



**INTERNATIONAL ELECTROTECHNICAL COMMISSION 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 CESI – Centro  
Elettrotecnico Sperimentale Italiano S.p.A as an IECEx Certification  
Body (ExCB)**

---

---

This document contains the IECEx Assessment Report for the acceptance of CESI–  
Centro Elettrotecnico Sperimentale Italiano S.p.A as an IECEx 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 25**. 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.

A handwritten signature in black ink, appearing to read 'C. Agius', is positioned above the name of the signatory.

**Chris Agius  
IECEX Secretariat**

**Address:  
IECEX Secretariat  
SAI Building  
286 Sussex Street  
Sydney 2000  
Australia**

**Tel: +61 2 8206 6940  
Fax: +61 2 8206 6272  
Email: [chris.agius@iecex.com](mailto:chris.agius@iecex.com)  
Internet: [www.iecex.com](http://www.iecex.com)**



## **IECEX ASSESSMENT REPORT** **For ExCB (IECEX Certification Body)**

**CESI – Centro Elettrotecnico Sperimentale  
Italiano S.p.A, Milano, Italy**

**November 22 – 24, 2004**

### **Type of Assessment: Initial Assessment**

Initial Assessment for Candidate ExCB  X  
Surveillance Assessment for existing ExCB

#### **1. OBJECT AND FIELD OF APPLICATION**

##### **1.1 Country:**

Italy

##### **1.2 Name of Candidate ExCB**

CESI– Centro Elettrotecnico Sperimentale Italiano S.p.A., Via. R. Rubattino 54,  
20134 Milano, Italy

##### **1.3 Members of the Assessment Team**

###### **On site:**

Jim Munro, (Lead Assessor)

Heinz Berger, (Expert Assessor)

###### **Off site: Document review and support**

Wolf Dill (Expert Assessor)

##### **1.4 Place and Date of Assessment**

CESI – Centro Elettrotecnico Sperimentale Italiano S.p.A.  
Via. R. Rubattino 54, 20134 Milano, Italy

22 -24 November 2004



## 1.5 Assessment References

Documents:

- i) IECEx 02 Second edition
- ii) IECEx Operational Document OD/003 (ExMC/100/CD)
- iii) ISO/IEC Guide 65 1996
- iv) ExCB application documents
- v) Checklist according to ISO/IEC Guide 65 (OD 007)

## 1.6 Scope of Application

Standards:

Title	Number
General Requirements	IEC 60079-0
Flameproof Enclosures "d"	IEC 60079-1
Pressurised Enclosures "p"	IEC 60079-2
Sand-filled Apparatus "q"	IEC 60079-5
Oil-immersed Apparatus "o"	IEC 60079-6
Increased Safety "e"	IEC 60079-7
Intrinsic Safety "i"	IEC 60079-11
Electrical Apparatus with Type of Protection "n"	IEC 60079-15
Encapsulation "m"	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 dusts	IEC 61241-1-1
Combustible dust – Type of protection "pD"	IEC 61241-4
Combustible dust – Type of protection "mD"	IEC 61241-18

## 1.7 Candidate ExCB Persons Interviewed

Name	Position
Dr. Ulisse Colombo	Manager Certification Business Unit
Mirko Balaz	Ex Certification Manager
Damiano Cavanna	Ex Senior Certification Officer
Sergio Giugno	Leader Manufacturer Assessment Team

## 1.8 Legal Entity of the Candidate ExCB

CESI – Centro Elettrotecnico Sperimentale Italiano G. Motta S.p.A.

## 1.9 Associated Testing Laboratories



All the laboratory work is performed in CESI, except minor testing such as on sinter material and on certain plastics, which is subcontracted to Istituto di Ricerche e Collaudi M. Masini S.r.l. for the sinter testing and Cerisie, Laboratorio per la Certificazione e Ricerca sui Sistemi Elastomerici for plastics. The companies will be subcontracted on a single job basis with CESI maintaining control over tests. Both companies are accredited by SINAL (national accreditation body for laboratories).

### **1.10 Associated Certification Functions**

CESI holds an accreditation certificate, issued by SINCERT for certification activities according to IEC, CENELEC, CEI, and NEMA. However, Ex standards are covered by the Ministero delle Attività Produttive in Roma, dated March 20, 2003 under number 829559 for the scope of protection techniques covered by standards listed in Clause 1.6 of this report (see Clause 12 and Annex 3).

### **1.11 National Marks and Certificates**

CESI do not have a certification mark.

