

**SCHEME RULES FOR EX CERTIFICATION BY
ELEMENT MATERIALS TECHNOLOGY WARWICK LTD
January 2021**

Scope

The scope of these rules covers certification issued by Element Materials Technology Warwick Ltd in the United Kingdom in its role as a Certification Body under the IECEx equipment scheme, an Approved Body under the UKEX Regulations, and/or as a certification body for ATEX and UKEX category 3 equipment.

Definitions

Applicant	A manufacturer or a person which acts on behalf of the manufacturer and who applies to an Ex Certification Body for obtaining an ATEX Category 3 Type Examination Certificate, a UKEX UK Type Examination Certificate, a UKEX UK Unit Verification Certificate, a UKEX UK Quality Assurance Notification, an IECEx Certificate of Conformity, an IECEx Test Report or an IECEx Quality Assessment Report.
Manufacturer	An organization, situated at a stated location or stated locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection.
Certification Body and Approved Body	Element Materials Technology, Pendle Place, Skelmersdale, West Lancashire, WN8 9PY, United Kingdom. UKEX Approved Body number 0891.
IECEX Certified Equipment Scheme	The IECEx Certified Equipment Scheme of conformity assessment for equipment for use in potentially explosive atmospheres as defined by IEC document IECEx 02 (Edition 5.1, 2013-12).
UKEX Regulations	Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016, SI 2016 No. 1107 (as amended).
UK Type Examination Certificate	Approved Body certificate as defined in Schedule 3A, Part 1 of the UKEX Regulations.
UK Unit Verification Certificate	Element certificate for UKEX compliance covered by Schedule 3A, Part 1 of the UKEX Regulations.
Type Examination Certificate	Element certificate for UKEX compliance of category 3 equipment covered by Schedule 3A, Part 6 of the UKEX Regulations.
ATEX Type Examination Certificate	Element certificate for ATEX type compliance covered by Annex VIII of the ATEX Directive.
UK Quality Assurance Notification (UKQAN)	Element certificate for ATEX compliance of the manufacturing and production facilities covered by Schedule 3A, Parts 2 and 5 of the UKEX Regulations.
Technical File Retention	UKEX Technical File as communicated to (or lodged with) the Approved Body.

Responsibilities of the Applicant

- 1.0 The Applicant must:
- 1.1 Abide by these scheme rules and the relevant provisions of the UKEX Regulations and/or the IECEx Certified Equipment Scheme as appropriate;
- 1.2 co-operate fully with Element and make all necessary arrangements for the conduct of the evaluation, including provision for examining documentation and access to all areas, records (including internal audit

- reports) and personnel for the purposes of evaluation (e.g. testing, inspection, assessment, surveillance, reassessment) and resolution of complaints;
- 1.3 only make claims regarding certification in respect of the scope for which the certification has been granted (as detailed on the UKQAN) and within the valid dates of that certification;
 - 1.4 upon expiry, suspension, withdrawal or cancellation of a certificate or UKQAN, discontinue its use of all advertising matter that contains any reference thereto and return any certification documents as required by the certification body;
 - 1.5 endeavour to ensure that no certificate or report nor any part thereof is used in a misleading manner;
 - 1.6 inform the certification body of any intended or actual modifications to the product or production control process which may effect the validity of the certification (note that responsibility for continued conformity remains with the Applicant);
 - 1.7 operate a complaints procedure and keep a record of all complaints made known to the Applicant relating to a product's compliance with requirements of the relevant standard and to make these records available to the certification body when requested;
 - 1.8 take appropriate action in response to a complaint (as detailed in paragraph 1.7) and document these actions;
 - 1.9 notify the certification body in writing if non-compliant product (covered by a certificate or UKQAN issued by Element) is released onto the market or otherwise supplied;
 - 1.10 pay all fees in association with the application and ongoing certification activities such as surveillance and product modification;
 - 1.11 inform the certification body of any change to details listed on the certificate or UKQAN, including address details (failure to keep Element informed of these details may invalidate your certificate or UKQAN);
 - 1.12 advise the certification body of the name and contact details (address, telephone and email) of the person responsible for liaising with the certification body in respect of certificates and/or production certificates (including UKQAN and QAR).
- 2.0 The Applicant must not:
- 2.1 Use its product certification in such a manner as to bring the certification body into disrepute;
 - 2.2 make any statement regarding its certification which the certification body may consider misleading or unauthorised;
 - 2.3 use the name of the certification body in any advertising or promotional media without prior written permission of the certification body;
 - 2.4 use the certificate number, UKQAN number or Approved Body number of the certification body except as authorised by the certification body (note that authority may be withdrawn at any time in accordance with these scheme rules - see also section 3.3.2) and with validity of the certificate or UKQAN;
 - 2.5 mark the IECEX Certificate of Conformity number or UK Type Examination or UK Unit Verification certificate number on a product except where authorised to do so by the certification body, if permitted to mark then as described within the certification documents;
 - 2.6 use the UKAS, IECEX, Element logo or Element certification mark except with the expressed permission of Element Materials Technology.

