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25 years of ATEX directive: the real role of each stakeholder

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Some general conclusion may be expressed regarding categories of interest and their contribution regarding explosion prevention and protection. These elements are based on over 25 years of findings regarding Ex regulations through recent revision of ATEX Directive 94/9/CE to 2014/34/EU, standardisation development, Ex product testing and participation in various colleges, observing the whole market and organisation rules in EU.

The actual system is mainly driven by regulators and testing body side, the manufacturer impact, although officially possible, not balance the other two sides.

The delicate balance between market and required safety is illustrated through some key points due to learnt lessons, such as voluntary ATEX certification system, reaction on state of the art changes, certification of specific equipment, potential support from Ex NBs, preferring IEC standard solution instead of clearly defined requirements in ATEX directive, practically not equal market surveillance in all EU countries and some gaps required to enhance actual 1999/92/CE directive.

The start of discussion regarding this topic should be helpful mainly for manufacturers and end users to reach some practical situations and/or to solve some practical problems.

Keywords: *explosion hazards, regulation, best practice, conformity assessment*

Foreword

The scope and the objective of the ATEX Directive remain unchanged from the previous Directive 94/9/EC to the new Directive 2014/34/EU, to ensure free movement for the products to which it applies in the EU territory. Therefore, the ATEX Directive provides for harmonised requirements and procedures to establish compliance for products placed on the EU market for the first time.

The ATEX Directive carries specific obligations for the person (natural or legal) who makes products available on the market and/or puts products into service, be it the manufacturer, its authorised representative, the importer or the distributor. The Directive does not regulate the use of equipment in a potentially explosive atmosphere which is covered by different EU or national legislation: for instance, the ATEX "workplace" Directive 1999/92/EC

It is the duty of Member States to protect, on their territory, the health and safety of persons, especially workers, and, where appropriate, domestic animals and property, especially against the hazards resulting from the use of equipment and systems providing protection against potentially explosive atmospheres.

1. Introduction

The ATEX directive, initially as 94/9/CE, later as 2014/34/EU [1] was implemented or into force in 1 March 1996. Initially, it was used voluntarily (until 2003) to later (from July 1, 2003) become obligatory.

It is important to reminder that this Directive shall apply to the following, hereinafter referred to as “products”:

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(a) equipment intended for use in potentially explosive atmospheres;
(b) protective systems
(c) safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion;
(d) components intended to be incorporated into equipment and protective systems.

During this time some changes took place.

For example, it turned out that the weight of the device's certificate is no longer the same as before, and that for a significant number of products, products certification is not required at all. If we look at the size of explosion hazard zones, we will notice that the largest areas are zones 2 and 22, in which certification or, speaking the language of the ATEX directive, the participation of a Notified Body is not required.

Zoning are optimised but also, they are in line with obligations and recommendations due to environmental codes and protection of workers from hazards.

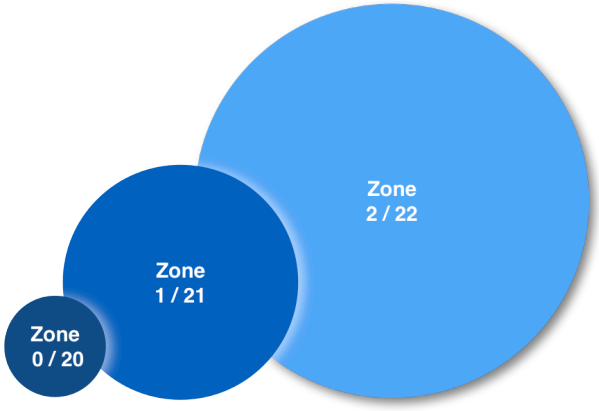

Fig. 1. *An overview of the size of hazardous areas. Zones 2 and 22 are the largest areas.*

2. Findings

The flow chart below indicates the conformity assessment procedures for according to ATEX directive, we can highlight that a large part of products is assessed without third party certification.

