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Ad Hoc Team of Specialists on Standardization and Regulatory Techniques

A Common Regulatory Framework for Equipment Used in Environments with an Explosive Atmosphere

Second Edition

Submitted by the subgroup Chair

Summary

The Common Regulatory Framework for Equipment Used in Environments with an Explosive Atmosphere was developed and finalized in 2019. This second edition is an updated version of the original 2011 document (ECE/TRADE/391). It provides significant changes, including the participation in proficiency testing, independent conformity assessment bodies to support market surveillance, certification services and update to the most recent IEC standards.

Proposed decision

“The Working Party takes note of the updated Common Regulatory Framework for Equipment Used in Environments with an Explosive Atmosphere (ECE/CTCS/WP.6/2022/INF.4).”.

Common Regulatory Arrangement (CRA) – Version 2019

I. Background

1. Explosion protection is an essential part of the overall risk management to be conducted for industrial sectors such as coal mining, oil, gas and chemical industries, to ensure safety in industrial processes using or producing hazardous materials like – for example – combustible gas, dusts or vapours. The risks to life and health of persons and the risk of loss of property when using the equipment which operates in the presence of explosive atmospheres are high. Primarily necessary is to prevent the occurrence of explosive atmospheres or to have the area defined by Zones. Secondly the ignition sources have to be eliminated in relation with the definition of the probability of explosive atmospheres by explosion protection levels. Thirdly, the consequences of an explosion have to be minimized if the primary and secondary actions have no effect.

2. The basic principles of explosion protection have been applied in industry and mines for over 100 years. They have been codified in international standards such as the International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO). They are also at the basis of certification systems –such as the IECEx, the IEC System for Certification to Standards relating to Equipment for Use in Explosive Atmospheres, Repair Facilities or Personal Competency in this field, www.iecex.com. IECEx specifies rules of procedures and Operational Documents (see Annex F.1).

3. The ISO and IEC International Standards are increasingly adopted by participating countries at the regional and national level, either in full, without any variation, or in part, with supplementary requirements contained in national standards. The significance of the international standards upon which the industry relies can be seen by the increased participation in IEC Technical Committee, TC 31: Equipment for explosive atmospheres, which reached 51 countries as of December 2018, either participating or observing.

4. The IEC/ISO standards are being updated continuously to implement new technologies and the “State of Art” with respect to safety aspects. Further information concerning the work of IEC TC 31 can be found at www.iec.ch.

5. The equipment for use in explosive atmospheres has to be selected, installed, inspected, maintained and repaired by using national rules or international IEC-standards. Due to the extended risk, a full “life cycle approach” is required.

6. Countries use standards and certification systems in their regulations in different ways, including:

- by making standards mandatory and using national certification systems and services through a legislative act.
- by making compliance with the standards a means of proving compliance with the essential health and safety requirements laid out in the legislation: under this approach, equipment that complies with the provisions of the standards is “deemed to comply” with the requirements specified in the regulations.
- by using the IECEx Certification System for equipment, repair facilities or personal competence.

II. Purpose of the Sectoral Initiative on Equipment Used in Environments with an Explosive Atmosphere

7. The purpose of the Sectoral Initiative on Equipment Used in Environments with an Explosive Atmosphere is to

- promote the convergence of national technical regulations currently in place in this sector towards a shared framework. This will reduce barriers to trade for this equipment and services in this field, as well as costs.

- ensure safety for life and health of persons and preservation of property
- achieve convergence of national technical regulations
- create conditions for mutual recognition of conformity assessment results obtained in different countries that will reduce barriers to trade for this equipment, as well as costs

III. Scope statement of the Common Regulatory Arrangements contained in this document

8. The Common Regulatory Arrangements (CRAs) presented in this document have been drawn up in accordance with Recommendation D and L of the Working Party on Regulatory Cooperation and Standardization Policies (WP. 6) of the United Nations Economic Commission for Europe (ECE/TRADE/378–UNECE Recommendations on Standardization Policies).

9. The scope of the Common Regulatory Arrangements includes the following:

- Equipment for use in explosive atmospheres.
- Electrical and non-electrical equipment.
- Life-cycle approach to the equipment: on placing on the market, on commissioning during the use, after repair.

