ORIGINAL ARTICLE

Internal Auditing Risk Analysis for Medical Laboratories Seeking Accreditation through the Hong Kong Laboratory Accreditation Scheme (HOKLAS)

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ABSTRACT

Objectives. The primary aim of this study was to determine quantitatively the extent of coverage of the Hong Kong Laboratory Accreditation Scheme (HOKLAS 015) requirements by guidance checklists (HOKLAS 016-02 and HOKLAS 021).

Methods. The level of conformance requirement coverage of HOKLAS 015 by HOKLAS 016-02 and HOKLAS 021 was calculated by an evaluation checklist based on conformance requirements in HOKLAS 015. A distribution analysis of conformance requirements relating to the International Standard ISO 15189:2012 process-based quality management system model was also performed to elicit further coverage information.

Results. HOKLAS 016-02 was found to provide coverage of 76% while HOKLAS 021 was found to provide coverage of 11%. HOKLAS 015 was also found to have a distribution coverage of 78% relating to the International Standard ISO 15189:2012 process-based quality management system model.

Conclusion. The results of this analysis should be of value to medical laboratories wishing to maintain the internal auditability required by HOKLAS 015 by gaining an awareness of the extent of coverage provided by HOKLAS 016-02 and HOKLAS 021.

Keywords: accreditation, internal audit, ISO 15189:2012, management audit, quality management

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INTRODUCTION

The Hong Kong Accreditation Service (HKAS)[1] operating under the Innovation and Technology Commission is the accreditation body in Hong Kong. The HKAS operates according to International Standard ISO/IEC 17011:2017[2] prepared by the International Organization for Standardization[3] and the International Electrotechnical Commission,[4] and is therefore able to provide accreditation to medical laboratories located in Hong Kong through the Hong Kong Laboratory Accreditation Scheme (HOKLAS). The HKAS grants accreditation to medical laboratories

when relevant accreditation criteria are fulfilled according to the regulations for HKAS accreditation (HKAS 002).[5] One key criterion is to demonstrate reasonable coverage of conformance requirements (CReqs) according to the technical criteria for medical laboratory accreditation (HOKLAS 015).[6] The technical criteria incorporate mandatory requirements of International Standard ISO 15189:2012[7] prepared by the International Organization for Standardization and additional HOKLAS policies.

The HKAS supports the accreditation of medical laboratories by providing a structured approach to the implementation process. Thus far, it has provided additional administrative support for HOKLAS applications by publishing two guidance documents that are readily available for self-auditing purposes. The management system checklist for conformity with HOKLAS requirements (HOKLAS 016-02)[8] has been developed for medical laboratories applying for an initial application, extension of scope of accreditation to a new discipline or reaccreditation when there has been a major change of the quality management system, whereas the general checklist for HOKLAS supplementary criteria (HOKLAS 021)[9] is for all initial applications. The guidance checklists, HOKLAS 016-02 and HOKLAS 021, can also be used for internal auditing purposes by medical laboratories to fulfil CReqs of Clause 4.14 of HOKLAS 015. Overall, the ultimate objective is to achieve absolute conformity according to the regulations for accreditation.

The present study offers useful insights into accreditation compliance management of HOKLAS 015. Maintaining continuous compliance to the relevant regulations and standards that relate to the HOKLAS remains an unparalleled challenge for the medical laboratory and if compliance is delayed or obligations are only partially met, the medical laboratory may face increased vulnerability to various forms of business, legal, and risk liability. These can range from issues relating to patient safety to reputation management.[10-13] This study aims to address this knowledge gap by providing a quantitative view of compliance management in line with studies showing the value of the importance of quantitative analysis for implementation of International Standards, especially ISO 15189:2012[14,15] and ISO 22870:2016[16]. However, these studies have produced information for implementation at the generic level only; therefore, the generalisability of much published research on this subject has limited specificity to any accreditation body that provides accreditation according to ISO/IEC 17011:2017. More specifically, thus far there has been limited research on the internal auditing aspects of HOKLAS 015, especially in CReq conformity management. Furthermore, no known research has concentrated on the quantitative analysis of CReqs in Clauses 4 (Management requirements) and 5 (Technical requirements) of HOKLAS 015. The current study is the first quantitative analysis of HOKLAS 015, and the results that are subsequently used for further guidance checklist evaluations are highly likely to offer useful insights into conformity necessities that are operationally feasible to implement during internal auditing, potentially leading to the reduction of susceptibility to risk relating to accreditation implementation. The main aim of this investigation is to quantitatively analyse the extent of coverage of HOKLAS 015 offered by HOKLAS 016-02 and HOKLAS 021.

The analysis of HOKLAS 015 was conducted through content analysis and divided into five phases. First, the CReqs were identified by conducting content analysis on Clauses 4 and 5 of HOKLAS 015 for quantitation purposes. Second, an evaluation checklist was developed based on the quantification of CReqs in Clauses 4 and 5 of HOKLAS 015. Third, evaluability assessments of HOKLAS 016-02 and HOKLAS 021 were conducted using the developed evaluation checklists. Fourth, a distribution analysis of CReqs was performed for the four major stages of the ISO 15189:2012 process-based quality management system model.[15] Finally, the shortfalls of the guidance checklists were analysed to address potential internal audit gap risks. Overall, the information produced by this research is highly likely to serve as a useful performance indicator for maintaining the internal auditability as required by HOKLAS 015.

