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Regulatory cooperation: Sectoral projects

Progress report on the sectoral initiative on Explosive Environments Equipment

Note by the secretariat¹

Summary

Facilities such as mines, refineries, chemical plants and mills, expose their workers and the surrounding areas to high risks. To minimize these risks and contain their potential consequences, all equipment used in these environments needs to be designed, installed, maintained and repaired in a way to avoid the risk of causing an explosion.

The goal of the Sectoral Initiative is to promote and increase safety, while at the same time eliminating barriers to the free trade and use of the equipment.

This document contains a status update on the Initiative. It also includes two annexes: (a) the text of a publication, printed in April 2011 in English only, and containing the common regulatory objectives, approved by the Working Party at its 2010 session; and (b) the proposed Guidelines for Market Surveillance of Equipment for Explosive Environments.

The progress report is submitted to the Working Party for information and discussion.

¹ At its eighteenth session, the Working Party asked the secretariat to provide annual updates on the work of all the sectoral initiatives (ECE/TRADE/C/WP.6/2008/18, para. 63).

I. Project objective and key deliverables

1. Over the last few years, accidents and explosions in mines and offshore facilities throughout the world have cost many lives and caused unprecedented environmental damage. This highlights the urgent need to increase safety in all environments that expose workers and the surrounding areas to high risk. The equipment used in these environments should be made as safe as possible to minimize the risks of explosions and to contain their potential consequences.
2. The equipment used in these environments is highly sophisticated. Checking that it conforms to international best practice and current regulations is a complex task, even for those regulatory authorities who have substantial resources and modern equipment at their disposal.
3. Regulators therefore need to cooperate closely with the industry and independent third-party conformity-assessment bodies, since it is in these two communities that expertise is continuously being updated in accordance with technological progress.
4. The main goal of the Sectoral Initiative on Explosive Environments Equipment is to promote and enhance safety, while at the same time eliminating barriers to the free trade and use of the equipment.
5. Specifically, the purpose of the Sectoral Initiative is to develop and promote a common regulatory framework for the “Equipment for Explosive Environments” sector. The framework includes not only common regulations, but also common and agreed conformity-assessment practices and market-surveillance procedures. As it is based on a shared understanding of the regulatory objectives to be pursued, it will be referred to in the text as “common regulatory objectives” or CROs.

II. Current status of the project

6. At its twentieth session, in 2010, the Working Party approved a revised version of the CROs. This revised version was published in a bound brochure thanks to inkind support from the International Electrotechnical Commission. The brochure – which can be downloaded from the UNECE and on the IEC websites - was launched by the two organizations in April 2011 (see press release: http://live.unece.org/press/pr2009/09trade_p11e.html).
7. The brochure is reproduced in Annex I to this document, for immediate reference especially by the French and Russian-speaking delegates.
8. Additionally, in 2011, the task force also prepared guidelines for market surveillance authorities responsible for equipment used in Explosive Environments (Hazardous Locations). These guidelines will be further discussed and approved to form part of a revised version of the CROs. These guidelines are reproduced as Annex II to this document.
9. Reference materials prepared previously by the Sectoral Initiative are:
 - a compilation of the legal framework in force in this sector on the world main markets in the sector Explosive Environments, available as an annex to document ECE/TRADE/C/WP.6/2009/6, available on the website: http://live.unece.org/fileadmin/DAM/trade/wp6/documents/2009/wp6_09_006E.pdf
 - a project proposal for organizing capacity-building events worldwide to raise awareness by regulators of the high risks and challenges that are inherent to the sector, and highlighting best practice in industry, standardization and certification

bodies. The project proposal is available as an Annex to ECE/TRADE/C/WP.6/2010/12 available at http://live.unece.org/fileadmin/DAM/trade/wp6/documents/2010/wp6_10_012e.pdf.

III. Meetings held in 2011

10. In 2011, the Initiative met in Stockholm, on 5 June, as part of the Annual Planning Meeting of WP.6 activities. It will also organize an event on 7 September in Split, Croatia as part of the Annual Meeting of the International Electrotechnical Commission (IEC) Scheme for Certification to Standards relating to Equipment for Use in Explosive Atmospheres (IECEx Scheme).

11. At the June meeting, the Bureau of the Working Party and the Chair of the ATEX Administrative Cooperation Committee (ATEX ADCO) expressed broad support for the initiative. Some comments on the text of the CROs were noted. Participants said they would like a more formal and structured setting for the work of the Sectoral Initiative, based on stable participation by national members. They also agreed that the CROs should be further revised.

