ORIGINAL ARTICLE

Implementation of Class II biological safety cabinet good maintenance practice: protective countermeasures against SARS-CoV-2 for ISO 15189:2012 accredited medical laboratories

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ABSTRACT

Objectives: The aim of this study was to develop a good maintenance practice for the Class II biological safety cabinet that can be implemented by the medical laboratory when accreditation for SARS-CoV-2 testing is specified.

Methods: The good maintenance practice was developed by adapting appropriate criteria and requirements from International, national, and regional guidance documents: International Standard ISO 15189:2012, Australian Standard AS 2252.2—2009, China National Standard YY 0569—2011, Japanese Industrial Standard JIS K 3800:2009, American National Standard NSF/ANSI 49-2018 and European Standard EN 12469:2000 as well as accreditation related documents (*n* = 76) of the 83/101 (82 %) accreditation bodies in 80/249 (32 %) countries.

Results: A total of 64/1515 (4 %) conformance requirements relating to equipment maintenance were identified in ISO 15189:2012. Clauses 4 and 5 of ISO 15189:2012 contained 8/64 (12.5 %) conformance requirements and 56/64 (87.5 %) conformance requirements, respectively. Comparative analysis of national and regional guidance documents determined that AS 2252.2—2009 contained 8 requirements, YY 0569—2011 contained 8 requirements, JIS K 3800:2009 contained 3 requirements, NSF/ANSI 49-2018 contained 10 requirements, and EN 12469:2000 contained 5 requirements. Accreditation related documents from 7/83 (8.4 %) national accreditation bodies in 7/80 (8.8 %) countries were found to contain supplementary criteria with the following results: Australia (AUS) had 2 requirements, Hong Kong (HKG) had 5 requirements, New Zealand (NZL) had 2 requirements, Singapore (SGP) had 3 requirements, Sri Lanka (LKA) had 2 requirements, the United Arab Emirates (ARE) had 2 requirements and Viet Nam (VNM) had 7 requirements. Overall, conformance requirements (*n* = 64) from ISO 15189:2012 and further testing requirements (*n* = 15) were found to be suited to good maintenance practice for Class II biological safety cabinets.

Conclusions: The current study strengthens the medical laboratory's good practice associated with protective countermeasures against SARS-CoV-2 during the entire examination process. The findings have provided reasonably practical heightened control measures for the medical laboratory to implement to help ensure a safe laboratory environment.

Key words: compliance, conformity, ISO 15189:2012, laboratory safety, quality management, SARS-CoV-2.
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INTRODUCTION

The implementation of International Standard ISO 15189:2012 (1) prepared by the International Organization for Standardization (ISO) (2,p.857) for the medical laboratory quality management system remains the recognised benchmark for confirming the competence of medical laboratory practices in the pathology services industry (3,4). The maintenance of such a quality management system has posed formidable challenges to medical laboratories (5), mainly due to the continuous release of relevant guidance documents and recommendations that effect the implementation (6,7). More recently, the emergence of the 'Wuhan virus' (8), officially known as the 'SARS-CoV-2' by the International Union on Microbiological Societies (2,p.903) has resulted in further emphasis on the implementation of a safe environment for laboratory personnel during the entire examination process, especially during aerosol-generating procedures (9,10). Competent implementation of ISO 15189:2012 to ensure relevant infection control measures are effective remains a formidable task for medical laboratories. The medical laboratory needs to ensure the protection level is adequate for laboratory personnel during the examination processes, as specified in Subclause 4.1.1.4 e) of ISO 15189:2012 (1,p.7). This is especially important when the medical laboratory has specified accreditation for SARS-CoV-2 testing.

In addition, the medical laboratory must fulfil the relevant supplementary criteria of accreditation bodies that pertain to protective measures for laboratory personnel. More specifically, the medical laboratory must fulfil relevant conformance requirements (CRs) to ensure laboratory equipment is maintained and fully serviceable; and is at least maintained, repaired and used in accordance with the manufacturer's instructions, as specified in Subclause 5.3.1.5 (Equipment maintenance and repair) of ISO 15189:2012 (1,pp.24-25); however, the relevant CRs relating to equipment maintenance remain unspecified. Although it has been determined that the medical laboratory has 1515 CRs to consider during ISO 15189:2012 implementation (11), and the extent of requirement coverage by guidance checklists prepared by accreditation bodies to support the implementation has been quantified (12), there has been no attempt to quantify the CRs relating to equipment maintenance and supplementary criteria of accreditation bodies that are signatories to the International Laboratory Accreditation Cooperation mutual recognition arrangement.

