

Policy paper for the revision of the Common Safety Methods on Conformity Assessment (Commission Regulations n°1158/2010/EU and 1169/2010/EU) and the Common Safety Method on Supervision (Commission Regulation n°1077/2012/EU)

1. Introduction

1.1. Purpose

This paper sets out an analysis of the application of the Common Safety Method (CSM) for assessing conformity with the requirements for obtaining railway safety certificates¹ (hereinafter the “CSM on Conformity Assessment 1158/2010/EU”), the CSM for assessing conformity with the requirements for obtaining a railway safety authorisation² (hereinafter the “CSM on Conformity Assessment 1169/2010/EU”) and the CSM on supervision³ (hereinafter the “CSM on Supervision”). This analysis is required to support the Mandate from the Commission agreed by Rail Interoperability and Safety Committee that the CSMs need to be reviewed and revised in order to ensure that a more consistent approach across NSAs is adopted. Although the CSMs on Conformity Assessment have been applied for less than 4 years and less than 2 years for the CSM on Supervision, the European Rail Agency (hereafter called the ‘Agency’) has, through a number of sources, been able to analyse the information and come to a conclusion that further harmonisation can only be achieved through the revision of the CSMs.

Article 16(2) of the Railway Safety Directive 2004/49/EC only lists a set of tasks that shall be performed by NSAs, without determining the way to perform them. This is one of the main reasons for the actual diversity of application and implementation of the existing legal framework amongst NSAs. Indeed, Member States (MS) and National Safety Authorities (NSAs) have developed their own approach based on their own understanding, knowledge and experiences and often using their existing national frameworks. The Agency would like to work towards better harmonisation of assessment and supervision processes based on an agreed EU framework whilst preserving a degree of flexibility.

1.2. Scope

This paper describes and analyses some of the key issues underpinning the current implementation and application of the safety certification regime within the EU. It focuses on identifying the key areas and potential changes that need to be considered to existing EU safety regulatory framework; including the setting up of new working parties (or task forces) to support the Agency in its work and also to propose a work plan satisfying at best the milestones set in the Single Safety Certificate (SSC) programme plan.

The key areas are aimed at identifying the necessary changes for a more detailed description of the standard processes to be applied for safety certification (both the assessment before issuing the certification and the post award supervision) to ensure the establishment of a well-controlled SMS-based certification regime at European (EU) level.

¹ Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates (OJ L 326, 10.12.2010, p. 11).

² Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation (OJ L 327, 11.12.2010, p. 13).

³ Commission Regulation (EU) No 1077/2012 of 16 November 2012 on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation (OJ L 320, 17.11.2012, p. 3).

The development and implementation of these changes are necessary for the facilitation and the achievement of the SSC regardless of the future 4th Railway package (hereafter called '4RP'). As identified in the SSC programme plan, it has already been envisaged that change is necessary and a policy document (i.e. the present document) setting out the requirements for change with proposals will be produced.

It is important to note that, even if the Agency (as part of the current proposals for the 4RP) undertakes the pre-certification assessment and issuing of the safety certificate in certain circumstances, there should be consistency and transparency in the process for both the Agency and the NSAs. This means that a detailed and prescribed standard process for applying and granting of a safety certificate which can be applied by either the Agency or the NSAs will ensure that railway undertakings are subject to the same agreed fundamental elements. In addition, there will need consistency and transparency of the way NSAs approach and take forward their supervision role.

1.3. Background

The need for harmonisation of safety certification at European level was already clearly identified in Articles 6.3(b), 15 and 17.4 of the Railway Safety Directive. The first step was the development of the Commission Regulation (EC) No 653/2007 on the use of a common European format for safety certificates and application documents. Following this, the CSMs on Conformity Assessment were developed by the Agency Working Group on Safety Certification based on criteria which had been circulated in draft form to all NSAs in 2007. The idea was to encourage NSAs to work on developing their own decision-making criteria in advance of the publication of the EU Regulations but, at the same time, to use the draft criteria to have a consistent European approach. However, this voluntary approach was not always adopted as reported by the Agency's paper on the migration towards a single safety certificate⁴. Both CSMs on Conformity Assessment introduced the concept of post award supervision to meet the requirements in Article 16(2)(e) of the Railway Safety Directive. This was further elaborated in the CSM on Supervision to be used by NSAs after issuing a safety certificate or safety authorisation. However, despite the development of the EU Regulations, the Agency is aware that the harmonisation of safety certification is not achieved throughout the European Union. In order to have a Single European Rail Area, a harmonisation in the assessment of safety certificates/authorisations combined with effective post award supervision is an absolute necessity.

