FELLOWSHIP TREATISE

ISO 15189:2012 implementation checklists for conformity assessment by accreditation bodies: a comparative analysis

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ABSTRACT

Objectives: The aim of this research was to determine the extent of conformance requirement coverage provided by ISO 15189:2012 guidance checklists produced by accreditation bodies. The contributing objectives include the identification of conformance requirements in ISO 15189:2012 for the development of evaluation checklists and determination of the level of conformance requirement coverage by quantitative analysis.

Methods: The conformance requirements were identified and located in Clauses 4 and 5 of ISO 15189:2012 by content analysis. The identified conformance requirements were used to develop evaluation checklists for further evaluability assessment. The distribution of conformance requirement coverage was allocated to the ISO 15189:2012 process-based quality management system framework for comparative analysis.

Results: A total of 51/109 (47 %) accreditation bodies offered ISO 15189:2012 accreditation to medical laboratories and 6/51 (12 %) of these accreditation bodies have published guidance checklists for use in preparation for accreditation assessment. An evaluability assessment of the checklists published by these 6/51 (12 %) accreditation bodies was conducted and the extent of coverage by the evaluand checklists was classified into four major stages based on the ISO 15189:2012 process-based quality management system framework. The overall conformance requirement coverage by the checklists was analysed with the following results: 'orange status' coverage (≤ 50 %) was provided by the Finnish Accreditation Service, the South African National Accreditation System and the National Association of Testing Authorities, Australia; 'yellow-green status' coverage (51 % to 84 %) was provided by the Danish Accreditation Fund; and, 'green status' coverage (85 % to 100 %) was provided by the Hong Kong Accreditation Service and the Singapore Accreditation Council. Three selected compliance management issues were also identified in areas with limited coverage (0 %); these include Subclauses 4.11, 5.6.1 and 5.9.1 of ISO 15189:2012. The implications of identified issues for the management of risk mitigation are highlighted and recommendations made.

Conclusions: Medical laboratories planning to conduct gap analysis in preparation for accreditation should take into account that the guidance checklists recommended by accreditation bodies are not intended to identify all relevant conformance requirements, and they need to conduct their own initial internal audits to support the implementation process.

Key words: continuous quality management, quality control, quality improvement, total quality management.

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INTRODUCTION

Quality management plays a significant role in ensuring the diagnostic serviceability of the medical laboratory is maintained at a technically competent level at all times. The International Organization for Standardization (ISO) has been producing guidance documents to support continual improvements in quality performance in the medical laboratory since 1978 (1). The ISO collaborates extensively with many international organisations to produce relevant guidance documents (2,3). One such international non-governmental organisation is the International Electrotechnical Commission (IEC) (4). Together with the IEC, the ISO has produced guidance documents for the pathology services industry for implementation purposes by fulfilling conformance requirement (CR) coverage to an acceptable level. The foundation guidance documents were ISO Guide 25 (5) and ISO/IEC Guide 25 (6,7). However, these documents were not designed for purposes of medical laboratory accreditation. It was subsequently revised and replaced by ISO/IEC 17025 (8-10). ISO/IEC 17025 offered more specific requirements for accreditation purposes. As of 2003, the ISO released ISO 15189 guidance documents that are specific for the pathology services industry (11-14).

The latest edition, ISO 15189:2012 entitled 'Medical laboratories — Requirements for quality and competence' (14), aligns with the relevant requirements of current medical laboratory practices and remains the standard of choice for accreditation purposes. Implementation of ISO 15189:2012 requires the medical laboratory to fulfil specific CRs ranging from bench to strategic levels in relation to management system and technical competence. Specifically, Clause 4 (management requirements) of ISO 15189:2012 (14,pp.6-19) concentrates on the management system requirements containing 682/1 515 (45 %) CRs for the medical laboratory to consider if all areas are related to the areas of operations (15). By contrast, Clause 5 (technical requirements) of ISO 15189:2012 (14,pp.19-39), which relates to the implementation of technical competence requirements, contains 833/1 515 (55 %) CRs for consideration (15). Together with the specific requirements of accreditation bodies, ISO 15189:2012 enables accreditation bodies to customise the overall requirements for accreditation. The implementation of ISO 15189:2012 by the medical laboratory represents significant investment of effort and resources in order to competently accomplish all of the relevant CRs and while achieving desired economy, effectiveness and efficiency (16-18).

Since 2013, accreditation bodies have been granting ISO 15189 accreditations to medical laboratories that have achieved satisfactory on-site assessments globally. These specific accreditation bodies have the option of joining the International Accreditation Forum or the International Laboratory Accreditation Cooperation to demonstrate that they meet operational criteria as specified in ISO/IEC 17011:2004 entitled 'Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies' (19). Such accreditation bodies become signatories to an international mutual recognition arrangement that allows their accredited medical laboratories to produce mutually recognised test results. These accreditation bodies also provide guidance and recommendations to medical laboratories interested in becoming accredited, especially in the implementation of ISO 15189:2012.

Guidance documents for ISO 15189:2012 implementation are presented either in the format of checklists, such as the National Association of Testing Authorities, Australia (NATA) (20) or explanatory commentaries, such as the International Accreditation New Zealand (21). These specific guidance documents are supposed to provide self-assessments to produce the gap analysis results necessary to achieve accreditation. Despite the recent quantification that ISO 15189:2012 has 1,515 CRs for implementation purposes (15), there has been no detailed quantitative analysis of the extent of CR coverage provided by these guidance checklists nor has there been a suitable analytical tool available to conduct such an evaluation. The degree of coverage of the 1 515 CRs in ISO 15189:2012 offered by guidance checklists released by accreditation bodies remains unknown.

The focus of this dissertation is to quantitatively analyse the extent of CR coverage by ISO 15189:2012 guidance checklists produced by accreditation bodies. This is the first study to undertake an in-depth quantitative analysis of the comprehensiveness of guidance checklists. The evaluation of ISO 15189:2012 guidance checklists was conducted through content analysis (CA) and divided into four phases. First, an evaluation checklist was developed based on the quantification of 1 515 CRs (15) for Clauses 4 and 5 of ISO 15189:2012 (14,pp.6-39). An evaluation checklist can be defined as 'list of questions, each of which is designed to check for conformity of a product, process or service to one or more provisions within a particular International Standard' (22). A well-prepared checklist if deployed correctly can provide insights into workplaces by collecting objective evidence (23). Second, ISO 15189:2012 guidance checklists were identified that are intended to provide guidance from signatories to the International Accreditation Forum multilateral recognition arrangement (IAFMLA) or the International Laboratory Accreditation Cooperation mutual recognition arrangement (ILACMRA) using standardised selection criteria. Third, evaluability assessments of the selected ISO 15189:2012 guidance checklists were conducted using the 1 515 CRs framework-derived evaluation checklists.

The results were classified into four major stages based on the models of process-based quality management systems in ISO 9001:2015 entitled 'Quality management systems — Requirements' (24,pp.vii-ix) and ISO 15189:2012 (25) (Figure 1). Relevant subclauses were then allocated to each of the four stages for analytical purposes. Finally, the checklists' shortfalls were analysed in order to generate recommendations for organisations intending to use these guidance checklists for gap analysis. Overall, this research provides information on the usefulness of ISO 15189:2012 guidance checklists supplied by accreditation bodies for organisations who intend to use them.

