

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

TITLE: IECEx Assessment Report for the acceptance of Technology Institution of Industrial Safety (TIIS), Japan, to participate as an ExCB and ExTL in the IECEx System, Equipment Scheme, 02,

Circulation to: ExMC – IECEx Management Committee

INTRODUCTION

This document contains the IECEx Assessment Report for the acceptance of *Technology Institution of Industrial Safety (TIIS), Japan*, to become an Accepted Certification Body (ExCB) and an Accepted Ex Test Laboratory (ExTL), within the IECEx Equipment Scheme, 02.

The report is hereby submitted for voting by the ExMC.

Please consider the assessment report and return the completed voting form to the Secretariat by **2014 04 12**.

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

Chris Agius

IECEX Secretariat

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**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 TIIS

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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)	Department Director, 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
Bernard Piquette	Expert 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)

Tuesday, 3 to Friday, 6 December 2013

1.5 Application information

Date of application: 1 July 2013

1.6 Scopes

1.6.1 ExCB scope for equipment certification scheme

Number	Title
IEC 60079-0 Edition 6	Explosive atmospheres - Part 0: Equipment - General requirements
IEC 60079-1 Edition 6	Explosive atmospheres - Part 1: Equipment protection by flameproof enclosures "d"
IEC 60079-2 Edition 5	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.

1.6.2 ExTL scope

The ExTL scope is 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.

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

The International Affairs Department is responsible for:

- a) The international cooperation with overseas laboratories and other bodies
- b) Matters regarding the IECEX System but excluding the testing
- c) Collection of information and research on international standards related to certification
- d) Other international matters not covered by other departments or divisions.

It represents TIIS at IECEX meetings and is responsible for ensuring relevant standards and IECEX documents are available for the ExCB and ExTL. It is also involved in the development and implementation of quality systems for the ExCB and ExTL. The members of this department are:

Name	Title
Katsuya ENOMOTO(Mr)	Department Director, International Affairs Department
Yuko YAMAMOTO (Mrs)	National Certification Officer

2.2 Legal entity of body

The Technology Institution of Industrial Safety (TIIS) is registered as a legal entity (in its Japanese name of 産業安全技術協会) as a legal entity under the Civil Law of Japan, under the registration number of 0300-05-004315. TIIS is also a Public Interest Corporation (公益社団法人) authorized by the Cabinet Office, the Government of Japan, on March 28, 2011 under Fu-Eki-Tan No.2761. Two original documents showing the above registrations were viewed. The registration of the company as a Public Interest Corporation was also viewed on-line at a site for Public Interest Corporations (www.koeke.info.go.jp). The TIIS name is mainly used for international work.

2.3 Financial support

TIIS is self-financed by its income which is primarily from testing and certification, safety evaluation, safety consultancy (see 3.17), safety seminars, and sales of technical documents. It also receives grants from the Government for research. A copy of the of TIIS's audited financial report for 2012 fiscal year was reviewed and showed income exceeded expenditure for that year.

2.4 History

In April 1965, TIIS was founded as a private organization. The initial name was Research Institution of Industrial Safety.

In June 1970, it was approved as a corporate legal entity by the Minister of Labour, Japan.

In January 1971, it was designated for a testing and certification body of Ex-equipment by the Director-General of Labour Standards Bureau of the Ministry of Labour.

In October 1972, it was approved for a Designated Type Examination Agency on Ex-equipment by the Minister of Labour, Japan.

In August 1976, it changed its name to the existing name of TIIS.

In March 2004, TIIS was registered as a Registered Type Examination Agency for 11 machines and equipment including Ex-equipment in accordance with the enactment of amended Occupational Safety and Health Law of Japan. The registration was made by the Minister of Health, Labour and Welfare of Japan.

In March 2009, TIIS received a notice of the renewal of the Registered Type Examination Agency for 11 machines and equipment from the Ministry of Health, Labour and Welfare of Japan. The current registration is valid until 2014-3-30.

In March 2011, TIIS was authorized as a Public Interest Corporation by the Cabinet Office of the Government of Japan.

2.5 Documentation

2.5.1 Quality manual

There are two quality manuals. One is related to certification and inspection (Guide 65), TIIS-ExCB-00000-A, and the other is related to testing and evaluation (ISO/IEC 17025), ExTL-00000-A.