12. At the September meeting, to be held in Croatia, regulators from the world's most important markets will share information about their respective regulatory systems and will discuss how to use the UNECE WP.6 CROs to achieve increased convergence among existing regulatory frameworks.

13. Activities planned for 2012 include two key promotional events, which will be jointly organized by IECEX and UNECE:

- addressing the Petroleum Chemical Industry Committee for Europe (PCIC Europe) at their next annual conference in Prague on 19-21 June 2012
- addressing authorities of the Gulf regions at an event to be held in June 2012 in Dubai.

IV. Deliverables for the annual session

14. The main outcomes of the work of the Initiative in 2011 are the publication of the revised version of the CROs, and the guidelines for market surveillance authorities responsible for equipment used in Explosive Environments (Hazardous Locations).

15. The Working Party is invited to further discuss how to foster an increased convergence in the regulatory frameworks applied in this sector, using the CROs prepared by the Sectoral Initiative.

V. Responsibility for the continuation of the work

16. The current Coordinator of the Sectoral Initiative is Mr. Frank Lienesch.

VI. Role of the secretariat

17. The secretariat will continue supporting the work of the Initiative by trying to raise funds for the proposed project, as well as servicing its meetings (prepare the invitation, agenda and supporting documents) and preparing the reports of the meetings. The website of the Initiative will be kept up to date. The secretariat could assist the Convener in maintaining and developing contacts with the counterparts of the Initiative in the national Governments.

Annex I

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

1. 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.
2. The UNECE Working Party on Regulatory Cooperation and Standardization Policies (WP.6) has adopted a model for legislation in the sector of equipment used in environments with an explosive atmosphere. The text is contained in this publication. The model provides for adequate risk mitigation, without creating excessive costs or red tape for business.
3. 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

4. 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 therefore an urgent need for an international approach to increase safety wherever workers and communities are exposed to high risk of explosions occurring.
5. Mines and offshore facilities are obvious places where explosions may occur. But these 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, among others.
6. The equipment used in these environments and the overall design of the plants is increasingly based on a single engineering approach. This is based on the basic principles of explosion protection, which have been applied in industry and mines for over 100 years, and 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, the IEC System for Certification to Standards relating to Equipment for Use in Explosive Atmospheres.
7. 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. Additionally, many regulatory environments emphasize the mandatory approval by domestically recognized notified bodies of all imported equipment.
8. This makes it very difficult to open markets for explosion protected equipment and services and is against the interest of industry as well as of the consumers.

Objectives

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

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

Achievements of the UNECE Sectoral Initiative

10. The UNECE WP.6:

- (a) Approved the common regulatory objectives at its session in 2009 and amended them at its 2010 session;
- (b) 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
- (c) Established a partnership with the IEC 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

11. The UNECE aims at developing a project to raise awareness and build capacity worldwide among regulatory authorities responsible for this sector. Activities such as workshops and online courses will alert regulatory authorities about the high risks and challenges that are inherent in the sector, and share best practice available internationally with the local industry, standardization and certification bodies, test houses etc.

Common Regulatory Objectives

Background

12. 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.

13. 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 IEC 60079-0 series, and conformity assessment best practice such as the 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.

14. 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.

15. 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).

16. 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.

17. 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.

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

18. 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.

Scope statement of the Common Regulatory Objectives contained in this document

19. The Common Regulatory Objectives (CROs) presented in this document have been drawn up in accordance with Recommendation L of the WP.6 of the UNECE (ECE/TRADE/378 – UNECE Recommendations on Standardization Policies).

20. 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.

21. 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.

22. 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).

23. 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”.² This concept classifies hazardous locations as high, medium and low risk zones based on a standard risk-assessment methodology.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. 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

30. 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).

31. 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

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

System that complies with the requirements of the applicable ISO/IEC International Standard (see appendix A.3).

32. 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

33. Compliance with these 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

34. 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).

35. 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).

36. 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).

37. 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).

38. 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).

39. 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.

40. 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.

41. 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

42. 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.

43. 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

44. 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).

45. Certificates have to be in line with ISO System No. 5 requirements of the applicable ISO/IEC Guide (see appendix D.2).

46. 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

47. 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.

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

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

50. 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

51. 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).

52. 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.

