



**Accreditation & Recognition scheme within Regulation on the
CSM on Risk Assessment.**

Questionnaire for impact assessment

Version: Final

Reference: N10/003

Date: 17/12/2010

Author Safety Assessment Sector & Economic Evaluation Unit

1. DOCUMENT INFORMATION

1.1 Amendment Record

Table 1: Status of the Document.

Version Date	Author(s)	Section Number	Modification Description
0.1	Torben Holvad Nathalie Duquenne	All	Internal review
0.2	Torben Holvad Nathalie Duquenne	All	Amendments and additional questions
0.4	Torben Holvad Nathalie Duquenne	All	Outstanding issues raised by Task Force members
0.5	Torben Holvad Nathalie Duquenne	All	Final internal review
1.0	Torben Holvad Nathalie Duquenne	All	Final version distributed

1.2 Reference Documents

Table 2: Table of Reference Documents.

Title	Reference	Version
{Ref. 1} Commission Regulation (EC) N° 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council	EC 352/2009	24 April 2009
{Ref. 2} Note on Assessment Bodies roles and responsibilities in the CSM on risk assessment	C495-10	14 September 2010

Table 2: Table of Reference Documents.

Title	Reference	Version
{Ref. 3} Applied Methodology Guidelines – Accreditation & Recognition schemes: CSM on Risk Assessment	N10/004	15 September 2010
{Ref. 4} Commission Regulation (EC) N° 765/2008 requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93	EC 765/2008	9 July 2008

2. INTRODUCTION

The first set of CSM on risk assessment requires that the risk assessment process to be applied by a Proposer for a significant change shall be assessed by an Assessment Body appointed by the proposer. Based on evidence of the correct application of the risk management process described in Annex 1 of the CSM regulation{Ref. 1} and on the results of this application, the Assessment Body should then deliver a safety assessment report to the proposer, containing its opinion on the correct application of the risk management process and of the results of its application. The main purpose of this CSM application assessment is to support the proposer in its decision to accept the significant change it wants to introduce. Furthermore, where the significant change concerns structural subsystems requiring an authorisation to place in service from the NSA, CSM application assessment should be taken into account by the NSA in the authorisation process.

The CSM regulation requires that a safety assessment report concerning a system that has been accepted following the risk management process specified in the CSM regulation shall, under certain conditions, not be called into question by any other assessment body assessing the same system (or part of it). It is important, therefore, to ensure that there is sufficient trust in the work performed by the assessment bodies, in order to ensure the mutual recognition of risk assessment results. For this reason, a task force conducted by the Agency was set up with the aim to better define the role and responsibilities of the assessment body within the CSM framework.

For the future revision of the CSM, it is however important to further define how assessment bodies should do their assessment work in order to create, as a minimum, a common framework with clear guidelines regarding CSM application assessment. This is to facilitate mutual recognition of risk assessments done for similar applications, by increasing trust about the quality of CSM application assessment (and consequently of the risk assessment itself). It is an objective pursued to make mutual recognition of risk assessment (on similar applications and for similar conditions of use) systematic in the future and thus avoid unnecessary work and costs. A scheme for ensuring the competence of assessment bodies, such as accreditation, might have to be introduced in order to achieve this objective

The work achieved by the task force has clarified:

- who can be assessment body,
- what they should do and when they should perform their work,
- how their work interact with other assessment, certification or authorisation processes and which requirements will be necessary due to these interactions
- how they should perform their work
- Which scheme needs to be put in place to provide trust

According to the current CSM regulation {Ref. 1}, an assessment body has to fulfil the criteria of Annex II of the regulation, but it is not stated in the regulation who has to check that the assessment body fulfils these criteria. This open point could lead to a lack of trust in the work performed by assessment bodies. This is currently a concern especially for the cases in which this work has to be recognized by another assessment body according to art 7 §4 of the CSM regulation. The task force established a common framework for evaluating and supervising the ability of assessment bodies to carry out CSM application assessment. Within this framework, two different alternative options could be envisaged:

- The assessment body is accredited by a national accreditation body, according to a specific accreditation scheme covering the CSM application assessment activity;
- the assessment body is recognized by the Member State, according to similar requirements as those used in the accreditation scheme.

