

Assessment of NSA activities in the Office of Rail Regulation

Audit final report

Version Control

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1 TABLE OF CONTENT

1	Table of content	4
2	Executive summary	5
2.1	Overall summary of the conclusions.....	5
2.2	Main observations	5
2.2.1	All three processes	5
2.2.2	Safety certification and safety authorisation	6
2.2.3	Supervision	6
2.2.4	Authorisation for placing in service	7
3	Cross-audit process	8
3.1	Cross-audit process & resources.....	8
3.2	Cross-audit scope & objectives.....	8
4	result of the Cross audit.....	10
4.1	Safety certification and safety authorisation.....	10
4.2	Supervision.....	13
4.3	Authorisation for placing subsystems in service	17
4.4	Conclusions on the business level	19
5	Final conclusion.....	20
6	Confidentiality statement	20

2 EXECUTIVE SUMMARY

This document is the audit final report from the conduct of the audit to the Office of Rail Regulation, within the framework of the NSA Cross-audit Programme. According to the cross-audit manual, the audit scope covered the following 3 processes:

- Safety certification/ safety authorisation;
- Supervision of safety performance;
- Authorisation for placing subsystems into service.

For the conduct of the audit the following documents were followed:

- The Audit Charter, version 1.1;
- the cross-audit manual, version 07;
- the audit protocols, version 13;
- the guidance to the protocols, version 12.

2.1 Overall summary of the conclusions

ORR appears prepared to:

- process applications regarding safety certification/ safety authorisation
- process applications regarding authorisation for placing subsystems into service
- perform supervision of safety performance.

ORR has established procedures and extensive guidance for

1. Safety certification/safety authorization
2. Supervision of safety performance
3. Authorisation for placing subsystems in service

This guidance is available both internal and for the applicants/industry.

The implementation of procedures for all three activities was audited at ORR offices in London, York and Manchester. There was evidence that the procedures apply throughout the ORR organisation.

2.2 Main observations

2.2.1 All three processes

ORR has identified and described procedures to deliver all three activities and related tasks in a structured way. Relevant guidance on how to perform tasks is available for all relevant staff. The implementation of procedures for all three activities was audited at ORR offices in London, York and Manchester. There was evidence that the procedures are transparent and consistently applied throughout the organisation. Furthermore necessary resources, deadlines and milestones to deliver all three activities are in place and internal control is performed on whether these are respected.

For performance of the activities experienced staff are used and the necessary competences to deliver tasks are identified and staff are trained.

Strengths

- ORR has produced (in conjunction with the industry) good and easily accessible guidance documents for both applicants and ORR staff dealing with the different processes. They provide detailed information of the requirements and the way the application will be subject to

assessment.

- ORR co-operates well with applicants working with them to find new ways of doing things and keeping them informed on future developments
- ORR encourage stakeholders to adopt best practice
- The processes are consistently applied throughout the organisation
- ORR has performed several evaluations involving stakeholders
- ORR has very detailed competence requirements for inspectors carrying out inspections and an SMS audit/inspection. Inspectors are trained on inspection and audit techniques and also on what constitutes an effective SMS.

Issues for possible improvements

- ORR has developed a CMS that partially covers ORR staff undertaking SCA/SP. ORR could consider developing specific competency requirements for the different roles within the SCA/SP/APS processes. This should include engineers involved in these processes.
- ORR should consider having a consistent method of hand over when the account holder changes. The audit team said that there were 2 different cases of hand over: in one case there is overlapping of 4 months, whereas in another case there was no overlapping at all. The new account holder who assessed the application for the safety certificate renewal was not informed about the remedial actions the RU has done after an accident which took place some months before the application of the certificate renewal.

2.2.2 Safety certification and safety authorisation

Strengths

- ORR has written procedures which applies in its organisation;
- ORR has detailed manuals detailing what is expected of applicants and inspectors
- ORR has published their internal assessment procedure on their website
- The use of templates during the assessment process helps ORR to keep track of key decisions

Issues for possible improvements

- The use of the “ROGS assessment check list” & “the assessment plan calculator” help the Assessment Managers to easy monitor deadlines and take immediate action when required and ORR should consider making these forms mandatory
- Procedures are not up to date after the restructuring of ORR & change of IT systems, although there is a project running at the moment to review procedures

2.2.3 Supervision

Strengths

- ORR performs planned supervision and encouraging excellence by applying the Railway Management Maturity Model (RM3 model). This model is used to assess an organisation’s ability to achieve excellence by controlling its safety risks.

Issues for possible improvements

- ORR should consider clarifying and explaining in their manual how the results from the supervision activity are taken into account during the reassessment of a safety certificate/ safety authorisation
- ORR has a system interface risk team as part of its planning team to ensure the interface risks are covered across the Network Rail and Transport Undertaking teams. ORR should review this process to see if it is adequately dealing with system safety issues. ORR has a System Interface risk team. That team’s role is to look at risk at all interfaces, a key priority is looking at Level Crossing risk, but it does cover other interface risk areas. However ORR should consider

evaluating whether, separating Network Rail and Transport undertakings work into discrete units, poses risks to supervising system safety issues and consider improving working arrangements on system safety issues between the different units in a systematic way.

