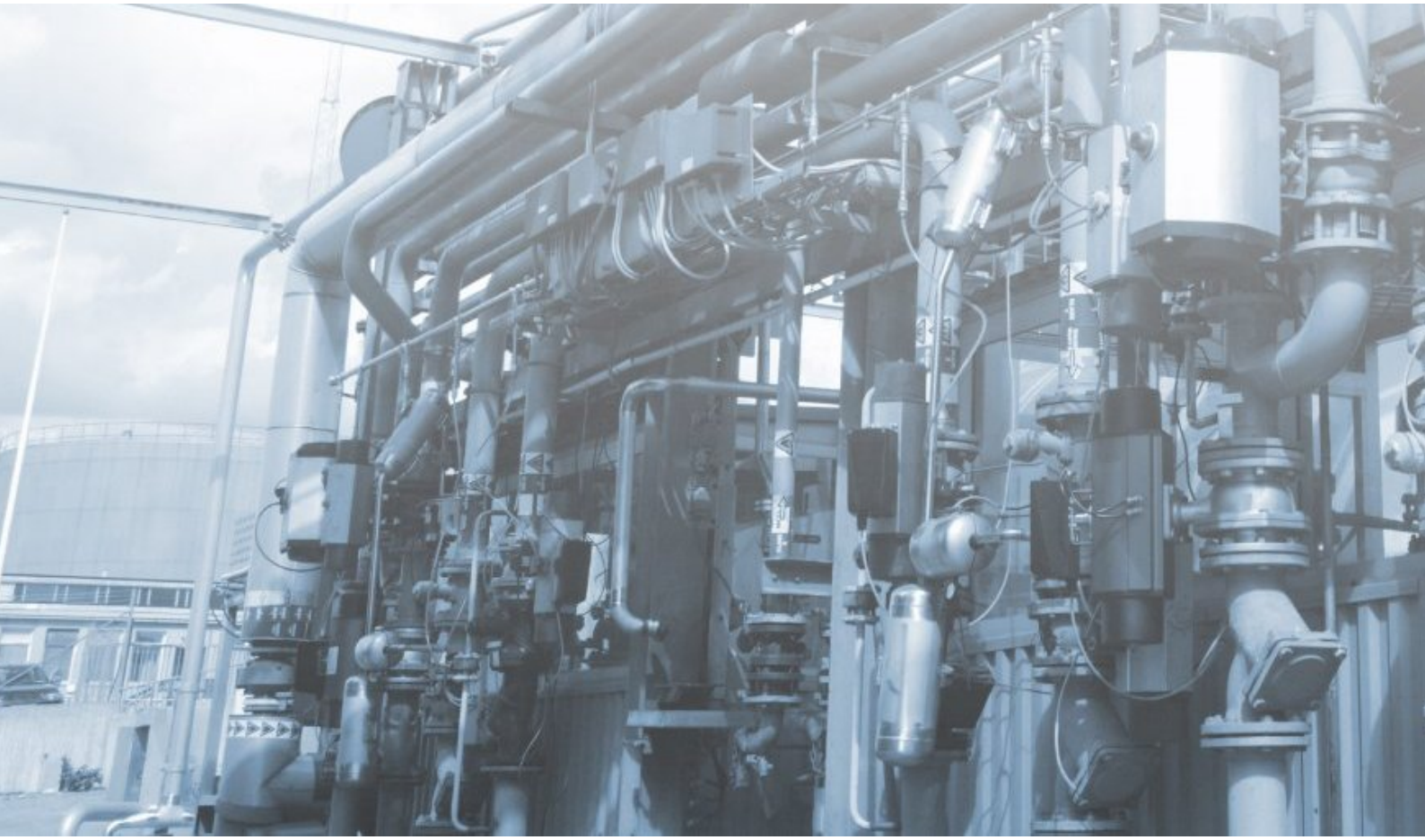
UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE

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



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UNITED NATIONS
New York and Geneva 2011

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The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies and operates Conformity Assessment Systems. IECEx is the IEC worldwide certification system covering Equipment, Services and Personnel associated with the use of Equipment in Explosive Atmospheres. Further information on IEC and its IECEx Conformity Assessment System may be obtained via:

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A common regulatory framework for equipment used in environments with an explosive atmosphere

The United Nations, through the United Nations Economic Commission for Europe (UNECE), is a multilateral platform that facilitates greater economic integration and cooperation among Member States and promotes sustainable development and economic prosperity.

