Conformity Evaluation of Afinion 2 Analyzer Maintainability: Compliance Practicality for Philippine National Standard PNS ISO 15189:2013 Accreditation

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ABSTRACT

Objectives. The implementation of Philippine National Standard PNS ISO 15189:2013 to support the medical laboratory to produce competent results is a recognised challenge. It is apparent that the approach of ensuring the equipment availability can be specifically optimised. No known research has focused on exploring on the conduct of conformity evaluation of Afinion 2 Analyzer maintainability for the PNS ISO 15189:2013 accredited medical laboratory. The aim of the current study was to develop a practical tool for the medical laboratory to support the internal audit process by determining the compliance status of Afinion 2 Analyzer maintainability.

Methods. The relevant conformance requirements in Clauses 4 (Management requirements) and 5 (Technical requirements) of PNS ISO 15189:2013, manufacturer requirements and specific requirements for accreditation from 70/101 (69%) accreditation bodies in 80/249 (32%) countries were identified as specific audit criteria for Afinion 2 Analyzer conformity evaluation checklists for the maintenance and reference equipment.

Results. This study identified a total of 44/1515 (2.9%) conformance requirements and 33/1515 (2.2%) conformance requirements was associated with the hardware and software component of Afinion 2 Analyzer, respectively in Clauses 4 and 5 of PNS ISO 15189:2013. In addition, manufacturer requirements (n = 5) were identified relating to preventive maintenance. Further, specific requirements for accreditation for maintenance of reference equipment were identified and selected from 13/75 (17%) accreditation bodies in 26/90 (29%) countries; together these requirements were used to develop conformity evaluation of Afinion 2 Analyzer checklists (n = 3) and an interpretation checklist.

Conclusion. The present study has offered a practical contribution to existing knowledge of PNS ISO 15189:2013 accreditation compliance management by providing the medical laboratory with a practicable tool to determine the conformity status of Afinion 2 Analyzer maintainability in accordance with PNS ISO 15189:2013 conformance requirements, manufacturer and specific requirements for accreditation.

Keywords: Afinion 2 Analyzer, ISO 15189:2012, management review, quality compliance, quality conformity, quality management

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INTRODUCTION

The pathology services industry provides critical diagnostic information for treatment of human disorders around the world. There is one approach that can be used by the medical laboratory to ensure the processes are producing competent results and that is to implement a relevant management system to support the operations, such as International Standard ISO 15189:2012[1] prepared by the International Organization for Standardization (ISO)[2] or country specific version Philippine National Standard PNS ISO 15189:2013[3] prepared by the Bureau of Product Standards that has the equivalent content of ISO 15189:2012. The medical laboratory can seek accreditation with the Philippine Accreditation Bureau if it is practical to align with current operations.

Organizations continue to face strategic challenges with the implementation of PNS ISO 15189:2013, which is characterized by a drain on resources to keep it functional.[4-8] The medical laboratory holding PNS ISO 15189:2013 accreditation is required to ensure the processes in the quality management system are in compliance with relevant conformance requirements (CReqs) of Clause 4 (Management requirements) of PNS ISO 15189:2013 and Clause 5 (Technical requirements) of PNS ISO 15189:2013. In terms of material management, a significant portion of resources must be allocated to material maintenance to sustain optimal equipment availability. The medical laboratory must do what is reasonably practicable to retain equipment in a task worthy condition while complying with relevant CReqs of PNS ISO 15189:2013. It is also apparent that it is technically difficult to apply a one-size-fits-all solution to address equipment maintainability; however, the medical laboratory can establish operationally feasible measures in the most efficient manner for each piece of equipment. This way the necessities of compliance and maintainability obligations can be managed.

The medical laboratory performs continual monitoring on its compliance level by conducting internal audits at planned intervals, as specified in Subclause 4.14.5 (Internal audit) of PNS ISO 15189:2013. It has been established ISO 15189:2012 contains 1515 CReqs[9] for the medical laboratory to fulfil and 64/1515 (4%) CReqs[10] were found to be associated with the conformity evaluation of generic equipment maintainability or same quantity of CReqs in the application of PNS ISO 15189:2013; however, exactly what is required to conduct a conformity evaluation of Afinion 2 Analyzer maintainability remains unelucidated, given that Afinion 2 Analyzer is a simple-to-operate and relatively easily maintained system. Moreover, the Afinion 2 Analyzer is a portable, fast, multi-assay platform that streamlines and makes it easier to offer reliable measurements at the point of care. The technology provides healthcare providers with the data they need to make quick and accurate medical decisions, allowing them to spend more time counselling patients within a single office visit. The goal of this study is to create a useful tool that the medical laboratory can use to help the internal audit procedure by assessing the maintainability of the Afinion 2 Analyzer's compliance. The development comprised of five steps. First, identification of relevant CReqs relating to Afinion 2 Analyzer maintenance according to PNS ISO 15189:2013. Second, identification of relevant CReqs relating to reference equipment that supports the operational requirements of the Afinion 2 Analyzer according to PNS ISO 15189:2013. Third, identification of relevant manufacturer requirements (MReqs) according to the operator's manual. Fourth, identification of relevant specific requirements for accreditation that relate to the Afinion 2 Analyzer and reference equipment according to accreditation guidance documents. Finally, checklists based on the CReqs, MReqs and specific requirements for accreditation were developed and the overall results were then summarised in a final interpretation checklist. The conformity evaluations of the Afinion 2 Analyzer maintainability checklists have been designed to provide the accredited medical laboratory with the means to ensure relevant requirements are fulfilled according to the quality management system specifications.

METHODS

Elicitation of conformance requirements relating to Afinion 2 Analyzer maintenance in accordance with Philippine National Standard PNS ISO 15189:2013

The technique of content analysis offers a reasonably practicable approach for analysing relevant requirements in PNS ISO 15189:2013,[9,10] International Standard ISO 22870:2016[11] prepared by the ISO and accreditation-related documents; therefore, content analysis was selected for the quantitative analysis of CReqs in Clauses 4 and 5 of PNS ISO 15189:2013. Relevant CReqs pertaining to the conformity evaluation of equipment were identified, as previously described.[12,13] It is important to note that laboratory equipment includes hardware and software of instruments, as specified in Subclause 5.3 (Laboratory equipment, reagents, and consumables) of PNS ISO 15189:2013.

Elicitation of conformance requirements relating to reference equipment maintenance in accordance with Philippine National Standard PNS ISO 15189:2013

The operational requirements of the Afinion 2 Analyzer require the use of relevant reference equipment to support the examination process. The reference equipment needs to be calibrated, as specified in Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of PNS ISO 15189:2013. Relevant CReqs pertaining to the conformity evaluation of reference equipment were identified, as previously described.[14]

Elicitation of specific requirements relating to Afinion 2 Analyzer maintenance in accordance with the operator's manual

Content analysis was used for the quantitative analysis of MReqs in the Afinion 2 Analyzer operator's manual prepared by Abbott Diagnostic Technologies.[15] More specifically, relevant information relating to maintenance, as specified in Subclause 7.10.10 (Maintenance of the supported product by non-skilled and skilled persons) of International Standard IEC/IEEE 82079-1:2019[16] prepared by the International Electrotechnical Commission (IEC) and the Institute of Electrical and Electronics Engineers, were extracted from the operator's manual.