2.2.4 Authorisation for placing in service

Strengths

- ORR expects industry to comply with a common format developed through amendment to the NB Rail RFU on the structure of the technical file which is a pan-European requirement.
- ORR has developed a checklist to ensure that all the required documentation for On-board GSM-R authorizations has been submitted.

Issues for possible improvements

- ORR should consider introducing procedures and decision making criteria for identifying a substantial risk in case of APIS for a non TSI conforming vehicle.
- ORR should consider having a documented process to ensure continuous improvement of the APIS activities.
- There is no process securing a link between post APS and Supervision activities, e.g. how to incorporate supervision of projects that have been awarded an authorization for placing in service. ORR commented here that the CSM SP is a key issue. Audits from engineering point of view and from SMS point of view should be part of their strategy.

3 CROSS-AUDIT PROCESS

3.1 Cross-audit process & resources

The procedures of the Cross-audit Programme manual have been followed during the whole audit process. The duration of the audit is October 2011 – November 2012. The key steps of the procedure are given here:

- The request for establishment of communication was sent on 13/01/2012;
- The NSA appointed the contact person on 18/01/2012;
- The confirmation letter to conduct the audit was sent on 19/10/2011;
- The request for submission of documents was made on 29/11/2011;
- Documents were submitted on 19/12/2011;

The Kick-off meeting took place on 21/05/2012.

The on-site audit lasted 4 days: 18/06/2012 – 21/06/2012. The on-site audit activities included conduct of interviews, review of selected process documentation and cases related to scope of the audit. Additional meetings with the auditee and internal audit meetings were carried out. Meetings with the auditee included entry and closing meeting as well as ad hoc meetings for briefing of the auditee about the progress of the audit.

During the 4 days of the on-site audit audits was carried out in the following departments:

- Railway Safety
- Railway Planning & Performance

and at the following locations:

- ORR Head Office, London
- ORR Office, Manchester
- ORR Office, York

All interviews but one took place as planned. One interview planned at the ORR office in Manchester was cancelled due to absence of the person planned to be interviewed. Conducted interviews are listed in annex IV.

For the entry meeting and closing meeting the following documents were created:

- Agenda for the entry meeting;
- Agenda for the closing meeting;
- Minutes for the entry meeting;
- Minutes for the closing meeting;

3.2 Cross-audit scope & objectives

The audit took place within the pilot audit cycle of the NSA Cross-audit Programme. The objectives of the audit, as described in the Cross-audit Charter is to:

- evaluate delivery by NSAs of their duties and responsibilities set out in Directives 2004/49/EC and 2008/57/EC;
- exchange knowledge and good practice on NSA processes to facilitate the harmonisation of decision-making criteria as foreseen by Article 17.4 of Directive 2004/49/EC;
- identify issues faced by the NSA when applying the requirements of the EU legislation, and possible solutions to keep meeting the requirements of Directive 2004/49/EC.

The scope of the audit is to assess 3 processes against the audit protocols:

- Safety certification/ safety authorisation;
- Supervision of safety performance;
- Authorisation for placing subsystems in service.

The audit protocols were used to assess the three processes. The protocols are divided into the three audited activities.

Each activity is split into a number of stages, which cover the process from start to finish. The protocols have three key elements:

- The requirement identifiers which are the individual requirements for each activity;
- A status for each requirement identifier, which indicates at which degree there is sufficient evidence that the requirement identifier is fulfilled;
- A comment for each requirement identifier which is a short summary of key information to support its status.

Each set of protocols is split in 5 levels:

- Purpose achieved (*the desired output is delivered without having identify desired inputs/ outputs, resource requirements, etc*);
- Performance managed (*requirements of inputs/ outputs are identified and reviewed, activities are planned and performance is monitored, responsibilities are defined, resources are identified and are made available*);
- Process established (*a standard process is defined and implemented, the required competencies are identified, personnel performing process is competent, process efficiency is monitored*);
- Process controlled (*measurement results are used to ensure that process performance supports defined business goals*);
- Process improved (*process improvement opportunities are identified based on innovation and good practice*).

4 RESULT OF THE CROSS AUDIT

4.1 Safety certification and safety authorisation

ORR's procedure for safety certification/safety authorization is in line with the steps described in the safety certification/safety authorization protocol. ORR:

- has a system to receive applications for safety certification and safety authorisation;
- undertakes the first screen of applications and checks if all the required information is included in the application;
- undertakes the initial assessment to determine whether they are deficiencies in the content of the application serious enough for it, not to be worth spending further time on;
- undertakes the formal assessment to determine compliance against the assessment criteria;
- records and confirms its final decision.

The objectives of the assessment are:

- a) to determine whether the SMS meets the requirements of the national legislation and demonstrates the applicant's organizational capability to operate safely;
- b) to identify points for later inspection after issue of the safety certificate/ safety authorization, during the supervision.

Receive application for safety certification or safety authorisation and first screen of application

ORR provides guidance to the applicants to understand the requirements for a safety certification/safety authorization application in many ways e.g.:

- a number of documents are available on the web site:
 - the relevant legislation and guidance to the requirements of the legislation "A guide to ROGS";
 - the "assessment criteria for safety certificate and authorization applications for mainline railways". This manual describes each criterion and a summary with a list of evidence the applicant is expected to cover;
 - the "HM Railway Inspectorate safety certificate and authorization assessment manual" is available which provides detailed information on the assessment process.
- the Account Holder informs the applicant on what is expected from the application before the submission of the application. In the cases of a certificate/ authorisation renewal there was evidence that Account Holders had explained to the applicant the changes in the assessment criteria since the previous application.
- during the assessment in case of identified deficiencies the applicant is informed as soon as possible: the lead assessor documents to the applicant what information is required, by making reference to the relevant assessment criterion.
- after the formal assessment a meeting is organized with the applicant where ORR specifies with the applicant what is required by him, agrees with the applicant on what further actions are required and specifies the timeframe for the compliance.

