

Quality Manual

10.12.1.1 Rev. 7

Date: 2011-03-07

Copyright 2011, Canadian Light Source Inc. This document is the property of Canadian Light Source Inc. (CLSI). No exploitation or transfer of any information contained herein is permitted in the absence of an agreement with CLSI, and neither the document nor any such information may be released without the written consent of CLSI.

Canadian Light Source Inc.
University of Saskatchewan
101 Perimeter Road
Saskatoon, Saskatchewan
S7N 0X4 Canada

Signature

Date

Original on File – Signed by:

Author

A. Ahmad, Quality Manager

Reviewer #1

B. Lepage, Chief Finance and Administration Officer

Reviewer #2

J. Cutler, Deputy Director and Director of Industrial Science

Reviewer #3

T. Ellis, Director of Research

Approver

Josef Hormes, Executive Director

REVISION HISTORY

<i>Revision</i>	<i>Date</i>	<i>Description</i>	<i>Author</i>
0	2002-07-05	Issued for use.	E. Matias
1	2004-02-12	Incorporate comments from managers. Issued for use.	E. Matias
2	2004-09-30	Issued for use.	E. Matias
3	2004-10-04	Issued for use.	E. Matias
4	2005-12-09	Issued for use.	E. Matias
5	2006-07-20	Incorporated comments from CNSC on S-213, design QA, and beamline operation logs. Issued for use.	E. Matias
5A	2007-04-07	Incorporated requirements of CAN/CSA-ISO 13485:3.	E. Matias
6	2007-05-11	Issued for use.	E. Matias
6A	2009-12-15	Re-written for transition to operations	A. Ahmad
6B	2010-04-13	Amended to incorporate Comments from User/Engineering/Admin/Exec Director	A. Ahmad
6C	2010-04-14	Amended to incorporate Comments from User/Engineering/Admin/Exec Director	A. Ahmad
6D	2010-06-04	Amended to incorporate Comments from A. Ahmad /E. Matias /M. Silzer/S. Abell-Smith User/Engineering/Admin/Exec Director	A. Ahmad
6E	2010-07-12	Issued for CNSC Review	A. Ahmad
6F	2010-11-15	Amended to incorporate CNSC Comments	A. Ahmad
6G	2011-01-14	Amended to include core processes. Sections 6.3.1 and 6.3.2 added	A. Ahmad
6H	2011-01-26	Work Management and Doc Control sections edited, Doc numbers added	A. Ahmad

6I	2011-02-17	Edited to include CNSC Comments	A. Ahmad
6J	2011-02-24	Issued for CNSC review	A. Ahmad
7	2011-03-07	Section 6.3.1 refs changed from Configuration Management Process to Procedure Issued to CNSC Commission for License Amendment	A. Ahmad

TABLE OF CONTENTS

QUALITY POLICY.....	1
1.0 PURPOSE	2
1.1 SCOPE.....	2
2.0 FACILITY INFORMATION.....	2
3.0 TERMS	2
4.0 QUALITY MANAGEMENT SYSTEM.....	3
4.1 CLSI POLICIES	3
4.2 PROCESSES AND PROCEDURES	3
4.2.1 Quality Manual	3
4.2.2 Control of Documents	4
4.2.3 Control of Records.....	4
5.0 MANAGEMENT RESPONSIBILITY.....	4
5.1 MANAGEMENT COMMITMENT	4
5.2 STAKEHOLDER REQUIRMENTS.....	5
5.3 QUALITY POLICY	5
5.4 PLANNING.....	5
5.4.1 Quality Objectives	5
5.4.2 Quality Management System Planning.....	5
5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION	6
5.5.1 Responsibility and Authority.....	6
5.5.2 Management Representative.....	6
5.5.3 Internal Communications	6
5.5.4 External Communications and Use of Experience	6
5.6 MANAGEMENT REVIEW	7
5.6.1 General.....	7
5.6.2 Review Input.....	7
5.6.3 Review Output	7
6.0 RESOURCE MANAGEMENT	8
6.1 PROVISION OF RESOURCES.....	8
6.2 HUMAN RESOURCES.....	8
6.2.1 General.....	8

6.2.2	Competence, Training and Awareness	8
6.3	INFRASTRUCTURE	8
6.3.1	Work Management and Configuration Management	9
6.3.2	Maintenance	9
6.4	EXPERIMENTAL CONDITIONS AND WORK ENVIRONMENT	9
7.0	MEETING USER, CLIENT AND STAKEHOLDER EXPECTATIONS.....	10
7.1	PLANNING FACILITY OPERATIONS	10
7.2	USER CLIENT AND STAKEHOLDER RELATED PROCESSES	10
7.2.1	Determining Requirements	10
7.2.2	Reviewing Requirements.....	10
7.2.3	User Communication	11
7.3	DESIGN AND DEVELOPMENT.....	11
7.3.1	Design and Development Planning	11
7.3.2	Design and Development Inputs.....	12
7.3.3	Design and Development Outputs	12
7.3.4	Design and Development Review.....	12
7.3.5	Design and Development Verification	12
7.3.6	Design and Development Commissioning (Validation).....	13
7.3.7	Control of Design and Development Changes.....	13
7.3.8	Configuration Control	13
7.4	PURCHASING	14
7.4.1	Purchasing Process	14
7.4.2	Technical Specifications or Statements of Work	14
7.4.3	Verification of Purchased Product	14
7.5	ACCELERATOR AND BEAMLINER OPERATIONS.....	14
7.5.1	Control of Operations and Beamline Services	14
7.5.2	Validation of Processes for Operations and Beamline Services....	15
7.5.3	Identification and Traceability.....	15
7.5.4	User Property and Equipment	15
7.5.5	Preservation of Product – Excluded From Scope.....	16
7.6	CONTROL OF MONITORING AND MEASURING EQUIPMENT.....	16
8.0	MEASUREMENT, ANALYSIS AND IMPROVEMENT	17
8.1	GENERAL.....	17

