

INTERNATIONAL ELECTROTECHNICAL COMMISSION IEC SYSTEM FOR CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE IN EXPLOSIVE ATMOSPHERES (IECEX SYSTEM)

Circulation to: Ex Management Committee, ExMC

TITLE: IECEx Re-Assessment Report for the continued acceptance of the Slovenian Institute of Quality and Metrology, SIQ Ljubljana, as an Accepted Ex Certification Body (ExCB) and an Extension of Scope to include the following Standards, IEC 60079-31 (Dusts), IEC 60079-35-1 and IEC 62013-1 (Caplights) within their scope.

INTRODUCTION

This document contains the IECEx scheduled 5 Year Re-assessment Report for SIQ, an Accepted IECEx Certification Body, (ExCB). During the re-assessment visit an assessment for an Extension of Scope to include IEC60079-31, 60079-35-1 and 62013-1 was also carried out.

ExMC Members are asked to vote on the IECEx Assessment Team's recommendation for the scope extension of the Accepted ExCB, SIQ, to include the following Standards, IEC 60079-31 (Dusts), IEC 60079-35-1 and IEC 62013-1 (Caplights) within their scope.

Please complete and return the voting form, separate Word Document, for the scope extension to the Secretariat by –

2012 12 31

Your speedy response to the voting process will be very much appreciated. Contact details:

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IECEx ASSESSMENT REPORT FOR Slovenian Institute of Quality and Metrology (SIQ Ljubljana) (IECEx Certification Body ExCB)

Х

Type of Assessment: (please mark)

Initial Assessment for Candidate ExCB

Re-Assessment of ExCB X

Scope Extension of ExCB

1. OBJECT AND FIELD OF APPLICATION

1.1. Country:

SLOVENIA

1.2. Name of Candidate ExCB

Slovenian Institute of Quality and Metrology (SIQ Ljubljana)

1.3. Members of the Assessment Team

Xu Jianping, Team Leader Herbert Peters, Expert Assessor

1.4. Place and Date of Assessment

Slovenian Institute of Quality and Metrology (SIQ Ljubljana) Trzaska cesta 2 SI-1000 Ljubljana SLOVENIA

19th - 20th April, 2012

1.5. Assessment References

- i) IECEx 02 IECEx Certified Equipment Scheme rules of procedure
- ii) IECEx OD 003-2 IECEx Assessment procedures
- iii) IECEx OD 005-1 Quality System requirements for manufacturers
- iv) IECEx OD 009 Issuing of CoCs, ExTRs and QARs



- v) IECEx OD 025 Management of assessment and surveillance programs for manufacturers (includes QAR forms)
- vi) ISO/IEC Guide 65:1996
- vii) OD 017 Drawing and documentation guidance for IECEx certification
- viii) SIQ's application of scope for the re-assessment by email dated 1 March 2012 and 19 April 2012

1.6. Scope of Assessment

Number	Title		
60079-0	Explosive atmospheres -		
Edition 6	Part 0: Equipment - General requirements		
60079-1	Explosive atmospheres -		
Edition 6	Part 1: Equipment protection by flameproof enclosures "d"		
60079-7	Explosive atmospheres -		
Edition 4	Part 7: Equipment protection by increased safety "e"		
60079-11	Explosive atmospheres -		
Edition 6	Part 11: Equipment protection by intrinsic safety "i"		
60079-18	Explosive atmospheres -		
Edition 3	Part 18: Equipment protection by encapsulation "m"		
60079-31	Explosive atmospheres -		
Edition 1	Part 31: Equipment dust ignition protection by enclosure "t" Scope extension		
62013-1 Edition 2	Caplights for use in mines susceptible to firedamp - Part 1: General requirements - Construction and testing in relation to the risk of explosion Scope extension		
60079-35-1 Edition 1	Explosive atmospheres - Part 35-1: Caplights for use in mines susceptible to firedamp - General requirements - Construction and testing in relation to the risk of explosion Scope extension		

1.7. Candidate ExCB Persons Interviewed

Name	Position
Igor Likar	Managing Director
Alja Pregl	Certification and Quality Manager
Andrej Rakuša	Approval of ExTR, Review and approval of QAR

1.8. Legal Entity of the Candidate ExCB

SIQ was founded at the end of 1992, as the successor of the Institute of Quality and Metrology (IKM) by the Contract on foundation. SIQ is a public, non-profit-distributing institution founded according to the law on institutions (OG 12/92-1).

