

Record of Proceedings, Including Reasons for Decision

In the Matter of

Applicant

Canadian Light Source Incorporated

Subject

Application to Amend Class IB Particle
Accelerator Operating Licence

Date of
hearing

September 18, 2008

RECORD OF PROCEEDINGS

Applicant: Canadian Light Source Incorporated (CLSI)
Address/Location: 101 Perimeter Road, Saskatoon, Saskatchewan, S7N 0X4
Purpose: Application to amend Class IB Particle Accelerator Operating Licence
Application received: June 9, 2008
Date of hearing: September 18, 2008
Location: Delta Bessborough, 601 Spadina Crescent East, Saskatoon, Saskatchewan
Members present: M. Binder, Chair A.R. Graham
 C.R. Barnes M. J. McDill
 A. Harvey D. Tolgyesi
General Counsel: L. Thiele
Secretary: M. Leblanc
Recording Secretary: S. Dimitrijevic

Applicant Represented By	Document Number
<ul style="list-style-type: none">• M. Benmerrouche, Manager of Health, Safety and Environment• J. Hormes, Executive Director• E. Hallin, Director of Beamline Development	CMD 08-H19.1 CMD 08-H19.1A
CNSC staff	Document Number
<ul style="list-style-type: none">• D. Howard• H. Rabski• J. Schmidt	CMD 08-H19 CMD 08-H19.A
Intervenors	Document Number
See appendix A	

Licence: Amended

Table of Contents

Introduction	1
Decision	2
Issues and Commission Findings	2
Radiation Protection	3
Human Performance	3
Fire Protection	4
Security	4
Operations	5
Application of the <i>Canadian Environmental Assessment Act</i>	5
Decommissioning Plan and Financial Guarantee	6
Public Information Program	6
International Obligations	7
Proposed Changes to the Licence	7
Conclusion	7

Introduction

1. Canadian Light Source Incorporated (CLSI) has applied to the Canadian Nuclear Safety Commission¹ (CNSC) for an amendment of the Class IB particle accelerator operating licence PA1OL-02.00/2012, which expires on May 31, 2012. The amended licence would allow CLSI to complete Phase 1 and Phase 2 of a three-phase commissioning and operations plan for its biomedical imaging and therapy beamline (BMIT) at the Canadian Light Source (CLS) facility.
2. The facility consists of a 2.9 GeV (giga-electronvolts) electron synchrotron installation that encompasses a 300 MeV (mega-electronvolts) linear accelerator, a booster ring which accelerates electrons up to 2.9 GeV and a storage ring that keeps electrons circulating at 2.9 GeV for several hours. Experiments take place in optical beamlines tangential to the storage ring. The facility includes four experimental hutches, office and laboratory support space.
3. The operation of the BMIT facility will be dedicated to biomedical research. Phase 1 includes conventional beamline commissioning, while Phase 2 involves commissioning and operating with human and animal tissues, and live animals. It is planned for Phase 3 to provide experimental therapy and imaging methods for human subjects. CLSI's application does not include a request to operate the BMIT with live human subjects.

Issues

4. In considering the application, the Commission was required to decide, pursuant to subsection 24(4) of the Nuclear Safety and Control Act² (NSCA):
 - a) if CLSI is qualified to carry on the activity that the amended licence would authorize; and
 - b) if, in carrying on that activity, CLSI would 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.

¹ 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.

² S.C. 1997, c. 9.

Public Hearing

5. The Commission, in making its decision, considered information presented for a public hearing held on September 18, 2008 in Saskatoon, Saskatchewan. The public hearing was conducted in accordance with the *Canadian Nuclear Safety Commission Rules of Procedure*³. During the public hearing, the Commission received written submissions and heard oral presentations from CNSC staff (CMD 08-H19 and CMD 08-H19.A) and CLSI (CMD 08-H19.1 and CMD 08-H19.1A). The Commission also considered submissions from 5 intervenors (see Appendix A for a detailed list of interventions).

Decision

6. Based on its consideration of the matter, as described in more detail in the following sections of this *Record of Proceedings*, the Commission concluded that CLSI is qualified to carry on the activity that the amended licence will authorize. The Commission also determined that CLSI, in carrying on that activity, 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 Commission, pursuant to section 24 of the *Nuclear Safety and Control Act*, amends the Class IB particle accelerator operating licence issued to Canadian Light Source Incorporated for its biomedical imaging and therapy beamline at the Canadian Light Source facility located in Saskatoon, Saskatchewan. The amended operating licence, PA1OL-02.01/2012, is valid until May 31, 2012.

7. The Commission includes in the licence the conditions and revised Appendix B, recommended by CNSC staff as set out in the draft licence attached to CMD 08-H19.