8.2	MONITORING AND MEASUREMENT	17
8.2.1	User, Client and Stakeholder Satisfaction	17
8.2.2	Internal Audit	17
8.2.3	External Audits	18
8.2.4	Monitoring and Measurement of Operations	18
8.3	CONTROL OF NONCONFORMANCE.....	18
8.4	ANALYSIS OF QUALITY PERFORMANCE DATA	19
8.5	IMPROVEMENT	19
8.5.1	Self-Assessment and Continual Improvement.....	19
8.5.2	Corrective Action	19
8.5.3	Preventive Action	20
8.6	HEALTH, SAFETY AND ENVIRONMENT (HSE)	20

LIST OF FIGURES

	Page
Figure 1 – Overall Structure of the CLSI Quality Management System.....	3

QUALITY POLICY

CLSI is committed to being a national centre of excellence and repository of academic and operational expertise in synchrotron science and its applications. It is the policy of CLSI to develop and maintain a quality program complying with regulatory requirements and considering best industry practice.

The quality program is based on specified requirements, processes and procedures. CLSI conducts internal reviews and audits of its quality program on a regular basis. The CLSI quality program is structured to maintain compliance with The Quality Requirements of the Class 1B Particle Accelerator Operating Licence issued by the Canadian Nuclear Safety Commission.

CLSI complies with Acts and regulations imposed by various levels of government. These include all applicable Acts and regulations imposed on federal works and incorporated entities with the Province of Saskatchewan as well as specific regulatory requirements defined in the Class 1B Particle Accelerator Operation License issued by the Canadian Nuclear Safety Commission. These requirements are reflected in CLSI policies, processes and procedures and include HSE requirements.

CLSI is committed to the following:

- Providing the resources and training required for implementation of the Quality System;
- Complying with requirements, safe operation and to continually improving the effectiveness of the Quality System
- Maximizing the performance and availability of the Facility
- Fostering a strong safety culture

CLSI staff are required to comply with the Quality Policy and are responsible for applying the Quality System in their respective areas, and to contribute to the development of the Quality System. The Quality Manager has the responsibility of ensuring that the Quality System is implemented and maintained.

1.0 PURPOSE

This document defines the quality activities undertaken by Canadian Light Source Inc. (CLSI). The quality and HSE systems foster a strong safety culture regarding licensed activities.

1.1 SCOPE

This document covers the licensed activities, more specifically, the operations of accelerator systems, beamlines and support facilities. This manual does not apply to the scientific program of external Users. External Users are governed by the quality programs of their home institution. Preservation of product is not applicable to CLSI.

2.0 FACILITY INFORMATION

Canadian Light Source Inc. (CLSI) is a legally incorporated entity; and a wholly owned subsidiary of the University of Saskatchewan. CLSI operates the Facility pursuant to a license agreement with the University of Saskatchewan. Under this agreement, CLSI is responsible for and has the authority to direct all aspects of operations, including aspects related to health, safety and environmental compliance and quality. The CLSI Facility is a national synchrotron research Facility operated for the production of high brightness synchrotron radiation from the infrared, visible, and ultraviolet to x-ray region of the electromagnetic spectrum. CLSI is a third-generation light source Facility and is accessible to researchers from the academic, government, and private sectors.

The CLSI Facility consists of a linear accelerator, which nominally operates between 200 and 250 MeV, a 2.9 GeV electron synchrotron (BR1), a 2.9 GeV electron storage ring (SR1), and synchrotron light beamlines used for experiments.

External and internal Users, through the peer-review process, use the CLSI to conduct experiments that form part of their own scientific programs. CLSI provides scientific research and analytical services to commercial clients on a fee-for-service basis.

The quality program at CLSI, where relevant and practical, has taken into account certain/specific elements of Good Lab Practice (GLP).

3.0 TERMS

Quality Policy - The CLSI Board's commitment to Quality

Quality Manual - This document

Quality Management System - The CLSI system that deals with quality

Quality Objectives - The CLSI objectives related to quality

Quality Requirements - The CLSI requirements for quality

Quality Activities - The activities carried out by CLSI staff related to quality

External User – People who are not CLSI employees and use the Facility for experiments

Internal User – CLSI staff who use the Facility for experiments

User – People who are Clients, External or Internal Users

Clients – People who pay a fee-for-service (industrial/commercial sector)

Licensed Activities – accelerators and beamlines

4.0 QUALITY MANAGEMENT SYSTEM

The Quality Manual defines the quality requirements for CLSI's quality management system including Facility policies, manuals, and procedures that are issued. The CLSI Quality Management System is available to all staff on the CLSI Intranet.

