ExMC/589/DV
February 2010

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

TITLE: IECEx Assessment Report for the acceptance of *Electrosuisse* as an IECEx Certification Body (ExCB) within the IECEx System

Circulation to: Members of the IECEx Management Committee, ExMC

INTRODUCTION

This document contains the IECEx Assessment Report for the acceptance of *Electrosuisse* as an IECEx Certification Body (ExCB) within the IECEx System.

This report is hereby submitted for voting.

Please consider this assessment report and return the completed voting form, (a separate document - in Word Format), to the IECEx Secretariat by 26th March 2010.

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

Chris Agius

IECEx Secretariat

Address: **IECEx Secretariat** **SA Building** **286 Sussex Street** **Sydney 2000** **Australia**	**Tel: +61 2 8206 6940** **Fax: +61 2 8206 6272** **Email: chris.agius@iecex.com** **Internet: www.iecex.com**

IECEx ASSESSMENT REPORT FOR Electrosuisse (IECEx Certification Body, ExCB)

Type of Assessment: (please mark)

Initial Assessment for Candidate ExCB **X**

1. OBJECT AND FIELD OF APPLICATION

1.1. Country:
Switzerland

1.2. Name of Candidate ExCB
Electrosuisse

1.3. Members of the Assessment Team
Xu Jianping – Director of NEPSI - IECEx Lead Assessor and Team Leader
Herbert Peters – TUV Nord - Expert Assessor
Alain Czyz – Expert Assessor

1.4. Place and Date of Assessment
Luppmenstrasse 1
CH-8320 Fehraltorf
Switzerland

Tel: +41 (0)44 956 13 18
Fax: +41 (0)44 956 18 18
Website: www.electrosuisse.ch

24-26 March 2009
9 man-days

1.5. Assessment References

i) IECEx 02 Third Edition 2006-11 IECEx Equipment Certification Program Rules of Procedure
ii) IECEx OD 003 V1 IECEx Assessment procedures
iii) IECEx OD 005 V2 Quality System requirements for manufacturers
iv) IECEx OD 009 V1 Issuing of CoCs, ExTRs and QARs
v) IECEx Document OD 025 (ExMC/161/CD) Management of assessment and surveillance programs for manufacturers (includes QAR forms)
vi) ISO/IEC Guide 65:1996
vii) IECEx Document OD 017 V3 Drawing and documentation guidance
viii) ExCB application documents dated 26 September 2008

1.6. *Scope of Application*

Number	Title
60079-0	Electrical apparatus for explosive gas atmospheres Part 0: General requirements
60079-1	Electrical apparatus for explosive gas atmospheres Part 1: Construction and verification test of flameproof enclosures of electrical apparatus
60079-2	Electrical apparatus for explosive gas atmospheres Part 2: Electrical apparatus, type of protection 'p' (Pressurization)
60079-7	Explosive atmospheres Part 7: Equipment protection by increased safety “e”
60079-11	Electrical apparatus for explosive gas atmospheres Part 11: Intrinsic safety 'i'
60079-15	Electrical apparatus for explosive gas atmospheres Part 15: Electrical apparatus with type of protection 'n' (Non-Sparking)
60079-18	Electrical apparatus for explosive gas atmospheres Part 18: Encapsulation 'm'
60079-26	Explosive atmospheres Part 26: Equipment with equipment protection level (EPL) Ga
61241-0	Electrical apparatus for use in presence of combustible dust Part 0: General requirements
61241-1	Electrical apparatus for use in presence of combustible dust Part 1: Electrical apparatus protected by enclosures
61241-1-1	Electrical apparatus for use in presence of combustible dust Part 1: electrical apparatus protected by enclosures Section 1: Specification for apparatus
61241-4	Electrical apparatus for use in presence of combustible dust Part 4: Type of protection ‘pD’
61241-11	Electrical apparatus for use in presence of combustible dust Part 11: Protection by intrinsic safety ‘iD’
61241-18	Electrical apparatus for use in presence of combustible dust Part 18: Protection by encapsulation ‘mD’

1.7. *Candidate ExCB Persons Interviewed*

Name	Position
Fritz Beglinger	Head of Industry and Commerce, Manager Product Qualification and Certification
Bernardo Rieder	Deputy Head of Industry and Commerce, Deputy Manager Product Qualification and Certification, Quality Manager

Name	Position
Hermann Gull	Team Ex Leader
Jürg Rellstab	Head of Product Certification
Erich Obrist	Deputy Head of Product Certification, Engineer Certification
Martin Plüss	Engineer Certification, Deputy Quality Manager

1.8. *Legal Entity of the Candidate ExCB*
Electrosuisse is 100% owned by the Swiss Electrotechnical Association (SEV) for Electrical Engineering, Power and Information Technologies.

