How big should Zones be, if there at all? – Practical experience from PharmaChem and Food & Drink sectors

Pat Swords BE CEng PPSE FIChemE, Principal Process and Environment, Health and Safety Consultant, PM Group, Killakee House, Belgard Square, Tallaght, Dublin 24, Ireland
Kayley Oseman AIChemE (Process Safety), Process Safety Engineer, PM Group, Birmingham, UK

Hazardous area classification is much formalised in the Petroleum sector, but the PharmaChem and Food & Drinks sectors in the English speaking world has suffered from a lack of uniformly accepted guidance on applicable zone extents. This paper therefore reviews the latest guidance available in this area from various countries, but also concludes that with a proper risk management strategy, do we need a lot of these zones at all?

1. Introduction

PM Group is an engineering, project management and architectural firm operating in Europe, Asia and the USA and is particularly active in the PharmaChem and Food & Drink sectors. Hazardous area classification is by no means limited solely to the EU's ATEX legislation on explosive atmospheres, there being a much wider global dimension. However, considerable experience in the EU has been gained in the 15 years since the introduction of ATEX and PM Group engineers are now expanding that experience in explosion protection measures in a wider international context. The intent of this paper for Hazards 28 is to share this experience and point to what are emerging trends.

The methodology of hazardous area classification has been with us for quite some time, after all the IEC 60079-10 standard on "Classification of hazardous areas" originally dated to 1972, and is still in an updated form with us today. The problem was, and for many still is, in determining how large the zones should be. For the Petroleum sector, a common approach has been widely accepted and adopted through what is now called the Energy Institute's Model Code of Safe Practice 15 "Area classification for installations handling flammable fluids" (Energy Institute, 2015). Not only was this of limited applicability to non-petroleum sectors, but neither was there an equivalent English language guidance document, which in a similar manner suited the non-petroleum sector.

In this vacuum, a wide range 'solutions' emerged. One could do calculations from first principles, but their validity rested upon a 'crystal ball' with respect to unknown release rates. Exemplars of commonly accepted zonings could be gleaned from a multitude of industry and in-house standards, but were they representative, suitable for the applicable jurisdiction or current? No little confusion resulted and in all too many cases classifications were adopted, which were too conservative and have subsequently led to compliance measures, which were unnecessarily costly and complex.

PM Group has used for many years an internal translation of the very comprehensive German Ex regulations (ExRL), developed originally in the 1950s and 1960s by the Statutory Accident Insurers division of the chemical industry and updated regularly since. The collection of exemplars is very broad ranging from lab scale to large scale production, includes gas, liquid and dust hazards and both the internal and external zoning of equipment. However, it was not something which could be automatically accepted for application outside of Germany.

This changed when IEC 60079-10-1 "Explosive atmospheres - Part 10-1: Classification of areas - Explosive gas atmospheres" was updated in 2015[1], with a new Annex K added listing a range of national and industry codes and clarifying that: *"examples of classification may be accepted in accordance with national or industry codes where their application to the particular situation can be clearly demonstrated"*. This certainly aids in supporting the use of these codes, such as from Germany above, Switzerland and the USA, in a wider international context, many of which have a broader application outside of the Petroleum sector.

An emerging trend though, is that as the specification and quality of process plants improves, do we really need all these external zones and particularly in a GMP environment, large volumes of conditioned air solely on a once through basis? A holistic approach focusing on designing out zones and concentrating on where the hazard actually is, i.e. inside the equipment, actually yields a more appropriate risk reduction.

2. Establishing the 'Context' for Hazardous Area Classification

While hazardous area classification is an important part of the context of overall risk management related to explosion protection, it cannot be seen in isolation from it. Therefore, the starting point needs to be, how as engineers, we should manage risk and demonstrate that we have done so in a competent fashion, such that the residual risk is tolerable. The importance of this tolerable risk has to be understood within the definitions provided by the ISO/IEC Guide 51:2014 "Safety aspects - Guidelines for their inclusion in standards", which defines:

[1] IEC 60079-10-1 ed.2.0 "Copyright © 2015 IEC Geneva, Switzerland. www.iec.ch"

- *"Residual risk: Risk remaining after risk reduction measures have been implemented.*
- *Safety: Freedom from risk which is not tolerable.*
- *Tolerable risk: Level of risk that is accepted in a given context based on the current values of society".*

The same ISO/IEC guidance points out, as to how tolerable risk can be determined, not just by the current values of society, but also by:

- *"The search for an optimal balance between the ideal of absolute safety and what is achievable;*
- *The demands to be met by a product or system;*
- *Factors such as suitability for purpose and cost effectiveness".*

As to how we go about this in practice, ISO 31000:2009 "Risk management – Principles and guidelines" then goes on to provide us with the necessary principles, framework and process for managing risk.