Figure 1 illustrates the overall structure of the CLSI policies, processes, and procedures. Corporate policies are developed for application by processes, procedures and guidelines. Detailed work requirements are defined in specific procedures where required.

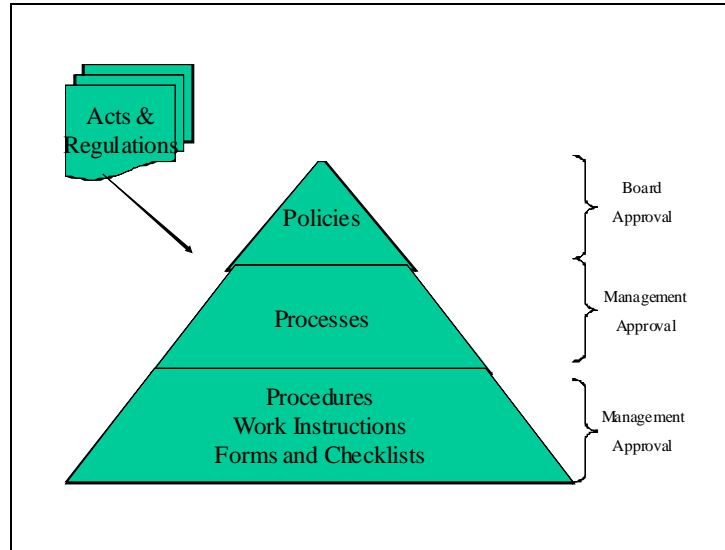


Figure 1 – Overall Structure of the CLSI Quality Management System

4.1 CLSI POLICIES

CLSI policies prefix the relevant document for the area covered by the policy. The policies provide direction to CLSI management on the development of work-processes and procedures for CLSI. The Board of Directors approves CLSI policies. Policies will be added or updated as required by the Board.

4.2 PROCESSES AND PROCEDURES

CLSI implements the policies defined by the Board through processes and procedures that are followed by management and staff in the day-to-day operation of the Facility.

The Quality Management System is divided into a series of sections; each section containing one or more processes/guides/procedures that define work requirements and standards. This structure permits individual processes and procedures to be extracted and used as standalone documents as required.

4.2.1 Quality Manual

This document defines the high level guidance for the operation of the CLSI Facility. Canadian Nuclear Safety Commission guidelines and internationally accepted best practices for similar facilities have been considered in the development of this manual.

The Quality Manual defines the quality management system, and its scope, used by the CLSI. This is augmented with area-specific processes, procedures and work instructions that are referenced in each section where appropriate.

4.2.2 Control of Documents

Documents required by the Quality System are controlled. A documented procedure is established that defines the controls needed

- a) To approve documents for adequacy prior to issue
- b) To review and update as necessary and re-approve documents
- c) To ensure that changes and the current revision status of documents are identified
- d) To ensure that relevant versions of applicable documents are available at points of use
- e) To ensure that documents remain legible and readily identifiable
- f) To ensure that documents of external origin, determined by CLSI to be necessary for the planning and operation of the Quality System, are identified and their distribution controlled, and
- g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose

4.2.3 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the Quality System are controlled.

A documented procedure is established to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

The Facility ensures that records remain legible, readily identifiable and retrievable.

References:

Document and Record Control Process

Doc. No. 0.1.1.41

5.0 MANAGEMENT RESPONSIBILITY

5.1 MANAGEMENT COMMITMENT

CLSI is committed to the development, implementation and continual improvement of the quality management system by:

- Communicating to staff the importance of meeting provincial and federal regulatory requirements, the needs of Users, clients, stakeholders, and funding agencies,
- Establishing a quality policy approved by the CLSI Board;
- Ensuring quality objectives are established;
- Conducting management reviews; and
- Ensuring the availability of resources to ensure the operation of quality systems.
- Fostering a strong safety culture in providing a safe and healthful working environment for all staff and to the general public and the environment from unacceptable risks

5.2 STAKEHOLDER REQUIREMENTS

CLSI will ensure that the quality and performance requirements of Users, clients, stakeholders and funding agencies are established, documented and met by CLSI. The aim of this is to enhance the quality of service (Facility reliability and availability) delivered.

These requirements are defined in contracts, memorandums of understanding and agreements that are established between CLSI and the stakeholders.

References:

Process of Allocating and Scheduling Beam time	Doc. No. 8.1.1.2
CLSI User Appeal Guidelines	Doc. No. 8.1.1.13
End of Run Procedure	Doc. No. 22.7.1.1
Relevant contracts, MOUs and agreements.	

5.3 QUALITY POLICY

CLSI has ensured that the quality policy:

- Is appropriate to the purpose of the Facility;
- Includes a commitment to comply with requirements, safe operation and to continually improve the effectiveness of the quality management system;
- Provides a framework for establishing and reviewing quality objectives;
- Is communicated and understood within CLSI; and
- Is reviewed for continuing suitability.

References:

Quality Policy (page 1)	Doc. No. 10.12.1.1
Management Review	Doc. No. 0.7.1.5
HSE Manual	Doc. No. 11.9.1.1

5.4 PLANNING

5.4.1 Quality Objectives

CLSI management ensures quality (performance) objectives are established at the division and department levels. These objectives are measurable and consistent with the quality policy.

