

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

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Table S1. Selected international organisations ($n = 14$) providing relevant guidance documents in support of the implementation of strategic management stage of ISO 15189:2012.

Organisations ($n = 14$)	Classification (Type A to Type F)	References ($n = 14$)
CEN	D	1,p.902
IAEA	B	1,pp.1587-1588
IARC	E	1,p.1503
ICNIRP	D	1,p.1641
IEC	C	1,pp.1715-1716
IFBLS	C	1,p.1736
IFCC	B	1,pp.1739-1740
ILO	B	1,pp.1428-1430
ISO	B	1,pp.1874-1875
ISSA	B	1,p.1921
TI	F	1,pp.2591-2592
UN	A	1,pp.2658-2661
WHO	B	1,pp.2734-2738
WHO/Europe	E	1,p.2739

Abbreviations:

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

Descriptions (1,pp.xiv-xx):

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

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

Type C: intercontinental membership organisation: comprises \geq 10 countries in \geq 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 \geq 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.

Type F: organisation having a special form: no criteria for membership; structure is non-formal, unconventional or unusual.

Type G: internationally-oriented national organisation: no criteria for membership; management and policy-making organisation reflect participation of only one or two countries; formal links with \geq one other international organisation.

Table S2. Recommended guidance documents associated with the strategic management stage of ISO 15189:2012.

Subclauses (n = 8)	Organisations (n = 22)	References (n = 79)
4.1	IFCC	Basic training in managerial skills, in: Essentials of clinical laboratory management in developing regions (2) Managerial guidelines to set up a clinical laboratory under difficult circumstances, in: Essentials of clinical laboratory management in developing regions (3)
4.1.1.3	IFBLS	Code of ethics for biomedical laboratory scientists (4)
	ILO	Technical and ethical guidelines for workers' health surveillance (5)
	ISO	ISO 19600:2014 Compliance management systems — Guidelines (6) ISO 37001:2016 Anti-bribery management systems — Requirements with guidance for use (7)
	TI	Business principles for countering bribery, 3rd edn (8) International principles for whistleblower legislation (9)
4.1.1.4	ISO	ISO 22301:2012 Societal security — Business continuity management systems — Requirements (10) ISO 22313:2012 Societal security — Business continuity management systems — Guidance (11) ISO 22324:2015 Societal security — Emergency management — Guidelines for colour-coded alerts (12)
4.1.1.4 e)	CEN	CWA 15793:2011 Laboratory biorisk management (13) CWA 16393:2012 Laboratory biorisk management – Guidelines for the implementation of CWA 15793:2008 (14) EN 166:2001 Personal eye protection — Specifications (15) EN 407:2004 Protective gloves against thermal risks (heat and/or fire) (16) EN 420:2003+A1:2009 Protective gloves — General requirements and test methods (17) EN 421:2010 Protective gloves against ionizing radiation and radioactive contamination (18) EN 511:2006 Protective gloves against cold (19) EN 840-6:2012 Mobile waste and recycling containers — Part 6: safety and health requirements (20)
	IAEA	Fundamental safety principles: safety fundamentals (21) Governmental, legal and regulatory framework for safety (22) International basic safety standards for protection against ionizing radiation and for the safety of radiation sources (23) Radiation protection and safety of radiation sources: international basic safety standards (24)
	IARC	Arsenic, metals, fibres, and dusts (25) Chemical agents and related occupations (26) Non-ionizing radiation, Part 1: static and extremely low-frequency (ELF) electric and magnetic fields (27) Non-ionizing radiation, Part 2: radiofrequency electromagnetic fields (28) Radiation (29)
	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 <i>Health Physics</i> (30) Guidelines for limiting exposure to time-varying electric and magnetic fields (1 Hz to 100 kHz) <i>Health Physics</i> (31) Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz) <i>Health Physics</i> (32) Guidelines on limits of exposure to broad-band incoherent optical radiation (0.38 to 3 µm) <i>Health Physics</i> (33) Guidelines on limits of exposure to static magnetic fields <i>Health Physics</i> (34) Guidelines on limits of exposure to ultraviolet radiation of wavelengths between 180 nm and 400 nm (incoherent optical radiation) <i>Health Physics</i> (35) ICNIRP guidelines on limits of exposure to incoherent visible and infrared radiation <i>Health Physics</i> (36) ICNIRP guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1,000 µm <i>Health Physics</i> (37) Revision of guidelines on limits of exposure to laser radiation of wavelengths between 400 nm and 1.4 µm <i>Health Physics</i> (38)