1.9. Associated Testing Laboratories

The associated ExTL is integral with the ExCB at the same site of SIQ Ljubljana, but the Ex d testing facility is located in Podvine 36, SI-1410 Zagorje ob Savi, a part of



premises of Slovenian Institute of Quality and Metrology (SIQ). It is about 60 km away from the SIQ Ljubljana and was included as part of the ExTL assessment.

1.10. Associated Certification Functions

There is a large amount of other certification functions at SIQ. SIQ is accepted into the CB Scheme as an NCB and CBTL. It also does a range of other certification and testing, particularly as a notified body for low-voltage, medical, measuring, Ex, machinery devices and EMC. It is also a member of European certification schemes such as ENEC. It is a member of IQNet in the field of management systems certification.

1.11. National Marks and Certificates

SIQ is a notified body under ATEX and 9 other European directives. There is also an SIQ voluntary certification mark **SI**

1.12. Financial Support

As a professional, independent and impartial institution, SIQ is a self-funding organization relying on the income from its testing, calibration and certification of electrical products, assessment of management systems as well as relevant training to fund its operating and investment costs. There is no financial support from government and/or other social organizations.

1.13. *History*

SIQ was founded in 1992 to succeed the Institute of Quality and Metrology (IKM) with the transfer of all goods, including staff, values, rights and obligations agreed between SIQ and IKM (ratified by IKM Council on 1993-01-18). A total of over 45 years involvement in testing and certification of electrical products, and metrology at the same premises in Ljubljana. Ex testing was commenced in the mid 1990s. Since 2002, SIQ has been becoming as an ExCB and ExTL of IECEx certified equipment scheme.

1.14. Standards Accepted

See clause 1.6 of this report

1.15. *National Differences to IEC Standards*

National differences to IEC standards are listed in the latest version of the IECEx Bulletin.

2. ORGANISATION

2.1. Names, Titles and Experience of the Senior Executives

Name	Title	Experience
Igor Likar	Managing Director	32 years at SIQ, 17 years in Ex
Alja Pregl	Certification & Quality	10 years as quality manager, 5
	Manager	years as certification manager



2.2. Name, Title and Experience of the Quality Management Representative

Name	Title	Experience
Alja Pregl	Certification & Quality Manager	10 years as quality manager, 5 years as certification
		manager

2.3. Name and Title of Nominated Principal Contact

Name	Title	Comments
Igor Likar	Managing Director	Tel: +386 1 4778 100
		Fax: +381 1 4778 444
		Email: igor.likar@siq.si

2.4. Name and Title of Signatories for Certification

Name	Title	Comments
Igor Likar	Managing Director	32 years at SIQ, 17 years in
		Ex. Detailed in CR104 (for
		products), also in TDEx02
Zoran Svetik	Director of PMT (testing and	29 years at SIQ, 6 years in Ex.
	measurement technologies)	Detailed in CR104 (for
	department	products), also in TDEx02
Alja Pregl	Certification Manager &	15 years at SIQ, 5 years in Ex
	Quality manager	as certification manager. 10
		years as Quality Manager.
		Detailed in CR104 (for
		products), also in TDEx02

2.5. Other Employees in ExCB activity

Name	Title	Responsibility and Experience in Ex
Andrej Rakuša	Review and approval of QAR; Approval of ExTR; Manufacturer auditor	6 years in Ex; 2 years for auditor
Matej Debenc	Review and approval of QAR; Manufacturer auditor	5 years in Ex; 1.5 years for auditor
Andrej Lukšič	Approval of ExTR	11 years in Ex
Franc Cencelj	Approval of ExTR	44 years in Ex

Note: Refer to clause 3 of this report.

2.6. Organizational Structure

The overall organizational chart of SIQ is shown in Annex 1.

2.7. Administration (including Indemnity Insurance)

2.7.1. Administrative Structure

The administrative structure of SIQ is shown in Annex 2.