### **1.12 Financial Support**

There is no financial support, CESI derives its funding from the charges for its services. As part of the assessment the Assessment Team confirmed that there are sufficient financial resources for CESI to meet its obligations.

### **1.13 History**

#### 1956: Foundation

CESI was founded with the support of the Italian electrical utilities and electromechanical manufacturers with the aim of concentrating:

- large investments in testing facilities to qualify Italian electromechanical industry
- skills on power system analysis for the development of the national grid

#### 1962: Nationalization of the Italian electrical industry

Enel acquires the majority of CESI share capital and CESI acts as:

- technical support to Enel in transmission and distribution fields
- supplier of testing, certification and consulting services on the international market

#### 2000: Liberalization of the Italian Electrical System

CESI incorporates Enel Research activities with the aim of:

- concentrating all research knowledge and expertise in a unique company
- widening the range of services offered to the national & international market in the electro-energetic and environmental sectors
- developing "full range" approaches and solutions for the market



2002: CESI acquires

- Piacenza Laboratory from Enel Power Generation, which integrates and strengthen the packages of services dedicated to O&M in thermo-electrical power plants
- Polo Idraulico e Strutturale specializing in structural and hydraulic engineering for hydroelectric and thermoelectric systems and relevant infrastructures.

**1.14 Standards Accepted**

<b>Title</b>	<b>Number</b>
General Requirements	IEC 60079-0
Flameproof Enclosures "d"	IEC 60079-1
Pressurised Enclosures "p"	IEC 60079-2
Sand-filled Apparatus "q"	IEC 60079-5
Oil-immersed Apparatus "o"	IEC 60079-6
Increased Safety "e"	IEC 60079-7
Intrinsic Safety "i"	IEC 60079-11
Electrical Apparatus with Type of Protection "n"	IEC 60079-15
Encapsulation "m"	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 dusts	IEC 61241-1-1
Combustible dust – Type of protection "pD"	IEC 61241-4
Combustible dust – Type of protection "mD"	IEC 61241-18

**1.15 National Differences to IEC Standards**

Italy does not provide national differences but declares compliance with the European Group differences and standards listed in the IECEx Bulletin edition 2.

**2. ORGANISATION**

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

<b>Name</b>	<b>Title</b>	<b>Experience</b>
Giulio Santagostino	Managing Director	30+ Years
Ulisse Colombo	Manager Certification Business Unit	19 Years

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

<b>Name</b>	<b>Title</b>	<b>Experience</b>
Gabriele Villafranca Soissons		5 Years (for overall CESI)
Francesco Gallucci		15 Years (for certification)



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

<b>Name</b>	<b>Title</b>	<b>Experience</b>
Mirko Balaz	Ex Certification Manager	30 Years

**2.4 Name and Title of Signatories for Certification**

<b>Name</b>	<b>Title</b>
Ulisse Colombo	Manager Certification Business Unit

**2.5 Other Employees in ExCB activity**

A list of Ex Certification Body Staff was provided by CESI (a total of 19 people)

**2.6 Organizational Structure**

See Annex 1 and Annex 2 for organizational charts of CESI and Business Unit Certification.

**2.7 Administration**

**2.7.1 Administrative Structure**

See Annex 1 and Annex 2. The assessment team concluded that there is sufficient administrative support for CESI to meet its IECEx obligations.

**2.7.2 Terms of Reference of the Governing Board**

The Governing Board for Certification is mentioned in Clause 4.2.1 of the certification Quality Manual and the operation document procedure A2/013779

**3. RESOURCES**

A team of two people are designated to perform manufacturer inspections in the Ex field. As a back up, a large team of experts from Quality System Management and experts from the Ex testing field are available. There is an ongoing education/training program.

CESI maintains an instrumentation file (called matrix) listing all relevant equipment used in the Ex operation. This is a comprehensive list, including serial numbers and calibration dates.

The team of experts meets on a regular basis in order to discuss issues coming up in the Ex field.



## 4. COMMITTEES

The Technical Certification Committee (CTC) comprises 11 members with three members from CESI, and the rest from stakeholders and industry. The CTC normally meets twice a year or more frequently if necessary. Each member is required to sign a document concerning confidentiality and impartiality.

A large number of CESI personnel are active on professional committees.