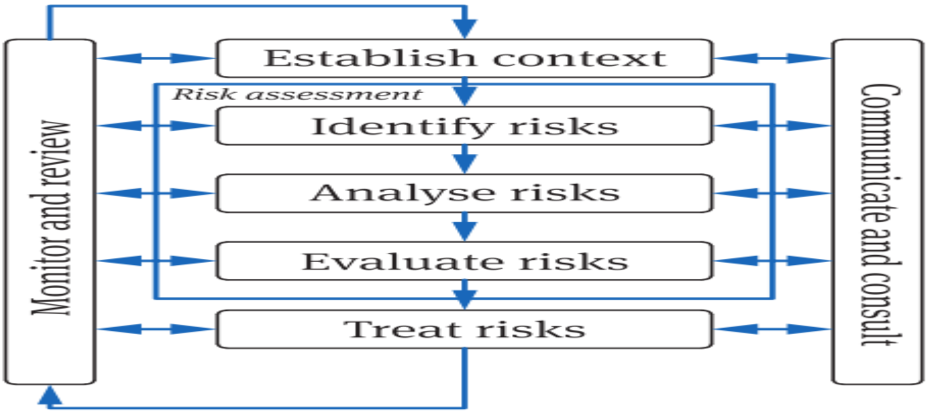

Figure 1: *The ISO 31000:2009 risk management process - Source "ISO 31000 Risk Management a practical guide for SMEs", a preview of which is available on the ISO website.*

Regretfully, in too many cases these principles are not always followed. Instead a project team will rush into designs, get them documented and call a quorum for the risk assessment to 'give it the necessary blessing'. In general engineers know how to assess risk; they even know how to put a qualitative and sometimes an element of quantitative analysis to it. However, they have now 'hit the wall', as the risk hasn't gone away and they have to evaluate that residual risk for acceptability, but where is the benchmark? Hazardous area classification, which in itself is a form of risk assessment, is often no different in this regard, as all too regularly the facility design is first completed and somebody is then tasked with superimposing 'appropriate' zones on it. Indeed, quite detailed quantitative calculations can be done, but as previously mentioned, are they representative or appropriate?

Indeed, such forms of risk assessment can be taken a step further into risk treatment, which is an iterative process in which different options are developed and assessed. However, the usual outcome is to end up with a different residual risk, which may have advantages or disadvantages, but it is still necessary to evaluate, as to if that residual risk is tolerable. So clearly the design team are now stuck in 'circular reasoning', which often generates lots of opinions and burns technical hours, but nobody is quite in a position to reason and justify, as to when it is acceptable to 'jump out' of this circle, and accept a given option, as providing a residual risk which is tolerable.

So really the design team should have started with the first step in the figure above and established the 'context' of risk management. As both ISO 31000 and IEC 301010:2009 "Risk management -- Risk assessment techniques" explain the context; "*includes considering internal and external parameters relevant to the organization as a whole, as well as the background to the particular risks being assessed".* The external context can include: *"Cultural, political, legal, regulatory, financial, economic and competitive environment factors, whether international, national, regional or local".* The internal context can include such as: *"Perceptions, values and culture, policies and processes, standards and reference models adopted by the organization".*

Engineers often struggle with this concept, but let's take the example of the range of vehicles on the roads; they are all, if properly maintained, essentially legal, which we can attribute to the 'external context'. However, some manufacturers stress characteristics such as reliability and safety, while as the head of Ferrari was renowned for putting it "*We don't sell a car, we sell a dream*". In the process sector, different companies have different appetites for residual risk; there are differences between operational standards, which can be achieved in highly developed countries versus developing countries; the standards in the nuclear industry are exemplary, but not really warranted in other sectors; etc. Striving for a 'one size fits all model' simply doesn't make sense. However, at the same time, the risk management context can also be considered as the regulatory, technical and economic scope in which one has to operate, or equally the design and operational envelope. To take the car analogy, there is a design envelope of technical regulations and standards, which all manufacturers have to work within. No different for hazardous area classification, it's just that we are generally poor at identifying it up front.

3. Technical Regulations, Standards and Acknowledged Rules of Technology

Regulatory compliance is a key element of the 'external context' and can be thought of as a pyramid like structure. At the top are the overarching technical regulations, supported by standards at the next level and then acknowledged rules of technology. The ISO/IEC Guide 2:2004 "Standardization and related activities - General vocabulary" defines:

- *Technical regulation: Regulation that provides technical requirements, either directly or by referring to or incorporating the content of a standard, technical specification or code of practice.*

- *Standard: Document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.*

- *Acknowledged rule of technology: Technical provision acknowledged by a majority of representative experts as reflecting the state of the art.*

In a paper presented at Hazards 27 (Swords, 2017) entitled "*In a Globalised World is Process Safety becoming harmonised?*" the impact of the World Trade Organisation's (WTO) 1995 "Technical Barriers to Trade Agreement" was pointed out. In particular, as to how on account of this agreement, technical regulations are on a global basis increasingly based on international standards from the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC).

In the EU the technical regulations comprise the various Directives, Decisions and Regulations, which are supported by European (EN) standards. Indeed, about twenty percent of all EN standards are developed following a standardisation request (mandate) from the EU Commission to the European Standardisation Organisations, to draw up and adopt EN standards in support of European policies and legislation. Increasingly though these EN standards are an adoption of relevant ISO and IEC standards. In the EU, the use of standards remains voluntary, as in general the EU legislator refrains from making direct reference for a requirement to comply with a specific standard, as standards can and do go out of date or could provide a barrier to free trade. Instead the approach in the EU is that only the overarching requirements or objectives are set in the technical regulations. For example, for products falling within the scope of 'New Approach' Directives as requiring CE marking, which includes equipment for potentially explosive atmospheres as regulated by the ATEX Directive 2014/34/EU, the 'Blue Guide' on the implementation of EU product rules (EU Commission, 2016) clarifies:

- *"A large part of Union harmonisation legislation limits legislative harmonisation to a number of essential requirements that are of public interest. Essential requirements define the results to be attained, or the hazards to be dealt with, but do not specify the technical solutions for doing so".*

The technical details then follow in the supporting standards, and while specific harmonised standards provide a 'presumption of conformity' with the essential requirements defined in the applicable 'New Approach' Directives, the use of standards remains a voluntary activity in the EU. The manufacturer or operator is always free to develop and demonstrate an equivalent level of safety. Other jurisdictions do not quite follow this same approach, for example in both the US and China standards can be adopted as mandatory National standards, de facto becoming the applicable technical regulations. However, in both jurisdictions the numbers of such standards, which are adopted as mandatory in this manner, are limited. The bottom line though, which applies in all jurisdictions, is don't expect the regulator to specifiy all your technical details for you. For starters, it's not really their job and how would they have the competency in it?

