1. REQUEST

Enquiry title: *	Use by the AsBo of external experts and sub-contractors – Mutual recognition of				
	reports from other conformity assessment bodies				

Enquiry description: *

By virtue of point 4 in Annex II of Regulation 402/2013, an AsBo is accredited or recognised for one or several "areas of competence"⁽¹⁾. Furthermore, every AsBo must comply with all criteria and requirements in point 1 of Annex II of that Regulation.

When an AsBo, for whatever reason, uses external experts, (exceptionally) subcontracts/outsources parts of inspection activities, or must take into account inputs from other conformity assessment bodies, it is necessary to clarify:

- (a) the differences between the following three cases:
 - (1) the use of individuals or employees of other organisations, known also as "use of external experts" or "hiring-in experts".

As these terminologies designate the same concept, for the simplicity of reading, "hiring-in experts" will only be used in the rest of this document.

(2) the use of subcontractors, known also as outsourcing.

As these two terminologies designate the same concept, for the simplicity of reading, "sub-contract" or "sub-contracting" will only be used in the rest of this document.

(3) the mutual recognition of reports from other conformity assessment bodies (e.g. NoBo, DeBo, another AsBo) with which the AsBo does not have a legally binding contract, nor the choice to subcontract, or involve in the project.

As the AsBo does not have a legally binding contract with another (conformity assessment) body, this third case can neither be considered as hiring-in experts nor sub-contracting by the AsBo.

- (b) the permissions granted through the accreditation/recognition for those three cases;
- (c) the responsibility of the AsBo, the mutual recognition of its reports, and the restrictions concerning the use of the accreditation logo, or of the recognition logo (where existing).

Mutual recognition of inputs/reports from other (conformity assessment) bodies, as well as the relations of the AsBo with the NoBo, DeBo and other AsBos, are objects of specific recommendations for use.

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Date of submission:	26/09/2018

Related documents:

- {Ref. 1} Regulation 402/2013
- {Ref. 2} ISO/IEC 17020:2012 and its subsequent amendments
- {Ref. 3} ILAC-P15:05/2020-1 Application of ISO/IEC 17020:2012 for the accreditation of inspection bodies
- {Ref. 4} Recommendation for use 03 on the AsBo technical knowledge and competence requirements for the different areas

The recommendations for use are available on the Agency web page under the following link https://www.era.europa.eu/activities/Commons Safety Methods for risk evaluation and assessment/Related guidance

⁽¹⁾ The terminologies "technical area or area of competence of the AsBo" of Regulation 402/2013, and "scope of accreditation/recognition of the AsBo" of the ISO/IEC 17020:2012 standard, are synonymous.

2. TRACEABILITY

RFU number:	08
Version number:	1.0
Version comment:	First version of the AsBo-RFU

3. SOLUTION

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Introduction

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- 1. According to point 1 in Annex II of Regulation 402/2013 on the CSM for risk assessment (CSM-RA), as company, the AsBo shall fulfil all requirements of the ISO/IEC 17020:2012 standard, and of its subsequent amendments.
- 2. By virtue of Clause 6.3.1 of the ISO/IEC 17020:2012 standard, the AsBo "… *shall itself* normally perform the inspections that it contracts to undertake". However, if for some reason it does not a have sufficient number of own staff, the standard explicitly allows the AsBo to involve experts from outside its company, or to involve other companies, to be able "to perform the type, range and volume of its inspection activities". The CSM-RA does not specify any further requirements than compliance with the ISO/IEC 17020:2012 standard, regarding those two cases.
- 3. In addition to those two cases, a third case, not explicitly addressed in the ISO/IEC 17020:2012 standard, is also encountered very often in practice. The European railway legislation, or the proposer, can request the AsBo to take into account inputs from another conformity assessment body (e.g. from a NoBo, a DeBo or another AsBo), with which the AsBo has no contractual relationship. In that case, the AsBo does not have the choice to carry out itself the assessment, or to sub-contract a part of its inspection activities to another conformity assessment body of its choice.
- 4. Those three cases differ significantly in the organisation, allocation of inspection activities and responsibilities. This document clarifies the differences between those three cases. For each case, it explains the requirements the AsBo shall fulfil, as well as the impacts on the AsBo responsibility and on the mutual recognition of its report.

II Quote of the ISO/IEC 17020:2012 standard requirements

- *"6.1.2 The inspection body shall employ, or have contracts with, a sufficient number of persons with the required competencies, including, where needed, the ability to make professional judgements, to perform the type, range and volume of its inspection activities.*
- 6.3.1 The inspection body shall itself <u>normally</u> perform the inspections that it contracts to undertake. Where an inspection body subcontracts any part of the inspection, it shall ensure and be able to demonstrate that the subcontractor is competent to perform the activities in question and, where applicable, complies with the relevant requirements stipulated in this International Standard or in other relevant conformity assessment standards.
 - NOTE 1 Reasons to subcontract can include the following:
 - an unforeseen or abnormal overload;
 - *key inspection staff members being incapacitated;*
 - key facilities or items of equipment being temporarily unfit for use;
 - part of the contract from the client involving inspection not covered by the inspection body's scope or being beyond the capability or resources of the inspection body.
 - NOTE 2 The terms "subcontracting" and "outsourcing" are considered to be synonyms.
 - NOTE 3 Where the inspection body engages individuals or employees of other organizations to provide additional resources or expertise, these individuals are not considered to be subcontractors provided they are formally contracted to operate under the inspection body's management system (see 6.1.2).
- 6.3.2 The inspection body **shall inform the client of its intention to subcontract any part** of the inspection.
- 6.3.3 Whenever subcontractors carry out work that forms part of an inspection, the **responsibility** for any determination of conformity of the inspected item with the requirements shall remain with the inspection body.
- 6.3.4 The inspection body **shall record and retain details of its investigation of the competence of its subcontractors** and of their conformity with the applicable requirements of this International Standard or in other relevant conformity assessment standards. The inspection body shall maintain a register of all subcontractors.

7.4.4 All information listed in 7.4.2 shall be reported correctly, accurately, and clearly. Where the inspection report or inspection certificate contains **results supplied by subcontractors**, these results **shall be clearly identified**."

III Hiring-in experts

III.A Description

- 1. This is the simplest case, described in note 3 in Clause 6.3.1 of the ISO/IEC 17020:2012 standard. The AsBo "... engages individuals or employees of other organizations to provide additional resources or expertise ..." to enable it "to perform the type, range and volume of ... inspection activities" it contracted. Those external persons are referred to in this document as hired-in experts.
- 2. The AsBo has contractual arrangements with the hired-in experts to work under the AsBo management system. All requirements in Clause 6.1 of the ISO/IEC 17020:2012 standard apply equally to both own staff and hired-in experts. Competence, independence, impartiality, etc. requirements are ensured by the application of the processes of the AsBo management system. The check of the AsBo compliance with all bounding requirements is subject to accreditation/recognition and surveillance by the accreditation/ recognition body.
- 3. The hired-in experts are to be considered as personnel of the AsBo team, at least as far as ISO 17020 requirements are concerned. They operate under the direct management, supervision, and allocation of inspection activities, of the AsBo.
- 4. Without excluding the possibility of remote assessments (where appropriate and/or necessary), usually the external experts are physically part of the AsBo assessment team.