Issues and Commission Findings

8. In making its decision, the Commission considered a number of issues related to CLSI's qualification to carry out the proposed activities and the adequacy of the proposed measures for protecting the environment, the health and safety of persons, national security and international obligations to which Canada has agreed. The Commission's findings, based on consideration of all of the information and submissions available on the record for the hearing, are summarized below.

³ S.O.R./2000-211.

Radiation Protection

9. As part of its evaluation of the adequacy of provisions for protecting the health and safety of persons, the Commission considered the radiation risks associated with the proposed activities.
10. CLSI informed the Commission on the procedures for performing calculations on beamline radiation and on the specific shielding requirements for radiation protection in the experimental hutches. CLSI stated that the estimated risk for health and safety of operators was negligible.
11. CNSC staff informed the Commission that it had reviewed the *CLSI Safety Report* and BMIT documentation and found that it adequately addresses the inclusion of the BMIT facility into CLSI's Radiation Protection Program.
12. CNSC staff also informed the Commission on its assessment of the shielding design for the hutches. CNSC staff stated that the design had been found safe and that hutches were designed to provide an adequate radiation shield for workers. Furthermore, access to hutches will be restricted by an Access Control and Interlock System (ACIS) during the beamline operating time.
13. CNSC staff noted that it reviewed the documentation for the BMIT experimental hutch ACIS and deemed it satisfactory and accurate for description of the design and validation and verification procedures.
14. Based on the above information and considerations, the Commission concludes that, the operation of the CLS facility, with implemented mitigation measures, represents a low radiological risk to the workers and the public. The Commission is of the opinion that CLSI has made and will continue to make adequate provision for the protection of people from radiation at the facility including the BMIT area.

Human Performance

15. CLSI stated that human factors were integrated into the development of the BMIT facility. CLSI added that it had used the services of a human factors consultant who trained CLSI staff in regards of the CLSI human factor plan.
16. CNSC staff reported that CLSI had developed and submitted a *Human Factors Work Scope* and a *Human Factors Engineering Program Plan* specific to the BMIT facility.
17. CNSC staff noted that it had reviewed the two documents and found that they had met the regulatory requirements and were deemed acceptable.

18. The Commission inquired on CLSI's track record regarding accident history. CLSI responded that accidents were tracked and information provided to the CLSI committees. CLSI emphasized that, since the facility is a low-risk one, the number of accidents was small and the related injuries were only minor ones, without a single major injury.
19. The Commission sought more details about training of the operators and external users of the facility. CLSI explained that, similarly to the facilities of the same kind in other countries, each user has to complete a training procedure specific to the BMIT facility in order to be granted access to the facility and perform planned experimental work.
20. Based on this information, the Commission is satisfied with CLSI's accident track record and documents covering human performance at the facility.

Fire Protection

21. CNSC staff informed the Commission that CLSI had updated its *Safety Plan* and *Building Evacuation Plan*, including the handling of animals in case of emergency. CNSC staff added that it considers the updated plans acceptable.
22. CNSC staff also informed the Commission that CLSI had submitted a third party review of compliance with the fire safety requirements of the National Building Code (2005) and the National Fire Code (2005), which included the BMIT additions and the experimental hutches. CNSC staff stated that it had reviewed the submission and accepted it as a fulfillment of the requirements of the licence conditions.
23. Based on this information, the Commission is satisfied that CLSI has an adequate fire protection system in place for its BMIT facility.

Security

24. With respect to site physical security issues, the Commission was provided with a separate, protected document, CMD 08-H19.A for its consideration.
25. The Commission sought more information about security with respect to visitors and external users of the facility. CLSI explained that its procedure is similar to the measures taken in similar facilities around the world, where guided tours and visiting parties are always accompanied by a member of the facility staff and each external user has to complete a training procedure, including safety measures, specific to the BMIT facility, in order to be granted access to the facility.
26. The Commission concludes that CLSI has made, and will continue to make, adequate provisions for ensuring the physical security of the BMIT facility.

