Fiditas
explosion safety solutions

Technical Guide

CERTIFICATION OF MANUFACTURER'S

QUALITY ASSURANCE SYSTEM IN PRODUCTION OF

EXPLOSIVES FOR CIVIL USES AND PYROTECHNIC ARTICLES

Directives 2013/29/EU and 2014/28/EU

Fiditas d.o.o. Karlovačka cesta 197, 10250 Zagreb-Lučko, Hrvatska
Phone: +385 1 5578565; info@fiditas.com ; www.fiditas.com

1. INTRODUCTION

The purpose of this Guide is to clarify the procedure of certifying manufacturer's quality assurance system in production of explosives for civil uses and pyrotechnic articles (explosive materials). This procedure applies to the certification of the quality assurance system, based on Modules C2, D and E of Directive 2014/28/EU and Modules C2, D, E and H of Directive 2013/29/EU.

This Guide does not contain the procedure of type certification (per Module B of the Directives) which is described in the Guide on Equipment Certification (TU-CERT-EXPL).

2. INITIAL ASSESSMENT, SURVEILLANCE AND RE-ASSESSMENT

Production quality assurance certification by Fiditas consists of examination of the documentation (with regard to conformity and preparation for audit), on-site audit of the quality assurance system and elimination of any nonconformity ascertained. Once these nonconformities have been successfully eliminated within the given timeframe, a Quality Assurance notification (Modules D, E and H) is issued with mandatory surveillance assessment to be performed regularly. The quality assurance certification procedure is repeated before the certificate expires.

In Module C2, a sample control test is carried out for each series of explosive substances in accordance with the corresponding parts of the harmonized standards and / or equivalent tests as established by other relevant technical specifications to check the quality of the internal production control and conformity to type. When the test results on the test samples and the conformity assessment of the product with the requirements are satisfactorily issued, the Certificate of Conformity for that series of explosive product produced.

Fiditas prepares an audit program for independent on-site audit of the quality assurance system. This program and the time necessary to implement it are determined according to the complexity of quality assurance system and the production plant, the number of type certificates as well as any other relevant information (e.g. the existence of other certificates for the quality assurance system, or number of production sites if production is carried out at various locations). If there are several manufacturing locations, the assessment of the quality assurance system is performed at those locations deemed necessary. During assessment according to Module C2 Fiditas examine documentation of products that are subject of certification and define number of products for testing in laboratory.

If the Client is interested in a revision or supplement to the scope of the notification already issued, the Client shall submit a request in writing. Fiditas will evaluate the request and notify the Client within 14 days regarding approval/denial of the request and specify the activities and deadlines necessary for completion of work.

The surveillance assessment for Module D, E and H is performed according to the following schedule:

- before expiration date of current Notification,
- immidiately, in the case of huge and important changes of the quality system which are important for conformity of the products (like changing of production location).

Fiditas d.o.o. Karlovačka cesta 197, 10250 Zagreb-Lučko, Croatia
Phone: +385 1 5578565; info@fiditas.com ; www.fiditas.com

The surveillance assessment involves evaluation of any changes in quality assurance documents and a control audit at the production site. The purpose is to check the function of the system and its continuous compliance with the requirements of the quality assurance notification issued.

Periodic re-assessment is performed following the same procedure as for the initial assessment, along with the results and remarks from previous assessments which are now taken into consideration. More emphasis is placed on the efficiency of the quality system, the pursuit of continuous improvement, the achievement of its own goals and expected outcomes, and the monitoring and adaptation of internal and external (eg. legal or normative) changes to maintain the compliance of the certified system scope with the requirements of the relevant standards and regulations.

3. SUBMITTING AN APPLICATION

To initiate the certification process, manufacturers or their representatives submit request and relevant information about its quality system and scope of assessment. Application form is available at Fiditas website for this purpose. The application is then assessed and if found suitable, Fiditas will generate and send the offer to the Client together with the Agreement. If the offer is acceptable the Client submits an order and a signed copy of the Agreement and delivers documentation on the quality assurance system. Fiditas confirms receipt of the order and initiates work. The same procedure manufacturers or their representatives submit request for extension of notification or periodic re-assessment.

