1. REQUEST

Enquiry title: *	Harmonised template for the AsBo safety assessment report

Enquiry description: *

The purpose of this AsBo-RFU is to detail and harmonise further the structure of AsBo safety assessment report defined in Annex III of Regulation 402/2013.

The advantage of having a standardised layout of the AsBo safety assessment report is to enable any interested stakeholder to easily find out the necessary information in exactly the same sections, when the report complies with this AsBo-RFU. An easy access to all relevant information, needed for the mutual recognition of the proposer's results from the risk assessment, reduces demands for additional information, and/or additional checks and verifications.

The project-specific content of each section of the AsBo report is dependent on the nature and complexity of the change under assessment (project context, assumptions, sub-systems and stakeholders involved, etc.).

Submitted by User:	Dragan JOVICIC
Organisation:	ERA
Country:	France
Date of submission:	26/09/2018

Related documents:

{Ref. 1} Regulation 402/2013
{Ref. 2} ISO/IEC 17020:2012 and its subsequent amendments

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

2. TRACEABILITY

RFU number:	02
Version number:	1.0
Version comment:	First version, voted by the plenary

3. SOLUTION

Index ..... Page

I	Introduction	(Legal basis in CSM-RA)
1.	The proposer, as defined in Article 3(11) of Regulation 402/2013 on the CSM for risk assessment (CSM-RA), is responsible for applying the CSM-RA whenever making a technical, operational or organisational change to the railway system.	**Article 2(1)** **Article 5(1)**
2.	For a significant change, the proposer has to also appoint an independent assessment body (AsBo). The AsBo is responsible for the independent assessment of :	**Article 6(1)**
	(a) the suitability of the application of the risk management process defined in Annex I of the CSM-RA; (b) the suitability of the results from that risk management process.	**Article 6(1)** **Article 6(1)**
3.	The AsBo has to formally document the independent assessment activities, the associated results and the applicable limitations (if any) in a safety assessment report.	**Article 15(1)** **Clause 5.3 in Ax I, Ax III** **Clause 7.4 of ISO/IEC 17020** **Ax B(d) of ISO/IEC 17020**
4.	The proposer is required to take into account the conclusions of the AsBo safety assessment report for the safety acceptance of the change subject to risk assessment.	**Article 15(1)** **Article 16**

II Legal bases in the CSM-RA

1. The legal bases are given with regard to each of those requirements of the CSM-RA in the previous section. They are not duplicated.

III Structure of the AsBo safety assessment report

III.A General information on the report

1. Based on the minimum information that Annex III of the CSM-RA requires, the content and structure/ format presented below is essential, to avoid the accepting entities asking for additional information, or having to carry out additional checks and verifications.

   Note : by virtue of Clause 7.4.5 of the ISO/IEC 17020:2012 standard, in specific and justified cases, to avoid unnecessary administrative burden, a shorter AsBo report, with an adjusted structure, can be accepted, provided it complements, and explicitly refers to, an existing report produced by the same AsBo, which is fully compliant with the structure presented below. Typical examples are changes to non-safety relevant components (e.g. replacement of a GSM-R sub-system of an onboard ETCS sub-system), or software bug-fixing by a manufacturer for a CCS component that was already assessed and covered by an AsBo safety assessment report. In those specific cases, the AsBo report can be limited to the independent assessment, and to the follow up, of the correct implementation and management by the proposer of the considered change/corrections and to the assessment that the change does not adversely impact the non-modified parts of the sub-system under assessment. Nonetheless, in case a shorter AsBo report is produced, for the mutual recognition of the proposer's risk assessment, the AsBo shall provide both the short version of the independent safety assessment report, and the long version on which it is based.

2. To ensure a correct and proper traceability and control of the document, the AsBo safety assessment report shall fulfil all requirements in Clause 7.4 of the ISO/IEC 17020:2012 standard and have:

   (a) a cover page with a title of the change under independent assessment;
   (b) a unique document identification or reference, and date of issue, as foreseen through the AsBo documentation management system;

(c) a version control (including a short description of changes in the respective versions of the same report);
(d) signature or other indication of approval, by authorised personnel, as foreseen through the AsBo documentation management system;
(e) a table of contents compliant with the structure requested in section 3 of point III.B below;
(f) optional: (if available) symbol of accreditation, or recognition, to be used in compliance with the applicable rules of the accreditation[(1)] (respectively recognition) body.

3. The AsBo safety assessment report shall also number every page of the report, using the "Page Number format "Page n/nn or Page n out of nn", where 'nn' designates the total number of pages of the report. That allows a quick verification of completeness of the report.

4. In case a project does not need/use a specific section, the number should be kept and marked as "not used" (or similar text). It is essential to keep the recommended section numbering identical across all AsBo safety assessment reports to facilitate finding easily and quickly the information necessary for the mutual recognition of the AsBo report, in particular when the project language is different from English.

5. For every heading/sub-heading, the AsBo shall provide an overall summary concerning its independent assessment activities. Where convenient, the AsBo may reference separate/external documents of either the AsBo's documentation, or evidence provided by the proposer, for further details on a sub-heading.

Where necessary (e.g. complex projects with multiple suppliers), it is allowed to add sub-headings underneath the mandatory headings/sub-headings in order to describe separately the roles of, and interfaces with, all relevant sub-suppliers.

III.B Harmonised structure of the AsBo safety assessment report

1. The section numbers and titles of the headings below shall be respected in the report for the reasons explained in section 4 of point III.A above. Where needed for the project, the AsBo may use another official language of the European Union, as defined by the proposer.

2. Where the title of the heading is not explicit enough:

(a) *the text below, written in italic blue colour formatting (as the present one)*, describes the information the AsBo is expected to document formally in the report. The italic text is not a mandatory sub-title; it has to be replaced by the project specific information and evidence related to the outcomes of the independent safety assessment activities;

(b) if despite that explanatory text in italic, the expected content of the heading is not understandable, the reader can find more details on the expected inputs in Annex A below.

3. Headings and sub-headings of the AsBo safety assessment report:

Abstract (Optional)

When the project language is different from English, a short presentation of the report in English would help the mutual recognition with the points below:

- *Identification of the object under assessment and inspection activities assigned to the AsBo;*
- *An overall summary of the project objectives and organisation;*
- *A clear statement on whether the AsBo confirms the compliance of the proposer's risk assessment with the CSM-RA and the suitability of the system under assessment to fulfil safely the intended objectives;*
- *If the AsBo statement is conditional, refer the section of the report with the conditions that must be complied with for a safe use and maintenance of the system under assessment.*

(1) *The "EA conditions for the use of Accreditation Symbols, Logos and other claims of accreditation and reference to the EA MLA Signatory status" are defined in the European Co-operation for Accreditation document EA-3/01 M: 2021.*

1 Identification information

1.1 Identification of the assessment body (AsBo)

The AsBo is expected to include here the information contained in the ERADIS database.

1.2 Identification of the proposer

1.3 Identification of the item/system under assessment

For consistency with the title of the chapter, the AsBo shall <write the name of the project>. For further details about the project and its organisation, refer to heading 3 below.

2 Legislation, standards and guidance material applicable to the AsBo for the independent assessment activities of the proposer's risk management

This chapter lists the references against which the proposer's organisation and work will be independently assessed. It shall not list the reference requirements against which the AsBo is accredited/recognised.

2.1 Mandatory European regulations and standards
2.2 National regulation (*where relevant*)
2.3 Applicable codes of practice and standards *(where relevant, e.g. for ETCS sub-systems)*
2.4 European guidance material and non-legislative acts non-legally binding

(Optional sub-sections) If the AsBo wishes to add more sub-headings, it may.

