MEMUN-2016-SA2-RPT

CONFIDENTIAL

MANAGEMENT SYSTEM (MS) AUDIT REPORT
For
Technical Services, Memorial University

DATE OF AUDIT: February 9 & 10, 2016

DATE OF REPORT: April 2, 2016

AUDIT CRITERIA: **ISO 9001:2008**
APPLICABLE DOCUMENTS:
Your Company's Management System (MS) Documents (Manual, Procedure, Work Instruction, Forms)
QUASAR Audit Documents

AUDIT TYPE: Surveillance Audit 2

SCOPE OF THE MANAGEMENT SYSTEM: Technical Services provides electronic and mechanical design, fabrication and repair services to the Research, Academic and Administrative and infrastructure activities of Memorial University and the External Community. These services include refrigeration, machining, welding, model making and glass blowing

EXCLUSIONS: None

SITES: (* - visited at this audit):

*	# of Employees	Address
*	67	Technical Services, Memorial University, Chemistry Building, Room C-1025, 253 Prince Philip Drive, St. John's, NL A1B 3X7

AUDIT TEAM: Lead Auditor: Ray Kavanagh
Auditor: N/A

MANAGEMENT REPRESENTATIVE: James Titford, Quality Manager
Richard Meaney, Director, Technical Services

LANGUAGE OF AUDIT: English

LANGUAGE OF DOCUMENTATION: English

CONFIDENTIALITY: QUASAR 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 9001:2008 is recommended.

a)	Conformity to the AUDIT CRITERIA	Y
b)	The ability to meet applicable statutory, regulatory and contractual requirements.	Y
c)	Effectiveness of the MS to ensure that specified objectives are met.	Y

AUDITOR's COMMENTS

Technical Services, Memorial University Management System (MS) is documented and implemented to meet the requirements of ISO 9001:2008 and customer, statutory and regulatory requirements. This report is based on a Surveillance Two Audit (SA2) performed in February 2016. The SA2 included selected processes in the Management System (MS) with a focus on internal audit, management review, customer complaints, corrective and preventive actions, and services provision. No nonconformities were found during the audit.

Opportunities for improvement are included in this report for consideration. Implementation of these opportunities would strengthen the MS and contribute to preparing the MS for the transition to ISO 9001:2015 which was published on September 23, 2015. There is a three year transition period. On September 23, 2018 ISO 9001:2008 will be obsolete. Organizations can transition to ISO 9001:2015 at any time pending readiness and completion of a successful audit to the requirements of ISO 9001:2015. Content of this Report includes information to create awareness of and preparation for the transition to ISO 9001:2015.

A review of records and interview with the appropriate persons including the Director and several others found the MS to be capable of achieving objectives at corporate and functional levels. The procedure for control of nonconformities is effectively implemented to notify management of instances where a stated requirement is not met.

The internal audit was performed in house and was found to be moderately effective to identify opportunities for improvement. Keep in mind that it is essential to select internal auditors to ensure objectivity and impartiality. The findings of internal audits are presented to top management at the annual management review where decisions for allocations to improve processes are made by top management. All processes contribute to conversion of customer orders to customer deliverables. The NCR opened in SA1 that resulted from an incomplete internal audit has been closed based on acceptable disposition and corrective action.

The ISO 9001:2015 standard is a 'risk-based standard'. The identification of risks and opportunities are important steps in implementing ISO 9001:2015. The ISO 9001:2015 requires companies to determine the context of their company. It will be necessary to identify the internal and external factors that have an influence or potential influence on your Division. A useful tool for determining context is the SWOT Analysis whereby you determine Strengths, Weaknesses, Opportunities and Threats within the Division and other competing organizations and the potential influence of factors such as the current and future economic and sociopolitical environments, legislation and regulations.