10. The purpose of the CRAs is twofold. On the one hand, they can be used as a model to draw up legislative instruments in countries that do not currently have regulations in this sector. On the other hand, they can be used to align existing national regulation with an internationally harmonized best practice.

11. The CRAs are drawn up with reference to international standards and conformity assessment procedures developed by IEC and ISO and to best practice in the assessment of conformity to such standards, within the IECEx. The basic terms and definitions of the international electrical vocabulary are used.

12. The CRAs address the requirements both for electrical and mechanical equipment being placed on the market (part one of the present document). The equipment is verified with respect to explosion protection levels to cover normal operation, expected and/or rare malfunction.

13. Explosion protection in industry can be assured through a variety of legitimate means. The present document is based on one of them, namely, the “IEC Zone Concept”¹ This concept classifies hazardous locations as high, medium and low risk zones based on a standard risk-assessment methodology.

14. Additionally, the present document is based on the life-cycle approach, which requires proper selection, installation, inspection, maintenance and repair of explosion protected equipment. This approach guarantees effective and efficient explosion protection and the elimination of potential ignition risk, always when a facility or product is in use (part two of the present document).

15. The conformity assessment system adopted in this document takes into account very high-risk levels when the equipment is used in environments with explosive atmosphere. The conformity assessment shall cover the Ex-equipment and the organizations which produce Ex-equipment and perform its installation, maintenance and repair, and the corresponding personnel. The IECEx-System offers procedures of conformity assessment and has to be seen as appropriate.

16. Most national regulatory frameworks require that conformity assessment be conducted by independent, third-party inspection bodies. This is a prerequisite for safety in a sector where hazards are substantial and may involve many casualties.

¹ See: IEC 60079-10-1 and IEC 60079-10-2.

17. The main drawback of such a system is that equipment traded internationally may have to undergo repeated testing and conformity assessment for each of the national markets to which it is exported. This greatly increases the cost of the equipment without a corresponding increase in safety for workers and end-users.

18. Additionally, the existence of disparate safety procedures in a sector that operates as a truly global and integrated industry may in and of itself constitute a hazard. Indeed, as workers move from one location to another, they may be insufficiently familiar with local safety procedures.

19. For these reasons, an internationally recognized certification scheme, such as the IECEx, is of essential importance in order to reduce unnecessary costs associated with duplication of testing and assessment and as the basis for sound risk management. In time, this should be flanked by a system of personnel certification aimed at ensuring competencies within a system of standard safety procedures, such as the IECEx Certification of Personnel Competence Scheme.

20. One final and essential element of the present document relates to market surveillance. Market surveillance is necessary to monitor the proper application of the CRAs by industry and increase confidence in the effectiveness of the CRAs. Common guidelines will be defined to support the national authorities defining and implementing actions and procedures, including for the removal of unsafe products from the national market.

Common Regulatory Arrangement – Part one

Requirements for placing products and equipment on the market

A. Definition of applicable standards

21. Potential ignition sources that may occur when electrical and mechanical equipment are used in accordance to its intended use must be eliminated. The list of potential ignition sources published in the applicable international standards assists in identifying risks caused by stand-alone equipment (see appendix A.1).

22. To eliminate the ignition sources, validated protection concepts (“types of protection”) with explosion protection levels have to be applied, as laid down in applicable IEC International Standards or other international standards (see appendix A.2). Some equipment requires for safe use additional safety device which has to be included in the verification. Equipment is to be manufactured under ongoing third-party surveillance. The manufacturer has to operate a Quality Management System that complies with the requirements of the applicable ISO/IEC International Standard (see appendix A.3).

23. The documentation accompanying the equipment has to cover instructions about the intended use, and details for installation, maintenance and repair. The documentation has to be available in English. On request of the customer of the equipment, the manufacturer must provide a translation into a national language. By using electronic documentation the access and legibility has to be guaranteed during the lifetime of the equipment.

B Definition of applicable conformity assessment procedures

24. Compliance with this CRA shall be by use of an international certification scheme such as the IECEx for direct market acceptance of products carrying IECEx Certification (see appendix F1). Certificates and supporting documents have to be available for the public (e.g. by internet data access). Alternatively, where national legislation does not allow for use of IECEx Certificates, national certification of compliance should be based on IECEx testing and assessments.

