



ExMC/1199/DV
December 2016

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

**Title: Scope Extension Assessment Report for CESI SpA, Italy, an Accepted ExCB and
ExTL within the IECEx System, Equipment Scheme 02**

To: Members of the IECEx Management Committee, ExMC

Introduction

Following an application for a scope extension by CESI SpA, Italy, to include ISO 80079-36 and ISO 80079-37 within their scope, a special site assessment visit was arranged and conducted.

This report details the assessment findings of this scope extension with the IECEx Assessment Team recommending the acceptance of the above scope extension. It is now hereby submitted for voting by ExMC.

Please consider the report and return the completed voting form, separate Word document, to the Secretariat by **2017 01 27**

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

Chris Agius
IECEx Secretary

Address:

**IECEx Secretariat
Australia Square
Level 33, 264 George Street
Sydney NSW 2000
Australia**

**Tel: +61 2 4628 4690
Fax: +61 2 46 27 5285
Email: chris.agius@iecex.com**



ExMC/1199/DV
December 2016

IEC System for certification to standards relating to equipment for use in Explosive Atmospheres (IECEX System)

IECEX Assessment Report Form

IECEX Assessment Report Form for use by IECEx Assessment Teams to report Assessments conducted according to the IECEx Assessment Procedures of

- a) Operational Document IECEx OD 003-2 for the Certified Equipment Scheme
- b) Operational Document IECEx OD 016 for the Certified Service Facility Scheme
- c) Operational Document IECEx OD 022 for the IECEx Conformity Mark Licensing System

IECEX ExCB/ExTL assessment report for CESI SpA

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION



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1 Assessment information

1.1 Type of Body covered by this assessment: <retain appropriate marks>

| | |
|--|---|
| ExCB for IECEx Certified Equipment Scheme | ✓ |
| ExTL for IECEx Certified Equipment Scheme | ✓ |
| ExCB for IECEx Certified Service Facilities Scheme | |
| ExCB for IECEx Conformity Mark Licensing System | |

NOTE 1 ExCB - IECEx Certification Body

NOTE 2 ExTL - IECEx Testing Laboratory

1.2 Type of assessment: <retain appropriate marks>

| | |
|---------------------------------------|---|
| Pre-assessment for candidate body | |
| Initial assessment for candidate body | |
| Surveillance | |
| Re-assessment | |
| Scope extension | ✓ |

This site assessment is part of the processing of a scope extension request from CESI SpA for inclusion of the ISO 80079-36 and 37 non-electrical Standards.

Note: The standards were published at the end of February 2016

It should also be known that the Lead Assessor, Mr Ron Webb has been intimately involved in the preparation of the new non electrical standards as well as a member ExMC WG15 (non electrical expert Working Group).

1.3 Details of body

1.3.1 Country

Italy

1.3.2 Name of body

CESI SpA

1.3.3 Name and title of nominated principal contact

| Name | Title | E-mail address |
|-------------|-------------------|---------------------|
| Mirko Balaz | Technical Manager | mirko.balaz@cesi.it |

1.4 Assessment information

1.4.1 Members of the assessment team

| Name | Role (modify as necessary) |
|----------|----------------------------|
| Ron Webb | Lead Assessor |

1.4.2 Place(s) of assessment

| |
|---|
| Via Rubattino, 54, 20134 Milano (Italy) |
|---|



1.4.3 Assessment date

7-8 November 2016

1.5 Scopes

1.5.1 Additional Standards for ExCB scope for equipment certification scheme

| Number | Title |
|----------------------------------|---|
| ISO 80079-36 Edition 1 (2016) | Explosive atmospheres - Part 36: Non-electrical equipment for explosive atmospheres - Basic method and requirements |
| ISO 80079-37 Edition 1 (2016) | Explosive atmospheres - Part 37: Non-electrical equipment for explosive atmospheres - Non electrical type of protection constructional safety "c", control of ignition source "b", liquid immersion "k" |

1.5.2 Additional Standards for ExTL scope for equipment certification scheme

| Number | Title |
|----------------------------------|---|
| ISO 80079-36 Edition 1 (2016) | Explosive atmospheres - Part 36: Non-electrical equipment for explosive atmospheres - Basic method and requirements |
| ISO 80079-37 Edition 1 (2016) | Explosive atmospheres - Part 37: Non-electrical equipment for explosive atmospheres - Non electrical type of protection constructional safety "c", control of ignition source "b", liquid immersion "k" |



2 Common information

2.1 Legal entity of body

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

2.2 Financial support

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

2.3 History

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

2.4 Documentation

2.4.1 Quality manual

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

2.4.2 Procedures

While covered in the assessment reported in ExMC/1119/R, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.

2.4.3 Work instructions

While covered in the assessment reported in ExMC/1119/R, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.

2.4.4 Records (including test records where relevant)

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

2.4.5 Document change control

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

2.5 Confidentiality

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

2.6 Publications (Hard cover and Electronic)

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

2.7 Recognition and agreements

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.