## 5. CERTIFICATION OPERATIONS

### 5.1 National Approval/Certification Methods

The certification process covering IECEx certification was noted in draft document number A4500664, dated November 18, 2004. CESI takes into account new IECEx Scheme documents as well as modified versions of existing documents. CESI had indicated that this draft document would be updated after the assessment but, in fact, it was completed during the assessment to the satisfaction of the assessment team

### 5.2 Certification Policy

Ex Certification policy is covered in the quality manual for the line Ex of the Business Unit certification in Clause 1.2.

### 5.3 Staff Work Instructions

The IECEx certification process is described in Chapter 4 of the IECEx certification document mentioned in Clause 5.1 of this report.

### 5.4 Application for Certification

A certification application document is available under number A1/022695 as well as the general conditions for certification services. Furthermore, the customer asking for Ex certification will be provided with document A4520217. CESI require the customer to sign this document if he is asking for an IECEx CoC, a QAR or an ExTR.

## 6. STATISTICS

The following certificates were issue under ATEX and other standards (IEC) in the period of 2002 and October 2004:

flameproof	d	284
intrinsic safety	i	72
oil-immersion	o	3
increased safety	e	63
special	s	none
powder filled	q	none



encapsulated	m	7
type	n	51
pressurized	p	32
Gas Detectors		2
Apparatus for Dusts		141

**86 manufacturer assessments** were performed between 1999 and 2004.

## 7. DOCUMENTATION

### Document and Change Control

Document and change control is covered in the Quality Manual for the line Ex of the Business Unit certification in Clause 4.8. Detailed procedures are available under the following paragraphs:

2.1.3, e): archiving of CESI certificates; f): numbering and filing of documents; g): issue and preparation of documents; h): central management of technical documents. Document history is according to CESI rules. Document History is mentioned in all documents on the front sheet and in the chapter on document history.

## 8. RECORDS

Presently, the issued ATEX certificates are available to the public as a book according to general sale conditions for certification services under Clause 3.2.

IECEx CoCs will be available to the customer using the IECEx Website under [www.iecex.com](http://www.iecex.com), as soon CESI is cleared as an ExCB and CoCs have been issued.

## 9. CONFIDENTIALITY

Each person involved in Ex activities (internal and external) is required to sign a declaration of confidentiality and impartiality. The blank document is number CERT – A4519864

## 10. PUBLICATIONS

All relevant information is available through the CESI homepage: [www.cesi.it](http://www.cesi.it). CESI organises meetings with customers in order to update them with the latest developments in the schemes (ATEX, and IECEx in the future).

Based on the information material seen during the assessment CESI is very active in promoting the ATEX procedure and the IECEx Scheme.





## 11. APPEALS

The Governing Board for Certification is mentioned in Clause 4.2.1 of the certification Quality Manual and the operation document procedure A2/013779

## 12. NATIONAL ACCREDITATION

CESI has an accreditation letter issued by the Ministero delle Attività Produttive in Roma, dated March 20, 2003 under number 829559 for the scope of protection techniques covered by standards listed in Clause 1.6 of this report. The document is shown in Annex 3.

A surveillance visit by the Ministry took place on 7<sup>th</sup> and 8<sup>th</sup> of October, 2004, and continued acceptance of CESI was granted. For this visit a checklist against ISO/IEC Guide 65 was completed by CESI to show which of their policies or procedures met each of the requirements of the standard. Each of these requirements was then verified and checked off with a tick and each page of the checklist endorsed with an official stamp and signed by two representatives from the Ministry.

## 13. RECOGNITION AND AGREEMENTS

CESI has been active in Ex procedures since 1968 and has listed with reference to the "Old Approach" EU-Directives (76/117/EEC, 82/130/EEC) since 1982 and since 1998 with reference to the New Approach "ATEX" Directive (94/9/EC) as Notified Body No. 0722.

CESI has recognition as an independent testing laboratory from the U.S. Department of Homeland Security (U.S. Coast Guard).

CESI has also a co-operation agreement with the "Agency for Explosive Atmosphere Hazardous Areas", an organization of the Croatian Government.

## 14. QUALITY MANUAL

The latest version of the Quality Manual of CESI, is the 5<sup>th</sup> revision, dated May 28<sup>th</sup>, 2004, with the number A4004390.

The current Quality Manual covering Ex certification was issued on October 31<sup>st</sup>, 2003 with the number A3/021488.

CESI holds an SQS Accreditation Certificate (SQS: The Swiss Association for Quality and Management Systems) for ISO 9001:2000. The certificate was issued on June 1<sup>st</sup>, 2004 under registration number 24295-01 and is valid until May 31<sup>st</sup>, 2007.