III.B Permissions granted through accreditation/recognition

- According to Clause 6.3.1 of the ISO/IEC 17020:2012 standard, the AsBo "... shall itself <u>normally</u> perform the inspections that it contracts to undertake". To fulfil that requirement, Clause 6.1.2 of the standard requires the AsBo either to:
 - (a) "...employ" a sufficient number of own staff, or to;
 - (b) "...have contracts with, a sufficient number of ..." external "...persons.

with the required competencies ... to perform the type, range and volume of its inspection activities."

- 2. Note 3 in Clause 6.3.1 of the ISO/IEC 17020:2012 standard states also clearly that "where the inspection body engages **individuals or employees of other organisations** to provide additional resources or expertise, these individuals **are not considered to be subcontractors** provided they are formally contracted to operate **under the inspection body's management system**".
- 3. For example, in a complex project, the AsBo can hire-in technical experts for the evaluation of the correct implementation of technical measures by the proposer intended to control a risk arising from a technical design choice. In this example, where requested by the AsBo safety experts, the hired-in technical experts will assist the safety experts in charge of the independent safety assessment of the correct application of the risk management process, and of the correctness of the results from that risk management.
- 4. It is important to emphasise that the requirement to "... operate under the inspection body's management system" obliges the AsBo to fulfil all requirements of the ISO/IEC 17020:2012 standard for both own staff and hired-in experts. This implies among others that the management system of the AsBo :
 - (a) according to Clause 6.1.1 of the standard, "... shall define and document the competence requirements ..."
 (and criteria) for both own staff and hired-in persons, "... involved in inspection activities, including requirements for education, training, technical knowledge, skills and experience";
 - (b) according to Clause 6.1.5 of the standard, shall have "... documented procedures for selecting, training, formally authorising, and monitoring inspectors and other personnel involved in inspection

activities". This assumes also that the AsBo has appropriate contractractual arrangements with external experts, or external companies, to hire-in competent experts to work under the AsBo management system;

- (c) according to Clause 6.1.3 of the standard, shall ensure that the AsBo hires-in personnel with "...appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the inspections to be carried out";
- (d) fulfils the requirements of Clauses 6.1.7 to 6.1.12 of the standard equally for own staff and hired-in experts. The AsBo shall not make difference in terms of impartiality, training needs, monitoring of performance of inspection personnel, keeping records of "monitoring, education, training, technical knowledge, skills, experience and authorization of each member of its personnel involved in inspection activities".
- 5. The ISO/IEC 17020:2012 standard <u>does not forbid</u> the AsBo to hire-in competent experts <u>on a regular</u> <u>basis</u>, provided the AsBo has the capability to ensure continual compliance with all clauses of the standard.

III.C Responsibility of the AsBo and impacts on the mutual recognition of its report

- 1. The AsBo is responsible for the results and decisions of both own staff and hired-in experts.
- 2. The use of hired-in experts does not impact the mutual recognition of the AsBo report, as required by Articles 6(3), 15(2), 15(3), 15(4) and 15(5) of the CSM-RA.

IV Use of subcontractors

IV.A Description

IV.A.1 General requirements from the ISO/IEC 17020:2012 standard

- 1. Use of sub-contractors differs significantly from hiring-in experts. It is dealt within Clause 6.3 of the ISO/IEC 17020:2012 standard.
- 2. An AsBo contracts inspection activities to a client but does not have (for whatever reasons) a sufficient capacity/number of own staff to be able "to perform the type, range and volume of …" those "… inspection activities". To fulfil its contract, the AsBo decides to sub-contract an entire, and clearly identifiable, part of the inspection activities to an external company^{[2)} which has the required competencies for the contract. The AsBo shall thus have a "legally binding contract" with that external company in charge of the sub-contracted parts of inspection activities, including provisions for confidentiality and conflicts of interests as specified in Clauses 6.1.13 and 4.1 of the standard.
- 3. Although the external company is subject to coordination and supervision by the contracting AsBo, the external company works standalone (i.e. utilising its own management system and processes, and the AsBo onces) to fulfil its contract with respect to the contracting AsBo. The experts of the external company are not members of the AsBo assessment team. They work separately and provide a separate assessment report to their client, i.e. to the AsBo which purchased the service.

⁽²⁾ For the purposes of this recommendation for use, the terminology "external company" does not refer to the AsBo subsidiary companies, or branches. When an AsBo company operates across several countries, and uses experts from different physical locations of the mother company, such organisational structures must be covered by the AsBo management system. Such structures are assessed, at the moment of accreditation/recognition, and subject to regular supervision, by the accreditation or recognition body.

On the contrary, the terminology "external company" can cover the parts of a holding structure to which an AsBo company can belong.

IV.A.2 Ranking between the possible levels of "granularity of sub-contracting activities" by an AsBo

