



ExMC/975/DV  
December 2014

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

**Title: Surveillance and Scope Extension Assessment Report for Technology  
Institution of Industrial Safety (TIIS) an Accepted ExCB and ExTL within  
the IECEx System, Equipment Scheme 02**

**To: Members of the IECEx Management Committee, ExMC**

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### Introduction

During a routine annual surveillance assessment of *Technology Institution of Industrial Safety (TIIS)* (an Accepted Ex Certification Body (ExCB) and an Accepted Ex Test Laboratory ExTL), an assessment was also conducted concerning the a scope extension application to include the following Standards within their scope.

IEC 60079-15 Edition 4	Explosive atmospheres – Part 15: Equipment protection by type of protection "n"
IEC 60079-18 Edition 3	Explosive atmospheres – Part 18: Equipment protection by encapsulation "m"
IEC 60079-25 Edition 2	Explosive atmospheres – Part 25: Intrinsically safe electrical systems
IEC 60079-26 Edition 2	Explosive atmospheres - Part 26: Equipment with equipment protection level (EPL) Ga
IEC 60079-30-1 Edition 1	Explosive atmospheres – Part 30-1: Electrical resistance trace heating – General and testing requirements
IEC 60079-31 Edition 2	Explosive atmospheres – Part 31: Equipment dust ignition protection by enclosure "t"

This report details the assessment findings of this scope extension with the IECEx Assessor, recommending acceptance of the above scope extension for both the ExCB and ExTL operations of TIIS and is now hereby submitted for voting by ExMC.

Please consider the assessment report and return the completed voting form, separate Word document, to the Secretariat by **2015 01 31**

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

*Chris Agius*  
IECEx Secretary

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ExMC/975/DV  
December 2014

**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

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**IECEx ExCB/ExTL assessment report for TIIS**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

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## 1 Assessment information

### 1.1 Type of Body covered by this assessment:

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:

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

### 1.3 Details of body

#### 1.3.1 Country

Japan

#### 1.3.2 Name of body

Technology Institution of Industrial Safety (TIIS)

#### 1.3.3 Name and title of nominated principal contact

Name	Title	E-mail address
Katsuya ENOMOTO(Mr)	Executive Managing Director, Director of International Affairs Department	enomoto@tiis.or.jp

### 1.4 Assessment information

#### 1.4.1 Members of the assessment team

Name	Role (modify as necessary)
Jim Munro	Lead assessor

#### 1.4.2 Place(s) of assessment

Technology Institution of Industrial Safety(TIIS)	2-16-26 Hirosedai, Sayama-shi, Saitama 350-1328, JAPAN
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#### 1.4.3 Assessment date(s)

Wednesday, 12 to Thursday, 13 November 2014

### 1.5 Application information

Date of application for scope extension: 6 October 2014

## 1.6 Scopes

### 1.6.1 ExCB scope for equipment certification scheme

#### 1.6.1.1 Current Scope

Number	Title
IEC 60079-0 Edition 6	Explosive atmospheres - Part 0: Equipment - General requirements
IEC 60079-1 Edition 7	Explosive atmospheres - Part 1: Equipment protection by flameproof enclosures "d"
IEC 60079-2 Edition 6	Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure «p»
IEC 60079-6 Edition 3	Explosive atmospheres - Part 6: Equipment protection by oil immersion «o»
IEC 60079-7 Edition 4	Explosive atmospheres - Part 7: Equipment protection by increased safety "e"
IEC 60079-11 Edition 6	Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i"

NOTE 1 Standards shown with an asterisk (\*) are superseded standards

NOTE 2 Unless otherwise indicated, earlier editions of standards (even if with a different number) are considered to be covered in the above scope for the purposes of the assessment.

NOTE 3 The above list highlights any extension of scope in the list above for new standards or later editions of standards already in scope.

#### 1.6.1.2 Proposed scope extension

Number	Title
IEC 60079-15 Edition 4	Explosive atmospheres – Part 15: Equipment protection by type of protection "n"
IEC 60079-18 Edition 3	Explosive atmospheres – Part 18: Equipment protection by encapsulation "m"
IEC 60079-25 Edition 2	Explosive atmospheres – Part 25: Intrinsically safe electrical systems
IEC 60079-26 Edition 2	Explosive atmospheres - Part 26: Equipment with equipment protection level (EPL) Ga
IEC 60079-30-1 Edition 1	Explosive atmospheres – Part 30-1: Electrical resistance trace heating – General and testing requirements
IEC 60079-31 Edition 2	Explosive atmospheres – Part 31: Equipment dust ignition protection by enclosure "t"

### 1.6.2 ExTL scope

The ExTL scope and proposed scope extension are the same as for the ExCB.