2.8 Internal audit and periodic management review

While covered in the assessment reported in ExMC/1119/R, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.

2.9 Contracting, subcontracting, use of other labs and use of other locations

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R

2.10 Training and competence

There is a competency matrix for the IECEx Scheme. Interviews were undertaken with staff to ensure that they had the required level of understanding. These are included in a TCD document which is held by the Secretariat. Training records for each staff member are held on an Intranet system and are very comprehensive.

2.11 Complaints and appeals (including appeals to IECEx)

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

2.12 Special facts to be noted

2.12.1 Supporting documentation

Copies of additional supporting information for this assessment have been provided to the applicant and the IECEx Secretariat. These are included in a site assessment report and include:

- Completed technical capability document (TCD)

2.13 Recommendations

Based on the assessment performed on 7-8 November 2016, CESI SpA is recommended for scope extension to include the Standards listed in 1.5 in the IECEx scheme as:

- An ExCB in the IECEx Certified Equipment Scheme
- An ExTL in the IECEx Certified Equipment Scheme

With scope extension as indicated in 1.5

Ron Webb

Lead Assessor

Date: 8 November 2016



3 ExCB for IECEx Certified Equipment Scheme

3.1 Assessment references

- a) IECEx02 IECEx Certified Equipment Scheme covering equipment for use in explosive atmospheres – Rules of Procedure
- b) OD003-2 Assessment, surveillance assessment and re-assessment of ExCBs and ExTLs operating in the IECEx 02, IECEx Certified Equipment Scheme
- c) OD005-2 IECEx Quality System Requirements for Manufacturers – Part 2: Audit Checklist. (This is available in a Word format for use by ExCBs)
- d) OD005-3 IECEx Quality System Requirements for Manufacturers – Part 3: supplementary requirements for non-electrical equipment to ISO/IEC 80079-34, Edition 1.
- e) ISO/IEC 80079-34 Edition 1, Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture
- f) OD009 Issuing of CoCs, ExTRs and QARs
- g) IECEx Document OD 025 Guidelines on the Management of Assessment and Surveillance programs for the assessment of Manufacturer's Quality Systems in accordance with the IECEx Scheme
- h) OD0026 IECEx Certified Equipment Scheme – Guidelines for the qualification of Lead Auditor and Auditors, in accordance with the IECEx System
- i) ISO/IEC 17065, General requirements for bodies operating product certification systems
- j) IECEx Document OD17 Drawing and documentation guidance
- k) IECEx Technical Capability Document (TCD)
- l) ExTAG decision sheets (DSs)
- m) ExMC/1031/CD
- n) IECEx OD 280, Guide to Certification of Non-electrical Equipment and Protective Systems

NOTE The latest editions of the above documents were applied

3.2 Candidate ExCB persons interviewed

| Name | Position |
|-----------------|-------------------------------------|
| Giorgio Crippa | Product Certification Unit Manager |
| Mirko Balaz | ATEX & IECEx CB - Technical Manager |
| Enrico Radaelli | ExCB specialist |
| | |
| | |

3.3 Associated ExTL(s)

The ExCB is integral with the ExTL

3.4 Associated certification functions

While covered in the assessment reported in ExMC/1119/R, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.



3.5 National marks and certificates

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

3.6 Standards accepted in scope extension

See clause 1.5 of this report

3.7 National differences to IEC standards

National differences to IEC standards are in the process of being generated for insertion in the IECEx Scheme Bulletin.

3.8 Organisation

3.8.1 Names, titles and experience of the senior executives

| Name | Title | Experience |
|------------------|--|----------------|
| Domenico Villani | Testing & Certification Division Manager | 26 years |
| Roberto Piccin | Certification Business Area Manager | 26 years |
| Giorgio Crippa | Product Certification Unit Manager | 36 years |
| Mirko Balaz | ATEX & IECEx CB - Technical Manager | 41 years in Ex |

3.8.2 Name, title and experience of the quality management representative

| Name | Title | Experience |
|------------------|---|------------|
| Mauro de Stefano | Quality and Safety Manager | |
| Giorgio Crippa | Quality and Safety Manager for the Ex field | 36 years |

3.8.3 Name and title of signatories for certification

| Name | Title |
|----------------|-------------------------------------|
| Mirko Balaz | ATEX & IECEx CB - Technical Manager |
| Roberto Piccin | Certification Business Area Manager |

3.8.4 Other employees in ExCB activity

| Name | Title | Responsibility and Experience in Ex |
|----------------|--|-------------------------------------|
| Enrico Radelli | Senior Engineer, Deputy of Mirko Balaz | ExTR reviewer, 17 years |
| Tiziano Cola | Engineer | QAR Assessor, 12 years |
| Sergio Giugno | Senior Engineer | QAR Lead Assessor, 17 years |
| Katia Zampori | Technical Staff | Administration |

3.9 Organizational structure

Included in the Site Assessment Report



3.10 Administration

3.10.1 Administrative structure

Included in the Site Assessment Report

3.10.2 Indemnity insurance

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

3.11 Resources

Adequate staffing resources were available

3.12 Committees (such as governing or advisory boards)

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

3.13 Certification operations

3.13.1 National approval/certification methods

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

3.13.2 Certification policy

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

3.13.3 Application for certification

While covered in the assessment reported in ExMC/1119/R, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.

