Assessor toolkit

23/04/2021

1. Scope and purpose of the training module
2. Background information
   – Role of the assessor
   – Legal framework and guidance
   – General considerations
3. Procedure for issuing single safety certificates

- Training for the assessment team – mainly covers the role of the assessor

- Explain the basic tools an assessor has to use, together with illustration on how the process is supported by the [one-stop shop](#)

- Create a common understanding on how the safety assessment process is applied at ERA
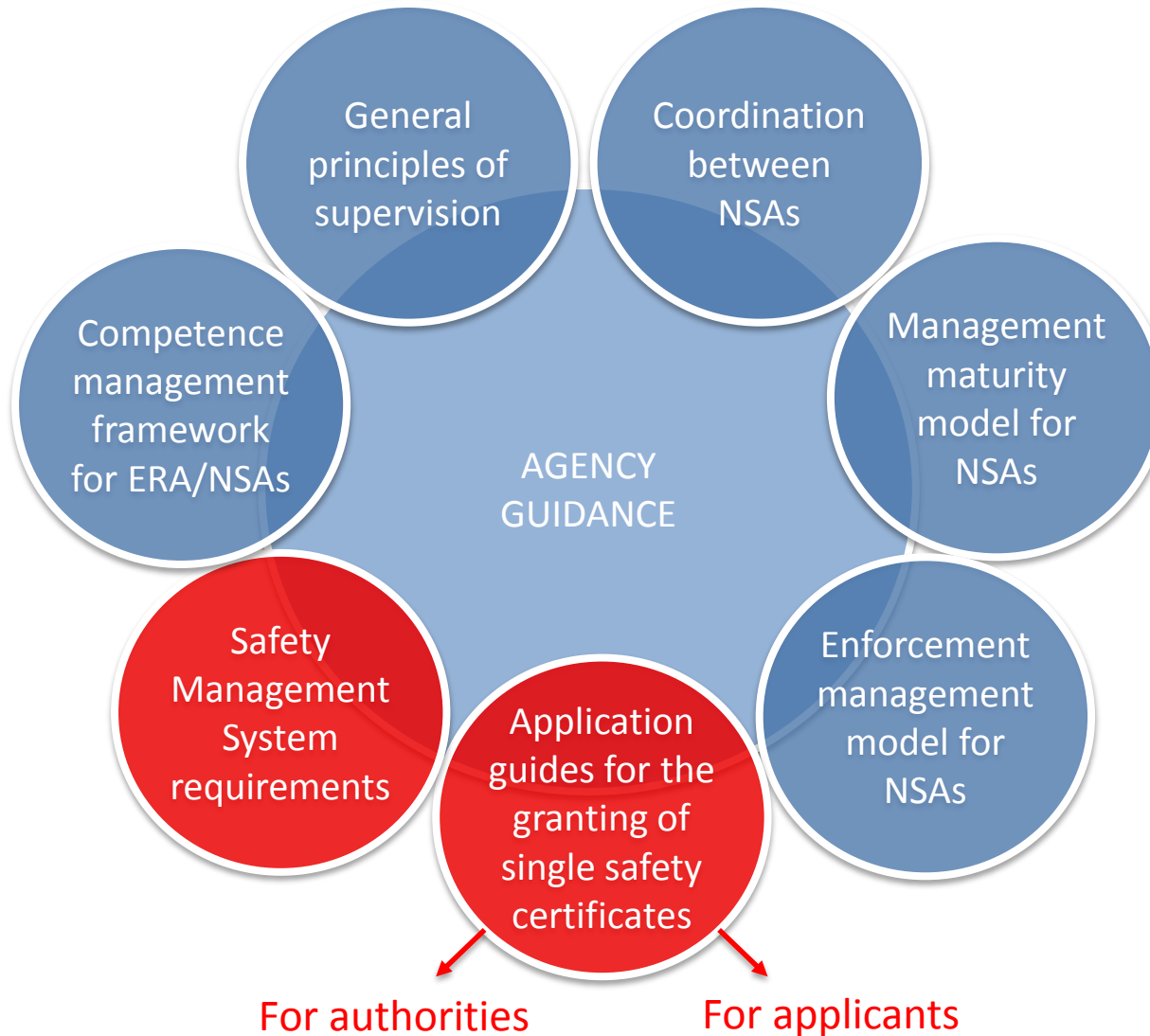
- BoA: Board of Appeal

- ERA: European Union Agency for Railways

- CSM: Common Safety Method(s)