The SEV association was founded in 1889 in the form of a registered society in accordance with Article 60 et seq. of the Swiss Civil Code, and started their testing activities in 1901. Currently around 4300 professionals and 1750 companies and institutions are members of the association. After being located in Zurich, SEV moved in1994 to Fehraltorf (20km east of Zurich), where the laboratories and all testing equipment was completely renewed. SEV changed its name to Electrosuisse in 2002.

As an accredited certification body by Swiss Accreditation Service (SAS), Electrosuisse is the recognized professional organization for electrical-, energy- and information technology, offering services for the whole of the electrical sector. Electrosuisse is a member of IECEE-CB scheme since 1961 and member of the European CENELEC Certification Agreement (CCA Scheme) since 1973 and ATEX Notified Body since 2004.

1.9. *Associated Testing Laboratories*
The ExTL used by Electrosuisse is integral with Electrosuisse itself and has same legal identity.

1.10. *Associated Certification Functions*
Electrosuisse does electrical product certification in a number of fields, including electrotechnical products, Luminaries, computer equipment, cables/data lines, household appliances and other industrial equipment.

1.11. *National Marks and Certificates*
Electrosuisse is a Notified Body under the European ATEX Directive 94/9/EEC with identification number 1258. The corresponding regulations and requirements are applicable for Switzerland. Electrosuisse is also an operator for various national marks, for example the SEV mark of conformity for safety and EMC, CERTIFEL certification schemes with type testing and factory surveillance or lot testing/container inspection of specific products. All these national certification marks are owned by Electrosuisse, and officially registered by the Swiss Federal Institute of Intellectual Property.

1.12. *Financial Support*
Electrosuisse does not receive any financial support. Their operation is financed from its testing, certification, surveillance and license fees.

1.13. *History*
See Clause 1.8 above.

1.14. *Standards Accepted*

Number	Title
60079-0	Electrical apparatus for explosive gas atmospheres Part 0: General requirements
60079-2	Electrical apparatus for explosive gas atmospheres Part 2: Electrical apparatus, type of protection 'p' (Pressurization)
60079-7	Explosive atmospheres Part 7: Equipment protection by increased safety “e”
60079-11	Electrical apparatus for explosive gas atmospheres Part 11: Intrinsic safety 'i'
60079-15	Electrical apparatus for explosive gas atmospheres Part 15: Electrical apparatus with type of protection 'n' (Non-Sparking)
60079-18	Electrical apparatus for explosive gas atmospheres Part 18: Encapsulation 'm'
60079-26	Explosive atmospheres Part 26: Equipment with equipment protection level (EPL) Ga
61241-0	Electrical apparatus for use in presence of combustible dust Part 0: General requirements
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61241-11	Electrical apparatus for use in presence of combustible dust Part 11: Protection by intrinsic safety ‘iD’
61241-18	Electrical apparatus for use in presence of combustible dust Part 18: Protection by encapsulation ‘mD’

NOTE: Comparing with the original application scope as listed in clause 1.6 of this report, because of lack of sufficient experience and knowledge it was agreed that the following items were removed from the ExTL scope:
a) IEC60079-1;
b) Ex e motor with voltage high than 1000V and Ex e luminaire from IEC60079-7;
c) Ex nC and Ex n motor are excluded from IEC 60079-15.

1.15. *National Differences to IEC Standards*

Electrosuisse adopts CENELEC standards for ATEX testing and certification. The differences to IEC standards are listed as group differences in the latest version of the IECEx Bulletin.