METHODS

Quantitative analysis of conformance requirements in Clauses 4 and 5 of HOKLAS 015

The technique of content analysis for quantitative analysis of International Standards has become a reasonably practicable approach to elicit relevant CReqs, such as in the analysis of ISO 15189:2012 and ISO 22870:2016. For this investigation, the same technique was used to perform the quantitation of CReqs within Clauses 4 and 5 of HOKLAS 015. Briefly, content analysis was used to identify the occurrences of the specific term 'shall' within the areas of interest. The verbal form of 'shall' indicates a requirement according to Subclause 7.2 of ISO/IEC DIR 2:2021.[17] The implied requirements indicated by the verbal form 'shall' were then elicited as CReqs of HOKLAS 015. The identification of CReqs was expressed as a black stacked line column figure with the support of data visualisation software [RAWGraphs (Version 2.0) designed by DensityDesign, Milan, Italy].

Development of evaluation checklist for the evaluability assessment of HOKLAS 016-02 and HOKLAS 021

The use of customised checklists to analyse relevant guidance documents for implementation is an established approach, as previously described.[15] Briefly, CReqs were elicited from the verbal form of 'shall' which indicates either a quality, regulatory or statutory requirement in Clauses 4 and 5 of HOKLAS 015 and were used to develop an evaluation checklist for the analysis of HOKLAS 016-02 and HOKLAS 021.

Evaluability assessment of HOKLAS 016-02 and HOKLAS 021

The distribution of CReqs in HOKLAS 016-02 and HOKLAS 021 was quantitatively evaluated using the evaluation checklist. The quantitation of CReqs was expressed as coloured stacked line column figures with the support of RAWGraphs, and the level of coverage for each clause was classified using a four-colour code classification.

Distribution analysis of conformance requirements of HOKLAS 016-02 and HOKLAS 021 in the ISO 15189:2012 process-based quality management system model

The distribution of CReqs of ISO 15189:2012 can be represented effectively in the ISO 15189:2012 process-based quality management system model for further productivity analysis.[15] The distribution of CReqs that HOKLAS 016-02 and HOKLAS 021 could identify for auditing purposes were represented using this model to show the extent of coverage at different stages. The CReq distributions of evaluand checklists among the four major stages were analysed.

Gap analysis of conformance requirements by using HOKLAS 016-02 and HOKLAS 021 for auditing of Clauses 4 and 5 of HOKLAS 015

In order to address the audit risk, the potential internal auditing gap was identified and the CReq distribution gap classified into three sectors that contain the relevant clause number using a three-colour code classification.

Limitations of the evaluability assessment

The evaluability assessment has two limitations relating to the content analysis. First, the elicitation of CReqs in Clauses 4 and 5 of HOKLAS 015 did not include additional CRs specified in HKAS and HOKLAS supplementary criteria (Table 1). It is important to note that these additional CReqs are inextricably linked to the implementation of HOKLAS 015 for all medical laboratories. Second, the evaluand checklists of HOKLAS 016-02 and HOKLAS 021 were developed to guide medical laboratories in addressing potential areas of vulnerability in the quality management system. The evaluand checklists are highly unlikely to cover all aspects of HOKLAS 015, because they have been designed to selectively audit certain clauses to reduce the susceptibility to quality risk.

RESULTS

Identification and location of conformance requirements in Clauses 4 and 5 of HOKLAS 015

Content analysis identified a total of 1946 CReqs to 1947 CReqs in Clauses 4 and 5 of HOKLAS 015 (Figure 1). It was found that 1947 CReqs are applicable to Category S MLs and 1946 CReqs are applicable to Category P medical laboratories. The differentiation is according to the appointment type of laboratory director as specified in Clause 5.1.H of HOKLAS 015. Category P medical laboratories appoint a pathologist as laboratory director referred to as 'Pathologist Director' and Category S medical laboratories appoint a medical laboratory scientist as laboratory director referred to as 'Biomedical Scientist Director.' For Category S medical laboratories, Clause 4 of HOKLAS 015 contained 819/1947 (42%) CReqs and Clause 5 of HOKLAS 015 contained 1128/1947 (58 %) CReqs. For Category P medical laboratories, Clause 4 of HOKLAS 015 contained 819/1946 (42%) CReqs and Clause 5 of HOKLAS 015 contained 1127/1946 (58%) CReqs. The number of CReqs identified

Table 1. Relevant Guidance Documents that are Specified in Clauses 4 (Management requirements) and 5 (Technical requirements) of HOKLAS 015

International and Australian Standards as well as normative documents	Clauses of HOKLAS 015
Australian Standard AS 2706—2003 Numerical values—Rounding and interpretation of limiting values	Clause 5.8.H (a) of HOKLAS 015
HKAS 002 Regulation for HKAS accreditation	Clause 4.8.H of HOKLAS 015 Clause 5.1.H of HOKLAS 015 Clause 5.1.H of HOKLAS 015 Clause 5.3.H (c)(ii) of HOKLAS 015 Clause 5.8.H of HOKLAS 015
HKAS SC-01 Use of HKAS accreditation symbols and claims of accreditation status	Clause 5.8.H (c)(i) of HOKLAS 015
HKAS SC-05 Internal audits and management reviews	Clause 4.14.H of HOKLAS 015 Clause 4.15.H of HOKLAS 015
HOKLAS SC-33 Internal audits and management reviews	Clause 4.5.H of HOKLAS 015 Clause 5.8.H (c)(i) of HOKLAS 015 Clause 5.8.H (d) of HOKLAS 015
International Standard ISO 17511:2003 In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials	Clause 5.3.H (f) of HOKLAS 015

