV linear accelerator that serves as the injector to the synchrotron facility. This area currently forms part of the exclusion zone established under CLSI's Class IB operating licence, and access to it is restricted by a control system. To allow full occupancy in EA2 during the operation of this 250-MeV accelerator, the area's shielding will have to be modified. This shielding modification will require an amendment of the Class IB operating licence for the synchrotron facility, since facility drawings are part of the CLSI safety report (which is included in the licence's appendix).

CLSI will be required to submit a safety case demonstrating that the additional shielding to be installed in EA2 meets the design dose criteria found in the CNSC Regulatory Guide G-129, rev 1, *Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)".* The requirements for additional shielding should consider the occupancy factor in EA2 and the use factor (or duty factor) of the 250-MeV accelerator.

Along with the shielding modifications, the Access Control Interlock System (ACIS) must also be modified, as EA2 is part of the lock-up zone for operation of the synchrotron. The proposed modifications to the ACIS should be part of the safety case submitted to the CNSC for review.

In summary, CLSI must submit a formal request to amend their Class I Nuclear Facility operating licence that contains:

- a safety analysis of the shielding modifications required to allow full occupancy in EA2 during operation of the 250-MeV linear accelerator
- the proposed changes to the ACIS to exclude EA2 from the lock-up zone
- the proposed change of access to EA2 from the 250-MeV linear accelerator.

(c) Authority for Class II licence

In its submission to the Commission, CNSC staff will also inform the Commission that decisions related to Class II nuclear facility licensing will be done under the authority of a Designated Officer (DO), as set out in CMD 08-M10. This will help CLSI meet the tight deadlines that the NISP has imposed on the project. Currently, the CNSC's Director of the Accelerators and Class II Nuclear Facilities Division (ACFD) and the Director General of the Directorate of Nuclear Substance Regulation have the delegated authority to issue licences for Class II nuclear facilities. The following licensing actions, all related to the Class II linear accelerator, will be made under the DO authority of the Director, ACFD:

- issuance of a construction licence for the Class II nuclear facility (35 MeV linear accelerator)
- issuance of an operating licence, including a commissioning licence, of the Class II nuclear facility
- issuance of any other amendment to the Class II nuclear facility licence(s) required during the course of this project

(d) Application for Class II construction licence

A facility comprising a 35-MeV linear accelerator is a Class II nuclear facility and must meet the requirements specified in the *Class II Nuclear Facilities and Prescribed Equipment Regulations* (CNFPER). Accordingly, CLSI must apply for a construction licence to install and use the 35MeV particle accelerator in EA2. The CNSC draft regulatory guide G-289, *Class II Isotope Production Accelerator Licence Application Guide* (revised September 2009) provides clear requirements for the application of a construction licence for an isotope production accelerator. For additional clarity, a summary of the relevant sections is provided in Appendix A of this protocol.

A Class II construction licence will allow the licensee to construct the facility and install Class II prescribed equipment, but not to operate the accelerator. A Class II operating licence is required in order to produce radiation.

Section 10 of the CNFPER stipulates that no person shall use Class II prescribed equipment unless it is a certified model or used for research that is not conducted on humans. CLSI's proposed 35-MeV accelerator facility meets the criteria for exemption from the certification requirement, as the accelerator will be used to conduct feasibility studies and will not be used on humans. Some aspects of certification, such as the target design, will be incorporated into the licensing process. However, certification of the equipment will be required when CLSI converts the research facility to an isotope production facility.

Section 15 of the CNFPER stipulates that all operating Class II nuclear facilities must have a CNSC-certified radiation safety officer (RSO). CLSI must apply for the certification of a RSO before the operate-to-commission licence can be issued.

(e) Application for Class II operate-to-commission licence

An operate-to-commission licence will restrict CLSI to acceptance testing and commissioning of the Class II prescribed equipment and performing safety testing of the Class II facility. Section I of the draft regulatory guide G-289 indicates the information required in an application for an operate-to-commission licence. For clarity, a summary of the section I requirements is repeated in Appendix A of this protocol.

