

A high-speed train and a tram are shown on tracks in a rural setting. The high-speed train is on the left, and the tram is on the right. The background features a hillside with trees and a utility pole. The text "SMS Assessment" is overlaid in the center.

SMS Assessment

Caoimhe Boland

Introduction – SMS and who needs what

- **Railway Undertaking (RU) – Single Safety Certificate (SSC)**
 - In order to operate on the railway system in Ireland, a Railway Undertaking (RU) must hold a valid Single Safety Certificate (SSC).
 - The certificate may cover the whole network or a defined part of the network.
- **Infrastructure Manager (IM) – Safety Authorisation (SA)**
 - An Infrastructure Manager (IM) must hold a valid Safety Authorisation (SA) to operate and manage railway infrastructure that forms the whole, or part, of the railway system in Ireland.
- **Railway Organisation (RO), responsibility in operating a light rail system – Safety Management Certificate (SMC)**
 - A Railway Organisation (RO) with responsibility in operating a light railway shall hold a Safety Management Certificate (SMC) as required by Section 39 of the Railway Safety Act 2005.

Introduction – The Legal Basis

Changes to the European legal framework under the 4th Railway Package

- Directive (EU) 2016/798 Railway Safety Directive – Article 9 stipulates the requirement of a safety management system.
- The aim of the RSD is to simplify and harmonise the safety assessment process to the benefit of applicants. It is hoped this will help to reduce the burden and costs being borne by them irrespective of the intended area of use or authority issuing the SSC.
- Regulation (EU) 2016/798 Agency Regulation – outlines the role and responsibilities of the Agency in relation to granting SSCs.

Introduction – The Legal Basis (2)

- Commission Implementing Regulation (EU) 2018/763 – establishes the practical arrangements for issuing SSCs, including responsibilities of the Agency, NSAs and applicants.
- Annex II provides a process for competent authorities (i.e. the Agency and NSAs) to take similar decisions in similar circumstances – consistency across NSAs and the Agency in assessing applications.
- Commission Delegated Regulation (EU) 2018/762 – establishes the CSMs on SMS requirements, see Annex I. This replaces 1158/2010 and 1169/2010.
- Commission Implementing Regulation (EU) 2018/764 – sets out the fees and charges payable to the Agency and the conditions of payment.
- Commission Implementing Regulation (EU) 2018/867 – sets out the rules of procedure of the Board(s) of Appeal of the Agency.

Commission Delegated Regulation (EU) 2018/762 - main changes

2018/762 introduces changes to the SMS requirements.

- Overall order changed, criteria letters no longer used.
 - Integration of human and organisational factors – new requirement.
 - Organisation and leadership requirements expanded.
 - Safety Policy – requirement expanded and more detail specified.
-
- Additionally, there are TSI OPE requirements to be met by the SMS.

How this is applied in Ireland

The CRR aim to have one consistent approach across the industry in Ireland, this is achieved this by:

- Aligning SMS conformity assessment approaches.
- Adapting the SMS criteria for other Railway Organisations such as Transdev and TII.
- Appropriately scaled criteria for Heritage Railway.

The CRR encourages early engagement with us, and we encourage the use of pre-engagement for a first review of the SMS against the criteria prior to making any formal application to the OSS or CRR directly.

Early Engagement

THE CRR ENCOURAGES EARLY ENGAGEMENT

Early Engagement

Checklists for evidence provision and feedback

CRR-CL-002A-R02 – Safety Certification

Basis: Commission Regulation (EU) No 2018/762 ANNEX I	Topic	(Section of SMS) Assessment Criteria:	(Submission Evidence) RU Response:	CRR Comments
Annex I 1. CONTEXT OF THE ORGANISATION				
Annex I 1.1.	Organisation	The organisation shall:		
Annex I 1.1. (a)	Organisation	a) describe the type, extent and area of its operations;	RU Evidence References	
Annex I 1.1. (b)	Organisation	b) identify the serious risks for safety posed by its railway operations whether they are carried out by the organisation itself, or by contractors, partners or suppliers under its control;	RU Evidence References	
Annex I 1.1. (c)	Organisation	c) identify interested parties (e.g. regulatory bodies, authorities, infrastructure managers, contractors, suppliers, partners), including those parties external to the railway system, that are relevant to the safety management system;	RU Evidence References	
Annex I 1.1. (d)	Organisation	d) identify and maintain legal and other requirements related to safety from the interested parties referred to in point (c);	RU Evidence References	

