MEMOUNIV02-2021-SA1.RPT

CONFIDENTIAL

MANAGEMENT SYSTEM (MS) AUDIT REPORT
For
Memorial Univeristy of Newfoundland, Technical Services

DATE OF AUDIT:	October 18 - 19, 2021 (REMOTE Audit using Microsoft Teams)
DATE OF REPORT:	December 9, 2021
AUDIT CRITERIA:	**ISO 9001:2015** APPLICABLE DOCUMENTS: MS Documents (Manual, Procedure, Work Instruction, Forms) CWB Registration Audit Documents
AUDIT TYPE:	Surveillance One (SA1)
SCOPE OF THE MANAGEMENT SYSTEM:	The Department of Technical Services, repairs and maintains laboratory equipment and designs and fabricates custom research apparatus. The department also installs and maintains core infrastructure and produces cryogenic liquids. All sections of the ISO-9001:2015 standard apply and Technical Services operates under the policy structure of Memorial University.

SITES ("*" – visited at this audit)

	Address	Scope	# of Employees
*	Technical Services Memorial University Chemistry Building,Room C-1026 Finance & Administration (Director & Quality Manager(Mechanical Department Electronic Despartment	The Department of Technical Services, repairs and maintains laboratory equipment and designs and fabricates custom research apparatus. The department also installs and maintains core infrastructure and produces cryogenic liquids. All sections of the ISO-9001:2015 standard apply and Technical Services operates under the policy structure of Memorial University.	85

AUDIT TEAM:	Ray Kavanagh, Lead Auditor
MANAGEMENT REPRESENTATIVE:	Richard Meaney, Director Jim Titford, Director of Finance & Administration / Quality Assurance Manager Denis Cramm, Mechanical Division Manager Jennifer Ann Murray, Electronic Division Manager
LANGUAGE OF AUDIT:	English
LANGUAGE OF DOCUMENTATION:	English
CONFIDENTIALITY:	CWB Registration ensures that client information will be maintained in confidence.
SIGNATURE OF LEAD AUDITOR:	Ray Kavanagh

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CONCLUSIONS

No nonconformities were found during the audit. Continued registration to **ISO 9001:2015** is recommended.

With regards to the AUDIT OBJECTIVES, the MS has demonstrated:

a)	Conformity to the AUDIT CRITERIA.	YES
b)	The ability to meet applicable statutory, regulatory and contractual requirements.	YES
c)	Effectiveness of the MS to ensure that specified objectives are met.	YES
d)	The certification scope is appropriate to the context of the organization.	YES
e)	The audit objectives were achieved.	YES

Audits are based on a sampling process. Evidence collected during the audit is a representative sample of the overall operations of an organization; the results and conclusions include an element of uncertainty.

AUDITOR COMMENTS

The Scope of Memorial University, Technical Services is: *The Department of Technical Services, repairs and maintains laboratory equipment and designs and fabricates custom research apparatus. The department also installs and maintains core infrastructure and produces cryogenic liquids. All sections of the ISO-9001:2015 standard apply and Technical Services operates under the policy structure of Memorial University.* The Scope statement is approprite to the mandate and context of Technical Services and is reviewed on an annual basis. The Director and his top management team collectively provide operational and strategic direction with an emphasis on customer satisfaction and continual improvement. Individually and collectively the Director and his top management team provide exemplary leadership and commitment.

This Report is based on a surveillance one audit performed remotely using Microsoft Teams and included all processes in the Management System and ISO 9001:2015 that are included in the surveillance one (SA1) audit. The audit included interviews with appropriate persons including the Director, the Quality Assurance Manager, the Manager of the Mechanical Department and the Manager of the Electronic Department. The Lead Auditor is familiar with the operations in each Department by virtue of previous on-site audits. The Director and his team provided excellent support for this Remote Audit.

No nonconformities were found during this audit. Each office is staffed by competent employees who take pride in their work. ISO 9001-2015 contains several new sub-clauses that were the subject of opportunities that were included in the re-registration audit report. Given that Quality Manager's date for decision on implementation of the opportunities for improvement is January 2022 these opportunities for improvement are included again in this SA1 report for follow up. These include Clause 7.1.6 Organizational Knowledge, Clause 7.3 Awareness, Clause 4, Context of the Organization, Clause 6, Planning for the Management System, Clause 7, Support, Clause 8, Operation and Clause 9, Performance Evaluation.