- NSA: National Safety Authority

- OPE: Operation and Traffic Management Sub-system

- OSS: One-Stop Shop

- PgM: Programme Manager

- SCB: Safety Certification Body

- SMS: Safety Management System

- TSI: Technical Specifications for Interoperability

Main responsibilities and tasks:

- Ensure effective, timely and technically sound assessment of applications for single safety certificates in accordance with quality standards
- Coordinate with the applicant as appropriate, e.g. to request supplementary information or clarification or to agree on action plan(s) set by the applicant
- Identifie any issues that could prevent the completion of the assessment
- Liaise with the lead assessor and/or project manager to share issues that may impede his/her part(s) of the assessment or the one(s) of other assessor(s)
- Manage the results of his/her part(s) of the assessment
- Report on the progress of his/her part(s) of the assessment to the lead assessor and/or project manager

- Directive (EU) 2016/798 (Railway Safety Directive), in particular its Articles 4, 9 and 10

- Commission Implementing Regulation (EU) 2018/763 of 9 April 2018 establishing practical arrangements for issuing single safety certificates to railway undertakings

- Commission Delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements (CSM SMS)

- Commission Implementing Regulation (EU) 2019/773 of 16 May 2019 on the technical specification for interoperability relating to the operation and traffic management subsystem (TSI OPE)

- Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment

- 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

EUROPEAN UNION AGENCY FOR RAILWAYS

AGENCY GUIDANCE

- General principles of supervision
- Coordination between NSAs
- Management maturity model for NSAs
- Enforcement management model for NSAs
- Application guides for the granting of single safety certificates
- Safety Management System requirements
- Competence management framework for ERA/NSAs

For authorities — For applicants

+

NSA application guide:

- List of national requirements
- Explanation of requirements
- NSA language policy
- Border stations
- Fees & charges
- Appeal procedure

Responsibility of the NSA to publish its guide

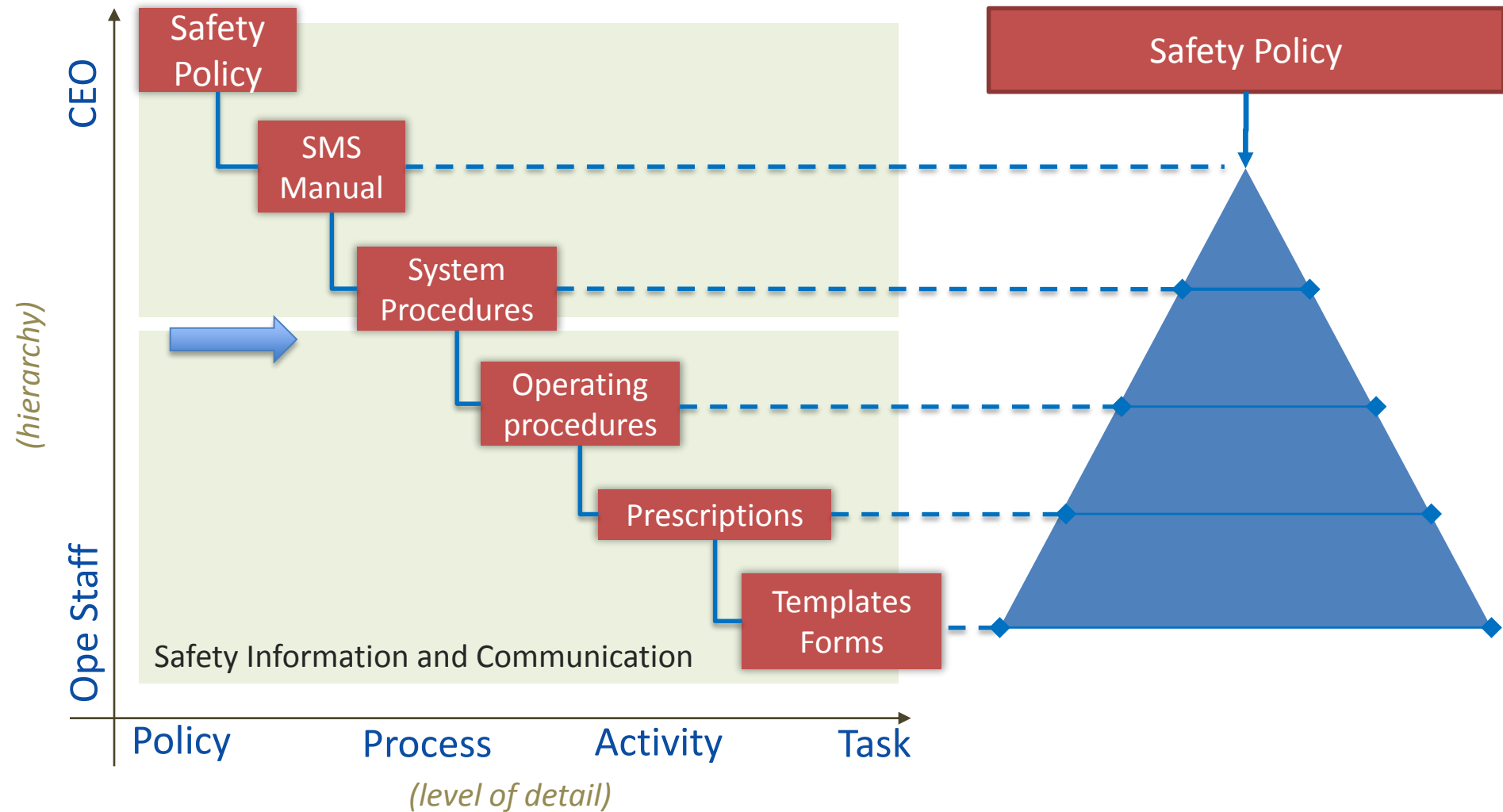Go to ERA website > Applicants > Applications for single safety certificates