In the EU the principles of integrated explosion safety are defined in both ATEX Directives; Directive 2014/34/EU on equipment for explosive atmospheres and Directive 1999/92/EC on the protection of workers potentially at risk from explosive atmospheres. Namely, that appropriate technical and organisational measures should be taken in the following order of priority: (i) To prevent the formation of explosive atmospheres. (ii) To avoid the ignition of explosive atmospheres. (iii) To mitigate the detrimental effects of an explosion and; (iv) these measures shall where necessary be combined and / or supplemented with measures against the propagation of explosions.

To stress a point, which will be returned to later, one cannot simply assign zones to a design. One must first challenge it to reduce the formation of the explosive atmospheres from occurring in the first place. In other words, answer, i.e. document, as to why the zones are there in the first place. Indeed, the same principles as above are to be found in the relevant IEC and ISO standards for explosion protection, where for hazardous area classification the two principal standards are:

- IEC 60079-10-1:2015 "Explosive atmospheres - Part 10-1: Classification of areas - Explosive gas atmospheres"

- IEC 60079-10-2:2015 "Explosive atmospheres - Part 10-2: Classification of areas - Explosive dust atmospheres"

These standards, and the previous editions which preceded them, describe in detail the methodology one should use in assessing the appropriate hazardous area zone. However, they are essentially silent on the extent of the zone, such as in Annex F of IEC 60079-10-1:2015 on the "Schematic approach to classification of hazardous areas", in which the schematics there conclude with: *"Using an appropriate code or calculations determine the extent of zone"*.

In essence the clear intent is that relevant 'acknowledged rules of technology' appropriate to each industry sector, etc., will provide further assistance with the determination of the extent of these zones. Indeed, as Annex K of IEC 60079-10-1:2015 describes it: "*In general, examples of classification may be accepted in accordance with national or industry codes where their application to the particular situation can be clearly demonstrated. Any criteria or limitations identified in the national or industry code should be followed"*. One such 'acknowledged rule of technology' is clearly the Model Code 15 (Energy Institute, 2015), which is now in its fourth edition dating back originally to 1990. It is a well-established and internationally recognised code for the petroleum industry. It is also worthwhile stressing here, that it is entirely appropriate that such a code should be prepared by recognised industry experts from a particular sector, the limitation though being that one cannot expect a code specifically prepared for one industry sector to be directly applicable to other sectors. For example, the PharmaChem and Food & Drink sectors exhibit fundamental differences to the petroleum sector; volumetric flow rates are much lower, often by a factor of at least ten, facilities are predominately indoors instead of outdoors, operating pressures and temperatures are generally lower and the relevant explosion hazards also include dust hazards.

4. 'Sins of the Past'

As the English speaking world was, and in many cases still is, lacking in an appropriate hazardous areas classification guidance document applicable to the PharmaChem and Food & Drink sectors, in this vacuum some sub-optimum 'solutions' developed. Illustration of this can be found in the earlier IEC 60079-10-1:2008[2], which did not provide a specific list of national and industry codes, but instead in its Annex C (informative) provided some examples of hazardous area classifications. Plenty of caveats (warnings) were provided, such as: "*The figures shown are taken from, or correspond closely to, those in various national or industrial codes. They are intended only as a guidance to the magnitude of the zones"*. A particularly relevant example to the subject matter of this paper is Example No. 8:

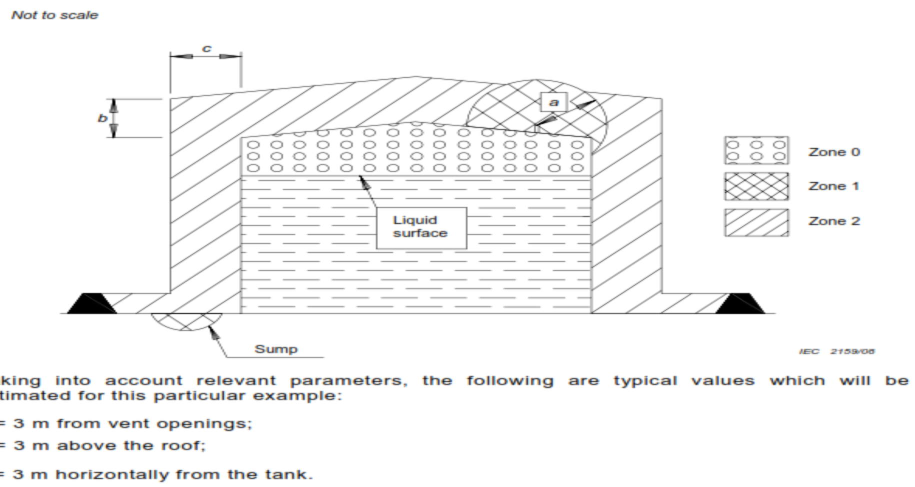

Figure 2: *Example No. 8 of IEC 60079-10-1:2008*

[2] IEC 60079-10-1 ed.1.0 "Copyright © 2008 IEC Geneva, Switzerland. www.iec.ch"