Due to the limitations imposed by the COVID-19 pandemic the internal audits were completed in part remotely and were somewhat effective in identifying opportunities for improvement as recorded in the internal audit reports of April 23, 2021 and September 24, 2021.

The structure of this Surveillance One audit included interviews with the Director and the Quality Manager on Clause 4, 5, 6, snd 7.5. The Divisional Managers of the Mechanical Division and the Electronics Division were interviewed separately on Clauses 8.1, 8.2, 8.3, 8.4, for their respective Divisions, and the Quality Manager was interviewed on Clauses 9, and 10. A list of documents and records was forwarded to the Lead Auditor for review including internal audit reports, management review meeting minutes, corrective actions, project design files, and calibration Certificates. The documentation was detailed and no nonconformities were found during the interviews and the review of documentation.

Department Managers and Supervisory Personnel are documentation nonconforming process outputs (interna) as well as product nonconformities (external) and implementing corrective actions. Emphasis is placed on continual improvement, client satisfaction, and repeat requests for services to meet client needs as they are requested,

Overall this was a successful audit of Memorial University, Technical Services. The Director and his top management team are commended for ensuring the integrity of the management system was maintained during the operational adjustments required by COVID-19. The requirement to work from home (when possible and required) proved effective and use of information and communication technology is widely used.

Thank you for making this remote audit successful using Microsoft Teams. I commend the Quality Assurance Manager for his exemplary support in the preparations for this audit. I look forward to a return to im-person auditing when the Department of Health reports that the Province has progressed to an appropriate Level.

I extend sincere thanks to Rick, Jim, Dennis, and Jennifer for their excellent support and participation in this audit.

Keep up the excellent work in maintaining and improving your management system and meeting client requirements. I wish you continued success.

Tentative date for the next audit:	**Next audit type:**	**Date of expiry on the current certificate:**
October 2022	SA2	Cert. # 7116 Expiry 07/10/2023
Re-Registration audits should be booked eight to six weeks prior to the date of expiration.		

Planned requirements / processes to be audited according to ISO 9001:2015

Requirements	**4**	**5**	**6**	**7.1**	**7.2**	**7.3**	**7.4**	**7.5**	**8.1**	**8.2**	**8.3**	**8.4**	**8.5**	**8.6**	**8.7**	**9.1**	**9.2**	**9.3**	**10.1**	**10.2**	**10.3**
ST 2 / Re-Reg.	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
1st Surveillance	X	X	X					X	X	X	X	X				X	X	X	X	X	
2nd Surveillance		X	X	X	X	X	X						X	X	X		X	X		X	X

NONCONFORMITIES

# of Minor:	**# of Major:**	**Target response date:**	**Follow-up audit required:**
0	0	NA	NO

Notes:
- Please ensure that you include responses for Disposition/Correction(s), Cause(s) and Corrective Action(s).
- For initial registration, if CWB Registration is unable to verify the implementation of corrections and corrective actions of any major nonconformity within six months after the last day of Stage 2, a new Stage 2 Audit is required.

OPPORTUNITIES FOR IMPROVEMENT (Carried over from RRA Report - delayed action due to pandemic)

Clause #	OIs are opportunities for improvement to the management system and an opportunity for CWB Registration to contribute to our productive partnership. OI's are generic in nature and are not intended to be specific / prescriptive advice.
4.2	Expand each category of 'interested parties' to provide a more specific understanding of needs and expectations
4.2	Place document on 'needs and expectations in Appendix to revise as necessary without revising entire MS documentation
4.4	Development of separate process matrix for each Department if relevant
4.4	Place the 'process matrix' in Appendix to revise as necessary without revising entire MS documentation
6.2	Implement a plan to achieve objectives in accordance with Clause 6.2 of IO 9001:2015
7.1	Develop and present a session to all employees by Quality Assurance Manager on Organizational Knowledge to illustrate and explain the relevant details of your process management system and the importance of each persons contribution to the effectiveness of the management system
7.3	Develop and present a session to all employees by Quality Assurance Manager on Awareness of the Quality Policy, Corporate and Functional Objective and the responsibility of each employee to understand the Quality Policy and how each employee contributes to the fulfillment of the Policy
7.4	Implement a communication plan in accordance with Clause 7.4 of ISO 9001:2015
8.4	Retain a record of supplier evaluation in accordance with established criteria for supplier evaluation for suppliers uniquely providing product and services to Technical Services
9.2	Retain a record of all the evidence reviewed during internal audits