2.7.2. Indemnity Insurance

SIQ has an insurance policy from Triglav insurance company. A copy of the insurance certificate (no 0100020992) was sighted and valid to 9 March 2013 with a total of 2,800,000 EUR in a year for professional liability. The territorial scope covered by the insurance is the whole World.

3. RESOURCES

SIQ is equipped with all the necessary resources for IECEx certification. There is an extensive range of procedures for support of the operation at SIQ. The total size of SIQ is just over 100 people. Nine of these have some involvement with the Ex certification and testing, in which five staff are qualified as ExTR approver, QAR reviewer/approver, manufacturer auditors and signatory of CoC. Because there is little Ex business currently, some of the staff working in ExCB also work in ExTL as Ex test engineers and ExTR reviewers.

At the time of site assessment the assessment team noted that, for compliance with the separation between testing and certification, questions were raised concerning the proper procedure being in place to ensure that the ExCB staff do not serve on projects that they have been involved in the ExTL. This issue has been subsequently resolved to the satisfaction of the assessment team and meets IECEx requirements.

4. COMMITTEES / Governing Board / Appeals / Advisory Board

SIQ has a number of key bodies associated with its operations. These include:

- Board of Appeal this comprises 3 members, including the representatives from the consumers association of Slovenia, the University and the Director of PMT Department.
- SIQ Council as the governing board of SIQ, it consists of the representatives of the founders, the representatives of SIQ employees as well as the representatives of the public/economic/industrial associations and institutions representing the customers of SIQ's services. Its function covers approval of business plans, acceptance of annual reports, and definition of policy for fees and charges for services.
- Board of Certification Body this consists of representative of all interested parties. This meets at least twice a year.
- Certification Commissions for these the Quality Manual states 'The members of certification commissions can be elected exclusively from the SIQ staff. They shall be qualified for their functions and shall in no way be connected with products, services, and interests of the suppliers involved in the certification.' There are three staff members on each of these commissions, in which there is one commission special for Ex product certification.



5. CERTIFICATION OPERATIONS

5.1. National Approval/Certification Methods

Slovenia is a member of the European Union, the ATEX certification system has been adopted as national certification methods for Ex products. As a notified body with registration number 1304 under ATEX directive, SIQ issue type examination certificates and QANs for ATEX products.

In addition, in the Ex field the main activity carried out by SIQ is site inspection of Ex products which covers Ex installations, maintenance, repair and overhaul.

5.2. Certification Policy

SIQ has a specific certification policy that states they are open to everyone who wishes to use their services, they will treat everyone equally, they will try to establish themselves internationally, they will ensure a staff situation with no conflict of interest, they will follow requirements of standards and internal procedures, and they will use income to improve the operation continuously.

5.3. Application for Certification

SIQ have application forms including a general one and amendment where necessary for the field. All the application forms are published on SIQ's website. There is an application form relating to Ex certification (TOEx02), and it is written in Slovene as they generally deal with the local market.

They also have an open document at SIQ website to provide a Guide how to apply for IECEx certification.

5.4. Certification Decision

Certification Decision is always made by the Certification Commission, based on evaluation of the results performed by the certification personnel nominated in CN219.

The detailed CD306E for certification decision is addressed in CD306E Certification within IECEx scheme. The procedure as well as examples of records of certification decision were reviewed and found to meet the requirements of the IECEx Certified Equipment Scheme.

5.5. Suspension and Cancellation of Certificates

For the IECEx suspension and withdrawal of certificates is covered in CD306E Certification within the IECEx scheme. More detail is contained in Rules on Product Certification, CR201. The process is managed through the Certification Commission.



6. STATISTICS

6.1. Certificates Issued

Number of certificates issued under the IECEx, national or regional schemes in the preceding four years for each type of protection:

Standards	Title	umber certif				
		2009	2010	2011	2012	Total
60079-0	Explosive atmospheres - Part 0: Equipment - General requirements	Part	t 0 incl	uded ir	n numbe	ers below
60079-1	Explosive atmospheres - Part 1: Equipment protection by flameproof enclosures "d"	0	3	6	2	11
60079-7	Explosive atmospheres - Part 7: Equipment protection by increased safety "e"	0	1	4	2	7
60079-11	Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i"	1	1	5	3	10
60079-18	Explosive atmospheres - Part 18: Equipment protection by encapsulation "m"	0	1	3	0	4
60079-31	Explosive atmospheres - Part 31: Equipment dust ignition protection by enclosure "t"	0	0	0	0	0
62013-1	Caplights for use in mines susceptible to firedamp - Part 1: General requirements - Construction and testing in relation to the risk of explosion	0	0	0	0	0
60079-35-1	Explosive atmospheres - Part 35-1: Caplights for use in mines susceptible to firedamp - General requirements - Construction and testing in relation to the risk of explosion	0	0	0	0	0