2. ORGANISATION

2.1. *Names, Titles and Experience of the Senior Executives*

Name	Title	Experience
Fritz Beglinger	Head of Industry and Commerce, Manager Product Qualification and Certification	12 years at Electrosuisse, 6 years in current position
Bernardo Rieder	Deputy Head of Industry and Commerce, Deputy Manager Product Qualification and Certification, Quality Manager	8 years at Electrosuisse, 6 years in the field of Quality Management
Jürg Rellstab	Head of Product Certification	4 years in Certification, 4 years at Electrosuisse

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

Name	Title	Experience
Bernardo Rieder	Deputy Head of Industry and Commerce, Deputy Manager Product Qualification and Certification, Quality Manager	8 years at Electrosuisse, 6 years in the field of Quality Management

2.3. *Name and Title of Nominated Principal Contact*

Name	Title	Comments
Jürg Rellstab	Head of Product Certification	Juerg.rellstab@electrosuisse.ch Tel: +41 44 956 13 18 Fax: +41 44 956 18 18

2.4. *Name and Title of Signatories for Certification*

Name	Title	Comments
Jürg Rellstab	Head of Product Certification	4 years in Ex, 4 years at Electrosuisse
Erich Obrist	Deputy Head of Product Certification, Engineer Certification	22 years at Electrosuisse, 6 years in the field of certification Only when Jürg Rellstab is absent.

2.5. *Other Employees in ExCB activity*

Name	Title	Responsibility
Martin Plüss	Engineer Certification,	9 years at Electrosuisse, 9

Name	Title	Responsibility
	Deputy Quality Manager	year in the field of QMS, 1 year in cetification
Hanspeter Leserf	Key Account Manager Certification	Customer Service
Albert Suter	Auditor, Test Engineer of Team Ex	15 years in Ex, 25 years at Electrosuisse
Hermann Gull	Auditor, Test Engineer of Team Ex	33 years in Ex, 33 years at Electrosuisse
*Peter Bosshard	Auditor, Test Engineer of Team Ex	12 years in Ex, 14 years at Electrosuisse

***Note:** Mr Peter Bosshard, an expert in the Ex field with a long leading experience at Electrosuisse, retired at end of August 2009 but following the site assessment he has now been rehired and is supporting the certification team, mainly in charge of doing the review of the test reports as well as training work.

2.6. *Organizational Structure*

Organizational Structure is shown in Annexes 1 and 2. Annex 1 is the overall organization chart of Electrosuisse, and Annex 2 indicating Ex function of ExCB and ExTL an Electrosuisse.

2.7. *Administration*

2.7.1. Administrative Structure

See above.

2.7.2. Indemnity Insurance

There is a policy covering professional indemnity/legal liability that was viewed during the site assessment. ELectrosuisse has indemnity insurance with value of 10 million CHF (approximately 7 million Euro), which is applicable to all over the world.

3. RESOURCES

Electrosuisse employs 210 people at its head offices in Fehraltorf and at its location in Lausanne. Their Ex activities with necessary resources at Fehraltorf include 42 staff in total, with 29 for testing activities. There are a total of 4 personnel in the ExCB and 4 in the ExTL. Electrosuisse currently has three qualified IECEx auditors by using staff from ExTL. The specific certification activities are supported by a comprehensive range of manuals and procedures, as well as the assistance from the team of Customer Service.

At the time of the assessment it was noted that Ex expertise in the ExCB staff was limited. Electrosuisse was advised that systems needed to be put in place to ensure this expertise was available when reviewing test plans, ExTRs and QARs. As mentioned above (in 2.5), to address this issue, Mr Peter Bosshard, an expert in the Ex field with a long leading experience at Electrosuisse has now been added to the certification team. This subsequent solution seems to be reasonable and acceptable to the Assessment Team.

4. COMITTEES / Governing Board / Appeals / Advisory Board

The certification committee (ZAC) of Electrosuisse with 7 members is elected by the Supervisory Board of Electrosuisse. All the members from both certification committee and supervisory board include the representatives from industry, manufacturer, consumer and Electrosuisse management. The certification committee meets once a year or upon request. Certification policy, processes and fees matters are normally dealt by the certification committee and periodically present report to the Board. The Chairman of ZAC is nominated by Director of Electrosuisse.

5. CERTIFICATION OPERATIONS

5.1. *National Approval/Certification Methods*

Electrosuisse operates as a Notified Body under ATEX directive in the field of testing and certification of electrical apparatus used for explosive atmospheres.

5.2. *Certification Policy*

The quality policy statement of the body is involved in the quality manual and meets the principles of the IECEx System.

5.3. *Application for Certification*

This process is covered in part 20.00 of VHB-ZP01.01. The application forms and information are available at Electrosuisse.