Unfortunately in life a little knowledge can be a dangerous thing. There are in the authors' experience many facilities in the PharmaChem and Food & Drink sectors with small buffer type vessels containing flammable solvent blends in the range of 1 to 2 m^3. These often have simple venting arrangements into the production rooms, as for GMP reasons, one does not want to have a direct connection to the external 'non-controlled environment'. In accordance with 'a' in the above example, all too often a Zone 1 of 3 m extent was assigned to the vent. This as a result effectively led to the whole production room obtaining a Zone 1 classification. While this by and large does not lead to a problem with electrical equipment, which is generally by default Zone 1 compliant anyhow, there are other disconnects. An explosive atmosphere is a concentration several orders of magnitude above the relevant occupational exposure levels, while a Zone 1 classification infers that in normal operation such concentrations will be regularly reached. As the webpage of the UK's Health and Safety Executive (HSE) on "Hazardous Areas Classification and Control of Ignition Sources" states:

- "*The alternative of specifying the extent of zones more conservatively is not generally recommended, as it leads to more difficulties with equipment selection, and illogicalities in respect of control over health effects from vapours assumed to be present. Where occupiers choose to define extensive areas as Zone 1, the practical consequences could usefully be discussed during site inspection".*

Classifying large external areas as Zone 1 also leads to additional cost and complexity with respect to the compliance of non-electrical equipment and the requirements for personnel earthing. Germany has had a series of technical regulations and guidance documentation on explosion protection for many decades, which has addressed hazardous area classification in detail. TRGS 509 is one such technical regulation entitled "Storage of liquid and solid hazardous substances in stationary vessels as well as filling and empting systems for non-stationary containers" (AGS, 2015). It provides long established zoning details, such as for filling storage tanks with flammable liquids. For example, if the flashpoint of the liquid is < 0 °C and the filling rate reaches 180 m^3/h, then such a 3 m Zone 1 vent radius applies. If the flashpoint is between 0 °C and 21 °C, which is typical for many situations in the PharmaChem and Food & Drinks sector, then the filling rate would have to reach 450 m^3/h in order to approach this Zone 1 radius of 3 m. In reality filling rates for such small buffer vessels rarely exceed 15 m^3/h.

Such an example is typical of circumstances where parameters, which are representative of the petroleum and large volume organic chemical sectors, have also been applied to the PharmaChem and Food & Drink sectors with resulting disconnects and compliance requirements, which are simply not justified.

5. Annex K of IEC 60079-10-1:2015 – National Standards or Industry Codes

5.1 Germany

Annex K also clarifies: *"Where examples from industry codes or national standards are used, then they shall be quoted as the basis for classification and not IEC 60079-10-1. Examples of national standards or industry codes include, but are not limited to those shown in Table K.1. The countries of origin are set in alphabetical order".* It is worthwhile clarifying the background to some of these tabulated codes. In Germany and Switzerland through their long standing system of Statutory Accident Insurers, central provisions are made for financial claims related to injuries and occupational illnesses. As a consequence there is a 'non-adversarial' culture with the provision of in-depth guidance for occupational safety in each industry sector, which is reinforced by appropriate statutory controls from the Statutory Accident Insurers.

Annex K references the German ExRL "Explosion Protection- Rules – Rules for avoiding the dangers of explosive atmospheres with examples collection", which originated in the 1950s and 1960s from the chemical industry division of the Statutory Accident Insurers (BG Chemie) and has been constantly updated since then. The ExRL essentially existed as two discrete sections, the first describing the relevant explosion prevention and protection measures, while the second section contains a detailed collection of hazardous area examples. Much of content of the first section of the ExRL led to the technical content now to be found in the overarching standard EN 1127-1:2011 "Explosive atmospheres - Explosion prevention and protection Part 1: Basic concepts and methodology", which dates in its original format back to 1997. Indeed, a much reduced version of this technical content is also to be found in the EU Commission's non-binding guide of good practice for implementing Directive 1999/92/EC (ATEX) (EU Commission, 2003). Currently in Germany the technical content from the first section of the ExRL has been legally adopted into a series of technical regulations related to operational safety (TRBS) and chemical safety (TRGS).

The second section of the ExRL (DGUV-Regel 113001) has not been adopted as a technical regulation, as this contains a detailed collection of hazardous area classifications, which serves solely for guidance purposes. The collection of examples is structured into three main sections. "Point 1: Flammable gases, vapours and mists". "Point 2: Flammable liquids" and "Point 3: Combustible dusts". These are the generic universally applicable examples, which are then reinforced by Point 4, which contains sector specific examples for waste water treatment plants, general gas supply infrastructure, coal processing, coating materials, medical rooms, acetylene plants and biogas plants. Point 5 is a list of some 26 relevant German technical regulations and guidance documentation on explosion protection, which contain information on zoning examples, which have been agreed with the German Statutory Accident Insurers. This includes the previously referred to TRGS 509 in relation to the filling of tanks.