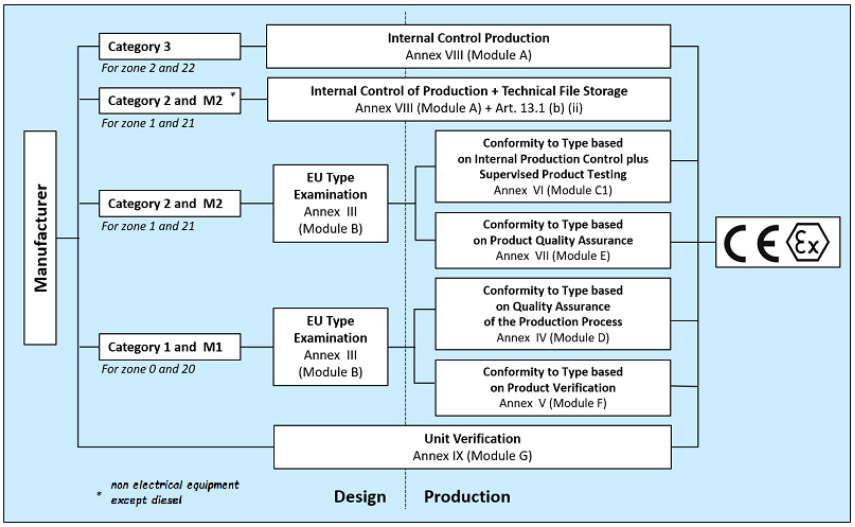

Fig. 2. *An overview of ATEX conformity assessment system.*

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In the specific case of category 3 products intended to be used in zones 2 and/or 22, the manufacturer may make his own assessment and, on this basis, declare the conformity of the product. Therefore, manufacturers had to become proficient in the technical assessment of their products. At the same time, recipients of these products have not relinquished their expectations regarding certification, i.e. assessment by a third party. Hence the quite large "voluntary ATEX certification" market is already important.

Even if tests are used by manufacturers to demonstrate compliance, they need to respect at least principles of requirements regarding quality of tests (e.g. EN 17025) like those observed by testing houses. Rarely, manufacturers are fitted with specific tests facilities dealing with required tests linked to Ex standards.

For complex equipment like a fan, often observed as a source of ignition during accidents survey, we can highlight several cases for which hazards are delicate to prevent.

- The fan can be installed in hazardous area and handled air
- The fan can be installed in hazardous area and handled explosive fluid
- The fan can be installed in safe area and handled explosive fluid

In all cases hazards are present even hidden hazard like electrostatic charges.

In all applications the involvement of Ex agencies should be required to consider requirements of harmonized standard like EN 14986.

3. Actual situation

To harmonize the interpretation of the directive, an ATEX guide has been developed, which has taken on a new shape since the new edition of the directive and makes it easier to understand the provisions of the directive. However, it is only a guide and does not constitute a law. Legal requirements, including technical ones, are given only in the ATEX directive.

Although the technical requirements of the ATEX directives do not change (the update of Directive 94/9 / CE to 2014/34 / EU did not introduce any changes to the technical requirements), the change in the current state of knowledge takes place in the standards harmonized with the directive. Standards are replaced by newer editions, and withdrawn ones are commented that "the presumption of conformity has ceased". This approach imposes on the manufacturer (and notified bodies) the obligation to track changes in the list of harmonized standards, fortunately these changes are communicated in advance.

One of the undoubted advantages of the EU approach to conformity assessment is the increased role of the instruction manual. The requirements for the instruction are one of the essential requirements (EHSR 1.0.6). The buyer of the product agrees to the provisions in the user manual - he must comply with its provisions. If any record or requirement of the user manual is unfavourable for the buyer - it remains only not to buy this product.

The compliance assessment system is partially balanced by market surveillance, whose task is to oust the dishonest participants from the market, i.e. those who unreasonably declare the appropriate level of safety for their products.

It is worth noting, however, that although market surveillance principles are agreed at EU level, each Member State oversees its own market.

