

RSC-G-032-A Guideline for the Process of Authorisation for Placing in Service (APS) of Light Railway Subsystems

Guidance for RSC Inspectors, Railway Organisations and other Applicants for APS

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1 Introduction

This Guideline is intended to give guidance and explanation on the related Irish and European legal provisions for the Authorisation to Place in Service (PIS) of **New and Altered (Upgraded/Renewed)** Light Railway Infrastructure, Light Railway Control Command and Signalling Equipment, Light Railway Energy Supply Equipment and Light Railway Rolling Stock.

This guideline is based on the requirements of the Railway Safety Act 2005 as amended by SI 61 of 2008 and SI 444 of 2013 and the Railway Safety Directive 2004/49/EC(RSD). Note: While the RSD does not legally apply to Light Rail, it is seen by the RSC as an important guidance on safety management for any form of rail operation.

This guideline is applicable to all parts of the Light Rail Network in the State and includes the processes for

- assessing the technical compatibility of subsystems with the system into which they are being integrated,

- assessing the safe integration of subsystems in accordance with the spirit of Articles 4(3) and 6(3) of Directive 2004/49/EC.

- checking, before subsystems are placed in service, that the requirements for operation and maintenance have been identified.

Term / Meaning Abbreviation APS Authorisation for Placing in Service (by RSC) Applicant The organisation applying for APS by the RSC. ASPSC Application Specific Project Safety Case Command, Control and Signalling, Onboard CCO CCT Command, Control and Signalling, Trackside ENE Enerav Generic Application Safety Case GASC Generic Product Safety Case GPSC HR Hazard Record Independent Assessor according to RSA 2005 (Providing an Independent IA Assessment Report on the full scope of the project safety management activities) IM Authorised Infrastructure Manager to RSD INF Infrastructure Independent Professional Review, providing independent assessment IPR reporting on certain parameters within the scope of a project, in accordance with RSC Guidelines. ISA Independent Safety Assessment, providing Assessor reporting as defined in EN50126-1/EN50126-2/EN50128/50129 NSA National Safety Authority A metro, tramway or other light rail system (S.I. 444 of 2013) RO RSA Railway Safety Act 2005, including Amendments Railway Safety Commission (Irish NSA) RSC 2004/49/EC Railway Safety Directive, including Amendments RSD RST **Rolling Stock** Certified Railway Undertaking to RSD RU Safety Case, (where this term is used, it is understood to have meaning from SC EN50126, and not the meaning of a 'Railway Undertaking Safety Case' as defined by RSA (which is equivalent to an SMS to RSD). SCM Safety and Compliance Matrix SP Safety Plan **Technical File** Documented evidence of all compliance and safety requirements V&V Verification and Validation as defined by EN 50126-1/-2, EN50128, EN50129. This may include activities of Testing and Commissioning.

2 Abbreviations and Definitions

3 References

RSD	DIRECTIVE 2004/49/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004(Railway Safety Directive) + related amendments
2008/110/EC	(amendment to RSD)
RSA	Railway Safety Act 2005 + related amendments (SI 61 of 2008 and SI 444 of 2013)
EN 50126-1	Railway applications – The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS) – Part 1: Basic requirements and generic process
EN 50126-2	Railway applications – The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS),- Part 2: Guide to the application of EN 50126-1 for Safety
EN 50128	Railway applications- Communications, signalling and processing systems – Software for railway control and protection systems
EN 50129	Railway applications – Communication, signalling and processing systems – Safety related electronic systems for signalling
ISO 17020	Conformity assessment – General criteria for the operation of various types of bodies performing inspection
ISO 17021	Conformity assessment - Requirements for bodies providing audit and certification of management systems (ISO/IEC 17021:2011)
ISO 17025	General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)
ISO 9001	Quality management systems - Requirements (ISO 9001:2008)

4 Definitions: Light Railway System, Subsystems, Parameters, Vehicle

4.1 Light Railway System, Subsystems

Similar to the 'European Rail System' the 'Light Railway System shall be segmented into a number of predefined 'Subsystems'.



4.2 Parameters

Subsystems are further broken down into Parameters.

S	ubsystem XXX	
	Parameter 1	
	Parameter 2	
	Parameter 3	
	Parameter 4	

For list of parameters for placing in service light rail infrastructure, energy and command-control subsystems see RSC-G-033-Annex 1.