### 1.6.3 ExCB scope for Service Facilities Scheme

Not applicable

### 1.6.4 ExCB scope for ExMark Scheme

Not applicable



## **2 Common information**

### **2.1 Description of the overall operation**

For the purposes for of operation within IECEx TIIS has three major departments with totally separate personnel as follows:

1. The Certification Department being the IECEx ExCB
2. The Testing Department being the IECEx ExTL
3. The International Affairs Department

The above are also supported by the Management Representative on QMS.

A fourth department has recently been added: General Affairs Department.

The details of the ExCB and ExTL are shown later in this report.

### **2.2 Legal entity of body**

Not relevant for scope extension. This was previously covered during the site assessment conducted in December 2013 and was included in ExMC/910/DV.

### **2.3 Financial support**

Not relevant for scope extension. This was previously covered during the site assessment conducted in December 2013 and was included in ExMC/910/DV.

### **2.4 History**

TIIS was accepted as an ExCB and ExTL on 14 April 2014.

#### **2.4.1 Quality manual**

There are two quality manuals. One is related to certification and inspection (ISO/IEC Guide 65), TIIS-ExCB-00000-C, and the other is related to testing and evaluation (ISO/IEC 17025), ExTL-00000-C. These have changed from issue A to issue C since the initial IECEx assessment. The revised versions were reviewed during the assessment visit and found to meet the requirements of IECEx and to address changes being brought about as a result of the scope extension request.

The quality manuals, rules, procedures, checklists, etc are stored on an exclusive server of TIIS, and available to all personnel concerned. The latest version document is available. There was a potential issue that a controlled quality document could accidentally be changed once a person has access to it. This was subsequently resolved to the satisfaction of the assessor.

The quality manuals and procedures include text in Japanese and English. The two quality manuals and many of the procedures are written specifically for IECEx, not for local certification.



## 2.4.2 Procedures

All relevant procedures are described in the two quality manuals, and where appropriate, they are also described in relevant rules. Where there are common requirements, for example control of records, there is one procedure for both the ExCB and ExTL. Table 2 of the ExCB manual lists all the procedures.

Many of the procedures had changed to issue C since the initial IECEx assessment. The revised versions were reviewed during the assessment visit and found to meet the requirements of IECEx and to address changes being brought about as a result of the scope extension request

## 2.4.3 Work instructions

There is a range of test procedure documents, forms and checklists. A register is also kept of relevant IECEx ODs and other IECEx documents such as decision sheets. All are accessible through the TIIS intranet. There were procedures and associated forms produced for all tests in the standards sought in the proposed scope extension. They were reviewed and found to meet the requirements of the standards, although some areas for improvement were identified. These areas were subsequently addressed to the satisfaction of the assessor.

## 2.4.4 Records (including test records where relevant)

All test and assessment records were found to be made and retained in appropriate form with provision to also have all relevant data for tests in the standards covered in the scope extension.

NOTE 1 Example records should be sought of oldest records both in electronic and hard copy to test the retrieval and existence of records, including archival records.

NOTE 2 Information should be sought on whether there is a method of secure disposal of hard copy records once they have been placed on an electronic system.

## 2.4.5 Document change control

Clause 4.8.2 of the ExCB Quality Manual refers to the procedure TIIS-ExCB-02000-C Rules for control of documents. TIIS is in the process of moving from a hard copy system to a computer based system and the revised procedure reflects this. At this stage all printed hard copies are still controlled.

## 2.5 Confidentiality

Not relevant for scope extension. This was previously covered during the site assessment conducted in December 2013 and was included in ExMC/910/DV.

## 2.6 Publications (Hard cover and Electronic)

Not relevant for scope extension.

## 2.7 Recognition and agreements

Not relevant for scope extension/

## 2.8 Internal audit and periodic management review

### 2.8.1 Internal audit

Not relevant for scope extension. However, internal audit was reviewed as part of surveillance visit and found to meet the requirements for IECEx.