At the time of the assessment visit there some inconsistencies in titles of personnel between the two manuals. These inconsistencies were later removed.

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 and documents are protected from alteration.

The quality manuals and procedures included text in Japanese and English. All are at original issue A as previous manuals and associated procedures had undergone extensive changes to accommodate the requirements of IECEX. The two quality manuals and many of the procedures are written specifically for IECEX, not for local certification.

2.5.2 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.

2.5.3 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.

2.5.4 Records (including test records where relevant)

All test and assessment records are processed in hard copy form. Then at the end of a project all information is scanned, including all the drawings, with the information being stored on a dedicated server. Then the hard copy document is destroyed. All documents are scanned in TIFF format.

Clause 4.9 of the ExCB Quality Manual refers to the procedure 'Rules for control of records' (TIIS-ExCB-03000-A and incorporates requirements for control of records. At the time of the assessment visit it stated that 'records shall be kept for more than 5 years'. This period was subsequently revised to 30 years.

The procedure covers quality records and technical records. It addresses all relevant requirements required for the production, correction, transfer, checking, retention and disposal of records. For electronic data produced under IECEx system, TIIS has installed an exclusive server for IECEx. But the data in that server will be backed up to another server.

Existing test records concerning national certificates are maintained on a secured site and accessible by authorized persons only.

A test of the electronic archival system was carried out looking at old records. The system was able to retrieve certification records back to 1994 complete with test data.

The process of disposal of records through a contracted was reviewed. For a batch of records than had been disposed there was documented evidence that they had been shredded and dissolved.

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.

2.5.5 Document change control

Clause 4.8.2 of the ExCB Quality Manual refers to the procedure 'Rules for control of documents' (TIIS-ExCB-02000-A). It is also referred to in Clause 4.3 of the ExTL Quality Manual.

TIIS operates a hard copy system for its documents and clearly identifies documents that are controlled or not controlled. Documents are generally grouped in two categories, internal and external documents. Internal documents are broken down into three classes A, B and C for the purposes for defining the details of the control method. The procedure also references typical external documents to be controlled including IECEx documents and standards. It was subsequently revised to also make reference to documents impacting on standards such as corrigenda and interpretation sheets (I-SHs).

2.6 Confidentiality

Confidentiality described in 4.10 and 5.2.2 a) of ExCB Manual and 4.1.5 c) of ExTL Manual. All personnel of TIIS are required not to disclose confidential information in accordance with "Working Regulation" of TIIS.

All personnel involved with IECEx certification are required to sign a "Letter of Promise" specific to IECEx, by which they commit themselves

- to comply with the rules of TIIS, including those relating to confidentiality and independence from commercial and other interest; and
- to declare that they have no interest at present in the company once they worked for, which designs, manufactures or supplies Ex-products.

The signed agreements were viewed and found to meet the requirements for IECEx.

After the assessment visit a Certification Control Committee was established. Evidence was provided the members are also signing appropriate agreements relevant to confidentiality and conflict of interest.

TIIS does not employ subcontractors.

2.7 Publications (Hard cover and Electronic)

TIIS is presented on the Internet under <http://www.tiis.or.jp/>. Printed brochures are available as well.

2.8 Recognition and agreements

There are 11 mutual recognition agreements with overseas testing laboratories in eight countries/economies in the area of Ex-equipment. Based on those agreements, TIIS's test and audit reports are accepted by those laboratories. The organisations include PTB (Germany); NEPSI, CQST, CSST (China); KOSHA, KTL (South Korea); LCIE (France); ITRI (Taiwan); DEKRA (Netherlands); BKI (Hungary); and Sira (UK).

2.9 Internal audit and periodic management review

2.9.1 Internal audit

Internal audits are described in 4.7.1 of ExCB Manual and 4.14 of ExTL Manual. Internal audits are to be conducted twice a year in accordance with "Rules for Conducting Internal Audits" (TIIS-ExCB-04000-A). The procedure comprehensively addresses all requirements of the relevant standards. However, it had not been implemented at the time of the assessment visit as the procedures for IECEx were only finalised in November 2013.

There are internal audits under the General Rules (rule 04-13D) for JSQ 17025:2005. These are carried out twice a year (August and February).

There are also internal audits for ISO 9001. These audits are done twice a year (August and February). These audits are done on the same day as the 17025 audits.

