ORIGINAL ARTICLE

The strategic management stage of ISO 15189:2012 management system standard: an implementation update

Dennis Mok and Sharfuddin Chowdhury

ABSTRACT

Objectives: The primary aim of this paper is to provide an update on selected international standards, guidance documents and relevant literature at the application level that are associated with the implementation of the 'strategic management' stage of ISO 15189:2012.

Methods: Additional relevant international standards and guidance documents were identified from the Union of International Associations segmented organisations (Types A, B, C, D, E and F) and supplemented with additional literature.

Results: Selected international organisations (*n* = 14), inclusive of additional organisations (*n* = 6), were found to provide relevant international standards and guidance documents (*n* = 79), inclusive of additional documents (*n* = 47), in support of implementation of the strategic management stage of ISO 15189:2012. An updated list of literature (*n* = 49) was also provided for further reference.

Conclusions: The present study contributes to the medical laboratory's development of implementations of ISO 15189:2012 in areas of operations as targeted interventions using reasonably practical references to achieve an acceptable level of conformance.

Key words: clinical competence, conformity, ISO 15189:2012, quality control, quality improvement, total quality management.

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INTRODUCTION

The implementation of a relevant management system standard to support the delivery of pathology services is a common strategy for medical laboratories to maintain their technical competencies. The International Organization for Standardization (ISO) (1,pp.152-153, 2,pp.1874-1875) has been supporting such a strategy by collaborating with key international organisations, including the International Electrotechnical Commission (1,pp.138-139, 2,pp.1715-1716) and the International Telecommunication Union (2,pp.2001-2002), to produce relevant management system standards for implementation by the pathology services industry. The third edition of the ISO 15189 management system standard, ISO 15189:2012 entitled 'Medical laboratories - Requirements for Quality and Competence' (3), produced by the ISO remains the preferred management system standard in the pathology services industry for the provision of requirements against which the medical laboratory can claim conformance and achieve accreditation by an accreditation body (4).

ISO 15189:2012 can be represented using the ISO 15189:2012 process-based quality management system model (5) and one of the major processes is the 'strategic management' stage that comprises subclauses from both Clauses 4 (Management requirements) and 5 (Technical requirements) of ISO 15189:2012 (3,pp.6-39), and it has been determined that the strategic management stage of ISO 15189:2012 contains 19/119 (16%) administrative requirements (6) and 399/1515 (26%) conformance requirements (CRs) (5). The strategic management stage plays a significant role for the medical laboratory, especially in supporting the laboratory management to craft and execute strategic decisions (7), therefore management considerations need to be included to ensure long-term objectives and plans can add value to the medical laboratory operational processes.

The main challenge of the implementation of the subclause relating to the strategic management stage requires the medical laboratory to turn strategic activities into actual practices (8) while gaining and sustaining organisational competitive advantages (9,10). The updating process requires continual consideration in order to keep current regulatory and statutory requirements fulfilled in alignment with the organisation's strategic maturity (11). Nevertheless, the implementation effort is a continuous search for moving targets in continuous space (12,pp.121-153).

This paper provides an update on international standards and guidance documents associated with the strategic management stage of ISO 15189:2012 at the application level in the areas of interest and highlights areas of concern that may require reasonably practicable effort for the fulfilment of CRs. This update should be used in conjunction with the previously published 'ISO 15189:2012 implementation: an update of related international standards and guidance documents for medical laboratory quality management in the *New Zealand Journal of Medical Laboratory Science* (13). Overall, this update provides relevant information for medical laboratories on the implementation of subclauses relating to the strategic management stage of ISO 15189:2012.

MATERIALS AND METHODS

Selection criteria of international organisations

International organisations that were accepted by the Union of International Associations as either Type A, B, C, D, E or F (2,pp.xiv-xx) and published in 'Yearbook of international organizations 2018 - 2019: guide to global civil society networks' (2) were selected for inclusion.

Selection of recommended guidance documents associated with the strategic management stage of ISO 15189:2012

This update focused on the strategic management stage of ISO 15189:2012 published by the ISO. The subclauses of interest in the strategic management stage were Subclauses 4.1 (Organization and management responsibility) (3,pp.6-9), 4.2

(Quality management system) (3,pp.9-10), 4.3 (Document control) (3,pp.10-11), 4.4 (Service agreements) (3,pp.11-12), 4.13 (Control of records) (3,pp.15-16) and 4.15 (Management review) (3,pp.18-19) of ISO 15189:2012. Selected international organisations that have guidance documents that could provide reasonable support to the subclauses of interest were selected for inclusion.