References:

Strategic Plan

5.4.2 Quality Management System Planning

CLSI senior management ensure that:

- The planning of the quality management system is carried out to meet the requirements of the quality policy and quality objectives; and
- The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Reference:

5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

5.5.1 Responsibility and Authority

For each position within the CLSI, a job description exists that defines (1) job title, (2) supervisor, (3) direct and functional reports, (4) position mandate, (5) representative duties (authority), (6) accountabilities, (7) education and experience, and (8) job scope.

Supervisors and managers are responsible and accountable for ensuring that staff are provided with a safe work environment, have the resources necessary to meet quality and safety objectives, and comply with CLS policies, processes and procedures.

Changes to the Organization's management and structure are referenced in the Annual Compliance Report.

References:

Organization Management	Doc. No. 0.1.1.15
Guidelines for Writing Job Descriptions	Doc. No. 0.1.1.40
Annual Compliance Report	Doc. No. 11.18.40.x

5.5.2 Management Representative

The Quality Manager (appointed by the Executive Director) is responsible for:

- Ensuring that processes needed for the quality management system are established, implemented and maintained;
- Reporting to the Executive Director on the performance of the quality management system and any need for improvement;
- Ensuring the promotion of awareness of User, client and stakeholder requirements throughout the Facility; and
- Liaising with the CNSC on quality management system matters.

5.5.3 Internal Communications

Appropriate internal communications processes are established within the Facility to assess the effectiveness of the quality management system and carry out licensed activities. Meetings, email messages, phone calls, internet/intranet, plans, schedules, specifications and documents are used as required.

5.5.4 External Communications and Use of Experience

Communications with the CNSC regarding the conduct of licensed activity is carried out by the Health Safety and Environment Manager and Quality Manager, as appropriate, or their delegates.

Business Development oversees communications between CLSI and the media, and the general public. External communication with other stakeholders and other regulators (e.g. Worker's Compensation Board) is coordinated by the relevant department within CLSI.

Industry experience is gathered through the Board HSE Committee, the Scientific Advisory Committee, the User Advisory Committee, and the Machine Advisory Committee

(see section 8.2.1). Collaboration Agreements exist with relevant organizations. CLSI Facility staff liaise with other synchrotron facilities on an on-going basis.

References:

HSE Manual	Doc. No. 11.9.1.1
Public Information Plan	Doc. No. 0.12.1.5
Crisis Communications Plan	Doc. No. 0.7.1.6
Annual Compliance Report	Doc. No. 11.18.40.x
Activity Report	
CLSI website www.lightsource.ca	

5.6 MANAGEMENT REVIEW

5.6.1 General

The CLSI quality management system is reviewed at planned intervals to ensure its continuing suitability, adequacy and effectiveness.

5.6.2 Review Input

The inputs to the review include:

- Review of previous management reviews;
- Health Safety and Environment performance;
- User feedback;
- Results of external and internal quality audits;
- Process performance and service conformity;
- Status of corrective and preventative actions;
- Changes that could impact the quality management system;
- Recommendation for improvement;
- New and revised regulatory requirements;
- Resource requirements;
- Training and competence requirements; and
- Self-assessment review.

5.6.3 Review Output

The outputs of the review include:

- plans for improvements related to the quality management system and its processes;
- User and clients requirements; and
- the resources needed for achieving Facility objectives.

Reference:

Management Review	Doc. No. 0.7.1.5
-------------------	------------------

6.0 RESOURCE MANAGEMENT

6.1 PROVISION OF RESOURCES

The Facility has determined and provided the resources needed:

- To implement and maintain the quality management system and continually improve its effectiveness, and
- To meet User, client, stakeholder, funding agency and regulatory requirement needs and satisfaction.

Reference:

Management Review

Doc. No. 0.7.1.5

6.2 HUMAN RESOURCES

6.2.1 General

CLSI ensures that staff are trained to perform their duties safely while meeting quality objectives.

6.2.2 Competence, Training and Awareness

Staff job descriptions define the prerequisite education and experience requirements for the position. Supervisors are responsible for ensuring that work assignments are consistent with individual staff qualifications. A training matrix has been developed defining specific training, including safety, for each class of position and records are kept. Periodically individual staff training requirements are reviewed.

Staff training needs are identified, provisioned and assessed for effectiveness.

References:

Training Process

Doc. No. 0.24.1.2

Organization Management

Doc. No. 0.1.1.15

6.3 INFRASTRUCTURE

Infrastructure at the CLSI consists of: the conventional Facility (building, HVAC, mechanical services, power distribution), technical facilities (accelerator and beamlines), supporting laboratories, and the information technology infrastructure.

This technical infrastructure is operated in accordance with documented operating procedures and processes.

The conventional and technical Facility are maintained following a preventative maintenance plan.

Human factors are taken into account in the scheduling of operations and maintenance work. The Health, Safety and Environment Department monitor and provide advice on the safe operation and maintenance of the infrastructure.

6.3.1 Work Management and Configuration Management

The Facility implements a graded approach to planning and controlling work. Work categorized as "Controlled Work" requires authorization to start the work and independent verification to ensure the work has been completed correctly.