Freedom should be left to choose between either of these options; however the same criteria as well as a similar control of their fulfilment should be applied in all cases in order to provide equivalent guarantees regarding the quality of the work performed by assessment bodies (as stipulated in Commission Regulation (EC) N° 765/2008, see {Ref. 4}).

To have more information on this process including general information about the roles and responsibilities of CSM Assessment Bodies, please refer you to the {Ref. 2}. For your convenience this document has been attached to the email you received with the present questionnaire.

3. General information about the questionnaire

The Agency's recommendation on accreditation / recognition of assessment bodies will be accompanied by an Impact Assessment Report in order to inform the decision-makers about the options available and their consequences. The Agency's Economic Evaluation Unit is responsible for preparing the Impact Assessment Report. In order to support this work the following questionnaire has been designed such that basic information about stakeholder views are collected and also to facilitate further data collection among key stakeholders.

Below, a series of questions are put forward and your answers to these would be much appreciated. Answers to these questions will support our impact assessment work enabling us to verify that the costs incurred are not disproportionate to the benefits realised with respect to introducing an accreditation / recognition scheme.

The questionnaire is composed of several parts each directed to different stakeholders as follows:

- European cooperation for Accreditation
- National Accreditation Bodies
- Assessment Bodies (via NBRail)
- National Safety Authorities
- Sector Organisations and their members (EIM, CER, UNIFE, ERFA, UIP)

It is only necessary to answer the part of the questionnaire that refers to your organisation. In addition (at the beginning of the questionnaire) there is a group of general questions that concerns all stakeholders. The last page of the questionnaire asks all respondents if they have additional information (e.g. details regarding costs involved) and also whether they are interested in participating in follow-up bilateral meetings. Finally, there is a text-box where all respondents can raise any other comments on this issue.

Organisations / individuals that are not covered by the stakeholders listed above are welcome to complete such questions as they feel are applicable and provide additional input as they see fit.

Please note that if there are questions you cannot answer you can still submit the questionnaire with your responses to the remaining questions included.

The questionnaire contains both factual oriented questions as well as attitudinal ones. It includes both closed and open-ended questions. As far as possible 'check-boxes' are used to facilitate completion of the questionnaire. For most questions 'text-boxes' are included in order for the respondent to provide explanations concerning their answers given.

Please send the completed questionnaire or any enquiries regarding the questionnaire, preferably by e-mail before **15 February 2011**, to:

Nathalie Duquenne (Nathalie.duquenne@era.europa.eu) and

Torben Holvad (torben.holvad@era.europa.eu)

The European Railway Agency would like to thank the respondents for taking the time to answer the questionnaire.

3.1 Terms and Abbreviations

Table: Terms

Term	Definition
Agency	The European Railway Agency (ERA)
Working Party	Working group which follows the composition rules of Art3. of the Regulation 881/2004

Table : Abbreviations

Abbreviation	Definition
CBA	Cost Benefit Analysis
CR	Conventional Rail
EC	European Commission
EE	Economic Evaluation
IA	Impact assessment
IM	Infrastructure Manager
MS	Member State
MLA	Multilateral Agreement
NSA	National Safety Authority
RU	Railway Undertaking
WP	Working Party

Information about respondent

COMPANY:
Mr/Ms/Mrs:
First name:
NAME:
Position:
Address:
Post Code:
City:
Country:
Phone:
E-mail:
Respondent answers on behalf of a sector organisation <input type="checkbox"/> Yes <input type="checkbox"/> No

Please tick the appropriate box indicating your type of organisation:

- European cooperation for Accreditation
- National Accreditation Body
- Assessment Body
- National Safety Authority
- Sector organisation or member of sector organisation
- Other

If you have only ticked 'other' please give further details in the following text box

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Any personal data included to the questionnaire shall be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

http://www.europarl.europa.eu/tools/disclaimer/documents/l_00820010112en00010022.pdf.

It shall be processed solely for the purposes of the impact assessment of an ERA recommendation by the ERA Economic Evaluation Unit . The personal data shall be kept the time necessary for the ERA to answer to possible questions on its recommendation.

The data subject shall have the right of access to his personal data and the right to rectify or block any such data that is inaccurate or incomplete. Should the data subject have any queries concerning the processing of his personal data, he shall address them to the ERA Economic Evaluation Unit (EconomicEvaluation-info@era.europa.eu). The data subject shall have right of recourse at any time to the European Data Protection Supervisor edps@edps.europa.eu , www.edps.europa.eu.

