

IAF Frequently Asked Questions

COV-ID-19 Outbreak

COV-ID-19 (新冠疫情) 爆发期间

IAF 的常见问题

The FAQs are some of the questions that we are frequently asked in some (but not all) of the areas in which IAF Accreditation Body (AB) members and their accredited Certification Bodies (CBs) practice. The questions and answers are not intended to be exhaustive; however, they constitute a common understanding and a guidance to manage, in a harmonized way, the conformity assessment activities under the specific situation of COVID-19.

常见问题是我们经常被问到的一些问题 (但不是全部), 这些问题来自于 IAF 成员认可机构(AB)及其认可的合格评定机构(CBs) 的实践。虽然 , 问题和解答做不到详尽全面 , 然而 , 它们构成了一个共同的理解和指南 , 以协调一致的方式管理 COVID-19 (新冠疫情) 特定情况下的合格评定活动。

Q34

Q34: Can Accreditation Bodies carry out consecutive assessments during the COVID lockdown period using remote techniques? ISO/IEC 17011 states in 7.9.3 "The time between consecutive on-site assessments shall not exceed 2 years. However, if the accreditation body determines that an on-site assessment is not applicable, it shall use another assessment technique to achieve the same objective as the on-site assessment being replaced and justify the use of such techniques (e.g. remote assessment)." Therefore is it correct that the AB can justify using alternative techniques in this situation?

A34: Yes, considering the current restrictions on travel it would be a suitable justification, subject to risk assessment, to use remote techniques in consecutive assessments within a 2 year period.

问题 34 : 认可机构能否在 COVID 疫情导致的封闭期间内使用远程技术进行连续评审 ? 国际标准化组织/IEC 17011 在 7.9.3 中规定 "连续现场评审之间的时间不得超过两年。但是 , 如果认可机构确定现场评审不适用 , 则应使用另一种评审技术来实现与被替代的现场评审相同的目标 , 并证明使用此类技术(例如远程评审)的合理性。" 因此 , 在这种情况下 , 认可机构使用替代技术是合理的 , 这样理解正确吗 ?

2021 年 1 月 22 日 IAF FAQ 常见问题 特别工作组发布

A34 : 是的 , 考虑到目前的旅行限制 , 基于风险评价 , 在两年内连续评审中使用远程技术将是一个合适的理由。

Q33

Q33: If the recertification audit is conducted remotely after the 12-month extension allowed per FAQ 31, then to demonstrate an effective QMS, are the 2 subsequent surveillance audits to be conducted in a shorter time, therefore doing more than one audit per year, or is it possible to complete the certification cycle effectively skipping an audit?

Posted on November 8, 2020 by IAF FAQ TF

A33 : it depends on the situation and the associated risks.

问题 33 :如果再认证审核是在 FAQ 31 允许的 12 个月延期后通过远程审核进行的,那么为了证明质量管理体系是有效的,后续的两次监督审核是否可以在更短的时间内进行?因此每年将会实施一次以上的审核,或者,是否有可能跳过一次审核而有效地完成认证周期?

2020 年 11 月 8 日 IAF FAQ 常见问题 特别工作组发布

A33 : 这取决于实际的情况和相关风险。

Q32

Q32: According to ISO/IEC 17021-1:2015, § 9.1.3.3, "Surveillance audits shall be conducted at least once a calendar year, except in recertification years. The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date" . Is this clause still valid?

Posted on September 7, 2020 by IAF FAQ TF

A32: Yes. However, given the specific circumstances, all the time limits indicated in the standard have to be reconsidered according to the IAF FAQ Q10 that allows the postponements of any conformity assessment activities. This means that:

It is not necessary to conducted a surveillance audit at least once a calendar year; the date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date plus the postponement allowed by the IAF FAQ Q10.

In the case it is not possible to perform any surveillance activity within the timeframe of 12+6 months (see above second bullet point), the accredited CB shall inform the customer and suspend the accredited certificate.

In these specific circumstances, the suspension could exceed six months (see the note of ISO/IEC 17021-1:2015, § 9.6.5.4).

In order to lift the suspension and continue with the accredited certificate validity, at least a Stage 2 shall be conducted.

问题 32 : 根据 ISO/IEC 17021-1:2015 , 9.1.3.3 , “监督审核应至少每年进行一次,除了在再认证的年份。首次认证后的第一次监督审核日期不得超过认证决定日期的 12 个月”。这个条款还有效吗?

2020 年 9 月 7 日 IAF FAQ 工作组发布

A32:是的。然而,鉴于具体情况,必须根据 IAF FAQ 的 Q10 重新考虑标准中规定的所有时

限，该标准允许推迟任何合格评定活动。这意味着：没有必要每年至少进行一次监督审核；首次认证后的第一次监督审核日期不得超过认证决定日期后的 12 个月，加上 IAF FAQ 的 Q10 允许的延长期限。如果在 12+6 个月的时间框架内依然无法进行任何监督活动(见上文第二点)，获认可的 CB 应通知客户并暂停认证证书。在这些特定情况下，暂停可能超过六个月(见 ISO/IEC 17021-1:2015，9.6.5.4 的注释)。为了恢复暂停并持续保持获认证证书的有效性，至少应进行一次第 2 阶段审核。

Q31

Q31: According to ISO/IEC 17021-1:2015 Clause 9.6.3.1.1, planning for recertification shall conducted in due time to enable for timely renewal before the certificate expiry date. Is this clause still valid?

