Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

UNPROTECTED/NON PROTÉGÉ

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A Licence Renewal

Un renouvellement de permis

Canadian Light Source Incorporated

Centre canadien de rayonnement synchrotron

Particle Accelerator

Accélérateur de Particules

Commission Public Hearing

Audience publique de la Commission

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Submitted by:

CNSC Staff

Soumise par :

Le personnel de la CCSN

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Summary

This CMD presents information about the following matters of regulatory interest with respect to Canadian Light Source Incorporated (CLSI):

- CNSC staff's review and assessment of and recommendations regarding CLSI's application for the renewal of particle accelerator licence PA1OL-02.01/2022
- Revision of the financial guarantee for the Canadian Light Source (CLS) synchrotron facility

CNSC staff recommend that the Commission take the following actions:

- Renew CLSI's licence to operate a synchrotron particle accelerator until 2032
- Accept the proposed revised financial guarantee amount for the CLSI facility
- Authorize the delegation of authority as set out in section 4.6 of this CMD

The following items are attached:

- Current licence PA1OL-02.01/2022
- Proposed licence PA1OL-02.00/2032
- Current licence conditions handbook
- Proposed licence conditions handbook

Résumé

Le présent CMD présente de l'information sur un ensemble de questions d'ordre réglementaire concernant le Centre canadien de rayonnement synchrotron (CCRS) :

- L'examen, l'évaluation et la recommandation du personnel de la CCSN à l'égard de la demande du CCRS visant le renouvellement du permis d'accélérateur de particules PA1OL-02.01/2022
- La révision de la garantie financière pour l'installation du CCRS

La Commission pourrait considérer prendre les mesures suivantes :

- Renouveler le permis du CCRS visant l'exploitation d'un accélérateur de particules de type synchrotron jusqu'en 2032
- Accepter le montant proposé de la garantie financière révisée pour l'installation du CCRS
- Autoriser la délégation de pouvoirs telle qu'elle est établie à la section 4.66 du présent CMD

Les pièces suivantes sont jointes :

- Le permis actuel, PA1OL-02.01/2022
- Le permis proposé, PA1OL-02.00/2032
- Le manuel des conditions de permis actuel
- Le manuel des conditions de permis proposé

Signed/signé le

8 December 2021

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EXECUTIVE SUMMARY

The Canadian Light Source (CLS) is a 2.9 GeV synchrotron particle accelerator located in Saskatoon, Saskatchewan. The CLS is owned by the University of Saskatchewan and operated by Canadian Light Source Incorporated (CLSI). The CLS synchrotron facility began operating in 2000 and was fully commissioned and operational by 2005.

Pursuant to section 24 of the *Nuclear Safety and Control Act*, the Canadian Nuclear Safety Commission (CNSC) issued licence PA1OL-02.00/2022 to CLSI in 2012. The Commission amended the licence at CLSI's request to include the processing of nuclear substances and the addition of a basic-level lab (CMD 15-H102) in 2015. A change in licensing basis was granted by the Commission in 2017 (CMD 17-H112) for top-up operation, and in 2021 for the establishment of the Electron Source Laboratory (CMD 21-H109).

In January 2021, CLSI applied to the CNSC to renew its operating licence. In its application, CLSI requested a 10-year licence to continue operating the synchrotron facility.

CNSC staff conducted a sufficiency check to ensure that CLSI had submitted all required information, and subsequently completed technical assessments of CLSI's submissions, an environmental review, and a review of CLSI's financial guarantee. CNSC staff conclude that CLSI has met regulatory requirements over the course of the licensing period, that its regulatory performance is satisfactory, and that the financial guarantee is adequate.

CNSC staff recommend that the Commission:

1. Renew the Class 1B particle accelerator operating licence to authorize CLSI to operate the CLS facility until June 30, 2032.
2. Authorize the delegation of authority as set out in this CMD.
3. Accept the proposed financial guarantee of approximately $11.6 million through 2 proposed instruments, namely, a cash account for $1 million and a line of credit for $10.6 million; accept CLSI's plan to increase the amount of the instruments annually, starting in 2023; and direct CLSI to provide the original instruments within 90 days of the issuance of a decision on this matter.

This CMD has 2 parts. Part One presents a summary of CNSC staff's assessment of CLSI's licence application and past performance since 2012, and staff's conclusion and recommendations in respect of CLSI's request for renewal of the synchrotron operating licence.

Part Two provides the documentation pertaining to this hearing, including the proposed licence, the current licence, and the licence conditions handbook (LCH). A proposed LCH that accompanies the proposed licence is also included for information only. Referenced documents in this CMD are available to the public upon request.

PART ONE

This Commission Member Document (CMD) is presented in 2 parts.

Part One includes:

1. An overview of the matter being presented
2. Overall conclusions and overall recommendations
3. General discussion pertaining to the safety and control areas (SCAs) that are relevant to this submission
4. Discussion about other matters of regulatory interest
5. Addenda material that complements items 1 through 4

Part Two provides all available information pertaining directly to the current and proposed licence.

1. Proposed licence PA1OL-02.00/2032
2. Current licence PA1OL-02.01/2022
3. Proposed changes to the current licence
4. Proposed licence conditions handbook

1. OVERVIEW

1.1 Background

Canadian Light Source Incorporated (CLSI) is licensed to operate a Class 1B particle accelerator facility, under licence PA1OL2.01/2022. The Canadian Light Source (CLS) synchrotron facility is located in Saskatoon, on Treaty 6 territory, the traditional territory of Cree peoples, and the homeland of the Métis Nation of Saskatchewan. CLS is owned by the University of Saskatchewan, and is located on the University of Saskatchewan campus

Figure 1 Aerial view of the CLS facility and surrounding area. Source: CLSI.

The particle accelerator operating licence, PA1OL-2.01/2022 authorizes CLSI to operate its synchrotron facility until May 31, 2022. CLSI has been a licensee since 2000. Since the issuance of the most recent licence in 2012, the Commission has granted one licence amendment and several changes in licensing basis. These changes are summarized in Table 1.

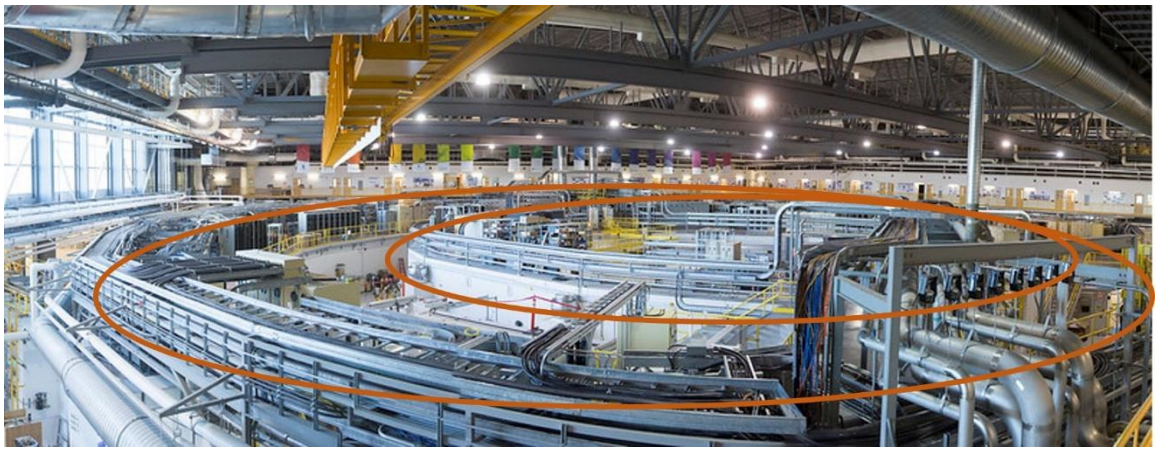
Table 1 - Summary of CLSI licensing actions 2012-2021

CMD	Licensing Action Summary
CMD15-H102	Licence amendment to add a radiation laboratory to the licence and to permit the processing of used targets to

	recover non-radioactive ^{100}Mo for medical isotope production.
CMD17H-112	a change in licensing basis to permit top-up operation
CMD21H-109	change in licensing basis to permit occupancy of a portion of the subbasement for the Electron Source Laboratory (ESL)

The CLS produces intense, focused light that is used for scientific experiments. Three major accelerator systems are the main components of the synchrotron. First, the electron gun and associated linear accelerator accelerate electrons to 250 MeV. The electrons are then injected into the booster ring, which further accelerates the electrons to 2.9 GeV. Finally, the storage ring keeps the electrons circulating at 2.9 GeV. Two transfer lines move the electron beam from the linac to the booster ring, and from the booster ring to the storage ring. Magnetic devices produce synchrotron light as they bend the path of the electrons circulating in the storage ring. The spectrum of the light produced ranges from infrared through visible, ultraviolet, and x-rays. Experiments take place in shielded beamlines that are tangential to the storage ring. The experiments support research in diverse fields such as biology, materials research, agriculture, atomic and molecular science, earth science, biomedical research, pharmacology and electronics.

Figure 2 - View of the CLS from the mezzanine level. The booster ring (inner circle) and storage ring (outer circle) shielding structures are shown. Credit: CLSI.



At the CLS, the main radiation hazard is gamma rays and neutrons produced by when electrons in the accelerators colliding with air or components of the accelerators less than a second after the interaction. This prompt radiation produces dose rates in excess of 1 mSv/h in the areas housing the three accelerator

systems and associated electron transfer lines. These areas are designated prohibited access areas, and are divided into 9 Access Control Interlock Systems (ACIS) zones. CLSI staff search and secure each ACIS zone prior to beam-on. The ACIS guard all potential entry points to the accelerators or beamlines by automatically shutting off the beam in the area if access is attempted.

Permanent shielding reduces the dose rates to acceptable levels in areas that are accessible when the beam is on. Active Area Radiation Monitoring System (AARMS) stations monitor the dose rates throughout the areas of the facility that are accessible during beam on and report the doses to the control room. The AARMS have pre-set alarm thresholds, and shut down the beam injection into the booster ring if the integrated dose exceeds pre-set thresholds.

When the beam is off, residual dose rates are present in the accelerator areas due to the beam activating materials in the accelerator components. The radiation hazards from activated materials are significantly less than the dose rates present when the beam is on. The activity of the activated material decreases over time due to radiation decay. Activated components are contained within the accelerator or associated structures. They are not dispersible and cannot be released to the air. Activated components do not contain fissile material and do not require cooling or other special storage conditions.

Access to the accelerator areas is only permitted when the beam is off. Procedural controls outlined in CLSI's Radiation Protection and Control Manual control doses to those who access the area.

1.2 Highlights

CLSI's Licence Application Requests

In January 2021, CLSI submitted an application for the renewal of its particle accelerator operating licence. CNSC staff assessed all aspects of CLSI's licence renewal application for the renewal of PA1OL-02.01/2022 for a 10-year period. CLSI is requesting the following:

- to operate the particle accelerator with no changes in operational limits
- to possess, process, transfer, use, import and store the nuclear substances that are associated with the operation of the particle accelerator
- to update its financial guarantee to $11,599,000 through two proposed instruments: a cash account for $1,050,000 and a line of credit for $10,549,000, and stepped annual increases to the instruments from 2023-2026 to meet the inflationary increases in decommissioning costs.

CNSC staff assessment of CLSI's application

CNSC staff assessed CLSI's licence renewal application for operation of a particle accelerator under subsection 24(4) of the Nuclear Safety and Control Act (NSCA). This assessment determined whether CLSI has met all the regulatory requirements, and whether its performance over the licensing period has been acceptable.

Based on compliance verifications conducted at CLSI by CNSC staff during the June 1, 2012 to June 30, 2021 review period, CNSC staff have confirmed that CLSI continued to improve the safety performance of the facility. CNSC staff rated CLSI's performance for 13 safety and control areas (SCAs) as satisfactory. CLSI's overall performance ratings are shown in Table 2.2.

Requested Licence Period

CLSI has requested a 10 year licence term, consistent with the current licence. CLSI is required by its licence to report on its performance in the Annual Compliance Report. The CNSC has a standardized licence and licence conditions handbook (LCH) framework which provides for effective regulatory oversight of operating facilities. The documents listed in the LCH must be provided to the CNSC for review and acceptance prior to implementation. CNSC staff verify compliance through desktop reviews, inspections and event reviews. CNSC staff report on CLSI's performance and the CNSC's oversight activities through the Regulatory Oversight Report for Class1B Accelerators. CNSC staff maintain adequate oversight of CLSI, and CNSC staff recommend that the Commission accept CLSI's request for a 10-year licence to operate the synchrotron facility.

Financial Guarantee

CLSI is also requesting approval of an updated financial guarantee, totaling $11,599,000. The financial guarantee is in the form of a cash account for $1,050,000 and a line of credit for $10,549,000. The proposed financial guarantee adequately covers the decommissioning costs up to 2022. CLSI has proposed adding more funds to match the anticipated costs of decommissioning on an annual basis in 2023, 2024, and 2025. The proposed funding plan, with total amount of the guarantee for each year is being proposed to the Commission for approval. CNSC staff propose that the Commission delegate authority for approving the annual increases to the financial guarantee value to CNSC staff, as long as the increases match or exceed the total amount indicated in the funding plan approved by the Commission. Any change in instrument type, or decrease from the amounts listed in this CMD would be put before the Commission for decision. .

1.3 Overall Conclusions

CLSI has programs, resources, and measures in place to ensure the health and safety of persons and the environment and of the measures related to security and Canada's international obligations during the proposed licence period. CLSI has met regulatory requirements and its performance has been satisfactory throughout the licensing period. CLSI's proposed financial guarantee amounts and instruments are acceptable to CNSC staff.

1.4 Overall Recommendations

CNSC staff recommend the Commission:

1. Conclude, pursuant to paragraphs 24(4)(a) and (b) of the Nuclear Safety and Control Act in that CLSI:
    i. **Is qualified** to carry on the activities authorized by the licence
    ii. **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
2. Renew the Class 1B Particle Accelerator Operating Licence PA1OL-02.01/2022 for a period of 10 years commencing on June 1 2022 and ending on May 31, 2032, as proposed.
3. Delegate authority as set out in section 4.6 of this CMD.
4. Approve CLSI's proposed Financial Guarantee amount and instruments.

2. MATTERS FOR CONSIDERATION

2.1 Environmental Review

CNSC staff reviewed the licence application to determine what type of environmental review was required to be conducted, if applicable. CNSC staff determined that an impact assessment under the Impact Assessment Act (IAA) was not required because the proposed activities are not captured in the IAA's Physical Activities Regulations nor are they considered a project on federal lands.

CNSC staff conduct Environmental Protection Reviews (EPRs) for all licence applications with potential environmental interactions, in accordance with CNSC's mandate under the NSCA and associated regulations. The EPRs help support the Commission's conclusion on whether the proposal provides adequate protection of the environment and the health of people.

An EPR was conducted for this licence application. More information on CNSC staff's EPR can be found in section 3.6 of the CMD. CNSC staff conclude that the information provided by CLSI regarding environmental protection is sufficient to meet the applicable regulatory requirements under the NSCA and associated regulations for particle accelerator licences.

CNSC staff will continue to verify and ensure that, through ongoing licensing and compliance activities and reviews, the environment and the health of persons are protected and will continue to be protected over the proposed licence period.

2.2 Relevant Safety and Control Areas (SCAs)

The functional areas of any licensed facility or activity consist of a standard set of safety and control areas (SCAs). Each SCA is comprised of "specific areas" of regulatory interest; however, the specific areas associated with each SCA vary between facility types. See Appendix D, "Safety and Control Framework", for further information about SCAs.

Table 2.1 lists the CLSI risk ranking for each SCA, indicates whether they are relevant for this CMD, and the overall compliance with regulatory requirements for implementation at CLSI. Appendix A provides additional information related to "Risk Ranking" and Appendix B further defines the "Rating Levels".

Table 2.2- Safety and Control Areas, their risk rankings and ratings for CLSI.

Functional Area	Safety and Control Area	Risk Ranking *	Relevant to this CMD?	Rating Level **
Management	Management System	H	Yes	SA
	Human Performance Management	H	Yes	SA
	Operating Performance	H	Yes	SA
Facility and Equipment	Safety Analysis	H	Yes	SA
	Physical Design	H	Yes	SA
	Fitness for Service	M	Yes	SA
Core Control Processes	Radiation Protection	M	Yes	SA
	Conventional Health and Safety	M	Yes	SA
	Environmental Protection	L	Yes	SA
	Emergency Management and Fire Protection	L	Yes	SA
	Waste Management	L	Yes	SA
	Security	L	Yes	SA
	Safeguards and Non-Proliferation	n/a	No	-
	Packaging and Transport	L	Yes	SA
	Indigenous Consultation	-	Yes	-

*H = High, M = Medium, L= Low, SA= Satisfactory

**Overall rating level for the current licence period 2012-2021

2.3 Other Matters of Regulatory Interest

The following table identifies other matters that are relevant to this CMD.

Table 2.3 Other matters of regulatory interest relevant to this CMD

OTHER MATTERS OF REGULATORY INTEREST	
Area	**Relevant to this CMD?**
Other Consultation	No
Cost Recovery	No
Financial Guarantees	Yes
Improvement Plans and Significant Future Activities	No
Licensee's Public Information Program	Yes
Nuclear Liability Insurance	No

The relevant "other matters" of regulatory interest are discussed in section 4.

2.4 Regulatory and Technical Basis

The regulatory and technical basis for the matters discussed in this CMD arise directly from the *Class I Nuclear Facility Regulations* and the *General Nuclear Safety and Control Regulations* (GNSCR) as well as other regulatory requirements associated with the NSCA. Further information regarding the regulatory and technical basis for the matters discussed in this CMD are provided in appendix C of this document.

3. GENERAL ASSESSMENT OF SCAS

CNSC staff's assessments provided in the following sections are based on a comprehensive review of CLSI's past performance and a thorough evaluation of the safety and control measures to be implemented for the next licence period, if approved. These areas are outlined in CLSI's licence application and supporting documentation submitted for this application.

The CNSC implements a risk-informed approach in the regulation of nuclear facilities and activities. The depth of regulatory reviews of the SCAs and the baseline frequency of regulatory compliance activities is informed by the risk ranking of that SCA (section 2.2, table 2.1).

The specific areas that comprise the SCAs for this facility or activity type are identified in Appendix D, section D.1. If specific areas are listed for an SCA in section 3, then the related details about them are provided in Appendix D.2 to this document. If specific areas are not listed for a given SCA in section 3, then a decision has been made to encompass them in an overall approach to that SCA. The assessment period referenced within this report is from June 2012 to September 2021.

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.

The specific areas that comprise this SCA at CLSI are:

- Management System and Organization
- Performance Assessment, Improvement and Management Review
- Operating Experience (OPEX)
- Change Management, Configuration Management and Records Management
- Safety Culture
- Management of Contractors

3.1.1 Trends

The following table indicates the overall rating trends for the Management System over the current licensing period:

MANAGEMENT SYSTEM SCA								
Overall Compliance Ratings								
2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
SA	BE	SA	SA	BE	SA	SA	BE	SA

Comments

When the licence was issued in 2012, CLSI was in the midst of addressing actions resulting from a 2011 Management Systems inspection. CNSC staff found during a subsequent follow-up inspection in 2013 that the actions from the 2011 were not addressed satisfactorily, resulting in performance BE. CNSC staff continued to assess CLSI's follow up actions resulting from the 2013 inspection and deemed the progress satisfactory.

In 2016 during the next regularly scheduled inspection, CNSC staff found that CLSI's progress in addressing some of the 2013 findings was too slow. CNSC staff were also concerned about adherence to procedures. These findings resulted in a BE rating for 2016. . The CNSC introduced CSA N286-12 *Management System Requirements for Nuclear Facilities* as a new regulatory requirement for CLSI in 2016, with full implementation required in 2018. CNSC staff assessed CLSI's progress toward closing the 2016 actions and working towards N286-12 compliance as satisfactory in 2017 and 2018.

In 2019, CNSC staff performed an inspection and found that CLSI had not implemented N286-12 across all activities, resulting in a BE rating. CLSI was issued several notices of non-compliance, and CNSC staff opted to close those actions by inspection in 2020. At the 2020 follow-up inspection

CNSC staff observed that CLSI's performance had improved sufficiently to warrant a satisfactory rating.

3.1.1 Discussion

From 2012- 2016, the management system requirements were based on the licence condition handbook compliance verification criteria, with no external standard referenced. In 2016, CSA N286-12 *Management Systems Requirements for Nuclear Facilities* was introduced as a licensing basis publication. At the time of introduction, CLSI committed to being fully compliant with the N286-12 by 2018.

CNSC staff conducted a compliance verification inspection in 2019 and determined that although CLSI had a documented management system that met the regulatory requirements, CLSI had not implemented it across the entire organization. CNSC staff also noted CLSI lacked its top management's support in the push for N286-12 compliance. CNSC staff issued a BE rating to CLSI in 2019 based on the results of the inspection. CLSI provided an action plan to CNSC staff to show how it would address the non-compliances issued in the 2019 inspection. CNSC staff continued to monitor the progress of CLSI's submitted action plan and followed up with a remote inspection in September 2020 to verify the implementation of the outstanding actions prior to closure. CNSC staff observed significant improvements overall, and noted some deficiencies in problem identification and resolution, supply chain and management oversight. CNSC staff closed many of the 2019 actions as a result of the 2020 inspection, and issued other notices of non-compliance. CNSC staff have accepted CLSI's action plan for all notices of non-compliance, and will continue to monitor the implementation of the remaining corrective actions for completion. At time of writing, 2 notices of non-compliance are open. CLSI has made significant progress towards closing the open actions. The risk significance of the open actions are low. CNSC staff will plan compliance activities in the next licensing period to focus on the deficiencies noted.

3.1.2 Summary

A summary of the licensee's performance, challenges and proposed improvements are presented in the following subsections.

3.1.2.1 Past performance

Management System and organization

CNSC staff determined that Canadian Light Source Incorporated (CLSI) has a management system that meets the requirements of CSA N286-12, *Management*

System requirements for Nuclear Facilities. CLSI's governance documents adequately define and document the organizational structure, roles and responsibilities.

CLSI's Management System describes the structure of CLSI documentation, processes, and expectations. CLSI's Quality Manual provides a description of how CLSI's business works. CNSC staff reviewed licensee documents listed in the LCH during desktop reviews, and assessed implementation of the processes during inspections. CNSC staff concluded that CLSI has a process in place to continually improve the management system documentation.

As a result of the follow-up inspection in 2019, CLSI incorporated comments from the CNSC staff for improving the program documents to better align with the regulatory requirements. CLSI addressed and incorporated CNSC staff's comments in the document following the inspection.

Performance assessment, improvement and management review

CNSC staff determined that CLSI programs on performance assessment and management review met the requirements of CSA N286-12, however, the implementation phase of the program is still in progress. In the 2019 inspection, CNSC staff identified non-compliances related to CLSI's failure to conduct self-assessments consistently across the organization; for not conducting independent assessments and for not conducting management reviews in accordance with its governance. CLSI submitted an action plan to correct the deficiencies and the CNSC accepted the action plan and monitored the progress through status reports from CLSI at set intervals.

CNSC conducted a remote inspection in September 2020 to follow-up on the implementation of the corrective actions resulting from the 2019 inspection. CNSC staff are satisfied with the improvements implemented into the self- and independent assessments. However, it was not evident to the CNSC staff that CLSI top management had evaluated the effectiveness of the management system to achieve its planned results in accordance with its own governance. CLSI staff have committed to an action plan and provided the CNSC staff with several progress updates since the inspection. The most recent update, provided in August 2021, was assessed by CNSC staff and found to be acceptable. CNSC staff have requested an additional update in January 2022. This final update will mean an entire year of self- and independent assessments can be assessed by CNSC staff in order to gauge CLSI's progress in implementing the management review against the regulatory requirements.

Operating Experience (OPEX)

CNSC staff determined that CLSI has an OPEX program as outlined in its governance. CNSC staff noted that CLSI addresses lessons learned from problem identification and from events. CNSC staff have not assessed the implementation of the OPEX program by inspection since the adoption of N286-12. CNSC staff

perform desktop reviews of events and reports to assess the effectiveness of the OPEX program.

CNSC staff will verify the CLSI OPEX program in future compliance verification activities.

Change Management, Configuration Management and Records Management

CNSC staff determined that change management, configuration management and records management at CLSI met the regulatory requirements in 2020.

During the 2019 inspection, CNSC staff observed that engineering changes were not always completed in accordance with the requirements of the CLSI procedure. In addition, changes affecting the management system such as organizational changes, introduction of a new system, program or processes were not managed according to a change process. CLSI has now corrected this deficiency to the satisfaction of CNSC staff. CNSC staff will continue to monitor the improvements in future compliance activities.

CLSI has a configuration management program in place for managing changes of safety system components.

CLSI's records management program meets the regulatory requirements.

Management of Contractors

CNSC staff determined that CLSI has a process in place for management of contractors and supply chain; however, it is not fully in compliance with the requirements of CSA N286-12.

In 2019, CNSC staff identified deficiencies related to supply management program where CLSI did not perform supplier audits. CLSI was in the process of updating its internal governance regarding supplier acceptability and evaluation process to meet the requirements of CSA N286-12 at the time of the inspection. CLSI implemented corrective actions such as making improvements to documents related to supply chain management and specifying quality assurance requirements for non-engineering service contracts. However, in the follow-up inspection in September 2020, CNSC staff observed that there was no information or acceptance criteria for qualification and acceptance of vendors. CNSC staff issued a notice of non-compliance to correct this deficiency. CNSC staff has accepted the action plan and will monitor the implementation of the remaining corrective action over the next licensing period. An in-depth contract management inspection will be on the agenda for the next management system inspection to verify the whole scope of the supply chain element of the standard.

3.1.2.2 Regulatory Focus

CNSC staff's compliance activities in the management system SCA has focused on N286-12 implementation. CLSI currently has 2 open notices of non-compliance (NNC) related to management systems. These NNCs direct CLSI to ensure top management performs its critical periodic oversight activities and performance assessment of its programs and overall management system to

ensure it achieve the planned results consistently and safely, and to develop acceptance criteria for supplier acceptability.

3.1.2.3 Proposed Improvements

In the next licensing period CNSC staff will focus compliance activities on the OPEX program, procurement, and top management support at CLSI. Top management support and teamwork at CLSI is key in ensuring that the management system processes are applied to all licensed activities to meet objectives and requirements.

3.1.3 Conclusion

Despite some weaknesses identified in the September 2020 inspection, CNSC staff have noted progress in the implementation of the CLSI's management system since the inspection in July 2019. CLSI's 2 open notices of non-compliance are not safety-significant and CLSI has made considerable progress toward their closure.

The CLSI executive team has launched a number of initiatives for ongoing development, implementation and improvement of its management system.

Additionally, CLSI have allocated resources and prioritized its commitments, and taken actions to ensure consistency in carrying out the management system processes across the organization.