Early Engagement

Checklists for evidence provision and feedback

CRR-CL-002A-R02 – Safety Certification

Basis: Commission Regulation (EU) No 2018/762 ANNEX I	Topic	(Section of SMS) Assessment Criteria:	(Submission Evidence) RU Response:	CRR Comments
Annex I 1. CONTEXT OF THE ORGANISATION				
Annex I 1.1.	Organisation	The organisation shall:		
Annex I 1.1. (a)	Organisation	a) describe the type, extent and area of its operations;	RU Evidence References	CRR Review Comments
Annex I 1.1. (b)	Organisation	b) identify the serious risks for safety posed by its railway operations whether they are carried out by the organisation itself, or by contractors, partners or suppliers under its control;	RU Evidence References	CRR Review Comments
Annex I 1.1. (c)	Organisation	c) identify interested parties (e.g. regulatory bodies, authorities, infrastructure managers, contractors, suppliers, partners), including those parties external to the railway system, that are relevant to the safety management system;	RU Evidence References	CRR Review Comments
Annex I 1.1. (d)	Organisation	d) identify and maintain legal and other requirements related to safety from the interested parties referred to in point (c);	RU Evidence References	CRR Review Comments
Annex I 1.1. (e)	Organisation	e) ensure that the requirements referred to in point (d)		

Early Engagement

Checklists for evidence provision and feedback

CRR-CL-002A-R02 – Safety Certification

Basis: Commission Regulation (EU) No 2018/762 ANNEX I	Topic	(Section of SMS) Assessment Criteria:	(Submission Evidence) RU Response:	CRR Comments
Annex I 1. CONTEXT OF THE ORGANISATION				
Annex I 1.1.	Organisation	The organisation shall:		
Annex I 1.1. (a)	Organisation	a) describe the type, extent and area of its operations;	RU Evidence References DD/MM/YY updated references/information	CRR Review Comments
Annex I 1.1. (b)	Organisation	b) identify the serious risks for safety posed by its railway operations whether they are carried out by the organisation itself, or by contractors, partners or suppliers under its control;	RU Evidence References DD/MM/YY updated references/information	CRR Review Comments
Annex I 1.1. (c)	Organisation	c) identify interested parties (e.g. regulatory bodies, authorities, infrastructure managers, contractors, suppliers, partners), including those parties external to the railway system, that are relevant to the safety management system;	RU Evidence References DD/MM/YY updated references/information	CRR Review Comments
Annex I 1.1. (d)	Organisation	d) identify and maintain legal and other requirements related to safety from the interested parties referred to in point (c);	RU Evidence References	CRR Review Comments

Early Engagement

Checklists for evidence provision and feedback

CRR-CL-002A-R02 – Safety Certification

Basis: Commission Regulation (EU) No 2018/762 ANNEX I	Topic	(Section of SMS) Assessment Criteria:	(Submission Evidence) RU Response:	CRR Comments
Annex I 1. CONTEXT OF THE ORGANISATION				
Annex I 1.1.	Organisation	The organisation shall:		
Annex I 1.1. (a)	Organisation	a) describe the type, extent and area of its operations;	RU Evidence References DD/MM/YY updated references/information	CRR Review Comments DD/MM/YY CRR updated comments
Annex I 1.1. (b)	Organisation	b) identify the serious risks for safety posed by its railway operations whether they are carried out by the organisation itself, or by contractors, partners or suppliers under its control;	RU Evidence References DD/MM/YY updated references/information	CRR Review Comments DD/MM/YY CRR updated comments
Annex I 1.1. (c)	Organisation	c) identify interested parties (e.g. regulatory bodies, authorities, infrastructure managers, contractors, suppliers, partners), including those parties external to the railway system, that are relevant to the safety management system;	RU Evidence References DD/MM/YY updated references/information	CRR Review Comments DD/MM/YY CRR updated comments
Annex I 1.1. (d)	Organisation	d) identify and maintain legal and other requirements related to safety from the interested parties referred to in point (c);	RU Evidence References	CRR Review Comments

Application Information – Language and Fees & Charges

Language - Where a national safety authority acts as safety certification body, the language to be used for the application file must be an official language of the Member State for the intended area of operation, as indicated in the application guide of the competent national safety authority.