To date there has been limited research into the management requirements for equipment maintenance associated with ISO 15189:2012 accreditation of the medical laboratory.

No previous study has focused on the routine maintenance aspects of the Class II biological safety cabinet, which is essential equipment that offers protective measures against SARS-CoV-2 during the examination processes. The primary aim of this paper was to develop good maintenance practice (GMxP) for the Class II biological safety cabinet. The development process allowed clarification of the requirements of Class II biological safety cabinet re-certification by quantifying the CRs and relevant supplementary criteria of accreditation bodies that are associated with ISO 15189:2012 accreditation purposes. The development comprised four steps. First, relevant CRs that relate to routine equipment maintenance were identified in Clause 4 (Management requirements) of ISO 15189:2012 (1,pp.6-19) and Clause 5 (Technical requirements) of ISO 15189:2012 (1,pp.19-39). Second, guidance documents prepared by accreditation bodies that are signatories to the International Laboratory Accreditation Cooperation mutual recognition arrangement from countries listed in International Standard ISO 3166-1:2020 (13) prepared by the ISO were analysed. Third, relevant national and regional guidance documents relating to maintenance of Class II biological safety cabinets were also analysed. Finally, the GMxP was developed by adapting appropriate requirements from Clauses 4 and 5 of ISO 15189:2012, relevant national and regional guidance documents, and accreditation related documents. The GMxP has been designed for medical laboratories to implement; if followed, medical laboratories could provide a reasonably practical level of safety to laboratory personnel during the SARS-CoV-2 testing as well as competently meeting the relevant CRs specified in ISO 15189:2012 with an appropriate level of scientific certainty.

MATERIALS AND METHODS

Elicitation of International Standard ISO 15189:2012 conformance requirements relating to equipment maintenance by content analysis

The technique of content analysis offers a reasonably practicable approach for analysing requirements in accreditation guidance documents (12) and International Standards (11,14). In this study, content analysis was used to identify relevant CRs that relate to routine equipment maintenance in Clauses 4 and 5 of ISO 15189:2012. Briefly, content analysis was used to identify the occurrences of the specific term 'shall', which indicates a requirement (15,p.13), and the specific term 'should', which indicates a recommendation (15,pp.13-14). The implied requirements indicated by the verbal form 'shall' were elicited as CRs, as previously described (11).

Guidance document selection criteria for routine maintenance of Class II biological safety cabinets

The criteria for selecting the guidance documents consisted of two fields. First, the guidance document is prepared by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation mutual recognition arrangement. Second, the country of the accreditation body is listed in ISO 3166-1:2020. In addition, guidance documents containing national or regional testing requirements that apply to maintenance of Class II biological safety cabinets were also included, as specified in Clause 1 (Scope) of ISO 15189:2012 (1, p.1).

Elicitation of supplementary criteria of guidance documents relating to routine maintenance of Class II biological safety cabinets

The technique of content analysis was also used to identify supplementary criteria and in guidance documents as well as their referred documents. Briefly, the implied requirements indicated by the verbal form 'shall' were elicited as supplementary criteria, as previously described (11). In addition, specific tabulated information prepared by accreditation bodies was also analysed for elicitation of supplementary criteria.

Comparative analysis of testing requirements relating to routine maintenance

The routine maintenance tasks were segmented into commonly defined headings (n = 20) for comparative analysis. The tabulated information represents the recommendations and testing requirements identified in accreditation related documents.

Development of good maintenance practice for Class II biological safety cabinets

To develop the GMxP, all supplementary criteria and CRs that fulfil relevant maintenance functions were gathered and practices that are reasonably practicable to ensure the relevant safety aspects are included in the proposed GMxP list for the medical laboratory to implement.