Common Regulatory Arrangements – Part two

Requirements for the safe use of the equipment and competence of services

25. All substances intended for use in a plant or facility characterized by an explosive atmosphere have to be classified concerning their safety characteristics by applying the applicable ISO/IEC International Standards (see appendix B.1).
26. Primarily the first approach should be that an explosive atmosphere is avoided. If it is not possible to avoid explosive atmospheres, the different risk levels in an area according to the IEC Zone classification concept have to be assessed by applying the applicable IEC International Standards (see appendix B.2).
27. The selection of equipment in a classified area (Zones 0, 1, 2, 20, 21 and 22) has to be aligned with the applicable Equipment Protection Level Ga, Gb, Gc, Da, Db, Dc, Ma and Mb installed accordingly.
28. The equipment has to be installed properly by taking into account specific local conditions (e.g. ambient temperature, environmental conditions, potentially aggressive materials) and the intended use of the equipment, specified in the product documentation (see appendix B.3).
29. The installation and the equipment need to be inspected and maintained by appropriate and effective procedures that have to be implemented in the quality system of the plant (see appendix B.4). In the case of personnel performing work functions that govern the selection, installation and use of equipment, the personnel shall be appropriately qualified as being competent.
30. Compliance with this requirement may be demonstrated by use of an international certification scheme such as IECEx Certification of Personnel Competence Scheme for acceptance of persons carrying an IECEx Certificate of Personnel Competence. The CRA cites the IECEx Certified Service Facility Scheme as the vehicle used for the conformity assessment of Organisations providing an installation and inspection service (see appendix F1). Alternatively, where national legislation does not allow for use of IECEx Certificates, national certification of compliance should be based on IECEx assessment of persons according to IECEx requirements.
31. In case of necessary repair of equipment, appropriate repair procedures have to be implemented in the quality system of the plant (see appendix B.5).
32. Compliance with this requirement may be demonstrated by use of an international certification scheme such as IECEx Certified Service Facilities Scheme for acceptance of repair facilities according to the applicable IEC International Standard (e.g. IEC 60079-19). Alternatively, where national legislation does not allow for use of IECEx certified repairers, national certification of compliance should be based on IECEx assessment and audit of such facilities.
33. All rationales and concepts related to the explosion risk assessment and the adequate measures to eliminate these risks have to be documented in the “Explosion Protection Document” by the user.

Common Regulatory Arrangements – Part three

Reference list to international standards providing the presumption of conformity with this regulation model

34. Standards providing the presumption of conformity with the requirements in part one and two are listed in the appendix, chapters A and B. The list of standards is to be updated as frequently as necessary depending on the publication output of IEC or ISO/IEC International Standards relevant to the objectives of this regulation model.
35. The group of countries that have implemented this regulation model can form an UNECE Standard Acceptance Group (UNECE-ExSAG) which will concern itself with the

acceptance of IEC or ISO/IEC International Standards providing the presumption of conformity with this regulation model. The members of this group seek for access to all standardization work of IEC (drafts, meetings) in order to influence standardization with concerns of regulators in an early stage. After the working group has accepted it, the standard will be listed in the appendix to this regulation model. If there is a former edition of the standard, this former edition will be withdrawn from the list within three years.

36. The countries can instruct IEC/ISO to create new standards if they identify safety concerns or to change existing standards

Common Regulatory Arrangements – Part four

Recognition of conformity assessment bodies

37. The accreditation of conformity assessment bodies and test laboratories has to follow the applicable ISO/IEC International Standards (see appendix C.1). The accreditation body has to be member of International Laboratory Accreditation Cooperation/International Accreditation Forum (ILAC/IAF). To ensure technical scrutiny, the IECEx system for TL and CB assessments incorporates peer assessment with at least one member of the assessor team coming from an established ExTL and/or ExCB (see e.g. the list of approved IECEx Assessors). The conformity assessment is performed by the «third party» who does not depend on the manufacturer and the organizations which use Ex-equipment (see appendix F1).

38. The conformity assessment bodies have to demonstrate their competence by the participation in proficiency testing programs (see appendix C.1).

39. Certificates have to be in line with ISO Type 5 Certification System requirements of the applicable International Standard. (see appendix C.2).

40. The acceptance within the IEC Conformity Assessment System IECEx provides the presumption of conformity with the requirements of Part four.