4. Actual state of knowledge

The technical requirements contained in Annex II of the ATEX Directive (EHSR) do not change from the very beginning of the Directive. Technical progress, or as the ATEX directive specifies, the

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current state of knowledge is reflected in technical standards, especially in harmonized standards. Let us remind that harmonized standards are standards that were ordered by the European Commission.

The number of harmonized standards has steadily increased, especially in "new" areas, ie for non-electrical equipment and protective systems.

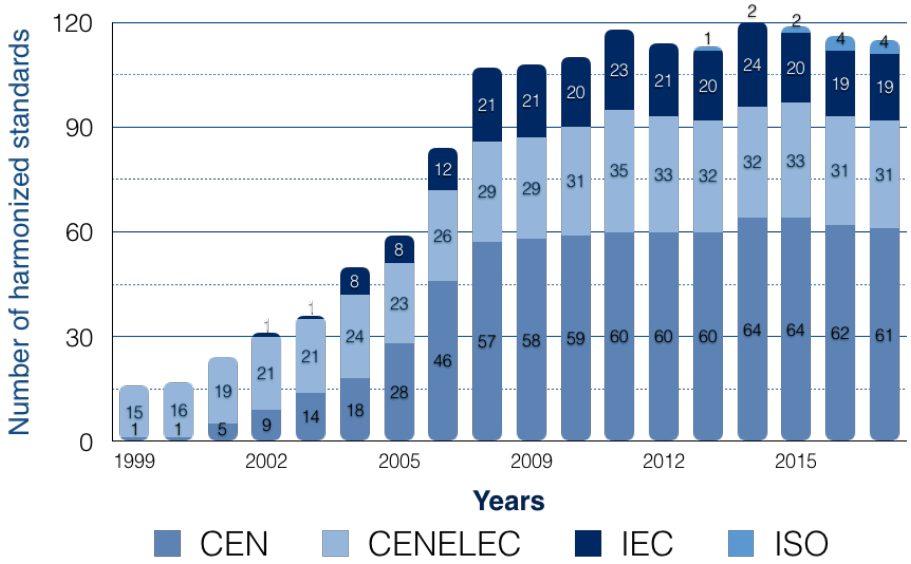

Fig. 3. *Increase in the number of standards harmonized with the ATEX directive over the years: CEN, CENELEC, IEC and ISO standards.*

The current (2020) list of harmonized standards contains 124 items [2]. Considering the average period of 5 years of review and update of standards, virtually every year a standard (or standards) changes.

A change in the current state of knowledge (change in the standard) entails the need for the manufacturer to assess whether the new provisions of the standard relate (i.e. whether they are relevant) to the product of its production.

There is the first discussion point between the manufacturer and NB who took part in the conformity assessment (if any). Does every change of the standard require a re-assessment or even acceptance of the manufacturer's assessment by NB?

Since during the EU type examination a "representative specimen" was tested, only the facts need to be assessed whether it is still "representative" in relation to the new standard. In addition, the standards contain lists of introduced changes with categorization as to whether they are significant changes. A skilled manufacturer has the opportunity to assess whether these changes are significant in relation to his product.

The documentation accompanying the EU-type examination certificate obtained from NB is also helpful for the manufacturer.

The manufacturer's own assessment may also be questioned by NB supervising production. Although, referring to the content of the ATEX directive, can be found that:

> *Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.* (Article 29, p. 2)

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And that:

> *Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies, it shall require the manufacturer…* (Article 29, p. 4)

Moreover:

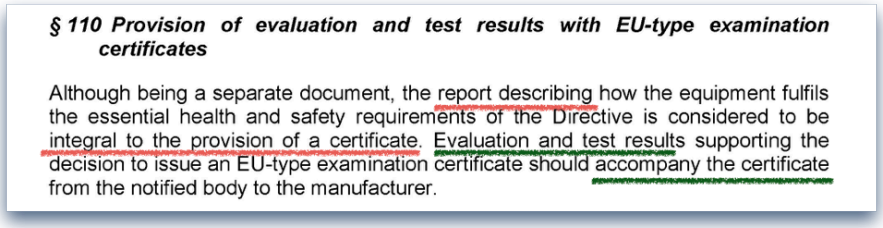
> *The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type …* (Annex III, p. 6)