While these are in German, one of them is available as an English translation on the website of the German Federal Institute for Occupational Safety and Health (BAuA), namely TRGS 510 "Storage of hazardous substances in non-stationary containers" (AGS, 2015). Its Annex 5 describes the relevant zoning for both indoor and outdoor storage of flammable liquids in containers. From the perspective of the Food & Drink sector, the Statutory Accident Insurers for that sector (BGN) has a research division (FSA), which is not only engaged in explosion protection, but is also 'notified body' for the approval of ATEX rated equipment and protective systems. The FSA has produced a number of practice guides for preparing explosion protection documents, some of which are listed in Point 5 of the ExRL. These now include; (i) grain processing and storage; (ii) small grain mills; (iii) distilleries and spirits processing; (iv) breweries and; (v) sugar production and processing. Of relevance also is the VDI 2263 range of standards from the German Association of Engineers (VDI), which are entitled "Dust fires and dust explosions; hazards, assessment, protective measures" and include parts (Blatt) relating to fluid bed dryers, dust extraction (filters), spray dryers and elevators. These are in both German and English and include appropriate examples on zoning.

If we refer to Mr Justice Haddon-Cave, who not only delivered an excellent keynote lecture at the Hazards 26 conference, but was also responsible for writing the Nimrod Review (Haddon-Cave, 2009), in which he stated: *As Lord Cullen pointed out in the Ladbroke Grove Rail Inquiry, the purpose of the Safety Case regime was to "encourage people to think as actively as they can to reduce risks".* Some of the shortcomings he focused on were: *"Bureaucratic length: Safety Cases and Reports are too long, bureaucratic, repetitive and comprise impenetrable detail and documentation. This is often for 'invoice justification' and to give Safety Case Reports a 'thud factor'.* Plus: *Wood-for-the-trees: Safety Cases do not see the wood for the trees, giving equal attention and treatment to minor irrelevant hazards as to major catastrophic hazards, and failing to highlight, and concentrate on the principal hazards".*

Hazardous area classification is, as has already been highlighted, a form of risk assessment and the comments above can equally be directed at circumstances where detailed assessments, such as complex calculations, can be applied to designs, without first focusing on approaches which will aid in reducing the risk at source, which is the overarching requirement of the regulatory 'context'. This is why the fundamental layout, see below, used in Points 1 to 4 of the ExRL is of significance. The fourth column refers to the technical regulation TRBS 2152 Part 2 "Avoidance or reduction of hazardous potentially explosive atmospheres", which describes the applicable explosion protection measures in this regard, such as the degree of equipment sealing, the degree of ventilation, inerting, etc. The fifth column then gives the recommended zoning applicable to the avoidance of ignition sources (TRBS 2152 Part 3), while the final sixth column refers to the constructive explosion protection measures (TRBS 2152 Part 4), which only become applicable if the ignition protection measures applicable to that zone cannot be fully implemented. Note: Constructive explosion protection measures refer to explosion resistant design, explosion venting and explosion suppression.

Number	**Example**	**Features / Observations / Conditions / Notes**	**Protection measures according to TRBS 2152 Part 2**	**Stipulation of the zones for avoidance of ignition sources according to TRBS 2152 Part 3**	**Protection measures according to TRBS 2152 Part 4**

Because one is presented with relevant options and as to how an inherent safety approach prioritising preventative measures thereby reduces or even eliminates the subsequent zoning, it 'encourages' one to think about the risk and justify one's position. For example Point 2.2.6 of the ExRL in relation to laboratories, shows as to how with *"usage of flammable liquids in fume cupboard in non-laboratory typical quantities, e.g. rotation evaporator with 10 l of flammable liquid above the flashpoint"*, a Zone 2 arises in the fume cupboard. However, if laboratory typical quantities are used, no such zoning occurs. Another example is Point 2.2.3.1 in relation to the indoor taking of samples of flammable liquids. With a sealed sampling system and technical (room) ventilation, no zone is applicable. With open sampling and object extraction a Zone 2 of negligible extent occurs, which increases to 0.5 m if there is instead only room ventilation. While with natural ventilation the applicable classification is a Zone 1 of negligible extent with a Zone 2 extending a further 2 m.

With respect to the PharmChem and Food & Drinks sectors, the collections of examples in the ExRL are particularly suited, as they not only reflect the scale of processing in those sectors, but also with respect to Point 3 and combustible dusts, there is comprehensive treatment of the mills, filters, dryers, etc., which one finds in those sectors. Indeed, there is a practical handbook on zone classification (Dyrba, 2012), with over a hundred graphical representations of the examples in ExRL, although unfortunately only to date available in German.

5.2 Switzerland

The Swiss Statutory Accident Insurers Suva also have an official guidance document entitled "Explosion protection basics minimal requirements zones", which is available as a German, French or Italian download on the Suva website. It is structured like a very 'light' version of the ExRL, in that the first section describes the explosion prevention and protection measures; while the second section provides a limited number of graphically represented zoning examples, which also have relevance to the PharmaChem and Food & Drink sectors. While undoubtedly it is a useful guidance document, it is as previously highlighted, a far reduced version of the extensive detail in the ExRL.

The International Social Security Association (ISSA) in Geneva not only co-operates with the International Labour Organisation (ILO), a specialised agency of the UN, but it also draws heavily on the technical knowledge of the Statutory Accident Insurers in Germany and Switzerland. While the ISSA is not specifically referred to in Annex K of IEC 60079-10-1, it is worth mentioning their recent and excellent "Collection of Examples - Dust Explosion Protection for Machines and Equipment", which comprises two separate parts. "Part 1: Mills, crushers, mixers, separators, screeners" and "Part 2: Conveyers, transfers and receivers", both of which address relevant zoning requirements within the overall context of explosion protection and are available on the ISSA website. An older guidance document (2006) from the ISSA on "Practical Assistance for Preparation of an Explosion Protection Document" is also useful, as it provides sixteen practical examples, pictorially illustrated, of flammable vapour and dust classifications appropriate to a range of industry sectors.

