IECEx
QUALITY ASSESSMENT REPORT

CONFIDENTIAL

IECEx QAR Reference No.: **NO/NEM/QAR08.0001/05**
Audit Report No.: **NEM-QAR-271301**

Manufacturer Include Address with post code	:	Barel AS Havneveien 8 N-9917 Kirkenes NORWAY
Production Site(s) audited Include Address with post code	:	Barel AS Havneveien 8 N-9917 Kirkenes NORWAY ZAO BR Electronics (BRE) Sverdlova 39 Murmansk RUSSIA
Product Description	:	Electronic ballast for fluorescent light; Lamp holder.
Number of Employees	:	Totally 22 employees. About 10 of them are involved in Ex production and related activities.
Scope of Audit	:	Surveillance Assessment
List all applicable IECEx Certificates,	:	IECEx NEM 09.0002U Issue 4; IECEx ITS 09.0016U Issue 0; IECEx NEM 08.0001U issue 4.
Electrical equipment with type(s) of protection of	:	Ex e, Ex m, Ex em, Ex emb
Audit Team Leader	:	Reidar Syversen
Audit Date	:	2014-10-08 to 10

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1. Summary Report

Assessment Summary and Conclusions:

(*State the most important **results** and **conclusions** of the quality assessment)*

The audit was conducted according to the agreed audit programme. The auditors were met with a positive and professional atmosphere. In general, the QA system seems to be well implemented and are functioning satisfactorily, however some improvements may be possible.
As a result of the audit 1 finding and 8 observations / suggestions for improvement were found and noted – see findings and observations pages in this report.

There are totally 22 employees in Barel AS, in Kirkenes. 10 employees are involved in the Ex production or related activities. The manufacturer has moved into a new building located only 30 meters from the previous location. The building is new and specially built for Barel and their production.
Factory 2, ZAO BR Electronics (BRE) in Murmansk, have 43 employees and 11 of them are involved Ex production or related activities for Barel. BRE is ISO 9001:2008 by Russian Register Certification System, cert. no. 12.1304.026 valid until 2015-12-20. Many procedures and instructions are directly supplied from Barel in translated Russian language. BRE is conducting several checks and tests documented according to instruction and checklist. All physical production, assembly and testing are carried out by factory 1 and 2 listed on the first page of this report. The production at BRE is all done with parts 100% delivered from Barel. The final process with encapsulating, final safety tests and checks/verifications required in Annex A5, A7 and A3.4 are conducted by Barel for all products. The processes, documentation and records are reviewed during this audit.

(Cl. 4.2.3 / 7.5.5) Reviewed certificates: NEMKO 09ATEX1103U and IECEx NEM 09.0002U model HFX,
electronic ballast.
Applicable routine tests: Dielectric strength test and visual inspection.

Supplier of plastic/metal enclosures and moulding components are considered as safety critical.

The audit covered in this report is for Barel and ZAO BR Electronics (BRE) (manufacturer/factory 1 and 2).

Ex production is done for customers order as well as for stock.

This audit was carried out in combination with an ATEX surveillance audit.
Ref. ATEX Notification Nemko 01ATEX452Q, issued by Nemko AS, acc. to
EN ISO/IEC 80079-34:2011 incl. A.2, A.5 and A.7, valid to 2016-11-30.

The audit is partly conducted in connection with ISO 9001:2008 surveillance audit by Lars Farinha, lead auditor Nemko AS. In future the Ex audits will be combined with ISO audits as far as possible. The expiring date for the ISO 9001:2008 certificate is the same as for the ATEX QAN and IECEx QAR.

Next Quality Audit due : 2016-09 (Combined re-assessment audit for IECEx QAR and ATEX QAN)

Non-Conformities **1**

NCR No.(s): **NEM-QAR-271301/1**

Audit Team Leader Recommendations

- **Certification to be maintained / issued.**

Audit Team Leader Signature
2014-10-27

IECEx CB
2014-10-28

2. Audit Information

2.1 Scope of Audit:

Type C surveillance of manufacturer with a certified QMS

EN-ISO 9001:2008, Certificate No. 800308 issued by Nemko AS
valid to 2016-11-30, Scope:
'Marketing, sales and production of electronics, including explosion proof (Ex) products.'