Responsibilities of the certification body

- 3.0 The certification body shall:
- 3.1 Evaluate the products of the Applicant against the standards covered by the scope defined in the certification application form against all certification criteria specified in the rules of the scheme;
 - 3.2 adopt reporting procedures that suits its needs and that clearly demonstrate conformity with all of the certification requirements;
 - 3.3 provide to each supplier offering certified products formal certification documents including certificates and UKQAN;

- 3.3.1 subject to the Applicant's continued compliance with the requirements of the certification scheme, re-issue UKQAN when required;
- 3.3.2 authorise in writing the Applicant to utilize the certificate number, UKQAN number or Approved Body number in accordance with these scheme rules;
- 3.3.3 if required, revoke authority in writing in respect of the use of certificate number, UKQAN number or Approved Body number in accordance with these scheme rules;
- 3.4 decide as to whether or not to certify a product on the basis of the information gathered during the evaluation process and any other information;
- 3.5 determine whether changes or modifications to the product or production control process effect the certification and what, if any, further evaluation is required to confirm continued certification;
- 3.6 not delegate authority for granting, maintaining, extending, suspending or withdrawing certification to an outside person or body;
- 3.7 have documented procedures to enable surveillance to be carried out in accordance with the relevant criteria of the IECEx Certified Equipment Scheme and/or UKEX certification scheme and document the findings of such surveillance;
- 3.8 grant certification only in respect of products that conform with the relevant conformity assessment procedures of the IECEx Certified Equipment Scheme and/or UKEX Regulations;
- 3.9 may at the discretion of the certification body include the product name, manufacturer's name, certificate number within documents listing EX products that are or have been certified under these scheme rules. These documents will be held in the public domain and may contain details of current certificates as well as those certificates subject to withdrawal or suspension;
- 3.10 maintain a complaints, disputes and appeals process whereby complaints regarding certification can be resolved (details of the Element appeals process, including access to the IECEx appeals process, are available upon request);
- 3.11 maintain current copies of the certification scheme rules in the public domain and make changes only after notification period of at least three months;
- 3.12 adhere to the rules governing the operation of certification bodies as set out within ISO IEC 17065:2012 and within the scope of UKAS and IECEx accreditation;
- 3.13 take necessary action, including suspension or withdrawal of certification, if the certification body has reason to believe that the rules of this certification scheme have been breached (see also section 5 of these scheme rules for further information);
- 3.14 Inform the manufacturer of any major changes which would have an implication on the validity of the certificate.