Selection of relevant literature associated with the strategic management stage of ISO 15189:2012

This update provides additional resources associated with the strategic management stage of ISO 15189:2012. Relevant literature was screened and selected for inclusion. Literature listed in the previous update (13) is not included in this update.

RESULTS

Selected international organisations providing relevant guidance documents

This update includes additional international organisations (*n* = 6) that provide relevant guidance documents for the implementation of the strategic management stage of ISO 15189:2012 (Table 1).The full list of international organisations (*n* = 14), including the additional ones (*n* = 6), is listed in the supplementary section (Table S1).

Recommended guidance documents associated with the strategic management stage of ISO 15189:2012

This update has additional guidance documents (*n* = 47) to provide relevant information for the implementation of the strategic management stage of ISO 15189:2012 (Table 2). Recommended guidance documents were identified and classified in relation to relevant ISO 15189:2012 subclauses (Table S2).

Table 1. Additional international organisations providing relevant guidance documents in support of the implementation of strategic management stage of ISO 15189:2012.

Organisations	Classification (Type A to Type E)	References
CEN	D	2,p.902
IARC	E	2,p.1503
ICNIRP	D	2,p.1641
ISSA	B	2,p.1921
UN	A	2,pp.2658-2661
WHO/Europe	E	2,p.2739

CEN: European Committee for Standardization; IARC: International Agency for Research on Cancer; ICNIRP: International Commission on Non-Ionizing Radiation Protection; ISSA: International Social Security Association; UN: United Nations; WHO/Europe: WHO Regional Office for Europe.

Descriptions (2,pp.xiv-xx)**:**

Type A: federation of international organisations: comprises ≥ three international organisations; management and policy-making organisations reflect a well-balanced geographical distribution.

Type B: universal membership organisation: comprises either ≥ 60 countries or ≥ 30 countries in ≥ two continents with a well-balanced geographical distribution; management and policy-making organisations reflect a well-balanced geographical distribution.

Type D: regionally defined membership organisation: comprises ≥ three countries within one continental or sub-continental region; management and policy-making organisations reflect a well-balanced geographical distribution.

Type E: organisation emanating from places, persons or other bodies: no criteria for membership; reference to, and to some degree limited by, another international organisation, or a person, or a place.

Table 2. Additional relevant guidance documents associated with the strategic management stage of ISO 15189:2012.

Subclauses	Organisations	References
4.1.1.3	ISO	**ISO 37001:2016** Anti-bribery management systems — Requirements with guidance for use
4.1.1.4 e)	CEN	**CWA 15793:2011** Laboratory biorisk management **CWA 16393:2012** Laboratory biorisk management – Guidelines for the implementation of CWA 15793:2008 **EN 166:2001** Personal eye protection — Specifications **EN 407:2004** Protective gloves against thermal risks (heat and/or fire) **EN 420:2003+A1:2009** Protective gloves — General requirements and test methods **EN 421:2010** Protective gloves against ionizing radiation and radioactive contamination **EN 511:2006** Protective gloves against cold **EN 840-6:2012** Mobile waste and recycling containers — Part 6: safety and health requirements

