ORIGINAL ARTICLE

Management review input checklist for ISO 15189:2012 internal auditing: an optimisation guide for medical laboratories

Dennis Mok, Rana Nabulsi and Sharfuddin Chowdhury

ABSTRACT

Objectives: The primary aim of this study was to develop an analytical tool based on conformance requirements (CRs) identified in ISO 15189:2012, which can be used by internal auditors to evaluate the extent of management review input information as specified in Subclause 4.15.2 (Review input) of ISO 15189:2012.

Methods: The CRs were identified in Subclause 4.15.2 of ISO 15189:2012 and its referred subclauses for quantification purposes by content analysis.

Results: A total of 25 CRs were identified in Subclause 4.15.2 of ISO 15189:2012 and these 25/399 (6.3%) CRs are distributed in the 'strategic management' stage of the ISO 15189:2012 process-based quality management system model. A further 252 CRs were identified in Subclause 4.15.2 of ISO 15189:2012 referred subclauses. These 26/477 (5.5%) CRs are distributed in the 'process control, design and planning' stage and 226/252 (90%) CRs are in the 'process evaluation and improvement' stage. The results were used for the development of management review input checklists and a conformity status map to support the interpretation.

Conclusions: The application of a quantitative approach to facilitate internal auditing of the effectiveness of management review performance should improve the quality of information that feeds into the management review which, in turn, influences the crafting of organisational strategy.

Key words: checklist; internal audit; ISO 15189:2012; management review; quality management.
Supplementary material for this article may be found at https://www.nzimls.org.nz/journals-recent.html

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INTRODUCTION

The pathology services industry constitutes a significant capability in the provision of diagnostic information for the diagnosis, monitoring and treatment of health conditions. The services are integrated with other health elements and are intended to conform to the highest levels of professional ethics (1), practices (2) and standards (3). The delivery of services is performed by the medical laboratory, which is structured to provide specific diagnostic information within its areas of responsibility and to contribute as a specialised component of the broader health logistics system. The structure of a modern medical laboratory is relatively complex and requires significant logistic support to operate effectively and efficiently. A marked characteristic of the medical laboratory is the level of commitment to deliver the best standards of health support care in all situations. The contemporary medical laboratory aims to demonstrate its competence and quality by implementation of a relevant international consensus management system standard.

International organisations continue to provide relevant standards that can be implemented by the medical laboratory to demonstrate its ability to operate in conformance to specifications, such as the European Committee for Standardization (4,p.902) and the International Organization for Standardization (ISO) (4,pp.1874-1875). The implementation of management system standards developed by the ISO enables the medical laboratory to enhance its productivity and maximise the benefits derived from the application of those standards (5). One such specific management system standard is ISO 15189:2012 (6) that remains a hallmark of the medical laboratory's ability to provide high quality of service (7). ISO 15189:2012 specifies the minimum necessary activities and requirements to deliver competent medical laboratory services (8,9). The competent implementation of ISO 15189:2012 and accreditation by an accreditation body represent a significant achievement in raising confidence, expectation and morale within a combined health system.

The implementation of ISO 15189:2012 requires innovative strategic quality management considerations in response to the changes in the marketplace. These changes can commonly range from hard (technical) to soft (human) aspects, such as regulatory updates (10) and physical structures (11), to more challenging aspects of cultural change (12). Despite the ever-changing environment, well-structured strategic management can support the medical laboratory in crafting strategy that aligns with the medical laboratory's capabilities and resources (13). Overall, strategic management fulfils a critical role in the ISO 15189:2012 process-based quality management system model (14) (Figure 1) and is a support activity in the value chain of the medical laboratory (15,16). The medical laboratory needs to craft and make strategic choices in order to meet all strategically relevant prerequisites in preparation for the management review process.