The last internal audit was conducted in August, 2013 based on the General Rules and ISO 9001. The audit took place from 5 to 8 August 2013. The majority of each day was spent on ISO 9001. The next audit is planned for February, 2014.

It was advised that ISO/IEC 17025 is not required for testing for certification of equipment in Japan.

2.9.2 Management review

Management reviews are described in 4.7.2 of ExCB Manual and 4.15 of ExTL Manual. They are to be conducted twice a year, as a rule, in September and March. At present the requirements for management review are specified to ISO/IEC Guide 65 and separately to ISO/IEC 17025, although many elements are the same. It was advised that it is proposed that both management reviews will be held on the same day.

No management review had been held for IECEX at the time of the assessment visit with the first one planned for March 2014.

The last management review was performed on 12 September, 2013, this was a combined review for ISO9001 and ISO/IEC 17025. The report was reviewed and found to meet the requirements of the various standards.

2.10 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, TIIS also does not subcontract any test work. This is described in 1.1) of ExTL Manual.

Off-site or witness testing is conducted in case of necessity in accordance with 4.1.3 of ExTL Manual, and performed in compliance with Rules for control of test facilities (Clause 8), Rules for control of testing of Ex-products and relevant ODs of IECEX.

At the time of the assessment visit the requirements for offsite and witness testing to OD024 were not been clearly addressed. These were subsequently included in TIIS-ExTL-23000-B Rules for control of testing of Ex-products.

(The following should be addressed during the assessment to address compliance with OD024:

- That if off-site and witness testing is done, or proposed to be done, OD024 is referenced and incorporated in procedures
- If it is being done, that contracts have been put in place
- For witness testing (only) - according to 6.3.5 of OD024 - Registration of the manufacturer or user test facility has been made with the IECEX Secretariat and updating of the current information in the Register
- That ExTRs reviewed clearly indicate when there has been witness testing done)

2.11 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. Training, competence and records of training are controlled according to "Rules for training/education of personnel".

There is a spreadsheet showing the record of qualifications, work experiences and training of staff. It also includes information on other areas of activity where staff may have gained relevant experience such as participation on technical committees.

There is also a list of qualified personnel as approved by the Executive Managing Director on 28 November 2013. This covers testing engineers, certification engineers, internal auditors, internal calibration specialists, operators and quality assessors.

After the assessment visit comprehensive competency matrices were developed to define the competence of personnel in regard to the various explosion protection techniques or standards and also for auditing of manufacturers.

At the time of the assessment visit There was no evidence of training plans for new personnel or those training for new activities. These plans were subsequently developed.

2.12 Complaints and appeals (including appeals to IECEX)

Complaints and appeals are described in 7 of ExCB Manual and 4.8 of ExTL Manual. Complaints and appeals are dealt with according to Rules for dealing with appeals and complaints (TIIS-ExCB-05000-1). The procedure includes appropriate processes and includes provision for appeal to IECEX.



Secretariat

Applicants are advised of their rights of complaint or appeal in a document Application guide for IECEX Certificate of Conformity (IECEX CoC), Test Report (ExTR) and Quality Assessment Report (QAR). This document was in draft form at the time of the assessment visit and later finalised. It includes advises to applicants on their right of appeal to IECEX.

2.13 Special facts to be noted

2.13.1 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
- Checklist for ISO/IEC Guide 65
- Checklist for ISO/IEC 17025
- Completed technical capability document for the scope of standards sought, which includes photos of the facilities/tests witnessed
- Assessors' notes
- Competency matrices are referred to in the report and provided separately.

2.14 Recommendations

Based on the assessment performed on 3 to 6, TIIS is recommended for 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	Bernard Piquette
Lead Assessor	Expert Assessor

Date: 13 February 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 Guidance Documents (TGDs)
- 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
Tatsuo MOTOYAMA (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

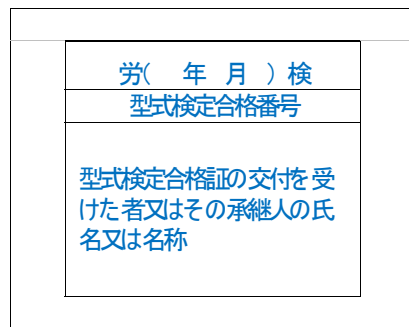
TIIS has been issuing national certificates of Ex-equipment as Examination Agency since 1971. In 1972, the scope of certification of TIIS was expanded to 12 machines and equipment including Ex-equipment in accordance with the enactment of Occupational Safety and Health Law of Japan. TIIS currently issues national certificates for the following machines and equipment in addition to Ex-products.