(f) Application for Class II routine operation licence

In order to begin routine experiments using the new linear accelerator, following successful commissioning of the Class II facility (safety system and shielding design), CLSI must apply for a routine operating licence. The application for routine operation shall include the information requested in section J of the draft regulatory guide G-289, summarized in Appendix A. As the processing of the Mo-99 target will be one of the activities authorized by the accelerator operating licence, CLSI should also provide the information requested in the regulatory guide GD-52, *Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms*.

7. Timelines

- **Amendment of Class IB licence:**

This amendment will be done through a one-day public hearing scheduled for June 8, 2011. The deliverables associated with this project are listed in Appendix B of this protocol.

To allow sufficient time to CNSC staff to review the safety case and to prepare and submit its recommendations to the Commission, CLSI should submit a safety case that is as complete as possible in a timely fashion. This will also allow time, if necessary, for CLSI to respond to any issues raised by CNSC staff in their review of the safety case.

The first deliverable for the amendment of the Class IB licence is the EA determination. CLSI shall submit a project description to CNSC by January 21, 2011. Within **10 working days** of its receipt (by February 4, 2011) CNSC staff will inform CLSI if an EA is required under the CEAA for the proposed project.

Next, CLSI will submit a draft safety case to CNSC staff by February 11, 2011. Within **five working days** of its receipt (by February 18, 2011), CNSC staff will perform a cursory review to verify conformity with the information requirements and to identify any obvious deficiencies. Any such problems will be communicated to CLSI within that period of time. Within **20 working days** of its receipt (before March 10, 2011), CNSC staff will complete the review of the submission and will provide the results of the assessment to CLSI.

As long as CNSC staff has had 20 working days to review the draft safety case and all technical issues have been resolved to the CNSC's satisfaction, CNSC staff will prepare and submit its CMD to the CNSC Secretariat within **20 working days** (by April 8, 2011) of receiving CLSI's formal safety case to modify the EA2 area for the medical isotope project.

- **Issuance of Class II nuclear facility licences**

Provided a complete application is received:

- the CNSC business standard for issuing a Class II construction licence under a DO authority is **8 weeks**

- the CNSC business standard for issuing a Class II commissioning licence under a DO authority is **4 weeks**
- the CNSC business standard for issuing a Class II routine operating licence under a DO authority is **2 weeks**

8. Issue Resolution

The parties to this protocol will use their best efforts to resolve any differences of opinion in the interpretation or application of this protocol in an effective and timely manner.

The following review and dispute resolution mechanism will be used during the review, should any issues arise.

Step 1: Issue identification by Project Managers

It is the intention of both parties to resolve issues relating to the submission of the technical information and the regulatory review through direct discussions and collaboration between the Project Managers (Jacinthe Plante and Mohamed Benmerrouche).

If an issue cannot be resolved at this level, the Project Managers will document it (typically, with a brief factual summary of the issue and a paragraph representing the view of each organization) and forwarded it to the Management Representatives within three working days of failure to resolve it.

Step 2: Meeting of Management Representatives

Where an issue cannot be resolved through the Project Managers, the Management Representatives (Kavita Murthy and Mark de Jong) agree to meet within three working days of notification of the dispute, with the intention of expeditiously resolving it. Issue resolution is to be documented.

If an issue cannot be resolved at this level, it will be referred to the signatories of this protocol within three working days of the Management Representatives' meeting, and supported by the original or revised documentation from step 1.

Step 3: Meeting of Signatories

An issue that remains unresolved after Step 2 will be referred, with documentation, to the signatories of this protocol (Ramzi Jammal and Josef Hormes) for resolution. A meeting will be called, normally within five working days, to resolve the issue and document its resolution.

9. Reporting

CLSI and the CNSC will meet quarterly to review progress and highlight any potential major issues or disputes. For urgent matters, additional meetings may be called as required.

The Managers will jointly produce a one-page dashboard-style report on a quarterly basis demonstrating progress, status of activities, and items of concern or that present risks to project completion. The report shall be submitted to the Management Representatives on the following dates:

- March 31, 2011
- June 30, 2011
- September 30, 2011
- December 31, 2011
- March 31, 2012

CNSC inspections of the Class II facility of the medical isotope project will be scheduled as needed. CLSI will be informed in advance of the inspection.