2.2 Audit Criteria : OD 025 Ed. 2.0; (Checklist acc. to) EN ISO/IEC 80079-34:2011; ISO/IEC 17050-1/-2; ISO 9001:2008

2.3 Date(s) and Duration of Audit : 2014-10-08…10,
3 auditor days on site (Ex)

2.4 Composition of Audit Team:

Name	Position	Role in Audit *(Sole Auditor, Team Leader, Auditor, Technical Specialist, etc)*
Reidar Syversen	ATEX & IECEx Lead Auditor	ATEX & IECEx Lead Auditor
Lars Farinha	ISO Lead Auditor	ISO Lead Auditor
Jon Corneliussen	ATEX & IECEx trainee	ATEX & IECEx trainee

2.5 Interviewed Representatives of Manufacturer (Auditee):

Name	Position
Bjørn Dikkanen	QA responsible Ex, Development
Lars Jensen	QA Manager
Liss Hansen	Warehouse Manager
Trine Gustavsen	Managing Director
Oddrun Sandnes	Purchasing
Alexander Vassiliev	Coordinator (between Barel and BRE)
Mikhail Matskevitch	Main Engineer, QA responsible, Ex coordinator BRE
Viacheslav Zverev	Quality Engineer BRE
Sergey Krutikov	Director BRE
Julia Zatsepina	Assistant Director-interpreter

2.6 Critical Suppliers:

Name of Supplier	Critical item or service provided
Oma Plast AS	Enclosure supplier

Note: All suppliers of PCB's and enclosures / enclosure components & parts are considered safety critical.

3. Documentation Review and Assessment of Implementation

(For surveillance audits, major document changes only may be reviewed)

	IECEx OD005 clauses	Assessed (Y, N or N/A)	Manufacturer's Doc. Ref. List document(s) viewed, with revision status, and Comments List any pertinent details / compliance with requirements of clause	NCR Ref.
4.	**Quality Management System**			
4.1	General requirements	N		
4.2	Documentation requirements	Y	QA manual	
4.2.2	Quality Manual	Y	QA manual	
4.2.3	Control of documents	Y	P_P2, P_K1, P_K2, P_K3, P_K7, P_U21, P_I1	
4.2.4	Control of records	Y	QA manual (P & I), P_A23, P_I1, P_I40, P_I41, P_P2, P_P4, P_P31, P_U21	
5.	**Management Responsibility**			
5.1	Management commitment	N		
5.2	Customer focus	N		
5.3	Quality Policy	N		
5.4	Panning & Quality objectives	N		
5.5	Responsibility, authority, internal communications	Y	QA manual, P_K4, P_P2, P_U21	
5.6	Management review	Y	P_K4, P_K5, P_K6, P_K7	
6.	**Resource Management**			
6.2	Human Resources	Y	QA manual, P_A21, P_A22, P_A23, P_K4	
6.3	Infrastructure	N		
6.4	Work environment	N		
7.	**Product Realisation**			
7.1	Planning of product realization	N		
7.2	Customer related processes	N		
7.3	Design and development	N		
7.4	Purchasing	Y	QA manual, P_I1, P_I2, P_U21, P_P31, P_P4, P_L2	1
7.5	Production and service provision	Y	QA manual, manuals and datasheets, P_P2, I_U83, P_L1, P_P1, I_L3, P_P4	
7.6	Control of monitoring & measuring devices	Y	P_P31	
8.	**Measurement, Analysis & Improvement**			
8.2	Monitoring & measurement	N		
8.2.2	Internal Audit	Y	P_K7	
8.2.4	Monitoring & measurement of product	Y	P_P4	
8.3	Control of non-conforming product	Y	P_P4, P_K5, P_K6	
8.4	Analysis of data	N		
8.5	Improvement	N/A		