RESULTS

Identification of International Standard ISO 15189:2012 conformance requirement frequency relating to equipment conformity evaluation

Content analysis was used to detect CRs relating to equipment maintenance (Table S1). A total of 64/1515 CRs was identified in Subclauses 4.3 (Document control) (1,pp.10-11), 4.13 (Control of records) (1,pp.15-16), 5.2.1 (General) (1,p.21), 5.2.3 (Storage facilities) (1,p.22), 5.3.1.2 (Equipment acceptance testing) (1,p.23), 5.3.1.4 (Equipment calibration and metrological traceability) (1,p.24), 5.3.1.5 (Equipment maintenance and repair) (1,pp.24-25) and 5.3.1.7 (Equipment records) (1,p.25) of ISO 15189:2012. Clauses 4 and 5 of ISO 15189:2012 contained 8/64 (12.5 %) CRs and 56/64 (87.5 %) CRs respectively.

Selection of guidance documents for comparative analysis

A total of 83/101 (82 %) accreditation bodies in 80/249 (32 %) countries was identified as International Laboratory Accreditation Cooperation mutual recognition arrangement signatories to ISO 15189:2012 (16) (Table S2). Relevant guidance documents [national documents (n = 4) and regional document (n = 1)] were found to be associated with routine maintenance of Class II biological safety cabinets (Table 1). It was found that 29/83 (35 %) accreditation bodies of member countries of the European Committee for Standardization (2,p.857) used European Standard EN 12469:2000 (17) prepared by the European Committee for Standardization, 8/83 (10 %) accreditation bodies used EN 12469:2000 and 21/83 (25 %) accreditation bodies used a harmonised version of EN 12469:2000; 1/83 (1.2 %) accreditation bodies, China National Accreditation Service for Conformity Assessment used China National Standard YY 0569—2011 (18) prepared by the Standardization Administration of the People's Republic of China, 1/83 (1.2 %) accreditation bodies, the Japan Accreditation Board used Japanese Industrial Standard JIS K 3800:2009 (19) prepared by the Japanese Industrial Standards Committee, 2/83 (2.4 %) accreditation bodies, the National Association of Testing Authorities, Australia and International Accreditation New Zealand used Australian Standard AS 2252.2—2009 (20) prepared by Standards Australia, and 3/83 (3.6 %) accreditation bodies, the American Association for Laboratory Accreditation, Perry Johnson Laboratory Accreditation, and the ANSI National Accreditation Board, used American National Standard NSF/ANSI 49-2018 (21) prepared by NSF International.

Identification of recommendations and requirements of guidance documents relating to routine maintenance of Class II biological safety cabinets

Testing requirements (n = 20) were used for comparative analysis (Figure 1). It was determined that AS 2252.2—2009 contained 8 requirements (Table S3), EN 12469:2000

contained 5 recommendations and 5 requirements (Table S4), YY 0569—2011 contained 8 requirements (Table S5), JIS K 3800:2009 contained 6 recommendations and 3 requirements (Table S6), and NSF/ANSI 49-2018 contained 10 requirements (Table S7).

Identification of supplementary criteria of accreditation guidance documents relating to routine maintenance of Class II biological safety cabinets

Of the 83/101 (82 %) accreditation bodies, 7/83 (8.4 %) accreditation bodies (Table S2) were identified that provide additional supplementary criteria for accreditation when Class II biological safety cabinets are used in the medical laboratory. These include the National Association of Testing Authorities, Australia, the Hong Kong Accreditation Service, International Accreditation New Zealand, the Singapore Accreditation Council, the Sri Lanka Accreditation Board for Conformity Assessment, the Emirates International Accreditation Centre and the Bureau of Accreditation.

Proposed good maintenance practice for Class II biological safety cabinets

The GMxP was developed for the medical laboratory to implement as a baseline. Testing requirements (*n* = 15) containing specific calibration intervals (*n* = 4) and checking intervals (*n* = 14) (Figure 2) as well as CRs (*n* = 64) relating to equipment maintenance in ISO 15189:2012 (Table S1) were proposed for implementation.

Table 1. The availability of national and regional guidance documents for comparative analysis.

