

INTERNATIONAL ELECTROTECHNICAL COMMISSION

IEC SCHEME FOR CERTIFICATION TO STANDARDS FOR SAFETY OF ELECTRICAL EQUIPMENT FOR EXPLOSIVE ATMOSPHERES (IECEX SCHEME)

Ex Management Committee, ExMC

Compilation of Comments received concerning document:

ExMC/94/CD : Draft rev IECEX 02 Rules of Procedure of the IEC Scheme for Certification to Standards for Electrical Equipment for Explosive Atmospheres (IECEX Scheme)

Introduction

This document is a compilation of comments received regarding document ExMC/94/CD, *Revised version of IECEX 02*.

Document ExMC/94/CD was prepared by Working Group ExMC WG1 with ExMC/94A/CD issued to indicate changes to IECEX 02 incorporated in ExMC/94/CD.

These comments are to be considered during the 2001 ExMC Meeting, in Bern, 10 –12 October 2001.

Address: IECEX Secretariat c/o QAS GPO Box 5420 Sydney 2001 Australia	Visiting Address: 286 Sussex Street Sydney 2000 Australia	Tel: +61 2 8206060 Fax: +61 2 8206 6061 Email: chris.agius@gas.com.au
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COMPILATION OF COMMENTS ON COMMITTEE DRAFT

Reference number of the CD ExMC/94/CD	Date of Circulation: 2001 07
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Title of the Committee Draft

ExMC/94/CD : Draft rev IECEX 02 Rules of Procedure of the IEC Scheme for Certification to Standards for Electrical Equipment for Explosive Atmospheres (IECEX Scheme)

The above-mentioned document was circulated to National Committees, ACBs, Candidate ACBs, ExTLs and Candidate ExTLS with a request that comments be submitted by 31 August 2001

Comments received – AU DE FR SE

ACTION:

Comments to be considered during the 2001 ExMC meeting in Bern

Comment No.	National Committee	Clause/ Subclause	Paragraph Figure/ Table	COMMENTS	Proposed change	OBSERVATIONS OF THE SECRETARIAT on each comment submitted
1	DE			The German National Committee agrees in principle with the scope, structure and general contents of the above-mentioned paper		General Comment
2	FR			<p>Upon careful reading the above referenced text, the French National Committee recognizes that positive changes have been brought, nonetheless it has the feeling that, still, many provisions are not totally in line with the founding principles of Certification Schemes.</p> <p>Therefore we should like to express our serious worries to see many persisting cause of confusions that may lead, in too many occasion, to a, <i>de facto</i>, non respect of the ISO 17025 and ISO 65.</p> <p>This will appear in the detailed comments that can be found below. We do hope these will be found useful</p>		General Comment
3	FR		Figure 1 Page 7	<p>The asterisk appears to provide an inaccurate information. It may lead to the belief that the IECEx Sheme and the IECEx Scheme are similar although this is not true.</p> <p>Comment 1)</p> <p>The information provided with the asterisk is, in fact, misleading</p> <p>In the CB Scheme a TR(Test Report) can only be accepted by receiving NCB (Certification Body) only if the TR <i>issued</i> by a CTL(Testing laboratory) has been endorsed by a NCB <i>The endorsement is demonstrated by the fact that a Certificate (CB-Test certificate) has been issued by an issuing NCB. The TR given to any receiving NCB is not valid if not accompanied by a Certificate and reciprocally the Certificate can only have a meaning if accompanied by the TR</i></p>		General Comment. Agree that IECEx is fundamentally different to IECEE CB Scheme and therefore should not create confusion by making such comparisons

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3 Continued	FR		Figure 1 Page 7 Continued	<p>This is, fully, in conformity with the general concept and practice of any known Certification Scheme (IECEE, CCA, KeyMARK, ENEC, UL Certification Scheme, VDE certification Scheme,...)</p> <p>The endorsement and its demonstration is a practice fully in line with the requirements of the ISO 25/ 17025 and ISO 65.</p> <p>We should like to draw the attention on the fact that the IECEx Scheme may not correspond to these International , Regional or National well established practice.</p> <p>It is clear that this in turn may lead accreditation bodies to, seriously, questioned our status of Certifying body in this Scheme</p> <p>It would be appreciated if this situation could be avoided.</p> <p>It could also affect the credibility of the Scheme as a Certification scheme</p>		
4	AU	1	NOTE	<i>Sand-filled apparatus</i> and <i>Oil-immersed apparatus</i> 'o' are out of date.	It should read: <i>powder-filling</i> 'q' and <i>oil-immersion</i> 'o'	Editorial, agree
5	FR	2, (page 8)		<p>Comment 1) Reference to ISO/IEC 17025 looks like already mandatory. In our opinion this should be left to the ExTAG to decide upon. This decision becoming applicable once endorsed by the ExMC.</p> <p>Comment 2) It is purely editorial : reference to ISO/IEC17025 should not be dated 1990</p> <p>.</p>	Therefore we would suggest to keep a reference to ISO25 and simply add : "and when appropriate, ISO/IEC 17025 will be used"	The implementation of ISO 17025 should be discussed before being made mandatory
6	FR	3.2 Page 9		We suggest this definition to be aligned on the one provided in document ExMC/103/CD article 3.9. In that		All definitions should be aligned with the