3.13.4 Certification decision

While covered in the assessment reported in ExMC/1119/R, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.

3.13.5 Suspension and cancellation of certificates

Not relevant as this is a scope extension assessment. This was covered in the reassessment ExMC/1119/R.

3.14 Certificates issued

CESI SpA are able to demonstrate experience with non-electrical standards, noting the number of certificates and reports issued under the ATEX Directive as the Notified Body in the last 4 years:

| Standard numbers | Type of protection or other identifying information | Total |
|------------------|---|-------|
| | | |



| | | |
|-------------|--------------------------|-----|
| EN 13463-xx | Non-electrical equipment | 21. |
| | (ATEX Certificates) | |

3.15 National accreditation

CESI SpA are accredited by Accredia to ISO/IEC 17065 as a certification body and ISO/IEC 17020 as an inspection body.

3.16 Assessment of manufacturers and issue of QARs

CESI SpA already carry out QAN assessments to ATEX for non-electrical equipment as a Notified Body. This will extend to cover QARs under the IECEx Scheme.

3.17 Comments (including issues found during assessment)

The staff interviewed had a good understanding of the non-electrical standards in the EN13463-xx series. These were used as a basis for development of ISO 80079-36 and ISO 80079-37.

A review of previous files relating to the EN 13463 series revealed that CESI SpA staff are well versed and have a full understanding of the assessment approaches for non-electrical equipment for Ignition Hazard Assessments



4 ExTL for IECEx Certified Equipment Scheme

4.1 Assessment references

- a) IECEx02 IECEx Certified Equipment Scheme covering equipment for use in explosive atmospheres – Rules of Procedure
- b) IECEx OD003-2 Assessment, surveillance assessment and re-assessment of ExCBs and ExTLs operating in the IECEx 02, IECEx Certified Equipment Scheme
- c) IECEx OD009 Issuing of CoCs, ExTRs and QARs
- d) ISO/IEC 17025:2005 Edition 2, General requirements for the competence of testing and calibration laboratories
- e) IECEx Document OD17 Drawing and documentation guidance
- f) IECEx Technical Capability Document (TCD)
- g) ExTAG decision sheets (DSs)
- h) ExMC/1031/CD

NOTE The latest editions of the above documents were applied.

4.2 Candidate ExTL persons interviewed

| Name | Position |
|-----------------|-------------------------------------|
| Giorgio Crippa | Product Certification Unit Manager |
| Mirko Balaz | ATEX & IECEx CB - Technical Manager |
| Guido Prazzoli | ExTL specialist |
| Sergio Mezzetti | ExTL specialist |
| Tiziano Cola | ExTL specialist |
| Enrico Radaelli | ExTL specialist |

4.3 Associated ExCB(s)

The ExCB is integral with the ExTL

4.4 Organisation

4.4.1 Names, titles and experience of the senior executives

| Name | Title | Experience |
|---------|-------|------------|
| As ExCB | | |
| | | |

4.4.2 Name, title and experience of the quality management representative

| Name | Title | Experience |
|---------|-------|------------|
| As ExCB | | |
| | | |

4.4.3 Other employees in ExTL activity

| Name |
|---------------------------------|
| Indicated on organization chart |



4.5 Organizational structure

Included in the Site Assessment Report

4.6 Resources

Adequate staff resources are available both technical and administrative

4.7 Test reports issued

CESI SpA are able to demonstrate experience with non-electrical standards, noting the number of reports issued under the ATEX Directive in the last 4 years:

| Standard numbers | Type of protection or other identifying information | Total |
|------------------|---|-------|
| EN 13463-xx | Non-electrical equipment (ATEX) | 27 |

4.8 National accreditation

Application for accreditation for the standards involved in this scope extension will be made through Accredia, in the absence of national accreditation CESI will be subjected to annual surveillance assessment visits.

4.9 Calibration

While covered in the assessment reported in ExMC/1119/R, it was confirmed that the procedures also cover the new Standards listed under the scope extension request.

4.10 Comments (including issues found during assessment)

The staff interviewed had a good understanding of the non-electrical standards in the EN13463-xx series. These were used as a basis for development of ISO 80079-36 and ISO 80079-37.

It is further acknowledged that CESI SpA are an active ExTL with an extensive scope of acceptance, refer to IECEx OD 001, therefore are in possession of the necessary test equipment and resources to undertake tests according to ISO 80079-36 and 80079-37.