3 Definition of the project and scope of the independent assessment

3.1 Description of the context and background of the project (change under assessment)

Explain shortly the technical, operational and organisational nature of the change, the mutual impacts between those three aspects and the interfaces with the rest of the railway system.

The AsBo report is not expected to summarise the proposer's safety files (e.g. Safety Case); this remains the responsibility of the proposer.

3.2 Proposer's organisation of the project under assessment

The AsBo is expected to provide a summary of the project organisation and of the actors involved in the project, including the description of roles of various conformity assessment bodies. For further details the AsBo can reference a proposer's document.

3.3 Scope and objectives of the independent assessment and of the present report

Describe the services the proposer assigned to the AsBo. Where for whatever reasons the AsBo sub-contracts any part of its independent assessment activities, the AsBo shall clearly describe which part is sub-contracted, and who is the sub-contractor, as this is requested by Clauses 6.3.2 and 7.4.4 of the ISO/IEC 17020:2012 standard.
Report in particular the stage of the project when the proposer contracted the AsBo, and when the AsBo started the inspection activities (early on the project, or much later).

3.4 Limitations of the scope and assumptions of the independent assessment

List the exclusions to the scope/elements outside of the system boundaries, or contractual restrictions for the inspection activities.

3.5 Relationships with the assessment activities carried out by other bodies

Describe the interfaces with, and where relevant, the approval roles/activities of, other assessment bodies.

4 Independent assessment plan of the AsBo

4.1 Overall strategy and methodology for the independent assessment

This part shall outline in the AsBo report the main principles/steps of the independent safety assessment plan[(2)] (roadmap/overview) for building its expert judgement on:

- *the correct application by the proposer of the requirements of the CSM-RA for every step of the risk management process in Annex I of the CSM-RA;*
- *the suitability of the results from the proposer's risk management to enable the system under assessment to fulfil safely the intended objectives.*

This assessment plan does not relate to contractual agreements that can exist between the AsBo and the proposer concerning the coordination and management of the independent assessment activities. If needed, specific documents should address separately such contractual arrangements. They do not need to be documented in the present report

Note : it is normal practice that both the assessment plan and detailed assessment activities are updated in the course of assessment, e.g. based on the identified issues, during in-depth assessments of the selected highest risk areas.

The overview shall enable the authorising entity to understand how the AsBo arrived at the expert judgement, without requesting additional explanations, and therefore how the recommendation for use N° 1 is implemented for the assessment of compliance with Regulation 402/2013 and the ISO/IEC 17020:2012 referenced therein. It shall give an overview of:

- *the assessment of the proposer compliance with the quality and safety management processes;*
- *the assessment of competence of the staff in charge of risk management activities;*
- *the use of risk based sampling and vertical slice-assessment techniques, as well as the methodology and criteria applied for selecting the key areas/highest risks for in-depth assessments, or another approach;*
- *the combined use of inspections of documents, complemented by audits or interviews;*
- *if the independent assessment activities are limited to inspections of documents, reasons for not cross-checking the actual application of the processes by competent staff, e.g. through audits/interviews with the proposer's staff;*
- *the ways to report to the proposer the issues identified along the project (e.g. verbally, via telephone, using e-mails, formal reports, etc.) to enable the proposer to take timely any necessary remedial actions, and;*
- *the way to assess and follow-up the adequacy of the proposer's remedial actions for addressing those issues.*

4.2 Independent assessment team

- *List the AsBo assessment personnel and their roles in the team*

5 Evidence of independent assessment activities vs. every step of the risk assessment process of the CSM-RA

This section shall give an overview of the activities the AsBo carried out for implementing the independent assessment plan introduced in point 4 above. It shall also :

- *list and justify the key areas and samples the AsBo selected for in-depth assessment and verification of both the correct application of the CSM-RA by the proposer, and the suitability of the results from the risk assessment;*
- *indicate the date(s) of the independent assessment activities, as required in Clause 7.4.2(c) of the ISO/IEC 17020:2012 standard.*

Regarding the identified issues, they are to be reported in point 6.

This RFU does not impose any mandatory sub-structure for providing the evidence that the independent assessment verifies the compliance of the proposer's risk management with the requirements of Annex I of

---

(2) *If necessary for the mutual recognition of the AsBo independent safety assessment report, on demand the complete independent safety assessment plan shall be made available to an authorising entity, or to another conformity assessment body, with the prior permission of the proposer (refer to the confidentiality clause in section 4.2 of the ISO/IEC 17020:2012 standard).*

the CSM-RA. This can be achieved in different ways, following for example every step of the risk management process in Annex I of the CSM-RA, or using any other equivalent structure (e.g. mapping the independent assessment activities onto the structure of the proposer's safety case specified in the CENELEC 50129 standard).

Whatever sub-structure the AsBo uses, it shall include a mapping/traceability table that provides the evidence of coverage (i.e. of an independent assessment) of every step of the CSM-RA process:

- *System definition;*
- *Proposer has quality and safety management processes in place for supporting the risk management activities;*
- *Proposer assigns competent resources to risk management;*
- *Management of interfaces and joint identification and control of risks across interfaces shared between sub-systems and/or other actors;*
- *Systematic and "exhaustive" hazard identification and classification into broadly, or non-broadly, acceptable risks;*
- *Registration of all identified hazards in a Hazard Record/Log;*
- *Choice of risk acceptance principle and risk evaluation:*
  - *Use of Codes of practice (CoP);*
  - *Comparison to similar Reference systems;*
  - *Explicit risk estimation;*
- *Comparison with risk acceptance criteria (risk evaluation step);*
- *Setting of safety requirements to be implemented;*
- *Hazard Management through a Hazard Record/Log;*
- *Demonstration of compliance with the safety requirements[(3)];*
- *Check of overall risk management process and of the safe integration;*

6 Results from the independent assessment

This section shall provide a list of all issues and AsBo's observations. Depending on the project organisation described in point 3.2 above, point 6.1 below might need to reference the results of assessments carried out by other bodies, where those later ones interact with the AsBo independent assessment activities.

6.1 Project organisation and relationships with the assessments carried out by other bodies

- *Reference to the project organisation in section 3 above justifies the reasons for the use of results from conformity assessments carried out by other bodies, as presented in section 6.3 below;*
- *If any evaluation results from other involved bodies is considered, justify the reasoning for using them in section 6.2 below (e.g. compliance with safety requirements assessed by a NoBo or a DeBo).*

6.2. If relevant, issues from the AsBo independent assessment activities

---

(3) *For specific projects, it can happen that the design and implementation phases of the project are assigned to different AsBos. In such cases, the AsBo assigned for the independent assessment of the design phase is not able to verify the correctness of the proposer's demonstration of compliance with the safety requirements. The AsBo shall clearly describe in sections 3.3 and 3.4 of the report the limits of its independent assessment activities, and therefore the non-applicability of this step of the CSM RA for its part of work.*

Typically, this can happen on large infrastructure projects spread over many years. As considerable time can elapse between the "design and implementation" phases of the project, the infrastructure manager might assign another AsBo for the implementation of the change. The AsBo assessing the design phase will thus not be able to verify this clause of the CSM RA.