## **15. INTERNAL AUDIT AND PERIODIC REVIEW**

Internal Audit procedures are covered in the Ex certification quality manual under Clause 4.7.1. However, CESI advised that the 2004 internal audit will not be performed due to the various audits received from SQS, from Ministry and SINAL (accreditation body for laboratories). The internal audit program of 2004 will be delayed to January 2005. The regular internal audit of 2005 will take place later in 2005.

Furthermore, the Technical Certification Committee (CTC) is performing every year their surveillance audit on certification activities. The last report was issued on March 5<sup>th</sup>, 2004 prior to one of the two regular biannual meetings of the CTC.

CESI will improve the detailed schedule for all the areas to be covered under the CESI quality manual. This is to include the IECEx Scheme activities.

## **16. COMPLAINTS**

Complaints are handled according to Certification Quality Manual, Chapter 7.

Usually complaints are directed to the Certification Business Unit Manager. However, the customer may directly approach the Technical Certification Committee.

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

The withdrawal and cancellation process is described in the Quality Manual and in more detail in the certification procedure given to the customers to sign.

## **18. SPECIAL FACTS TO BE NOTED**

CESI has a liability insurance covering the requirements of international certification systems. Insurance contracts were presented and found to be satisfactory.

Manufacturer assessment file number CESI 04 ATEX 015 Q was reviewed with the team leader of the manufacturer assessment team present. The review showed positive results. However, there was a need for certain documents to be adapted in order to meet IECEx Scheme operations and rules.

## **19. COMMENTS**

**19.1** The issue of a lack of a deputy for signing certificates was raised. Subsequent actions were taken by CESI to resolve the matter.

**19.2** The need to improve scheduling of internal audits in relation to the IECEx Scheme activities was identified. Subsequent actions were taken by CESI to resolve the matter.



- 19.3** Some procedures covering the specifics related to the IECEx Scheme, such as auditing of manufacturers and issuing of Quality Assessment Reports, needed further development, or were still in draft form. These have now been completed and issued.

## **20. RECOMMENDATION**

Based on the initial assessment performed during November 22<sup>nd</sup> to 24<sup>th</sup> and follow-up actions, CESI is recommended to operate in the IECEx scheme as a Certification Body according to the scope of standards listed in this document under Clause 1.14.

## **LIST OF ANNEXES**

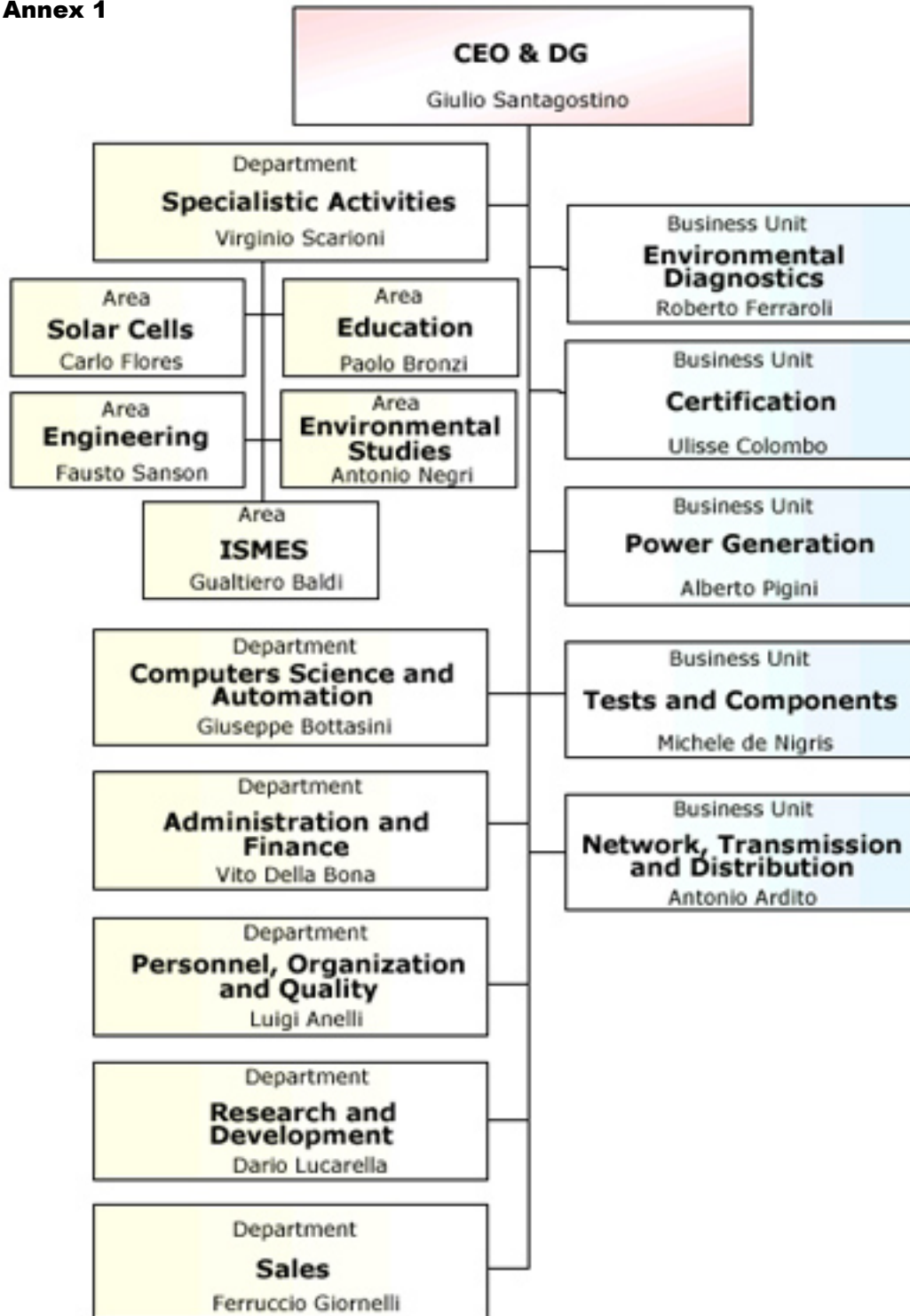
- Annex 1: Organizational Chart of CESI Management  
Annex 2: Organizational Chart of CESI Ex Certification  
Annex 3: CESI Accreditation Letter "Ministero delle Attività Produttive", March 2003