For list of parameters for placing in service light rail rolling stock subsystems see RSC-G-016 – Annex 1

The applicant promoting the APS Project must also investigate if due to the specific design solutions and operational concepts additional Parameters may need to be added to the Project related

Parameter list. The same applies, if the RSC Parameter lists are considered to not completely covere all safety related aspects of a design.

5 Placing in Service Light Railway Systems

Current Irish and European legislation provides for a large number of variants relating to the concept of APS. For the light railway system the applicable legislation is the Railway Safety Act 2005 including amendments. The applicant must follow a structured and regulated process when placing in service new or modified structural subsystems.

To avoid inconsistencies in the definition and handling of APS projects, the previously used Letters of Acceptance of New Works Assessment or New Rolling Stock Assessment (RSA 42+43) will in future be termed:

- RSA-APS-NW (Authorisation for Placing in Service of New Works according to RSA)
- RSA-APS-NRS (Authorisation for Placing in Service of New Rolling Stock according to RSA)

The concept of Subsystems and Parameters shall be applied to RSA-APS projects.

6 Compliance and Risk Management within PIS projects

6.1 SMS of Railway Organisation (RO)

Irish legal provisions require ROs as duty holders to ensure the safety of their activities. (RSA Reg.36, see for guidance also RSD Art.4(3) in combination with RSD Art.6(3) and)

It is a legal obligation that ROs install a structured SMS, have this SMS certified/authorised as suitable for operating safety related railway activities by the RSC and fully comply with this SMS at all times.

In relation to those activities of an RO which are connected to PIS of New or Altered (Upgraded/Renewed) Subsystems, the RO SMS must ensure that all relevant legal requirements relating to that project are identified and satisfied. These requirements can at large be separated into:

- Compliance activities and
- Safety management activities.

6.2 Project SMS

The typical format of managing PIS of New or Altered (Upgraded/Renewed) Subsystems is that of a project SMS

The Project SMS needs to mirror all relevant SMS provisions of the RO SMS.



The purpose of the Project SMS is to reduce the incidence of safety-related human errors throughout the life-cycle, and thus minimise the residual risk of safety-related systematic faults. It shall also ensure that all activities are in full compliance with all Irish or European legal requirements.

If the Project SMS is in parts not performed by an RO, it is highly recommended to seek close cooperation with that RO that will place the Subsystem in service.

6.3 Requirements for Compliance activities within Project SMS

6.3.1 The Applicant must demonstrate evidence that the new or modified Subsystem is **technically compatible** with the existing Light Railway System.

6.3.2 The Applicant must demonstrate evidence that the new or modified Subsystem will be **safely integrated** into the existing Light Railway System.

6.3.3 The Applicant must demonstrate evidence that the new or modified Subsystem will comply, where applicable, with the **relevant** Irish and European legal provisions.

6.3.4 The RO must demonstrate that as part of the intended PIS all applicable **Technical** standards, Operational and Maintenance standards and other Prescriptive Conditions have been identified, implemented and monitored for compliance.

6.3.5 The RSC may need to place conditions on an APS to ensure that permanent compliance with the above mentioned requirements will be maintained.

6.3.6 In case of any under-fulfilment of these requirements, the RSC may have to deny APS until full compliance is demonstrated, or may provide conditional APS based on a plausible corrective action plan submitted by the applicant.

6.4 Requirements for Safety Management activities within Project SMS

6.4.1 The Project SMS must ensure that as part of the PIS Project risks are managed in line with the requirements derived from a certified RO SMS. It is considered to be good industry practice to apply EN50126-1/-2, EN50128, EN50129, EN50159-1/-2 when establishing the project SMS.

6.4.2 The Applicant must demonstrate evidence that the new or modified Subsystem has been designed, constructed and installed in such a way as to meet the requirements of the RSA.

6.4.3 The Applicant must demonstrate evidence that the new or modified Subsystem will be **safely integrated** into the Light Railway System and that **safety related provisions for operation and maintenance** have been established.

6.5 Main Activities relating to Compliance and Safety Management

For any Project the following activities must be performed:

General Project Management Activities

- G1 based on technical and geographical project scope the correct type of APS process must be initiated,
- G2 a competent project organisation must be established,
- G3 all affected Subsystems and Parameters and their Interfaces to the Light Rail System must be identified.