Common Regulatory Arrangements – Part five

UNECE Explosion Protection Steering Committee

41. To monitor the application experience within the countries that have based their national legislation on the UNECE regulation model and to update the regulation model in the light of their experience, a UNECE Explosion Protection Steering Committee (UNECE-ExSC) is to be formed and operated under the umbrella of UNECE WP.6. Recommendation L, Annex B recommends the administrative procedures and institutional provisions.

42. The ExSC agrees on a constitution and other governing rules and procedures of the daily operations (e.g. voting procedures).

43. The ExSC notifies the members of the UNECE Standard Acceptance Group (UNECE-ExSAG).

44. Members of the ExSC with the right to vote are the representatives of those countries having implemented the regulation model. Observers who are also invited to attend the meetings are: representatives from IEC Standardization Management Board (IEC SMB), IEC Conformity Assessment Board (IEC CAB), IEC Technical Committee 31, IECEx, “MARS” group.

Common Regulatory Arrangements – Part six

Market surveillance

44. To monitor proper compliance with the requirements of this model regulation in the marketplace, a network of market surveillance experts in explosion protection (UNECE-

ExMARS) is to be formed and operated (see appendix E.1). Recommendation L, Annex A “Market surveillance clause” recommends the administrative procedures and institutional provisions.

45. In case of critical non-conformance, an international alert system (ExAlertSystem) has to be used to inform all UNECE Members about recently detected risks or faulty products. Certification schemes using the common regulatory objective systems have to implement a procedure to handle safety concerns against products covered by their certificates. Cooperation with UNECE-ExMARS group is obligatory.

Appendix

List of accepted standards and guidelines under maintenance of the UNECE-(IECEX) ExSAG

A.1 Basic concepts and methodology

EN 1127-1, EN 1127-2 (IEC SC 31M project will supersede EN),

A.2 Design requirements for electrical and non-electrical equipment

Electrical Equipment:

IEC 60079-0 - Explosive atmospheres - Part 0: Equipment - General requirements

IEC 60079-1 - Explosive atmospheres - Part 1: Equipment protection by flameproof enclosure "d"

IEC 60079-2 - Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure "p"

IEC 60079-5 - Explosive atmospheres - Part 5: Equipment protection by powder filling "q"

IEC 60079-6 - Explosive atmospheres - Part 6: Equipment protection by liquid immersion "o"

IEC 60079-7 - Explosive atmospheres - Part 7: Equipment protection by increased safety "e"

IEC 60079-11 - Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i"

IEC 60079-13 - Explosive atmospheres - Part 13: Equipment protection by pressurized room "p" and artificially ventilated room "v"

IEC 60079-15 - Explosive atmospheres - Part 15: Equipment protection by type of protection "n"

IEC 60079-18 - Explosive atmospheres - Part 18: Equipment protection by encapsulation "m"

IEC 60079-25 - Explosive atmospheres - Part 25: Intrinsically safe electrical systems

IEC 60079-26 - Explosive atmospheres - Part 26: Equipment with Equipment Protection Level (EPL) Ga

IEC 60079-28 - Explosive atmospheres - Part 28: Protection of equipment and transmission systems using optical radiation

IEC 60079-29-1 - Explosive atmospheres - Part 29-1: Gas detectors - Performance requirements of detectors for flammable gases

IEC 60079-29-2 - Explosive atmospheres - Part 29-2: Gas detectors - Selection, installation, use and maintenance of detectors for flammable gases and oxygen

IEC 60079-29-3 - Explosive atmospheres - Part 29-3: - Gas detectors - Guidance on functional safety of fixed gas detection systems

IEC 60079-29-4 - Gas detectors - Part 29-4: Performance requirements of open path detectors for flammable gases

IEC 60079-30-1 - Explosive atmospheres - Part 30-1: Electrical resistance trace heating - General and testing requirements.

IEC 60079-30-2 - Explosive atmospheres - Part 30-2: Electrical resistance trace heating - Application guide for design, installation and maintenance.