The UNECE Working Party on Regulatory Cooperation and Standardization Policies (WP. 6) has worked in close cooperation with the International Electrotechnical Commission (IEC) and the IEC System for Certification to Standards relating to Equipment for Use in Explosive Atmospheres (IECEx) to develop a model for legislation in the sector of equipment used in environments with an explosive atmosphere. The Model has been adopted by the WP. 6 at its 20th session, in November 2010. The text is contained in this publication. The model provides for adequate risk mitigation, without creating excessive costs or red tape for business.

Any Member State that has no regulatory framework in the explosive equipment sector can use the model as a blueprint for legislation. If countries already have such a framework, they could consider gradually converging towards this international model. Once the model has been adopted as national legislation, the sector will operate under a single common regulatory framework in all participating countries.

Background

Recent explosion-related industrial accidents throughout the world have caused unprecedented environmental damage and cost many lives. While national regulations exist in some countries, there is an urgent need for an international approach to increase safety wherever workers and communities are exposed to high risk of explosions occurring.

Mines and offshore facilities are obvious places where explosions can occur. But they could also happen where flammable liquids, vapours, gases or combustible dusts are likely to occur in quantities sufficient to cause a fire or explosion; for instance, in the chemical and oil industry, gas stations, facilities for handling and storage of grains, woodworking areas and sugar refineries.

The equipment used in these environments and the overall design of the plants is increasingly based on a single engineering approach and on the fundamental principles of explosion protection, which have been applied in industry and mines for over 100 years. These are codified in international standards such as the International Electrotechnical Commission (IEC) 60079 series, and conformity assessment best practice such as the International Organization for Standardization (ISO) System No. 5 for product certification schemes – including IECEx.

Many national and regional regulations already use the technical requirements contained in the International Standards drawn up by IEC. However, national laws and regulations are still diverging, and at times indeed conflicting in their requirements. In addition, many regulatory environments emphasize the mandatory approval by domestically recognized notified bodies of all imported equipment.

This makes it difficult to open markets for explosion-protected equipment and services and is against the interest of both industry and consumers.

Objectives

The UNECE Working Party 6 established a “sectoral initiative” to tackle existing challenges in this sector. Specifically, the project aimed at:

- Fostering the use of relevant IEC and ISO International Standards by the industry.
- Promoting a globally harmonized legislation.
- Ensuring mutual acceptance of test procedures and test results among the test houses.
- Striving for comparable installation, maintenance and repair procedures of the equipment.

Achievements of the UNECE sectoral initiative

The UNECE Working Party on Regulatory Cooperation and Standardization Policies (WP. 6):

- Approved the common regulatory objectives at its session in 2009 and amended them at its 2010 session.
- Collected information about the legal framework in force in the main markets (including the European Union, North America, the Russian Federation and Australia). This information is available on the Working Party’s website http://www.unece.org/trade/wp6/SectoralInitiatives/EquipmentForExplosiveEnvironment/SIEEE_updatedreplies.pdf.
- Established a partnership with the International Electrotechnical Commission System for Certification to Standards relating to Equipment for Use in Explosive Atmospheres (IECEx System) which has been actively supporting the project since its establishment.

Current activities

UNECE is launching a project on organizing awareness-raising and capacity-building events worldwide. The project will aim at showing regulatory authorities the high risks and challenges that are inherent in the sector, and highlighting best practice in industry, standardization and certification bodies.

Common Regulatory Objectives

1 Background

1. Explosion protection is an essential part of the overall risk management to be conducted for industrial plants and appliances, to ensure safety in industrial processes using or producing hazardous materials like – for example – combustible gas, dusts or vapours.
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) 60079-0 series, and conformity assessment best practice such as the International Organization for Standardization (ISO)/IEC Guide 67. They are also at the basis of product certification systems – such as the IECEx, the IEC System for Certification to Standards relating to Equipment for Use in Explosive Atmospheres, www.iecex.com.
3. 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 44 countries as of April 2009, either participating or observing. Further information concerning the work of IEC TC 31 can be found at www.iec.ch.
4. Many national and regional regulations already use the technical requirements contained in the international standards drawn up by IEC TC 31, which, in cooperation with ISO, also develops standards covering non-electrical equipment (mechanical).
5. 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.
6. Countries use standards in their regulations in different ways, including:

    a) by making standards mandatory through a legislative act;

    b) 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.

2 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, as well as costs. It will also increase the safety of the installations and the well-being of personnel working in the sector, as well as that of the communities living near the installations.

3 Scope statement of the Common Regulatory Objectives contained in this document

8. The Common Regulatory Objectives (CROs) presented in this document have been drawn up in accordance with Recommendation 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 purpose of the CROs 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.

10. The CROs 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.

11. The CROs address the requirements both for electrical and mechanical equipment being placed on the market (part one of the present document) and for the safe installation and use of the equipment in the workplace (part two of the present document).