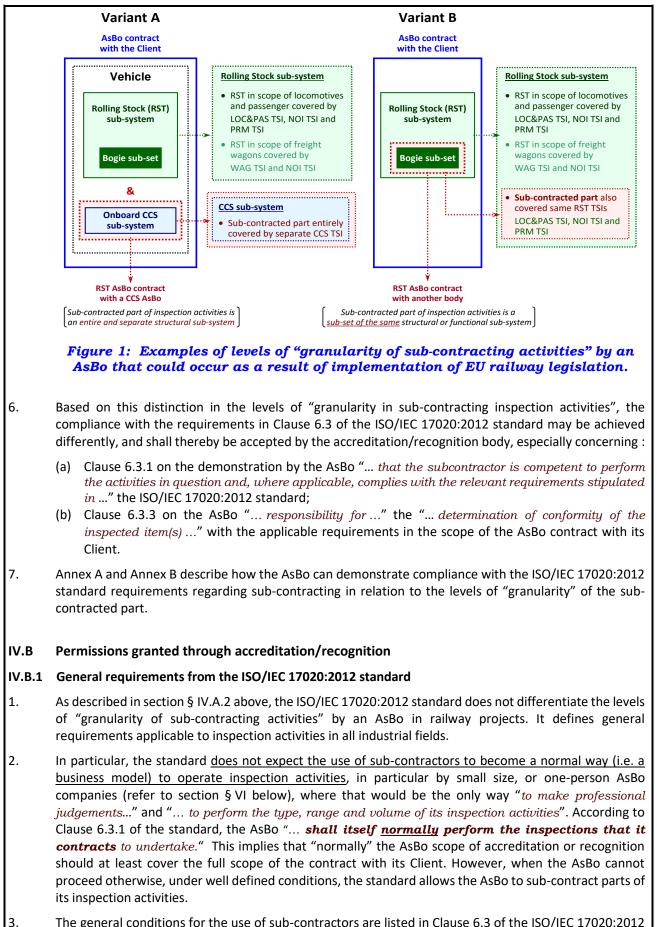
- 1. ISO/IEC 17020:2012 is a general standard. It is applicable to a very broad range of industrial fields, or types of items for inspection (see introduction chapter⁽³⁾ of the standard). While it harmonises the general requirements with which the inspection bodies must comply, it does not take into account, and cannot foresee, the specificities of each industrial field. For that purpose, the standards for accreditation (ISO/IEC 17011:2017), and inspection activities (ISO/IEC 17020:2012) foresee that, where necessary, specific requirements for the industrial field are addressed in a sector specific "inspection scheme".
- 2. As owner of a "future scheme for the AsBo assessment", the Agency (ERA) shall complement and further detail the general criteria and requirements, in Annex II of CSM-RA and the ISO/IEC 17020:2012 standard referenced therein, with the specific needs of the railway sector. The future scheme for the AsBo assessment has thus to include the specific rules on sub-contracting that shall be considered for the accreditation or recognition of railway AsBos.
- 3. Indeed, accreditation and recognition of railway inspection bodies (AsBos) shall take into account :
 - (a) the complexity of the "railway system architecture", and;
 - (b) the specific "requirements in the EU railway legislation".

Railway projects can involve one, several, or many structural or functional sub-systems. Their management could require complex project organisations, that involve many railway actors, and several accredited or recognised conformity assessment bodies (NoBos, DeBos, AsBos), with dedicated roles and responsibilities.

A "binary interpretation" of the requirements on sub-contracting in Clause 6.3 of the ISO/IEC 17020:2012 standard could then unnecessarily prohibit current practices, although they correctly implement the relevant EU railway legislation.

- 4. Considering the railway sector specificities, Figure 1 below illustrates a typical railway example of possible levels of "granularity of sub-contracting activities" by an AsBo for mobile sub-systems; same levels exist also for other parts of the railway system architecture. The applicable levels of granularity result directly from the railway actor obligation to comply with the applicable railway legislation (Interoperability Directive 2016/797, Safety Directive 2016/798, TSIs, Regulation 402/2013, Regulation 2018/545, etc.).
- 5. With regard to the scope of the contract between the AsBo and its Client (see Figure 1 below), the following variants of "sub-contracting parts of inspection activities" by the AsBo shall be distinguished, in function of the applicable legalisation :
 - (a) <u>Variant A (i.e. macroscopic granularity)</u>: two separate items, each one covered by a dedicated legal act, are subject to inspection. The AsBo assesses one item and sub-contracts the assessment of the other one to another body. The second item is "an entire structural or functional sub-system", covered by its own legal act (e.g. a TSI);
 - (b) <u>Variant B (i.e. microscopic granularity)</u>: a single item is subject to inspection. The AsBo assesses the whole item, except one or several identifiable "parts of the same item", where it sub-contracts the assessments to another body. Being "a sub-set of the same structural or functional subsystem", the same legal act covers both the assessments by the AsBo and the sub-contracted part.

⁽³⁾ Quote from the ISO/IEC 17020:2012 standard : "Inspection bodies carry out assessments ... with the objective of providing information about the conformity of inspected items with regulations ... Inspection parameters include matters of ... fitness for purpose..." The ISO/IEC 17020:2012 standard "harmonizes the general requirements with which these bodies are required to comply ..." It "covers the activities of inspection bodies whose work can include the examination of ... processes, work procedures or services, and the determination of their conformity with requirements ... Such work normally requires the exercise of professional judgement in performing inspection, in particular when assessing conformity with general requirements".



3. The general conditions for the use of sub-contractors are listed in Clause 6.3 of the ISO/IEC 17020:2012 standard. Where the AsBo sub-contracts any part of the inspection:

- (a) according to Clause 6.3.1 of the standard, the AsBo "...shall ensure and be able to demonstrate that the subcontractor is competent to perform the activities in question and ...complies with the relevant requirements stipulated in this International Standard ..."
- (b) according to Clause 6.3.2 of the standard, the AsBo shall be transparent with the client. The AsBo "shall inform the client of its intention to subcontract any part of the inspection". The client shall give formally its consent on the use of sub-contractors for a specific part of inspection activities;

<u>Recommendation for sub-contracting</u>: to increase the transparency of the AsBo process, in addition to the requirements in clauses 6.3.1 to 6.3.4, any sub-contracting of parts of inspection activities shall be clearly identified in the AsBo safety assessment report.

(c) according to Clause 6.3.3 of the standard, normally "the responsibility for any determination of conformity of the inspected item with the requirements shall remain with" the ordering AsBo. However, given the specificities of the EU railway legislation, that responsibility will be dependent of the level of granularity of the sub-contracted inspection activities (sub-contracting of an internal part, or of a complete and separate structural or functional sub-system, covered by a dedicated TSI : refer to section § IV.A.2 above).

The responsibility of the different conformity assessment bodies within the context of mutual recognition are not described in the present document; they are dealt within the dedicated Recommendation For Use 15; that latter one is not yet written at the moment of publication of the present RFU;

- (d) according to Clause 6.3.4 of the standard, the AsBo "shall record and retain details of its investigation of the competence of its subcontractors and of their conformity with the applicable requirements of" the ISO/IEC 17020:2012 standard. This implies that the AsBo shall have documented evidence of the check of competence of the inspection team of the sub-contractor.
- 4. According to section § 6.3.1 n1⁽⁴⁾ of the ILAC-P15:05/2020-1 note {Ref. 3} concerning sub-contracting by the AsBo, and the use of results of sub-contracted inspection activities :
 - (a) "accreditation ...", and by analogy recognition, "... cannot be granted for activities referred to in the fourth⁽⁵⁾ bullet point under note 1..." in Clause 6.3.1 of the ISO/IEC 17020:2012 standard, "... if the inspection body does not have the required competence and/or resources";
 - (b) "... accreditation ...", and by analogy the recognition, "... is limited to conformity assessment tasks which ..." the AsBo "... has demonstrated competence to perform itself";
 - (c) "the task of assessing and interpreting the results of such activities for the purpose of determining conformity may be included in the scope of accreditation, provided adequate competence for this has been demonstrated".