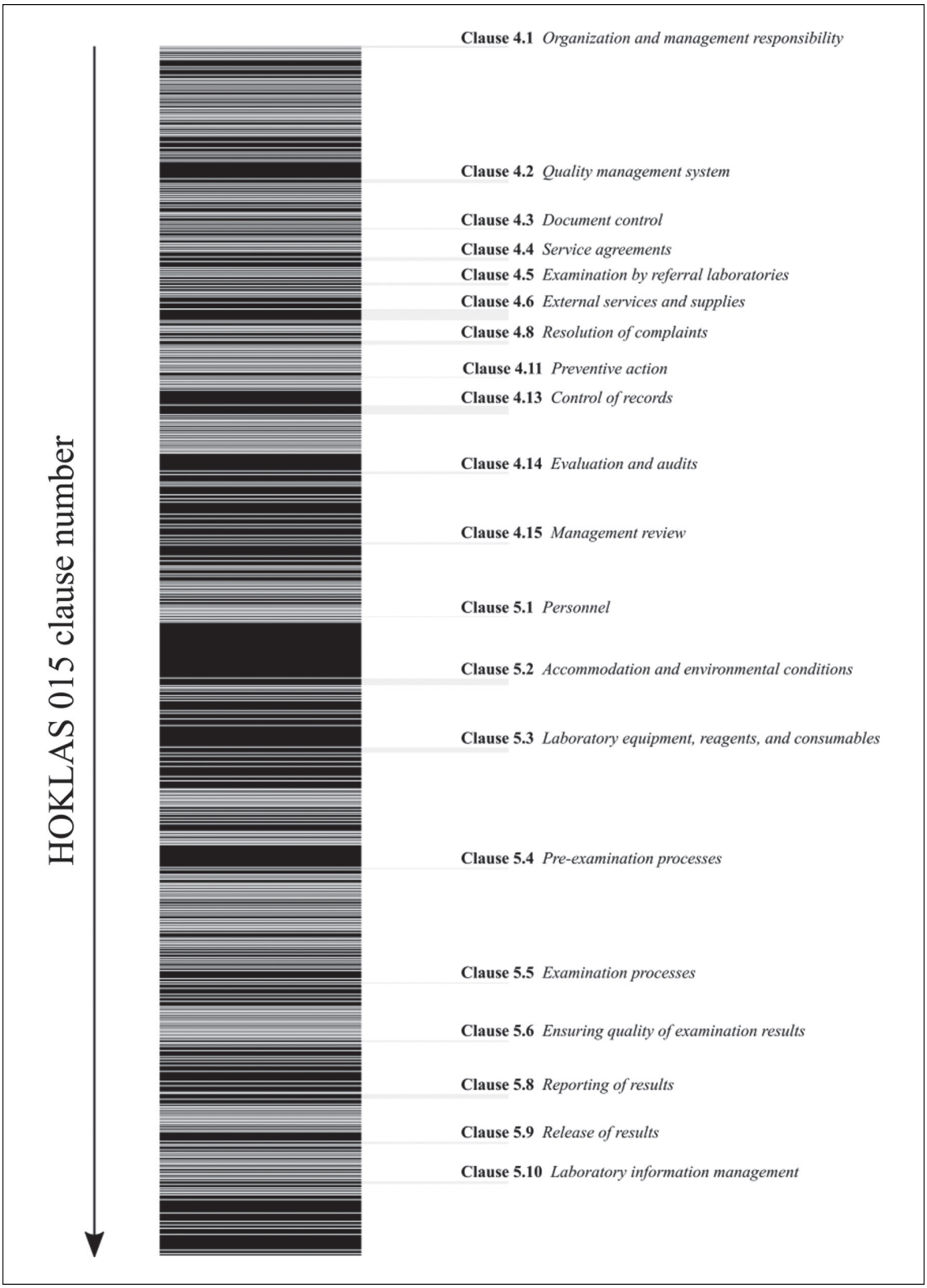

Figure 1. ***Quantitative analysis of conformance requirements in Clause 4 (Management requirements) and 5 (Technical requirements) of HOKLAS 015.*** The quantitation of conformance requirements is expressed as a black stacked line column. The thickness of the line is proportional to the frequency of conformance requirements. Clauses 4 and 5 of HOKLAS 015 contain 1947 conformance requirements for Category S medical laboratories and 1946 conformance requirements for Category P medical laboratories.

in each clause ranged from 1 CReq to 123 CReqs: 1 CReq each in Clauses 4.9.H, 4.15.H and 5.7 of HOKLAS 015; and 123 CReqs in Clause 5.10.3 of HOKLAS 015. Clauses 4 and 5 of HOKLAS 015 contained 431 CReqs relating to relevant HOKLAS policies. These HOKLAS policies are specified following the main text of each clause. Clause 4 of HOKLAS 015 contained additional HOKLAS policies in Clauses 4.1.H to 4.11.H and Clauses 4.13.H to 4.15.H of HOKLAS 015. Clause 5 of HOKLAS 015 contained additional HOKLAS policies in Clauses 5.1.H to 5.6.H, 5.7, 5.8.H, 5.9 and 5.10 of HOKLAS 015.

Evaluability assessment of evaluand checklists of HOKLAS 016-02 and HOKLAS 021

Evaluand checklists HOKLAS 016-02 and HOKLAS 021 were used for the evaluability assessment. The overall coverage was quantified for comparison purposes. The evaluability assessment indicated that the extent of coverage ranged from 224 (12%) CReqs by HOKLAS 021 to 1491 (77%) CReqs by HOKLAS 016-02. However, when HOKLAS 016-02 and HOKLAS 021 were combined it was found that they covered 1501 (77%) CReqs (Figure 2). The specific distribution of CReqs of the evaluand checklists was further quantified and expressed in a stacked line column figure using a four-colour code classification. The distribution status was presented for HOKLAS 021 (Figure 2A), HOKLAS 016-02 (Figure 2B) as well as HOKLAS 016-02 and HOKLAS 021 (Figure 2C).