7. DOCUMENTATION

7.1. Quality Manual

Quality Manual with identification number SR001, addresses all the major quality requirements with cross reference tables for all the relevant international or regional standards. The manual is issued in Slovene and English. This latest version has the number SR001E-14. The Manual is available in an electronic version on the SIQ



intranet and is regarded as the valid version for use. The manual meets the IECEx requirements.

7.2. Procedures

There are a significant number of detailed procedures dealing with the operation at SIQ. All these procedures are referenced and electronically linked in the above Quality Manual at the end of each chapter and also within the document. Again these documents are available on the intranet.

The procedure CD306E relating to IECEx operation was reviewed during the site assessment, and found that the procedure did not properly reference to all latest relevant IECEx rules, procedures, operational documents and decision sheets. This deficiency has been subsequently resolved to the satisfaction of the assessment team and meets the IECEx requirements.

7.3. Work Instructions

In addition there are many work instructions available and a range of other documentation such as guides. All those documents are accessible via a comprehensive menu system on the intranet.

7.4. Records

SIQ establishes suitable procedures dealing with quality records. All critical records are in hard copy, especially in the Explosion Protection Department, although increasingly SIQ is receiving documentation in electronic form. All records are retained for a minimum of 10 years at SIQ according to the relevant procedure.

Example of the project archive was reviewed, and found that the records are detailed, and information is sufficient to the satisfaction of the assessment team and meets the requirements of the IECEx.

7.5. Document Change Control

Documents are all subject to a change control procedure. The detail is specified in Clause 4.5.9 of Quality Manual, which includes regular checks of those being used. Only documents published on the intranet are regarded as controlled for the purpose of staff use. Two hard copies of each document are signed and retained. When a document is revised an indication, such as a marginal bar, is included in the document to show where changes have occurred.

The use of the correct standard is controlled through having forms that are released according to the appropriate edition of the standard to be used. In the case of the IECEx Scheme these forms will be used in conjunction with the ExTRs. SIQ is involved with committee work for the IEC standards and so are aware when IEC standards are being changed.



8. CONFIDENTIALITY

There is a statement in the quality manual that stipulates all personnel including the internal staff as well as the outside members of Boards listed in clause 4 of this report, are required to sign an agreement on declaration of confidentiality (Statutory Statement). Personnel are also trained to ensure they follow the confidentiality requirements to protect the integrity and reputation of the business. Examples of the written agreement and training records were reviewed and satisfactory.

9. PUBLICATIONS

SIQ periodically publishes a range of booklets and leaflets. One leaflet has contains brief information about the IECEx Certificate of Conformity. There is information about the IECEx Certification on the SIQ website at <u>www.siq.si</u>.

10. NATIONAL ACCREDITATION

SIQ holds a national accreditation for product certification body (CP-001) according to SIST EN 45011 (ISO/IEC Guide 65) from Slovenian Accreditation (SA), a member of International Accreditation Forum (IAF).

In the past the accreditation for product certification (DAP-ZE-3964.00) in the Ex field were achieved from DAP in Germany. According to the new EU Decree all accreditations in the Ex field were transposed to Slovenian Accreditation (SA), a signatory of Multilateral Agreements of the European Co-operations of Accreditation (EA).

The current SA accreditation certificate for the product certification body of SIQ is attached in Annex 3 of this report. It is noted that the accreditation scope covers all the standards listed in Clause 1.6 of this report, including Standards IEC 60079-31, IEC 62013-1 and IEC 60079-35-1, the subject of a scope extension. The accreditation was last updated June 2012.