IV.B.2 AsBo competence to assess and interpret the results from sub-contracted inspection activities
 By virtue of the last sentence in section § 6.3.1 n1⁽⁴⁾ of the ILAC-P15:05/2020-1 note {Ref. 3}, the AsBo can include in the scope of its accreditation/recognition the "competence to assess and interpret the

(5) The fourth bullet point in note 1 of Clause 6.3.1 of the ISO/IEC 17020:2012 standard relates to a "part of the contract from the client involving inspection not covered by the inspection body's scope or being beyond the capability or resources of the inspection body"

⁽⁴⁾ <u>Extract of section § 6.3.1 n1 from ILAC-P15:05/2020-1:</u>

By definition (ISO/IEC 17011, clause 3.1), accreditation is limited to conformity assessment tasks which the inspection body has demonstrated competence to perform itself. Thus, accreditation cannot be granted for activities referred to in the fourth bullet point under note 1, if the inspection body does not have the required competence and/or resources. However, the task of **assessing and interpreting the results of such activities** for the purpose of determining conformity may be **included in the scope of accreditation**, provided adequate competence for this has been demonstrated.

results⁽⁶⁾" from inspection activities carried out by a sub-contractor. To permit that, the AsBo shall demonstrate to the accreditation/recognition body that it actually has this competence.

2. Does the AsBo need to demonstrate compliance with additional competence requirements for the specific needs of the railway sector?

In practice, for a given scope/area of accreditation/recognition, an AsBo which fulfils the requirements of Recommendation For Use 03 (RFU N°3) {Ref. 4} also fulfils the requirement in the last sentence of section § $6.3.1 n1^{(4)}$ of the ILAC-P15:05/2020-1 note {Ref. 3}. The ordering AsBo has thus the "competence to assess and interpret the results" of inspection activities carried out by another AsBo (including a sub-contractor) for risks that could arise across the interfaces of the sub-system under the ordering AsBo accreditation/recognition with any other sub-system (assessed by another AsBo).

- 3. By virtue of <u>section § V.B of the Recommendation For Use 03 {Ref. 4}</u>, when an ordering AsBo subcontracts the inspection activities of a complete structural or functional sub-systems to another AsBo, accredited/recognised for at least the sub-contracted scope :
 - (a) the sub-contracted AsBo has the competence to independently assess :
 - (1) the correctness of the proposer's risk assessment, and suitability of its results, for the subcontracted structural or functional area, and;
 - (2) the safe integration at the level of that structural or functional sub-system. This includes the competence of the sub-contracted AsBo to independently assess :
 - (i) the safe integration of all internal parts constituting the sub-contracted sub-system, including all internal interfaces between those individual parts of the sub-system;
 - (ii) the requirements (SRACs) for the safe integration of the sub-contracted sub-system within the directly connected layer (direct interfaces) with the other sub-systems, human operators and human actions;
 - (b) the ordering AsBo has automatically the following competencies :
 - (1) the competence to independently assess the correctness of risk assessments, suitability of results from risk assessments, and safe integration for areas within the scope of its accreditation/recognition, and;
 - (2) the "competence to assess and interpret the results" of inspection activities carried out by other AsBos for risks that could arise across the interfaces between the sub-system under its accreditation/recognition and any other sub-system.
- 4. Thereby, for the railway sector, the accreditation/recognition body has to acknowledge, <u>as part of the AsBo scope of accreditation/recognition</u>, the AsBo "competence to assess and interpret the results" of inspection activities carried out by another accredited, or recognised, conformity assessment body for risks that could arise across the interfaces of the sub-system under the scope of its accreditation/recognition and the neighbouring sub-systems.

IV.B.3 Sub-contracting inspection activities by an AsBo for a complete structural or functional sub-system (Variant A in Figure 1)

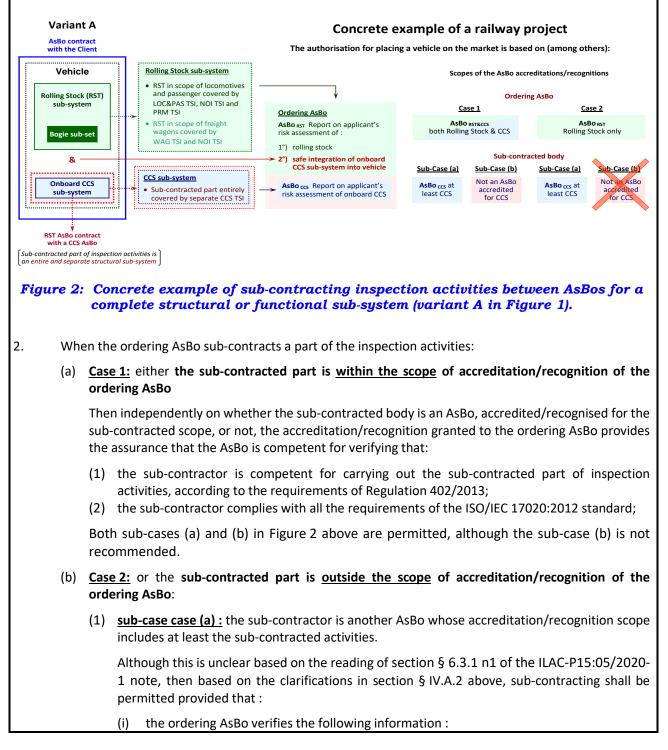
1. Figure 2 below presents a typical example⁽⁷⁾, where two different items are subject to inspection. The ordering AsBo assesses one item, and sub-contracts to another body the inspection activities for another item, that it has undertaken to perform in the contract with its Client. The example illustrates the Variant A represented in Figure 1 above. Unlike the requirements in Clause 6.3 of the ISO/IEC 17020:2012

⁽⁶⁾ In the example of Figure 1, in practice this means that the rolling stock AsBo has the competence to understand and interpret the hazards, and the associated safety related application conditions (SRACs), exported by the on-board ETCS sub-system manufacturer and the associated CCS AsBo Report for the safe integration of the on-board ETCS sub-system into the vehicle.

⁽⁷⁾ *Reminder : the "rolling stock" structural sub-system is covered by the LOC&PAS TSI, NOI TSI and PRM TSI. The "onboard CCS" structural sub-system is covered by the CCS TSI, i.e. another and separate TSI.*

standard, this type of situations it not expected to occur exceptionally. As explained in section § IV.A.2 above, it is likely to be used frequently in the railway industry field.

This example illustrates a practical case of a new Vehicle Authorisation project; it can be transposed to other parts of the railway system. The project is a locomotive, or an EMU, to be fitted with an on-board ETCS sub-system. The manufacturer appoints an AsBo for the independent assessment of the whole vehicle, i.e. for both the rolling stock (1st inspected item), the on-board ETCS structural sub-systems (2nd inspected item), and the safe integration between those two sub-systems (i.e. between the two items). Depending on whether the AsBo is accredited/recognised for the rolling stock scope only, or for both the rolling stock and CCS scopes, the implementation of the inspection activities by the AsBo will be different, and compliance with the ISO/IEC 17020:2012 standard and the text in point 6.3.1 n1 in the ILAC_P15_05_2020-1 note {Ref. 3} can be achieved differently.