CNSC staff conclude that CLSI is performing satisfactorily with respect to the management system SCA.

3.1.4 Recommendation

CNSC staff recommend that licence condition 2.1 be retained.

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.

The following specific areas apply to CLSI:

- Personnel training
- Human Performance Management
- Human Performance Program
- Work Organization and Job Design
- Fitness for Duty

Although these specific areas are applicable to the CLSI facility, the CMD will focus on Personnel Training, Human Performance Management, and Work Organization and Job Design, in order to provide a more integrated picture of CLSI's performance.

3.2.1 Trends

The following table indicates the overall rating for the Human Performance Management over the current licensing period:

HUMAN PERFORMANCE MANAGEMENT								
Overall Compliance Ratings								
2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
SA	BE	SA	BE	SA	SA	SA	SA	SA

Comments

CLSI has implemented and maintains a Systematic Approach to Training (SAT). The initial challenges of implementing a SAT that met the compliance verification criteria of the LCH in 2013 and the delay of completion of the associated corrective actions to meet the requirements of REGDOC-2.2.2 *Personnel Training* in 2015, both resulted in a BE rating. Since then the trend for this SCA has remained stable and consistently rated as SA. Recently, CLSI has assigned additional resources to update and improve the training programs for specific operations groups.

CLSI has moved towards a more integrated approach to safety during this licensing period, such as linking the safety documents to the Quality Manual, and implementing practices that aim to improve the focus on safety.

The updated problem identification and resolution process provides information that enables CLSI to learn and improve. While there have been short periods of non-compliance with minimum staff complement, these cases were quickly identified and resolved.

The licensee has been improving aspects of work organization and job design and fitness for duty specific areas to maintain minimum staff complement and to support conformance with its hours of work requirements.

3.2.2 Discussion

CLSI is required to ensure there is a sufficient number of qualified workers to carry on the licensed activity safely. Every person is required to use health and safety-related equipment, and comply with measures established by CLSI related to health, safety, security and the environment. Workers must take all reasonable precautions to ensure their own safety and the safety of others, and inform CLSI of a significant increase in risk to the environment, health and safety or failure to comply with the Act, regulations or the licence. CLSI must implement and

maintain training programs for workers in accordance with the requirements set out in REGDOC-2.2.2 *Personnel Training*.

3.2.3 Summary

A summary of the licensee's performance, challenges and proposed improvements are presented in the following subsections.

3.2.3.1 Past performance

Personnel Training

In 2013, CLSI commenced implementing a Systematic Approach to Training (SAT) that met the compliance verification criteria of the LCH. The initial challenges of implementing a SAT that met the compliance verification criteria of the LCH in 2013 and the delay of completion of the associated corrective actions to meet the requirements of REGDOC-2.2.2 *Personnel Training* in 2015, both resulted in a BE rating. A SAT was established and fully implemented for safety-significant roles to ensure the provision of trained, qualified and competent workers, by the end of 2015. Health and Safety training at CLSI ensures that all personnel are competent to work safely. The requirement for specific safety training courses are determined by the SAT.

CLSI maintains training governance documentation and has implemented training procedures that meet the requirements of REGDOC-2.2.2 *Personnel Training*.

CLSI continues to demonstrate several best practices in timely, accessible training, with the majority of training required to access the site available to researchers and visitors online, prior to their arrival on site.

CLSI added additional resources to its training program; a Training Specialist position was introduced to oversee the implementation of training and qualification programs at CLSI.

During the current licensing period CNSC staff conducted 3 inspections and numerous document reviews of the training program at CLSI. Seven action notices pertaining to: development and implementation of training system manual, SAT procedures, training change management procedures and implementation of a job hazard analysis process resulted from the 3 inspections performed. Following the corrective actions taken and demonstrated by CLSI, all action notices were closed.

Human Performance Program

This specific area considers all practices and activities that aim to improve human performance, and how these are planned, managed, implemented, controlled, and monitored.

CLSI has moved towards a more integrated approach to safety during this licensing period, such as linking safety documents to the Quality Manual. Safety documents now sit above other aspects of the management system to demonstrate the importance of integrating safety in all of CLSI's processes.

Events in this licensing period relating to safety culture include the disconnection of the oxygen monitoring horn event initially reported in 2012 and again in 2014. In 2019, a vestibule door lock was bypassed with a piece of paper. CNSC staff review CLSI's actions taken to prevent recurrence of these events. Practices that aim to improve the focus on safety have been implemented, such as making safety a priority agenda item in the managers meetings, encouraging and enabling staff to identify and report hazards, and a focus on completing work requests. CLSI undertook an external Safety Culture assessment in 2021, and the results have been presented to the executive team for consideration.

The implementation of CSA N286-*12 Management System Requirements for Nuclear Facilities* has resulted in improvements to the problem identification and resolution process. CLSI has moved from only identifying direct causes of events to identifying root causes employing Taproot ®, a root cause analysis methodology, and training several staff in its use. CLSI also trained select staff in cause analysis methodology in 2020.

Other human performance-related initiatives in this licensing period include:

- in 2014, the CEO drove an initiative to remove clutter from the experimental floor and to improve housekeeping. Orderly, less cluttered workspaces can result in decreased fire hazards and fewer slip and trip accidents.
- in 2019, the Field Level Hazard Assessment process was implemented. This enables personnel to review the work to be done, to identify any safety issues and to raise and resolve them before starting work.

Work Organization and Job Design

While there have been short periods of non-compliance with minimum staff complement, these cases were quickly identified and resolved. Operators were retrained and reminded that if the full minimum staff complement is not on site, the beam must be turned off.

In 2019, CLSI altered its staffing approach, creating full time operator positions that can act in the operator and floor coordinator roles. Staff hired as operators are also trained in development mode duties, to increase the number of people who can take on this role to maintain minimum staff complement. In development mode, the synchrotron may be set up differently than during normal operations to test new components, new configurations, or to commission beamlines. Only

workers who have undergone the development mode training can be counted as part of the minimum shift complement during development mode shifts.

3.2.3.2 Regulatory Focus

There are currently no open NNC's in the human performance management SCA.

3.2.3.3 Proposed Improvements

There are no proposed improvements for this SCA.

3.2.4 Conclusion

Overall, CLSI has strengthened the training system and associated training programs and provided a robust methodology to assure the competence of its operational staff.

CLSI has been improving aspects of work organization and job design and fitness for duty specific areas to maintain minimum staff complement and to support conformance with its hours of work requirements.

The licensee has made improvements to the problem identification and resolution process.

CNSC staff conclude that CLSI has met regulatory requirements and is performing satisfactorily with respect to this SCA.

3.2.5 Recommendation

CNSC staff recommend that the current licence conditions associated with the Human Performance Management, LC 3.1 and 3.2, be retained.

3.3 Operating Performance, Safety Analysis, Physical Design and Fitness for Service

This section groups together several SCAs: safety analysis, physical design, fitness for service, and operating performance. Addressing these SCAs together provides a more integrated picture of CLSI's performance over the licensing period.

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

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.

Physical Design 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.

Fitness for Service 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.

3.3.1 Trends

The following table indicates the overall ratings for the safety analysis, physical design, fitness for service, operating performance SCAs over the current licensing period:

	Overall Compliance Ratings								
	2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
Safety Analysis	SA	SA	FS	SA	SA	SA	SA	SA	SA
Physical Design	SA	SA	FS	FS	FS	FS	FS	FS	SA
Operating Performance	SA	SA	SA	SA	SA	SA	FS	FS	SA
Fitness for Service	SA	SA	FS	FS	FS	FS	FS	FS	SA

Comments

CLSI's performance in the safety analysis, physical design, operating performance and fitness for service SCA's has been satisfactory over the course of the licensing period. Changes between FS and SA reflect changes in the CNSC's grading methodology and does not reflect an increase or decrease in CLSI's performance. CNSC staff verify compliance through inspections and desktop reviews.

CLSI has a mature program that ensures the facility is operated according to the limits outlined in the safety analysis. Engineered controls are designed according to the physical design program. CLSI maintained and calibrated key equipment and systems to ensure they can perform their protective functions.

3.3.2 Discussion

Table 3.4- Main hazards, mitigation measures and supporting programs at CLSI.

CLS State	**Hazard**	**Mitigation Measures**	**Supporting Programs**

On	Prompt radiation: very high radiation dose rates (>1000 µSv/h)	Access Control Interlock Systems (ACIS) for 3 accelerators, beamlines Active Area Radiation Monitoring System (AARMS) Shielding	Verification and validation program for ACIS, AARMS Calibration program Physical Design program Controlled work program Dosimetry program
Off	Residual radiation: radiation dose rates < 100 µSv/h that decay over time due to activated components	Active Area Radiation Monitoring System (AARMS) Shielding Procedural controls: Surveys, radiation work permits, delaying of work	Verification and validation program for ACIS, AARMS Calibration program Controlled work program Dosimetry program
The Safety Analysis underpins the hazard analysis and mitigation measures.			

CLSI maintains a safety analysis, the Safety Report, which identifies the hazards of the facility and their mitigation measures. Operating Performance, Fitness for Service and Physical Design all center on the mitigation measures for the main hazard at CLS, high radiation doses.

CLSI is required to keep the safety analysis up to date. CLSI revised its Safety Report once during the licence period, after a licensing basis change request was granted by the Commission in 2017 (CMDH17-112) to permit top-up operation of the synchrotron.

Access Control Interlock Systems (ACIS) are one of the main engineering systems in place to protect people at CLS from radiation. The ACIS for the accelerators and beamlines are designed according to CLSI's design program. The Active Area Radiation Monitoring System (AARMS) stations continuously monitor radiation levels at various points in the facility, and shut down the beam if they detect an increase in radiation levels above a certain pre-set threshold. The

AARMS measurements is an ongoing validation of the adequacy of CLS's shielding. CNSC staff confirmed through compliance activities that CLSI's maintenance, calibration, and verification and validation programs are strong, and allow the ACIS and AARMS to continue to meet their intended functions.

CLSI is required to implement and maintain programs for operating the CLS and operating and commissioning beamlines. CLSI is also required to report unplanned events at the facility and take necessary corrective actions to prevent recurrence.

CNSC staff review all reported events to identify if there are any regulatory concerns and report significant events at public meetings of the Commission. Reported events from the licensing period include spills, injuries, a COVID-19 outbreak, and violations of operational policies. Section 3.5 discusses injuries and near-misses as part of the Conventional Health and Safety SCA.

CNSC staff review and accept CLSI's specific programs for safe facility operation, including management of controlled work, and problem identification and resolution. CNSC staff also assess CLSI's compliance with these core processes through Management Systems desktop reviews and inspections, discussed in Section 3.1.

CNSC staff have confirmed that CLSI's procedures adequately describe the operation of the facility, and that CLSI operated in accordance with its operating procedures throughout the licensing period. CLSI reported several events to the CNSC where operating policies were violated for short periods of time. For each reported incident, CNSC staff assessed CLSI's immediate actions and follow up actions taken to prevent recurrence. CNSC staff confirm that CLSI took effective measures to prevent repeat incidents and address the factors that led to the events. These events are discussed further in Section 3.2.

CNSC staff conclude based on its review of the submitted application and supporting documents that CLSI has maintained a safety analysis, implemented an effective operating program in order to ensure that licensed activities are conducted safely and in accordance with regulatory requirements.

3.3.3 Summary

A summary of the licensee's performance, challenges and proposed improvements are presented in the following subsections.

3.3.3.1 Past performance

CNSC staff assessed CLSI's performance in the operating performance, safety analysis, physical design and fitness for service SCAs in several ways over the licensing period:

- CNSC staff performed desktop reviews of events and annual reports;
- CNSC staff reviewed, provided comments, and when appropriate, accepted CLSI documents listed in the LCH; and
- CNSC staff performed SCA-specific compliance activities at CLSI as per Table 3.5.

Table 3.5- Safety analysis, operation performance, fitness for service and physical design specific inspection activities at CLSI from 2012-2021.

SCA	Year(s) SCA-specific inspections performed
Safety Analysis	Compliance with the safety analysis SCA is assessed by performing desktop reviews of the outputs of the safety analysis, and SCA-specific inspections of Operating Performance, Fitness for Service, Radiation Protection, Fire Protection.
Operating Performance	2012, 2018
Fitness for Service	2012, 2021
Physical Design	Compliance with the physical design SCA is assessed by performing SCA-specific inspections of Fitness for Service, Radiation Protection

Safety Analysis

Based on the results of desktop reviews and compliance assessments of related SCAs, CNSC staff rated CLSI's overall performance in the Operating Performance, Safety Analysis, Physical Design and Fitness for Service SCA are satisfactory for the current licensing period.

3.3.3.2 Regulatory Focus

There are no challenges with respect to the safety analysis, operating performance, fitness for service, physical design SCAs. There are no open NNC's relating to these SCAs.

3.3.3.3 Proposed Improvements

CLSI has proposed adding an Electron Source Lab to the existing facility in the coming years. This multiphase project required a change to the Class IB licensing basis, granted in September 2021 (CMD 21-H109), and subsequent changes to the Facility Safety Report, ACIS design, and revision of CLSI documents included in

the LCH are ongoing. CNSC staff are in the process of reviewing, providing comments and, if appropriate, accepting the modifications made to the safety analysis as the Electron Source Lab project gets underway.

3.3.4 Conclusion

CNSC staff confirm that CLSI meets regulatory requirements in the operating performance, safety analysis, physical design, and fitness for service SCAs. CLSI's performance in these SCAs is satisfactory.

3.3.5 Recommendation

CNSC staff recommend the following for the draft CLSI licence:

Operating performance: CNSC staff recommend that licence conditions 4.1, 4.2, and 4.4 be retained without change, and licence condition 4.3 be removed. Part Two of this CMD describes the rationale and assessment of the proposed change.

Safety analysis: CNSC staff recommend that licence conditions 5.1, 5.2, and 5.3 be retained without change.

Physical design: CNSC staff recommend that the licence condition 6.1 be retained without change.

Fitness for service: CNSC staff recommend that the licence condition 7.1 be retained without change.

3.4 Radiation Protection

The Radiation Protection Safety and Control Area (SCA) covers the implementation of a radiation protection program in accordance with the *Radiation Protection Regulations*. The program must ensure that contamination levels and radiation doses received by individuals are monitored, controlled and maintained As Low As Reasonably Achievable (ALARA).

The specific areas that comprise the Radiation Protection SCA at CLSI are as follows:

- Application of ALARA
- Worker Dose Control
- Radiation Protection Program Performance
- Radiological Hazard Control

3.4.1 Trends

The following table provides the overall rating for the Radiation Protection SCA over the current licensing period:

RADIATION PROTECTION								
Overall Compliance Ratings								
2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
SA	SA	FS	FS	FS	FS	FS	FS	SA
Comments								
CLSI has implemented and maintained an effective radiation protection program that protects the health and safety of workers, as required by the *Radiation Protection Regulations*. Over the current licencing period, no worker received a radiation dose in excess of regulatory limits as a result of the licensed activities conducted at CLSI. Changes between FS and SA reflect changes in the CNSC's grading methodology and does not reflect an increase or decrease in CLSI's performance.								

3.4.2 Discussion

The CNSC requires CLSI to implement a radiation protection (RP) program. As part of that program, CLSI must also keep effective and equivalent doses received by and committed to persons ALARA, taking into account social and economic factors, through the implementation of:

- management control over work practices,
- personnel qualification and training,
- control of occupational and public exposures to radiation, and
- planning for unusual situations.

The *Radiation Protection Regulations* also prescribe dose limits for Nuclear Energy Workers (NEWs) and persons who are not NEWs.

3.4.3 Summary

A summary of the licensee's performance, challenges and proposed improvements are presented in the following subsections.

3.4.3.1 Past performance

Application of ALARA

CLSI's commitment to the ALARA principle has been demonstrated through the implementation of its RP program, outlined in the Radiation Protection and Control Manual. CLSI's application of ALARA includes management commitment and oversight, personnel qualification and training, and facilitation of ongoing dialogue and promotion of a culture of continuous improvement.

CLSI establishes annual radiation safety objectives. An Occupational Health Safety Committee has also been established at CLSI, consisting of both management and worker representatives. ALARA related initiatives are proposed and completed annually to improve monitoring and reduce worker exposures.

CNSC staff are satisfied with CLSI's efforts in applying the ALARA principle to keep doses to workers ALARA over the current licensing period.

Worker Dose Control

CLSI uses a combination of action levels, staff training and qualification, and dose management tools (work planning and management oversight) to ensure radiation doses to workers are controlled and kept ALARA. Engineered and administrative controls such as shielding are also established to ensure protection of workers at CLSI.

Radiological exposures associated with work activities at CLSI are primarily due to gamma/x-ray radiation emitted from activated components or prompt radiation when the accelerator is active.

CLSI's dosimetry program includes the ascertainment of dose for both Nuclear Energy Workers (NEWs) and non-NEWs. In 2018, CLSI restructured its personnel dosimetry assignment process, whereby many non-NEWs were no longer required to wear individually assigned dosimeters. Doses for these groups of individuals are now ascertained using CLSI's extensive network of passive area radiation monitors in various areas of the facility. CNSC staff assessed this proposed change prior to implementation and are satisfied that CLSI continues to retain adequate control over non-NEW dose. In 2019 for example, the passive area radiation monitors in occupied locations used to ascertain doses did not measure any doses above reporting thresholds.

External Dosimetry

Optically stimulated luminescent dosimeters (OSLDs) sensitive to gamma/x-ray, beta and neutron radiation are used to measure external whole body and skin doses. Due to the nature of the work at CLSI, the monitoring of extremity doses is

not required. Skin doses are essentially identical to whole body doses and are not reported separately. CLSI uses a CNSC licensed dosimetry service provider for all external dosimeters. CLSI's external dosimetry program is acceptable.

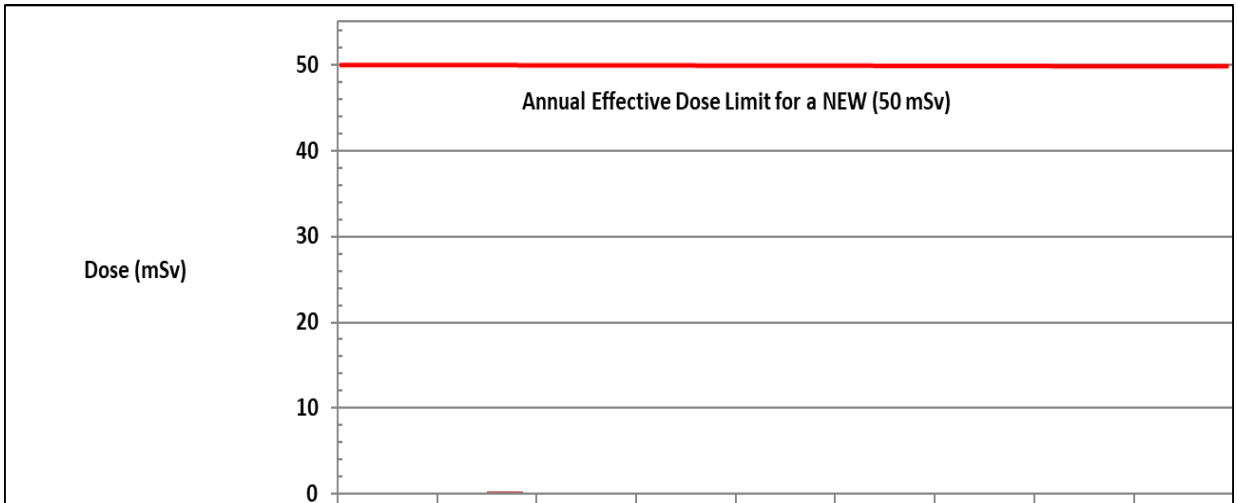
Effective Doses for NEWs and non-NEWs at CLSI

Workers who have the potential of receiving an occupational dose greater than 1 mSv in a one year dosimetry period are identified as NEWs at CLSI.

During the current licensing period, CLSI consistently maintained doses to NEWs and non-NEWs well below the applicable regulatory dose limits. Figure 3 and Figure 4 depict the total effective dose statistics for NEWs and non-NEWs monitored by personal dosimetry at CLSI over the current licensing period. The maximum annual effective dose received by a NEW during the current licensing period was 0.31 mSv, received in 2013, which is approximately 0.6% of the regulatory effective dose limit of 50 mSv in a one-year dosimetry period. The maximum annual effective dose received by a non-NEW during the current licensing period was 0.19 mSv, received in 2013, which is approximately 19% of the regulatory effective dose limit of 1 mSv in a one-year dosimetry period.

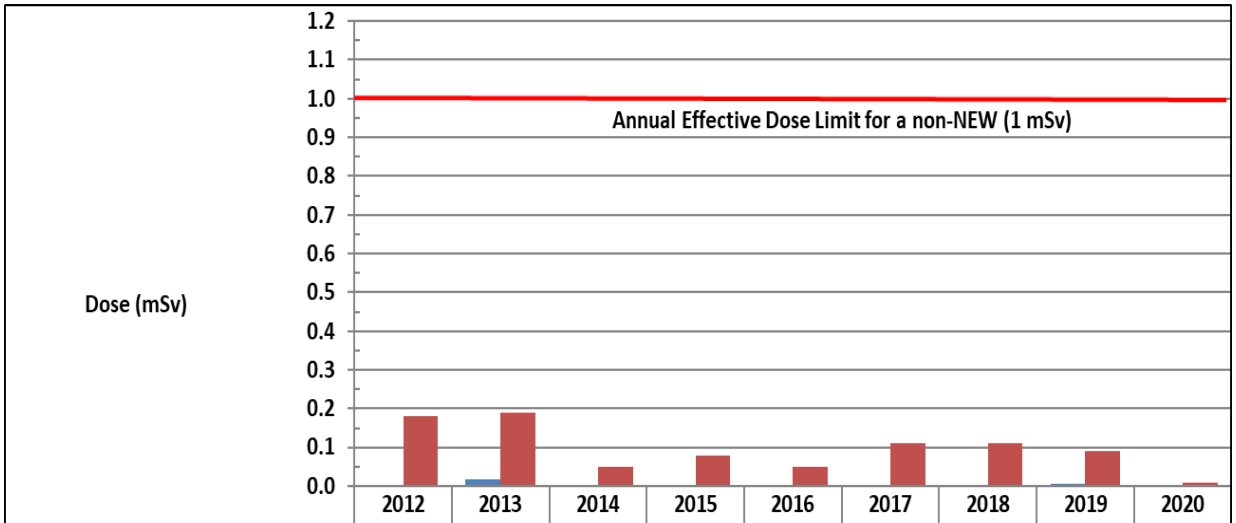
The trend of total effective doses received by NEWs and non-NEWs over the current licensing period have remained relatively constant and extremely low. The sharp decrease in monitored non-NEWs in 2019 is due to CLSI's 2018 decision to no longer assign individual dosimeters to all non-NEWs, as explained above.

Figure 3 - Total effective dose statistics for NEWs at CLSI, 2012-2020



	2012	2013	2014	2015	2016	2017	2018	2019	2020
Average Effective Dose (mSv)	0.041	0.061	0.007	0.006	0.007	0.004	0.008	0.024	0.01
Maximum Effective Dose (mSv)	0.23	0.31	0.14	0.19	0.12	0.08	0.17	0.15	0.17
Number of NEWs Monitored	152	151	154	165	174	176	171	139	131

Figure 4 - Total effective dose statistics for non-NEWs at CLSI, 2012-2020



	2012	2013	2014	2015	2016	2017	2018	2019	2020
Average Effective Dose (mSv)	0.003	0.016	0.001	0.000	0.001	0.004	0.002	0.006	0.001
Maximum Effective Dose (mSv)	0.18	0.19	0.05	0.08	0.05	0.11	0.11	0.09	0.01
Number of non-NEWs Monitored	1032	1111	921	844	955	1023	755	74	45

During the current licensing period, there have been two (2) five-year dosimetry periods. For the five-year dosimetry period from 2011 to 2015, the maximum cumulative effective dose received by a NEW at CLSI was 0.53 mSv. For the five-year dosimetry period from 2016 to 2020, the maximum cumulative effective dose received by a NEW at CLSI was 0.48 mSv. These radiation dose results both represent approximately 0.5% of the CNSC regulatory dose limit of 100 mSv in a five-year dosimetry period.

CNSC staff are satisfied that effective and equivalent doses to NEWs and non-NEWs at CLSI are being controlled below CNSC regulatory dose limits.

Radiation Protection Program Performance

CNSC Compliance Activities

CNSC staff assessed RP program performance at CLSI during the current licensing period through various compliance verification activities, including desktop reviews of annual compliance reports. All CNSC inspection activities cover aspects of the Radiation Protection SCA. In addition, 2 focused RP inspections at CLSI occurred in 2014 and early 2021. CNSC staff's assessment of CLSI's RP program performance identified areas of strength and some opportunities for improvement that are of low safety significance, such as aligning all RP program documentation with the amended *Radiation Protection Regulations*. As a result, CLSI implemented positive enhancements to the RP program and established appropriate corrective actions to address areas requiring improvement. CLSI has adequately addressed all action items raised during inspections focused on the Radiation Protection SCA over the current licensing period.

Radiological Action Levels

CLSI has established action levels for external whole body quarterly doses for both NEWs and non-NEWs, well below regulatory dose limits, that when reached, may be indicative of a potential loss of control for that specific parameter. These action levels serve as early warnings of conditions that warrant further investigation and reporting to the CNSC if reached. In addition, CLSI has also established a lower-tier internal administrative level, which is set well below the action level to provide very early warnings of potential concerns, and if reached, would trigger an internal investigation.

During the current licensing period, CLSI has not exceeded any of its radiation protection-related action levels. The most recent set of action levels continue to be acceptable to CNSC staff and have been incorporated into the proposed LCH for CLSI.

Radiation Protection Program Improvements

During the current licensing period, CLSI revised its RP program documentation as part of its continual improvement activities, and subsequent to findings arising from CNSC compliance verification activities. Other areas where CLSI strengthened its RP program included improvements to shielding, access control and interlock systems, additions to the active area radiation monitoring system, purchase of new radiation detection equipment, and new and improved training modules.

CNSC staff are satisfied with the performance of CLSI's RP program over the current licensing period.

Radiological Hazard Control

CLSI have established radiation and contamination mitigation measures to control and minimize radiological hazards and the spread of radioactive contamination. Access to and within the facility is controlled via a card access system. Areas have been classified based on the expected radiation levels for each area. Different levels of training are specified for access into these areas. Any area that may have a radiation dose rate greater than 1 mSv/h is designated as a Prohibited Access Area when the source is present and is controlled via the Access Control and Interlock System.

An active area radiation monitoring system is deployed around the storage ring outer wall to monitor dose rates and hourly-integrated dose due to beam use. Radiation levels measured by each monitoring station are displayed locally and in the control room. CLSI also monitor and report radiation levels around the facility to ensure dose rates in areas such as machine shops, administrative offices and public access zones remain at background levels.