Elicitation of specific requirements for accreditation relating to the Afinion 2 Analyzer and reference equipment maintenance in accordance with accreditation guidance documents

Relevant specific requirements for accreditation that relate to Afinion 2 Analyzer and reference equipment maintenance were identified from accreditation bodies that are conforming to International Standard ISO/IEC 17011:2017 prepared by the ISO and the IEC and are signatories to the International Laboratory Accreditation Cooperation (ILAC) mutual recognition arrangement and operating in recognised countries (n = 249), as specified in Subclause 6.1 (Specification for use) of International Standard ISO 3166-1:2020 prepared by the ISO, as previously described.[10,17-19]

Selection of graphical symbols for use in the development of conformity evaluation of Afinion 2 Analyzer maintainability checklists in accordance with International Standards IEC 60417:2002 DB and ISO 7000:2019

Relevant graphical symbols (n = 10) were selected from International Standard IEC 60417:2002 DB prepared by the IEC and International Standard ISO 7000:2019 prepared by the ISO, to present internationally representative information.[20,21] The following symbols were selected: ISO 7000-0632 (2014-06), ISO 7000-1640 (2004-01), ISO 7000-2620 (2004-01), ISO 7000-3650 (2009-04), ISO 7000-5662 (2002-10), IEC 60417-5009 (2015-03), IEC 60417-5031 (2002-10), IEC 60417-5664 (2002-10), IEC 60417-5988 (2006-09) and IEC 60417-6343 (2015-06). The calendar dates adjacent to graphical symbols [Symbol ISO 7000-5662 (2002-10)] were presented in the extended format, as specified in Subclause 5.2.2.1 b) of International Standard ISO 8601-1:2004 prepared by the ISO.[22]

Development of conformity evaluation of Afinion 2 Analyzer maintainability checklists

The Afinion 2 Analyzer, both hardware and software of the instrument, requires continual maintenance to ensure quality of examination results, as specified in Subclause 5.3.1.5 (Equipment maintenance and repair) of PNS ISO 15189:2013. To develop the checklists, all relevant information selected from maintenance-related CReqs (n = 64) from PNS ISO 15189:2013, the Afinion 2 Analyzer operator's manual, and specific requirements for accreditation from accreditation bodies that are signatories to the ILAC mutual recognition arrangement, were taken into consideration.[10] The Afinion 2 Analyzer is required to operate at specific environmental conditions to support its maintainability, as specified in Subclause 5.2.3 (Storage facilities) of PNS ISO 15189:2013. The conditions are required to be verified before use in examinations. The reference equipment used to assess the conditions of the testing environment need to be calibrated, as specified in Subclause 5.3.1.4 of PNS ISO 15189:2013. The following conditions need to be determined by reference equipment and should be expressed in alignment with the operator's manual. The temperature information should be expressed in degrees Celsius, as specified in Item 5-2 of International Standard ISO 80000-5:2019 prepared by the ISO, the relative humidity information should be expressed in percent, as specified in Item 5-33 of ISO 80000-5:2019 and the altitude information should be expressed in metres, as specified in Item 3-1.3 of International Standard ISO 80000-3:2019 prepared by the ISO.[23,24] Relevant calibration and environmental status information can be established from records, as previously described.[14]

RESULTS

Quantitation of conformance requirements for the conformity evaluation of Afinion 2 Analyzer maintainability in accordance with Philippine National Standard PNS ISO 15189:2013

Content analysis was used to identify relevant CReqs in Clauses 4 and 5 of PNS ISO 15189:2013. Specific CReqs (n = 64) relating to equipment conformity evaluation were identified.[10] By using the same specific CReqs as a model, a total of 44 CReqs were identified as relevant (Table 1) and used for conformity evaluation of Afinion 2 Analyzer (instrument hardware) maintainability and a total of 33 CReqs were identified as relevant (Table 2) and used for the conformity evaluation of Afinion 2 Analyzer (instrument software) maintainability.

Quantitation of conformance requirements for reference equipment maintenance in accordance with Philippine National Standard PNS ISO 15189:2013

Specific CReqs (n = 6) relating to reference equipment maintenance were identified.[14] By using the same specific CReqs as a model, a total of 18 CReqs were identified as relevant for reference equipment (n = 3) (Figure 1) and used to support the final interpretation.

Quantitation of manufacturer requirements for the conformity evaluation of Afinion 2 Analyzer maintainability in accordance with the operator's manual

Specific MReqs (n = 5) relating to the conformity evaluation of Afinion 2 Analyzer maintainability were identified from the Afinion 2 Analyzer operator's manual (Figure 1 and Table 3).[15] The identified MReqs were used to support the conformity evaluation.

Quantitation of specific requirements for accreditation for the conformity evaluation of Afinion 2 Analyzer and reference equipment maintainability in accordance with accreditation guidance documents

A total of 75/104 (72%) accreditation bodies in 90/249 (36%) countries were identified as ILAC mutual recognition arrangement signatories to PNS ISO 15189:2013;[18] of these, 62/75 (83%) accreditation bodies in 64/90 (71%) countries have not expressed any specific requirements for

Table 1. The conformance requirement frequency relating to the conformity evaluation of Afinion 2 Analyzer (instrument hardware) maintainability according to Philippine National Standard PNS ISO 15189:2013

Relevant contents of Philippine National Standard PNS ISO 15189:2013 (n = 7)	Frequency (n = 44)
Subclause 4.13 (Control of records) of PNS ISO 15189:2013 Records shall include, at least, the following: i) instrument maintenance records, including internal and external calibration records; k) quality control records;	2/44 (4.5%)*
Subclause 5.2.1 (General) of PNS ISO 15189:2013 The laboratory shall have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors.	8/44 (18.2%)†
Subclause 5.2.3 (Storage facilities) of PNS ISO 15189:2013 Storage space and conditions shall be provided that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results.	2/44 (4.5%)‡
Subclause 5.3.1.2 (Equipment acceptance testing) of PNS ISO 15189:2013 Each item of equipment shall be uniquely labelled, marked or otherwise identified.	1/44 (2.3%)
Subclause 5.3.1.5 (Equipment maintenance and repair) of PNS ISO 15189:2013 Equipment shall be maintained in a safe working condition and in working order. This shall include examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. At a minimum, manufacturer's schedules or instructions, or both, shall be used.	7/44 (15.9%)§
Subclause 5.3.1.7 (Equipment records) of PNS ISO 15189:2013 Records shall be maintained for each item of equipment that contributes to the performance of examinations. These equipment records shall include, but not be limited to, the following: a) identity of the equipment. b) manufacturer's name, model and serial number or other unique identification. c) contact information for the supplier or the manufacturer. d) date of receiving and date of entering into service; e) location; f) condition when received; g) manufacturer's instructions; h) records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory; i) maintenance carried out and the schedule for preventive maintenance; j) equipment performance records that confirm the equipment's ongoing acceptability for use; k) damage to, or malfunction, modification, or repair of the equipment. The performance records referred to in j) shall include copies of reports/certificates of all calibrations and/or verifications including dates, times and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, to fulfil part or all of this requirement. These records shall be maintained and shall be readily available for the lifespan of the equipment or longer, as specified in the laboratory's Control of Records procedure.	24/44 (54.5%)**
Total	**44/44 (100%)**

* *CReqs relating to calibration were not selected for inclusion.*

† *Only CReqs for the health and safety of laboratory personnel and visitors were selected for inclusion.*

‡ *Only CReqs for space and conditions relating to equipment were selected for inclusion.*

§ *The power supply unit is a separate component of instrument hardware, therefore the examination of electrical safety requirement was not selected for inclusion; the instrument is not equipped with an emergency stop device, therefore the examination of emergency stop devices requirement was not selected for inclusion; and the safe handling and disposal of radioactive materials by authorised persons requirements were not selected for inclusion.*

** *CReqs relating to calibration were not selected for inclusion.*

Afinion 2 Analyzer maintenance (Table 4), but 13/75 (17%) accreditation bodies in 26/90 (29%) countries have expressed specific requirements for reference equipment calibration and intermediate check (Figure 2 and Table 4).