4.1.1.4 e)	IARC	Arsenic, metals, fibres, and dusts Chemical agents and related occupations Non-ionizing radiation, Part 1: static and extremely low-frequency (ELF) electric and magnetic fields Non-ionizing radiation, Part 2: radiofrequency electromagnetic fields Radiation
	ICNIRP	Guidelines for limiting exposure to electric fields induced by movement of the human body in a static magnetic field and by time-varying magnetic fields below 1 Hz *Health Phys* Guidelines for limiting exposure to time-varying electric and magnetic fields (1 Hz to 100 kHz) *Health Phys* Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz) *Health Phys* Guidelines on limits of exposure to broad-band incoherent optical radiation (0.38 to 3 μm) *Health Phys* Guidelines on limits of exposure to static magnetic fields *Health Phys* Guidelines on limits of exposure to ultraviolet radiation of wavelengths between 180 nm and 400 nm (incoherent optical radiation) *Health Phys* ICNIRP guidelines on limits of exposure to incoherent visible and infrared radiation *Health Phys* ICNIRP guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1,000 mm *Health Phys* Revision of guidelines on limits of exposure to laser radiation of wavelengths between 400 nm and 1.4 μm *Health Phys*
	IEC	**IEC 60825-1:2014** Safety of laser products – Part 1: equipment classification and requirements **IEC 61010-1:2010** Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: general requirements **IEC 61010-1:2010/COR1:2011** Corrigendum 1 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: general requirements **IEC 61010-1:2010/COR2:2013** Corrigendum 2 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: general requirements **IEC 61010-1:2010/AMD1:2016** Amendment 1 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: general requirements
	ISO	**ISO 11014:2009** Safety data sheet for chemical products — Content and order of sections **ISO 15190:2019** Medical laboratories — Requirements for safety **ISO 30061:2007** Emergency lighting **ISO 45001:2018** Occupational health and safety management systems — Requirements with guidance for use
	ISSA	ISSA guidelines on prevention of occupational risks
	UN	Globally harmonized system of classification and labelling of chemicals (GHS)
	WHO	Electromagnetic fields (400 Hz to 300 GHz) Extremely low frequency fields Guidance on regulations for the transport of infectious substances 2017—2018 International minimum requirements for health protection in the workplace Lasers and optical radiation Magnetic fields Noise Radiofrequency and microwaves Static fields Ultraviolet radiation
	WHO/Europe	WHO guidelines for indoor air quality: dampness and mould WHO guidelines for indoor air quality: selected pollutants

4.2	ISO	**ISO 9004:2018** Quality management — Quality of an organization — Guidance to achieve sustained success
4.13	ISO	**ISO 30301:2019** Information and documentation — Management systems for records — Requirements

CEN: European Committee for Standardization; IARC: International Agency for Research on Cancer; ICNIRP: International Commission on Non-Ionizing Radiation Protection; IEC: International Electrotechnical Commission; ISO: International Organization for Standardization; IFCC: International Federation of Clinical Chemistry and Laboratory Medicine; ISSA: International Social Security Association; UN: United Nations; WHO: World Health Organization; WHO/Europe: WHO Regional Office for Europe.

Relevant literature associated with the strategic management stage of ISO 15189:2012
Additional references (*n* = 49) that were found to provide further relevant information for the implementation of the strategic management stage of ISO 15189:2012 were identified (Table S3).

DISCUSSION

Strategic management stage of ISO 15189:2012
The strategic management stage of ISO 15189:2012 comprises Subclauses 4.1, 4.2, 4.3, 4.4, 4.13 and 4.15 of ISO 15189:2012, containing 399/1 515 (26 %) CRs (5). Additional international organisations (*n* = 6) (Table 1) were identified to provide further guidance documents (*n* = 47) (Table 2) to support the implementation. The completed list of selected international organisations (Table S1), recommended guidance documents (Table S2) and additional resources (Table S3) that could support the implementation are presented. It is highly recommended that this update should be used by medical laboratory implementers and internal auditors in conjunction with the previously published update in the *New Zealand Journal of Medical Laboratory Science* (13).

Subclause 4.1 (Organization and management responsibility) of ISO 15189:2012
Subclause 4.1 of ISO 15189:2012 specifies the strategic management implementation aspects of the medical laboratory. Additional guidance documents were identified and the medical laboratory should extract the relevant 'good practice and applicable requirements' for implementation as specified in Subclause 4.1.1.4 e of ISO 15189:2012 (3,p.7).

Implications for implementers: additional resources should be allocated for the control of relevant factors that may affect the safety of medical laboratory personnel, such as electric, magnetic and electromagnetic fields, as appropriate to the areas of operations as specified in Subclause 4.1.1.4 e) of ISO 15189:2012 (3,p.7). More environmental conditions are specified in Subclause 5.2.6 (Facility maintenance and environmental conditions) of ISO 15189:2012 (3,p.23).

Implications for internal auditors: the internal audit process should ensure the medical laboratory is in alignment with all principal good practices and regulatory requirements for ethical conduct arrangements as specified in Subclause 4.1.1.3 d) of ISO 15189:2012 (3,p.6) as well as safety of personnel aspects as specified in Subclause 4.1.1.4 e) of ISO 15189:2012.