5.4. *Withdrawal and Cancellation of Certificates*

There is a general procedure for withdrawal and cancellation. At the time of site assessment the procedure did not make reference to the IECEx system, this issue was subsequently resolved to the satisfaction of the assessment team.

6. STATISTICS

6.1. Certificates Issued

number of ATEX certificates issued in the preceding three years for each type of protection:

Number of ATEX certificates issued			
Standards	Year		
	2006	2007	2008
IEC 60079-1 EN 50018	3	4	3
IEC 60079-7 EN 50019	5	4	6
IEC 60079-11 EN 50020 IEC 60079-26 EN 50284 IEC 61241-11	8	8	8

Number of ATEX certificates issued			
Standards	Year		
	2006	2007	2008
IEC 60079-18 EN50028 IEC 61241-18	5	0	5
IEC 60079-15 EN50021	8	9	8
IEC 60079-2 EN50016 IEC 61241-4	1	1	1
IEC 61241-1 EN50281-1-1	12	4	11

7. DOCUMENTATION

7.1. Quality Manual

The quality system is described in the Electrosuisse quality manual and is based on ISO/IEC 9000:2000 and ISO 14000 as well as ISO/IEC Guide 65/EN 45011 and ISO/IEC 17025/17020. It contains all necessary policies and procedures relevant to the testing and certification processes.

The Electrosuisse Quality Manual is divided into:

- Electrosuisse General Management Handbook (MHB 01.01)
- Electrosuisse Process Handbooks
  (VHB-PQ 01.01 for testing, VHB-ZP 01.01 for certification)

The quality manuals are written by the quality manager in close co-operation with the relevant business sections. Their control and release are performed by the CEO. The distribution of the documents and the implementation into Intranet is under the responsibility of the quality manager. The quality manual is stored on the Intranet no paper copies exist. This version is always the latest and consequently the valid one. All staff has access to the relevant parts which apply to their field.

7.2. Procedures

All the procedures for the operation of certification body, including granting, maintaining, extending, suspending, withdrawing and cancelling certificates are well documented in the Electrosuisse process handbook VHB-ZP 01.01. It is noted that the reference to IECEx rules, procedures and operational documents have also been made within section 55.11 of the handbook, and the certification policy is based on the document IECEx OD 009. All the decisions on certification are taken by the head of product certification, and supervised by the certification committee (ZAC)

7.3. Work Instructions

A series of certification instructions/procedures is included in the management system, giving detailed information for the implementation of critical certification activities within the scope of ATEX accreditation. At the time of the site assessment reference to all the relevant requirements of IECEx system were not included. This issue has

been subsequently resolved properly and the instructions now meet the requirements of the IECEx System.

7.4. Records

The control of quality records is laid down in the main quality manual MHB51.01. The detailed procedure is sighted and examples of quality records are well maintained with a minimum period of 10 years.

7.5. Document Change Control

All documents developed by the quality manager and relevant key persons are always reviewed and approved prior to publication via Intranet. The details of document control including data are also covered by the procedure MHB51.01.

8. CONFIDENTIALITY

Confidentiality is applied within Electrosuisse. It is addressed in the procedure MHB 11.02 of main quality manual (MHB 01.01). All the employees including all the members of certification committee (ZAC) are required to sign a contract/agreement with statement on confidentiality and conflict of interest. Examples of such signed agreements are viewed during the assessment. In addition control and security of access to the premises and the data on the servers is also maintained.

9. PUBLICATIONS

Most information about Electrosuisse's activities can be found on their website at www.electrosuisse.ch . All the issued certificates and certified products, as well as various technical books, manuals and bulletins periodically produced in German, French or Italian are also available on their homepage.

10. NATIONAL ACCREDITATION

The accreditation for being a certification body for electrical equipment is from the Swiss Accreditation Service (SAS). The latest renewal of accreditation was in September 2006 in accordance with the standard EN45011 (idt ISO/IEC Guide 65). The certificate with identification SCESp 035 is valid until 23 September 2011. A copy is included at Annex 3 of this report. The accreditation scope covers devices and protective systems for use in potentially explosive atmospheres under ATEX Directive.