Posted on September 7, 2020 by IAF FAQ TF

A31: IAF FAQ 10 allows the recertification date to be extended up to six months, which would allow the planning to be extended accordingly. If that six months may not provide sufficient opportunities for CBs to conclude recertification audits, the decision on recertification must be made within 3 months of the lifting of restrictions (e.g. travel) that were preventing the on-site audit taking place. However, if this time-frame, from the certification date exceeds 12 months, the CB should complete the reassessment as possible using remote means for witnessing the certified processes during their execution (real-time video of production and workplaces remotely guided by the auditor and/or review by the auditor of recorded videos in those areas where no direct connection is available, with a possible request of specific new partial video, when deemed necessary). In all those cases where the processes cannot be remotely assessed in an effective way to the satisfaction of the team leader, the certification scope shall be partially reduced consequently or the certificate shall be completely withdrawn, and a new initial audit will be required. In any case, a decision shall be made taking also into consideration the updated risk associated with the operational control capability of the organization in the COVID 19 emergency conditions and the type of certification scheme.

Q31:根据 ISO/IEC17021-1:2015 第 9.6.3.1.1 条，应及时进行再认证的策划，以便在证书到期日之前及时更新。这个条款还有效吗？

2020 年 9 月 7 日由 IAF FAQ 工作组发布

A31: IAF FAQ 10 允许再认证日期延长至六个月，相应地这将允许策划时间延长。如果这六个月依然无法为 CBs 提供足够的机会来完成再认证审核，则机构必须在阻止实施现场审核的限制措施(如旅行)取消的三个月内做出再认证的决定。但是，如果这个时间段从认证日期开始的时间超过了 12 个月，CB 应尽可能使用远程方式完成再认证审核，以便在认证有效期内见证获认证的过程(由审核员远程指导的生产和工作场所的实时视频和/或审核员对那

些没有直接联系的区域的录制视频进行审查,必要时可能要求提供特定部分的新录制视频)。在所有这些情况下,如果不能以令审核组长满意的有效方式对过程进行远程审核,则应部分缩小认证范围或直至完全撤销证书,并要求进行新的初次审核。在任何情况下,在 COVID 19 疫情导致的紧急情况下,还应考虑与组织运行控制能力相关的最新风险以及认证制度的类型,以便做出认证决定。

Q30

Q30: The pandemic emergency is very different between the various locations in the world. Do the rules defined in this FAQ apply in all the locations subject to Covid-19 restrictions, and until when?

Posted on September 7, 2020 by IAF FAQ TF

A30: Yes. The validity of the FAQ published on www.iaffaq.com website are confirmed, until a different official communication from IAF.

In all locations which do not have Covid-19 access restrictions, activity such as on-site audits shall continue according to usual procedures

问题 30 :世界各地的疫情流行导致的紧急情况非常不同。在这个 FAQ 文件中确定的规则是否适用于受新冠肺炎限制的所有地点,适用时间到何时可以结束?

2020 年 9 月 7 日由 IAF FAQ 工作组发布

回答 30 :是的。在 www.iaffaq.com 网站上发布 FAQ 文件的有效性已经得到确认,直到 IAF 官方发布不同的确认通知。

在所有的没有因新冠肺炎导致限制准入的地方,某些活动,例如现场审核,还应按照通常的程序继续实施。

Q29

Q29: Where can I find a list of IAF Accreditation Bodies recognized for the IAF MLA Medical Devices Management Systems (MDMS) sub-scope, and a link to the Certification Bodies accredited by each?

A29: See below the list of the recognized ABs under the IAF MLA Medical Devices Management Systems (MDMS) sub-scope and the links to their accredited bodies databases where you can find the certification bodies accredited to provide ISO 13485 certification.

You can also check the IAF Certsearch database which, although incomplete at this time, currently includes 2593 ISO 13485 certificates worldwide from 150 accredited certification bodies for ISO 13485 scopes.

Posted on July 6, 2020 by IAF FAQ TF

问题 29 :我在哪里可以找到 IAF 认可机构被承认的 IAF MLA 医疗器械管理体系(MDMS)的子范围清单,以及被每个认可机构认可的认证机构的链接?

回答 29 :参见以下 IAF MLA 医疗器械管理体系(MDMS)子范围内被承认的认可机构清单,

以及获认可的机构数据库的链接,您可以在这些数据库中找到被认可的可以提供 ISO13485 认证的认证机构。

您还可以查看 IAF 的 Certsearch 数据库,尽管目前该数据库不完整,但已经包括了世界范围内 2593 个 ISO13485 证书的信息,来自 150 个获认可的 ISO 13485 认证机构。

Q28

Q28: Based on the answer to IAF COVID-19 FAQ Q20 which has extended the transition arrangements of such standards as ISO 50001: 2018 and ISO 22000:2018 by 6 months, can it be confirmed that the dates related to all intermediate requirements contained in these transition arrangements, for example the dates to stop auditing against the previous version of the standard, are also extended by 6 months?

Posted on May 19, 2020 by IAF FAQ TF

问题 28 : 基于对 IAF COVID-19 常见问题 Q20 的回答,该问题将诸如 ISO 50001: 2018 和 ISO 22000:2018 等标准的过渡安排延长了 6 个月,是否可以确认与这些过渡安排中包含的与所有中间要求相关的日期,例如,停止对标准的前一版本进行审核的日期,也延长了 6 个月?