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				case reference to IEC 60079-0: 2000 is no longer needed.		relevant IEC Standards
7	FR	3.7 Page 10		Last sentence : For simplification purposes,	could it be replaced by : " The certificate can relate to Ex Equipment."	See response to comment 6
8	FR	3.9 Page 10		<p>This article should be written in such a way that the spirit of ISO/IEC17025 is not modified. Therefore we suggest the following writing:</p> <p>" IECEx Assement Test Report (ATR) a document that presents product design assessment and test results and other relevant information in order to contribute to demonstrate that an Ex equipment is in conformity with a specified standard. The ATR is prepared, signed and issued by the ExTL. To be used in the IECEx Scheme the ATR is to be endorsed by the ACB.</p> <p><i>Note : This may also impact the document ExMC/81/CD on Guidance for the preparation of IECEx ATRs by issuing ACBs and the processing by receiving ACBs</i></p>	<p>" IECEx Assement Test Report (ATR) a document that presents product design assessment and test results and other relevant information in order to contribute to demonstrate that an Ex equipment is in conformity with a specified standard. The ATR is prepared, signed and issued by the ExTL. To be used in the IECEx Scheme the ATR is to be endorsed by the ACB.</p>	For discussion
9	FR	3.14 Page 10		We would like to know if an" assessment laboratory " is a good english wording.(same remark applies to article 11.2)		For discussion
10	SE	3.16		" to align with the requirements we propose to change "and" to "or", to read ..."not identical with the IEC standard or in which"...	to align with the requirements we propose to change "and" to "or", to read ..."not identical with the IEC standard or in which"...	Agree
11	FR	3.17 Page 11		This article may be reconsidered		For discussion

Comment No.	National Committee	Clause/ Subclause	Paragraph Figure/ Table	COMMENTS	Proposed change	OBSERVATIONS OF THE SECRETARIAT on each comment submitted
12	FR	3.18 Page 11		<p>It should be reminded that the direct responsibility of the test report remains to the (Ex) TL which prepares, signs and issues it.</p> <p>Therefore an applicant cannot request an ATR from an ACB. The applicant may only request an “endorsed” ATR. Endorsement being materialized separately from the Test Report which has to be issued (therefore signed) by the laboratory.</p> <p>This can be done by a Certificate or by an Attestation or by a Notification of Test Report (NTR), documents that are issued only by an (A)CB. This is an already very common practice in different Schemes.</p> <p>Otherwise the full concept of Certification is jeopardised</p> <p>The French National Committee would like in this occasion to express its strong worries because the IECEX Scheme seems not to correspond to the Certification Scheme it intends to be.</p> <p>In the event an ATR would be allowed to actually be issued by the ACB during solely the transitional period , this would be contrary to the general principles of Certification.</p> <p>In the event an “endorsed” ATR would be materialized by a document different from a certificate (this is possible) this would mean that there will be two types of “<i>certificate</i>” in the IECEX Scheme.</p> <p>There is a risk of discrimination between the members and there is an additional risk of confusion in the market.</p> <p>Our recommendation is therefore to allow all the ExMC members to issue the same type of certificate. (This not</p>	<p>Our recommendation is therefore to allow all the ExMC members to issue the same type of certificate. (This not contradictory with the possible maintain of a transitional period)</p> <p>By so doing this would certainly give the IECEX Scheme a rapidly growing activity, which is not the case at the moment</p>	For discussion