10. External Communications

Throughout the duration of this protocol, all parties agree that communications will be open and transparent. Information destined for public release will be coordinated through the Project Managers (or alternates, where designated) with support from each party's communications division. These communications will be done in coordination with and in consideration of each party's communications protocols.

11. Future Revisions of the Protocol

Revisions of this protocol will be coordinated by the Project Managers and must be approved in writing by the protocol signatories. Revisions may include adjustments to timelines and any other revisions as required.

12. Agreement

The parties hereto have signed the protocol, in counterpart, on the dates indicated below.

_____ *Date:*

Josef Hormes
Executive Director
Canadian Light Source Incorporated

_____ *Date:*

Ramzi Jammal
Executive Vice-President and
Chief Regulatory Operations Officer
Regulatory Operations Branch
Canadian Nuclear Safety Commission

Appendix A

Relevant Extracts from draft Regulatory Guide G-289, *Class II Isotope Production Accelerator Licence Application Guide*

CNSC staff will forward a complete guide to CLSI. The following extracts highlight information of particular interest in the context of the Medical Isotope Project.

1. Construction licence

Section G and H contain the technical information that must be submitted in a construction application for a non medical accelerator. In addition, an application for Class II construction must contain a preliminary decommissioning plan of the facility. A financial guarantee for the decommissioning of a Class II facility may be required based on the cost of the decommissioning of the facility.

- Section G – Facility Design

In this section, CLSI must provide the safety analysis of the shielding design for the operation of the 35 MeV accelerator. The safety analysis shall contain the detailed plans and drawings, the purpose and the occupancy of all adjacent areas and both the estimated radiation dose rates and the resulting annual radiation doses in the adjacent area resulting from the operation of the 35 MeV accelerator.

Although not all the information regarding the processing laboratory is required at this time, the following details must be provided with the construction application:

- the location of the processing facilities with respect to the accelerator and occupied areas;
- the shielding design of the hot cells;
- the location/pathway of any transfer tube for delivering isotopes from the accelerator to the processing facilities (including details of shielding along the tube);
- the ventilation system; and
- any other safety system associated with the hot cells.

The regulatory guide GD-52, "Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms" highlights the requirements for processing laboratories.

- Section H – Safety Requirements

CLSI must describe the safety systems to be installed in the Class II facility. Section 15 of *Class II Nuclear Facilities and Prescribed Equipment Regulations* lists the safety system requirements for this facility.

CLSI must also provide the wiring schematics for any safety interlocks that are external to the accelerator.

2. Commissioning licence

Section I indicates the information that an application must contain for a Class II facility commissioning licence.

- Section I – Operating Licence to Commission

Before beginning tests involving the production of radiation, CLSI must first ensure that all safety systems are functioning properly. The next step is a thorough radiation survey to evaluate the room shielding, using worst case operating parameters.

At this stage, the radioisotope processing lab shall be tested as well. Tests should be performed on the ventilation, the hot cell shielding, the transfer line shielding and any safety system associated with the processing laboratory.

3. Operating licence

Section J provides the information that an application must contain for a Class II facility operating licence.

- Section J – Licence for routine operation

In this section, CLSI must submit the results of the tests performed on the safety systems of the Class II facility; the results of the radiation surveys to validate the shielding design of the facility; and the results of the tests performed on the processing laboratory. In addition, CLSI needs to provide the operating procedures of the Class II facility as well as the operating procedure of the processing laboratory.

Appendix B

Deliverables

Protocol Deliverables	Content	Section of Protocol for Reference	Submission Date to CNSC Staff
Project description	Project description for EA determination	6(a)	January 21, 2011
Draft safety case for amendment of CLSI licence	Safety analysis for the modification in EA2 and the access control interlock system changes	6(b)	February 11, 2011
Formal request to amend CLSI licence	Formal safety analysis for the modification of EA2	7	March 10, 2011
Class II construction licence	Facility design and safety system of the facility	6(d)	June 3, 2011
Class II commissioning licence	Plan to test the safety system and perform radiological survey of the shielding	6(e)	September 16, 2011
Class II operating licence	Result of commissioning test and operating procedures of Class II facility and processing laboratory	6(f)	November 18, 2011