Main guidance

- Application guide for the granting of single safety certificates – A guide for the authorities (available in all languages)
- Guide on safety management system requirements (available in all languages)

Other supporting guidance

- Guide for the application of the Common Safety Methods on risk assessment (available in all languages)
- Guide for the application of the Common Safety Method for monitoring
- Introduction to the European Railway Safety Culture Model
- Guide for the application of the TSI OPE (2019 version)

CEO

Ope Staff

(hierarchy)

Safety Policy

SMS Manual

System Procedures

Operating procedures

Prescriptions

Templates Forms

Safety Information and Communication

Policy   Process   Activity   Task

*(level of detail)*

Safety Policy

- The application is not a Safety Management System (SMS) per se but a reflection of it

- The SMS structure should not be driven by legal requirements – it's a business decision

- Decisions on whether enough evidence is provided may not be black or white they are more likely to be shades of grey
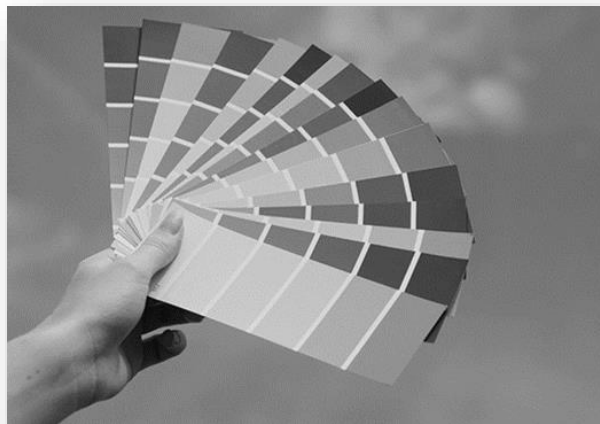
Procedure for issuing single safety certificates
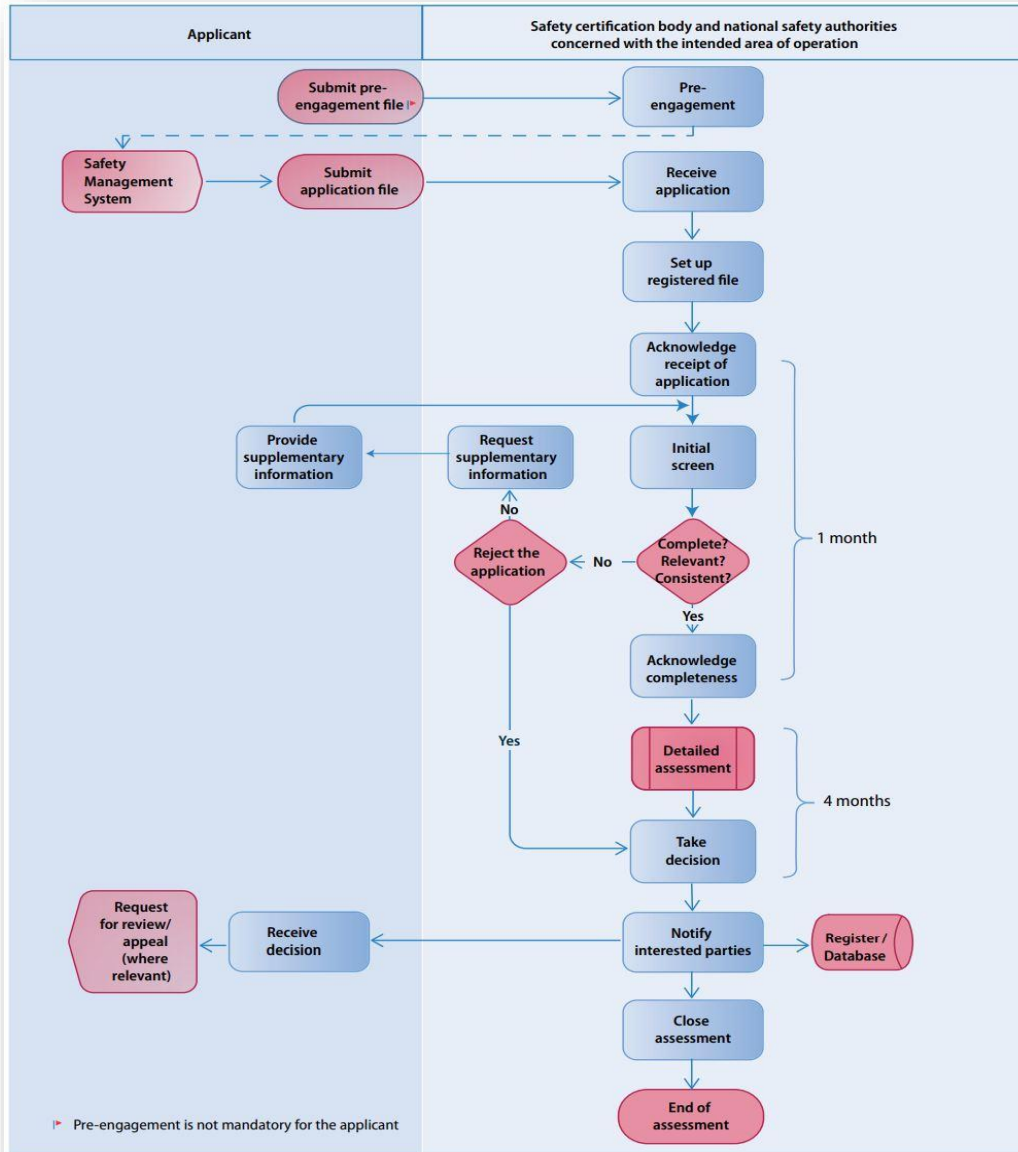
- Annex II of Regulation (EU) 2018/763 (Practical arrangements)