**Jim Munro**  
**Lead Assessor**

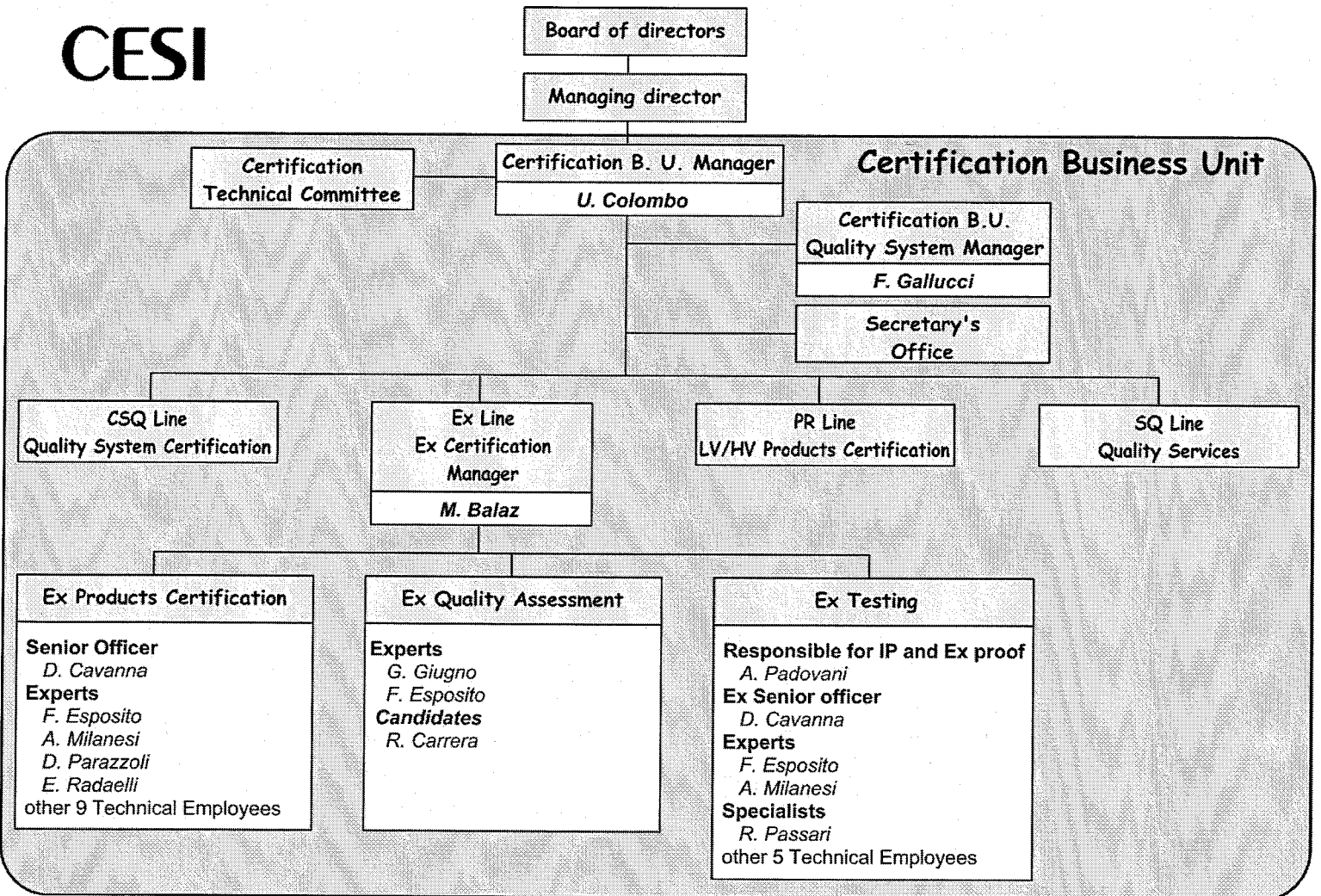
**Heinz Berger**  
**Assessor**

**Wolf Dill**  
**Assessor**

**Annex 1**



**CESI**



20-MAR-03 11:51

Da-

T-891 P.02/02 F-184

MOD 25 P

MODULARIO  
M.43P. - 22



PROT. A3/00071

20 MAR. 2003

20

Notifica CESI-P

20 MAR. 2003

Archivio CERT/PR, EX

Copia a: Balaz *ALL*

CESI S.p.A.

c.a. Ing. U. COLOMBO

Via Rubattino, 54

20134 MILANO

Ministero  
delle Attività Produttive  
DGSPC - Ispettorato Tecnico  
Ufficio F2 - Normativa Tecnica

Prot. N. 29559 Allegati  
Proposta al Foglio N. A3/007038  
del 27 febbraio 2003

OGGETTO : Notifica del CESI ad operare ai sensi della Direttiva 94/9/CE (ATEX).

In relazione alla nota sopra citata concernente la notifica in oggetto, si precisa che le verifiche ispettive svolte dal Ministero delle Attività Produttive nell'ambito dell'accreditamento del CESI ad operare quale Organismo notificato n. 722 dalla Commissione Europea ai sensi della Direttiva 94/9/CE (ATEX) per la certificazione di apparecchi e sistemi destinati ad atmosfere potenzialmente esplosive, comprendono, tra gli altri, controlli atti ad accertare:

- a) la competenza del CESI a svolgere le funzioni di Organismo di certificazione in conformità ai requisiti della norma EN 45011:1998 *General requirements for bodies operating product certification system (ISO/IEC Guide 65:1996)* per i prodotti destinati ad essere utilizzati in atmosfere potenzialmente esplosive