Countries	Guidance documents	References
Australia (AUS)	**Australian Standard AS 2252.2—2009** Controlled environments: part 2: biological safety cabinets Class II—Design	(20)
Belgium (BEL) *	**European Standard EN 12469:2000** Biotechnology - Performance criteria for microbiological safety cabinets	(17)
China (CHN)	**China National Standard YY 0569—2011** Class II biological safety cabinets	(18)
Japan (JPN)	**Japanese Industrial Standard JIS K 3800:2009** Class II biological safety cabinets	(19)
United States (USA)	**American National Standard NSF/ANSI 49-2018** Biosafety cabinetry: design, construction, performance, and field certification	(21)

*The European Committee for Standardization prepared European Standard EN 12469:2000 for its members; therefore, European Standard EN 12469:2000 has national standard status for the European Committee for Standardization members.

DISCUSSION

This study set out with the aim of determining good practice for routine maintenance of Class II biological safety cabinets in ISO 15189:2012 accredited medical laboratories. The term good practice' has been defined by the ISO as a 'method that has been proven to work well and produce good results, and is 'therefore recommended as a model' in Item 3.1.3 of International Standard ISO 14055-1:2017 (23,p.2) prepared by the ISO. This was achieved by the identification of relevant requirements that could provide support to routine equipment maintenance from Clauses 4 and 5 of ISO 15189:2012, national and regional guidance documents (*n* = 5), and accreditation related documents (*n* = 76). The current study found that CRs (*n* = 64) in Clauses 4 and 5 of ISO 15189:2012 and testing requirements (*n* = 15) from relevant guidance documents could offer enhanced protective countermeasures against SARS-CoV-2.

The proposed GMxP for Class II biological safety cabinets offers a practical approach that can be implemented by technical support services personnel. The implementation has two potential areas that are likely to add value to the medical laboratory. The first area is the enhancement of situational awareness in relation to routine maintenance of Class II biological safety cabinets for the laboratory personnel who contribute to the implementation of the medical laboratory quality management system and laboratory personnel who are the users of Class II biological safety cabinets. A good sense of situational awareness (24), especially in the safety aspects of laboratory personnel, is paramount to the maintenance of a safe working condition, as specified in Subclause 5.2.1 (General) of ISO 15189:2012 (1,p.21). The awareness of maintenance requirements should be part of the authorisation process for the laboratory personnel who undergo training before becoming authorised users of Class II biological safety cabinet, as specified in Subclause 5.3.1.3 (Equipment instructions for use) of ISO 15189:2012 (1,pp.23-24). However, the examination of electrical safety is already a routine maintenance practice for laboratory equipment (25), as specified in Subclause 5.3.1.5 of ISO 15189:2012, therefore it is not repeatedly stated in the proposed GMxP. It is important to note that the manometer that measures differential pressure across the exhaust and negative side of supply blower is subject to routine maintenance (26) and must be calibrated according to the manufacturer's recommendations, as specified in Subclause 5.3.1.4 (Equipment calibration and metrological traceability) of ISO 15189:2012 (1,p.24). Another conformity necessity is the serviceability of the annunciators and alarms management system (27), the associated items must be fully serviceable and inspected for functionality at least once per working day (Figure 2). The proposed GMxP could also support the medical laboratory in the implementation of International Standard ISO 15190:2020 (28) prepared by the ISO relating to relevant safety practices. The proper use of relevant engineering controls (29), such as Class II biological safety cabinets, as specified in Subclause 7.1.2 c) of ISO 15190:2020 (28,p.18), to suppress infectious aerosols, as specified in Subclause 7.4 c) of ISO 15190:2020 (28,p.21), could contribute directly to the implementation of good practice for a safe laboratory environment, as specified in Subclause 4.1.1.4 e) of ISO 15189:2012 (1,p.7).

The second area which is closely connected with the implementation is internal auditing of activities that are related to Class II biological safety cabinet work practices. The medical laboratory is required to conduct internal audits at planned intervals to determine whether equipment maintenance activities are within the specifications of the medical laboratory quality management system, as specified in Subclause 4.14 of ISO 15189:2012 (1,p.17). For laboratory personnel who have roles in conducting internal audits, the maintenance requirements should also be part of the mandatory training to ensure relevant work practices are audited thoroughly, as specified in Subclause 5.1.5 b) of ISO 15189:2012 (1,p.20). The internal auditors may also wish to ensure the Class II biological safety cabinets are subject to relevant certification annually, as specified in Subclause 7.7 c) of ISO 15190:2020 (28,p.22). The identification of 64/1515 (4 %) CRs in ISO 15189:2012 associated with equipment maintenance should provide a more standardised approach for the internal auditors to use, this is highly likely to produce consistent auditing of information (30).