- (1) automatic electric-shock prevention devices in AC arc welding equipment,
- (2) personal insulation equipment in high- or low-voltage electrical work,

- (3) Insulation equipment for use on electrically live-parts,
- (4) safety devices for press and shear machines,
- (5) press machines equipped with a safety device,
- (6) emergency stop devices for rubber, rubber-compound or plastic-compound mixing rolls (for controlled types other than electrically controlled type only),
- (7) safety devices for circular saws used in wood work,
- (8) safety helmets,
- (9) particulate respirators, and
- (10) gas masks.
- (11) emergency stop devices for rubber, rubber-compound or plastic-compound mixing rolls (for electrically controlled type only)

3.5 National marks and certificates

The following is the national mark that is applied to equipment certified by TIIS:



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.

3.8 Organisation

3.8.1 Names, titles and experience of the senior executives

Name	Title	Experience
Haruki NAGAISHI	President of TIIS	40 years in Ex
Tatsuo MOTOYAMA (Mr)	Executive Managing Director	Not involved in Ex
Minari KOGANE (Mr)	Certification Department Director	21 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	7 years in quality management

3.8.3 Name and title of signatories for certification

Name	Title	Comments
Minari KOGANE(Mr)	Certification Department Director	21 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	44 years in Ex
Takeo SEKINE(Mr)	Senior Certification Engineer	30 years in Ex
Yutaka ISHIDA(Mr)	Senior Quality Assessor	4 years in Ex, 11 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

TIIS holds an "Indemnity Insurance Policy for Professional Work" from Tokio Marine & Nichido Fire Insurance Co. Ltd, under policy number of 9877090641. The current contract covers the period of 1 February 2013 to 1 February 2014, and can be renewed every year. The cover viewed was for YEN100,000,000 public liability and YEN10,000,000 professional indemnity. This cover currently only covered national certification and other related activities and is now being changed to cover international activities.

3.11 Resources

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

3.12 Committees (such as governing or advisory boards)

At the time of the assessment visit there was provision for a Certification Unit with its roles and activities described in 4.2 c) of ExCB Manual, but it only comprised internal staff of TIIS. Subsequently procedure TIIS-ExCB-01100-A was developed to cover the operation of a Certification Control Committee to assist in ensuring the impartiality of the ExCB and to provide an appeal mechanism. Members of this committee are being appointed and represent a appropriate spread of interests. The operation of this committee will met the requirements of ISO/IEC Guide 65 and IECEX.

There is also a Board of TIIS. The role of the Board is addressed in the articles of association for TIIS. It meets three times a year. There are 21 members of the Board including some staff from TIIS. Its role includes:

- Oversight of the finances of TIIS and for this it has two independent auditors
- Deciding the annual plan of business
- Appointment of senior management
- Review of work performance of senior management

3.13 Certification operations

3.13.1 National approval/certification methods

TIIS is a Registered Examination Agency under Occupational Safety and Health Law, and required by the Ministry of Health, Labour and Welfare to comply with Ordinance on Examination of Machines and Other Equipment (Ordinance of the Ministry of Health, Labour and Welfare) and Constructional Requirements for Electrical Equipment for Explosive Atmospheres (Notice of the Ministry of Health, Labour and Welfare) for national certification of Ex-products.

The system for certification of Ex products is different to IECEx. Certificates are issued on the basis of a type test and there is no assessment of manufacturers. Manufacturers are normally required to test their products prior to submission to TIIS and their test results may be used for the purpose of issuing TIIS certification. Manufacturers are required to have in place a QMS system and test facilities for Ex but these are not subject to inspection by TIIS.

3.13.2 Certification policy

TIIS has a Quality Policy that states:

- 1) TIIS executes the work fairly and promptly with high credibility.
- 2) TIIS pursues continuous improvement of the quality management system, and the improvement of customer satisfaction.
- 3) TIIS continuously improves its technical capability so as to be an examination agency deserving a worldwide certification body/testing laboratory, thereby contributes to industries.

The above policy addresses its role as a certification body.

3.13.3 Application for certification

Application for certification is described in 4 to 9 of "Rules for certification of Ex-products".

