



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

Circulated to: Ex Management Committee, ExMC

TITLE: IECEx Assessment Report for the acceptance of *Fyzikálně technický zkušební ústav (Physical Technical Testing Institute - FTZU)* as an IECEx Certification Body (ExCB)

INTRODUCTION

This document contains the IECEx Assessment Report for the acceptance of *Fyzikálně technický zkušební ústav (Physical Technical Testing Institute - FTZU)* as an Ex Certification Body (ExCB) within the IECEx Scheme.

Please consider this report, which is hereby issued for approval during the ExMC meeting to be held in Shanghai in September 2006.

Any comments relating to this report should be forwarded to the Secretariat prior to the meeting.

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IECEX ASSESSMENT REPORT FOR FTZU, CZECH REPUBLIC

IECEX Certification Body

Type of Assessment:

Initial Assessment for Candidate ExCB

1. OBJECT AND FIELD OF APPLICATION

1.1 *Country:*

Czech Republic

1.2 *Name of Candidate ExCB*

Fyzikálně technický zkušební ústav (Physical Technical Testing Institute - FTZU)

1.3 *Members of the Assessment Team*

Jim Munro, Lead Assessor
Alexander Zalogin, Assessor
Wolf Dill, Assessor

1.4 *Place and Dates of Assessment*

Fyzikálně technický zkušební ústav (FTZU)
Pikartská 7, 716 07 Ostrava – Radvanice
Czech Republic

14-16 June 2006

1.5 *Assessment References*

- i) IECEx 02 Second Edition 2003-06
- ii) IECEx Operational Document OD/003
- iii) IECEx Operational Document OD/009
- iv) ISO/IEC Guide 65 1996
- v) ExCB application documents dated 6 March 2006



1.6 Scope of Application

Product Category	Standard
General Requirements	IEC 60079-0
Flameproof Enclosures “d”	IEC 60079-1
Pressurised Enclosures “p”	IEC 60079-2
Powder Filling “q”	IEC 60079-5
Oil Immersion “o”	IEC 60079-6
Increased Safety “e”	IEC 60079-7
Intrinsic Safety “i”	IEC 60079-11
Type “n” Protection	IEC 60079-15
Type “m” Protection (encapsulation)	IEC 60079-18
Intrinsically Safe Systems	IEC 60079-25
Group II Zone “0” Electrical Apparatus	IEC 60079-26
Fieldbus, FISCO & FNICO	IEC 60079-27
Combustible dust - General requirements	IEC 61241-0
Apparatus for combustible dust atmospheres	IEC 61241-1-1
Combustible dust - Protection by Enclosures tD”	IEC 61241-1
Combustible dust – Type of protection “pD”	IEC 61241-4
Combustible dust – Type of protection “iD”	IEC 61241-11
Combustible dust – Type of protection “mD”	EC 61241-18
Gas detectors – Part 1	IEC 61779-1
Gas detectors – Part 2	IEC 61779-2
Gas detectors – Part 3	IEC 61779-3
Gas detectors – Part 4	IEC 61779-4
Gas detectors – Part 5	IEC 61779-5
Caplamps	IEC 62013-1
Trace heating	IEC 62086-1

1.7 Candidate ExCB Persons Interviewed

Name	Position
Jaromir Hruby	Director
Jaroslav Sindler	Vice-Director – Head of Certification Body
Jan Pohludka	Quality Manager

1.8 Legal Entity of the Candidate ExCB

FTZU (Physical Technical Testing Institute) is a government owned company. It is a registered company with number 005 77 880. It operates similar to any company and pays tax on its profits, with part of its profits generally being used to improve and expand its facilities.

1.9 Associated Testing Laboratories

The ExTL is integral with the ExCB. There are procedures to ensure appropriate separation of the roles of the ExCB and ExTL.



1.10 **Associated Certification Functions**

FTZU carry out the following activities additional for certification of Ex equipment:

- inspections of hazardous area installations;
- classification of hazardous areas;
- inspection and certification of companies involved in repair facilities; and
- standardisation activities regarding the IEC TC31 range of standards.

FTZU is officially the Czech Republic member of the IECEx Scheme.

1.11 **National Marks and Certificates**

There is no national Ex mark. FTZU is a European notified body and issues ATEX certificates.

They are a member of the Czech body CQS which is a member of IQNet. Hence they can issue ISO 9001 certificates under the CQS mark.

They can also issue Czech certification for EMC and electrical safety.

1.12 **Financial Support**

There is no financial support. FTZU relies on income from its activities to finance its operation.