- Flowchart and detailed description of each process step in the ERA Application Guide
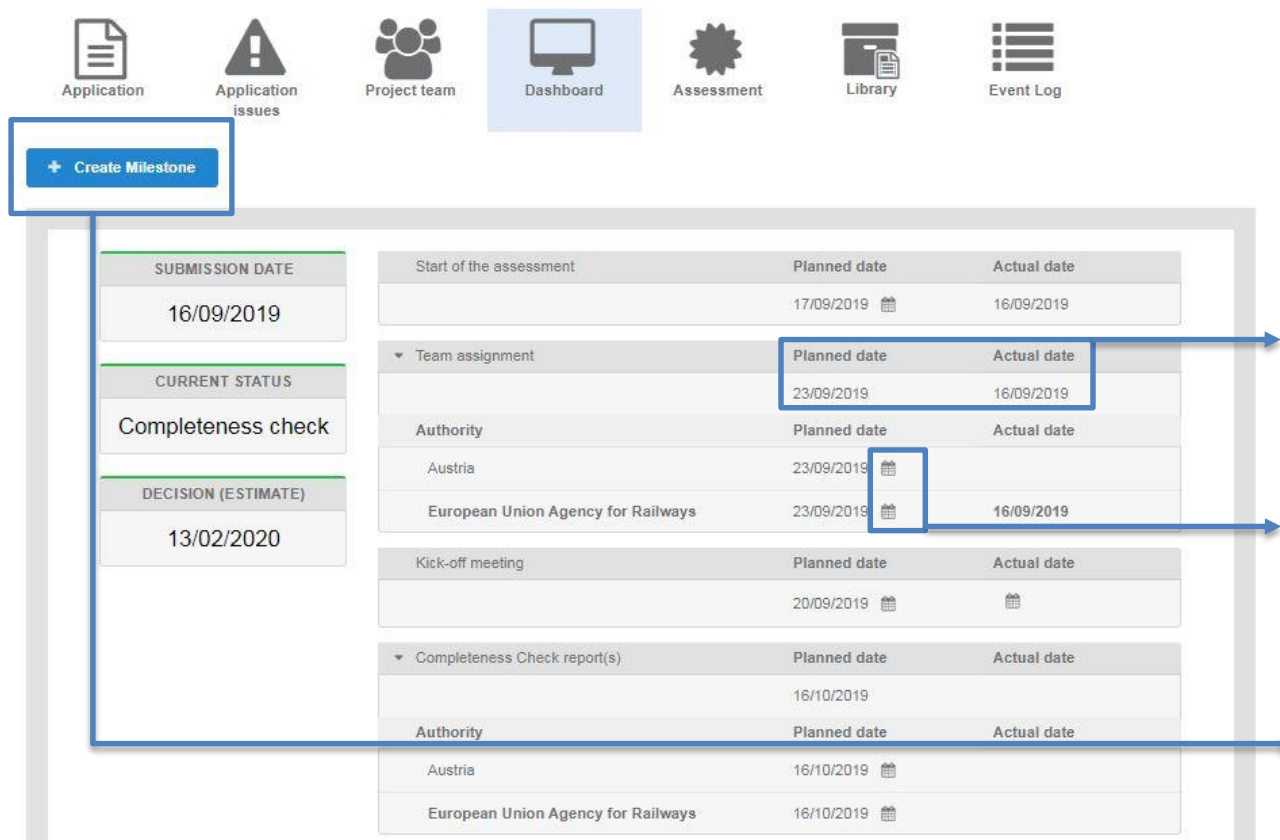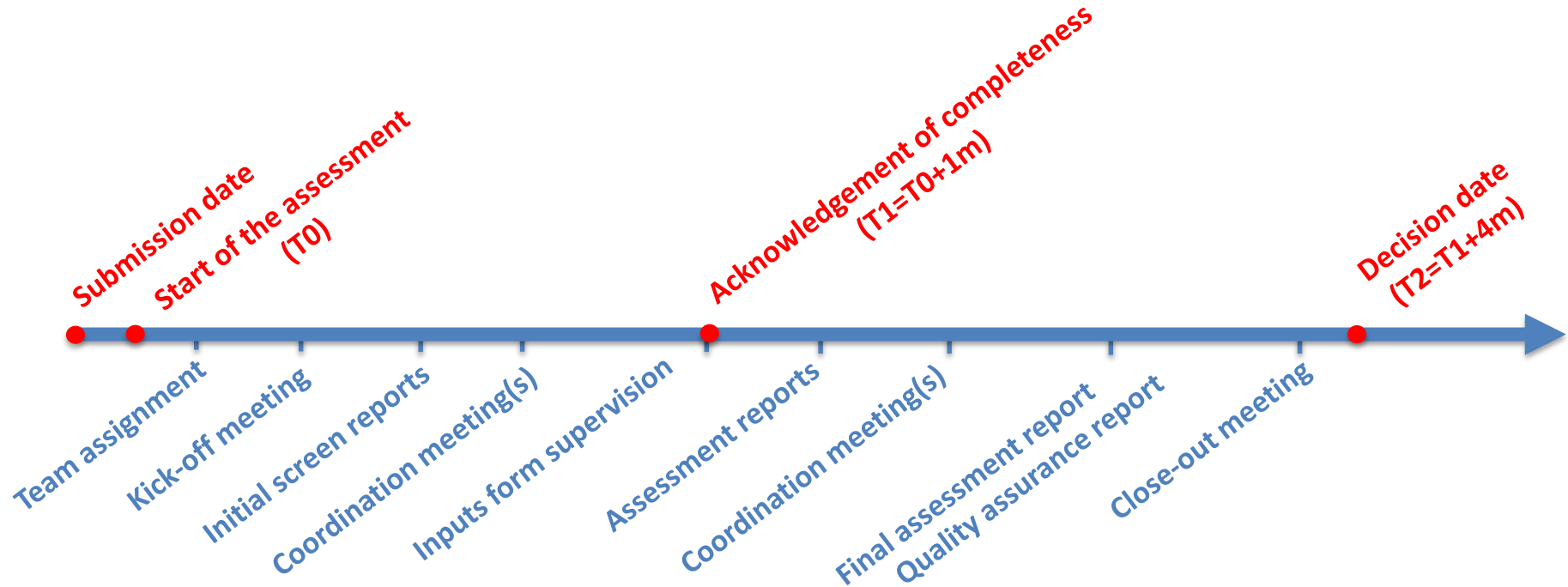
RED — Legal milestones (updated only when there is a need to extend the timeframe of the assessment)

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

The timeline is transposed directly to the dashboard of the OSS

Dashboard structure based on planned dates and dates of accomplishment of the specific tasks.