All decisions are recorded in COIN/Mosaic.

The ORR procedure for safety certification/safety authorization assessment sets deadlines for the intermediate steps of the assessment process. The ORR manual foresees "the assessment plan calculator" and the "assessment checklist", which both help the lead assessor and the Assessment Manager (Account Manager) to monitor the progress of the assessment. ORR could not provide evidence that both of these practices are continuously followed in all cases; the "assessment checklist" according to the manual is not

mandatory. There are other means with which the lead assessor informs the Account Manager on the progress of the applications: the monthly meetings. In addition, the audit team was informed that the lead assessor regularly briefs the Account Manager on the progress of an assessment during informal discussions.

ORR should consider making the use of the template "assessment checklist" obligatory. This will enable the Account Manager and ORR organisation better to follow the assessment process of safety certificates/safety authorisations.

At the time of the audit some roles and responsibilities which are mentioned in the assessment manual do not correspond to the current ORR organogram (e.g. Head of Inspection). When updating the manual ORR should ensure that it reflects the actual structure of the organisation. This will define clear roles and responsibilities and avoid confusions during the implementation of the manual.

Initial assessment of the application for deciding on the sufficiency of the application

Currently ORR uses the 3rd version of the "HM Railway Inspectorate safety certificate and authorization assessment manual", the first version was published in 2006. ORR's assessment criteria are in line with Regulations 1158/2010 & 1169/2010. ORR revised the assessment criteria after these regulations came into force in 2011.

The Account Manager is responsible for managing the application. The Account Manager knows the date of an application by monitoring the expiry dates of the safety certificates/ safety authorisations and by information from the Account Holder during his/her inspections and his/her routine contacts with the RU/IMs. When an application is submitted the Account Manager appoints the lead assessor who will undertake the assessment. The lead assessor is responsible for managing all the steps of the assessment. The role of the lead assessor is usually combined with the role of the Account Holder for the specific RU or IM.

The ORR assessment manual makes distinction between major and minor deficiencies, although in the cases which were reviewed there was no such distinction.

Formal assessment of the application

ORR is independent in its decisions of RU/IM/ affected parties. ORR provides the opportunity to the affected parties to make representation to ORR after the submission of an application. The lead assessor collects all the points raised by the affected parties and takes them into account for the assessment.

ORR applications for safety certificates part A and B are in line with Regulation 653/2007. Part A and Part B are assessed and issued together. The assessment of applications for part B certificates is limited to annex III of Commission Regulation 1158/2010. ORR liaises with the NSA Channel Tunnel for part B safety certificates cases.

The interviewees who undertake safety certification/safety authorization assessment have a wide experience in Safety Management Systems, Occupational Health and Safety, auditing experience. Furthermore, in some cases ORR assigns experts who undertake the formal assessment of particular topics of the SMS: for example risk assessment expert, issues related to interoperability, level crossings (this was the case in the renewal of Network Rail safety authorization). The lead assessors who were interviewed knew the latest version of the assessment procedure, have used the templates during the assessment and have participated in a training session in June 2011, after the latest changes of the assessment criteria.

ORR performs quality checks at the end of the assessment. ORR very much relies on the detailed assessment manual, the guidance with the assessment criteria and the competence of the staff undertaking assessment of safety certification/safety authorization applications. The final check includes a review of the entire application, the quality check of the decisions taken in each step and a check if the process has been followed. In one case, a safety certificate which was the first assessment for the lead assessor, there was evidence of quality checks undertaken by the Account Manager at the end of each step of the assessment.

Although the national legislation gives the possibility for ORR to reset the 4 months period after the receipt of supplementary information, it is ORR's policy to meet the four-month deadline (from the end of the

period allowed for representations) without resetting the clock. In the cases which were reviewed by the audit team ORR's final decision was within 4 months of receipt of the application.

Recording and confirmation of final decision

All decisions taken by ORR at the end of each step of the assessment are recorded in COIN/Mosaic (templates: F1S1, F1S2, F2). Furthermore, these templates are also available inside the folder of the application in hard copy. ORR justifies its decisions based on factual evidence from the information included in the application. The lead assessor links each decision to the relevant assessment criterion to ensure applicants understand the reasons for decisions, providing clear reasons why it is not fulfilled and explaining to the applicant what additional information is required. ORR assessment is undertaken at management system level, taking into account the risks, the character and the extent of the operation.

ORR issues safety certificates using the format of the Commission Regulation (EC) No 653/2007. The validity of the safety certificates do not exceed 5 years, the type and extend of operation is clearly mentioned and a unique EU Identification Number is given. The safety certificates are notified to ERADIS database and the safety authorisations to ERA Safety Unit. ORR has replaced all safety certificates which were issued according to Directive 2001/14/EC.

