

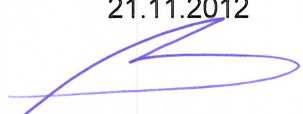
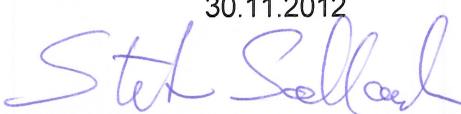
Cross Acceptance Unit

REFERENCE DOCUMENT PART 3: SWEDEN

NATIONAL LEGAL FRAMEWORK APPLIED IN CONJUNCTION WITH THE AUTHORISATION OF RAILWAY VEHICLES IN ACCORDANCE TO ART.27 OF DIRECTIVE 2008/57/EC IN SWEDEN

DOCUMENT TYPE: TECHNICAL DOCUMENT

VERSION: 1.6.1

	Edited by	Approved by
Name	Ny Tiana TOURNIER	Stefan SOLLANDER
Position	Cross Acceptance Unit Head of Authorisation Processes Sector	National Safety Authority of Sweden
Date & Signature.	21.11.2012 	30.11.2012 

Background information

The 3 sheets: Back Info-General, Back Info - Roles and Resps, and Back Info - Timeframe shall be filled in with the relevant information.

The cells coloured in:  are those to be filled in.




Additional information

Additional information to the flowcharts is requested where the objects are bordered with a thick black line. Reference N° of these objects have been introduced.

The 8 sheets: Stage 1, Stage 2, Stage 3, Stage 4, Stage 6, Stage 7, Sub-stage 7.1 and Stage 8 shall be filled in with the relevant information.

The cells coloured in:  are those to be filled in.

Colour coding from the flowcharts

	legal option
	non mandatory/commom practice
	legal option at the national level

Contact details for National Legal Framework		
Reporting country	Organisation Name	Office phone number
Sweden	Transportstyrelsen	+46 10 4955512
Contact name	E-mail	Mobile phone number
Stefan Sollander	stefan.sollander@transportstyrelsen.se	+46 70 7246012

	Is there (Yes/No)	Classification: (general, specific, detailed)	Detailed reference of the rule(s)	Language(s) that the rule(s) are available in	MSS
Interoperability Directive transposed	Yes	N/A	Lag (2011:1118) om ändring i järnvägslagen (2004:519)	SE	
National guideline	Yes	N/A	Guide TS JV 2009:002	SE	
Additional authorisation required	Yes	N/A	TSFS 2010:116 §16	SE; EN*	N/A
Definitions:	Vehicle type	Yes	General	Railway act SFS 2004:519 §4	SE
	Time validity of a type	No	N/A		
	Upgrading	No			
	Renewal	No			
Specific national arrangements for on track tests	Yes	N/A	TSFS 2010:116 §3; Guide TS JV 2009:002 2.1	SE; EN* / SE	N/A
Coordination with other MSS	Procedure for simultaneous application	No	N/A		

Fees	Is there (Yes/No)	Amount (Euro)	Conditions (fixed/hourly rate)	Detailed reference of the rule	Language(s) that the rule(s) are available in
To obtain the National guideline	No				
For the acknowledgement of receipt of application	No				
For issuing authorisation	Yes	150	hour	TSFS 2011:79 Chapter 4	SE
For refusal of authorisation	Yes	150	hour	TSFS 2011:79 Chapter 4	SE
For the appeal procedure to NSA	No				
For the appeal procedure to Appeal Body	No				
For the NSA acting as assessment body (DeBo/CSM)	Yes	150	hour	TSFS 2011:79 Chapter 4	SE
For NSA issuing certificates (DeBo/CSM)	Yes	150	hour	TSFS 2011:79 Chapter 4	SE

*) EN version not legally binding

The following roles/actors might be involved in the authorisation procedure for the placing in service of vehicles: applicant, RU, IM, keeper, NoBo, DeBo, NSA, MS, Assessment body (CSM)

Requirement on the actor for the role	Applicant	IM	NoBo	DeBo	NSA	MS	Assessment Body (CSM)	Appeal Body
Detailed reference of the rule(s)	TSFS 2010:116 §9	No	TSFS 2010:116 §12; Guide TS JV 2009:002 Chapter 4; SFS 2011:791	Guide TS JV 2009:002 Introduction	Railway act SFS 2004:519 §13; §25	Railway act SFS 2004:519 §13a; Railway Ordinance SFS 2004:526 §14c	EC Regulation 352/2009	Railway act SFS 2004:519 Chapter 11, 2 §; 22 – 28 §§ Förvaltningslagen (1986:223); 14 § Lagen (1971:289) om allmänna förvaltningsdomstolar; 33 § Förvaltningsprocesslagen (1971:291)
Language(s) that the rule(s) are available in:	SE; EN*		SE; EN* / SE / SE	SE	SE	SE	EU languages	SE
List of acceptance criteria								
List of actors entitled to act as:		N/A	N/A	NSA SE	Transportstyrelsen	NSA SE	NSA SE; Competent bodies	Förvaltningsrätten i Falun / Kammarrätten

*) EN version not legally binding

Is there a National timeframe		Specify timeframe	Detailed reference of the rule(s)	Language(s) that the rule(s) are available in
For new authorisation case after upgrading/renewal: for MS/NSA to make decision according to Art.20.1 of Directive 2008/57/EC		4 months	Railway Ordinance 2004:526 §14.d	SE
For all authorisation cases where there is a refusal of authorisation according to Art 21.7 of Directive 2008/57/EC:	Request for review of the refusal by the applicant to the NSA	1 month	Railway act 2004:519 Chapter 11 §1	SE
	Maintain of the refusal by the NSA	2 months		
	Request for review of the refusal by the applicant to the appeal body – Possible opinion of the Agency if required by the appeal body	3 weeks	Förvaltningslagen SFS 1986:223 §22; §23	SE
For additional authorisation case of TSI conform vehicles	NSA decision to be taken as soon as possible and not later than, according to Art. 23.7 of 2008/57/EC:			
	(a) after submission of the authorisation file	2 months		
	(b) after provision of any additional information requested by the national safety authority, where applicable	1 month	Railway Ordinance 2004:526 §18	SE
	(c) after provision of the results of any tests requested by the national safety authority, where applicable	1 month		
For additional authorisation case of non-TSI conform vehicle	NSA decision to be taken as soon as possible and not later than, according to Art. 25.5 of 2008/57/EC :			
	(a) after submission of the authorisation file	4 months		
	(b) after provision of any additional information requested by the national safety authority, where applicable	2 months	Railway Ordinance 2004:526 §20	SE
	(c) after provision of the results of any tests requested by the national safety authority, where applicable	2 months		
For all additional authorisation cases: TSI and non-TSI conform vehicles	For tests/checks (including network compatibility) with the identified actors, in particular the IM, to take place not later than, according to Art. 23.6 and Art.25.4 of Directive 2008/57/EC	3 months	Railway ordinance 2004:526 §22	SE
	when there is a deemed authorisation according to Art.21.8 of Directive 2008/57/EC	4 months	Railway ordinance 2004:526 §20	SE

Reference No in flowcharts	Reference to object in flowchart	Requirement that needs additional information	The detailed reference of the rule(s) that specify the requirements	Language(s) that the rule(s) are available in
1.I	Submit the file describing the project to the MS	Requirements for the content of the file describing the project	TSFS 2010:116 §6; Guide TS JV 2009:002 Chapter 2.3	SE; EN* / SE
1.II	Examine: file of the previous authorisation(s) records on maintenance, operation and technical modifications	Requirements for the content of the file of the previous authorisation(s)	TSFS 2010:116 §16; Guide TS JV 2009:002 Chapter 5.5	SE; EN* / SE
		Requirements for the content of the records on maintenance, operation and modifications	TSFS 2010:116 §16; Guide TS JV 2009:002 Chapter 5.5	SE; EN* / SE
1.III	Submit the file describing the project to the MS	Requirements for the content of the file describing the project	No	
1.IV	Is a new authorisation required for the project?	The criteria for a new authorisation	TSFS 2010:116 §6; Guide TS JV 2009:002 Chapter 2.3	SE; EN* / SE

*) EN version not legally binding

Reference no in flowcharts	Reference to object in flowchart	Requirement that needs additional information	The detailed reference of the rule(s) that specify the requirements	Language(s) that the rule(s) are available in
2.I	Request for track access to run on track test, when necessary	Procedure for establishing the conditions to run on track tests	TSFS 2010:116 §3; Guide TS JV 2009:002 Chapter 2.1	SE; EN* / SE
2.II	Compile pre-engagement baseline	Procedure for establishing pre-engagement baseline	Guide TS JV 2009:002 Chapter 3.1.1	SE
*) EN version not legally binding				

