General Information
Conformity Assessment Systems Directive 2014/34/EU and IECEx-System

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1. General Introduction

The sector 1 „Explosion Protection“ of the conformity assessment body (KBS) of the Physikalisch-Technische Bundesanstalt (PTB) is a notified body according to the European Direction 2014/34/EU [2]. The Sector 1 “Explosion protection” is furthermore Certification Body (ExCB) and Test Laboratory (ExTL) in the IECEx System acc. IECEx Rules IECEx 01-S / IECEx 02 [13].
Both conformity assessment systems are applied at PTB for performance of tests and certification of electrical and non-electrical equipment.

2. Conformity assessment systems

For conformity assessment according to the European Direction 2014/34/EU (ATEX) the health and safety requirements according to annex II of the Directive shall be fulfilled. In case of application of harmonized EN-standards the presumption of conformity with the relevant health and safety requirements of the Directive applies. [11].

For conformity assessment in the IECEx-System acc. IECEx Rules IECEx 01-S / IECEx 02 compliance with the relevant IEC/ISO Standards shall be verified.

For explosion-protected electrical products, the same requirements generally apply in both assessment systems for conformity assessment (IEC/EN 60079-0 ff) and for quality assurance, related to the manufacturing process, the requirements of EN ISO IEC 80079-34.

For explosion-proof non-electrical products, both conformity assessment systems apply the requirements of ISO 80079-36 and ISO 80079-37 for conformity assessment and the requirements of EN ISO IEC 80079-34 for quality assurance in relation to the manufacturing process.

2.1 Conformity assessment according to the European Directive 2014/34/EU (ATEX)

2.1.1 Market introduction resp. placing on the market of products in the European Union

The market introduction resp. placing on the market of products for appropriate use in potentially explosive atmospheres is in the European Union determined in the Directive 2014/34/EU [2]. By means of the eleventh regulation of the product safety law (explosion protection regulation – 11.ProdSV) the Directive 2014/34/EU was implemented into national law in Germany. [3]

Konformitätsbewertungsstelle, Sektor Explosionsschutz

Differences between the European Directive 94/9/EG, which was valid until April 19, 2016, and Directive 2014/34/EU are described in the document „GUIDANCE DOCUMENT ON THE ATEX DIRECTIVE TRANSITION FROM 94/9/EC TO 2014/34/EU". [5]

According to Directive 2014/34/EU explosion protected products are classified into categories. The certification procedures differ depending on categories and are described in the following section.