- the sub-contractor is an AsBo, accredited/recognised in compliance with the requirements and criteria in Annex II of Regulation 402/2013. For that the AsBo shall check that the sub-contractor is registered in the ERADIS database, or if not yet registered there, published on the website of the associated national accreditation or recognition body;
- the scope of the sub-contractor's accreditation/recognition covers at least the subcontracted inspection activities;
- ✤ the accreditation/recognition is still valid;
- (ii) the ordering AsBo has the "competence to assess and interpret the results" of the inspection activities carried out by the sub-contractor in order to determine the overall conformity of the entire independent assessment, including thus the integration of the part assessed by the sub-contractor. The associated AsBo competence is explained in section § IV.B.2 above.

The accreditation/recognition granted to the sub-contractor provides the assurance that the sub-contractor is an AsBo competent for carrying out the sub-contracted part of inspection activities according to the requirements of Regulation 402/2013.

(2) <u>sub-case (b)</u>: the sub-contractor is not an AsBo accredited or recognised for the scope of the subcontracted inspection activities.

When the ordering AsBo does not have accreditation/recognition for a part of the inspection activities, it is not possible to "fill this gap" by sub-contracting to a body that is not accredited/recognised for the scope of those inspection activities.

3. Annex A describes how the ordering AsBo can demonstrate compliance with the ISO/IEC 17020:2012 standard requirements regarding sub-contracting of inspection activities for an entire structural or functional sub-system covered by a dedicated legal act.

IV.B.4 Sub-contracting inspection activities by an AsBo for a sub-set of the same structural or functional subsystem as the assessed one (Variant B in Figure 1)

- 1. This case is represented in Figure 3. One item is subject to inspection activities that the AsBo decides to share with a sub-contractor.
- 2. Unlike the variant A represented in Figure 1, and described in section § IV.A.2 above, the variant B should be used exceptionally. This case relates to sub-contracting inspection activities for "a sub-set of the same structural or functional sub-system" as the one assessed by the ordering AsBo; the same legal act covers the assessments by both the ordering AsBo and the sub-contracted body. Although hiring-in of competent external experts should preferably be used (refer to section § III above), theoretically this option is also possible. However, it is to be used exceptionally, and only for the reasons in the first three bullet points in Note 1⁽⁸⁾ in Clause 6.3.1 of the ISO/IEC 17020:2012.
- 3. Independently on whether the sub-contracted body is an AsBo, accredited/recognised for the same scope as the ordering AsBo, or not, the accreditation/recognition granted to the ordering AsBo provides the assurance that the ordering AsBo is competent for verifying that:

(8) Quote of Note 1 in Clause 6.3.1 of the ISO/IEC 17020:2012 standard

"NOTE 1 Reasons to subcontract can include the following:

- an unforeseen or abnormal overload;
- *key inspection staff members being incapacitated;*
- key facilities or items of equipment being temporarily unfit for use;
- part of the contract from the client involving inspection not covered by the inspection body's scope or being beyond the capability or resources of the inspection body".

- (a) the sub-contractor is competent for carrying out the sub-contracted part of inspection activities, according to the requirements of Regulation 402/2013;
- (b) the sub-contractor complies with all the requirements of the ISO/IEC 17020:2012 standard;
- 4. Regarding the scopes of accreditation/recognition of the ordering AsBo, and of the sub-contracted body, the case 2 (sub-cases (a) and (b)) is not possible. It would imply that the Client appoints a non-accredited/non-recognised body for the independent assessment of its risk assessment vs. the CSM-RA; that choice is not compliant with the EU railway legislation.

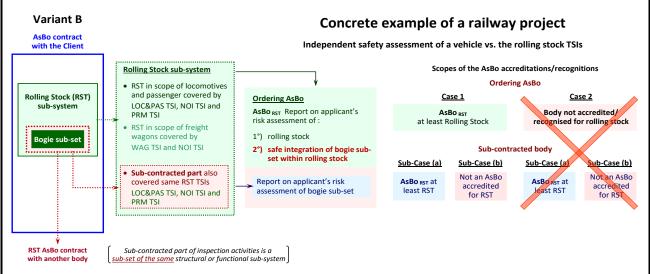


Figure 3: Concrete example of sub-contracting inspection activities between AsBos within the same structural or functional sub-system (variant B in Figure 1).

- 5. Concerning the Clause 6.3.3 of the ISO/IEC 17020:2012 standard, the ordering AsBo is responsible for the determination of conformity of the inspected item with all applicable requirements, including thus its own assessments and the sub-contracted part.
- 6. Annex B describes how the ordering AsBo can demonstrate compliance with the ISO/IEC 17020:2012 standard requirements regarding sub-contracting of inspection activities for a sub-set (i.e. a part) of a structural or functional sub-system covered by the same legal act, applicable to both the ordering AsBo abd the sub-contractor.

IV.C Responsibility of the AsBo and impacts on the mutual recognition of its report

IV.C.1 General requirements from the ISO/IEC 17020:2012 standard

- 1. According to Clause 6.3.3 of the ISO/IEC 17020:2012 standard, the ordering AsBo is expected to be responsible for the entirety of the inspection activities, and for the determination of conformity of the inspected item, including the parts of inspection activities that it decided to sub-contract.
- 2. As this general requirement does not consider the specificities of the railway sector :
 - (a) an AsBo using sub-contracting should be always responsible for the part of the work carried out by its sub-contractor;
 - (b) the responsibility should also extend down to cases in which serial sub-contracting⁽⁹⁾ is used. This means that an AsBo using a sub-contractor should, regardless of the number of serial sub-contracting, be responsible for the work performed by its sub-contractor, as well as the inspection activities performed down through the sub-contracting chain.

⁽⁹⁾ Serial sub-contracting designates the use of sub-contractors by sub-contractors. This means that a subcontractor sub-contracts itself a part of its contract to another sub-contractor further down the chain.

3. As described in section § IV.A.2 above, considering the specificities of the EU railway legislation, the demonstration of the AsBo compliance with those general requirements can be achieved in different ways. This will be dependent on the level of granularity of the sub-contracted inspection activities.

