

**QUESTIONS ASKED AND ANSWERS GIVEN
AT THE INSPECTION COMMITTEE MEETINGS
FROM 2000 TO 2008**

<p>Sampling</p> <p>Can a body doing sampling be accredited for that activity as a stand alone activity to ISO/IEC 17020?</p>	<p>No, sampling should not be accredited as a stand-alone activity under ISO/IEC 17020.</p> <p>Sampling + inspection = ISO/IEC 17020</p>
<p>Accreditation of assay offices</p> <p>Is the marking of precious metals a testing activity or an inspection activity?</p>	<p>The area is normally regulated and the regulator defines the rules. There is always a mark put on the product and it is the regulator's mark. Most countries deal with this as an inspection activity.</p>
<p>Can a conformity assessment body making measurement of stack gas emission (gas, dust, organic components) be accredited as an IB?</p> <p>If not, should it be accredited as a testing laboratory in accordance with ISO/IEC 17025?</p>	<p>Different countries have different policies on this issue.</p> <p>The Inspection Committee agreed that <i>stack emissions could be a laboratory activity under ISO/IEC 17025 and an inspection activity under ISO/IEC 17020</i>. The accreditation body has a choice.</p> <p>If it is <i>accredited under ISO/IEC 17020</i>, the planning of when and how to take samples, how many samples to take, etc. based on the production process and when the emission is maximal, will fall under an assessment to ISO/IEC 17020. The same will apply for the judgment of whether the emissions meet the requirements of regulations or any other specifications.</p> <p>However, if the inspection body decides that there is a need for analyzing samples, which will be most of the time, they will be assessed to ISO/IEC 17025 for the analysis of the samples. This will happen whether they are applying for accreditation to ISO/IEC 17025 or not. If they do not want to analyze themselves, they will have to subcontract an accredited laboratory.</p> <p>If the conformity assessment body is <i>accredited as a laboratory for stack emissions</i>, the sampling and analyzing will fall under ISO/IEC 17025 and so will the decision on whether each chimney meets requirements. As this standard allows opinions and interpretations, they will be able to judge whether the emission per chimney meets the regulatory requirements within the scope of their ISO/IEC 17025 accreditation.</p> <p>However, it would not be a laboratory activity within ISO/IEC 17025 to decide where to do the sampling and how much and how often, i.e. the decision process before sampling activities would not fall within the work of the laboratory under ISO/IEC 17025. Neither would it be laboratory work to decide on whether the plant in general is compliant with specifications.</p>

Annex A to the Minutes of the 18th IC Meeting, Point 5.1

<p>Accreditation in the field of risk assessment</p> <p>An AB had been approached to develop an accreditation scheme for the regulatory area in the field of risk assessment. There is a law by which all employers must carry out risk assessment of the work place. Public authorities intend to give the task to 3rd party bodies and they want to make sure that 3rd party bodies involved are competent.</p> <p>Would risk assessment carried out by 3rd party be considered a CA activity and, if yes, which standard would apply?</p>	<p>Risk assessment is carried out once, not on a continuous basis. It was suggested to use inspection but not certification because of lack of commitment on the long term. The IB would be expected to develop the relevant tools for assessing risk. There is a lot of professional judgement behind this activity.</p> <p>The Inspection Committee decided that this can be accredited as an inspection activity under the following conditions:</p> <ul style="list-style-type: none"> - accreditation needs to be granted to bodies and not to natural persons; - there needs to be specific or general requirements to which the risks can be assessed; - there needs to be a real assessment of the risks.
<p>“The inspection body, or the organization of which it forms part, shall have independently audited accounts.”</p> <p>In some countries, the fact that this is not a legal requirement makes it difficult to enforce this on the accredited IBs. How far do we need to go to meet the requirements?</p>	<p>Different countries seem to have different legal requirements on this point.</p> <p>When the <i>local legal requirements coincide with the requirements of the standard</i>, then there are not any problems in enforcing the requirement.</p> <p>However, there are sometimes <i>small companies which are not covered by the legislation</i> and for those the following applies: “Independently” does not necessarily mean that the person doing the audit is officially appointed or is a registered accountant. The requirement is that the person doing the audit should be independent of the activities, the accounts of which it is auditing.</p>
<p>Remuneration of inspectors</p> <p>Remuneration of inspectors is covered by Clause 8.6 of the standard.</p> <p>The case at hand is the following: an applicant IB pays its inspectors per inspection activity, which seems to be directly in conflict with the requirement. However the body in question puts safeguards in place: for example, they set up a very comprehensive reporting process.</p>	<p>It was pointed out that the requirement aims to prevent those situations where inspectors speed up inspection visits to increase their salary. However there are several tools for the AB to assess whether the requirement is met, such as monitoring, statistics, customer feedback, etc.</p> <p>To conclude, the Inspection Committee agreed that it is not against the requirements of the standard as long as there are safeguards in place.</p>