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

Content analysis of HOKLAS 015 identified and located the CReqs in the ISO 15189:2012 process-based quality management system model (Figure 3).[15] Clauses 4 and 5 of ISO 15189:2012 has 1515 CReqs to consider for conformity management.[14] Therefore, Clauses 4 and 5 of HOKLAS 015 contain 1515 (78%) CReqs relating to ISO 15819:2012. The CReq stage-by-stage coverage provided by HOKLAS 016-02 and HOKLAS 021 was presented in this sequence: strategic management, process control, design and planning, analytical processes, and process evaluation and improvement. The strategic management stage comprised 388/1515 (26%) CReqs. The process control, design, and planning stage comprised 460/1515 (31%) CReqs. The analytical processes stage comprised 384/1515 (26 %) CReqs. The process evaluation and improvement stage comprised 252/1515 (17%) CReqs.

Evaluability assessment of evaluand checklists of HOKLAS 016-02 and HOKLAS 021 on the coverage of clauses of Hong Kong Laboratory Accreditation Scheme policies of HOKLAS 015

The analysis revealed that the guidance checklists of HOKLAS 016-02 and HOKLAS 021 could provide limited CReq auditing coverage (n = 23) of the clauses of HOKLAS policies in HOKLAS 016-02 (Table 2). The extent of coverage ranged from 1 (0.1%) CReq each in Clauses 4.13.H (c) and 5.2.H of HOKLAS 015 to 8 (0.4%) CReqs in Clause 4.13.H of HOKLAS 015.

Results for determination of course of corrective action to address internal audit gap of HOKLAS 015

The gap analysis of CReqs by using HOKLAS 016-02 and HOKLAS 021 indicated coverage of 1501 (77%) CReqs (Table 3). The gap analysis results were used to determine corrective actions required for the implementation. The CReq coverage of Clauses 4 and 5 of HOKLAS 015 was plotted and the corrective action prioritisation was presented in three sectors using a three-colour code classification (Figure 4).

DISCUSSION

This study set out with the aim of quantitatively analysing the extent of coverage of HOKLAS 015 by HOKLAS 016-02 and HOKLAS 021. This has not been considered previously due to the lack of a suitable evaluation tool for analytical purposes. The emergence of a quantitative estimation of CReqs in ISO 15189:2012 in a recent analysis makes it possible to perform a meaningful gap analysis for HOKLAS 015 on any guidance checklist. The quantitative approach produces clarification on the level of certainty provided by HOKLAS 016-02 and HOKLAS 021. The information can support medical laboratory management considering implementation of HOKLAS 015 with enhanced coordination, especially in the planning of internal auditing. It was found that when HOKLAS 016-02 and HOKLAS 021 were used simultaneously, they could provide CReq auditing coverage of 1501 (77%) CReqs in HOKLAS 015; and they could provide coverage of 1484 (98%) CReqs in ISO 15189:2012. Since ISO 15189:2012 is the core content of HOKLAS 015, it was possible to identify that the clauses of HOKLAS policies in HOKLAS 015 require further auditing considerations. These findings have specific implications for Clause 4.14.5 of HOKLAS 015 and Subclause 6.3.4 of ISO 19011:2018 where customised documented information, such as checklists developed by medical laboratories must be able to provide reasonable CReq coverage to all activities in the medical laboratory quality management system.[18] Medical laboratories need to ensure that the internal audit checklists can cover relevant CReqs in all relevant clauses of HOKLAS 015.

The results have general implications relating to the situational awareness of management system standards, especially in the training aspects of the medical laboratory personnel. Three potential implications identified are discussed below.

The first potential implication is the manageability of training of medical laboratory personnel. The medical laboratory needs to manage training for all personnel who