- In Ireland the operating language of the railway is English, as such all applications must be made in English.

Fees & Charges - In the case where the national safety authority acts as safety certification body, the fees and charges are levied by the national safety authority in accordance with its national legislation. There is an application fee for the OSS.

- **Fees:** Amounts levied to obtain, maintain, update or revoke single safety certificates;
- **Charges:** Amounts levied for other services such as pre-engagement, audits, inspections or visits.

Railway Undertakings – SSC

- Where its area of operation is limited to one Member State, the applicant can choose in the One Stop Shop (OSS) which authority, either the Agency or the national safety authority of the Member State concerned, will be responsible for issuing the single safety certificate.
- Where the area of operation is not limited to one Member State, the Agency is the safety certification body by default.
- The choice of the safety certification body is binding until the safety assessment process is completed or terminated once an application for a single safety certificate is submitted in the One Stop Shop.
- During the pre-engagement phase, where the area of operation is limited to one Member State, the applicant may decide to address its request to another authority. A new request for pre-engagement must be submitted in the OSS after the first request is terminated.
- For an RU operating in Ireland only, they must apply to the OSS and may select the CRR or ERA as the authority to carry out the assessment and issue the SSC.

Infrastructure Managers – Safety Authorisation

- Infrastructure Managers apply for safety authorisation directly from the CRR.
- Infrastructure managers may need to use - within the limit of their activities - trains, infrastructure inspection vehicles, on-track machines or other special vehicles for different purposes, such as the transport of materials and/or staff for construction or infrastructure maintenance, the maintenance of its infrastructure assets or the management of emergency situations.
- In such cases, the infrastructure manager is deemed to operate in the capacity of a railway undertaking under its safety management system and safety authorisation without the need to apply for a separate single safety certificate, irrespective of whether it owns the vehicles or not.

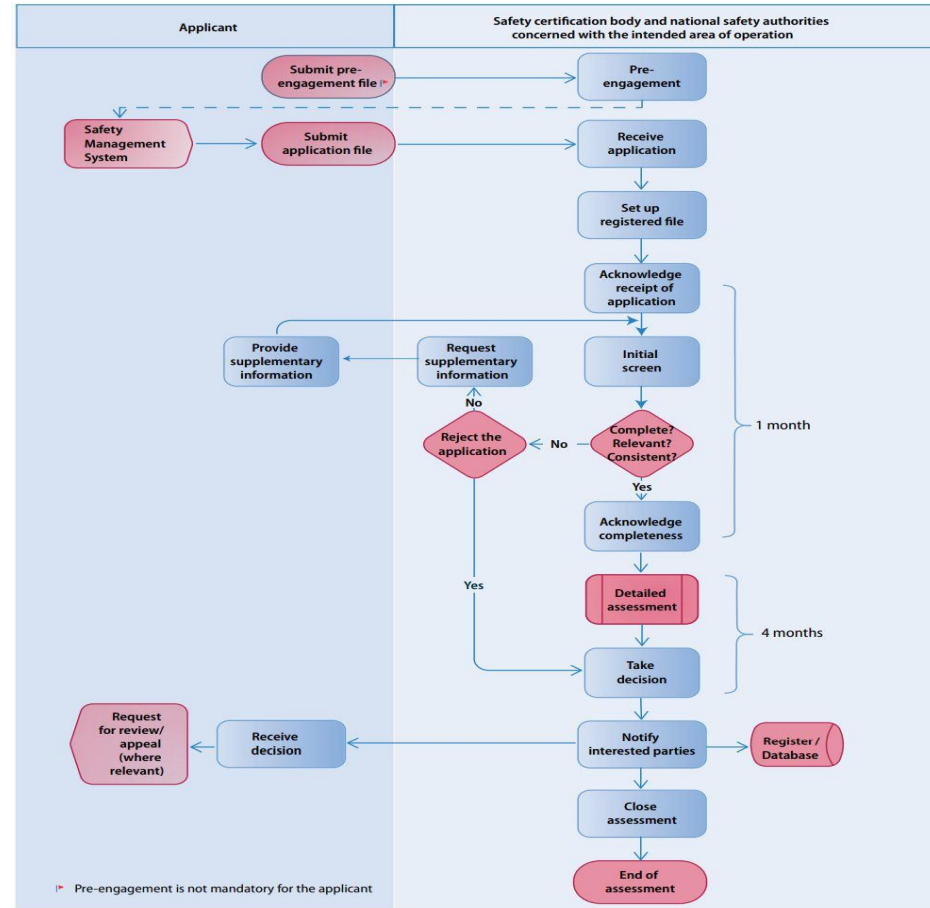
Railway Organisations – Safety Management Certificate