Annex A: Information relevant to particular types of protection

A.2	General - Material composition of (parts of) enclosures	Y	CoC / Mat. cert.	1
A.3	**Ex d - flameproof enclosures**			
A.3.1	Verification	N/A		
A.3.2	Castings	N/A		
A.3.3	Machining	N/A		
A.3.4	Cemented joints and potted assemblies	N/A		
A.3.5	Routine pressure testing	N/A		
A.3.6	Flanged joints	N/A		
A.3.7	Sintered components	N/A		
A.4	**Ex i - intrinsic safety**			
A.4.1	Components for intrinsically safe products	N/A		
A.4.2	Printed circuit boards (PCB)	N/A		
A.4.2.1	Non-populated PCB's	N/A		
A.4.2.2	Populated PCB's	N/A		
A.4.3	Sub-assemblies and assemblies	N/A		
A.4.4	Tests	N/A		
A.4.5	Intrinsically safe circuits and assemblies housed in Ex d, Ex p or Ex q enclosures	N/A		
A.5	**Ex e – increased safety**			
A.5.1	Ingress protection	N/A		
A.5.2	Internal wiring and contact integrity	N/A		
A.5.3	Rotating machines	N/A		
A.5.4	Windings	N/A		
A.5.5	Terminal boxes	Y	Production process / Visual	
A.5.6	Cable glands, terminals and other accessories	N/A		
A.5.7	Routine verifications and tests	Y	I_U175, I_U178	
A.6	**Ex p – pressured apparatus**			
A.6.1	Ingress protection	N/A		
A.6.2	Tests	N/A		
A.7	**Ex m – encapsulation**			
A.7.1	Production documentation	Y	I_P402, I_P404	
A.7.2	Tests	Y	I_U175, I_U178	
A.8	**Ex o – oil immersion**			
-	Tests	N/A		
		N/A		
A.9	**Ex q – powder filling**			
A.9.1	Material control	N/A		
A.9.2	Filling	N/A		
A.9.3	Ingress protection	N/A		
A.9.4	Tests	N/A		

4. Observations

Appendix 1 – Summary of observations.

OBSERVATIONS:		
No	**Clause**	**Summary of observations**
1	4.2.3 b) / 5.5.1 d)	It is not documented that the Ex responsible person has verified several changes in related documents as described. (Change 14_06, 14_04 and several other changes.) All changes in related documents must be documented to be verified by the Ex responsible person. It seems that change of Technical Datasheets has not followed the described workflow for changes of documents.
2	4.2.3 i)	The manufacturer shall have a documented process to annually check the validity of all Ex related certificates, standards, regulations and other external specifications.
3	5.5.1	According to the work instruction and organization chart at BRE the Ex responsible at this location will communicate Ex issues to the Ex coordinator between Barel and BRE (Alexander). It must be described that the coordinator must report all Ex issues and specially any non-conformity to the Ex responsible in Barel.
4	5.6.2	All relevant issues regarding Ex, including non-conformities and internal audits, must be included in the Management Review meetings.
5	6.2.2	The manufacturer shall ensure that all persons having an impact on Ex compliance receive appropriate training. This must be described and documented for all relevant workers.
6	7.4.1	Audits of Ex critical suppliers must be performed within a 12 months period of time as described and required. The audit of the factory BRE was done 2014-03-24 and 2012-11-30. Audits of Ex critical Suppliers should be performed be sufficient trained audit and Ex personnel.

7	8.2.2	Yearly Ex internal audits must ensure that relevant Ex products and production processes are audited.
8	**8.3 b)c) d) e) 3)**	The two documented procedures for nonconformity, P_K6 and P_K5 are not in line. Procedure P_K6 is update and seems to cover the remark from last audit: *"The procedure shall specifying that a risk analysis is to take place following the delivery of a non-conforming Ex product to a customer, either the cause seems to be related to a supplier, to internal practice, or a general customer complaint.* *(It is recommended that the issuer of the Ex certificate is contacted if in doubt.)* *Possible actions to be taken, depending on the degree of risk, should be considered in advance.* *If the result of this risk analysis is that there is a safety issue (unsafe non-conforming product), written notifications shall be sent to the notification body for the QAN/QAR and the issuer of the Ex certificate, as well as to all customers potentially concerned by this issue. (If it is not possible to trace unsafe nonconforming products a notice shall be placed in appropriate publications providing recommended action to be taken.)* *Actions taken to inform customers, notification body for the QAN/QAR and the issuer of the Ex certificate shall also be included in the NCR reports."* P_K5 must also be updated.