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12 Continued	FR	3.18 Page 11 Continued		contradictory with the possible maintain of a transitional period) By so doing this would certainly give the IECEx Scheme a rapidly growing activity, which is not the case at the moment		
13	AU	3.23		'quality control system' is not appropriate.	It should read: 'quality management system'	Agree
14	FR	3.23		Could a clear reference to a document containing these requirements be made?		Agree
15	FR	5.1 Page 11		<p>Comment 1) Second sentence</p> <p>From reading the present document we feel it is far exaggerated to say that a certificate can be obtained from <i>any certification body accepted in</i> the IECEx Scheme. This will be true if the modification proposed by our Committee are taken on board.</p> <p>Comment 2) Third sentence.</p> <p>In order to maintain the credibility of the IECEx Scheme we would recommend that the certificate issued for an Ex Equipment relates only to a test of a type of equipment which of , of course, includes the relevant design aspects.</p> <p>By keeping the present wording, we fear that the customer may understand that only the design has been assessed</p> <p>Comment 3) Last sentence</p> <p>A Mark is usually governed by rules. IECEx02 should not contain these rules but a reference should be made to this type of document e.g.: IECEx03. It is not the design which is certified but the tested product Therefore we would recommend this sentence to be reworded accordingly.</p>	<p>the certificate issued for an Ex Equipment relates only to a test of a type of equipment which of , of course, includes the relevant design aspects.</p>	<p>Comment 1 – For discussion</p> <p>Comment 2 – For discussion</p> <p>Comment 3 - Agree</p>

Comment No.	National Committee	Clause/ Subclause	Paragraph Figure/ Table	COMMENTS	Proposed change	OBSERVATIONS OF THE SECRETARIAT on each comment submitted
16	FR			Second part of the sentence should be removed from “ <i>and to... Standards</i> ”, because from this part of sentence it may be understood that countries using an older edition of IEC standards would be forced to declare a... transitional period!	Second part of the sentence should be removed from “ <i>and to... Standards</i> ”,	For discussion
17	FR	5.5 Page 12		Article may be reconsidered.		For discussion
18	FR	5.6 Page 12		To be aligned on IECEE practice.		For discussion
19	AU	5.7	Sentence 2	Sentence no clear enough.	It should read: <i>‘It is the responsibility of the ACB receiving an ATR or QAR to review the documentation for completeness and correctness’.</i>	For discussion
20	FR	5.7 Page 12		First sentence and second sentence Could the word ATRs be replaced by “ endorsed ATRs ”		Agree on the basis of comment 12
21	FR	7 Page 13		In general this article should be reviewed in light of the CAB policy relating to “Participation of non IEC Countries”.		Agree.
22	FR	7.2 Page 13		The reference to a transitional period may be reconsidered		For discussion
23	FR	7.3 Page 13		Article to be removed to align on IECEE-Scheme		For discussion
24	FR	7.5 Page 13		As done in the IECEE Scheme, could a “Group difference” be taken into consideration through a proper discussion between CENELEC TC31 and IEC TC? This would simplify the administrative aspects of declaring the national differences and would certainly contribute to accelerate the process of eliminating the divergences that exist between IEC standards and CENELEC standards		Agree. This already exists in the IECEx Bulletin. IECEx 02 needs to reflect this.
25	FR	7.6		This article may be reconsidered		For discussion

Comment No.	National Committee	Clause/ Subclause	Paragraph Figure/ Table	COMMENTS	Proposed change	OBSERVATIONS OF THE SECRETARIAT on each comment submitted
		Page 13				
26	AU	7.8	2nd line	Reference to QARs is missing; 2nd sentence not clear enough.	It should read: 'In the event ... Conformity, QARs and ATRs. IECEX Certificates previously issued shall....'.	Agree
27	FR	7.8 Page 13		<p>The modification brought, so far, is not totally satisfactory. It does not take, sufficiently, on board the strong worry expressed in the letter of the French National Committee dated October 1999 and officially addressed to the Responsible of IEC Conformity Programs.</p> <p>According to the rules of any certification scheme and according to this very rules, ACBs are supposed to be independent third party. As a consequence they are supposed to be independent in all respect from the manufacturers they are servicing.</p> <p>We would like to remind that in a <i>normal</i> conformity scheme, manufacturers are never penalized by the behaviour (e/g. : financial, withdrawal of the Scheme) of their ACBs.</p> <p>Therefore a provision which satisfies these principles should be devised in this article</p> <p>In our view, right to use of granted certificates or "endorsed" ATRs shall remain normally valid, without limit. (with the exception of the obsolescence or the cancellation of a standard for safety reason).</p> <p>But in the best event, QARs shall remain valid until the next assessment is performed, but no longer.</p>		FR raised this matter previously and while the revised wording attempted to address this point, further consideration is required to address FR's concerns.
27 Continued	FR	7.8 Page 13		<p>The real question is the maintain of the right of affixing the Mark or the use of a certificate (in the sense of present</p>		For discussion.