References:

Work Management and Configuration Management Process	Doc. No. 0.24.1.3
Configuration Management Procedure	Doc. No. 0.7.1.9
Normal Operations – Machine Operating Procedures	Doc. No. 8.7.91.1
Routine Operation limits and Conditions	Doc. No. 8.1.1.6
Personnel Work Schedule	Doc. No. 0.1.1.14
Work Order Process	Doc. No. 0.7.1.4
HSE Manual	Doc No. 11.9.1.1

6.3.2 Maintenance

The Facility has developed a maintenance plan ensuring that maintenance activities are planned and carried out under controlled conditions.

References:

CLSI Maintenance Plan	Doc. No. 8.12.1.2
-----------------------	-------------------

6.4 EXPERIMENTAL CONDITIONS AND WORK ENVIRONMENT

The Facility determines and manages the work environment needed to achieve conformity to User requirements and operation of the Facility.

Performance parameters have been established for environmental conditions that impact the operation of the Facility. For individual hutches, these parameters are defined in the room data sheets and beamline design specifications.

For storage ring operation, these parameters are routinely measured and monitored during operations. These measurements are made available to Users as needed to assess the impact on their experiment.

As required, to maintain quality of experimental results and conditions, CLSI has established documented requirements for health, cleanliness and clothing of personnel where it would compromise experimental conditions, manufacturing/assembly, or contaminate samples. Training is provided to staff and Users as required.

References:

Individual Beamline Specifications	
Normal Operations – Machine Operating Procedures	Doc. No. 8.7.91.1
Routine Operation limits and conditions	Doc. No. 8.1.1.6

7.0 MEETING USER, CLIENT AND STAKEHOLDER EXPECTATIONS

CLSI provides a diversity of services to meet the needs of Users, clients and stakeholders. These activities can be divided into two broad areas:

- Operations, and
- Beamline and accelerator development.

Operations encompass the operation of the Facility to deliver photons to beamlines and the support of Users performing experiments at the CLSI, and CLSI conducting work for clients.

7.1 PLANNING FACILITY OPERATIONS

CLSI operations are divided into run cycles and experiments that are scheduled on individual beamlines within these cycles.

In planning experiments, CLSI establishes, as appropriate:

- Quality objectives for the performance of the accelerator and each beamline;
- Processes to review experiment proposals and determine their suitability to be undertaken on a specific beamline based on safety, scientific merit (peer-review) and technical capabilities of the beamline;
- Verification, validation monitoring, measurement, inspection and testing activities as required, to ensure operational performance objectives are achieved, and
- Records, as required, for these activities.

7.2 USER CLIENT AND STAKEHOLDER RELATED PROCESSES

7.2.1 Determining Requirements

For experiments at the Facility, requirements are established in the experiment proposal submitted by the User.

As part of the proposal submission process, CLSI, in consultation with the User, establishes requirements related to:

- Safety (including federal and provincial regulatory requirements);
- Pre-experiment and post-experiment activities;
- Other requirements not identified by the User but required for the success of the experiment, and
- Other requirements determined to be necessary by CLSI.

For design and development projects, requirements are captured in contractual or project planning documents and reviewed for similar criteria (see Section 7.3).

7.2.2 Reviewing Requirements

Experiment proposals are reviewed for:

- Safety (including federal and provincial regulatory requirements) by HSE;
- Scientific merit (by a peer-review for Users);
- Technical ability to perform the experiment by the beamline scientist within Experimental Facilities, and
- Contractual or other financial requirements for clients by Finance and Administration.

Records of the reviews are maintained by the User Services Office. Commercial records are maintained by Finance and Administration. Processes are in place for the amendment of a proposal and permit.

References:

Process of Allocating and Scheduling of Beam Time	Doc. No. 8.1.1.2
Process of Allocating and Scheduling Beam Time for CMCF Beamlines	Doc. No. 22.4.1.3
Standard Operating Procedure for the Industrial Program	Doc. No. 27.7.1.1

7.2.3 User Communication

Users communicate with the CLSI on the following issues:

- Beamline performance (through the beamline scientist);
- Enquiries on proposal, training and scheduling (through the User Services Office);
- Contractual issues (through Finance and Administration), and
- User feedback (through the end-of-run form).

Users provide advice on the operation of the Facility through the Users' Advisory Committee (UAC). The UAC meets regularly with CLSI management.

References:

User Advisory Committee Terms of Reference	Doc. No. 0.13.1.5
End-of-Run Procedure	Doc. No. 22.7.1.1

7.3 DESIGN AND DEVELOPMENT

The CLS System Engineering Guide defines specific engineering standards, codes, and regulatory requirements that must be followed for design activities.

7.3.1 Design and Development Planning

During design and development planning, the Facility determines

- The design and development stages;
- The review, verification and validation that are appropriate to each design and development stage, and
- The responsibilities and authorities for design and development.

The Facility manages the interfaces between different groups involved in the design and development to ensure effective communications and clear assignment of responsibility

References:

System Engineering Guide
CID Department Guide
CAD/Drawing Guide

Doc. No. 0.1.69.1
Doc. No. 7.1.39.1
Doc. No. 0.1.1.8

7.3.2 Design and Development Inputs

Inputs relating to design requirements are determined and records maintained. Inputs include:

- Functional and performance requirements;
- Applicable engineering codes, federal and provincial regulatory requirements;
- Information derived from previous similar designs, where applicable, and
- Other requirements essential for design and development.