4.1.1.4 e)	IEC	<p>IEC 60825-1:2014 Safety of laser products – Part 1: equipment classification and requirements, 3rd edn (39)</p> <p>IEC 61508-1:2010 Functional safety of electrical/electronic/programmable electronic safety-related systems – Part 1: general requirements, 2nd edn (40)</p> <p>IEC 61508-2:2010 Functional safety of electrical/electronic/programmable electronic safety-related systems – Part 2: requirements for electrical/electronic/programmable electronic safety related systems, 2nd edn (41)</p> <p>IEC 61508-3:2010 Functional safety of electrical/electronic/programmable electronic safety-related systems – Part 3: software requirements, 2nd edn (42)</p> <p>IEC 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: general requirements, 3rd edn (43)</p> <p>IEC 61010-1:2010/COR1:2011 Corrigendum 1 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: general requirements, 3rd edn (44)</p> <p>IEC 61010-1:2010/COR2:2013 Corrigendum 2 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: general requirements, 3rd edn (45)</p> <p>IEC 61010-1:2010/AMD1:2016 Amendment 1 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: general requirements, 3rd edn (46)</p>
	ILO	<p>Ambient factors in the workplace (47)</p> <p>Fundamental principles of occupational health and safety, 2nd edn (48)</p>
	ISO	<p>ISO 374-1:2016 Protective gloves against dangerous chemicals and micro-organisms — Part 1: terminology and performance requirements for chemical risks (49)</p> <p>ISO 374-1:2016/Amd.1:2018 Amendment 1 — Protective gloves against dangerous chemicals and micro-organisms — Part 1: terminology and performance requirements for chemical risks (50)</p> <p>ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms — Part 5: terminology and performance requirements for micro-organisms risks (51)</p> <p>ISO 4849:1981 Personal eye-protectors — Specifications (52)</p> <p>ISO 11014:2009 Safety data sheet for chemical products — Content and order of sections (53)</p> <p>ISO 13688:2013 Protective clothing — General requirements (54)</p> <p>ISO 15190:2019 Medical laboratories — Requirements for safety, 2nd edn (55)</p> <p>ISO 30061:2007 Emergency lighting (56)</p> <p>ISO 45001:2018 Occupational health and safety management systems — Requirements with guidance for use (57)</p>
	ISSA	ISSA guidelines on prevention of occupational risks (58)
	UN	Globally harmonized system of classification and labelling of chemicals (GHS), 8th edn (59)
	WHO	<p>Biorisk management: laboratory biosecurity guidance (60)</p> <p>Electromagnetic fields (400 Hz to 300 GHz) (61)</p> <p>Extremely low frequency fields (62)</p> <p>Guidance on regulations for the transport of infectious substances 2017—2018 (63)</p> <p>International minimum requirements for health protection in the workplace (64)</p> <p>Laboratory biosafety manual, 3rd edn (65)</p> <p>Lasers and optical radiation (66)</p> <p>Magnetic fields (67)</p> <p>Noise (68)</p> <p>Radiofrequency and microwaves (69)</p> <p>Static fields (70)</p> <p>Tuberculosis laboratory biosafety manual (71)</p> <p>Ultraviolet radiation, 2nd edn (72)</p>
	WHO/Europe	<p>WHO guidelines for indoor air quality: dampness and mould (73)</p> <p>WHO guidelines for indoor air quality: selected pollutants (74)</p>

4.1.2.4	ISO	ISO 10005:2018 Quality management systems — Guidelines for quality plans, 3rd edn (75)
4.2	IFCC	Managing the work process of laboratory work flow, in: Quality management & quality of analysis: a handbook of developing countries jointly developed by C-CLM and C-AQ of the EMD (76)
	ISO	ISO 9004:2018 Quality management — Quality of an organization — Guidance to achieve sustained success, 4th edn (77)
4.4	ISO	ISO 37500:2014 Guidance on outsourcing (78)
4.13	ISO	ISO 30301:2019 Information and documentation — Management systems for records — Requirements, 2nd edn (79)
		ISO 30302:2015 Information and documentation — Management systems for records — Guidelines for implementation (80)

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Table S3. Additional resources associated with the strategic management stage of ISO 15189:2012.