During the initial development of the CSMs, the idea was to develop high-level principles which could be handled with supporting guidance. This strategy was leaving a certain degree of flexibility while ensuring that the principles were met. The detailed guidance was to be developed by a NSA task force on assessment & supervision. The development of such detailed process requirements and related application guidance for safety certification was only partially successful due to the diversity of the application of the CSMs by NSAs and the different interpretation of the EU legal framework. The Impact Assessment

⁴ Report on the 2012 consultation with stakeholders on proposals for migrating to a single EU safety certificate, 01/06/2012

undertaken by the Commission on the revision of the institutional framework⁵ states that there is a divergent interpretation of EU law. In addition, some NSAs found it difficult to use guidance to support the development of their decision-making as it was not a legal requirement.

In January 2014, the content of the programme plan for the development and implementation of the SSC was discussed and endorsed during the RISC meeting. This programme plan identified a 'survey phase' during which the nature of the changes to the existing EU safety regulatory framework was to be defined prior to proceeding to a 'development phase' with the effective implementation of the proposed changes.

At the same time, the Agency was given a mandate to draw up a revised CSM on Conformity Assessment 1158/2010/EU, a revised CSM on Conformity Assessment 1169/2010/EU and a revised CSM on Supervision. The Agency was also asked to consider the future revision of the Commission Regulation (EU) No 445/2011 on a system of certification of entities in charge of maintenance for freight wagons⁶.

⁵ Impact assessment support study on the revision of the institutional framework of the EU railway system, with a special consideration to the role of the European Railway Agency, Final report, June 2012 (<http://ec.europa.eu/transport/modes/rail/studies/doc/2012-06-ia-support-study-era-final-report.pdf>)

⁶ OJ L 122, 11.5.2011, p. 22–46.

2. Technical proposals

Theme 1 – Safety certification/safety authorisation

Issue: how NSAs assess the sufficiency of the application in a proportionate, consistent and targeted way

The development of the CSMs on Conformity Assessment 1158/2010/EU and 1169/2010/EU was started by ERA in 2005 and initial draft criteria on the assessment of applications for safety certificates/authorisations were made available for all NSAs in 2007. The criteria were developed by the SafeCert Working Group which included members from NSAs. The original aim of the criteria, published in 2010, was to keep the process flexible so that NSAs could adapt their existing decision-making process but still ensure consistency by sharing the same criteria.

In addition, the criteria provided more clarity on the relationship between the Part A and the Part B safety certificate. In the CSM, the Part B assessment relating to the compliance with the network specific rules should be less extensive and linked to the Part A assessment of the Safety Management System (SMS) arrangements. The NSA should assess how the railway undertaking applies the rules in their SMS process and it should not be a separate assessment.

However, there is evidence that there are several problems with the criteria.

1. **Consistency and proportionality in the assessment:** it is clear that there is a wide variety of assessment made by the NSAs. The CSMs on Conformity Assessment require to have a structured and auditable process which ensures that NSAs take similar decisions in similar circumstances and that there is a degree of assurance that the Part A/Part B assessment process is undertaken in a similar way by all NSAs. The Impact Assessment undertaken by the Commission on the revision of the institutional framework states that a big concern by the sector is the cost and time it takes to obtain a safety certificate. This may partly be because the CSMs do not give sufficient detail to support the decision-making process. In addition the Impact Assessment also states that the attitude the NSA has towards the railway undertakings is often bureaucratic and insufficiently attentive to market needs.