11. RECOGNITION AND AGREEMENTS

SIQ has a wide range of recognitions and agreements, mainly including:

- Notified Body under ATEX Directive and other 9 Directives
- IECEE CB Scheme as an NCB and CBTL
- European certification scheme (ENEC)
- Member of IQNet for management systems
- Member of the European CENELEC Certification Agreement

12. INTERNAL AUDIT AND PERIODIC MANAGEMENT REVIEW

The requirements for internal audit are specified in general procedure SN012 Internal Audits. Auditing is done at least once a year. The plan of internal audit is normally released at the middle of April. The latest audit was conducted on 15 July 2011. It covers two audits, one is so-called vertical audit which is technical and the other is so-called horizontal covering general requirements of the relevant standards. There are quite a large number of staff trained and accepted for internal auditing. A



comprehensive chart (SN018) shows their qualifications, training and areas that they are considered competent to audit.

The detailed processes on management review are contained in clause 4.10 of Quality Manual. The management review is specified to be conducted once a year. The latest meeting of management review was held on 22 March 2012. A documented report on management review was viewed and satisfactory.

13. SUBCONTRACTING, USE OF OTHER LABS AND USE OF OTHER LOCATIONS

SIQ has not yet had the need to subcontract for Ex but does use subcontractors for other fields. Procedures for sub-contracting are included in the Product Certification procedure CN218E. This procedure also covers testing at manufacturers' premises where SIQ do the testing or they witness testing by the manufacturer. In each case SIQ assumes full responsibility for the testing which includes control over the process, but the assessment team noted that the existing procedure did not accordingly incorporate with IECEx policy on the off-site test and/or witness test by reference to IECEx OD024. Subsequently, this deficiency has been resolved to the satisfaction of the assessment team and meets IECEx requirements.

In addition, SIQ doesn't have the necessary test facilities for resistance to light, small component ignition test and etc, although they have enough personnel competence. They declared that they always use the facilities of accepted ExTL within IECEx system, for example PTB and/or CESI, but SIQ did not establish a list of subcontractors for their absent test equipment. This has been subsequently resolved.

14. TRAINING

There is a document procedure on training, and the detailed requirements can be found in Clause 5.5 of quality manual. Training plans are made annually, supplemented on demand and checked by management review. Records are kept of the trainings are carried out. This details the staff and the training that they have undertaken, and particularly noted that training was arranged for a new staff, and qualification document was sighted and satisfactory.

In particular, there is a process in place where information about the IECEx system is communicated to staff. For example, when the Managing Director returns from IECEx meetings there is a report sent to all relevant staff with information about all committee documents that were connected with the meeting. The report includes specific actions for staff that arise from the meetings. All staff have access to the IECEx website for access to documents such as ExTRs and ExTAG Decision Sheets and can use these documents for their work where required.

15. ASSESSMENT OF MANUFACTURERS AND ISSUE OF QARS

There is a documented procedure for assessment of manufacturers and issue of QARs according to IECEx operational documents. Guide on Personnel Competence Management AD013 addresses the approaches used for selecting auditors and experts. Currently SIQ has two qualified auditors for IECEx.



In the last three years, SIQ has issued 7 QARs and 7 CoCc. During the site assessment, the QARs SI/SIQ/QAR11.0002/00, SI/SIQ/QAR11.0003/00 and SI/SIQ/QAR11/0004/00 as well as their corresponding certificates were checked. The assessment team noted that the majority of them are comprehensive and satisfactory, but there are some mistakes made with Ex marking and standards. Subsequently, all the deficiencies have been successfully resolved to the satisfaction of the assessment team.

16. COMPLAINTS AND APPEALS (Including appeals to IECEx)

Complaints are collected in each department and dealt with in accordance with procedure SN029 which also covers appeals. In addition there is a procedure CR105E that covers appeals against the decisions taken by the Certification Commission. SIQ has a Board of Appeals to which all appeals go. But there is no particular document on information for customers/applicants that includes a part on their rights of appeal to IECEx secretariat. This issue has been subsequently resolved.

It was advised that there has not been any appeals in the Ex area since last IECEx assessment.

17. SPECIAL FACTS TO BE NOTED

17.1. Supporting Documentation

Copies of additional supporting information for this assessment have been provided to the applicant and the IECEx Secretariat. These include:

- Details of issues raised and how these have been resolved
- Checklist for ISO/IEC Guide 65
- Completed TGDs for OD 005
- Competence matrix

17.2. Others

N/A

18. COMMENTS (Including issues found during assessment)

A number of issues mentioned above, were raised during this re-assessment and reported to SIQ management at the end of this re-assessment. Subsequently all the issues relating with ExCB have been resolved to the satisfaction of the assessment team.