5.3 UK

In addition to the Model Code 15 (Energy Institute, 2015), Annex K also lists the IGEM/SR/25 "Hazardous area classification of Natural Gas installations" from the Institution of Gas Engineers & Managers (IGEM). This recognises that for natural gas pipelines in adequately ventilated non-confined locations, where the gas pressure is less than or equal to 10 bar g, a zone of negligible extent (NE) ensues around pipeline fittings, such as flanges or valves. This is a point, which will be returned to later. While not specifically listed in Annex K, the Scotch Whisky Association has a guidance document dating from 2008 on "The Management of Flammable & Explosive Atmospheres", which was drawn up in conjunction with the HSE and is particular useful for that sector. In particular it once again highlights the advantage of relevant industry experts preparing appropriate 'acknowledged rules of technology' for their sector, as the two previous guidance documents listed for the UK, have little or no applicability to the production of alcoholic beverages.

5.4 Australia / New Zealand

Australia and New Zealand traditionally had a 'National Annex' called 'ZA' to IEC 60079-10-1, which was informative and in which the examples were not mandatory and considered to provide guidance for selected specific applications. These examples were in general based on experience or generally accepted practices for risk management in some industries and the Annex 'ZA' in the current AS/NZS 60079.01.1:2009 runs to nearly a hundred pages. While the main emphasis is on the Petroleum sector, some other sectors related to flammable solvent processing are also addressed. It is now recognised in the AS/ NZS 60079.10.1 Development Plan that there are inconsistencies in these examples and that some could even be 'challenged' based on the calculation methods now adopted in IEC 60079-10-1:2015. As a result with the AS/NZS adoption of this latest version of IEC 60079-10-1, it is understood that there will no longer be an Annex 'ZA', but a supplementary document, which will accompany it and provide greater clarification on the relevant examples. However, completion is not scheduled until mid-2019.

5.5 USA

In the USA the National Fire Protection Association (NFPA) is responsible for publishing many of the recognised 'consensus' standards in the field of explosion protection. Annex K lists; (i) NFPA 59A, which is a standard for the liquefied natural gas sector; (ii) the American Petroleum Institute's (API) recommended practice for classification of locations at petroleum facilities and; (iii) NFPA 497 "Recommended Practice for the Classification of Flammable Liquids, Gases, or Vapours and of Hazardous (Classified) Locations for Electrical Installations in Chemical Process Areas". There is also a NFPA 499, which is for the classification of combustible dusts in chemical process areas. In the USA the National Electrical Code (NFPA 70) recognises both the traditional US approach of 'divisions' and the ATEX / IECEx derived usages of zones, the choice of which to use, as the Occupational Safety and Health Administration (OSHA) also confirms, rests with the preference of the operator. As a result, the area classification codes in the US now show both approaches.

NFPA 497:2017 dates in its original form back to early 1970s and contains nearly fifty useful diagrams, which are intended to serve as an aid to classification. It explicitly recognises that the limits of classified locations for petroleum installations are more stringent than are warranted for more traditional chemical processing facilities that handle smaller quantities, although some large chemical facilities approach the size found in the petroleum sector. Therefore NFPA 497 addresses differing process equipment size, flow rate, and pressure for three magnitudes of process equipment and piping comprising "Small (Low), Moderate and Large (High)". However, with the diagrams, which are based on generic leakage sources, some judgement is required, as do those leakage rates actually correspond to your conditions?

It is useful that NFPA 499 clarifies that if the "surface colour is discernible under the dust layer" then the area is non-hazardous, while if the dust layer is "< 3.0 mm and the surface colour is not discernible", then a Zone 22 applies. While a number of diagrams are also provided, their applicability to the PharmaChem and Food & Drink sectors is questionable, as they reflect large dust release rates.

5.6 Other

Annex K lists additional guidance from the Netherlands, Italy and Sweden, although these are languages with a more limited reach than those previous discussed. NPR 7910-1 is the Netherlands' code of practice and national guideline describing the principles of classification of hazardous areas with respect to the gas explosion hazards given in IEC 60079-10-1:2009. While not listed in Annex K, as it relates to dust hazards, there is also an NPR 7910-2, which is for classifications related to the dust explosion hazards given in IEC 60079-10-2:2009. The approach adopted in these is more one of calculations than specific exemplars and as the relevant IEC codes have since been updated, in particular IEC 60079-10-1:2015 now contains a quite detailed calculation section relating to ventilation, etc., these Dutch code of practices will now have to be updated. Note: They have already been subject to some criticism from several industry sectors there, such as iron and steel, with regard to their complexity and lack of flexibility.

In Italy CEI 31-35 is a guide for classification of hazardous areas for the presence of gas in application of CEI EN 60079-10-1 (CEI 31-87), which is supported by CEI 31-35A providing actual worked examples of the calculation methodologies defined in CEI 31-35. An English version of CEI 31-35 was also published in 2011. However, the situation with these is very similar to the Dutch codes above in that their content, which is primarily calculation based, having been overtaken by the new IEC 60079-10-1:2015 and the Italian standards website is now showing these guides to be no longer in force.

