

IAF-TC-12.03-19

International Accreditation Forum Technical Committee Discussion Paper

Name of party submitting issue for discussion: IIOC

Statement of the issue: Pre-audit acceptable under ISO/IEC 17021-1 ISO/IEC 17021-1 において許容される予備審査(pre-audit)

Discussion:

An AB has recently issued an e-mail addressed to their accredited CABs underlining the following:

Quote

'Pre-audit of client is not acceptable as per ISO/IEC 17021-1

This is to inform you that ISO/IEC 17021-1 envisages stage 1 and stage 2 audits but no pre-audit. Also, carrying out of internal audits by the CBs and any part of the same legal entity to its certified clients is a significant threat to impartiality and unacceptable.

Any activity of pre-audit would amount to internal audit which is not acceptable.' Unquote

In IIOC's view, the following considerations are to be made in relation to a Pre-audit:

- It is not an Internal Audit activity. It is a mis-interpretation and not correct to consider execution of a pre-audit as being equal to performing internal audit with regard to impartiality. The reason is that by performing internal audit on behalf of the client the CB is doing activities explicitly required to be fulfilled by the customer to comply with an MS standard (internal audit is a requirement in all MS standards). Therefore, a CB is considered to not be able to perform a certification audit in an impartial manner if they have executed the internal audit.
- It is to be performed on a one-spot basis and before the accredited certification activities
- Its output is a report with a list of findings and not any solution (therefore no issue about impartiality and/or consultancy issue)
- It is performed outside the certification contract (i.e. when the customer is requesting it (as it is an optional activity). It shall be covered by a separate contract
- It is not an accredited activity and therefore not covered by any AB accreditation scope
- ISO 17021-1 is not defining requirements about it and therefore it can't be said that it is not acceptable as per ISO/IEC 17021-1
- For many accredited CABs, it is and has been for many years a common practice.

Furthermore, there is a previous IAF Technical Committee Discussion Paper presented at the 2010 IAF/ILAC Joint Annual meetings, on the same subject (see below)

IAF Technical Committee Meeting Held 16-17 March 2010 in Rio de Janeiro

Extract from the MoM – DP section (IAF Decision Log 10/03/08 Rio 12.2)

'12.2 certification audit process, stage 1 and stage 2

Mr. Balakrishnan of NABCB submitted a paper regarding certification audit stage 1 and 2 process (TC-04-10rev.1). In TC they discussed

(1) Would a "pre-audit" between stage 1 and stage 2 audits be acceptable in terms of the process described in ISO/IEC 17021 or would such audits be considered as presenting a conflict of interest situation?

(2) Is a repeat of stage 1 audit acceptable and if so under what circumstances?

(3) Would a pre-audit before a stage 1 audit be acceptable?

Consensus of the TC: There was consensus in IAF TC

- that more than one stage 1 audit is possible with proper justification (2);
- that pre-audits prior to stage 1 are acceptable as long as impartiality is not compromised
 (3), but not appropriate between stage 1 and stage 2 (1).'

ある認定機関が、認定先の適合性評価機関に対して「顧客への予備審査は、ISO/IEC 17021-1 上は認められていない」と通知したことに端を発した議論。予備審査が許容されるかという議論 に加えて、予備審査と、内部監査、第一段階審査、第二段階審査の関係に関する議論。 2010 年の IAF/ILAC 年次総会における IAF TC の議論結果を参照。

Requested action by the IAF TC:

The IAF Technical Committee to confirm the decision made at the 2010 IAF Technical Committee meeting at the IAF/ILAC Joint Annual meetings (above) remains valid and that the AB in question withdraws its position.

上記の 2010 年 IAF TC の議論結果は有効であり、当該認定機関は見解を撤回すべきである。

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

- Additional note to TC Decision 10/03/08
- Pre-audits prior to transition/ migration is acceptable.
- TC 決議 10/03/08 に対して追加の注記
- 移行 (transition/migration) の前に行う事前審査は許容される



Further Discussions within the WG: 更なる WG 議論

If a CB is offering this type of service/activity (e.g. pre-audit, gap audit); the CB is defining the process within their system and are considering the activity within their risk analysis process. The AB would be able to review this process and how the CB is managing risk associated with the activity. The pre-audit is also usually outlined in the contract, which is transparent to the ABs and most ABs are already reviewing pre-audit activity/records within the CB.

The paper does not specify if the pre-audit is completed prior to the contract; however, some preaudits tend to be provided after a contract has been executed.

Consensus that pre-audits are not considered internal audits. What is the difference between an internal audit and pre-audit? The scale and depth of a pre-audit v internal audit is different as well as the responsibilities and objectives (e.g. pre-audit doesn't review corrective actions). The internal audit will go into extensive detail and the pre-audit is looking for readiness of a certification. The internal audit is an activity that is audited and judged by the CB, the pre-audit is not part of the certification activity.

Understand some CBs may not perform this pre-audit activity properly; however, the previous TC decision was clear that the pre-audit could not compromise impartiality.

The pre-audit is different than the Stage 1; whether there is a pre-audit or not there must be a stage 1 and there are different objectives.

CB(認証機関)がこの種のサービス/活動(例:予備審査、ギャップ審査)を提供している場合、CBは、自身のシステム内でプロセスを定義し、リスク分析プロセス内での活動を検討する。AB(認定機関)は、このプロセスと、CBが活動に関連したリスクをどのように管理しているかをレビューできる。予備審査についても通常、契約書で説明されており、契約書はABが確認できるようになっている。ほとんどのABは、すでにCBが行っている予備審査の活動/記録をレビューしている。

その文書は、予備審査が契約の前に完了しているかどうかを明記していない。ただし、予備審査 は、契約の締結後に行われる傾向がある。

予備審査は内部監査とはみなされないというのが合意事項。内部監査と予備審査の違いは何か? 予備審査と内部監査の規模と深さは、責任と目的の同様に、異なるものである(例:予備審査は 是正措置をレビューしない)。内部監査は広範囲かつ詳細に行われるものであり、予備審査は認 証の準備ができているかどうかみるものである。内部監査はCBによって監査され判断される活



動であり、予備審査は認証活動の一部ではない。

一部の CB が、この予備審査活動を適切に実施していない可能性があることは理解できる。しか し、前回の TC の決定は明確で、その内容は、予備審査は公平性を損なうものではないというこ とである。

予備審査は第一段階審査とは異なる。予備審査の有無にかかわらず、第一段階審査が必要であり、それらの目的はそれぞれ異なる。