1.13 **History**

The operation was originally established in 1952 with the first 'National Testing and Approval Authority' established in 1968. In 1991 the testing and approval department was separated from the Mining Research Institute to become an independent Physical Technical Testing Institute based at Ostrava-Radvanice. It was formally registered as a company on 27 December 1990, No. 005 77 880.

In 1997 FTZU was awarded a statute of National Authorized Body No. AO 210 to the new law regulation (Act No.22/1997 Coll.) for technical requirements for products.

In 2001 it became a Notified Body No.NB 1026 for 94/9/EC Directive (ATEX100).

1.14 **Standards Accepted**

Product Category	Standard
General Requirements	IEC 60079-0
Flameproof Enclosures "d"	IEC 60079-1
Pressurised Enclosures "p"	IEC 60079-2
Powder Filling "q"	IEC 60079-5
Oil Immersion "o"	IEC 60079-6
Increased Safety "e"	IEC 60079-7
Intrinsic Safety "i"	IEC 60079-11
Type "n" Protection	IEC 60079-15
Type "m" Protection (encapsulation)	IEC 60079-18
Intrinsically Safe Systems	IEC 60079-25
Group II Zone "0" Electrical Apparatus	IEC 60079-26
Fieldbus, FISCO & FNICO	IEC 60079-27



Combustible dust - General requirements	IEC 61241-0
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Combustible dust – Type of protection “iD”	IEC 61241-11
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Gas detectors – Part 2	IEC 61779-2
Gas detectors – Part 3	IEC 61779-3
Gas detectors – Part 4	IEC 61779-4
Gas detectors – Part 5	IEC 61779-5
Caplamps	IEC 62013-1
Trace heating	IEC 62086-1

1.15 *National Differences to IEC Standards*

CENELEC standards are used by FTZU for its normal certification activities for ATEX. National differences to IEC standards are listed in the latest version of the IECEx Scheme Bulletin.

2. ORGANISATION

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

Name	Title	Experience
Jaromir Hruby	Director	20 Years
Jaroslav Sindler	Vice-Director Head of Certification Body	37 Years

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

Name	Title	Experience
Jan Pohludka	Quality Manager	19 Years

2.3 *Name and Title of Nominated Principal Contact*

Name	Title
Jaromir Hruby	Director

2.4 *Name and Title of Signatories for Certification*

Name	Title	Comments
Jaroslav Sindler	Vice-Director	

2.5 *Other Employees in ExCB activity*

Name	Title	Responsibility
Svatopluk Necas	Deputy Head of Certification Body	



Jaroslav Basel Deputy Head of Certification Body

There are a total of 12 people in the certification body, all with experience in the field and many with significant years of experience. These are responsible for all assessment requirements associated with the standards and the specification of tests to be done. The quality manual sets out the required competence criteria for the staff.

2.6 **Organisational Structure**

See Annex 1.

2.7 **Administration**

2.7.1 Administrative Structure

All work coming into FTZU comes via the ExCB. It addresses all assessment aspects of the standards and specifies the tests to be carried out by the ExTL. Once these tests are done, the ExTL produces formal internal test reports for each test. The ExCB is then responsible for putting together the final test report, carrying out the assessment of the manufacturer and issuing the certificate.

2.7.2 Terms of Reference of the Governing Board

FTZU has a Certification Board comprising two representatives each from:

- Government bodies
- Manufacturers
- Users

Annex 3 of the Certification Body Quality Manual contains the '**Rules of procedure of the certification board**'. It covers:

- Nomination, withdrawal etc for members
- Duties and rights of members
- Scope of activities, including policing of body, supervision of finances, establishment of commissions of inquiry, right to withdraw rights of certification body, checking of certification procedures, provision of comments and recommendations to the Director, dealing with complaints not resolved by Director.
- Meetings and decision processes; including need to meet at least once a year and voting rules.
- Election of Chair and Vice-Chair
- Confidentiality

2.7.3 Indemnity Insurance

FTZU hold indemnity insurance for 10,000,000 Czech Crowns. The policy number is 2901299939.

3. **RESOURCES**

The certification body comprises a Head of Certification and two deputies together with 8 other professional/technical staff. The Director may also work on certification activities.

4. **COMMITTEES**

There are no other committees than the Certification Board.



5. CERTIFICATION OPERATIONS

5.1 *National Approval/Certification Methods*

Only ATEX is used for the certification of Ex equipment.

