The process evaluation and improvement stage of ISO 15189:2012 management system standard: an implementation update

Dennis Mok, Naira Eloyan and Sharfuddin Chowdhury

ABSTRACT

Objectives: The primary aim of this paper is to provide an update on selected internationally oriented guidance documents and relevant literature at the application level that are associated with the implementation of the process evaluation and improvement stage of ISO 15189:2012.

Methods: Additional relevant internationally oriented guidance documents were identified from international organisations (Type A to Type F), segmented by the Union of International Associations, and supplemented with additional literature.

Results: Selected international organisations (n = 6) were found to provide relevant guidance documents (n = 19) in support of the implementation of the process evaluation and improvement stage of ISO 15189:2012. An updated list of literature (n = 101) has been provided for further reference.

Conclusions: The present study contributes to the medical laboratory’s development and improvement of implementations of ISO 15189:2012 in areas of responsibilities by fulfilling management system and technical competence requirements to an acceptable level of conformance by using reasonably practical means that are within the medical laboratory’s managerial and technical specifications.

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

INTRODUCTION

The primary task of the International Organization for Standardization (1.p.1886) is to set global standards. The International Organization for Standardization promotes collective action among other international organisations by collaboration, such as the International Electrotechnical Commission (1.p.1729), to promote sustainable development. More specifically, the International Organization for Standardization produced International Standard ISO 15189:2012 (2), classified as a Type A management system standard (3.p.118), for supporting medical laboratories. ISO 15189:2012 is intended to be used for the purposes of accreditation (not certification), with the associated benefit that medical laboratories deliver technically competent results (4.5). Another advantage of this accreditation is the associated internationally recognised mutual recognition arrangement scheme, administered by the International Laboratory Accreditation Cooperation (1.p.1830), to promote acceptance and confidence of results.

According to the ISO 15189:2012 process-based quality management system model (6.p.85), one of the major processes is the process evaluation and improvement (PEI) stage of ISO 15189:2012 which comprises six subclauses from Clause 4 (Management requirements) of ISO 15189:2012 (2,pp.6-19) and two subclauses from Clause 5 (Technical requirements) of ISO 15189:2012 (2,pp.19-39). It has been determined that the PEI stage contains 21/119 (17%) administrative requirements (7) and 252/1515 (17%) conformance requirements (CRs) (8). The PEI stage contains CRs that provide direct input as referred subclauses of Subclause 4.15.2 (Review input) of ISO 15189:2012 (2,p.18). More specifically, Subclauses 4.15.2 a) to 4.15.2 i), 4.15.2 k) and 4.15.2 l) of ISO 15189:2012 (2,p.18) containing 17/25 (68 %) CRs are directly correlated with the PEI stage (9). The PEI stage fulfills an essential role in providing feedback to the strategic management stage of ISO 15189:2012 for crafting and executing strategic managerial processes (10,pp.3-37).

The main challenge of the PEI stage implementation is that the medical laboratory needs to have an acceptable level of awareness of its internal environment, especially relating to capabilities and resources (11,pp.45-84;12,pp.78-114). Understanding the complexity of such processes can ensure that the outputs are within specifications by the medical laboratory and the level of resources allocated provides evaluation and improvement actions that are both effective and efficient. Competent implementation of the PEI stage can provide relevant support to medical laboratories claiming compliance to ISO 15189:2012.

This article provides an update on internationally oriented guidance documents associated with the PEI stage at the application level in the areas of interest where the medical laboratory should make reasonably practicable effort to fulfil the relevant CRs of ISO 15189:2012. This update should be used in consultation with previously published papers in the New Zealand Journal of Medical Laboratory Science: ‘ISO 15189:2012 implementation: an update of related international guidance documents for medical laboratory quality management’ (13), ‘The strategic management stage of ISO 15189:2012 management system standard: an implementation update’ (14) and ‘The process control, design and planning stage of ISO 15189:2012 management system standard: an implementation update’ (15).