The potential for activating accelerator components at CLSI is present due to the energy and power of the electron beam. Since these components may rust, collect dust, or otherwise deteriorate there is also a risk of spreading loose contamination from the accelerator areas through the facility. Contamination limits are set for each zone, and boundaries between zones are delineated by appropriate signage. Personnel leaving these zones are required to perform a survey of their person, as well as any equipment. The surface contamination monitoring program at CLSI encompasses various sample locations within the facility such as the entrances to restricted access zones and the countertops of work areas used by employees that frequently work in restricted access areas.

CNSC staff are satisfied that radiological hazards have been adequately controlled at CLSI during the current licensing period.

3.4.3.2 Regulatory Focus

CNSC staff will continue to monitor performance in the Radiation Protection SCA through regulatory oversight activities including inspections and desktop reviews of CLSI's compliance reporting and revisions to relevant program documentation pertaining to this SCA. There are no open NNC's relating to the Radiation Protection SCA.

3.4.3.3 Proposed Improvements

There are no proposed improvements for this SCA.

3.4.4 Conclusion

CNSC staff assessed CLSI's documentation and analyses under the Radiation Protection SCA and found them to be acceptable. CNSC staff conclude that the overall performance for this SCA is satisfactory and that CLSI is qualified to carry out the authorized activities at its facility in this SCA.

3.4.5 Recommendation

CNSC staff recommend that licence condition 8.1 be retained without change. CNSC staff recommend minor changes to licence condition 8.2, as described in Part Two of this CMD.

3.5 Conventional Health and Safety

The Conventional Health and Safety SCA covers the implementation of a program to manage workplace safety hazards and to protect workers. The specific areas of this SCA discussed in this CMD are:

- Practices
- Performance

3.5.1 Trends

The following table indicates the overall rating for the Conventional Health and Safety over the current licensing period:

CONVENTIONAL HEALTH AND SAFETY								
Overall Compliance Ratings								
2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
SA	SA	SA	SA	SA	FS	FS	FS	SA
Comments								

CLSI's performance in the conventional health and safety SCA has been satisfactory throughout the licencing period. The changes in grades from FS to/from SA are due to changes in grading methodology used by the CNSC and do not indicate a change in CLSI's performance.

3.5.2 Discussion

CLSI is a federally regulated facility, and is required to implement and maintain a conventional health and safety program, in accordance with the *Canada Labour Code Part II*, and the Public Health Agency of Canada (PHAC) *Human Pathogens and Toxins Act*.

The CNSC requires CLSI to manage workplace safety hazards, including biological and chemical hazards. CLSI's occupational health and safety program is well-established and integrated into the overall management system. The top-tier document at CLSI, the Quality Manual, sets safety as the overriding priority. Lower-tier documents describe specific safety programs in more detail.

CLSI's Health, Safety and Environment Manual is the overarching document that dictates the overall safety program at CLSI, including inspections, hazard identification and control, and training. The Occupational Health and Safety Manual and the Biological, Chemical and Nanomaterial Safety Manual provide additional details that support the conventional health and safety program for those specific hazards.

CLSI reported a significant near miss in 2016. An employee incorrectly locked out a 600V power supply prior to the start of work. The investigation and follow up resulting from this near miss resulted in improvements to the control of hazardous energy procedure and a fitness for duty program that includes human factors. CNSC staff performed a focused conventional health and safety inspection in 2017 in addition to desktop reviews of the corrective actions implemented after this event. The inspection concluded that CLSI met the regulatory requirements as described in the LCH.

In April 2021, CLSI reported an outbreak of COVID-19 among facility staff. This was reported to the Commission at the April 27, 2021 meeting. CLSI immediately put the facility into standby mode, and collaborated with public health officials to facilitate contact tracing. After the outbreak, CLSI performed an internal investigation to determine the contributing and mitigating factors of the outbreak, and shared their lessons learned with peers. Changes in procedures that resulted from this investigation included further reducing the occupancy limits in some areas and implementing more stringent requirements for the type of masks worn at the facility.

During compliance activities focused on other SCAs, CNSC staff discussed any potential conventional health and safety hazards noted and issued notices of non-compliance when required.

Performance

A key performance indicator for the conventional health and safety SCA is lost-time injuries (LTI). A LTI is an injury that takes place at work resulting in lost days beyond the date of the injury as a direct result of an occupational injury or illness incident. The number of lost-time injuries and injuries requiring medical attention are reported to the CNSC staff in the annual compliance report. CLSI has a target of 0 lost-time injuries.

Table 3.6 shows the number of injuries requiring medical attention, and LTIs at CLSI for the current licensing period. All 3 LTIs were minor injuries. Details of the nature of each LTI and the actions taken to prevent recurrence are provided in Section E.1.

Table 3.6 - Occupational Injuries at CLSI from 2012 - Q2 2021

	2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**Q1-Q2 2021**
LTIs	0	0	0	1	0	1	0	0	1	0
Injuries requiring medical attention	3	4	4	2	3	2	0	0	2	0

Practices

CLSI must comply with all applicable federal health and safety regulations. CLSI has a joint occupational health and safety committee, in accordance with the Canada Labour Code part II. CLSI's conventional health and safety program includes the following programs and provisions:

- work permits for specialized work;
- safety training program;
- hazard communication;
- permit system for contractor facility access; and
- regular workplace inspections with non-compliances tracked and monitored for closure.

3.5.3 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

3.5.3.1 Past Performance

CNSC staff routinely verify CLSI's conventional health and safety program through several means, including desktop review of annual reports and review of CLSI's Health and Safety Committee minutes.

For the current licensing period, CNSC staff rated CLSI's overall performance for the conventional health and safety SCA as satisfactory.

3.5.3.2 Regulatory Focus

CNSC staff conducted 11 inspections throughout the licensing period that included conventional health and safety criteria, including 1 focused inspection conducted in July 2017. CLSI addressed all conventional safety non-compliances identified during the current licensing period.

CNSC staff will continue to monitor CLSI's performance in this SCA through onsite and remote inspections, and desktop reviews of relevant program documentation. There are no open NNC's for this SCA.

3.5.3.3 Proposed Improvements

There are no proposed improvements for this SCA.

3.5.4 Conclusion

Based on CNSC staff assessments of CLSI's application, supporting documents and past performance, CNSC staff conclude that CLSI continues to implement and maintain an effective conventional health and safety program in accordance with regulatory requirements.

3.5.5 Recommendation

CNSC staff recommend that licence condition 9.1 be retained without change.

3.6 Environmental Protection

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

This SCA encompasses the following specific areas:

- effluent and emissions control (releases)
- environmental management system (EMS)

- assessment and monitoring
- protection of people
- environmental risk assessment (ERA)

3.6.1 Trends

The following table indicates the overall rating for the environmental protection over the current licensing period:

ENVIRONMENTAL PROTECTION								
Overall Compliance Ratings								
2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
SA	SA	FS	FS	FS	FS	FS	FS	SA
Comments								
During the licensing term, CNSC staff rate CLSI's performance in the environmental protection SCA as satisfactory. CLSI has developed, implemented and maintained an effective environmental protection program that protects the environment and the public in accordance with CNSC regulatory requirements. Changes between FS and SA reflect changes in the CNSC's grading methodology and does not reflect an increase or decrease in CLSI's performance.								

3.6.2 Discussion

As per the *Nuclear Safety and Control Act*, licensees are required to make adequate provisions for the protection of the environment. Licensees achieve this by developing and maintaining an environmental protection program to control releases of nuclear and hazardous substances and to assess the effects of these releases on the environment. The design and implementation of the environmental protection program at CLSI is in accordance with REGDOC 2.9.1 *Environmental Protection: Policies, Programs and Procedures* (2013).

During the current licence period, CNSC staff verified CLSI's performance with respect to environmental protection through inspections and desktop reviews. In total, CNSC staff conducted 1 focused environmental protection inspection in 2017. CNSC staff classified all findings from the inspection as low safety significance and did not issue any enforcement actions from the inspection.

3.6.3 Summary

A summary of the licensee's performance, challenges and proposed improvements are presented in the following subsections.

3.6.3.1 Past performance

Effluent and emissions control (releases)

The operation of the CLSI accelerators and beamlines does not result in any direct releases of radionuclides or hazardous substances to the environment. To confirm this, CLSI implements a basic effluent monitoring program that consists of monitoring at any potential discharge locations from the facility

CLSI monitors any potential radioactive airborne releases by using a gamma probe system installed in the stack to monitor the real time gamma radiation dose rate. The results are consistently within background levels.

Any potentially contaminated wastewater generated at all locations across the facility during maintenance is collected through a sump and stored in a holding tank. CLSI samples and analyzes the contents of the tank prior to releasing to the municipal sewer system to ensure that it meets the city of Saskatoon bylaws. The results are consistently below detection levels.

Environmental management system (EMS)

For CLSI, due to its small environmental protection program, the environmental management system (EMS) is integrated in the facility's overall management system. CNSC staff review the outcomes of the EMS during compliance inspections.

Assessment and monitoring

Since CLSI does not have any releases to the environment, CLSI has a basic environmental monitoring program that consists of environmental/low-level dosimeters located around the perimeter of the building. These dosimeters are exchanged quarterly for processing and are used to determine exposures to members of the public.

Protection of people

CLSI is required to demonstrate that the health and safety of the public are protected from exposures to hazardous and radioactive substances released from the facility. There are no releases to the environment from the CLSI facility and this is confirmed through its effluent monitoring program.

Based on review of the results of the programs at CLSI, CNSC staff conclude that the public continues to be protected from the operation of the facility.

In 2019, there was a spill of approximately 5000 liters of 30% ethylene glycol to the sewer caused by the failure of an expansion joint. CNSC staff reviewed the incident and concluded that the risk to the environment was minimal since the release was diluted in the sewer system and was treated by the municipal water treatment plant prior to discharge. CNSC staff also reviewed the corrective actions taken by CLSI in response to the event and concluded that they were satisfactory.

Estimated dose to public

Throughout the licensing term, the environmental/low-level dosimeter results show that the estimated dose to the public is less than 0.01 mSv, which is at natural radiation background levels.

Environmental risk assessment (ERA)

With the publication of the 2020 version of REGDOC-2.9.1 Environmental Protection: Environmental Principles, Assessments, and Protection Measures, a stand-alone environmental risk assessment (ERA) became a requirement for CLSI. A screening level ERA is a broad, very conservative risk assessment generally used to eliminate potential stressors that are clearly not of concern for a particular facility. CLSI has many aspects of a screening level ERA located in different documents currently listed in the LCH: they have evaluated effluent and emissions releases, environmental monitoring and estimated doses to the public, and confirmed that gaseous radiological releases from their facility to the environment are negligible. However, to meet in the intent of section 4.1 of the 2020 version of REGDOC-2.9.1, there must be one stand-alone ERA document detailing all interactions with the environment from the facility along with any potential impacts. In accordance with the 2020 version of the REGDOC, CLSI has provided an initial screening level ERA to the CNSC in August 2021. The screening level ERA considers the guidance in CSA N288.6-12 *Environmental risk assessments at Class I nuclear facilities and uranium mines and mills*. CNSC staff reviewed the submission and have provided feedback to CLSI to ensure that it meets regulatory requirements and to ensure effective implementation. Once CNSC staff accept the updated submission, CLSI will have fully implemented the 2020 version of REGDOC-2.9.1.

3.6.3.2 Regulatory Focus

CNSC staff performed 1 Environmental Protection-focused inspection during the current licensing period.

CNSC staff will continue to monitor performance in this area through regulatory oversight activities, inspections, and desktop reviews of CLSI's compliance reporting and revisions to relevant program documentation pertaining to this SCA. There are no open NNC's for this SCA.

3.6.3.3 Proposed Improvements

There are no proposed improvements for this SCA.

3.6.4 Conclusion

CLSI has implemented and maintained an environmental protection program that adequately protects the environment and the public in accordance with regulatory requirements. CNSC staff expect no adverse effects on human health during the operation of the facility.

The environmental protection program at CLSI continues to be effective in protecting the environment and minimizing adverse impacts to human health. CLSI has and will continue to make adequate provision for the protection of the environment and the health and safety of persons.

3.6.5 Recommendation

CNSC staff recommend retaining licence conditions 10.1 and 10.2 without change.

3.7 Emergency Management and Fire Protection

Emergency management and fire protection 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.

The specific areas that comprise this SCA at CLSI are:

- Conventional Emergency Preparedness and Response
- Fire Emergency Preparedness and Response

Trends

The following table indicates the overall rating trends for the Emergency Management and Fire Protection over the current licensing period:

EMERGENCY MANAGEMENT AND FIRE PROTECTION								
Overall Compliance Ratings								
2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
SA	SA	SA	SA	SA	SA	SA	SA	SA
Comments								
CLSI has a Fire Protection Program (FPP) in place to minimize both the probability of occurrence and the consequences of fire at the facility. CLSI has an acceptable emergency preparedness and response program that meets CNSC regulatory requirements.								

3.7.1 Discussion

Conventional Emergency Management and Response

CLSI is required to have emergency plans in place to address on-site and off-site events that may affect the facility. CLSI has developed an Emergency Response Plan that provides information on how to respond to the various emergencies that could be reasonably expected to occur at the CLS.

Emergency plans and procedures explain which process to follow in the event of specific types of emergencies. These plans and procedures include response to any release of radioactive material or hazardous substance from the CLS, fires, medical, weather, electrical, HAZMAT, security and animal escape.

CLSI developed the Emergency Response plan to comply with the requirements of CNSC regulatory document *G-225, Emergency Planning at Class I Nuclear Facilities and Uranium Mines*.

G-225 has since been superseded by REGDOC 2.10.1 *Nuclear Emergency Preparedness and Response, Version 2*. The main requirements that were added to this REGDOC are for licensees of reactor facilities with a thermal capacity greater than 10 MW, and a requirement to formally document policies, and establish and document arrangements with offsite response organizations as per RD/GD-99.3, *Public Information and Disclosure*.

CLSI will prepare a gap analysis and action plan to outline the changes required to their program in order to meet the new expectations.

CLSI's documentation currently provides for emergency response measures commensurate with the requirements of its facilities.

Fire Emergency Preparedness and Response

CLSI has a Fire Protection Program (FPP) in place to minimize both the probability of occurrence and the consequences of fire at the facility. The FPP has been established to comply with the requirements of the "*National Building Code of Canada (2015)"*, the "*National Fire Code of Canada (2015)"* (NFCC) and *"National Fire Protection Association NFPA-801(2014)".* The FPP identifies the procedures, processes and supporting analyses necessary to demonstrate a planned, coordinated and controlled approach to fire protection at the facility.

CLSI submits Inspection, Testing and Maintenance (ITM) Biennial Review and third-party reviews of any changes or modifications to the fire protection systems for CNSC assessment. CNSC staff has reviewed the previous ITM report and found it to be acceptable.

In 2020, CNSC staff indicated to CLSI that the licensing basis document for their FPP would become CSA N393-13 *Fire Protection for Facilities that Process, Handle, or Store Nuclear Substances.*

CLSI has performed and submitted an analysis showing the gaps between its current FPP and CSA N393-13. This gap analysis has been assessed by CNSC staff and found to be acceptable. CSA N393-13 requires a Fire Hazard Analysis (FHA) to be performed. The FHA is typically conducted to ensure that the mitigation measures in place provide adequate life safety and environmental protection, and that the applicable fire code requirements were satisfied. CLSI has submitted their FHA roadmap and it is currently undergoing CNSC staff assessment. CNSC staff have requested implementation timelines for the N393-13 gap analysis and will continue to follow CLSI's progress to ensure that their fire protection program continues to meet regulatory requirements.

Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

3.7.1.1 Past Performance

CLSI's performance in the emergency management and fire protection SCA during the license period was satisfactory. CLSI continues to maintain emergency management and fire protection programs in accordance with regulatory requirements.

3.7.1.2 Regulatory Focus

CNSC staff's assessment of CLSI's performance in this SCA consisted of desktop reviews of events, program documentation, and reviews of third-party reviews submitted after changes to the fire protection program are completed.

3.7.1.3 Proposed Improvements

REGDOC 2.10.1 *Nuclear Emergency Preparedness and Response* and CSA N393-12 have been included as Licensing Basis Publications in the proposed LCH. CLSI will submit a gap analysis and implementation plan for REGDOC 2.10.1 by December 31, 2022 to CNSC staff. CLSI has provided the CNSC with a gap analysis for CSA N393-12, and CNSC staff are now assessing this analysis. CNSC staff will monitor the implementation of these new requirements at CLSI through desktop reviews and inspections.

3.7.2 Conclusion

Based on desktop reviews, CNSC staff conclude that CLSI is in compliance with regulatory requirements and that CLSI is performing satisfactorily with respect to this SCA.

3.7.3 Recommendation

CNSC staff recommend that licence conditions 11.1 and 11.2 be retained without change.

3.8 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 for storage, treatment, or disposal at another licensed location. This area also covers the planning for decommissioning.

This CMD covers the following specific areas of Waste Management:

- Waste characterization;
- Waste minimization;
- Waste management practices; and
- Decommissioning plans.

3.8.1 Trends

The following table indicates the overall rating for the Waste Management SCA over the current licensing period:

WASTE MANAGEMENT								
Overall Compliance Ratings								
2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
SA	SA	FS	FS	FS	FS	SA	SA	SA
Comments								
CLSI's waste management program met applicable CNSC regulatory and performance objectives. CNSC staff monitor CLSI's implementation of this program through regular compliance verification activities. Changes between FS and SA reflect changes in the CNSC's grading methodology and does not reflect an increase or decrease in CLSI's performance.								

3.8.2 Discussion

CLSI has a waste management program that is satisfactory to CNSC staff. In accordance with paragraph 3(k) of the *Class I Nuclear Facilities Regulations*, CLSI is required to maintain a decommissioning plan throughout the life of the facility. CLSI maintains a preliminary decommissioning plan (PDP) for its facility as per CSA Group standard N294-09, *Decommissioning of facilities containing nuclear substances* and CNSC regulatory guide *G-219, Decommissioning Planning for Licensed Activities*. REGDOC-2.11.2, *Decommissioning*, was published in January 2021, after the PDP assessment by CNSC staff. REGDOC-2.11.2 will be used as a licensing basis document for CLSI's next preliminary decommissioning plan submission in 2026.

CLSI regularly assesses its waste management program and PDP to ensure the adequacy and effectiveness of its programs.

Based on CNSC staff's assessment of the licence renewal application, supporting documents and CLSI's past performance in this SCA, CNSC staff conclude that CLSI continues to maintain and implement a documented waste management program in accordance with CNSC regulatory requirements. CLSI has demonstrated satisfactory performance at its facility for this SCA.

3.8.3 Summary

A summary of the licensee's performance, challenges and proposed improvements are presented in the following subsections.

3.8.3.1 Past performance

Waste characterization, minimization, and management practices

CLSI's application for licence renewal included the Procedure for the Storage/Release of Potentially Activated Material, and Biological, Chemical and Nanomaterial Safety Manual. These 2 documents encompass the waste management program for the facility.

CNSC staff have reviewed both documents, along with the information contained in the application, and rated them satisfactory.

CLSI segregates wastes generated at its facility into chemical, biological, and radiological waste streams. CLSI maintains waste inventories for each stream, along with records of the destruction of biological wastes. The volume of radioactive waste generated at CLSI is minimal, and is further minimized where possible. CLSI characterizes potentially radioactive wastes in accordance with Procedure for the Storage/Release of Potentially Activated Material. CLSI maintains detailed records of items released from regulatory control, in accordance with the *Nuclear Substances and Radiation Devices Regulations*.

Decommissioning plans

In July 2019, CLSI submitted an updated PDP [and cost estimate for the decommissioning of its facility.

Decommissioning must be conducted in a manner that ensures that the health, safety, and security of workers, the public, and the environment are protected. CLSI has selected an immediate decommissioning strategy for its facility. The final end-state objective of decommissioning the CLSI facility is to release the property to the University of Saskatchewan for unrestricted use and termination of licence with the CNSC. The building and its associated conventional services will not be dismantled, rather they will remain for other uses by the University. CLSI's strategy for managing radioactive wastes is to transfer the material to a CNSC licensed waste management facility, location or site. At this time, the proposed timeframe for permanently shutting down the CLSI facility is not public information.

The CNSC requires CLSI to revise its PDP for its facility at a minimum every 5 years or when requested by the Commission or a person authorized by the Commission. CNSC staff have reviewed the updated PDP for CLSI and found that it meets the applicable regulatory requirements and provides an acceptable basis for a decommissioning cost estimate.

Additional details of the financial guarantee and its assessment are provided in Section 48 of this CMD.

3.8.3.2 Regulatory Focus

CNSC staff will continue to monitor and evaluate CLSI's compliance with regulatory requirements through regulatory oversight activities including inspections, review of compliance reports, and revisions to relevant program documentation. There are no open NNC's for this SCA.

3.8.3.3 Proposed Improvements

Both REGDOC-2.11.1, *Waste Management, Volume I: Management of Radioactive Waste* and REGDOC-2.11.2, *Decommissioning* were published in January 2021 and apply to CLSI facility operations. CLSI will undertake a gap analysis and submit an implementation plan to align the waste management program with the regulatory requirements set out in the newly published regulatory document REGDOC-2.11.1, *Waste Management, Volume I: Management of Radioactive Waste* by December 2022. CNSC staff will assess the proposed plans, and follow CLSI's progress in implementing the accepted plan through compliance activities.

CLSI will undertake a gap analysis and submit an implementation plan by December 31, 2022 to align the waste management program for CLSI with the regulatory requirements set out in CSA Group standard N292.0-19, *General principles for the management of radioactive waste and irradiated fuel*, and CSA Group standard N292.3-14, *Management of low- and intermediate-level radioactive waste*. CNSC staff will assess CLSI's next PDP against CSA Group standard N294-19, *Decommissioning of facilities containing nuclear substances* for the next submission of the PDP expected in 2026. CNSC staff evaluate CLSI's implementation of these two new licencing basis publications through compliance activities.

3.8.4 Conclusion

Based on the assessment of CLSI's waste management program, CNSC staff conclude that CLSI has a waste management program in place that is satisfactory to CNSC staff.

Based on the assessment of CLSI's revised PDP, CNSC staff conclude that the PDP meets the current licencing basis requirements described in CSA Group standard N294-09, *Decommissioning of facilities containing nuclear substances* and CNSC regulatory guide *G-219, Decommissioning Planning for Licensed Activities*.

3.8.5 Recommendation

CNSC staff recommend retaining licence conditions 11.1 and 11.2 without change.

3.9 Security

This 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.

The specific areas that comprise this SCA at CLSI include:

- Facilities and Equipment

- Response Arrangements
- Security Practices

Although these three specific areas are applicable to the CLSI facility, the proposed CMD content will be presented for the security SCA as a whole.

3.9.1 Trends

The following table indicates the overall rating for the Security SCA over the current licensing period:

SECURITY								
Overall Compliance Ratings								
2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
SA	SA	SA	FS	FS	FS	SA	SA	SA
Comments								
CLSI has implemented and maintained a security program that meets regulatory requirements under the *General Nuclear Safety and Control Regulations* (GNSCR) to prevent the loss, unauthorized removal and sabotage of nuclear substances, nuclear materials, prescribed equipment or information. Changes between FS and SA reflect changes in the CNSC's grading methodology and do not reflect an increase or decrease in CLSI's performance.								

3.9.2 Discussion

CLSI is subject to the *General Nuclear Safety and Control Regulations* (GNSCR), which provide obligations for licensees across all SCAs. CLSI is required to make adequate provisions for the security of nuclear substances, implement of measures to alert the licensee to the illegal use or removal of nuclear substances, or sabotage or attempted sabotage anywhere at the site. CLSI must instruct all workers on the facility's security program and its obligations therein.

CLSI submitted a site Security Plan to the CNSC on February 16, 2021. CNSC staff assessed the Site Security Plan and confirmed that it met applicable regulatory requirements and was acceptable

CLSI's application has identified that all security systems and devices required by the CNSC have been implemented and maintained for the facility. Specific details on the measures implemented by CLSI to meet regulatory requirements of the Security SCA are considered prescribed information pursuant to section 21 of the *General Nuclear Safety and Control Regulations*. CLSI has submitted program documentation with its licence renewal application that adequately identifies how

it will meet regulatory expectations related to the Security SCA. This documentation has been reviewed by CNSC staff and has been accepted, as it satisfactorily meets the requirements of the GNSCR.

CNSC staff will continue to monitor and verify CLSI's performance for the Security SCA through regulatory oversight activities, including on-site inspections and technical assessments of relevant program documentation.

3.9.3 Summary

A summary of the licensee's performance, challenges and proposed improvements are presented in the following subsections.

3.9.3.1 Past performance

The specific results of performance evaluations for security are identified as security sensitive information and have been designated as Confidential – Prescribed Information. This information is not available for public release.

CLSI has maintained a security program that provides sufficient technical and administrative security measures for the facility and the areas that involve the processing, use or storage of nuclear substances. Alarm detection and assessment systems are continually monitored and meet regulatory requirements. Additionally, CLSI has implemented processes for effective testing and maintenance of security-related devices and equipment.

CLSI has provided training to its staff on security-related procedures, and has a program in place to provide refresher training on a regular basis. CLSI has also implemented measures for controlling access to its facility. These measures were assessed as meeting regulatory requirements.

One security focused inspection was been conducted at CLSI over the current licensing period, in 2019. CLSI does not have any unresolved actions from these inspections.

3.9.3.2 Regulatory Focus

CNSC staff have not identified any challenges with respect to the Security SCA. CLSI does not have any unresolved actions from inspections or technical assessments of the Security SCA conducted throughout the current licensing period. CNSC staff will continue to monitor and verify CLSI's performance for the Security SCA through regulatory oversight activities, including on-site inspections and technical assessments of relevant program documentation.

3.9.3.3 Proposed Improvements

There are no proposed improvements for this SCA.

3.9.4 Conclusion

CNSC staff confirm that CLSI has met regulatory requirements for the Security SCA throughout the licensing period. CLSI's performance rating of Satisfactory is supported by CNSC staff's regulatory oversight activities. CNSC staff will continue to monitor and provide regulatory oversight of CLSI's implementation and operation of its security program.

3.9.5 Recommendation

CNSC staff recommend retaining licence condition 13.1 without change.

3.10 Safeguards and Non-Proliferation

This SCA is not relevant to this CMD.

CLSI has not possessed, does not currently possess and is not planning to possess any safeguarded material.

3.11 Packaging and Transport

The Packaging and Transport SCA pertains to programs that cover the safe packaging and transport of nuclear substances to and from the licensed facility.

