

## STORAGE OF THE TECHNICAL DOSSIER OF EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES

### 1. PURPOSE

The purpose of this procedure is to regulate the order, activities and responsibilities during the storage of technical dossiers of equipment and protective systems intended for use in potentially explosive atmospheres. It happens when the manufacturer or his authorized representative under article 4, paragraph 3 in The Law of the Technical requirements of Products, applies the procedures for conformity assessment “INTERNAL CONTROL OF PRODUCTION” (Appendix No 7 to article 35, paragraph 1, clauses 3 and 4 and article 39 in the Ordinance for essential requirements and conformity assessment of the equipment and protective systems, intended for use in potentially explosive atmospheres, bringing Directive 94/9/EC into use).

The procedure has been made on the grounds of article 35, paragraph 1, clause 3 in the Ordinance for essential requirements and conformity assessment of the equipment and protective systems, intended for use in potentially explosive atmospheres (article 8(1) clause B(ii) of Directive 94/9/EC).

### 2. RESPONSIBILITIES

The leading appraiser bears the whole responsibility for following the procedure with respect to the storage of the technical dossiers.

### 3. DESCRIPTION

#### 3.1 Applying

If the client wishes a preliminary conversation can be carried on with the leading appraiser of Minproekt EAD Division “Scientific and Research Activity”, when the client received information for the procedure for keeping of the technical dossier as well as the documents, describing the rights and duties of the client.

The manufacturer or his authorized representative states his intention for delivering the technical dossier for being kept at the Notified Body, which can be accomplish with an assigning letter and a signed declaration, that the client is aware of and is responsible to observe the procedure for keeping of the technical dossier and that the technical dossier has not been given to another Notified by the European Commission Body, whose identification numbers are declared in the Information System for Notified and authorized bodies in the area of the Directives from “The New approach”.

#### 3.2 Preparation

The leading appraiser presents a “Contract for storage of the technical dossier” to the client in order to be coordinated.

#### 3.3 Activities

The manufacturer or his authorized representative presents a coordinated “Contract for storage of the technical dossier” and the technical dossier itself to the leading appraiser, which has to be on a paper and an electronic carrier. The technical dossier has to be made in Bulgarian. When the manufacturer is not situated in Bulgaria, the presented technical dossier has to be in the manufacturer’s language and also a legalized translation in Bulgarian has to be provided.

The leading appraiser goes through the technical dossier for its thoroughness and completes a List for the thoroughness of the product technical dossier.

If the dossier does not contain the requirements in clause, 3 Appendix No 7 from article 35, paragraph 1, clauses 3 and 4 and article 39 in the Ordinance for essential requirements and conformity assessment of the equipment and protective systems, intended for use in potentially explosive atmospheres (ANEX VIII, clause 3 from article 8(1), (b), (ii) of the Directive 94/9/EC), the documents have to be returned for additional completing.

When the technical dossier contains all required documents they are described with their names, identifications and content in the Receiving-transmitting report of the technical dossier of the equipment and protective systems, intended for use in potentially explosive atmospheres. This report has to be signed and sealed by the manufacturer or his authorized representative and the leading appraiser.

The leading appraiser registries the presented technical dossier in a Register for recording of the dossiers of the equipment and protective systems, intended for use in potentially explosive atmospheres, intended for a storage.

The technical dossiers have to be stored for a period ending 10 years after the last product was manufactured. After this period has run out of storage, the dossier has to be destroyed by a committee and has to be registered in an “List for destroyed documents”.

The technical dossier cannot be returned to the manufacturer on request. It can be supplemented. For additionally presented documents a Receiving-transmitting report of the technical dossier of the equipment and protective systems, intended for use in potentially explosive atmospheres has to be completed as it has to be registered that it is a supplement to the Receiving-transmitting report which has already been issued.

The technical dossier can be presented on request from the authorized bodies for the purposes of the Surveillance of the market.

The Notified Body has to inform the State Agency for Metrology and Technical Surveillance and Notified by the European Commission Bodies whose identification numbers were announced in the Information System for Notified and Authorized bodies in the field of the directives of the "New approach" about the necessary data regarding the manufacturer and the product whose record is stored.

#### **4 APPENDIX**

- 4.1 List for the thoroughness of the product in the area of the equipment and protective systems, intended for use in potentially explosive atmospheres
- 4.2 Declaration
- 4.3 Contract for storage of the technical dossier
- 4.4 Receiving-transmitting report of the technical dossier of the equipment and protective systems intended for use in potentially explosive atmospheres

NOTIFIED BODY

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„MINPROEKT” EAD