发布于 2020 年 5 月 19 日, IAF FAQ 特别工作组

回答 28 : 是的,过渡安排的延长适用于这些安排中引用的所有日期,因此所有日期都延长了 6 个月。

IAF FAQ 特别工作组 2020 年 5 月 19 日

Q27

Q27: In consideration of this extraordinary period, may all assessments (e.g. surveillances, reassessment) be postponed for up to 6 months, and the validity of all output of accreditation activity (e.g. a certificate) be extended for a corresponding period of up to 6 months?

Posted on May 14, 2020 by IAF FAQ TF

A27 : No. In cases that ABs are still able to perform evaluation activities physically or when these can be fully replaced with evaluation activities as per IAF ID 12, normal scheduled conformity assessment activities (e.g. surveillances, reassessment) should be performed.

Otherwise, if the conditions recommended by IAF ID 3: 2011 are satisfied, the normal scheduled conformity assessment activities may be postponed for up to 6 months, and the validity of all output of the conformity assessment activity (e.g. a certificate) may be extended for a corresponding period of up to 6 months.

This means that an accreditation certificate would be valid for a maximum for 5 years (see ISO/IEC 17011, § 7.9.1) plus 6 months.

If there is a postponement of 6 months in the deadline of a certificate, according to Q8, the next accreditation cycle starts from the original one and not from the new accreditation decision.

Posted on May 14, 2020 by IAF FAQ TF

问题 27：考虑到这一非常时期，是否可以将所有评审（例如，监督、复评）推迟最多 6 个月，并将认可活动的所有输出（例如，认可证书）的有效期相应延长最多 6 个月？

发布于 2020 年 5 月 14 日，IAF FAQ 工作组

回答 27：否。如果认可机构仍然能够实施现场评审活动，或者当这些活动能够完全被 IAF ID12 文件所规定的远程评审替代时，则应执行正常计划的认可评审活动(例如监督、复评)。否则，如果满足 IAF ID 3: 2011 建议的条件，正常计划的合格评定活动可推迟最多 6 个月，并且合格评定活动的所有输出(例如证书)的有效期可相应延长最多 6 个月。

这意味着认可证书的有效期最长为 5 年(见 ISO/IEC 17011, 7.9.1 条款)加 6 个月。

根据常见问题 Q8，如果证书的截止日期推迟了 6 个月，下一个认可周期将从原认可周期开始，而不是从新的认可决定开始。

IAF FAQ 特别工作组 2020 年 5 月 14 日

Q26

Q26: If the certificate has already expired, can the period during which the certification body may restore certification (according to ISO/IEC 17021-1 § 9.6.3.2.5) be extended by a further 6 months (to a maximum of 12 months from certificate expiry) provided that the outstanding recertification activities are completed?

Posted on May 14, 2020 by IAF FAQ TF

A26: Yes. Otherwise at least a stage 2 shall be conducted. (See Q8 for details of certificate validity and possible modifications to subsequent surveillance activities).

问题 26：如果证书已经到期，认证机构可以恢复认证的期限(根据 ISO/IEC17021-1 的 9.6.3.2.5 条款)能否再延长 6 个月(从证书到期之日起最多 12 个月)，前提是完成了再认证活动？

发布于 2020 年 5 月 14 日，由 IAF 常见问题工作组发布

A26：是的。否则，至少应进行第二阶段审核。(有关证书有效性的详细信息以及对后续监督活动的可能修改，请参见 Q8)。

IAF FAQ 特别工作组 2020 年 5 月 14 日

Q25

Q25: During the COVID-19 crisis, if a CAB conducts a part of the recertification of a management system with remote audit activities and plans to complete the remainder of the audit onsite within six months, is it possible to reissue the

certificate at the conclusion of the remote audit activities?

A25:

- If the CAB is not able to perform evaluation activities physically or when these cannot fully be replaced with evaluation activities as per IAF MD 4, then the normal scheduled recertification activities may be postponed for up to 6 months (see Q13)
- Despite of this, if the certificate is expired, according to ISO/IEC 17021-1 § 9.6.3.2.5, the certification body can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted.
- a certificate can only be renewed if the CAB is able to evaluate all the applicable requirements of ISO/IEC 17021-1 (9.6.3.2) through a complete and effective audit of the client' s management system, followed by a successful review and decision making activities

by IAF FAQ TF May 7, 2020

问题 25 : 在 COVID-19 新冠疫情危机期间, 如果一个合格评定机构通过远程审核活动实施了一部分的管理体系再认证, 并计划在六个月内完成剩余部分的现场审核, 是否有可能基于远程审核活动的结论重新颁发证书?

回答 25 :

- 如果 CAB 不能在现场实施评价活动, 或者评价活动也不能完全由依据 IAF MD 4 规定的评价活动所取代时, 那么正常计划的再认证活动可能会推迟 6 个月(见 Q13)
- 尽管如此, 如果认证证书过期了, 根据 ISO/IEC17021-1 9.6.3.2.5, “如果认证机构能够在 6 个月内完成未尽的再认证活动, 则可以恢复认证, 否则应至少进行一次第二阶段才能恢复认证。”
- 只有合格评定机构通过对客户管理体系进行完整而有效的审核, 确保 ISO/IEC17021-1 (9.6.3.2) 的所有适用要求都得到满足, 并随后实施了成功的复核和 (认证) 决定活动, 认证证书才能更新

IAF FAQ 特别工作组 2020 年 5 月 7 日

Q24

Q24: What will happen to IAF MDs that are in transition (e.g. MD5, MD22)?; Will these be extended?