The specific areas that comprise this SCA at the CLS are:

- Packaging and Transport

The following table indicates the overall rating trends for the Packaging and Transport over the current licensing period:

PACKAGING and TRANSPORT								
Overall Compliance Ratings								
2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
SA	SA	SA	SA	SA	SA	SA	SA	SA

Comments

CLSI has a packaging and transportation program that ensures compliance with the *Packaging and Transport of Nuclear Substances Regulations, 2015*, and the *Transportation of Dangerous Goods Regulations*. CNSC staff monitor CLSI's implementation of this program through compliance verification activities.

CNSC staff conclude that the packaging and transport activities are conducted in a safe manner and meet regulatory requirements.

3.11.1 Discussion

CLSI is required to implement and maintain a packaging and transport program for nuclear substances.

The *Packaging and Transport of Nuclear Substances Regulations, 2015* apply to the packaging and transport of nuclear substances, including the design, production, use, inspection, maintenance and repair of packages, and the preparation, consigning, handling, loading, carriage and unloading of packages.

CLSI is required to have appropriate training for personnel involved in the handling, offering for transport and transport of dangerous goods, and must issue a training certificate to those workers in accordance with the *Transportation of Dangerous Goods Regulations*.

CLSI's packaging and transport of nuclear substances mainly involves receiving commercially available sealed sources purchased for use in calibration and testing, and shipping or receiving samples that relate to user experiments on beamlines.

3.11.2 Summary

A summary of the licensee's past performance, challenges and proposed improvements are presented in the following subsections.

3.11.2.1 Past Performance

CLSI has developed and implemented a packaging and transport program to ensure all shipments leaving its facility are in compliance with the *Packaging and Transport of Nuclear Substances Regulation, 2015* and the *Transportation of Dangerous Goods Regulations*. CLSI's packaging and transport program covers elements of package design and maintenance, and the registration for use of certified packages as required by the regulations.

There were no events reported under the *Packaging and Transport of Nuclear Substances Regulations, 2015* for consignments transported to or from the CLSI facility during the licencing period.

3.11.2.2 Regulatory Focus

CNSC staff assessed CLSI's performance in this SCA through desktop assessments of reports. No packaging and transport inspections were performed during the licensing period. There are no open NNC's for this SCA.

3.11.2.3 Proposed Improvements

There are no proposed improvements for this SCA.

3.11.3 Conclusion

Based on CNSC staff assessments of CLSI's licence application, supporting documents and past performance, CLSI implementation of the packaging and transport SCA continues to meet all applicable regulatory requirements. CNSC staff rate this SCA as satisfactory.

3.11.4 Recommendation

CNSC staff recommend retaining licence condition 14.1 without change.

3.12 Indigenous Engagement

As an agent of the Government of Canada and as Canada's nuclear regulator, the CNSC recognizes and understands the importance of consulting and building relationships with Indigenous peoples in Canada.

The common law duty to consult with Indigenous peoples applies when the Crown contemplates actions that may adversely affect potential or established Indigenous and/or treaty rights. The CNSC ensures that all of its licensing decisions under the NSCA uphold the honour of the Crown and involve Indigenous peoples' potential or established Aboriginal and/or treaty rights pursuant to section 35 of the Constitution Act, 1982.

The CLS is a low risk research facility. The activities to be conducted under this decision do not involve any changes to the site and therefore will not cause any adverse impacts on potential or established Indigenous and/or treaty rights. The CNSC has not been made aware of any specific interest or concerns from Indigenous communities in relation to CLSI licence renewal. However, CNSC staff are committed to providing any information and engaging Indigenous communities with regards to CLSI licence renewal should interest be expressed.

4. OTHER MATTERS OF REGULATORY INTEREST

4.1 Public Engagement

As per its normal public notification process for Commission proceedings, CNSC staff informed the public via the CNSC's website, email subscription list, and social media channels of the public Commission hearing and availability of participant funding.

Part of CNSC's mission is to provide objective scientific and regulatory information to the public concerning nuclear activities. The availability and clarity of information pertaining to nuclear activities is essential to establishing an atmosphere of openness, transparency and trust between the licensee and the public. Licensees have an important role to inform the public about its nuclear facility and activities. Since 2012, the CNSC requires major licensees to develop

and implement a public information program supported by a robust disclosure protocol that addresses local communities and stakeholders' needs.

CNSC staff report to the Commission and the public on the regulatory oversight of all Class 1B particle accelerators, including CLSI. The list of regulatory oversight reports is presented in the references within this CMD [1] and are also available on the CNSC's website. The public has the opportunity to review, question and comment on the regulatory oversight report.

For CLSI's current licence renewal hearing, the CNSC made available up to $35,000 through its participant funding program to support the funding recipients in providing value-added information to the Commission. The Funding Review Committee (FRC), independent from CNSC staff, did not receive any applications for funding.

The CNSC is committed to keeping interested communities informed of regulatory activities occurring at CLSI and will continue to look for ways to enhance the involvement of interested groups.

4.2 Cost Recovery

It is a requirement of the NSCA under paragraph 24(2)(c), that the licence application is accompanied by the prescribed fee. The *CNSC Cost Recovery Fees Regulations* (CRFR) set out the specific requirements based on the activities to be licensed. CLSI is entirely owned by the University of Saskatchewan. Paragraph 2(b) of the *Cost Recovery Regulations* states these regulations do not apply to a not-for-profit research organization that carries out research and is wholly owned by a specified educational institution. CLSI is considered by the CNSC to be exempt from any fees associated with the planned regulatory effort in accordance with these regulations.

4.3 Financial Guarantee

The *Nuclear Safety and Control Act* and its associated GNSCR require licensees to make adequate provision for the safe decommissioning of their facilities. Requirements and guidance for establishing a financial guarantee for decommissioning are provided CNSC regulatory guide G-206, *Financial Guarantees for the Decommissioning of Licensed Activities*.

Under licence condition 15.2, a Financial Guarantee for decommissioning must be established to fund the activities described in a decommissioning plan. The financial guarantee must be accepted by the Commission. CLSI currently maintains a financial guarantee for decommissioning of its facility as per licence condition 15.2 of its current licence.

4.3.1 Discussion

Under its existing licence, CLSI currently maintains a financial guarantee in the amount of $10,549,000 for the decommissioning of its facility, in the form of a

letter of credit with the Royal Bank of Canada with the CNSC named as beneficiary.

In March 2021, CLSI submitted an updated preliminary decommissioning plan (PDP) and cost estimate for decommissioning its facility. CNSC staff have reviewed the PDP and found that it meets the applicable regulatory requirements and provides an acceptable basis for a decommissioning cost estimate.

Based on the updated PDP, CLSI has estimated the cost for decommissioning its facility from 2020 to 2026 as seen in the table below.

Table 7 - Estimated costs for decommissioning of CLSI facility 2020-2016

Year	Estimated cost for Decommissioning
2020	$11,256,200
2021	$11,593,900
2022	$11,941,700
2023	$12,299,900
2024	$12,668,900
2025	$13,049,000
2026	$13,440,500

The proposed amounts include 25% contingency and an escalation of 3% annually over the years to account for inflation.

CLSI is proposing to continue to use the Letter of Credit with the Royal Bank of Canada in an amount of $10,549,000 [2] to fund its financial guarantee, with the addition of a cash fund in an amount of $1,050,000 [3] held by the University of Saskatchewan. A letter of credit and cash are acceptable financial instruments for the financial guarantee as identified in CNSC regulatory guide G-206: *Financial Guarantees for the Decommissioning of Licensed Activities.*

The proposed total amount of the financial guarantee is $11,978,300. CNSC staff have assessed the cost estimate against the criteria set in the CNSC regulatory guide G-206: *Financial Guarantees for the Decommissioning of Licensed Activities.* The proposed amount is adequate for decommissioning of the CLSI facility to the end of 2022, at which time the estimated cost of decommissioning will increase to beyond the value of the current financial guarantee.

By the end of 2022, CLSI will be required to increase the value of its financial guarantee, to meet the cost estimate for 2023 through 2026. CNSC staff will include a table showing the planned increases, if the Commission agrees with this proposal, within the proposed LCH for CLSI, along with annual reporting to a person authorized by the Commission on the sufficiency of the financial guarantee.

CNSC staff have reviewed the cost estimates provided by the licensee for decommissioning through to 2026 and have also reviewed the financial guarantee instruments utilized – a letter of credit combined with a cash sum - and find them to be satisfactory. The licensee will not be changing the financial guarantee instruments other than increasing the value in 2023, 2024, 2025 and 2026 to either

meet or exceed the cost estimates presented in the CMD that were found to be satisfactory to CNSC staff. CNSC staff see this as an administrative change to the financial guarantee and therefore request that the acceptance of the increase to the financial guarantee in 2023, 2024, 2025 and 2026 be delegated to a Person Authorized by the Commission. If any other changes to the financial guarantee are requested, such as changes to clauses in the letter of credit, or a decrease in the total amount, this will be directed back to the Commission.

CLSI has provided a draft of the irrevocable letter of credit with terms and conditions acceptable to CNSC staff. The University of Saskatchewan has provided a letter to CNSC staff outlining the sum and purposes of the cash fund, which CNSC have deemed sufficient. The current financial guarantee will continue to remain valid until the revised financial guarantee is in place.

Regulatory Requirements

Regulatory guide G-206 was in effect when reviewing the financial guarantee for CLSI.

CNSC staff will assess the next full revision of CLSI's financial guarantee, to enter into effect in 2027, against REGDOC-3.3.1.

4.3.2 Conclusion

CNSC staff conclude that CLSI currently has in place a valid, in effect and acceptable financial guarantee and recommend that the Commission accept the proposed new financial guarantee.

4.3.3 Recommendation

CNSC staff recommend that the Commission accept the proposed new financial guarantee in the form of a Letter of Credit for an amount of $10,549,000 and a cash fund for an amount of $1,050,000 and direct CLSI to provide the original instruments within 90 days from the issuance of a decision on this matter.

CNSC staff recommend that the Commission delegate acceptance of the increase in CLSI's financial guarantee instruments in 2023, 2024, 2025 and 2026 to meet or exceed the costs outlined in Table 7 to a person designated by the Commission.

CNSC staff recommend licence condition 15.2 be retained without change.

4.4 Licensee Public Information Program

A Public Information and Disclosure Program (PIDP) is a regulatory requirement for licence applicants and licensees of Class I nuclear facilities, uranium mines and mills and certain Class II nuclear facilities. These requirements are found in REGDOC-3.2.1, *Public Information and Disclosure*.

The primary goal of the PIDP is to ensure that information related to the health, safety and security of persons and the environment, and other issues associated with the lifecycle of nuclear facilities are effectively communicated to the public.

The program must include a commitment to, and protocol for ongoing, timely communication of information related to the licensed facility during the course of the licence period.

CNSC's expectations of a licensee's public information program and disclosure protocol are commensurate with the level of risk of the facility, as well as the level of public interest in the licensed activities. The program and protocol may be further influenced by the complexity of the nuclear facility's lifecycle and activities, and the risks to public health and safety and the environment perceived to be associated with the facility and activities.

4.4.1 Discussion

CLSI is required by LC 15.1 to maintain a PIDP as per REGDOC-3.2.1, *Public Information and Disclosure*.

Over the course of the last 10 years, CLSI has been successful in meeting its public disclosure and reporting obligations. It has made improvements to its website, adopted social media platforms and documented its areas of community engagement (tours, media, government and stakeholder relations, and community events).

As expected, the COVID-19 pandemic has provided challenges for CLSI. Despite the cancellation of in-person meetings and events, CLSI was still able to reach the community by increasing its online activities and efforts through its website and social media channels. It provided detailed information in its annual compliance reports about social media use and platforms, website updates and public tours of the facility.

CNSC staff have reviewed CLSI's current PIDP and determined that it:

- Identifies clear goals and objectives in terms of dissemination of information to targeted audiences;
- Identifies multiple target audiences such as residents and businesses in close proximity to the licensed facility, facility staff and stakeholders from the University of Saskatchewan, elected and government representatives, academic government and industrial users, media, local schools, and the general public of Saskatoon and Saskatchewan;
- Provides contact information for members of the public who want to obtain additional information;
- Provides key topics intended for sharing with target audience and/or other interested parties; and
- Outlines communications tactics that CLSI deploys to reach target audiences (newsletters, email lists, website content, facility tours, social media, public meetings, public advertisements, volunteering, community investment and community relations activities).

CNSC staff will continue to monitor CLSI's compliance with public information requirements and ongoing implementation of the PIDP.

CNSC staff will monitor CLSI's efforts in expanding its public, promotional activities through virtual events/webinars and increased visibility of public disclosures when events are posted on its website.

CNSC staff will also monitor CLSI's implementation of its commitment to refine and update its PIDP to meet the changing information needs of its target audiences.

4.4.2 Conclusion

CNSC staff conclude that CLSI's PIDP meets the regulatory requirements for public information and disclosure. CNSC staff continue to oversee CLSI's implementation of the PIDP to ensure that it meets obligations regarding disseminating and notifying the general public and on its licensed activities.

4.4.3 Recommendation

CNSC staff recommend retaining licence condition 15.1 without change.

4.5 Licence Condition Handbook

The LCH associated with CLSI provides compliance verification criteria used to determine whether the conditions listed in the licence have been met. The LCH sets out how CNSC staff will assess CLSI's compliance with the licence. It provides details associated with each licence condition that form part of the licensing basis, such as: applicable CSA Group standards and CNSC regulatory documents, regulatory interpretation, compliance verification criteria, version-controlled documents, licensees' written notification documents and guidance. This structure allows more freedom for the facility to evolve and update its documentation within the licensing basis.

4.6 Delegation of Authority

The Commission may include in a licence any condition it considers necessary for the purposes of the NSCA. The Commission may delegate authority to CNSC staff with respect to the administration of licence conditions, or portions thereof.

There are 4 proposed licence conditions in the CLSI particle accelerator operating licence that contain the phrase "the Commission or a person authorized by the Commission":

- LC 1.3 Resolution of Conflict or Inconsistency,

- LC 8.2 Dose Action Levels,
- LC 12.2 Planning for Decommissioning,
- LC 15.2 Financial Guarantee.

CNSC staff recommend the Commission delegate its authority for the purposes described in the above licence conditions to the following staff:

- Director, Accelerators and Class II Facilities Division (ACFD);
- Director General, Directorate of Nuclear Substance Regulation (DNSR),
- Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch.

5. OVERALL CONCLUSIONS AND RECOMMENDATIONS

CNSC staff conclusions and recommendations consider an overall assessment of CLSI's compliance with the NSCA and its regulations during the current licence period (2012 to 2021).

5.1 Overall Conclusions

CLSI has programs, resources, and measures in place to ensure the health and safety of persons and the environment and of the measures related to security and Canada's international obligations during the proposed licence period. CLSI has met regulatory requirements and its performance has been satisfactory throughout the licensing period.

5.2 Overall Recommendations

CNSC staff recommend the Commission:

1. Conclude, pursuant to paragraphs 24(4)(a) and (b) of the Nuclear Safety and Control Act in that CLSI:
    i. **Is qualified** to carry on the activities authorized by the licence
    ii. **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
2. Renew the Class 1B Particle Accelerator Operating Licence PA1OL-02.01/2022 for a period of 10 years commencing on June 1 2022 and ending on May 31, 2032, as proposed.
3. Delegate authority as set out in section 4.6 of this CMD.
4. Approve CLSI's proposed Financial Guarantee amount and instruments.

REFERENCES

The following documents are referenced in the CMD, and available upon request except as indicated.

[1] CNSC Regulatory Oversight Reports that discuss CLSI:

- Regulatory Oversight Report on the Use of Nuclear Substances in Canada: 2018-2019, 2014
- Regulatory Oversight Report for Research Reactors and Class 1B Accelerators: 2016-2017
- Regulatory Oversight Report for Nuclear Processing, Small Research Reactor and Class 1B Accelerator Facilities: 2015

[2] Letter of Credit, University of Saskatchewan and Royal Bank of Canada, April 6, 2018. e-Doc 6528392.

[3] University of Saskatchewan, Office of the Vice-President, Finance and Resources, CLSI Financial Guarantee Instrument Confirmation, June 3, 2021. e-Doc 6593751.

GLOSSARY

For definitions of terms used in this document, see CNSCs REGDOC-3.6, Glossary of CNSC Terminology, which includes terms and definitions used in the *Nuclear Safety and Control Act* and the regulations made under it, and in CNSC regulatory documents and other publications. Certain facility specific acronyms (indicated with a *) are not available in REGDOC-3.6.

ACRONYMS

Acronym	Term
AARMS	Active Area Radiation Monitoring System *
ACIS	Access Control Interlock Systems *
ALARA	As Low As Reasonably Achievable
BE	Below expectations
CLS	Canadian Light Source *
CLSI	Canadian Light Source Inc. *
CMD	Commission Member Document
CNSC	Canadian Nuclear Safety Commission
CRFR	*Cost Recovery Fees Regulations*
CSA	CSA Group (formerly Canadian Standards Association)
EIR	Event Initial Report
EMP	Environmental Management Program
EMS	Environmental Management System
EPR	Environmental Protection Reviews
ERA	Environmental Risk Assessment
ESL	Electron Source Laboratory *
FG	Financial Guarantee
FHA	Fire Hazard Analysis

FPP	Fire Protection Program
FRC	Funding Review Committee
FS	Fully Satisfactory
FSP	Fire Safety Plan
FTE	Full-time equivalents
GNSCR	*General Nuclear Safety and Control Regulations*
IAEA	International Atomic Energy Agency
LCH	Licence Conditions Handbook
LTI	Lost-time Injury
mSv	Millisievert
NEW	Nuclear Energy Worker
NNC	Notice of Non-Compliance
NSCA	*Nuclear Safety and Control Act*
OPEX	Operating Experience
PAA	Prohibited Access Area
PDP	Preliminary Decommissioning Plan
PFP	Participant Funding Program
PIDP	Public Information and Disclosure Program
REGDOC	Regulatory Document
ROR	Regulatory Oversight Report
RP	Radiation Protection
SA	Satisfactory
SAT	Systematic Approach to Training
SCA	Safety and Control Area
UA	Unacceptable

µSv	MicroSievert

A. RISK RANKING

The CNSC uses a risk-informed regulatory approach in the management and control of regulated facilities and activities. CNSC staff have therefore established an approach to identifying appropriate levels of regulatory monitoring and control for specific classes of licensed facilities and types of licensed activities based on risk ranking.

Risk ranking is applied to each SCA, and is determined by considering the probability and consequence of adverse incidents associated with each SCA as it relates to the given facility and activity types.

The methodology used to determine risk ranking is based on Canadian Standards Association guideline CAN/CSA-Q850, Risk Management: Guideline for Decision Makers. This guideline provides a description of the major components of the risk management decision process and their relationship to each other, and describes a process for acquiring, analyzing, evaluating, and communicating information that is necessary for making decisions.

In section 2.2 of the CMD, in the Relevant Safety Control Areas table, the "Risk Ranking" column shows a high (H), moderate (M) or low (L) indicator for each SCA that is relevant to the current facility and activities being addressed in this CMD. The risk rankings are not static and will change over time for a given facility and activities (e.g., facilities age, facilities and equipment are upgraded, activities cease or begin, licensees change, technology and programs mature, knowledge and understanding of impacts and probabilities increase, etc.).

The following matrix provides a high-level overview of risk ranking, and the management and monitoring approach associated with the various degrees of risk.

APPROACH TO ASSESSING AND MANAGING POTENTIAL RISK			
CONSEQUENCE	**MANAGEMENT/MONITORING APPROACH**		
Significant Impact	Considerable management of risk is required	Must manage and monitor risk with occasional control	Extensive management is essential. Constant monitoring and control
Moderate Impact	Occasional monitoring	Management effort is recommended	Management effort and control is required
Low Impact	Random monitoring	Regular monitoring	Manage and monitor
Probability of Occurrence	Unlikely to Occur	Might Occur	Expected to Occur

RISK RANKING SCALE					
L	Low Risk	**M**	Moderate Risk	**H**	High Risk

On this basis, a high-risk SCA would be subject to increased regulatory scrutiny and control while a low-risk SCA would generally require minor verification and control.

B. RATING LEVELS

Fully Satisfactory (FS)

Safety and control measures implemented by the licensee are highly effective. In addition, compliance with regulatory requirements is fully satisfactory, and compliance within the safety and control area (SCA) or specific area exceeds requirements and CNSC expectations. Overall, compliance is stable or improving, and any problems or issues that arise are promptly addressed.

Satisfactory (SA)

Safety and control measures implemented by the licensee are sufficiently effective. In addition, compliance with regulatory requirements is satisfactory. Compliance within the SCA meets requirements and CNSC expectations. Any deviation is minor and any issues are considered to pose a low risk to the achievement of regulatory objectives and CNSC expectations. Appropriate improvements are planned.

Below Expectations (BE)

Safety and control measures implemented by the licensee are marginally ineffective. In addition, compliance with regulatory requirements falls below expectations. Compliance within the SCA deviates from requirements or CNSC expectations to the extent that there is a moderate risk of ultimate failure to comply. Improvements are required to address identified weaknesses. The licensee is taking appropriate corrective action.

Unacceptable (UA)

Safety and control measures implemented by the licensee are significantly ineffective. In addition, compliance with regulatory requirements is unacceptable and is seriously compromised. Compliance within the SCA is significantly below requirements or CNSC expectations, or there is evidence of overall non-compliance. Without corrective action, there is a high probability that the deficiencies will lead to unreasonable risk. Issues are not being addressed effectively, no appropriate corrective measures have been taken and no alternative plan of action has been provided. Immediate action is required.

C. BASIS FOR THE RECOMMENDATION(S)

C.1 Regulatory Basis

The recommendations presented in this CMD are based on compliance objectives and expectations associated with the relevant SCAs and other matters. The regulatory basis for the matters that are relevant to this CMD are as follows.

Management Systems

The regulatory foundation for the recommendation(s) associated with management systems includes the following:

Paragraph 3(k) of the *General Nuclear Safety and Control Regulations* requires that a licence application contain information related to the applicant's organizational management structure including the internal allocation of functions, responsibilities and authority.

Paragraph 4(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain *"the proposed quality assurance program for the licensed activity"*.

Human Performance Management

The regulatory foundation for the recommendation(s) associated with human performance management includes the following:

Paragraphs 12(1)(*a*) and 12(1)(*b*) of the *General Nuclear Safety and Control Regulations* require that a licensee shall ensure the presence of a sufficient number of qualified workers to carry on the licensed activity safely and in accordance with the Act, the regulations made under the Act and the licence; and shall train the workers to carry on the licensed activity in accordance with the Act, the regulations made under the Act and the licence.

Paragraph 14(2)(e) of the *Class I Nuclear Facilities Regulations* requires every licensee to keep a record of the status of each worker's qualifications, requalification and training, including the results of all tests and examinations completed in accordance with the licence.

Paragraphs 12(1)(a) and 12(1)(b) of the *General Nuclear Safety and Control Regulations* require that licensees ensure that there are a sufficient number of properly trained and qualified workers to safely conduct the licensed activities. Applicants for a Class I facility operating licence are required to describe the programs which have been implemented to achieve these requirements under paragraphs 6(m) and 6(n) of the *Class I Nuclear Facilities Regulations*, which require that licence applications include the proposed responsibilities, qualification requirements, training program and requalification program for workers; along with the results that have been achieved in implementing the program for recruiting, training and qualifying workers. Subsection 14 (2) of the *Class I Nuclear Facilities Regulations* further requires *"every licensee to keep a record of the status of worker's qualifications, requalification and training, including the results of all tests and examinations"*.

Operating Performance

The regulatory foundation for the recommendation(s) associated with operating performance includes the following:

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain *"the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility"*.

Paragraph 24(5) of the *Nuclear Safety and Control Act* specifies that a licence may contain *"any term or condition that the Commission considers necessary for the purposes of this Act"*. Every facility operating licence includes the requirement to submit an "Annual Compliance Report". This report provides a summary of key facility operating performance parameters related to the safe operation of the facility and the safe conduct of the licensed activities.

Safety Analysis

The regulatory foundation for the recommendation(s) associated with safety analysis includes the following:

Paragraph 3(1)(i) of the *General Nuclear Safety and Control Regulations* requires that a licence application contain *"a description and the results of any test, analysis or calculation performed to substantiate the information included in the application"*.

Paragraphs 6(a), (c) and (d) of the *Class I Nuclear Facilities Regulations* require that a licence application contain: *"a description of the structures, systems and equipment at the facility, including their design and their design operating conditions; a final safety analysis report demonstrating the adequacy of the design of the nuclear facility; and the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility"*.

Paragraph 3(1)(c) of the *General Nuclear Safety and Control Regulations* requires that every licence application contain *"the name, maximum quantity and form of any nuclear substance to be encompassed by the licence"*.

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain *"the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility"*.

Paragraph 12(1)(c), (d), and (f) of the *General Nuclear Safety and Control Regulations* require that licensees take all reasonable precautions to protect the environment and the health and safety of persons and to maintain security; provide the devices required by the

licence and maintain them; and take all reasonable precautions to control the release of radioactive nuclear substances or hazardous substances.

Physical Design

The regulatory foundation for the recommendation(s) associated with physical design includes the following:

Paragraphs 6(a), (b) and (d) of the *Class I Nuclear Facilities Regulations* require that a licence application contain: *"a description of the structures, systems and equipment at the facility, including their design and their design operating conditions; and the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility"*.

Fitness for Service

The regulatory foundation for the recommendation(s) associated with fitness for service includes the following:

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain *"the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility"*.

Radiation Protection

The regulatory foundation for the recommendation(s) associated with radiation protection includes the following:

- The *General Nuclear Safety and Control Regulations* require, under subsection 3(1), that a licence application contain the following information under paragraphs:
  - 3(1)(*e*), the proposed measures to ensure compliance with the *Radiation Protection Regulations*.
  - 3(1)(*f*), any proposed action level for the purpose of section 6 of the *Radiation Protection Regulations*.
  - The *Radiation Protection Regulations* require, under sections 4 to 6, that the licensee implements a radiation protection program, ascertain and record doses, and take the required actions in the case that an action level has been reached.
- The *Class I Nuclear Facilities Regulations* require that an application for a licence to operate a Class I nuclear facility contain:
  - Under paragraph 6(*e*), the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances.
  - Under paragraph 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 measure that will be taken to prevent or mitigate those effects.

Conventional Health and Safety

The regulatory foundation for the recommendation(s) associated with Conventional Health and Safety includes the following:

Paragraph 3(f) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence in respect of a Class I nuclear facility, other than a licence to abandon, shall contain the proposed worker health and safety policies and procedures.

CLSI's activities and operations must comply with the *Canada Labour Code*, Part II: *Occupational Health and Safety*.