And finally, what is best for the manufacturer:

> *The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.* (Annex III, p. 7)

That is, the NB supervises the issued certificate and assesses whether it can still be used, and this is not about general supervision, but specific - for each issued certificate. Meanwhile, the generally accepted practice is only general informing by NB as a duty that a new edition of a given standard has been issued - this requirement is not treated by the ATEX directive cited above.

In addition, the unit provides all information used to issue the certificate (the costs of which were borne by the client) - see § 110 ATEX Guidelines [3] - which greatly facilitates the assessment of changes by the manufacturer with the introduction of the new standard. By querying manufacturers, it was confirmed that such documentation was not forwarded. NBs hide behind alleged confidentiality. To the manufacturer who incurred the costs?



§ 110 Provision of evaluation and test results with EU-type examination certificates

Although being a separate document, the report describing how the equipment fulfils the essential health and safety requirements of the Directive is considered to be integral to the provision of a certificate. Evaluation and test results supporting the decision to issue an EU-type examination certificate should accompany the certificate from the notified body to the manufacturer.

Fig.4. *An explanation in the ATEX Guidelines on providing the manufacturer with all information (including test results and assessments) that was used to decide to issue an EU type-examination certificate.*

The gate is open for debate but it is important reminder, that state of art is mandatory. All stakeholders ask for a clarification from EU commission for this issue. To respect the last Ex standard is one of the efficient answers.

5. Manufacturer's impact on the organization of the ATEX system

All interested parties, including manufacturers, governmental bodies (regulators), notified bodies, consumer organizations and recipients, standardization organizations participate in the management of the ATEX directive. The figure below schematically shows the participants involved in managing the directive.

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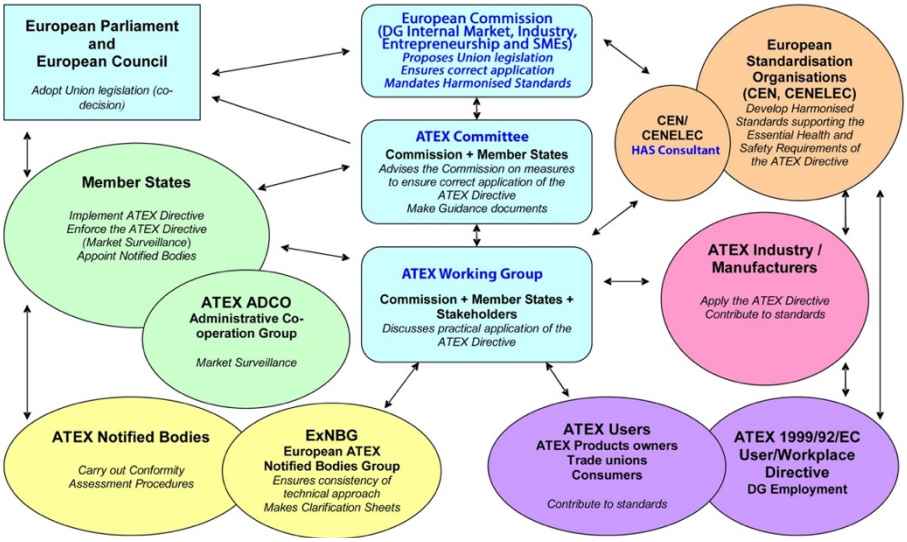

Fig.5. *Management of the ATEX directive - individual participants*

The ATEX Directive uses early (from the beginning of the 20th century) expert knowledge in the construction and testing of explosion-proof electrical equipment. Before the entry into force, these devices were tested, evaluated, certified and kept up with changes in the current state of knowledge. The introduction of the ATEX directive has expanded the area to include non-electric devices and devices for dust atmospheres.

