

IECEX PUBLICATION

**IEC System for Certification to Standards relating to Equipment for use
in Explosive Atmospheres**

An Informative Guide comparing various elements of both IECEx and ATEX





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INTRODUCTION

Since the introduction of the IECEX On-Line Certificate of Conformity in 2003 there has been a constant flow of inquiries seeking an explanation of the differences between the IECEX System and the European Union ATEX Directives.

This document aims to provide a brief overview of the differences between the IECEX and ATEX relating to specific items.

This document is not a full listing of the differences and the reader is encouraged to consult an appropriate organization, body or individual when in need of a more detailed explanation of such differences.

Likewise, the information contained in this document is for information purposes with the rules of the IECEX System and ATEX taking precedence at all times.

Document History

Date	Summary
August 2008	Original Issue (Version 1)
May 2014	Restructuring of format, addition of details about IECEX Certified Persons Scheme, and a general update of content
April 2016	ATEX Directive 2014/34/EU replaces the previous ATEX Directive 94/90/EC

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Fundamental Differences between IECEx and ATEX

IECEx System	ATEX Directives
<p>The IECEx System is one of four Conformity Assessment Systems operated by the International Electrotechnical Commission (IEC)</p> <p>The IECEx System includes the following four separate International Certification elements:</p> <ol style="list-style-type: none"> 1. IECEx Certified Equipment Scheme 2. IECEx Certified Services Scheme 3. IECEx Conformity Mark Licensing System 4. IECEx Certified Competent Persons Scheme 	<p>“ATEX” = <i>Atmospheres Exposables</i></p> <p>ATEX refers to three separate (but related) European Union (EU) Directives:</p> <ol style="list-style-type: none"> 1. In March 2014 the European Commission published a revised version of 94/9/EC numbered 2014/34/EU. Although significantly extended in some areas, there is very little change that affects this comparison. The new directive will be effective from 20 April 2016 onwards. The main changes the Regulations introduced relate to alignment of the New Legislative Framework (NLF) principles. The NLF is a set of legislative acts aim to create a more coherent and consistent legal framework for the marketing of products in the European Union across all sectors. Very little practical change fro manufacturers. Clarifies responsibilities for importers and distributors. 2. 94/9/EC Equipment Directive – this is primarily concerned with trade and the manufacture and sale of Ex equipment (electrical and non-electrical equipment with a potential ignition source). It applies minimum Essential Health and Safety Requirements (EHSRs) to avoid concerns over safety being a barrier to trade. The responsibility for compliance is with the manufacturer. 3. 1999/92/EC Use Directive – this is primarily concerned with the safety of workers and applies to the Classification of Hazardous Areas and the correct selection, installation, inspection and maintenance of Ex equipment. The responsibility for compliance is with employers and workers.
<p>Full compliance to IEC International Standards is mandatory and an IECEx Certificate confirms compliance with a specified IEC Standard(s)</p>	<p>An ATEX Certificate does NOT confirm compliance with any particular Standard.</p> <p>Compliance to Standards (CENELEC or others as ‘harmonised (eg. the IEC 60079 series)) is NOT a mandatory requirement however they are often used to assess products and most manufacturers use relevant Standards to demonstrate compliance with the Essential Health and Safety Requirements (EHSR) of Annex II of the ATEX Directive.</p>
<p>The target jurisdiction is the world - all countries.</p> <p>The IECEx System is the only Certification scheme to be formally endorsed by the United Nations as “world’s best</p>	<p>The 2014/34/EU Equipment Directive is not, itself, law but becomes law in each EU member state when it is “adopted” by that member state.</p>