MATERIALS AND METHODS

Selection of organisations for inclusion as international organisations

The Union of International Associations classifies international organisations into 15 types (1,pp.xii-xl), but only organisations classified as either Type A, Type B, Type C, Type D, Type E or Type F, and published in ‘Yearbook of international organizations 2019-2020: guide to global civil society networks’ (1) were selected for inclusion. Internationally oriented national organisations, Type G (1,p.xix), were excluded from the selection.
Selection of recommended guidance documents associated with the process evaluation and improvement stage of ISO 15189:2012

This update focused on the PEI stage. The subclauses of interest included eight subclauses: Subclauses 4.8 (Resolution of complaints) (2,p.13), 4.9 (Identification and control of nonconformities) (2,pp.13-14), 4.10 (Corrective action) (2,p.14), 4.11 (Preventive action) (2,p.14), 4.12 (Continual improvement) (2,pp.14-15), 4.14 (Evaluation and audits) (2,pp.16-18), 5.6.3 (Interlaboratory comparisons) (2,pp.34-35) and 5.6.4 (Comparability of examination results) (2,p.35) of ISO 15189:2012. Internationally oriented guidance documents that could provide reasonable support for subclauses related to the PEI stage were selected for inclusion.

Selection of relevant literature associated with the process evaluation and improvement stage of ISO 15189:2012

Additional resources associated with the PEI stage were selected for inclusion. Literature presented in the previous update (13) is omitted from in this update.

RESULTS

Selected international organisations providing relevant guidance documents

This update includes additional international organisations (n = 4) that provide relevant guidance documents for the implementation of the PEI stage (Table 1). The full list of international organisations (n = 6), including the additional ones (n = 4), is presented in the supplementary section (Table S1). Recommended guidance documents associated with the process evaluation and improvement stage of ISO 15189:2012

This update has identified internationally oriented guidance documents (n = 19) that provide relevant information for the implementation of the PEI stage (Table 2). Recommended guidance documents were identified and classified in relation to relevant ISO 15189:2012 subclauses (Table S2).

Relevant literature associated with the process evaluation and improvement stage of ISO 15189:2012

Additional references (n = 101) that were found to provide further relevant information for the implementation of the PEI stage were identified (Table S3).

Table 1. Additional international organisations providing relevant guidance documents in support of the process evaluation and improvement stage of ISO 15189:2012.

<table>
<thead>
<tr>
<th>Organisations (n = 4)</th>
<th>Classification (Type A to Type F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooperative on International Traceability in Analytical Chemistry</td>
<td>F</td>
</tr>
<tr>
<td>Eurachem</td>
<td>F</td>
</tr>
<tr>
<td>European Committee for Electrotechnical Standardization</td>
<td>D</td>
</tr>
<tr>
<td>International Union of Pure and Applied Chemistry</td>
<td>B</td>
</tr>
</tbody>
</table>

Descriptions (1, pp. xiii-xii):

Type B: universal membership organisations: from either at least 60 countries or at least 30 countries in at least two continents and with a well-balanced geographical distribution; management and policy-making organs reflect a well-balanced geographical distribution;

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

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

DISCUSSION

Process evaluation and improvement stage of ISO 15189:2012

The PEI stage comprises Subclauses 4.8, 4.9, 4.10, 4.11, 4.12, 5.6.3 and 5.6.4 of ISO 15189:2012, containing 252/1515 (17 %) CRs. Additional international organisations (Table 1) were identified to provide further relevant guidance documents to support the implementation. The complete list of selected international organisations (Table S1), recommended guidance documents (Table S2) and additional resources (Table S3) that could support the PEI stage implementation are presented. It is highly recommended that this update is used in conjunction with the published updates (13,15).

Subclause 4.8 (Resolution of complaints) of ISO 15189:2012


Implications for internal auditors: the internal audit process must ensure all relevant records are maintained effectively.