11. RECOGNITION AND AGREEMENTS

Electrosuisse has agreements and recognitions including:

- Notified Body under ATEX Directive
- IECEE CB Scheme
- CENELEC Certification Agreement (CCA) Scheme
- ENEC Scheme
- HAR Scheme

12. INTERNAL AUDIT AND PERIODIC MANAGEMENT REVIEW

Internal audits are carried out in accordance with the management procedures MBH22.02. This covers a series of audits through the last year with coverage of all the quality elements and departments/activities. The latest internal audit for certification body was conducted on 19 Feb. 2009. The periodic management reviews was conducted annually. The latest management reviews covering both the certification body and the testing

laboratory were fulfilled on 17 March 2009. These processes with its records were checked and found to be satisfactory.

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

There is a procedure for evaluating sub-contractors a register is maintained of those that have been evaluated and approved. The assessment team noted that the following testing facilities relating with the application scope of the standards listed in clause 1.6 of this document is not available at Electrosuisse:

- Flameproof pressure determination
- Flame transmission test
- Resistance to light
- Ignition test for nC

While an agreement exists with PTB Germany, a testing and certification body under IECEx System, to subcontract such testing, this will not be applicable to the IECEx System, as these do not fall within the recommended scope of acceptance set out in 1.14 above.

14. TRAINING

There is a well documented process on training and competence evaluation. It was advised that internal training has been done on IECEx rules and procedures. However the corresponding records were not available at the time of the assessment. Subsequently, an effective, recording system as well as an extensive training plan for both ExTL and ExCB staff has been subsequently developed and put in place meeting the requirements of the IECEx System.

15. ASSESSMENT OF MANUFACTURERS AND ISSUE OF QARS

Electrosuisse issued a few auditing reports for ATEX certification purposes. During the site assessment, the interview with auditors of Electrosuisse indicated that further auditor training is necessary for a clear understanding and application of OD 005 and OD 025. This issue has been subsequently resolved to the satisfaction of the assessment team.

16. COMPLAINTS AND APPEALS (Including appeals to IECEx)

Appeals, complaints and disputes are brought to the certification body's management and are subjected to the procedures outlined in the document "Basic previsions CERTIFEL certification system". When no solution is achieved by the management, Customer complaints and appeals also can be forwarded to the certification committee (ZAC) where a final decision will be made. The quality manager of Electrosuisse has the responsibility to monitor the complete process.

The assessment team also noted that the procedure on appeals did not at the time of the assessment cover appeals to the IECEx System or how this is conveyed to customers. The procedure has subsequently been revised to address this to the satisfaction of the assessment team.

17. SPECIAL FACTS TO BE NOTED

17.1 Supporting Documentation

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

- Site Assessment Report incorporating details of issues raised and how these have been resolved
- Checklist for ISO/IEC Guide 65

17.2 Production of reports

Electrosuisse had experience producing auditing reports of manufacturers along the lines required for the ATEX certification. The assessment team felt these provided sufficient evidence of their ability to produce QARs in IECEx System after a completion of further training mentioned in clause 15 of this report.

18. COMMENTS (Including issues found during assessment)

A number of issues were found during the assessment and reported to Electrosuisse. All were resolved to the satisfaction of the assessment team. They are also listed in Annex A of the site assessment report, held by the IECEx Secretariat, together with the details of how they were resolved.

19. RECOMMENDATION

Based on the initial assessment performed on 24-26 March 2009, Electrosuisse is recommended for acceptance in the IECEx system as an IECEx Certification Body (ExCB) according to the accepted scope of the standards listed in clause 1.14 of this document with following exclusions:

a) Ex e motor with voltage high than 1000V and Ex e luminaire from IEC60079-7;
b) Ex nC and Ex n motor are excluded from IEC 60079-15.