In Sweden SEK Handbook 426 is entitled "Classification of explosion hazardous areas - Areas with explosive gas atmosphere", the first part of which contains the standard SS-EN 60079-10-1: 2016 in Swedish and English. The examples of calculations and zone classification have been revised compared to previous editions and are included as National Annexes; Annex NL expands on the examples provided in Annex E of EN 60079-10-1, which show how ventilation can have a dilution effect; Annexes NM and NN contain recommendations on the classification of laboratories and refrigeration and heat pump systems; Annexes NO and NP describe the classification of lacquering plants; Annex NP also contains examples of place where mists of flammable liquid may occur.

6. How do they differ?

Naturally the first question of many will be, as to how do they differ and which then is right and wrong? However, to even attempt to answer this, let us look first at the definition of zones; Zone 0/20 is defined as where the explosive atmosphere is present continuously or for long periods or frequently; Zone 1/21 as where the explosive atmosphere is likely to occur in normal operation, while Zone 2/22 is where the explosive atmosphere is not likely to occur in normal operation and, if it occurs, will only exist for a short time. The UK's HSE in their webpage on Hazardous Area Classification refer as to how the following commonly applied time limits can be appropriately applied to the above, namely; Zone 0/20 where the explosive atmosphere is present for more than 1,000 hours per year, Zone 1/21 for a period between 10 and 1,000 hours a year and Zone 2/22 for a period of less than 10 hours per year.

The Dutch NPR refers to Zone 0/20 being applicable where the explosive atmosphere is present for greater than 10% of the operating time, Zone 1/21 applicable for the range 0.1 - 10% of the operating time and Zone 2/22 being applicable when the explosive atmosphere is present for less than 0.1% of the operating time. A similar approach is taken by the Italian guidance above. However, in the ExRL it is discussed as to how the definition of Zone 0/20 specifically refers to the terms 'continuously' and 'frequently', this is then interpreted as the explosive atmosphere being present for more than 50% of the operating time. Rather than getting into an argument as to which is right, it is far more appropriate to point out that none is actually wrong, and all are relevant to the risk management 'context', which applies in the relevant jurisdiction.

One might also ask as to if the zoning examples represent national characteristics, for instance a geographical location like Australia is characterised by high ambient temperatures, therefore evaporation rates and the resulting extent of the zones would be expected to be greater there than in the temperate climate of the British Isles. Another relevant question is as to if there is commonality between the leakage rates being used to support these exemplars? The German Ex-RL are clear in that the collection is examples is based on the fact that the various protection measures, such as sealed equipment or ventilation, defined in the overarching technical regulations (TRBS /

TRGS) have been complied with. While long standing German statutory requirements required regular independent inspections of process plants with explosion hazards, operating such plants to a high standard is also something, which equally occurs in increasing frequency in many other jurisdictions.

However, a review by the authors of the different exemplars available from the various national codes concluded that there were no clean cut answers or visible trends. If anything many showed a tendency towards larger processing sectors, which for the PharmaChem and Food & Drink sector leads to the conclusion that unless utilised judiciously, they could quickly lead to overly conservative outcomes. If anything one could only conclude, is that if there is a specific national code, then that would naturally be part of the regulatory context applicable to that jurisdiction and one would definitely have to refer to and consider it. However, at the same time such codes are not mandatory and as IEC 60079-10-1:2015 clarifies in its Annex K, "*examples of classification may be accepted in accordance with national or industry codes where their application to the particular situation can be clearly demonstrated".*

Indeed, maybe a fundamental question needs to be first answered when zone extents turn out to be significant, are the leakage rates applicable to them actually representative or justifiable? For example NFPA 497 provides two useful insights, the first with respect to the origin of leaks:

- *"The most numerous of offenders are probably packing glands. A packing gland leaking 0.95 l/min, or 1,360 l/day, certainly would not be commonplace. Yet, if a 947 ml bottle were emptied each minute outdoors, the zone made hazardous would be difficult to locate with a combustible gas detector".*

The second with respect to two experiences monitored by combustible gas detectors:

- *"Gasoline spilled in a sizable open manifold pit gave no indication of ignitable mixtures beyond 0.9 m to 1.2 m from the pit when the breeze was 13 to 16 km/hr. A slightly smaller pool of a more volatile material, blocked on one side, was monitored during a gentle breeze. At grade, vapors could be detected for approximately 30 m downwind; however, at 46 cm above grade, there was no indication of vapor as close as 9 m from the pool".*

Maybe the answer doesn't lie with evermore sophisticated calculation methods for assessing the extent of the zones, but rather with the simple task of improving the sealing of potential leakage points and taking the precaution to raise potential ignition sources above ground level, where heavier than air flammable vapours will sink to. After all in a well-designed laboratory installation, the electrical sockets are raised above the work bench, because if flammable solvents spill, the vapours will accumulate at low level on the work bench.

There is also merit in actual measurements to confirm one's position, not only the examples of NFPA 497 above being relevant in this regard, but also some recent research worked published by the German Statutory Accident Insurers for the food sector (BGN) in relation to distilleries and spirits processing (Wenzel, 2017). With the introduction of the EU's ATEX legislation in Germany in 2003, a more stringent regulatory structure had to replace the previous national approach to the regulation of ethanol water mixtures, for while experience had shown that fire and explosions occurred in distillations units, this was not replicated with the processing and storage of such alcohol blends at ambient temperatures. As a consequence the pre-ATEX German Ordinance on Flammable Liquids (VbF) only applied to storage, filling and conveying of ethanol water mixtures, when the alcohol concentration exceed 87 vol.%. Therefore some orientation measurements were recently taken by the BGN in spirits processing plants, such as at vodka filling lines; the results show that concentrations were much less than expected. An alcohol water mixture can indeed generate an explosive mixture above its surface, but in closed tanks this took several hours, if not days to occur. In an open situation, such as a spill, at ambient temperature and reasonable air movement, there was an immediately quick dilution in the concentration range to well under the Lower Explosion Limit (LEL). For example measurements taken during filling a 30 m^3 tank at 40,000 l/h with 68 vol.% alcohol in still air conditions: At 10 cm from the DIN 50 vent nozzle 90% of the LEL was measured, dropping to 47% of the LEL at 15 cm from the nozzle and down to 12% of LEL at 100 cm from the nozzle. Indeed, if one was filling the small buffer type vessels highlighted previously in Section 4 at 10,000 l/h, the measurements taken shown that the LEL would not even be reached at 5 cm from the vent nozzle during filling.