A24: Yes, transition periods of all IAF mandatory documents are extended for six months.

by IAF FAQ TF April 26, 2020

问题 24 : 处于转换过渡阶段的 IAF MD 文件(如 MD5、MD22)将会发生什么? 这些文件的转换期会延长吗?

回答 24 : 是的, IAF 所有的强制性文件的转换过渡期延长六个月。

IAF FAQ 特别工作组 2020 年 4 月 26 日

Q23

Q23: In consideration of this extraordinary period, if a Management Systems Certification Body is not able to perform audits, physically or with remote audit technique, can an Accreditation Body replace a witness assessment, as required in IAF MD17, with a remote office assessment or with other assessment activities (IAF MD17, § 2.2.1)?

A23: If witnessing cannot be delayed, instead of observing a CAB carrying out conformity assessment services, an Accreditation Body may either :

use other mechanisms (office assessment activities or other assessment activities IAF MD17, § 2.2.1) to assess the scope of accreditation.

or maintain the scope of accreditation providing that the witnessing assessment shall still be conducted immediately once it is possible.

by IAF FAQ TF April 22, 2020

问题 23:考虑到这一非常时期,如果管理体系认证机构不能实施审核,无论是现场审核还是使用远程审核技术,认可机构能否按照 IAF MD17 的要求,用远程办公室评审或其他评审活动 (IAF MD17 , 2.2.1) 取代见证评审?

回答 23 : 如果见证不能延期,认可机构可以不用观察认证机构的合格评定服务活动,而是采取:

- 使用其他机制(办公室评审活动或其他评审活动, IAF MD17 , 2.2.1)来评审认可的范围。
- 或者保持认可范围,只要有可能,恢复正常后仍应立即进行见证评审。

IAF FAQ 特别工作组 2020 年 4 月 22 日

Q22

Q22: Could time duration for closure of Non Conformities be prolonged taken into consideration the COVID-19 outbreak? If so, what will be the mechanism / procedure and who is responsible for decision making?

A22: Yes, If it is not possible to perform evaluation activities to effectively close the nonconformities (physically or as per IAF MD4: 2018), and if the conditions recommended by IAF ID3: 2011 are satisfied, closure of nonconformities could be prolonged. However, the postponement of any conformity assessment activity (e.g. surveillances, recertification) can only be postponed for up to 6 months in accordance with FAQ 10.

by IAF FAQ TF April 11, 2020

问题 22:考虑到 COVID-19(新冠疫情)的爆发,关闭不符合项的时限可以延长吗?如果是,什么机制/程序以及谁负责决策?

A22:是,如果无法实施评价活动来有效地关闭不符合项(在现场或按照 IAF MD4: 2018 的方式),并且如果 IAF ID3: 2011 推荐的条件都可以满足,不符合项的关闭可能会延长。然而,根据常见问题 FAQ10,任何合格评定活动(例如,监督、再认证)的延期最多只能延期 6 个月。

IAF FAQ 特别工作组 2020 年 4 月 11 日

Q21

Q21: A number of CB clients are, as a result of the COVID-19 outbreak, switching their manufacturing to manufacture items such as face masks or ventilators, some governments are requesting that they have these items within their scope of management system certification approvals. Can such scope extension be done by remote means using MD4?

A21: Yes, following what was already clarified in Q5.

by IAF FAQ TF April 11, 2020

问题 21:由于 COVID-19 的爆发,许多认证机构 CB 的客户正在将其生产转向,生产诸如口罩或呼吸机等产品,一些政府要求将这些产品纳入其管理体系认证批准的范围。这样的扩大范围审核可以通过使用 MD4 的远程方式来完成吗?

回答 21:可以,遵循问题 5 中已经阐明的内容。

IAF FAQ 特别工作组 2020 年 4 月 11 日

Q20

Q20: What will happen to the Transition periods (e.g. ISO 22000:2018, ISO 50000:2018); will these be extended?

A20: Yes, transition periods are extended for six months. The audit for transition can be done with remote audit techniques, following what has already been clarified in Q5.

by IAF FAQ TF April 11, 2020

问题 20: 标准转换的过渡期将如何安排(例如,ISO22000:2018, ISO 50000:2018);这些转换期会延长吗?

回答:是的,过渡期延长了六个月。根据 Q5 中已经阐明的内容,可以使用远程审核技术进行转换审核。

IAF FAQ 特别工作组 2020 年 4 月 11 日

Q19

Q19: According ISO/IEC 17021-1, § 7.2.4, "The initial competence evaluation of an auditor shall include the ability to apply required knowledge and skills during audits, as determined by a competent evaluator observing the auditor conducting an audit". Is it possible to conduct this observation if the observer is using remote

audit techniques?

A19: Yes, provided that the remote audit being observed can fully replace physical audit.

by IAF FAQ TF April 11, 2020

Q19:根据 ISO/IEC 17021-1, 7.2.4, “审核员的初始能力评价应包括在审核中应用所需知识与技能的本领的证实。在审核中应用所需知识与技能的本领应由有能力的评价者在对审核员审核的见证中确定。”。如果观察者使用远程审核技术, 是否有可能进行这种观察?

回答 19 : 是的, 只要被观察的远程审核可以完全取代在现场实施的审核。

IAF FAQ 特别工作组 2020 年 4 月 11 日

Q18

Q18: IAF ID 3:2011 §3 says that “If the risk of continuing certification is low, and based on the collected information the CAB may need to consider alternative short-term methods of assessment to verify continuing system effectiveness for the organization. This may include requesting relevant documentation (for example, management review meeting minutes, corrective action records, results of internal audits, test/inspection reports, etc.) to be reviewed off site by the CAB to determine continuing suitability of the certification (on a short-term basis only)” . Is this time, used to off-site review the documentation provided by the company, to be considered as “audit time” according to IAF MD 5:2019?

