International Accreditation Forum, Inc.

参考和訳

IAF-TC-12.04-19

International Accreditation Forum
Technical Committee Discussion Paper

Name of party submitting issue for discussion: IIOC

Statement of the issue: Clarification of clause 7.7.1 of IAF MD1 2018 against ISO 17021-1:2015 ISO 17021-1:2015 に対する IAF MD1 2018 の 7.7.1 の明確化

Discussion

Clause 4.3.1 MD1 2007 reads:
When nonconformities, as defined in ISO/IEC 17021-1 clause 9.1.15 (b), are found at any individual site, either through the organization's internal auditing or from auditing by the certification body, investigation should take place to determine whether the other sites may be affected. Therefore, the certification body should require the organization to review the nonconformities to determine whether they indicate an overall system deficiency applicable to other sites or not. If they are found to do so, corrective action should be performed and verified both at the central office and at the individual affected sites. If they are found not to do so, the organization should be able to demonstrate to the certification body the justification for limiting its follow-up corrective action.

ISO/IEC 17021-1:2011 paragraph 9.1.15 b) reads:
b) it has reviewed, accepted and verified the effectiveness of correction and corrective actions, for all nonconformities that represent

1) failure to fulfil one or more requirements of the management system standard, or
2) a situation that raises significant doubt about the ability of the client's management system to achieve its intended outputs;

The Note to Clause 9.1.9.6.4 then states that:
NOTE: Nonconformities, consistent with the requirements of 9.1.15 b), can be classified as major, whereas other nonconformities [9.1.15 c)] can be classified as minor nonconformities.

As a result, the clause in MD1 2007 refers to Major Non-conformities only.

We now come to MD1:2018 clause 7.7.1 which states:
When nonconformities, as defined in ISO/IEC 17021-1, are found at any individual site, either through the organization's internal auditing or from auditing by the Certification Body,

investigation shall take place to determine whether the other sites may be affected. Therefore, the Certification Body shall require the organization to review the nonconformities to determine whether or not they indicate an overall system deficiency applicable to other sites.

If they are found to do so, corrective action shall be performed and verified both at the central function and at the individual affected sites. If they are found not to do so, the organization shall be able to demonstrate to the Certification Body the justification for limiting its follow-up corrective action.

The definitions of a non-conformity in ISO/IEC 17021-1:2015 are:

3.11 nonconformity

non-fulfilment of a requirement

3.12 major nonconformity

nonconformity (3.11) that affects the capability of the management system to achieve the intended results

Note 1 to entry: Nonconformities could be classified as major in the following circumstances:

— if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;

— a number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

3.13 minor nonconformity

nonconformity (3.11) that does not affect the capability of the management system to achieve the intended results

This means that clause 7.7.1 in the new MD1 is being interpreted by some AB auditors as now covering both Major and Minor Non-conformities rather than just the Majors which was the intention in the previous version of MD1

The authors or editors of the new MD1 have rightly changed the reference in the document to the new version of ISO/IEC 17021-1, however was it their intention to also change the type of non-conformity covered by this clause, or is this an error and the requirement should only relate to major non-conformities which are the non-conformities which call into question the continued certification of the organization?

If it is intentional then this then conflicts with the requirements of ISO/IEC 17021-1:2015, which does not require such action on Minor Non-conformities.

IAF MD 1:2018 7.7.1項では、認定機関によってはメジャーもマイナーも含む不適合事項を意図しているように解釈される。改定MD1はISO/IEC 17021-1に準拠して変更したと思われる。その変

更はこの項 (IAF MD1:2018 7.7.1項)の意図も変更してしまっている。IAF MD 1:2018 7.7.1項では、マイナーな不適合事項は含んでいないのではないか？

Requested action by the IAF TC:
Clarification is requested as to the intent of clause 7.7.1 of IAF MD1 2018

Consensus of the IAF TC (also to be documented in the meeting summary):

Regarding IAF MD 1, section 7.7.1:
IAF MD 1, 7.7.1 について:

- The organization is responsible for investigating ALL NCRs (minor and major) per 7.7.1.
- The CB is to verify corrective actions in accordance with ISO/IEC 17021-1 (e.g. sections 9.4.10 Effectiveness of corrections and corrective actions, 9.5.2.b and 9.5.3.2 Actions prior to making a decision, etc.)
- 組織は、7.7.1 に従って全ての不適合（minor 及び major)を調査する責任がある。
- CB は、ISO/IEC 17021-1 に従って是正処置を検証すること（例：9.4.10 修正及び是正処置の有効性、9.5.2.b 及び 9.5.3.2 （訳注：正しくは 9.5.2）決定を行う前の処置、など）。

Further WG Discussions
MD1:2018 clause 7.7.1:

When nonconformities, as defined in ISO/IEC 17021-1, are found at any individual site, either through the organization's internal auditing or from auditing by the Certification Body, investigation shall take place to determine whether the other sites may be affected. Therefore, the Certification Body shall require the organization to review the nonconformities to determine whether or not they indicate an overall system deficiency applicable to other sites.

If they are found to do so, corrective action shall be performed and verified both at the central function and at the individual affected sites. If they are found not to do so, the organization shall be able to demonstrate to the Certification Body the justification for limiting its follow-up corrective action.

The co-conveners of MD 1 recall that it was intentional to call out nonconformities; meaning minor and major, not just major NCRs.

更なるWG議論
IAF MD1:2018 7.7.1項:

組織の内部監査又は認証機関の審査のいずれでも、ISO/IEC 17021-1 に規定されている不適合があるサイトで検出された場合は、その他のサイトにも影響があるかどうかを判断するための調査を行わなければならない。したがって認証機関は、不適合が他のサイトにも当てはまるシステム全体の不備を示唆しているかどうかを決定するために、組織が不適合をレビューするよう要求しなければならない。

不適合がシステム全体の不備を示唆していることが判明した場合は、中央機能及び影響を受ける個別のサイトにおいて是正処置を実施及び検証しなければならない。不適合がシステム全体の不備を示唆するものではないということが判明した場合は、組織は、是正処置のフォローアップを限定的なものとする正当な理由を認証機関に実証できなければならない。

MD 1 の共同主査は、不適合は重大な不適合だけを指すのではなく、軽微と重大と両方を指す意図であったことを確認した。