Operations

27. CLSI informed the Commission that it had prepared a revised document on the methods used to test and integrate the hardware and software needed for the BMIT facility. The document provides additional detail on commissioning processes for devices within the optical enclosures, and for the software that controls them.
28. CNSC staff reported that CLSI had submitted a *Revised Safety Report* encompassing a description of the BMIT beamlines and their proposed use for research, a description of the expansion of the use of the facility and a description of BMIT's unique ACIS design. The document also includes clarification regarding the review of the approval process for all experiments and a description of ethical protocols for experiments involving animals. It further describes the provisions for biosafety, and safe handling and containment of animals during experiments.
29. The Commission inquired if the commissioning plan has been updated to include all relevant Phase 1 and Phase 2 activities. CLSI responded that the plan has been updated, with the exception of the commissioning of some specific equipment that would be chosen depending on the specific research procedures still to be determined.
30. Considering the qualification of the proponent to operate the facility, the Commission inquired into the proponent's internal organisation structure and asked if CLSI had submitted organisational charts. CLSI responded that it had revised the organisational charts and submitted them to CNSC staff. CNSC staff confirmed that the revised charts had been found acceptable and were included in the Health Safety and Environment Manual, which is one of the documents listed in the Appendix B of the proposed licence.
31. All intervenors have expressed their support for amendment to the operating licence for the BMIT facility emphasizing the importance of the commissioning of Phases 1 and 2 for future development of the fields of biomedical imaging and therapy using synchrotron radiation.
32. Based on the above information and considerations, the Commission is satisfied that CLSI has sufficient controls in place for a safe operation of the facility under the amended licence.

Application of the *Canadian Environmental Assessment Act*

33. Before making a decision, the Commission must be satisfied that all applicable requirements of the *Canadian Environmental Assessment Act*⁴ (CEAA) have been fulfilled.

⁴ S.C. 1992, c. 37.

34. CNSC staff noted that the amendment of a licence under subsection 24(2) of the NSCA represents a project and is listed as a “trigger” under the *Law List Regulations*⁵ of the CEEA. However, this project is included in the *Exclusion List Regulations*⁶, which is applicable to this licence amendment application.
35. Based on the above information and considerations, the Commission is of the opinion that there is no requirement for an environmental assessment pursuant to subsection 5(1) of the CEEA.

Decommissioning Plan and Financial Guarantee

36. CNSC staff informed the Commission that the updated Preliminary Decommission Plan (PDP) and financial guarantee have been maintained since the last licence renewal.
37. CNSC staff noted that CLSI had committed to revise the PDP every five years. The submission of the next PDP revision is expected in November 2008, with a recommendation that licence condition 10 be modified to ensure that an acceptable PDP is submitted by April 30, 2009.
38. The Commission is of the opinion that CLSI has an adequate PDP and financial guarantee in place.

Public Information Program

39. CLSI informed the Commission that it has a public information program in place since the beginning of construction of the CLS facility. The program includes regular public tours and public lectures, as well as a regularly updated website that shows the evolution of the beamlines operation and the research activities.
40. CLSI further informed the Commission that it had organized summer workshops for high school teachers and created opportunities for students to participate in synchrotron research activities.
41. The Commission is satisfied that CLSI has in place an adequate public information program.

⁵ S.O.R./94-636.

⁶ S.O.R./2007-108, section 8, Part 1, Schedule 1.

International Obligations

42. CNSC staff reconfirmed the information, provided to the Commission during the last re-licensing hearing, that there were no applicable safeguard requirements for the CLS facility.

Proposed Changes to the Licence

43. CNSC staff recommended that the Commission modify Appendix A to the operating licence so to include the latest *CLSI Safety Report, Revision 9*, to change Appendix B so to include only high-level documentation pertaining to the facility's operation, and to revise Appendix C in order to clarify information to be submitted to the CNSC in the Annual Compliance Report by CLSI.
44. CNSC staff also recommended the modification of ten other licence conditions, related to reporting, deviations, quality assurance, commissioning and financial guarantees, as presented in section 5 of the CMD 08-H19 and in the proposed licence.

Conclusion

45. The Commission has considered the information and submissions received from CLSI, CNSC staff and intervenors as presented in the material on the record.
46. The Commission concludes that an environmental assessment under the CEAA is not required before the Commission may make its decision with respect to the application for the amendment to the licence.
47. The Commission is of the opinion that CLSI is qualified to carry on the activities that will be permitted under the amended licence. The Commission is also of the opinion that in carrying on those activities, CLSI 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.
48. The Commission therefore amends, pursuant to section 24 of the *Nuclear Safety and Control Act*, the particle accelerator operating licence issued to CLSI for its facility located in Saskatoon, Saskatchewan.

49. The Commission includes in the licence the conditions recommended by CNSC staff, as set out in the draft licence attached to CMD 08-H19.



Michael Binder
President
Canadian Nuclear Safety Commission

OCT 28 2008

Date

Appendix A – Intervenors

Intervenors	Document Number
Bernhard H.J. Juurlink	CMD 08-H19.2 CMD 08-H19.2A
Saskatoon Health Region, represented by Dr. Casson	CMD 08-H19.3 CMD 08-H19.3A
Memorial University Faculty of Medecine	CMD 08-H19.4
Helen Nichol	CMD 08-H19.5
College of Medicine of the University of Saskatchewan	CMD 08-H19.6