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## Subsystem authorisation process

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New infrastructure or rail vehicles cannot be placed into service on the UK parts of the Trans-European Network unless the asset is authorised by the relevant Safety Authority in accordance with the Railways (Interoperability) Regulations 2006. The same applies for major works of renewal or upgrade, unless, on application to the Competent Authority (which is the DfT for Great Britain and the Department for Regional Development in Northern Ireland) it is decided that no authorisation is required.

It is essential that anyone proposing to embark on a project for new build, or for the renewal or upgrade of an existing asset, takes the requirements of these Regulations into account in his project planning from the outset, because there are likely to be mandatory standards applicable to the project, because appointment of a NoBo[4] to carry out independent verification must take place relatively early in the life of the project, and because the verification process has to happen throughout the design and build phases: it cannot simply be bolted on at the end of the project.

Here is the [list of NoBo appointments](#) (PDF, 44KB) made by the Secretary of State. NoBos can similarly be appointed by other Member States, and a [full list of appointments](#) can be found on the European Commission website.

DfT's forthcoming revision of the Guidance will describe the interoperability 'process' in full detail: the paragraphs below provide a very condensed, 7-step overview.

### Project definition

Scoping and defining the project enables the Contracting Entity to determine whether his project falls within the scope of the Railways (Interoperability) Regulations 2006, and if so, to identify the standards that will be applicable and against which it must be independently verified. Authorisation is always required for new assets, but the Contracting Entity must apply to the DfT (or DRDNI, as appropriate) for a decision as to whether authorisation is required for the upgrade or renewal of an existing asset (a 'Regulation 5 Decision').

If authorisation is required, the Contracting Entity must identify the applicable standards for his project, against which compliance must be verified by a NoBo. Careful scoping and standards identification also enables the Contracting Entity to decide whether he should seek any derogation, or whether other technical or commercial obstacles exist to the relevant standards being met, in which case he will almost certainly need to seek urgent help from DfT (or DRDNI, as appropriate).

The Contracting Entity may also find it useful to establish a dialogue at this early stage with the relevant Safety Authority to which application for authorisation will ultimately be made.

## **Appointment of the NoBo**

A NoBo is a body which has been appointed by the Secretary of State (or the SRA whilst it had responsibility under the now-revoked High Speed Regulations) having been assessed as meeting the criteria for competence, independence and integrity that are laid down in the Directives for bodies that may carry out independent verification of compliance with TSIs and NNTRs. The Secretary of State in practice acts on the advice of the United Kingdom Accreditation Service (UKAS), and must notify the European Commission of the appointment, hence the organisation becomes a Notified Body.

A Contracting Entity for a project which requires authorisation under the Regulations must retain the services of a NoBo. In relation to a project for new build, or upgrade or renewal of an existing asset which requires authorisation, the Contracting Entity must appoint a NoBo before completion of the design stage, or before commencement of the manufacture stage of the project, whichever is the earlier.

Nothing in the Regulations prevents the Contracting Entity from terminating his contract with one NoBo and appointing another NoBo to his project at any time. However, the Contracting Entity must ensure that a NoBo is in place from the required start time until an authorisation decision is made: there must be no gap or discontinuity between one NoBo and the next.

## **Conformity Assessment (covering Design and Production)**

In most cases, the NoBo assessment will cover both the design and production phases of the project. There are different assessment options available for the Contracting Entity to choose from: the most appropriate choice will depend on specific details of the project and the extent to which conformity can be established by quality system assessment and surveillance. The Contracting Entity should specify the Assessment Modules that it requires the NoBo to follow, together with the standards that will form the scope of the assessment. It is advisable to discuss and agree the process and applicable standards with the NoBo and other interested parties.

The conformity assessment process will consist of verifying that the design and finished product is compliant with the applicable standards. The range of assessment methodologies available includes clause-by-clause assessment of design compliance and each and every compliance inspection through to a full quality assurance based approach for both design and production compliance.

## **Assessment of Compatibility**

The NoBo is required by the Regulations to verify that compatibility has been established between the subsystem and the rail system in which it is being placed into service. The NoBo can generally do this simply by including the output of the relevant compatibility process (eg as defined by GE/RT8270 Issue 2) in the Technical File, but it is permissible for the NoBo to have more involvement in the process if desired by the Contracting Entity.

## **Certification of Verification**

On satisfactory completion of the assessment process, the NoBo will issue conformity certification as required by the chosen Assessment Modules. These certificates will be supported by a Technical File, also compiled by the NoBo.

## **Verification Declaration**

The Contracting Entity is required to make a written Declaration of Verification confirming that

- the subsystem meets the Essential Requirements
- the verification assessment procedure has been carried out by a NoBo in accordance with the Regulations;
- a certificate of Verification has been drawn up by the NoBo in accordance with the Regulations; and
- a technical file has been prepared containing the information and documents specified in the Regulations.

## **Application for Authorisation**

Application for Authorisation of a subsystem must be made in writing to the relevant Safety Authority, and must be accompanied by:

- the complete Technical File including the Certificate of Verification issued by the NoBo; and
- the Verification Declaration made by the Contracting Entity.

The NoBo is responsible for providing a complete Technical File to the Contracting Entity. If any Contracting Entity or NoBo requires project-specific advice on this, they should contact their Safety Authority.

[4] NoBo = Notified Body

## **Notified Bodies and their role in the verification and approval process**

The design and construction of a new, renewed, or upgraded railway asset must be verified by a Notified Body (NoBo) as being compliant with the relevant standards.

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## **Guidelines for the assessment of bodies applying for Notified Status**

The railways (interoperability) (high-speed) regulations 2002.

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**For related documents, pages and internet links, see the column on the right.**