<p>practise and recommended model” for use by regulators when regulating the use of Ex equipment and Services.</p>	<p>The target jurisdiction is the European Economic Area (EEA) which includes the European Union PLUS Switzerland PLUS Iceland, Liechtenstein and Norway (as European Free Trade Association (EFTA) members). ATEX is sometimes used on a voluntary basis outside the EEA.</p>
<p>Rather than being qualified within a certification body’s or test laboratory’s own country, IECEX Certification Bodies (ExCB) and IECEX Test Labs (ExTL) are evaluated and qualified according to a single International process managed and approved by the single International IECEX Management Committee. Each ExTL and ExCB is visited and assessed by an expert team of assessors from IECEX.</p>	<p>Bodies offering ATEX certification are known as “the “European ATEX Notified Bodies Group” (ExNBG) these “third party” bodies are appointed by EEA member states and ‘notified’ to the European Commission by a National Government to perform specific actions in relation to particular Directives. 2014/34/EU introduced, for the first time, a requirement for a ExNBG to have national accreditation.</p>
<p>An IECEX “Certificate of Conformity” is issued by an IECEX approved Certification body (similar to a European ATEX Notified Bodies Group) and is made publicly available (at the IECEX Website) to provide proof that an IECEX Test report has been issued to cover the samples tested (and complying with all parts of the relevant IEC Standards) and also that a Quality Assessment Report has been issued and is current to cover the factory inspection at the manufacturer’s premises.</p>	<p>ATEX ExNBG issue certificates called “EU Type Examination Certificate”– these are NOT the same as an IECEX “Certificate of Conformity” and have more in common with the IECEX Test Report. The certificate does not directly relate to subsequently manufactured items, but only to the “type” or sample that was examined.</p> <p>EU Type Examination Certificates indicate that the product complies with EHSR requirements Standards that have been used to support the justification of compliance. The EHSRs will be listed in the EU-Type Examination Certificate, but complete compliance with those standards is not guaranteed.</p> <p>Varies with category of Equipment (EPL of Equipment) and does not require compliance with standards.</p>
<p>IECEX Certificates of Conformity require that samples are fully tested against the relevant IEC Standard(s) regardless of the zone of use of the product. Test results and assessment to IEC Standards can be used for both IECEX and ATEX, in accordance with the respective rules.</p>	<p>The assessment and testing/certification process of ATEX as with EU Directives is risk based, meaning that for lower risk areas ATEX allows full manufacturer’s declaration of conformity without involvement of an NB. Other higher risk areas may require the involvement of an NB.</p> <p>Test results and assessment to IEC Standards can be used for both IECEX and ATEX, in accordance with the respective rules.</p>
<p>ATEX documentation alone is NOT sufficient to satisfy IECEX certification requirements.</p>	<p>The test reports backing up an ATEX EU Type Examination Certificate may, in some cases, be used to satisfy some of the requirements for obtaining an IECEX Certificate of Conformity.</p>

IECEX System and ATEX Directives – Common Key Elements

1. Organisation and management
2. Aims and objectives
3. Fields of application
4. Coverage
5. Validity and legal basis
6. Technical Standards
7. Certification procedures and outputs
8. Conformity Assessment system requirements
9. Manufacturer surveillance
10. Workplace requirements
11. Assessment of certification organisations

Elements in detail	IECEX System	ATEX Directives
<p>1. Organised and managed by:</p>	<p>IECEX operates within the International Electrotechnical Commission (IEC) that helps to promote the adoption of international certification of products, services and personnel operating in hazardous areas as but one segment of electrotechnology.</p> <p>The IECEX System is owned by the IEC but is designed and managed for <u>and</u> by the explosive atmospheres (Ex) sector via representation from manufacturers, certification bodies, training providers, service providers, Ex equipment end users, Ex industry personnel and experts, government regulators, and community interests.</p> <p>IECEX operates a dedicated Technical Secretariat with the IECEX Executive Secretary appointed with the Chief Executive Officer function of the IECEX System and its Scheme to handle day to day matters, reporting to the IECEX Executive and Management Committee.</p>	<p>ATEX is a Regulatory Framework (it is NOT a Certification Scheme) applied within the European Union (E. U.). The EU Commission governs the permission for suppliers to offer Ex products for sale in the EU based on the seller's declaration of product compliance with the Essential Health and Safety Requirements (EHSR) of Annex II of the ATEX Directive.</p> <p>In order to achieve a risk based approach to safety in hazardous areas, the equipment directive assigns "Categories" to equipment. The Use Directive then gives the installation requirements such that: Category 1 equipment can be installed in Zones 0, 1 and 2; Category 2 equipment can be installed in Zones 1 and 2; Category 3 equipment can be installed in Zone 2 only. Categories M1 and M2 are used for mining equipment where, traditionally, zoning is not employed.</p> <p>The level of technical assurance against becoming an active ignition source, and the rigour of proof of compliance with the technical requirements vary according to the category.</p>

	<p>The IECEX operates the On-Line Certificate of Conformity System whereby every IECEX Certification Body (ExCB) (currently there are 79 bodies across 31 countries) accesses the http://www.iecex.com website using unique password protocols to generate and maintain live versions of master controlled versions of all IECEX Certificates from all ExCBs that are free for public access. Meaning that every IECEX certificate issued by every IECEX Certification Body is in the one single and central location.</p> <p>The IECEX System is NOT a Regulatory Framework - instead it is a true Certification Scheme where an IECEX “Certificate of Conformity” is issued by an IECEX approved Certification body (ExCB) which is similar to a European ATEX Notified Bodies Group (in fact many Notified Bodies also operate as an ExCB) and publicly available to provide proof that an IECEX Test report has been issued to cover the samples tested and also that a Quality Assessment Report is also issued and current to cover the ongoing surveillance of certified manufacturing sites, service facilities and competent personnel.</p> <p>The other main difference between IECEX and ATEX is that the ATEX Directive requires that the “Essential Health and Safety Requirements” be satisfied and compliance with a relevant standard can be ‘deemed’ to satisfy these requirements. It should be noted that ATEX does <u>not</u> require compliance with the relevant IEC Standard(s). Conversely the IECEX Certification Scheme requires full compliance with the IEC Standard that is listed on the IECEX Certificate.</p>	<p>The legislation covers both electrical and non-electrical products.</p> <p>The basis of this legislation is to set out a regulatory framework that requires a manufacturer that wishes to sell their products for use in a hazardous area to declare that they have undertaken the necessary steps to assure safety and minimise risk prior to placing the product on the EU market.</p> <p>This declaration, referred to as the “EU Declaration of Conformity”, is prepared by the manufacturer stating that they are in the possession of the necessary instruments required by the ATEX Directive (noting that the testing and factory auditing requirements are different and depend upon the category of risk). This is usually in the form test reports issued by a test house; however, this is not always the case.</p> <p>In the case of equipment intended for use in a Zone 0 (Category 1) or for electrical equipment intended for use in Zone 1 (Category 2) the manufacturer needs to engage a European ATEX Notified Bodies Group for Examination/Testing of the samples and also a European ATEX Notified Bodies Group for the Factory inspection.</p> <p>The declaration by the manufacturer is that they have done this and are in possession of the Type Examination Certificate (which covers the assessment of samples) as well as a Quality Assessment Notification (QAN) which covers the factory inspection (current manufacturing of products).</p> <p>Products deemed to be of lower risk, for example those intended for use in a Zone 2 atmosphere, the directive may not require inspection by a European ATEX Notified Bodies Group but they must still issue a Declaration of Conformity.</p>
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<p>2. Aims and objectives</p>	<p>The objective of the IECEx System is to provide a single globally recognised and accepted Certification System for hazardous area products, services providers and competent personnel related to explosive atmosphere equipment and locations. This System allows certified products, services and personnel to be accepted and used in any of the participating countries without restriction and without further testing/documentation.</p> <p>The IECEx System does not develop standards but provides verification that products comply with existing internationally recognised standards. This is of particular interest to oil companies whose rigs frequently move to wherever they are required and avoidance of the need, via IECEx certification, to obtain additional and / or different certifications or replace equipment on the rig to meet the local legislation is a significant advantage. More recently the US Coast Guard has recognised the IECEx System and accepts Certifying Bodies that are IECEx approved for certification of equipment on off-shore installations.</p>	<p>The scope and the objective of the ATEX Directive remain unchanged from the previous Directive 94/9/EC to the new Directive 2014/34/EU. The objectives of ATEX are to</p> <p><i>remove barriers to trade and improve safety for equipment and workers by regulating equipment. Therefore, the ATEX Directive provides for harmonised requirements and procedures to establish compliance for products placed on the EU market for the first time.</i></p> <p>and these are similar to those of IECEx in that both exist to do as much as possible to minimise the risk to life, property and the environment, but the methods each use to meet the objective differ in a number of areas.</p>

<p>3. Fields of Application</p>	<p>Electrical products and systems used in locations where substances, gases, liquids or vapours that can explode and dusts that are an explosion risk are present. Note that the IECEx System will extend to cover non-electrical equipment and systems when the relevant standards are published as ISO/IEC documents (currently forecast for 2015)</p>	<p>Directive 2014/34/EU provides for harmonised requirements for electrical and non-electrical equipment, intended for use in environments which are potentially explosive due to dust or gas hazards, and protective systems.</p>
<p>4. Coverage</p>	<p>IECEX covers products, personnel competencies and services such as equipment design, selection, installation, inspection, maintenance, repair, overhaul, and reclamation.</p> <p>IECEX certification can therefore involve a whole enterprise – thereby encouraging a more safety orientated culture and closer alignment with other stakeholders.</p>	<p>ATEX refers to three separate European Union (EU) Directives:</p> <ol style="list-style-type: none"> 1. 2014/34/EU Directive – is a total harmonisation directive and a “New Approach” directive aligned to the New Legislative Framework. It lays down essential health and safety requirements and leaves it to standards, primarily European harmonised standards, to give technical expression of the relevant requirements contained in the Directive. 2. 94/9/EC Equipment Directive – this is primarily concerned with trade and the manufacture and sale of Ex equipment (electrical and non-electrical equipment with a potential ignition source). 3. 1999/92/EC Use Directive – this is primarily concerned with the safety of workers and applies to the Classification of Hazardous Areas and the correct selection, installation, inspection and maintenance of Ex equipment.
<p>5. Validity and Legal Basis</p>	<p>IECEX Certification is voluntary for a manufacturer however it may be a requirement of local government regulation, customers or end-users.</p> <p>The IECEx International Certification System for certification of equipment suitable for use in hazardous atmospheres has been developed by industry representatives (including manufacturers, certifying bodies, end users, regulatory agencies and</p>	<p>The 2014/34/EU Equipment Directive is not, itself, law but becomes law in each European Union (EU) member state when it is “adopted” by that member state. It has also been adopted in Switzerland, Norway, Lichtenstein, Iceland and Turkey, who have signed agreements to that effect with the EU.</p> <p>In practice it is also used in some other countries outside the EU and may be accepted on a voluntary basis by the buyer if no other regulations for that</p>

	<p>community interests) is broader than and quite different from the ATEX Directives.</p> <p>The IECEx System is an international system in which any country can participate. As of April 2014 there were 31 fully participating countries (including Australia, Brazil, Canada, China, Croatia, Czech Republic, Denmark, Finland, France, Germany, Hungary, India, Italy, Japan, Korea, Malaysia, Netherlands, New Zealand, Norway, Poland, Romania, Russia, Singapore, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, UK and USA.) supporting 79 Independently Approved Certifying Bodies located across the participating countries and servicing the four IECEx Schemes.</p> <p>Products, personnel and services with IECEx Certification are accepted in many countries without the need for further testing or documentation and this is supported by the mutual recognition arrangements with which ExCBs must comply as a condition of IECEx System membership.</p> <p>Local certification in some countries can be provided a locally accepted ExCB on the basis of an appropriate IECEx test report (ExTR).</p> <p>Unlike ATEX, it does not matter where the product is intended to be used as all products covered by an IECEx Certificate of Conformity (issued by independent Certification Bodies approved by IECEx and not by the manufacturer) must have been independently tested and the manufacturing location subjected to a surveillance audit program by the IECEx Certification Body.</p> <p>One key advantage of IECEx from a manufacturer's perspective is the cost saving in avoiding duplication of testing by having one certification system that is</p>	<p>jurisdiction exist. In such cases the EU Commission has no legal jurisdiction. In many cases such countries will have their own governing body, usually a government department which will wish to examine the relevant documentation before issuing approval for equipment to be operated in hazardous areas within their territory.</p> <p>Whilst, from a legislative perspective, all that is required to place Ex products on the market within the EU is compliance with the ATEX Directive, it is common for customers to also request proof of IECEx Certification.</p>
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	accepted worldwide. Regular QA audits to ensure continued compliance are required by IECEx hence the costs and efforts of surveillance activities can be minimised where a manufacturer is producing equipment for both systems.	
6. Technical Standards	IECEX is a true System 5 Certification Scheme (as per ISO / IEC 17065) where full compliance with IEC International Standards is mandatory for certification purposes.	<p>ATEX requires compliance with the EHSR listed in Annex II and uses compliance with Standards as a “deemed to comply with EHSR requirements” approach – this means that strict compliance with Standards is NOT a requirement of ATEX. Manufacturers, however, often use standards as their means to assess products and to demonstrate compliance with the EHSRs.</p> <p>Any recognised Standard or local health and safety regulation may be applied, provided it matches the Essential Health and Safety Requirements of the Directive. The E.U. Commission issues a list of Harmonised Standards.</p> <p>These harmonised CEN/CENELEC standards have been developed specifically to allow a presumption of conformity with the EHSRs via conformity to the relevant harmonised standard. The word ‘<i>presumption</i>’ means that full compliance is not automatic when applying CEN/CENELEC standards.</p> <p>It should also be noted that Ex CENELEC standards are generally technically identical to the related IEC standards.</p>
7. Certification Procedures and Outputs	IECEX ExCBs issue [<i>for Certified Equipment Scheme</i>]: <ul style="list-style-type: none"> i. ExTR (IECEX Test Report) ii. QAR (IECEX Quality Assessment Report) 	ExNBG issue <ul style="list-style-type: none"> i. EU Type Examination Certificates – these document the evaluation and testing of the

	<p>iii. IECEX CoC (Certificate of Conformity - Equipment)</p> <p>IECEX ExCBs issue [<i>for Certified Service Facility Scheme</i>]:</p> <ol style="list-style-type: none"> i. FAR (Facilities Assessment Report Form) ii. IECEX CoC (Certificate of Conformity – Service Facility) <p>IECEX ExCBs issue [<i>for Certified Competent Person Scheme</i>]:</p> <ol style="list-style-type: none"> i. PCAR (Personnel Competence Assessment Report) ii. IECEX CoPC (Certificate of Personnel Competence) <p>Where the IECEX On-Line Certificate of Conformity System publically accessible at http://www.iecex.com is used to :</p> <ul style="list-style-type: none"> • officially register reports • make the master controlled version of certificates available for full public view on the IECEX website's On-line Certification System <p>The processes underpinning the above activities are defined in:</p> <ul style="list-style-type: none"> • IECEX Rules of Procedure for each Scheme (IECEX 02, IECEX 03, IECEX 04 and IECEX 05) • Operational Documents (ODs) that provide standard operating procedures to be followed by all ExCBs • Technical Decision Sheets that are all publically accessible at http://www.iecex.com 	<p>equipment to the applicable EN 60079 Standards</p> <ol style="list-style-type: none"> ii. Ex Quality Assessment Notifications (QAN) - these document the suitability of the manufacturer's QA system as related to ISO/IEC 80079-34. The preparation of these follows an identical process to that for IECEX QARs. <p>and are only available in a 'hard copy' paper format.</p>
<p>8. Conformity Assessment System Requirements</p>	<p>The IECEX System is a set of four separate elements (of which one relates to Ex Equipment) that were developed to satisfy the calls from the Ex industry for international recognition and coordination of the outputs of various certification systems and test</p>	<p>An EU Declaration of Conformity is the declaration made on the sole responsibility of the manufacturer that he is in possession of necessary documents and reports regarding the specific equipment. The manufacturer attests the full compliance with the</p>