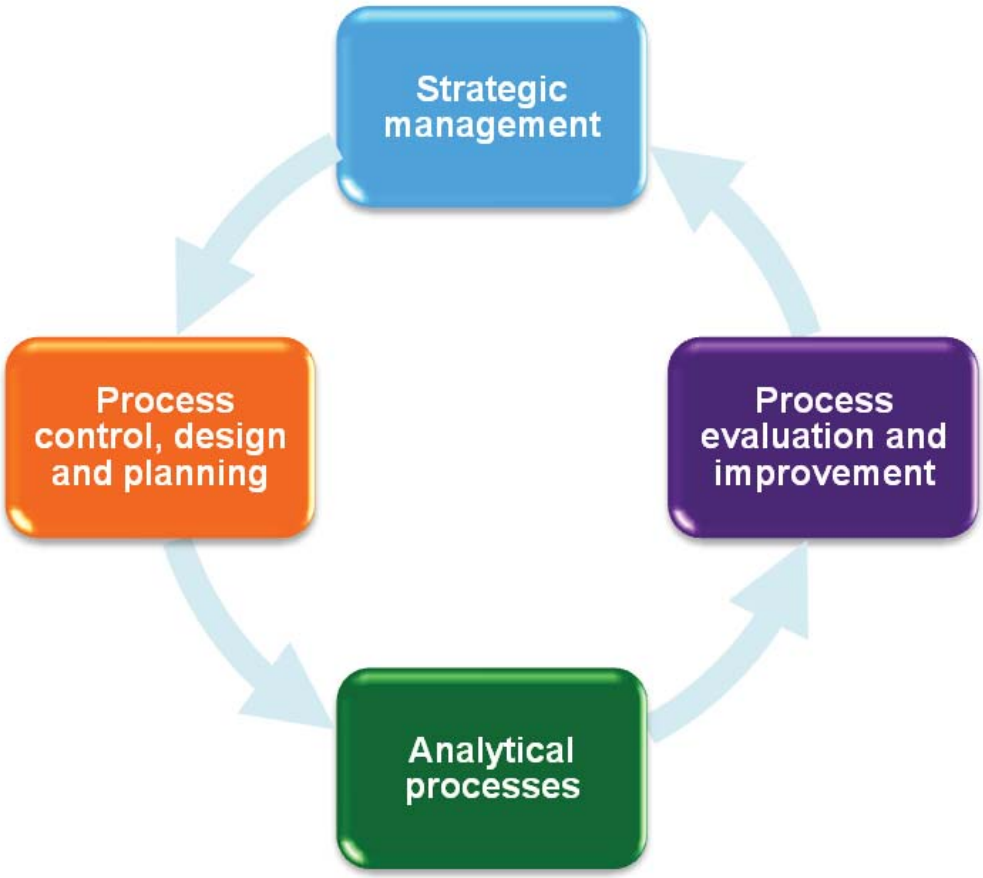


Figure 1. Representation of ISO 15189:2012 in a process-based quality management system framework. The four boxes represent the major stages of ISO 15189:2012 processes. This modified format is based on ISO 9001:2015 and ISO 15189:2012 models of process-based quality management systems (24,25).

MATERIALS AND METHODS

Content analysis of Clauses 4 (management requirements) and 5 (technical requirements) of ISO 15189:2012

CA is an established approach for analysing ISO 15189:2012 (15,26), and is highly suitable for the quantitation of CRs. In this investigation, CA was used to locate instances of the word 'shall' within Clauses 4 and 5 of ISO 15189:2012 (14,pp.6-39). According to the ISO, the use of the verb 'shall' indicates a mandatory requirement (27). The specific locations of the word 'shall' were identified using a computer-aided qualitative data analysis software, NVivo™ 10 (version 10.0.418.0 SP4) (QSR International, Doncaster, Victoria, Australia), as previously described (15). The implied CRs indicated by the word 'shall' were then elicited as previously described (15). The identification of CRs within Clauses 4 and 5 of ISO 15189:2012 (14,pp.6-39) was used for the development of evaluation checklists for the comparative analysis and evaluability assessment. An acceptable result was recorded when the evaluand subclause had an equivalent subclause on the evaluation checklist.

Guidance checklist selection criteria for evaluability assessment

The criteria for selecting the evaluands consisted of five areas (Table 1). Briefly, ISO 15189:2012 guidance checklists were sought from accreditation bodies of signatories to the IAFMLA or the ILACMRA. Accreditation bodies were sought from countries and a dependent territory published in ISO 3166-1:2013 entitled 'Codes for the representation of names of countries and their subdivisions — Part 1: country codes' (28) and whose evaluand checklists were published in English, classified as 'eng' in ISO 639-2:1998 entitled 'Codes for the representation of names of languages — Part 2: alpha-3 code' (29).

Point distribution for comparative analysis

The distribution of CRs in Clauses 4 and 5 of ISO 15189:2012 (14,pp.6-39) is represented by a radar chart. The advantage of a radar chart is that several dimensions can be viewed simultaneously (30,31). The radar chart represents the distribution of 1,515 CRs in Clauses 4 and 5 of ISO 15189:2012 (14,pp.6-39) by placing each subclause on a spoke. The subclauses are on a sequence of radii (n = 28) representing the number of CRs. The maximum magnitude of the point is joined by a continuous line between each data value for each spoke.

Limitations of the evaluability assessment

The investigation had a major limitation: the evaluand checklists were highly unlikely to cover all aspects of Clauses 4 and 5 of ISO 15189:2012 (14,pp.6-39) because they were developed to guide the medical laboratory to address potential gaps. Different accreditation bodies have produced checklists with different levels of coverage; such as the NATA states that 'this worksheet provides only a brief summary of the clauses of the Standard' (20), and the Danish Accreditation Fund (DANAK) states that the checklist 'is much shortened compared to the text of DS/EN ISO 15189:2013 and it is therefore important that the checklist is used together with ISO 15189' (32).

RESULTS

Identification and location of conformance requirements in Clauses 4 (management requirements) and 5 (technical managements) of ISO 15189:2012

CA was used to detect the word 'shall' which implies the presence of a CR. A total of 1,515 CRs was identified in Clauses 4 and 5 of ISO 15189:2012 (14,pp.6-39) (Table 2); Clause 4 of ISO 15189:2012 (14,pp.6-19) contained 682/1 515 (45 %) CRs and Clause 5 of ISO 15189:2012 (14,pp.19-39) contained 833/1 515 (55 %) CRs. A positive correlation was found between these results and previously reported results (15).

Table 1. Selection criteria for evaluand ISO 15189:2012 checklists.

Selection criteria (n = 5)
The checklist is published by an accreditation body that is a signatory of the International Laboratory Accreditation Cooperation mutual recognition arrangement;
The country or dependent territory of the accreditation body is listed in ISO 3166-1:2013;
The checklist is published in English, classified as 'eng' in ISO 639-2:1998;
The checklist is freely and readily available; and
The checklist is not an exact duplicate of Clauses 4 and 5 of ISO 15189:2012.

Table 2. Stage-by-stage coverage summary of ISO 15189:2012 conformance requirements.

		ISO 15189:2012
Strategic management	**Subclause 4.1** *Organization and management responsibility*	159/399 (40 %)
	Subclause 4.2 *Quality management system*	66/399 (16 %)
	Subclause 4.3 *Document control*	31/399 (8 %)
	Subclause 4.4 *Service agreements*	35/399 (9 %)
	Subclause 4.13 *Control of records*	59/399 (15 %)
	Subclause 4.15 *Management review*	49/399 (12 %)
	Subtotal	**399/399 (100 %)**
Process control, design and planning	**Subclause 4.6** *External services and supplies*	26/477 (6 %)
	Subclause 5.1 *Personnel*	67/477 (14 %)
	Subclause 5.2 *Accommodation and environmental conditions*	88/477 (18 %)
	Subclause 5.3 *Laboratory equipment, reagents, and consumables*	154/477 (32 %)
	Subclause 5.10 *Laboratory information management*	142/477 (30 %)
	Subtotal	**477/477 (100 %)**
Analytical processes	**Subclause 4.5** *Examination by referral laboratories*	32/387 (8 %)
	Subclause 4.7 *Advisory services*	11/387 (4 %)
	Subclause 5.4 *Pre-examination processes*	144/387 (37 %)
	Subclause 5.5 *Examination processes*	71/387 (18 %)
	Subclause 5.6.1 *General*	4/387 (1 %)
	Subclause 5.6.2 *Quality control*	12/387 (3 %)
	Subclause 5.7 *Post-examination processes*	21/387 (5 %)
	Subclause 5.8 *Reporting of results*	47/387 (12 %)
	Subclause 5.9 *Release of results*	45/387 (12 %)
	Subtotal	**387/387 (100 %)**
Process evaluation and improvement	**Subclause 4.8** *Resolution of complaints*	4/252 (2 %)
	Subclause 4.9 *Identification and control of nonconformities*	23/252 (9 %)
	Subclause 4.10 *Corrective action*	10/252 (4 %)
	Subclause 4.11 *Preventive action*	10/252 (4 %)
	Subclause 4.12 *Continual improvement*	34/252 (13 %)
	Subclause 4.14 *Evaluation and audits*	133/252 (53 %)
	Subclause 5.6.3 *Interlaboratory comparisons*	26/252 (10 %)
	Subclause 5.6.4 *Comparability of examination results*	12/252 (5 %)
	Subtotal	**252/252 (100 %)**
	Total (of 1 515)	**1 515 (100 %)**

The frequency of conformance requirements in the ISO 15189:2012 process-based quality management system framework

CA successfully identified and located the CRs in the four-stage process-based quality management system framework (Figure 2). The 'strategic management' stage contained a total of 399/1 515 (26 %) CRs. The 'process control, design and planning' stage contained a total of 477/1 515 (31 %) CRs. The 'analytical processes' stage contained a total of 387/1 515 (26 %) CRs. The 'process evaluation and improvement' stage contained a total of 252/1 515 (17 %) CRs. The number of CRs identified in each subclause ranged from 4 CRs in Subclause 4.8 (resolution of complaints) (14,p.13) and Subclause 5.6.1 (general) of ISO 15189:2012 (14,p.33), to 159 CRs in Subclause 4.1 (organization and management responsibility) of ISO 15189:2012 (14,pp.6-9).

Selection of evaluand checklists for comparative analysis

To ensure comprehensive coverage, accreditation bodies that are signatories to the IAFMLA (33) or the ILACMRA (34) were identified for selection purposes (Table 3). A total of 51/109 (47 %) accreditation bodies were identified that provide ISO 15189:2012 accreditation in accordance with the requirements of ISO/IEC 17011:2014 (19). A final 6/51 (12 %) accreditation bodies were selected because they met the selection criteria for evaluand checklists (Table 1).