## 2.8.2 Management review

Not relevant for scope extension. However, management review was reviewed as part of surveillance visit and found to meet the requirements for IECEx.

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

TIIS does not subcontract any certification work according to 4.4 of ExCB Manual. Regarding testing and evaluation activities, at present TIIS also does not subcontract any test work. However, changes have been made to the procedures to address the situation for subcontracting should the need arise (for example if they seek a scope extension for IEC 60079-28). They have also included provision for a record of subcontractors. These new requirements for subcontracting meet the requirements of IECEx.

## 2.10 Training and competence

Training of personnel and securing necessary personnel are described in 4.2 and 4.5.3 i) of ExCB Manual and 5.2 of ExTL Manual.

TIIS-ExCB-08000-C Rules for education and training of personnel, has been changed to address a change in the way competence is addressed. There are now 'rating lists for competence' addressing each member of staff and their level of competence from 1 to 3. There is an education/planning plan that is approved by the Management Representative on QMS. The competence rating lists cover all standards being sought in the scope extension. The competence of staff for the those standards was evaluated during the assessment and found to be of a satisfactory level. It was noted that extensive training of staff for the new standards had been carried out with all relevant staff.

## 2.11 Complaints and appeals (including appeals to IECEx)

Not relevant for scope extension. However, this was evaluated for the surveillance visit. Some changes have been made in the complaints and appeals process. Now all unresolved complaints and all appeals are considered by the Certification Control Committee with the process addressed in TIIS-ExCB-05000-C Rules for dealing with appeals and complaints. This process meets the requirements of IECEx.

## 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:

- Details of issues raised and how these have been resolved
- Completed technical capability document for the standards sought in the scope, including photos of the facilities/tests witnessed. The TCD completed for the initial assessment for used as the base document for this process so the final document covers all standards in the current scope and scope extension.
- Assessor's notes
- Competency matrices..

## 2.13 Recommendations

Based on the assessment performed on 12 to 13 November 2014, TIIS is recommended for a change of scope acceptance in the IECEx scheme as:

- An ExCB in the IECEx Certified Equipment Scheme



- An ExTL in the IECEx Certified Equipment Scheme

This is according to the scope of the standards listed in this document.

Jim Munro
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Lead Assessor
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Date: 8 December 2014



### 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) OD005-1 IECEx Quality System Requirements for Manufacturers – Part 1: Guidance on the establishment and maintenance of a quality system
- d) OD005-2 IECEx Quality System Requirements for Manufacturers – Part 2: Audit Checklist. (This is available in a Word format for use by ExCBs)
- 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 Guide 65:1996, Edition 1, General requirements for bodies operating product certification systems
- j) IECEx Document OD17 Drawing and documentation guidance
- k) IECEx Technical Capability Documents (TCDs)
- l) ExTAG decision sheets (DSs)

NOTE The latest editions of the above documents were applied

#### 3.2 Candidate ExCB persons interviewed

Name	Position
Minari KOGANE(Mr)	Certification Department Director
Yutaka ISHIDA(Mr)	Senior Quality Assessor, Technical Support Department Director
Kazuo YAMAMOTO(Mr)	Management Representative on QMS, Quality System Improvement Section
Katsuya ENOMOTO (Mr)	Executive Managing Director

#### 3.3 Associated ExTL(s)

Testing Department of TIIS is an associated ExTL as it is the only department having testing and evaluation functions within TIIS. The Testing Department (ExTL) is completely separate to the ExCB with different personnel.

#### 3.4 Associated certification functions

Not relevant for scope extension. This was previously covered during the site assessment conducted in December 2013 and was included in ExMC/910/DV.

#### 3.5 National marks and certificates

Not relevant for scope extension. This was previously covered during the site assessment conducted in December 2013 and was included in ExMC/910/DV.

### 3.6 Standards accepted

See clause 1.6 of this report

### 3.7 National differences to IEC standards

National differences to IEC standards are those for the country differences listed in the latest version of the IECEx Scheme Bulletin or have been submitted to IECEx as part of the request for scope extension. TIIS also undertook to publish these on TIIS website.