Security

The regulatory foundation for the recommendation(s) associated with Security includes the following:

Paragraph 12(1)(c) of the *General Nuclear Safety and Control Regulations* requires that *Every licensee shall take all reasonable precautions to protect the environment and health and safety of persons and to maintain the security of nuclear facilities and of nuclear substances;*

Paragraph 12(1)(g) of the *General Nuclear Safety and Control Regulations* requires that *Every licensee shall implement measures for alerting the licensee to the illegal use or removal of a nuclear substance, prescribed equipment or prescribed information, or the illegal use of a nuclear facility;*

Paragraph 12(1)(h) of the *General Nuclear Safety and Control Regulations* requires that *Every licensee shall implement measures for alerting the licensee to acts of sabotage or attempted sabotage anywhere at the site of the licensed activity;* and

Paragraph 12(1)(j) of the *General Nuclear Safety and Control Regulations* requires that *Every licensee shall instruct the workers on the physical security program at the site of the licensed activity and on their obligations under that program.*

Furthermore, sections 21 to 23 of the *General Nuclear Safety and Control Regulations* provide obligations for all licensees on the identification, storage, handling, and transfer requirements of information designated as "prescribed information".

Environmental Protection

The regulatory foundation for the recommendation(s) associated with Environmental Protection includes the following:

Paragraphs 3 (g) and (h) of the *Class I Nuclear Facilities Regulations*, require that an application for a licence to operate a Class I Nuclear Facility contain: the *"proposed environmental protection policies and procedures"* and *"the proposed effluent and environmental monitoring programs"*. Paragraphs 6 (h), (i) and (j) of the same regulations further require that the licence application contain: *"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"*, *"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"*, and *"the proposed measures to control releases of nuclear substances and hazardous substances into the environment"*, respectively.

Paragraph 12(1)(c) and (f) of the *General Nuclear Safety and Control Regulations* require every licensee to take all reasonable precautions to protect the environment and to take all reasonable precautions to control the release of nuclear substances or hazardous substances.

Subsection 13(1) of the *Radiation Protection Regulations* prescribes the radiation dose limit for the general public of 1 mSv per calendar year.

Emergency Management and Fire Protection

The regulatory foundation for the recommendation(s) associated with Emergency Management and Fire Protection includes the following:

Paragraph 6(k) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information on the licensee's *"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 security, including measures to:*

(i) assist off-site authorities in planning and preparing to limit the effects of an accidental release;
(ii) notify off-site authorities of an accidental release or the imminence of an accidental release;
(iii) report information to off-site authorities during and after an accidental release;,
(iv) assist off-site authorities in dealing with the effects of an accidental release; and
(v) test the implementation of the measures to prevent or mitigate the effects of an accidental release."

Paragraph 6(k) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information on the licensee's "*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 security"*. These measures must include the implementation of a fire protection program which complies with all applicable national codes and standards.

Waste Management

The regulatory foundation for the recommendation(s) associated with Waste Management includes the following:

Paragraph 3(1)(j) of the *General Nuclear Safety and Control Regulations* requires that an application for a licence include the name, quantity, form 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.

Security

The regulatory foundation for the recommendation(s) associated with Security includes the following:

Paragraphs 3(1)(g) and 3(1)(h) of the *General Nuclear Safety and Control Regulations* require that a licence application contain information related to site access control and measures to prevent loss or illegal use, possession or removal of the nuclear substance, prescribed equipment or prescribed information.

- Paragraph 6(l) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain "the proposed measures to prevent acts of sabotage or attempted sabotage at the nuclear facility".

Packaging and Transport

Paragraph 6(e) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence to operate a Class I facility shall contain information on *"the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances"*. Every person who transports radioactive material, or requires it to be transported, must act in accordance with the requirements of the Transportation of Dangerous Goods Regulations (TDGR) and the *Packaging and Transport of Nuclear Substances Regulations, 2015* (PTNSR).

Decommissioning Strategy and Financial Guarantees

The regulatory foundation for the recommendation(s) associated with CLSI's Decommissioning Strategy and Financial Guarantees includes:

- The *General Nuclear Safety and Control Regulations* requires under paragraph 3(1)(l) that a licence application contains a description of any proposed financial guarantee relating to the activity to be licensed.
- Paragraph 3(k) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence in respect of a Class I nuclear facility, other than a licence to abandon, shall contain the proposed plan for the decommissioning of the nuclear facility or of the site.

Licensee's Public Information Program

The regulatory foundation for the recommendation(s) associated with CLSI's public information and disclosure program includes:

- Paragraph 3(j) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain the "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".

C.2 Technical Basis

The technical basis for the recommendations presented in this CMD, including guidance documents, national standards and regulatory documents is addressed in detail in the proposed LCH in Part 2.

D. SAFETY AND CONTROL AREA FRAMEWORK

D.1 Safety and Control Areas Defined

The safety and control areas identified in section 2.2, and discussed in summary in sections 3.1 through 3.11 are comprised of specific areas of regulatory interest which vary between facility types.

The following table provides a high-level definition of each SCA. The specific areas within each SCA are to be identified by the CMD preparation team in the respective areas within section 3 of this CMD

SAFETY AND CONTROL AREA FRAMEWORK		
Functional Area	**Safety and Control Area**	**Definition**
Management	Management System	Covers the framework which establishes the processes and programs required to ensure an organization achieves its safety objectives and continuously monitors its performance against these objectives and fostering a healthy safety culture.
	Human Performance Management	Covers activities that enable effective human performance through the development and implementation of processes that ensure that licensee staff is sufficient in number in all relevant job areas and that licensee staff have the necessary knowledge, skills, procedures and tools in place to safely carry out their duties.
	Operating Performance	This includes an overall review of the conduct of the licensed activities and the activities that enable effective performance.
Facility and Equipment	Safety Analysis	Maintenance of the safety analysis that supports that 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.

SAFETY AND CONTROL AREA FRAMEWORK		
Functional Area	**Safety and Control Area**	**Definition**
	Physical Design	Relates to activities that impact on the ability of systems, components and structures to meet and maintain their design basis given new information arising over time and taking changes in the external environment into account.
	Fitness for Service	Covers activities that impact on the physical condition of systems, components and structures to ensure that they remain effective over time. This includes programs that ensure all equipment is available to perform its intended design function when called upon to do so.
Core Control Processes	Radiation Protection	Covers the implementation of a radiation protection program in accordance with the RP Regulations. This program must ensure that contamination and radiation doses received are monitored and controlled.
	Conventional Health and Safety	Covers the implementation of a program to manage workplace safety hazards and to protect personnel and equipment.
	Environmental Protection	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.
	Emergency Management and Fire Protection	Covers emergency plans and emergency preparedness programs which exist for emergencies and for non-routine conditions. This also includes any results of exercise participation.
	Waste Management	Covers internal waste-related programs which 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. Also covers the planning for decommissioning.
	Security	Covers the programs required to implement and support the security requirements stipulated in the regulations, in their licence, in

SAFETY AND CONTROL AREA FRAMEWORK		
Functional Area	**Safety and Control Area**	**Definition**
		orders, or in expectations for their facility or activity.
	Safeguards and Non-Proliferation	Covers the programs and activities required for the successful implementation of the obligations arising from the Canada/IAEA safeguards agreements as well as all other measures arising from the *Treaty on the Non-Proliferation of Nuclear Weapons*.
	Packaging and Transport	Programs that cover the safe packaging and transport of nuclear substances and radiation devices to and from the licensed facility.

D.2 Specific Areas for this Facility Type

The following table identifies the specific areas that comprise each SCA for CLSI.

SPECIFIC AREAS FOR THIS FACILITY TYPE		
Functional Area	**Safety and Control Area**	**Specific Areas**
Management	Management System	▪ Management System ▪ Organization ▪ Performance Assessment, Improvement and Management Review ▪ Operating Experience (OPEX) ▪ Change Management ▪ Safety Culture ▪ Configuration Management ▪ Records Management ▪ Management of Contractors
	Human Performance Management	▪ Human Performance Programs ▪ Personnel Training ▪ Fitness for Duty
	Operating Performance	▪ Conduct of Licensed Activity

SPECIFIC AREAS FOR THIS FACILITY TYPE		
Functional Area	**Safety and Control Area**	**Specific Areas**
		▪ Procedures ▪ Reporting and Trending
Facility and Equipment	Safety Analysis	▪ Hazard Analysis
	Physical Design	▪ Design Governance ▪ Site Characterization ▪ Facility Design ▪ Structure Design ▪ System Design ▪ Components Design
	Fitness for Service	▪ Equipment Fitness for Service/Equipment Performance ▪ Maintenance ▪ Periodic Inspection and Testing
Core Control Processes	Radiation Protection	▪ Application of ALARA ▪ Worker Dose Control ▪ Radiation Protection Program Performance ▪ Radiological Hazard Control ▪ Estimated Dose to Public
	Conventional Health and Safety	▪ Performance ▪ Practices ▪ Awareness
	Environmental Protection	▪ Effluent and Emissions Control (releases) ▪ Environmental Management System (EMS) ▪ Assessment and Monitoring ▪ Protection of People ▪ Environmental Risk Assessment

SPECIFIC AREAS FOR THIS FACILITY TYPE		
Functional Area	**Safety and Control Area**	**Specific Areas**
	Emergency Management and Fire Protection	▪ Conventional Emergency Preparedness and Response ▪ Fire Emergency Preparedness and Response
	Waste Management	▪ Waste Characterization ▪ Waste Minimization ▪ Waste Management Practices ▪ Decommissioning Plans
	Security	▪ Facilities and Equipment ▪ Response Arrangements ▪ Security Practices ▪ Drills and Exercises
	Safeguards and Non-Proliferation	▪ Nuclear Material Accountancy and Control ▪ Access and Assistance to the IAEA ▪ Operational and Design Information ▪ Safeguards Equipment, Containment and Surveillance ▪ Import and Export
	Packaging and Transport	▪ Package Design and Maintenance ▪ Packaging and Transport ▪ Registration for Use

E. SUPPORTING DETAILS

E.1 Conventional Health and Safety

Performance

The nature of lost-time injuries that occurred at CLSI from January 1, 2012- June 30, 2021 and the remedial action take to prevent recurrence.

Table 5.8 - Summary of lost-time injuries at CLSI, January 1 2012- June 30 2021

Year	Nature of Injury	Remedial Action
2015	Fall. Employee contacted only front edge of chair while sitting down, chair rocked forward slightly and employee fell onto the floor.	Incident reviewed, no further actions taken.
2017	Laceration. Worker was removing insulation from a wire with a knife and knife slipped.	Reviewed glove types in inventory, various communication from supervisors to staff regarding knife safety.
2020	Chemical burn. A worker was using a wet saw to cut concrete shielding blocks. Cooling water saturated the wrist of the worker between the gloves and long-sleeved shirt worn, resulting in a prolonged alkaline exposure and causing a chemical burn.	A root cause analysis was completed, resulting in several work process improvements aimed at reducing the risk of this type of injury.

E.2 Events related to human error at CLSI 2012-2021

Notable events over the licensing period related to human error are:

- in 2015, there were two events where an Active Area Radiation Monitoring System (AARMS) station was powered down. In one instance, the worker turned off a breaker that was not the one described in the work order. In the other, a piece of equipment was plugged into the same circuit that powers the AARMS station, causing it to power down. No injuries occurred as a result of these errors.
- a near-miss electrical event in 2016 where a 600V power supply switch was not properly locked and tagged out when a staff member was working in the area. The Lock Out – Tag Out (LOTO) process was revised, a SAT-compliant training program was developed, and the fitness for duty program was expanded to further discuss mental fitness when performing tasks that may pose an unusual risk to health and safety. No injuries occurred due to this near-miss.
- in 2017, a planned removal of an AARMS gamma probe for annual calibration was completed in accordance with an approved work permit. After work was completed, the worker did not re-enable the switch at the AARMS station, resulting in de-activation of the electron gun interlock. Contrary to the licensee's management system, the work permit had been created after the work has been completed, and the work was not been independently verified. The worker received additional training on the controlled work process, and improvements were made to the probe calibration work planning.
- in 2019, one AARMS station's interlock and alarm setpoints were set at incorrect, lower values. This was the result of AARMS verification and validation testing the week before, during which the inspectors change values in the programmable logic controller (PLC) to simulate alarm conditions. The setpoint was properly reset in the Input / Output controller, but this was not replicated in the PLC. The Controls Engineer must now verify the continuity of setpoints after verification and validation testing.
- in 2020 during the annual oxygen monitoring validation and verification testing, there was an uncontrolled release of liquid nitrogen. Two fill lines had recently been upgraded and the control switches had been incorrectly wired. An error in a drawing had led to the mis-wired switches. The issue was escalated to the Problem Reporting System for investigation. No injuries occurred because of this event.

No injuries resulted from the events described above. Occupational injuries are discussed further in Section 3.5 in the Conventional Health and Safety SCA.

PART TWO

Part Two provides all relevant information pertaining directly to the licence, including:

1. Any proposed changes to the conditions, licensing period, or formatting of an existing licence;
2. The proposed licence;
3. The proposed licence conditions handbook; and
4. The current licence.

PROPOSED LICENCE CHANGES

Overview

The following changes to the licence and licence conditions are recommended:

- Incorporating changes made in the 2015 licence amendment (CMD15-H102)
- Removing the licence condition that prohibits the use of the BioMedical Imaging and Therapy (BMIT) beamline on humans
- Changing the timeframe for provision of a written report regarding an dose action level exceedance to 21 days, from 30 working days

Details of each of these changes can be found below.

Licence Conditions

2015 licence amendment

In CMD15-H102, the Commission approved a licence amendment that updated the licensee's address and added the verb "process" to the list of licensed activities. The change was issued as an amendment consolidated with the licence issued in 2012. The changes made in the amendment have been incorporated into the proposed licence proper.

Operating Performance

CNSC staff recommend that licence condition 4.3 be removed. Licence condition 4.3 is a non-standard condition that requires CLSI to seek approval from the CNSC prior to operating the BMIT beamline on humans. CLSI has abandoned their plans to use the BMIT on humans, and requested that the CNSC remove this Licence Condition. Removal of this licence condition does not imply permission to use the BMIT on humans. There are no operating procedures in the LCH that permit the use of BMIT on humans. CLSI does not have authorization from other regulatory bodies that would permit this use.

Radiation Protection

CNSC staff recommend changing licence condition 8.2, which requires that CLSI report any exceedance of radiation protection action levels. The current licence condition requires a written report to be submitted within 30 working days. CNSC staff recommend changing the reporting timeframe to within 21 days, to align with the other reporting requirements listed in *REGDOC 3.1.2 Reporting Requirements Volume I: Non-Power Reactor Class I Facilities and Uranium Mines and Mills*, and to align with the same requirement in the Class II CLSI licence.

Licence Format

No changes are proposed to the licence format.

Licence Period

CLSI requested a 10-year licence term in their application to renew the synchrotron operating licence. CNSC has a standardized licence and licence conditions handbook (LCH) framework that provides for effective regulatory oversight of operating facilities. CLSI's license requires them to report on their compliance through annual compliance reports, including significant changes to its operations. CNSC staff verify compliance through desktop reviews, inspections and event reviews. In addition, CNSC report on CLSI's performance to the Commission every 2 years, through the regulatory oversight reports [12] for nuclear substance licensees in Canada. Therefore, CNSC staff recommend that the Commission retain the current 10 year licensing period.

PROPOSED LICENCE

eDoc 6624363 (Word)

eDoc 6682885 (PDF)

CLASS IB PARTICLE ACCELERATOR OPERATING LICENCE

CANADIAN LIGHT SOURCE INCORPORATED

I) LICENCE NUMBER: **PA1OL-02.00/2032**

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

Canadian Light Source Incorporated
44 Innovation Boulevard
University of Saskatchewan
Saskatoon, SK S7N 2V3

III) LICENCE PERIOD: This licence is valid from **1 June 2022** to **31 May 2032**, unless otherwise suspended, amended, revoked or replaced.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

(a) Operate the Canadian Light Source at the location referred to in Part II of this licence (hereinafter "the facility");

(b) Possess, transfer, use, and store the nuclear substances arising from the activities referred to in paragraph (a) at the facility, and

(c) Possess, process, transfer, use, import and store other nuclear substances at the facility, subject to condition 4.3.

V) EXPLANATORY NOTES:

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

(b) The Canadian Light Source Incorporated Facilities Licence Conditions Handbook (LCH) provides

(i) compliance verification criteria in order to meet the conditions listed in the licence;

(ii) information regarding delegation of authority to CNSC staff; and

(iii) applicable versions of documents and a process for version control of codes, standards or other documents that are used as compliance verification criteria in order to meet the conditions listed in the licence.

VI) CONDITIONS:

G. GENERAL

G.1 Licensing Basis

The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis, defined as:

(i) the regulatory requirements set out in the applicable laws and regulations;
(ii) the conditions and safety and control measures described in the facility's licence and the documents directly referenced in that licence;
(iii) the safety and control measures described in the licence application and the documents needed to support that licence application;

unless otherwise approved in writing by the Canadian Nuclear Safety Commission (CNSC, hereinafter, "the Commission")

G.2 Changes to CLSI Documents

(a) Changes to the safety and control measures described in the application and the documents needed to support that application are permitted provided that the objective of the licensing basis is met.

(b) Changes that are outside of the licensing basis are not permitted without the prior written approval of the Commission.

G.3 Resolution of Conflict or Inconsistency

The licensee shall, in the event of any conflict or inconsistency, actual or potential, between licence conditions or codes, standards or regulatory documents referenced in this licence, direct the conflict or inconsistency in writing to the Commission or a person authorized by the Commission, for resolution.

1. MANAGEMENT SYSTEM

1.1. Management System

The licensee shall implement and maintain a management system, including a written safety policy which places safety paramount within the management system, overriding all other demands, for activities carried out under this licence.

2. HUMAN PERFORMANCE MANAGEMENT

2.1. Human Performance Program

The licensee shall implement and maintain a human performance program.

2.2. Training Program

The licensee shall implement and maintain a training program.

3. OPERATING PERFORMANCE

3.1. Operations Program

The licensee shall implement and maintain a program for operation of the facilities. This shall include direction and documentation for safely operating the nuclear facility and shall at a minimum reflect the safety analyses that have been previously submitted to the Commission.

3.2. Beamlines

The licensee shall maintain an up to date procedure for commissioning and operating beamlines.

3.3. Reporting Requirements

The licensee shall submit to the Commission each year a written annual compliance report that covers the previous year's operation.

4. SAFETY ANALYSIS

4.1. Safety Analysis Program

The licensee shall conduct and maintain safety analyses that are of appropriate detail for the complexity of the facility or process analyzed.

4.2. Documentation

The licensee shall maintain an updated set of documents and technical references comprising detailed technical descriptions and safety analysis specific to each major sub-facility on-site.

4.3. Operational Specifications and Limits

The licensee shall maintain an up to date set of operating limits for the facilities and activities authorized under the licence, including limits for the possession, processing, use, transfer, storage, import and export of nuclear substances and operational limits for accelerators.

5. PHYSICAL DESIGN

5.1. Design Program

The licensee shall implement and maintain a design program.

6. FITNESS FOR SERVICE

6.1. Testing, Calibration and Maintenance Program

The licensee shall implement and maintain a testing, calibration and maintenance program for the facility.

7. RADIATION PROTECTION

7.1. Radiation Protection Program

The licensee shall implement and maintain a radiation protection program.

7.2. Dose Action Levels

The licensee shall notify the Commission or a person authorized by the Commission within 24 hours of becoming aware that an action level has been reached or exceeded and shall file a written report within 21 days of becoming aware of the matter.

8. CONVENTIONAL HEALTH AND SAFETY

8.1. Occupational Health and Safety Program

The licensee shall implement and maintain a conventional health and safety program.

9. ENVIRONMENTAL PROTECTION

9.1. Environmental Protection Program

The licensee shall implement and maintain an environmental protection program.

9.2. Release of Hazardous or Nuclear Substances

The licensee shall control, monitor and record the releases of hazardous or nuclear substances.

10. EMERGENCY MANAGEMENT AND FIRE PROTECTION

10.1. Emergency Preparedness Program

The licensee shall implement and maintain a program for emergency preparedness to address on-site and off-site events which can affect the nuclear facility.

10.2. Fire Protection Program

The licensee shall implement and maintain a fire protection program.

11. WASTE MANAGEMENT

11.1. Waste Management Program

The licensee shall implement and maintain a waste management program.

11.2. Planning for Decommissioning

The licensee shall maintain a decommissioning plan.

12. SECURITY

12.1. Security Program

The licensee shall implement and maintain a security program.

13. PACKAGING AND TRANSPORT

13.1. Packaging and Transport

The licensee shall implement and maintain a packaging and transport program of nuclear substances.

14. SITE SPECIFIC

14.1. Public Information and Disclosure

The licensee shall implement and maintain a public information program for the facility.

14.2. Financial Guarantee

The licensee shall maintain, in effect, a financial guarantee for decommissioning of the facility that is acceptable to the Commission.

SIGNED at OTTAWA, this day of May 2022

_____

Rumina Velshi, President,
on behalf of the Canadian Nuclear Safety Commission

PROPOSED LICENCE CONDITIONS HANDBOOK

eDoc 6623383 (Word)

eDoc 6631482 (PDF)

Canada's Nuclear Regulator

e-DOC 6623383 (Word)
e-DOC 6631482 (PDF)

LICENCE CONDITIONS HANDBOOK

LCH-CLSI-R000
CANADIAN LIGHT SOURCE INCORPORATED ACCELERATOR OPERATING LICENCE

PA1OL-02.00/2032

Revision 0

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire

Canada

Licence Conditions Handbook **Effective Date: June 1, 2022**
LCH-CLSI-R000
Canadian Light Source Inc.
Accelerator Operating Licence
PA1OL-02.00/2032

SIGNED at OTTAWA the

_____ (signed version: E-DOCS # 6631452)
Mark Broeders
Director
Directorate of Nuclear Substance Regulation
CANADIAN NUCLEAR SAFETY COMMISSION

Revision History:

Effective Date	Revision #	LCH E-DOCS #	Description of the Changes	DCR List E-DOCS #
June 1, 2012	0	6623383		

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INTRODUCTION

Licence Conditions Handbook

The general purpose of the Licence Conditions Handbook (LCH) is to identify and clarify the relevant parts of the licensing basis for each licence condition (LC). This will help ensure that the licensee maintains facility operation in accordance with the licensing basis for the facility and the intent of the licence. The LCH should be read in conjunction with the licence.

The LCH has three parts under each LC: Preamble, Compliance Verification Criteria (CVC), and Guidance. The Preamble explains, as needed, the regulatory context, background, and/or history related to the LC. The CVC are criteria used by CNSC staff to verify and oversee compliance with the LC. The Guidance is non-mandatory information, including direction, on how to comply with the LC.

Authorized Persons

Throughout the licence, the statement "a person authorized by the Commission" refers to whom the Commission may delegate certain authority to CNSC staff. Unless otherwise indicated in the CVC of specific LCs in this LCH, the delegation of authority by the Commission to act as a "person authorized by the Commission" is only applied to the incumbents of the following positions:

- Director, Accelerators and Class II Facilities Division (ACFD);
- Director General, Directorate of Nuclear Substance Regulation (DNSR),
- Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch.

In addition, these incumbents may approve changes to the LCH.

Change Control

A change control process has been developed for revisions to the LCH to ensure that its preparation and use is controlled and that all references are identified and maintained. Request to change this document can be initiated by either CNSC staff or the licensee. The licensee is to be consulted on any change proposed by CNSC staff.

A change request form is included in Appendix A of the LCH. The change will be assessed by CNSC staff. Provided the change is consistent with the conditions of the licence and the objectives of the licensing basis, a recommendation to proceed will be made to one of the authorized persons. Once approved, the LCH will be updated and distributed to the licensee and made available to all relevant CNSC staff.

Dispute Resolution

In the event of disagreement concerning the LCH, the following conflict resolution process will apply:

- The Project Officer handling the licence will arrange a meeting between the appropriate parties, including persons authorized by the licensee and the Director of the Accelerator and Class II Facilities Division of the CNSC.
- If a mutually acceptable decision is reached at this meeting, the rationale supporting the decision will be documented and referenced in Appendix G of the LCH.
- If a mutually agreeable decision is not reached, the disagreement will be brought to the next level of authorized persons.
- Any unresolved issue will be referred to the Commission.

Appendices

This LCH has the following appendices:

- APPENDIX A which describes the change control process;
- APPENDIX B which is a list of definitions used in this LCH;
- APPENDIX C which is the operational limits of this facility;
- APPENDIX D which is the list of nuclear substances allowed at the facility;
- APPENDIX E which is the list of safeguard nuclear substances allowed at the facility;
- APPENDIX F which is a list of documents that are referred in this LCH; and
- APPENDIX G which is a list of all resolution of inconsistencies.

1. GENERAL

Licence Condition 1.1 – Licensing Basis

The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis described in the LCH, unless otherwise authorized in this licence.

Preamble

The licensing basis for a regulated facility or activity is a set of requirements and documents comprising:

(i) the requirements set out in the applicable laws and regulations;
(ii) the conditions and safety and control measures described in the facility's or activity's licence and the documents directly referenced in that licence; and
(iii) the safety and control measures described in the licence application and the documents needed to support that licence application.

The licensing basis sets the boundary conditions for acceptable performance at a regulated facility or activity, thus establishing the basis for the CNSC's compliance program with respect to that regulated facility or activity.

Compliance Verification Criteria

Canadian Light Source Incorporated (CLSI) shall operate its nuclear facility in accordance with the licensing basis. This means that CLSI shall conduct the licensed activities in accordance with the laws, regulations, requirements and documents included in (i) through (iii) above.

The "documents needed to support the licence application" under item iii) above are referenced in this LCH. As improvements are made to CLSI's programs and documents throughout the licence period, provisions have been made under licence condition 1.2 to allow CLSI to make changes to these documents.

Guidance

None provided.

Licence Condition 1.2 – Changes to CLSI Documents

(a) **Changes to the safety and control measures described in the application and the documents needed to support that application are permitted provided that the objective of the licensing basis is met.**
(b) **Changes that are outside of the licensing basis are not permitted without the prior written approval of the Commission.**

Preamble

CLSI is encouraged to make continuous improvements to all aspects of its operations, but at all times shall remain within the licensing basis authorized by the Commission. Consequently, if changes are made which improve safety and remain within the licensing basis, then CLSI does not need prior written approval of the Commission. However, CLSI is required to notify the CNSC staff when **any** changes are made to the core documents identified in each Safety Control Area (SCA). For these documents, the licensee must submit prior notice of proposed changes sufficiently far in advance of the implementation date to enable CNSC staff to review the changes made and verify that all changes remain within the licensing basis **prior to implementation**.

Changes outside of the existing licensing basis require written approval of the Commission. Such changes will typically require the licensee to apply for a licence amendment to modify the scope of the licensing basis.

Compliance Verification Criteria

The licensee shall not make any change that would result in an impact on health and safety of persons, environment, national security, or to measures of control and international obligations to which Canada has agreed that is different in nature or greater in magnitude or probability than that described in the licensing basis documents without prior written approval of the Commission. All other changes are subject to the written approval of the authorized persons as designated in the introduction of this LCH.