5.2 *Certification Policy*

FTZU has the following certification policy:

FTZÚ is a testing organisation with a long-term tradition and good position on the domestic market, and partially abroad. Therefore, the priority task of FTZÚ is to ensure tests to the extent of competence on a high quality level so that the testing process would be on a level of notified foreign testing laboratories in the EU and built authority of certification body in field of product certification and conformity assessment in accordance with Government Order and European Directive 94/09/EC, providing technical requirements for equipment and protective systems intended to be used in hazardous areas at the level complying with the European certification scheme, based on standard EN 45011 and create conditions for good position of FTZÚ on a foreign market as notified body in that scheme.

5.3 *Staff Work Instructions/Procedures*

The Quality Manual contains the following relevant annexes:

Annex 2 – Certification procedures- ATEX conformity assessment

Annex 8 – IECEx certification procedures. These were sighted in draft form at the visit. Subsequently final versions incorporated into the quality system were provided.

5.4 *Application for Certification*

An application form for applicants for IECEx certification was reviewed at the assessment visit and will be placed on the website when FTZU gains acceptance as an IECEx CB.

6. STATISTICS

Number of certificates issued in the preceding two years for each type of protection covered by the IEC Standards

Type of protection	2004	2005
Flameproof enclosure	93	65
Increased safety	17	12
Intrinsically safe apparatus	112	65
Pressurisation	8	4
Type of protection “n”	16	17
Encapsulation “m”	9	13
Electrical apparatus for use in the presence of combustible dust	22	25
Gas detectors	8	7
Miners’ caplights	5	5
Electrical trace heating	2	-

The numbers are for original certificates only, not supplementary certificates.



7. DOCUMENTATION

7.1 *Document and Change Control*

Responsible personnel perform the document change control process to Director's Order 1/97. There are hard copies of documents that are subject to individual control when changes are made; for example there are 6 copies of the Certification Quality Manual. A book is used to record what has happened with the distribution of copies for the two quality manuals. An electronic master copy of each document is also available to staff.

A record of standards issued to each person is maintained. Generally staff work with Czech translations of the standards. FTZU advised that these systems will be used for IEC standards when producing ExTRs where the IEC standards are different to those already in use.

IECEX Decision sheets are on a server and available to staff. Translations are also made of each decision sheet and embedded in the text. A similar approach is used for other IECEx documents including TGDs, ExTRs, ODs etc. At the time of assessment there was no procedure to cover this approach, but this was subsequently rectified to the satisfaction of the assessment team.

8. RECORDS

A log-book is used to allocate numbers for files. For example, for ATEX certificates the number is allocated as two digits for the year then 'ATEX' then a running number. This then becomes the number of the issued certificate. The book shows the date of issue and the validity date. Occasionally the number will be used as a file number only.

The files contain all relevant information such as the application, drawings etc., This includes the test plan that is developed by the engineers in the certification body. It is anticipated that a new log-book will be started for IECEx certificates. The inside of the file cover contains a list of the documentation in the file. The testing body issues an internal report for each test with all results. The technician who did the test and the head of the testing laboratory Josef Krupica sign the reports. On request a consolidated report is sent to the customer. If required the report will be provided in English.

All records have been kept since the formation but there is a formal commitment to retain these for 10 years should they decide to start disposing of records. Recent records are kept in a compactus in the main building and older ones are stored elsewhere on site. All records are retained in hard copy form.

9. CONFIDENTIALITY

There are orders on access to certification area and test area. All records are required to be kept confidential. Details are covered in Clause 4.10 of the Quality Manual. All employees are required to sign a declaration of confidentiality as part of their employment contract. A sample of such a declaration was viewed. Reference in QM to Clause 9.2 should be 4.9.2.

There is a directive 2/1991 that covers controls for access of visitors and customers. There is a control at the front gate for the site (which includes other



companies and the research institute) and also at FTZU reception. There is a security patrol in the evenings of the whole site.

10. PUBLICATIONS

Every year a certification list is issued. Information on certification and testing, including pricing, is issued each year.

11. APPEALS

Details on appeals, complaints and disputes are included in Clause 7 of the QM. This includes direct approaches to FTZU and then the Certification Board. At the time of assessment there was no reference to the appeals procedures within the IECEx Scheme but this was subsequently rectified to the satisfaction of the assessment team.

12. NATIONAL ACCREDITATION

FTZU hold national accreditation as a certification body from the Czech Accreditation Institute No 511/2001. This is valid until 31 January 2007. This certificate states that Jaroslav Sindler shall act on behalf of the accreditation body and that Jaroslav Sindler, Svatopluk Necas and Jaroslav Basel shall be responsible for the correctness of the relevant certificates.

Currently the accreditation does not show the IEC Standards, only the European/Czech equivalents. FTZU will be seeking a change to their accreditation to include the IEC standards. These will then also be added to the certification body QM. IEC standards are shown in the ExTL accreditation.

