L.N. 56 of 2009

PRODUCT SAFETY ACT (CAP. 427)

Interoperability of the Trans-European High-speed Rail System (Amendment) Regulations, 2009

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, the Minister of Finance, the Economy and Investment, on the advice of the Malta Standards Authority, has made the following regulations:-

Title.

1. (1) The title of these regulations is the Interoperability of the Trans-European High-speed Rail System (Amendment) Regulations, 2009 and they shall be read and construed as one with the Interoperability of the Trans-European High-speed Rail System Regulations, 2002, hereinafter referred to as "the principal regulations".

L.N. 332 of 2002.

(2) These regulations shall be deemed to have come into force on the 30 April, 2006.

Substitutes Schedule VI to the principal regulations.

2. For Schedule VI to the principal regulations there shall be substituted the following new Schedule:

“Schedule VI

Based on Annex VI of the Directive

VERIFICATION PROCEDURE FOR SUBSYSTEMS

1. INTRODUCTION

“EC” verification is the procedure whereby a notified body checks and certifies that a subsystem:

— complies with the Directive

— complies with the other regulations deriving from the Treaty, and may be put into operation.

2. STAGES

The subsystem is checked at each of the following stages:

— overall design,

— production: construction of subsystem, including, for example civil-engineering activities, manufacturing, constituent assembly, overall adjustment,

— final testing of the subsystem.

For the design phase (including the type tests) and for the production phase the main contractor (or the manufacturer) or its authorised representative established within the Community may apply for an assessment as a first step.

In this case, this (these) assessment(s) lead to intermediate statement verification(s) (ISV) issued by the Notified Body chosen by the main contractor (or the manufacturer). This one in turn draws up an “EC declaration of intermediate subsystem conformity” for the relevant phase(s).

3. CERTIFICATE

The Notified Body responsible for the “EC” verification draws up the certificate of verification intended for the contracting entity or its authorised representative established within the Community, which in turn draws up the “EC” declaration of verification intended for the supervisory authority in the Member State in which the subsystem is located and/or operates.

The Notified Body responsible for "EC" verification assesses the design and production of the subsystem.

If available, the Notified Body takes into account the "Intermediate Statements of Verification" (ISV(s)), and, in order to issue the "EC" certificate of verification, it:

— Checks that the subsystem:

— is covered by relevant design and production ISVs delivered to the main contractor (or the manufacturer) if it has asked the Notified Body for these two phases,

— or corresponds as produced to all aspects covered by the design ISV delivered to the main contractor (or the manufacturer) if it has asked the Notified Body only for the design phase,

— Verifies that they cover correctly the requirement of the TSI and assesses the design and production elements that are not covered by the design and/or production ISV(s) delivered to the main contractor (or the manufacturer).

4. TECHNICAL FILE

The technical file accompanying the declaration of verification must be made up as follows:

— for the infrastructure: engineering-structure plans, approval records for excavations and reinforcement, testing and inspection reports on concrete, etc.,

— for the other subsystems: general and detailed drawings in line with execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems, operating and maintenance manuals, etc.,

— list of interoperability constituents, as referred to in Article 3, incorporated into the subsystem,

— copies of the "EC" declarations of conformity or suitability for use with which the above mentioned constituents must be provided in accordance with Article 13 of the Directive accompanied, where appropriate, by the corresponding calculation notes and a copy of the records of the tests and examinations carried out by the notified bodies on the basis of the common technical specifications,

— if available, the intermediate statement(s) of verification (ISV) and, in such a case, the "EC" declaration(s) of intermediate subsystem conformity, that accompany

the "EC" certificate of verification, including the result of verification by the Notified Body of their validity,

— certificate from the Notified Body responsible for "EC" verification, accompanied by corresponding calculation notes and countersigned by itself, stating that the project complies with this Directive and mentioning any reservations recorded during performance of the activities and not withdrawn; the certificate should also be accompanied by the inspection and audit reports drawn up by the same body in connection with its task, as specified in sections 5.3 and 5.4.

5. MONITORING

5.1. The aim of "EC" monitoring is to ensure that the obligations deriving from the technical file have been met during production of the subsystem.

5.2. The Notified Body responsible for checking production must have permanent access to building sites, production workshops, storage areas and, where appropriate, prefabrication or testing facilities and, more generally, to all premises which it considers necessary for its task. The contracting entity or its authorised representative within the Community must send it or have sent to it all the documents needed for that purpose and, in particular, the implementation plans and technical documentation concerning the subsystem.

5.3. The Notified Body responsible for checking implementation must periodically carry out audits in order to confirm compliance with the Directive. It must provide those responsible for implementation with an audit report. It may require to be present at certain stages of the building operations.

5.4. In addition, the Notified Body may pay unexpected visits to the worksite or to the production workshops. At the time of such visits the Notified Body may conduct complete or partial audits. It must provide those responsible for implementation with an inspection report and, if appropriate, an audit report.

6. SUBMISSION

The complete file referred to in paragraph 4 must be lodged with the contracting entity or its authorised agent established within the Community in support of the certificate of verification issued by the Notified Body responsible for verification of the subsystem in working order. The file must be attached to the "EC" declaration of verification which the contracting entity sends to the supervisory authority in the Member State concerned.

A copy of the file must be kept by the contracting entity throughout the service life of the subsystem. It must be sent to any other Member States which so request.

7. PUBLICATION

Each Notified Body must periodically publish relevant information concerning:

— requests for “EC” verification received;

— intermediate statements of verification (ISVs) issued or refused;

— certificates of verification issued or refused.

8. LANGUAGE

The files and correspondence relating to the “EC” verification procedures must be written in an official language of the Member State in which the contracting entity or its authorised representative within the Community is established or in a language accepted by the entity.”.