To accredited and applicant certification bodies providing management system certifications

Our ref.: DC2017SSV336 *Milan,* 23/11/2017

Object: **Informative circular N° 26/2017 – Department of Certification and Inspection**
Revision of MD documents, IAF clarifications, ISO 17021-2 and ISO 17021-3 transitions

In June 2017, the IAF website published the new revisions of three mandatory documents: IAF MD 2, IAF MD 8, IAF MD 9, applicable from June 2018.

Below there is some useful information concerning the changes introduced by the new editions of the documents.

IAF MD 2:2017

The document introduces many new elements with respect to the previous one, which was also rather old (2007).

It is suggested that CABs analyse the document carefully and below we highlight the following aspects:
- it is applicable not only for certificates covered by accreditation at IAF MLA level, but also at EA MLA level;
- the EA resolution was implemented (already applied by ACCREDIA in its decisions) whereby a certificate issued by a CAB which has had its accreditation suspended or withdrawn, or which has stopped operating, can be transferred, within a maximum of six months. In these cases the accreditation body must always be informed before the transfer. After six months the file must be managed as a new certification;
- the pre-transfer visit performed during the transfer is obligatory only if requested after the pre-transfer document review (e.g. if there are outstanding major NC). The pre-transfer visit is not an audit;
- CABs must define the competence criteria for persons doing the pre-transfer review whilst the competences of persons doing the pre-transfer visit must be equal to those of an auditor qualified for the technical areas which are the object of the visit;
- for the conduct of the pre-transfer review the documentation of the initial audit/last renewal audit, in addition to the documentation of the last surveillance, is necessary. Without this documentation, the organization shall be treated as a new client;
- during the phase of the pre-transfer review the accepting CAB is required to set and record its audit plan and program, if necessary revising those of the issuing CAB;
- the transfer of a certificate must not coincide with a surveillance or renewal audit. This means that it is necessary, beforehand, to complete the transfer activities (document review plus the pre-transfer visit, if necessary), and only afterwards it is possible to do the surveillance or renewal audit;
- after the transfer activities (document review plus the pre-transfer visit, if necessary) the normal decision-taking process follows, carried out by independent personnel from those who performed the document review and pre-transfer visit (if done);
- if the certificate issued upon completion of the transfer activities gives the date of initial certification, it must indicate that the certificate has been issued previously by another CAB;
- the obligation among CABs to collaborate is upgraded (upon request, the issuing CAB must give to the accepting CAB all the documents and information in accordance with IAF MD 02: audit documents, information on the validity of the certificate, NCs and their status), otherwise sanctions may be imposed by the accreditation body (suspension/withdrawal of accreditation);

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- a CAB cannot withdraw a certificate only because a company communicates its intention to transfer certification to another CAB, otherwise sanctions may be imposed by the accreditation body (suspension/withdrawal of accreditation);
- following completion of the transfer activities and the issue of the relative certificate, the receiving CAB must inform the issuing CAB.

With reference to requirement 2.2.4 (iv) "that the site or sites wishing to transfer certification hold a valid accredited certification", due to the fact that only the issuing CAB can confirm the validity of a certificate, it is considered acceptable that, during the pre-transfer review, the accepting CAB can demonstrate to ACCREDIA that it has respected this requirement by presenting a self-declaration issued by the company which asked for the transfer.
This self-declaration must confirm the validity of the certificate.
Following receipt of the communication from the accepting CAB of the transfer of the certificate, the issuing CAB (as stated in § 2.4.5 of IAF MD 2), must inform, without delay, the accepting CAB if its certificate is not covered by accreditation and is not valid.
If the accepting CAB, after issuing its own certificate, obtains knowledge from the issuing CAB or from another source, of the non-validity of the certificate of the organization at the time of the transfer, it must immediately withdraw the certification issued, after having established the fraudulent behavior of the organization in question.