SURVEILLANCE ONE AUDIT REPORT
FOR
Memorial University Technical Services

ISO 9001:2015 AUDIT SUMMARY

	ELEMENTS	NCR#	EVALUATION
	==========		
	ISO 9001:2015		
1	SCOPE		S
4	CONTEXT OF THE ORGANIZATION		S
4.1	Understanding the organization and its context		S
4.2	Understanding the needs and expectations of interested parties		S/OI
4.3	Determining the scope of the quality management system		S
4.4	Quality management system and its processes		S/OI
4.4.1	The organization shall establish, implement,maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of		S
4.4.2	a) maintain documented information to support the operation of its processes;		S
5	LEADERSHIP		S
5.1	Leadership and commitment		S
5.1.1	General		S
5.1.2	Customer focus		S
5.2	Quality policy		S
5.2.1	Establishing the quality policy		S
5.2.2	Communicating the quality policy		S
5.3	Organizational roles, responsibility and authorities		S
6	PLANNING FOR THE QUALITY MANAGEMENT SYSTEM		S
6.1	Actions to address risks and opportunities		S
6.1.1	planning for the quality management system		S
6.1.2	The organization shall plan:		S
6.2	Quality objectives and planning to achieve them		S/OI
6.2.1	The organization shall establish quality objectives at relevant functions, levels and processes.		S
6.2.2	When planning how to achieve its quality objectives, the organization shall determine:		S
6.3	Planning of changes		S
7	SUPPORT		S
7.1	Resources		S
7.1.1	General		S
7.1.2	People		S
7.1.3	Infrastructure		S
7.1.4	Environment for the operation of processes		S

7.1.5	Monitoring and measuring resources		S
7.1.5.1	General		S
7.1.5.2	Measurement Traceability		S
7.1.6	Organizational Knowledge		S
7.2	Competence		S
7.3	Awareness		S
7.4	Communication		S/OI
7.5	Documented Information		S
7.5.1	General		S
7.5.2	Creating and Updating		S
7.5.3	Control of Documented Information		S
7.5.3.1	Document Controled information required by the quality management system and by this International Standard shall be controlled to ensure:		S
7.5.3.2	Activities for control of information		S
8	OPERATION		S
8.1	Operational Planning and Control		S
8.2	Requirements for Products and Services		S
8.2.1	Customer Communication		S
8.2.2	Determining the Requirements for Products and Services		S
8.2.3	Review of the Requirements for Products and Services		S
8.2.3.1	Conduct review		S
8.2.3.2	The organization shall retain documented information, as applicable:		S
8.2.4	Changes to Requirements for Products and Services		S
8.3	Design and Development of Products and Services		S
8.3.1	General		S
8.3.2	Design and Development Planning		S
8.3.3	Design and Development Inputs		S
8.3.4	Design and Development Controls		S
8.3.5	Design and Development Outputs		S
8.3.6	Design and Development Changes		S
8.4	Control of externally provided processes, products and services		S/OI
8.4.1	General		S
8.4.2	Type and extent of control		S
8.4.3	Information for External Providers		S
8.5	Production and Service Provision		S
8.5.1	Control of Production and Service Provision		S
8.5.2	Identification and Traceability		S
8.5.3	Property belonging to customers or external providers		S
8.5.4	Preservation		S
8.5.5	Post-delivery activities		S
8.5.6	Control of Changes		S
8.6	Release of Products and Services		S
8.7	Control of Nonconforming Outputs		S
8.7.1	Delivery of non-conforming outputs		S
8.7.2	Retention of documented information		S

9	PERFORMANCE EVALUATION		S
9.1	Monitoring, measurement, analysis and evaluation		S
9.1.1	General		S
9.1.2	Customer Satisfaction		S
9.1.3	Analysis and Evaluation		S
9.2	Internal Audit		S/OI
9.2.1	The organization shall conduct internal audits at planned intervals		S
9.2.2	The organization shall:		S
9.3	Management Review		S
9.3.1	General		S
9.3.2	Management Review Inputs		S
9.3.3	Management Review Outputs		S
10	IMPROVEMENT		S
10.1	General		S
10.2	Nonconformity and Corrective Action		S
10.2.1	When a non-conformity occurs		S
10.2.2	Retain documented information		S
10.3	Continual Improvement		S

Elements noted by asterisk are performed at all stage two, re-registration, and surveillance audits
EVALUATION CODE:
S=Satisfactory; **OI**=Opportunity for Improvement; **MI**=Minor Nonconformity; **MA=**Major Nonconformity; **N/A**=Not Applicable