- *There is no obligation to include by default the detailed history of issues that were identified, but successfully closed[4] by the proposer, at the moment of delivering the AsBo report. Nevertheless, transparency is essential to build trust. So, the AsBo is requested to provide an overall statement and description of the main issues the independent assessment found out, and the proposer successfully addressed.*
- *If any, detail the issues still open, the proposer's plans for closing them, etc.*
- *Using its own terminology, the AsBo shall categorise those open issues into either "blocking" ones, that prevent, or "non-blocking" ones, that do not prevent, the delivery of a positive assessment report. The AsBo shall justify why an issue is non-blocking.*
- *Where for whatever reasons the AsBo sub-contracts any part of its independent assessment activities, according to Clause 7.4.4 of the ISO/IEC 17020:2012 standard, the AsBo shall clearly identify the results that are supplied by the sub-contractor(s).*

6.3 If relevant, results from the assessments carried out by other conformity assessment bodies, or other parties:

- *from other AsBos (e.g. in case of involvement by the proposer, or by its suppliers, of several AsBos on the same project), but that are not sub-contractors of the AsBo writing the present report;*
- *from the <NoBo 'EC' verification of conformity>;*
- *from the <DeBo verification of conformity vs. the applicable national rules>;*

6.4 Non-blocking issues (if any) for the current project in future phases

6.5 Non-blocking issues (if any) for further improvements of quality, safety and risk management processes of the proposer for future projects (not in scope of current project)

7 Conditions and limits for the use of the system under assessment

7.1 Project organisation and relationships with the assessments carried out by other bodies

- *Reference to the project organisation justifies the reasons for relying on results from conformity assessments carried out by other bodies*
- *Depending on the project organisation described in point 3.2 above, where relevant provide the reference to the conditions and limits for use arising from the assessments carried out by other bodies, where those later ones impact the safe use and maintenance of the system under assessment.*

7.2 If relevant, conditions and limits for use from the AsBo independent safety assessment

- *List, or where relevant provide the reference to, the safety related application conditions, limits of use of the independent safety assessment, the implications, etc.;*
- *These conditions and limits are the outcomes of the AsBo assessments covered by the present report;*
- *State the timescales for the resolution of conditions and limits of use (if necessary).*

7.3 If relevant, conditions and limits for use transferred through the conformity assessment activities of other conformity assessment bodies, or other parties :

- *from other AsBos (e.g. in case of involvement of several AsBos on the same project);*
- *from the <NoBo 'EC' verification of conformity>;*
- *from the <DeBo verification of conformity vs. the applicable national rules>.*

8 Conclusions

Describe the conclusions from the independent safety assessment, and give a clear status of the project:

- *for a final report*

---

(4) *If necessary for the mutual recognition of the AsBo independent safety assessment report, on demand the history log of identified and closed issues shall be made available to an authorising entity, or to another conformity assessment body, with the prior permission of the proposer (refer to the confidentiality clause in section 4.2 of the ISO/IEC 17020:2012 standard).*

- *give a clear statement on both the compliance of the proposer's risk assessment process with the CSM RA, and the suitability of the results from that process to enable the change under assessment to fulfil safely the intended objectives. This fulfils the requirement in Clause 7.4.2(f) of the ISO/IEC 17020:2012 standard;*
- *if relevant (most likely often the case), give a clear reference to the conditions and limits for a safe use of the change under assessment;*

- *for an intermediate report, describe clearly the remaining issues and the outstanding independent assessments still to be carried out.*

Annex 1 Abbreviations

Annex 2 List of proposer's documents used for the independent assessment

Annex 3 (Optional) Record and traceability of the assessment of proposer's documentation vs. Annex I of Regulation 402/2013

This would then include the records produced by the AsBo during the independent assessment

Annex 4 (Optional) History of identified issues closed by the proposer

Annex 5 Optional elements of the assessment report referenced in the informative Annex B of the ISO/IEC 17020:2012 standard

Enclosure 1 (Optional) Independent assessment plan

4. DECISION

Decision of Cooperation:	Accepted
Plenary meeting number:	15
Date of decision:	29 March 2023

5. ANNEX

Additional details on the solution: No further details needed		
Annex documents:	Annex A :	Example of a detailed structure of the AsBo report in compliance with this AsBo-RFU

Annex A Example of a detailed structure of the AsBo report in compliance with this AsBo-RFU

<**Warning :** (*text to be deleted when producing the report*) this non-binding annex of the AsBo-RFU proposes to use either the template below, or at least the enclosed structure for the AsBo independent safety assessment report. The structure of the present report is to be incorporated into a template of the AsBo documentation management system, provided it includes the necessary information listed in this document. The AsBo which does not agree with some parts/text, is free to amend, or delete, them/it provided it reliably and unambiguously reports on how they actually performed the independent safety assessment, and what are all limits and conclusions of the independent safety assessment. In case a project does not need/use a specific section, the number should be kept and marked as "not used" (or similar text) to keep the section numbering identical across all AsBo safety assessment reports>

<The COVER PAGE of the AsBo safety assessment report shall contain the name of the AsBo company, under the template of the AsBo management system[(5)], with the following information:

(a) a title of the change under independent assessment, e.g. "**Report on the independent safety assessment of the proposer's risk management process according to Annex I of Regulation (EU) 402/2013 on the <write the name of the project>;**

(b) a unique document identification or reference number, as foreseen through the AsBo documentation management system;

(c) a version control;

(d) in compliance with the AsBo management system, the relevant information concerning for example:

(1) the author of the report;
(2) the verifier(s) of the report;
(3) the approver of the report;

and their functions/roles on the project/in the company>

(e) optional : (if available) symbol of accreditation, or recognition, to be used in compliance with the applicable rules of the accreditation/recognition body.

DOCUMENT INFORMATION

Amendment record

<The report shall contain an amendment record (e.g. a table), with a short description of changes in the respective versions of the same report). The table below is an example of such a history table of the AsBo report. Whatever other solution that provides equivalent information is acceptable.>

Table 1: Status/(history) of the document.

Version Date	Section Number	Description of the main modifications
0.1 dd-1/mm-1/YYYY-1	Whole	<This table is expected to trace the history of evolution of the report> <For example: First intermediate version of the report delivered at the concept level of the project>
0.2 dd-2/mm-2/YYYY-2	5, 6, 7, 8 Appendices 2, 3, 4	<For example: Second version of the report following the hazard identification and classification step of the risk assessment process>

(5) *Where necessary, the AsBo shall coordinate with the national accreditation/recognition body to notify the need for revising the model/template of their independent safety assessment report to match with the recommendations contained in the present RFU.*

Table 1: Status/(history) of the document.

Version Date	Section Number	Description of the main modifications
		<Add as many lines as necessary>

Abstract (Optional)

[A 1.] When the project language is different from English, a short presentation of the report in English in the abstract could help the mutual recognition.

[A 2.] This independent safety assessment report has been produced by Name of the AsBo. The purpose of this report is to provide the results and the conclusions of an independent and acknowledged body on the <write the name of the project>, as required in Article 6 of Regulation (EU) 402/2013. It provides an expert judgement concerning:

(a) the correct application by the proposer of the risk management process in Annex I of Regulation (EU) 402/2013, and its effectiveness for the identification, assessment and proper management of hazards and risks that arose from the implementation of <write the name of the project>, and;
(b) the suitability of the results from the risk management for the <write the name of the project> to fulfil safely the intended objectives.

[A 3.] <Where relevant, the AsBo shall explicitly state whether it mutually recognised the results from another conformity assessment body, and for which part(s)>

[A 4.] <The present explanatory text [with YELLOW background colour] shall be deleted when the requested information is summarised.>

[A 5.] <The abstract is the last part of the report to be written. It shall provide a brief overview of the report and enable to get a quick overview of the content of the report. It shall present the key points necessary to support the conclusions, including in particular the stage of the project when the independent safety assessment started. It shall permit the reader to understand those main points and to make an informed decision on whether they need, or wish, to read in detail some sections, or the whole report.>

[A 6.] <The abstract shall provide the answers to the six following questions:>

(a) <What is the purpose of the independent assessment? (this question is addressed by the proposed text in section [A 5.] above)>;
(b) <At what stage of the project was the AsBo contracted (early on the project or much later)?>
(c) <What methods did the AsBo use to perform the independent safety assessment of the change under assessment?>;
(d) <Does the independent safety assessment lead to any observations for future actions?>;
(e) <What are the outstanding blocking issues and conclusions reached as a result of the independent assessment?>;
(f) <Can the system under assessment be used and maintained safely and (if any) what are the safety related application conditions/limits of use? Concerning this last point, the AsBo can give a cross reference to another section of the report where those conditions/limits are precisely identified>.

