Fiditas
explosion safety solutions

Technical Guide

CERTIFICATION OF MANUFACTURER'S

QUALITY ASSURANCE SYSTEM IN PRODUCTION OF

Ex PRODUCTS

Directive 2014/34/EU

IECEx Scheme

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1. INTRODUCTION

The purpose of this Guide is to clarify the procedure of certifying manufacturer's quality assurance system in production of Ex-products. This procedure applies to the certification of the quality assurance system, based on Annexes IV and VII of the Directive 2014/34/EU (the Directive), and the corresponding harmonized standards for quality assurance. The procedure of quality assurance assessment is specified in the IECEx Scheme, based on publications IECEx 02, IECEx OD 009, IECEx OD 025 and other appropriate documents (www.iecex.com).
To assess compliance with requirements of the Directive, European and international standard EN ISO/IEC 80079-34 is used.

This Guide does not contain the procedure of certification (per Annex III and IX of the Directive) or IECEx Rules which is described in the Guide on Equipment Certification (TU-CERT-ATEX).

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 assessment),
- on-site assessment of the quality assurance system and elimination of any nonconformity ascertained,
- issuing of Quality Assurance Notification (QAN for ATEX) / Quality Assessment Report (QAR for IECEx), once all nonconformities have been successfully eliminated within the given timeframe,
- setting the maintenance of QAN/QAR (initial QAN/QAR is issued with an expiration date of 3 years, with mandatory surveillance assessment to be performed regularly - the quality assurance certification procedure is repeated before the certificate expires.

Fiditas prepares an audit program for independent on-site assessment 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 and protection types applied, 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.

If the Client is interested for a revision or supplement to the scope of the QAN/QAR 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 will specify activities and deadlines necessary for completion of work.

The surveillance assessment is performed according to the following schedule:

- annually, no more than 12 months between two audits, for quality assurance systems that are not certified or covered by standard ISO 9001 (or by other equivalent quality standard), or
- no more than 18 months between two audits for quality assurance systems that are also certified by ISO 9001 (or by other equivalent quality standard).

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The surveillance assessment involves evaluation of any changes in quality assurance documents and a control assessment at the production site. The purpose is to check the function of the system and its continuous compliance with the requirements of the QAN/QAR issued with an expiration date of 3 years.

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 OBR-C-1-05 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, as specified in Annexes IV and VII of the Directive or IECEx Scheme Rules. Fiditas confirms receipt of the order and initiates work.
The Client also accepts (as needed) the presence of a third-party observer during the assessment of the quality assurance system; e.g. assessors from the Croatian Accreditation Agency or IECEx assessment team.

4. ASSESSMENT OF THE QUALITY ASSURANCE SYSTEM

The assessment of the quality assurance system is carried out in accordance with Annexes IV and VII of the Directive, IECEx Rules and standard EN ISO/IEC 80079-34. If the results are satisfactory at the end of the procedure, Fiditas issues Quality Assurance Notification to the Client with a following mark form “FIDI yy ATEX Qxxx” or IECEx QAR. This QAN/QAR is issued with an expiration date of 3 years, 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/IECEx. 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 audit.

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 the Directive/IECEx Scheme Rules.

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The Client may request exclusion of any member of the assessment 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.

During the audit Fiditas observes implementation of the quality assurance system, and its compliance with the Directive, IECEx Scheme Rules, EN ISO/IEC 80079-34 and other 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:

a) information to the Client about confidentiality with all information received and collected during the assessment,
b) reporting and time frame for preparation of audit report;
c) further procedure and obligation of manufacturer regarding closing of nonconformities as far as consequences if nonconformities are not closed in due time,
d) limit dates for delivery of proposals for corrective actions,
e) further steps of Fiditas in the assessment’s procedure,
f) 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 QAN/QAR

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 executed, 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 QAN/QAR is issued for the manufacture of Ex-products.
If the results of the assessment do not comply with requirements, Fiditas will notify the Client accordingly, citing the reasons for denying issuing of the QAN/QAR.

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5. SUSPENSION, WITHDRAWAL AND SCOPE REDUCTION OF THE QUALITY ASSURANCE NOTIFICATION/QAR

There are four main reasons for suspending a QAN/QAR:

- 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 re-assessment,
- if the Client requests a suspension of the QAN/QAR.

QAN/QAR is temporarily invalid during suspension. If the QAN/QAR has been suspended, per the Agreement the Client is obligated to cease using the Fiditas's Notified Body Number with CE marking for EU market and discontinue all references to the Fiditas QAN/QAR 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 QAR/QAR or will reduce its scope.

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 scope of the QAN/QAR to incorporate only those parts of the system that comply with regulations and standards.

6. OBJECTIONS AND COMPLAINTS

Any objections/complaints the Client may have concerning the quality assurance notification/QAR 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/QAR,
- denial, suspension or withdrawal of the quality assurance notification/QAR,
- any other activities that prevent the Client from acquiring and/or maintaining the quality assurance notification/QAR.

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 appeal/complaint is rejected, the Applicant may appeal to the Croatian Notified authority, the Impartiality Committee of Fiditas or, in the case of IECEx QAR, to IECEx and IEC in accordance with IEC CA 01 and IECEx 01.
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.

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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. OTHER

Fiditas notifications that bear the accreditation symbol of the Croatian Accreditation Agency (HAA) are issued in accordance with accreditation regulations of HAA. However, it should not be assumed that the notification has been approved by HAA.
Fiditas acceptance of a drawing showing marking details which include the European Community CE Marking should not be construed as implying that Fiditas gave their permission for the CE Marking to be applied to any particular product. Applying the CE Marking remains the sole responsibility of the Applicant in accordance with appropriate EU legislation.
IECEx logo shall only be used in accordance with IECEx Guide 01B, available at www.iecex.com.

8. USEFUL INFORMATION

List of EU harmonized standards for Directive 2014/34/EU:
https://ec.europa.eu/growth/sectors/mechanical-engineering/atex_en

List of a Clarification Sheets of ExNBG for Directive 2014/34/EU
https://ec.europa.eu/growth/sectors/mechanical-engineering/atex_en
and
https://www.tuev-verband.de/en/industrial-plants/fire-and-explosion-protection/exnb-group

List of ExTAG Decision Sheets
https://www.iecex.com/publications/extag-decision-sheets/

Information on the current edition of international Ex standards and any Corrigendums, Amendments
https://webstore.iec.ch/

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