The inputs are reviewed for adequacy, completeness, ambiguity and conflicts.

7.3.3 Design and Development Outputs

Design and development outputs are in a form suitable for verification against the design and development inputs. Formal design documents, specifications and drawings are approved prior to release. Design and development outputs:

- Meet the input requirements for design and development;
- Provide appropriate information for purchasing, production and servicing/maintenance;
- Contain or reference acceptance criteria, and
- Specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements:

- To evaluate the ability of the results of the design and development to meet requirements, and
- To identify any problems and propose necessary actions.

Participants in such reviews include representatives of functions concerned with the design and development stages being reviewed. Reviews are conducted by qualified persons who have access to pertinent background information, and who understand the design intent and requirements. Records of the results of the reviews and any actions are maintained.

7.3.5 Design and Development Verification

Verification is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the verification and any necessary actions are maintained.

In the case of safety critical systems, verification is performed by an independent qualified person who has not participated in the work being verified, to confirm that

results meet requirements. The extent of inspection will vary depending upon the complexity of the work and the potential impact on safety. Where verification reveals unacceptable work, a non-conformance will be created.

7.3.6 Design and Development Commissioning (Validation)

Design and development commissioning is carried out in accordance with planned arrangements to ensure that the resulting system is capable of meeting the requirements (as defined in Section 7.3.2). Where practical, the commissioning is completed prior to regular service. Records of the validation and any necessary actions are maintained.

References:

CLS Commissioning Phase III Frontends, Insertion Devices, Beamlines	Doc. No. 8.12.90.1
HSE Manual	Doc. No. 11.9.1.1
CLS Mechanical Services Design Criteria for Systems & Components	Doc. No. 6.1.15.1

7.3.7 Control of Design and Development Changes

Design and development changes are identified and records maintained. The changes are reviewed, verified and validated as appropriate before implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already completed. Records of the results of the review of changes and any necessary actions are maintained.

Where the safe operation of the Facility may be affected, additional controls are placed on the configuration of systems, structures, equipment or components.

References:

Engineering Change Request & Engineering Change Order Procedure	Doc. No. 0.7.1.3
Problem Reporting and Tracking System	Doc. No. 0.7.91.1
Safety System Development Strategy	Doc. No. 0.2.37.2
HSE Manual	Doc. No. 11.9.1.1

7.3.8 Configuration Control

Where it impacts the operation of the Facility, configuration management processes are in place to ensure that the configuration information, the physical and operations configuration of the Facility and its systems, structures, components and equipment are effectively controlled and maintained.

For configuration control related to the operation of the machine, see section 8.2.4.

References:

Engineering Change Request & Engineering Change Order Procedure	Doc. No. 0.7.1.3
System Engineering Guide	Doc. No. 0.1.69.1
CID Department Guide	Doc. No. 7.1.39.1
Document and Record Control Process	Doc. No. 0.1.1.41
CAD Drawing Guide	Doc. No. 0.1.1.8
HSE Manual	Doc. No. 11.9.1.1
Work Management and Configuration Management Process	Doc. No. 0.24.1.3

7.4 PURCHASING

7.4.1 Purchasing Process

The ownership of responsibility lies with CLSI for all sub-contracted safety related activities and services.

For small purchases a requisition is created by the requisitioner. The requisitioner identifies specific part numbers where it is important in meeting safety, quality or performance requirements. Any proposed substitutions where a specific part number is requested are reviewed by the requisitioner for suitability and approval.

For major procurements (request for proposal or request for tender), a tender process is followed where the evaluation committee assess safety, quality and performance requirements. Criteria for selection, evaluation and re-evaluation are established. Records of the result of evaluations, and any necessary actions arising from the evaluation are maintained.

7.4.2 Technical Specifications or Statements of Work

Technical Specifications and/or Statements of Work are used to describe the product or service to be purchased, including, where appropriate:

- Requirements for approval of the product or service, procedures, processes and equipment;
- Requirements for the qualification of personnel, and
- Quality management system requirements.

The Facility ensures the completeness of the technical specification or statement of work prior to release to suppliers

7.4.3 Verification of Purchased Product

The Facility has established and implemented the inspection or other activity necessary for ensuring that the product or service meets specified purchase requirements

Where the Facility intends to perform verification at the supplier's premises, this is stated in the purchasing information, including product release method and verification process.

References:

Procurement Policy	Doc. No. 0.13.1.9
Purchase Requisition Guidelines	Doc. No. 0.1.1.17

7.5 ACCELERATOR AND BEAMLIN OPERATIONS

7.5.1 Control of Operations and Beamline Services

The Facility plans and carries out accelerator and beamline operations under controlled conditions, including, as applicable:

- Supply of accelerator and beamline performance criteria to Users, as appropriate;
- Using procedures and work instructions, where necessary;
- Using suitable equipment;
- Using suitable diagnostics for monitoring and measurement of performance, and

- Operating performance is monitored and measured and recorded as appropriate.