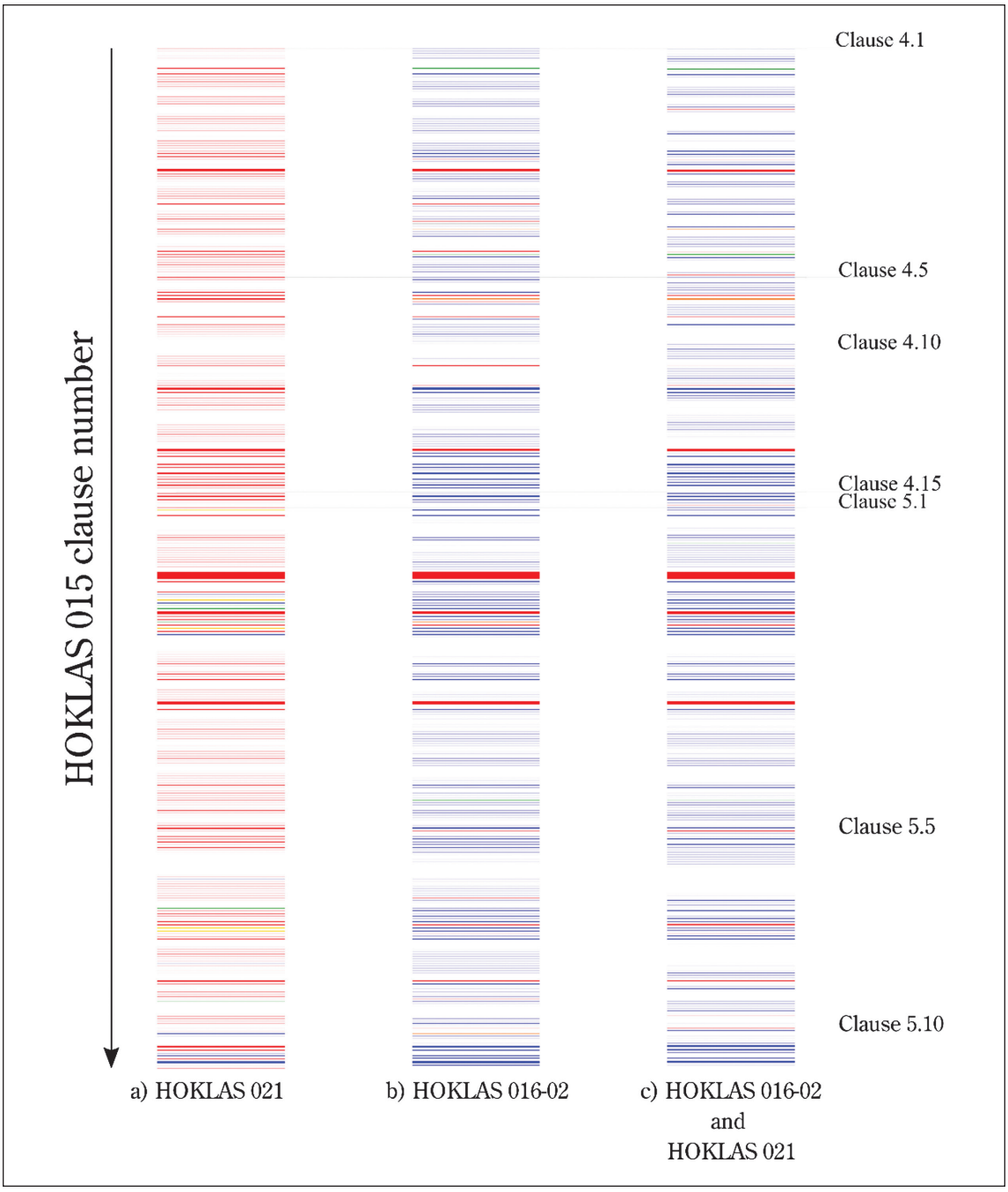

Figure 2. ***Distribution analysis of conformance requirements of guidance checklists of HOKLAS 016-02 and HOKLAS 021.*** The quantitation of conformance requirements is expressed in a stacked line column using a four-colour code classification. Blue indicates the evaluand checklist achieved a total coverage of 100%; green indicates the evaluand checklist achieved a total coverage of 76% to 99%; amber indicates the evaluand checklist achieved a total coverage of 51% to 75%; and red indicates the evaluand checklist achieved a total coverage of ≤ 50%. **(2A)** represents the distribution of coverage by the guidance checklist of HOKLAS 021. **(2B)** represents the distribution of coverage by the guidance checklist of HOKLAS 016-02. **(2C)** represents the distribution of coverage by guidance checklists of HOKLAS 016-02 and HOKLAS 021.

Notes. Subclause 5.6 (Ensuring quality of examination results) of ISO 15189:2012 is spread across four divisions. Subclauses 5.6.1 (General) and 5.6.2 (Quality control) of ISO 15189:2012 are segmented into the analytical processes stage. Subclauses 5.6.3 (Interlaboratory comparisons) and 5.6.4 (Comparability of examination results) of ISO 15189:2012 are segmented into the process evaluation and improvement stage.

participate in the relevant managerial and technical processes. The manageability of training is particularly important because it reflects the way in which knowledge and skill are applied to meet routine challenges. More specifically, Clause 5.1.5 of HOKLAS 015 requires the medical laboratory to provide training related to the implemented quality management system; however, it does not specify the topics that the training must cover. This potentially has further implications in the competence assessment as specified in Clause 5.1.6 of HOKLAS 015 where relevant criteria need to be established for competence assessment purposes. Ideally, the medical laboratory should implement a comprehensive training programme followed by competence assessments of all personnel.

The second potential implication is associated with the maintenance of professional credibility of medical laboratory personnel. Another essential consideration to be addressed is continuing education for all personnel. While Clause 5.1.8 of HOKLAS 015 requires personnel to keep knowledge of medical laboratory practices up-to-date, it does not contain specific obligatory requirements for the medical laboratory on how to maintain the level required necessary for success in the implementation followed by competence assessment as specified in Clause 5.1.6 of HOKLAS 015. More importantly, customers and users of the medical laboratory expect the personnel to possess the necessary skills and capacities in the delivery of relevant medical laboratory services with an appropriate level of scientific certainty. This includes the employment of competent personnel and allocation of such personnel in the major stages of ISO 15189:2012 processes, especially in the analytical processes stage. This particular obligation appears