- Railway Organisations such as LUAS, TII and Heritage Railway Organisations apply directly to the CRR for a Safety Management Certificate.
- Adapted criteria from the RU and IM SMS criteria are applied for ROs.

The Conformity Assessment Process of an SMS and Timeline



The Safety Assessment Process



Source: ERA Application guides for authorities and applicants

Application requirements for renewal or update



An application should still include all the constituent elements of an application file.

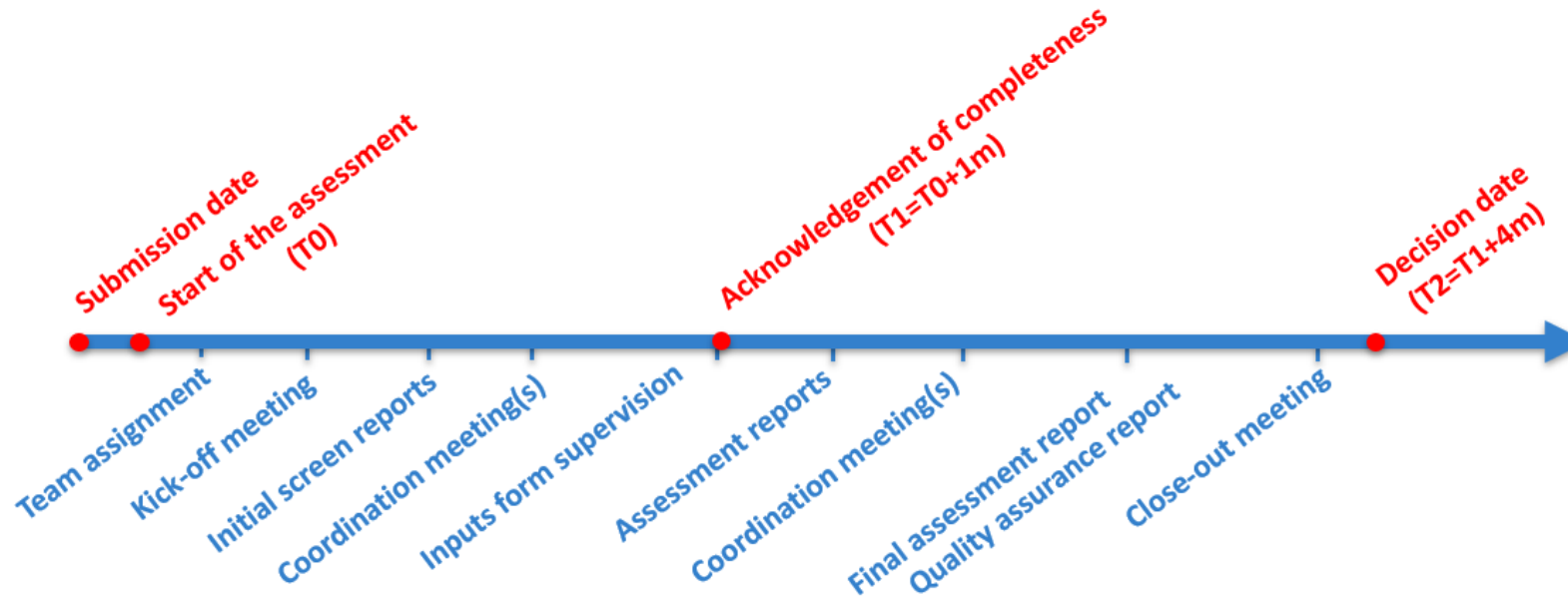


The applicant shall identify and describe the changes to the documentary evidence since the previous application (for which an SSC was granted).