- b) che il laboratorio CESI EX (Prove di apparecchiature antideflagranti e a prova di esplosione) è conforme ai requisiti della norma ISO/IEC 17025:1999 *General requirements for the competence of testing and calibration laboratories*, per quanto attiene l'effettuazione delle prove di tipo di cui alle seguenti norme tecniche: CEI EN 50014; CEI EN 50015; CEI EN 50016; CEI EN 50017; CEI EN 50018; CEI EN 50019; CEI EN 50020; CEI EN 50021 : CEI EN 50281-1-1 ; CEI EN 50284 ; CEI EN 50303 ; CEI EN 60529 ; EN 13463-1, e a quelle riportate negli elenchi riepilogativi delle norme armonizzate, adottate ai sensi dell'art. 3 del decreto del Presidente della Repubblica 23 marzo 1998, n. 126.

Pertanto l'autorizzazione rilasciata da questo Ministero ad operare quale Organismo notificato per la Direttiva 94/9/CE, comprende il riconoscimento del CESI come Organismo di certificazione ai sensi della EN 45011 Ed. 1998 e come laboratorio di prova ai sensi della ISO/IEC 17025:1999 per i prodotti e le prove di cui ai precedenti punti a) e b).

IL DIRETTORE GENERALE

(M. Goti)

Federici/Celeste

ISTITUTO PD, DMASCO E ELCA DELLO STATO - S. Sp. per la produzione, per la certificazione, per la gestione degli organismi di certificazione notificati n. 722