Evaluability assessment of evaluand checklists from selected accreditation bodies

Evaluand checklists from the 6/51 (12 %) accreditation bodies were used for the evaluability assessment. The CRs stage-by-stage coverage is presented in this sequence: 'strategic management', 'process control, design and planning', 'analytical processes' and 'process evaluation and improvement' (Table 4). The evaluability assessment indicated that the extent of coverage ranged from 353/1 515 (23 %) CRs to 1 479/1 515 (98 %) CRs. The interpretation of results was based on a three-colour colour-coded classification (Figure 3). Those accreditation bodies with the highest classification, indicated by green, achieved coverage of 85 % to 100 %. The Singapore Accreditation Council (SAC) (93 %) and the Hong Kong Accreditation Service (HKAS) (98 %) have 'green status'. Those accreditation bodies classified as yellow-green achieved coverage of 51 % to 84 %. The DANAK (55 %) has 'yellow-green status'. Those accreditation bodies classified as orange achieved coverage of 0 % to 50 %. The Finnish Accreditation Service (FINAS) (23 %), the South African National Accreditation Service (SANAS) (24 %) and the NATA (45 %) have 'orange status'.

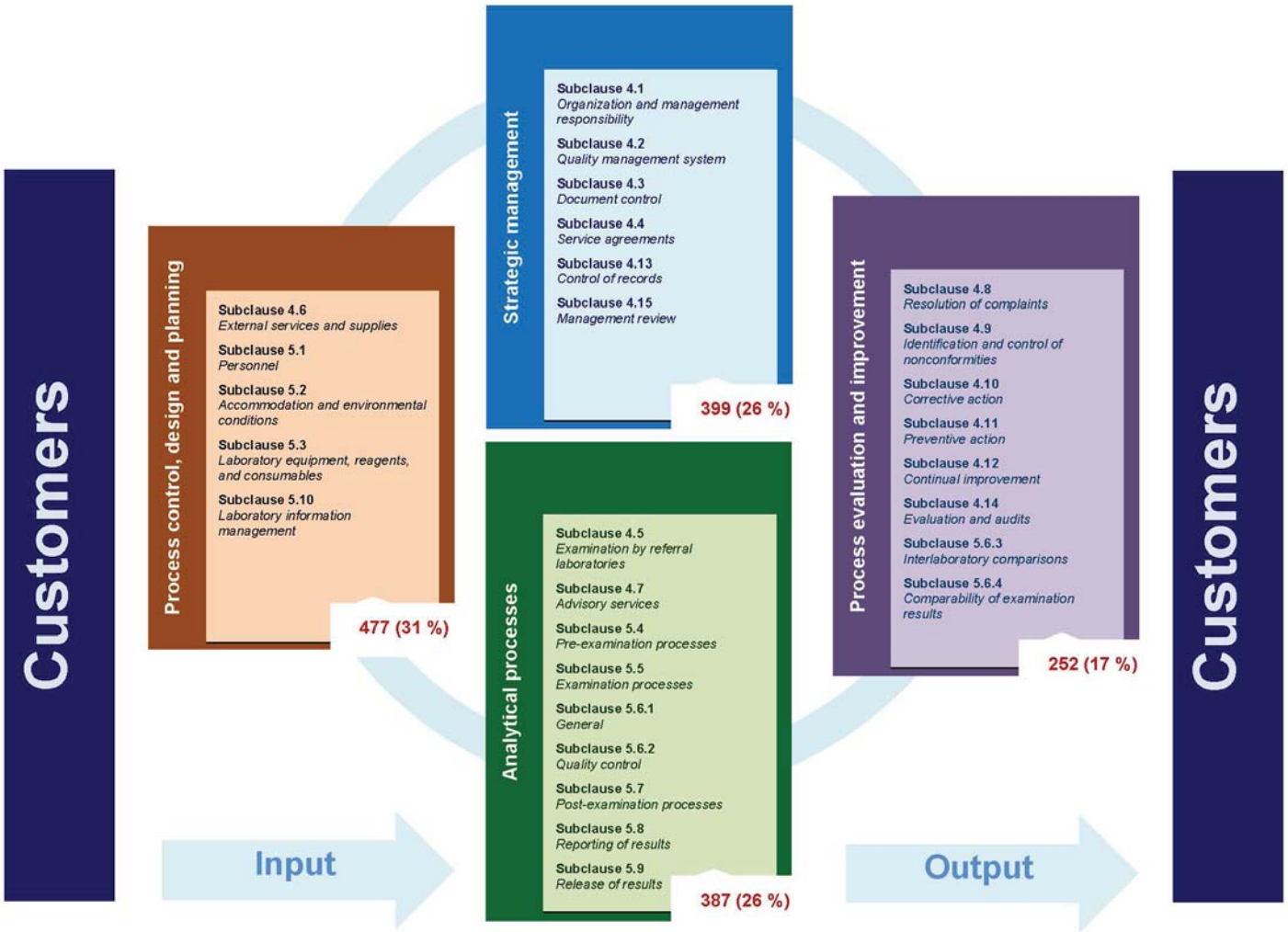


Figure 2. Distribution of conformance requirements among the four major stages of ISO 15189:2012 processes. The 'strategic management' stage contains 399/1 515 (26 %) conformance requirements. The 'process control, design and planning' stage contains 477/1 515 (31 %) conformance requirements. The 'analytical processes' stage contains 387/1 515 (26 %) conformance requirements. The 'process evaluation and improvement' stage contains 252/1 515 (17 %) conformance requirements.

Table 3. The availability and eligibility of ISO 15189:2012 guidance checklists for evaluability assessments by selected countries and dependent territory.

Countries/ Dependent territory (n = 12)	**Accreditation bodies** (n = 20)	**Availability/ Eligibility**
Australia (AUS)	Joint Accreditation System of Australia and New Zealand	Unavailable/Ineligible
	National Association of Testing Authorities, Australia*	**Available/Eligible**
Belgium (BEL)	Belgian Accreditation Structure*	Available/Ineligible
Denmark (DNK)	Danish Accreditation Fund*	**Available/Eligible**
Finland (FIN)	Finnish Accreditation Service*	**Available/Eligible**
Hong Kong† (HKG)	Hong Kong Accreditation Service*	**Available/Eligible**
India (IND)	National Accreditation Board for Testing and Certification Laboratories*	Available/Ineligible
Malaysia (MYS)	Department of Standards Malaysia*	Available/Ineligible
Singapore (SGP)	Singapore Accreditation Council*	**Available/Eligible**
South Africa (ZAF)	South African National Accreditation System*	**Available/Eligible**
Turkey (TUR)	Turkish Accreditation Agency*	Available/Ineligible
United Arab Emirates (the) (ARE)	Dubai Accreditation Centre*	Available/Ineligible
United States (the) (USA)	American Association for Laboratory Accreditation*	Available/Ineligible
	AIHA® Laboratory Accreditation Programs	Unavailable/Ineligible
	American National Standards Institute	Unavailable/Ineligible
	American Society of Crime Laboratory Directors	Unavailable/Ineligible
	International Accreditation Service	Unavailable/Ineligible
	Laboratory Accreditation Bureau	Unavailable/Ineligible
	National Voluntary Laboratory Accreditation Program	Unavailable/Ineligible
	Perry Johnson Laboratory Accreditation	Unavailable/Ineligible

* Signatory members of the International Laboratory Accreditation Cooperation mutual recognition arrangement.

† Hong Kong (HKG) is a special administrative region of China, therefore it is a dependent territory. The official name is Hong Kong Special Administrative Region of the People's Republic of China and is referred to as 'Hong Kong, China' by the International Accreditation Forum; and 'China, Hong Kong' by the International Laboratory Accreditation Cooperation.

Table 4. Coverage of ISO 15189:2012 conformance requirements by the evaluand checklists from selected accreditation bodies: the National Association of Testing Authorities, Australia (NATA); the Danish Accreditation Fund (DANAK); the Finnish Accreditation Service (FINAS); the Hong Kong Accreditation Service (HKAS); the Singapore Accreditation Council (SAC); and the South African National Accreditation Service (SANAS).