The Project Manager can update milestone
in agreement with NSA(s) and Applicant where relevant

The Project Manager can add milestone(s)
to the generic planning

- Applicant's choice, but recommended
- Authorities have to provide the service when the applicant requests it
- Is **not free consultancy** on how to make an application
- Request submitted through the OSS
- The applicant is advised to submit a pre-engagement file containing an overview of its SMS
- Purpose:
  - Help the applicant understand what is expected of it
  - Provide further information on the assessment process
  - Familiarise with the applicant's SMS
- It is still possible to contact ERA before submitting the request for pre-engagement e.g. to discuss possible scenarios plan the process or clarify some doubts – we recommend this.

- A Project Manager is appointed – and perhaps a limited number of assessors – responsible for the organisational details and the coordination of the assessment

- The applicant sets the agenda of the coordination meeting, drafts the minutes (if not decided otherwise) and records them (after being reviewed) in the OSS

- Issues are recorded by the assessor(s) in the OSS if these are relevant for future assessment

- Pre-engagement is closed by the Project Manager <u>on request of the applicant</u> or when the latter submits its application for a single safety certificate

- Documents submitted by the applicant and issues identified remain available in the OSS

- Once the applicant submits its application, the ERA Programme Manager appoints a Project Manager and one or more assessors

- The Project Manager organises a kick-off meeting with the applicant and all members of the assessment team to discuss the:
  - detailed schedule of the assessment
  - organisational arrangements and task assignment
  - feedback from the pre-engagement (when applicable)
  - information from past supervision (when applicable)
  - context of the organisation submitting an application and the overview of its safety management system

- Ahead of that meeting, the Project Manager may also arrange a meeting between authorities to share common views and agree on the lines to take

- Lasts one month – consider carefully how to use the time available

- Assessors assess the application file: A **simple check** that the application is readable and that there is enough to be able to proceed to a full assessment

- Easiest way to do this is check that information is provided against **each** of the CSM SMS and TSI OPE requirement, by means of the mapping table (that is part of the application form) and it is understandable

- Initial screen ends after one month at the latest following the start date of the assessment (as set out in the OSS dashboard), unless it is decided to extend the timeframe for the provision of supplementaty information

- If there are issues then these should be dealt with using the issue log in the OSS, try and close these out but remember they can be transferred to the detailed assessment if necessary

- Evaluate the applicant's responses

- Initial screen report (web form available in the OSS) has to be drafted by the assessor(s) in coordination with the Project Manager – Based on the reports of the different authorities concerned with the area of operation, the Project Manager acknowledges (or not) the completeness of the application. If not, s/he must extent the timeframe of the assessment based on issue(s) previously registered by the authority or authorities in the issue log

- Read the key documents first: SMS Manual, description of the Context, Risk Management, Competence Management System – what impression do you get?

- Read through as many additional documents as you can to check your observations.

- Is equal weight given to different sections?

- How practical is it – does it appear to be an administrative exercise?

- Does it feel like the author/authors know what they are doing, link this with your thoughts from initial meetings with your contact?

- Do the judgements on risk control seem correct?

- Look for what they are doing and how they are doing it – Context of the Organisation is a critical area for the applicant to get right.

- If in doubt raise an issue to ask for clarification from the applicant

- If you are unsure about something ask the Project Manager for help

- Read the whole application first and check that you understand it
  – It should be a step by step guide to how the applicants SMS works.
  – Any references should allow the assessor - should he wish - to identify key documents for further analysis.
  – If you find that some areas are unclear note this for clarification later.

- Use the Guide on SMS requirements - start checking whether there is enough information provided against each requirement

- If not, create issues using the issue log in the OSS and evaluate the applicant's responses

- Detailed assessment ends after 4 months at the latest following the acknowldgement of completeness (as set out in the OSS dashboard), unless it is agreed with the applicant to extend the timeframe for the provision of supplementaty information

- Detailed assessment report (web form available in the OSS) has to be drafted by the assessor(s) in coordination with the Project Manager – Based on the reports of the different authorities concerned with the area of operation, the Project Manager drafts a final assessment report which compiles all the assessment reports and makes a recommendation for the decision-maker, including the single safety certificate to be issued as appropriate

- Evaluate how important are the gaps?