13. RECOGNITION AND AGREEMENTS

FTZU cooperates in its fields with government technical supervisor organisations CUBP, CBU and with professional Department of Ministry for Internal Affairs, ensuring the fire safety and Czech trade inspection. It also cooperates with other Czech testing houses. It is a notified body under ATEX.

FTZU manages the standardisation commission TNK 121 'Apparatus and protective systems for potentially explosive atmospheres' and actively takes part in international standardisation committees for IEC TC 31, CENELEC and CEN.

14. QUALITY MANUAL

There is a comprehensive quality manual for the certification body. The version current at the time of the assessment visit did not cover the IECEx Scheme. However, a draft was provided of the changes that would be made to cover the involvement of FTZU in the Scheme. Comments in this report relate to that draft and at the time of assessment included:

1. Roles for signing the parts of the ExTR were not clearly defined.
2. Under 4.9.1 Records IECEx ExTRs and QARs were not shown on the list of issued documents.
3. There were no procedures about how IECEx documents will be maintained on the FTZU server

The above issues were all subsequently rectified to the satisfaction of the assessment team.



15. INTERNAL AUDIT AND PERIODIC REVIEW

An internal audit program is prepared for each year. The program aims to cover all accreditation criteria to CSN EN 45011 which is identical to ISO/IEC Guide 65. FTZU's auditors perform the audits. Extraordinary audits may also be performed. The audits for 2005 were carried out in the fourth quarter. The reports from these audits, together with a summary report were viewed.

Management review takes place once a year. The review that took place on 25 January 2006 was reviewed. It had a comprehensive coverage of matters affecting the operation of FTZU. All senior staff were present at the meeting.

16. COMPLAINTS

Covered in Quality Manual Clause 11, appeals. There is a complaints register. The last complaint listed in this was on 17/7/03.

17. WITHDRAWAL AND CANCELLATION OF CERTIFICATES

There is a procedure for this, Clause 4.6, of the QM. However, at the time of assessment it did not address the specific requirements of the Scheme as addressed in the Rules IECEX02. This was subsequently rectified and found to meet the IECEX Scheme's requirements.

18. SPECIAL FACTS TO BE NOTED

Subcontracting/Witness testing

Clause 4.4 of the QM indicates that FTZU does not utilise subcontractors. However, there are some requirements included in the clause should they decide to subcontract.

Witness testing is mentioned in the testing laboratory QM with a statement "If the measurement is performed outside the testing laboratory (using external devices), it is necessary to specify also a metrological traceability of utilized gauges". In Annex 2 of the certification body QM for ATEX testing there is statement that the testing at manufacturers must be under the control of the certification body personnel.

Quality Assessment Reports (QARs)

To date FTZU have been issuing QANs under ATEX. A sample of such an assessment was reviewed. The assessment followed a logical process of planning, assessment with definition of non-conformities, resolution of non-conformities and issue of QAN. The assessment was based on EN 13980 which has the same requirements as IECEX OD005.

Training

Qualification levels for the various positions are specified in Clause 5 of the QM. A program is prepared by the Head of Certification each year. Progress is then reviewed at the end of the year and a decision made on competency by the Head of Certification. Examples of programs were seen to cover a comprehensive range of competencies.



Supporting Documentation

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

- Details of issues raised and how these have been resolved.
- A completed assessment report using IECEx Checklist for ISO/IEC Guide 65, re OD007
- OD 006 Site Assessment Report

19. COMMENTS

As noted earlier, some issues were found during the assessment on IECEx procedures. These were all subsequently rectified. No other issues were found for the ExCB.

FTZU was found to be a very well resourced operation with a comprehensive range of equipment, staff with many years of experience and a mature quality system.

20. RECOMMENDATION

Based on the initial assessment performed on 14 to 16 June 2006 FTZU is recommended for acceptance into the IECEx scheme as a Certification Body (ExCB) according to the scope of the standards listed in this document, subject to resolution of the issues listed above.