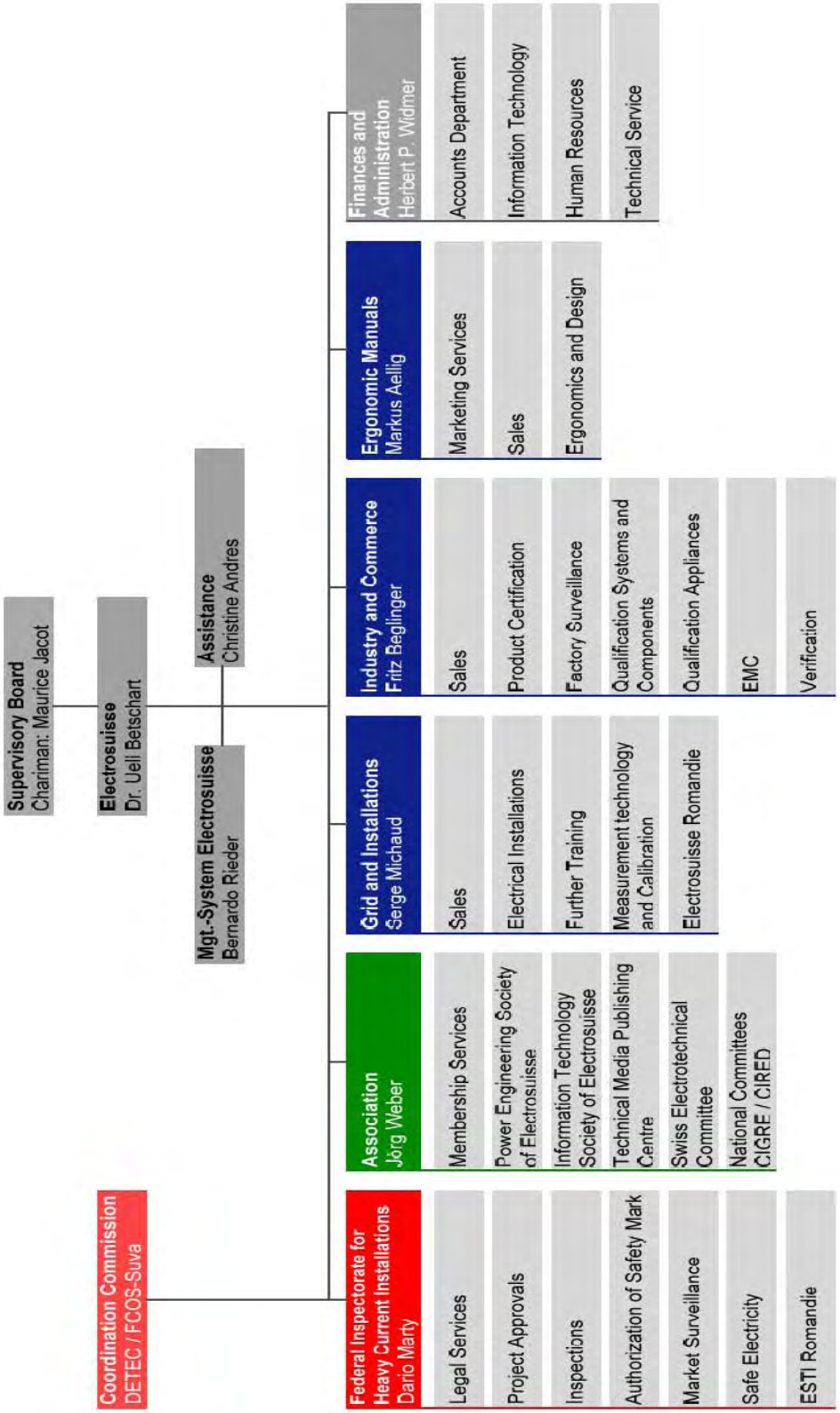
Xu Jianping Team Leader Leader Assessor	Herbert Peters Expert Assessor	Alain Czyz Expert Assessor