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<p>“The remuneration of persons engaged in inspection activities shall not directly depend on the number of inspections carried out and in no case on the result of such inspection.”</p> <p>Does this clause imply that the owner of an IB should not perform inspections himself, since in this case, his remuneration, as the owner of the IB, depends upon the number of the inspections, which are carried out by the IB?</p>	<p>The purpose of this clause is to prevent bonus schemes and other incentive building as the basis of salaries. It was therefore concluded that it is perfectly acceptable for an owner of an inspection body to perform inspections.</p>
<p>Can a one-man company become a Type A IB?</p>	<p>The Inspection Committee decided that a one-person company can be a Type A inspection body as long as it meets all requirements for a type A body.</p> <p>It should however be clear that persons as such cannot be accredited. Accreditation is granted to companies.</p> <p>The person would not need monitoring as he/she would be the only competent person and his/her competence would be assessed by the accreditation body. For internal audit, he/she would have to hire an independent auditor.</p>
<p>One legal entity having both Types A and C</p> <p>A question was raised about the situation of an IB offering Type C services in one technical area and Type A services in a totally different area.</p>	<p>The independence requirement of the standard is in relation to the product, item, process, etc being inspected.</p> <p>It was reminded that the Inspection Committee already resolved that accreditation certificates should be separate in order not to confuse the market but total impartiality must be demonstrated. Related activities should be well separated. Such a situation is much likely to exist with consultancy agencies.</p> <p>A few examples were given supporting that the situation is realistic and acceptable for economical and practical reasons.</p> <p>Some participants objected that it is difficult to imagine that a single legal entity can have both statuses, independent and not independent. It was objected that independence should be addressed also from the technical point of view.</p> <p>It was confirmed that the standard allows for such a situation provided the inspection services carried out under each of the two types are completely different. The relevant question is therefore how much “different” the activities need to be.</p>

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<p>Inspection of structural strength through numerical methods</p> <p>Has the sub-contractor of a Type A body to be a Type A body as well?</p>	<p>An IB is allowed to subcontract only in exceptional cases.</p> <p>The sub-contractor should have the same level of independence; otherwise the independence of the sub-contracting party is affected.</p>
<p>Type B inspection body</p> <p>In Directive no 99/36 on TPED, the requirements for IBs are defined in Annex I with minimum criteria for notified or approved bodies. Annex II sets out supplementary criteria for notified bodies, and Annex III supplementary criteria for approved bodies. The requirements in Annex III are very similar to the requirements for Type B set out in ISO/IEC 17020, Clause 4.2.2 and annex B except for the requirement set out in B.3 that reads: "Inspection services shall only be supplied to the organisation of which the IB forms a part".</p> <p>The question is the following: can a parent organisation that delivers repair and other maintenance services on gas cylinders to external customers have the gas cylinders inspected by its in-house IB before the gas cylinders are returned to the customer?</p>	<p>The Committee resolved that to work under the TPED Directive, an IB may be accredited as a Type B or a Type C but satisfying also the additional requirements from Annex III of the Directive. (The answer is based on the conditions that applied in March 2007.)</p>
<p>Interpretation of Clause 4.2.3 a) of ILAC/IAF A4 about accreditation of a Type C inspection body</p> <p>The assessment team issued a NC based on the finding that the IB used the same person both for the inspection and servicing activities for transportable gas cylinders (and related).</p> <p>In the case in point, a realistic analysis evidenced that practice of carrying out servicing and inspection was low risk and had little impact, if none, on the impartiality and independence for Type C inspection.</p> <p>The Inspection Committee's opinion was requested on interpretation of the clause in this particular case.</p>	<p>There were a few comments supporting the conclusion that risk was low to use the same individual in the particular case.</p> <p>The Inspection Committee concluded as follows:</p> <p><i>In the voluntary area</i>, in the absence of a regulation, Type C IBs shall have two persons, one responsible for changing valves etc. and the other to perform the inspection because it constitutes then a maintenance activity.</p> <p><i>In the mandatory field</i>, directives have annexes providing that the inspectors may be asked to carry out the maintenance tasks and can be done by a Type C IB. In such a case, the regulator holds the responsibility to have one person doing the whole lot.</p> <p>The IC therefore supported the AB's conclusion that the IB in question can be accredited even if using the same person for both activities under the conditions mentioned above.</p>