Jim Munro
Lead Assessor

Alexander Zalogin
Assessor

Wolf Dill
Assessor

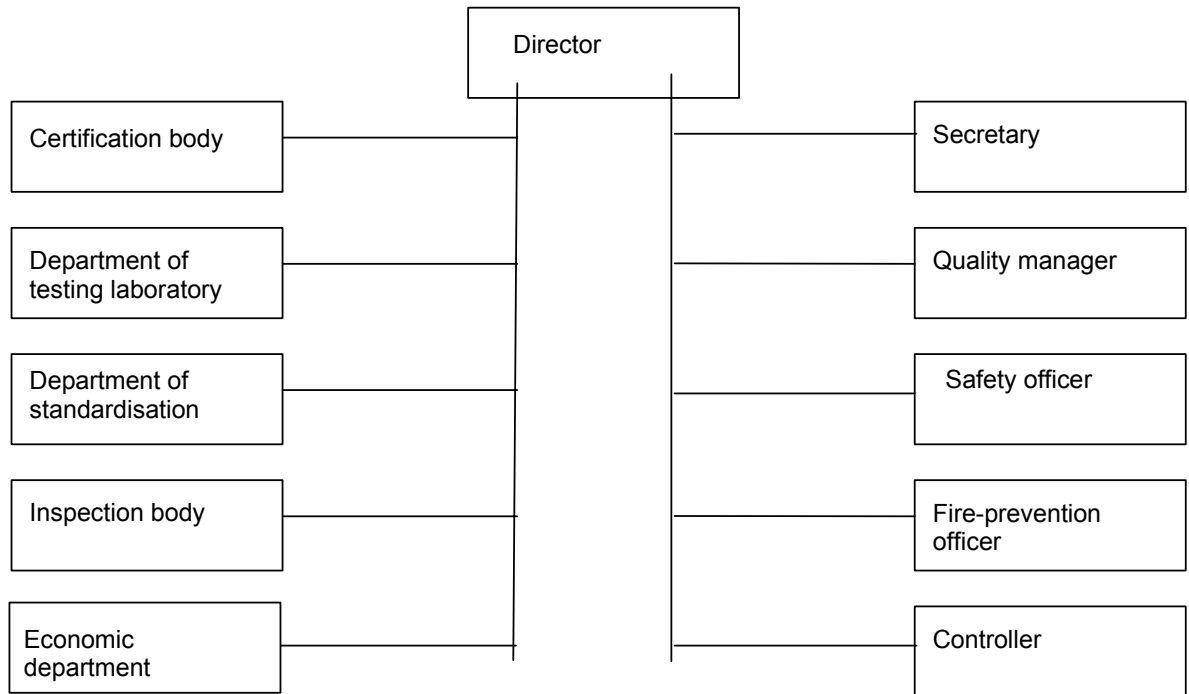
28 June 2006

List of Annexes:

- Annex A: FTZU Organisation Chart
Annex B: FTZU certifying body accreditation from Czech Accreditation Institute which is a member of IAF

ANNEX A

FTZU Organisational structure





NÁRODNÍ AKREDITAČNÍ ORGÁN

Czech Accreditation Institute
Public Service Company
110 00 Praha 1 - Nové Město, Opletalova 41
issues this

CERTIFICATE OF ACCREDITATION

for certification of products

No. 511 / 2001

to

Certification Body No. 3051

FYZIKÁLNĚ TECHNICKÝ ZKUŠEBNÍ ÚSTAV, státní podnik

Certifikační orgán

Pikartská 7, 716 07 Ostrava - Radvanice

Scope of accreditation:

Certification of electrical and non-electrical equipment and protective systems for the rooms with risk of explosion, pumps, switchboards, electric motors, spray guns, electrical equipment of machines and gas analyzers to the extent as specified in the appendix to this Certificate which is attached in the Czech language.

Ing. Jaroslav Šindler shall act on behalf of the accredited certification body, and Ing. Jaroslav Šindler, Ing. Svatopluk Nečas, CSc. and Ing. Jaroslav Basel shall be responsible for the correctness of relevant certificates.

This Certificate of Accreditation has been issued by Czech Accreditation Institute, a public service company, on the basis of assessment of fulfilment of the accreditation criteria in accordance with

ČSN EN 45011

and after having found that the certification body has been qualified for objective and independent certification to the extent of the scope of accreditation.

In its activities, performed within the scope and for the period of validity of this Certificate, the holder of this Certificate is entitled to use the identification "Accredited Certification Body No. 3051" next to its name (including official stamp) provided it observes all relevant regulations relating to the activity of accredited certification body, including regulations issued by Czech Accreditation Institute, a public service company.

Should it be proved that the holder of this Certificate fails to meet the accreditation criteria decisive for the issue hereof and the obligations conditioning accreditation, Czech Accreditation Institute, a public service company, may either suspend the validity of or withdraw or change this Certificate.

This Certificate is valid until: **31 January 2007**

Prague: 31 December 2001



Jiří Růžička

Director

Czech Accreditation Institute
Public Service Company

Instruction:

The holder can enter a written caveat against this Certificate in 15 days from the receipt hereof. Timely submitted caveat has dilatory effect.