Procedures were revised to make it clear that that review of the QAR is done by an independent person.

Clause 4.3 7) - After review of the application the Certification Department hands over the job to the Testing Department using a delivery sheet (Form 63) but there is no mention of the test plan. This does exist as Form 6 Plan for Test/Evaluation. It is prepared by the ExTL as shown in TIIS-ExTL02300A Rules for the control of testing of Ex products Clause 5.2 2). Procedures were revised to ensure that the ExCB agrees to the Plan for Test/Evaluation prior to commencement of work.

At the time of the assessment visit procedures and form only referenced only to OD005-1 and not to ISO/IEC 80079-34. These were subsequently revised to include reference to ISO/IEC 80079-34.

Procedures were revised to ensure that a quality assessor who is not a lead assessment cannot do the job alone.

At the time of the assessment Form 9 for review of the QAR included only information that is relevant to the ExTR but this was subsequently revised to include appropriate information.

Form 8 for review of the ExTR covers appropriate information to be reviewed.

At the time of the assessment there was draft procedure IECEX-ExCB-OD009 'Rules for the issuing of IECEXCoCs, ExTR and QARs' which is a modification of IECEX OD009. This subsequently revised to include all relevant requirements and issued.

Procedure TIIS-ExTL-23000-A 'Rules for control of testing of Ex-products' provides more details on the test part of the application process. Some revisions were made to this procedure after the assessment visit to resolve issues raised by the assessment team.

3.13.4 Certification decision

Certification decision is described in 12 of ExCB Manual and Clause 4.5 of the rules for certification of Ex-products. At the time of the assessment visit this showed only the Head of the Certification Department could make the certification decision and make the certificate current in the IECEX website. This was subsequently revised to make provision for additional people to take the decision in the absence of the Head of the Certification Department. The revised procedures made clear that the person making the decision has not been involved in the evaluation processes.

3.13.5 Suspension and cancellation of certificates

Suspension and cancellation of certificates are described in 4.6 of ExCB Manual and 8 of "Rules for certification of Ex-products" (TIIS-ExCB-01000). There is also a form Cancellation/Suspension Report (Form 23). After the assessment visit the above rules was amended so as to clarify the procedures for suspension or cancellation of a certificate. In addition, information regarding the procedures was included in the "Application Guide".

3.14 Certificates issued

Number of TIIS certificates issued under for the preceding four years for each type of protection.

Standard numbers	Type of protection or other identifying information	Number of issued certificates (for 4 years)				Total
		2009	2010	2011	2012	
IEC60079-1	Flameproof enclosure	276	226	264	97	863
IEC60079-2	Pressurized enclosure	12	5	1	0	18
IEC60079-6	Oil immersion	0	0	0	0	0
IEC60079-7	Increased safety	36	18	11	15	80
IEC60079-11	Intrinsic safety	94	135	140	84	453

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.

3.15 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.

3.16 Assessment of manufacturers and issue of QARs

At present TIIS does not perform QAR assessments by its personnel under national certification scheme. However, TIIS conducts the audit of manufacturer' QMS by its personnel upon the requests from overseas certification bodies according to technical agreements with those bodies. Eleven audits were carried out from April 2013 to September 2013. Mr Ishida has done audits for Sira.

At the time of the assessment there was some information in Clause 7 of Rules for certification of Ex-products about surveillance audits but it was brief. Subsequently TIIS amended "Rules for certification of Ex-products", "Rules for control of testing of Ex-products" and prepared a totally new OD009 for detailed procedures. These providing significantly more information satisfying the requirements of IECEx.

TIIS-ExCB-0800-A rules for education and training of personnel, refers to OD026 for the required qualifications for Quality Assessor and Senior Quality Assessor.

At the time of the assessment visit there was no training plan or the auditor in training, Shigeaki Tanabe. This was subsequently developed.

3.17 Comments (including issues found during assessment)

A number of issues were raised during the assessment visit. The above information in Clause 3 and its sub clauses shows most of the issues and how they were resolved to the satisfaction of the assessment team and in accordance with IECEx requirements. More detail is included in the site assessment report.

One issue that required careful considered was the issue of consulting by TIIS. TIIS has now made it clear in their documentation that TIIS does not accept an application for IECEx certification if it involves Ex-equipment for which TIIS has provided a consultancy service. In addition, they prohibit the provision of any consultancy service for Ex-equipment in the process of certification. The above are described in the ExCB Manual and the ExTL Manual. Relevant. Information is also provided to applicants in the " Application Guide".