Reference no in flowcharts	Reference to object in flowchart	Requirement that needs additional information	The detailed reference of the rule(s) that specify the requirements	Language(s) that the rule(s) are available in
3.I	Perform verification (including tests and on track tests where necessary) against applicable TSIs and NRs, and establish evidences	The requirements for evidences	TSFS 2010:116 §9; §11; §12; §13; §15; §16, Guide TS JV 2009:002 Chapter 4 and 5	SE; EN* / SE
3.II	Perform verification of conformity to type, and establish evidences	The requirements for evidences	TSFS 2010:116 §10, Guide TS JV 2009:002 Chapter 3.1.3	SE; EN* / SE
3.III	Supply evidences on the completion of the relevant assessment of conformity to type	The requirements for evidences	No	
3.IV	Supply evidences on the completion of the relevant assessment of conformity to type	The requirements for evidences	No	
3.V	Apply CSM Regulation for safe integration	The requirements for risk assessment	EC Regulation 352/2009; EC	EU languages
3.VI	Provide certificate(s) from assessment against applicable TSIs requirements to applicant	The requirements for evidences	TSFS 2010:116 §12, Guide TS JV 2009:002 Chapter 4	SE; EN* / SE
3.VII	Provide certificate(s) from assessment against applicable NRs requirements to applicant	The requirements for evidences	TSFS 2010:116 §13; §15, §16, Guide TS JV 2009:002 Chapter 5	SE; EN* / SE
3.VIII	Provide safety assessment report to applicant	The requirements for the content of the safety assessment report	EC Regulation 352/2009 Article 7; EC recommendation 2011/217/EU	EU languages

*) EN version not legally binding

Reference no in flowcharts	Reference to object in flowchart	Requirement that needs additional information	The detailed reference of the rule(s) that specify	Language(s) that the rule(s) are available in
4.1	Decision on the remedial action?	Possible remedial actions: Alternative method, Design modification, Change of the conditions of use/restrictions,and	Guide TS JV 2009:003 Chapter 1	SE
		The criteria for decision on the remedial action.	Guide TS JV 2009:003 Chapter 1	SE

Reference no in flowcharts	Reference to object in flowchart	Requirement that needs additional information	The detailed reference of the rule(s) that specify the requirements	Language(s) that the rule(s) are available in
6.I	<ul style="list-style-type: none"> - Make a copy of the initial technical file (previous authorisation(s)) - Collect records on operation and technical modifications 	Requirements for the content of the authorisation file (including the "technical files") : - If there is a clear check list to be adhered to when compiling the authorisation file	TSFS 2010:116 §16, Guide TS JV 2009:002 Chapter 5.5	SE; EN* / SE
		- The accepted documentation for authorisation granted before the implementation of Directive 2008/57/EC.	TSFS 2010:116 §16, Guide TS JV 2009:002 Chapter 5.5 ¹	SE; EN* / SE
6.II	Identify the content of the technical file for the DeBo(s) part	Requirements for the content of the authorisation file (including the "technical files") : - If there is a clear check list to be adhered to when compiling the authorisation file	TSFS 2010:116 §16, Guide TS JV 2009:002 Chapter 5.5	SE; EN* / SE
		- The accepted documentation for authorisation granted before the implementation of Directive 2008/57/EC.	No	
6.III	Identify the content of the technical file for the Assessment body (CSM) part	Requirements for the content of the authorisation file (including the "technical files") : - If there is a clear check list to be adhered to when compiling the authorisation file	EC Regulation 352/2009	EU languages
		- The accepted documentation for authorisation granted before the implementation of Directive 2008/57/EC.	No	
6.IV	Compile the authorisation file	The requirements and the content for the official application	TSFS 2010:116 §9-13; §15-16, Guide TS JV 2009:002 Chapter 4 and 5	SE; EN* / SE
6.V	Identify the format and documentation of the application for authorisation: - Vehicle type and/or - Vehicle placing in service	The requirements and the content for the official application	TSFS 2010:116 §9-13; §15-16, Guide TS JV 2009:002 Chapter 4 and 5	SE; EN* / SE
6.VI	Submit the official Application for authorisation	Time frame for the submission of the official application from the pre-	No	

*) EN version not legally binding

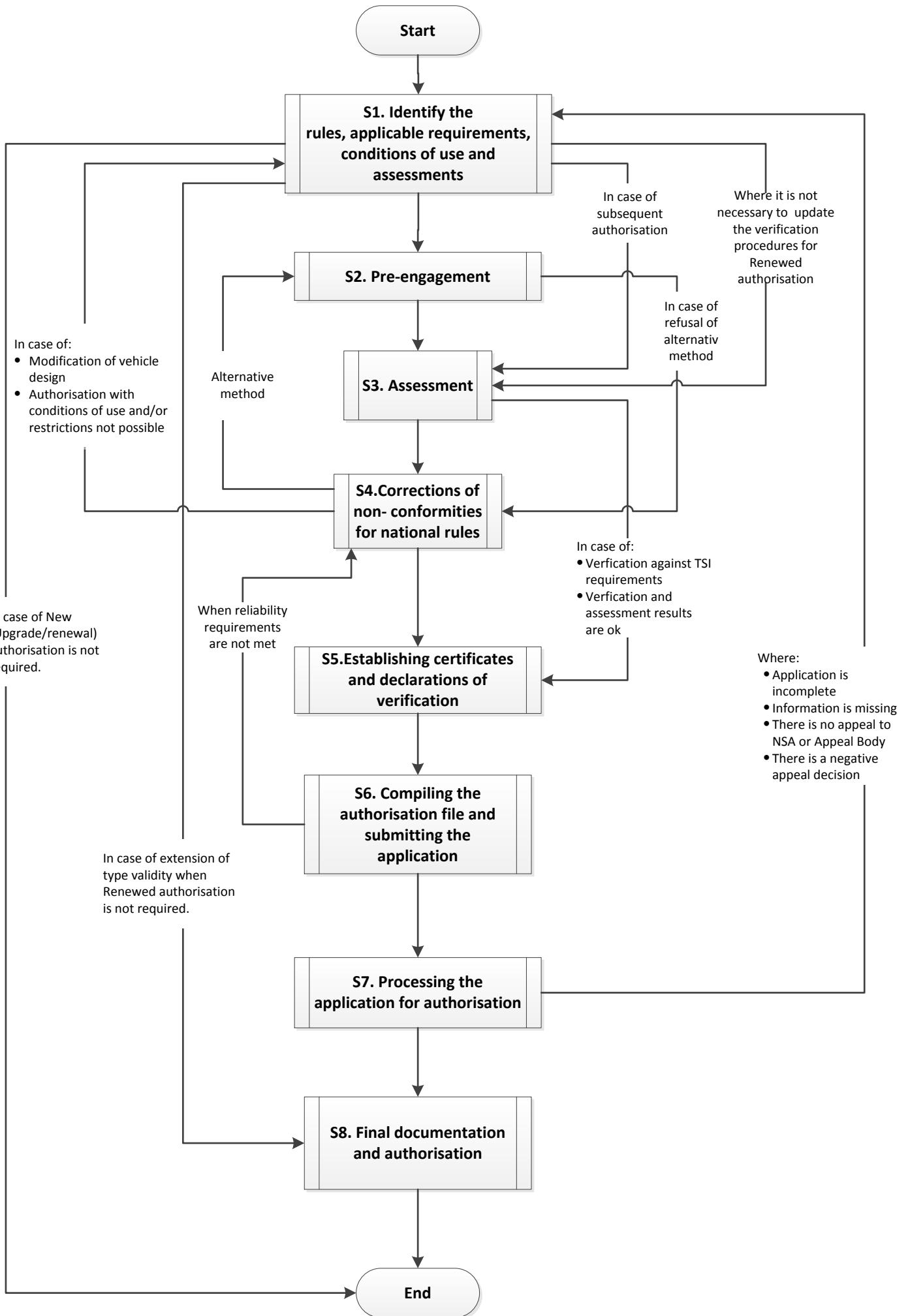
¹Vehicles "authorised" in Sweden before implementation of Directive 2008/57/EC, even before 1991, are deemed authorised in Sweden if registered in the SE-NVR. The same principle is applied for vehicles from other MSs.