[A 7.] <Although not foreseen in this template, this example does neither oblige, nor forbid, the proposers and CSM assessment bodies to produce, where relevant, either a single report or several separate reports for the following independent assessment activities. For example in the scope of a vehicle authorisation in compliance with Regulation 2018/545, the proposer can contract the same AsBo for:

(a) the independent assessment activities of the proposer's process for the capture and management of all requirements applicable to the design of a vehicle, as required in Article 13 of Regulation (EU) 2018/545;

(b) the independent safety assessment of the proposer's risk identification and management of safety according to Annex I of Regulation (EU) 402/2013 (object of the present report), and;
(c) any other relevant independent assessment activities required by the organisation of the project and sharing of responsibilities between different conformity assessment bodies.

Those different independent assessments can be documented in either several separate reports (one for each scope), or in a single report, provided the single report clearly identifies the specific scopes (e.g. in different and separate chapters).>

[A 8.] <Provide a summary for the remaining questions in bullets (b) to (f) in section [A 6.] above (moment of project when AsBo got involved, methodology, any observations, outstanding blocking issues, conditions and limits for use, conclusions)>.

Table of contents

1. Identification information

1.1 Identification of the assessment body (AsBo)

[L 1.] Table 2 below contains the contact and identification information of the CSM assessment body as registered in the ERADIS database.

Table 2: Identification information of the CSM assessment body (AsBo) from ERADIS.

Type of information	Information
AsBo name	
Legal denomination of the AsBo	
Acronym of the AsBo (if any)	
AsBo EIN number in ERADIS	
Date of validity of accreditation/recognition	
Areas of competence(6) covered by the accreditation/recognition (classification in section 5 of ERADIS)	<The AsBo shall at least be accredited or recognised for the area/scope of the system under assessment>.
Complete postal address of the AsBo	
First name, surname, title or function of AsBo contact person	
Additional information about the AsBo, when applicable	<Add any additional relevant information in a new line of the table (e.g. telephone number, e-mail contacts, website, etc.), if you feel that information necessary>

1.2 Identification of the proposer

Table 3: Identification information of the proposer.

Type of information	Information
Proposer name	
Legal denomination of proposer	
Acronym of proposer (if any)	
Complete postal address of proposer	
First name, surname, title or function of proposer contact person	

(6) *<Select the scope/area applicable to the <name of the project> among :*

(a) Infrastructure;
(b) Energy;
(c) Control Command and Signalling (CCS);
(d) Rolling stock;
(e) Traffic operation and management;
(f) Maintenance;
(g) System safe integration>

1.3 Identification of the item/system under assessment

[L 1.] <The item/sub-system subject to independent assessment is <write the name of the project>. For further details, refer to section3 below.>

2. Legislation, standards and guidance material applicable to the AsBo for the independent assessment activities of the proposer's risk management

2.1 Mandatory European regulations and standards

[L 1.] The legislation and standards applicable to the independent assessment of the proposer's process for the risk management of <write the name of the project> are :

(a) Regulation 402/2013 and the risk management process in Annex I of that Regulation;
(b) Article 6(2) of Regulation 402/2013;
(c) <where relevant, list also the additional applicable legislation (e.g. TSI) and/or standards (e.g. CCS TSI and the CELENEC 50126, 50128, 50129 and 50159 standards)>.

2.2 National regulation

[L 1.] <List any national regulations or rules that are applicable for the project. In most countries, there are no national rules for the AsBos.>

2.3 Applicable codes of practice and standards

[L 1.] <Where relevant, e.g. for the ETCS sub-systems, where for example CENELEC standards are applicable to the project, they shall be listed in this section.>

2.4 European guidance material and non-legislative acts non-legally binding

[L 1.] In addition to the legal basis in section 2.1 above, the following sources are used for defining the plan and strategy for the independent assessment:

(a) the "*recommendation for use 1*" on the working method of the Assessment Body;
(b) the "*recommendation for use 2*" on the structure of the AsBo report;
(c) the "*recommendation for use 11*" for tracking the history of issues identified by the AsBo and successfully closed by the proposer before the end of the project;
(d) the "*ERA explanatory note on the CSM Assessment Body referred to in Regulation (EU) N°402/2013 and in OTIF UTP GEN-G of 1.1.2016 on the Common Safety Method (CSM) for risk assessment*" (Reference: ERA/GUI/01-2014/SAF);
(e) the "*ERA guide for the application of the Commission Regulation on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of the Railway Safety Directive*" (Reference : ERA/GUI/01-2008/SAF, version 1.1 of 06/01/2009);
(f) the ERA guide on the "*collection of examples of risk assessments and of some possible tools supporting the CSM Regulation*" (Reference : ERA/GUI/02-2008/SAF, version 1.1 of 06/01/2009);
(g) the "*ERA guideline for the application of harmonised design targets (CSM DT) for technical systems as defined in (EU) Regulation 2015/1136 within the risk assessment process of Regulation 402/2013*" (Reference : ERA-REC-116-2015-GUI, version 1.1 of 18/05/2017);
(h) the "*ERA clarification note on safe integration*" (Reference : ERA 1209/063, version 1.0);
(i) <complete the list with any other document the AsBo estimates necessary>.

3. Definition of the project and scope of the independent assessment

3.1 Description of the context and background of the project (change under assessment)

[L 1.] <This section shall explain what the proposer's project is about. It shall give a summary to enable the reader to understand the context and background of the project:

(a) change made to the railway system;
(b) nature of the change and its technical, operational and organisational impacts;
(c) interfaces with the rest of the railway system;
(d) object of the risk management process;
(e) etc.

For more details, reference can be made to proposer's documentation>

[L 2.] <Identification information of the system under assessment. Write the name of the project.>

3.2 Proposer's organisation of the project under assessment

[L 1.] <This section shall give a summary of the organisation of the project, with all involved actors and who is in charge of which activities. If possible, an organisational flowchart or organigram would be appreciated.>

[L 2.] <Considering that Article 6(3) of Regulation 402/2013 requires the avoidance of duplication of conformity assessments by different bodies, where relevant, describe the approval roles of all other involved conformity assessment bodies [NoBos, DeBos, other AsBos – if any (e.g. on-board ETCS integrated within rolling stock), proposer's in-house assessment, and your own role]. Describe how those other checks/assessments affect or interface with your independent assessment work. This is of prime importance, knowing that, in principle, the proposer can use their reports to demonstrate compliance with relevant European, national and legal requirements.>

[L 3.] <For more details, the AsBo can reference any relevant proposer's documentation on the project background, the project organisation, and the description of the different parties involved and their respective roles and responsibilities.>

3.3 Scope and objectives of the independent assessment and of the present report

[L 1.] The present independent assessment is a systematic review by an independent body of the proposer's risk management process for the <write the name of the project>.

[L 2.] This section describes the services the proposer assigned to <the AsBo> within the project, as well as the limits of the independent assessment.

<Where for whatever reasons the AsBo sub-contracts any part of its independent assessment activities, the AsBo shall clearly describe the part(s) it sub-contracted, and whom it sub-contracted, as this is requested by Clauses 6.3.2 and 7.4.4 of the ISO/IEC 17020:2012 standard. For those purposes, the AsBo should preferably describe in separate sub-headings of this section on one hand, its own independently assessment activities, and on the other hand those carried out by the sub-contractor(s).>

[L 3.] This report documents the applied methodology, the results and the conclusions of the independent safety assessment, as required in Article 6 of Regulation (EU) 402/2013. In the sections below, it provides an expert judgement concerning the independent assessment of:

(a) the assessment of the correct application by the proposer of the risk management process in Annex I of Regulation (EU) 402/2013, and of its effectiveness for the identification, assessment and proper management of hazards and risks that arose from the implementation of <write the name of the project>, and;
(b) the suitability of the results from the risk management for the <write the name of the project> to fulfil safely the intended objectives.