As part of the formal assessment the lead assessor specifies the areas for follow up inspection after issue of the safety certificate/ safety authorisation. These issues are taken into account for the implementation of the supervision plan.

ORR decisions are subject to judicial review. There is a process for appeals on ORR decisions which is made available to the applicants.

ORR is going to act as certification body for the ECM certificates. For that, some preparation has already been made:

- A number of documents are available on its web site:
 - The updated guidance to ROGS,
 - A summary guide for applicants,
 - The assessment criteria and guidance manual,
 - The engineering plans for ECM certificates,
 - The application form.
- The "consultation group for entities in charge of maintenance" workshop has been organized with the sector,
- A trial assessment has been organised,
- At the moment the management of ORR is working to ensure that ORR will have the required resources. A training programme will be organised for the relevant staff.

ORR has an internal auditable procedure related to safety certification/safety authorization with clear steps, the "HM Railway Inspectorate safety certificate and authorization assessment manual" (first published version was in 2006). The procedure covers the ORR policy and principles for assessing an application for:

- Issuing/ amending/ renew/ revoke a safety certificate/ safety authorisation,
- the quality monitoring and improvement arrangements of the assessment process,
- the performance standards, the roles/ responsibilities,
- the assessment process in detail,
- the process assurance and the final decision,
- the notification of the final decision,
- rules for exceptions,
- the procedure for appeals of ORR decisions

4.2 Supervision

Setting up the supervision activity

ORR has developed a strategy (ORR business plan) and plan (annual work plan) for taking forward the supervision activities for checking the safety certificate/authorisation, that the sub-systems are operated and maintained in accordance with the essential requirements including monitoring, promoting, enforcing and developing the regulatory framework. ORR business plan and annual work plan shows how ORR manages its supervision activities. ORR aim to achieve excellence in safety culture and management because it is an essential element of their strategy as they seek to ensure a zero tolerance to industry-caused passenger, workforce and public fatalities, with an ever decreasing overall safety risk. There is also an increased emphasis on occupational health management to ensure the industry's approach demonstrates good practice and also contributes to increased efficiency.

As a key driver of the supervision strategy ORR analyses risks across the GB Railways and set down areas of priority risk in *ORR's strategy for health and safety risks* [<http://www.rail-reg.gov.uk/upload/pdf/orr-safety-risk-strategy.pdf>]. The supervision strategy and plan also takes into account existing information from inspection/audit/certification/authorisation and supervising the interoperability systems and other sources such as incidents and accidents investigations, NIB (Rail Accident Investigation Branch (RAIB)) recommendations, Rail Safety and Standards Board (RSSB) recommendations and the outcomes of their risk model and complaints from the duty holders. The supervision plan is mainly driven through the elements of the SMS i.e. over 5 years ORR plans to inspect all SMS elements. ORR plans its activities using information collected from the safety certification/authorisation assessment process, but not from the authorisation to place into service processes. ORR should consider incorporating supervision of projects that have been awarded an authorisation for placing in service.

ORR has sufficient resources and allocated staff to undertake the supervision tasks and activities. Usually, there are about 2 – 4 inspections/audits of each duty holder per year. There is a significant resource difference between inspections and audits.

ORR supervision activities are prioritised using 3 priority levels (low, medium, high). These levels are established using a risk based approach. ORR also has established internal procedures for agreement within ORR for the supervision plan. ORR has discussed and agreed the priorities with staff involved in the safety certification/authorization assessment, authorisation to place into service and supervision activities to ensure that all key information has been taken into account.

ORR has a method (annual work plan and internal procedures) for deciding how the supervision activity will be developed, including the estimation of required resources. ORR uses its limited resources effectively, so it takes into account the risks of the operators on the network against the available staff, their time and budget. Usually every ORR inspector has about 100 days for supervision activities. There is a time management system, when the supervision plan is planned. Thus, every audit/inspection is defined for a time period and how many working days inspector needs to do the audit/inspection. Inspectors use rolling stock, infrastructure and etc. experts from other ORR departments. Mostly, one inspector is responsible for 2 – 4 duty holders. During the inspection/audit normally there are 1-2 inspectors.

ORR ensures that the supervision plan includes the identification of key risk activities (9 steps program in business plan). ORR has information from the inspections/audits of the RUs/IMs safety management systems (RM3 model, inspection/audit reports and annual strength & weakness reports) which highlights whether they have any concerns on how they are managing the safety risks.

ORR ensures that the supervision activity sets out how the overview of the effectiveness of the regulatory framework will be delivered (business plan). ORR:

- monitors through inspections/audits,
- promotes through guidance/manuals/workshops,
- enforces through prohibitions notices/improvement notices/prosecutions and
- develops the Regulatory framework through reviews and recommendations to the Member State (Department for Transport) on how the regulatory framework can be reviewed.

ORR has an internal method which sets out an estimate of the number of supervision activities in the supervision plan. ORR identifies the numbers of activities and what they relate to (e.g. inspections/audits/NIB recommendations/enforcement/follow up checks). ORR also relates each supervision activity to their key risk activities.

ORR has plans to co-ordinate with other competent authorities such as RSSB and RAIB, the UK National Investigation Body. However, ORR has not developed their co-operation arrangements with other NSAs (except for Channel Tunnel Safety Authority). This cooperation could relate to discussing Part B safety certificates with an NSA who issued a Part A safety certificates and understanding any concerns/issues that have been identified by that NSA (e.g. Eurostar, DB Schenker).

