

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Ex Management Committee, ExMC

Collation of comments on Document ExMC/52/CD – Requirements for manufacturers' quality planning

Introduction

ExMC Working Group WG5 prepared document ExMC/52/CD which was issued to ExMC members, during May 2000, for consideration for consideration.

To date comments have been received by the following:

Mr Roger Turton of GB and also member of WG5
Mrs Bo Yumin-WG5 CN
Mr Roy Jacobi-WG5 AU

The comments received have been collated and are contained in this document (ExMC/74/CD), which will be considered at the ExMC Braunschweig 2000 meeting. Members are asked to consider these comments and be prepared to discuss these comments.

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
1	0	Mrs Bo Yumin-WG5 CN	<p><u>Proposal</u> Delete “where a quality system in compliance with Annex C is used” and content of Note</p> <p><u>Reason</u> Manufacturers should have established and maintained a quality system in compliance with this document (ExMC/52/CD)</p> <p><u>Proposal</u> Delete the 3rd paragraph “ISO/DIS 9000...purposes</p>		
2	1.1	Mrs Bo Yumin-WG5 CN	<p><u>Proposal</u> “with respect to Annex C” in the end of the 1st paragraph should be deleted</p>		
3	1.2	Mr Roger Turton – WG5 GB	<p>delete from the 1st line "that are allowed by an "</p> <p>insert "within clause 7,with the agreement of the"</p>		
4	2	Mrs Bo Yumin-WG5 CN	<p><u>Proposal</u> Add “ISO/DIS9001:2000 Quality Management Systems – Requirements”</p>		

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
5	4.1	Mr Roy Jacobi-WG5 AU	<p><u>Proposed change</u> Change to read “The quality system shall ensure conformity of the equipment with relevant standards as described in the IECEx Assessment and Test Report.”</p> <p><u>Reason</u> It is important that focus for conformity be on the standards rather than the ATR (which could contain undetected errors).</p>		
6	5.4.1	Mr Roy Jacobi-WG5 AU	<p><u>Proposed change</u> Change to read “Objectives shall include evidence of commitment for ensuring that product certified under the scheme shall comply etc”</p> <p><u>Reason</u> The requirement should allow sufficient flexibility for the manufacturer to establish goals which match business strategy.</p>		

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
7	5.4.2	Mr Roy Jacobi-WG5 AU	<p><u>Proposed change</u> Change to read “The quality system shall ensure that the product conforms to the Standards described in the IECEx ATR.</p> <p><u>Reason</u> Irrespective of other requirements in “technical documentation” the most important issue is conformity with the relevant Standards. (technical documentation may be in error).</p> <p><u>Proposed change</u> Delete last paragraph “Training needs shall also be clearly identified.”</p> <p><u>Reason</u> Training is covered in 6.2.2 and importantly relates to “competency needs”.</p>		
8	5.5.6 d)	Mr Roger Turton – WG5 GB	Delete this as it has nothing to do with control of documents, it is to do with planning and has already been addressed in clause 5.4.2		

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
9	5.5.6 h)	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u> Change to read “the quality system shall ensure that product (----) defined within the IECEx ATR is not modified etc.</p> <p><u>Reason</u></p> <ul style="list-style-type: none"> • Presume that “factor” should read “product”. • Grammatical change to improve sense of paragraph 		
10	5.5.6 l)	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u> Change to read “The system shall provide change control where IECEx ATR’s have common schedule drawings and are subject to etc”</p> <p><u>Reason</u></p> <ul style="list-style-type: none"> • Change control is the important feature here. • Editorial. “and” included between “drawings” and “are”. 		

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
11	5.5.7 (NOTE)	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u> Insert “the standards identified in the “ between “with” and “IECEEx”.</p> <p><u>Reason</u> Emphasis for conformity must be with Standards rather than the ATR which may contain errors.</p>		
12	5.6.2 and 5.6.3	Mrs Bo Yumin-WG5 CN	<p><u>Proposal</u> “Revision” should be replaced by “Review”</p>		
13	6.1	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u> Replace “recourses” with “resources”</p> <p><u>Reason</u> Editorial</p>		
14	7.3	Mr Roger Turton-WG5 GB	Delete in it's entirety for 2 reasons, firstly some of the items eg design changes, have already been covered in clause 5.5.6. Secondly we are introducing issues that are outside the remit of the quality system in that they are issues dealt with during the assessment of the		

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
			product design. It is vital that we do not get design and manufacture mixed up.		
15	7.3	Mrs Bo Yumin-WG5 CN	<u>Proposal</u> "The following ... of ISO/DIS9001:2000 should be deleted.		
16	7.4.1 3)	Mr Roger Turton-WG5 GB	2nd line insert after shall include "an initial and"		
17	7.4.2 a)	Mr Roger Turton-WG5 GB	1st line delete "any" insert "the" 1st line delete "for process, control, testing or inspection"		
18	7.4.3 a)	Mr Roy Jacobi-WG5 AU	<u>Proposed changes</u> The manufacturer shall maintain a listing of product that may compromise finished product conformity with standards identified in the ATR. Product so listed shall be subject to verification methods that demonstrate conformity with relevant specifications or standards		