Subclauses (n = 9)	References (n = 49)
4.1.1.2	Mastering corporations and other business entities (81)
4.1.1.3	(Dis)honesty in organizations: ethical perspectives, in: (Dis)honesty in management (82) A short guide to fraud risk: fraud and corruption resistance and detection, 2nd edn (83) Bribery and corruption, in: Business law and ethics: concepts, methodologies, tools, and applications (84) Business ethics, in: The SAGE encyclopedia of quality and the service economy (85) Confidentiality, in: The SAGE encyclopedia of business ethics and society, 2nd edn (86) Conflict of interest, in: Encyclopedia of applied ethics, 2nd edn (87) Conflict of interest, in: The international encyclopedia of ethics (88) Conflict of interest, in: The SAGE encyclopedia of business ethics and society, 2nd edn (89) Ethical challenges in healthcare, in: Handbook of healthcare management (90) Ethical efficiency: responsibility and contingency (91) Ethical leadership in organizations: concepts and implementation (92) Ethics in health informatics and information technology, in: Encyclopedia of information science and technology, 3rd edn (93) Improper payments and gifts, in: Encyclopedia of applied ethics, 2nd edn (94) Operational transparency <i>Harvard Business Review</i> (95) Personal responsibility for the greater good, in: Business and the greater good: rethinking business ethics in an age of crisis (96) Privacy, vulnerability, and affordance, in: The Cambridge handbook of consumer privacy (97) Theories of ethics, in: Contemporary debates in applied ethics, 2nd edn (98) What is integrity? in: Business and corporate integrity: sustaining organization compliance, ethics, and trust (99) Why leaders fail ethically: a paradigmatic evaluation of leadership (100)
4.1.1.4	Financial management, in: Henry's clinical diagnosis and management by laboratory methods, 23rd edn (101) General concepts and administrative issues, in: Henry's clinical diagnosis and management by laboratory methods, 23rd edn (102) Good practice guidelines: 2018 edition: the global guide to good practice in business continuity (103)
4.1.2.1	Laboratory organisation, management and safety, in: Dacie and Lewis practical haematology, 12th edn (104) Leadership for quality, in: The SAGE encyclopedia of quality and the service economy (105) TQM: an overview and the role of management, in: 'Managing quality: an essential guide and resource gateway', 6th edn (106)

4.1.2.6	<p>Communication measurement as a key factor for organizational strategy success, in: Strategic employee communication: building a culture of engagement (107)</p> <p>Communication, in: Handbook of healthcare management (108)</p> <p>Internal communications flourishes at the grassroots: the growing importance of managers in employee engagement, in: Strategic employee communication: building a culture of engagement (109)</p> <p>Interpersonal communication: a strategic perspective, in: Encyclopedia of strategic leadership and management (110)</p> <p>Organizational communication, in: The SAGE encyclopedia of quality and the service economy (111)</p> <p>Successful communication, in: Clinical laboratory management, 2nd edn (112)</p>
4.2.1	<p>Business process frameworks, in: Handbook on business process management 2: strategic alignment, governance, people and culture, 2nd edn (113)</p> <p>Business process management, in: A handbook of business transformation methodology (114)</p> <p>Business process management: practical guidelines to successful implementations, 4th edn (115)</p> <p>Business process quality management, in: Handbook on business process management 1: introduction, methods, and information systems (116)</p> <p>Delivering business strategy through process management, in: Handbook on business process management 2: strategic alignment, governance, people and culture, 2nd edn (117)</p> <p>Quality management and quality assurance in medical laboratories, in: Laboratory management information systems: current requirements and future perspectives (118)</p> <p>The handbook for quality management: a complete guide to operational excellence, 2nd edn (119)</p>
4.3	<p>Building successful information systems: five best practices to ensure organizational effectiveness and profitability, 2nd edn (120)</p> <p>Creating a culture for information systems success (121)</p> <p>Document review checklists for ISO 15189:2012 internal auditing: an applied tool for medical laboratories <i>Australian Journal of Medical Science</i> (122)</p> <p>Essentials of MIS, 13th edn (123)</p> <p>Predicting information retrieval performance (124)</p>
4.4	<p>A manual of style for contract drafting, 3rd edn (125)</p> <p>Barron's dictionary of legal terms: definitions and explanations for non-lawyers! 5th edn (126)</p> <p>Outsourcing, in: Encyclopedia of human resource management (127)</p>
4.13	<p>Laboratory records, in: Clinical microbiology procedures handbook, 4th edn (128)</p> <p>Records management, 10th edn (129)</p>

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