As a conclusion, it is unlikely that a railway undertaking operating over a number of MS will be able to submit and be subject to a similar application process for each of the MS in which they operate. As a result there may be a preference to continue with the system that was in place previous to the Railway Safety Directive or adapt their business to the requirements of each MS.

To help with consistency and transparency there are a number of existing standards which could be used. For example, an on-site audit (as the one forming part of stage 2 audit in ISO 17021) could be included for assessment purpose which would help the assessor understand what SMS arrangements are in place and that are possibly not well-defined (or even lacking) in submitted SMS documentation. This approach could be clarified in a certification scheme. Flexibility might be proposed to NSAs to follow worldwide recognised ISO 19011 and ISO 17021 audit framework

provided that it does not impede the application of new entrants. However, this approach needs to be further reviewed and discussed (as part of the CSM revision process) to assess its suitability.

No	Possible output	Impact on CSM	Description
1	Standardised safety assessment process	Revised CSM on Conformity Assessment 1158/2010/EU & 1169/2010/EU – Annex I	<p>Structured, auditable and harmonised approach to safety certification process, including the revision of Commission Regulation (EC) No 653/2007 for the development and adoption of common templates and forms. Consistent approach between Part A and Part B assessment should be sought.</p> <p>This task includes the examination of current practices, studies and relevant literature. In particular, the application of ISO 17000 series standards is to be evaluated in the light of the above objectives. It would also include the development of more specific information which could help with the decision making on whether the documents provided gave sufficient indication that the SMS of the RU is capable of ensuring safety.</p>

2. **Links to the SMS guidance:** Many NSAs require railway undertakings to dovetail their SMS with the CSM on Conformity Assessment criteria rather than encouraging them to develop it according to their business needs and requirements. Although the Agency's guidance for the design and implementation of a SMS⁷ explicitly maps the criteria with the SMS constituting elements, it does not help solve this issue. The Agency believes that the criteria themselves do not need refining but instead proposes to develop a process which structures how a railway company's business will develop its SMS and how this can be assessed against the criteria. The review will be based on NSA good practices whenever it is available and also the above SMS guidance.

No	Possible output	Impact on CSM	Description
2	SMS functions	New annex and/or revised SMS guidance	Functional breakdown of a SMS round the key functions to be designed and implemented by RUs and IMs similarly to the approach taken by the ECM Regulation with the maintenance system. In addition more guidance on how an SMS is developed from a business need and risk point of view to fulfil the assessment criteria of the CSMs

⁷ Application guide for the design and implementation of a Railway Safety Management System – A system approach, ERA/GUI/01-2011/SAF 1.0 (<http://www.era.europa.eu/Document-Register/Pages/application-guide-for-SMS.aspx>)

			on Conformity Assessment.
3	Restructuring of assessment criteria	Revised CSM on Conformity Assessment 1158/2010/EU & 1169/2010/EU – Annex II	Provide clear links between the assessment criteria (of the Annex II of the CSMs on Conformity Assessment) and the SMS requirements (or functions).

3. **Part A/B:** There is a wide variance in how the NSAs assess the Part B requirements. The Impact Assessment undertaken by the Commission on the revision of the institutional framework states that some NSAs tend to ‘over-regulate’ the Part B (in relation to the compliance with the network specific rules), leading to arbitrary decisions, lengthy procedures and discrimination. The wide variance in how the NSA undertakes the assessment can lead to a lack of acceptance of the Part A process and more globally, a devaluation of the Part A of a European wide certificate. The assessment of rules is important but they must be linked back to a process and/or procedure of the SMS so that it can be checked (via monitoring) that the rule remains effective in controlling the risks. From the review of available guidance documents published by some NSAs for safety certificate/authorisation applicants, an imbalance exists between the type of and content of Part B requirements the applicants have to comply with. Sometimes it is not easy to understand where those requirements fit into each of the three existing categories set out in Annex III of the CSM on Conformity Assessment 1158/2010/EU.