[L 4.] <The AsBo shall clearly indicate the stage of the project development process when it was contracted and started the inspection activities (early on the project, or if much later, the precise moment when you started the assessment of project.>

[L 5.] <Explain the aim and the specific objectives of your independent assessment. In particular, explain whether your company is also in charge of the independent assessment of other proposer's activities for the same project (e.g. where relevant, independent assessment of vehicle requirement capture process), and where this is documented (e.g. a separate assessment report or another chapter of the present report). The description shall be consistent with [L 2.] in section 3.2.>

[L 6.] <For projects involving several structural sub-systems (e.g. vehicles fitted with on-board CCS equipment), it is important to describe whether all sub-systems are part of the assessment or whether they are subject to the mutual recognition of reports from other AsBos. The description shall be consistent with [L 2.] in section 3.2.>

[L 7.] <For more details, the AsBo can reference any relevant proposer's documentation on the project background information.>

3.4 Limitations of the scope and assumptions of the independent assessment

[L 1.] <Explain the limitations and assumptions (if any) of the scope of the independent assessment.>

[L 2.] <Identify any exclusions to the scope of the independent assessment in terms of elements outside the system boundary, details not considered and/or out of scope of the AsBo contract with the proposer. Interfaces which are out of scope, extent to which operational and maintenance details are in the scope of the independent assessment and how they relate to the independent safety assessment report.>

3.5 Relationships with the assessment activities carried out by other bodies

[L 1.] <This section shall describe the interfaces of the AsBo independent assessment with conformity assessment activities carried out by other bodies. It shall describe the cases where either by the compliance with EU legislation, or on proposer's request, the AsBo has to mutually recognise the evidence from the conformity assessments performed by other bodies (as described in section 3.2 above) to support the demonstration of compliance with given safety requirements from the risk management.>

[L 2.] <For understanding the relationships between conformity assessment bodies, reference can be made to section 3.2 above.>

4. Independent assessment plan of the AsBo

4.1 Overall strategy and methodology for the independent assessment

[L 1.] <Chapter 4 explains the overall plan, strategy, prioritisation and methodology for carrying out and formally documenting the evidence of the independent assessment activities. Considering that independent assessment is an iterative process, it is likely that the assessment plan is updated regularly, based on strengths or weaknesses in the proposer's project development and risk management processes. The AsBo is neither requested to provide the details of the independent assessment plan[7], nor to include the plan in an annex. That remains optional, if the AsBo so wishes.>

<It is to note that this assessment plan does not relate to contractual agreements that can exist between the AsBo and the proposer concerning the coordination and management of the independent assessment

[7] *If necessary for the mutual recognition of the AsBo independent safety assessment report, on demand the complete independent safety assessment plan shall be made available to an authorising entity, or to another conformity assessment body, with the prior permission of the proposer (refer to the confidentiality clause in section 4.2 of the ISO/IEC 17020:2012 standard).*

activities. If needed, specific documents should address separately such contractual arrangements. They do not need to be documented in the present report>

[L 2.] The present section summarises the overall independent assessment strategy. It shall enable the reader (to understand how the AsBo arrived at the expert judgement on the correct application of the CSM RA and on the suitability of its outcomes. The overall strategy is based on the references listed in sections 2.1, 2.4 and 2.2 above, that include the AsBo-RFU 01.

[L 3.] <If the AsBo does not apply those principles, but for example assesses 100 % of the proposer's documentation, the text below shall be replaced by a summary of what the AsBo actually plans to do. The details shall be included in the independent safety assessment plan.> The strategy for the independent assessment is the four step approach, built on the following four complementary pillars, described in the recommendation for use N°01 on the working method of the CSM assessment body :

❶ based on proposer's documentation, get a **clear and thorough understanding** of :

(i) the scope and context of the project, in order to plan the intensity of independent assessment activities, and the particular areas where in-depth assessments are needed;
(ii) the proposer's plans, project organisation, competencies of staff involved in the project, and quality and safety processes in place for managing the project and implementing the risk management process of Annex I of Regulation 402/2013;

❷ **plan and prioritise** the independent assessment activities necessary to :

(i) cover every step of the risk management process in Annex I of Regulation 402/2013;
(ii) check the effectiveness of the project organisation and of those processes for the correct application of the risk management process.

This includes the identification of highest or most critical risk areas, judged sufficiently representative of the <write the name of the project>. Those sample areas are subject to in-depth assessment to build an expert judgement on whether the proposer's process is systematic and effective to correctly identify and control the risks associated with <write the name of the project>

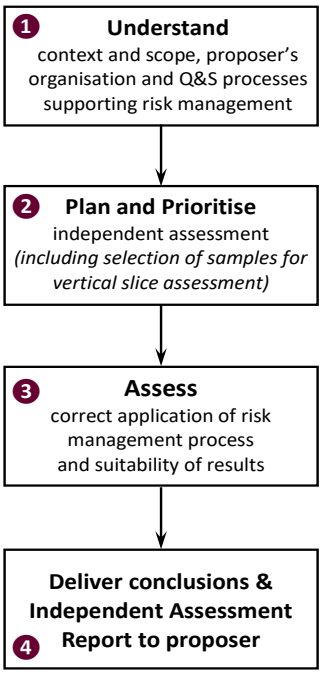

Figure 1: Independent safety assessment based on a 4-step approach, with sample checks and vertical slice assessments.

❸ according to the plan and priorities:

(i) carry out the **independent assessment** of the correct implementation by the proposer of every step of the risk management process;
(ii) conduct a **thorough vertical slice assessment and/or sample check**[(8)] at least on the areas considered to be of highest risk (i.e. on samples selected for in-depth assessment);
(iii) build an expert judgement on the suitability of the results from the proposer's risk management process to enable the <write the name of the project> to fulfil safely the intended objectives.

---

(8) *The terminology "**vertical slice assessment**" refers to a thorough end-to-end review of the application of the risk management process contained in the Appendix to Annex I of Regulation 402/2013 at least for the areas of highest or most critical risk(s) of the change under assessment. The purpose is to check a representative cross-sectional slice of the results from the risk management and to cover all the steps of the risk management process of Regulation 402/2013.*

This includes the gathering and reporting to the proposer of documented evidence of all identified issues, and of the follow up of their effective and correct management by the proposer;

❹ **deliver** the independent safety assessment **conclusions**, and the present **report**, to the proposer. <Depending on the moment (e.g. very beginning of the project or not) at which the proposer contracted the AsBo, several versions of this report might need to be provided to the proposer.>

[L 4.] The objective of this four-step approach is to :

(a) identify systematically, and proactively (when appointed at the very early stages of the project), the root causes in either the proposer's project management and safety and quality processes, or in the way those processes are actually implemented by the proposer's project team, and which result in a failure to meet the requirements in Annex I of Regulation 402/2013, and;
(b) enable the proposer to take any necessary remedial actions.