It was obvious during the audit that the Director and the Quality Manager and the team of Managers and employees are advocates of quality management. The level of expertise within Technical Services is evidenced by the commercialization of patented unique inventions. The audit found that Technical Services has Department Leaders who function at a high level of knowledge, skill and attitude

The role of top management has expanded significantly in ISO 9001:2015 and active leadership is required. The leader of the MS will be the top manager or Director of Technical Services, MUN. The Director will be required to demonstrate leadership in areas that include taking accountability for the effectiveness of the MS, promoting the process approach and risk-based thinking and promoting improvement. The Director will be required to take a hands-on direct role in the MS as the visible leader of the Quality/Business MS and promote that reality that every employee is a 'quality manager' with regard to the processes included in her/his assigned responsibilities and

accountabilities. The role of 'management representative' is not included in ISO 9001:2015 but it is recognized that the top manager will require assistance in the day to day management of the quality management system.

The description of your MS in terms of 'processes' in a requirement of the new Standard. As Craig Cochran points out in his book **ISO 9001:2015 in Plain English:** The concept of a process approach has been strengthened and reinforced in ISO 9001:2015….The standard requires documentation of the various components of a process such as inputs, outputs, criteria and methods, responsibilities and authorities, risks and opportunities, and evaluation.

Please read the following information to help prepare your Division for registration to ISO 9001:2015 (the following information will be included in all reports to ISO 9001:2008 until a request for registration to ISO 9001:2015 is made):

Please note there is NO requirement to structure your Management System (MS) in accordance with the structure of ISO 9001:2015. Document N1224 (ISO/TC 176/SC2) "Correlation matrices are available at no cost at www.iso.org (or Auditor). ISO 9001:2008 and ISO/DIS 9001 **Draft International Standard (DIS ISO 9001:2015) states: in Appendix A:**

> *The structure of clauses (in ISO 9001:2015) is intended to provide a coherent presentation of requirements rather than a model for documenting an organization's policies, objectives and processes. There is no requirement for the structure of an organization's quality management system documentation to mirror that of this International Standard.*

(Please read carefully the excerpts from DRAFT INTERNATIONAL STANDARD ISO/DIS 9001 and IAF INFORMATIVE DOCUMENT Transitional Planning Guidance for ISO 9001:2015 at the end of this section.)

Please read carefully the following information on preparation for transition to ISO 9001:2015. There will be a three-year period to transition from ISO 9001:2008 to ISO 9001:2015. In the meantime it should be noted that Appendix A of the DIS (Draft International Standard) states:

"The clause structure and some of the terminology of this International Standard, in comparison with ISO 9001:2008, have been changed to improve alignment with other management system standards. (Emphasis added, i.e. the flow of work from the receipt of customer orders to release of deliverables to the customer will follow the logical order of: sales/contract review; design if applicable; purchasing, receiving, production processes; release to customer; invoicing, obtaining customer feedback; supporting the production of customer deliverables will continue to be: resource management – human resources, technology, infrastructure, work environment; management/leadership responsibilities; and monitoring, measurement and analysis – the goal will continue to be 'doing every process right the first time and every time' and 'improving customer satisfaction').

The consequent changes in the structure and terminology do not need to be reflected in the documentation of an organization's management system.

The structure of clauses is intended to provide a coherent presentation of requirements rather than a model for documenting an organization's policies, objectives and processes. There is no requirement for the structure of an organization's quality management system documentation to mirror that of this International Standard.

There is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use the terms which suit their operations (for example, using 'records, 'documentation' 'protocols', etc. rather than 'documented information'; 'supplier', 'partner', 'vendor' etc. rather than use 'external provider'."

The Transition Planning Guidance for ISO 9001:2015 published by the International Accreditation Forum (IAF) states the main changes in the new version of ISO 9001:2015 are:

i) The adoption of the Higher Level Structure set out in the Annex SL of ISO Directives Part 1
(This will standardized the format and terminology of ISO 9001:2015 with other ISO Management System Standards)

ii) An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach

iii) Fewer prescribed requirements
iv) Less emphasis on documents

v) Improved applicability for services

vi) A requirement to define the boundaries of the QMS

vii) Increased emphasis on organizational context

viii) Increased leadership requirements

ix) Great emphasis on achieving desired outcomes to improve customer satisfaction

I wish you continued innovation, invention and success.