Details of issues and how these have been resolved are listed in Annex A of the site assessment report.

19. RECOMMENDATION

Based on the assessment performed from 19th to 20th April 2012, SIQ is recommended for continued acceptance in the IECEx System as an IECEx Equipment Certification



Body (ExCB) according to the scope of the standards listed in Clause 1.6 of this document.

Lead Assessor Xu Jianping Expert Assessor Herbert Peters Date: 20 October 2012

List of Annexes:

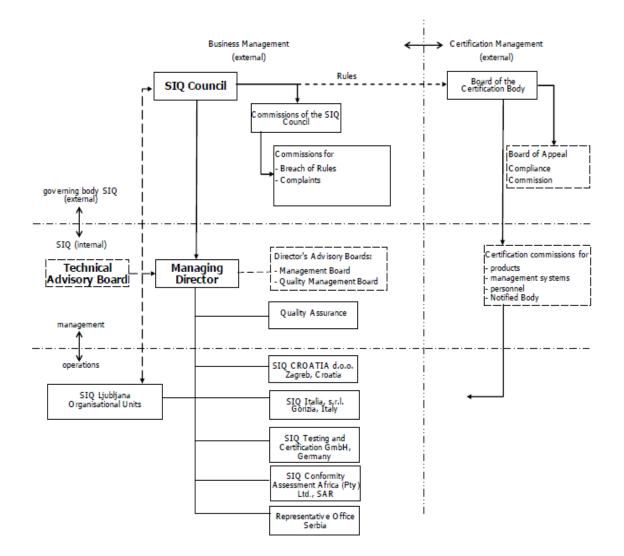
- 1. Overall Organization Chart of SIQ
- 2. Administrative Structure of SIQ
- 3. Accreditation Certificate according to SIST EN 45011 (ISO/IEC Guide 65)



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Changes: shaded (yellow) fields Normal text: technical responsibility Italic: business responsibility		Testing and measurement technologies zaran SVETIK Explosion protection Andrej RAXUSA Andrej RAXUSA A

Annex 1: Overall organization Chart of SIQ





Annex 2: Administrative Structure of SIQ



Annex 3: Accreditation Certificate according to SIST EN 45011 (ISO/IEC Guide 65)



CP-001

akreditacijska listina accreditation certificate

Slovenski institut za kakovost in meroslovje, Ljubljana

Tržaška cesta 2, 1000 Ljubljana

Organizacija je akreditirana pri Slovenski akreditaciji (SA), kot certifikacijski organ za proizvode. S to listino se priznava izpolnjevanje zahtev standarda

SIST EN 45011:1998

za dejavnosti, ki so opisane v prilogi te listine, označeni z isto številko.

Datum podelitve akreditacije: 27. november 2000

Akreditacija je veljavna, če akreditirani organ v celoti izpolnjuje zahteve za akreditacijo, kar SA ugotavlja s postopki nadzora. Veljavnost akreditacije je mogoče preveriti na spletni strani SA, www.sa.gov.si.

Slovenska akreditacija je podpisnica sporazumov o medsebojnem priznavanju akreditacij na področju certifikacijskih organov za sisteme vodenja in proizvode pri Evropskem združenju za akreditacijo (EA) in pri Mednarodnem akreditacijskem forumu (IAF).

The above entity has been accredited by Slovenian Accreditation (SA) as a certification body for products. This is to signify compliance with the requirements of the Standard SIST EN 45011:1998 for the approved scope of accreditation as described in the Annex hereto marked with the same number.

Initial accreditation date: 27 November 2000

This accreditation shall remain in force provided that the accredited body fully complies with the accreditation requirements, which is determined by SA through surveillance. Information on current accreditation status is available at the SA website, www.sa.gov.si.

Slovenian Accreditation (SA) is a signatory of the Multilateral Agreements of the European Co-operation for Accreditation (EA) and International Accreditation Forum (IAF) for certification bodies for management systems and products.

Ljubljana, 20. april 2009

Direktor dr. Boštjan Godec