    – Is this critical? What if the risk assessment element under planning is entirely theoretical?

    – Do I need clarification? E.g. the sentence is unclear as to who is responsible for what

    – Can I live with it? E.g. the written material is not put together very well but shows that they do understand what is required and all the references are there

    – The structure is weak; you can find answers to SMS Requirements but not necessarily where they should be

    – How likely is it that the company will be able to resolve the raised issues?

- Key points are whether the gaps mean that risk is not controlled – or that they cannot explain how it is controlled

- Register to one of the **OSS training sessions** organised by ERA

- Short video tutorials are available on the **ERA website**:
  - **OSS - How to create and submit an issue**
  - **OSS - How to submit a report**

- Watch first the [video tutorial on how to manage issues](#)
- Different categorisation of issues:
  - Type 1 is a simple query for which you expect the applicant to resolve it reasonably easily
  - Type 2 Here you are basically saying ok there is a minor problem here but we trust you to solve this during the life of the certificate. You must make it clear to the applicant that at the next assessment these will be checked and failure to address these issues might result in a different type of issue being raised next time. Remember to record these issues in the detailed assessment and final report with a clear explanation of what is required
  - Type 4 Issues these are blocking. They have to be closed out to allow the applicant to get an SSC. Remember that one option is to close the Type 4 issue but include in the final decision a restriction in time, type, extent or area of operation. If this option is chosen it must be clearly stated in the issue resolution the detailed assessment, final report and cover letter giving the reasoning. The applicant should of course be made aware, ideally they agree to the approach, however, we can proceed without their agreement if necessary. The applicant should be clearly advised what they need to do to resolve the problem so that they can make an update of the certificate in the future if required

– Type 3 Issues are for minor deficiencies **OR** residual concerns for supervision

- For the first an Action Plan should be agreed with the applicant to resolve the outstanding issues. Importantly the timescales should be identified for resolution of the issues set out in Action Plan and the authority responsible for checking this should be agreed. The responsible authority could be one or more NSAs or the Agency. In the latter case it is likely that resolution will be linked to some limitation in time of the Certificate which has been granted.

- For the residual concerns for Supervision the concerned NSAs must agree as above in writing and the issues which are covered by this should be clearly set out in the detailed assessment, final report and cover letter as above.

- In addressing issues via the OSS it is possible to move issues from one type to another as matters are clarified e.g. an initial Type 4 issue might become a Type 3 or Type 2 if the applicant can provide the necessary information

- The status of an issue, up to the moment it is closed by an assessor, will be shown as pending in the OSS

- Remember to choose resolution and put description before closing of an issue

- Reminder
  - Restrictions and conditions of use can only be linked to Type 4 issues
  - It is possible to have multiple Type 3 issues resulting in a decision that cumulatively make them a Type 4. In this case you should create a Type 4 issue addressing the point and use this to deal with the restrictions and conditions of use OR,
  - It can be justified the use of cumulative Type 3 issues being effectively a Type 4 (although not necessarily creating a Type 4 issue) and covers this in the assessment report, in accordance with Annex II point 4.9 (b) of Regulation (EU) 2018/763
  - Only Type 4 issues can result in restrictions and conditions of use

Possible scenarios:

Issue	Quantity	Intermediate action	Possible resolutions	Result
Type 1	-		**Closed out**	SSC issued
	-	Re-evaluated to Type 3	See Type 3 Issue	See Type 3 Issue
	-	Re-evaluated to Type 4	See Type 4 Issue	See Type 4 Issue
Type 2	-		**Closed out**	**SSC issued**
	-	Re-evaluated to Type 3	See Type 3 Issue	See Type 3 Issue
	-	Re-evaluated to Type 4	See Type 4 Issue	See Type 3 Issue
Type 3	Single	-	**Closed out**	**SSC issued**
	-	-	**Residual concern (action plan)**	**SSC issued with an action plan**
	-	-	**Residual concern (NSA supervision)**	**SSC issued with agreed supervision**
	-	-	**Residual concern (action plan + NSA supervision)**	**SSC issued with an action plan to be checked through supervision**
	-	Re-evaluated to Type 4	See Type 4 Issue	See Type 4 Issue
	Multiple	Assimilated to Type 4	See type 4 issue	See Type 4 issue
Type 4	-	-	**Closed out**	**SSC issued**
	-	-	**Pending**	**Rejection**
	-	-	**Closed out with restrictions**	**SSC issued with restriction:** - **Restricted time** - **Restricted scope** - **Restricted area of operation**