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
			<u>Reason</u> Change of sense of paragraph for clarification and to ensure appropriate identification of critical components /materials.		
19	7.4.3 b) 2)	Mr Roy Jacobi-WG5 AU	<u>Proposed changes</u> Change to read “where Standards identified in the ATR specify routine tests or inspections, these shall be carried out on each and every product.” <u>Reason</u> Emphasis should be on the standard rather than the ATR (ATR may have errors).		
20	7.4.3 c)	Mr Roger Turton-WG5 GB	2nd line 2nd para delete "(eg. Notification of the quality system)" 3rd line 2nd para delete "ISO9001" insert "this scheme(eg. notification of the quality system)"		
21	7.5.1	Mr Roy Jacobi-WG5 AU	<u>Proposed changes</u> <ul style="list-style-type: none"> • Replace “compliance” with “conformity”. • Replace “type as” with “standards” • Delete “and with the requirements of IECEx ATR 		

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
			<u>Reason</u> <ul style="list-style-type: none"> • Consistency • Focus on Standards Editorial. Repeated sentence.		
22	7.5.2 c)	Mr Roy Jacobi-WG5 AU	<u>Proposed changes</u> Delete “have a documented procedure to ensure”. Replace with “maintain records which provide evidence” <u>Reason</u> ISO 9000: 2000 has less emphasis on documented procedures. Records of traceability are the important issue here		
23	7.5.2 d) to j) inclusive	Mr Roger Turton-WG5 GB	Delete these requirements in total, as again we are mixing design issues with quality issues. It is not the job of the assessor of the quality system to get involved in issues such as the method of affixing the mark. This should be dealt with at the design stage and specified in the certified drawings. The quality system assessor then only has to ensure the marking is as detailed in the certified design. There are other issues that need more		

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
			thought eg in i) it refers to serially numbered labels etc, but this is not practical for high volume items such as cable glands.		
24	7.5.2 g) first dot point	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u> Delete “of the type and size”. Insert “those” between “specifically” and “listed”.</p> <p><u>Reason</u> Superfluous information.</p>		
25	7.5.2 l) first dot point	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u> Delete or rephrase as an optional possibility.</p> <p><u>Reason</u> This may be an unsatisfactory overhead for ACB to carry inventory of labels</p>		
26	7.5.3	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u> Change to read “ -----verify the compatibility of customer supplied product to ensure conformity of finished product with standards detailed in the ATR.”</p>		

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
			<u>Reason</u> Focus should be on conformity with relevant standards.		
27	7.5.4	Mr Roger Turton-WG5 GB	Again this is not a quality issue, this document should only concern itself with ensuring that the specified instructions as detailed in the design certification are being provided		
28	7.6 Note	Mr Roy Jacobi-WG5 AU	<u>Proposed changes</u> Delete ISO/IEC Guide 25 or change wording to "ISO 17025 (formally ISO/IEC Guide 25)" <u>Reason</u> Guide 25 is now redundant and is replaced with ISO 17025		
29	7.6(list of alternatives)	Mr Roy Jacobi-WG5 AU	<u>Proposed changes</u> Add "and identification" between "description" and "of" in second alternative. <u>Reason</u> For traceability, the reference standard must be positively identified (by serial number if possible).		

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
30	8.2.2	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u> Change to read “----to ensure that the products are in conformity with the standards identified in the ACB”</p> <p><u>Reason</u> Focus on conformity to standards</p>		
31	8.2.4	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u> Are these “individual tests” additional to the requirements of the standard? If so, should they be in an ATR?</p> <p><u>Reason</u> ATR is meant to reflect requirements of Standard.</p>		
32	8.3 a)	Mrs Bo Yumin-WG5 CN	<p><u>Proposal</u> Replace the clause with the following: “The manufacturer shall maintain a system, such that the products non-conforming with the IECEx Assessment and Test Report may not be supplied to customer and if these products have been supplied, then in the event of these products the customer can be identified”</p>		

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
			<p><u>Reason</u> The control of non-conformity for Ex-products shall firstly prevent the products non-conforming from the supplying to the customer</p> <p>.</p>		
33	8.3 e)	Mrs Bo Yumin-WG5 CN	<p><u>Proposal</u> Cancel this clause.</p> <p><u>Reason</u> In principle the products non-conforming to Ex-standards shall not be supplied to the customer.</p>		
34	8.5.1-8.5.3	Mrs Bo Yumin-WG5 CN	<p><u>Proposal</u> Content of 8.5.1 should be deleted. After deleting, 8.5.2 and 8.5.3 should be changed to 8.5.1 and 8.5.2</p>		
35	ANNEX C	Mr Roger Turton-WG5 GB	<p>Clause 4.1,2nd para,2nd line</p> <p>After Section 3.1 insert "with respect to both its documentation and implementation".</p>		

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
36	Annex C	Mrs Bo Yumin-WG5 CN	<u>Proposal</u> Add “if having” after “....IECEEx Certificate of Conformity” of 4.1		
37	ANNEX C	Mr Roger Turton-WG5 GB	Clause 4.1 2nd para Insert at the end of the last sentence "with a list of IECEx Assessment and Test Reports"		
38	ANNEX C	Mr Roger Turton-WG5 GB	Clause 4.5 3rd para insert the same text as above		