General rules for EX certification

- 4.0 This section of the rules applies specifically to the operation of this scheme.
- 4.1 Application fees, product evaluation fees and production control (surveillance) fees for product certification are payable by the Applicant on demand by the certification body. Delay in paying these fees will delay granting of certification.
 - 4.1.1 The details included by the Applicant on a signed and dated EX certification application form (form CSF351) will be taken as the definitive request for product certification.
- 4.2 Products listed on the ATEX UKQAN or which have been the subject of a UK Unit Verification certificate must carry the Approved Body number of the certification body adjacent to the UKCA mark (Schedules 3A, Part 2 to Part 5, and Part 7).
 - 4.3.1 Only products listed on a valid UKQAN or which have been the subject of a UK Unit Verification certificate may carry the Approved Body number.
 - 4.3.2 Products assessed under UKEX Schedule 3A, Part 6 and issued with an UKEX Category 3 Type Examination certificate are not listed on a UKQAN and must not carry the Approved Body number.
- 4.4 Products listed on a UKQAN may at the discretion of the manufacturer carry the Element certification mark on product or packaging (see section 6 of these rules for mark use conditions).

- 4.5 By granting of certification under the IECEx Certified Equipment Scheme or this EX certification scheme, the certification body does not imply conformity with the Applicant's other obligations under any other regulation or directive.
- 4.6 The IECEx QAR and UKEX specific QA inspection required under Schedules 3A, Part 2, Part 4 and Part 5 will be conducted by Element Materials Technology.
- 4.7 Applications for IECEx QAR shall be processed as per IECEx 02 and IECEx operational documents IECEx OD005 (ISO IEC 80079-34), OD009 and OD025. Audit visits may be combined with ATEX audit visits. Copies of these IECEx documents are available on request from Element.
- 4.8 Applications for UKEX Schedule 3A, Part 4 require an EX focussed QA inspection. A UKQAN for products covered under UKEX Schedule 3A, Part 4 is re-issued annually only after continued conformity has been confirmed by an UKEX focussed QA inspection.
- 4.8.1 The UKEX QA system inspection for Annex 3A, Part 4 will be conducted (with reference to ISO IEC 80079-34:2011):
- (i) Before a UKQAN is granted;
 - (ii) annually, prior to the renewal of the UKQAN;
 - (iii) when a new UK Type Examination certificate is added to the UKQAN;
 - (iv) at a time period determined by Element following an inspection where major non-conformities have been found.
- 4.9 Applicants for UKEX production control modules Schedules 3A, Part 2 and Part 5 require an ISO 9001 assessment supplemented by an UKEX specific factory inspection.
- 4.9.1 Where an ISO 9001 assessment certificate is provided by the Applicant then it must be from an ISO 17021 accredited certification body. Separate fees may apply for this activity if an acceptable certificate is not provided by the applicant.
- 4.10 A UKQAN for products covered under Schedules 3A, Part 2 or Part 5 are issued every three years and only after continued conformity has been confirmed by an UKEX focussed QA inspection in accordance with the current edition of ISO IEC 80079-34.
- 4.10.1 The procedure for UKEX Annex 3A, Part 2 or Part 5 requires both an ISO 9001 certification and an UKEX focused QA system inspection audit (to ISO IEC 80079-34:2011):
- (i) before a UKQAN is granted (initial inspection);
 - (ii) within one year of the initial inspection or 18 months after a re-assessment (surveillance audit);
 - (iii) three years after the first inspection (re-assessment audit);
 - (iv) when a new UK Type Examination certificate is added to the UKQAN and the QA parameters for that certificate are different to those certificates already included on the UKQAN.
 - (v) at a time period determined by Element following an inspection where major non-conformities have been found.
- 4.11 The detail for IECEx QAR audits is covered by IECEx document IECEx OD025 (available on request from Element).
- 4.12 Certification may be suspended or withdrawn if the certification body has reason to believe that the rules of this certification scheme have been breached.
- 4.12.1 UKEX Certification under Schedules 3A, Part 2 to Part 5 will be suspended if major non-conformities are found during an inspection audit.
- 4.12.2 If major UKEX non-conformities are found then the frequency of audit may be increased at the discretion of the Certification body.
- 4.13 The rules for addressing IECEx non-conformities are covered by IECEx operational document IECEx OD009.
- 4.14 The certification body reserves the right to make unannounced factory surveillance visits in accordance with these scheme rules, the current fee structure and at the client's expense.
- 4.15 In conducting the evaluation of products the Certification Body will take account of technical guidance in the form of UKEX ExABG decisions / ATEX clarifications / interpretations and IECEx TAG Decisions. These area available on-line from:

ATEX - <http://ec.europa.eu/enterprise/atex/nb/sheets.htm>

IECEx - http://www.iecex.com/extag_decisions.htm

- 4.16 The certification body at Element is self-funding from the certificates that it issues. Element maintains adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations, and has the financial stability and resources required for its operations. Fees for certification activities are applied on a project by project basis according to established fee schedules. Certification fees vary with the complexity of the project.