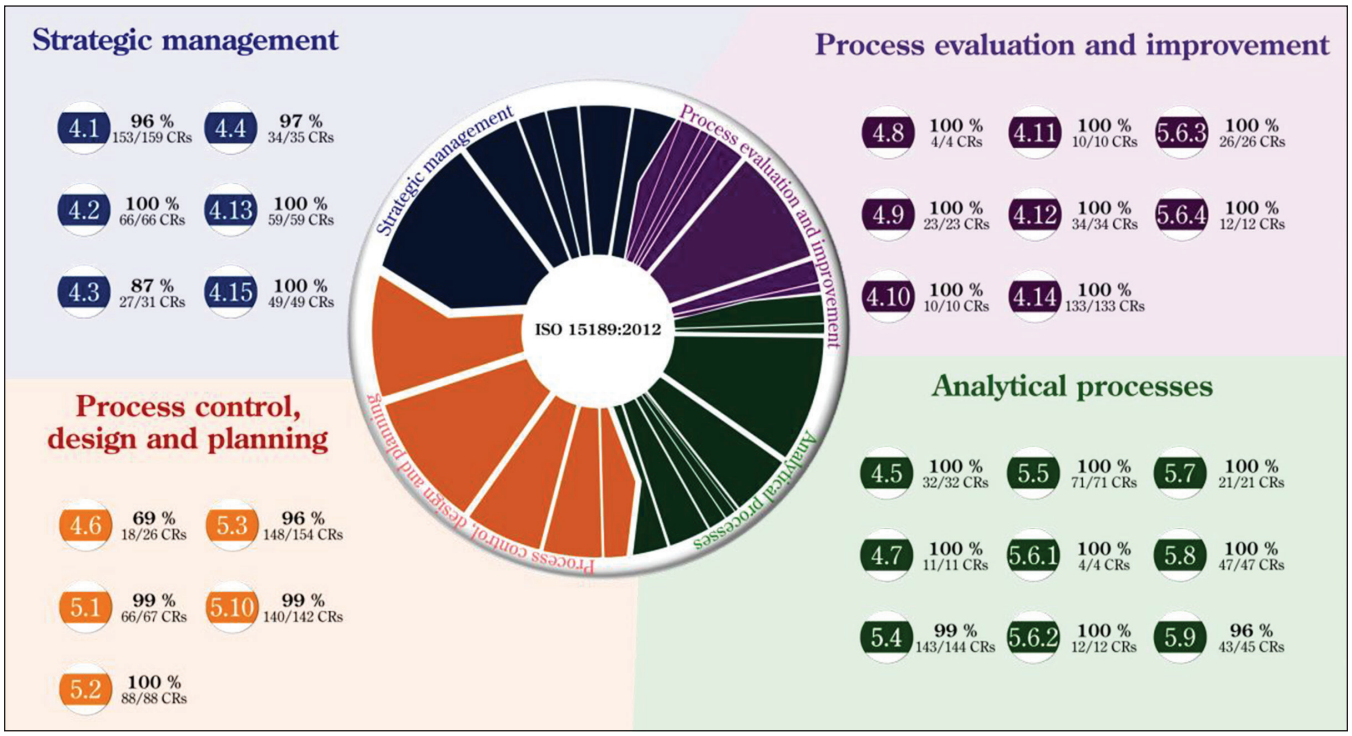

Figure 3. ***Distribution analysis of conformance requirements of HOKLAS 016-02 and HOKLAS 021 checklists.*** The distribution of conformance requirements is presented according to the framework of the ISO 15189:2012 process-based quality management system model. The distribution of coverage across Clauses 4 (Management requirements) and 5 (Technical requirements) of ISO 15189:2012 is presented in four major stages. The strategic management stage comprises six subclauses containing 388/1515 (26%) conformance requirements and is represented by six blue segments. The process control, design, and planning stage comprises five subclauses containing 460/1515 (31%) conformance requirements and is represented by five orange segments. The analytical processes stage comprises nine subclauses containing 384/1515 (26%) conformance requirements and is represented by nine green segments. The process evaluation and improvement stage comprises eight subclauses containing 252/1515 (17%) conformance requirements and is represented by eight purple segments.

Notes. Subclause 5.6 (Ensuring quality of examination results) of ISO 15189:2012 is spread across four divisions. Subclauses 5.6.1 (General) and 5.6.2 (Quality control) of ISO 15189:2012 are segmented into the analytical processes stage. Subclauses 5.6.3 (Interlaboratory comparisons) and 5.6.4 (Comparability of examination results) of ISO 15189:2012 are segmented into the process evaluation and improvement stage.