- Write clearly and precisely what the problem is and what they need to do to resolve it including (where relevant), giving possible examples of the additional information required

- Set deadlines for reply and monitor them informing the applicant if there is a chance that failing to close out the issue could jeopardise the application

- Do not write anything which the applicant might find offensive or is otherwise unprofessional

- Coordinate with the other assessors (or authorities) before submitting an issue to the applicant – The Project Manager ensures consistency

- Remember the applicant will need to resolve the issue so make sure that you do not write anything which will affect the ability of the applicant to do this

- Remember that an issue not resolved will be transferred to the assessment report where you will be required to justify your decision

- Dialogue with the applicant to resolve or to agree how to proceed with the issues raised via the Issue Log in the OSS

- Ensure the title of the issue is self-explanatory; it is recommended to add the reference to the document and the legal base in the issue title:

VIEW	S-2020	Type 3 (minor non-compliance or residual concern)	Mathieu	Closed	12/02/2021	01/03/2021	Handbook "MIK" (HB_QM_01 V7B) - Req.1.1 a) of Annex I to Reg. 2018/762

Application issue: S-2020

Basic Information

Title *

Handbook "MIK" (HB_QM_01 V7B) - Req.1.1 a) of Annex I to Reg. 2018/762

- Set a deadline reasonable and proportionate for replying to the issue
- If not specified in the issue title (see previous slide), make sure the issue description includes the legal base (i.e. relevant part(s) of the EU law)
- Identify in the issue description the part(s) of the document(s) that is/are relevant for the issue
- For type 3 or 4 issue:
  – Check with the Project Manager for uniformity in decision (incl. the adequate legal base)
  – If already decided, which NSA will follow them up
  – The issue resolution shall clearly state whether this is a residual concern to be followed up by NSA (➔ Resolution status = "Residual concerns for supervision") and/or corrective actions are expected of the applicant - If the action plan + dates cannot be agreed upon during the assessment (discuss with applicant during assessment), the deadline for submitting it shall be specified.

- Example of resolution for type 3 issue with action plan requested from the applicant
  - Resolution status is set to 'Residual concerns for supervision'
  - The resolution description shall always provide the justification for the decision (irrespective of the resolution status !). If an action plan is requested from the applicant, it should be explained the reasoning for such a request.

Resolution

Resolution	Residual concerns for supervision ⌄
Resolution description	As regards specific operational and technical requirements applicable to border/changeover stations in neighbouring countries, the applicant is requested to complement the document FO_PR_34 with the specific rules applying for border stations in Poland and Germany in accordance with requirement 1.1 (d) of Annex I to Regulation (EU) 2018/762.

  - If no plan is requested, it shall be described why NSA follow-up supervision is sufficient.

Resolution description	ERA agrees with the applicant's reply above and also its reply given to issue 24. As mentioned in the issue description, since no accident/indicident was reported, ERA could not check the correct implementation of the procedures. No specific action is requested by the applicant. However, the competent national safety authority or authorities are requested to check during their supervision the correct implementation of the procedures, in particular how accident hazard analysis and preliminary risk assessment can nurture the risk assessment and monitoring processes.

- In the case where the applicant has selected a language for the application that is not mastered by all the project team members, it is recommended to have the <u>issue title in EN</u> and the <u>issue description in both languages</u>: first in the target language of the applicant, starting with the translation of the issue title, and then in EN

- The Project Manager coordinates ERA assessors with the aim to reach a consistent approach to the assessment.
- The Assessor completes the relevant parts of the assessment reports (initial screen, detailed assessment) making recommendations to the Project Manager, for instance:
  – to acknowledge (or not) the completeness of the application
  – to issue a single safety certificate (with or without residual concerns differed to supervision and/or restrictions or conditions of use) or to refuse it
- Diverging opinions between assessors (of a same organisation) should be recorded in the report ('*Additional information*' field in the OSS)
- In case of diverging opinions between organisations, this should be identified by means of issues (to be recorded in the issue log), recorded in the minutes of coordination meeting as appropriate

- The Project Manager, after having received the assessment reports of the NSAs, organises a closing meeting with all the concerned parties (including the applicant) before the deadline for taking the decision, to agree on:
  - conclusions of the assessment carried out by each authority
  - any residual concerns to be deferred for later supervision
  - any restrictions and conditions of use to be included in the certificate

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