[L 5.] <For the implementation of that strategy, the AsBo can reference the inspection methods and procedures of its management system (refer to Table 4) used for the independent assessment. The ISO/IEC 17020:2012 standard requires the AsBo to have such documents.>

[L 6.] <It is not necessary to include them in the present report. A short summary of the principles of those methods and procedures is sufficient, provided it includes:

(a) the list and justification of the highest risk areas selected for in-depth assessment;
(b) the sub-sequent sampling to be carried out for the vertical slice assessments throughout the whole risk management and project development processes;
(c) the combined use of document reviews with audits (if any) using either remote tools, or directly on the field, interviewing staff from the proposer's project organisation;
(d) when independent assessment activities are limited to paper reviews, without cross-checking the process application through audits/interviews with the proposer's staff, explain how the AsBo verifies that the project actually uses competent staff, actually applies the safety and quality processes for implementing the risk management process of the CSM-RA.>

Table 4: Table of applicable reference documents from the AsBo management system.

Ref. N°	Title	Document reference	Version and/or date
{AsBo–Ref 1}	<Insert as many lines as necessary>		
{AsBo–Ref 2}			
{AsBo–Ref 3}			

4.2 Independent assessment team

[L 1.] <The AsBo shall list all personnel involved in the independent assessment and their respective roles on the project.>

5. Evidence of independent assessment activities vs. every step of the risk assessment process of the CSM-RA

[L 1.] <Chapter 5 shall document the activities and results of the AsBo independent assessment activities for every step of the CSM risk management process according to the plan presented in chapter 4 above. The results of those activities are presented in chapter 6 below.>

[L 2.] <The AsBo shall be as transparent as possible to enable the Authorising Entity to mutually accept the results of the AsBo independent assessment, without performing additional checks or assessments, or without requesting the proposer to carry out additional risk assessment>.

[L 3.] <This example of report does not impose any mandatory sub-structure for providing the evidence that the independent assessment checks the compliance of the proposer's risk management with the requirements in Annex I of the CSM-RA, as well as the suitability of the results from the risk management. This can be achieved in different ways, following for example every step of the risk management process in Annex I of the CSM-RA, or using any other equivalent structure (e.g. mapping the independent assessment activities onto the structure of the proposer's safety case specified in the CENELEC 50129 standard).>

[L 4.] <Whatever sub-structure the AsBo uses, it shall include a mapping/traceability table that provides the evidence that the independent assessment also covers every step of the risk management process in Annex I of the CSM-RA. Such a traceability table shall describe where to find the evidence of the AsBo independent assessment of :

(a) system definition and its update by the proposer, based on the outcomes of the risk assessment;
(b) the effectiveness of the proposer's quality and safety management processes in supporting the correct implementation of the risk management activities according to the CSM-RA;
(c) the allocation by the proposer of competent resources for the risk identification and risk management activities;
(d) based on the project organisation presented in section 3.2 above, the management of interfaces and the joint identification and control of risks across interfaces shared between sub-systems and/or with other actors;
(e) a systematic and "exhaustive" hazard identification and classification into broadly, or non-broadly, acceptable risks (risk ranking);
(f) registration by the proposer of all identified hazards in a Hazard Record/Log;
(g) choice of risk acceptance principle, the evaluation of its applicability to the identified hazards and the acceptability of the associated risks (risk evaluation) :

(1) where the proposer uses a Code of Practice (CoP) for controlling a risk, explain the AsBo checks related to:

(i) the proposer's compliance with Clause 2.3.2 in Annex I of Reg. 402/2013;
(ii) the correct application by the proposer of the selected Code of Practice.

This is of prime importance for the ETCS sub-systems, where the proposer can apply the CENELEC standards as an acceptable means of compliance with the CSM RA. In that case, the AsBo independent assessment activities shall assess whether the proposer correctly applies the applicable CENELEC standards;

(2) where the proposer compares the system under assessment to a similar Reference System for controlling a risk, explain the AsBo checks related to:

(i) the proposer's compliance with Clause 2.4.2 in Annex I of Reg. 402/2013;
(ii) the correct application and deriving of the safety requirements for <write the name of the project.

The AsBo shall document the checks the AsBo carried out to assess that the proposer has actually access to updated documentation of the reference system in order to retrieve the safety requirements for the system under assessment;

(3) where the proposer uses explicit risk estimation for controlling a risk, explain the AsBo checks related to the proposer's tools for qualitative, and/or quantitative risk estimation, risk evaluation and acceptance of residual risk (if any).

(h) comparison with risk acceptance criteria (risk evaluation step). This section shall contain an overall AsBo statement concerning the consistent and correct use by the proposer of the three risk acceptance principles for a consistent and proper control of the identified risks;
(i) setting of the safety requirements that are to be implemented based on all risk control measures identified by the risk assessment;
(j) hazard management through a Hazard Record/Log;

(k) demonstration of compliance with the safety requirements[9]. In particular, the AsBo shall describe how it verifies the requirements of Clause 3.3 in Annex I of the CSM-RA, i.e. that the proposer correctly implements, verified and validates the safety requirements from the risk assessment throughout the entire development process of the change under assessment;

(l) check of the overall risk management process and of the safe integration ensuring that the proposer consolidates properly the results from both its own project activities and inputs from all other actors involved in the project. This is particularly important where:

(1) the project organisation is complex and involves many actors, or;
(2) several iterations on either the proposer's, or AsBo, or both sides, are necessary for managing the project development, the risk management, and the independent assessment by the AsBo, or;
(3) results from other bodies need to be taken into account to avoid unnecessarily duplicating independent assessments;
(4) etc.

The AsBo shall describe the coordination of the overall assessment activities and the comprehensive path to its final expert judgement. This is of prime importance to give the assurance to the proposer, and to the Authorising Entity, that the independent assessment is a robust verification of the proposer's risk management activities, and not just paperwork for satisfying the legislator. The report of independent assessment activities shall not be a copy/paste of results from the proposer's risk management documentation. Instead it shall transparently report the checks that the AsBo carried out on the proposer's activities.>

[L 5.] <Clause 7.4.2(c) of the ISO/IEC 17020:2012 standard requests the AsBo to provide the date(s) of the independent assessment activities. That shall thus also be documented, consistently with the description in section 4.1[L 6.](d) above concerning the methodology the AsBo applied for the independent assessment activities.>

6. Results from the independent assessment

6.1 Project organisation and relationships with the assessments carried out by other bodies

[L 1.] Based on the organisation of the project presented in chapter 3 above, and the need to avoid a duplication of assessments between different conformity assessment bodies involved in the project, the independent assessment of the <write the name of the project> does not redo the work of those other bodies.

[L 2.] However, in order to state on the compliance of the proposer's risk management process with the requirements in Annex I of Regulation 402/2013, this report integrates also the outcomes or results from the conformity assessment activities carried out by the other conformity assessment bodies referenced in section 3.2 above (i.e. NoBos, DeBos, other relevant assessment parties, and other AsBos – where relevant [e.g. for the on-board CCS sub-system]).

[L 3.] <This separation remains necessary even when the same company fulfils several roles on the same project (e.g. the same company is acting as NoBo, DeBo, AsBo for the independent safety assessment of the application of the process in Annex I of Regulation (EU) 402/2013, and for example AsBo for the independent assessment of the requirement capture for a Vehicle Authorisation). If the same company fulfils more than one role, there shall be a separate section/chapter for every of the roles the AsBo fulfils.>

---

[9] *For specific projects, it can happen that the design and implementation phases of the project are assigned to different AsBos. In such cases, the AsBo assigned for the independent assessment of the design phase is not able to verify the correctness of the proposer's demonstration of compliance with the safety requirements. The AsBo shall clearly describe in sections 3.3 and 3.4 of the report the limits of its independent assessment activities, and therefore the non-applicability of this step of the CSM RA for its part of work.*

Typically, this can happen on large infrastructure projects spread over many years. As considerable time can elapse between the "design and implementation" phases of the project, the infrastructure manager might assign another AsBo for the implementation of the change. The AsBo assessing the design phase will thus not be able to verify this clause of the CSM RA.