Experts participating in particular bodies come mainly from notified and certification bodies. They participate in the ExNBG group, in the work of the ATEX committee (in support of their government delegations), in the work of the working group of the ATEX committee, in standardization work (CEN and CENELEC). These experts have specialist and unique knowledge. Most often this is their main activity. However, looking from the manufacturer's perspective, the requirements of the ATEX directive are one of the many requirements their product must meet. Hence, manufacturers are not able to match the level of involvement of experts from NB.

The system seems unbalanced, the participation of experts from NB is dominant in view of a much smaller share of manufacturer representatives. This is particularly adverse for small and medium enterprises.

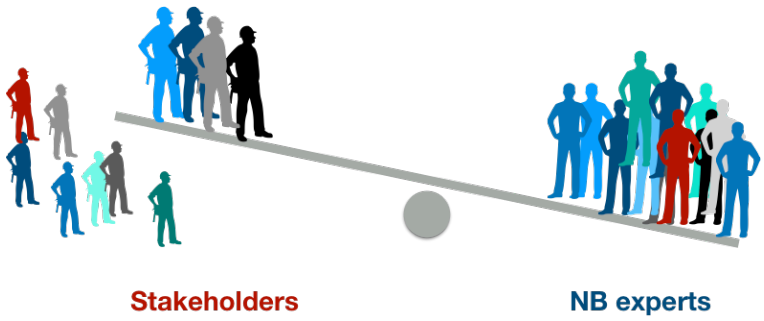

Fig.6. *System imbalance - significantly greater participation and influence of experts from notified bodies than manufacturers*

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Small and medium-sized enterprises are also not properly represented in standardization work. The costs of such activity in the case of SMEs are significant. If the development of standards based on the mutual agreements of CENELEC-IEC and CEN-ISO is beneficial, then the costs of active participation in the work when meetings of committees and working groups take place in various parts of the world outside the EU are already significant.

It is important to reminder that manufacturers must follow all procedures to demonstrate compliance. As a first reminder, it is also important to apply others directives and regulations if any and industrial standards if any before Ex standards.

As a second fact, it is also important to respect routine tests even to verify periodically through internal audit the quality of equipment to put into the market. NB in charge of quality has to share responsibilities, they need to be stricter during audit but also during mandatory unexpected audit through FAT, Ex plants inspections, etc.

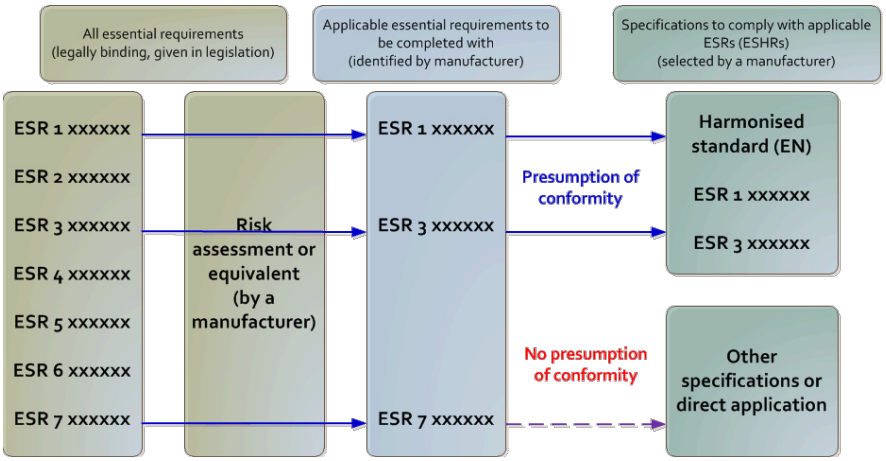

Fig.7. *Manufacturer's risk assessment (Blue Guide [12])*

6. Needs of participants (stakeholders)

Meetings and discussions with manufacturers allowed to indicate the most important support needs in the ATEX directive. The most important are given below.