### 3.8 Organisation

#### 3.8.1 Names, titles and experience of the senior executives

Name	Title	Experience
Haruki NAGAISHI	President of TIIS	41 years in Ex
Katsuya ENOMOTO (Mr)	Executive Managing Director	2 years in Ex
Minari KOGANE(Mr)	Certification Department Director	22 years in Ex

#### 3.8.2 Name, title and experience of the quality management representative

Name	Title	Experience
Kazuo YAMAMOTO(Mr)	Management Representative on QMS, Quality System Improvement Section	8 years in quality management

#### 3.8.3 Name and title of signatories for certification

Name	Title	Comments
Minari KOGANE(Mr)	Certification Department Director	22 years in Ex
Masaki KANEKO(Mr)	Deputy Department Director of Certification Department Senior Certification Engineer	20 years in Ex

#### 3.8.4 Other employees in ExCB activity

Name	Title	Responsibility and Experience in Ex
Masaru TANAKA(Mr)	Senior Certification Engineer	45 years in Ex
Takeo SEKINE(Mr)	Senior Certification Engineer	31 years in Ex
Yutaka ISHIDA(Mr)	Senior Quality Assessor	5 years in Ex, 12 years in QA
Hiroko FURUSAWA(Ms)	Clerk	-
Naomi TAKISHITA(Ms)	Clerk	-

### 3.9 Organizational structure

See attached organization charts in Annexes A and B and the description in Clause 2.1 of this report.

### 3.10 Administration

#### 3.10.1 Administrative structure

TIIS has completely separate branches for certification and testing. This ensures separation between ExCB and ExTL activities and there are no staff common to both areas.



### 3.10.2 Indemnity insurance

Not relevant for scope extension.

### 3.11 Resources

Seven persons are active in the IECEx field in the ExCB of which two are administrative personnel. The people have significant experience in the Ex field appropriate for the work of the ExCB.

### 3.12 Committees (such as governing or advisory boards)

There is a Certification Control Committee the rules for which are covered in TIIS-ExCB-01100-A.

There is also a Board of TIIS.

#### 3.12.1 National approval/certification methods

Not relevant for scope extension. This was previously covered during the site assessment conducted in December 2013 and was included in ExMC/910/DV.

#### 3.12.2 Certification policy

Not relevant for scope extension. This was previously covered during the site assessment conducted in December 2013 and was included in ExMC/910/DV.

#### 3.12.3 Application for certification

Not relevant for scope extension. However, as part of surveillance two IECEx projects currently being handled by TIIS were reviewed and found to meet the requirements of IECEx.

#### 3.12.4 Certification decision

This was previously covered during the site assessment conducted in December 2013 and was included in ExMC/910/DV. The staff involved in the certification decision also have the relevant competencies for the standards sought in the scope extension.

#### 3.12.5 Suspension and cancellation of certificates

Not relevant for scope extension. This was previously covered during the site assessment conducted in December 2013 and was included in ExMC/910/DV.

### 3.13 Certificates issued

Number of TIIS national certificates issued under for the preceding five years for three of the standards sought in the scope extension request.

IEC Standard numbers	Type of protection or other identifying information	Number of issued certificates (for 5 years)					
		0	1	2	3	4	5
60079-15	Ex n	0	1	1	0	1	3
60079-18	Ex m	1	2	2	0	0	5
60079-31	Ex t	8	15	7	15	0	45

Note 1. Above include certificates to IEC 60079-0.



**Note 2.** The number of issued certificates above may include certificates for a type of protection combined with other type(s) of protection.

### **3.14 National accreditation**

TIIS does not hold an accreditation on ISO/IEC Guide 65 from an accreditation agency such as Japan Accreditation Board for Conformity Assessment (JAB) since TIIS is authorized by the Ministry of Health, Labour and Welfare of Japan to issue certificates under Occupational Safety and Health Law. Hence this visit was a surveillance visit as well as a scope extension visit.

### **3.15 Assessment of manufacturers and issue of QARs**

Technical competence for the purpose of auditing manufacturers to the standards sought in the scope extension will be addressed through the provision of assessment/testing staff with appropriate competence documented in the rating lists for compliance. At the time of the assessment visit, the use of technical experts as part of the assessment team was not covered in TIIS procedures. The procedures were subsequently revised to include this.

As part of the surveillance visit, an ATEX audit using the IECEx documentation done by TIIS for a notified body in Europe was reviewed and it demonstrated the competence of TIIS to do a manufacturing assessment equivalent to IECEx.

### **3.16 Comments (including issues found during assessment)**

A couple of issues were identified during the assessment visit. As outlined above these were subsequently resolved to the satisfaction of the assessor. More detail is included in the site assessment report.