ORR ensures feedback for reviewing the supervision plan. ORR review the supervision plan and take into account any changes that may arise following their supervision activities (e.g. complaints/investigations). Every year ORR looks at RU/IM SMS, ORR business plan, all information regarding particular RU/IM and decides what to audit/inspect during the annual year.

ORR has developed a structured and auditable process for the setting up and agreeing the plan and priorities. ORR has a clear and structured set of processes applied by all the staff. The decision making is consistent, transparent and targeted.

The process should be consistently applied throughout the organisation. The assessment process should be periodically internally reviewed to ensure its continued effectiveness and efficiency. This should also cover whether the process can be followed and ORR undertakes checks to ensure that staff are following it. However, so far the supervision process has not been periodically internally reviewed. Only a line management quality check is done to ensure that staff are following the assessment process. Thus, ORR should consider introducing a formal procedure for reviewing the supervision activities. This notwithstanding ORR is currently developing a quality control programme for supervision activities in their Network Rail unit.

Communicating and delivering the plan

ORR delivers the supervision activity according to the plan. ORR has internal monitoring procedures for ensuring that the supervision activities identified are implemented. There could be changes in the supervision plan because of limited time caused by other responsibilities: investigation, complaint etc. If the supervision activity is not implemented, it is postponed to the next year's supervision plan with higher priority. ORR does actually take the action it said it will do, particularly in ensuring that the safety performance of the railway system is maintained. Mostly the supervision plan is delivered as planned.

ORR is independent in its organisation, legal structure and decision making from the RU, IM and procurement entity.

ORR is free to carry out all its tasks and is granted access to all necessary documents, premises, installations and equipment of RUs/IMs (Health & Safety at Work etc Act 1974). Every ORR inspector has a warrant.

ORR decisions are subject to judicial review (The Employment Tribunals, Courts).

ORR has allocated staff and resources to undertake the supervision task.

ORR undertakes enforcement activity with clear justifiable reasons. ORR has a system (Enforcement Management Model) which determines the decision to take any enforcement action such as enforcement notice and/or prosecutions (ranging from the provision of advice to enforcement notices). Generally if there is an issue, there is dialogue with the duty holder. Mostly inspectors issues improvement notices. Inspectors issue improvement notices regarding compliance with the law provisions (e.g. ROGS). Improvement notices or other enforcement notice usually expire after 3 months.

ORR has decision making criteria explaining how it deals with non-compliances which are publicly available. ORR has information made available to both RUs/IMs on what they can expect following findings of non-compliances and what the time frame should be. ORR expectations and non-compliances are discussed with the duty holder. The inspector decides the time frame for remedial actions, which is a minimum of 3 weeks, maximum – unlimited. Inspector can extend the improvement notice, if there are justified reasons.

If the duty holder fails to comply, then the inspector has to prosecute. Details of non-compliances are written in improvement notices.

ORR undertakes enforcement activity in line with published decision making criteria, including transparency criteria. ORR has a system for making decisions to take any enforcement action, including transparent criteria. In particular any proposed enforcement action is proportionate to the risk.

Stakeholders are clear of what is required of them and what they can expect from ORR. ORR has published and made freely available clear and transparent information on what a RU and IM need to do in relation to an identified risks or safety concern. ORR also keeps records of their advice and requirements to RUs/IMs.

ORR has a structured system for recording and reviewing the supervision activities, how these relate to the risks of the operation and ensuring that safety performance is maintained. ORR has a document management system where they record the supervision activities (Coin, Mosaic).

ORR records communications, meetings, reviews and corrective actions. ORR keeps records of how it communicated with the RUs/IMs (on Coin, Mosaic). In particular, how ORR communicated any necessary and specific corrective action to the RU/IM. ORR has regular 3 – 4 liaison meetings per year with each duty holder.

The quality of ORR action is monitored and reviewed. There is a line management form of quality check of the work/decisions undertaken. This is structured but relates to checking only the intermediate outputs instead of monitoring the process as such. Also there was a quality check (peer review) of issued improvement notices by inspectors to duty holders.

There are means for applicants to appeal against any decision made by ORR and this is communicated to the RU/IM. ORR appeals process is a national legal requirement. ORR informs the RU/IM what subsequent action is taken in relation to the appeal and this is communicated.

ORR uses competent staff. The tasks are undertaken by suitably competent persons with the necessary skills, experience, knowledge and training.

The quality of the outputs & decisions are monitored at key stages. There is a line management form of quality check of the supervision activity and this is followed through from identification of the safety risk/concern through to the necessary action undertaken.

There is guidance for staff on the delivery of the plan. ORR demonstrated that guidance and/or work instructions have been provided to all staff undertaking the supervision activities of what is required of them.

ORR promotes and explains the regulatory framework. ORR has their system for promoting the regulatory framework in cooperation with the Department for Transport.

ORR provides communication to stakeholders on the wider objectives of supervision. ORR communicates the objectives of their supervision activity to RUs/IMs i.e. what they are trying to achieve and how.

ORR does not undertake Assessment Body for CSM on risk assessment or DeBo (assessing NNTRs for Interoperability). Thus, there is no potential for a conflict of interest. However, ORR undertakes other activity which is not part of the Safety Directive – ORR is the Regulatory body, but decisions within ORR are made separately.