Compliance Activities

- C1 all relevant compliance requirements must be systematically and comprehensively identified,
- C2 compliance measures must be implemented,
- C3 compliance measures must be evidenced and assessed,
- C4 corrective actions must be taken if non-compliance is found.

Safety Management Activities

- S1 a Safety Plan shall establish a competent Project Organisation, life cycle phases for the Project SMS and SMS activities for the various phases of the Project Life Cycle
- S2 all relevant Hazards and related Risks must be systematically and comprehensively identified and evaluated,
- S3 Safety Requirements must be derived from the initial risk evaluation,
- S4 safety measures must be implemented,
- S5 safety measures must be verified and validated, independently assessed, evidenced and monitored,
- S6 corrective actions must be taken if non-compliance is found,
- S7 residual risk must be assessed and found to be acceptable for safe light rail operation,
- S8 a hazard record must document close out of hazard and risk related activities,
- S9 a project safety case must summarise the project related SMS activities and any application conditions

6.6 RO duties

ROs are the primary duty holders to ensure railway safety.

All other stakeholders defined by Irish and European legislation or SMS concepts are either:

- contractual partners to them (Maintenance-Workshops, Supplier) supporting their activities. In this case ROs remain fully responsible and must ensure that they make suitable contractual arrangements and exercise suitable supervision of their contractors in order to extend their responsibilities onto their contractual partners.

competent Experts/Organisations performing an independent activity of assessment or supervision (e.g. ISA, V&V, NSA, IA, IPR) in order to evaluate or supervise the effectiveness of the activities of the RO and their contractors. In principle the RO must define the required scope and suitable level of independence and competence of such Experts/Organisations. This must reflect the level of critically of the activities and must also consider current industry standards such as EN 50126-50129 and ISO 17020, 17021 and 17025. In a number of cases however legal provisions or RSC guidance require certain minimum levels of independence or competence (e.g. IA, IPR)

6.7 Relationship between Compliance and Safety Management elements

Compliance requirements are mainly derived from legislation in the areas of:

- Safety,
- Health,
- Environmental Protection,
- Technical Compatibility,
- Reliability and Availability.

Due to the inherent relationship of the Requirements for Safety, Health and Environmental Protection and to a lesser degree Technical Compatibility, Reliability and Availability to any Safety Management activities, it becomes obvious that a large overlap exists between the Compliance activities and Safety Management activities.

In order to avoid unnecessary duplication of work and potential contradictions between the need for compliance and the outcome of any safety management activities, it is highly recommended, that both elements are addressed as an integrated Project Safety Management Approach. This guidance assumes that the term Project SMS includes all activities relating to both Compliance and Safety Management.

7 PIS Project SMS Activities

All PIS project related SMS activities must be performed in line with the principles of a certified RO SMS and the principles of EN 50126-50129.

7.1 Activity G1 – Initiation of APIS process

Depending on the project scope, the applicant must apply for either an RSA-APS-NW or an RSA-APS-NRS

The required APS variant shall be identified within the SP.

Please note, that only an Application Specific Project Safety Case may be used to receive APS.

7.2 Activity G2 – Establishment of competent project organisation

The information on roles and responsibilities, staff competence and project organisation shall be supplied within the SP. This must include at least a Project Manager and a Project Safety Manager (based on individual competence and complexity of Project, both tasks can be performed by the same person). Other roles are defined by Irish legislation or RSC Guidelines.

All applications for PIS should in principle be done by a certified RO which can avail of an SMS. In the stages 1 to 3, it is however acceptable, that the Approval process is managed/ prepared by a

representative (e.g. the Supplier). For the Stages 4 to 6 an Application to test/operate in a life Light Rail environment can only be granted to a certified RO with an established SMS.

7.3 Activity G3 – identification of all affected Subsystems and their Parameters

7.3.1 Sub Systems

The following table provides clarification on Sub Systems:.

RSA – references	Sub Systems of Light Rail System (IOD Annex II)	
New Works - Infrastructure	Structural Subsystem Infrastructure	
	Structural Subsystem trackside Control - Command	
	Structural Subsystem Energy	
	Functional Subsystem Operation	
	Functional Subsystem Maintenance	
New Rolling Stock	Structural Subsystem Rolling Stock	
	Structural Subsystem onboard Control - Command	
	Functional Subsystem Operation	
	Functional Subsystem Maintenance	

To avoid inconsistencies in approach, the structure of any RSA-APS application must use the Subsystem structure indicated in the table above.