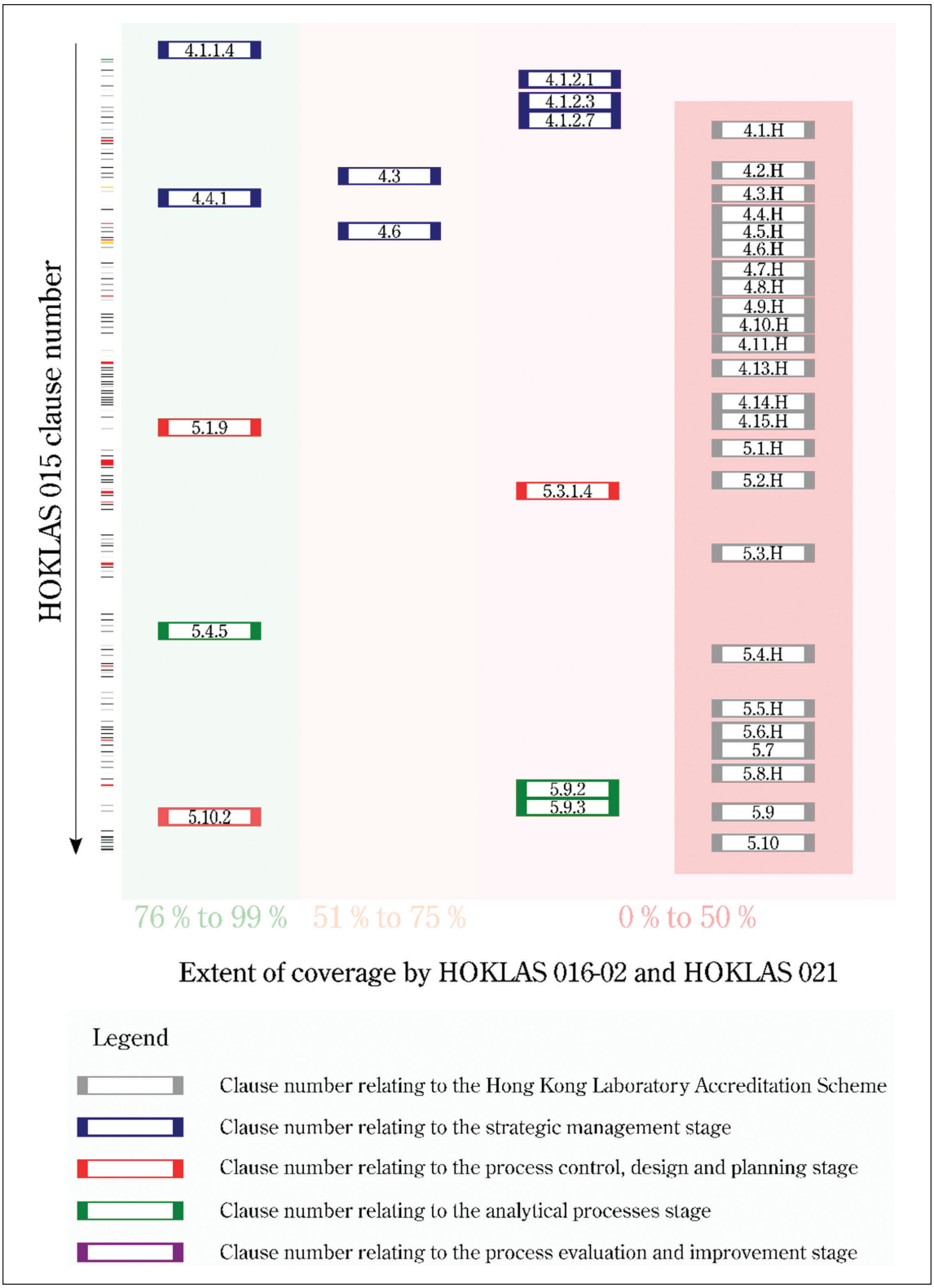

Figure 4. ***Course of action analysis to determine corrective actions necessary for conformance requirement implementation.*** The corrective action prioritisation is divided into three sectors that contain the relevant clause number using a three-colour code classification. Green indicates the evaluand checklists achieved a total coverage of 76% to 99%, amber indicates the evaluand checklists achieved a total coverage of 51% to 75%, and red indicates the evaluand checklists achieved a total coverage of ≤50%.

in Clause 4.4.1 of HOKLAS 015, where each examination request accepted by the medical laboratory needs to be treated as a service agreement. Failure to deliver or delayed compliance with the obligation to fulfil a service agreement is highly likely to give rise to an unacceptable level of corporate risk and reduced levels of patient safety.[19,20]

The third potential implication is associated with legibility and literacy in connection with quality-related activities of the medical laboratory. First, when the level of training is inappropriate and therefore misaligned with the minimum level of expectation of personnel, then personnel may be unable to interpret information that pertain to quality activities.[21] This is particularly difficult for medical laboratory personnel with limited practical experience. Second, the legibility issues can further compound communication issues.[22] This can form an obstacle for senior personnel to promulgate information and junior personnel to express feedback and opinions effectively.[23,24] This can hinder the process evaluation and improvement stage of ISO 15189:2012, especially in Clauses 4.10, 4.11 and 4.14.4 of HOKLAS 015. Quality management training remains a specialised form of training and should be provided by the medical laboratory and linked inextricably to the relevant processes.[25] The inability of the medical laboratory

Table 2. Coverage of Clauses of Hong Kong Laboratory Accreditation Scheme Policies presented in HOKLAS 015 by HOKLAS 016-02 and HOKLAS 021

Clauses of HOKLAS 015	Checklist questionnaires of HOKLAS 016-02 and HOKLAS 021	Coverage of conformance requirements
Clause 4.3.H of HOKLAS 015	*Are all controlled documents reviewed and revised, if necessary, at least annually?*	Clause 4.3.H of HOKLAS 015 contained 10 CReqs. The questionnaire covered 2/10 (20%) CReqs in Clause 4.3.H of HOKLAS 015.
Clause 4.13.H of HOKLAS 015	*Does the laboratory retain records (electronic and/or hardcopy format) for an appropriate time interval pursuant to the professional, statutory, legislative, and HOKLAS requirements?*	Clause 4.13.H of HOKLAS 015 contained 41 CReqs. The questionnaire covered 8/41 (20%) CReqs in Clause 4.13.H of HOKLAS 015.
Clause 4.13.H (c) of HOKLAS 015	*Are raw data/original observations kept for the test results?*	Clause 4.3.H (c) of HOKLAS 015 contained 2 CReqs. The questionnaire covered 1/2 (50%) CReqs of Clause 4.13.H (c) of HOKLAS 015.
Clause 4.13.H (d) of HOKLAS 015	*Is the operator performing the test and checking the result traceable from the laboratory records?*	Clause 4.3.H (d) of HOKLAS 015 contained 12 CReqs. The questionnaire covered 2/12 (17%) CReqs of Clause 4.13.H (d) of HOKLAS 015.
Clause 4.13.H (f) of HOKLAS 015	*Are there procedures for checking data transcription, calculation, or data entry? Is the checking initialled or signed by a second person?*	Clause 4.3.H (f) of HOKLAS 015 contained 4 CReqs. The questionnaire covered 2/4 (50%) CReqs of Clause 4.13.H (f) of HOKLAS 015.
Clause 5.1.H (d) of HOKLAS 015	*Does the supervisor in charge of a test area has relevant experience in the test area for at least three years and has at least one year one — Part I working experience in the area for which he / she is responsible?*	Clause 5.1.H (d) of HOKLAS 015 contained either 31/1947 (1.6%) CReqs (Category S medical laboratory) or 30/1946 (1.5%) CReqs (Category P medical laboratory). The questionnaire covered either 2/31 (6.5%) CReqs or 2/30 (6.6%) CReqs of Clause 5.1.H (d) of HOKLAS 015.
Clause 5.2.H of HOKLAS 015	*If radioactive substances are handled in the laboratory, does the laboratory carry a valid license?*	Clause 5.2.H of HOKLAS 015 contained 50 CReqs. The questionnaire covered 1/50 (2%) CReqs of Clause 5.2.H of HOKLAS 015.
Clause 5.2.H of HOKLAS 015	*If radioactive substances are handled in the laboratory, are guidelines for safe handling or radioactive substances available?*	Clause 5.2.H of HOKLAS 015 contained 50 CReqs. The questionnaire covered 1/50 (2%) CReqs of Clause 5.2.H of HOKLAS 015.
Clause 5.3.H (f) of HOKLAS 015	*Is your laboratory aware of and does it comply with the following requirements?* *"An autoanalyser or **a commercial** test kit shall be evaluated to confirm its suitability for the intended use before it is put into service. An evaluation report with details of the studies and conclusions shall be prepared. For any change of autoanalysers or commercial test kits used for any HOKLAS accredited tests, the evaluation report shall be provided to HKAS Executive for review before the analyser or test kit is put into service."*	Clause 5.3.H (f) of HOKLAS 015 contained 4 CReqs. The questionnaire covered 4/4 (100%) CReqs of Clause 5.3.H (f) of HOKLAS 015.

