Module D

Conformity to Type Based on Quality Assurance of Production Process

Conformity to type based on production process quality assurance is that part of the conformity assessment procedure whereby the manufacturer guarantees and declares under his sole responsibility that the products concerned are in conformity with the type described in the type examination certificate and satisfy the essential safety requirements of The Pyrotechnic Articles (Safety) Regulations 2015, SI 2015 No. 1553 as amended respectively.

This module can only be implemented if the applicant is a physical producer of the products concerned.

The applicant shall send a list of pyrotechnic articles (preferably in a tabular form) for which it is requested to carry out the said module and the quality system documentation (quality manual). In case that module B on these products was performed by another Conformity Assessment Body (CAB), the applicant shall also provide a copy of all final documents issued by this CAB (type certificates including all amendments, final reports, final protocols, certificate attachments, etc.) to enable to determine individual product parameters at the time of completed type examination. At the same time, the applicant shall also send complete technical documentation of these products, if it is not part of the certification documentation. The applicant shall also make a proposal for the place and date of the audit performance.

The CAB will send the applicant a price proposal for the assessment including a plan of the audit (form KOTA D-505_EN). If the applicant approves the price proposal, he shall send the CAB completed form “Application for conformity assessment UKCA” KOTA D-608. The form shall be completed legibly and completely. The applicant shall confirm truthfulness and binding of the provided data by his signature and imprint of the company stamp.

The CAB shall carry out an audit at the manufacturer's seat. The aim of the audit is a comprehensive review of the established quality assurance system of the production process with the emphasis on verifying the following:

- the quality objectives and the organizational structure, responsibilities and competences of the management with regard to product quality,
- the corresponding manufacturing processes, quality control and quality assurance techniques and systematic actions that will be used,
- examinations and tests that will be carried out before, during and after manufacture, including the time intervals at which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

Upon completion of the assessment, CAB shall draw up the Quality System Assessment Certificate (form KOTA D-603) and the Assessment report (form KOTA D-611). The certificate indicates the period of validity of the certificate. Basically, validity of the certificate is 12 months. This always applies in case of initial audit performance. The period can be granted for 24 months in accordance with requirements given below.

The CAB will send these documents together with a commercial invoice to the applicant. It shall also authorize the manufacturer to affix the UKCA marking to relevant products, to which number 1395 shall be attached.

The audit is performed in 1-year or 2-years interval. Length of the interval is determined upon the following criteria:

- the audit is carried out one year after performance of the initial audit;
- if no deficiencies that would require to intervene the quality management system were found during the audit, the next audit is conducted within two years after the audit performance; otherwise the audit is performed within a year.

In case that minor deficiencies in the system under assessment have been detected during the audit, the applicant is required to rectify the deficiencies within 60 days of issuance of the Assessment Report, and submit evidence on rectification of the deficiencies.

If significant deficiencies have been identified in the system, the CAB shall refuse to certify the system concerned and shall send the applicant a Final Report explaining its decision. At the same time, the CAB shall instruct the applicant about the possibility to appeal against the decision and how to file the appeal.

The manufacturer shall inform the CAB of any intended change to the quality system. The CAB shall evaluate the modifications proposed and decide whether the modified quality system will continue to satisfy the requirements or whether a reassessment is required.

The CAB shall notify the manufacturer of its decision. The notification shall include the conclusions of the examination and reasoned assessment decision.

If it is not possible to carry out the next audit within the period of validity of the Quality System Assessment Certificate due to force majeure, upon request of the manufacturer, the CAB may administratively extend validity of the certificate for the time strictly necessary (max. for 6 months).

As soon as the reasons for the force majeure have subsided, the CAB shall carry out the audit and issue new Quality System Assessment Certificate and Assessment Report. The CAB shall indicate the validity of the certificate determined upon the criteria for audit interval determination shortened by the time of the administrative extension.