

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 IECEX).

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 “I”: 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.