A18: yes, the off-site review of the documentation provided by the company is needed to plan and accomplish a complete and effective audit of the client organization’ s management system. This time is to be considered as “audit time” according to IAF MD 5:2019. Audit duration may be reduced due to such off-site documentation review.

by IAF FAQ TF April 11, 2020

Q18 : IAF ID 3:2011 文件的第 3 节提到 “如果持续认证的风险较低, 并且基于收集到的信息, 合格评定机构 (CABs) 可能需要考虑替代的短期评审方法, 以验证组织的管理体系的持续有效性。这可能包括要求组织提供相关文件 (例如, 管理评审会议记录、纠正措施记录、内审结果记录、检测/检验报告等)。由合格评定机构 (CABs) 实施非现场的审查, 以确定认证的持续适宜性 (仅短期)” 根据 IAF MD 5:2019, 用于对公司提供的文件进行非现场审核的时间是否被视为 “审核时间” ?

回答 18 : 是的, 需要对公司提供的文件进行非现场审核, 以计划和完成对客户组织管理体系全面有效的审核。根据 IAF MD 5:2019, 该时间将被视为 “审核时间”。由于这样的非现场文件审查占用了时间, 审核持续时间可能会缩短。

IAF FAQ 特别工作组 2020 年 4 月 11 日

Q17

Q17: During the COVID-19 crisis, if a CAB conducts a part of the initial certification of a management system with remote audit activities and plans to complete the remainder of the audit onsite within six months, is it possible to issue the certificate at the conclusion of the remote audit activities?

A17: No, a certificate can only be issued if the CAB is able to evaluate all the applicable requirements of ISO/IEC 17021-1 (9.3.1.2 Stage 1 and 9.3.1.3 Stage 2) through a complete and effective audit of the client's management system, followed by a successful review and decision making activities. However, this could change for specific schemes.

by IAF FAQ TF April 7, 2020

问题 17：在新冠肺炎疫情危机期间，如果 CAB（合格评定机构）在对客户管理体系进行初次认证时，一部分审核通过远程审核的方式进行，并计划在六个月内完成剩余部分的现场审核，是否有可能基于远程审核活动的结论颁发证书？

回答 17：不可以。如果认证机构能够评审所有适用的 ISO/IEC 17021-1 (9.3.1.2 第一阶段和 9.3.1.3 第二阶段)的要求，通过对客户管理体系全面有效的审核，以及随后的成功复核并做出（认证）决定，才能颁发证书。然而，对于特定的认证制度，这种情况可能会有所不同。

IAF FAQ 特别工作组 2020 年 4 月 7 日

Q16

Q16: in order to transfer an Accredited Certification of Management Systems (IAF MD2:2017), is it possible to conduct the pre-transfer visit with remote auditing techniques?

A16: Yes, if all the points listed in § 2.2.4 of IAF MD2:2017 and any issues arising from the document review, for example major nonconformities (2.2.2) can be evaluated remotely. However, this could change for specific schemes.

by IAF FAQ TF April 3, 2020

问题 16:为了转换一个获认可的管理体系认证证书 (IAF MD2:2017)，是否可以使用远程审核技术进行转换前的访问？

回答 16：可以。如果 IAF MD2:2017 的 2.2.4 中列出的所有要点以及文件评审中提出的任何问题，例如，严重不符合项(2.2.2)，都可以通过远程的方式评价。然而，对于特定的认证制度，这种情况可能会有所不同。

IAF FAQ 特别工作组 2020 年 4 月 3 日

Q15

Q15: What will happen to the Migration period for ISO 45001; will it be extended?

A15: OHSAS 18001 certification can be extended by up to six months as detailed in FAQ 10. This means that transition period for migrating accredited certifications from OHSAS 18001:2007 to ISO 45001:2018 is extended to:

30 September 2021.

The audit for migration can be done with remote audit technique, following what already clarified in Q5.

(Answer updated 11/04/2020)

问题 15 : ISO 45001 的转换期将会发生什么? 会延长吗?

回答 15 : 如 FAQ 第 10 项所述, OHSAS 18001 认证可以延长六个月。这意味着将获认可的认证从 OHSAS 18001:2007 转换到 ISO 45001:2018 的过渡期延长至:

2021 年 9 月 30 日。

转换审核可以使用远程审核技术来完成, 遵循问题 5 中已经阐明的内容。

(答案更新于 2020 年 4 月 11 日)

Q14

Q14: For OH&SMS, according to IAF MD5:2019 (applicable from 7 May 2020), remote auditing techniques shall be limited to reviewing documents/records and to interviewing staff and workers. In addition for OH&SMS, process control and OH&S risk control cannot be audited using remote audit techniques. Considering the specific circumstances, is this valid?

A14: No, considering the specific circumstances, and that the applicability of IAF MD5:2019 has been extended from 7 May 2020 to 7 November 2020 (see Q24), the restriction placed on remote audit activities by IAF MD 5 shall not apply. This means that process control and OH&S risk control can be audited using remote audit techniques until the end of the COVID-19 emergency.

Posted 1st of April and updated the 26th of April

问题 14:对于职业健康安全管理体系, 根据 IAF MD5:2019(自 2020 年 5 月 7 日起生效), 远程审核技术应仅限于审查文件/记录和采访员工和工人。另外, 对于职业健康管理, 过程控制和职业健康安全风险控制不能使用远程审核技术进行审核。考虑到具体情况, 这是是否还有效?