12. 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, in accordance with IEC 60079-10 Parts 1 + 2". This concept classifies hazardous locations as high, medium and low risk zones based on a standard risk-assessment methodology.

13. Additionally, the present document is based on the life-cycle approach, which requires proper inspection, maintenance and repair of explosion protected equipment. This approach guarantees effective and efficient explosion protection and the elimination of potential ignition risk, at all times when a facility or product is in use.

14. 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.

15. 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.

16. 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.

17. 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 Competencies Scheme.

18. One final and essential element of the present document relates to market surveillance. Market surveillance is necessary to monitor the proper application of the CROs by industry and increase confidence in the effectiveness of the CROs. 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 Objectives – Part one
Requirements for placing products and equipment on the market

A. Definition of applicable standards

19. 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).

20. To eliminate the ignition sources, validated protection concepts (“types of protection”) have to be applied, as laid down in applicable IEC International Standards or other international standards (see appendix A.2). 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).

21. The documentation accompanying the equipment has to cover instructions about the intended use, and details for installation 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.

B. Definition of applicable conformity assessment procedures

22. Compliance with this CROs shall be by use of an international certification scheme such as the IECEx for direct market acceptance of products carrying IECEx Certification. 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 Objectives – Part two
Requirements for the safe use of the equipment

23. 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).

24. If it is not possible to avoid explosive atmospheres, the different risk levels in an area according the IEC Zone classification concept have to be assessed by applying the applicable IEC International Standards (see appendix B.2).

25. 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 (see appendix B.3).

26. The equipment has to be installed properly by taking into account specific local conditions (e.g. ambient temperature, potentially aggressive materials) and the intended use of the equipment, specified in the product documentation (see appendix B.3).

27. 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).

28. 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. 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. 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.

29. 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). 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 (see appendix B.5). 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.

30. 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".

Common Regulatory Objectives – Part three
Reference list to international standards providing the presumption of conformity with this regulation model

31. 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.
32. The group of countries that have implemented this regulation model shall form a 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.

Common Regulatory Objectives – Part four
Recognition of conformity assessment bodies

33. The accreditation of conformity assessment bodies and test laboratories has to follow the applicable ISO/IEC International Standards (see appendix D.1). The accreditation body has to be member of International Laboratory Accreditation Cooperation/International Accreditation Forum (ILAC/IAF). One member of the assessor team needs competence in the field of explosion protection (see e.g. the list of approved IECEx Assessors).
34. Certificates have to be in line with ISO System No. 5 requirements of the applicable ISO/IEC Guide (see appendix D.2).
35. The use of the IEC Conformity Assessment System IECEx provides the presumption of conformity with the requirements of Part four.

Common Regulatory Objectives – Part five
UNECE Explosion Protection Steering Committee

36. 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.
37. The ExSC agrees on a constitution and other governing rules and procedures of the daily operations (e.g. voting procedures).
38. The ExSC notifies the members of the UNECE Standard Acceptance Group (UNECE-ExSAG).
39. 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 Objectives – Part six
Market surveillance

40. 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 F.1).

41. 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.

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, IEC 60079-1, IEC 60079-2, IEC 60079-5, IEC 60079-6, IEC 60079-7, IEC 60079-11, IEC 60079-15, IEC 60079-18, IEC 60079-25, IEC 60079-26, IEC 60079-27, IEC 60079-28, IEC 60079-29-1, IEC 60079-29-4, IEC 60079-30-1, IEC 60079-31, IEC 61241-0, IEC 61241-4, IEC 61241-11, IEC 62013-1

Non-electrical equipment:

EN 13463-1, EN 13463-5, EN 13463-6, EN 13463-8, EN 14373, EN 14460, EN 14797, EN 14994, EN ISO 16852 (IEC/SC 31M project, developing ISO/IEC 80079-36, ISO/IEC 80079-37 and 80079 series, will supersede EN)

A.3 Production of equipment

EN 13980 (IEC SC 31M project, developing ISO/IEC 80079-34, will supersede EN)

B.1 Material characteristics for gas and vapour classification

IEC 60079-20-1, EN 13821, EN 14034 (IEC MT 80079-20-2 project, developing IEC 60079-20-2, will supersede EN)

B.2 Classification of areas

IEC 60079-10-1, IEC 60079-10-2

B.3 Electrical installations design, selection and erection

IEC 60079-14

B.4 Electrical installations inspection and maintenance

IEC 60079-17

B.5 Equipment repair, overhaul and reclamation

IEC 60079-19

D.1 Conformity assessment standards

ISO/IEC Guide 65, ISO/IEC 17021, ISO/IEC 17024, ISO/IEC 17025

D.2 Fundamentals of product certification

ISO/IEC Guide 67

F.1 Guidelines for market surveillance

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