A. Examples of EU declaration of conformity

According to the manufacturers, the ATEX Guidelines could be supplemented with examples of compliance declarations for various products. The biggest problems for manufacturers are the conformity assessment of assembly, or as defined by the directive for devices built from other devices. It is known that the declaration may take the form of a document file and the (final) manufacturer is only responsible for his part of the device's safety - he does not have to declare again the conformity of the devices used. But what if the final device is partly category 1 and does not create any new sources of ignition (potential or effective). An example of such a product may be a mixer in which all the devices used (propulsion engine, agitator assembly, other accessories) have their own appropriate declarations of conformity and the final manufacturer only assembles these devices in the tank, and each device works in the intended use. How to prepare a declaration of compliance and is NB participation required?

The situation is similar in the case of complex protective systems. Even if all parts of this assembly are already assessed. They have their declarations of conformity, or even EU type-examination certificates and NB control the production process, the function of the system (suppression of the arising explosion) appears only after the elements are interconnected. And this system should be

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evaluated and the manufacturer of this system should be supervised by NB. There is no place for final "suppliers" or "assemblers". Either they become manufacturers or act on behalf of the manufacturer.

B. Equipment user manual

The assessment of the manufacturer's instructions manual is not part of the EU-type[1] . Admittedly, some NBs make such an assessment, but such an assessment is outside the scope of the EU-type examination. The operating instructions are not part of the agreed documentation. However, if NB has assessed such a manual, changes to this manual make it necessary to include changes to the list of scheduled documentation.

Additionally, according to EN 60079-0, a manual should be provided which defines those parts of the user instructions which will ensure safe operation related to explosion protection, including special conditions of safe use and the requirements of EN 60079-0 for instance. Manufacturers may alter their user instructions following issue of the certificate if any provided that the changes do not detract from the requirements for safe operation as defined at the time of certification and provided that changes can be tracked for verification during audits. Any Specific Conditions of Use or Schedule of Limitations cannot be changed

In addition, as users say, copying solutions from outside the EU does not necessarily contribute to improving or maintaining an adequate level of device safety during operation.

If the manufacturer's reference manual for maintenance contains a reference to EN 60079-17 [4], this is not sufficient. The directive explicitly requires that the operating instructions should contain all necessary maintenance information. The product and thus the user will not be exposed to any mistakes resulting from incorrect classification of the product for inspection according to EN 60079-17.

Recall: point 1.06 a) of Annex II of the Directive (EHSR) requires:

> *All equipment and protective systems must be accompanied by instructions ... instructions for safe ... use, assembling and dismantling, maintenance (servicing and emergency repair), installation, adjustment ...*

So, the manufacturer should specify what maintenance (scope, when, conditions) are required for the device.

The same applies to the repair (reclamation) of equipment. If the manufacturer refers to the EN 60079-19 [5] standard in the instruction manual, does it mean that he accepts, for example, repairs that result in a lack of conformity (marking R in a triangle)?

Also, in this case, the recipients expect detailed and approved repair procedures for a given device.

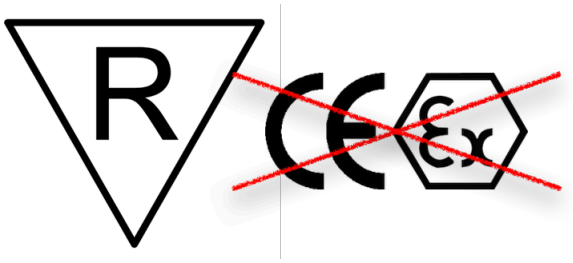

Fig.8. *A post-repair device with explicit conformity marking (R in a triangle) indicates that a significant change has been made.*

At the end, user will perform an assessment to assess the suitability of modified equipment versus zone in view to respect explosion protection document.

[1] Differences between IECEx conformity assessment system and ATEX system are not part of this paper.