Comment No.	National Committee	Clause/ Subclause	Paragraph Figure/ Table	COMMENTS	Proposed change	OBSERVATIONS OF THE SECRETARIAT on each comment submitted
		Continued		<p>IECEX02) in absence of the originator of the QAR that had normally the responsibility to assess the manufacturer on a regular basis. One can imagine that the manufacturer can ask an other ACB to perform this task . This should be provisioned accordingly. If no successor to the originator of the QAR is found the right to use the Mark or the use of a certificate (in the sense of present IECEX02) must fall.</p> <p>Consequently Manufacturers shall loose their rights solely on the basis of <u>article 9.13 and if no update of QAR is done.</u></p> <p>As proposed in the IECEX02 only the ATRs and QARs should remain valid but as shown above only “ endorsed” ATRs can remain valid, but QARs should have a limited life if the cycle of assessment and reassessment is not achieved</p> <p>Bearing in mind that the right to use the Mark, according to the present rule, is related to the possession of the certificate, it is clear that the solution proposed does not satisfy at all the worries expressed by the French National Committee. So the Certificate should maintain its validity.</p> <p>We kindly ask to reconsider this article on the basis of the above reflection</p>		
28	FR	8.1.1 Page 13		<p>Comment 1)</p> <p>In order to clarify the process and to benefit from the experience of other Certification Schemes, in connection with a Mark, we do consider that :</p> <ul style="list-style-type: none"> - a Certificate of Conformity to type or an “endorsement document of conformity to type” is to be issued by the ACBx. - a QAR is issued by the ACBx, (it may be based on 		
28 Continued	FR	8.1.1 Page 13				

Comment No.	National Committee	Clause/ Subclause	Paragraph Figure/ Table	COMMENTS	Proposed change	OBSERVATIONS OF THE SECRETARIAT on each comment submitted
		Continued		<p>an inspection report produced by an ACB y and endorsed by ACB x) .</p> <ul style="list-style-type: none"> - Licence to use a Mark is to be issued on the basis of the two previous documents. - This mark is necessarily the “ National/Regional” Mark of the receiving ACB during the interim period (and/or is the IECEX Mark issued by ACBx, if it's a body able to issue a certificate as set by the present rules.) <p>So there should be a decoupling between the Certificate, the QAR and the Licence(s) The Certificate + QAR gives access to a Mark (admission phase to the mark) The Licence + QAR gives manufacturers the right to continue to use a Mark (maintain phase of the Mark).</p> <p>Comment 2)</p> <p>Decoupling is, also, necessary for a very pragmatic reason : Certificate should normally be issued in one place by one ACBx and inspection report could be performed totally or partially by ACBy located closer to the manufacturing site, on behalf of ACBx which issues the QAR (similar to an endorsement) . The Licence may concern the IECEX Mark or the National Mark. By so doing, acceptable costs are reached</p> <p>Comment 3) Last sentence</p> <p>We persist in suggesting that reference to certification of type (<i>standard related</i>) is more appropriate than “certification of conformity with the design</p>		<p>Comment 1 – Agree</p> <p>Comment 2 – For discussion</p> <p>Comment 3 – For discussion</p>

Comment No.	National Committee	Clause/ Subclause	Paragraph Figure/ Table	COMMENTS	Proposed change	OBSERVATIONS OF THE SECRETARIAT on each comment submitted
29	FR	8.2.1 Page 14		<p>In this paragraph it is rightly said that an ATR, is <i>endorsed</i> by the ACB. This should be, normally, materialised by a document separate from the ATR itself that is prepared, signed and issued by the ExTL. <i>Separation of responsibility is the founding of the Certification.</i></p> <p>The ExTL is directly responsible for the data it provides, this in agreement with ISO 17025. The role of the ACB (Certification body) is to guaranty that : the whole process (this includes assessment of the ATR) for issuing the certificate or <i>any other endorsement document</i> has been fully respected.</p> <p>So the wording of this article should reflect the need to comply to ISO17025 and to ISO 65. Therefore the word "prepared" should be complemented by the words " ,signed and issued".</p>		<p>The original aim of the ATR was to provide the separation as described by FR.</p> <p>suggest further discussion</p>
30	FR	8.2.6 Page 14		<p>This article should reflect what has been said above. So the following wording is suggested : "An ATR shall be reproduced in its entirety and has no validity without its endorsement by an ACB".</p>	<p>: "An ATR shall be reproduced in its entirety and has no validity without its endorsement by an ACB"</p>	Agree
31	AU	8.3.1	2nd, 3rd and 4th lines	<p>The words 'control/controls' are not correct.</p>	<p>In 2nd and 3rd lines it should be replaced with '<i>management</i>'; in 4th line, it should read '<i>plans</i>'.</p>	Agree
32	FR	8.3.1 Page 14		<p>A clear reference to the document containing the requirements of the IECEx Scheme should be made.</p>		Agree
33	FR	9.4 Page 15		<p>"we suggests to replace "compile" by " prepared, signed and issued" to satisfy the requirements of ISO17025 and ISO 65 and to be consistent with the wording used in article 8.2.6. See other similar observations.</p>	<p>"we suggests to replace "compile" by " prepared, signed and issued"</p>	Agree