4. Questionnaire

4.1 General questions

Question 0

Could you outline the current arrangements of relevance to your company / country with respect to assessment bodies?

Please use the following textbox for your answer

Question 1

What do you see as the main strengths of an accreditation scheme compared to the current arrangements (as identified in question 0)?

Please use the following textbox for your answer

Question 2

What do you see as the main weaknesses of an accreditation scheme compared to current arrangements (as identified in question 0)?

Please use the following textbox for your answer

Question 3

What do you see as the main opportunities of an accreditation scheme compared to current arrangements (as identified in question 0)?

Please use the following textbox for your answer

Question 4

What do you see as the main threats of an accreditation scheme compared to current arrangements (as identified in question 0)?

Please use the following textbox for your answer

Question 5

What do you see as the main strengths of a recognition scheme compared to current arrangements (as identified in question 0)?

Please use the following textbox for your answer

Question 6

What do you see as the main weaknesses of a recognition scheme compared to current arrangements (as identified in question 0)?

Please use the following textbox for your answer

Question 7

What do you see as the main opportunities of a recognition scheme compared to current arrangements (as identified in question 0)?

Please use the following textbox for your answer

Question 8

What do you see as the main threats of a recognition scheme compared to current arrangements (as identified in question 0)?

Please use the following textbox for your answer

Question 9

What are your views on the added value of a formal (mandatory) accreditation / recognition scheme for assessment bodies (please tick one of the boxes below as appropriate)

- No added value from such a scheme
- Some added value from such a scheme
- High added value from such a scheme
- Mandatory scheme will be counter-productive
- Other

Explanations for your answers can be provided in the following textbox particularly if you ticked "Other"

Question 10

Which type of scheme (if any) would you prefer being implemented? *(please tick one of the boxes below as appropriate)*

- Accreditation scheme only
- Recognition scheme only
- Both accreditation and recognition schemes should be available
- None
- Other

Explanations for your answers can be provided in the following textbox

Question 11

Do you agree that it should be possible for the National Safety Authority (NSA) to be a CSM Assessment Body?

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

Explanations for your answers can be provided in the following textbox

Question 12

Do you agree that a formal (mandatory) accreditation / recognition scheme would solve any current problems regarding mutual recognition of risk assessments?

(please tick one of the boxes below as appropriate)

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

Explanations for your answers can be provided in the following textbox (this should also make reference to any current problems that you consider may be solved through such a scheme)

Question 13

Do you agree with the statement that freight operators and rolling stock manufacturers have a relative higher need for mutual recognition regarding risk assessment compared to (domestic) passenger operators and infrastructure managers?

(please tick one of the boxes below as appropriate)

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

Explanations for your answers can be provided in the following textbox.

Question 14

Do you agree with the statement that the rules / requirements should be relaxed for CSM assessment bodies assessing changes that are domestic only?
(please tick one of the boxes below as appropriate)

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

Explanations for your answers can be provided in the following textbox, particularly if you ticked 'somewhat agree' or 'strongly agree' we would appreciate if you indicate the aspects that in your view should not be required in these cases

Question 15

What is your view on the effect of introducing such a scheme (accreditation / recognition) on the current level of costs involved for the work of CSM assessment bodies?
(please tick one of the boxes below as appropriate)

- Significant increase
- Small increase
- Stay the same
- Small decrease
- Significant decrease

Explanations for your answers can be provided in the following textbox, (indicate whether your answers depend on whether it is an accreditation or a recognition scheme). Please mention if your answer is linked or not to the answer given in Question 0 (current arrangements)

4.2 To European cooperation for Accreditation

Question 16 :

- A. How is EA peer evaluation of national accreditation bodies are carried out (what are the processes / main activities involved)?

Please use the following textbox for your answer

- B. Could you indicate cost and time involved for cross auditing?

Cost of cross-auditing (Euro):

Specify currency if not Euro:

Time resources for cross-auditing (person days):

- C. How often are national accreditation bodies being cross-audited?