IAF MD 8:2017 and IAF MD 9:2017 – *applicable for the QMS scheme 13485*

The main change consists in the introduction of a new Main Technical Area ("1.7 – PARTS AND SERVICES"), which includes the Technical Areas regarding the parts and processes of support related to medical devices (e.g. raw materials, components, distribution services etc.) which, in the previous versions of the IAF documents, were included within the Technical Areas which included medical devices.
In cases of companies undertaking production/manufacturing activities, also providing transport, support services, installation, assistance and/or maintenance of devices for production, it is acceptable to consider as unique Technical Area of reference the Area related to the category of the device, when such services come within the life-cycle of the device made by the organization. In all other cases the specific Technical Areas of the new Main Technical Area 1.7 must be assigned to the companies.

The attached document shows the list of updated ACCREDIA Technical Areas.
The requests for extension of accreditation to Technical Areas included in the Main Technical Area "1.7" will be processed in accordance with the applicable ACCREDIA General Regulations (document review plus witness assessment) except if, in the three years before the request for extension, the Technical Area has already undergone – with a positive result – an ACCREDIA assessment (witnessing or as part of the sampling of files during the office assessment): in such cases it is sufficient to perform only the document review, during which it is necessary to provide also the reference of the ACCREDIA assessment already performed.
CABs must update files already under management by introducing the new Technical Areas by 06/11/2019.

Clarifications regarding the application of requirements 2.3.2 and 4.4 of IAF MD 5:2015

On the occasion of the IAF meeting held in Vancouver, Oct. 21-30, 2017, the level of detail required on the part of CABs to meet the requirements 2.3.2 e 4.4 of the document IAF MD 5:2015 was discussed, relating to information which the CAB must give to companies as part of the contract.
The aim of introducing new requirements for ensuring transparency in market comparisons was reaffirmed, developing the knowledge of companies and preventing unfair competition which would damage the entire certification system.

It was decided that CABs must provide sufficient information to enable companies to understand how the quotation was calculated. CABs are requested to state at least:
- what criterion/criteria was/were used for determining the effective equivalent personnel among the following:

- Part time personnel and employees partially in scope (IAF MD 5, § 2.3.3)
- Ripetitive processes within scope (IAF MD 5, § 2.3.4)
- Shift work employees (IAF MD 5, § 2.3.5)
- Temporary unskilled personnel (this point is applicable only for activities performed in developing countries - IAF MD 5, § 2.3.6)

– the number of audit days
– the factors of reduction/increase (without the need to indicate also the percentage value) applied by the CAB on the basis of information provided by the organization, for all reference normative documents (e.g. also the document IAF MD 11).

Information must also be given to the client of the fact that the CAB is available to provide more detailed clarifications concerning the criteria used for setting the times of the audit, including the identification of equivalent personnel (as stated in § 2.3.2 of IAF MD 5). This information must already be included in the quotation documents which, if accepted by the client, become contractual documents: the information can also be given in attachments, provided that they are a part of the contractual documentation between the CAB and the company.
A simple reference to the document IAF MD 05 is not adequate to comply with the requirements.

Clarifications regarding the transition period for the reissue of certificates containing both accredited and non-accredited areas

In the light of the requests for clarifications received, it is to be remembered that, as reported in the ACCREDIA Circulars N° 24/2015 and N° 32/2016, certificates with the accreditation logo cannot show non-accredited sectors/areas: it is compulsory to issue two different certificates (one with the ACCREDIA logo in accredited areas and one without the ACCREDIA logo in the non-accredited areas).
This obligation has been applicable since November 2016 for new certifications.
For certifications already issued the transition period is valid as decided during the IAF General Assembly in New Delhi, permitting the re-issuance of certificates until 06/11/2019.

Verification of adaptation to ISO/IEC 17021-2:2016 and ISO/IEC 17021-3:2017

The transition period defined by the IAF General Assembly is two years from the date of publication for both standards (transition must be completed by 01/12/2018 for 17021-2 and by 01/04/2019 for 17021-3).

ACCREDIA will verify the adaptation of CABs to the new version of the standards starting in 2018 as a part of surveillance and renewal activities in accordance with the normal cycle of accreditation, as set out in § 1.5.1.5.1 of ACCREDIA Regulation RG-01 rev. 04.

We are available for any clarifications

With kind regards

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