No	Possible output	Impact on CSM	Description
4	Revisit of harmonised Part B requirements	Revised CSM on Conformity Assessment 1158/2010/EU – Annex III	<p>Examination of existing guidance for application of Part B certificate to evaluate whether existing requirements should be adapted or complemented to avoid as far as reasonably practicable overlap between Part A and Part B assessment. The assessment criteria should also show where the Part B rules should link to the main SMS processes.</p> <p>In addition, the guidance to be published by NSAs for RUs operating in more than one MS could benefit from the structure and content of the (revised) Annex III of the CSM. This may contribute to decrease the risk of having a wide range of national requirements that cannot be attributed down to each of the category set out in Annex III of the CSM and then, that should be out of an application for a Part B certificate.</p>

4. **Priority criteria:** The scope of the assessment is to form a view whether the applicant is capable to operate safety. No set of CSM on Conformity Assessment criteria carries more weight than any other set. This principle is not consistently applied as it should be, mainly because the criteria are set

at a high level and do not provide the level of detail necessary to help with the decision-making process. All criteria must be assessed but the decision as to whether the railway company can operate safely is to be sought with the sufficiency of the evidence based on the decision-making criteria. A non-compliance with (parts of) criteria does not necessarily prevent the granting of the safety certificate/authorisation. It depends on the risks incurred by the railway company if not complying with (parts of) the criteria. The key should be that the NSA has effective decision-making criteria which allocate the potential non-compliance to major or minor deficiencies and for the latter these should be the basis of decisions made of when and how to supervise the application of the safety certificate/authorisation.

No	Possible output	Impact on CSM	Description
5	Revisit of assessment criteria	Revised CSM on Conformity Assessment 1158/2010/EU & 1169/2010/EU – Annex II and/or new guidance	The evidence the certification bodies (i.e. NSAs) should expect from applicants (for a safety certificate or safety authorisation) to fulfil for each criteria (of the Annex II of the CSMs on Conformity Assessment). This will require more detail in the CSM on how a NSA can decide whether the evidence is sufficient and how to allocate them to major and minor non-conformities (which should also be defined to ensure consistency and better targeting for supervision). Using some of the information in ISO 9001 will help.
6	Decision-making criteria	Revised CSM on Conformity Assessment 1158/2010/EU & 1169/2010/EU – Annex II and/or new guidance	The decision making criteria on how these criteria shall be checked by the NSAs to ensure the RUs/IMS capability to operate safely and to ensure consistency across NSAs. More advice on the process may need to be developed in a revised CSM.

- Application for safety certificate:** Some NSAs believe the safety responsibility of railway undertakings lies with the train path ownership irrespective of the contractual arrangements or partnerships existing between railway undertakings. It is recognised as common business practice that railway undertakings delegate their safety responsibility to other railway undertakings and so operate under their safety certificate. The shared use of (Part B) safety certificates is recognised being a tool for “win-win reciprocity” allowing quick and effective operations between partner Railway Undertakings. This approach is widely used across Europe and based on local agreements. The Agency is currently undertaking a study to understand the business needs behind this approach and the results will be included in the review of the CSMs.

The assessment of the Infrastructure Manager’s capacity to operate vehicles on its own network (directly or via subcontractors) for maintenance purpose (i.e. transport of materials for construction or for infrastructure maintenance activities) is part of its assessment for a safety authorisation, providing it is within the limit of their activities and they are not offering additional

services such as transport of goods for others and/or passengers. In this case, in addition to the requirements and criteria of the CSM on Conformity Assessment 1169/2010/EU, the NSA issuing the safety authorisation should assess the criteria in Annex II of the CSM on Conformity Assessment 1158/2010/EU. However, it is not clear which criteria (including operational aspects) of the CSM on Conformity Assessment 1158/2010/EU have to be additionally assessed. In addition, it is questioned whether the companies providing infrastructure maintenance services for the Infrastructure Manager have to apply for a safety certificate. This should be clarified in the revised CSMs.