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 Guidance Documents (TGDs)
- 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
All staff of the ExTL were involved in the assessment process and their names appear below.	

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	40 years in Ex
Tatsuo MOTOYAMA (Mr)	Executive Managing Director	Not involved in Ex
Shunsuke YOSHIHARA(Mr)	Testing Department Director	19 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	7 years in quality management

4.4.3 Other employees in ExTL activity

Name	Title/responsibility	Experience in Ex
Norio NIINUMA(Mr)	Senior Testing Engineer	42 years in Ex
Takashi GOTOH(Mr)	Senior Testing Engineer	17 years in Ex
Masanobu	Senior Testing Engineer,	25 years in Ex

HATANAKA(Mr)	Internal Calibration Specialist	
Yoshikatsu YAMAMOTO(Mr)	Testing Engineer	35 years in Ex
Shinji OGAWA(Mr)	Testing Engineer	6 years in Ex
Hidenori SATOU(Mr)	Testing Engineer	5 years in Ex
Takuro KUBO(Mr)	Testing Engineer	3 years in Ex
Zhihong KANG(Mr)	Testing Engineer	5 years in Ex
Mitsuhiro WATANABE(Mr)	Testing Engineer	5 years in Ex
Shigeaki TANABE(Mr)	Test Technician	1 year in Ex
Shinpei SAKAGUCHI(Mr)	Test Technician	6 months in Ex
Rika SAKABAYASHI(Ms)	Clerk(assistant)	-

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

Thirteen persons are active in the IECEX field including one administrative person. The ExTL has a wide range of very good test facilities covering all test necessary in the IECEX standards, with the exception of the charging tests of Edition 5 of IEC 60079-0. There are a comprehensive range of test procedures and forms for the tests that are done. The environmental conditions in the laboratory are appropriate for the testing.

4.7 Test reports issued

Number of internal TIIS test reports for the preceding four years for each type of protection.

Standard numbers	Type of protection or other identifying information	Number of internal reports (for 4 years)				Total
IEC60079-1	Flameproof enclosure	276	226	264	97	863
IEC60079-2	Pressurized enclosure	12	5	1	0	18
IEC60079-6	Oil immersion	0	0	0	0	0
IEC60079-7	Increased safety	36	18	11	15	80
IEC60079-11	Intrinsic safety	94	135	140	84	453

NOTE1. Above include reports to IEC 60079-0

NOTE2. Under the national certification scheme in Japan, certificates are the only document issued and test reports are not. Therefore, the figures shown above are not the number of issued tests reports, but the number of produced test reports for internal use. One internal report is prepared for each certificate and hence the number of reports is the same as the number of certificates.

4.8 National accreditation

TIIS hold an accreditation of ISO/IEC 17025 from Japan Accreditation Board for Conformity Assessment (JAB) under Accreditation Number RTL01930. The initial accreditation date is April 28th, 2006. The current accreditation is valid until April 27th, 2014. See Annex C.

The accreditation covers IEC 60079-0 -1, -11 and hence does not cover all standards in the requested IECEX scope. This is based on another quality system at TIIS, not the one that has been developed for IECEX for the ExTL and that was evaluated as part of this assessment.

4.9 Calibration

Calibration is described in ExTL Manual, and its procedures are described in 5 of “Rules for control of test facilities”. All equipment viewed was in calibration. There were issues raised regarding calibration periods and for traceability of one of the gas mixtures and these were subsequently resolved to the satisfaction of the assessment team.

4.10 Tests witnessed during the assessment

The following tests were witnessed during the assessment visit:

- Flameproof pressure determination for Group IIB - IEC 60079-1 Clause 15.1.2
- Flameproof non-transmission test with hydrogen - IEC 60079-1 Clause 15.2
- Flameproof over-pressure test - IEC 60079-1 Clause 15.1.3
- Temperature rise of a luminaire - IEC 60079-0 Clause 26.5.1
- Use of the spark test apparatus - IEC 60079-11 Clause 10.1
- Electrolyte leakage test for cells and batteries, short circuit test of battery to IEC 60079-11 Clause 10.5.2 a).
- IP6X/5X test to IEC 60529 and IEC 60079-0 Clause 26.4.5
- IP X4 test to IEC 60529 and IEC 60079-0 Clause 26.4.5

4.11 Comments (including issues found during assessment)

TIIS only produces internal test reports. Hence it was not possible to properly evaluate their ability to produce an ExTR report in the form required by IECEx. Hence it is recommended that when the first reports are produced for each type of protection they are subject to review by the assessment team. This might occur at a surveillance visit.