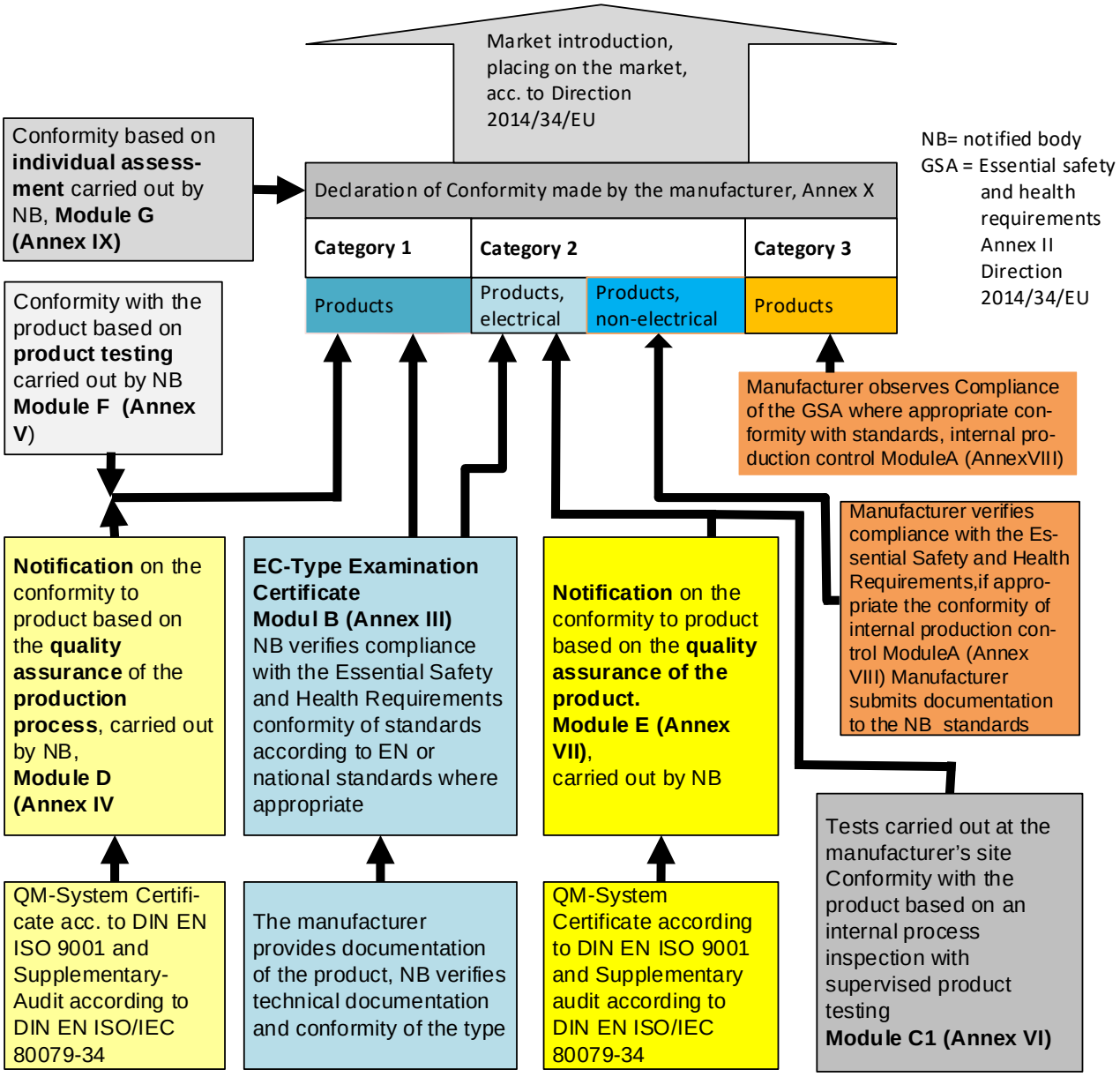

Figure 1: Conformity assessment procedure according to Directive 2014/34/EU

Further information concerning the conformity assessment procedure can be taken from the ATEX 2014/34/EU GUIDELINES 1st Edition-April 2016) [4].

2.1.2 Consequences from the expiring of standards

The following note from the Official Journal of the European Union [11] „Veröffentlichung der Titel und der Bezugsnummern der harmonisierten Normen im Sinne der Harmonisierungs-rechtsvorschriften der EU“ („Publication of the title and the reference number of the harmonized standards according to the harmonization legislation of the EU”) is significant when the former and the new standards have the same scope of application:

Note 2.1: The new (or changed) standard has the same application field as the replaced standard. To a fixed date the presumption of conformity with the basic or further requirements of the relevant legal stipulations of the Union are no longer valid for the replaced standard.

Usually changes of standards represent a supplement and specification, which are relaunched for reason of the structure of the standards or because of the technical progress. The safety level shall only exceptionally be modified in such a way, that by means of the change of the standard the “state of the art” is also modified. This shall possibly be described in annex ZY or in the foreword of the relevant standard.

According to Directive 2014/34/EU the manufacturer shall place a product on the market which corresponds to the “state of the art”. For this reason, he has to verify, to what extent his product is affected by the modification of the standard and to assess whether changes are necessary. If the product fulfills the requirements of the new standard, this shall be noted in the notification of conformity. When a standard is modified the presumption of conformity of the Directive does not automatically expire.

To manage the transition to new standards in a pragmatic way the Physikalisch-Technischen Bundesanstalt (PTB) applies the following procedure:

- New EU-Type Examination Certificates are basically issued applying of harmonised standards.
- Exceptionally harmonized standards may not be applied. Under Point 18 of the EU-Type Examination Certificate compliance with the applicable health- and safety requirements of Direction 2014/34/EU shall be mentioned. The test specifications applied are listed.
- Current tests are completed as applied for, even if the standard has changed in the meantime.