回答 14 : 不, 考虑到具体情况, 并且 IAF MD5:2019 的适用期已从 2020 年 5 月 7 日延长至 2020 年 11 月 7 日(见问题 24), IAF MD5 对远程审核活动的限制将不再适用。这意味着过程控制和职业健康安全风险控制可以使用远程审核技术进行审核, 直到 COVID-19 紧急事件结束。

IAF FAQ 特别工作组 4 月 1 日发布, 4 月 26 日更新

Q13

Q13: In consideration of this extraordinary period ,may all of:

- the conformity assessment activities (e.g. surveillances, recertification) be postponed for up to 6 months, and
- The validity of any output of any conformity assessment activity (e.g. a

certificate or report) be extended for a corresponding period of up to 6 months?

A13: No. In cases where CABs are still able to perform evaluation activities physically or when these can be fully replaced with evaluation activities as per IAF MD 4, then normal scheduled conformity assessment activities (e.g. surveillances, recertification) should be performed. Otherwise, if the conditions recommended by IAF ID 3: 2011 are satisfied, the normal scheduled conformity assessment activities may be postponed for up to 6 months, and the validity of any output of the conformity assessment activity (e.g. a certificate or report) may be extended for a corresponding period of up to 6 months.

by IAF FAQ TF April 1, 2020

问题 13 考虑到这个非常时期。是否所有的

- 合格评定活动，例如监督、再认证，可推迟六个月
- 任何输出或任何合格评定活动(例如证书或报告)的有效期可相应延长至六个月

回答 13:否。如果认证机构仍然能够实施到现场的审核活动，或者根据 IAF MD4 可以完全实施代替审核的活动，则应执行正常计划的合格评定活动(例如监督、再认证)。否则，如果满足 IAF ID 3: 2011 建议的条件，正常计划的合格评定活动可以推迟最多 6 个月，并且合格评定活动的任何输出(例如证书或报告)的有效性可相应延长最多 6 个月。

IAF FAQ 特别工作组 2020 年 4 月 1 日

Q12

Q12: Is IAF MD4:2018 exclusively applicable for management systems, persons, and product?

A12: No, Although the scope of IAF MD4:2018 is for the auditing /assessment of management systems, persons, and product (see IAF MD4:2018 Section 1-Scope), it can also be used for other types of conformity assessment activities under the IAF MLA, e.g. validation or verification, as referenced in Section 2 – para. 2 of MD4.

by IAF FAQ TF March 23, 2020

问题 12:IAF MD4:2018 是否仅适用于管理体系、人员和产品？

回答 12:否，尽管 IAF MD4:2018 的范围是针对管理体系、人员和产品的审核/评审(参见 IAF MD4:2018 第 1 节-范围)，但它也可用于 IAF MLA 框架下的其他类型的合格评定活动，例如，审定或者核查，如 MD4 文件第 2 节第二段所述。

IAF FAQ 特别工作组 2020 年 3 月 23 日

Q11

Q11: Is IAF ID3:2011 exclusively applicable for management systems certification?

A11: No, IAF ID3:2011 is primarily applicable for management systems certification, but it can be applied to all the accreditation and conformity assessment activities

under the IAF MLA (see IAF ID3:2011 para. 1): Management systems certification
Product certification Certification of persons Validation and Verification
by IAF FAQ TF March 23, 2020

问题 11 : IAF ID3:2011 是否仅适用于管理体系认证 ?

回答 : 否 , IAF ID3:2011 主要适用于管理体系认证 , 但它也可以适用于 IAF 多边协议下的所有认可和合格评定活动(见 IAF ID3:2011 第 1 段) : 管理体系认证、产品认证、人员认证、审定与核查。

IAF FAQ 特别工作组 2020 年 3 月 23 日

Q10

Q10: For schemes under IAF MLA (Management system certification, Product certification, Certification of persons, Validation and Verification), how are conformity assessment activities to be managed in this extraordinary period?

A10: In consideration of this extraordinary period, for schemes of management system certification, product certification and certification of persons under IAF MLA, if it is not possible to perform evaluation activities (physically or as per IAF MD4: 2018), such as audits or exams, and if the conditions recommended by IAF ID3: 2011 are satisfied, all the conformity assessment activities (e.g. surveillances, recertification) may be postponed for up to 6 months, and the validity of any output of any conformity assessment activity (e.g. a certificate or report) may be extended for a corresponding period of up to 6 months. In this last instance, in order to document this to the client, if applicable, it is strongly suggested to issue an extension letter, which ratifies this extended validity and its period. This is essential to guarantee transparency and a correct communication to the external market. Appropriate records should also be updated. However, this could change for specific schemes. For validation and verification, particularly the greenhouse gas (GHG) validation and verification at project or organizational level, they are normally one-off conformity activities, therefore the IAF ID3 guidelines related to surveillance, recertification, extension of certification and recertification cycle etc. may not be applicable. However, for the assessment and accreditation of validation and verification bodies (VVBs), IAF ID3 can be used (see A11), and the remote approaches as per IAF MD4:2018 can be used by both ABs and VVBs (see A12).

Updated on 23/03/2020 to include all IAF MLA main scopes.

问题 10 :对于 IAF MLA 下的认证制度(管理体系认证、产品认证、人员认证、审定和核查) , 在此非常时期应该如何管理合格评定活动 ?