Tentative date for the next audit:	**Next audit type:**	**Date of expiry on the current certificate:**
January 2017	RRA	xxx
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

Requirements	4	5	6.1	6.2	6.3	6.4	7.1	7.2	7.3	7.4	7.5	7.6	8.1	8.2	8.3	8.4	8.5
Stage 2 / Re-Reg.	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
2nd Surveillance		**X**		**X**	**X**		**X**		**X**	**X**	**X**	**X**		**X**			**X**

NONCONFORMITIES

# of Minor:	**# of Major:**	**Target response date:**	**Follow-up audit required:**
None	None	N/A	N/A
Please ensure that you include responses for Disposition/Correction(s), Cause(s) and Corrective Action(s).			

OPPORTUNITIES FOR IMPROVEMENT

Clause #	OIs are opportunities for improvement to the management system and an opportunity for QUASAR to contribute to our productive partnership. OI's are generic in nature and are not intended to be specific / prescriptive advice.
4.1	Description of the 'Context of the Company' – internal and external strengths, weaknesses, opportunities and threats including customers, competitors, government policies, statutory acts, regulations etc.
4.2.1	Description of the Management System in terms of processes: activities, inputs, outputs, customers internal & external, documentation, risk and opportunities, rationale for continuation of the process etc.
5.6	Inclusion of date in management review meeting minutes a) person delegated to complete assigned action, b) target completion date and c) follow up date to check effectiveness of completed actions
6.2	Leadership training for all employees on the theme 'leadership is about action not position'
7.6	Use of correct terminology in policies and processes for calibration (external calibration lab) and verification (in house comparison against a similar device that is subject to calibration in an external calibration lab.)
7.6	Implementation of policy and procedure for frequency of Calibration in an external lab and Verification in-house.
8.2.2	Internal audit focus on each process in collaboration with the process owner with regard to productivity improvement, innovation and results
6.2/8.5	Training in ''risk based thinking" for all employees to establish an effective working knowledge and application of risk based thinking (ISO 9001:2015) to replace the procedural requirement for preventive action (ISO 9001:2008).

ISO 9001:2008 AUDIT FINDINGS SUMMARY

ELEMENTS		NCR#	EVALUATION				
			S	OI	MI	MA	NA
1. SCOPE							
1.1	General		X				
1.2	Application		X				
4.1	General requirements			X			X
4.2.1	Documentation requirements			X			X
4.2.2	Quality Manual						X
4.2.3	Control of documents						X
4.2.4	Control of records						X
5.1	Management commitment						X
5.2	Customer focus						X
5.3	Quality Policy						X
5.4	Planning						X
5.5	Responsibility, authority and communication						X
5.6*	Management review		X	X			
6. RESOURCE MANAGEMENT							
6.1	Provision of resources						X
6.2	Human resources		X	X			
6.3	Infrastructure		X				
6.4	Work environment						X
7. PRODUCT REALIZATION							
7.1	Planning of product realization		X				
7.2	Customer-related processes		X				
7.3	Design and development		X				
7.4	Purchasing		X				
7.5	Production and service provision		X				
7.6	Control of monitoring and measuring equipment		X	XX			
8.1	General						X
8.2.1	Customer satisfaction		X				
8.2.2*	Internal audit		X	X			
8.2.3	Monitoring and measurement of processes		X				
8.2.4	Monitoring and measurement of product		X				
8.3	Control of non-conforming product						X
8.4	Analysis of data		X				
8.5*	Improvement		X	X			
ACCREDITATION-RELATED ELEMENTS							
17021 (9.1.15)	Review of Previous Audit OIs and NCRs		X				
17021 (8.4)	Use of Marks and Certificates		X				

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