(please tick one of the boxes below as appropriate)

- More than one time per year
- One time per year
- Between once and twice over two year period
- One time every second year
- One time every third year
- Less often than once every third year

Explanations for your answers can be provided in the following textbox

D. During a peer audit, are all accreditation schemes for inspection that are covered by the Multilateral Agreement (MLA), or just a sample of them, evaluated?
(please tick one of the boxes below as appropriate)

- All schemes are covered
- Sample of schemes
- Sometimes all schemes, sometimes only sample
- Other

Further explanations for your answers can be provided in the following textbox

Question 17 :

A. Does EA have possibilities / powers for enforcing changes according to problems identified?

Please use the following textbox for your answer

B. What are these possibilities/powers ?

Please use the following textbox for your answer

C. Are there procedures for ensuring compliance with recommendations resulting from cross-auditing findings ?

Please use the following textbox for your answer

Question 18 :

A. Are there country variations in the application of accreditation schemes?
(please tick one of the boxes below as appropriate)

- Significant variations
- Some variations
- Minor variations
- No variation
- Not sure

Explanations for your answers can be provided in the following textbox

B. If you have selected one of the following options 'significant variations', 'some variations' please indicate the type of variations

Please use the following textbox for your answers

C. Are you aware of the existence of recognition process in other industries ?

Explanations for your answers can be provided in the following textbox

4.3 To National Accreditation Bodies (NAB):

Question 19 :

A. Number of accreditation schemes in place in your country

Number of schemes in total:

Number of schemes involving inspection activities:
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B. Prices charged to applicant and days involved in delivering and maintaining accreditation for inspection activities (e.g. average number of auditors, price per auditor/day, number of audit days for initial and surveillance audits)

Average number of auditors:

Price per auditor per day:

Number of audit days, initial:

Number of audit days, surveillance:

C. What is the frequency of surveillance audits for accredited inspection bodies ?
(please tick one of the boxes below as appropriate)

- More than one time per year
- One time per year
- Between once and twice over two year period
- One time every second year
- One time every third year
- Less often than once every third year

Explanations for your answers can be provided in the following textbox

Question 20 :

- A. Could you indicate the costs of implementation a new accreditation scheme in addition to the schemes already covered by the Multilateral Agreement (MLA)?

Cost of setting up new scheme (Euro):

Specify currency if not Euro::

- B. Time required to establish a new accreditation scheme

Time resources of setting up new scheme (person days):

- C. Main challenges for putting in place a new scheme (to list the 3 main challenges)

Please use the following textbox for your answer

4.4 To Assessment Bodies (Via NBRail and sector organisation members if they already had a role of Assessment Body)

Question 21 :

- Could you give indications in terms of extra workload and costs in your organization for preparing for accreditation (e.g. against ISO 17020)?

Please use the following textbox for your answer

Question 22 :

- A. Which aspect(s) in this preparation do you see as requiring the most effort and resources in order to fulfil the requirements of ISO 17020 ?

Please use the following textbox for your answer

- B. Would that be related to changes of your quality system for instance ?

Please use the following textbox for your answer

- C. How long does it take for your organization to prepare for surveillance audit ?

Please use the following textbox for your answer

Question 23 :

- A. Could you provide indications regarding order of magnitude for resources involved for assessment bodies in audits (by accreditation bodies)?

Please use the following textbox for your answer

- B. What were the main reasons for seeking accreditation (if not mandatory)?

Please use the following textbox for your answer

C. Has accreditation been beneficial for your organisation, i.e. what does the business case for accreditation look like)?

(please tick one of the boxes below as appropriate)

- Yes, definitely
- Yes, probably
- Not sure
- No, probably not
- No, definitely not

Explanations for your answers can be provided in the following textbox (in particular, addressing why it has been beneficial or has not been beneficial)

D. Could you outline your perceptions in terms of confidence of safety assessment reports produced by other assessment bodies?

(please tick one of the boxes below as appropriate)

- High level of confidence
- Medium level of confidence
- Low level of (or no) confidence
- Not sure

Please use the following textbox for your answer

E. How often do you have concerns about the assessment reports from other assessment bodies?

(please tick one of the boxes below as appropriate)

- Never
- Very seldom
- Sometimes
- Often
- Always

Please use the following textbox for your answer

4.5 To National Safety Authorities

Question 24 :

Do you expect to take the role of CSM Assessment body ?