7.3.2 Parameters

The level of Sub System is a high level grouping only and must for practical engineering work and for practical SMS activities be further elaborated into Parameters.

The RSC publishes separate guidance containing lists of Parameters, relating to each Sub System. All Parameters related to the project scope must be identified and managed by the Project SMS.

Sub Systems of Light Rail System (IOD Annex II)	RSC Guidance on Parameters
Structural Subsystem Infrastructure	RSC-G-033
Structural Subsystem trackside Control - Command	RSC-G-033
Structural Subsystem Energy (ENE)	RSC-G-033
Functional Subsystem Operation and Traffic Management	RSC-G-033
Functional Subsystem Maintenance	RSC-G-033
Structural Subsystem Rolling Stock	RSC-G-016
Structural Subsystem onboard Control - Command	TBD
Functional Subsystem Operation and Traffic Management	RSC-G-016
Functional Subsystem Maintenance	RSC-G-016

7.3.3 Interfaces between Parameters or to external parties

Interfaces between Parameters or to external systems or parties must be systematically identified and managed within all Parameters affected by that interface.

7.3.4 Documentation

A list of project related Subsystems and Parameters must be created and referenced within the SP. If more affected Parameters are identified during the course of the project, these must be added.

Note: Preparation and maintaining of a SCM according to Annex 4 is considered to satisfy this task.

7.4 Activity C1 – identification of compliance requirements

Based on

- the project scope,
- the required type of APIS,
- the nature of affected Subsystems,
- the affected Parameters,
- the affected Interfaces and,
- the project timeline and schedule,

all compliance requirements must be identified.

The scrutiny shall cover at least RSA and any applicable EU legislation (e.g. the New Approach Legislative Framework). The RSC will be able to provide guidance on current compliance requirements.

For each Subsystem and Parameter (including Interfaces) identified under activity G3 the relevant Compliance Requirements shall be systematically listed.

It is highly recommended to organise this list according to the RSC lists of Parameters. This list should be the starting point of a Project Safety- & Compliance-Matrix (see Annex 4).

7.5 Activity C2 – Implementation of compliance measures

The Change must be designed and implemented in a way that enables compliance with all Compliance Requirements to be achieved. The RO must ensure this by their own activities as well as by the activities of their suppliers/ contractors.

7.6 Activity C3 – Evidencing and assessing of compliance measures

Evidence of Compliance must be documented in the format of a Technical File, presenting all functional-, technical-descriptions, design drawings and part lists, simulations, calculations, test procedures, test results, material certificates, etc. as relevant for the assessment of compliance.

The evidence must be self explanatory and understandable for an expert in the area.

The compliance for all requirements must be assessed.

Any assessment process shall follow ISO EN 17020, any auditing of management systems shall follow ISO EN 17021 any testing activities shall follow ISO EN17025 and any Certification Process shall follow ISO EN 17065.

In order to ensure completeness of the supplied evidence against the Compliance Requirements, the evidence shall be referenced within the Project Safety- & Compliance-Matrix (see Annex 4).

7.7 Activity C4 - Corrective action on non-compliance

If any non-compliance is found during the course of the project, corrective action must be taken until compliance is achieved.

7.8 Activity S1 – Safety Plan

The Safety Plan shall describe the Project SMS, project organisation, processes and activities that will be employed in the project development and how the Project Safety Case will provide documented evidence on the safety of the project. Each project must provide at least one Project Safety Manager. The SP and the Project SMS shall respect the requirements of EN 50126-50129, in

co-ordination with those requirements derived from a certified RO SMS. The extension of the Project SMS to Sub-contractors, Suppliers and other parties involved with any safety related activity in the project must be managed by the Project Safety Manager. This may include subcontracting of certain SMS activities or interfacing with the sub-contractors or suppliers own SMS activities.

The SP shall be developed in accordance with Annex 1 of this Guidance, and updated for each stage as necessary

7.9 Activity S2 – PHA, Hazard Record, Risk Evaluation

Using the list of project related Subsystems, Parameters (and associated Interfaces) (Activity G3) as an initial starting point, all relevant Hazards and related Risks must be systematically and comprehensively identified and evaluated.