7.5.2 Validation of Processes for Operations and Beamline Services

Where it is not possible to verify that accelerator and beamlines performance specifications are being achieved during operation, additional validation is performed as required.

As a validation, the Facility measures appropriate performance benchmarks for each beamline and the accelerator on a routine basis.

Validation may consist of reviewing or comparing experimental results after performing the experiment to ensure correct operation by qualified personnel. Systems are revalidated periodically.

References:

Floor Coordinator Roles, Responsibilities, and Training Plan	Doc. No. 0.12.1.4
Normal Operations – Machine Operating Procedure	Doc No. 8.7.91.1
Performance Monitoring of Beamlines Process	Doc. No.6.7.1.2

7.5.3 Identification and Traceability

Accelerators and beamlines are uniquely named. Accelerator, beamlines and support Facility equipment components are uniquely named.

Each proposal and experiment is uniquely named and identified. The status of a proposal or experiment is tracked through its workflow.

Reference:

Photon Port Allocation Design Note	Doc. No. 6.2.1.1
Document and Record Control Process	Doc. No. 0.1.1.41
Process of Allocating and Scheduling Beam Time	Doc. No. 8.1.1.2

7.5.4 User Property and Equipment

The Facility exercises care with User samples while they are in the Facility's control. Samples are identified, protected and safeguarded until Users prepare them for the experiment. Where samples are lost, damaged or otherwise found to be unsuitable, the User is informed and records maintained.

Procedures are in place for the transportation, receipt, handling, protection, storage, retention, and disposal of samples, including provisions to protect the integrity of the experiment, the interests of the laboratory and User, safety and environment. These procedures are designed to ensure that samples can be found within the Facility and are not subjected to environmental conditions that may damage the sample. Any handling instructions with the sample are followed.

Samples are uniquely identified and tracked through their life within the Facility.

Provisions are made for basic inspection of sample containers for damage during shipment upon arrival at the Facility.

Where User equipment is to be used during experiments, the User is responsible for ensuring that it is suitable for the experiment and is set up in accordance with the Permit and HSE requirements.

Intellectual property is safeguarded, where required, by confidentiality agreements.

References:

Purchasing, Shipping & Receiving of Hazardous Material
Procedure

Doc. No. 11.7.56.3

7.5.5 Preservation of Product – Excluded From Scope

7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

The Facility has determined the monitoring and measurements to be undertaken and the equipment needed to maintain safe operation of the Facility to meet the Users' needs while maintaining the conventional and technical facilities.

The Facility has established processes to ensure that monitoring and measurement can be carried out and are carried out consistent with Users' needs.

Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to NIST. Where no such standard exists, the basis used for calibration or verification is recorded;
- Adjusted or re-adjusted as necessary;
- Identified in order to determine its calibration status;
- Safeguarded from adjustments that would invalidate the measurement results, and
- Protected from damage and deterioration during handling, maintenance and storage.

The Facility assesses and records the validity of previous measurement results when the equipment is found not to conform to requirements. Appropriate action is taken on the equipment and any User service affected.

Records of the results of calibration and verification are maintained.

When used in the monitoring and measurement of User needs, the ability of computer software to satisfy the intended application is confirmed prior to initial use, and is re-confirmed as necessary by the User.

Software developed by CLSI for monitoring and measurement is maintained in a configuration management and versioning system. Generally accepted software engineering principles and methods are applied to custom-developed software.

For radiological safety instruments, the equipment is calibrated to R1-17 by a recognized calibration laboratory on an annual basis.

Necessary controls are placed on equipment when used by or in the possession of non-CLSI staff to maintain the equipment within calibration when returned to CLSI control

References:

CLS Naming and Numbering Convention

Doc. No. 0.2.1.1

Test Equipment and Process Instrumentation Calibration

Procedure

Doc. No. 7.7.38.1

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 GENERAL

The Facility has planned and implemented the monitoring, measurement, analysis and improvement processes needed:

- To determine conformity to operational requirements;
- To ensure the conformity of the quality management system, and
- To continually improve the effectiveness of the quality management system.

Applicable methods have been determined, including statistical techniques and the extent of their use.

Reference:

End of Run Procedure

Doc. No. 22.7.1.1

8.2 MONITORING AND MEASUREMENT

8.2.1 User, Client and Stakeholder Satisfaction

The Facility monitors information related to User, client or stakeholder perception to determine whether expectations have been met. The methods for obtaining and using this information have been determined.

The CLSI Board of Directors has established a series of Board Committees to review CLSI operations, including the Health Safety and Environment Committee.

The Scientific Advisory Committee reviews the scientific performance of the beamlines and provides feedback on best practices.

The Machine Advisory Committee reviews the performance of the accelerator systems and provides feedback on best practices.

The Users' Advisory Committee, representing the interests of the Users, provides advice on the operation of the Facility and areas for improvement.

Funding agencies periodically review CLSI performance against established criteria.

References:

Health Safety and Environment Committee	
Terms of Reference	Doc. No. 0.13.1.14
Scientific Advisory Committee Terms of Reference	Doc. No. 0.13.1.3
User Advisory Committee Terms of Reference	Doc. No. 0.13.1.5
Machine Advisory Committee Terms of Reference	Doc. No. 0.13.1.27
End-of-Run Procedure	Doc. No. 22.7.1.1

8.2.2 Internal Audit

CLSI conducts internal audits at planned intervals to determine that the Quality Management System:

- Conforms to planned arrangements, CNSC requirements and the Quality Management System, and
- Is effectively implemented and maintained.