Table 3. Frequency of Conformance Requirements in various Relevant Normative Documents that Pertain to the Accreditation of Medical Laboratories for Hong Kong Laboratory Accreditation Scheme

International Standard and normative documents	Frequency of conformance requirements
HOKLAS 015 Technical criteria for laboratory accreditation (medical laboratories)	**Category S medical laboratory:** Clause 4 of HOKLAS 015 contained 819/1947 (42%) CReqs Clause 5 of HOKLAS 015 contained 1128/1947 (58%) CReqs Clauses 4 and 5 of HOKLAS 015 contained 1947/1947 (100%) CReqs **Category P medical laboratory:** Clause 4 of HOKLAS 015 contained 819/1946 (42%) CReqs Clause 5 of HOKLAS 015 contained 1127/1946 (58%) CReqs Clauses 4 and 5 of HOKLAS 015 contained 1946/1946 (100%) CReqs
HOKLAS 016-02 Checklist on conformity with HOKLAS requirements (medical laboratories)	HOKLAS 016-02 covered 1491 (77%) CReqs of HOKLAS 015
HOKLAS 021 General checklist for HOKLAS supplementary criteria for medical laboratories	HOKLAS 021 covered 224 (12%) CReqs of HOKLAS 015
HOKLAS 016-02 Management system checklist **HOKLAS 021** General checklist for HOKLAS supplementary criteria for medical laboratories	HOKLAS 016-02 and HOKLAS 021 covered 1501 (77%) CReqs of HOKLAS 015
International Standard ISO 15189:2012 Medical laboratories — Requirements for quality and competence	Clause 4 of ISO 15189:2012 contained 682/1515 (45%) CReqs Clause 5 of ISO 15189:2012 contained 833/1515 (55%) CReqs Clauses 4 and 5 of ISO 15189:2012 contained 1515/1515 (100%) CReqs

to provide training relating to the implemented quality management system is a non-conformity. In addition, while the provision of an inappropriate level of quality management training is not a non-conformity, it has the potential to enhance vulnerability in the areas of operations. The training requirements of internal auditors also need to be addressed adequately by the medical laboratory. According to Clause 5.1.2 of HOKLAS 015, the qualifications required for each position, including internal auditors, need to include relevant training and be appropriate to the tasks performed. Although it is reasonably practicable to use internal auditors that have been trained in auditing techniques in Clause 6 of ISO 19011:2018, it remains unjustifiable for medical laboratories to use internal auditors that have been trained in other non-equivalent schemes. The medical laboratory must employ internal auditors who have been trained and who are competent to conduct scheme-specific auditing activities in order to support the risk analysis. Ideally, the qualification of internal auditors should be aligned with the relevant accreditation scheme, followed by an initial competence assessment by a training provider, and then certified by a relevant certification body.[26-28]

CONCLUSION

In this investigation, the aim was to determine the extent of HOKLAS 015 CReq coverage by HOKLAS 016-02 and HOKLAS 021. The results of this research provide clarification of CReq coverage limitations of HOKLAS 016-02 and HOKLAS 021. This research has two major practical implications. First, medical laboratories need to ensure that the coverage of HOKLAS 015 CReqs in their internal audit checklists is reasonably auditable. Second, medical laboratory personnel, including internal auditors, must have adequate training in the medical laboratory quality management system to support the accreditation implementation. A suitable level of comprehension of both HOKLAS 015 and ISO 15189:2012 must be achieved by all medical laboratory personnel. Overall, medical laboratories need to ensure that the implementation of HOKLAS 015 is supported by robust internal auditing checklists with scheme-specific certified internal auditors to provide assurance that the processes are operating effectively at all times.

Statement of Authorship

GBD contributed in the supervision and project administration, and writing, review and editing of manuscript; DM contributed in conceptualization, methodology, formal analysis and visualization, writing the original draft, and review and editing of manuscript; RN and NE contributed in the conceptualization and formal analysis, and writing, review and editing of manuscript; SC and ACYM contributed in the conceptualization, and writing, review and editing of manuscript.

Author Disclosure

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