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34	AU	9.5	1st sentence	Sentence not clear.	It should read: <i>'The ACB ... plan(s) incorporated in its quality management system ...'</i>	Agree
35	AU	9.5	3rd sentence	Not clear enough.	It should read: <i>'Manufacturer's certification/registration to ISO 9001 by a competent body may provide evidence of the suitability of its quality management system.'</i>	Disagree. See comment 26
36	FR	9.5 Page 15		We suggest to use only a reference to ISO 9001-2000 for two reasons : Because ISO 9001, 9002 and 9003 are about to merge very soon and because the IECEx document that will be used for QAR is based on ISO 9001-2000. Therefore a reference to ISO 9001 may not longer be appropriate.		Agree
37	FR	9.6 Page 15		to be reviewed in light of the decoupling issue raised above in comments relating to article 8.1.1		Agree
38	FR	9.13 Page 16		We would like to stress firmly that these are the sole set of reasons for which a manufacturer shall loose partially or totally its rights. As seen before , one can add the following reason : "-absence of updated QAR" See our comments on article 7.8		Agree
39	AU	10.1	1st sentence	Intent not totally clear.	Add at the end of the sentence: <i>'...ACBs, in accordance with Clause 5.7'.</i>	For discussion
40	FR	10.1 Page 16		To be reviewed in light of our observations in order to respect the basic principle of certification. .		For discussion
41	FR	10.2 Page 16		see above comment		For discussion

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42	FR	10.4 Page 17		In order to clarify the process we would suggest to add the word “ receiving ” before the first ACB.		Agree
43	FR	11.1 Page 17		We suggest this article to be revisited in light of the CAB policy for “Participation of non IEC countries” and in light of the decoupling principle previously exposed		Agree
44	FR	11.1.1 Page 17		An ACB cannot issue ATRs. ACBs can only endorse them. Could this be corrected by using the wording “endorsed ATRs”? This suggestion is of course applicable in many other places.		Agree with the principle. Discussion required to clarify.
45	AU	11.1.1d	1st and 2nd lines	Current wording not clear enough.	It should read: <i>‘The certification body shall be formally associated with any ExTL accepted by the ExMC according to these Rules, for the relevant types of protection.’</i>	Agree
46	SE	11.1.4 and 11.2.3		to facilitate appointment of assessors and to reduce assessment costs	we suggest to consider assessment teams with two instead of three assessors, if the scope of the candidate body is adequately covered by the competence of the assessors.	The matter of assessments requires discussion. There is a need to maintain balance between minimising costs and maintaining integrity of the Scheme.
47	AU	11.1.11	1st line	The word ‘ <i>acceptance</i> ’ is not appropriate.	Replace with: ‘ <i>scope</i> ’.	For discussion
48	AU	11.1.15	End of clause	‘* <i>under development</i> within 11.2.2 is misplaced.	Move to the end of 11.1.15.	Editorial
49	FR	11.1.15 Page 18		The only cause of rejection can only be based on a professional failure when acting as an ACB in the IECEx Scheme. Consequently, we do believe that the only reason to reject an ACB is the non respect of the rules, as written in IECEx01 and IECEx02.		Disagree. ACBs and ExTL should not remain if their conduct is damaging to the Scheme

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49 Continued	FR	11.1.15 Page 18 Continued		As a consequence, it would seem appropriate to suppress the following wording coming after ...of 11.1.1 <i>"or in the opinion of the EXMC, the ACB hampers the aim , operation of development of the IECEx Scheme"</i>		
50	FR	11.2.2 Page 20		Editorial : to what is connected the asterisk?		Editorial
51	AU	11.2.9	1st line	The word ' <i>acceptance</i> ' is not appropriate.	Replace with: ' <i>scope</i> '.	For discussion
52	AU	13	2nd line	Reference to the ' <i>CAB</i> ' is incorrect.	Replace ' <i>CAB</i> ' with ' <i>Board of Appeal</i> '.	Agree. The Board of Appeal is the first course of action and if this fails then CAB.
53	FR	13 Page 22		Should not a clear reference be made to the board of appeal of the ExMC?		Agree. See Comment 52
54	AU	Annex D	Last page	Words in some sentences/titles are displaced	Fix what is incorrect	Editorial