		NATA	DNK	FINAS	HKAS	SAC	SANAS
Strategic management	**Subclause 4.1** *Organization and management responsibility*	47/159 (30 %)	47/159 (30 %)	12/159 (8 %)	153/159 (96 %)	156/159 (98 %)	46/159 (29 %)
	Subclause 4.2 *Quality management system*	30/66 (45 %)	40/66 (61 %)	8/66 (12 %)	64/66 (97 %)	60/66 (91 %)	12/66 (18 %)
	Subclause 4.3 *Document control*	30/31 (97 %)	29/31 (94 %)	5/31 (16 %)	29/31 (94 %)	31/31 (100 %)	12/31 (39 %)
	Subclause 4.4 *Service agreements*	9/35 (26 %)	7/35 (20 %)	2/35 (6 %)	34/35 (97 %)	17/35 (49 %)	4/35 (11 %)
	Subclause 4.13 *Control of records*	35/59 (59 %)	46/59 (78 %)	12/59 (20 %)	59/59 (100 %)	59/59 (100 %)	9/59 (15 %)
	Subclause 4.15 *Management review*	41/49 (84 %)	38/49 (78 %)	7/49 (14 %)	49/49 (100 %)	49/49 (100 %)	4/49 (8 %)
	Subtotal	**192/399 (48 %)**	**207/399 (52 %)**	**46/399 (12 %)**	**388/399 (97 %)**	**372/399 (93 %)**	**89/399 (22 %)**
Process control, design and planning	**Subclause 4.6** *External services and supplies*	11/26 (42 %)	8/26 (31 %)	10/26 (38 %)	18/26 (69 %)	14/26 (54 %)	9/26 (35 %)
	Subclause 5.1 *Personnel*	44/67 (66 %)	53/67 (79 %)	24/67 (36 %)	66/67 (99 %)	66/67 (99 %)	23/67 (34 %)
	Subclause 5.2 *Accommodation and environmental conditions*	34/88 (39 %)	49/88 (56 %)	9/88 (10 %)	88/88 (100 %)	80/88 (91 %)	11/88 (13 %)
	Subclause 5.3 *Laboratory equipment, reagents, and consumables*	57/154 (37 %)	80/154 (52 %)	4/154 (3 %)	143/154 (93 %)	148/154 (96 %)	31/154 (20 %)
	Subclause 5.10 *Laboratory information management*	91/142 (64 %)	96/142 (68 %)	116/142 (82 %)	140/142 (99 %)	142/142 (100 %)	8/142 (6 %)
	Subtotal	**237/477 (50 %)**	**286/477 (60 %)**	**163/477 (34 %)**	**455/477 (95 %)**	**450/477 (94 %)**	**82/477 (17 %)**
Analytical processes	**Subclause 4.5** *Examination by referral laboratories*	20/32 (63 %)	25/32 (78 %)	6/32 (19 %)	32/32 (100 %)	24/32 (75 %)	6/32 (19 %)
	Subclause 4.7 *Advisory services*	4/11 (36 %)	7/11 (64 %)	11/11 (100 %)	11/11 (100 %)	11/11 (100 %)	3/11 (27 %)
	Subclause 5.4 *Pre-examination processes*	48/144 (33 %)	90/144 (63 %)	25/144 (17 %)	143/144 (99 %)	131/144 (91 %)	68/144 (47 %)
	Subclause 5.5 *Examination processes*	7/71 (10 %)	48/71 (68 %)	7/71 (10 %)	71/71 (100 %)	71/71 (100 %)	5/71 (7 %)
	Subclause 5.6.1 *General*	0/4 (0 %)	1/4 (25 %)	0/4 (0 %)	4/4 (100 %)	4/4 (100 %)	0/4 (0 %)
	Subclause 5.6.2 *Quality control*	0/12 (0 %)	6/12 (50 %)	1/12 (8 %)	12/12 (100 %)	12/12 (100 %)	1/12 (8 %)
	Subclause 5.7 *Post-examination processes*	1/21 (5 %)	9/21 (43 %)	2/21 (10 %)	21/21 (100 %)	19/21 (90 %)	18/21 (86 %)
	Subclause 5.8 *Reporting of results*	26/47 (55 %)	33/47 (70 %)	26/47 (55 %)	47/47 (100 %)	47/47 (100 %)	32/47 (68 %)
	Subclause 5.9 *Release of results*	25/45 (56 %)	17/45 (38 %)	0/45 (0 %)	43/45 (96 %)	45/45 (100 %)	16/45 (36 %)
	Subtotal	**131/387 (34 %)**	**236/387 (70 %)**	**78/387 (20 %)**	**384/387 (99 %)**	**364/387 (94 %)**	**149/387 (39 %)**
Process evaluation and improvement	**Subclause 4.8** *Resolution of complaints*	4/4 (100 %)	4/4 (100 %)	1/4 (25 %)	4/4 (100 %)	4/4 (100 %)	1/4 (25 %)
	Subclause 4.9 *Identification and control of nonconformities*	22/23 (96 %)	5/23 (22 %)	8/23 (35 %)	23/23 (100 %)	20/23 (87 %)	11/23 (48 %)
	Subclause 4.10 *Corrective action*	10/10 (100 %)	9/10 (90 %)	8/10 (80 %)	10/10 (100 %)	8/10 (80 %)	2/10 (20 %)
	Subclause 4.11 *Preventive action*	8/10 (80 %)	9/10 (90 %)	3/10 (30 %)	10/10 (100 %)	9/10 (90 %)	0/10 (0 %)
	Subclause 4.12 *Continual improvement*	4/34 (12 %)	7/34 (21 %)	12/34 (35 %)	34/34 (100 %)	16/34 (47 %)	24/34 (71 %)
	Subclause 4.14 *Evaluation and audits*	72/133 (54 %)	58/133 (44 %)	24/133 (18 %)	133/133 (100 %)	128/133 (96 %)	10/133 (8 %)
	Subclause 5.6.3 *Interlaboratory comparisons*	3/26 (12 %)	13/26 (50 %)	10/26 (38 %)	26/26 (100 %)	26/26 (100 %)	0/26 (0 %)
	Subclause 5.6.4 *Comparability of examination results*	0/12 (0 %)	5/12 (42 %)	0/12 (0 %)	12/12 (100 %)	12/12 (100 %)	0/12 (0 %)
	Subtotal	**123/252 (49 %)**	**110/252 (44 %)**	**66/252 (26 %)**	**252/252 (100 %)**	**223/252 (88 %)**	**48/252 (19 %)**
	Total (of 1 515)	**683 (45 %)**	**839 (55 %)**	**353 (23 %)**	**1 479 (98 %)**	**1,409 (93 %)**	**368 (24 %)**

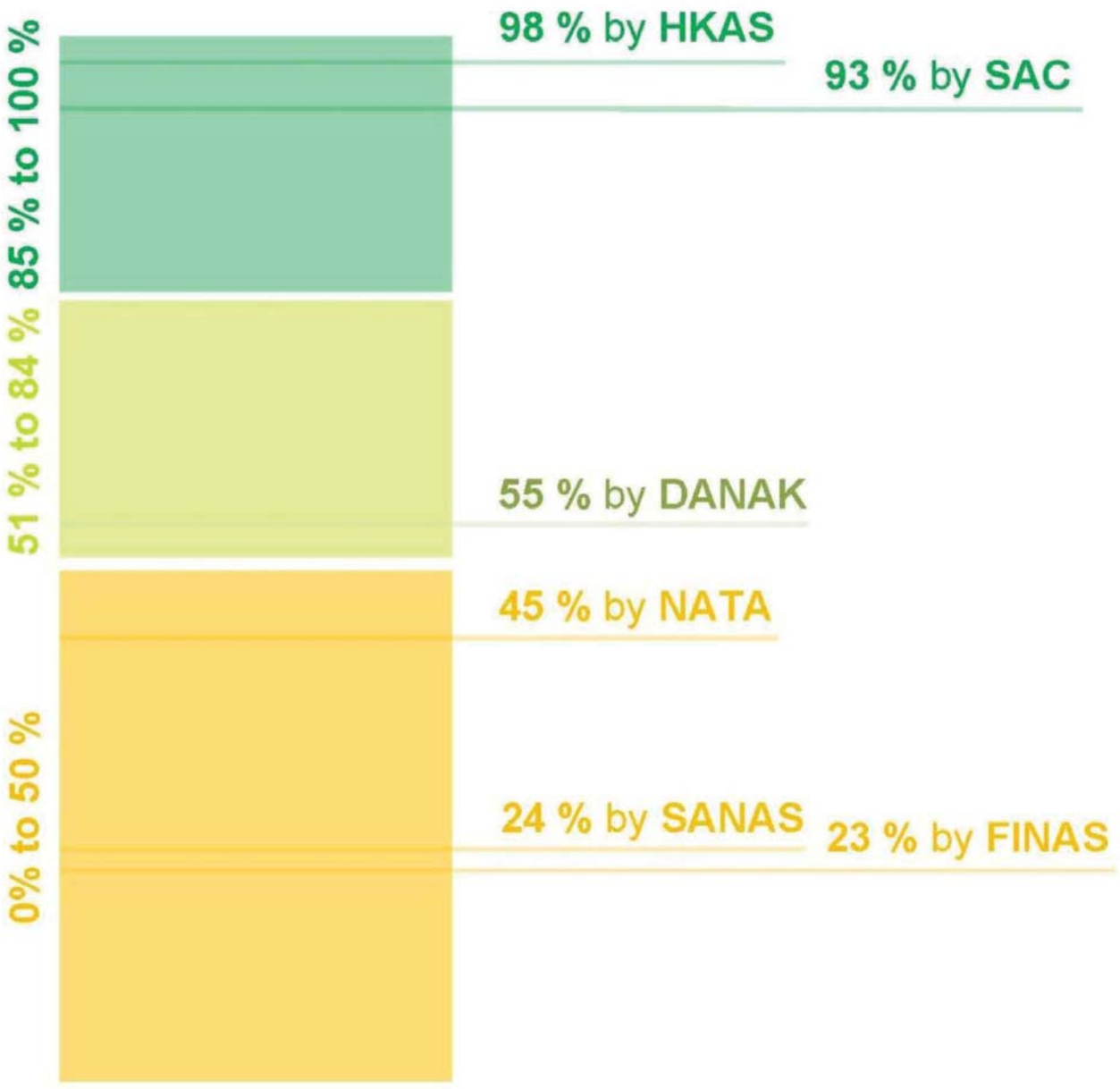
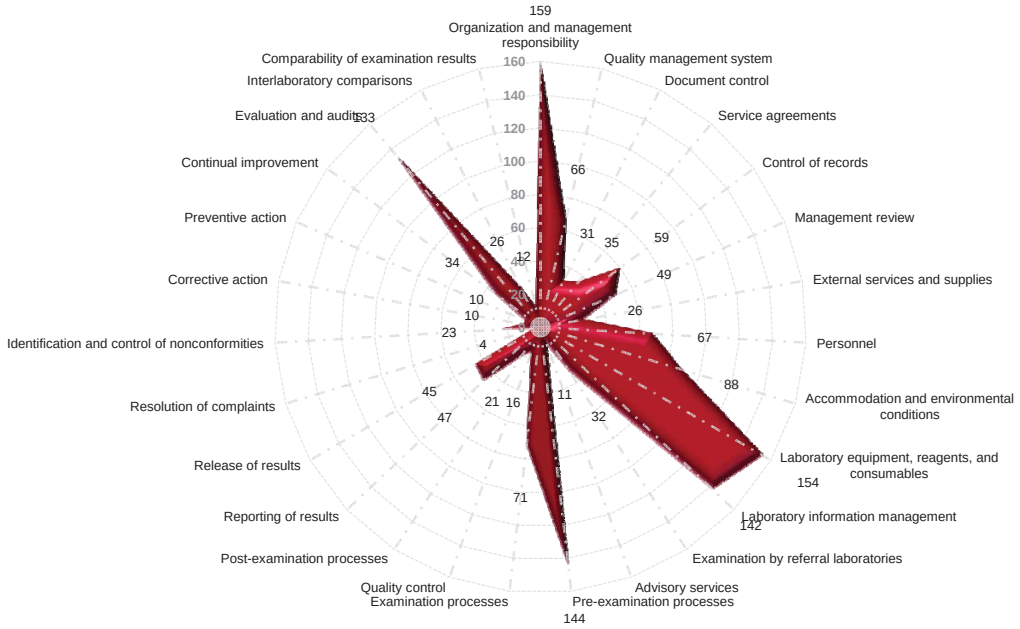