Subclause 4.9 (Identification and control of nonconformities) of ISO 15189:2012

Subclause 4.9 of ISO 15189:2012 specifies that the medical laboratory must manage nonconformities in all aspects of the quality management system by the implementation of a documented procedure. Implications for implementers: no additional notes.

Implications for internal auditors: no additional notes.

Subclause 4.10 (Corrective action) of ISO 15189:2012

Subclause 4.10 of ISO 15189:2012 specifies that the medical laboratory must implement corrective action practices by the implementation of a documented procedure. Implications for implementers: no additional notes.

Implications for internal auditors: no additional notes.

Subclause 4.11 (Preventive action) of ISO 15189:2012

Subclause 4.11 of ISO 15189:2012 specifies that the medical laboratory must implement preventive action practices by the implementation of a documented procedure. Implications for implementers: no additional notes.

Implications for internal auditors: no additional notes.

Subclause 4.12 (Continual improvement) of ISO 15189:2012

Subclause 4.12 of ISO 15189:2012 specifies that the medical laboratory must participate in appropriate continual improvement activities pertaining to the quality management system effectiveness. Implications for implementers: no additional notes.

Implications for internal auditors: no additional notes.


Subclause 4.14 of ISO 15189:2012 specifies that the medical laboratory must implement evaluation and internal audit processes to ensure continuous conformity to the quality management system. Implications for implementers: the medical laboratory should take user feedback seriously, especially negative criticism (20,pp.422-423). User feedback can provide valuable insights into the medical laboratory’s performance, as specified in Subclause 4.14.3 (Assessment of user feedback) of ISO 15189:2012 (2,pp.16-17).
The medical laboratory must take reasonable steps to conduct risk management in consultation with the latest guidance [International Standard ISO 22367:2020 (21)], as specified in Subclause 4.14.6 (Risk management) of ISO 15189:2012 (2,p.17). Ways to eliminate or minimise the risk should be evaluated according to suitability and effectively implemented. Implications for implementers: the internal audit process must ensure all relevant practices are aligned with the latest auditing management guidance document [International Standard ISO 19011:2018 (22)], as specified in Subclause 4.14.5 (Internal audit) of ISO 15189:2012 (2,p.17). It is also important for the medical laboratory to employ suitably qualified internal auditors to conduct audits, as specified in Subclause 5.1.2 (Personnel qualifications) of ISO 15189:2012 (2,p.19).

Subclause 5.6.3 (Interlaboratory comparisons) of ISO 15189:2012 Subclause 5.6.3 of ISO 15189:2012 specifies that the medical laboratory must participate in interlaboratory comparison programmes appropriate to the examination process. Implications for implementers: the medical laboratory should consult a guide relating to selection and use of proficiency testing schemes for a limited number of participants (23) prepared by the International Union of Pure and Applied Chemistry and the Cooperative on International Traceability in Analytical Chemistry, if applicable. Implications for internal auditors: the internal audit process must ensure the performance of interlaboratory comparisons undergoes a review process with relevant staff.

Subclause 5.6.4 (Comparability of examination results) of ISO 15189:2012 Subclause 5.6.4 of ISO 15189:2012 specifies that the medical laboratory must conduct comparative analysis relating to examination results. Implications for implementers: no additional notes. Implications for internal auditors: no additional notes.

CONCLUSIONS This update has provided further references to support the implementation of the medical laboratory quality management system, especially in the PEI stage of ISO 15189:2012. The PEI stage implementation plays a vital role for the medical system, especially in the PEI stage of ISO 15189:2012. The implications for implementers, involving the internal audit process for audits, as specified in Subclause 5.1.2 (Internal audit) of ISO 15189:2012 (2,p.17). It is also important for the medical laboratory to employ suitably qualified internal auditors to conduct audits, as specified in Subclause 5.1.2 (Personnel qualifications) of ISO 15189:2012 (2,p.19).

REFERENCES


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