An internal audit program is planned and takes into consideration the status and importance of the processes and areas being audited as well as previous audit results.

The audit criteria, scope, frequency and methods are defined.

To the extent possible, the auditor(s) shall be independent of managing, overseeing, or performing the work being audited.

A documented procedure has been established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Audit records are retained and maintained.

The managers (or delegates) responsible for the area audited ensure that any necessary corrective/preventive actions are taken without undue delay.

Corrective/Preventive actions are verified.

An audit schedule is created periodically.

Reference:

Internal Quality Audit Procedure

Doc. No. 10.7.1.2

8.2.3 External Audits

Regulators may perform audits of CLSI. The external body drives the timeline and format of these audits. CLSI participation in these audits are coordinated by the Manager who normally oversees the activity / function to be audited and the Quality Manager.

8.2.4 Monitoring and Measurement of Operations

During normal operations, accelerator operations personnel monitor and measure the characteristics of the stored beam prior to enabling the beam to be used by the beamlines.

Beamline personnel measure and monitor the characteristics of the beamline synchrotron radiation on a routine basis.

Evidence of conformity with the acceptance criteria is maintained.

Configuration control of the machine is maintained and communicated to Control Room personnel.

Reference:

Accelerator Operations Configuration Process

Doc. No. 0.7.91.4

Normal Operations – Machine Operating Procedure

Doc. No. 8.7.91.1

Floor Coordinator Roles, Responsibilities, and Training Plan

Doc. No. 0.12.1.4

8.3 CONTROL OF NONCONFORMANCE

The Facility ensures that services that do not conform to established criteria related to safety, User needs and Facility operations are identified and controlled. For example, CLSI has established beam stability and quality objectives. When these objectives are not achieved Users are informed so that decisions can be made on the use of non-conforming beam. Non-conformances are recorded and tracked.

A documented procedure has been established which defines the controls and related responsibilities and authorities for dealing with non-conformances.

Non-conformances are dealt with by:

- Taking action to eliminate the detected non-conformance;
- Ensuring Users are aware of the impact of the non-conformance, and/or
- Removing the system or service from use.

Non-conformance corrective actions are verified for effectiveness. Records of the nature of the non-conformance's and any subsequent actions taken are maintained.

References:

Non-conformance Reporting and Tracking Process Doc. No. 0.24.1.1

8.4 ANALYSIS OF QUALITY PERFORMANCE DATA

The Facility collects and analyses data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. This includes data generated as a result of monitoring and measurement. For example, at the end of each run the performance of the accelerator systems, beamline and User satisfaction are analyzed and reviewed.

The analysis of data provides information relating to:

- User satisfaction;
- Conformity to service requirements;
- Characteristics and trends of processes and opportunities for preventive action,
and
- Suppliers' performance and capabilities.

References:

End-of-Run Procedure Doc. No. 22.7.1.1
Non-conformance Reporting and Tracking Process Doc. No. 0.24.1.1
Procurement Policy Doc. No. 0.13.1.9

8.5 IMPROVEMENT

8.5.1 Self-Assessment and Continual Improvement

The Facility continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. Self-assessments are carried out by Floor Coordinators and HSE at planned regular intervals.

References:

Internal Quality Audit Procedure Doc. No. 10.7.1.2
Non-conformance Reporting and Tracking Process Doc. No. 0.24.1.1
Management Review Doc. No. 0.7.1.5
HSE Manual Doc. No. 11.9.1.1
Floor Coordinator Roles, Responsibilities and Training Plan Doc. No. 0.12.1.4

8.5.2 Corrective Action

The Facility takes appropriate required action to eliminate the causes of non-conformance in order to prevent recurrence.

A documented procedure is established defining requirements for:

- Reviewing non-conformities including User feedback

-
- Determining the causes of non-conformances;
 - Evaluating the need for action to ensure that non-conformances do not recur;
 - Determining and implementing action needed;
 - Records of results of action taken, and
 - Reviewing the effectiveness of corrective action taken.

Reference:

Non-conformance Reporting and Tracking Process

Doc. No. 0.24.1.1

8.5.3 Preventive Action

The Facility determines, where appropriate, actions to eliminate the root causes of potential non-conformances in order to prevent their future occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure is established to define the requirements for:

- Determining potential non-conformances and their causes;
- Evaluating the need for action to prevent occurrence of non-conformances;
- Determining and implementing action needed;
- Records of results of action taken, and
- Reviewing the effectiveness of the preventive action taken.

Reference:

Non-conformance Reporting and Tracking Process

Doc. No. 0.24.1.1

8.6 HEALTH, SAFETY AND ENVIRONMENT (HSE)

CLSI maintains a safe work environment for staff, Users and visitors. To this end a radiological and dose management program is in place to monitor and track radiological exposure to staff, Users, and visitors. A Health, Safety and Environment review is conducted of each User experiment prior to approval being given for the experiment (as defined in Section 7.2)

Reference:

Health, Safety, and Environment Manual,

Doc. No. 11.9.1.1