Breaches of the scheme rules

- 5.0 This section of the rules applies specifically to breaches of the scheme rules by the Applicant or any third party.
- 5.1 If the certification body has reason to believe that any aspect of the rules of this certification scheme have been breached by the Applicant then the certification will be suspended or withdrawn, pending a full investigation.
- 5.1.1 Failure of the Applicant or third party to fully cooperate with the certification body (see paragraph 1.2 of these rules) is considered to be a breach of these rules.
- 5.2 If the certification body has reason to believe that the rules of this certification scheme have been breached by the Applicant or any third party then appropriate measures will be taken to prevent potential safety hazards and to preserve the integrity of the certification body.
- 5.2.1 If the safety of certified product is compromised or certification markings improperly used then the certification body is obliged to inform the UK or EU regulatory authorities (via the UK Department for Business, Innovation and Skills) to enable them to take appropriate enforcement action across the UK or EU in accordance with the provision of the UKEX Regulations or the ATEX Directive.
- 5.2.2 Breaches of the IECEx scheme rules will be reported to the IECEx Secretariat.

Post-Certification Requirements

- 6.0 This section of the scheme rules addresses requirements applicable upon receipt of certificates.
- 6.0.1 Please report any errors within 10 days of receipt of this letter to avoid the fee associated with making changes.
- 6.0.2 A copy of the stamped technical documentation will be sent by e-mail. Please retain these documents in a safe place and make them available for any associated surveillance audits (e.g. UKQAN).
- 6.0.3 This certification is only valid whilst the schedule drawings are used for production. The manufacturer is not permitted to make concessions for the use of revised drawings without written permission from the Element Certification Body. Please contact Element if changes are required.
- 6.0.4 Certification is dependent upon continued conformity with all of the requirements of the EX Certification Scheme as set out in the latest edition of these scheme rules. Please read these rules carefully and contact us if you have any questions.
- 6.1 [Schedule 3A Parts 2 and 5 under an Element UKQAN](#)
- 6.1.1 Upon receipt of the Element UKQAN you are authorised to apply the Element Materials Technology Approved Body number 0891, adjacent to the UKCA mark, on the products listed on the schedules to the UKQAN, until the stated expiry date. This authorisation is subject to satisfactory completion of the required Element surveillance audits and maintenance of your ISO 9001 certification. The date due for completion of your next Element Materials Technology surveillance or re-assessment audit will be found on your UK QAN.

- 6.2 UKEX Schedule 3A, Part 1 without an Element UK QAN
- 6.2.1 An UKEX UK Type Examination certificate is only valid for equipment manufactured under a current UKEX quality notification to Schedule 3A, Part 2, to Part 5 of the UKEX Regulations.
- 6.3 UKEX Technical File Retention, zone 1 or 21 equipment
- 6.3.1 The six digit Element file reference number (beginning “DIF”) must be stated on your UK Declaration of Conformity.

RECORD OF REVISION

Revision	Description	By	Date
4.0	Addition of section 6 – Post-certification requirements	SKB	2017-01-25
5.0	Addition of new section 4.17	SKB	2018-09-01
6.0	Remove superfluous clause 4.10	SKB	2019-01-07
7.0	Addition of definitions for Quality Assurance Notification (QAN) and Technical File Retention	SKB	2020-01-20
8.0	Change to UKEX following Brexit (though retaining ATEX Annex VIII, category 3 certification)	SKB	2021-01-01