Further hazard identification shall be informed by expert-work-shops, checklists, experience from similar projects, FMECA, or other suitable tools until all conceivable hazards have been considered.

This shall be documented within the Project Hazard Record. The Hazard Record shall respect the requirements of EN 50126-50129, in connection with those requirements derived from a certified RO SMS (see Annex 2).

7.10 Activity S3 – Safety Requirements Specification

Based on hazards and the proposed safety measures to control these hazards within the Hazard Record, the Safety Requirements Specification shall be established. Care must be taken in order to coordinate this activity with activity C1 on the identification of compliance requirements. Contradictions between Safety and Compliance Requirements are not acceptable and must be resolved.

The Safety Requirements Specification shall be documented. This should be done within the Project Safety- & Compliance-Matrix Annex 4).

7.11 Activity S4 – Implementation of Safety Measures

The change must be designed and implemented in a way which enables compliance with all Safety Requirements to be achieved. The RO must ensure this compliance by their own activities as well as by the activities of their contractors / suppliers.

7.12 Activity S5 – Independent Assessment, Safety Evidence and ongoing Monitoring

The RO must invite competent Experts/Organisations to perform an independent activity of assessment or supervision (e.g. ISA, V&V, NSA, IA, IPR, self monitoring/auditing by RO) in order to evaluate or supervise the effectiveness of the activities of the RO and their contractors /suppliers.

In principle the RO may define the required scope and suitable level of independence of such Experts/Organisations. This shall reflect the level of critically of the activities and current industry standards such as EN 50126-50129. In a number of cases however legal provisions or RSC guidance require certain minimum levels of independence or competence. The independent assessment must in all cases be evidenced by an assessment report.

Any assessment process shall follow ISO EN 17020, any auditing activities ISO EN 17021 any testing activities shall follow ISO EN17025 and any Certification Process shall follow ISO EN 17065. Where applicable, other requirements shall be respected (e.g. RSA)

Safety Evidence must be documented in the form of a Technical File, presenting all functional-, technical-descriptions, design drawings and part lists, simulations, calculations, test procedures, test results, material certificates, etc. as relevant for the assessment.

Evidence to be provided in the format of a logical and systematic document controlled suite of documentary evidence. The evidence must be self explanatory and understandable for an expert in the area.

The RO must indicate the intended activities to monitor the safety behaviour of the change. This shall be documented within the SP and Safety Case.

7.13 Activity S6 - Corrective action on non-compliance

If any non-compliance with Safety Requirements is found, corrective action must be taken until compliance is achieved.

7.14 Activity S7 – Acceptance of residual risk

After implementing and independent assessment of a safety measure the RO must evaluate the residual risk of the related hazards. This must be done in line with the risk acceptance principles of a certified/authorised RO SMS and principles of EN 50126, and RSA. The residual risk must be acceptable for light rail operation.

This must be documented within the Hazard Record. (see Annex 2)

7.15 Activity S8 – Hazard Record

A project related Hazard Record must be prepared in line with the principles of EN 50126-50129.

This must demonstrate an evaluation of all residual risks to be acceptable for safe railway operation. Any Application Conditions must be identified, documented and applied.

The Hazard Record must comply with Annex 2 to this RSC Guidance.

7.16 Activity S9 – Project Safety Case

A project related Safety Case must be prepared in line with the principles of EN 50126-50129. The project safety case must summarise the project related SMS activities.

The Project Safety Case should be based on a staggered approach of Generic Product Safety Case, Generic Application Safety Case and Application Specific Project Safety Case. Whether GPSC or GASC are not used is usually depending on the degree of expected further use of the Generic Product or its Generic Application in further projects.

For any operation (including test and interim operation) on the Light Rail System an Application Specific Safety Case is required.

Each Safety Case must comply with Annex 3 of this Guideline.

RSA Reg.42 and 43 require the preparation of a Safety Assessment of New Works (NWA) or a Safety Assessment of New Rolling Stock (NRSA). An Application Specific Project Safety Case developed in accordance with EN 50126-50129 and this Guidance is considered to satisfy this requirement.



Relationship between Safety Plan, Hazard Record, Safety-& Compliance-Matrix, V&V/Assessment/Audit-Reporting and Safety Case.

