



ISO/CASCO CLARIFICATION REQUEST FORM

Date of submission: 12 April 2018

1. Requesting ISO Member or A liaison member: IFIA
2. Contact person: Samuel Hill
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5. Please specify the ISO/CASCO document by name and number (ISO/IEC 17XXX) and clause number: ISO/IEC 17025:2017 4.1.4 & 4.1.5
6. Clarification request, please formulate the request clearly and where possible in a format that enables a YES or NO answer: ISO/IEC 17025 Section 1 (Scope) states that ISO/IEC 17025 “specifies general requirements for the competence, impartiality and consistent operation of laboratories.” The standard itself thus establishes that all requirements therein pertain to the competence, impartiality and consistent operation of laboratories. ISO/IEC 17025:2017 clause 8.5 is titled “Actions to address risks and opportunities”. ISO/IEC 17025:2017 4.1.4 and 4.1.5 state requirements regarding risks to impartiality. The requirements in 4.1.4 and 4.1.5 are additional to the requirements in 8.5 but the requirements in 4.1.4 and 4.1.5 apply ONLY when the risks being considered in accordance with 8.5 relate to impartiality. Is this correct?
7. Consensus position of the maintenance group (This section is only to be completed by the maintenance group members) The clarifications requested appear to be hypothetical as insufficient information has been supplied related to these specific problems associated with the implementation of the standard. Clauses 4.1 and 4.5 specifically require risks to impartiality to be identified and managed. Clause 8.5 requires risks (and opportunities) associated with all laboratory activities to be addressed and is more general in nature. This is clear from the Standard. Furthermore, the Working Group’s intention of limiting the impact of “Risk” only relates to the methodology applied. “Risk Management” and the implementation of a formal risk management system (e.g, ISO 31000) is not a requirement.

Send the filled form to casco@iso.org