Outcomes of the supervision plan

ORR shares results with the RU/IM (verbally or in writing) regarding the effectiveness of their SMS. ORR informs RUs/IMs of its review of their SMS. ORR is encouraging RUs/IMS to adopt best practice and achieve excellence by applying the RM3 model (management maturity model, good practice). ORR could also consider indicating SMS criteria requirements in ORR RM3 inspection/audit reports to duty holders in order to clarify cross reference between RM3 and SMS.

Sufficient resources are available and used. ORR has allocated staff to undertake the task and this is part of their job description.

ORR deals with areas of non-compliance using its decision making criteria after the RU/IM has developed and implemented action plans to remedy non-compliances. ORR also monitors the corrective actions that

the RU/IM has undertaken. In particular, any necessary changes to the RUs/IMs SMS (RM3 audit/inspection). ORR also does follow up inspections after RU/IM implement action plans to remedy non-compliances. Duty holders are informed that they complied with the requirements of improvement notices. All non-compliances of RU/IM SMS are addressed immediately in the particular SMS audit.

ORR has an overview of overall safety performance in the Member State. ORR monitors the overall safety performance of the rail network.

The quality of the outputs & decisions are monitored at key stages. There is a line management form of quality check of the supervision activity and this includes ensuring that identification of a safety risk/concern is followed through to checking that necessary action is undertaken.

Reviewing supervision activities

ORR assesses the suitability and sufficiency of the supervision activities. ORR reviews and revises their supervision activities in particular to ensure that action is targeted at the areas which create the most risks. Sufficient resources are available and used. ORR has allocated staff to undertake the task and this is part of their job. ORR also has sufficient resources to undertake the tasks.

ORR has a system for checking the outcomes of each of the activities i.e. whether the activities have had the desired result in maintaining the safety performance. There is an internal process for making changes based on the results. The outcomes of each of the supervision activities are reported in the audit/inspection reports and in the annual strength & weakness reports of supervision activities of particular RU/IM.

There is a process for ORR to make any necessary recommendations to the Member State to overcome any deficiencies in the regulatory framework. ORR communicates to the MS any problems that they have found with the current regulatory framework and what improvements, if any, should be made. The Department for Transport is responsible for drafting national legislation, but ORR is always involved in consultation processes.

Information shared between NSAs should be taken into account. ORR could not provide evidence of how they systematically take into account any information from other NSAs, in their supervision activities including revising the types of activities if risks have increased.

There is a means by which relevant information is taken on from stakeholders. ORR systematically takes into account any complaint from RUs/IMs or any risks/problems identified by them if they can adversely affect the safety performance of the rail system. Stakeholders concerns are addressed during the supervision. Also there is an Advisory group established between ORR and the stakeholders which meets twice per year.

The quality of ORR action is monitored and reviewed. There is a line management form of quality check of the process review and this includes ensuring that identification of a concern is followed through to checking that necessary action is undertaken.

Review should be undertaken of all supervision activities, including both planned and unplanned to assess whether resources are correctly allocated. ORR has a clear and structured process for how it undertakes the review of all its activities, including taking into account any risks identified during the supervision activity. ORR also provided evidence of how they allocate resources if there are additional areas which require effort.

Recommendations and/or lessons learned from accidents are taken into account and implemented in the revised supervision plan. ORR takes into account recommendations and lessons learned from accidents both from recommendations from NIB and notifications from RUs/IMs.

Linking supervision plan to the reassessment

The results from the supervision activity should be linked to the reassessment of safety certificates/ the issuing of authorisations and the prioritisation of those activities. ORR does not take into account any information on the safety performance of the RUs/IMs into any amendment or replacement of safety certificates/authorisations. ORR does the reassessment only by checking the SMS through the assessment

criteria (EU regulation 1158/2010 and 1169/2010). All results from the supervision activities are dealt at that time of the audit i.e. then the reassessment is done, SMS is completely checked in supervision and all necessary changes in the SMS are implemented during audit of SMS.

There is a means of communication between the staff responsible for supervision and those for assessment. ORR staff involved in the different activities share key information which could affect the decisions in the activities. In most cases, the same person is responsible for assessment of SCA and taking the SP activities. However, ORR should consider having a consistent method of hand over when the account holder changes. There were 2 different cases of hand over observed: in one case there was overlapping of 4 months, whereas in another case there was no overlapping at all. The new account holder who assessed the application for the safety certificate renewal was not informed by previous account holder about the remedial actions the RU has done after an accident which took place some months before the application of the certificate renewal.

There is a process for recording communications, meetings, reviews and corrective actions. ORR has records of how it managed communications with the RUs/IMs. In particular, how ORR communicated any necessary and specific corrective action.

Corrective actions are agreed and closed out. ORR ensures that the corrective actions that the RU/IM has been asked to undertake have been closed out.

ORR should co-operate and co-ordinate with other NSAs, where appropriate. ORR is participating at the NSAs Network meetings, ERA working groups and ILGGRI (informal cooperation of NSAs). However, ORR should consider developing co-operation arrangements with other NSAs in terms of supervision activities. This should cover discussing Part B certificates with the relevant Part A-issuing NSA and understanding any concerns/issues that have been identified by that NSA. It should also cover issues where there are breaches of safety requirements and how any action will be co-ordinated across a number of NSAs or other competent authorities (i.e. those responsible for the health and safety of those who work in the rail sector).