	<p>houses with different practises with different levels of expertise.</p> <p>The IECEX Certified Equipment Scheme operates on</p> <ul style="list-style-type: none"> ○ having a single qualification process for the assessment and evaluation of Certification Bodies (ExCBs) and Test Laboratories (ExTLs) to ensure that they have the necessary test equipment and facilities and also staff with the necessary level of technical expertise to conduct testing and certification, and ○ establishing a single way of conducting Ex testing and certification – under IECEX there is <u>NO</u> difference in the treatment of Zones 0, 1, or 2 (as allowed in ATEX). All equipment under IECEX must be independently tested and certified in order to carry the IECEX certificate number and have an IECEX Certificate issued on the IECEX website. <p>In particular:</p> <p>..... in the IECEX Certified Equipment Scheme:</p> <ul style="list-style-type: none"> ○ ExTR + QAR = IECEX CoC ○ Self-certification is <u>not</u> permitted ○ The use of Manufacturer Data or un-witnessed testing results for certification purposes is <u>not</u> generally accepted. ○ In most cases an IECEX ExTR can underpin an ATEX EC Type Examination Certificate where the technical requirements in IEC and EN Standards are identical (normally this is the case) ○ In all cases an IECEX QAR can underpin an ATEX QAN ○ In many cases European ExCBs will issue IECEX Certification and ATEX Documentation at the same time for particular equipment. 	<p>ATEX Directive. The use of such equipment must not create dangerous situations. The manufacturer is responsible for the foreseeable misuse if the user is not able to fulfil the specific conditions of use correctly.</p> <p>NOTE that an IECEX Certificate can directly underpin a EU Declaration of Conformity for Category 3 Equipment without involving an ExNBG.</p> <p>ATEX provides many routes fro Conformity Assessment. Not all involve Certification (the intervention fo a 3rd party). The Internal control of production is done entirely by the manufacturer on his own responsibility.</p>
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	<p>.... in the IECEx Certified Service Facility Scheme:</p> <ul style="list-style-type: none"> ○ FAR + Assessment of Facility staff competencies = IECEx CoC ○ re-assessment required every three years ○ Self-certification is <u>not</u> permitted <p>.... in the IECEx Certified Personnel Competency Scheme:</p> <ul style="list-style-type: none"> ○ PCAR + Assessment of applicant's competencies = IECEx CoPC ○ CoPC issued according to Competency Unit requirements ○ re-assessment required every three years ○ Self-certification is <u>not</u> permitted ○ Training is <u>not</u> provided nor is it necessarily required as a path to competence. 	
9. Manufacturer Surveillance	IECEx ExCBs maintains the Status of the IECEx Certificate of Conformity based on the outcome of follow up Quality Audits as reported by Quality Assessment Reports (QARs)	<p>A Notified Body (ExNBG) is a “third party” body NOTIFIED to the European Commission by a National Government to perform specific actions in relation to a directive.</p> <p>-2014/34/EU introduced, for the first time, a requirement for a ExNBG to have national accreditation.</p> <p>ExNBG conduct regular audits of manufacturers in respect of all Category 1 equipment and electrical equipment of Category 2. There is no audit in respect of non-electrical Category 2 equipment or in respect of all Category 3 equipment.</p>
10. Workplace Requirements	Nil – this is outside the scope of the IECEx System. For further details refer to relevant National regulations	ATEX “User” Directive contains special requirements for workers and employers.

<p>11. Assessment of Certification organisations</p>	<p>All IECEX ExCBs and ExTLs are subject to the following assessment regime:</p> <ol style="list-style-type: none"> 1. an initial Peer Assessment by an IECEX Assessment Team, prior to acceptance for entry to the IECEX System 2. ongoing surveillance assessment audits 3. 5 Year re-assessment audits <p>The assessments and other administrative activities of the IECEX System are managed by the IECEX Technical Secretariat under the direction of the:</p> <ul style="list-style-type: none"> ○ IECEX Management Committee (ExMC) ○ IECEX Technical Assessment Group (ExTAG) ○ IECEX Conformity Mark Committee (ExMarkCo) ○ IECEX Personnel Certification Committee (ExPCC) <p>supported by specialist Working Groups as required.</p>	<p>ATEX Notified Bodies (ExNBG) are appointed by individual nomination of the governments of their countries – a common assessment system does <u>not</u> exist.</p> <p>The ongoing surveillance of ExNBG is dependent upon national government requirements.</p> <p>ATEX is supervised by:</p> <ul style="list-style-type: none"> • An ATEX Working Group • An EU Commission Standing Committee Working Group (Legal)
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