Reference no in flowcharts	Reference to object in flowchart	Requirement that needs additional information	The detailed reference of the rule(s) that specify the requirements	Language(s) that the rule(s) are available in
7.I	Acknowledge receipt of application	The requirements for the acknowledgement of the receipt of application	SFS 1986:223 §16	SE
7.II	Declare the vehicle deemed authorised	The requirements for deemed authorisation	No	
7.III	Is there an appeal to NSA?	The requirements for appeal to NSA	SFS 1986:223 §23	SE
		The requirements for the content of justification of appeal to NSA	SFS 1986:223 §22	SE
		The requirements for launching appeal to the appeal body	SFS 1986:223 §23	SE
7.IV	Issuing the authorisation	The requirements for issuing authorisation	SFS 1986:223 §21	SE
7.V	Identify conditions for archiving the authorisation file	The requirements for NSA archiving the authorisation file	SFS 1986:223 §10	SE

Reference no in flowcharts	Reference to object in flowchart	Requirement that needs additional information	The detailed reference of the rule(s) that specify the requirements	Language(s) that the rule(s) are available in
8.I	Forms for: - authorisation for placing in service of vehicle(s) and - authorisation for type of vehicle	The format of issued authorisation (of vehicle type and of placing in service of vehicle)	(Internal procedure) Planned to be updated according to new law	
8.II	Form for authorisation for type of vehicle	The format of issued authorisation of vehicle type	(Internal procedure) Planned to be updated according to new law	
8.III	Inform ERA on deemed vehicle type authorisation	The procedure for informing the Agency on deemed vehicle type authorisation	(Internal procedure) Planned to be updated according to new law	

Annex A: Master diagram
Process for Authorisation for placing in service of vehicles and/or type of vehicles

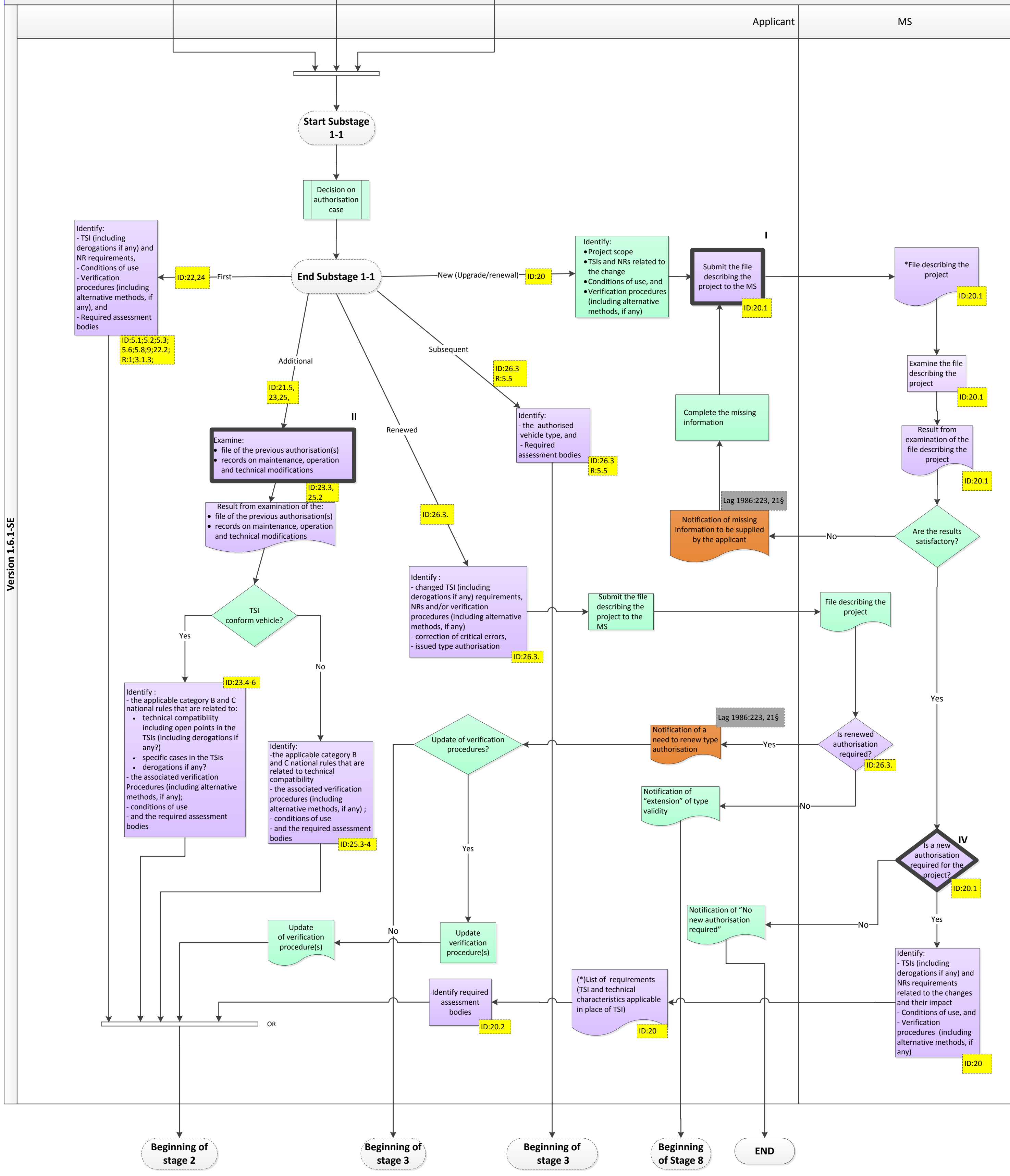
Version 1.6.1-SE



End of stage 4
Where:
 • there is a modification of vehicle design, or
 • authorisation with conditions of use and/or restrictions is not possible

End of stage 7 where:
 • the application is not complete, or
 • there is a negative appeal decision, or
 • there is a refusal of authorisation without appeal

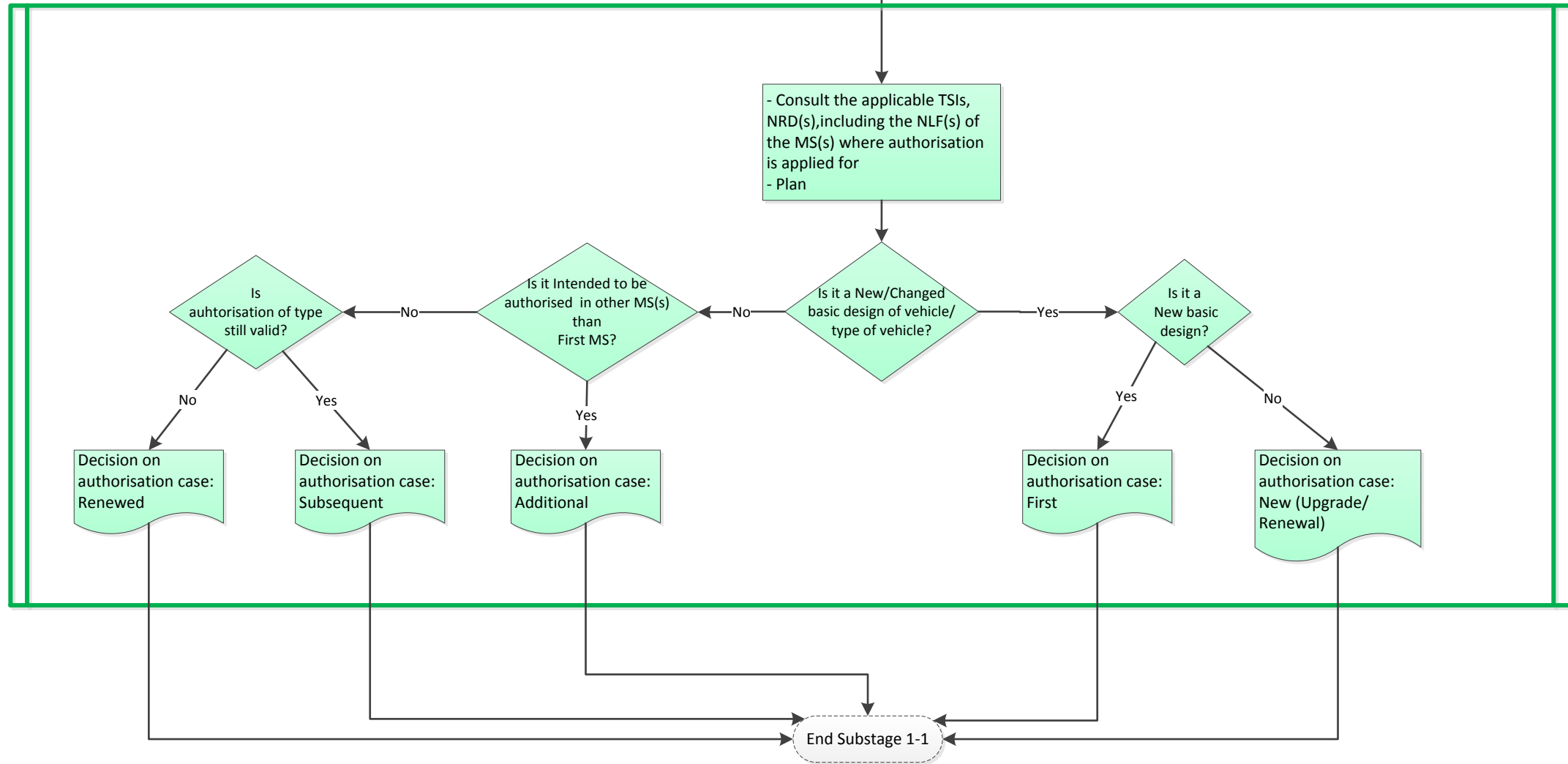
Stage 1 – Identify the rules, applicable requirements, conditions of use and assessments