2.1.3 Risk analysis and - assessment

In annex III, number 3. c), annex VIII, number 2. as well as annex IX, number 2.1 of the Directive 2014/34/EU as well as in the resolution No. 768/2008/EG of the European commission it is explicitly stipulated that **the technical documentation** shall include an appropriate risk analysis and assessment.

The risk analysis shall cover and assess all risks, including risks which are **not** typical for explosion protection (compare annex II figure 1.2.7 of Directive 2014/34/EU); this includes e.g. risks caused by voltage, noise, hot surfaces or moving parts. Additional harmonization legislation applicable to the product shall also be observed. Application of harmonized standards might facilitate the risk analysis and assessment (see section 4.1.1 of the “Blue Guide”, Edition 2014). Standard DIN EN 1127-1 “potentially explosive atmosphere – Explosion protection – part 1: Basics and methods” provides useful information for risk analysis and -assessment.

With the application form for type examination, the manufacturer confirms that he has performed a risk analysis and assessment. The part of the risk analysis, which contains risks which are not relevant for explosion protection, has not to be submitted as a test document. The manufacturer shall ensure access to these documents for PTB if required.

2.2 Conformity assessment in the IECEx System

When applying the conformity assessment procedure according to IECEx-System acc. IECEx Rules IECEx 01-S / IECEx 02 for explosion proof equipment for issuing a Certificate of Conformity (CoC, online certificate) it shall be verified whether the product complies with the requirements of the applicable standards and the production site conforms to the requirements of quality assurance according to DIN EN ISO/IEC 80079-34.

2.2.1 General

Since 2003 the „IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres“ (IECEx-System) exists under the roof of the “International Electrical Commission (IEC). The Certification Bodies (ExCB) issue IECEx-Certificates for products (IECEx Certificate of Conformity (CoC)). The PTB carries out type tests in accordance with the IECEx rules IECEx 01-S / IECEx 02 (further information on the IECEx-System see website of the IECEx-System (http://www.iecex.com).

The IECEx CoC with the associated Ex Test Report package (ExTR) as well as the Quality Assessment Report (QAR) serve as a basic for the national certificates in IEC-member states (so called “Fast Track Procedure). For this purpose, an agreement with the certification body which shall issue the national certificate is necessary.

2.2.2 Assessment procedures

The rules of the IECEx System are determined in the „IECEx rules“ and the „Operational Documents“ (OD). They are online available for the user (https://www.iecex.com).

IECEx Certificates are uploaded and managed online (https://www.iecex.com). The basis for the assessment are the IEC-standards which are listed on the IECEx website under the regarding certification body.

A “Quality Assessment Report” (QAR) according to DIN EN ISO/IEC 80079-34 is issued as proof of the Quality Assurance of the Production Process. This may be identical to the Audit-Report for acknowledgement of quality assurance system production / product according to the requirements stipulated in Directive 2014/34/EU (ATEX).

2.3 Comparison ATEX – IECEx

In the European Economic Area Declaration of Conformity of the manufacturer (see figure 1) is necessary for the placing on the market of products. He declares under sole responsibility, that the requirements of all relevant European Directives (i.a. Directive 2014/34/EU) for the products are met.

At the IECEx system, the certification body (ExCB) confirms the conformity of the product with the relevant IEC standards confirms by the Certificate of Conformity (CoC). For the placing on the market further national and regional certificates may be required.

3. Application

3.1 Responsibilities

At PTB the Sector 1 of the Conformity Assessment Body „Explosion protection“ is responsible for the processing of test- and certification applications for conformity assessment procedures of explosion proof electrical and non-electrical products [1].

3.2 Test- and certification application

For assessment and certification of a product a written application shall be sent to the conformity assessment body of the PTB, Sektor 1 “Explosionsschutz”. For placing an application the corresponding application form shall be used (see table 1). If the application form is transmitted electronically, it shall be accepted, when the signed form and the necessary signed declarations are attached as a scanned file.