Summary of special considerations for the conformity evaluation of Afinion 2 Analyzer and reference equipment maintainability

Special considerations were summarised in accordance with the conformity evaluation of Afinion 2 Analyzer maintainability (Figure 3).

Graphical symbols for conformity evaluation of Afinion 2 Analyzer maintainability checklists in accordance with International Standards IEC 60417:2002 DB and ISO 7000:2019

Selected symbols (n = 10) were used in checklists to support the transmission of information (Figures 2 to 7).

Conformity evaluation of Afinion 2 Analyzer maintainability checklists

The conformity evaluation checklists (n = 3) were developed to support the conformity evaluation. First,

Table 2. The conformance requirement frequency relating to the conformity evaluation of Afinion 2 Analyzer (instrument software) maintainability according to Philippine National Standard PNS ISO 15189:2013

Relevant contents of Philippine National Standard PNS ISO 15189:2013 (n = 5)	Frequency (n = 33)
Subclause 4.3 (Document control) of PNS ISO 15189:2013 The laboratory shall control documents required by the quality management system and shall ensure that unintended use of any obsolete document is prevented. The laboratory shall have a documented procedure to ensure that the following conditions are met. c) Current authorized editions and their distribution are identified by means of a list (e.g., document register, log or master index).	4/33 (12.1%)††
Subclause 4.13 (Control of records) of PNS ISO 15189:2013 Records shall include, at least, the following: i) instrument maintenance records, including internal and external calibration records; k) quality control records;	2/33 (6.1%)‡‡
Subclause 5.3.1.2 (Equipment acceptance testing) of PNS ISO 15189:2013 Each item of equipment shall be uniquely labelled, marked or otherwise identified.	1/33 (3.0%)
Subclause 5.3.1.5 (Equipment maintenance and repair) of PNS ISO 15189:2013 Equipment shall be maintained in a safe working condition and in working order. This shall include examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. At a minimum, manufacturer's schedules or instructions, or both, shall be used.	2/33 (6.1%)§§
Subclause 5.3.1.7 (Equipment records) of PNS ISO 15189:2013 Records shall be maintained for each item of equipment that contributes to the performance of examinations. These equipment records shall include, but not be limited to, the following: a) identity of the equipment; b) manufacturer's name, model and serial number or other unique identification; c) contact information for the supplier or the manufacturer; d) date of receiving and date of entering into service; e) location; f) condition when received; g) manufacturer's instructions; h) records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory; i) maintenance carried out and the schedule for preventive maintenance; j) equipment performance records that confirm the equipment's ongoing acceptability for use; k) damage to, or malfunction, modification, or repair of the equipment. The performance records referred to in j) shall include copies of reports/certificates of all calibrations and/or verifications including dates, times and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, to fulfil part or all of this requirement. These records shall be maintained and shall be readily available for the lifespan of the equipment or longer, as specified in the laboratory's Control of Records procedure.	24/33 (72.7%)***
Total	**33/33 (100%)**

†† *Subclause 4.3 (Document control) of Philippine National Standard PNS ISO 15189:2013 is applicable to laboratory equipment that incorporates software to support the operational process. Software that bears a version number required by the medical laboratory quality management system must be subject to document control. The term 'version' has been defined by the ISO and the IEC as a 'unique string of number and letter values indicating a unique revision of an item' in Item 3.54 of International Standard ISO/IEC 19770-5:2015.[25] It is also important to note that the obsolete version becomes unavailable automatically during the upgrade, therefore the ensurance requirement was not selected for inclusion.*

‡‡ *Only CReqs for instrument maintenance records and quality control records relating to software of instrument were selected for inclusion.*

§§ *Only CReqs for working order maintenance and the use of manufacturer's schedules or instructions were selected for inclusion.*

*** *CReqs relating to calibration were not selected for inclusion.*

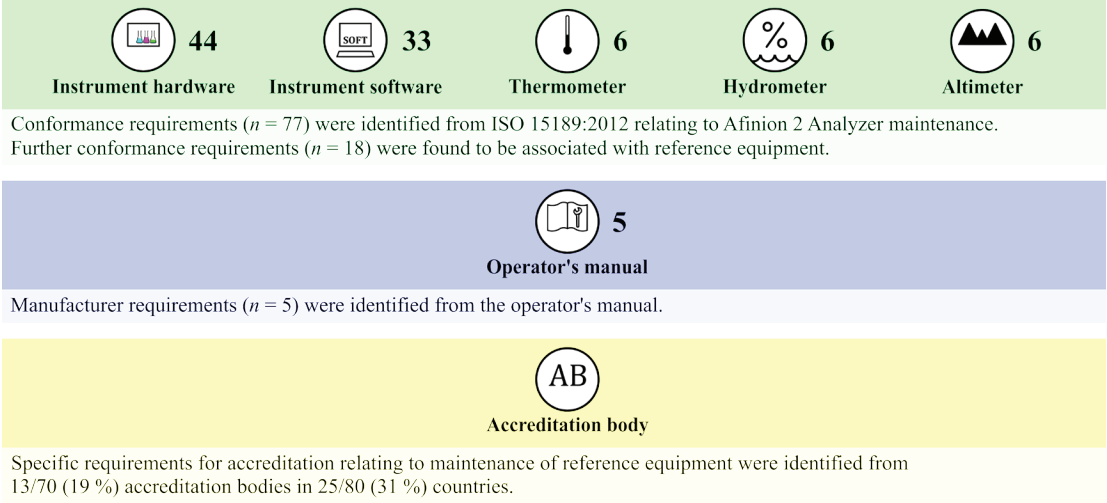

Figure 1. The frequency of requirements relating to the conformity evaluation of Afinion 2 Analyzer maintainability. The Afinion 2 Analyzer, including hardware and software of the instrument, has relevant conformance requirements (*n* = 79) for implementation. The relevant conformance requirements were elicited from Philippine National Standard PNS ISO 15189:2013. In addition, relevant manufacturer requirements (*n* = 5) for maintenance were also elicited from the operator's manual. Moreover, relevant conformance requirements (*n* = 18) were also elicited from Philippine National Standard PNS ISO 15189:2013 relating to maintenance of reference equipment. Finally, specific requirements for accreditation relating to maintenance of these reference equipment were also identified from 13/70 (19%) accreditation bodies that are signatories to the International Laboratory Accreditation Cooperation mutual recognition arrangement.

Table 3. The manufacturer requirement frequency relating to the conformity evaluation of Afinion 2 Analyzer maintainability according to the operator's manual

Relevant contents of the Afinion 2 Analyzer operator's manual (*n* = 4)	Frequency (*n* = 5)
No maintenance of the Afinion 2 Analyzer is required other than cleaning the exterior and cartridge chamber.	2/5 (40%)†††
15-32°C	1/5 (20%)‡‡‡
10-80%, non-condensing	1/5 (20%)‡‡‡
Max 4000 MASL	1/5 (20%)‡‡‡
Total	**5/5 (100%)**

††† *Routine maintenance requirements to support maintenance of Afinion 2 Analyzer in working order, as specified in Subclause 5.3.1.5 (Equipment maintenance and repair) of Philippine National Standard PNS ISO 15189:2013.*

‡‡‡ *Environmental conditions during operations to support maintenance in a safe working condition, as specified in Subclause 5.3.1.5 (Equipment maintenance and repair) of Philippine National Standard PNS ISO 15189:2013.*

the conformity evaluation of the Afinion 2 Analyzer maintainability checklist for non-technical inspection was developed based primarily on Subclause 5.3.1.5 (Equipment maintenance and repair) of PNS ISO 15189:2013. The Afinion 2 Analyzer non-technical inspection evaluated the Afinion 2 Analyzer functionality by non-skilled personnel (Figure 4), as specified in Subclause 7.10.10.2 (Maintenance by non-skilled persons) of IEC/IEEE 82079-1:2019.[16] The information provided could support the implementation of Subclause 5.3.1.5 of PNS ISO 15189:2013. Second, the conformity evaluation of Afinion 2 Analyzer (instrument hardware) maintainability checklist was developed based primarily on the relevant CReqs (*n* = 44) identified in this analysis (Figure 5). Third, the conformity evaluation of Afinion 2 Analyzer (instrument software) maintainability checklist was developed based primarily on the relevant CReqs (*n* = 33) identified in this analysis (Figure 6).