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Instructions and EU Declaration of conformity shall accompany the equipment. NB in charge of quality has to share responsibilities regarding these documents. A part of the audit must be dedicated to this issue.

C. Equipment on the borderline between MD and ATEX

The mixer described earlier is a good example of a device that not all manufacturers can handle. If the manufacturer qualifies that there is a "zone 0" inside the mixer instead of saying that the explosive mixture is often or permanently present, does this mean that the user should develop a EPD (Explosion Protection Document required by 1999/92/CE directive) even if no hazard zones are specified in the workplace of the device?

This question always raises lively discussion and it may be time to reactivate the Committee on Directive 1999/92/CE (ATEX users) [6]. Such a committee could be a forum for presenting the views of manufacturers and users. *"Non-binding guide ..."* [7] also requires refreshing after observations of learnt lessons in each European State (e.g. through a survey).

If the purpose of the ATEX users directive is, among others ensuring the absence of technical barriers to the free movement of goods, this approach should be consistent across the EU.

D. ATEX voluntary certification

Since zones 2 and 22 are the largest in terms of area, the voluntary certification market for category 3 equipment is also significant. Users often expect third party confirmation that the products are safe.

Meanwhile, apart from the reservation issued by ExNBG that notified bodies may issue so-called voluntary certificates (however, this decision is questionable from the legal side - NBs decided in the area outside the notification) no common certification program was developed.

This means that each certification body develops its own certification program. This is not an advantageous situation, hence a very good position in the field of voluntary certification of the IECEx certification scheme, in which CBs act equally.

Perhaps in this respect (voluntary certification) it would be possible to create in the EU a group of auditors and a system of mutual evaluation of CBs, as is the case with IECEx. Currently, NBs are assessed at national level using local experts, who, however, most often come from NBs in a given country. The effects of NBs activities cover the entire EU, so maybe we should also ensure the same level of assessment of the competence of individuals with the use of peer evaluation.

This proposal or approach can be tested for countries under MRA as first observation.

E. Distinguishing between modules D and E

An earlier standard EN 13980 [8] specified which areas are subject to assessment for individual modules (D or E). The current EN ISO / IEC 80079-34[2] [9] standard does not specify this requirement - it is precisely specified in the directive.

The EN ISO/IEC 80079-34 standard is used by manufacturers not only for certified products, but also applies to other products (category 3, non-electrical category 2) under voluntary basis.

So why in the scope of NB's assessment of the production system was copied the overall assessment of compliance with this standard from the IECEx certification scheme. NB should operate in a way that does not cause unnecessary burdens for the manufacturer. So, the assessment of the production system (basically technical) should consider the differences in individual modules.

Certainly, the scope of the assessment (audit) used by NB, i.e. the overall assessment of compliance with the EN ISO/IEC 80079-34 standard affects the time of assessment and thus the cost of the audit.

[2] The new edition soon published through annex Z indicates clearly links with directive 2014/34/EU

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Table 1: *Comparison of assessment requirements according to module D and Module E. The differences are highlighted in colour*

Module D	**Module E**
The quality system documentation shall … in particular, contain an adequate description of:	
the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,	
the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,	-
the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,	the examinations and tests that will be carried out after manufacture,
the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and	
the means of monitoring the achievement of the required product quality and the effective operation of the quality system.	the means of monitoring the effective operation of the quality system.

F. Market surveillance

We expect increased market surveillance activity. ATEX products are not sold in stores, most often they are made to order. Honest manufacturers expect their efforts to ensure an appropriate level of product safety to be a market asset and not offset by cost savings in other manufacturers' production costs.

If statistically it is known what number of devices according to ATEX is assessed in a given country over a year, the dishonest manufacturer (if there are any) can estimate the risk of "control". Market surveillance has broad powers and has the right to also apply to assessments carried out by NB - it can verify the correctness of operations. Active market surveillance is also desired by users. They want to be sure that the products they use are properly designed and operated (which they declare in EPD).