Given the relative importance of strategic management in the medical laboratory, it should be a priority for resources to concentrate on the management review process. The strategically relevant factors can also be used in support of risk management (17). Although the process of strategic management via management review is crucial to the medical laboratory quality management system, the term 'management review' remains undefined by the ISO; however, the term 'management' is clearly equivalent to 'laboratory management' and synonymous with the term 'top management' (6), and laboratory management has been defined by the ISO as 'person(s) who direct and manage the activities of a laboratory' in Subclause 3.10 of ISO 15189:2012 (6,p.3). In addition, the term 'review' has been defined by the ISO as 'determination of the suitability, adequacy or effectiveness of an object to achieve established objectives' in Subclause 3.11.2 of ISO 9001:2015 (18,p.27). Nevertheless, it is apparent that prior to conducting a management review, a range of results must be collected from evaluations of various aspects of the medical laboratory's operations, as specified in Subclause 4.15 (Management review) of ISO 15189:2012 (6,pp.18-19). Overall, there is a

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strong linkage between the sufficiency of management review input and the effectiveness of management review performance.

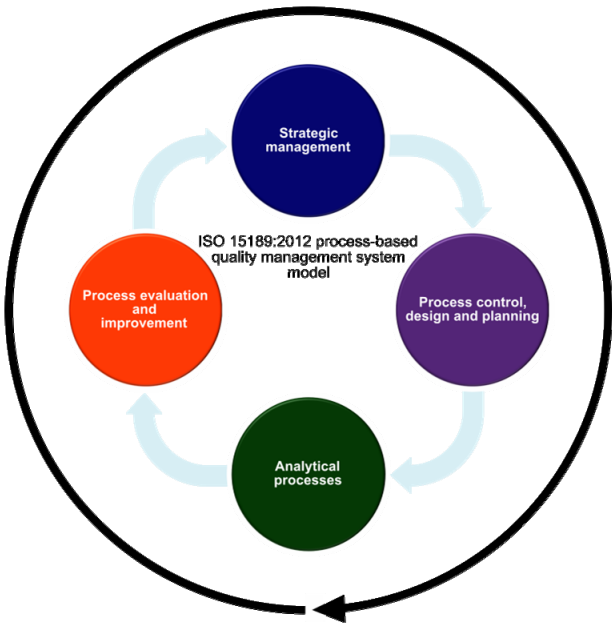

Figure 1. The ISO 15189:2012 process-based quality management system model. The four circles represent the major stages of ISO 15189:2012 processes: the strategic management stage; the process control, design and planning stage; the analytical processes stage; and the process evaluation and improvement stage.

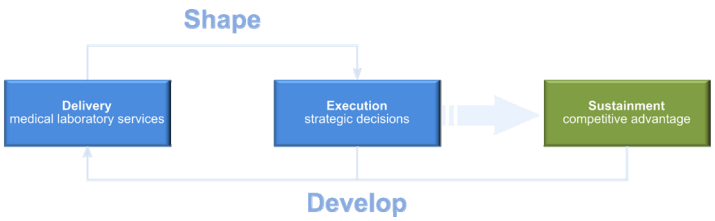

Figure 2. The relationship between resource endowments, strategies and sustained competitive advantage. Competent medical laboratory services are delivered by organisations that are confirmed by an accreditation body that operates according to ISO/IEC 17011:2017. The service delivery supports the shaping the strategic decisions, especially in the areas of adequacy, effectiveness, suitability and supports the care of patients as specified in Subclause 4.15.1 (General) of ISO 15189:2012. Specific competitive advantage is crafted with the competent execution of strategic decisions.

Thus, so far there has been no quantitative analytical tool, such as a conformance management checklist, available for internal auditors to evaluate the relevant management review input factors that constitute the main source of input for the management review process in ISO 15189:2012. Although an attempt using a qualitative approach has been made to analyse the review input points (19), unfortunately the study could not produce a conclusive outcome at the completion of analysis. The present study is based on a quantitative approach and the checklists produced should enable the internal auditors to evaluate the extent of usage of management review input information as listed in Subclause 4.15.2 (Review input) of ISO 15189:2012 (6,pp.18-19) in an accurate manner. Although it has been determined that Subclause 4.15.2 (Review input) of ISO 15189:2012 has 25 CRs (20) and refers to more subclauses in Clauses 4 (Management requirements) and 5 (Technical requirements) of ISO 15189:2012 (6,pp.6-39), the internal audit process should evaluate the cross-referenced CRs to ensure comprehensive coverage of such management review input factors. This action should enable a more detailed situational awareness of the effectiveness of the management review performance through the linkage to sufficiency of management review input information, and this in turn should enable improvement of the relevant processes that shape the organisational strategy.