Summary of results for the conformity evaluation of Afinion 2 Analyzer maintainability

The final results were summarised in accordance with the conformity evaluation of Afinion 2 Analyzer maintainability checklists (Figures 5 and 6). The summary of results can be presented in an interpretation checklist (Figure 7).

DISCUSSION

The present study aimed to develop a practical measure and to determine whether the conformity status of Afinion 2 Analyzer maintainability was at an acceptable level for a medical laboratory claiming compliance to PNS ISO 15189:2013. The results of this study indicate that by using the specific CReqs (*n* = 64) relating to equipment conformity evaluation as a model, a reasonable measure could be developed for

the determination of Afinion 2 Analyzer maintainability compliance according to PNS ISO 15189:2013.[10] The most compelling finding is that by using the relevant CReqs (n = 77), MReqs (n = 5) and specific requirements for accreditation from 13/70 (19%) accreditation bodies relating to maintenance of reference equipment, a specific measure for determination of maintainability relating to compliance practicality for PNS ISO 15189:2013 could be structurally defined. Such a measure has the potential to provide valuable support in PNS ISO 15189:2013 implementation, especially to Subclause 4.14.5 of PNS ISO 15189:2013. Overall, the developed checklists could support the medical laboratory in maintaining internal audit effectiveness and efficiency.

The use of conformity evaluation of Afinion 2 Analyzer maintainability checklists has three technical considerations that need to be considered by the internal auditor. First, the internal auditor should ensure the alarm serviceability is acceptable at all times.[48] The audible signal that provides

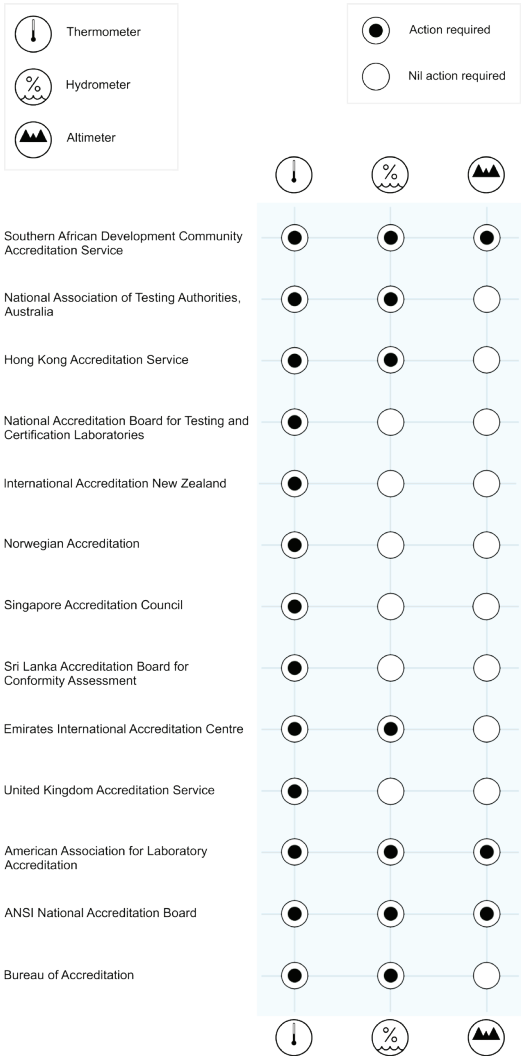

Figure 2. Specific requirements for accreditation analysis of calibration and intermediate check of thermometer, hydrometer [Symbol ISO 7000-1640 (2004-01)] and altimeter. Specific requirements relating to maintenance are provided by 13/70 (19%) accreditation bodies in 25/80 (31%) countries.

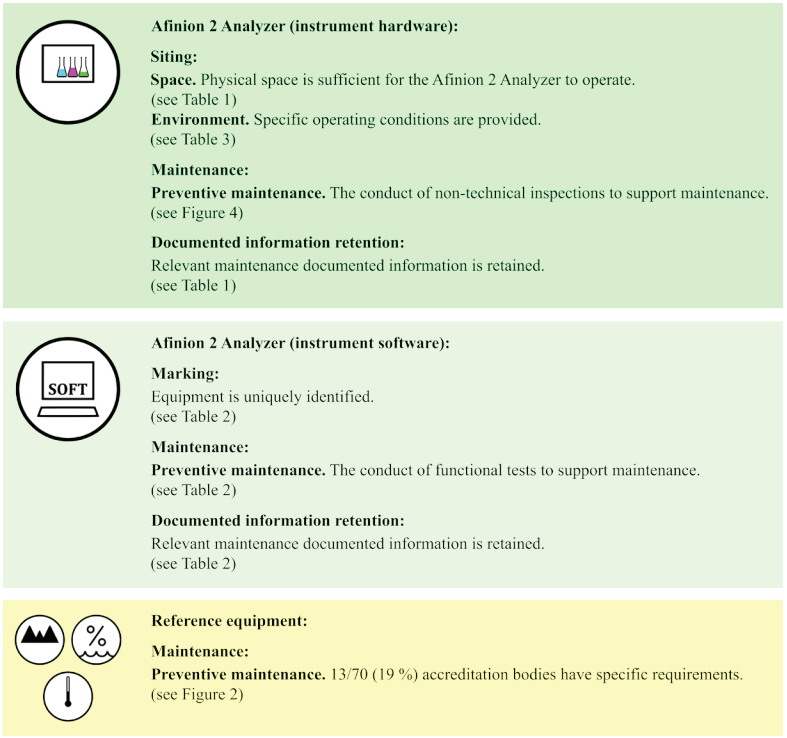

Figure 3. Summary of special considerations for the conformity evaluation of Afinion 2 Analyzer maintainability. For the Afinion 2 Analyzer (instrument hardware), the medical laboratory needs to provide relevant physical space (Table 1) with specified environmental conditions (Table 3) during operations. The instrument hardware is to be uniquely labelled or identified (Table 1). The instrument hardware does not require regular calibration by the medical laboratory, therefore relevant calibration information from Abbott Diagnostics Technologies is to be audited for its currency. The conduct of non-technical inspections can also provide support to the program of preventive maintenance. Finally, relevant maintenance documented information is to be retained (Table 1). For the Afinion 2 Analyzer (instrument software), the medical laboratory needs to ensure it is uniquely identified (Table 2). The conduct of functional tests can provide support to the program of preventive maintenance. Finally, relevant maintenance documented information is to be retained (Table 2). For the reference equipment, the medical laboratory is required to identify the specific requirements for accreditation from the relevant accreditation body (Figure 2).