回答 : 考虑到这一非常时期 , 对于在 IAF 多边互认制度下的管理体系认证、产品认证和人员认证制度 , 如果无法开展审核活动(到现场或按照 IAF MD4: 2018 的方法) , 如审核或考试 , 并且如果符合 IAF ID3: 2011 建议的条件 , 所有合格评定活动(如监督、再认证)可推迟 6 个

月，任何合格评定活动(如证书或报告)的任何输出的有效性可推迟 6 个月。在最后一种情况下，为了向客户证明这一点，如果适用的话，强烈建议签发一份延期信，批准延长有效性和延长期限。这对于保证透明度和与外部市场的正确沟通至关重要。适当的记录还应保持更新。然而，对于特定的认证制度，这种情况可能会有所不同。对于审定与核查，尤其是项目或组织层面的温室气体(GHG)审定与核查，它们通常是一次性的符合性活动，因此，IAF ID3 准则涉及的监督、再认证、扩大认证和再认证周期等，可能不适用。然而，对于审定与核查机构的评审和认可，可以使用 IAF ID3(见 A11)。并且认可机构和核查机构也可以按照 IAF MD4:2018 使用远程审核的方法(见 A12)。

于 2020 年 3 月 23 日更新，以包括所有 IAF MLA 多边互认的主要范围。

Q9

Q9: Is IAF ID3:2011 still applicable even though ID3:2011 refers to an accreditation standard that is no longer valid (ISO/IEC 17021:2011)?

A9: Yes. It is applicable. IAF General Assembly Resolution 2015-15 was taken to confirm this. For the maintenance of IAF Technical Committee documents it states: "The General Assembly, acting on the recommendation of the Technical Committee, resolved that references to ISO/IEC 17021 in IAF documents shall be understood to refer to ISO/IEC 17021-1:2015 in relation to CABs that have completed the transition and after the transition period. However, ABs and CABs will need to take account of the changes in ISO/IEC 17021-1 when using IAF documents which may not be revised until after the transition period to reference ISO/IEC 17021-1."

问题 9：即使 ID3:2011 引用的标准 (17021:2011) 是失效的，IAF ID3:2011 是否仍然适用？

回答：是的。它是适用的。IAF 全会第 2015-15 号决议已经确认了这一点。关于 IAF 技术委员会文件的维护，该决议指出：“全会根据技术委员会的建议，决定在 IAF 文件中提及的 ISO/IEC17021 应理解为是 ISO/IEC17021-1:2015，涉及已完成转换和转换过渡期后的合格评定机构。然而，在使用 IAF 文件时，认可机构 ABs 和合格评定机构将需要考虑到 ISO/IEC17021-1 中的变化，这些文件可能在转换期结束后才能修订，以参考 ISO/IEC17021-1。”

IAF FAQ 特别工作组 2020 年 3 月 20 日

Q8

Q8: If there is a postponement of 6 months in the deadline of a certificate, according to IAF ID3, will the next accreditation/certification cycle start from the new deadline, or does the original one need to remain?

A8 :The deadline remains the original one. However, it could happen that in specific circumstances the timeline of surveillance could be modified accordingly.

by IAF FAQ TF March 13, 2020

问题 8：根据 IAF ID3，如果证书的截止日期延期了 6 个月，下一个认可/认证周期是从新的截止日期开始，还是需要保留原来的周期？

回答：截止日期仍然是按照原来的认证周期。然而，在特定情况下，监督审核的时间表可能会做相应修改。

IAF FAQ 特别工作组 2020 年 3 月 13 日

Q7

Q7: What happens if a Company/CB is not comfortable in this period to give access to its location to the AB audit / assessment team for witnessing?

A7 :IAF ID3 allows, in extraordinary events or circumstances like this, postponement of the assessment / audits. Moreover, according to IAF MD17:2015 Witnessing Activities for the Accreditation of Management System Certification Bodies and/or relevant timeline modified accordingly, it is justifiable and understandable in this situation that a CB or its client refuses a witness assessment by the AB. It is important to make audits only when there is agreement of all the parties involved (client, CB and AB). See MD17, 2.2.2 and 2.4.2. It is also possible to perform partial witnessing (2.4.10).

问题 7：如果一个公司/认证机构在此期间不愿意让认可机构 AB 的审核/评审组进入其所在地进行见证，会发生什么情况？

回答：在特殊事件或类似情况下，IAF ID3 允许推迟评审/审核。此外，根据 IAF MD17:2015《管理体系认证机构的认可见证活动》和/或相关的已修改的时间表，在这种情况下，一个认证机构 CB 或者他的客户拒绝认可机构 AB 的见证评审是合理和可以理解的。只有在所有相关方(客户、CB 和 AB)同意的情况下，安排审核才是重要的。参见 MD17 文件的 2.2.2 和 2.4.2 条款。也可以进行部分见证(参见 2.4.10 条款)。

IAF FAQ 特别工作组 2020 年 3 月 13 日

Q6

Q6: Is the limit imposed by ISO/IEC 27006 (maximum 30% of remote audit) still valid?

A6 : ISO/IEC 27006 was published in 2015, while IAF MD4 was published in 2018 (Issue 2, Issued 04 July 2018, application from 04 July 2019). So, considering the specific circumstances, for ISO/IEC 27006 the relevant rules of IAF MD4 also are applicable. This means that is possible to adopt to ISO/IEC 27006 the MD4 approach, that is to exceed 30% "off-site" and allow a 100% off-site, during this COVID-19 period.