Testing requirements (n = 20)	AS 2252.2 (n = 8)	EN 12469 (n = 5)	YY 0569 (n = 8)	JIS K 3800 (n = 3)	NSF/ANSI 49 (n = 10)
Airflow alarm serviceability	Requirement	Recommendation See †	See ‡		Requirement
Airflow balance				Recommendation See §	
Airflow direction orientation (downflow)		Requirement	Requirement	Recommendation See **	Requirement
Airflow direction orientation (sash seal)			Requirement	Recommendation See ††	Requirement
Airflow direction orientation (view screen)			Requirement	Recommendation See ‡‡	Requirement
Airflow direction orientation (working access opening)		Requirement	Requirement	Recommendation See §§	Requirement
Airflow rate (uniform downflow velocity)		Recommendation See ***			
	Requirement	Requirement	Requirement	Requirement	Requirement
Airflow rate (uniform inflow velocity)	Requirement	Requirement	Requirement	Requirement	Requirement
Carcass leaktightness				Recommendation See †††	
Electrical safety		See ‡‡‡	See ‡‡‡		See ‡‡‡
Front aperture containment efficiency	Requirement				
Installed filter system integrity	Requirement	Requirement	Requirement	Requirement	Requirement
Internal supply fan interlock alarm serviceability	Requirement	Recommendation See §§§	See ****		Requirement
Sash alarm serviceability	Requirement	Recommendation See ††††	See ‡‡‡‡		Requirement
Sound pressure level (L_p)	See §§§§	See §§§§	See §§§§	See §§§§	See §§§§
Surface integrity		Recommendation See *****	Requirement		
Vibration	See †††††	See †††††	See †††††	See †††††	See †††††
Work surface illuminance (E_v)	See ‡‡‡‡‡	See ‡‡‡‡‡		See ‡‡‡‡‡	See ‡‡‡‡‡
Work surface irradiance (E_e)	See §§§§§		See §§§§§		
Work zone intergrity	Requirement				

Figure 1. Selected routine maintenance testing requirements for Class II biological safety cabinets: Australian Standard AS 2252.2—2009, European Standard EN 12469:2000, China National Standard YY 0569—2011, Japanese Industrial Standard JIS K 3800:2009, and American National Standard NSF/ANSI 49‑2018.
†European Standard EN 12469:2000 recommends (routine maintenance testing) that the alarm indicators be checked to the manufacturer's specification [see Subclause K.3 (Class II MSCs) of European Standard EN 12469:2000].
‡China National Standard YY 0569—2011 specifies a requirement (factory testing) that the airflow alarm test be performed [see Subclause 5.3.7.5 (Airflow alarm) of China National Standard YY 0569—2011].
§Japanese Industrial Standard JIS K 3800:2009 recommends (routine maintenance testing) that the airflow balance test be performed [see Clause 9 (Inspection) of Japanese Industrial Standard JIS K 3800:2009].

