

Notified Bodies and Designated Bodies

Help us to help you	If you have any comments or suggestions for further Helpline notes please e-mail interoperability@dft.gsi.gov.uk
Related Helpline notes	Roles and Responsibilities Scope
Audience	This Helpline note is applicable to Project Entities and third party conformity assessment bodies (Notified Bodies and Designated Bodies).
Background	The third party assessment of a project is undertaken by: Notified Bodies for Technical Specifications for Interoperability (TSIs) and they also check that interoperability constituents comply with the requirements of relevant Directives, and Designated Bodies for notified national technical rules (NNTRs).
Regulation 16	These bodies provide independent verification that the project outputs comply with the relevant standards. The Project Entity will make necessary arrangements with these bodies to enable it to make a verification declaration to obtain an authorisation. The Project Entity will need to comply with regulation 16 and the Notified Body and Designated Body will need to comply with regulation 17 (verification assessment procedure).
Regulation 19	The regulations provide that existing Notified Bodies will be able to continue to assess NNTRs without being appointed as a Designated Body until 16 January 2013. It will be possible for a Notified Body to also become a Designated Body . If the project engages a separate Notified and Designated Body each will have to compile a technical file. Once an authorisation has been granted the Project Entity will need to combine the two files and keep them as one.
Regulation 17	The Notified Body and Designated Body will carry out technical compatibility checks at the authorisation to place into service stage. These are based on a combination of sources, including: TSIs, the registers for infrastructure and vehicle types and NNTRs for technical compatibility.

The role of Notified and Designated bodies

The role of these bodies is to carry out the verification assessment procedure resulting in a certificate of verification for the project. The role of both bodies is set out via a cross reference to the applicable procedures under Annex VI of Directive 2008/57/EU (as revised by Commission Directive 2011/18/EU). The **Notified Body** must compile a technical file containing the items listed in regulation 17. The role of the **Designated Body** is to carry out a verification procedure for NNTRs. Paragraph 3.2 of Annex VI refers to the **Designated**

Regulation 31

Body dividing the certificate into two parts, one part including the references to those national rules strictly related to the technical compatibility between the vehicle and the network concerned, and the other part for all other national rules.

The appointment of notified and designated bodies

Under regulation 31 in order to appoint a **Notified Body**, or **Designated Body**, the Department needs to be satisfied that the criteria specified in Annex VIII of Directive 2008/57/EC are met by the body. For new appointments the Department relies upon recommendations from UKAS as a means of being satisfied this is the case. Under regulation 31 (7) the appointment of a **Notified Body**, or **Designated Body**, could be terminated by the Department if the body no longer meets the criteria of Annex VIII. UKAS undertakes an annual surveillance process as a means of checking the ongoing competence of bodies after their appointment. The Department wishes to rely upon this annual surveillance process as a means of being satisfied that any new or existing bodies continue to meet the Annex VIII criteria.

Note: An appointment may specify the subsystems that the body is capable of assessing. The list of bodies appointed by the Secretary of State for Transport, and the subsystems they are capable of assessing, is available on the DfT's website. A complete list of **Notified Bodies** notified to the European Commission by EU Member States is available on the Commission's NANDO website.

Existing notified bodies becoming designated bodies

If an existing **Notified Body** in the UK wishes to become a **Designated Body** it should inform UKAS and can use the annual surveillance process as a means of demonstrating competence to assess compliance with Technical Specifications for Interoperability (TSIs) and NNTRs. If appropriate, UKAS will recommend to DfT for the appointment of a **Notified Body** as a **Designated Body** in order for them to continue to assess projects against compliance with NNTRs after 16 January 2013. This recommendation will follow the annual surveillance of the body by UKAS. The notified body will also need to write to the Department requesting an appointment as a designated body and if the Department agrees with the UKAS recommendation we will issue a **Designated Body** appointment letter to the **Notified Body** on behalf of the Secretary of State shortly after receiving the recommendation.

New notified bodies and designated bodies

A new **Notified Body** can be recommended by UKAS for appointment as a **Designated Body** at the same time. UKAS would seek demonstration of their competence in relation to the assessment of compliance with Technical Specifications for Interoperability (TSIs) and NNTRs. After their appointment

they would be subject to the same annual surveillance process as referred to above.

Regulation 30 Foreign Notified Bodies operating in the UK

Under regulation 30 it is possible for a **Notified Body** from outside of the UK to assess TSIs and UK NNTRs, however, after 16 January 2013 they will need to be appointed by the Department as a **Designated Body** in order to assess UK NNTRs. A foreign **Notified Body** could assess compliance of a project solely against TSIs without being appointed as a **Designated Body**. However, if the foreign **Notified Body** wishes to assess projects against UK NNTRs, then it will need to be appointed as a **Designated Body**. In order for UKAS to make a recommendation to the Department on the suitability of the foreign **Notified Body** to be a **Designated Body**, UKAS will need to be satisfied that the foreign **Notified Body** has the competence to assess projects against UK NNTRs and also that the body satisfies the criteria under Annex VIII of Directive 2008/57. UKAS may make use of any existing assessments of Foreign **Notified Bodies** competence assessed by a member body of the International Accreditation Forum where appropriate.

The transition to Accreditation

Under Decision 768/2008 (*“common framework for the marketing of products”*) accreditation is the “preferred means” of demonstrating the technical competence of Conformity Assessment Bodies for the purposes of notification. Following a recommendation from the Department for Business, Innovation and Skills the Department has now moved to an accreditation system in the UK. This means that accreditation is the preferred means of demonstrating the technical competence of existing and new **Notified Bodies**. UKAS will now seek evidence that the accreditation criteria are met by existing and new **Notified Bodies**.

Reg 16 When should a Project Entity engage with a Notified Body?

Under regulation 16 this must occur:

- (a) before completion of the design stage of the project subsystem; or
 - (b) before commencement of the manufacture stage of the project subsystem,
- whichever is the earlier.

The project may wish to engage with the **Notified Body** at an earlier stage, to scope the project and identify relevant standards. This could also identify the need for a regulation 13 decision from the Competent Authority in the case of an upgrade or renewal, or a regulation 14 derogation request.

Document Control

Version No.	Issue date
1.0	April 2009
2.0	October 2012