Version 1.6.1-SE

Stage 1 - Identify the rules, applicable requirements, conditions of use and assessments – Substage 1: Decide on authorisation case

Applicant



Non mandatory/
Common practice

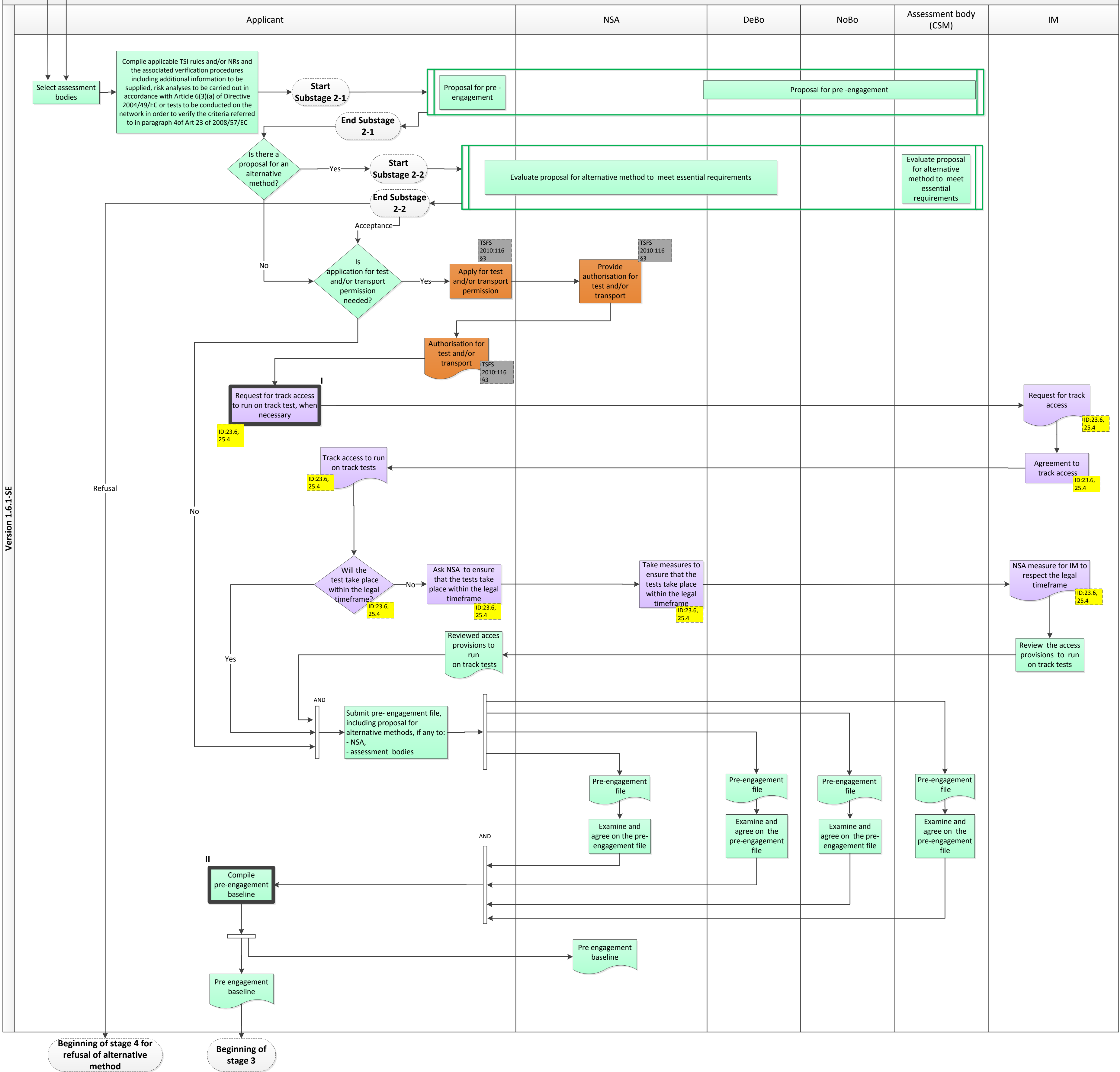
Legal option

Swedish legal
option

R: Recommendation 2011/217/EU
ID: Interoperability Directive 2008/57/EC
CSM: CSM Regulation 352/2009