IV.C.2 Responsibility in case of sub-contracting inspection activities by an AsBo for a complete structural or functional sub-system (Variant A in Figure 1)

- 1. At least two different items are subject to inspection activities, each one covered by a dedicated European specification. The ordering AsBo assesses all items, except one, for which it sub-contracts the inspection activities to another AsBo .
- 2. Referring to the example presented in Figure 2 above, the ordering AsBo is always responsible for ensuring that :
 - (a) all inspection activities, contracted to its Client, comply with the requirements of the CSM-RA and the ISO/IEC 17020:2012 standard referenced therein;
 - (b) the Client is provided with a clear reporting on how the AsBo managed the inspection activities for all items of the contract, in particular :
 - (1) how the ordering AsBo ensures the competence of the sub-contractor within the field of the sub-contracted item, and its compliance with the relevant requirements of the CSM-RA and ISO/IEC 17020:2012 standard;
 - (2) how the ordering AsBo takes into account in its report, the results from the inspection activities carried out by the sub-contractor.

3. <u>Case 1-sub-case (a) & Case 2-sub-case (a) in Figure 2 :</u>

The sub-contractor is accredited/recognised for the scope of the sub-contracted item. Independently on whether the scope of accreditation/recognition of the ordering AsBo includes that field, or not, the accreditation/recognition provides the assurance that both AsBos are competent for their respective parts of inspection activities. The ordering AsBo shall:

- (a) mutually recognise the results from the report on the inspection activities carried out by the subcontractor. This implies that the ordering AsBo shall :
 - (1) retrieve from the inspection report of the sub-contractor the conditions and limits of use related to the sub-contracted part;
 - (2) take those conditions and limits of use into account within its own inspection activities;
- (b) issue an inspection report with the results of its own inspection activities;
- (c) in compliance with Clause 7.4.4 of the ISO/IEC 17020:2012 standard, and for transparency reasons :
 - (1) indicate the inspection results that are supplied by the sub-contractor;
 - (2) describe how those results are taken into account within the ordering AsBo report.

4. <u>Case 1-sub-case (b) in Figure 2 :</u>

When the sub-contractor is not accredited/recognised for the scope of the sub-contracted item :

- (a) the accreditation/recognition provides the assurance that the ordering AsBo is competent in each field of the contract with the Client;
- (b) the ordering AsBo should preferably not sub-contract the assessment of the item to that body, as this latter one has not demonstrated compliance with the requirements in Annex II of the CSM-RA;
- (c) if however it still wishes to proceed with sub-contracting, as the ordering AsBo cannot rely on the accreditation/recognition of the sub-contractor, it shall demonstrate compliance with the requirements in Clause 6.3 of the ISO/IEC 17020, i.e. :
 - (1) assess that the sub-contractor is competent to perform the inspection activities in question and, where applicable, complies with the relevant requirements stipulated in ISO/IEC 17020:2012 standard;

- (2) determine the conformity of the item inspected by the sub-contractor with the applicable requirements;
- (3) provide to the Client a single inspection activity report with a statement on the conformity of all inspected items with the applicable requirements.

5. <u>Case 2-sub-case (b) in Figure 2 :</u>

Neither the ordering AsBo nor the sub-contractor is accredited/recognised for the scope of the item subject to sub-contracting. This project configuration shall be prohibited.

6. If the conditions described in this section are fulfilled, the mutual recognition of the AsBo report is mandatory. It automatically falls under the conditions of Articles 6(3), 15(2), 15(3), 15(4) and 15(5) of the CSM-RA.

IV.C.3 Responsibility in case of sub-contracting inspection activities by an AsBo for a sub-set of the same structural or functional sub-system as the assessed one (Variant B in Figure 1)

- 1. This case is represented in Figure 3. If used at all, it relates to one item subject to inspection. The AsBo wishes to sub-contract some inspection activities for "a sub-set of the structural or functional sub-system" subject to inspection.
- 2. As described in section § IV.B.4(2), the ordering AsBo is responsible for :
 - (a) the check of the sub-contractor's competence for carrying out the sub-contracted part of inspection activities according to the requirements of Regulation 402/2013;
 - (b) the verification that the sub-contractor complies with all the requirements of the ISO/IEC 17020:2012 standard;
 - (c) the determination of conformity of the inspected item with all applicable requirements, including thus its own assessments and the sub-contracted part.
- 3. If the conditions described in this document are fulfilled, the mutual recognition of the AsBo report is mandatory. It automatically falls under the conditions of Articles 6(3), 15(2), 15(3), 15(4) and 15(5) of the CSM-RA.

V Mutual recognition of reports from other conformity assessment bodies

V.A Description

- 1. The ISO/IEC 17020:2012 standard foresees the first two cases described above (i.e. hiring-in and subcontracting), where the AsBo decides to seek for support outside its company to fulfil the inspection activities it contracts.
- 2. That ISO standard does not explicitly address the third case (mutual recognition), or at least it does not contain any explicit requirements, where <u>the AsBo does not decide by itself</u> to use expertise outside its company. In practice, as mentioned in section § IV.A.2 above, European legislation, or the client of the AsBo, can explicitly request other bodies to assess the conformity of parts of the system under assessment with the rules defined in those other legal acts. In that case, by virtue of Articles 6(3), 15(2), 15(3), 15(4) and 15(5) of the CSM-RA:
 - (a) duplication of independent assessments is to be avoided between the AsBo and other bodies (e.g. NSA, ECM Certification Body, NoBo, DeBo, other AsBos) involved in the same project;
 - (b) instead all those bodies shall mutually recognise the results of independent conformity assessments carried out by another body, unless the accepting body is able to demonstrate the existence of a substantial safety risk.
- 3. The requirement for an AsBo to mutually recognise reports from another conformity assessment body can be the result of:
 - (a) the obligation to comply with Articles 6(3), 15(2), 15(3), 15(4) and 15(5) of the CSM-RA;

- (b) the obligation to comply with other European or national legislation, resulting from the implementtation of the Railway Interoperability Directive 2016/797 and Safety Directive 2016/798 (e.g. section 6.2.3.5 of the LOC & PAS TSI, where the applicant can select either the NoBo, or the AsBo, for the independent safety assessment of the applicant's demonstration of compliance with the specific safety requirements referenced in section 6.2.3.5 of that TSI);
- (c) the practical organisation of the project by the proposer, and the distribution of relevant conformity assessment tasks to different conformity assessment bodies involved in the project.
- 4. Thereby, depending on such external constraints of the project, independent from its own decisions, the AsBo can be brought in a situation, where in order to build its expert judgement, it has to take into account the results of other assessments carried out beforehand by those other bodies (e.g. NoBos, DeBos, other AsBos), whereas the AsBo did not have the choice to appoint them.
- 5. Although this third case could appear to be similar to the use of sub-contractors, the use of inputs from other conformity assessment bodies cannot be considered as sub-contracting. The AsBo does neither have a legally binding contract with those other conformity assessment bodies, nor can decide by itself to outsource or not; it is a legal, or project/customer, constraint.
- 6. In such a case, it is more appropriate to talk just about :
 - (a) "mutual recognition" of reports from other bodies, and;.
 - (b) assessment and interpretation of results from those reports concerning risks at an interface with the sub-system the AsBo is in charge of.