Date: 22 November 2009

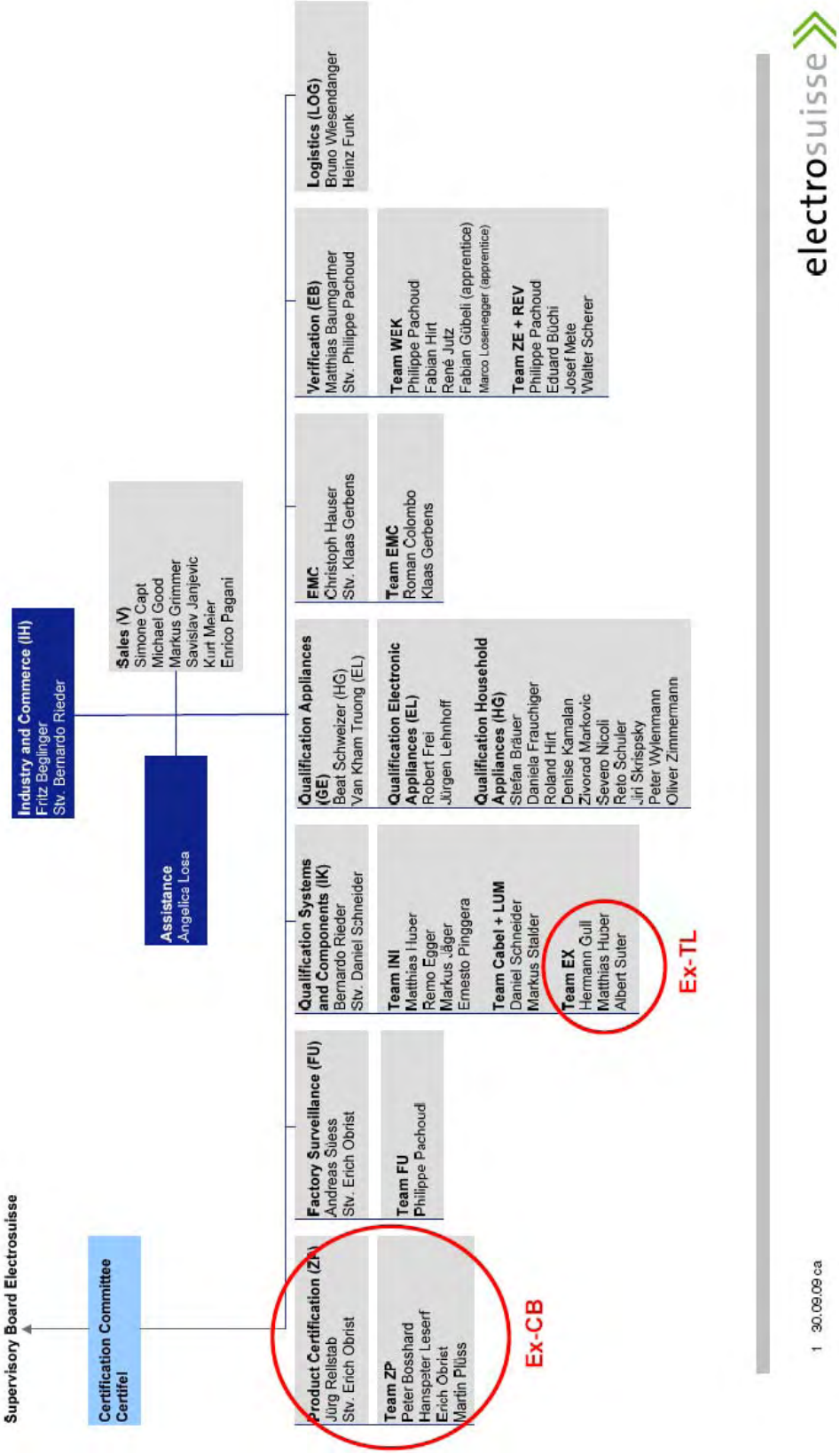
List of Annexes:

1. Overall Organization Chart of Electrosuisse
2. Organization Chart of Electrosuisse Ex operation
3. Accreditation from Swiss Accreditation Service (SAS)

Annex 1
Overall Organization Chart of Electrosuisse



Annex 2
Organization Chart of Electrosuisse Ex operation



Annex 3
Accreditation from Swiss Accreditation Service (SAS)

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Economic Affairs DEA
Swiss Accreditation Service SAS

Based on the Accreditation and Designation Ordinance dated 17 June 1996 (as of 4 April 2006) and on the advice of the Federal Accreditation Commission, the Swiss Accreditation Service (SAS) grants to

Electrosuisse
Product Certification
Luppmenstrasse 1
CH-8320 Fehraltorf

the accreditation as

Certification body for electrical equipment

in accordance with the Standard EN 45011. The scope of accreditation is defined in the Official Directory of the Accredited Certification Bodies.

Accreditation mark and number: SCESp 035
Date of accreditation: 24 September 1996
Date of the last renewal of accreditation: 24 September 2006
The accreditation is valid until: 23 September 2011

CH-3003 Berne-Wabern, 15 September 2006
Swiss Accreditation Service

The Head
Hanspeter Ischi

SAS is a signatory of the multilateral agreements of the European co-operation for Accreditation (EA) for calibration, testing, inspection and certification of products, personnel, quality and environmental management systems, of the International Accreditation Forum (IAF) for certification of products, quality and environmental management systems and of the International Laboratory Accreditation Cooperation (ILAC) for calibration and testing.