The documents which must be submitted to obtain CNSC approval for changes must demonstrate that the change:

- has been thoroughly developed, designed, analyzed, reviewed and approved by the licensee, and
- is in compliance with all regulatory requirements.

The documents required to be submitted by compliance verification criterion 1.2 must contain the complete set of information needed to enable CNSC staff to evaluate the proposed change and develop a regulatory position for decision by the Commission, or a person authorized by the Commission. Prior to submitting the request and documents related to the change approval, the licensee shall have assessed and approved the proposed change using the licensee's authorized change control process confirming the merit, validity and safety of the proposed change. The proposed change details shall have been developed and designed to the level which enables a sound and informed decision to be made. The proposed change must be supported by a

corresponding safety analysis and the licensee must demonstrate that it complies with all regulatory and licensing requirements. The design, review, control and implementation of the change must be in accordance with the requirements of applicable standards and reference publications specified in the LCH, unless otherwise accepted in writing by CNSC staff.

The approval for changes may be granted by the Commission or by the CNSC staff identified in the introduction of this LCH, depending upon on its risk significance. CNSC staff will submit to the Commission for consideration any matter that in CNSC staff's opinion:

(a) may pose an unreasonable risk;
(b) is potentially of significant interest to the Commission; or
(c) has the potential to attract national or international public or media interest or concern.

If the written approval of the Commission is needed for a change to proceed, a determination of the applicability of the *Canadian Environmental Assessment Act* (CEAA) must be made by CNSC staff. An environmental assessment under CEAA may or may not be required.

Guidance

None provided.

Licence Condition 1.3 – Resolution of Conflict or Inconsistency

The licensee shall, in the event of any conflict or inconsistency, actual or potential, between licence conditions or codes, standards or regulatory documents referenced in this licence, direct the conflict or inconsistency in writing to the Commission or a person authorized by the Commission, for resolution.

Preamble

This licence condition directs the licensee to seek CNSC resolution in the event that conflicts or inconsistencies are identified between the documents which form the licensing basis.

Compliance Verification Criteria

The licensee shall formally seek CNSC resolution of any conflict or inconsistency.

In the event of any conflict or inconsistency between any CNSC requirement made pursuant to the NSCA and its regulations, and the requirements of the licence, the licensee shall refer the matter to the Commission or a person authorized by the Commission for resolution.

Guidance

Any conflict or inconsistency identified should first be discussed between the licensee and CNSC Project Officer handling the licence. If the conflict or inconsistency cannot be resolved, the matter shall be referred to the dispute resolution process described in the introduction of this LCH.

The outcome will be documented to ensure a common understanding. CNSC staff will record all resolutions made pursuant to this licence condition in Appendix G of the LCH. This Appendix gives a description of the conflict or inconsistency and a reference to the CNSC electronic record (E-DOCS #) documenting the resolution.

If necessary, the LCH will be updated to reflect any changes required to resolve the conflict or inconsistency.

2. SCA – MANAGEMENT SYSTEM

Licence Condition 2.1 – Management System

The licensee shall implement and maintain a management system, including a written safety policy which places safety paramount within the management system, overriding all other demands, for activities carried out under this licence.

Preamble

Paragraph 3(k) of the *General Nuclear Safety and Control Regulations* requires that a licence application contain information related to the applicant's organizational management structure including the internal allocation of functions, responsibilities and authority.

Paragraph 3(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain *"the proposed quality assurance program for the licensed activity"*.

Compliance Verification Criteria

Licensing Basis Publications

Source	Title	Document Number
CSA	Management System Requirements for Nuclear Facilities	N286-12
CNSC	Safety Culture	REGDOC-2.1.2 (April 2018)

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Quality Manual	10.12.1.1	11	6617992	Y
CLSI	Organization Management	0.1.1.15	4	5692017	Y
CLSI	Purchasing Requisition Procedure	0.1.1.17	3	4685005	Y
CLSI	Document and Record Control Process	0.1.1.41	7	6658439	Y
CLSI	Engineering Change Request & Engineering Change Order Procedure	0.7.1.3	3	6293623	Y
CLSI	Quality Management System Review Procedure	0.7.1.5	2	5688228	Y
CLSI	Procurement Process	0.13.1.9	9	5877342	Y

CLSI	Training Process	0.24.1.2	1	5907205	Y
CLSI	Work Management Process	0.24.1.10	1	5750767	Y
CLSI	Science Work Management Process	0.24.1.12	1	6656956	Y
CLSI	Test Equipment and Process Instrumentation Calibration Procedures	7.7.38.1	4	6257013	Y
CLSI	Internal Quality Audit Procedure	10.7.1.2	3	6608871	Y
CLSI	Health, Safety and Environment Manual	11.9.1.1	6	6567075	Y
CLSI	University of Saskatchewan and Canadian Light Source License Agreement		2003	3429018	Y

(1) The licensee shall not modify the authorities or responsibilities of the Manager of Health, Safety and Environment Department without the prior written approval of the Commission, or a person authorized by the Commission.

Guidance

Guidance Publications

Source	Title	Document Number
CNSC	Management System	REGDOC 2.1.1 (May 2019)
CSA	Commentary on N286-12 Management System Requirements for Nuclear Facilities (Feb 2021)	CSA N289.0.1:21

The Manager of Health, Safety and Environment Department acts as the radiation safety officer for the facility. As the radiation safety officer, this person has the authority to take any action deemed appropriate and to stop any activity deemed unsafe. Any change to the authority and responsibility could impact the safety of the facility, therefore the written approval of the Commission or a person authorized by the Commission is required.

The management system documentation should contain sufficient directions for workers to comply with the regulatory requirements.

3. SCA – HUMAN PERFORMANCE MANAGEMENT

Licence Condition 3.1 – Human Performance Program

The licensee shall implement and maintain a human performance program.

Preamble

Paragraphs 12(1)(a), (b), (e) and section 17 of the *General Nuclear Safety and Control Regulations* require different elements related to the human performance program.

Compliance Verification Criteria

Licensing Basis Publications

Source	Title	Document Number
CNSC	Human Factors	REGDOC-2.2.1
CSA	N286-12 Management system requirements for nuclear facility	CSA N286-12

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	CLS Employee Hours of Work Procedure	0.1.1.14	8	6088509	Y
CLSI	Occupational Health and Safety Manual	11.9.37.1	3	6608871	Y
CLSI	Radiation Protection and Control Manual	11.9.53.3	4	6088497	Y
CLSI	Biological, Chemical and Nanomaterial Safety Manual	11.9.55.1	5	5920284	Y

(1) The licensee shall:

- define the expected personnel performance and behavior and communicate the expectations to personnel;
- define the expected results of personnel performance and communicate the expectations to personnel; and
- evaluate the personnel performance and compare it against expectations.

(2) The licensee shall ensure that work activities are authorized and carried out using approved documents (including those for software), materials, parts, tools, processes and practices.

(3) The licensee shall ensure that:

- verification activities are planned before starting the work;
- verification of work is performed to confirm that the work meets requirements; and
- verification is recorded.

(4) The licensee shall ensure that persons assigned to perform independent verification do not verify their own work; or work they have directly supervised.

(5) The licensee shall monitor and control the hours of work and shift schedules of personnel performing safety-related tasks or working on safety-related systems.

Guidance

Guidance Publications

Source	Title	Document Number
CSA	Management System Requirements for Nuclear Facilities	N286-12
CNSC	Fitness for Duty: Managing Worker Fatigue	REGDOC-2.2.4 (March 2017)
CNSC	Minimum Staff Complement	REGDOC-2.2.5 (April 2019)
CNSC	Safety Culture	REGDOC-2.1.2 (April 2018)
CSA	Commentary on N286-12, Management systems requirements for nuclear facilities	CSA N286-12.1:21

Human Performance Program:
Human performance is the real-world results or outcomes of the work that people do, including how people carry out the work. Both the results and the people's activities are important because good results can be achieved through work activities that cause damage or harm, either in real time, or later on.

A human performance program is the cross-cutting overview of considering and managing the human, technology and organizational factors that influence human performance. Factors that influence human performance can be called "human factors". Examples of human factors are organizational and management structures; policies and programs; allocation of functions to humans and technology; the design of user interfaces; staffing provisions; fitness for duty, job-design features; procedures; management and supervision; work schedules; design of procedures; training; competency; safety culture; and the physical work environment. The aim of the human performance program is to achieve the desired outcomes, including for safety, through supporting people to perform their work activities.

Understanding and improving human performance should take an integrated and strategic approach, which considers human error as a symptom of deeper issues and not the direct cause of failure. Improving human performance should be based on organizational learning and understanding of the factors that influence human performance. The licensee may follow industry good practices in developing the scope, content and approach of the human performance program.

Note that many of the topics considered under the Human performance program specific area are considered in detail by the CNSC elsewhere in the SCA framework. The human performance program specific area focuses on the overview of how the licensee manages the factors that influence human performance with the goal of supporting and achieving the desired human performance.

Human Performance should be managed via the management system, and where applicable, the human performance program should reference governing documentation for the facility. The documented human performance program can take the form of a "road map" that describes how the management system and other aspects of the organization are managed to support the desired human performance, or it may be a stand-alone document.

Independent Verification:
Clause 4.8 of CSA standard N286-12 define the generic requirements needed in order to ensure:

- personnel know what is expected of them;
- performance of work is controlled; and
- work is verified to confirm that it is correct.

The degree of independence and extent of verification can vary depending of the complexity of the work and the potential impact on safety.

Licence Condition 3.2 – Training Program

The licensee shall implement and maintain a training program.

Preamble

Paragraphs 12(1)(a) and 12(1)(b) of the *General Nuclear Safety and Control Regulations* require that licensees ensure that there are a sufficient number of properly trained and qualified workers to safely conduct the licensed activities. Applicants for a Class I facility operating licence are required to describe the programs which have been implemented to achieve these requirements under paragraphs 6(m) and 6(n) of the *Class I Nuclear Facilities Regulations*, which require that licence applications include the proposed responsibilities, qualification requirements, training program and requalification program for workers; along with the results that have been achieved in implementing the program for recruiting, training and qualifying workers. Subsection 14 (2) of the *Class I Nuclear Facilities Regulations* further requires *"every licensee to keep a record of the status of worker's qualifications, requalification and training, including the results of all tests and examinations"*.

Compliance Verification Criteria

Licensing Basis Publications

Source	Title	Document Number
CNSC	Personnel Training	REGDOC-2.2.2 Version 2, 2016

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	CLS Training Program	10.14.14.1	2	5907214	Y
CLSI	CLS Training Process	0.24.1.2	1	5906718	Y
CLSI	Floor Coordinator Roles Responsibilities and Training Plan	0.12.1.4	2	5785088	Y
CLSI	Accelerator Operations Personnel Qualification and Training Plan	0.12.91.1	8	4716938	Y

The licensee shall implement and maintain a training program. The training program shall comply with the requirements set out in CNSC regulatory document REGDOC-2.2.2, *Personnel Training*.

Guidance

None.

HUMAN PERFORMANCE MANAGEMENT

4. SCA – OPERATING PERFORMANCE

Licence Condition 4.1 – Operating Program

The licensee shall implement and maintain a program for operation of the facilities. This shall include direction and documentation for safely operating the nuclear facility and shall, as a minimum, reflect the safety analyses that have been previously submitted to the Commission.

Preamble

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain *"the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility"*.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Accelerator Operations Configuration Process	0.7.91.4	2	5907210	Y
CLSI	Problem Identification and Resolution Process	0.24.1.1	3	6608871	Y
CLSI	Work Management Process	0.24.1.10	1	5750767	Y
CLSI	Routine Operation Limits and Conditions	8.1.1.6	4	4892892	Y
CLSI	Canadian Light Source Normal Operations - Machine Operating Procedure	8.7.91.1	8	6088506	Y

(1) Operation of the facility shall be governed by formal developed and validated procedures which are reviewed and revised as necessary on a regular basis.

(2) The licensee shall use the safety analysis reports as a basis for continuous safe operation of its facilities and for assessing the safety implications of changes to the facility or to operating procedures.

(3) If operation outside permitted operating boundaries, limits and rules as defined in the facility safety analyses is discovered, the licensee shall take immediate action to return operations to within these limitations.

Guidance

None provided.

Licence Condition 4.2 – Beamlines

The licensee shall maintain an up to date procedure for commissioning and operating beamlines.

Preamble

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain *"the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility"*.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Performance Monitoring of Beamlines Process	6.7.1.2	0	3855386	Y
CLSI	CLS Commissioning - Phase III Frontends, Insertion Devices, Beamlines	8.12.90.1	1	3207972	Y

The design and operation of any new beamline shall follow the approved documented process described in *"CLS Commissioning Phase III Frontends, Insertion Devices, Beamlines"* when building, installing, commissioning and operating synchrotron beamlines.

Guidance

During the expected lifetime of the facility, new beamlines will be added to the facility. The purpose of this condition is to clarify the process for approval of new beamlines. As long as the addition of new beamlines follows the *"CLS Commissioning Phase III Frontends, Insertion Devices, Beamlines"*, there is no requirement for changing the LCH.

Licence Condition 4.3 – Reporting Requirements

The licensee shall submit to the Commission each year a written annual compliance report that covers the previous year's operation.

Preamble

Paragraph 24(5) of the *Nuclear Safety and Control Act* specifies that a licence may contain *"any term or condition that the Commission considers necessary for the purposes of this Act"*. Every facility operating licence includes the requirement to submit an "Annual Compliance Report". This report provides a summary of key facility operating performance parameters related to the safe operation of the facility and the safe conduct of the licensed activities.

Compliance Verification Criteria

Licencing Basis publications

Source	Title	Document Number
CNSC	Reporting Requirements for Non-Power Reactor: Class I Facilities and Uranium Mines and Mills	REGDOC 3.1.2

(1) The licensee shall submit in writing an annual compliance report covering the previous calendar year, by June 30 of each year.

(2) At a minimum, the Annual Compliance Report shall cover the topics outlined in Appendix B of REGDOC 3.1.2. In addition, the Annual Compliance Report must discuss the following topics:

Introduction

(a) A brief summary of facility operations during the year, providing an overview of the highlights or key activities, changes or events for each SCA for the year (e.g., an executive summary).

(b) A brief summary of major projects and changes to the facilities on the site during the reporting period.

Management System

(c) A high level overview of those Committees which have a role in Health and Safety at the site (e.g., the Radiation Safety Committee) including their respective roles and responsibilities. Include a summary of the activities of these Committees (e.g., number of meetings, major topics or issues addressed).

(d) A summary of the Quality Assurance program activities used to evaluate the effectiveness of the Management System (e.g. internal audits conducted, metrics used for program evaluation. summary of results, corrective actions required/completed). Include:

i. activities planned and completed during the reporting period,
ii. an explanation for any initiatives and activities that were planned but not conducted/completed,
iii. metrics used to evaluate the effectiveness of these activities and an evaluation of performance against these metrics,
iv. a summary of initiatives and targets for the upcoming year (next reporting period).

(e) An overview of the licensee performance related to Safety Culture (e.g., a list/description of any related initiatives with a summary of outcomes).

Operating Performance

(f) A summary of operations during the year. As applicable, this may include but is not limited to:
i. number of hours of accelerator operation in various operating modes,
ii. integrated charge (uA-hours) delivered to targets, or
iii. the total activity of isotopes produced.

The licensee should provide data on any parameter which is necessary to characterize the operation of the facility and to confirm that operation was compliant with the relevant limits as specified in the licence or the Licence Conditions Handbook.

(g) A review of individual beam-line operations, including new beam-line installation and commissioning.

Safety Analysis

(h) A summary of any Human Factor Engineering Design Analyses, Validations or Verification exercises conducted on the site.

(i) A list of documents which are referred into the LCH that were changed (including administrative changes).

(j) A current inventory of all nuclear substances (sealed and unsealed) and radiation devices. (Note: in general, this does not include items such as activated beam-line components or shielding materials which may become activated as an unwanted by-product of accelerator operations).

Physical Design

(k) A description of any significant physical design changes related to facility shielding. (Note: in general this is intended to encompass permanent shielding installed for the purpose of limiting radiation doses to personnel, rather than shielding installed for "machine protection" purposes. Short-term temporary shielding installed for a specific task, such as accelerator maintenance, need not be described).

(l) A description of any changes to the facility safety systems, (e.g. access control systems, radiation monitoring and alarm systems, etc.).

Fitness for Service

(m) A summary of testing and inspection program for fire safety equipment and systems.

Emergency Management and Fire Protection

(n) A summary of any emergency response exercises conducted.

Packaging and Transport

(o) An overview of the packaging and transport of nuclear substances during the reporting period (number of shipments, number of packages, types of packages (e.g., exempt, type A, type B) where to, total activity(s)).

Future Plans

(p) A summary of major projects or planned changes for which the CNSC approval may be requested during the next year.

Conclusion

The conclusion should include a basic statement summarizing licensee compliance with regulatory requirements during the reporting period. Any key non-compliances or issues identified during the reporting period should be noted. The licensee should confirm that any corrective actions necessary to address those issues have been or will be implemented. Planned major projects or initiatives to improve regulatory compliance in the upcoming year should be highlighted.

Guidance

None.

5. SCA – SAFETY ANALYSIS

Licence Condition 5.1 – Safety Analysis Program

The licensee shall conduct and maintain safety analyses that are of appropriate detail for the complexity of the facility or process analyzed.

Preamble

Paragraph 3(1)(i) of the *General Nuclear Safety and Control Regulations* requires that a licence application contain *"a description and the results of any test, analysis or calculation performed to substantiate the information included in the application"*.

Paragraphs 6(a), (c) and (d) of the *Class I Nuclear Facilities Regulations* require that a licence application contain: *"a description of the structures, systems and equipment at the facility, including their design and their design operating conditions; a final safety analysis report demonstrating the adequacy of the design of the nuclear facility; and the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility"*.

Compliance Verification Criteria

Licensing Basis Publications

Source	Title	Document Number
CSA	Fire protection for facilities that process, handle, or store nuclear substances	CSA N393-13
GOC	National Building Code, 2015	
GOC	National Fire Code, 2015	

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	CLS Safety System Development Strategy	0.2.37.2	4	6562265	Y
CLSI	Photon Beamlines Safety Guidelines - Personnel Protection and Equipment Protection	6.1.37.1	0	3855386	Y
CLSI	CLSI Safety Report	11.18.40.2	14	5516439	Y
CLSI	BMIT Hazard & Risk Analysis	26.2.37.1	8	5266325	Y

(1) The safety analysis program shall include:

- provisions to ensure that design of any facility incorporates the shielding and safety systems necessary to keep radiological doses to workers and members of the public below regulatory limits and ALARA;
- provisions to ensure that design of any facility incorporates measures to keep releases of radioactive materials into the environment below regulatory limits and ALARA;
- configuration management processes to ensure that the documented design basis for the facility is maintained up-to-date after design changes; and
- processes to ensure that the impacts of design changes are fully assessed and accurately reflected in the safety analyses prior to implementation.

(2) Modifications to the facility shall be made in accordance with the *National Building Code*, the *National Fire Code*, and *Canadian Standards Association* N393-13. The licensee shall, prior to implementation of any proposed modification of the facility with the potential to impact protection from fire:

- submit the proposed modification for third-party review for compliance with the above fire protection codes and standards;
- have the review carried out by one or more independent external reviewers having specific expertise with such reviews; and
- submit in writing the results of the review to the Commission, or a person authorized by the Commission.

(3) As a minimum, facility safety analyses shall include a description and analysis of:

- the design of the facility;
- the normal operating conditions and parameters for the facility;
- the radiological hazards related to the operation of the facility and the measures implemented to ensure that radiological doses to workers and members of the public are below regulatory limits and ALARA;
- the measures implemented to ensure that releases of radioactive materials into the environment are below regulatory limits and ALARA;
- all safety systems and their design basis;
- the potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena;
- the radiological consequences should such an accident occur; and
- the relevant aspects of the facility organization and the management of safety.

Guidance

None.

Licence Condition 5.2 – Documentation

The licensee shall maintain an updated set of documents and technical references comprising detailed technical descriptions and safety analysis specific to each major sub-facility on-site.

Preamble

Paragraph 3(1)(i) of the *General Nuclear Safety and Control Regulations* requires that a licence application contain *"a description and the results of any test, analysis or calculation performed to substantiate the information included in the application"*.

Paragraphs 6(a), (b), (c) and (d) of the *Class I Nuclear Facilities Regulations*, require that a licence application contain: *"a description of the structures, systems and equipment at the facility, including their design and their design operating conditions; a final safety analysis report demonstrating the adequacy of the design of the nuclear facility; and the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility"*.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	CLSI Safety Report	11.18.40.2	14	5516439	Y
CLSI	Photon Beamlines Safety Guidelines - Personnel Protection and Equipment Protection	6.1.37.1	0	3855386	Y
CLSI	BMIT Hazard & Risk Analysis	26.2.37.1	8	5266325	Y
CLSI	Facility Drawings			3879372 and 3879375	Y
CLSI	LINAC Access Control and Interlock System (ACIS) Design Manual	1.9.52.1	3	6608871	Y
CLSI	Booster/ Storage Ring/ Beamlines Access Control and Interlock System (ACIS) PLC Component Manual	7.9.39.4	6	6321294	Y
CLSI	Bio-Medical Imaging and Therapy Beamline (BMIT) Access Control and Interlock System (ACIS) Design	26.9.52.1	4	5530993	Y

	Manual				

The licensee shall maintain an up to date set of design documents, technical references, safety analysis reports and drawings for the nuclear facility.

Guidance

None provided.

Licence Condition 5.3 – Operational Specifications and Limits

The licensee shall maintain an up to date set of operating limits for the facilities and activities authorized under the licence, including limits for the possession, processing, use, transfer, storage, import and export of nuclear substances and operational limits for accelerators.

Preamble

Paragraph 3(1)(c) of the *General Nuclear Safety and Control Regulations* requires that every licence application contain *"the name, maximum quantity and form of any nuclear substance to be encompassed by the licence"*.

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain *"the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility"*.

Paragraph 12(1)(c), (d), and (f) of the *General Nuclear Safety and Control Regulations* require that licensees take all reasonable precautions to protect the environment and the health and safety of persons and to maintain security; provide the devices required by the licence and maintain them; and take all reasonable precautions to control the release of radioactive nuclear substances or hazardous substances.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	CLSI Safety Report	11.18.40.2	14	5516439	Y
CLSI	Industrial Science Laboratory Manual	11.9.37.2	4	6632816	Y
CLSI	Surface Contamination Surveys	11.7.53.6	5	6632817	Y

(1) The licensee shall operate its facility in accordance with the operating limits and specifications listed in Appendix C – OPERATIONAL LIMITS in this LCH.

(2) The licensee shall verify the effectiveness of the shielding of the storage ring and of the beamlines, when the beam current will exceed the present operating value.

The CLSI *Safety Report* has assessed the shielding of the storage ring for a beam current of 500 mA, but due to technical limitations, the shielding has not been verified up to 500 mA. The storage ring and the beamlines were commissioned up to 300 mA during developmental mode and is presently operating during normal mode at a maximum

current of 300 mA. Before allowing routine operation at a beam current greater than 300 mA, the licensee shall verify the effectiveness of the shielding.

(3) Except for nuclear substances listed in paragraph IV b) of this licence, the licensee shall possess, process, use, transfer and store within the facility only those controlled nuclear substances which are identified under Appendix E – NUCLEAR SUBSTANCES – LIMITS FOR POSSESSION, PROCESSING, USE, TRANSFER AND STORAGE in the LCH.

(4) Except for nuclear substances listed in paragraph IV b) of this licence, the licensee shall possess, process, use, transfer, import and store within the facility only those nuclear substances identified in Appendix D – NUCLEAR SUBSTANCES - LIMITS FOR POSSESSION, PROCESSING, USE, TRANSFER, IMPORT AND STORAGE in the LCH

Guidance

Activated components:
Note that this implicitly exempts any activated components or by-products which result from normal operation of CLSI accelerators. It is intended to apply only to radioactive sources used on the site. Also note that this licence does not authorize the licensee to import or export any "controlled nuclear substances" as defined in the *Nuclear Non-proliferation Import and Export Control Regulations*.

6. SCA – PHYSICAL DESIGN

Licence Condition 6.1 – Design Program

The licensee shall implement and maintain a design program.

Preamble

Paragraphs 6(a), (b) and (d) of the *Class I Nuclear Facilities Regulations* require that a licence application contain: *"a description of the structures, systems and equipment at the facility, including their design and their design operating conditions; and the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility"*.

Compliance Verification Criteria

Licensing Basis Publications

Source	Title	Document Number
CSA	Management systems	N286-12
CNSC	General Design Considerations: Human Factors (March 2019)	REGDOC 2.5.1
CNSC	Human Factors (March 2019)	REGDOC 2.2.1

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	CLS Safety System Development Strategy	0.2.37.2	4	6562265	Y
CLSI	LINAC Access Control and Interlock System (ACIS) Design Manual	1.9.52.1	3	6608871	Y
CLSI	Booster/ Storage Ring/ Beamlines Access Control and Interlock System (ACIS) PLC Component Manual	7.9.39.4	6	6321294	Y
CLSI	Oxygen Monitoring and Liquid Nitrogen Distribution Component Manual	7.9.52.1	4	5500649	Y
CLSI	CLSI Safety Report	11.18.40.2	14	5516439	Y

CLSI	Bio-Medical Imaging and Therapy Beamline (BMIT) Access Control and Interlock System (ACIS) Design Manual	26.9.52.1	4	5530993	Y
CLSI	Engineering Change Request & Engineering Change Order Procedure	0.7.1.3	3	6293623	Y
CLSI	Work Management Process	0.24.1.10	1	5750767	Y

(1) The design program shall include:

- processes to ensure that the design of any facility structure, system or component and any modification comply with applicable codes, standards and regulations, including adequate consideration of human factors;
- provisions to ensure that design of any facility incorporates the shielding and safety systems necessary to keep radiological doses to workers and members of the public below regulatory limits and ALARA;
- provisions to ensure that design of any facility incorporates measures to keep releases of radioactive materials into the environment below regulatory limits and ALARA; and
- provisions to ensure that systems and components important to safety are designed to be reliable, fail-safe and incorporate sufficient redundancy to ensure that the failure or the removal from service of a single component does not result in a loss of either the protection function or the minimum level of redundancy required.

(2) The licensee shall maintain up-to-date a set of documents which define the design basis for the facility.

These documents include, but are not limited to, technical descriptions of the Access Control System, Radiation Monitoring System, Beam Line/Experimental Area shielding, Accelerator/Storage Ring shielding, Accelerator & Beam Line control systems.

