	CONFORMITY ASSESSMENT PROCEDURE	*PYROTECHNICS*

Module H

Conformity based on full quality assurance

Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer ensures and declares on his/her sole responsibility, that pyrotechnic articles concerned fulfil the requirements of the Directive 2013/29/EU. This module can be performed only in a case when the applicant is also the manufacturer who produces the articles physically, and the pyrotechnic articles are exclusively of the category IV.

The applicant shall send a list of pyrotechnic articles (preferably in table form) for which he/she requests to perform module in question, and the technical documentation of relevant articles. At the same time, the applicant shall also send the quality management system documentation. The technical documentation shall contain at least the following:

- a general description of the pyrotechnic article;
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;
- a list of the harmonised standards applied in full or in part t, the references of which have been published in the Official Journal of the European Union; in the case of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied
- results of design calculations made, examinations carried out, etc.;
- test reports.

Documentation must be in Slovak, Czech or English language. Documentation in other language can be submitted only after mutual agreement.

Notified body shall send to the applicant a price proposal for assessment, including an audit program.

In case of approval of the price proposal, the applicant shall send filled form “Žiadosť na posudzovanie zhody“ KOTA D-414 in Slovak language, or “Application Form for Conformity Assessment“ KOTA D-523 in English language to the Notified Body. The form must be completed fully and legibly. The veracity of the information provided shall be confirmed by the applicant´s signature and if appropriate with a company stamp.

Notified body shall carry out an audit at the manufacturer's premises. The objective of the audit is to comprehensively review the established quality management system, however the primary focus is on verification of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- the technical design specifications, including standards that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full;
- the means that will be used to ensure that the essential safety requirements of Directive 2013/29/EU will be met;
- the design control and design verification techniques, processes and systematic actions that will be used when designing the respective types of articles;
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

Upon completion of the assessment, the Notified Body draws up the Certificate on assessment of the quality management system and Assessment Report. NB shall state the validity period in the Certificate. These documents together with the invoice are sent to the applicant's address. At the same time NB shall authorize the manufacturer to affix the CE marking to the relevant products, to which the number 1395 is attached. Using of CE marking on the products is checked during the audit.

In case of identifying serious deficiencies in the system under assessment during the audit, the Notified Body shall reject to certify the system in question and send the Assessment report to the applicant in which NB justifies such decision. At the same time, NB will inform applicant about the possibilities and method of appeal.

The manufacturer must inform the Notified Body about any intended change of the quality system.

Notified Body shall evaluate the proposed changes and decide whether the modified quality system will meet the requirements or whether a reassessment is necessary.

NB will announce to manufacturer his decision. The announcement shall include the conclusions of the review and the reasoned assessment decision.

In case that it is not possible to perform the follow-up audit within the period of validity of the Certificate on assessment of the quality management system due to “force majeure”, Notify Body will prolong the validity of the Certificate on assessment of the quality management system administratively for the necessary time period (however, the maximum limit is of 6 months).

After passing the abovementioned circumstances, Notified Body shall perform the audit and issue new Certificate on assessment of the quality management system and Assessment Report. NB shall state the period of Certificate validity defined in accordance with the rules for determination of the validity period shortened by the time of administrative prolongation.

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