Subclause 4.2 (Quality management system) of ISO 15189:2012
Subclause 4.2 of ISO 15189:2012 specifies that the medical laboratory must establish, implement and maintain an effective quality management system to support the medical laboratory service operations and processes.

Implications for implementers: the medical laboratory should establish processes by incorporating requirements from ISO 9004:2018 entitled 'Quality management — Quality of an organization — Guidance to achieve sustained success' (14) to optimise operational effectiveness.

Implications for internal auditors: no additional notes.

Subclause 4.3 (Document control) of ISO 15189:2012
Subclause 4.3 of ISO 15189:2012 specifies that all relevant documented information relating to the medical laboratory quality management system is maintained to provide effective operations.

Implications for implementers: no additional notes.
Implications for internal auditors: no additional notes.

Subclause 4.4 (Service agreements) of ISO 15189:2012
Subclause 4.4 of ISO 15189:2012 specifies that the medical laboratory must manage suitable service agreements relating to the provision of medical laboratory services.

Implications for implementers: the medical laboratory must treat each valid service request as a service agreement as specified in Subclause 4.4.1 (Establishment of service agreements) of ISO 15189:2012 (3,p.11) and determine the timeframe for retaining the agreement required at the completion of each request.

Implications for internal auditors: the internal audit process must check each valid service request is kept in an acceptable format and is retrievable within a reasonable timeframe when requested.

Subclause 4.13 (Control of records) of ISO 15189:2012
Subclause 4.13 of ISO 15189:2012 specifies that the medical laboratory must manage all relevant quality and technical records relating to access, amendment, collection, disposal, identification, indexing, maintenance and storage.

Implications for implementers: the medical laboratory must determine what types of records need to be retained and for how long. Additionally, the retention timeframes must be in alignment with all principal legal and regulatory requirements. It is important to note that the retention requirements vary greatly between locations, such as Australia (15) and the United Arab Emirates (16). The medical laboratory should consider requirements from ISO 30301:2019 entitled 'Information and documentation — Management systems for records — Requirements' (17) while establishing the documented procedure where it is operationally feasible.

Implications for internal auditors: the internal audit process must check carefully that the organisational, national, regional and international requirements pertaining to the particular activity and the nature of the records are competently fulfilled.

Subclause 4.15 (Management review) of ISO 15189:2012
Subclause 4.15 of ISO 15189:2012 specifies that laboratory management must review the medical laboratory quality management system at planned intervals to ensure continual adequacy, effectiveness, suitability and support of patient care.

Implications for implementers: the medical laboratory must ensure the review input information as specified in Subclauses 4.15.2 a) to 4.15.2 o) of ISO 15189:2012 (3,pp.18-19) are provided to the management review process.

Implications for internal auditors: the internal audit process must seek evidence that information in Subclauses 4.15.2 a) to 4.15.2 o) of ISO 15189:2012, including information in Subclauses 4.15.2 a) to 4.15.2 l) of ISO 15189:2012 (3,p.18) referred subclauses, is provided to the management review.

CONCLUSIONS

This update has provided further references to support the implementation of the medical laboratory quality management system, particularly in Subclauses 4.1, 4.2, 4.3, 4.4, 4.13 and 4.15 of ISO 15189:2012. These findings are relevant to both implementers and internal auditors. Considerably more work must be done by the medical laboratory to determine the pertinent content of relevant guidance documents and additional literature with an appropriate level of scientific certainty. In sum, ensuring reasonably practicable implementation of the strategic management stage of ISO 15189:2012 should be a priority for the medical laboratory if the sustainment of organisational competitive advantages becomes relevant for competition in the contemporary marketplace.

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AUTHOR INFORMATION

Dennis Mok, Chartered MCIPD CSci MIBMS MIHRM(HK) CMgr FCMI FIML FNZIMLS CPHR, L&D Consultant[1]
Sharfuddin Chowdhury, MBBS MMed FCS(SA) FACS, Director of Trauma Center[2]

[1]Medical Management Consulting, Birkdale, Queensland, Australia
[2]King Saud Medical City, Riyadh, Riyadh, Saudi Arabia

Author for correspondence: Sharfuddin Chowdhury.
Email: s.chowdhury@ksmc.med.sa

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