Certificate / Assessment report	**Basis**	**Order form** (http://www.ptb.de/cms/ptb/fachabteilungen/abt3/exschutz/merkblatt-ex.html)
EU-Type Examination Certificate or new issue resp. data sheet	RL 2014/34/EU, Module B (Annex III)	Application form for assessment and certification of products, components and protective systems by applying the regulations determined for the use in potentially explosive atmospheres according to Directive 2014/34/EU and IECEx System.
IECEx Certificate of Conformity or new Issue (CoC)	IECEx System	
EU Individual Assessment	RL 2014/34/EU, Module G (Annex IX)	
Test Report (without certification)		
Test Report (ExTR)	IECEx System	
Conformity Statement	RL 2014/34/EU, Module A (Annex VIII)	
Quality Assurance of the Production Process	RL 2014/34/EU, Module D (Annex IV)	Application form / sheet including information for recognition of a QS-system according to Directive 2014/34/EU (ATEX) / IECEx System.
Product Quality Assurance	RL 2014/34/EU, Module E (Annex VII)	
Product Assessment	RL 2014/34/EU, Module F (Annex V)	Application form for assessment and certification of products, components and protective systems by applying the regulations determined for the use in potentially explosive atmospheres according to Directive 2014/34/EU and IECEx System.
Conformity to Type Assessment	RL 2014/34/EU, Module C1 (Annex VI)	Application form / Assessment of Conformity according to Direction 2014/34/EU, Module C1.

Table 1

3.3 Documentation belonging to the Assessment and Certification application

Assessment applications with the associated technical documents, such as description, drawings, parts lists, data sheets and operating instruction, which enable the evaluation of the product can be sent electronically (explosionsschutz@ptb.de) or by post. In order to be quoted, they must be clearly identified (name and document number - controlled documents - of the customer, release date, version) as technical documents of the customer. Technical documents sent by post are required in a single copy. If further technical documents are required for processing the assessment application, they may be submitted subsequently in consultation with the employee responsible for the processing of the application.

Electronic technical documentation should be submitted in standard Office formats or as PDF files. Other formats (e.g. Gerber data, layout files, etc.) must be agreed with the employee responsible for the processing of the application.

The form "Application Form for testing and certification of equipment, components and protective systems intended for use in potentially explosive atmospheres (Directive 2014/34/EU / IECEx System IECEx Rules IECEx 01 S / IECEx 02)" [14] shall be used for the assessment application.

After successful completion of the evaluation, a final version of the technical documentation is produced. They are listed in the test report or the ExTR cover, depending on which conformity assessment procedure has been applied. This **fixes the design of the product**. Finally, the client receives the certificate(s) and the test report or ExTR by post.

3.4 Supplementation of a Certificate

If a supplement of a certificate is required, a new issue of an EU-Type Examination Certificate according to Directive 2014/34/EU resp. a new issue of an IECEx-Certificate shall be issued.

The transition from an EC-Type Examination Certificate to an EU-Type Examination Certificate is explained in the information sheet “Übergang von Richtlinie 94/9/EG zur Richtlinie 2014/34/EU Merkblatt für Hersteller” (“Transition from Directive 94/9/EG to Directive 2014/34/EU information sheet for manufacturer”) [7].

3.5 Fees

The Physikalisch-Technische Bundesanstalt charges fees according to their provision of service (fees and expenses) according to the **Kostenverordnung für Nutzleistungen (Regulations Governing Charges for Services) (PTBAKostO)** of the Physikalisch-Technische Bundes-#anstalt in their currently valid version. Binding quotations must not be made and submitted to the applicant.

The evaluation procedure for **assessment of QM systems** and the **deposit of technical documentation** of explosion proof of non-electrical equipment of category 2 and M2 equipment and components shall be accounted according to a **flat-fee rates** determined in the Regulations Governing Charges for Service of the PTBAKostO.

4 Cooperation Partners

The PTB cooperation partners Underwriters Laboratories (UL), USA and National Supervision and Inspection Centre for Explosions Protection and Safety of Instrumentation (NEPSI), China, established an office on the PTB site to be able to offer advisory concerning access to the respective markets to the manufacturers. The cooperation partners may be involved in the processing of applications on the proposal of PTB and by order from the customer. Certification shall be carried out by Sektor 1 “Explosionsschutz” of the PTB Conformity Assessment Body (KBS).