The quality of ORR action is monitored and reviewed. There is a quality check of how successfully supervision activity is linked to reassessment. , although this could be better explained in the ORR manual.

There is a process for applicants appealing against any decision made by ORR and this is communicated to the RU/IM. ORR has an appeal process which is a national legal requirement. ORR informs the RU/IM, what subsequent action was taken in relation to the appeal and how each step is communicated.

4.3 Authorisation for placing subsystems in service

The Department for Transport (Department for Transport) is the policy lead for interoperability in the UK. The Interoperability and Standards Team parallels this role for ORR.

Authorisation for placing in service is regulated in the UK by the Railways (Interoperability) Regulations 2011 No. 3066 (Department for Transport 00416) (RIR).

In the case of major upgrades and renewals it is the role of Department for Transport to decide if and when an authorisation is needed, Department for Transport can consult ORR in this process. Due to different reasons the number of application for authorisation for both infrastructure subsystems and for vehicles are relatively low.

ORR has been given the powers to enforce the RIR and it is Railway Planning and Performance engineers - working with assessing applications for authorisation.

The audit did not include activities outside ORR, thus activities under the responsibility of Department for Transport have not been assessed and is not included in this report.

ORR published the draft of National Legal Framework to facilitate applicants to know about the rules in UK ORR takes part in BeNeFLuCh Geographical Interest Group works whose task is categorization of the national technical rules applicable in APS process.

Receive complete application from the applicant for an authorisation to place into service

ORR has a policy for early involvement in project for authorisation to place into service, this is to avoid surprises and delays caused by the approval process. In the cases reviewed during the audit there was extensive evidence of communication with both the applicant and the notified body (NoBo) in question prior to the actual application.

ORR provides guidance for the applicants in published guidance and in direct communication in the early stages of the project.

The persons involved in the assessment of the applications have had internal training and extensive guidance is available.

Screen of application for authorisation

As a tool to secure a full and uniform level of screening of the applications ORR has developed a checklist for the entire process (Recommendation pro forma for authorisation for placing in service (APIS)). To support this one of the interviewees had developed a checklist to ensure that all the required documentation for On-board GSM-R authorizations has been submitted.

The different authorisation possibilities are defined in RIR, but only a few have been in use until now. All documentation and decisions are registered (COIN/Mosaic).

In the reviewed cases, ORR had been involved at an early stage, securing the application was complete at the time of applying. This, in fact, also provided a very smooth and fast assessment of the applications.

Authorisation to place into service

ORR is independent in its decision making from the contracting entity. This is supported both in the legal status of ORR and the organisation of the authorisation process.

Due to the early involvement the contacting entity is readily informed if further information is needed.

In all the cases reviewed, the decisions taken by ORR were well-argued and proportional.

The time frame for assessment counted from the time of receiving the application to the time for granting the authorisation for placing in service was from 1 day to 4 weeks in the reviewed cases. Generally it only takes a few days, indicating that even though the assessors were busy the allocated resources for this task seemed sufficient.

In all the cases reviewed there was evidence of applying the rules from TSI's and NNTR using the pro forma. There were not, in any of the reviewed cases, signs of demands outside these rules.

ORR does not act as an assessment body for CSM on risk assessment or designated body for assessing notified national technical rules (NNTR).

To facilitate the application and authorisation process ORR has, in association with the industry, encouraged the development of the use of generic technical files through NB Rail and the RFU process.

Additional authorisations to place vehicles into service

RIR contains rules applicable for additional authorisation, but there were not any examples of an application for this.

ORR could not demonstrate that criteria defining a substantial safety risk has been identified.

Recording and confirmation to the applicant of the final decision on authorisation to place into service

The process for finalizing the authorisation for placing in service is documented and followed as intended in all the reviewed cases. This includes the notification to the National Vehicle Register, which is performed by the administrative staff.

Issues that are relevant for supervision activities are identified, but there was no evidence of process or examples that this actually takes place. The quality of the output and decisions are monitored, but the process of authorisation for placing in service is not assessed and evaluated in a systematic way.

4.4 Conclusions on the business level

ORR has established a Competence Management System (CMS). The CMS includes required competences for SCA/SP activities, but not for APS. The competence criteria are taken into account for the selection and recruitment of the ORR staff.

There are training plans in place for all staff and internal training is established e.g. RM3, SMS criteria. The CMS includes annual self-assessment review for all staff. ORR has an IT system for self-assessment questionnaire (good practice). ORR has very detailed competence requirements for inspectors carrying out inspections. So far, there is not a process for the ORR to verify the effectiveness of the CMS.

ORR has established project activities together with the industry e.g. staff from Network Rail come to the ORR for 5 months. When they have accomplished the project, they go back to Network rail. This works also the other way around.

The ORR does not undertake Assessment Body for CSM on risk assessment or DeBo (assessing NNTRs for Interoperability). Thus, there is no potential for a conflict of interest. However, the ORR undertakes other activity which is not part of the Safety Directive – the ORR is the Regulatory body, but decisions within the ORR are made separately.