IEC 60079-31 - Explosive Atmospheres - Part 31: Equipment dust ignition protection by enclosure "t"

- IEC/TS 60079-32-1 - Explosive atmospheres - Part 32-1: Electrostatic hazards, guidance
- IEC 60079-32-2 - Explosive atmospheres - Part 32-2: Electrostatics hazards – Tests
- IEC 60079-33 - Explosive atmospheres -Part 33: Equipment protection by special protection 's'
- IEC 60079-35-1 - Explosive atmospheres - Part 35-1: Caplights for use in mines susceptible to firedamp – General requirements - Construction and testing in relation to the risk of explosion
- IEC 60079-35-2 - Explosive atmospheres - Part 35-2: Caplights for use in mines susceptible to firedamp – Performance and other safety – related matters
- IEC TS 60079-40 - Explosive atmospheres - Part 40: Requirements for process sealing between flammable process fluids and electrical systems
- IEC TS 60079-42 - Explosive atmospheres - Part 42: Electrical safety devices for the control of potential ignition sources for Ex-equipment
- IEC TS 60079-43 - Explosive atmospheres - Part 43: Equipment in adverse service conditions
- IEC TS 60079-46 - Explosive atmospheres - Part 46: Equipment assemblies
- Non-electrical equipment:
- ISO 80079-36 - Explosive atmospheres - Part 36: Non-electrical equipment for explosive atmospheres - Basic method and requirements
- ISO 80079-37 - Explosive atmospheres - Part 37: Non-electrical equipment for explosive atmospheres – Non electrical type of protection constructional safety 'c', control of ignition source 'b', liquid immersion 'k'
- ISO/IEC 80079-38 - Explosive atmospheres - Part 38: Equipment and components in explosive atmospheres in underground mines
- ISO/IEC 80079-41 - (EN 1834 All parts) Explosive atmospheres - Part 41. Reciprocating internal combustion engines

A.3 Production of equipment

- ISO/IEC 80079-34 - Explosive atmospheres - Part 34: Application of quality management systems for Ex product manufacture

B.1 Material characteristics for gas and vapour classification

- ISO/IEC 80079-20-1 - Explosive atmospheres - Part 20-1: Material characteristics for gas and vapour classification - Test methods and data
- ISO/IEC 80079-20-2 - Explosive atmospheres - Part 20-2: Material characteristics - Combustible dusts test methods

B.2 Classification of areas

- IEC 60079-10-1 - Explosive atmospheres - Part 10-1: Classification of areas - Explosive gas atmospheres
- IEC 60079-10-2 - Explosive atmospheres - Part 10-2: Classification of areas - Explosive dust atmospheres

B.3 Electrical installations design, selection and erection

- IEC 60079-14 - Explosive atmospheres - Part 14: Electrical installations design, selection and erection

B.4 Electrical installations inspection and maintenance

IEC 60079-17 - Explosive atmospheres - Part 17: Electrical installations inspection and maintenance

B.5 Equipment repair, overhaul and reclamation

IEC 60079-19 - Explosive atmospheres - Part 19: Equipment repair, overhaul and reclamation

C.1 Conformity assessment standards

ISO/IEC 17065 Conformity assessment - Requirements for bodies certifying products, processes and services

ISO/IEC 17021-1 Conformity assessment - Requirements for bodies providing audit and certification of management systems – Part 1: Requirements

ISO/IEC 17024 Conformity assessment - General requirements for bodies operating certification of persons

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

ISO/IEC 17043 Conformity assessment - General requirements for proficiency testing

C.2 Fundamentals of product certification

ISO/IEC 17067 Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes

E.1 Guidelines for market surveillance

Guidelines for market surveillance are prepared by this Sectoral Initiative in cooperation with the MARS group.

F.1 Rules of Procedures and Operational Documents by IECEx

IECEX 02 - IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEX System) IECEx Certified Equipment Scheme covering equipment for use in explosive atmospheres – Rules of procedure

IECEX 03-3 - IECEx Certified Service Facilities Scheme – Part 3: Ex installation and initial inspection – Rules of Procedure

IECEX 03-4 - IECEx Certified Service Facilities Scheme – Part 4: Ex inspection and maintenance – Rules of Procedure

IECEX 03-5 - IECEx Certified Service Facilities Scheme – Part 5: Repair, overhaul and reclamation of Ex equipment – Rules of Procedure

IECEX 05 - IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEX System) IECEx Scheme for Certification of Personnel Competence for Explosive Atmospheres – Rules of Procedure

IECEX 04 - Regulations - IECEx Conformity Mark Licensing System

The suite of IECEx Operational Documents, (ODs) can be found at www.iecex.com