<p>Accreditation of Inspection Bodies providing third party expertise of risk analysis</p> <p>A scheme was set up in France upon request of the Ministry of Environment. In France there are classified instalments covered by law: when representing a lower risk, a simple declaration is required. When higher risks are in question, an authorization is needed from the National Authorities for the site to be able to operate. In the second case, a danger study has to be carried out to identify all risks and how to manage them. When there is a doubt about the study, the authorities may call for a 3rd party expert to evaluate the study with a view to check that all risks are identified and management processes appropriate.</p> <p>The Ministry approached COFRAC asking for accreditation of the 3rd party expertise. The COFRAC Inspection Committee was requested to investigate the request.</p> <p>For the activity in question, there are no inspection specifications at the beginning of the process. There are danger studies that are provided by the manufacturer. The Inspector is expected to go through the study and eventually confirm that the analysis and management measures are acceptable. The report may include recommendations. During the expertise, the Inspector may look at the tools used by manufacturers; he/she carries out a certain number of checks including calculations.</p> <p>It was clarified that in the scheme, the manufacturer remains fully responsible for the risk analysis. Accreditation could cover the 3rd party expert, which is the body in charge of checking appropriateness of the manufacturer's analysis and management processes. It was clarified also that the activity is not an ongoing activity but a one-off, instant check.</p> <p>Which reference documents are meant to be used was discussed.</p>	<p>The fact that recommendations may be made as part of the inspection service raised a point that was much discussed.</p> <p>COFRAC confirmed that as it is designed, the scheme would allow for the expert to express recommendations, which can be taken for consultancy. It was recognised that this could cause a real difficulty because the objective in the end is to make the manufacturer fully risk-aware, and this is why the recommendations will be needed.</p> <p>That the existence of recommendations does not influence the type was finally recognised by the Inspection Committee, which believes that the proposed scheme is accreditable against ISO/IEC 17020 provided the consultancy issue is properly solved.</p> <p>As a conclusion to reinforce the rationale to go for inspection accreditation, the Inspection Committee pointed out that the “one-off effect” was the key point.</p> <p>COFRAC was recommended that the scheme be framed within the legislation.</p> <p>The Inspection Committee added that so far the manufacturer has a choice of solutions arising from the recommendations, the service is not a consultancy.</p>
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<p>Does risk analysis activity jeopardise the impartiality and independence of the inspection body?</p> <p>The point is to move away from the insurance context and go for a 3rd party. So far insurance had an incentive to provide solutions to reduce the risks. The service being developed does contain elements close to consultancy and the risk survey may include such consultancy elements. The CB asked whether the risk analysis activity would compromise their impartiality with regard to their OHSAS certification activity.</p> <p>This issue was also discussed within the Certification Committee, which agreed that the contents of service to be delivered should be analysed in the first place.</p>	<p>The CC and the IC supported that the service should be carried out by separate staff to preserve impartiality.</p>
<p>Can an IB subcontract all testing and only judge and decide on the classification (e.g. construction products can be classified based on their insulating capacity)?</p> <p>The question is whether it is possible to accredit a body as IB when it receives a test report from a reliable source and categorizes the tested features according to given specifications, while the IB does not have necessarily access to the product and does not observe the testing.</p>	<p>Provided the source is competent for the testing required, such an activity is accreditable in that the IB is making a judgement on whether the product meets a specification based on the test received and decides on the category to be used in different situations. Inspection is comparing products to specifications.</p>

<p>Traceability requirements</p> <p>In old EA-5/01 there was a clause on traceability by which in-house calibration and uncertainties were to be demonstrated. The clause was removed in EA ILAC IAF A4.</p> <p>The question was “Why” and how to treat IBs in this respect?</p>	<p>It appeared that EA members probably apply the same principles as provided before in 5/01.</p> <p>The Inspection Committee stated that if calibration is to be required, then measurement uncertainty is required and EA rules on measurements fully apply.</p>
<p>Implementation of Level 3 competence in NDT inspection</p> <p>There is in Finland a small NDT IB. Normally NDT bodies are accredited as IBs and FINAS uses EA-4/15. In the guidance there is a clause which is difficult to apply with small bodies that do not necessarily have the staff with all the required competence.</p> <p>FINAS’ question reads as follows: When Level 3 does not cover all the NDT procedures, what shall be required in terms of involvement?</p>	<p>The Inspection Committee agreed that situations have to be dealt with on a case-by-case basis.</p> <p>The critical elements to be considered are:</p> <ul style="list-style-type: none"> - the requirements from regulators; - the availability of the expert when need arises for the IB; - and the total amount of time during which the expert has to be on stand-by to help the IB.
<p>A body is accredited to both ISO/IEC 17025 and ISO/IEC 17020. Can this body issue a certificate containing both a statement on the calibration/testing results and the results of the inspections, for example according to the two directives: Automatic Weighing Instruments (MID-Directive 2004/22/EC) and Non Automatic Weighing Instruments (NAWI-Directive 90/384/EC)?</p>	<p>There was a consensus that clarity on the market shall be preserved as high priority. The need of the accredited body’s customer should be taken into consideration.</p> <p>The conformity assessment body can report on one single document provided that:</p> <ul style="list-style-type: none"> - the product or item is the same; - the reporting requirements for the two activities are met; - the scope of accreditation covers both activities for the relevant product/item.