[**]Japanese Industrial Standard JIS K 3800:2009 recommends (routine maintenance testing) that the airflow direction test be performed [see Subclause 8.9 a) of Japanese Industrial Standard JIS K 3800:2009].
[††]Japanese Industrial Standard JIS K 3800:2009 recommends (routine maintenance testing) that the airflow direction test be performed [see Subclause 8.9 d) of Japanese Industrial Standard JIS K 3800:2009].
[‡‡]Japanese Industrial Standard JIS K 3800:2009 recommends (routine maintenance testing) that the airflow direction test be performed [see Subclause 8.9 b) of Japanese Industrial Standard JIS K 3800:2009].
[§§]Japanese Industrial Standard JIS K 3800:2009 recommends (routine maintenance testing) that the airflow direction test be performed [see Subclause 8.9 c) of Japanese Industrial Standard JIS K 3800:2009].
[***]European Standard EN 12469:2000 recommends (routine maintenance testing) that the airflow rate be measured in accordance with the manufacturer's instructions [see Subclause K.3 (Class II MSCs) of European Standard EN 12469:2000].
[†††]Japanese Industrial Standard JIS K 3800:2009 recommends (routine maintenance testing) that carcass leak tightness test be performed [see Clause 9 (Inspection) of Japanese Industrial Standard JIS K 3800:2009].
[‡‡‡]European Standard EN 12469:2000 specifies a requirement (cabinet classification) [see Annex A.8 (Electrical safety) of European Standard EN 12469:2000], China National Standard YY 0569—2011 specifies a requirement (factory testing) [see Subclause 5.4.15 (Electrical safety) of China National Standard YY 0569—2011] and American National Standard NSF/ANSI 49:2018 specifies a requirement (worker comfort and safety) [see Annex F.8 (Electrical leakage and ground circuit resistance and polarity tests) of American National Standard NSF/ANSI 49‑2018] relating to electrical safety. The examination of electrical safety is a requirement of International Standard ISO 15189:2012 [see Subclause 5.3.1.5 (Equipment maintenance and repair) of International Standard ISO15189:2012].
[§§§]European Standard EN 12469:2000 recommends (routine maintenance testing) that the internal supply fan interlock alarm test be performed [see Subclause K.3 (Class II MSCs) of European Standard EN 12469:2000].
[****]China National Standard YY 0569—2011 specifies a requirement (factory testing) that the internal supply fan interlock alarm test be performed [see Subclause 5.3.7.2 (Internal supply/exhaust fan interlock alarm) of China National Standard YY 0569—2011].
[††††]European Standard EN 12469:2000 recommends (routine maintenance testing) that the sash alarm test be performed [see Subclause K.3 (Class II MSCs) of European Standard EN 12469:2000].
[‡‡‡‡]China National Standard YY 0569—2011 specifies a requirement (factory testing) that the sash alarm test be performed [see Subclause 5.3.7.1 (Front window operation port alarm) of China National Standard YY 0569—2011].
[§§§§]Australian Standard AS 2252.2—2009 specifies a requirement (worker comfort and safety) [see Subclause 5.3.3 (Sound level) of Australian Standard AS 2252.2—2009], European Standard EN 12469:2000 specifies a requirement (worker comfort and safety) [see Annex A.3 (Sound) of European Standard EN 12469:2000], China National Standard YY 0569—2011 specifies a requirement (factory testing) [see Subclause 5.4.3 (Noise) of China National Standard YY 0569—2011], Japanese Industrial Standard JIS K 3800:2009 specifies a requirement (factory testing) [see Subclause 5.7 (Noise) of Japanese Industrial Standard JIS K 3800:2009], and American National Standard NSF/ANSI 49‑2018 specifies a requirement (worker comfort and safety) [see Annex F.11.4 (Acceptance) of American National Standard NSF/ANSI 49‑2018] relating to sound pressure level generated by the cabinet.
[*****]European Standard EN 12469:2000 recommends (routine maintenance testing) that the external and internal surfaces are visually inspected for surface defects, cracks or other damage [see Subclause K.3 (Class II MSCs) of European Standard EN 12469:2000].
[†††††]Australian Standard AS 2252.2—2009 specifies a requirement (worker comfort and safety) [see Subclause 5.3.2 (Vibration) of Australian Standard AS 2252.2—2009], European Standard EN 12469:2000 specifies a requirement (worker comfort and safety) [see Annex A.3 (Sound) of European Standard EN 12469:2000], China National Standard YY 0569—2011 specifies a requirement (factory testing) (see Subclause 5.4.5 of China National Standard YY 0569—2011), Japanese Industrial Standard JIS K 3800:2009 specifies a requirement (factory testing) [see Subclause 5.9 (Vibration) of Japanese Industrial Standard JIS K 3800:2009] and American National Standard NSF/ANSI 49‑2018 specifies a requirement (worker comfort and safety) [see Annex F.10.4 (Acceptance) of American National Standard NSF/ANSI 49‑2018] relating to vibration level generated by the cabinet.
[‡‡‡‡‡]Australian Standard AS 2252.2—2009 specifies a requirement (worker comfort and safety) [see Subclause 5.3.4 (Lighting) of Australian Standard AS 2252.2—2009], European Standard EN 12469:2000 specifies a requirement (worker comfort and safety) [see Annex A.2 (Lighting) of European Standard EN 12469:2000], Japanese Industrial Standard JIS K 3800:2009 specifies a requirement (factory testing) [see Subclause 5.8 (Lighting intensity) of Japanese Industrial Standard JIS K 3800:2009] and American National Standard NSF/ANSI 49‑2018 specifies a requirement (worker comfort and safety) [see Annex F.9.4 (Acceptance) of American National Standard NSF/ANSI 49‑2018] relating to work surface illuminance level generated by the fluorescent lamp.
[§§§§§]Australian Standard AS 2252.2—2009 specifies a requirement (worker comfort and safety) [see Subclause 5.3.5 (Ultraviolet radiation) of Australian Standard AS 2252.2—2009] and China National Standard YY 0569—2011 specifies a requirement (factory testing) [see Subclause 5.4.14 (UV lamp) of China National Standard YY 0569—2011] relating to work surface irradiance generated by the ultraviolet lamp.