No	Possible output	Impact on CSM	Description
7	Application for safety certificates	Revised CSM on Conformity Assessment 1158/2010/EU (& 1169/2010/EU) – Annex II and/or new guidance, Regulation 653/2007/EC – guidelines for compilation	<p>Roles and responsibilities for the application of safety certificate. The CSM should establish the key business arrangements to ensure that the correct responsibilities are allocated irrespective of who owns the train path.</p> <p>For cross border operations particularly where the service is continuous, following the results from the study, the review should look at the provisions in the SMS which can provide a greater deal of flexibility to cover this.</p>

6. **Validity of safety certificate:** In case the Part B is granted close to the end of validity of the relevant Part A, there would be a need to re-issue a new Part B within a short period of time which may create administrative burden and possibly additional cost of renewal. Similarly, it often occurs that international RUs start their operations on a limited number of lines and apply after a few years for extending their services to more lines. In any case new Part B safety certificates should be re-issued as soon as the relevant Part A is renewed. The NSA should take a pragmatic approach and limit the Part B re-assessment to the key elements. If there is no major change in the Part A this may be minimal but the NSA should undertake a simple check of the relevant criteria in the Part A to ensure that they remain relevant for the Part B. This issue is not related specifically to ERADIS but to certification process itself and to mutual cooperation of NSAs, which should be strengthened in order to deal properly with Part B safety certificates issued to international RUs.

No	Possible output	Impact on CSM	Description
8	Management of validity of Part A/Part B certificates	Regulation 653/2007/EC – guidelines for compilation	<p>Analysis of good practices among NSAs and proposals for short term/long term solutions.</p> <p>This task includes the management of change requests in ERADIS database where necessary.</p>

7. **Update/amendment of safety certificate:** The RSD defines the conditions for update of safety certificate/authorisation and also identifies different type of changes (major, substantial) that

should be notified to the NSA. Those changes may lead to an update of the safety certificate. This makes the system reactive (rather than proactive) since the NSA awaits the RU/IM to submit an application. It would be helpful to provide more clarification on this point in the review of the CSMs.

No	Possible output	Impact on CSM	Description
9	Conditions for update of safety certificate	Regulation 653/2007/EC – guidelines for compilation	<p>Criteria to assess substantial change and to decide whether safety certificate needs to be updated (i.e. part) or completely reviewed and what the process should be.</p> <p>Information on what should be provided to the NSA if there are any changes and what the NSA should do.</p>

Theme 2 – Supervision

Issue: how NSAs undertake a consistent, targeted and proportionate approach to supervision following the issuing of the certificate

The development of the CSM on Supervision was started in 2009. The aim was to further enhance the supervision principles which were set out in the CSMs on Conformity Assessment. These were:

1. Proportionality;
2. Consistency;
3. Targeting;
4. Resourcing;
5. Transparency;
6. Co-operation.

The CSM was developed like the CSMs on Conformity Assessment through an ERA Working Group using and building on NSA experience. One of the key areas was the further development of cooperation and coordination requirements that would help NSAs to consider how they undertake their tasks, share good practice and use this as a key tool for promoting consistency.

The CSM on Supervision has only been in force for almost a year but experience has shown that many NSAs have difficulties in applying it. This might be caused by the CSM setting out the process at a high level and not providing sufficient detail on how to establish a risk based supervision strategy targeting its activities at those areas with the greatest risks for safety and prioritising the use of its resources. The importance and benefits of supervision in having a positive overview of safety performance in a MS rather than concentrating resources on certification needs to be developed further in the CSM in order to get more NSAs on board. The Agency believes that further work is needed on refining the CSM on Supervision to provide more detail on how to develop a targeted and proportionate approach to supervision, description of the range of techniques and enforcement tools that should be available, robust and sufficient co-operation arrangements which prevent the use of inconsistent bilateral arrangements. The review will be based on NSA good practice which is currently available.

Again the collected evidence (e.g. TRL study on the benchmarking of NSA enforcement powers⁸) has shown several problems which need to be improved:

1. **Targeting of supervision:** The review should cover how data can be collected and analysed which should then be used for targeting the high risk activities on a proactive basis. Predicting and preventing risks is a better way to supervise rather than react and fix which only gives a short term solution and may not be finding the fundamental problem. The publication of the strategies and

⁸ Benchmarking study of NSA enforcement powers, ERA/2011/SAF/OP/03, 06/07/2012 (<http://www.era.europa.eu/Document-Register/Pages/Benchmarking-study-of-NSA-enforcement-powers.aspx>)

plans also provides information to the railway companies on what the NSA will target and why. In turn this helps them to be more proactive particularly in the use of the CSM on Monitoring⁹.