Figure 3. Interpretation of results by quantitation of conformance requirements in Clauses 4 (management requirements) and 5 (technical requirements) of ISO 15189:2012 using three-colour colour-coded classification. Green indicates the evaluand checklist achieved a total coverage of 85 % to 100 %: the medical laboratory is highly likely to make excellent progress and to achieve planned deliverables by fulfilling the checklist requirements. The Singapore Accreditation Council (SAC) (93 %) and the Hong Kong Accreditation Service (HKAS) (98 %) have 'green status'. Yellow-green indicates the evaluand checklist achieved a total coverage of 51 % to 84 %; the medical laboratory is highly likely to make very good progress and certain to achieve planned deliverables by fulfilling the checklist requirements. The Danish Accreditation Fund (DANAK) (55 %) has 'yellow-green status'. Orange indicates the evaluand checklist achieved a total coverage of 0 % to 50 %; the medical laboratory is likely to achieve good progress and almost certain to achieve planned deliverables. The Finnish Accreditation Service (FINAS) (23 %), the South African National Accreditation System (SANAS) (24 %) and the National Association of Testing Authorities, Australia (NATA) (45 %) have 'orange status'.

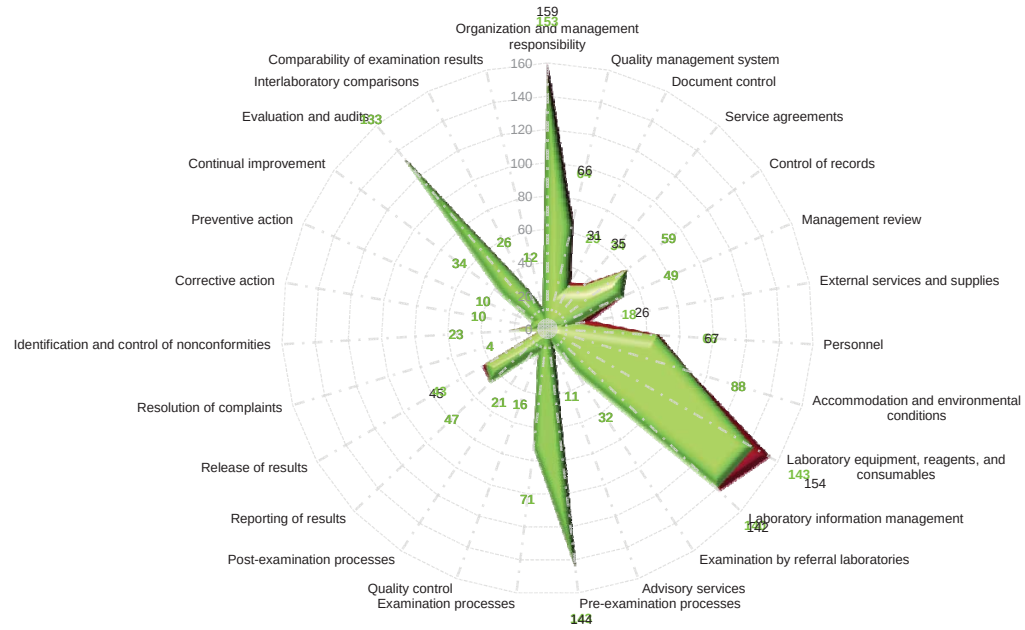
Point distribution analysis of conformance requirements in Clauses 4 (management requirements) and 5 (technical requirements) of ISO 15189:2012

A radar chart was used to plot the results for point distribution analysis (PDA) of CRs in Clauses 4 and 5 of ISO 15189:2012 (14,pp.6-39) (Figure 4). The CRs coverage of each subclause of the six evaluand checklists were also plotted onto radar charts for PDA. The distribution area is superimposed on the radar chart representing coverage of the 1 515/1 515 (100 %) CRs for visualisation purposes. The radar charts illustrate the overall results of the CA of the selected evaluand checklists and incorporate all stages of the management system framework (Figures 5 to 10).



■ International Organization for Standardization

Figure 4. Relative point distribution analysis of conformance requirements of Clauses 4 (management requirements) and 5 (technical requirements) of ISO 15189:2012 of the International Organization for Standardization. The distribution of 1 515 conformance requirements is represented by a radar chart. The subclauses are presented on a sequence of radii representing the number of conformance requirements. The sequence of representation follows the four stages of ISO 15189:2012 processes, starting at twelve o'clock and progressing anticlockwise, from 'strategic management' to 'process control, design and planning', 'analytical processes' and 'process evaluation and improvement'.



■ Hong Kong Accreditation Service

■ International Organization for Standardization

Figure 5. Relative point distribution analysis of conformance requirements of guidance checklist provided by the Hong Kong Accreditation Service. The distribution of conformance requirements by the Hong Kong Accreditation Service is represented in green and the International Organization for Standardization in red. Overall, the guidance checklist of Hong Kong Accreditation Service provided coverage of 98 % when compared with the International Organization for Standardization. The level of coverage by stage ranged from 69 % in Subclause 4.6 (external services and supplies) at 'process control, design and planning' stage to 100 % in Subclauses 4.13 (control of records) and 4.15 (management review) at 'strategic management' stage, Subclause 5.2 (accommodation and environmental conditions) at 'process control, design and planning' stage, Subclauses 4.5 (examination by referral laboratories), 4.7 (advisory services), 5.5 (examination processes), 5.6.1 (general), 5.6.2 (quality control), 5.7 (post-examination processes), 5.8 (reporting of results) at 'analytical processes' stage, and Subclauses 4.8 (resolution of complaints), 4.9 (identification and control of nonconformities), 4.10 (corrective action), 4.11 (preventive action), 4.12 (continual improvement), 4.14 (evaluation and audits), 5.6.3 (interlaboratory comparisons) and 5.6.4 (comparability of examination results) at 'process evaluation and improvement' stage.