(please tick one of the boxes below as appropriate)

- Yes, definitely
- Yes, probably
- Not sure
- No, probably not
- No, definitely not

If yes could you explain the reasons and the process that you want to put it place in your organisation

Please use the following textbox for your answer

Question 25 :

What is your opinion about the NSA functioning as the (implicit) body responsible for recognition of assessment bodies.

(please tick one of the boxes below as appropriate)

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

Explanations for your answers can be provided in the following textbox

Question 26 :

Would you expect a formal (mandatory) accreditation / recognition scheme to have a positive influence on the process for authorizing placing into service of rolling stock ?

(please tick one of the boxes below as appropriate)

- Yes, definitely
- Yes, probably
- Not sure
- No, probably not
- No, definitely not

Explanations for your answers can be provided in the following textbox

Question 27

The rules and requirements may be relaxed for CSM assessment bodies assessing changes that are related to pure domestic operation, this being subject to an agreement by the relevant NSA. Would you apply this possibility?

(please tick one of the boxes below as appropriate)

- Yes, definitely
- Yes, probably
- Not sure
- No, probably not
- No, definitely not

Explanations for your answers can be provided in the following textbox

Question 28

If the NSA will be acting as the assessment body should it only be recognised by the Member State or do you see any advantage for it also to be accredited?

(please tick one of the boxes below as appropriate)

- Yes, definitely
- Yes, probably
- Not sure
- No, probably not
- No, definitely not

Explanations for your answers can be provided in the following textbox

Question 29

A. Is there a legal obligation for you as NSA to publish on your public web-site the list of the entities that have been accredited as assessment bodies in a given year?

(please tick one of the boxes below as appropriate)

- Yes
- No
- Not sure

Explanations for your answers can be provided in the following textbox

B. Is there a legal obligation for you as NSA to publish on your public web-site the list of the entities whose accreditation as assessment body has been withdrawn?

(please tick one of the boxes below as appropriate)

- Yes
- No
- Not sure

Explanations for your answers can be provided in the following textbox

4.6 To the sector associations (EIM, CER, UNIFE, ERFA, UIP, ...) and their members

Question 30:

A. What is your process for carrying out CSM application assessment?

Please use the following textbox for your answer

B. If this process differ according to the type of system to be assessed (signalling, rolling stock, infrastructure etc.), please indicate the differences and provide some details about the different processes you apply.

Please use the following textbox for your answer

C. In your view what are the main challenges regarding CSM application assessment?

Please use the following textbox for your answer

D. Could you outline your views on best practice in this field?

Please use the following textbox for your answer

Question 31 :

Do you see benefits for your organisation from an accreditation scheme compared to a recognition scheme?

(please tick one of the boxes below as appropriate)

- Yes, definitely
- Yes, probably
- Not sure
- No, probably not
- No, definitely not

Explanations for your answers can be provided in the following textbox (incl. details of the kind of benefits)

Question 32 :

If an accreditation scheme was in place would you use it?

(please tick one of the boxes below as appropriate)

- Yes, definitely
- Yes, probably
- Not sure
- No, probably not
- No, definitely not

Explanations for your answers can be provided in the following textbox (incl. details of why you would use such a scheme / why you would not use such a scheme)

Question 33 :

What costs do you anticipate for your organisation from a mandatory accreditation scheme?

Explanations for your answers can be provided in the following textbox

Question 34

A. Does your company intend to act as a CSM assessment body?
(please tick one of the boxes below as appropriate)

- Yes, definitely
- Yes, probably
- Not sure
- No, probably not
- No, definitely not

Explanations for your answers can be provided in the following textbox



B. If yes, do you envisage this role only with respect to significant changes within your company or to act as a CSM assessment body also for other railway companies in your country and / or in other countries?

(please tick one of the boxes below as appropriate)

- Own company only
- Own company as well as for other companies in same country
- Own company as well as for other companies in same country and abroad
- Not sure

Explanations for your answers can be provided in the following textbox

4.7 All respondents:

A. Do you have any additional information (e.g. cost data) that you think could be useful for the impact assessment?

- Yes
- No

If you have answered 'yes' please indicate in the following text-box if it is possible for the Agency to get access to this information

B. Are you willing to discuss with ERA, issues related to CSM Assessment Bodies in more detail?

- Yes
- No

C. If you have any other comments to raise on this subject please include these in the following text-box: