

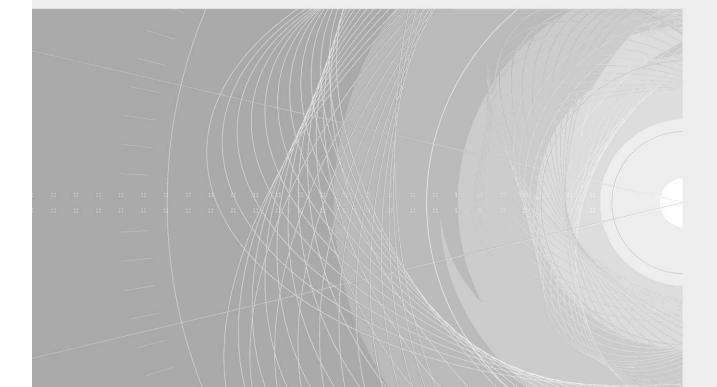


Edition 2.0 2018-11

## **IECEX PUBLICATION**

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

**Frequently Asked Questions and the Answers** 





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Frequently Asked Questions and the Answers

INTERNATIONAL ELECTROTECHNICAL COMMISSION

PRICE CODE ZZ



## IECEx - FAQs from Ex Equipment Manufacturers, Purchasers and Users

### [HINT: use the "Find" tool in Word or similar software to search for your answers by key word or term]

	QUESTION	ANSWER
1	What is the difference between IECEx and ATEX?	The IECEx System is a set of four separate Schemes (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 laboratories (house) with different practises with different levels of expertise.
		<ul> <li>The IECEx scheme operates from the platform of</li> <li>having a single Qualification Process for the assessment and evaluation of Certification Bodies and Test Laboratories to ensure that they have the necessary test equipment and facilities with staff holding the necessary level of technical expertise to conduct testing and certification, and</li> </ul>
		• establishing a single way of conducting Ex testing and certification - we refer to this as doing Ex certification the "IECEx Way". As an illustration, it is acceptable under ATEX to rely solely on a manufacturer's declaration for Zone 2 equipment (Ex 'n') whereas for IECEx we do not discriminate between Zone 0, 1, 2. <u>All</u> 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.
		Therefore, while we have some 57 ExCBs approved by IECEx to issue IECEx certificates, it is important to know that these bodies may still conduct testing and certification according to their local schemes, eg ATEX for EU based ExCBs and American for US based etc. So to be sure that the product is covered by an IECEx certification, the Ex equipment must carry on the marking plate the IECEx Certificate number "IECEx XXX 18.0001" where:
		'IECEx' shows that it is an IECEx certification 'XXX' identifies the ExCB that issued the IECEx certificate '18' Represents the last 2 digits of the year of issue '0001' represents the running certificate number issued in that year
		<ul> <li>The fundamental differences between ATEX and IECEx are:</li> <li>Targeted Jurisdiction for ATEX is the European Union but does get used on a voluntary basis outside EU</li> </ul>
		• ATEX requires compliance with the EHSR listed in Annex II and uses compliance with Standards as a "deemed to comply with EHSR requirements" meaning that strict compliance with Standards is NOT a requirement of ATEX. However most manufacturers use standards as their means to demonstrate compliance with the EHSRs
		• Bodies offering ATEX services are known as "Notified Bodies" (ExNB). These bodies are qualified by the official body within their own country with the official body in the country issuing a notification to the EU Commission.
		• A certificate issued by an ExNB is called "EU Type Examination Certificate" and is <u>not</u> a Certificate of Conformity.
		The assessment and testing/certification process of ATEX as with EU Directives is risk based, meaning that for lower [continued overpage]

QUESTION	ANSWER
	risk areas like previous zone 2 or Ex n, ATEX allows full manufacturer's declaration without involvement of an ExNB
	When it comes to IECEx
	Targeted Jurisdiction is the world, all countries
	As such, IECEx is a true International Certification Scheme where full compliance with IEC International Standards are required
	• Rather than being qualified within a certification body or Test Lab'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.
	• IECEx operates a Technical Secretariat with the IECEx Executive Secretary appointed with the Chief Executive Officer Function of the Scheme to handle day to day matters, reporting to the IECEx Executive and Management Committee
	• ExCBs issue IECEx Certificates of Conformity that require that samples be fully tested against the Standard regardless of the zone of use of the product.
	• IECEx Certificates are ALL publicly available for full viewing at the IECEx Website. This provides a single central On-Line location where Certificates issued by all IECEx approved ExCBs are located. In effect we say if the IECEx certificate does not appear on the website then it is not issued.
	<ul> <li>IECEx operates separate Schemes for         <ul> <li>IECEx Certified Equipment Scheme</li> <li>IECEx Certified Service Facility Scheme</li> <li>IECEx Certification of Personnel Competencies (CoPC) Scheme</li> </ul> </li> </ul>
	• IECEx is the only Certification scheme to be formally endorsed by the United Nations as "world's best practise and recommended model" for use by regulators when regulating the use of Ex equipment and Services.
	The point to understand is that ATEX has been set up and works effectively within EU where there exists EU legislation as the overarching requirement.
	As IECEx operates globally across many national and regional jurisdictions, the IECEx rules governing acceptance of ExTLs, ExCBs and the process of certification needs to be comprehensive to ensure that confidence and integrity in IECEx certifications are maintained.
	So while from a legislative perspective, all that is required to sell Ex products in EU is ATEX, customers are asking for IECEx as well.
	These and other differences are explained in more detail on our <i>IECEx Guidance Publication IECEx 01A</i> available for free download at <u>http://iecex.com/Publications/IECExGuides/IECEx</u> 01A

	QUESTION	ANSWER
2	If the company has an ATEX approval based on CENELEC standards similar to IEC, can this certificate easily be converted to an IEC Ex certificate without any additional tests, or is it only a question about paper works by any IECEx ExTL?	If the testing under ATEX has been done and satisfies all requirements of the relevant IEC Standard(s), then it is a case of transferring the test data into the IECEx Test Report format.
		The <i>IECEx Operational Document, OD 009</i> provides further explanation
		More information about the similarities and differences between IECEx System and ATEX Directives can be found in <a href="http://iecex.com/dmsdocument/464/IECEx 01A">http://iecex.com/dmsdocument/464/IECEx 01A</a>
3	Is an IECEx Certificate of Acceptance the same as an IECEx Certificate of	No, an IECEx Certificate of Acceptance confirms that a testing laboratory is an accepted / approved Test Laboratory for conducting testing to IEC Ex Standards.
		An IECEx Certificate of Conformity (Equipment) issued by a IECEx Certification Body (ExCB) to a manufacturer of equipment supplying products that satisfy the relevant requirements of appropriate IEC Standards AND are manufactured in factories that continue to satisfy requirements checked regularly by surveillance audits.
		IECEx Certificates of Conformity for Service Facilities and Personnel Competencies are also issued by ExCBs to demonstrate compliance of service facilities or individuals to relevant requirements. The ongoing compliance is also checked by audit.
4	Who do I contact if I have a question relating to a product covered by an IECEx Certificate?	The first point of contact should be the manufacture. If for whatever reason the question relates to the specifics of the Certificate, then the ExCB who issued the Certificate should be contacted. The list of ExCBs including their contact details can be found on the IECEx website at: <a href="https://www.iecex.com/information/excbs/httpwww-iecex-comdirectorybodiesbodies1-aspid5/">https://www.iecex.com/information/excbs/httpwww-iecex-comdirectorybodiesbodies1-aspid5/</a> Simply click on the Identifier and this will populate the ExCB details including email, phone, and Scope of IEC Standards they can issue and test to.
5	Who can issue an IECEx Certificate of Conformity?	Only approved IECEx Certification Bodies (ExCBs) can operate within the IECEx Certified Equipment Scheme and issue IECEx Test Reports (ExTRs), and IECEx Quality Assessment Reports (QARs). The list of IECEx Certification Bodies can be accessed from the IECEx website under Information/ExCBs: <u>https://www.iecex.com/</u> The Certified Equipment Scheme approved IECEx Certification Bodies can be accessed from the IECEx website from the following link: <u>https://www.iecex.com/information/excbs/httpwww-iecex- comdirectorybodiesbodies1-aspid5/</u> The IECEx webpage provides ExCBs by Country and Identifier. By clicking on the blue Identifier (company name) this will populate the specific details of the ExCB including their contact details and approved Scope of Standards they can test to.
6	Where is IECEx Certification accepted?	The cost of multiple certifications in terms of both certification costs and time to market are no longer acceptable to industry operating in a global marketplace. This aspect is the very reason IECEx was born in the first place.
		While accepting that many established markets will require their own national or regional certificate/approval to be issued, one must not overlook the markets that do not have their own Ex standards nor an Ex certification or approval scheme. These countries are ready to accept an International Certificate of Conformity issued

	QUESTION	ANSWER
		under the IEC framework. Many of these are developing economies where infrastructure is being built or upgraded.
		For other countries with their own certification/approval system, the IECEx Rules are very clear on those countries that are IECEx Members. They must recognise the conformity assessment data that is generated to achieve an IECEx Certificate.
7	Will an IEC Ex Certificate of Conformity be accepted into all the countries that are listed as IECEx Members <u>or</u> are some of these countries still to adopt fully the IEC Ex Scheme?	Most of the IECEx Member Countries still require some form of processing to issue their own national mark or certification or approval however every ExCB listed in the Scheme MUST accept the testing done by other bodies in the Scheme when issuing their own national system. Thereby the IECEx Scheme provides a "fast-track" process to achieving national certification in countries where regulations still require such.
		The current list of IECEx Member Countries is available at <a href="http://iecex.com/information/countries/">http://iecex.com/information/countries/</a>
		Also, there are a number of other countries that are not considered as participating members of IECEx but accept an IECEx CoC.
8	Do we need to have ISO 9001 Certification before we can obtain IECEx Certification?	No, but the frequency of ongoing surveillance audits on manufacturing or service facilities is reduced (the period is 18 months instead 12 months) if your company has ISO 9001 certification.
		More information is available in Clause 5.2.2.2.2 of <i>IECEx Operational Document</i> <u>OD 025</u>
9	My company has changed the certification body (ExCB) for the assessment of our QA system. What consequences does this have for our product certificates and the associated costs?	In the IECEx System, a change of Ex Certifying Body (ExCB) to conduct the Quality Assessment Report (QAR) surveillance is seen as a change to the Certificate and therefore the Certificate of interest and any other Certificates of Conformity (CoCs) related to the <u>original QAR</u> need to be updated to the next Issue number and then show the link to the <u>new QAR</u> . The link to the Ex Test Report (ExTR) related to your product and supporting the CoC can remain the same - there is no need for the new ExCB to issue a new ExTR.
		<ul> <li>In the Field "DETAILS OF CERTIFICATE CHANGES (for issues 1 and above):" on the new Issue of the CoC, the ExCB (responsible for issuing the CoC) will simply state: "This new Issue of the Certificate is to cover a change in the ExCB for conducting surveillance assessments and issuing of QARs".</li> <li>To progress this, we suggest the following steps:</li> <li>you arrange for the new ExCB to conduct the surveillance audit and issue a new QAR</li> <li>you then contact the ExCB that issued the original IECEx Certificates of Conformity (CoC) and request a new Issue of the CoC to link to the new QAR. The only work for the ExCB to create a new Issue of the CoC is to confirm that the QAR covers the same manufacturing location as already listed on the CoC.</li> </ul>
		The reason for the above process is to ensure that transparency is maintained to show that the CoC is being supported by a current and valid QAR at all times plus as a confirmation that the correct manufacturing locations and Ex technology match between the CoC and QARs.
		While the ExCB that needs to create the new Issue CoC to link to the new QAR may charge a small fee, this is largely an

	QUESTION	ANSWER
		administrative matter, the costs would be low in addition to the cost of Certificate fee.
10	Is it possible to obtain a Certificate of Conformity using an ExTR and QAR issued by different IECEx Certifying Bodies (ExCBs) or Ex Test Laboratories (ExTLs)?	<ul> <li>There are the three essential elements when achieving a product IECEx certificate of conformity (CoC):</li> <li>a Test Report (ExTR) to the relevant Standard(s)</li> <li>a Quality Assessment Report (QAR) for the facility where a product is manufactured or a service is provided</li> <li>the Certificate of Conformity (CoC) itself.</li> <li>It is both possible and common to obtain a CoC using an ExTR and QAR issued by different IECEx Certifying Bodies (ExCBs) or Ex Test Laboratories (ExTLs) – the control of this situation is provided by the IECEx Certification Body (ExCB) that issues the CoC and has ultimate responsibility for ensuring that:</li> <li>the ExTR and QAR are complete and correct</li> <li>they both relate to same product,</li> <li>the manufacturing site listed on the QAR is the same as that on the CoC.</li> <li>the ongoing surveillance program is carried, i.e. that annual surveillance audits are carried out and that they review such reports to ensure that there are no non-conformances raised.</li> </ul>
11	Must IECEx Certificates be issued to the current version of the relevant IEC Standard(s)?	<ul> <li>Item 8.1.1 of IECEx 02 Rules of Procedure requires that new Certificates only be issued against the current edition of the Standard or one edition prior.</li> <li>Note also that: <ul> <li>There is an exemption for IECEx Unit Verification Certificates which can be issued to any edition of the Standard</li> <li>At present there is NO requirement to upgrade a previously issued Certificate to a later edition of the Standard</li> <li>Changes may be made to previously issued certificates (the issuing of a New Issue of a Certificate) and the older editions of the Standard maybe used, that is, there is no need to upgrade the product to later editions of Standards when seeking a new issue of the Certificate.</li> </ul> </li> <li>The main rationale for the above is that in general, when a certificate number is issued, noting that IEC 60079-0 requires that the year of issue is to be incorporated into a certificate number say "IECEx XX <u>18</u>.0001" then the certificate would relate to an edition of the Standard or, to take the words of ATEX, reflect 'state of the art as at 20<u>18</u>'.</li> </ul>
12	When a new edition of a relevant Standard is published what happens to the current CoC?	The publication of a new Edition of a Standard does <u>not</u> require a new or supplementary issue of the certificate of equipment covered by IECEx Certificates of Conformity as a Certificate attests that the specified equipment satisfied the requirements of the previous Edition(s) of the Standard and this may be sufficient for the requirements of certain customers or users.
13	How is the manufacturer affected by a Standards change in relationship to the "CoC" for their IECEx certified product?	The applicant or manufacturer may however choose to request the ExCB to test and certify the equipment to the later Edition of the Standard by issuing an "up-issue" or "supplementary issue' of the original Certificate. The later issue of the Certificate will list the newer Edition of the Standard. The issue of an "up-issued" or "supplementary issue" Certificate does <u>not</u> cancel or supersede previous issues (that remain <i>Current</i> until <i>Cancelled</i> or <i>Suspended</i> ) The publication of a new Edition of a Standard does <u>not</u> necessarily mean that equipment certified to earlier Editions is not

	QUESTION	ANSWER
		safe and it is recommended that manufacturers, customers and users of equipment consider the impact of the changes in the new Edition of the Standard on the suitability of equipment certified to earlier Editions of the Standard.
14	Is it required for the CoC to be signed for it to be valid? I have seen a couple of online CoC's without signatures.	The role of the IECEx On-Line Certificate System on the IECEx Official Website is to provide a controlled and publicly available Master version of IECEx Certificates.
		Using the website version as the current and Master version provides industry with a tool to combat fake certificates. This way there is no doubt – if the certificate is not available on the system it does not exist.
		When reading an IECEx Certificate you will note the "Status" field in upper left of page 1 of every certificate – if the Status is listed as "Current" the certificate is valid and current.
		If you have printed a 'hard copy" or hold a "pdf" format electronic copy of the website Master version, you are in possession of what we call an uncontrolled copy. As the content of this may have changed or been superseded you should consult the IECEx On- Line Certificate System to confirm that it is still current and valid.
		When reading a printed "hard copy" certificate you will see that space for a signature and date has been added to the certificate near the bottom of page 1 to accommodate the situation where there is a need to have the Certification Body sign the copy to prove it is a legitimate copy – this field only appears when printing a certificate or creating a pdf format copy.
15	Is there a "life span" on the validity of IECEx Certificates of Conformity (CoCs)? If not, how would we know if a CoC submitted to us is still valid?	The role of the IECEx On-Line Certificate System is that the version you see on the IECEx Official Website, is the Master and Controlled version. In viewing an IECEx CoC you will see, towards top left of page 1 of every certificate the "Status" field – as long as the certificate status remains "Current" the Certificate is valid and current.
		As IECEx CoCs are considered living documents with a clearly defined status of Current / Suspended / Cancelled, there is no expiry date and the status can change at any time.
		For a manufacturer to keep their CoC current they must abide by the IECEx rules which include the successful auditing of their factories by an IECEx certification body every 12-18 months. So one can consider that the CoC is reconfirmed every 12-18 months.
		In more detail, see the following extract from of <u>IECEx 02 Rules of</u> <u>Procedure</u> Item 5.1 : "The certificate will attest that the equipment's design conforms to the relevant IEC Standards and that the manufacturer is manufacturing the product under a quality system and associated quality plan(s), meeting the requirements of this Scheme <u>and under the surveillance of an ExCB</u> ":
		Item 9.11 of <i>IECEx 02</i> details the rules regarding the suspension or cancellation of Certificates. One common reason for suspension or cancellation is when <i>"the manufacturer's quality</i> <i>system and associated quality plan no longer provides adequate</i> <i>confidence that Ex equipment will be produced in conformity with</i> <i>the design of the certified equipment".</i>
		A Certificate may also be temporarily "Suspended" so that the manufacturer can rectify matters identified by the ExCB as requiring attention before the Certificate is restored to "Current"

	QUESTION	ANSWER
		after which manufacture of certified equipment can recommence. The date of suspension of a Certificate will be specified on the <i>Suspended</i> status Certificate and equipment manufactured prior to this date is not affected by the suspension.
		Therefore, there is no expiry to a certificate, providing that the certificate holder (manufacturer) continues to allow the ExCB to enter their manufacturing premises and that surveillance audits are successful in enabling the ExCB to gain objective evidence that the quality management system first meets the requirements of IECEx (see <i>IECEx Operational Documents OD 005 and OD 025</i> ) and that the Ex product maintains compliance with the IEC Standards to which it was originally tested.
		So, by default, providing the manufacturer continues to comply with the IECEx rules his certificate does not expire, as there is on- going assessments of the manufacturer. The fact that the original master of the IECEx certificates are electronic and on-line, means that if suspended or cancelled then this is immediately noted on the website.
16	What is the process that the manufacturer shall follow if they decide to cease manufacture of the equipment/device permanently?	If the manufacture chooses to cease manufacture of equipment to the previous design they could elect to cancel Certificates that apply to the previous design.
17	If the manufacturer makes a change to the equipment/device from that listed on an "original Certificate of Conformity" is there a new "CoC" required?	If a manufacturer makes changes to the design of IECEx Certified Equipment they are required to advise the ExCB that issued the IECEx Certificate(s) covering that equipment – the ExCB will advise if an "up-issue" of the Certificate(s) is required to include the design changes that could impact on the ability of the equipment to satisfy the requirements of the IEC Standard listed on the Certificate. The up-issued (issue x) CoC will include a note in the "Details of Certificate Changes" (from issues 1 and above) describing the changes from the previous issue to the new "up-issued" version.
18	As the IECEx On-Line database is the "Controlled Version" of the Certificate of Conformity (CoC), how do I search the database to ensure the CoC I have is current and valid?	All CoCs remain visible on the <u>www.iecex.com</u> website to all users and can be viewed by selecting Certificate/ExTR/QAR number @ <u>http://iecex.iec.ch/iecex/exs.nsf/ex_eq.xsp?v=e</u> Please note that the top menu bar shows the 4 IECEx Schemes. If you are searching for Equipment, then ensure that Certified Equipment tab is selected. The Search menu is pretty intuitive but please note that you have click on the Search button as hitting Enter on your keyboard does initiate the Search. There is a link on this page to document OD- 011-1, (Click here for a link to the INSTRUCTIONS FOR USE) which provides more detailed instructions on the Search features. Please also note that you can search by ExTRs or ExQARs (under IECEx documents). If you already have the Certificate number, then simply type the number under the heading, <u>Certificate/ExTR/QAR number</u> and simple type in the CoC # as, 'Certifying Body Identifier < <i>space</i> > CoC number', Example: CSA 18.0001, then click on the Search button. The Certificate details will appear below, and you now have the option to click on the Certificate no. to open the document or you can click on the PDF icon to download the PDF version of the Certificate.
19	Is there somewhere on the IECEx website that shows the date of all cancelled and suspended certificates?	All Cancelled and Suspended CoCs remain visible on the <u>www.iecex.com</u> website to all users and can be viewed by selecting Status plus Cancelled or Suspended in the Status field of the search page @ <u>http://iecex.iec.ch/iecex/exs.nsf/ex_eq.xsp?v=e</u>

	QUESTION	ANSWER
		The actual date of the Cancellation or Suspension appears in the Note that the IECEx Secretariat adds to the "Equipment" field of the particular CoC at the time of suspension or cancellation.
20	What happens when an Ex Equipment Certificate of Conformity is suspended or cancelled?	Certification is a means of verifying manufacturing capability - that is, when the products were originally produced the manufacturer had confirmed their capability to an ExCB against the requirements of the IECEx Certified Ex Equipment Scheme.
		A Certificate may be cancelled on request from the manufacturer for a number of reasons (for example, that they may no longer manufacture the product) OR they may be suspended by an ExCB because it has found that the manufacturer cannot be confirmed as having the capability to produce complying product. Product manufactured before the date of suspension or cancellation may be offered for sale IF it can be shown that these items were produced when the certificate was still current.
21	<ul> <li>What are the differences between:</li> <li>Approval</li> <li>Certification</li> <li>Accreditation</li> <li>Acceptance</li> <li>Recognition</li> </ul>	<ul> <li>Guidance on the definitions of these and other terms in common use in the IECEx Schemes may be found at:</li> <li>Section 3 of <u>IECEx OD 025</u></li> <li>Section 3 of <u>IECEx 02</u></li> </ul>
22	What Responsibilities does the APPLICANT detailed on an IECEx Equipment Certificate of Conformity have?	The IECEx Rules of Procedure, IECEx 02 for the Ex Certified Equipment Scheme, define the responsibilities for parties to an IECEx Certificate. These state that (also in accordance with ISO/IEC 17065 and ISO/IEC 17067) the certificate remains the ownership and responsibility of the Certification Body with the applicant having responsibilities to the Certifier according to the Certifiers own terms and conditions via a contract between the two parties.
	What responsibilities does the MANUFACTURER(S) listed on the Certificate have?	The roles and activities of "applicant" and "manufacturer" are defined in Sections 3 and 9 of IECEx 02 Further information for applicants can be found in <i>IECEx Guidance</i>
		Publication 02A
	Who is considered to be the Owner of an IEC Ex COC? Is it the issuing Body, the Applicant or the Manufacturer?	IECEx Certificates are issued and controlled by the issuing Certification Body – in this respect they are 'owned' by that Certification Body and can be cancelled or suspended on request to the IECEx Secretariat by that Certification Body following their consultation with the Applicant.
	Who is responsible for ensuring that the Product complies?	As per Item 3.17 of <i>IECEx 02</i> it is the <u>manufacturer</u> "that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for <u>continued compliance of the product</u> with the relevant requirements and undertakes all obligations in that connection."
	What role does the IEC (as represented by IECEx) play in this process?	The IECEx System management structure confirms that an IECEx Certification body has been judged to meet the requirements of the IECEx Rules, which include compliance with ISO/IEC 17065, BUT the IECEx does not warrant the decision taken by an Ex Certification Body when they issue the certificate (refer to the <i>IEC Harmonised Basic Rules, and IECEx 01-S</i> , Section 10, Clause 10.3)

	QUESTION	ANSWER
		http://iecex.com/publications/iecex-rules/
23	Can an approved IECEx ExCBs issue Certification for non-electrical equipment that operates in a hazardous area?	Yes, as long as the ExCB hold ISO/IEC 80079-36 and ISO/IEC 80079-37 within their Scope of Standards as listed on the IECEx website. <u>https://www.iecex.com/information/excbs/httpwww-iecex-comdirectorybodiesbodies1-aspid5/</u>
24	Who can use the IECEx Logo?	The IECEx Logo shall only be used in accordance with instructions provided as published in IECEx 01B. It shall not be used in such a manner that it compromises the integrity of the IEC, IECEx or its members. Who may use the IECEx Logo The IECEx Logo may be used by the following: • IECEx Member Bodies • IECEx Certification Bodies (ExCBs) and Testing Labs (ExTLs) • IECEx Certified Equipment manufacturers • IECEx Service providers (e.g. Repair facilities) • IECEx Certified personnel • IECEX Recognised Training Providers