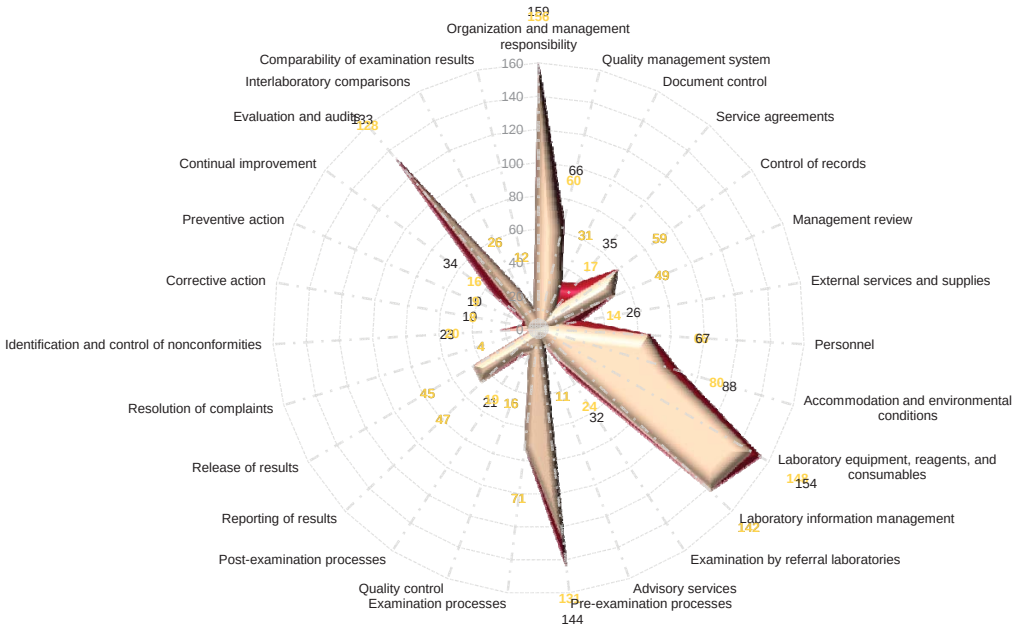


Figure 6. Relative point distribution analysis of conformance requirements of guidance checklist provided by the Singapore Accreditation Council. The distribution of conformance requirements by the Singapore Accreditation Council is represented in peach and the International Organization for Standardization in red. Overall, the guidance checklist of Singapore Accreditation Council provided coverage of 93 % when compared with the International Organization for Standardization. The level of coverage by stage ranged from 47 % in Subclause 4.12 (continual improvement) to 100 % in Subclauses 4.3 (document control), 4.13 (control of records) and 4.15 (management review) at 'strategic management' stage, Subclause 5.10 (laboratory information management) in 'process control, design and planning' stage, Subclauses 4.7 (advisory services), 5.5 (examination processes), 5.61 (general), 5.6.2 (quality control), 5.8 (reporting of results) and 5.9 (release of results) at 'analytical processes' stage, and Subclauses 4.8 (resolution of complaints), 5.6.3 (interlaboratory comparisons) and 5.6.4 (comparability of examination results) at 'process evaluation and improvement' stage.

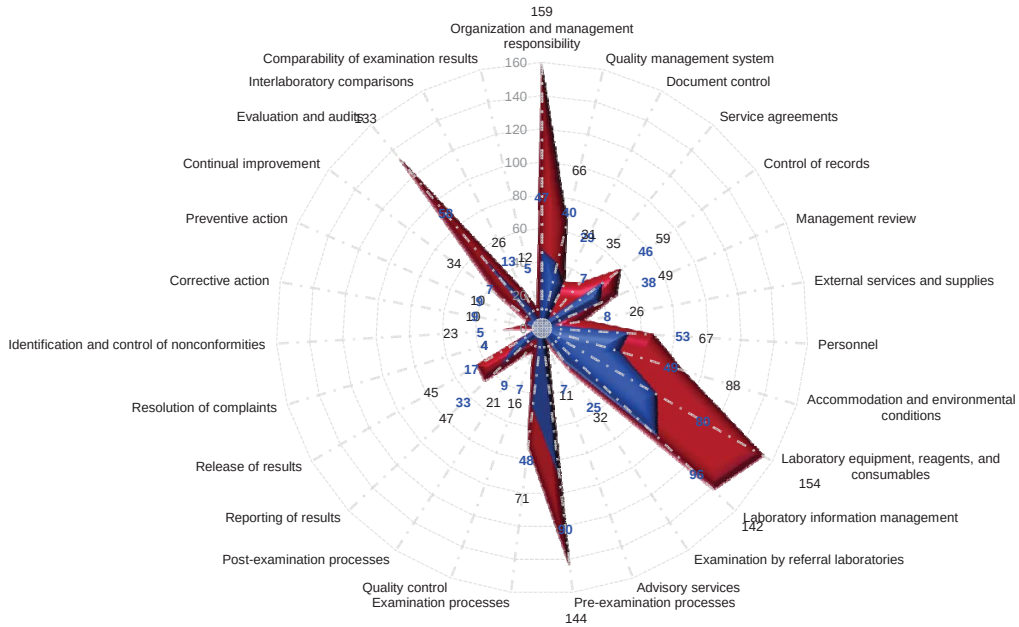
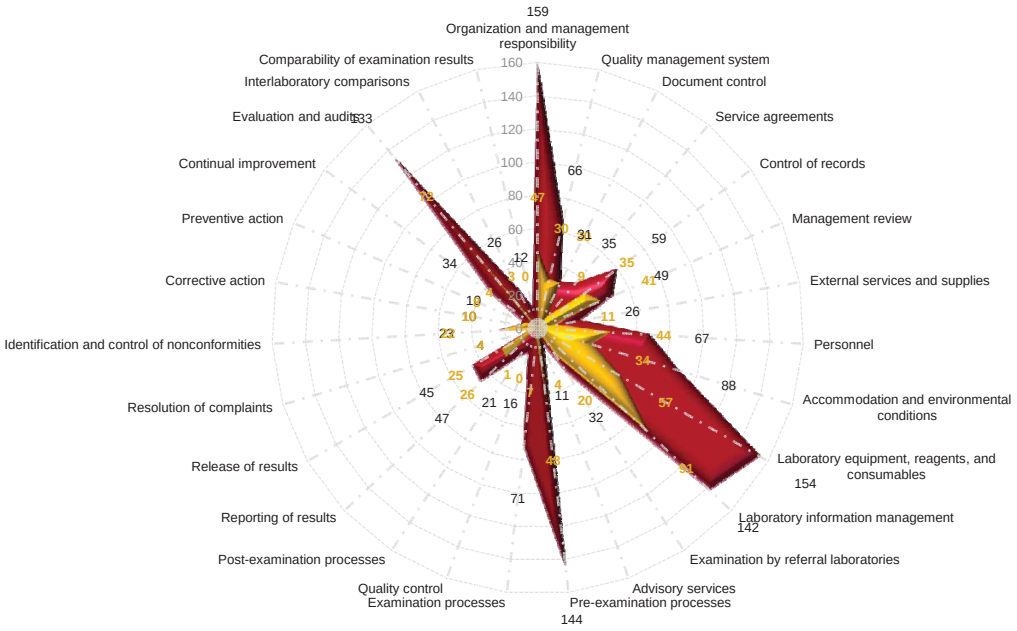


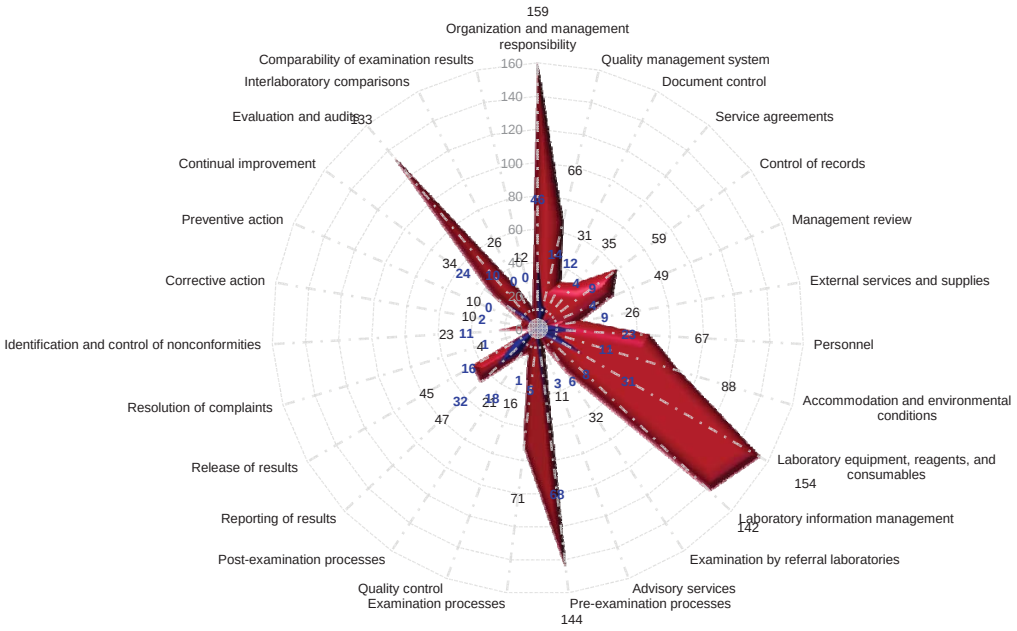
Figure 7. Relative point distribution analysis of conformance requirements of guidance checklist provided by the Danish Accreditation Fund. The distribution of conformance requirements by the Danish Accreditation Fund is represented in blue and the International Organization for Standardization in red. Overall, the guidance checklist of Danish Accreditation Fund provided coverage of 55 % when compared with the International Organization for Standardization. The level of coverage by stage ranged from 21 % in Subclause 4.12 (continual improvement) at 'process evaluation and improvement' stage to 100 % in Subclause 4.8 (resolution of complaints) at 'process evaluation and improvement' stage.



■ National Association of Testing Authorities, Australia

■ International Organization for Standardization

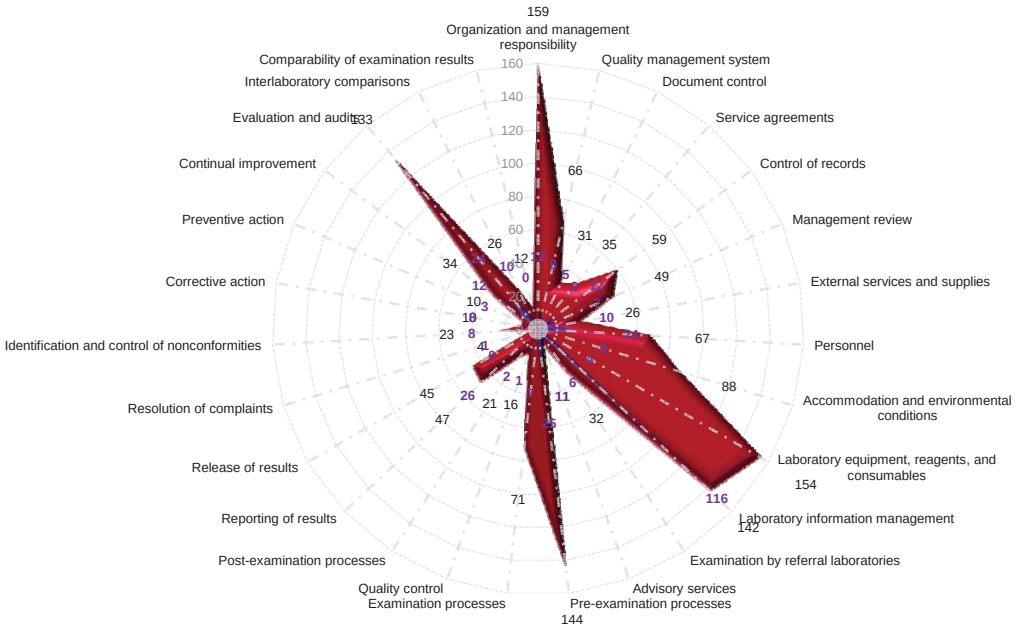
Figure 8. Relative point distribution analysis of conformance requirements of guidance checklist provided by the National Association of Testing Authorities, Australia. The distribution of conformance requirements by the National Association of Testing Authorities, Australia is represented in orange and the International Organization for Standardization in red. Overall, the guidance checklist of National Association of Testing Authorities, Australia provided coverage of 45 % when compared with the International Organization for Standardization. The level of coverage by stage ranged from 0 % in Subclauses 5.6.1 (general) and 5.6.2 (quality control) at 'analytical processes' stage and Subclauses 5.6.4 (comparability of examination results) at 'process evaluation and improvement' stage to 100 % in Subclause 4.8 (resolution of complaints) at 'process evaluation and improvement' stage.



■ South African National Accreditation System

■ International Organization for Standardization

Figure 9. Relative point distribution analysis of conformance requirements of guidance checklist provided by the South African National Accreditation System. The distribution of conformance requirements by the South African National Accreditation System is represented in dark blue and the International Organization for Standardization in red. Overall, the guidance checklist of South African National Accreditation System provided coverage of 24 % when compared with the International Organization for Standardization. The level of coverage by stage level ranged from 0 % in Subclause 5.6.1 (general) at 'analytical processes' stage and Subclauses 4.11 (preventive action), 5.6.3 (interlaboratory comparisons) and 5.6.4 (comparability of examination results) at 'process evaluation and improvement' stage to 86 % in Subclause 5.7 (advisory services) at 'analytical processes' stage.



■ Finnish Accreditation Service

■ International Organization for Standardization

Figure 10. Relative point distribution analysis of conformance requirements of guidance checklist provided by the Finnish Accreditation Service. The distribution of conformance requirements by the Finnish Accreditation Service is represented in purple and the International Organization for Standardization in red. Overall, the guidance checklist of Finnish Accreditation Service provided coverage of 23 % when compared with the International Organization for Standardization. The level of coverage by stage ranged from 0 % in Subclauses 5.6.1 (general) and 5.9 (release of results) at 'analytical processes' stage and Subclause 5.6.4 (comparability of examination results) at 'process evaluation and improvement' stage to 100 % in Subclause 4.7 (advisory services) at 'analytical processes' stage.

DISCUSSION

This CA study set out with the aim of quantitatively analysing the extent of CR coverage by ISO 15189:2012 guidance checklists provided by accreditation bodies. The recent emergence of a quantitative estimation of 1 515 CRs enables the formulation of an auditing tool to perform gap analysis on any ISO 15189:2012 guidance documents (15). This tool can assist organisations considering implementation of ISO 15189:2012 in the near future. The current study identified that 6/51 (12 %) accreditation bodies had readily available ISO 15189:2012 guidance checklists for medical laboratories to use for gap analysis (Table 3). The results provide four distinct areas for comparison purposes (Table 4). Each area is associated with a specific process of the ISO 15189:2012 process-based quality management system framework (Figure 1). Together with the information provided by PDA (Figures 5 to 10), the strengths and weaknesses of the evaluand checklists from the 6/51 (12 %) accreditation bodies are discussed below.

The use of the 1,515 CRs framework-derived evaluation checklists began with the in-depth quantitative analysis of CRs. The method to elicit CRs within Clauses 4 and 5 of ISO 15189:2012 (14,pp.6-39) involved the localisation of the word 'shall' in the text. Although the identification process located all related CRs (35,36), it is still possible to elicit CRs using other methods; but the relative percentages should remain very similar (Figure 2). It is important to note that quantitative analysis was conducted on Clauses 4 and 5 of ISO 15189:2012 (14,pp.6-39) only and the results of '1,515 CRs' represent the absolute minimum to consider. The potential variables address differences between countries and organisations and allow for customisation. This is set out in Clause 1 (scope) of ISO 15189:2012 (14,p.1), therefore the enumeration of '1,515 CRs' is the least quantity to consider if the medical laboratory wishes to conduct internal audit to all activities relating to the medical laboratory quality management system.

The evaluability assessment was conducted following the quantitation of CRs. It was decided that the document for evaluability assessment should be in checklist-based format and organised according to the identification and localisation of CRs in the four-stage process-based quality management system framework. It is understood that the format of the checklist varies depending on the intent of coverage comprehensiveness and it is possible to develop evaluation checklists using representative subclauses as audit criteria (37,38). This approach has been used by various organisations offering implementation support, such as the World Health Organization (39), where it has been demonstrated that it is impractical to provide complete coverage comprehensiveness in CRs to follow and difficult for implementers who need to establish the medical laboratory quality management system for planning purposes (40). With this in mind, the developed evaluation tool was able to offer assessment using a consistent, measurable and methodical approach as suggested (41). The evaluation findings were recorded as objective evidence to support conformity in the assessment results area against specific criteria, which are the subclauses of ISO 15189:2012. Overall, the use of checklists to conduct audit of fulfilment of CRs has met with marked effectiveness and efficiency.

Signatories to the ILACMRA must meet specific requirements imposed by the International Laboratory Accreditation Cooperation (42). One requirement is that all accreditation bodies are to operate in accordance with the requirements of ISO/IEC 17011:2004 (19). One such operating restriction is that accreditation bodies must ensure appropriate areas of expertise are available to the applicant while not providing direct consultancy. However, accreditation bodies can still provide general guidance in various formats to support medical laboratories for preparation for accreditation. Although the implementation process requires complex and detailed activities, the provision of support enables objectives and tasks

to be clearer and unequivocal. It was identified that 14/51 (27 %) accreditation bodies that are signatories to the ILACMRA have made available to provide general guidance documents to support medical laboratories for preparation for accreditation (Table 3). These documents represent extra effort on the part of accreditation bodies as they are not required by ISO/IEC 17011:2004 (19).

The presentation formats were largely divided into three types. The first type is provided by the International Accreditation New Zealand which operates within a specific accreditation process (43) while publishing explanatory commentaries for implementation purposes (21). The second type is provided by 7/51 (14 %) accreditation bodies that have listed duplicates of relevant subclauses of ISO 15189:2012 for medical laboratories to interpret; therefore, these checklists assemble in an exactly matching manner. The third type is provided by 6/51 (12 %) accreditation bodies that have checklists comprising modified ISO 15189:2012 content. The third type of accreditation bodies were eligible according to the selection criteria for evaluation (Table 1).

In relation to the overall distribution of CRs of Clauses 4 and 5 of ISO 15189:2012 (14,pp.6-39) in the four-stage process-based quality management system framework (Figure 2), the results are interpreted using a three-colour colour-coded classification (Figure 3). The evaluand checklists of the HKAS and the SAC achieved coverage of ≥ 85 % and 'green status'. The checklists comprised relevant contents of the subclauses rewritten as questions. This method may be useful for medical laboratories that have limited implementation experience because it enables the inclusion of almost all areas. The medical laboratories are highly likely to achieve all planned deliverables by using these checklists to track the CRs fulfilment progress in a highly structured manner. The evaluand checklists of the DANAK achieved coverage at 55 % and 'yellow-green status'. Although not as comprehensive as the HKAS and the SAC evaluand checklists, the DANAK's evaluand checklist can still give a good indication of whether CRs fulfilment is on the right track. Together with the medical laboratories own internal auditing process prior to the accreditation, it should enable the medical laboratories to make good implementation progress. The evaluand checklists of the NATA, the SANAS and the FINAS were classified as 'orange status'. Although their coverage of CRs ranged from 23 % to 45 %, it is important to understand that the checklists contain the majority of the main CRs for implementation. Although, the coverage figures appear less desirable for medical laboratories to use, medical laboratories are supposed to conduct their own initial internal audits with the support of guidance checklists. Using the results of both checking mechanisms, the medical laboratory is highly likely to achieve planned deliverables. When used together with the appropriate expertise from accreditation bodies and initial internal auditing information, medical laboratories are highly likely to undergo the accreditation in a more structured manner.

The distribution of 1,515 CRs in Clauses 4 and 5 of ISO 15189:2012 (14,pp.6-39) can be visualised by the use of radar charting (Figure 4). The main advantage of using a radar chart is to conduct relative PDA. The CRs distribution of the six selected accreditation bodies were charted and compared with the 1,515 CRs distribution as the standard. The evaluand checklist of the HKAS (44) (Figure 5) provided ≥ 93 % coverage of each subclause with the exception of Subclause 4.6 (external services and supplies) of ISO 15189:2012 (14,pp.12-13). The evaluand checklist of the SAC (45) (Figure 6) also provided ≥ 75 % coverage of each subclause with the exception of Subclause 4.4 (service agreements) (14,pp.11-12) at 49 %, Subclause 4.6 (14,pp.12-13) at 54 % and Subclause 4.12 (continual improvement) of ISO 15189:2012 (14,pp.14-15) at 47 %. The impressive coverage rate of both accreditation bodies allows medical laboratories to take a very structured approach to implementation. It is highly likely that the use of guidance checklists can support the implementation process effectively.

The guidance checklist of the DANAK (32) (Figure 7) achieved coverage of 55 % and 'yellow-green status'. However, it is important to note that the DANAK has declared that its guidance checklist 'is much shortened compared to the text of DS/EN ISO 15189:2013 and it is therefore important that the checklist is used together with ISO 15189' (32) and is a condensed summary of SFS-EN ISO 15189 entitled 'Medical laboratories. Requirements for quality and competence (ISO 15189:2012, corrected version 2014-08-15)' (46). Medical laboratories need to ensure their initial internal auditing is able to cover the CRs of Subclause 4.4 (14,pp.11-12), Subclause 4.9 (identification and control of nonconformities) (14,pp.13-14) and Subclause 4.12 of ISO 15189:2012 (14,pp.14-15) because the level of coverage by stage was ≤ 22 %. Overall, medical laboratories that use the checklist are still highly likely to make very good progress and certain to achieve planned deliverables.

The guidance checklists of the NATA (20) (Figure 8), the SANAS (47) (Figure 9) and the FINAS (48) (Figure 10) achieved ≥ 23 % of coverage and 'orange status'. This relatively low coverage rate is not an indication of the level of effectiveness. The NATA has declared that it is 'a brief summary of the clauses of the Standard' (49), while the SANAS indicates that it represents the general requirements only (47) and the FINAS has indicated that the checklist questions are representative of the relevant subclauses (48). Particular attention needs to be paid to the areas where ≤ 9 % of coverage was recorded. These include Subclause 5.6.1 (general) (14,p.33), Subclause 5.6.2 (quality control) (14,p.33), Subclause 5.6.3 (interlaboratory comparisons) (14,pp.34-35), Subclause 5.6.4 (comparability of examination results) (14,p.35) and Subclause 5.9 (release of results) of ISO 15189:2012 (14,pp.37-38). Medical laboratories need to ensure the initial internal audit process has the ability to cover these subclauses during the gap analysis.

Within the four major stages, there were specific areas of concern in the evaluand checklists involving subclauses (n = 3) that were unspecified (Table 5). It has been identified that these subclauses are associated with compliance requirements, including legislation and other non-legally binding documents (Table 5). Three potential implications are discussed below.

The first potential implication for compliance concerns Subclause 5.6.1 of ISO 15189:2012 (14,p.33), where the medical laboratory must not fabricate any results (Table 5). The intent relates to the potential for the emerging risk of theft, fraud and financial crime within the healthcare system (50). These risks can pose a serious threat to any organisation, especially in terms of reputational impact, organisational disruption and diminished patient safety (51). An effective method for medical laboratories to ensure comprehensiveness is to supplement any fraud and corruption detection elements with additional resources for internal auditors to implement mechanisms to identify corrupt or fraudulent activity (52,53). However, the additional resources need to implement an effective whistleblower protection policy to support internal auditors if findings require the involvement of law enforcement agencies (54,55). Further guidance can be sought from various external documents (56-62) (Table 5). The medical laboratory must generate reliable medical information, establish transparency in both financial and technical reporting and enforce accountability at all levels.

The second potential implication for compliance concerns Subclause 5.9.1 (general) of ISO 15189:2012 (14,p.37) where the medical laboratory must establish documented procedures for the release of examination results (Table 5). The medical laboratory must have manageable control of the release of information. The control process must be reasonably practicable to meet a privacy protection duty and the medical laboratory must be able to accept requests for the release of results, including from the laboratory information management system. One practical option is to achieve certification to demonstrate that the information security management system conforms to ISO/IEC 27001:2013 entitled 'Information technology — Security techniques — Information security management systems — Requirements' (63) and ISO/IEC 27001:2013/Cor.1:2014 entitled 'Information technology — Security techniques — Information security management systems — Requirements — Technical corrigendum 1' (64). Further guidance can be sought from various external documents (65-67) (Table 5). The medical laboratory must have effective documented procedures to grant access to relevant customers, meeting both contractual and legal requirements while operating within strict information security management system controls that address potential information security risks.

The third potential implication for compliance concerns Subclause 4.11 (preventive action) of ISO 15189:2012 (14,p.14), where the medical laboratory must determine actions to eliminate the causes of potential nonconformities in order to prevent their occurrence (Table 5). Subclause 4.11 of ISO 15189:2012 (14,p.14) contains 10/1 515 (1 %) CRs, and the one relating to the determination of preventive action poses a significant negligence risk. The medical laboratories must identify all potential causes and problems proactively (68,69). Compliance issues can be implicated if the medical laboratories violated the applicable standard of care or practice. An area that is an emerging concern is the prevention of human error. Lack of concentration and inadequate expertise are likely to cause diagnostic errors during processing (70,71). These two issues can be readily addressed. First, lack of concentration in the workplace is most likely due to human fatigue (72) resulting from sleep mismanagement (73). The control and monitoring of staff working hours is also an option to forecast and manage burnout of staff and, as an occupational risk control, highly likely to predict and prevent many unwanted issues (74). Second, an inadequate level of expertise at the allocated position should be addressed through the provision of ready access to training opportunities at the appropriate level to confirm competencies. Further guidance can be sought from various external documents (56,75-84) (Table 5).

CONCLUSIONS

The aim of the current study was to determine the extent of ISO 15189:2012 CR coverage provided by the accreditation bodies' guidance checklists. Accreditation bodies from five countries and a dependent territory were identified as having suitable checklists for the evaluability assessment. The findings of this research provide insights into the CR detection limitations of the recommended guidance checklists issued by accreditation bodies. This research has two major practical implications. Medical laboratories need to be aware that guidance from relevant accreditation bodies may need to be supplemented by consideration of further compliance issues with international, national, regional or local regulations or requirements. A second important practical implication is the possibility that accredited medical laboratories need to develop comprehensive checklists as an internal auditing tool to confirm that all CRs are fulfilled competently. Overall, ensuring the ISO 15189:2012 conformity status is adequate at all times should be a priority for the accredited medical laboratory. It will be interesting to see whether the same accreditation bodies will provide direct guidance for the implementation of the next edition of ISO 15189, so that the same evaluability assessment can be conducted.

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