V.B Permissions granted through accreditation/recognition

- 1. This case is not explicitly addressed by the ISO/IEC 17020:2012 standard.
- 2. Only Clause 7.1.6. of the standard can be linked to this third case. "When the ..." AsBo "...uses information supplied by any other party as part of the inspection process, it shall verify the integrity of such information".

According to section § 7.1.6 n1 of the ILAC-P15:05/2020-1 {Ref. 3}, "the information referred to in clause 7.1.6 of the standard is not information provided by a sub-contractor, but information received from other parties, e.g. a regulating authority or the client of the inspection body. The information may include background data for the inspection activity, but not results of the inspection activity".

- 3. Although this third case (mutual recognition) cannot be considered as an intentional sub-contracting, the AsBo is by analogy faced with situations similar to those described in section § IV above with respect to another conformity assessment body requested by either other European legislation or the proposer :
 - (a) If the other body is accredited or recognised for the scope of the inspected item, the AsBo can mutually recognise the assessment results from that body, applying the principles in section § IV.C.2(3) above.

This will usually be the case when implementing EU railway legislation. EU legal acts usually require the appointment of accredited or recognised bodies for carrying out conformity assessment activities defined in those legal acts.

(b) If the other body is not accredited or recognised for the scope of the conformity assessment activities it carries out, then the AsBo cannot mutually recognise the report of that other body.

This will usually be the case when the Client of the AsBo (i.e. the proposer) appoints a non-accredited, or a non-recognised, body for assessments that shall be carried out by an accredited or recognised one. As described in other sections of this document, such a situation should not happen.

If despite the requirements this case arises, the AsBo and its Client (i.e. the proposer) must find a solution on how to take into account the results of the other conformity assessment body. The Client of the AsBo shall provide evidence permitting the AsBo to :

(1) verify that the body, and its personel, whose results are to be mutually recognised, had the competence and qualifications for carrying out the related conformity assessment activities;

(2) independently assess the working methodology, the scope and the limits of the independent assessment, as well as the results of the work performed by that body.

V.C Responsibility of the AsBo and impacts on the mutual recognition of its report

- 1. Considering that the AsBo does not sub-contract the relevant assessment of conformity, Clause 6.3.3⁽¹⁰⁾ of the ISO/IEC 17020:2012 shall not apply. Therefore, the AsBo shall not be responsible for the correctness of the results of the conformity assessments carried out by the other conformity assessment body.
- 2. The most reasonable expectation is that the AsBo has "competence to assess and interpret the results" of the conformity assessment activities carried out by the other conformity assessment body to determine the conformity of its own inspection activities with the requirements of the CSM-RA. Section § IV.B.2 discusses the AsBo competence and capability "to assess and interpret the results" of inspection activities carried out by another conformity assessment body at an interface with the sub-system the AsBo is in charge of.
- 3. The AsBo shall be allowed to mutually recognise the results from the report on the inspection activities carried out by the other body. This implies that the AsBo responsibility shall be limited to the following :
 - (a) retrieve from the report of the other body the conditions and limits of use related to the part assessed by that other body;
 - (b) take those conditions and limits of use into account during the inspection activities carried out by the AsBo;
 - (c) issue an inspection report with the results of its own inspection activities;
 - (d) by analogy to Clause 7.4.4 of the ISO/IEC 17020:2012 standard, for transparency reasons indicate clearly in its assessment report:
 - (1) the results of the assessments carried out by the AsBo;
 - (2) the results of the assessments carried out by the other body;
 - (3) how those results, supplied by the other body, are taken into account (mutually recognised) within the AsBo assessment.
- 4. If the conditions described in this document are fulfilled, the mutual recognition of the AsBo report is mandatory. It automatically falls under the conditions of Articles 6(3), 15(2), 15(3), 15(4) and 15(5) of the CSM-RA.

VI Note for accreditation/recognition bodies concerning "one person AsBo companies"

- 1. The ISO/IEC 17020:2012 standard does not explicitly forbid the existence of a "one-person AsBo company"⁽¹¹⁾.
- 2. Theoretically a "one-person AsBo company" could be possible, where to compensate the lack of own resources, the company would exclusively hire-in experts and, or use sub-contractors "...with the required competencies, including, where needed, the ability to make professional judgements, to perform the type, range and volume of its inspection activities".
- 3. Unless the AsBo is capable to demonstrate the contrary⁽¹²⁾, despite a lack of own competent resources, in practice, it is highly unlikely that a "one-person AsBo company" gathers all required competencies to be able to comply successfully with all requirements of the CSM RA and ISO/IEC 17020:2012 standard

⁽¹⁰⁾ Clause 6.3.3 of the ISO/IEC 17020:2012 states that "whenever subcontractors carry out work that forms part of an inspection, the responsibility for any determination of conformity of the inspected item with the requirements shall remain with the inspection body".

⁽¹¹⁾ A one-person company is a company that has only one person as staff/member/employee.

⁽¹²⁾ A "one-person AsBo company" shall demonstrate compliance with all criteria and requirements in Annex II of the CSM-RA, and the ISO/IEC 17020:2012 standard referenced therein, as any other AsBo. This specific organisational structure does not allow to relax any criteria or requirements of the CSM-RA.

referenced therein. This is even more questionable when increasing the number of areas/scopes of the AsBo accreditation/recognition. The one-person AsBo shall have especially :

- (a) documented processes, procedures, and competence criteria and requirements for hiring-in external experts, or selecting sub-contractors as explicitly required in Clauses 6.1.1 to 6.1.6 of the ISO/IEC 17020:2012 standard;
- (b) fulfil the binding requirements in Clauses 6.1.7 to 6.1.12, and 6.3.4 of the ISO/IEC 17020:2012 standard. Clause 6.1.10 explicitly requires that "the inspection body shall maintain records of monitoring, education, training, technical knowledge, skills, experience and authorization of each member of its personnel involved in inspection activities". For a "one-person AsBo company" this requires the AsBo to have documented evidence that the hired-in experts, or sub-contractors, fulfil those requirements. The accreditation/recognition bodies are required to assess this evidence during their surveillance activities of the inspection body (AsBo);
- (c) the bullet (b) implies that, based on the results from the inspection activities carried out by the hired-in experts, or the sub-contractors, the AsBo has competence to :
 - (1) assess that all hired-in experts, or sub-contractors, are competent to perform the inspection activities the AsBo contracted to undertake;
 - (2) determine the conformity of the system under assessment with the requirements of the CSM-RA and the definition of the system;
 - (3) determine whether the results from the proposer's risk assessment are suitable for the change to fulfil safely the intended objectives.