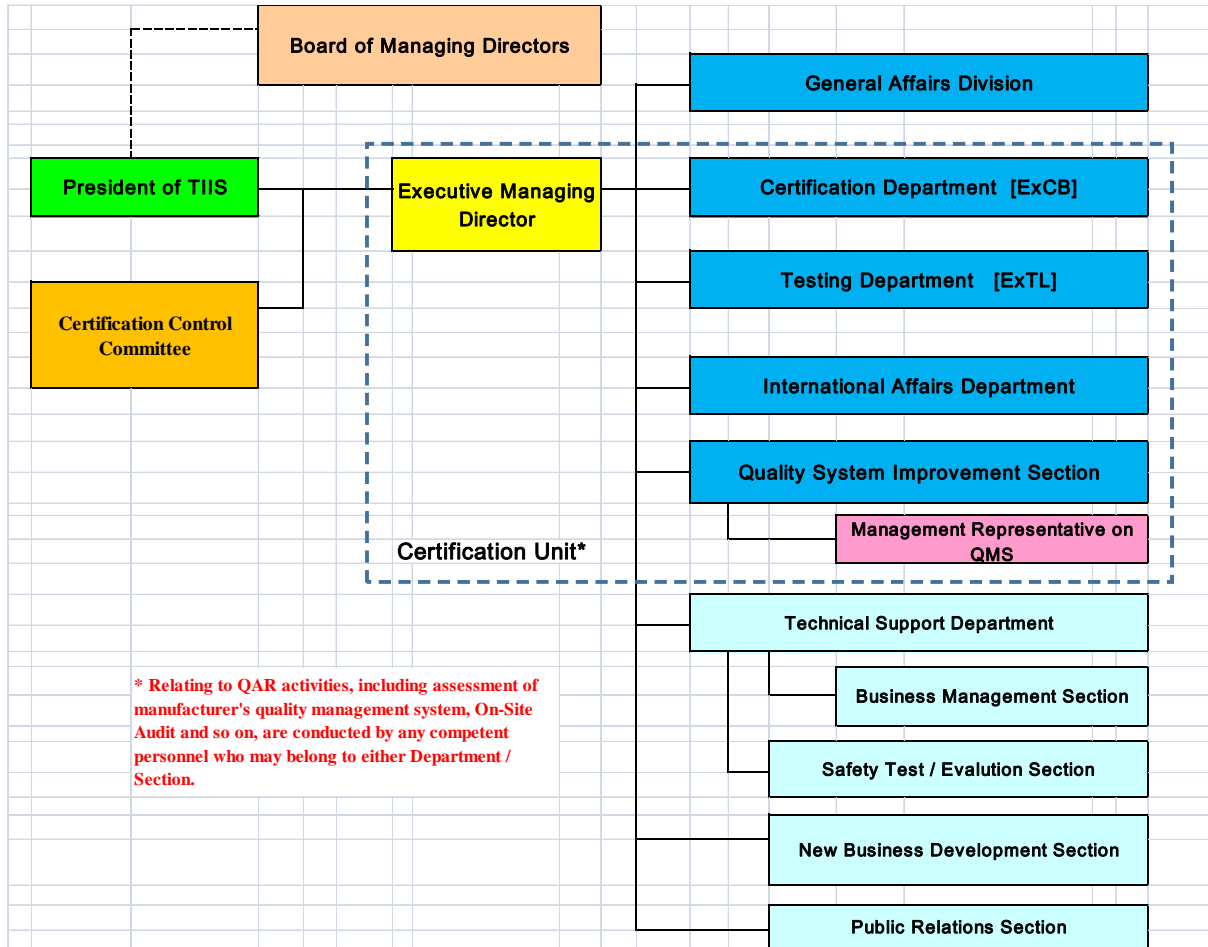
TIIS is participating in the PTB proficiency testing program.