6.2 If relevant, issues from the AsBo independent assessment activities

[L 1.] <This section lists the results of the AsBo independent assessment.>

[L 2.] <Where for whatever reasons the AsBo sub-contracts any part of its independent assessment activities (refer to section 3.3 above), the AsBo shall clearly identify the results that are supplied by the sub-contractor(s). This is requested by Clause 7.4.4 of the ISO/IEC 17020:2012 standard.>

<The AsBo shall describe how it interprets and takes into account the results of the sub-contracted independent assessment activities for determining the conformity of the <write the name of the project> with the requirements of the CSM RA.>

[L 3.] <There is no obligation to include by default the history of issues that were identified, but successfully closed[(10)] by the proposer, at the moment of delivering the AsBo report. Nevertheless, to facilitate the mutual recognition of results from the proposer's risk assessment a minimum of transparency is essential to build trust. So, the AsBo is requested to provide an overall statement and description of the main issues the independent assessment found out, and the proposer successfully addressed.>

[L 4.] <For example, typically the following text can serve as a model, if it reliably represents the life of the project. **<write the name of the project>**>

<The implementation of the independent assessment plan identified several temporary issues regarding:>

(a) <the actual project organisation compared to the one described in the proposer's project documentation>;
(b) <the compliance with the safety and quality processes of the proposer>;
(c) <the sharing of roles between own staff and other involved actors>;
(d) <the exchange of safety relevant information across interfaces shared with other actors impacted by the project>;
(e) <the correct implementation by the proposer of the risk management process in Annex I of the CSM RA>;
(f) <the appropriateness of some risk control measures, and therefore justification of the acceptability of the associated risks>.

<The proposer provided corrective actions and additional evidence to address all those temporary issues. Their independent assessment confirmed a successful handling by the proposer of all of them. More details on those temporary issues that were identified by the AsBo, and successfully addressed by the proposer before the closure of the project, can be found in the history log of the issues. Likewise, the necessary updates of the independent assessment activities, based on the identified strengths and weaknesses in the proposer's project development and risk management processes, can be found in the successive versions of the initial independent assessment plan.>

[L 5.] If any, at the time of release of this report, the following issues remain still open.

<"Blocking" issues prevent the delivery of a positive assessment report, whereas the non-blocking ones do not prevent it.>

<Although self-explaining, there is no obligation to use that terminology; the AsBo is allowed to use the terminology of its management system, provided it is clear which issues allow the delivery of a positive assessment report, and which do not allow it.>

(a) Blocking issues:

<If all issues, are closed, the paragraph shall be adapted accordingly>

(1) <describe in detail the issues>;
(2) <indicate the current status (on-going, open)>;
(3) <describe the proposer's plans for closing them>.

---

(10) *If necessary for the mutual recognition of the AsBo independent safety assessment report, on demand the history log of identified and closed issues shall be made available to an authorising entity, or to another conformity assessment body, with the prior permission of the proposer (refer to the confidentiality clause in section 4.2 of the ISO/IEC 17020:2012 standard).*

(b) Non-blocking issues:

<In the absence of non-blocking issues adapted the paragraph accordingly.>

(1) <describe in detail the issue >;
(2) <justify why the issue is non-blocking>.

6.3 If relevant, results from the assessments carried out by other conformity assessment bodies, or other parties

[L 1.] <This section relates to other AsBos (e.g. in case of involvement by the proposer, or by its suppliers, of several AsBos on the same project), that are not sub-contractors of the AsBo writing the present report.>

[L 2.] The other conformity assessment bodies involved in the project (refer to section 3.2 above), report the following results: <if there are no open issues, the paragraph shall be amended accordingly.>

[L 3.] <The AsBo is not obliged to copy/paste the open issues/non-conformities, from those other bodies. It is allowed to provide the reference of the corresponding report, and the accurate section in that report, where those issues can be found :>

(a) <where relevant, accurate reference to the NoBo report and to the section where the open issues/non-conformities, can be found>;
(b) <where relevant, accurate reference to the DeBo report and to the section where the open issues/non-conformities, can be found>;
(c) <accurate reference to the independent safety assessment report of the relevant AsBo and to the section where the results from their assessments can be found;>
(d) <add as many bullet points as necessary>.

<Where relevant, the AsBo shall indicate clearly whether it accepted, did not accept, or changed the expert judgement concerning the results coming from the verification activities carried out by those other conformity assessment bodies (i.e. NoBos, DeBos, other AsBos, etc.)>

6.4 Non-blocking issues (if any) for the current project in future phases

[L 1.] This section lists the observations of the AsBo concerning the improvement of non-blocking points, for the current project. <If the AsBo does not raise any observation, the paragraph shall be adapted accordingly.>

[L 2.] <Based on the independent assessment activities of the proposer's risk management process for the current project, the AsBo came to the following observations that could be improved by the proposer:>

(a) <for the next steps of the current project, when the proposer took the precautions to appoint the AsBo at the very early stages of the project in order to enable a proactive independent assessment>;
(b) <etc.>

[L 3.] <Provided that those observations do not affect the decision on the compliance of the <write the name of the project> with the requirements of Regulation 402/2013, there is no obligation for the AsBo to trace here the observations raised by the NoBo or DeBo. The proposer and Authorising Entity can find them in the respective reports.>

6.5 Non-blocking issues (if any) for further improvements of quality, safety and risk management processes of the proposer for future projects (not in scope of current project)

[L 1.] This section lists the overall observations by the AsBo concerning improvements of proposer's quality, safety and risk management processes for the management of projects in future. <If the AsBo does not raise any observation, the paragraph shall be adapted accordingly.>

[L 2.] <Based on the independent assessment activities of the proposer's organisation and processes in place for the risk management process on the current project, the AsBo found out the following observations that could be improved by the proposer:>

(a) <for next projects, so that the proposer implements better the requirements in Annex I of Regulation 402/2013 (e.g. improvement of the proposer's organisation and processes supporting the risk management process), based on the experience gained with the AsBo independent assessment on the present project. That should enable the proposer to avoid reproducing the same non-conformities.>
(b) <etc.>

7. Conditions and limits for the use of the system under assessment

7.1 Project organisation and relationships with the assessments carried out by other bodies

[L 1.] <The conditions and limits applicable for the safe use and maintenance of the system under assessment might not result only from the AsBo independent safety assessment, covered by the present report. Depending on the proposer's organisation, and the sharing of roles and responsibilities between different actors and bodies involved in the project, additional conditions and limits for use can be raised by other conformity assessments. The specificities of the project need therefore to be reflected in the present report to avoid unnecessary duplications of independent conformity assessments.>

[L 2.] <They shall be clearly listed with the implications on the use and maintenance of the system under assessment. In case the identified conditions and limits for use are temporary, the AsBo shall state the timescales for their resolution by the proposer, and any additional checks that might be necessary (if any).>

[L 3.] <The organisation of the project is presented in chapter 3 above. Several stakeholders and conformity assessment bodies can be involved in the project.>

[L 4.] The sections below list the conditions and limits for the use of the <write the name of the project> at the time of release of the present report. They are based on the results of the present independent assessment, as well as on issues presented in chapter 6 above.

7.2 If relevant, conditions and limits for use from the AsBo independent safety assessment

[L 1.] <The independent assessment by the AsBo has identified the following conditions and limits for the safe use and maintenance of the <write the name of the project:>

(a) <(if any) list clearly the conditions and limits for the use of the system under assessment>;
(b) <give an accurate reference of the proposer's documents where the safety related application conditions (SRACs) can be found>;
(c) <give an accurate reference to the proposer's Hazard Log/Register, or a Hazard Report, where the open hazards can be found>.