Testing requirements (n = 15)	Calibration interval (n = 4)	Checking interval (n = 14)	Procedures (n = 18)
Airflow alarm serviceability	≥ 1 per year		Calibration of the threshold limits according to the manufacturer's specifications.
		≥ 1 per each working day	Appropriate check to maintain serviceability quality.
Airflow direction orientation (downflow)		≥ 1 per year	Conformity with the manufacturer's specifications and a relevant certification standard.
Airflow direction orientation (sash seal)		≥ 1 per year	Conformity with the manufacturer's specifications and a relevant certification standard.
Airflow direction orientation (view screen)		≥ 1 per year	Conformity with the manufacturer's specifications and a relevant certification standard.
Airflow direction orientation (working access opening)		≥ 1 per year	Conformity with the manufacturer's specifications and a relevant certification standard.
Airflow rate (uniform downflow velocity)		≥ 1 per year	Conformity with the manufacturer's specifications and a relevant certification standard.
Airflow rate (uniform inflow velocity)		≥ 1 per year	Conformity with the manufacturer's specifications and a relevant certification standard.
Control knobs and switches serviceability		≥ 1 per each working day	Appropriate check to maintain serviceabililty quality.
Front aperture containment efficiency		≥ 1 per year	Conformity with the manufacturer's specifications and a relevant certification standard.
Installed filter system integrity		≥ 1 per year	Conformity with the manufacturer's specifications and a relevant certification standard.
Internal supply fan interlock alarm serviceability	≥ 1 per year		Calibration of the threshold limits according to the manufacturer's specifications.
		≥ 1 per each working day	Appropriate check to maintain serviceability quality.
Manometer serviceability	≥ 1 per year		Conformity with the manufacturer's specifications.
Sash alarm serviceability	≥ 1 per year		Calibration of the threshold limits according to the manufacturer's specifications.
		≥ 1 per each working day	Appropriate check to maintain serviceability quality.
Work surface irradiance (E_e)		≥ 1 per year	The work surface irradiance (E_e) conforms to ≥ 400 mW/m^2 when the E_e is unspecified by the manufacturer.
Work surface sterility ******		≥ 1 per week	Appropriate check to maintain sterility quality.

Figure 2. Suggested routine maintenance testing requirements for Class II biological safety cabinets.
******International Standard ISO 14698-1:2003 (22) provides relevant guidance information relating to determination of biocontamination on work surface [see Annex C (Guidance on determining biocontamination of surfaces) of International Standard ISO 14698-1:2003 (22, pp. 18-19)].

CONCLUSIONS

The present study was designed to develop GMxP for the Class II biological safety cabinet. This is particularly relevant for medical laboratories that provide SARS-CoV-2 testing service to ensure laboratory personnel to operate in a safe laboratory environment.

Overall, this study strengthens the idea that GMxP for the Class II biological safety cabinet should be implemented by medical laboratories as part of ensuring the practices relating to SARS-CoV-2 testing are performed with reasonably practicable protective countermeasures.

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