Guidance

Human Factors in Design

Human factors in design (also called Human Factors Engineering) is a part of the design program. Human factors in design is a systematic design approach, which applies knowledge of human characteristics, OPEX, design standards, guidelines and methods to optimize human and system performance, including for safety. Its application and scope are generally based on risk and safety considerations, as well as to improve productivity. Safe and reliable human

performance plays a major role in overall system safety and human factors in design aims to minimize human error and undesirable performance outcomes. The goal is for the design of the facility, system or equipment, including the work tasks and the working environment, to be compatible with the characteristics of the people who manage, operate, maintain and support it, to achieve optimal human and organizational performance.

The approach considers factors that influence human performance, such as characteristics of the workers, tasks, equipment, technology, procedures, organization, supervision and management practices, working environment, and training. Human factors in design work activities are usually integrated with engineering design, and extend to consider practical operational outcomes, such as workload, operability, maintainability, effectiveness and safety. These outcomes are evaluated through empirical verification and validation processes, to determine if the system or equipment has been designed as specified in the system requirements and standards, and to evaluate the degree to which the designed system achieves its safety and performance goals when used by people in the work environment.

Analyses related to people performing work and the equipment and processes that they use may be conducted in a variety of SCAs e.g., hazard analysis, training needs analysis, procedure verification and validation. Such analyses may trigger design projects, where they become important inputs to the human factors in design project activities.

Source	Title	Document Number
ISO	Ergonomics of human-system interaction Part 210 Human-centred design for interactive systems, 2019	ISO 9421-210
ISO	Ergonomic Principles in the design of work systems	ISO 6385

7. SCA – FITNESS FOR SERVICE

Licence Condition 7.1 – Testing, Calibration and Maintenance Program

The licensee shall implement and maintain a testing, calibration and maintenance program for the facility.

Preamble

Paragraph 6(d) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain *"the proposed measures, policies, methods and procedures for operating and maintaining the nuclear facility"*.

Compliance Verification Criteria

Licensing Basis Publications

Source	Title	Document Number
CSA	Fire protection for facilities that process, handle, or store nuclear substances	N393-13
GOC	National Fire Code, 2015	

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	CLS Safety System Development Strategy	0.2.37.2	4	6562265	Y
CLSI	CLSI Maintenance Plan	8.12.1.2	1	3844140	Y
CLSI	Test Equipment and Process Instrumentation Calibration Procedures	7.7.38.1	4	6257013	Y
CLSI	Radiation Protection and Control Manual	11.9.53.3	4	6088497	Y

(1) The licensee shall determine the extent and frequency of preventive maintenance, testing, surveillance, and inspection of structures, systems and components through a systematic approach, following operating experience and best industry practices. As a minimum, for each structure, system or component, this shall take into account:

- their importance to safety;
- their inherent reliability;
- their potential for degradation (based on operational and other relevant experience, research and vendor recommendations); and

- the consequences of failure.

(2) The licensee shall document the frequency that the various maintenance, inspection and testing tasks are performed.

(3) Following any abnormal event which may impact upon the safety functions and functional integrity of any structure, system or component, the licensee shall identify and revalidate the safety functions and carry out any necessary remedial actions, including inspection, testing, maintenance, and repair, as appropriate.

(4) The licensee shall record all maintenance, testing, and surveillance of structures, systems and components. The results of testing, maintenance and calibration program must be reviewed to look for evidence of incipient and recurring failures. The licensee shall initiate corrective actions and review the preventive maintenance programs accordingly.

(5) The licensee shall operate, maintain, test, and inspect the facility in accordance with the *National Fire Code*, 2015 and CSA N393-13. To demonstrate compliance with the applicable codes and standards the licensee shall:

- arrange for a third party review of compliance with the requirements of the *National Fire Code* and CSA N393-13 biennially;
- have the review carried out by one or more independent external agencies having specific expertise with such reviews; and
- submit the results of the review in writing to the CNSC.

(6) The licensee shall properly identify all equipment in the calibration records, and shall regularly verify the validity of the calibration in accordance with the quality management system.

(7) The licensee shall maintain an accurate inventory of monitoring instruments and associated/related equipment.

(8) The licensee shall ensure that the users of monitoring instruments and associated/related equipment verify the validity of calibration for the intended use, and record the instrument identifier and calibration expiry date.

Guidance

The range of maintenance activities includes monitoring, inspecting, testing, assessing, calibrating, servicing, overhauling, repairing, and parts replacing. The type of maintenance activity and frequency applied to each safety system components needs to be commensurate with importance to safety, design function and required performance.

8. SCA – RADIATION PROTECTION

Licence Condition 8.1 – Radiation Protection Program

The licensee shall implement and maintain a radiation protection program.

Preamble

The *Radiation Protection Regulations* require that the licensee implement a radiation protection program and also ascertain and record doses for each person who performs any duties in connection with any activity that is authorized by the NSCA or is present at a place where that activity is carried out. This program must ensure that doses to workers do not exceed prescribed dose limits and are kept as low as reasonably achievable (the ALARA principle).

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Radiation Protection and Control Manual	11.9.53.3	4	6088497	Y
CLSI	CLSI Safety Report	11.18.40.2	14	5516439	Y

(1) The licensee shall implement and maintain a radiation protection program that ensures radiation doses received by individuals and contamination are monitored, controlled and kept ALARA.

(2) The licensee shall review and revise the provisions of the radiation protection program as necessary to reflect changes in facility design and operations.

Guidance

Guidance Publications

Source	Title	Document Number
CNSC	Radiation Protection	REGDOC 2.7.1

The criteria set out in the CNSC REGDOC 2.7.1 *Radiation Protection* may be used by the licensee in the development of the radiation protection program.

Licence Condition 8.2 – Dose Action Levels

The licensee shall notify the Commission or a person authorized by the Commission within 24 hours of becoming aware that an action level has been reached or exceeded and shall file a written report within 30 working days of becoming aware of the matter.

Preamble

Section 6 of the *Radiation Protection Regulations* specifies the requirements related to action levels. This licence condition is required to provide the notification timeframe.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Radiation Protection and Control Manual	11.9.53.3	4	6088497	Y

(1) For the purpose of this licence condition, "a person authorized by the Commission" includes the Project Officer responsible for licensing and compliance issues related to CLSI and the persons identified in the introduction of this LCH.

(2) If any radiation exposure action level is exceeded, the licensee shall notify the Commission as required by licence condition 8.2.

(3) The licensee shall conduct a documented review of dose action levels at least once every five years in order to validate their effectiveness, and shall revise action levels as necessary to reflect changes in facility operations.

Guidance

Guidance Publications

Source	Title	Document Number
CNSC	Radiation Protection	REGDOC 2.7.1

The current action levels for CLSI workers are given in the following table:

Category of Worker	Dose Limit
Nuclear Energy Workers (NEWs)	2 mSv/quarter
Non-NEWs	0.2 mSv /quarter

(Measured above background – Radiation Protection and Control Manual s. 3.3)

Dose action levels are used as indicators to identify abnormal doses to staff, including both Nuclear Energy Workers (NEWs) and non-NEWs, during normal operation of the licensed facility. They are precautionary levels and should be set well below regulatory dose limits. If the dose action levels are exceeded, they may indicate a potential loss of control of the radiation protection program.

CNSC document REGDOC 2.7.1 *Radiation Protection* provides detailed guidance on establishing and using action levels.

While the licensee is expected to review and if necessary, to revise and reissue the dose action levels periodically, revisions to the action levels must be submitted to the CNSC for review and are subject to the normal assessment and approval processes as determined by the scope and nature of the changes proposed (see licence condition 1.2).

9. SCA – CONVENTIONAL HEALTH AND SAFETY

Licence Condition 9.1 – Conventional Health and Safety Program

The licensee shall implement and maintain a conventional health and safety program.

Preamble

Paragraph 3(f) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain *"the proposed worker health and safety policies and procedures"*.

Compliance Verification Criteria

Licensing Basis Publications

Source	Title	Document Number
GOC	Canada Labour Code Part II	
PHAC	Laboratory Biosafety Guidelines	
PHAC	Human Pathogens and Toxins Act	

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Machine Shop Procedure	8.1.15.1	3	5024018	Y
CLSI	Hot Work Procedure	11.7.54.3	5	5024018	Y
CLSI	Occupational Health and Safety Manual	11.9.37.1	3	6608871	Y
CLSI	Biological, Chemical and Nanomaterial Safety Manual	11.9.55.1	5	5920284	Y
CLSI	CLSI Safety Report	11.18.40.2	14	5516439	Y
CLSI	Board of Directors Health Safety and Environment Committee Terms of Reference	0.13.1.14	3	5874291	Y
CLSI	Control of Hazardous Energy	11.7.37.1	8	6608871	Y

(1) The licensee shall comply with the *Canada Labour Code Part II*.

(2) To manage workplace safety hazards, the following requirements shall be addressed:

- the workplace is maintained in a safe, clean, and orderly manner;

- hazards are evaluated, and eliminated or controlled, and the consequences of exposure to personnel are minimized;
- hazardous conditions are identified and, where practicable, physical barriers are installed; and
- hazardous materials are labeled.

(3) The licensee shall control the bulk chemicals, laboratory chemicals, corrosive agents, and cleaning agents to ensure proper handling, storage, and use.

(4) When biological hazards are present, the licensee shall comply with:

- *Public Health Agency of Canada's (PHAC) Laboratory Biosafety Guidelines*;
- *Canadian Food Inspection Agency*; and
- *Human Pathogens and Toxins Act*.

Guidance

None provided.

10. SCA – ENVIRONMENTAL PROTECTION

Licence Condition 10.1 – Environmental Protection Program

The licensee shall implement and maintain an environmental protection program.

Preamble

Paragraphs 3 (g) and (h) of the *Class I Nuclear Facilities Regulations*, require that an application for a licence to operate a Class I Nuclear Facility contain: the *"proposed environmental protection policies and procedures"* and *"the proposed effluent and environmental monitoring programs"*. Paragraphs 6 (h), (i) and (j) of the same regulations further require that the licence application contain: *"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"*, *"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"*, and *"the proposed measures to control releases of nuclear substances and hazardous substances into the environment"*, respectively.

Paragraph 12(1)(c) and (f) of the *General Nuclear Safety and Control Regulations* require every licensee to take all reasonable precautions to protect the environment and to take all reasonable precautions to control the release of nuclear substances or hazardous substances.

Compliance Verification Criteria

The licensee shall implement an environmental protection program for the facility. This program shall cover the control of releases to the environment and the assessment of the potential impacts of those releases.

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	CLSI Screening Level Environmental Risk Assessment				Y

Guidance

Guidance Publications

Source	Title	Document Number
CNSC	Environmental Protection: Environmental	REGDOC-2.9.1 (2020)

	Principles, Assessments and Protection Measures	

CNSC regulatory document REGDOC-2.9.1, *Environmental Protection: Environmental Principles, Assessments and Protection Measures* provides guiding principles and factors for the environmental protection as well as detailed guidance on the development, implementation and maintenance of environmental protection programs.

Licence Condition 10.2 – Release of Hazardous or Nuclear Substances

The licensee shall control, monitor and record the releases of hazardous or nuclear substances.

Preamble

Paragraph 3 (h) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence to operate a Class I Nuclear Facility contain *"the proposed effluent and environmental monitoring programs"*. Paragraphs 6 (i) and (j) of the same regulations further require that the licence application contain: *"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"*, and *"the proposed measures to control releases of nuclear substances and hazardous substances into the environment"*, respectively.

Paragraph 12(1)(c) and (f) of the *General Nuclear Safety and Control Regulations* require every licensee to take all reasonable precautions to protect the environment and to take all reasonable precautions to control the release of nuclear substances or hazardous substances.

Subsection 13(1) of the *Radiation Protection Regulations* prescribes the radiation dose limit for the general public of 1 mSv per calendar year.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	CLSI Safety Report	11.18.40.2	14	5516439	Y

Guidance

For hazardous substance releases, to avoid duplication of reporting to multiple regulatory agencies, CNSC requires only compliance with provincial law or municipal bylaws.

11. SCA – EMERGENCY MANAGEMENT AND FIRE PROTECTION

Licence Condition 11.1 – Emergency Preparedness Program

The licensee shall implement and maintain a program for emergency preparedness to address on-site and off-site events which can affect the nuclear facility.

Preamble

Paragraph 6(k) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information on the licensee's *"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 security, including measures to:*

(i) assist off-site authorities in planning and preparing to limit the effects of an accidental release;
(ii) notify off-site authorities of an accidental release or the imminence of an accidental release;
(iii) report information to off-site authorities during and after an accidental release;,
(iv) assist off-site authorities in dealing with the effects of an accidental release; and
(v) test the implementation of the measures to prevent or mitigate the effects of an accidental release."

This licence condition ensures appropriate regulatory oversight of the implementation by the licensee of the emergency preparedness program.

Compliance Verification Criteria

Licensing Basis Publications

Source	Title	Document Number
CNSC	Emergency Planning at Class I Nuclear Facilities and Uranium Mines	G-225

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Building Evacuation Procedure	0.7.37.2	9	4694163	Y
CLSI	Emergency Response Plan	11.12.57.1	6	5588893	Y

(1) The licensee shall have an emergency preparedness plan which satisfies the criteria set out in CNSC regulatory document G-225, *Emergency Planning at Class I Nuclear Facilities and Uranium Mines*.

(2) The licensee's emergency preparedness plan shall ensure that the licensee's resources are prepared to respond to any emergency outside of the laboratory's normal operation. The plan's objectives are:

- Protection of CLSI employees, public health and security, and the environment.
- Minimizing the effects of an emergency or disaster.
- Ensuring rapid organized response to an emergency or disaster.
- Protection and preservation of CLSI critical infrastructure and facilities.
- Timely release of factual information on the status of an incident or emergency.
- Restoration of normal operations in a timely manner.

Transition

CLSI shall perform a gap analysis and submit an implementation plan for the following documents by December 31, 2022: REGDOC-2.10.1, *Nuclear Emergency Preparedness and Response.*

Guidance

None provided.

Licence Condition 11.2 – Fire Protection Program

The licensee shall implement and maintain a fire protection program.

Preamble

Paragraph 6(k) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain information on the licensee's "*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 security"*. These measures must include the implementation of a fire protection program which complies with all applicable national codes and standards.

Compliance Verification Criteria

Licensing Basis Publications

Source	Title	Document Number
CSA	Fire protection for facilities that process, handle, or store nuclear substances	N393-13
GOC	National Building Code, 2015	
GOC	National Fire Code, 2015	

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Fire Protection Program	11.12.54.1	10	6105623	Y

The licensee's fire protection program shall clearly demonstrate compliance with the requirements of:

- the *National Building Code*;
- the *National Fire Code*; and
- the CSA N393-13 *Fire protection for facilities that process, handle, or store nuclear substances*

and that these requirements have been implemented into the facilities operations in a controlled, consistent and coordinated manner.

Guidance

Fire Safety requirements relating to the design and modification of facilities and to testing and maintenance of fire safety equipment can be found in licence condition 5.1 Safety Analysis Program and 7.1 Testing, Calibration and Maintenance Program.

12. SCA – WASTE MANAGEMENT

Licence Condition 12.1 – Waste Management Program

The licensee shall implement and maintain a waste management program.

Preamble

The "waste management" safety and control area 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.

CNSC Regulatory Document REGDOC-2.11, *Framework for Radioactive Waste Management and Decommissioning in Canada*, describes the national framework and philosophy underlying the CNSC's approach to regulating the management of radioactive waste.

CNSC Regulatory Document REGDOC-2.11.1, *Waste Management, Volume I: Management of Radioactive Waste* defines radioactive waste as any material (liquid, gaseous, or solid) that contains a radioactive nuclear substance, as defined in section 2 of the NSCA, for which no further use is foreseen. In addition to containing nuclear substances, radioactive waste may also contain hazardous substances that are not radioactive, as defined in section 1 of the *General Nuclear Safety and Control Regulations*.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Procedure for the Storage/Release of Potentially Activated Materials	11.7.56.1	2	6380028	Y
CLSI	Biological, Chemical and Nanomaterial Safety Manual	11.9.55.1	5	5920284	Y

(1) The waste management program must include provisions for waste minimization, waste segregation, waste classification and characterization, and waste management practices (including generation, handling, processing and storage)

(2) The licensee shall maintain adequate records of inventory of wastes maintained on site and report unauthorized loss of control.

Transition

CLSI shall perform a gap analysis and submit an implementation plan for the following documents by December 31, 2022:

- REGDOC 2.11.1 *Waste Management, Volume I: Management of Radioactive Waste*,
- CSA Group standard N292.3 Management of low- and intermediate-level radioactive waste,
- CSA Group standard N292.0 General principles for the management of radioactive waste and irradiated fuel.

Guidance

Guidance Publications

Source	Title	Document Number
CNSC	Waste Management, Volume I: Management of Radioactive Waste	REGDOC-2.11.1 Volume I
CSA	Management of low- and intermediate-level radioactive waste	N292.3-14
CSA	General principles for the management of radioactive waste and irradiated fuel	N292.0-19
CSA	Guideline for the exemption or clearance from regulatory control of materials that contain or potentially contain, nuclear substances	N292.5

Licence Condition 12.2 – Planning for Decommissioning

The licensee shall maintain a decommissioning plan.

Preamble

The "waste management" safety and control area 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.

CNSC Regulatory Document REGDOC-2.11, *Framework for Radioactive Waste Management and Decommissioning in Canada*, describes the national framework and philosophy underlying the CNSC's approach to regulating decommissioning.

CNSC Regulatory Document REGDOC-2.11.2, *Decommissioning* defines decommissioning as the administrative and technical actions taken to allow the removal of some or all of the regulatory controls from a facility, location or site where nuclear substances are managed, used, possessed or stored. Decommissioning actions are the procedures, processes and work activities (e.g., storage with surveillance, decontamination, dismantling or cleanup) that are taken to retire a facility, location or site from service with due regard for the health and safety of people and the environment.

Compliance Verification Criteria

Licensing Basis Publications

Source	Title	Document Number
CNSC	Decommissioning Planning for Licensed Activities	G-219
CSA	Decommissioning of Facilities Containing Nuclear Substances	N294-19

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Canadian Light Source Preliminary Decommissioning Plan	11.12.1.1	6	6616622	Y
CLSI	Canadian Light Source Preliminary Decommissioning Plan: Decommissioning Cost Estimates	11.12.1.2	6	6616622	Y
CLSI	CLSI Safety Report	11.18.40.2	14	5516439	Y

(1) CLSI shall maintain a preliminary decommissioning plan. The preliminary decommissioning plan shall be reviewed and submitted to CNSC staff, for acceptance, every five years or when requested by the Commission or a person authorized by the Commission.

(2) For the purpose of this licence condition, "a person authorized by the Commission" includes the persons identified in the introduction of this LCH.

(3) The next full update to the preliminary decommissioning plan is expected in 2026.

Transition

The next full update to the preliminary decommissioning plan, expected in 2026, must comply with REGDOC-2.11.2, *Decommissioning* and N294-19, *Decommissioning of facilities containing nuclear substances*.

Guidance

Guidance Publications

Source	Title	Document Number
CNSC	Decommissioning	REGDOC-2.11.2
CNSC	Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities	REGDOC 3.3.1

13. SCA – SECURITY

Licence Condition 13.1 – Security Program

The licensee shall implement and maintain a security program.

Preamble

Paragraphs 3(1)(g) and 3(1)(h) of the *General Nuclear Safety and Control Regulations* require that a licence application contain information related to site access control and measures to prevent loss or illegal use, possession or removal of the nuclear substance, prescribed equipment or prescribed information.

Paragraph 6(l) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain *"the proposed measures to prevent acts of sabotage or attempted sabotage at the nuclear facility"*.

The overall objective of a nuclear security program is to protect persons, property, society, and the environment from malicious acts involving nuclear material or other radioactive material that could cause unacceptable radiological consequences.

Compliance Verification Criteria

Licensing Basis Publications

Source	Title	Document Number
CNSC	Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material, Version 2	REGDOC-2.12.3

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Drawing 0038800			3855389	Y
CLSI	CLSI Safety Report	11.18.40.2	14	5516439	Y
CLSI	CLSI Security Plan **(Confidential-Prescribed Information)**	11.12.57.2	1	6491423	Y
CLSI	Health, Safety and Environment Manual	11.9.1.1	6	6567075	Y

(1) The licensee shall maintain the operation, design and analysis provisions specified in the Security Plan required to ensure adequate engineered safety barriers for the protection against malevolent acts.

(2) The licensee shall implement measures for alerting the licensee to the illegal use or removal of a nuclear substance, prescribed equipment or prescribed information, or the illegal use of a nuclear facility.

(3) Technical and administrative security measures shall be documented by the licensee in a site Security Plan which is appropriately designated in accordance with paragraph 12(j) and sections 21 to 23 of the General Nuclear Safety and Control Regulations, and must be clearly labelled as "CONFIDENTIAL – Prescribed Information" in the top right hand corner of every page.

(4) The site security plan shall be updated and verified by the licensee at least once a year, to address any changes within the licensed facility.

Guidance

Guidance Publications

Source	Title	Document Number
IAEA	Nuclear Security Recommendations on Radioactive Material and Associated Facilities	Nuclear Security Series No. 14

14. SCA – PACKAGING AND TRANSPORT

Licence Condition 14.1 – Packaging and Transport

The licensee shall implement and maintain a packaging and transport program of nuclear substances.

Preamble

Paragraph 6(e) of the *Class I Nuclear Facilities Regulations* requires that an application for a licence to operate a Class I facility shall contain information on *"the proposed procedures for handling, storing, loading and transporting nuclear substances and hazardous substances"*. Every person who transports radioactive material, or requires it to be transported, must act in accordance with the requirements of the *Transportation of Dangerous Goods Regulations* (TDGR) and the *Packaging and Transport of Nuclear Substances Regulations, 2015* (PTNSR). The TDGR and PTNSR provide specific requirements for the design of transport packages, the packaging, marking and labeling of packages and the handling and transport of nuclear substances.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Radiation Protection and Control Manual	11.9.53.3	4	6088497	Y

The licensee shall implement and maintain a packaging and transport program that will ensure compliance with the regulatory requirements set out in the *Transportation of Dangerous Goods Regulations* (TDGR) and in the CNSC *Packaging and Transport of Nuclear Substances Regulations 2015*.

Guidance

None provided.

15. SCA – SITE SPECIFIC

Licence Condition 15.1 – Public Information and Disclosure

The licensee shall implement and maintain a public information program for the facility.

Preamble

Paragraph 3(j) of the *Class I Nuclear Facilities Regulations* requires that a licence application contain the *"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"*.

Compliance Verification Criteria

Licensing Basis Publications

Source	Title	Document Number
CNSC	Public Information and Disclosure	REGDOC 3.2.1

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Canadian Light Source Inc. Crisis Communications Management Plan	0.7.1.6	1	5692017	Y
CLSI	Canadian Light Source Inc. Public Information Program Plan	0.12.1.5	4	6625303	Y

The licensee shall implement and maintain a public information program for the facility. The public information program shall comply with the requirements set out in CNSC regulatory document REGDOC 3.2.1 *Public Information and Disclosure*.

Guidance

None provided.

Licence Condition 15.2 – Financial Guarantee

The licensee shall maintain, in effect, a financial guarantee for decommissioning of the facility that is acceptable to the Commission.

Preamble

The licensee is responsible for all costs of implementing the proposed decommissioning plan (see LC 11.2) and providing an appropriate financial guarantee that is acceptable to the Commission.

Compliance Verification Criteria

Licensee Documents that Require Notification of Change

Source	Document Title	Document Number	Version	E-Doc	Prior Notice
CLSI	Canadian Light Source Preliminary Decommissioning Plan	11.12.1.1	6	6616622	Y
CLSI	Canadian Light Source Preliminary Decommissioning Plan: Decommissioning Cost Estimates	11.12.1.2	6	6616622	Y
University of Saskatchewan	CLSI Financial Guarantee Instrument Confirmation			6593751	Y

(1) The financial guarantee for decommissioning the nuclear facility shall be reviewed and revised by the licensee every five years, or when the Commission requires, or following a revision of the preliminary decommissioning plan that significantly impacts the financial guarantee.

(2) The next full update to the five-year reference plan for financial guarantee purposes is expected in 2026.

(3) The financial guarantee for CLSI is comprised of a letter of credit with the Royal Bank of Canada and a cash sum, held by the University of Saskatchewan. CNSC staff received a letter from the University of Saskatchewan, referenced in the table above, outlining the cash fund total and purpose. The total amount of the two instruments combined is sufficient to cover the estimated cost of decommissioning to the end of 2022. To meet the cost estimate for 2023 through to 2026, CLSI shall increase their financial guarantee

instruments to accommodate for the differences, and submit the proposed financial guarantee instruments to a Person authorized by the Commission for acceptance.

(4) The licensee shall submit annually to a Person authorized by the Commission a written report confirming that the financial guarantee for decommissioning costs remains valid, in effect, and sufficient to meet the decommissioning needs. The licensee shall submit this report by the end of February of each year, or at any time as the Commission may request.

Transition

The next full update to the financial guarantee, expected in 2026 must comply with REGDOC-3.3.1, *Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities*.

Guidance

Guidance Publications

Source	Title	Document Number
CNSC	Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities	REGDOC-3.3.1
CNSC	Decommissioning	REGDOC-2.11.2
CSA	Decommissioning of facilities containing nuclear substances	N294-19

APPENDIX A - LCH CHANGE CONTROL PROCESS AND LCH CHANGE REQUEST FORM

A change control process has been developed for revisions to the LCH to ensure that its preparation and use is controlled and that all references are identified and maintained. A request to change this document can be initiated by either CNSC staff or the licensee.

1. Authorized licensee representative or CNSC staff member submits the request to the CNSC Project Officer using the Licensee LCH Change Request Form in this Appendix.

2. Assessment of the change request by CNSC Project Officer:
   - Determine if the requested change is in line with the LCH change control process.
   - Determine whether the change is substantial enough to warrant an update to the LCH.
   - Refer for review by Specialist Divisions as appropriate.
   - Consult with licensee regarding the proposed change and obtain authorization from licensee.
     a. In the event the licensee is not in agreement with the proposed change, the Project Officer shall refer the issue to the dispute resolution process in the introduction of this LCH.
   - Draft the changes to the LCH and a recommendation for approval, including any Specialist recommendations as appropriate.
   - Submit recommendations and the draft LCH to one of the persons authorized in the introduction of this LCH.

3. Approval:
   - The change may be referred to a higher level of authority in accordance with the introduction of this LCH.
   - In the event that the change is not approved, the licensee may refer the issue to the dispute resolution process described in the introduction of this LCH.

4. Notification of Changes:
   - Once approved, the Project Officer will update the LCH to reflect the changes.
   - Formal notification will be sent to the licensee along with the updated LCH.