2. **Information on inspection/audit techniques:** The CSM requires the NSA to have a range of different techniques in order to supervise. However, it does not explain what these are; there is information in the guidance but because this is not a legal requirement. More information needs to be provided on how to undertake SMS audits and how they can link to technical inspections in order to test the SMS requirements and thereby help with reassessment. A clear definition of audit and inspection should be included in the revised CSM Supervision. The future ERA work should also capitalize on the VTT study on the review of SMS audit techniques and methods¹⁰.
3. **Links between assessment and supervision:** The information between assessment and supervision is very important because this information can be used to target those railway undertakings who had minor non conformities during the assessment. This information should be fed into the supervision strategy and plan. There are real benefits in linking both because it can potentially cut down the time needed for reassessment of the SC.
4. **Problems with national structures and requirements:** Many NSAs have adopted a hybrid approach to supervision by dovetailing national requirements. This is also not helped because the CSM does not contain sufficient information on how to manage the whole process in particular defining what is a strategy and plan and how to use information to target actions. In effect this means that the national requirements have not been either reviewed or replaced by the new requirements in the CSM. Railway undertakings working in several countries will therefore experience different supervision methods and requirements.
5. **Transparency:** NSAs have to publish and promote their decision-making criteria on supervision so that the railway companies know what is expected of them. It is also necessary for the purpose of accountability that the NSA has a complaints policy or a process for appealing against a decision by the NSA.
6. **Importance of effective cooperation arrangements:** NSAs have to coordinate their approach to supervision to ensure that the SMS of the railway undertaking is effective and covers all relevant activities. Most NSAs have informal agreements to co-operate on a local/border level. These are useful however, these often state what will be done by each NSA rather than working together to solve problems that will affect operation in each MS. The proposed Memorandum of Understanding for coordinated supervision of railway undertakings operating in other Member States¹¹ could be used as input to better detail the overarching principles of co-ordinated and/or

⁹ Commission Regulation (EU) No 1078/2012 of 16 November 2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance (OJ L 320, 17.11.2012, p. 8).

¹⁰ Review of SMS audit techniques and methods, VTT-S-07114-13, 15/10/2013 (<http://www.era.europa.eu/Document-Register/Pages/VTT-Final-Report-on-SMS-audit-techniques-and-methods.aspx>)

¹¹ Common approach to supervision of railway undertakings operating in more than one Member State – A guide for NSAs in applying Article 8 of CSM on Supervision, ERA/GUI/12-2013/SAF 1.0 (http://www.era.europa.eu/Document-Register/Pages/ERA-GUI-12-2013-SAF_MoU-on-Coordinated-Supervision-1-0.aspx)

joint supervision. Instead of being focused on sharing information and supervision strategies and developing coordinated approaches to dealing with non-compliances it could be encouraged more proactivity on behalf of the NSAs, for example agreeing areas to target in a coordinated or joint manner. Any agreed common approach to supervision should be transparent. Perhaps there should be more work to cover how Infrastructure Managers and Railway Undertakings should be made aware of the arrangements and agreements NSAs are reaching.

No	Possible output	Impact on CSM	Description
10	Harmonised approach to supervision	CSM on Supervision – new annex and/or article	<p>The harmonisation of NSAs approaches to supervision, including more technical based requirements on decision making etc.</p> <p>Synergy can be found with decision-making criteria developed for the safety certification process.</p> <p>This task includes the examination of current practices, studies and relevant literature. In particular, the experience gained from the aviation sector in using the safety oversight approach to develop efficient and coherent supervision by competent authorities.</p>
11	Supervision strategy and plan	CSM on Supervision – new annex and/or article	The development of more information on how to target and set up supervision strategies and plans and adoption of common templates and forms as part of the setting of a supervision strategy and plan.
12	Principles for co-ordinated and joint supervision	CSM on Supervision – Article 8	More information and direction on co-operation and collaboration.
13	Supervision techniques	CSM on Supervision	Harmonisation of audit and inspection techniques.