4. ASSESSMENT OF THE QUALITY ASSURANCE SYSTEM

The assessment of the quality assurance system is carried out in accordance with Modules D and E of Directive 2014/28/EU and Modules D, E and H of Directive 2013/29/EU. If the results are satisfactory at the end of the procedure, Fiditas issues Quality Assurance Notification to the Client. This notification is issued with an expiration date, under the condition that surveillance assessment is performed regularly.

Assessment of the quality assurance documentation

Fiditas evaluates compliance of the quality assurance documentation with the Directive. The quality assurance documentation should be written in either English or Croatian. The use of a third language can also be agreed upon if this is acceptable to both parties.
If the assessment of documentation identifies any deficiency (which are, or may become nonconformities) with requirements, Fiditas will notify the Client about these findings, which should be clarified and/or eliminated before the on-site assessment.

On-site audit of the production quality assurance system of the Client/manufacturer

After the documentation has been assessed, in agreement with the Client Fiditas prepares a program of on-site audit at the Client/manufacturer. The audit program, as needed, can also include an on-site audit of the supplier(s), who may be considered relevant to the explosion protection of Ex-equipment that the Client intends to produce, in accordance with Directive 2014/28/EU or Directive 2013/29/EU.
The Client may request exclusion of any member of the audit team or ask changes to the schedule. If the Client does not provide any objections to the program in writing, Fiditas presumes the Client has accepted the audit program.

Fiditas d.o.o. Karlovačka cesta 197, 10250 Zagreb-Lučko, Croatia
Phone: +385 1 5578565; info@fiditas.com ; www.fiditas.com

During the assessment Fiditas observes implementation of the quality assurance system, and its compliance with the Directives, EN ISO 9001 (Modules D, E and H) and other harmonized standards applied. The on-site audit includes the following mandatory steps:

- checking compliance with all requirements of regulations and standards applied,
- assessing the implementation of the quality assurance system, with regard to anticipated effects in accordance with the requirements of regulations and standards applied,
- assessing the quality assurance system with regard to legal requirements (e.g. the company's legal provisions through register with the Commercial Court or similar),
- monitoring processes within the company,
- executing internal audits and management reviews,
- management's responsibility for the policy and objectives of quality assurance.

At the end of the on-site audit, an Audit Report is prepared based on the data gathered and a meeting held with the Client in which all findings, observations and conclusions are reviewed. Nonconformities are presented to manufacturer in clear manner and deadlines for closing them are agreed by both parties.

Final meeting also includes:

- information to the Client about confidentiality with all information received and collected during the audit,
- reporting and time frame for preparation of audit report;
- further procedure and obligation of manufacturer regarding closing of nonconformities as far as consequences if nonconformities are not closed in due time,
- limit dates for delivery of proposals for corrective actions,
- further steps of Fiditas in the assessment's procedure,
- information about handling objections and complaints.

The Audit Report is presented during the final meeting and signed by all parties present. Based on this report the Client will, as needed, analyze causes and initiate corrective actions for any nonconformity determined and inform Fiditas accordingly.
If, in addition, supplier assessment is conducted (for suppliers considered to be critical for the explosion protection of Ex-products that the Client wishes to produce), an additional Audit Report is prepared.

Evaluating the results of production quality system compliance and issuing the Notification

Once all nonconformities have been eliminated, Fiditas evaluates compliance with the requirements. Based on the information gathered during the certification process and the corrective activities performed, a decision is made regarding certification of the Client's quality assurance system. If the corrective actions are satisfactory, the decision is positive and a quality assurance notification is issued for the manufacture of EXPL products.
If the results of the assessment do not comply with requirements, Fiditas will notify the Client accordingly, citing the reasons for denying issue of the notification.

Fiditas d.o.o. Karlovačka cesta 197, 10250 Zagreb-Lučko, Croatia
Phone: +385 1 5578565; info@fiditas.com ; www.fiditas.com

5. CONFORMITY TO TYPE BASED (Module C2)

In Module C2, a sample control test is carried out for each series of explosive substances in accordance with the corresponding parts of the harmonized standards and / or equivalent tests as established by other relevant technical specifications to check the quality of the internal production control and conformity to type. When the test results on the test samples and the conformity assessment of the product with the requirements are satisfactorily issued, the Certificate of Conformity for that series of explosive product produced.