4. DECISION

Decision of Cooperation:	Accepted
Plenary meeting number:	13
Date of decision:	15 June 2022

5. ANNEX

Additional details on the solution:			
No further details needed			
Annex documents:	Annex A :	Variant A – Demonstration of compliance with the ISO/IEC 17020 standard regarding sub-contracting of inspection activities for an entire structural or functional sub-system	
	Annex B :	Variant B - Demonstration of compliance with the ISO/IEC 17020 standard regarding sub-contracting of inspection activities for a sub-set of a structural or functional sub-system	

Annex A Variant A – Demonstration of compliance with the ISO/IEC 17020 standard regarding subcontracting of inspection activities for an entire structural or functional sub-system

Table 1: Variant A – Demonstration of compliance with the ISO/IEC 17020 standard regarding sub-	
contracting of inspection activities for an entire structural or functional sub-system (AREA 2).	

Variant A	C/	CASE	2	
	Ordering AsBo accredited/recognised for both technical areas ⁽¹³⁾ (AREA 1 + AREA 2)		Ordering AsBo accredited/recognised only for technical AREA 1	
Clauses	Sub-case (a)	Sub-case (b)	Sub-case (a)	Sub-case (b)
of ISO 17020 standard	Sub-contractor accred- ited/ recognised for technical AREA 2	Sub-contractor <u>not ac-</u> credited/recognised for technical AREA 2	Sub-contractor accred- ited/recognised for technical AREA 2	Sub-contractor <u>not</u> <u>accredited/recognised</u> for technical AREA 2
6.3.1	 Check scope and validity of sub- contractor accreditation/ recognition Trust accreditation/ recognition status of sub-contractor 	 Assess that sub-contractor fulfils all requirements in Clause 6.1 Assess that subcontractor complies with RFU 3 for area 2 Check that sub-contractor uses the method in RFU 1 	 Check scope and validity of sub-contractor accreditation/ recognition Trust accreditation/ recognition status of sub-contractor 	Not permitted because the ordering AsBo does not have the competence to assess that the sub-contractor complies with Clause 6.1 of the standard
6.3.1n1 of ILAC-P15:05/ 2020-1 note Last sentence	Accreditation/recognition in compliance with RFU 3 ensures that AsBo has the competence for "assessing and inter- preting the results of" inspection activities related to risks shared across the interfaces with the sub-system under its scope of accreditation	/	Accreditation/recognition in compliance with RFU 3 ensures that AsBo has the competence for "assessing and inter- preting the results of" inspection activities related to risks shared across the interfaces with the sub- system under its scope of accreditation	
6.3.2	Inform client about use of a sub-contractor	Inform client about use of a sub-contractor	Inform client about use of a sub-contractor	
6.3.3	 Each body is responsible for its part of work Mutually recognise the results from the sub- contractor (including assessment and interpretation of the results) 	Ordering AsBo responsible for the determination of conformity of the inspected item with all applicable requirements, including thus its own assessments and the sub-contracted part	 Each body is responsible for its part of work Mutually recognise the results from the sub- contractor (including assessment and interpretation of the results) 	
7.4.4	 Keep a trace of the checks of scope and validity of sub- contractor accreditation/ recognition Trust accreditation/ recognition status of sub-contractor 	 Keep evidence of checks and assessments the ordering AsBo carried out for Clause 6.3.1 above Be ready to show such evidence to accredita- tion/recognition body during surveillance 	 Keep a trace of the checks of scope and validity of sub-contractor accreditation/ recognition Trust accreditation/ recognition status of sub-contractor 	
7.4.4	Report correctly, clearly and accurately the use of results from the sub- contractor	Report correctly, clearly and accurately the use of results from the sub-contractor	Report correctly, clearly and accurately the use of results from the sub- contractor	

⁽¹³⁾ The terminologies "technical area or area of competence of the AsBo" of Regulation 402/2013, and "scope of accreditation/recognition of the AsBo" of the ISO/IEC 17020:2012 standard, are synonymous.

Annex B Variant B - Demonstration of compliance with the ISO/IEC 17020 standard regarding subcontracting of inspection activities for a sub-set of a structural or functional sub-system

Table 2: Variant B – Demonstration of compliance with the ISO/IEC 17020 standard regarding sub-	
contracting of inspection activities for a sub-set of a structural or functional sub-system.	

Variant B	CA	SE 1	CASE 2		
	Ordering AsBo accredited/recognised for the technical area ⁽¹⁴⁾		Ordering body is not an accredited/recognised AsBo for the technical area		
Clauran	Sub-case (a)	Sub-case (b)	Sub-case (a)	Sub-case (b)	
Clauses of ISO 17020 standard	Sub-contractor accred- ited/recognised for technical area	Sub-contractor <u>not ac-</u> <u>credited/recognised</u> for technical area	Sub-contractor accred- ited/recognised for technical area	Sub-contractor <u>not</u> accredited/recognised for technical area	
6.3.1	 Check scope and validity of sub-contractor accreditation/ recognition Trust accreditation/ recognition status of sub- contractor 	 Assess that sub-contractor fulfils all requirements in Clause 6.1 Assess that sub-contractor complies with RFU 3 for area 2 Check that sub-contractor uses the method in RFU 1 	The proposer shall not appoint a "non- accredited/ non-recognised" body for the independent assessment of the correct implementation of Regulation 402/2013. The EU legislation does not permit to a body, whose qualifications for a technical area are not acknowledged by accreditation/recognition, to sub-contract		
6.3.2	Inform client about use of a sub-contractor	Inform client about use of a sub- contractor	inspection activities to a recognised AsBo. In that		
6.3.3	 Can mutually recognise the results from the sub-contractor (including assessment and interpretation of the results) but "see next bullet point" Ordering AsBo remains responsible for the determination of conformity of the inspected item with all applicable requirements, including thus its own assessments and the sub-contracted part 	Ordering AsBo responsible for the determination of conformity of the inspected item with all applicable requirements, including thus its own assessments and the sub- contracted part	directly assign the contract to this latter AsBo, without passing through an non- accredited/non-recognised intermediate body		
6.3.4	 scope and validity of sub- contractor accreditation/ recognition Trust accreditation/ recognition status of sub- contractor 	 Keep evidence of checks and assessments the ordering AsBo carried out for Clause 6.3.1 above Be ready to show such evidence to accredita- tion/recognition body during surveillance 			
7.4.4	Report correctly, clearly and accurately the use of results from the sub-contractor	Report correctly, clearly and accurately the use of results from the sub-contractor			

⁽¹⁴⁾ The terminologies "technical area or area of competence of the AsBo" of Regulation 402/2013, and "scope of accreditation/recognition of the AsBo" of the ISO/IEC 17020:2012 standard, are synonymous.