In matters concerning regulation ORR Interoperability and Standards Team has a close cooperation with Department for Transport, who represent the Member State regarding interoperability. This cooperation ensures that if any non-compliance with essential requirements should be revealed the Commission would be notified.

The three processes should be periodically internally reviewed to ensure their continued effectiveness and efficiency. This should also cover whether the process can be followed and that ORR undertakes checks to ensure that staff are following it. However, so far the processes have not been periodically internally reviewed. Nevertheless, ORR has taken measures to ensure that the 3 processes are applied consistently within its organisation: Line management quality checks are undertaken to ensure that staff are following the assessment process. There have been peer reviews conducted, but there is no formal written procedure for internal audit or other form of high level evaluation of these three processes. This notwithstanding the ORR is currently developing a quality control programme for supervision activities in their Network Rail unit.

ORR is working closely with Department for Transport. The Department for Transport drafts laws, but ORR is consulted.

ORR does reviews of the regulatory framework to remove unnecessary administrative burdens. ORR has consultations with the stakeholders to secure that the legal requirements are reasonable and necessary.

Mostly impact assessment is done and there should be justified reasons whether legal requirements are necessary.

An advisory group has been established and meets twice per year (ORR and stakeholders).

Supervision regularly discussed within the ORR e.g. RM3 findings are reported to the ORR board. Also, there is a Safety regulatory committee.

ORR has a long term vision settled in the strategy that nobody gets killed and health problems and injuries are continuously reduced within the railway. ORR wants industry to be excellent in the management of safety risks and the management of business. For this purpose ORR has developed the RM3 model to assess management capability in the industry. The model is used to evaluate the performance of a company compared to a set of criteria tailored specifically for the railways.

5 FINAL CONCLUSION

Based on factual evidence which was made available during the on-site audit the audit team reaches the following conclusion:

ORR is carrying out its tasks required by the article 16.2 of the Safety Directive in an open, non-discriminatory and transparent way. In particular ORR has a range of procedures and guidance in place to deliver the tasks of a NSA set out in article 16.2 of the Safety directive.

This audit report does not provide a maturity level of each audited process as requested in the cross-audit manual version 07. The audit team believes that a cross-audit is a learning process for both the auditee and the audit team and what is most important is to highlight the strengths of the audited NSA and the scope for improvement items, which will be used by the auditee for further improvement of its processes.

6 Confidentiality statement

The intermediate audit report has been developed for the purpose of the audit of ORR. All the included information should remain confidential within the audit team and the recipients of the report. For this reason, after its revision by the APM, the intermediate audit report is disclosed to the audited contact person. Then, the audited contact person shall submit the report to the recipients of the distribution list, provided by the audited NSA [annex VI].

Table of annexes

Number	Description of the Annexes
I	List of attendants in the kick-off meeting, entry meeting & closing meeting
II	Audit plan
III	Completed cross-audit protocols
IV	List of conducted interviews
V	Communication of the audit interim report
VI	Table with abbreviations

Annex I: List of attendants

The attendants at the Kick-off meeting are listed here [\[KOM\]](#)

The attendants at the Entry meeting are listed here [\[Entry\]](#)

The attendants at the closing meeting are listed here [\[Closing\]](#)

The audit team members are listed here [\[Audit team\]](#)

Annex II: Audit plan

You can see the audit plan here [[Audit plan](#)]

Annex IV: List of conducted interviews

Item	Location	Interviewee	Audit team	Date
Safety certification/authorisation, processes	London	ORR 1	A	18/06/2012
Authorisation for placing in service, processes	London	ORR 2	A1	18/06/2012
Case: Safety authorisation, Infrastructure manager	London	ORR 3	A2	18/06/2012
Case: Safety certification, railway undertaking, freight	York	ORR 4	A1	19/06/2012
Case: Supervision, Infrastructure manager	York	ORR 5	A1	19/06/2012
Case: Authorisation for placing in service	York	ORR 6	A1	19/06/2012
Case: Authorisation for placing in service	York	ORR 7	A1	19/06/2012
Case: Safety certification and supervision, railway undertaking	Manchester	ORR 8	A2	19/06/2012
Competencies	London	ORR 9	A	20/06/2012
Case: Safety certification and supervision, railway undertaking	London	ORR 10	A2	20/06/2012
Case: Safety certification and supervision, railway undertaking	London	ORR 11	A2	20/06/2012
Case: Supervision, Infrastructure manager	London	ORR 12	A1	20/06/2012
Case: Supervision, Infrastructure manager	London	ORR 13	A1	20/06/2012
Legal frame work	London	ORR 14 (& 12)	A	21/06/2012

A: Adam Owsianik, Antanas Dubikaitis, Eleni Douvi, Leif Funch

A1: Adam Owsianik, Leif Funch

A2: Antanas Dubikaitis, Eleni Douvi

Persons interviewed [[Interviewee](#)]

Annex VI: Terms/ abbreviations

Abbreviation	Meaning
CSM	Common Safety Method(s)
CST	Common Safety Targets
EC	European Community
ERA	European Railway Agency
IM	Infrastructure Manager(s)
IOPD	Interoperability Directive
ISA	Independent Safety Authority
NoBo	Notified Body
DeBo	Designated Body
NSA	National Safety Authority
RU	Railway Undertaking(s)
SD	Railway Safety Directive
SU	Safety Unit of the European Railway Agency
TSI	Technical Specifications for Interoperability