There were a few issues raised relevant to traceability of gas mixtures, length of calibration periods and use of the oxygen analysers. Details of how these were resolved to the satisfaction of the IECEx assessment team and are included in the site assessment report.

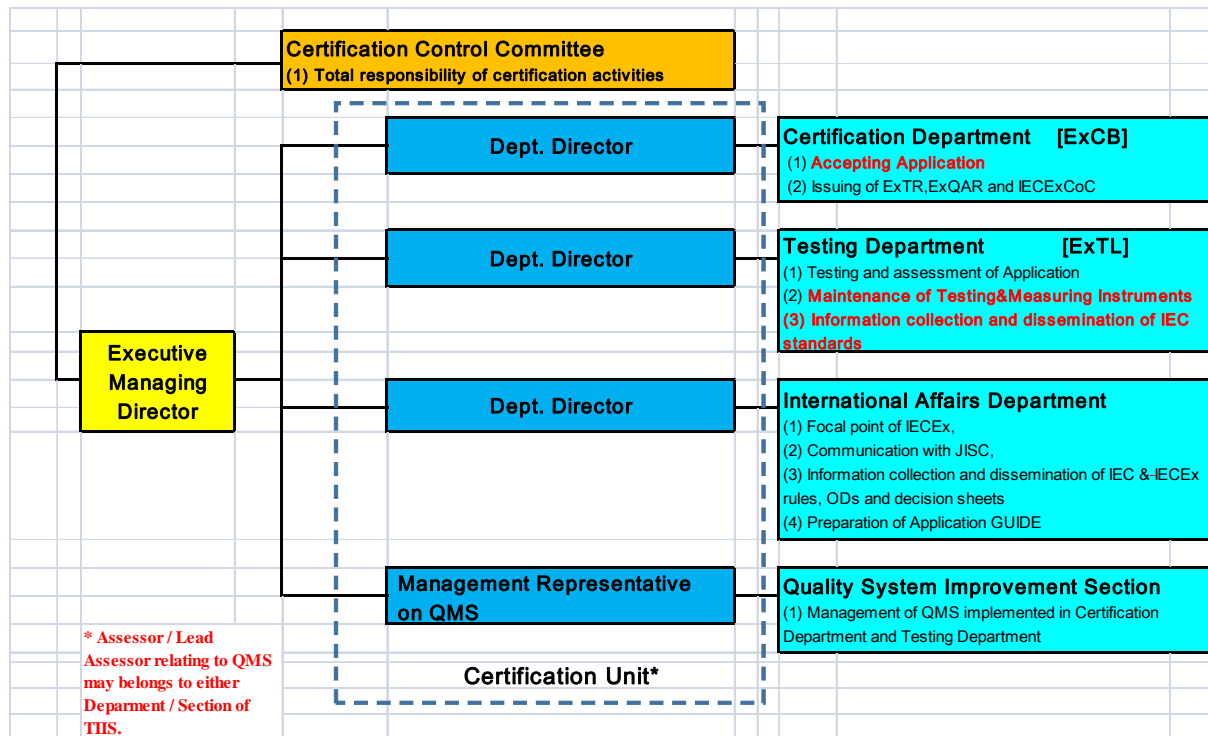
5 Annexes

See Contents.

Annex A TIIS Organisation Chart



Annex B Organisation Showing Responsibilities



Annex C
Accreditation Certificate to ISO/IEC 17025



JAB



Testing Laboratory

Accreditation
Certificate

Accreditation No. RTL01930

Technology Institution of Industrial Safety

2-16-26, Hirose-dai, Sayama-shi, Saitama, 350-1328 Japan

meets the following criteria. On the basis of this, Japan Accreditation Board (JAB) grants accreditation to the said testing laboratory.

Applicable accreditation criteria	: JIS Q 17025:2005 (ISO/IEC 17025:2005)
Scope of accreditation	: Testing for Industrial Safety Devices (As described in the appendix.)
Premises covered by accreditation	: As described in the appendix.
Expiry date of accreditation	: April 27, 2014

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system.

The management system requirements in ISO/IEC 17025:2005 meet the principles of ISO 9001:2008 and are aligned with its pertinent requirements.

Revised (6)	September 4, 2012
Renewed (1)	April 28, 2010
Initial accreditation	April 28, 2006

T. Nitta, Chairman
Laboratory Accreditation Committee

H. Kume, President
Japan Accreditation Board