Table 4. Specific requirements for accreditation in relation to the Afinion 2 Analyzer maintainability provided by signatory members (*n* = 13) of the International Laboratory Accreditation Cooperation mutual recognition arrangement

Countries (*n* = 26)	Relevant specific requirements for accreditation (*n* = 13)
Angola ***Botswana*** ***Comoros*** ***Congo*** ***Lesotho*** ***Madagascar*** ***Malawi*** ***Mozambique*** ***Namibia*** ***Seychelles*** ***Swaziland*** ***Tanzania*** ***Zambia*** ***Zimbabwe***	In Angola (AGO), Botswana (BWA), Comoros (COM), Congo (COD), Lesotho (LSO), Madagascar (MDG), Malawi (MWI), Mozambique (MOZ), Namibia (NAM), Seychelles (SYC), Swaziland (SWZ), Tanzania (TZA), Zambia (ZMB), and Zimbabwe (ZWE), the Southern African Development Community Accreditation Service (SADCAS) does not provide any specific requirements in relation to the use of equipment that affects the use of Afinion 2 Analyzer;[26] therefore, relevant requirements of International Standard ISO 15189:2012 [Clause 4 (Management requirements) of International Standard ISO 15189:2012 and Clause 5 (Technical requirements) of International Standard ISO 15189:2012] apply for accreditation. SADCAS specifies requirements in relation to the maintenance of altimeter (calibration and check), hydrometer (calibration and check) and thermometer (calibration and check) for accreditation purposes.[27] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions [Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012], including recommended calibration information [Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012], for implementation.[16]
Australia	In Australia (AUS), the National Association of Testing Authorities, Australia (NATA) does not provide any specific requirements in relation to equipment that affects the use of Afinion 2 Analyzer;[28] therefore, relevant requirements of Australian Standard AS ISO 15189—2013 [Clause 4 (Management requirements) of Australian Standard AS ISO 15189—2013 and Clause 5 (Technical requirements) of Australian Standard AS ISO 15189—2013] apply for accreditation.[29] NATA specifies requirements in relation to the maintenance of hydrometer [interval-specific calibration and interval-specific check] and thermometer [interval-specific calibration and interval-specific check], excluding altimeter, for accreditation purposes.[30] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions [Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012], including recommended calibration information [Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012], for implementation.[16]
Hong Kong	In Hong Kong (HKG), the Hong Kong Accreditation Service (HKAS) does not provide any specific requirements in relation to the use of equipment that affects the use of Afinion 2 Analyzer.[31] HKAS specifies recommendations in relation to the maintenance of hydrometer (interval-specific calibration) and thermometer (interval-specific calibration and interval-specific check), excluding altimeter, for accreditation purposes.[32] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions, including recommended calibration information, for implementation.[16]
India	In India (IND), the National Accreditation Board for Testing and Certification Laboratories (NABL) specifies requirements in relation to the use of equipmen that affects the use of Afinion 2 Analyzer;[33] in addition, the medical laboratory should identify relevant requirements of International Standard ISO 15189:2012 [Clause 4 (Management requirements) of International Standard ISO 15189:2012 and Clause 5 (Technical requirements) of International Standard ISO 15189:2012] for implementation. NABL specifies requirements in relation to the maintenance of thermometer (interval-specific calibration), excluding altimeter and hydrometer, for accreditation purposes.[33] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions [Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012], including recommended calibration information [Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012], for implementation.[16]
New Zealand	In New Zealand (NZL), the International Accreditation New Zealand (IANZ) does not provide any specific requirements in relation to the use of lateral flow immunochromatography that affects the use of Afinion 2 Analyzer;[34] therefore, relevant requirements of International Standard ISO 15189:2012 [Clause 4 (Management requirements) of International Standard ISO 15189:2012 and Clause 5 (Technical requirements) of International Standard ISO 15189:2012] apply for accreditation. IANZ specifies requirements in relation to the maintenance of thermometer (interval-specific calibration and interval-specific check), excluding altimeter and hydrometer, for accreditation purposes.[34] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions [Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012], including recommended calibration information [Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012], for implementation.[16]

Table 4. Specific requirements for accreditation in relation to the Afinion 2 Analyzer maintainability provided by signatory members (*n* = 13) of the International Laboratory Accreditation Cooperation mutual recognition arrangement *(continued)*

Countries (*n* = 26)	Relevant specific requirements for accreditation (*n* = 13)
Norway	In Norway (NOR), Norwegian Accreditation does not provide any specific requirements in relation to the use of equipment that affects the use of Afinion 2 Analyzer;[35] therefore, relevant requirements of Norwegian Standard NS-EN ISO 15189:2012 [Clause 4 (Management requirements) of Norwegian Standard NS-EN ISO 15189:2012 and Clause 5 (Technical requirements) of Norwegian Standard NS-EN ISO 15189:2012] apply for accreditation.[36] Norwegian Accreditation specifies requirements in relation to the maintenance of thermometer (interval-specific calibration and interval-specific check), excluding altimeter and hydrometer, for accreditation.[37] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions [Subclause 5.3.1.5 (Equipment maintenance and repair) of Norwegian Standard NS-EN ISO 15189:2012], including recommended calibration information [Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of Norwegian Standard NS-EN ISO 15189:2012], for implementation.[16,36]
Singapore	In Singapore (SGP), the Singapore Accreditation Council specifies requirements in relation to the use of equipment that affects the use of Afinion 2 Analyzer; therefore, relevant requirements of International Standard ISO 15189:2012 [Clause 4 (Management requirements) of International Standard ISO 15189:2012 and Clause 5 (Technical requirements) of International Standard ISO 15189:2012] apply for accreditation. Singapore Accreditation Council specifies recommendations in relation to the maintenance of thermometer (interval-specific check), excluding altimeter and hydrometer, for accreditation purposes.[38] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions [Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012], including recommended calibration information [Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012], for implementation.[16]
Sri Lanka	In Sri Lanka (LKA), the Sri Lanka Accreditation Board for Conformity Assessment (SLAB) does not provide any specific requirements in relation to the use of equipment that affects the use of Afinion 2 Analyzer;[39] therefore, relevant requirements of International Standard ISO 15189:2012 [Clause 4 (Management requirements) of International Standard ISO 15189:2012 and Clause 5 (Technical requirements) of International Standard ISO 15189:2012] apply for accreditation. SLAB specifies requirements in relation to the maintenance of thermometer (interval-specific calibration and interval-specific check), excluding altimeter and hydrometer, for accreditation purposes.[39] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions [Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012], including recommended calibration information [Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012] for implementation.[16]
United Arab Emirates	In the United Arab Emirates (ARE), the Emirates International Accreditation Centre (EIAC) does not any specific requirements in relation to the use of equipment[40] that affects the use of Afinion 2 Analyzer; therefore, relevant requirements of International Standard ISO 15189:2012 [Clause 4 (Management requirements) of International Standard ISO 15189:2012 and Clause 5 (Technical requirements) of International Standard ISO 15189:2012] apply for accreditation. EIAC specifies requirements in relation to the maintenance of hydrometer (interval-specific calibration) and thermometer (interval-specific calibration), excluding altimeter, for accreditation purposes.[40] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions [Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012], including recommended calibration information [Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012], for implementation.[16]
United Kingdom	In the United Kingdom (GBR), the United Kingdom Accreditation Service (UKAS) does not provide any specific requirements in relation to the use of equipment that affects the use of Afinion 2 Analyzer;[41] therefore, relevant requirements of British Standard BS EN ISO 15189:2012 [Clause 4 (Management requirements) of British Standard BS EN ISO 15189:2012 and Clause 5 (Technical requirements) of British Standard BS EN ISO 15189:2012] apply for accreditation.[42] UKAS specifies requirements in relation to the maintenance of thermometer (interval-specific calibration and interval-specific check), excluding altimeter and hydrometer, for accreditation purposes.[41,43] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions [Subclause 5.3.1.5 (Equipment maintenance and repair) of British Standard BS EN ISO 15189:2012], including recommended calibration information [Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of British Standard BS EN ISO 15189:2012], for implementation.[16,42]

Table 4. Specific requirements for accreditation in relation to the Afinion 2 Analyzer maintainability provided by signatory members (*n* = 13) of the International Laboratory Accreditation Cooperation mutual recognition arrangement *(continued)*

