



ExMC/254/DV  
August 2005

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

**Ex Management Committee, ExMC**

**TITLE: IECEx Assessment Report for acceptance of INERIS as an  
Ex Certification Body**

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**This document contains the IECEx Assessment Report for the acceptance of  
l'Institut National de l'environnement industriel et des risques (INERIS) as an Ex  
Certification Body (ExCB) within the IECEx Scheme.**

**The report is hereby submitted for voting**

**Please consider the assessment report and return the completed voting form  
to the Secretariat by **2005 09 30**. Your speedy response to the voting process  
will be very much appreciated.**

**You may return your completed voting form (available in Word format) via fax  
or e-mail. Details below.**

*Chris Agius*  
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# IECEx ASSESSMENT REPORT

## IECEx Certification Body (ExCB)

### 1. OBJECT AND FIELD OF APPLICATION

Initial Assessment for Candidate ExCB ☒  
Surveillance Assessment for existing ExCB ☐

1.1 **Country**  
France

1.2 **ExCB under Assessment**  
INERIS

1.3 **Members of the Assessment Team**  
Ian Cleare, Lead assessor  
Jim Munro, Assessor  
  
**Off site: Document review and support**  
Heinz Berger (Expert Assessor)

1.4 **Place and Date of Assessment**  
Verneuil-en-Halatte, France  
13 to 15 June 2005

1.5 **Assessment References**  
Documents:  
i) IECEx 02 Second Edition  
ii) IECEx Assessment Procedures OD/003 (ExMC/100/CD)  
iii) ISO/IEC Guide 65 1996  
iv) ExCB application documents  
v) IECEx Operational Document e.g. OD009

#### 1.6 **Assessed Scope of Acceptance**

Product Category	Standard
General Requirements	IEC 60079-0
Flameproof Enclosures	IEC 60079-1
Pressurised Enclosures	IEC 60079-2
Sand-Filled Apparatus	IEC 60079-5
Oil-Immersed Apparatus	IEC 60079-6
Increased Safety	IEC 60079-7
Intrinsic Safety	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
Field bus Intrinsically Safety concept (FISCO)	IEC 60079-27
Combustible dust - General requirements	IEC 61241-0
Combustible dust - Protection by Enclosures "tD"	IEC 61241-1
Apparatus for combustible dust atmospheres	IEC 61241-1-1
Combustible dust – Type of protection "pD"	IEC 61241-4
Combustible dust – Type of protection "mD"	IEC 61241-18

## 1.7 ExCB Persons Interviewed

Name	Position
Bernard Piquette	Deputy Director, DCE
Eric Faé	Project Manager, Quality
Alain Czyz	Technical Adviser, IECEx Certification Body Manager
Xavier Lefebvre	Test Laboratory Manager
Olivier Mirabel	Project Manager, Assessment
Stephanie Lemaire	Project Manager, INERIS Quality
Jean-Paul Malet	Quality Manager, INERIS
Jean-Marc Ambrosiani	Finance Director, INERIS

## 1.8 Legal Status of the ExCB

l'Institut National de l'Environnement Industriel et des Risques (INERIS) was established by a decree of the French Government in 1990 as a public research body of an industrial and commercial nature. INERIS works under the supervision of the French Ministry of the Environment and Sustainable Development. It has a special status and the organisation is not a Government body as such. The employees are employed by INERIS, not the Government.

A unit within the certification division DCE of INERIS carries out the ExCB functions. The legal responsibilities and liabilities of the ExCB are taken by INERIS.

### 1.9 Associated Testing Laboratories

The INERIS ExTL is part of the same division as the ExCB and for the purposes of the IECEx Scheme is regarded as being integral with the ExCB.

### 1.10 National Marks and Certificates

INERIS is a notified body for the European ATEX directive 94/9/EC under which the CE and



Marks are controlled.

### 1.11 Financial Support

Under the INERIS financial policies, the testing and certification activities of DCE are required to be run on a self-financing basis from the fees charged for their services. The current financial position was examined and appeared to comply with this requirement.

### 1.12 Standards Accepted

As a European ATEX notified body, INERIS works to the CENELEC standards, which are convergent with the IEC Ex standards.

### 1.13 National Differences to IEC Standards

As jointly declared by the European bodies and recorded in the Ex Bulletin.