问题 6:ISO/IEC27006(远程审核的时间占比最大不超过 30%)规定的限制仍然有效吗？

回答：ISO/IEC 27006 于 2015 年发布，而 IAF MD4 于 2018 年发布(第 2 版，2018 年 7

月 4 日发布，2019 年 7 月 4 日开始生效)。因此，考虑到具体情况，对于 ISO/IEC27006，IAF MD4 的相关规则也适用。这意味着 MD4 中的方法可以在 ISO/IEC27006 的审核中应用，即在 COVID-19 (新冠疫情) 期间超过 30% 的“非现场”，并允许 100% 的非现场。
IAF FAQ 特别工作组 2020 年 3 月 13 日

Q5

Q5: Is it possible to perform a full certification audit remotely?

A5 :Yes, in theory it is possible, if for the specific scheme all the requirements can be evaluated remotely, including observation of activities. However, this could change for specific schemes.

by IAF FAQ TF March 13, 2020

问题 5:是否有可能以远程的方式实施一次完整的认证审核？

回答 :是的，理论上这是可能的，如果对于特定的认证制度，所有的要求都可以被远程评审，包括对活动的观察。然而，对于特定的认证制度，这种情况可能会有所不同。

IAF FAQ 特别工作组 2020 年 3 月 13 日

Q4

Q4: Will the Nov. 2020 deadline for implementation of the new version of ISO/IEC 17011 still hold?

A4. The joint committee with ILAC that looks after all peer evaluations has developed a related document. The document has the agreement of the Regional MLA Chairs and is available on the IAF Website under:

https://www.iaf.nu/articles/ISOIEC_17011_Transition_and_COVID19/637

<https://www.iaf.nu/upFiles/IAF-ILAC%20Statement%20re%20delayed%20evaluations%2012%20March%202020.pdf>

by IAF FAQ TF March 13, 2020

Q4: 实施新版 ISO/IEC 17011 的截止日期是否仍然是 2020 年 11 月？

回答 : IAF 与 ILAC 联合委员会负责实施所有同行评审的事项，该委员会制定了一份相关的文件。该文件获得了区域 MLA 主席的同意，并可在 IAF 网站下获得:

https://www.iaf.nu/articles/ISOIEC_17011_Transition_and_COVID19/637

<https://www.iaf.nu/upFiles/IAF-ILAC%20Statement%20re%20delayed%20evaluations%2012%20March%202020.pdf>

IAF FAQ TF 2020 年 3 月 13 日

Q3

Q3: What is happening with IAF MLA peer evaluations during the outbreak?

A3. The joint committee with ILAC that looks after all peer evaluations has developed a related document. The document has the agreement of the Regional

MLA Chairs and is available on the IAF Website under:
<https://www.iaf.nu/upFiles/IAF-ILAC%20Statement%20re%20delayed%20evaluations%2012%20March%202020.pdf>
https://www.iaf.nu/articles/ISOIEC_17011_Transition_and_COVID19/637
by IAF FAQ TF March 13, 2020

问题 3:在疫情爆发期间, IAF MLA 同行评审是如何安排的?
A3. 负责所有同行评审的 ILAC 联合委员会制定了一份相关文件。该文件得到了区域 MLA 主席的同意, 并可在 IAF 网站上查阅, 网址为:
<https://www.iaf.nu/upFiles/IAF-ILAC%20Statement%20re%20delayed%20evaluations%2012%20March%202020.pdf>
https://www.iaf.nu/articles/ISOIEC_17011_Transition_and_COVID19/637
IAF FAQ TF 2020 年 3 月 13 日

Q2

Q2: Is it permissible to use remote assessments and audits to maintain the validity of accredited certifications during the COVID-19 crisis?

A2 : Yes. The IAF Statement on COVID-19 referenced the use of remote assessments and the mandatory document to be used by ABs and CBs, IAF MD4:2018 IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing and Assessment Purposes. In addition, there is also informative document on principles for remote assessments – IAF ID12:2015 Principles on Remote Assessment that can be used in this instance. It is necessary to bear in mind however, that regulatory bodies, scheme owners and purchasers may have specific requirements that may need to be adhered to, and which may take precedence. IAF ID3 may also assist readers.

问题 2:在新冠肺炎疫情危机期间, 是否允许使用远程评审和审核来维护认证的有效性?
回答: 是的。IAF 关于新冠肺炎疫情的声明中提到了远程评审的使用, 以及 ABs 和 CBs 使用的强制性文件, IAF MD4:2018, IAF 的强制性文件“信息和通信技术在审核和评审中的应用”。此外, 还有关于远程评审原则的资料性文件—IAF ID12:2015, 该文件中所规定的远程审核原则可在此时期使用。然而需注意是监管机构、方案所有者和购买者可能有其他首先需要遵守的具体要求。IAF ID3 也可以帮助其他适用的用户。

IAF FAQ 特别工作组 2020 年 3 月 13 日

Q1

Q1: Are IAF and ILAC going ahead with the Joint IAF-ILAC Mid-term meetings in Beijing in March considering the COVID-19 outbreak, and subsequent travel restrictions?

A1 : No, these meetings have been cancelled and not being re-scheduled. The work will be progressed by other means.

问题 1:考虑到新冠肺炎疫情的爆发以及随后的旅行限制，IAF 和 ILAC 是否会在 3 月份在北京举行 IAF-ILAC 联合中期会议？

回答：不，这些会议已经取消，没有重新安排。这项工作将通过其他方式进行。

IAF FAQ 特别工作组 2020 年 3 月 13 日