Graphical explanation of Interfacing between Hazard Record and Safety and Compliance Matrix



8 Application for APIS

8.1 Application for RSA-APIS-NW / RSA-APIS-NRS

Each application to the RSC must be provided in writing in English. It must be accompanied by the project specific SMS documentation in English. This must be developed further from stage to stage, covering eventually all stages and the full scope of the project.

Before submitting any application to the RSC, the applicant in execution of his or her duties must perform a self assessment on the correctness and completeness of the application and the related project specific Safety Case documentation. This must be documented and become attached to the submitted documentation.

In such cases as desired by the Applicant or requested by the RSC a conclusive Independent Assessor Report (according to RSA) – covering the full project scope – must accompany each application.

In such cases as desired by the Applicant or requested by the RSC a conclusive IPR on certain aspects of the project scope must accompany an application.

Please Note: To avoid loss of time or remedial work at the later project stages, it is highly recommended that the Applicant engages in regular project-progress meetings with the RSC and provide draft submissions of selected content of the Safety Assessment documentation to inform these meetings.

The project related safety management activities must result in an Application Specific Project Safety Case (and as far as used, a Generic Product Safety Case and a Generic Product Application Safety Case) according to EN 50126-50129.

If the applicant is obliged to maintain a certified SMS for Railway Operation the relevant provisions of that SMS must also be complied with. Documented evidenced must be available in this regard.

The Application must be provided to the RSC in a staged approach as indicated in the table overleaf:

Table of Stages relating to Application for RSA-APIS-NW / RSA-APIS-NRSRSA-APIS

Stage	NWA-	NRSA-	Typical activities at	Documents to be submitted
1 Concept	Application NWA Application for Concept Stage	Application NRSA Application for Concept Stage	After performing general concept studies or feasibility studies and prior to	- SP for Concept Stage
2 Preliminary Design	(Optional, not mandatory for NWA: NWA Application for Preliminary Design Stage)	NRSA Application for Preliminary Design Stage	After evaluation of tenders and preliminary decision on functional and technical design and prior to awarding a contract for execution of any work.	- SP - HR - SCM
3 Overall (detailed) Design	NWA Application for Overall Design Stage	NRSA Application for Overall Design Stage	After awarding a contract for execution of work, after detailed overall design has been elaborated and prior to production/ building.	- SP - HR - SCM
4 Testing	NWA Application for Testing Stage (if applicable)	NRSA Application for Testing Stage	After production (construction, including, in particular, civil-engineering activities, manufacturing, constituent assembly and overall adjustment) and prior to any Testing in the live Railway System.	 SP HR SCM ASPSC for Testing Stage IA (to RSA) Report (if applicable) IPR report (if applicable)
5 Interim Operation	(Optional, not mandatory for NWA: NWA Application for Interim Operation Stage)	(Optional, not mandatory for NRSA: NRSA Application for Interim Operation Stage)	After principal completion of project specific safety assessment activities (incl. final testing), prior to full close out of open issues and prior to interim operation.	 SP HR SCM ASPSC for Interim Operation IA (to RSA) Report (if applicable) IPR report (if applicable)
6 Operation	NWA Application for Operation Stage	NRSA Application for Operation Stage	After full completion of project specific safety assessment activities and prior to operation.	 SP HR SCM ASPSC IA (to RSA) Report (if applicable) IPR report (if applicable)

9 RSC Assessment & APIS

Upon receipt of a complete and valid application for a stage, the RSC will assess the Application for plausibility and completeness. In doing so, the RSC must consider whether the applicant has demonstrated that the requirements of this Guideline have been complied with.

This will typically be performed by spot-checking of the submitted documentation. If this does not permit a conclusive judgement, the RSC may enlarge the spot-check, request more or updated documentation or may perform audits on the SMS which has been employed for the project.

If it is not possible for the RSC by these activities, to reach the understanding that the applicant has provided a complete and valid application, the RSC must render the submitted application inadequate and the RSC will hand back the application documents to the applicant.

The same applies, if the application includes falsified evidence. In that case the RSC may also be required to take legal action.

If it is possible for the RSC to reach the understanding that the applicant has provided a complete and valid submission, the RSC will issue a related APIS with or without associated conditions.

10 Further Clarification

Further clarification on these Guidelines can be sought from the RSC.