The study described in this paper sought to achieve a comprehensive evaluation of management review input and comprised two main steps. First, a distribution analysis of CRs was performed for Subclause 4.15.2 of ISO 15189:2012 for quantification purposes by content analysis. The results were required for the development of management review input checklists. Second, a distribution analysis of CRs was performed for Subclause 4.15.2 of ISO 15189:2012 referred subclauses. This was performed for Subclauses 4.15.2 a) to 4.14.2 o) of ISO 15189:2012 (6,pp.18-19). The results were required for the development of a CRs checklist for Subclause 4.15.2 of ISO 15189:2012 referred subclauses. Finally, a management review input conformity status map was developed to aid in the interpretation of results of quantitative analysis of Subclause 4.15.2 of ISO 15189:2012. The findings should make a useful contribution to the field of internal auditing, especially to strategic management evaluation. The only practical constraint for the proposed evaluation methodology is whether the medical laboratory has competent internal auditors to identify the required information as set out by Clause 7 (Competence and evaluation of auditors) of ISO 19011:2018 (21,pp.28-34).

MATERIALS AND METHODS

Content analysis of Subclause 4.15.2 (Review input) of ISO 15189:2012

The content analysis was performed using ISO 15189:2012 published by the ISO. The specific areas of interest for analysis were primarily in Subclause 4.15.2 of ISO 15189:2012 and the referred subclauses in ISO 15189:2012.

Quantitative analysis of conformance requirements of Subclause 4.15.2 (Review input) of ISO 15189:2012

To establish specific audit criteria that could be performed against, a computer-aided qualitative data analysis package, NVivo 10 for Windows (version 10.0.638.0) (QSR International, Doncaster, Victoria), was used for the quantitation of CRs during the content analysis (22). The CRs were elicited using NVivo 10 and a previously described procedure (20). The same approach to quantitation as applied to ISO 15189:2012 and ISO 22870:2016 has been detailed elsewhere (20,23).

RESULTS

Quantitation of Subclause 4.15.2 of ISO 15189:2012 conformance requirements

Content analysis was used to identify the CRs in Subclause 4.15.2 of ISO 15189:2012 (Table S1). Subclause 4.15.2 of ISO 15189:2012 contains a total of 25 CRs. The overall range was 1/25 (4%) CR to 4/25 (16%) CRs in Subclause 4.15.2 n) of ISO 15189:2012 (Table S1).

Subclause 4.15.2 of ISO 15189:2012 refers to further specific subclauses (n=14) in Subclauses 4.15.2 a) to 4.15.2 l) of ISO 15189:2012 (6,p.18) and listed according to the format of Subclause 25.4 (Referencing) of ISO/IEC DIR 2:2018 (24,p.52). These referred subclauses were analysed and found to contain a total of 252 CRs (Tables S2 and S3).

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The frequency of Subclause 4.15.2 of ISO 15189:2012 conformance requirements in the ISO 15189:2012 process-based quality management system model

Subclause 4.15.2 of ISO 15189:2012 contains 25/1 515 (1.7%) CRs relative to Clauses 4 and 5 of ISO 15189:2012 and these 25 CRs are distributed in the 'strategic management' stage of the ISO 15189:2012 process-based quality management system model (Figure 1) with results of 25/399 (6.3%) CRs (Figure S1).

Subclause 4.15.2 of ISO 15189:2012 referred subclauses (*n*=14) contain 252/1 515 (17%) CRs relative to Clauses 4 and 5 of ISO 15189:2012 and these 252 CRs are distributed in the 'process control, design and planning' stage with 26/477 (5.5%) CRs (Figure S2) and the 'process evaluation and improvement' stage with 226/252 (90%) CRs (Figure S3).

The frequency of Subclause 4.15.2 of ISO 15189:2012 conformance requirements in the value chain model

Subclause 4.15.2 of ISO 15189:2012 operates within the strategic management stage of the ISO 15189:2012 process-based quality management system model which fits within the 'support activities and costs' of the value chain model (15) (Figure S4). The CRs of Subclause 4.15.2 of ISO 15189:2012 and its referred subclauses are distributed within the support activities and costs of the value chain (Figure S4).