Countries (*n* = 26)	Relevant specific requirements for accreditation (*n* = 13)
United States	In the United States (USA), the American Association for Laboratory Accreditation (A2LA) does not provide any specific requirements in relation to the use of equipment that affects the use of Afinion 2 Analyzer;[44] therefore, relevant requirements of International Standard ISO 15189:2012 [Clause 4 (Management requirements) of International Standard ISO 15189:2012 and Clause 5 (Technical requirements) of International Standard ISO 15189:2012] apply for accreditation. A2LA specifies requirements in relation to the maintenance of altimeter (calibration), hydrometer (calibration) and thermometer (calibration) for accreditation purposes.[45] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions [Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012], including recommended calibration information [Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012], for implementation.[16]
United States	In the United States (USA), the ANSI National Accreditation Board (ANAB) does not provide any specific requirements in relation to the use of equipment that affects the use of Afinion 2 Analyzer;[46] therefore, relevant requirements of International Standard ISO 15189:2012 [Clause 4 (Management requirements) of International Standard ISO 15189:2012 and Clause 5 (Technical requirements) of International Standard ISO 15189:2012] apply for accreditation. ANAB specifies requirements in relation to the maintenance of altimeter (calibration), hydrometer (calibration) and thermometer (calibration) for accreditation purposes.[46] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions [Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012], including recommended calibration information [Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012], for implementation.[16]
Viet Nam	In Viet Nam (VNM), the Bureau of Accreditation does not provide any specific requirements in relation to the use of equipment that affects the use of Afinion 2 Analyzer;[47] therefore, relevant requirements of International Standard ISO 15189:2012 [Clause 4 (Management requirements) of International Standard ISO 15189:2012 and Clause 5 (Technical requirements) of International Standard ISO 15189:2012] apply for accreditation. Bureau of Accreditation specifies requirements in relation to the maintenance of hydrometer (interval-specific calibration and interval-specific check) and thermometer (interval-specific calibration and interval-specific check), excluding altimeter, for accreditation purposes.[47] In addition, the medical laboratory should identify relevant maintenance information [Subclause 7.10.10.3 (Maintenance by skilled persons) of International Standard IEC/IEEE 82079-1:2019] from the manufacturer's instructions [Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO 15189:2012], including recommended calibration information [Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of International Standard ISO 15189:2012], for implementation.[16]

condition monitoring alerts and equipment fault status can be critical to the safety of operator; therefore it is necessary to ensure its serviceability by checking the functionality during the functional test and the volume level should also meet the medical laboratory specifications.[15] Equipment must be operated in perfect working order at all times, as specified in Subclause 5.3.1.5 of PNS ISO 15189:2013. Second, the internal auditor should seek information from the manufacturer relating to calibration. The Afinion 2 Analyzer is calibrated by the manufacturer prior to release and further calibration by the medical laboratory is not specified, therefore relevant records of calibration should be obtained from the manufacturer to fulfil relevant CReqs, as specified in Subclauses 5.3.1.4 and 5.3.1.7 of PNS ISO 15189:2013. The retention of all manufacturer's documentation as records is also a specific document retention requirement applicable to equipment maintenance matter, as specified in Subclause 4.13 i) of PNS ISO 15189:2013, and this can support the retention of manufacturer's documentation requirement, as specified in Subclause 13.1 (General considerations) of International Standard ISO 15190:2020 prepared by the ISO.[49] Third, the internal auditor may need to compile information from various resources to fulfil relevant CReqs of performance records showing continuous acceptability for use, as specified in Subclause 5.3.1.7 j) of PNS ISO 15189:2013. It is important to note that performance records are not necessarily verification records; therefore, the internal auditor may need to work with laboratory personnel to seek information from various places.

In addition to the technical considerations, there are two potential areas that are likely to add value to the medical laboratory by using the developed checklists. The first area is the enhancement of preventive maintenance activities by ensuring Afinion 2 Analyzer is in a committable and operable state. A documented program of preventive maintenance for equipment is required to be implemented, as specified in Subclause 5.3.1.5 of PNS ISO 15189:2013 and Subclause 13.1 of ISO 15190:2020. An effective preventive maintenance program can ensure equipment can produce technically competent results and support safety of laboratory personnel.[50] The information may be a valuable source of input to the laboratory management that performs management reviews at planned intervals, as specified in Subclause 4.15.2 (Review input) of PNS ISO 15189:2013.[51] The second area

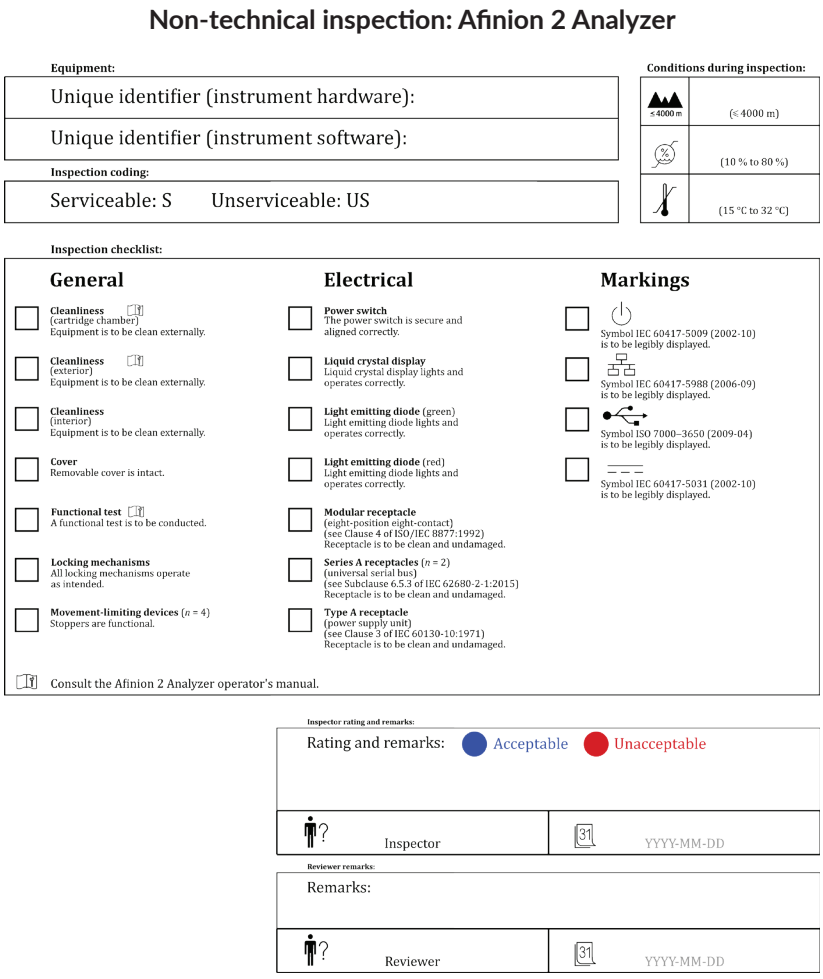

Figure 4. Conformity evaluation of Afinion 2 Analyzer maintainability checklist for non-technical inspection.

Note. The box entitled 'Equipment' requires the inspector to enter the following information: unique identifier (instrument hardware) and unique identifier (instrument software), in the relevant areas.

The box entitled 'Conditions during inspection' requires the inspector to enter the following information from reference equipment: 'Maximum altitude' [Symbol IEC 60417-6343 (2015-06)], 'Relative humidity limit' [Symbol ISO 7000-2620 (2004-01)] and 'Temperature limit' [Symbol ISO 7000-0632 (2014-06)], in the relevant areas.

The box entitled 'Inspection checklist' requires the inspector to indicate the inspection code of either 'S' or 'US'.

The box entitled 'Inspector rating and remarks' requires the inspector to indicate the rating of either 'Acceptable' or 'Unacceptable', to provide remarks, to provide the inspector's 'Person identification' [Symbol IEC 60417-5664 (2002-10)] and the 'Date' [Symbol ISO 7000-5662 (2002-10)] that the inspection was performed.