7.3 If relevant, conditions and limits for use transferred through the conformity assessment activities of other conformity assessment bodies, or other parties

[L 1.] <In addition to the conditions and limits for use presented in section 7.2 above, the following conditions and limits for the safe use and maintenance of the <write the name of the project> are identified by:>

<The AsBo is not obliged to copy/paste them in the present report. It can provide the following information:>

(a) <if relevant, conditions and limits for use from other AsBos (e.g. in case of involvement of several AsBos on the same project):>

<Add as many lines as needed to reflect the number of other AsBos involved in the project.>

(1) <accurate reference to the other AsBo report, and to the section, where the conditions and limits can be found>;

(b) <if relevant, conditions and limits for use from the NoBo 'EC' verification of conformity:>

<Add as many bullet points as needed to reflect the number of NoBos involved in the project.>

(1) <accurate reference to the NoBo report, and to the section, where the conditions and limits can be found>;
(2) <accurate reference to the proposer's Technical File.>

(c) <if relevant, conditions and limits for use from the <DeBo verification of conformity vs. the applicable national rules:>

<Add as many bullet points as needed to reflect the number of DeBos involved in the project.>

(1) <accurate reference to the DeBo report, and to the section, where the conditions and limits can be found;>
(2) <accurate reference to the proposer's Technical File.>

8. Conclusions

[L 1.] This section contains the conclusions of the independent assessment activities of the proposer's risk management process, referenced in the scope and objective chapter 3 above.

[L 2.] <The content of the conclusion is different depending on whether the report is an intermediate version in the development process, or if it is the final report. Therefore, the report shall clearly and explicitly indicate the status of the project (i.e. intermediate or final report)>

[L 3.] <As mentioned above, when the proposer appoints the AsBo at the very early stages of the project, the AsBo independent assessment activities are proactive. They enable the AsBo to identify as early as possible issues in either the proposer's organisation and processes supporting the risk management process, or in the correct application of those processes by the project team. Intermediate versions of the present report can be used to formally inform the proposer about the identified deficiencies that need to be corrected before the delivery of the final report.>

[L 4.] <If the proposer appointed the AsBo very late in the project, i.e. when all developments are almost finished, the independent assessment cannot be proactive. It will consist in giving a final photo of the proposer's risk management, with the identified issues. ERA expects such cases not to happen in practice.>

[L 5.] <Depending on the progress of the project, and thereby on the objective of the report (i.e. intermediate or final one), the conclusion section shall unambiguously give the status of the project.>

<According to Clause 7.4.2(f) of the ISO/IEC 17020:2012 standard the AsBo is required to give a clear statement on the compliance with the CSM RA. In practice, in the context of inspections related to the check of compliance with the general requirements of a process defined in a regulation (CSM RA), the AsBo shall give a clear statement on both (see section [L 6.] below):>

(a) <the compliance, and correct application, of the proposer's risk assessment process with the CSM RA, and;>
(b) <the suitability of the results from that process to enable the change under assessment to fulfil safely the intended objectives.>

[L 6.] Based on outcomes of the independent assessment activities, carried out according to the assessment plan (<give also the reference of the AsBo Plan>), and summarised and documented in chapters 4, 6 and 7 above, the AsBo concludes that :

<The text below is just a model. It shall be corrected to reflect reliably the precise picture of your specific project>

(a) <the independent assessment activities cover all steps of the risk management process specified in Annex I of Regulation 402/2013>;
(b) <the risk management process is correctly applied by the proposer, and it complies with the requirements in Annex I of Regulation 402/2013>;

(c) <the proposer's project organisation, competencies of staff involved in the project, and quality and safety processes supporting the risk management process are effective for>:

(1) <a systematic identification of all reasonably foreseeably hazards>;
(2) <a correct assessment of the associated risks, and>;
(3) <the control of the identified risks to an acceptable level>;

(d) <the safety requirements from the risk assessment are implemented by the proposer in the development process of <write the name of the project>;
(e) <at the moment of publication of the present report [delete the non-applicable text]:>

(1) <the remaining open issues in sections 6.2 and 6.3 above shall be addressed by the proposer, or>
(2) <all identified blocking issues are closed> <the proposer produced sufficient documentary evidence to :

(i) <address successfully all identified issues before the closure of the project>;
(ii) <demonstrate full compliance with the requirements in Annex I of Regulation 402/2013>;

<Consequently, the <write the name of the project> can be used safely only under the conditions and limits for use listed, or referenced to, in chapter 7 above>.

<Section 6.5 above identifies the areas in the proposer's organisation for further improvements of the quality, safety and risk management processes on future projects>.

(3) <the observations in section 6.4 above, raised for further improvements by the proposer, do not adversely impact the capacity of <write the name of the project> (i.e. of the change under assessment) to fulfil safely the intended objectives.>

[L 7.] <If this is an intermediate report, clarify any conditions arising from the independent assessment, including any remaining assessment activities still to be completed in accordance with the Independent safety assessment plan (<give the reference of the plan>)>

APPENDIX 1 : Abbreviations

[L 1.] <This annex shall include the list of all abbreviations used in the document>

Table 5: Table of abbreviations.

Abbreviation	Meaning
AsBo	CSM Assessment Body as defined in Regulation (EU) 402/2013
CSM	Common Safety Method
DeBo	Designated Body
EU	European Union
NoBo	Notified Body
RFU	Recommendation For Use
	<Complete the table, inserting as many lines as necessary>

APPENDIX 2 : List of proposer's documents used for the independent assessment

[L 1.] <The AsBo shall list all documents that were subject of the independent assessment. This is necessary to enable the independent assessment activities to be repeated (if necessary) and to arrive at equivalent conclusions. Table 6 recommends the minimum information to be provided; it can contain more information than suggested.>

Table 6: Table of proposer's reference documents subject to independent assessment.

{Ref. N°}	Title	Document reference	Version and/or date
{Ref. 1}	<Add as many lines as necessary>		
{Ref. 2}			
{Ref. 3}			
{Ref. 4}			

APPENDIX 3 : (Optional) Record and traceability of the assessment of proposer's documentation vs. Annex I of regulation 402/2013

[L 1.] <If included in the report, the section is expected to include also any form of records of the outcomes of the independent assessment by the AsBo. It could include for example>:

(a) <references of AsBo communication with the proposer (e.g. minutes of meetings, dates, exchanges of e-mails, etc.)
(b) <inventory of AsBo inspection activities and results>;
(c) <list of AsBo meetings and/or visits to the proposer>;
(d) <visits to various project locations (if applicable). In case on-site visits are not held, explain the reasons;
(e) <history log of issues and observation raised by the AsBo, including>:

(1) <the action plans undertaken by the proposer to resolve the open points, and>;
(2) <the independent assessment carried out by the AsBo to verify the appropriateness of the proposer's action plans>;

(f) <list of persons from proposer that were interviewed or took part to the independent assessment;
(g) <etc.>

APPENDIX 4 : (Optional) History of identified issues closed by the proposer

[L 1.] <If the AsBo wishes to include the history of the assessment, this can include a summary of :

(a) <the identified issues along the project that were successfully closed by the proposer>;
(b) <the proposer's corrective actions to manage and close those issues >;
(c) <the AsBo independent assessment of those actions>

[L 2.] <This summary can be completed with a reference to a separate AsBo document, for surveillance purposes by the accreditation/recognition body. That separate AsBo document usually contains more details on the history of all identified issues, as well as details about the proposer's corrective actions and the additional independent assessment activities on those actions.>

APPENDIX 5 : Optional elements of the assessment report referenced in the informative Annex B of the ISO/IEC 17020:2012 standard

[L 1.] <This annex is not mandatory. The AsBos may use it for documenting any additional and optional elements of the independent assessment activities that the AsBo estimates useful.>

Enclosure 1 (Optional) Independent assessment plan