Conformance requirement checklist for Subclause 4.15.2 of ISO 15189:2012

The CR checklist was developed using the CRs (*n*=252) of Subclause 4.15.2 of ISO 15189:2012 (Figure S5). The frequencies of CRs expressed as percentages ranged from 0/252 (0%) CR in Subclauses 4.15.2 m) to 4.15.2 o) of ISO 15189:2012 (6,pp.18-19) to 54/252 (21%) CRs in Subclause 4.15.2 l) of ISO 15189:2012 (6,p.18) (Table S2).

Management review input checklist for Subclause 4.15 of ISO 15189:2012

The management review input checklist was developed using the CRs (*n*=25) of Subclause 4.15 of ISO 15189:2012 (Figure S6). The frequencies of CRs expressed as percentages ranged from 1/25 (4%) CR to 4/25 (16%) CRs (Table S1).

Management review input conformity status map for Subclause 4.15 of ISO 15189:2012

The management review input conformity status map was developed for interpretation of results using colour-coded grading in three colours (Figure S7). Green highlights that the management review input checklist shows a total coverage of 100% and 'the medical laboratory is highly likely to make excellent progress and to achieve strategic management objectives'. Amber highlights that the management review input checklist shows a total coverage of 50% to 99% and 'the medical laboratory has the potential to make good progress and to achieve planned strategic management deliverables by addressing shortfalls'. Red highlights that the management review input checklist shows a total coverage of ≤ 49% and 'the medical laboratory is highly likely to operate in a strategic risk setting unacceptable to the current medical laboratory quality management system'.

DISCUSSION

This paper is primarily concerned with the optimisation of management review process in order to provide laboratory management with supportable and viable information for informed strategic decision-making. This was achieved by the development of practical checklists for medical laboratory professionals to perform internal audits with the intent of covering all possible considerations as specified in Subclause 4.15.2 of ISO 15189:2012. The results showed that Subclause 4.15.2 of ISO 15189:2012 contained its own CRs as well as additional CRs from its referred subclauses. The elicitation of these CRs enable the internal auditor to ensure comprehensive management review input results are included for evaluations by laboratory management. The proposed work documents, CR checklist for Subclause 4.15.2 of ISO 15189:2012 (Figure S5) and management review input checklist (Figure S6), should be used by internal auditors who have had training in auditing against ISO 15189:2012 in accordance with ISO 19011:2018 (21) in order to obtain optimal productivity. Overall, the analysis of CRs in Subclause 4.15.2 of ISO 15189:2012 has the potential to enhance continual improvement and optimisation of the management review process.

The medical laboratory conducts routine internal audits to determine whether all activities in the quality management system are meeting specifications of the medical laboratory as well as Clauses 4 and 5 of ISO 15189:2012. These auditing actions are imperative for the medical laboratory quality management system that intends to ensure that all practices conform to the specifications and, if required, implement corrective action. The ISO's recommended way to conduct such internal audit activities is detailed in Clause 6 (Conducting an audit) of ISO 19011:2018 (21,pp.18-28) followed by a document review of the relevant areas of interest as specified in Subclause 6.3.1 (Performing review of documented information) of ISO 19011:2018 (21,p.19). The document review is also a structured activity and should be performed using evaluation checklists (25). More specifically, the proposed checklists (Figures S5 and S6) enable medical laboratory professionals to conduct internal audits with a similarly consistent approach. This particular format of work document is highly likely to add value to the medical laboratory when completed by medical laboratory professionals.