The box entitled 'Reviewer remarks' requires the reviewer to provide remarks, the reviewer's 'Person identification' and the 'Date' that the review was performed.

is the identification of potential maintenance constraints in relation to Afinion 2 Analyzer routine maintenance in the medical laboratory. The use of a structural approach is highly likely to enhance the situational awareness of laboratory personnel.[52] The information may also be valuable for the support of training of laboratory personnel who are required to perform the maintenance tasks, as specified in Subclause 7.2.2 (Training) of IEC 60300-3-14:2004 prepared by the IEC, to conduct internal audits, as specified in Subclause 4.14.5 of PNS ISO 15189:2013, and may be required to demonstrate specific competence appropriate for the audit, as specified in Subclause 7.2.3.3 (Discipline and sector-specific competence of auditors) of International Standard ISO 19011:2018 prepared by the ISO as well as for becoming Afinion 2 Analyzer operators, as specified in Subclause 5.3.1.3 of PNS ISO 15189:2013.[53,54]

CONCLUSION

This study set out to develop a practical tool for PNS ISO 15189:2013 accredited medical laboratories to determine the conformity status of Afinion 2 Analyzer maintainability to ensure maintenance activities conform to the relevant CReqs, MReqs and specific requirements for accreditation. With the close support of this, the medical laboratory personnel should be able to interpret examination data and present reports competently to users.[55] An implication of this is that it is possible for a preventive maintenance program to ensure Afinion 2 Analyzer can increase equipment availability and produce technically reliable examinations. This study appears to be the first study to provide a new understanding of equipment maintainability evaluation in the context of PNS ISO 15189:2013 implementation. The implementation of checklists may lead the medical laboratory to identify information that laboratory personnel need for the task of supporting an effective internal audit process and an audit-ready medical laboratory. The information may also be a valuable source of input to the training contents of laboratory personnel. In sum, enhancement of technical skills and information resources are likely to be achieved. The present research has resulted in the development of a reasonably practicable solution for conformity evaluation relating to Afinion 2 Analyzer maintainability in PNS ISO 15189:2013 accredited medical laboratories.

Conformity evaluation: Afinion 2 Analyzer *(instrument hardware)*

4.13 Control of records

☑ Records of maintenance: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of verification:: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

5.2.1 General

☑ Relevant physical space: **Objective evidence** Audited space	Conformant Non-Conformant
☑ Relevant physical space to ensure the quality of operations: **Objective evidence** Audited space	Conformant Non-Conformant
☑ Relevant physical space to ensure the safety of operations: **Objective evidence** Audited space	Conformant Non-Conformant
☑ Relevant physical space to ensure the efficacy of operations: **Objective evidence** Audited space	Conformant Non-Conformant
☑ Relevant physical space to ensure the health of laboratory personnel: **Objective evidence** Audited space	Conformant Non-Conformant
☑ Relevant physical space to ensure the safety of laboratory personnel: **Objective evidence** Audited space	Conformant Non-Conformant
☑ Relevant physical space to ensure the health of visitors: **Objective evidence** Audited space	Conformant Non-Conformant
☑ Relevant physical space to ensure the safety of visitors: **Objective evidence** Audited space	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

5.2.3 Storage facilities

☑ Relevant physical space (storage): **Objective evidence** Audited space	Conformant Non-Conformant
☑ Relevant environmental conditions (storage): **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

5.3.1.2 Equipment acceptance testing

☑ Equipment is identified: **Objective evidence** Audited marking(s) (unique identifier)	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

Figure 5. Conformity evaluation of Afinion 2 Analyzer (instrument hardware) maintainability checklist according to Philippine National Standard PNS ISO 15189:2013.

Note. The box entitled '4.13 Control of records' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide the internal auditor's 'Person identification' [Symbol IEC 60417-5664 (2002-10)] and the 'Date' [Symbol ISO 7000-5662 (2002-10)] that the conformity evaluation was performed.

The box entitled '5.2.1 General' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide the internal auditor's 'Person identification' and the 'Date' that the conformity evaluation was performed.

The box entitled '5.2.3 Storage facilities' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide the internal auditor's 'Person identification' and the 'Date' that the conformity evaluation was performed.

5.3.1.5 Equipment maintenance and repair

☑ Equipment is maintained in a safe working condition: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Equipment is maintained in working order: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Safe handling of chemical materials by authorised laboratory personnel: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Safe disposal of chemical materials by authorised laboratory personnel: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Safe handling of biological materials by authorised laboratory personnel: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Safe disposal of biological materials by authorised laboratory personnel: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Equipment is maintained according to manufacturer's instructions: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

5.3.1.7 Equipment records

☑ Maintainance of records relating to the contribution to the performance of examinations: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing identity of the equipment: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing manufacturer's name or unique identifier: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing model number or unique identifier: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing serial number or unique identifier: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing supplier or manufacturer contact information: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing date of receiving the equipment: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing date of entering into service: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing location: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing condition when received: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of manufacturer's instructions: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of equipment's initial acceptability for use: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of maintenance: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of preventive maintenance schedule: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of performance relating to the acceptability for use: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of damage, malfunction, modification or repair of the equipment: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

Figure 5. Conformity evaluation of Afinion 2 Analyzer (instrument hardware) maintainability checklist according to Philippine National Standard PNS ISO 15189:2013. *(continued)*

5.3.1.7 Equipment records

☑ Records of verification showing dates: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of verification showing times: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of verification showing results: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of verification showing adjustments: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of verification showing the acceptance criteria: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of verification showing due date of the next verification: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Maintenance of records according to the laboratory's documented procedure: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Availability of records according to the laboratory's documented procedure: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

Internal auditor rating and remarks:

Rating and remarks: Conformant Non-Conformant

Internal auditor | YYYY-MM-DD

Reviewer remarks:

Reviewer | YYYY-MM-DD

Figure 5. Conformity evaluation of Afinion 2 Analyzer (instrument hardware) maintainability checklist according to Philippine National Standard PNS ISO 15189:2013. *(continued)*

Conformity evaluation: Afinion 2 Analyzer *(instrument hardware)*

4.3 Document control

☑ Software is controlled: **Objective evidence** Audited system	Conformant Non-Conformant
☑ Software is controlled by a documented procedure: **Objective evidence** Audited procedure (unique identifier)	Conformant Non-Conformant
☑ A list containing current authorisied editions: **Objective evidence** Audited list (unique identifier)	Conformant Non-Conformant
☑ A list containing distribution of current authorisied editions: **Objective evidence** Audited list (unique identifier)	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

4.13 Control of records

☑ Records of maintenance: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of verification: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

5.3.1.2 Equipment acceptance testing

☑ Equipment is identified: **Objective evidence** Audited marking(s) (unique identifier)	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

5.3.1.5 Equipment maintenance and repair

☑ Equipment is maintained in working order: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Equipment is maintained according to manufacturer's insutructions: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

Figure 6. Conformity evaluation of Afinion 2 Analyzer (instrument software) maintainability checklist according to Philippine National Standard PNS ISO 15189:2013.

Note. The box entitled '4.3 Document control' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide the internal auditor's 'Person identification' [Symbol IEC 60417-5664 (2002-10)] and the 'Date' [Symbol ISO 7000-5662 (2002-10)] that the conformity evaluation was performed.

The box entitled '4.13 Control of records' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide the internal auditor's 'Person identification' and the 'Date' that the conformity evaluation was performed.

The box entitled '5.3.1.2 Equipment acceptance testing' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide the internal auditor's 'Person identification' and the 'Date' that the conformity evaluation was performed.