## 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 Documents (TCDs)
- g) ExTAG decision sheets (DSs)

NOTE The latest editions of the above documents were applied.

### 4.2 Candidate ExTL persons interviewed

Name	Position
Shunsuke YOSHIHARA(Mr)	Testing Department Director
Relevant staff from the ExTL associated with the scope extension or surveillance activities.	

### 4.3 Associated ExCB(s)

The Certification Department of TIIS is an associated ExCB. The Testing Department (ExTL) is completely separate to the ExCB with different personnel.

### 4.4 Organisation

#### 4.4.1 Names, titles and experience of the senior executives

Name	Title	Experience
Haruki NAGAISHI	President of TIIS	42 years in Ex
Katsuya ENOMOTO (Mr)	Executive Managing Director	2 years in Ex
Shunsuke YOSHIHARA(Mr)	Testing Department Director	20 years in Ex

#### 4.4.2 Name, title and experience of the quality management representative

Name	Title	Experience
Kazuo YAMAMOTO(Mr)	Management Representative on QMS, Quality System Improvement Section	8 years in quality management

#### 4.4.3 Other employees in ExTL activity

Name	Title/responsibility	Experience in Ex
Norio NIINUMA(Mr)	Senior Testing Engineer	43 years in Ex
Takashi GOTOH(Mr)	Senior Testing Engineer	18 years in Ex

Masanobu HATANAKA(Mr)	Senior Testing Engineer, Internal Calibration Specialist	26 years in Ex
Yoshikatsu YAMAMOTO(Mr)	Testing Engineer	36 years in Ex
Shinji OGAWA(Mr)	Testing Engineer	7 years in Ex
Hidenori SATOU(Mr)	Testing Engineer	6 years in Ex
Takuro KUBO(Mr)	Testing Engineer	4 years in Ex
Zhihong KANG(Mr)	Testing Engineer	6 years in Ex
Mitsuhiro WATANABE(Mr)	Testing Engineer	6 years in Ex
Shigeaki TANABE(Mr)	Test Technician	2 years in Ex
Shinpei SAKAGUCHI(Mr)	Test Technician	1 year in Ex
Tatsuo IWASA(Mr)	Testing Engineer	8 years in Ex
Izumi YAMANE(Mr)	Testing Engineer	8 years in Ex

#### 4.5 Organizational structure

See attached organization charts in Annexes A and B and the description in Clause 2.1 of this report.

#### 4.6 Resources

TIIS has an adequate number of staff with appropriate competence for the revised scope of standards. There are a comprehensive range of test procedures and forms for tests in those standards. Test equipment is available for all tests in the standards. The environmental conditions in the laboratory are appropriate for the testing. Details of the above are documented in the Technical Capability Document completed at the initial assessment which has now been updated to address the new standards covering personnel competence, procedures and test equipment.

#### 4.7 Test reports issued

TIIS does not issue test reports for local certification. The figures provided in the previous section for certificates issued provides an indication of testing experience in the various types of protection sought for the scope extension.

#### 4.8 National accreditation

TIIS does not hold national accreditation for the standards sought in the scope extension and the national accreditation they do hold does not cover the quality system relevant to IECEx, and hence there will be a need for annual surveillance.

#### 4.9 Calibration

All equipment being used for the scope extension were found to be in calibration. It was also noted during the surveillance visit that some new equipment had been purchased. This was also found to be in calibration.

#### 4.10 Tests witnessed during the assessment

The following tests were witnessed during the assessment visit:

- IEC 60079-18 - 8.1.1 Water absorption test
- IEC 60079-31 - 6.1.1.3 Pressure test of at least  $4 \pm 0,4$  kPa for level of protection "ta" electrical equipment
- IEC 60079-30-1 - 5.1.5 Impact test





In addition the assessor looked at capability for other tests in standards in the scope. This is documented in the TCD.

#### 4.11 Comments (including issues found during assessment)

There were a few issues raised which included:

- the need for improved clarity in some procedures for the scope extension
- the need to, use appropriate measurement equipment; and
- demonstrating test apparatus complied with the dimensional requirements in the appropriate standards for the scope extension.

All issues were subsequently resolved to the satisfaction of the assessor. More detail is included in the site assessment report.