## 2. ORGANISATION

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

Name	Title	Experience
Christian Michot	Director, DCE	<ul style="list-style-type: none"> <li>• Certification Director since 1999.</li> <li>• Responsible for the certification of the explosives of civil use</li> <li>• International expert in explosions and dangerous products</li> </ul>



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Bernard Piquette	Deputy Director, DCE	<ul style="list-style-type: none"> <li>Chairman of the S66A committee</li> <li>Expert in ATEX since 1983</li> <li>Expert in working groups of TC 305</li> </ul>
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## **2.2 Name, Title and Experience of the Quality Management Representative**

<b>Name</b>	<b>Title</b>	<b>Experience</b>
Eric Faé	Project Manager, Quality	Quality manager in INERIS since 1997 (ISO 9001)

## **2.3 Name and Title of Nominated Principal Contact**

<b>Name</b>	<b>Title</b>	<b>Comments</b>
Alain Czyz	IECEx Certification Manager	Chairman of CENELEC TC 31

## **2.4 Names and Titles of Signatories for Certification**

<b>Name</b>	<b>Title</b>	<b>Comments</b>
Bernard Piquette	Deputy Director, DCE	/
Christian Michot	Director, DCE	Signs in absence of M Piquette

## **2.5 Other Employees in ExCB activity**

<b>Name</b>	<b>Title</b>	<b>Responsibility in CB</b>
Alain Czyz	IECEx Certification Manager	Certification Leader
Thierry Houeix	Project Manager	Certification Officer
Eric Fae	Project Manager, Quality	Certification Officer

## **2.6 Organisational Structure**

See Annex A. A section within the ExTL organisation carries out the auditing of manufacturers' production quality assurance systems. This arrangement was regarded as acceptable, since the final QARs are subject to the scrutiny and acceptance of the ExCB personnel. A sample of the quality assurance auditing activities and personnel involved with ATEX were examined during the assessment, with the need for some minor improvements being noted.

## **2.7 Administration**

### **2.7.1 Administrative Structure** See Annex A

### **2.7.2 Terms of Reference of the Governing Board/Certification Committee** The composition and terms of reference of the Certification Committee are given in DI0887. The committee comprises representatives of manufacturer, user, standardisation and governmental interests with no single interest predominating.

### 3. RESOURCES

INERIS was perceived to be a well-resourced organisation in terms of people, work equipment, operating systems and work environment. The people allocated to the ExCB activity appear to be sufficient in terms of numbers and competences for the anticipated level of activity. Succession plans are in hand to provide for continuity.

### 4. COMMITTEES AND APPEAL PROCEDURES

The Certification Committee (see 2.7.2) has as one of its functions the hearing of appeals. The certification rules (DI0886) include the further right of appeal to the IECEx Scheme. The committee was in the process of being formed at the time of the assessment and no records were available for examination.

### 5. CERTIFICATION OPERATIONS

#### 5.1 *National Approval/Certification Methods*

The national certification system for Ex products is that of the ATEX directive 94/9/EC. Under the directive Zone 0 and Zone 1 electrical products are required to undergo type examination by a notified body with the manufacture of the products being subject to quality assurance monitoring or product verification by a notified body. Because there is no requirement for the same notified body to undertake both design and manufacturing conformity assessments, the European ATEX system cannot be regarded as a true Type 5 system. The standards and methods used for the various conformity assessment activities do, however, relate closely to those employed within IECEx.

#### 5.2 *Certification Policy*

The certification policy is stated in PR0058 and DI0887 and was seen to be mainly in conformity with the requirements of ISO/IEC Guide 65 and IECEx 02. Some minor changes were made in response to issues raised during the assessment.

#### 5.3 *Procedures*

The certification procedure PR0058 implements all of the IECEx requirements. Certain changes in the INERIS procedure were agreed to clarify some areas. Access to all relevant IECEx documents is provided either through maintaining controlled copies on the INERIS network or by direct hyperlink to the IECEx website. Arrangements have been made to ensure that the latest IECEx documents are implemented effectively.

#### 5.4 *Staff Work Instructions*

While the facility exists within the INERIS quality system to issue work instructions (and many are used in the ExTL area) it has not been considered necessary at this stage to issue new work instructions for the ExCB activity, although reference is made to existing work instructions for commercial activities such as the processing of orders.

#### 5.5 *Application for Certification*

Following discussions during the assessment, an application form for IECEx certification has been introduced, which requires the customer to agree to the published terms, and conditions (DI0886), which include those of IECEx.

#### 5.6 *Sub-contracting*

Subcontracting is covered in Procedure PR0053AD, which relates principally to the ExTL activity. There are no plans at present to sub-contract the factory auditing work but should that become necessary it is intended that the above procedure would be used.

### 6. STATISTICS

Ex Certificates issued during 2003 and 2004:

Type	Code	Number of certificates
Flameproof	d	203
Intrinsic safety	i	148
Increased safety	e	72
Special	s	0
Powder filled	q	0
Encapsulated	m	34
Type n	n	0
Pressurised	p	51
Gas Detectors		0
Apparatus for Dusts		122

## 7. NATIONAL ACCREDITATION

While the INERIS ExTL activity is covered by COFRAC accreditation (see ExTL Assessment Report), the ExCB activity is not yet accredited. Discussions with COFRAC are under way and it is planned for their accreditation assessment to be carried out around September 2005. INERIS have been made aware that, in the absence of accreditation, an annual IECEx surveillance visit of the ExCB activity would be necessary.

## 8. LIABILITY INSURANCE

INERIS holds professional and public liability insurance. Certificates for both policies, valid until 31 December 2005, were seen during the assessment.