Annex II

Guidelines for Market Surveillance of Equipment for Explosive Environments (Hazardous Locations)

1. According to Recommendation L, market surveillance should be included as a flanking area of the Common Regulatory Objectives. The Guidelines are therefore proposed to complement to the CROs and – after further discussion and approval – would become an integral part of the CROs.
2. The Guidelines are based on the general approach of UNECE MARS Group and on the Procedural Guidelines for Market Surveillance within the scope of the 11th Ordinance on the Equipment and Product Safety Act (GPSGV) available at: http://ec.europa.eu/enterprise/sectors/mechanical/files/atex/guidelines_market_surveillance_en.pdf.
3. These guidelines are still at an early stage of elaboration and should be considered as the basis for further discussion and activities. Additional inputs are encouraged and appreciated.

I. Introduction

4. The Guidelines for Market Surveillance for Equipment for Explosive Environments aim at assisting Market Surveillance Authorities (MSAs) in organizing and carrying out their activities.
5. In most countries MSAs have limited human resources, technical equipment and operational resources. Effectively monitoring this sector, however, requires a thorough understanding of safety requirements and is a particularly demanding responsibility.
6. As noted in paragraph 13 of the CROs, most countries base their regulations on international standards, complemented by additional requirements. These guidelines aim then at associating the international standards more closely to the various functions undertaken by MSAs.

II. Actions of the MSAs

7. As per the paragraph 24 of the CROs, the safety of workers and workplaces in this sector requires a “life-cycle approach”. In this context, regulators, business operators, conformity assessment bodies (CABs) and MSAs have each their own responsibilities. The product life cycle starts with placing the product on the market, followed by its correct installation, maintenance, overhaul and repair.
8. The actions of the MSAs can be divided in a proactive and a reactive phase. All kinds of activities up to the time of the delivery to the user can be defined as pro-active. Reactive activities instead are aimed at addressing actual and suspected non-conformities.

A. Pro-active

9. During the pro active phase the MS should base their inspection activities on a number of sources, including:

- (a) Trade directories: list of manufacturers dealing with Ex-equipment;
- (b) Internet/catalogues: analysis of products manufactured by business;
- (c) Fairs: Understanding of market trends;
- (d) Manufacturer inspections: Information about the production processes.

10. A comprehensive overview of the market players and cooperation with all stakeholders – and in particular with CABs - is essential to support market surveillance actions. CABs have a sound understanding of the technical aspects of the product and up-to-date information about market trends.

11. MSAs should cooperate closely with CABs, particularly in the field of technical support where the MSA has no technical capacity to test the equipment. When this option is used, a system has to be devised and put in place to guarantee the independence of activities with respect to tests of suspected non-conforming products. Preferentially a governmental CAB or a designated “non-profit” CAB fulfils criteria of highest integrity.

12. MSAs shall prepare a public list of contact persons to whom the stakeholders can announce possibly non-conform equipment. Care should be taken to protect the anonymity and secrecy of these announcements.

B. Reactive

13. The purpose of the pro-active phase is to get an overview about the market activities and to establish a procedure with respect to technical support of selected conformity assessment bodies or comparable independent testing organisations.

14. Once the legal capacity is in place the MSA can define a reactive strategy to address suspected non-conformity of equipment.

15. Equipment that is announced or suspected to be non-conforming has to undergo an inspection. The inspection procedure is divided into formal and technical requirements. Once a non-conformity of the equipment is determined the MSA shall contact the manufacturer and demand a statement about the product non-conformity. Depending on the relevance of the safety issues of the non-conform equipment further steps may be deemed necessary.

16. A further explanation of the steps is available in the MARS Group “Guide to General Market Surveillance Procedure” document.

III. Cooperation and Exchange of Experience (with other stakeholders)

17. The MSA shall endeavour to cooperate with the other stakeholders and shall participate in national meetings, working groups and conferences (like for example technical committees). Continuous presence – also through the press and specialized media – contributes to making MSAs visible. MSAs should give an input to the national standardization groups to influence national safety concerns about the equipment.

18. Additionally the international cooperation among MSA is indispensable. The ATEX Administrative Cooperation Group on Market surveillance (ADCO) in the European Union sets a good example: see: http://ec.europa.eu/enterprise/sectors/mechanical/documents/contacts/atex-competent-authorities/index_en.htm.

A. Internet platform

19. A national internet platform has proved to be a useful tool. The internet platform should contain all necessary information about the MSAs activities, as well as a list of the contact persons to facilitate contacts with stakeholders.

20. The national internet platform should also contain links to websites of organizations that are active in the field of market surveillance (such as the MARS Group) and in that of Equipment used in Explosive Environments (like IECEEx).

B. Arbitration Board

21. In the case of non conforming equipment or unclear technical specifications about the equipment an arbitration board is yet another helpful tool, and is particularly effective at preserving the interest of stakeholders.