According to the data presented in the report [10] in 2014-2016 in 14 EU countries market surveillance controlled 739 devices, 35 devices were subjected to laboratory tests. Unfortunately, still can be found find countries where the number of checks is 0.

Due to that national market surveillance offers a distortion of the market. Only coordination at EU level and specific national support can secure consumers and confidence on the global market.

G. Electrostatic hazards

The scope is well understood by stakeholders, therefore the specific case of ignition due to electrostatic charges is always subject of debate. Even when we know that 40% of accidents are linked to electrostatic charges. It is really the time to assess all equipment/process able to generate this type of ignition. Assessment needs to ask only tests due to the large variety of materials and process involved. A first part of the assessment will be performed under tests (e.g. charge transfer) of equipment or parts of the equipment, a second part of the assessment through tests (continuity, at workplaces described in the explosion protection document.

H. End user’s role

Explosion Protection Document is well implemented to describe hazards at workplaces. The health and safety of persons will need technical and organizational measures to prevent explosion hazards. But all user’s (employer) decision should be based on explosion risk assessment. As answer, training of stakeholders is the key element. COMPEX ISMATEX COPCC and other national qualification schemes are now recognized as positive contribution. This training is also a part of the Explosion Protection Document. Definitions of equipment, installation and maintenance through suitable standards EN60079-14 and -17 and national regulations will secure safety at workplaces.

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7. Summary

The system of free movement of goods in the EU is guaranteed, among others, by the applicable ATEX and ATEX user directives. However, the economic freedoms of manufacturers and users should be balanced by market surveillance activity. This supervision could be particularly attentive to the attached operating instructions. In the interest of safety, they should be more specific.

It is desirable to increase the activity of product manufacturers. So far, decisions taken in the interpretation of the ATEX directive, the provisions of the ATEX Guidelines, are taken with increased influence of experts from notified bodies.

Small and medium-sized enterprises incur high costs of applying standards. Standards are changing, their number is constantly increasing, and their volume also unfortunately translates into increased costs for the purchase of standards. If the standards in some sense constitute a source of requirements (and e.g. in the case of the CPR Regulation, the CJEU has already issued a relevant judgment [11]) then perhaps the standards could be reimbursed to manufacturers in some way. Maybe it would be a good idea to read standards for free, e.g. via a specific internet connection.

As a summary in view to fuel the discussion with the relevant experts.:

a. The high technical level of assessments carried out by NB should be balanced by the activity of market surveillance and greater representation of manufacturers in the ATEX directive decision system.

b. It is expected to reactivate activity (committee) in the field of ATEX user directive 1999/92/CE.

c. Interpretative documents (ATEX Guidelines) should contain more guidelines for manufacturers and end users.

d. If ExNBG agrees on how to deal with manufacturers, the latter should influence these decisions.

e. Regular training of stakeholders will enhance dialogue between interested parts and safety at work places.

f. Complex equipment like fans, forklift, blower, gas turbine should be assessed by 3rd qualified part or certified, a specific survey made by market surveillance authorities can demonstrate the weaknesses of “self-assessment”.

g. Risks due to electrostatic charges shall be assessed by tests.

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[4] EN 60079-17:2014 *Explosive atmospheres -- Part 17: Electrical installations inspection and maintenance*

[5] EN 60079-19:2011 *Explosive atmospheres -- Part 19: Equipment repair, overhaul and reclamation*

[6] Directive 1999/92/Ec of The European Parliament and of The Council of 16 December 1999 *on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres* (OJEU L 23 dated 28.1.2000)

[7] *Non-binding guide to good practice for implementing the European Parliament and Council Directive 1999/92/EC*

[8] EN 13980:2002 *Potentially explosive atmospheres - Application of quality systems*

[9] EN ISO/IEC 80079-34:2011 *Explosive atmospheres - Part 34: Application of quality systems for equipment manufacture (ISO/IEC 80079-34:2011)*

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