An implication of this is the possibility that effective internal audits can add value to the medical laboratory quality management system by making contributions directly to the strategic management level. The contributions can shape the way medical laboratory makes competent strategic management decisions. However, this can be achieved more effectively and efficiently if trained medical laboratory professionals are used for performing auditing activities. This is more probable when the medical laboratory professionals have received effective auditing training and are deemed competent in internal auditing (26). This particular requirement is actually specified in Subclause 5.1.5 (Training) of ISO 15189:2012 (6,p.20) which states that training needs to be provided by the medical laboratory if they are assigned for evaluation and internal audit processes. Three potential implications when assigning medical laboratory professionals for performing internal auditing should be noted. First, when medical laboratory professionals from different disciplines are used to perform audits in order to enhance impartiality and objectivity of the internal audit process, the proposed checklists (Figures S5 and S6) are highly likely to enable them to provide consistent analytical judgement and productivity; despite the possibility of the audit being conducted by personnel who normally work in another scientific discipline. The checklists were developed according to the finding of 1 515 CRs in Clauses 4 and 5 of ISO 15189:2012 in a previous study (20) which can counter-balance the susceptibility to restricted technical expertise (27). The same CRs were used to support the development of checklists enabling the audit to adopt a consistent and measurable approach. Second, when medical laboratory professionals use the guidance principles of ISO 19011:2018 to perform audits using the proposed checklists, the combination of the auditing skills with the checklists is highly likely to ensure all audit activities are leading to a high level of reliability and validity of task performance.

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It is very important for the internal auditors to gather as much relevant information in the shortest possible timeframe. This can only be achieved by using the right audit methods according to the audit plan. The routine practice of these skills by trained internal auditors is likely to enable them to include improvement and maintenance of auditing competence as part of their personal development plan (28), as recommended in Subclause 7.6 (Maintaining and improving auditor competence) of ISO 19011:2018 (21,p.34) as well as meeting the CRs of Subclause 5.1.8 (Continuing education and professional development) of ISO 15189:2012 (6,p.21). Third, when medical laboratory professionals who work routinely in technical fields are used to perform audits in management system requirements of the medical laboratory, which is the main content of Subclause 4.15.2 of ISO 15189:2012, then they are highly likely to obtain further situational awareness of the operational aspects of the medical laboratory. Medical laboratory professionals who practise at the bench are not normally exposed to the management aspects of the medical laboratory. The enhancement of situational awareness is particularly important to the corporate knowledge management of the organisation (28). Overall, these advantages are likely to empower internal auditors to achieve optimal outcomes in addressing the areas of vulnerability and identifying opportunities for improvement in the medical laboratory quality management system.

CONCLUSIONS

When suitable ways to conduct management reviews are available to the medical laboratory, it should be possible to determine what is reasonably practicable to make optimum use of available resources to maximise management review productivity. The level of conformity for the input can be visualised using the management review input conformity status map, which displays the results using a three-colour colour-coded grading (Figure S7). This is to aid internal auditors in the creation of practical visualisations that can be used for reporting purposes to laboratory management. It is the ultimate aim of the medical laboratory to obtain a green grade because it represents a coverage rate of 100% with high probability of making excellent progress in achieving the planned strategic management objectives. The achievement offers a firm foundation for the medical laboratory to obtain meaningful information for the review analysis as specified in Subclause 4.15.3 (Review activities) of ISO 15189:2012 (6,p.19). The foundation contributes directly to the support activities and costs of the medical laboratory value chain (Figure S4). The value chain offers an explanation for the importance of conformity allowing strategic decision-making in the contemporary setting of rapid change (29). The ultimate aim is to execute strategic decisions that can sustain competitive advantage in contributing to patient care (Figure 2).

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2020 ANNUAL SCIENTIFIC MEETING SPEAKER PROFILES

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Professor Harding has undertaken teaching and research at the University of Auckland for much of her career. She is a paediatrician and practised as specialist neonatologist caring for newborn babies at National Women's Hospital. She was also Deputy Vice-Chancellor (Research), with overall responsibility for the University's research activities.

Her on-going research concerns the role of nutrition and growth factors in the regulation of growth before and after birth, blood glucose regulation in the newborn, and the longterm consequences of treatments given around the time of birth.

Amongst her many awards are the Howard Williams Medal from the Royal Australasian College of Physicians, the Beaven Medal from the Health Research Council of New Zealand, the Norman J Siegel Outstanding Science Award from the American Pediatric Society, and the Rutherford Medal from the Royal Society of New Zealand.

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Dr Ken Dutton-Regester is a cancer researcher at the QIMR Berghofer Medical Research Institute exploring new ways to treat late-stage melanoma. This includes a partnership with the Broad Institute of Harvard MIT to use CRISPR-knockout screens to identify new drug targets in rare forms of melanoma and understanding the mechanism of drug-resistant transcriptional cell-states.

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