## 9. DOCUMENTATION

The INERIS quality system appears to be fully ISO 9001:2000 compliant and certified and is well developed and maintained. All documents are accessible through the INERIS network. There was ample evidence that the system is properly used and that it is subject to continuous improvement. The quality management documents for the ExCB activity are controlled within the system.

## 10. RECORDS

The INERIS quality system includes a comprehensive set of controlled record pro formas. As there had been no ExCB activity at the time of the assessment, no records were available for inspection. Some records for ATEX type examination and quality assurance activities were examined and generally found to be well created and maintained. There is an archiving procedure in the INERIS system and this system was seen to be in operation within DCE.

## 11. CONFIDENTIALITY

All employees sign confidentiality agreements which are retained in their personal records. Examples were seen during the assessment. There is a system of security control at the main entrance gate and entrance to buildings is controlled by key, or in the case of newer buildings by key pad.

## 12. PUBLICATIONS

Two publications regarding the ExCB (DI0886 Rules and DI0887 Certification Committee) have been drafted, ready for the acceptance of INERIS as an ExCB. Some changes were agreed following the assessment in order fully to comply with Guide 65.

## 13. INTERNAL AUDIT AND PERIODIC REVIEW

The internal audit system is run centrally by the INERIS Quality Department. There is a follow up system operating on the network to enable corrective and preventive actions to be



recorded. The results of an audit carried out and the close out action during 2004 were examined. The plan for 2005 was studied, noting two audits, one technical and one quality system, planned for the Ex testing and certification activities by October 2005.

The Director General of INERIS with the directors of the operating divisions holds management reviews annually. Detailed presentations are required on quality performance including analysis of internal audit outcomes and customer satisfaction. The report for DCE for 2004 was seen.

#### **14. COMPLAINTS**

INERIS has a central system for the handling of customer comments, both positive and negative. The following up of complaints is handled by the same system used for following up on internal audits, with corrective actions being recorded on the system. One of the two complaints received during 2005 was examined and corrective action had been taken. Close out awaited customer response.

#### **15. WITHDRAWAL AND CANCELLATION OF CERTIFICATES**

There is a procedure (PR0058, DI0887) for withdrawal and cancellation of IECEx certificates but as none had been issued there had been no withdrawals or cancellations.

#### **16. REVIEW OF ISSUED CERTIFICATES, QARs AND ExTRS**

In the absence of IECEx certificates, QARs and ExTRS, files for ATEX type examinations and quality assurance notifications were examined. Reasonable records were observed to have been maintained but some observations were noted on the quality assurance records for the further consideration of INERIS.

#### **17. FINDINGS FROM THE ASSESSMENT**

INERIS is a well-established research and testing institute having been formed in 1990 from the former mining research institute CERCHAR. It has a comprehensive and well-managed quality system which is under continual development. The system is readily accessible to most personnel through the computer network.

The Certification Division DCE is responsible for testing and certification activities serving both government and industry. The Laboratory for Certification of ATEX Products LCMA is mainly engaged in providing Ex testing and certification services to industry. The staff include some who are very experienced in Ex technology and some who are new to the field but who demonstrated an enthusiastic approach to gaining the necessary knowledge.

As regards the IECEx Certification Body, it was clear that the unit is still in the process of being formed. A lot of work has been done already on developing the certification system, with the IECEx requirements of OD009 being incorporated in PR0058.

The staffing of the certification body provides a good level of expertise both in Ex technology and in quality assurance. We expressed concern about succession planning and were assured that plans were in hand.

In the absence of accreditation of the certification body activity, we carried out a detailed assessment of the conformity with ISO/IEC Guide 65. Because the certification body was not yet in operation we could not examine the implementation of the system and it will be recommended to the ExMC that a further visit is carried out after the system has been in operation for six months in order to verify that it is being implemented properly.

A number of improvements to the system were needed in order fully to meet the requirements of ISO/IEC Guide 65 and of the IECEx Scheme and these are referred to under the appropriate headings earlier in this report. Documentary evidence of the



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improvements was provided by INERIS and has been accepted by the assessment team as satisfying the concerns which had been raised.

We would like to record our thanks to INERIS management and staff for the excellent arrangements for the assessment and for the good level of cooperation and openness displayed by everyone.

## **18. RECOMMENDATIONS**

Having received documentary evidence that the issues raised during the assessment have been dealt with satisfactorily, we recommend:

- a) that INERIS is accepted as an ExCB for the scope recorded in Section 1.6;
- b) that a follow up visit is carried out within six months of the date of acceptance to examine the records of the ExCB and to verify that the quality management system is being properly and effectively implemented;
- c) in the absence of national CB accreditation, annual surveillance audits on the anniversary of the date of acceptance should be conducted, as required by ExMC/100/CD.

Ian Cleare  
Lead Assessor

Jim Munro  
Assessor

Heinz Berger  
Expert Assessor (Off site)

## **LIST OF ANNEXES**

A. Organisation Charts



## Annex A: Organisation Charts for INERIS IECEx Certification Body

← indicates ExCB activities





