

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

This document contains the response of WG5 to the comments contained in document ExMC/74/CD, following a meeting of WG5 held on 1 September 2000 in Braunschweig, Germany

Comment No.	Clause No	Commentator	Comment	WG5 comment	ExMC Decision
			Management Systems – Requirements”		
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>	<p>Disagree.</p> <p>WG 5 believes that matter is covered at the initial assessment of the manufacturer’s quality system by the ACB.</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>	<p>Disagree.</p> <p>WG5 wishes to maintain alignment with the CEN WG draft</p>	

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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>	<p>Disagree.</p> <p>Refer to WG 5 decision concerning Comment 5</p> <p>Agreed. WG5 members participating in CEN WG will propose this for the CEN document.</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Delete this as it has nothing to do with control of documents, it is to do with planning and has already been	Comment withdrawn by Mr Turton	

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			addressed in clause 5.4.2		
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 	Covered with proposed amendment to item h)	
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”. 	Covered with proposed modified version of l)	

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11	5.5.7 (NOTE)	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u> Insert “the standards identified in the “ between “with” and “IECEX”.</p> <p><u>Reason</u> Emphasis for conformity must be with Standards rather than the ATR which may contain errors.</p>	<p>Disagree.</p> <p>Refer to WG 5 decision concerning Comment 5</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>	Agree	
13	6.1	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u> Replace “recourses” with “resources”</p> <p><u>Reason</u> Editorial</p>	Agree, Editorial	
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	<p>Agreed.</p> <p>Covered by 5.5.6 . Refernce to changes in standards should be addressed in</p>	

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			issues that are outside the remit of the quality system in that they are issues dealt with during the assessment of the product design. It is vital that we do not get design and manufacture mixed up.	IECEX 02, not in this document	
15	7.3	Mrs Bo Yumin-WG5 CN	<u>Proposal</u> "The following ... of ISO/DIS9001:2000 should be deleted.	Agreed	
16	7.4.1 3)	Mr Roger Turton-WG5 GB	2nd line insert after shall include "an initial and"	Agreed. WG5 members participating within CEN WG are to propose this change within CEN	
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"	Agreed. WG5 members participating within CEN WG are to propose this change within CEN	
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	Disagree. Leave as worded	

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			<p>identified in the ATR. Product so listed shall be subject to verification methods that demonstrate conformity with relevant specifications or standards</p> <p>Reason Change of sense of paragraph for clarification and to ensure appropriate identification of critical components /materials.</p>		
19	7.4.3 b) 2)	Mr Roy Jacobi-WG5 AU	<p>Proposed changes Change to read “where Standards identified in the ATR specify routine tests or inspections, these shall be carried out on each and every product.”</p> <p>Reason Emphasis should be on the standard rather than the ATR (ATR may have errors).</p>	<p>Disagree.</p> <p>WG 5 believes that matter is covered at the initial assessment of the manufacturer’s quality system by the ACB</p>	
20	7.4.3 c)	Mr Roger Turton-WG5 GB	<p>2nd line 2nd para delete "(eg. Notification of the quality system)"</p> <p>3rd line 2nd para delete "ISO9001"</p> <p>insert "this scheme(eg. notification of the quality system)"</p>	Agreed	

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21	7.5.1	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u></p> <ul style="list-style-type: none"> • Replace “compliance” with “conformity”. • Replace “type as” with “standards” • Delete “and with the requirements of IECEx ATR <p><u>Reason</u></p> <ul style="list-style-type: none"> • Consistency • Focus on Standards <p>Editorial. Repeated sentence.</p>	Agreed with first the bullet point but disagree with last 2	
22	7.5.2 c)	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u></p> <p>Delete “have a documented procedure to ensure”. Replace with “maintain records which provide evidence”</p> <p><u>Reason</u></p> <p>ISO 9000: 2000 has less emphasis on documented procedures. Records of traceability are the important issue here</p>	Delete 7.5.2 © as this is covered by (a)	
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	Agree with comments but should move to the general rules of IECEx 02	

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			<p>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.</p> <p>There are other issues that need more thought eg in i) it refers to serially numbered labels etc, but this is not practical for high volume items such as cable glands.</p>		
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>	Disagree. Maintain alignment with the CEN Document	
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</p>	Disagree. Maintain alignment with the CEN Document	

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			for ACB to carry inventory of labels		
26	7.5.3	Mr Roy Jacobi-WG5 AU	<p>Proposed changes Change to read “ -----verify the compatibility of customer supplied product to ensure conformity of finished product with standards detailed in the ATR.”</p> <p>Reason Focus should be on conformity with relevant standards.</p>	<p>Disagree.</p> <p>WG 5 believes that matter is covered at the initial assessment of the manufacturer’s quality system by the ACB</p>	
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	Agree. This is an issue for the general scheme rules	
28	7.6 Note	Mr Roy Jacobi-WG5 AU	<p>Proposed changes Delete ISO/IEC Guide 25 or change wording to “ISO 17025 (formally ISO/IEC Guide 25)”</p> <p>Reason Guide 25 is now redundant and is replaced with ISO 17025</p>	Agree	

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29	7.6(list of alternatives)	Mr Roy Jacobi-WG5 AU	<p><u>Proposed changes</u> Add “and identification” between “description” and “of” in second alternative.</p> <p><u>Reason</u> For traceability, the reference standard must be positively identified (by serial number if possible).</p>	Disagree as not necessary. Covered during description	
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>	Disagree. WG 5 believes that matter is covered at the initial assessment of the manufacturer’s quality system by the ACB	
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>	Disagree. WG 5 believes that matter is covered at the initial assessment of the manufacturer’s quality system by the ACB However, change individual to	

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				“routine”	
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> <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>	Agreed. Modified text to be presented to the CEN WG	
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</p>	Comment withdrawn due to the acceptance of comment 32	

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			the customer.		
34	8.5.1-8.5.3	Mrs Bo Yumin-WG5 CN	Proposal 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	Comment withdrawn	
35	ANNEX C	Mr Roger Turton-WG5 GB	Clause 4.1,2nd para,2nd line After Section 3.1 insert "with respect to both its documentation and implementation".	Agreed	
36	Annex C	Mrs Bo Yumin-WG5 CN	Proposal Add "if having" after "...IECEX Certificate of Conformity" of 4.1	Agreed to modifies wording	
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"	Agreed	
38	ANNEX C	Mr Roger Turton-WG5 GB	Clause 4.5 3rd para insert the same text as above	Agreed	