TSFS: Transportstyrelsens författningssamling

Stage 2 – Pre-engagement



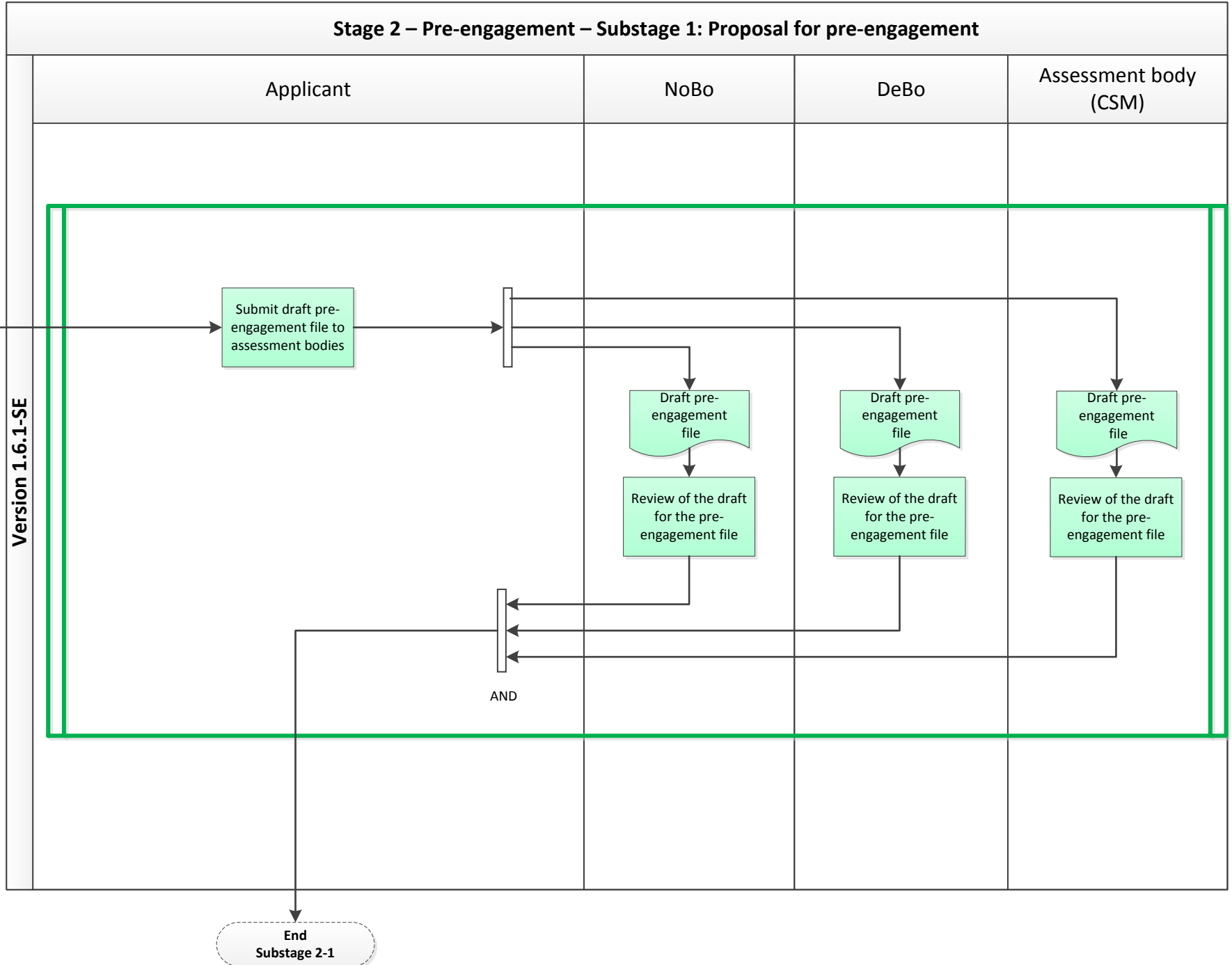
Version 1.6.1-SE

Beginning of stage 4 for refusal of alternative method

Beginning of stage 3

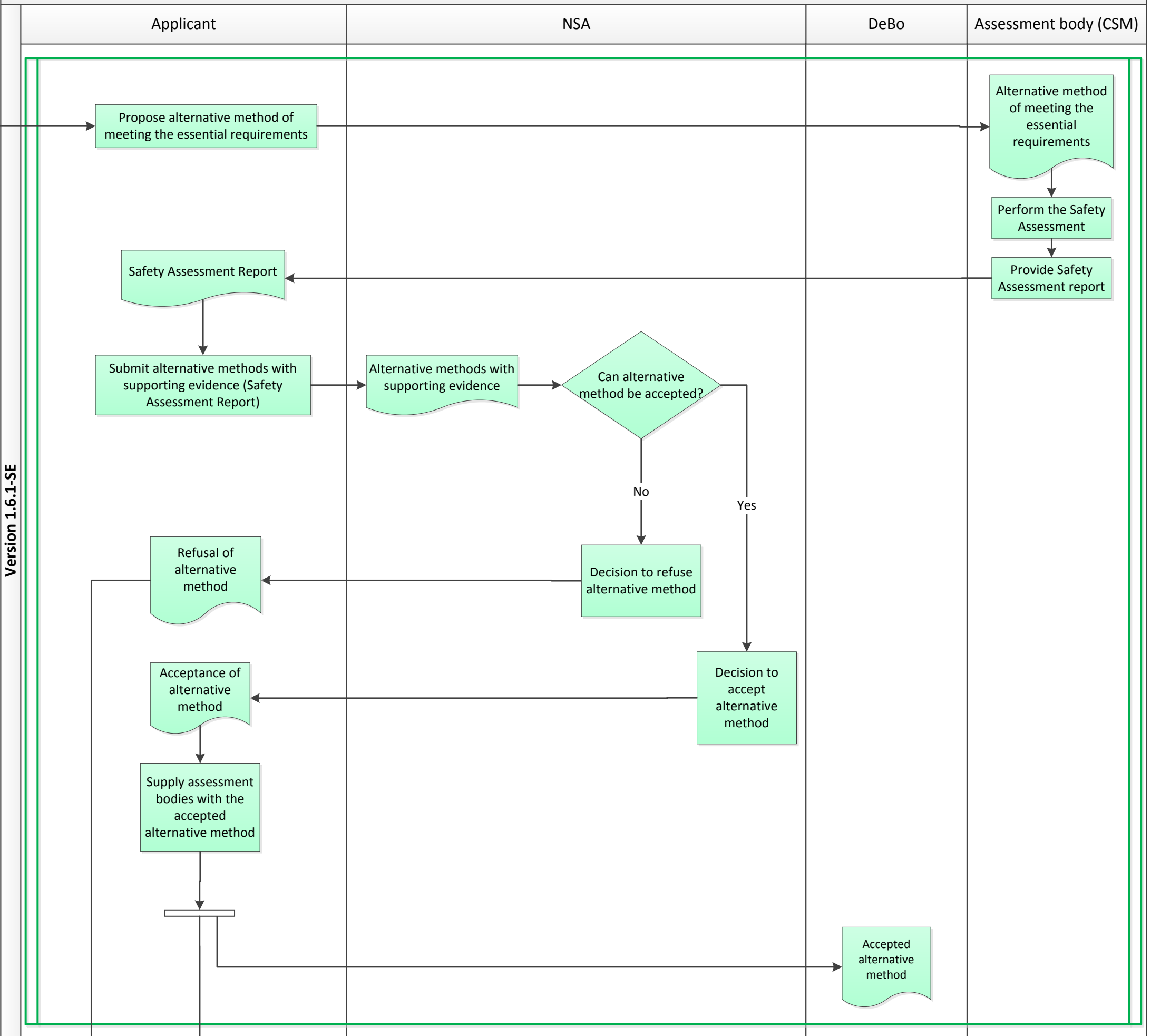
Non mandatory/
Common practice

Annex C



Stage 2 – Pre-engagement – Substage 2: Evaluate proposal for alternative method to meet essential requirements