Theme 3 – Decision-making

Issue: how NSAs undertake enforcement in a transparent and accountable way

Enforcement is an element of Article 16(2)(f) and Article 32 requires MS to put in place penalties applicable to infringement of national provisions. These must be effective, proportionate, non-discriminatory and dissuasive. Enforcement has been seen as an issue of subsidiarity and the Agency has not really provided much guidance and information on the issue.

1. **Enforcement powers:** It is important that NSAs have a range of enforcement tools to deal with minor problems right through to those with the potential to cause a serious risk/incident. This information should be transparent and be published so that the RUs/IMs know what will happen if a problem is found and how this can be escalated depending on the risk.

In collaboration with the NSA task force on assessment & supervision it was agreed that a prescriptive decision-making model would not be appropriate for the sector at present. However, a common approach to decision-making was desirable and the task force agreed that the commonality should focus on making decisions according to a ‘compliance gap’ model. The harmonisation of NSA enforcement management models was also part of the recommendation 3 from the Italian NIB following the investigation into the accident at Viareggio. It should be based on compliance gap analysis with proportionate response. The NSA should be accountable for its decisions and transparent in the decision-making. Further agreement was reached with the task force on recommending that each NSA documents and publishes its decision-making process (framework for arriving at decisions) in a transparent way.

No	Possible output	Impact on CSM	Description
14	Risk based decision-making model	CSM on Conformity Assessment, CSM on Supervision – new Annex and/or Article	The harmonisation of NSA approaches to decision making <u>and enforcement</u> to ensure that they take the similar decisions in similar circumstances (including possibly requirements for delivering enforcement). This should include proposals for sufficiently wide tools to response proportionality to different situations and could show a clear escalation in severity. It should include a simple model on how to prioritise and focus enforcement action.
15	Enforcement policy statement	CSM on Conformity Assessment, CSM on Supervision – new Annex and/or Article	Development of an enforcement policy statement which sets out the principles to be applied when carrying out enforcement.

Theme 4 – Competence management framework

Issue: how NSAs ensure that they have adequate resources and competent staff in order to take forward their activities

The adequacy between available resources and NSA's activities can be a key problem for these organisations. The CSMs on Conformity Assessment and the CSM on Supervision make a broad reference to competence but this could be further developed in order to give NSAs a lever of negotiations on resources at MS level. Competence is also wide ranging with some NSAs adopting a competence management system (CMS) similar to that required by the sector to others having an ad-hoc approach. The Impact Assessment undertaken by the Commission on the revision of the institutional framework noted that there were problems with some NSAs lacking resources or experiencing difficulties in recruiting competent staff.

1. **Understanding of the competence requirements:** It is important that there is a consistent understanding amongst NSAs on how to develop a CMS. This may be resolved by defining competence requirements for NSAs on assessment similar to that being developed for the Agency in preparation for taking forward the SSC. In addition, revised CSMs may need to describe in detail a framework for a CMS against which NSAs could be audited.
2. **Developing competent staff:** Improved information could also be provided on the role and subject of training NSAs and how this will help to develop and maintain staff competence. This might cover the principles of assessment and supervision including audits and targeting risks.
3. **Ensuring adequate resources:** Lack of resources is a key risk for any NSA in ensuring that they can sufficiently monitor the safety performance of their sector. As already mentioned above, many respondents of the Commission's Impact Assessment commented that there was a lack of adequate resources for NSAs. Whilst this is an issue for MS, defining a competence based approach in the revise CSMs ensures that the issue will be given a higher level of attention.

No	Possible output	Impact on CSM	Description
16	Harmonised competence requirements	CSM on Conformity Assessment, CSM on Supervision – new Annex and/or Article	<p>The development of competence requirements for NSA staff (including outsourcing and resources) which should be included in the revision of the CSMs.</p> <p>This task includes the examination of current practices, studies and relevant literature.</p>