International Accreditation Forum, Inc.

参考和訳

IAF-TC-12.02-19

International Accreditation Forum
Technical Committee Discussion Paper

Name of party submitting issue for discussion (optional): ACCREDIA

Statement of the issue: Clarification request for the interpretation of sub clause 5.2.3 of IAF MD 9:2017 point iii). IAF MD 9:2017 の 5.2.3iii)の解釈の明確化

Discussion: IAF MD 9: 2017 contains a list of examples to ascertain whether impartiality might be compromised. In particular, point 5.2.3 iii) refers to the case in which the auditor is "*a member of staff from research or medical institute or a consultant having a commercial contract or equivalent interest with the manufacturer or manufacturers of similar medical devices*". IAF MD 9: 2017 5.2.3 iii) 審査員が、研究機関又は医療機関のスタッフ、又はコンサルタント（契約又は同様の利害が医療機器メーカーとある）である場合の公平性が損なわれた例について

Requested action by the IAF TC: IAF TC is kindly requested to clarify whether this requirement is applicable only to "manufacturers of medical devices" or also to "marketing, installation, maintenance, servicing or supply of the medical device, or any associated parts and services"? 当該事例は、メーカーだけではなく、マーケティング、医療機器設置、メンテナンス等、関連する部品及びサービスへも適用できるのではないか？ Moreover, this requirement could have 2 kind of interpretations. On one hand a strongly restrictive reading would lead to having to exclude from the audits both professionals who carry out consultancy activities, of any type and level, both members of research institutions, such as Universities, etc. This would inevitably lead the certification bodies to renounce in full an auditor who also performs consultancy activities, over the broader term, or experts in university structures, losing an important wealth of expertise and experience. Or, a second interpretation, is linked to the term "commercial": it would means that the unacceptability is limited to those subjects (consultants, members of research centers) that have an economic advantage with the companies, such as commercial fees (and not for activities like consultancy for the Quality Systems). Which is the correct interpretation to follow?

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

Note: Refer to WG and send to TC by e-mail

備考：WG に照会し、e-mail で TC に(回答を)送る。