22. The decisions and recommendations of the Arbitration Board should be published on the internet platform.

23. The responsibility for consequences of a decision to withdraw equipment from the market should remain with the MSAs.

C. Alert-System

24. As non-conforming equipment may impact the safety of workers or workplaces, it is important that contingency plans and a public alert system be set up. Guidance on contingency plans for regulatory systems can be found in the Recommendations from the Group of Experts on Risk Management in Regulatory Systems established under WP. 6 (see Draft Recommendation on Crisis Management in Regulatory Systems ECE/TRADE/C/WP.6/2011/14).

25. The internet platform can also be used as one means of reacting to a contingency, among others, as it may be useful in organizing the necessary actions to address the products' non-conformity.

IV. Definition of Ex-Equipment and the boundary conditions

26. The safety of plants in the chemical or petrochemical industry depends upon a clear identification and assessment of potential risks. A risk of explosions can be determined by the existence of an explosive atmosphere together with an ignition source. The necessary level of safety of the equipment needs to be proportionate to level of risks of the different parts of the plant. To this effect, the "Zone concept" was established and is explained briefly below.

27. Some of the equipment used in explosive environments can't be clearly attributed to the "Ex-Sector". MSAs should define a reference list for "borderline" equipment and products. A possible reference can be found in the one prepared by the ATEX-ADCO – Group: see:

http://ec.europa.eu/enterprise/sectors/mechanical/documents/guidance/atex/application/annex2/index_en.htm

A. Zone Concept (Essential Requirements)

28. The Zone Concept was established to assess the likelihood of an explosive atmosphere occurring. Therefore the plants need to establish a document showing the various Zones in the field. The Zones are defined as follows:

(a) Zone 0: A place in which an *explosive atmosphere* consisting of a mixture of air with flammable substances in the form of gas, vapour or mist is present continuously or for long periods or frequently. Zone 0 conditions generally arise only inside containers or plant (evaporators, reaction vessels, etc.), but can also occur near vents and other openings.

(b) Zone 1: A place in which an explosive atmosphere consisting of a mixture with air of flammable substances in the form of gas, vapour or mist is likely to occur in normal operation occasionally. This may include:

- (i) The immediate vicinity of zone 0.
- (ii) The immediate vicinity of feed openings.
- (iii) The immediate area around fragile vessels or pipes made of glass, ceramics, and the like, unless the contents are too small to form a hazardous explosive atmosphere.
- (iv) The immediate area around inadequately sealed glands, e.g. at pumps and valves.
- (v) The inside of plant such as evaporators or reaction vessels.

(c) Zone 2: A place in which an explosive atmosphere consisting of a mixture with air of flammable substances in the form of gas, vapour or mist is not likely to occur in normal operation but, if it does occur, will persist for a short period only. Zone 2 may include, e.g. places surrounding zones 0 or 1.

(d) Zone 20: A place in which an explosive atmosphere in the form of a cloud of combustible dust in air is present continuously, or for long periods or frequently. Example: in general, these conditions arise only inside containers, pipes, vessels, etc., i.e. usually only inside plant (mills, dryers, mixers, pipelines, silos, etc.), when explosive dust mixtures in hazardous quantities can form continuously, over long periods or frequently.

(e) Zone 21: A place in which an explosive atmosphere in the form of a cloud of combustible dust in air is likely to occur in normal operation occasionally. Example: this zone can, for example, include places in the immediate vicinity of e.g. powder filling and emptying points and places where dust deposits occur and in normal operation give rise occasionally to an explosive concentration of combustible dust when mixed with air.

(f) Zone 22: A place in which an explosive atmosphere in the form of a cloud of combustible dust in air is not likely to occur in normal operation but, if it does occur, will persist for a short period only. This zone can include, e.g. places in the vicinity of plant containing dust, if dust can escape at leaks and form deposits in hazardous quantities.

29. Further information about the specification of the Zones can be found in IEC 60079-10-1 and -2.

B. Types of Protection (Applicable Standards)

30. The likelihood of an explosive atmosphere and the consequences of a hazard determine the requirements of the equipments. The actual standards of equipment for hazardous locations define the Explosions Protection Level (EPL) for the equipment. The

EPL describes the level of safety and distinguish dust “D”, gas “G” and mines “M” together with the 3 levels a, b and c.