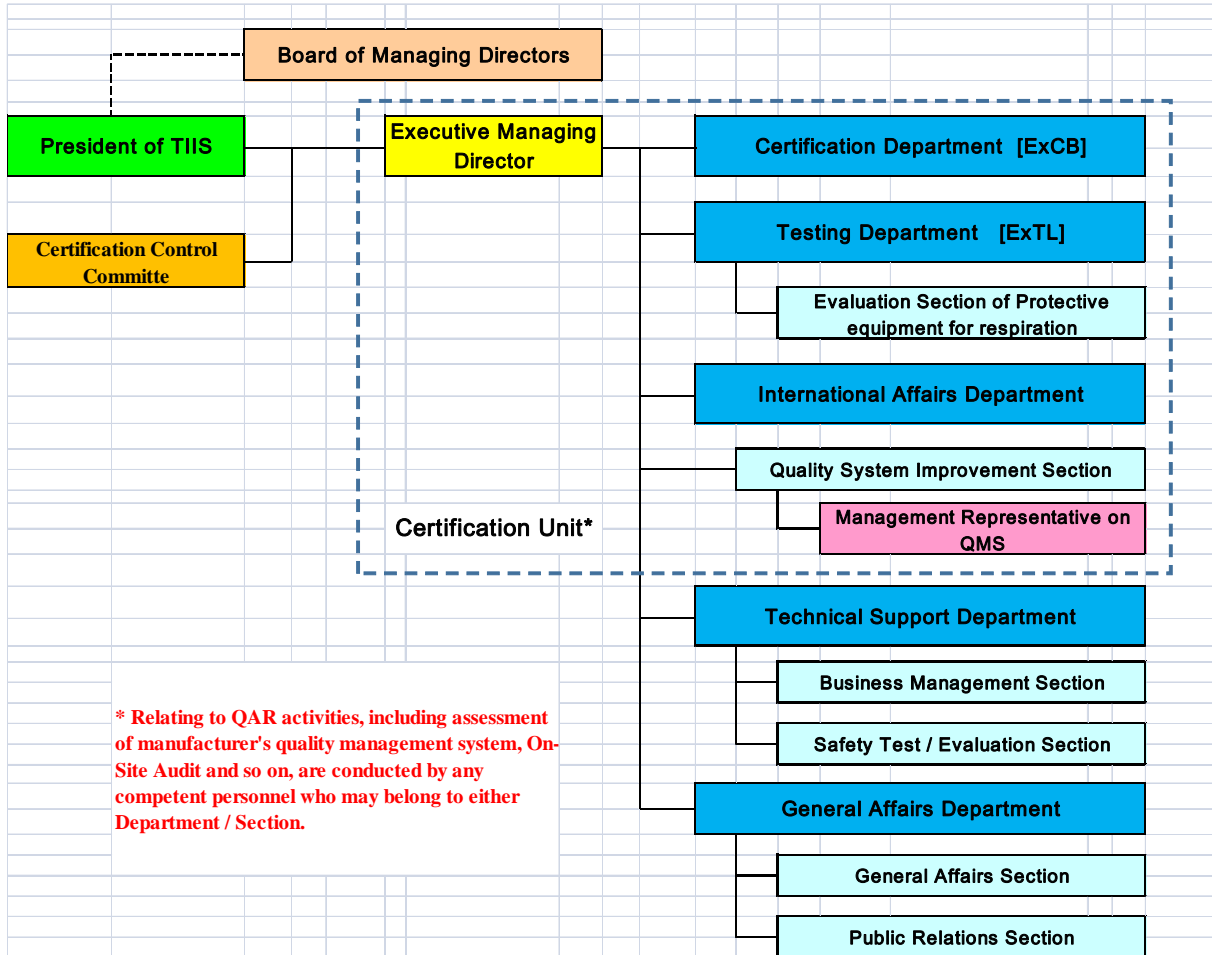
## 5 Annexes

See Contents. (add, modify or delete annexes as necessary). Please note the following instructions for the IEC template:

NOTE When creating a new annex **DO NOT** type the word Annex, just create a new empty page and then apply the styles ANNEX\_title to the first (empty) line. The word "Annex" followed by the letter "A" or "B", etc will automatically appear.

**TIP:** When typing annex titles, separate the lines of the title by "shift+return"

## Annex A TIIS Organisation Chart



## Annex B Organisation Showing Responsibilities