6. SUSPENSION, WITHDRAWAL AND COVERAGE REDUCTION OF THE QUALITY ASSURANCE NOTIFICATION

There are four main reasons for suspending a quality assurance notification:

- if Fiditas determines that the manufacturer is not adhering to conditions stipulated in the agreement,
- if the quality assurance system does not continuously fulfill the requirements of regulations and applicable standards,
- if the Client does not permit the performance of a surveillance assessment or does not want another reassessment,
- if the Client requests a suspension of the certificate.

A notification is temporarily invalid during suspension. If the notification has been suspended, per the Agreement the Client is obligated to cease using the Fiditas' Notified Body Number and discontinue all references to the Fiditas' quality assurance notification in any advertising media.

Fiditas will request an explanation from the manufacturer and will try to resolve any issue within a reasonable time-frame, but no longer than 6 months. In case an agreement cannot be reached, Fiditas will, in accordance with the Agreement, withdraw the notification (QAN) or reduce its coverage.

If the user's quality assurance system is only partially non-compliant with the requirements of regulations and standards, and the part in question can be excluded from coverage without significantly affecting the rest of the quality assurance system, Fiditas can reduce the coverage of the notification to incorporate only those parts of the system that comply with regulations and standards.

7. OBJECTIONS AND COMPLAINTS

Any objections/complaints the Client may have concerning the quality assurance notification issued, or any other unfavorable decision made by Fiditas throughout the certification process, shall be submitted to Fiditas in writing. If the complaint is not in writing, Fiditas will proceed in the manner it deems appropriate. Unfavorable decisions include:

- denial of applications,
- refusal to continue an assessment,
- requests for repair work,
- changes to the coverage of the quality assurance notification,
- denial, suspension or withdrawal of the quality assurance notification,
- any other activities that prevent the Client from acquiring and/or maintaining the quality assurance notification.

Fiditas d.o.o. Karlovačka cesta 197, 10250 Zagreb-Lučko, Croatia
Phone: +385 1 5578565; info@fiditas.com ; www.fiditas.com

Fiditas will process the objections/complaints according to procedure POS-C-10 which can be obtained on request. The complainant will be notified of Fiditas's position on the matter in writing. Fiditas will attempt to resolve the issues by agreement within a reasonable timeframe, but no longer than 30 days. If the objection/complaint has not been resolved in a positive manner, the Client may submit an appeal to the appropriate authority.

Before a decision is reached, the information in the complaint is reviewed and analyzed, and the Client is informed of the results in writing. Records are kept on all complaints and actions implemented.

Any person or organization is free to express dissatisfaction to Fiditas (where a response is expected) regarding its activities or the activities of the manufacturer whose quality assurance system has been certified by Fiditas.

Fiditas will assess the significance of the complaint and, if the complaint is justified, undertake the appropriate actions needed. The procedure of handling complaints is considered to be strictly privileged information, for the protection of both the complainant and Fiditas Clients.
Before a decision is reached, the information in the complaint is reviewed and analyzed, and the Client is informed of the results in writing. Records are kept on all complaints and actions implemented. Fiditas will attempt to resolve the issues by agreement within a reasonable timeframe, but no longer than 30 days.

If the complaint is not in writing, or is received from an unidentified source, Fiditas will proceed in the manner it deems appropriate. If such need is indicated, Fiditas will (with the permission of the complainant and the Client) stipulate the conditions under which the content and resolution of the complaint may become public information.

8. USEFUL INFORMATION

List of EU harmonized standards for Directive 2013/29/EU:
https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/pyrotechnic-articles_en

List of EU harmonized standards for Directive 2014/28/EU:
https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/explosives-civil-uses_en

Agreed interpretations adopted by the Forum of Notified Bodies for Explosives (Directive 2014/28/EU)
https://ec.europa.eu/growth/sectors/chemicals/legislation_en

Guidance documents and agreed interpretations of the Forum of Notified Bodies (Directive 2013/29/EU)
https://ec.europa.eu/growth/sectors/chemicals/legislation_en

Fiditas d.o.o. Karlovačka cesta 197, 10250 Zagreb-Lučko, Croatia
Phone: +385 1 5578565; info@fiditas.com ; www.fiditas.com