To help identify the changes made to the documentary evidence, the applicant should mark the changes in the updated documents and provide explanation of those changes.

Process Timeline



RED

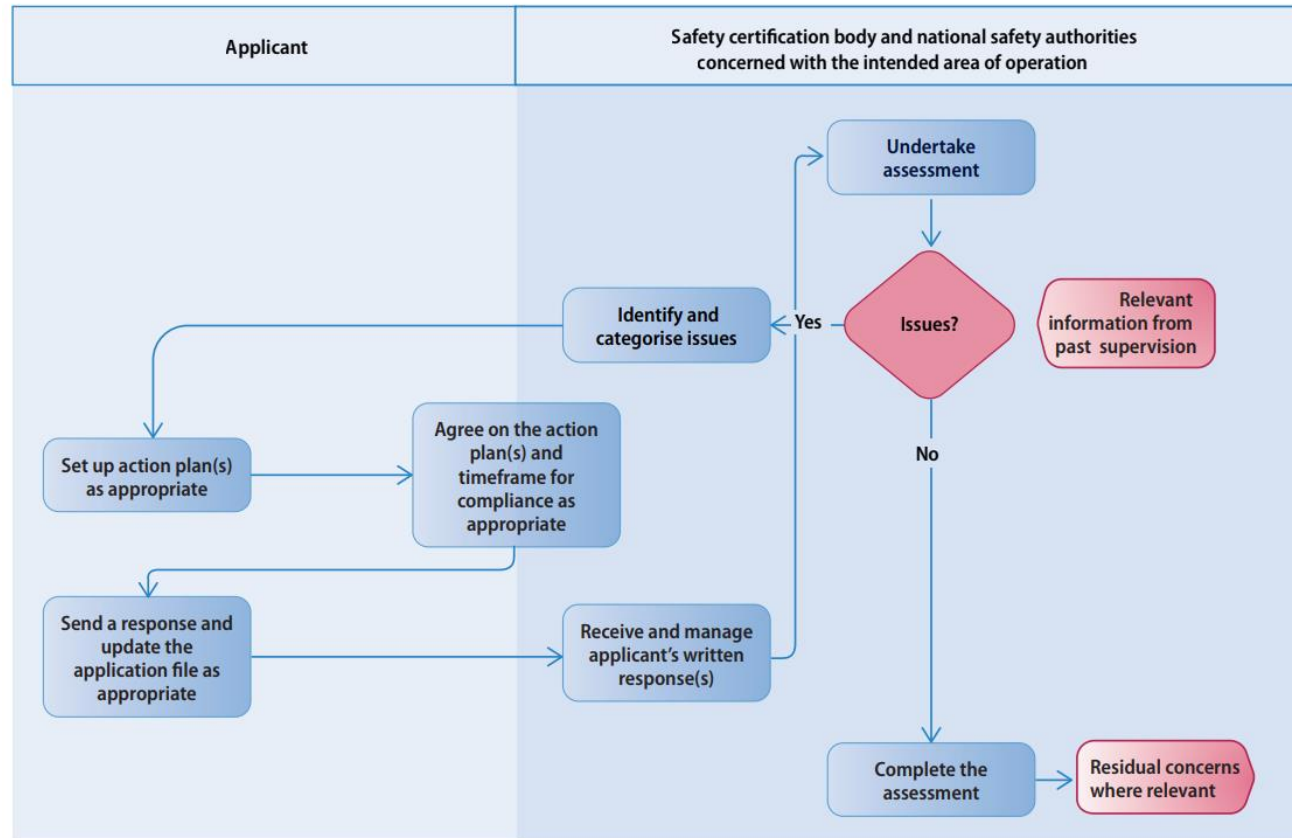
Legal milestones (updated only when there is a need to extend the timeframe of the assessment)

BLUE

Milestones pre-defined on the basis of internal procedure (updated following project planning)