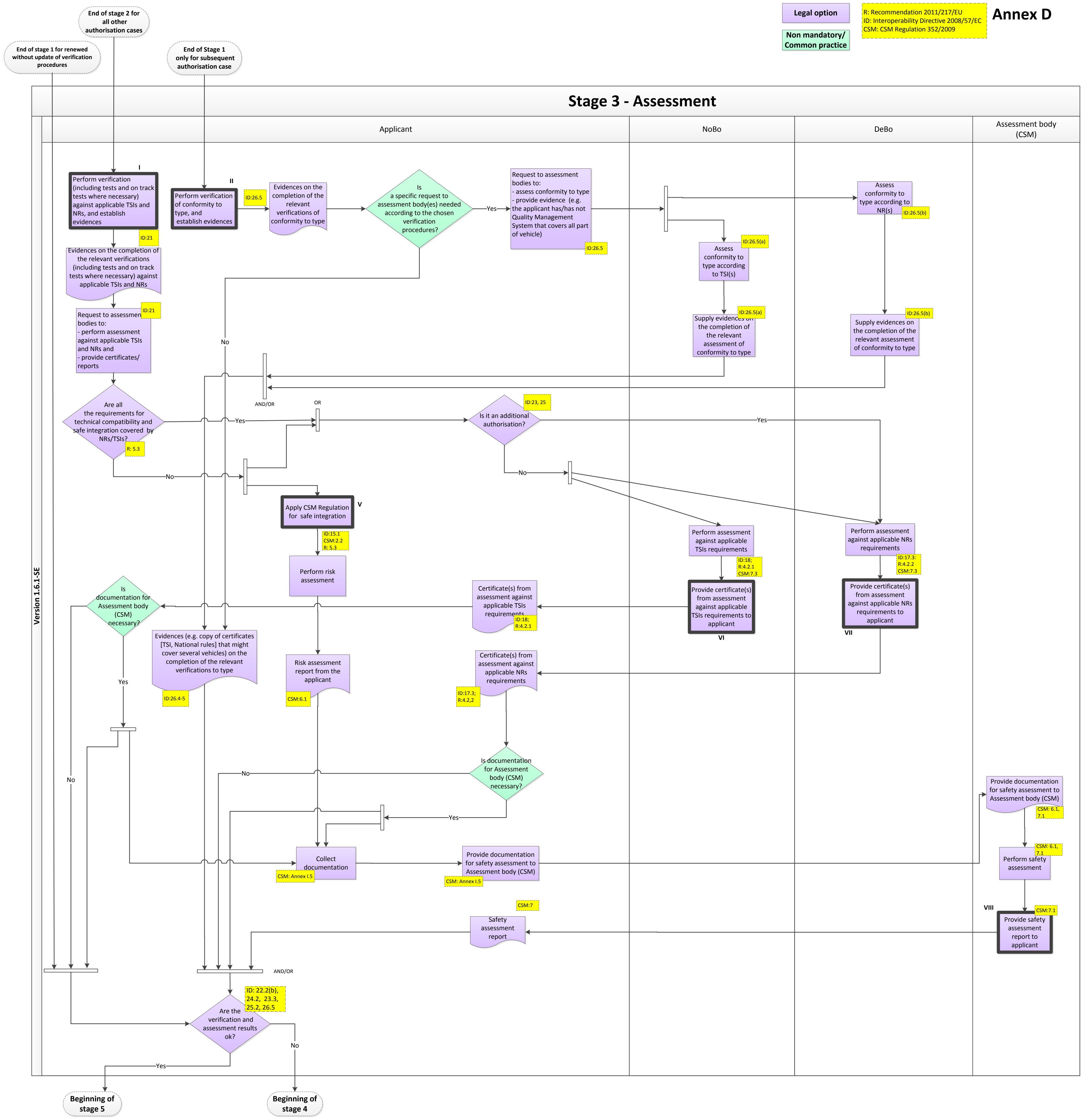
Start
Substage 2-2



Version 1.6.1-SE

End substage 2-2

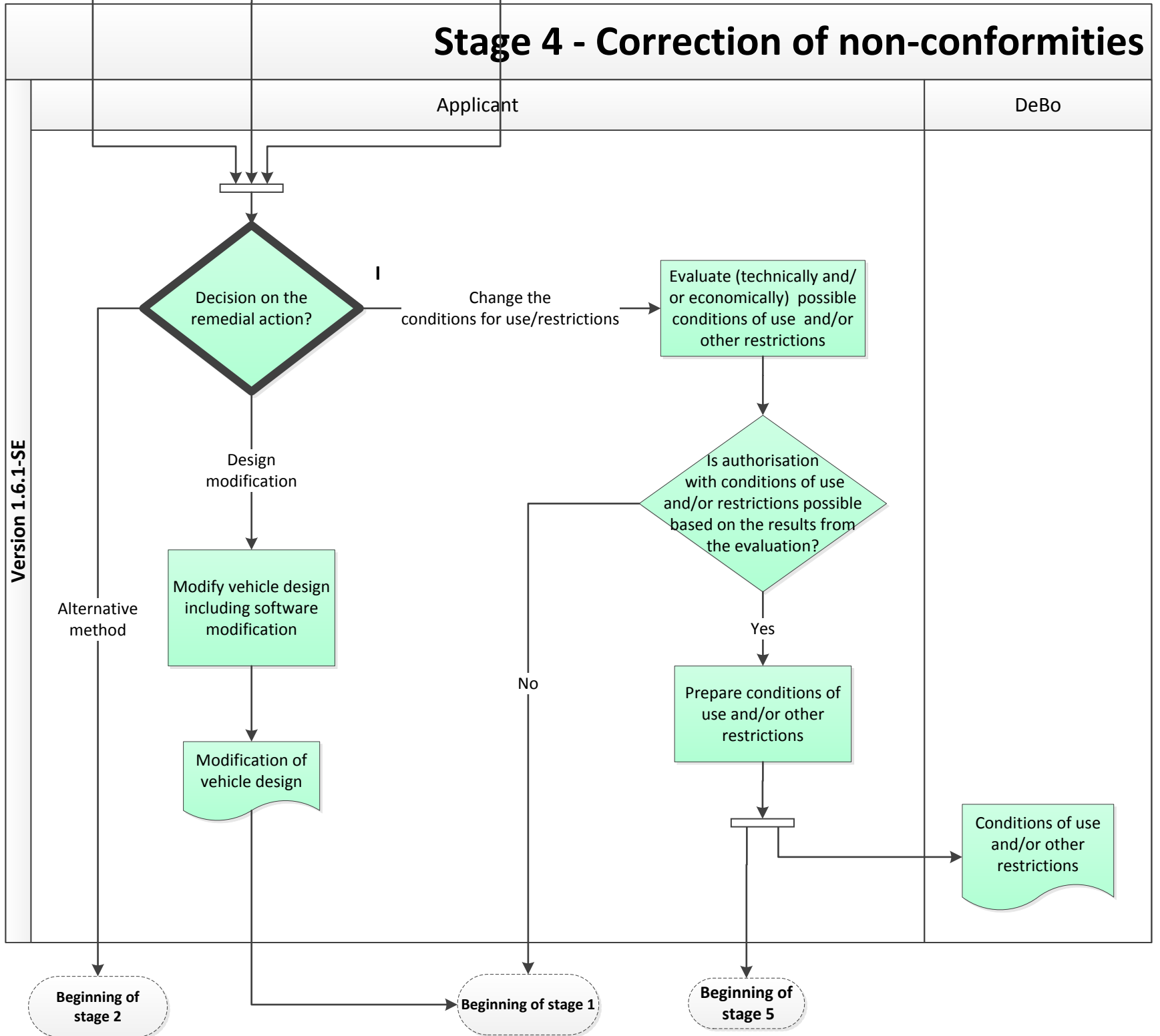
Stage 3 - Assessment

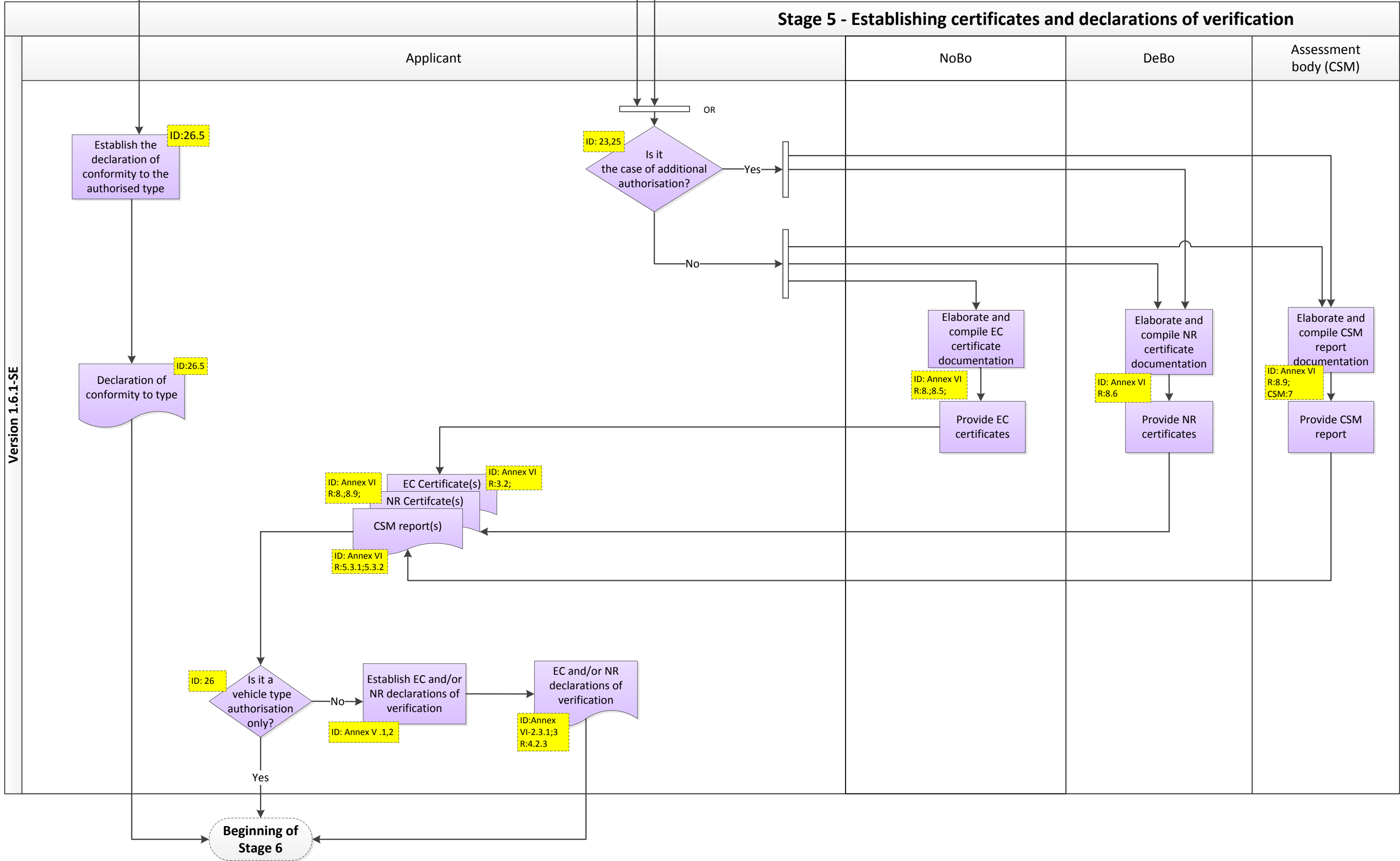


Version 1.6.1-SE

Non mandatory/
Common practice

Stage 4 - Correction of non-conformities





Version 1.6.1-SE

End of stage 3
when verification and
assessment results are ok for
subsequent authorisation

End of stage 3 when
verification and
assessment results are ok

End of stage 4

Stage 5 - Establishing certificates and declarations of verification

Applicant

NoBo

DeBo

Assessment
body (CSM)

OR

ID: 23,25

Is it
the case of additional
authorisation?

Yes

No

Establish the
declaration of
conformity to the
authorised type

ID:26.5

Declaration of
conformity to type

ID:26.5

Elaborate and
compile EC
certificate
documentation

ID: Annex VI
R:8.8,8.5;

Provide EC
certificates

Elaborate and
compile NR
certificate
documentation

ID: Annex VI
R:8.6

Provide NR
certificates

Elaborate and
compile CSM
report
documentation

ID: Annex VI
R:8.9;
CSM:7

Provide CSM
report

ID: Annex VI
R:8.8,8.9;

EC Certificate(s)

ID: Annex VI
R:3.2;

NR Certificate(s)

CSM report(s)

ID: Annex VI
R:5.3.1;5.3.2

ID: 26

Is it a
vehicle type
authorisation
only?