5 Experimental Tests

Experimental tests shall be agreed with the employee responsible for the processing of the application before they are carried out. A test plan is prepared before the test starts.
The tests can be carried out by PTB, a cooperating partner or another notified body.

It is possible to perform tests at the site of the manufacturer. When tests for assessment of conformity according to IECEx System are performed, the requirements according to IECEx OD 024 [10] and the leaflet „Prüfungen nach IECEx OD 024 Merkblatt für Hersteller“ (ExTL-MB-01) [8] “Tests according to IECEx OD 024 leaflet for manufacturers” (ExTL-MB-01) [8] and „Prüfungen nach IECEx OD 024 Spezielle Anforderungen an Temperaturmessung elektrischer Maschinen, Merkblatt für Hersteller“ (ExTL-MB-02) [9] “Tests according to IECEx OD 024 special temperature measurement requirements at electrical equipment, leaflet for manufacturers” (ExTL-MB-02) [9] are to be used.

6 Literature list

- [1] Explosionsschutz PTB (www.explosionsschutz.ptb.de) (10/2019)
- [2] RICHTLINIE 2014/34/EU DES EUROPÄISCHEN PARLAMENTS UND DES RATES vom 26. Februar 2014 zur Harmonisierung der Rechtsvorschriften der Mitgliedstaaten für Geräte und Schutzsysteme zur bestimmungsgemäßen Verwendung in explosionsgefährdeten Bereichen (Neufassung)
- [3] Elfte Verordnung zum Produktsicherheitsgesetz (Explosionsschutzverordnung - 11.ProdSV) vom 6. Januar 2016.
- [4] ATEX 2014/34/EU GUIDELINES 1st Edition – April 2016
  Guide to application of the Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the law of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres
- [5] GUIDANCE DOCUMENT ON THE ATEX DIRECTIVE TRANSITION FROM 94/9/EC TO 2014/34/EU"
  (http://ec.europa.eu/growth/sectors/mechanical-engineering/atex/) (10/2019)
- [6] Mitteilung der Kommission im Rahmen der Durchführung der Richtlinie 2014/34/EU des Europäischen Parlaments und des Rates vom 26. Februar 2014 zur Angleichung der Rechtsvorschriften der Mitgliedstaaten für Produkte und Schutzsysteme zur bestimmungsgemäßen Verwendung in explosionsgefährdeten Bereichen (Neufassung)
- [7] Merkblatt für Hersteller Übergang von der Richtlinie 94/9/EG zur Richtlinie 2014/34/EU (KBS-Sek1-Ex MB-03)
  (http://www.ptb.de/cms/ptb/fachabteilungen/abt3/exschutz/merkblatt-ex.html) (10/2019)
- [8] Prüfungen nach IECEx OD 024 Merkblatt für Hersteller (ExTL MB-01)
  (http://www.ptb.de/cms/ptb/fachabteilungen/abt3/exschutz/merkblatt-ex.html) (10/2019)
- [9] Prüfungen nach IECEx OD 024 Spezielle Anforderungen an Temperaturmessung elektrischer Maschinen, Merkblatt für Hersteller (ExTL MB-02)
  (http://www.ptb.de/cms/ptb/fachabteilungen/abt3/exschutz/merkblatt-ex.html) (10/2019)
- [10] IECEx Operational Document IECEx OD024 IECEx Rules of Procedure covering testing, or witnessing testing at a manufacturer's or user's facility
  (http://www.iecex.com/operational.htm) (10/2019)
- [11] Amtsblatt der Europäischen Union
  https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/equipment-explosive-atmosphere_en (10/2019)
- [12] Kostenverordnung für Nutzleistungen der Physikalisch-Technischen Bundesanstalt (PTBAKostO)
  (http://www.gesetze-im-internet.de/ptbakosto/index.html)
- [13] Regeln IECEx System
  http://www.iecex.com/publications/iecex-rules/ (10/2019)
- [14] Application Form for testing and certification of equipment, components and protective systems intended for use in potentially explosive atmospheres (Directive 2014/34/EU / IECEx System IECEx Rules IECEx 01 S / IECEx 02)