Source: ERA Application guides for authorities and applicants

Detailed Assessment Process



Source: ERA Application guides for authorities and applicants

Application requirements for renewal or update

Status of corrective action plans for Major Non-Compliances identified during Supervision activities

Status of corrective action plans established to resolve residual concerns (Type 3 issues) from the previous assessment

Types of issues to be raised

There are FOUR issue types:

- Type 1 – Issue or clarification for the understanding of the file.
- Type 2 – Issue that may lead to amendment of the file at the discretion of the applicant.
- Type 3 – Issue or Residual Concern for Supervision – can be resolved after the granting of the certificate.
- Type 4 – Major Non-Compliance or Deficiency requiring an update to the application file – must be resolved before the granting of the certificate.

Type 1 Issue

Type 1 – Issue or clarification for the understanding of the file.

- Requires the applicant to submit additional information. In this case the assessor may stop the clock until the issue is resolved. The applicant may be required to supply information to clarify a particular matter of concern.
- Example: the organogram submitted by the applicant appears to show responsibilities for safety related matters to align in a certain way. However, the supporting explanatory text appears to show a different alignment, demonstrating a lack of clarity of safety responsibilities.

Type 2 Issue

Type 2 – Issue that may lead to amendment of the file at the discretion of the applicant.

- An issue which is worthy of observation but which the applicant is free to deal with in their own time. It is left to their judgement how to proceed, however, it will be followed up at the next update or renewal.
- Example: the assessor has noticed in the application file that there are some inconsistencies between referenced standards of the company. These discrepancies relate to different standards applied by different departments of the company. They do not have safety implications but do need to be resolved by the Applicant since they reflect on the control of documented information.

Type 3 Issue

Type 3 – Issue or Residual Concern for Supervision – can be resolved after the granting of the certificate

- The assessor discusses with the applicant the problem and how long it will take to resolve. If it appears that the issue will persist beyond the period of assessment the assessor will discuss with the relevant NSA whether it is possible to transfer closure of the point to Supervision.
- Type 3 issues that are not closed before the issuing of the single safety certificate will be transferred into the issue log for re-evaluation during the next renewal/update application.
- When multiple issues have been categorised as Type 3, an authority may decide not to issue the single safety certificate until these are resolved.
- For Type 3 issues the Agency must agree with the relevant NSAs how ‘residual concerns’ to be deferred for Supervision are going to be dealt with - if action plans were established to resolve Type 3 issues, these will be checked by the NSA after the SSC has been issued.
- ERA won't use these without NSA agreement (transfer to supervision).

Type 4 Issue

Type 4 – Major Non-Compliance or Deficiency requiring an update to the application file – must be resolved before the granting of the certificate.

- Where an issue is raised by the absence of information or the lack of clarity of such information is so important that the application cannot be accepted as it stands, and a single safety certificate cannot be issued unless the issue is closed. It is critical that Type 4 issues are clearly stated, and the consequence of non-compliance noted. The applicant must be clear as to what they need to do to resolve the Type 4 issue.
- Example: an applicant submits an application where it has provided some evidence that a process for planning changes is in place. The analysis of the submitted information shows that there is no mention of Regulation (EU) 402/2013 as part of its risk management process. As there is a legal requirement to use this Regulation where appropriate, this is a major deficiency in the application file that must be corrected before the issue of the single safety certificate.

CRR Supervision

CRR Supervision Report

- A report on the supervision activities carried out on an RU, IM or RO during the life cycle of an SMS Certificate or Authorisation and highlight open findings.

For SSC

- The NSA (CRR) must provide a summary report to ERA of the supervision it has carried out on an RU for the previous certification period.
- Type 3 items raised in the previous certification should be addressed/captured in this report also.
- ERA want the NSA to inform them of any audits carried out on an RU during the four months of the SSC detailed assessment process.
- ERA can audit during the SSC process but have no powers except to not issue a certificate.

Resources available

CRR Guideline – [CRR-G-030-B](#)

Guides available from ERA:

- [Application guide for applicants](#)
- [Application guide for authorities](#)
- [SMS requirements for safety certification or safety authorisation](#)
- [Guide for Supervision](#)

Key points for you

Update to criteria

Early engagement

Tracking of changes

Status of corrective action plans