No

Establish EC and/or
NR declarations of
verification

ID: Annex V .1,2

EC and/or NR
declarations of
verification

ID: Annex
VI-2.3.1;3
R:4.2.3

Yes

Beginning of
Stage 6

End of stage 5

Stage 6 - Compiling the authorisation file and submitting the application

Applicant

NSA

Is it the case of additional authorisation?
ID:23,25

No

Yes

I

- Make a copy of the initial technical file (previous authorisation(s))
- Collect records on maintenance, operation and technical modifications

ID:23.3, 25.2

- File of the previous authorisation(s)
- Records on maintenance, operation and technical modifications

II

Identify the content of the technical file for the DeBo(s) part

R:8.6;4.2.2; ID Annex VI- 3.3

Technical file related to NRs

III

Identify the content of the technical file for the Assessment body (CSM) part

R:5.3.2; ID:Annex VI- 2.4

Assessment body (CSM) report on CSM

AND/OR

Compile the authorisation file
ID: 23.3, 25.2

IV

Authorisation file
ID: 23.3, 25.2

Archive authorisation file
ID: Annex VI-2.6

Archived authorisation file
ID: Annex VI-2.6

Start Substage 6-1

Submission of reliability evidences

End Substage 6-1

Subsequent authorisation

Reliability requirements are met

Reliability requirements not met

Application for permission to demonstrate reliability not granted

Identify the format and documentation of the application for authorisation:
•Vehicle type and/or
•Vehicle placing in servcie

ID:21.6;23.7;25.5
Annex VI:2.6
R:8.1;

V

Submit the official Application for authorisation
ID:21.6;23.7;25.5
Annex VI:2.6
R:8.1;

Application for authorisation
ID:21.6;23.7;25.5
Annex VI:2.6
R:8.1;

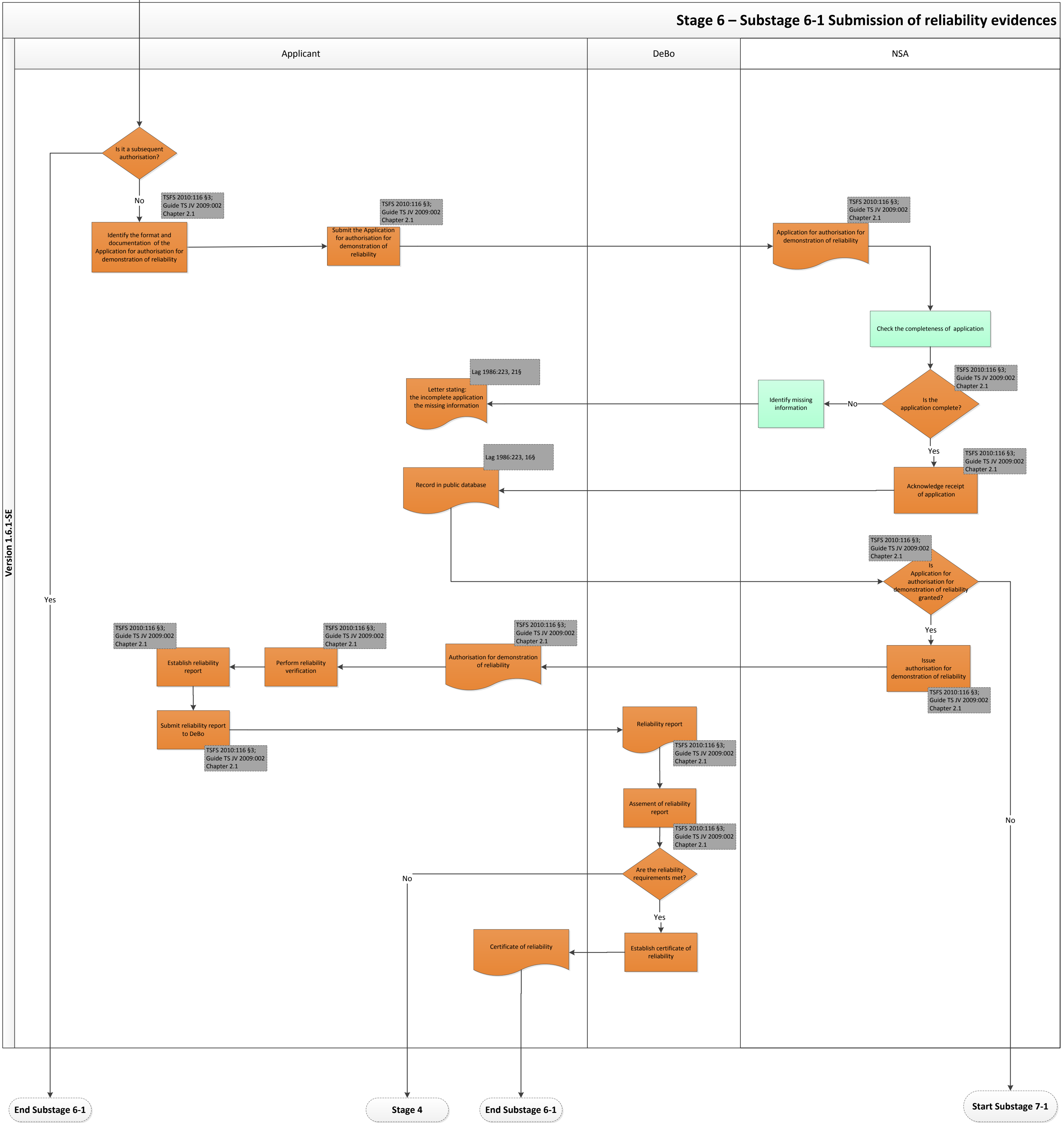
Beginning of stage 4

Beginning of Substage 7-1

Beginning of stage 7

Version 1.6.1-SE

Stage 6 – Substage 6-1 Submission of reliability evidences



Version 1.6.1-SE

(*)The timeline starts from the moment the application has been acknowledged

Legal option

Non mandatory/
Common practice

Swedish legal option

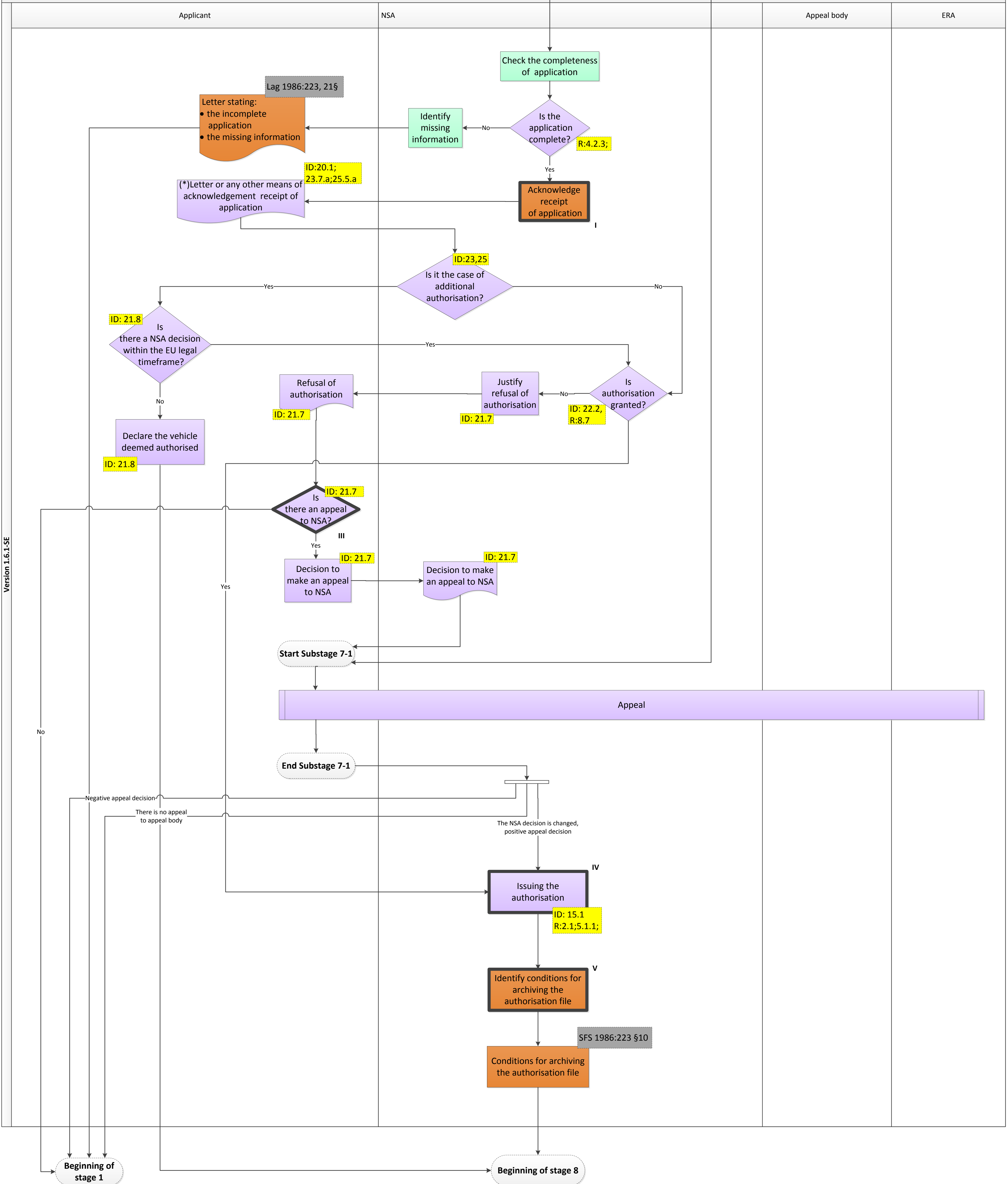
R: Recommendation 2011/217/EU
ID: Interoperability Directive 2008/57/EC
CSM: CSM Regulation 352/2009