The box entitled '5.3.1.5 Equipment maintenance and repair' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide the internal auditor's 'Person identification' and the 'Date' that the conformity evaluation was performed.

The box entitled 'Internal auditor rating and remarks' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide remarks, to provide the inspector's 'Person identification' and the 'Date' that the conformity evaluation was performed.

The box entitled 'Reviewer remarks' requires the reviewer to provide remarks, the reviewer's 'Person identification' and the 'Date' that the review was performed.

5.3.1.7 Equipment records

☑ Maintainance of records relating to the contribution to the performance of examinations: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing identity of the equipment: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing manufacturer's name or unique identifier: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing model number or unique identifier: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing serial number or unique identifier: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing supplier or manufacturer contact information: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing date of receiving the equipment: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing date of entering into service: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing location: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records showing condition when received: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of manufacturer's instructions: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of equipment's initial acceptability for use: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of maintenance: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of preventive maintenance schedule: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of performance relating to the acceptability for use: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of damage, malfunction, modification or repair of the equipment: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

Figure 6. Conformity evaluation of Afinion 2 Analyzer (instrument software) maintainability checklist according to Philippine National Standard PNS ISO 15189:2013. *(continued)*

Note. The box entitled '5.3.1.7 Equipment records' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide the internal auditor's 'Person identification' and the 'Date' that the conformity evaluation was performed.

The box entitled 'Internal auditor rating and remarks' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide remarks, to provide the inspector's 'Person identification' and the 'Date' that the conformity evaluation was performed.

The box entitled 'Reviewer remarks' requires the reviewer to provide remarks, the reviewer's 'Person identification' and the 'Date' that the review was performed.

5.3.1.7 Equipment records

☑ Records of verification showing dates: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of verification showing times: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of verification showing results: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of verification showing adjustments: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of verification showing the acceptance criteria: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Records of verification showing due date of the next verification: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Maintenance of records according to the laboratory's documented procedure: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
☑ Availability of records according to the laboratory's documented procedure: **Objective evidence** Audited record(s) [unique identifier(s)]	Conformant Non-Conformant
	Internal Auditor
	YYYY-MM-DD

Internal auditor rating and remarks:

Rating and remarks: Conformant Non-Conformant

Internal auditor | YYYY-MM-DD

Reviewer remarks:

Reviewer | YYYY-MM-DD

Figure 6. Conformity evaluation of Afinion 2 Analyzer (instrument software) maintainability checklist according to Philippine National Standard PNS ISO 15189:2013. *(continued)*

Note. The box entitled '5.3.1.7 Equipment records' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide the internal auditor's 'Person identification' and the 'Date' that the conformity evaluation was performed.

The box entitled 'Internal auditor rating and remarks' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide remarks, to provide the inspector's 'Person identification' and the 'Date' that the conformity evaluation was performed.

The box entitled 'Reviewer remarks' requires the reviewer to provide remarks, the reviewer's 'Person identification' and the 'Date' that the review was performed.

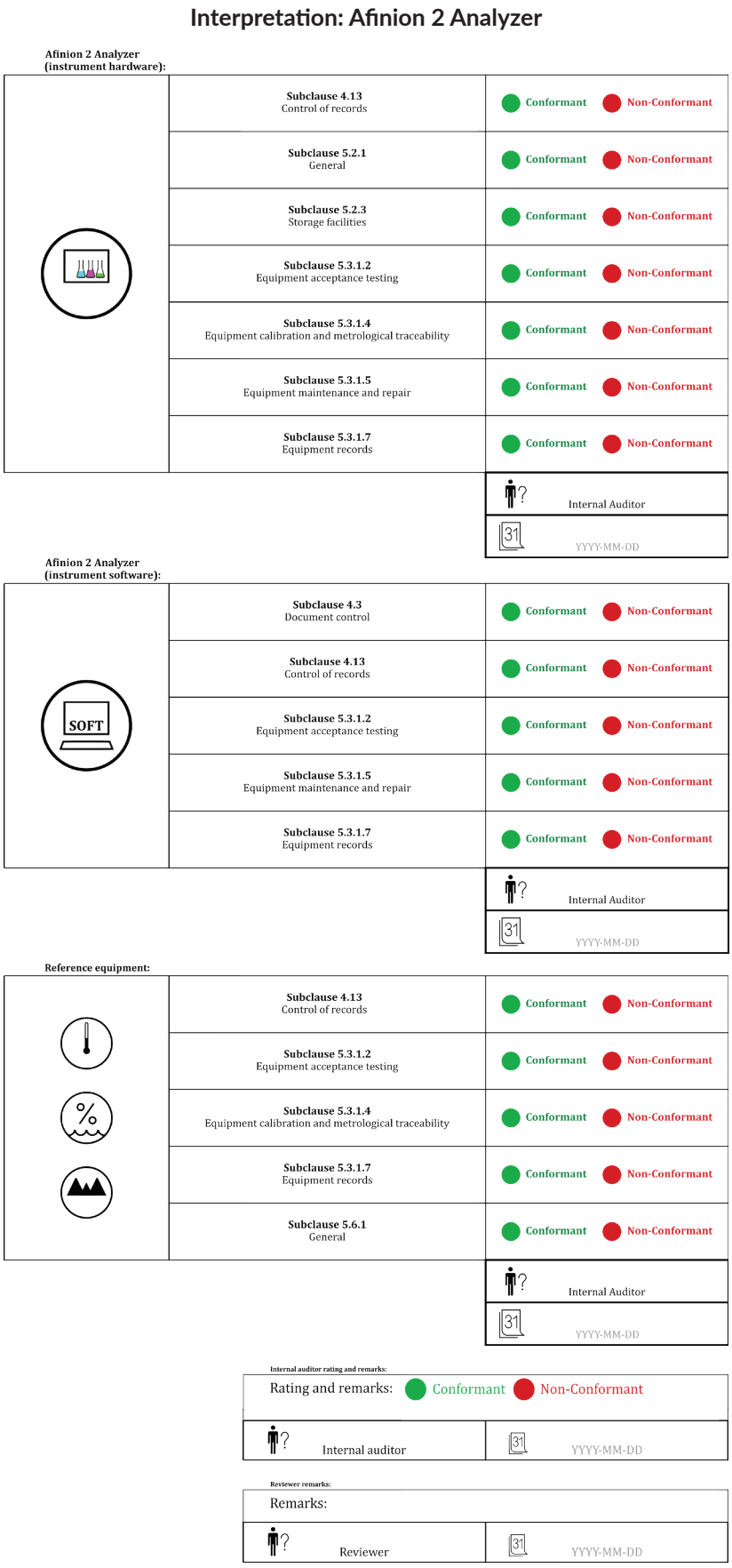

Figure 7. Interpretation checklist of Afinion 2 Analyzer maintainability checklists. Final results can be presented for review on completion of compilation of results.

Note. The box entitled 'Afinion 2 Analyzer (instrument hardware)' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide the internal auditor's 'Person identification' [Symbol IEC 60417-5664 (2002-10)] and the 'Date' [Symbol ISO 7000-5662 (2002-10)] that the interpretation was performed.

The box entitled 'Afinion 2 Analyzer (instrument software)' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide the internal auditor's 'Person identification' and the 'Date' that the interpretation was performed.

The box entitled 'Reference equipment' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide the internal auditor's 'Person identification' and the 'Date' that the interpretation was performed.

The box entitled 'Internal auditor rating and remarks' requires the internal auditor to indicate the rating of either 'Conformant' or 'Non-Conformant', to provide remarks, to provide the inspector's 'Person identification' and the 'Date' that the interpretation was performed.

The box entitled 'Reviewer remarks' requires the reviewer to provide remarks, the reviewer's 'Person identification' and the 'Date' that the review was performed.

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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