(a) “Very high” level of protection. The product has to be safe with respect to normal operation, expected malfunctions or rare malfunctions. To independent faults/malfunctions are assumed;

(b) “High” level of protection. The product has to be safe with respect to normal operation or expected malfunctions. One faults / malfunctions is assumed;

(c) “Enhanced” level of protection. The product has to be safe with respect to normal operation.

31. Additionally to the EPL the temperature class and gas groups are elementary. The temperature class (T1 ... T6) of the equipment has to be lower than the auto ignition temperature of the relevant gases. The gas groups IIA, IIB or IIC divide the various gases with respect to the ignition energy and the transmission of the flame through a flame path (flameproof protection).

32. The product is principally specified for an ambient temperature of -20°C to 40°C if not otherwise documented.

33. The Ex-marking shall include the following information in accordance to IEC 60079-0:

- (a) Ex;
- (b) Types of protection;
- (c) Temperature Class;
- (d) Gas Group;
- (e) Explosion Protection Level.

34. Variations to the general procedure are explained in the standard.

35. The following Types of Protection are suitable to protect the equipment for hazardous locations. They are specified in the IEC 60079-0 (general requirements) and following (types of protection). Some examples of the types of protection with a short description of the protective measures are listed:

(a) Flameproof protection “d”: Explosion-proof design, the transmission of flames to the outside environment is prevented, maximum gap dimensions are determined, the maximum surface temperature is limited, subdivision in ‘d IIA’, ‘d IIB’, ‘d IIC’ corresponding to the explosion group of the potentially explosive mixture;

(b) Pressurization “px, py or pz”: Overpressure of an inert gas or air inside equipment with a monitoring device, penetration of explosive atmosphere is impossible:

- (i) ‘px’- Zone 1 is reduced to ‘non-explosive’;
- (ii) ‘py’-Zone 1 is reduced to Zone 2;
- (iii) ‘pz’-Zone 2 is reduced to ‘non-explosive’.

36. The maximum surface temperature is limited, maximum component temperatures are limited, simplified Category 3 equipment possible (pz).

(a) Increased Safety “e”: No sparks or arcs during normal operation, clearance and creepage distances are determined, the maximum surface temperature is limited, maximum component temperatures are limited, special requirement for windings (conductor cross-section, insulation property, impact strength);

(b) Intrinsic Safety “T”: Sparks allowed during normal operation, live working possible, current and voltage are limited, internal and external inductance and capacity are limited, the maximum surface temperature is limited, maximum component temperatures are limited, Category 1 equipment possible;

(c) Type of protection “n”:

(i) nA: Non-sparking apparatus;

(ii) nR: Sparking apparatus with restricted-breathing enclosure.

37. The installation of the equipment for hazardous locations has to follow the requirements of the IEC 60079-14. For various types of protection further aspects has to be taken into account.

V. Main elements of inspections and controls (Compliance criteria)

38. MSAs have an important role within the system. A detailed check of the equipment for explosive environments requires adequate test equipment and a sound understanding of the technical requirements. Therefore close co-operation between the MSAs and local active test houses is essential, as mentioned in Para. 11 above. When cooperation is well established MSAs can focus their activities on an initial check to establish whether the product is formally correct. The relevant documents can be a basis for a brief technical inspection. The detailed technical inspection with a retesting of the product can be carried out by a test house.

A. Marking and Certification of Conformity

39. All equipment for explosive environments must be legibly and indelibly marked. The IEC 60079-0 describe the minimum content of the marking of the product. The marking must be in line with the Certification of Conformity. Inconsistent marking requires further actions.

B. Manual/Instruction

40. All equipments should be accompanied by an instruction manual. This instruction manual should include all relevant information about the equipment e.g.

(a) Putting into service;

(b) Use;

(c) Assembling and dismantling;

(d) Maintenance, overhaul and repair;

(e) Installation.

41. A detailed description and explanation of the marking is necessary that the user can classify correctly for the explosive areas in his plant (zones). The instruction must be offered in an English version and if required a nationally adopted language.

C. Technical Inspection

42. In addition to the formal fulfillment of marking and documentation obligations, certain characteristics may be checked, so as to screen manufacturers for suspected non-conformities. The standard IEC 60079-17 can provide a good basis for an initial inspection. The standard describes various levels of inspections namely visual, close and detailed inspection in form of tables.

VI. Further Input

43. An effective market surveillance system needs to be carried out and monitored by qualified civil servants. In contrast to the manufacturer of special equipments MSAs need a general understanding of the operation of equipment. MSAs could benefit from an adequate check lists for the various types of protections or product families. One basis could be the IEC 60079-17 “Electrical installations, Inspection and maintenance” of equipment in explosive environments.