Licence Conditions Handbook Change Request				
Current LCH	Version Date			
	CNSD Document #			
	Revision #			
Requestor Information	Date of Request			
	Name			
	Title			
	Signature			
Description of Changes	Overview of Changes Requested			
	Affected Sections of LCH			
New or Amended CLSI Documents	Title(s)			
	Document #(s)			
	Revision #(s)			
	Revision Date(s)			
CNSC staff use only				
Assessment	List each specialist Division consulted and the date(s) of referral			
	List the edoc # and date(s) of response for each specialist report			
	Project Officer summary and recommendation			
Approval	Title:	Director	Director General	Vice President
	Div/Dir/Branch			
	Name:			
	Signature:			
	Indicate approved, rejected or referred to next level of authority			
Referred to Dispute Resolution	Provide edocs#			

APPENDIX B – DEFINITIONS

The following is a list of definitions of words or expressions used in the LCH that may need clarification. Unless a reference source is provided in parenthesis, the words or expressions have been defined for the purpose of the LCH.

Accept/ed/able/ance
Meet regulatory requirements, which mean it is in compliance with regulatory documents or technical standards referenced in the licence.

Anticipated operational occurrence

Approval
1) Commission's permission to proceed, for situations or changes where the licensee would be:

- not compliant with a regulatory requirements set out in applicable laws and regulations; or
- not compliant with a licence condition; or
- not in the safe direction but the objective of the licensing basis is met.

2) Written permission to proceed, given by CNSC delegated authority, for situations or changes where the licensee would:

- comply with a regulatory requirements set out in applicable laws and regulations;
- comply with a licence condition; and
- not adversely impact the licensing basis.

Boundary conditions
Procedural, administrative rules and operating limits for ensuring safe operation of the facility based on safety analysis. It also includes any applicable regulatory requirements.

Compliance verification criteria
Are measures of conformity to the regulatory requirements. CNSC staff use these criteria to confirm that the licensee is meeting the corresponding provisions from the NSCA, the regulations and the licence conditions.

Defense-in-depth
The provision of multiple, redundant, nuclear safety provisions to protect workers, the public and the environment from radiological hazards of a nuclear facility.

Design basis
The range of conditions and events taken into account in the design of the facility, according to established criteria, such that the facility can withstand them without exceeding authorized limits for the planned operation of safety systems.

Design basis accident
Accident conditions against which a facility is designed according to established design criteria, and for which the damage and the release of radioactive material are kept within authorized limits.

Extent of condition
Means an evaluation to determine if an issue has potential or actual applicability to other activities, processes, equipment, programs, facilities, operations or organizations.

Graduated enforcement
A process for escalating enforcement action. If initial enforcement action does not result in timely compliance, gradually more severe enforcement actions may need to be used. It takes into account such things as:

- the risk significance of the non-compliance with respect to health, safety, security, the environment and international obligations;
- the circumstances that lead to the non-compliance (including acts of willfulness);
- previous compliance record; and
- operational and legal constraints (for example, Directive on the Health of Canadians)
- industry specific strategies.

Human factors engineering
Is the application of knowledge about human capabilities and limitations to plant or facility, system, and equipment design. Human factors engineering ensures that the plant or facility, system, or equipment design, human tasks, and work environment, are compatible with the sensory, perceptual, cognitive, and physical attributes of the personnel who operate, maintain, and support it.
[CNSC regulatory document G-276: "Human Factors Engineering Program Plans"]

Important to safety
Items important to safety include, but are not limited to:

- Structures, Systems or Components (SSC) whose malfunction or failure could lead to undue radiation exposure of the facility/site personnel, or members of the public;
- SSCs that prevent anticipated operational occurrences from leading to accident conditions;
- SSCs that protect the environment;
- those features that are provided to mitigate the consequences of malfunctions or failures of SSCs; and

- tasks, duties, activities, aging mechanisms, findings, or any work that improperly performed could lead to radiation exposure of, or other harm to, the facility/site personnel, or members of the public.

Licensee-produced licensing documents
Documents containing the safety and control measures described in the licence application and the documents needed to support that licence application.

Licensee documents requiring notification of change
As determined by CNSC staff, these are documents needed to support the licence application which contain the necessary safety and control measures. Depending on the risk significance of the document, changes may require either a "notification" or a "notification prior to implementation"

Program(s)
A documented group of planned activities, procedures, processes, standards and instructions coordinated to meet a specific purpose.

Programmatic failure
A programmatic failure (or programmatic non-compliance), arises under one or more of the following circumstances:

- Failure to establish a required program or program element.
- Failure of a program or program element to meet a mandated standard.
- Failure to comply with a specific, objective provision of a program.
- Aggravated or systemic failure(s) to adhere to applicable procedures.

Regulatory undertakings
Refers to high level commitments that ensure safety, not component work orders or regulatory predefined maintenance tasks.

Safe direction
Means changes in facility safety levels which would not result in:

- a reduction in safety margins,
- a breakdown of barrier,
- an increase (in certain parameters) above accepted limits,
- an increase in risk,
- impairment(s) of safety systems,
- an increase in the risk of radioactive releases or spills of hazardous substances,
- injuries to workers or members of the public,
- introduction of a new hazard,
- reduction of defense-in-depth provisions,

- causing hazards or risks different in nature or greater in probability or magnitude than those stated in the safety analysis of the nuclear facility.

Safety and control measures
The subset of measures described at a program level put in place by the applicant to protect the environment and the health and safety of persons at the nuclear facility which satisfy the regulatory requirements for safely carrying out the licensed activities.

Safety-related system(s)
Those systems, and the components and structures thereof, which, by virtue of failure to perform in accordance with the design intent, have the potential to impact on the radiological safety of the public or facility personnel from the operation of the nuclear facility. Those systems, and components and structures thereof, are associated with:

(i) control of the facility;
(ii) limiting the release of radioactive material and the exposure of facility personnel and/or the public to meet the criteria established by the licensing authority with respect to radiation exposure during and following normal, anticipated transient conditions and accident conditions.

Safety significance
Refers to the significance of a discovery/issue with respect to the impact on meeting the fundamental nuclear safety objectives as defined by the IAEA.

In general, a discovery/event has safety significance if it denotes a deviation away from the safety case accepted in the licence, in the direction detrimental to safety, such as:

- Reducing margins to, or exceeding the accepted limits;
- Increasing risk;
- Impairments (various degrees) of the safety systems or of the safety functions for accident mitigation;
- Human factor issues; and
- Events causing radioactive releases and spills of hazardous substances, injuries to workers, public, etc.

Shall
Is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the standard.

Version-controlled documents
Refers to documents which require CNSC control and are captured in this LCH. Such documents include regulatory/industry standards as referenced in the licence (may include regulatory/industry standards which require transition); and licensee documents defining the licensing basis.

Written notification
A physical or electronic communication between a CNSC delegated authority and a person authorized to act on behalf of the licensee.

APPENDIX C – OPERATIONAL LIMITS

(1) Injection Linear Accelerator

Electron Beam Energy Limitation: The electron energy shall not exceed 250 MeV.

Electron Beam Current Limitations: The average electron beam currents shall not exceed 14 nA.

(2) Booster Accelerator

Electron Beam Energy Limitation: The average electron energy shall not exceed 2.9 GeV.

Electron Beam Current Limitations: The circulating current shall not exceed 10 mA.

(3) Storage Ring

Electron Beam Energy Limitation: The average electron energy shall not exceed 2.9 GeV.

Electron Beam Current Limitations: The circulating current shall not exceed 500 mA.

APPENDIX D –NUCLEAR SUBSTANCES LIMITS FOR POSSESSION, PROCESSING, USE, TRANSFER, IMPORT AND STORAGE

Isotope	Maximum activity per sealed source*	Maximum activity per unsealed source	Location when stored
Fe-55	370 MBq		Room 1608.12 and Room 0014
Cs-137	7.4 MBq		Room 1608.12 and Room 0013.2
Ru-106	3.7 MBq		Room 1608.12
Am-241	37 MBq		Room 1608.12
Am-241/Be	1 GBq		Room 1608.12
Cf-252	3.7 MBq		Room 1608.12
Mo-99		1 GBq	Room 1608.12, 0013.1 and 0013.2
Tc-99m		46 GBq	Room 1608.12
Tc-99		1.3 GBq	Room 1608.12
Zn-65		255 MBq (per use) 1 GBq (possession)	Room 1608.12, 0013.1 and 0013.2
Ba-133	1 MBq		Room 1608.12
Cd-109	1 MBq		Room 1608.12
Co-57	185 MBq		Room 1608.12
Mn-54	1 MBq		Room 1608.12
Na-22	1 MBq		Room 1608.12
Eu-152	1 MBq		Room 1608.12
Co-60	1 MBq		Room 1608.12

* maximum activity in any single source. There is no limit on the number of sources.

APPENDIX E –NUCLEAR SUBSTANCES LIMITS FOR POSSESSION, PROCESSING, USE, TRANSFER AND STORAGE

Isotope	**Maximum activity per unsealed source**	**Location when stored**
H-3 in a gas chromatograph detector, Valco model 140	37 GBq	Room 0014
Uranium natural	300 kBq	Room 1608.12 and Room 1080

APPENDIX F – DOCUMENTS VERSION CONTROL

Table F-1: Licensee Documents that are subject to LCH Document Control.

Document Number	Revision Number	Title	Licence Condition
0.1.1.14	8	CLS Employee Hours of Work Procedure	3.1
0.1.1.15	4	Organization Management	2.1
0.1.1.17	3	Purchasing Requisition Procedure	2.1
0.1.1.41	7	Document and Record Control Process	2.1
0.2.37.2	4	CLS Safety System Development Strategy	5.1; 6.1; 7.1
0.7.1.3	3	Engineering Change Request & Engineering Change Order Procedure	2.1; 6.1
0.7.1.5	2	Quality Management System Review Procedure	2.1
0.7.1.6	1	Canadian Light Source Inc. Crisis Communications Management Plan	15.1
0.7.37.2	9	Building Evacuation Procedure	11.1
0.7.91.4	2	Accelerator Operations Configuration Process	4.1
0.12.1.4	2	Floor Coordinator Roles Responsibilities and Training Plan	3.2
0.12.1.5	4	Canadian Light Source Inc. Public Information Program Plan	15.1
0.12.91.1	8	Accelerator Operations Personnel Qualification and Training Plan	3.2
0.13.1.9	9	Procurement Process	2.1
0.13.1.14	3	Board of Directors Health Safety and Environment Committee Terms of Reference	2.1
0.24.1.2	1	Training Process	2.1
0.24.1.10	1	Work Management Process	2.1; 4.1; 6.1
0.24.1.12	1	Science Division Work Management Process	2.1
1.9.52.1	3	LINAC Access Control and Interlock System (ACIS) Design Manual	5.2; 6.1

Document Number	Revision Number	Title	Licence Condition
6.1.37.1	0	Photon Beamlines Safety Guidelines - Personnel Protection and Equipment Protection	5.1; 5.2
6.7.1.2	0	Performance Monitoring of Beamlines Process	4.2
7.7.38.1	4	Test Equipment and Process Instrumentation Calibration Procedures	2.1; 7.1
7.9.39.4	6	Booster/ Storage Ring/ Beamlines Access Control and Interlock System (ACIS) PLC Component Manual	5.2; 6.1
7.9.52.1	4	Oxygen Monitoring and Liquid Nitrogen Distribution Component Manual	6.1
8.1.1.6	4	Routine Operation Limits and Conditions	4.1
8.1.15.1	3	Machine Shop Guideline	9.1
8.7.91.1	8	Canadian Light Source Normal Operations - Machine Operating Procedure	4.1
8.12.1.2	1	CLSI Maintenance Plan	7.1
8.12.90.1	1	CLS Commissioning - Phase III Frontends, Insertion Devices, Beamlines	4.2
10.7.1.2	3	Internal Quality Audit Procedure	2.1
10.12.1.1	11	Quality Manual	2.1
10.14.14.1	2	CLS Training Manual	3.2
11.7.37.1	8	Control of Hazardous Energy	2.1
11.7.53.6	4	Surface Contamination Surveys	5.3
11.7.54.3	5	Hot Work Procedure	9.1; 11.2
11.7.56.1	2	Procedure for the Storage/Release of Potentially Activated Materials	12.1
11.9.1.1	6	Health, Safety and Environment Manual	2.1, 13.1
11.9.37.1	3	Occupational Health and Safety Manual	3.1; 9.1
11.9.37.2	3	Industrial Science Laboratory Manual	5.3
11.9.53.3	4	Radiation Protection and Control Manual	2.1; 3.1; 7.1; 8.1; 8.2; 14.1
11.9.55.1	5	Biological, Chemical and Nanomaterial Safety Manual	3.1; 9.1; 12.1; 13.1
11.12.1.1	6	Canadian Light Source Preliminary Decommissioning Plan	12.2; 15.2
11.12.1.2	6	Canadian Light Source Preliminary Decommissioning Plan: Decommissioning Cost Estimates	12.2; 15.2
11.12.54.1	10	Fire Protection Program	11.2
11.12.57.1	6	Emergency Response Plan	11.1
11.12.57.2	1	CLSI Security Plan **(Confidential-Prescribed Information)**	13.1

APPENDIX F– DOCUMENTS VERSION CONTROL

11.18.40.2	14	CLSI Safety Report	4.3; 5.1; 5.2; 5.3; 6.1; 8.1; 9.1; 10.2; 12.2; 13.1
26.2.37.1	8	BMIT Hazard & Risk Analysis	5.1; 5.2
26.9.52.1	4	Bio-Medical Imaging and Therapy Beamline (BMIT) Access Control and Interlock System (ACIS) Design Manual	5.2; 6.1
		University of Saskatchewan and Canadian Light Source License Agreement	2.1
		Facility Drawings	5.2
		Drawing 0038800	13.1

Table F-2: Standards and Other Documents

Document Number	Title	Licence Condition
N286-12	Management System Requirements for Nuclear Facilities	2.1; 3.1
NUREG-0711	Human Factors Engineering Program Review Model	3.1
N288.1	Guidelines for calculating derived release limits for radioactive material in airborne and liquid effluents for normal operation of nuclear facilities	10.2
GOC	National Building Code, 2015	5.1; 11.2
GOC	National Fire Code, 2015	5.1; 7.1; 11.2
N393-13	Fire protection for facilities that process, handle, or store nuclear substances	5.1; 7.1; 11.2
IAEA NSS 14	Nuclear Security Recommendations on Radioactive Material and Associated Facilities	13.1
GOC	Transportation of Dangerous Goods Regulations	14.1
GOC	Canada Labour Code Part II	9.1
PHAC	Laboratory Biosafety Guidelines	9.1
PHAC	Human Pathogens and Toxins Act	9.1
N294-19	Decommissioning of Facilities Containing Nuclear Substances	12.2; 15.2
N292.3-14	Management of low- and intermediate-level radioactive waste	12.1
N292.0-19	General principles for the management of radioactive waste and irradiated fuel	12.1
ISO 9421-210	Ergonomics of human-system interaction Part 210 Human-centred design for interactive systems, 2019	6.1
ISO 6385	Ergonomic Principles in the design of work systems	6.1

Table F-3: CNSC Documents

Document Number	Title	Licence Condition
REGDOC 2.1.1	Management System	2.1
REGDOC-2.2.1	Human Factors	3.1
REGDOC 2.1.2	Safety Culture	2.1
REGDOC 2.2.2	Personnel Training	3.2
REGDOC 2.2.4	Fitness for Duty: Managing Worker Fatigue	3.1
REGDOC 2.2.5	Minimum Staff Complement	3.1
REGDOC 2.5.1	General Design Considerations: Human Factors	6.1
REGDOC 3.1.2	Reporting Requirements, Volume 1: Non-Power Reactor Class I Nuclear Facilities and Uranium Mines and Mills	4.4
REGDOC 2.7.1	Radiation Protection	8.1, 8.2
REGDOC 2.9.1	Environmental Protection: Environmental Principles, Assessments and Protection Measures	10.1
REGDOC 2.10.1	Nuclear Emergency Preparedness and Response	11.1
REGDOC 2.11	Framework for Radioactive Waste Management and Decommissioning in Canada	12.1
REGDOC 2.11.2	Decommissioning	12.2; 15.2
REGDOC 2.12.3	Security of Nuclear Substances: Sealed Sources and Category I, II and III Nuclear Material	13.1
REGDOC 3.1.2	Reporting Requirements for Non-Power Reactor: Class I Facilities and Uranium Mines and Mills	4.3
REGDOC 3.2.1	Public Information and Disclosure	15.1
REGDOC 3.3.1	Financial Guarantees for Decommissioning of Nuclear Facilities and Termination of Licensed Activities	15.2
G-219	Decommissioning Planning for Licensed Activities	12.2
G-225	Emergency Planning at Class I Nuclear Facilities and Uranium Mines	11.1

APPENDIX G – RESOLUTION OF INCONSISTENCIES

Identifier	L.C.	Subject of Conflict or Inconsistency	E-DOCS #	Date of Resolution

CURRENT LICENCE

eDoc 3703047 (Word)

eDoc 3888349 (PDF)

LICENCE AMENDMENT

eDoc 4165333 (Word)

eDoc 4703454 (PDF)

e-Doc 3888349 (PDF)
e-Doc 3703047 (Word)
2.03
29-1-2-4-0

CLASS IB PARTICLE ACCELERATOR OPERATING LICENCE

CANADIAN LIGHT SOURCE INCORPORATED

I) LICENCE NUMBER: **PA1OL-02.00/2022**

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

Canadian Light Source Incorporated
101 Perimeter Road
University of Saskatchewan
Saskatoon, SK S7N 0X4

III) LICENCE PERIOD: This licence is valid from **1 June 2012** to **31 May 2022**, unless otherwise suspended, amended, revoked or replaced.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

(a) Operate the Canadian Light Source at the location referred to in Part II of this licence (hereinafter "the facility");

(b) Possess, transfer, use, and store the nuclear substances arising from the activities referred to in paragraph (a) at the facility, and

(c) Possess, transfer, use, import and store other nuclear substances at the facility, subject to condition 5.3.

V) EXPLANATORY NOTES:

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

(b) The Canadian Light Source Incorporated Facilities Licence Conditions Handbook (LCH) provides

(i) compliance verification criteria in order to meet the conditions listed in the licence;

(ii) information regarding delegation of authority to CNSC staff; and

(iii) applicable versions of documents and a process for version control of codes, standards or other documents that are used as compliance verification criteria in order to meet the conditions listed in the licence.

VI) CONDITIONS:

1. GENERAL

1.1 Licensing Basis

The licensee shall conduct the activities described in Part IV of this licence in accordance with the licensing basis described in the LCH, unless otherwise authorized in this licence.

1.2 Changes to CLSI Documents

(a) Changes to the safety and control measures described in the application and the documents needed to support that application are permitted provided that the objective of the licensing basis is met.

(b) Changes that are outside of the licensing basis are not permitted without the prior written approval of the Commission.

1.3 Resolution of Conflict or Inconsistency

The licensee shall, in the event of any conflict or inconsistency, actual or potential, between licence conditions or codes, standards or regulatory documents referenced in this licence, direct the conflict or inconsistency in writing to the Commission or a person authorized by the Commission, for resolution.

2. MANAGEMENT SYSTEM

2.1 Management System

The licensee shall implement and maintain a management system, including a written safety policy which places safety paramount within the management system, overriding all other demands, for activities carried out under this licence.

3. HUMAN PERFORMANCE MANAGEMENT

3.1 Human Performance Program

The licensee shall implement and maintain a human performance management program.

3.2 Training Program

The licensee shall implement and maintain a training program.

4. OPERATING PERFORMANCE

4.1 Operations Program

The licensee shall implement and maintain a program for operation of the facilities. This shall include direction and documentation for safely operating the nuclear facility and shall, as a minimum, reflect the safety analyses that have been previously submitted to the Commission.

4.2 Beamlines

The licensee shall maintain an up to date procedure for commissioning and operating beamlines.

4.3 BioMedical Imaging and Therapy Beamline used on Humans

The licensee shall not use the Biomedical Imaging and Therapy Beamlines (BMIT) on humans without prior written approval by the Commission or a person authorized by the Commission.

4.4 Reporting Requirements

The licensee shall submit to the Commission each year a written annual compliance report that covers the previous year's operation.

5. SAFETY ANALYSIS

5.1 Safety Analysis Program

The licensee shall conduct and maintain safety analyses that are of appropriate detail for the complexity of the facility or process analyzed.

5.2 Documentation

The licensee shall maintain an updated set of documents and technical references comprising detailed technical descriptions and safety analysis specific to each major sub-facility on-site.

5.3 Operational Specifications and Limits

The licensee shall maintain an up to date set of operating limits for the facilities and activities authorized under the licence, including limits for the possession, use, transfer, storage, import and export of nuclear substances and operational limits for accelerators.

6. PHYSICAL DESIGN

6.1 Design Program

The licensee shall implement and maintain a design program.

7. FITNESS FOR SERVICE

7.1 Testing, Calibration and Maintenance Program

The licensee shall implement and maintain a testing, calibration and maintenance program for the facility.

8. RADIATION PROTECTION

8.1 Radiation Protection Program

The licensee shall implement and maintain a radiation protection program.

8.2 Dose Action Levels

The licensee shall notify the Commission or a person authorized by the Commission within 24 hours of becoming aware that an action level has been reached or exceeded and shall file a written report within 30 working days of becoming aware of the matter.

9. CONVENTIONAL HEALTH AND SAFETY

9.1 Occupational Health and Safety Program

The licensee shall implement and maintain a conventional health and safety program.

10. ENVIRONMENTAL PROTECTION

10.1 Environmental Protection Program

The licensee shall implement and maintain an environmental protection program.

10.2 Release of Hazardous or Nuclear Substances

The licensee shall control, monitor and record the releases of hazardous or nuclear substances.

11. EMERGENCY MANAGEMENT AND FIRE PROTECTION

11.1 Emergency Preparedness Program

The licensee shall implement and maintain a program for emergency preparedness to address on-site and off-site events which can affect the nuclear facility.

11.2 Fire Protection Program

The licensee shall implement and maintain a fire protection program.

12. WASTE MANAGEMENT

12.1 Waste Management Program

The licensee shall implement and maintain a program for waste management for the facility.

12.2 Planning for Decommissioning

The licensee shall maintain a preliminary decommissioning plan for decommissioning the facility. This preliminary decommissioning plan shall be reviewed every five years or when requested by the Commission or a person authorized by the Commission.

13. SECURITY

13.1 Security Program

The licensee shall implement and maintain a security program.

14. PACKAGING AND TRANSPORT

14.1 Packaging and Transport

The licensee shall implement and maintain a packaging and transport program of nuclear substances.

15. SITE SPECIFIC

15.1 Public Information and Disclosure

The licensee shall implement and maintain a public information program for the facility.

15.2 Financial Guarantee

The licensee shall maintain, in effect, a financial guarantee for decommissioning of the facility that is acceptable to the Commission.

SIGNED at OTTAWA, this 29th day of May 2012

M. Binder

Michael Binder, President,
on behalf of the Canadian Nuclear Safety Commission

e-Doc 4703454 (PDF)
e-Doc 4165333 (Word)
2.03
29-1-2-4-0

AMENDMENT

CLASS IB PARTICLE ACCELERATOR OPERATING LICENCE

CANADIAN LIGHT SOURCE INCORPORATED

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

I) LICENCE NUMBER: **PA1OL-02.00/2022**

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

Canadian Light Source Incorporated
101 Perimeter Road
University of Saskatchewan
Saskatoon, SK S7N 0X4

III) AMENDMENT: **No. 1**

Pursuant to section 24 of the *Nuclear Safety and Control Act*, Class IB Particle Accelerator Operating Licence PA1OL-02.02/2022 is hereby amended as follows:

1) Section II to the proposed licence has been deleted and replaced by:

Canadian Light Source Incorporated
44 Innovation Boulevard
University of Saskatchewan
Saskatoon, SK S7N 2V3

2) Section III (c) to the proposed licence has been deleted and replaced by:

(c) Possess, process, transfer, use, import and store other nuclear substances at the facility, subject to condition 5.3

3) Condition 5.3 to the proposed licence has been deleted and replaced by:

5.3 Operational Specifications and Limits

The licensee shall maintain an up to date set of operating limits for the facilities and activities authorized under the licence, including limits for the possession, processing, use, transfer, storage, import and export of nuclear substances and operational limits for accelerators.

IV) AMENDMENT REQUESTED:

Licence Amendment Request for a Basic Level Radiation Laboratory, from Mr. Grant Cubbon, Manager, Health and Safety Environment Department of Canadian Light Source Inc., to Dr. J. Plante, Canadian Nuclear Safety Commission, dated October 29, 2014. CNSC Document Number 4548312.

The foregoing amendment is consolidated in the revised Class IB Particle Accelerator Operating Licence No. PA1OL-02.01/2022, attached hereto as Schedule 1, which replaces Particle Accelerator Operating Licence No. PA1OL-02.00/2022.

SIGNED at OTTAWA, this 30th day of March 2015.

Michael Binder, President,
on behalf of the Canadian Nuclear Safety Commission

e-Doc 4703454 (PDF)
e-Doc 4165333 (Word)
2.03
29-1-2-4-0

CLASS IB PARTICLE ACCELERATOR OPERATING LICENCE

CANADIAN LIGHT SOURCE INCORPORATED

I) LICENCE NUMBER: **PA1OL-02.01/2022**

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III) LICENCE PERIOD: This licence is valid from **1 June 2012** to **31 May 2022**, unless otherwise suspended, amended, revoked or replaced.

IV) LICENSED ACTIVITIES:

This licence authorizes the licensee to:

(a) Operate the Canadian Light Source at the location referred to in Part II of this licence (hereinafter "the facility");

(b) Possess, transfer, use, and store the nuclear substances arising from the activities referred to in paragraph (a) at the facility, and

(c) Possess, process, transfer, use, import and store other nuclear substances at the facility, subject to condition 5.3.

V) EXPLANATORY NOTES:

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

(b) The Canadian Light Source Incorporated Facilities Licence Conditions Handbook (LCH) provides

(i) compliance verification criteria in order to meet the conditions listed in the licence;

(ii) information regarding delegation of authority to CNSC staff; and

(iii) applicable versions of documents and a process for version control of codes, standards or other documents that are used as compliance verification criteria in order to meet the conditions listed in the licence.

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The licensee shall submit to the Commission each year a written annual compliance report that covers the previous year's operation.

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8.1 Radiation Protection Program

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8.2 Dose Action Levels

The licensee shall notify the Commission or a person authorized by the Commission within 24 hours of becoming aware that an action level has been reached or exceeded and shall file a written report within 30 working days of becoming aware of the matter.

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14. PACKAGING AND TRANSPORT

14.1 Packaging and Transport

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15. SITE SPECIFIC

15.1 Public Information and Disclosure

The licensee shall implement and maintain a public information program for the facility.

15.2 Financial Guarantee

The licensee shall maintain, in effect, a financial guarantee for decommissioning of the facility that is acceptable to the Commission.

SIGNED at OTTAWA, this 30th day of March 2015

M. Binder

Michael Binder, President,
on behalf of the Canadian Nuclear Safety Commission