Förvaltningslagen SFS 1986:223

End of stage 6

Stage 6 when application for permission to demonstrate reliability is not granted

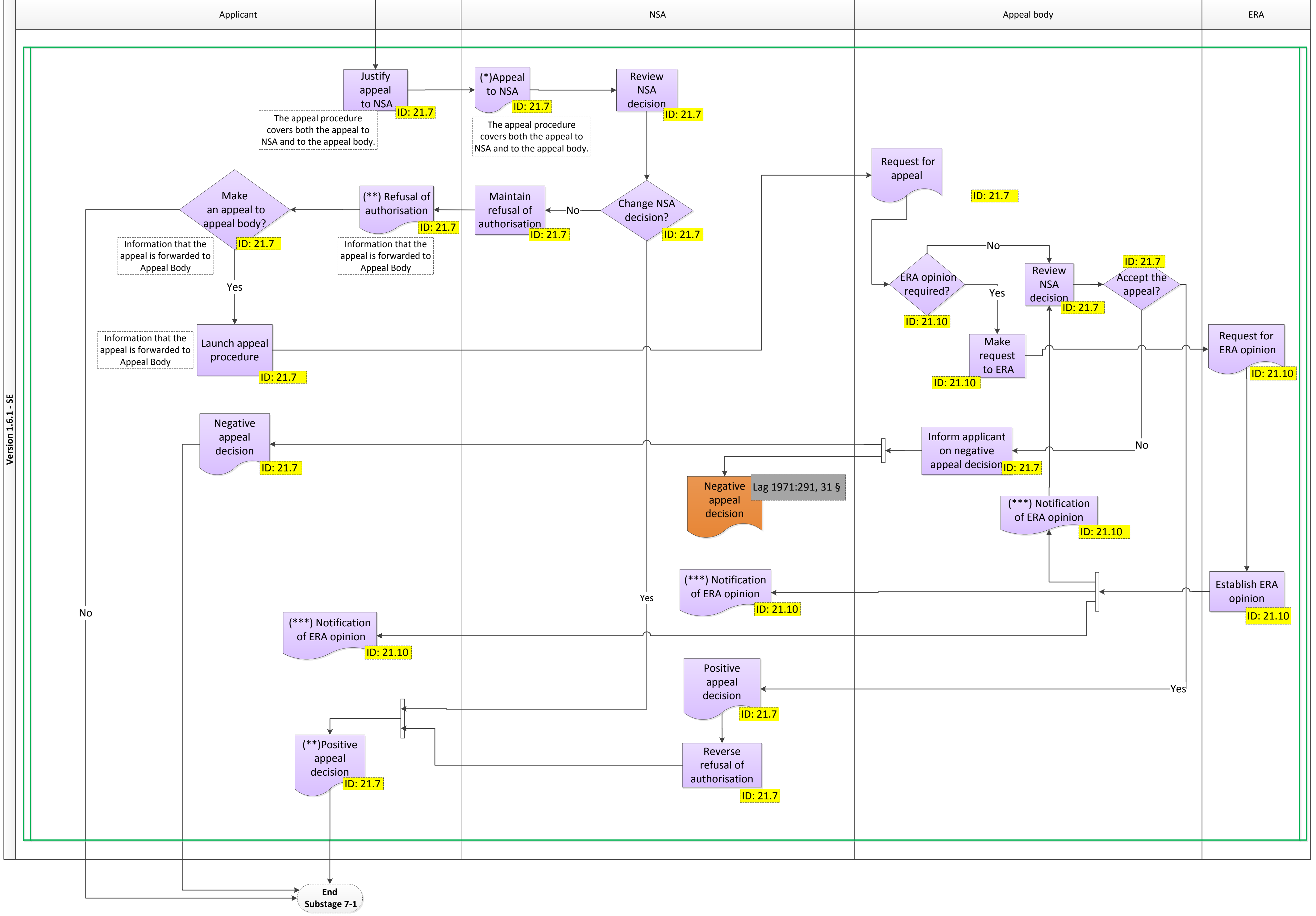
Stage 7 - Processing the application for authorisation



Version 1.6.1-SE

(*) Timeline starts from the moment the NSA has refused the autorisation
(**) Timeline starts from the receipt of the appeal from the applicant
(***) Timeline starts from the request of the appeal body to ERA for an opinion

Stage 7 - Processing the application for authorisation – Substage 1: Appeal



R: Recommendation 2011/217/EU
 ID: Interoperability Directive 2008/57/EC
 CSM: CSM Regulation 352/2009

Legal option

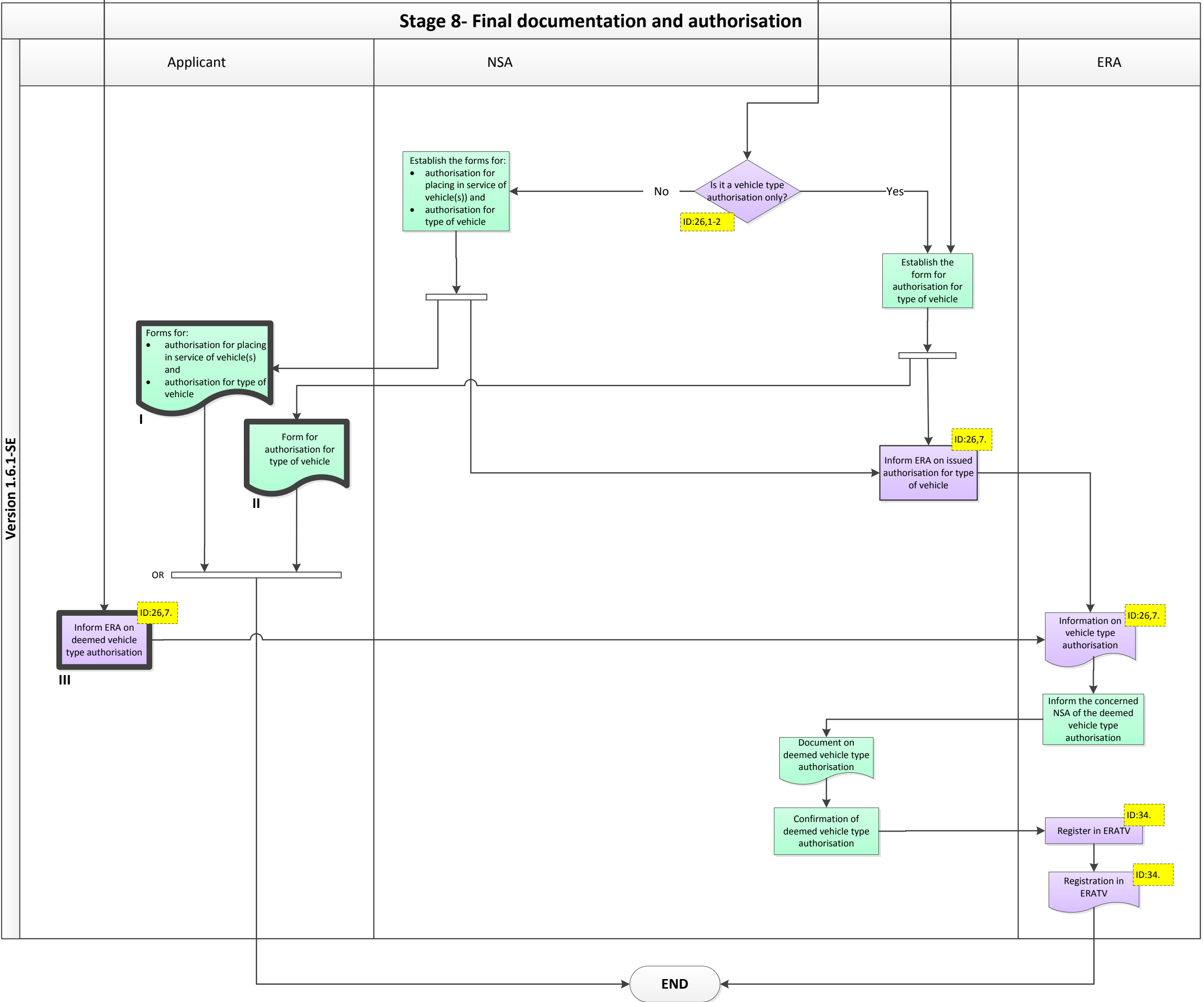
Non mandatory/
 Common practice

End of stage 7
 Deemed
 Authorisation

End of stage 7 Issued
 Authorisation

End of stage 1 for
 extension of type
 validity

Stage 8- Final documentation and authorisation



Version 1.6.1-SE