7. Do we need these Zones at all?

While the oil and gas sector with its higher pressures and volumetric flow rates has developed its own approaches, for the PharmaChem and Food & Drink sectors one really has to question, as if any significant degree of zoning is actually applicable. EN 1127-2:2011 "Explosive atmospheres - Explosion prevention and protection - Part 1: Basic concepts and methodology" is a type-A overarching standard harmonised to both the ATEX 'equipment' Directive and the Machinery Directive. On a global context the United Nations Economic Commission for Europe (UNECE) has "A Common Regulatory Framework for Equipment Used in Environments with an Explosive Atmosphere: ECE/TRADE/391". UNECE, as the most technically advanced of the five UN regional commissions, has already developed the Globally Harmonised System (GHS) for classification of chemicals and the Model Regulations on the Transport of Dangerous Goods. Their common framework for equipment for explosive atmospheres has been developed in close cooperation with the IEC and their IECEx certification scheme. It lists EN 1127-1 as an overarching standard, which will in time be replaced by a new IEC standard to be developed.

Section 6.2 of EN 1127-1 on the avoidance or reduction of the amount of explosive atmosphere lists the following measures: "*(i) Substitution or reduction of amount of substances which are capable of forming explosive atmospheres, (ii) Limitation of concentration, (iii) Inerting, (iv) Avoidance or reduction of releases of flammable substances, (v) Dilution by ventilation and (vi) Avoiding dust accumulations".* Indeed, the German TRBS 2152 Part 2 "Hazardous Potentially Explosive Atmospheres – Avoidance or reduction of hazardous potentially explosive atmospheres" also includes the avoidance of hazardous explosive atmospheres by pressure reduction (vacuum operation) and by monitoring of the concentration in the surroundings of plant (gas detection and alarms). There are therefore not only a number of applicable options for preventing explosive atmospheres from occurring available to plant and equipment designers, but they are also very much part of the applicable regulatory context.

In relation to dust hazards in the PharmaChem and Food & Drink sectors, processing equipment which is sealed and based on established principles of hygienic design should be the norm. Homemade flexible joints and hoses should be replaced by proprietary designs, not just to prevent leaks, but also to prevent inadvertent electrostatic discharges. Sealed powder transfer systems are available, such as for filling and unloading FIBCs (big bags), while even for 25 kg bags automated bag unloading systems are available. It is therefore possible to have a processing environment, which is essentially free of the persistent layers of dust, which would warrant a Zone 22 classification. Indeed the German Statutory Accident Insurer's guidance BGI 5151 on "Safe working in the pharmaceutical industry" states: *"Many leaks are visible as small product deposits. With Occupational Exposure Limits (OELs) below 10 µg/m^3 product deposits are an indication, that the OEL value can already be exceeded"*.

Given that the PharmaChem sector is increasingly associated with active ingredients of higher potency, from the perspective of occupational hygiene, it is simply not acceptable to have persistent layers of dust present. While occupational hygiene might not be so critical in the Food & Drink sector, there are other hygienic considerations and one should also consider the expenditure in cleaning resources, which have to be allocated to a plant, which is not sufficiently sealed. Furthermore, the impact which can be gained by the use of sealed equipment to avoid or reduce the releases of flammable substances is not limited to dust hazards. When EN 1127-1 was updated in 2011, it included a section on 'tightness of equipment', in this it clarified: "*The formation of a hazardous explosive atmosphere outside the equipment can be prevented or limited by means of the tightness of the equipment. Here, a differentiation is made between:*

- *equipment which is durably technically tight;*
- *technically tight equipment where the escape of flammable materials is due to operation*

In the case of equipment which is durably technically tight, no release is to be expected. Equipment is regarded as durably technically tight, if:

- *it is constructed such that it remains technically tight due to its design; or*
- *its technical tightness is permanently ensured by means of maintenance and supervision.*

Equipment with a durably technically tight construction does not cause any hazardous areas in its surroundings while closed". Annex B of EN 1127-1:2011 then provides further technical details on equipment sealing based on the long standing German approach, which was to be found in the ExRL. These details are of a general conceptual nature, rather than a detailed design, but they are there to make one 'think about it'. For example, at the Hazards 27 conference, Chris Beale of BASF gave one of the keynote presentations on "Managing Weak Signals – Driving Continuous Improvement in Process Safety in a Complex Organisation". He referred to how single seal pumps are responsible for a large number of material losses, but that retro-fitting them with the double seals, would simply prove to be impracticable, as there were so many of them. The phrase 'penny wise, pound foolish' certainly applies here, as double sealed shafts are durably technically tight under EN 1127-1 with no applicable external hazardous areas, while single seals are only technically tight for which external zones are applicable. It is the experience of PM Group electrical engineers that the cost of Ex rating an area to a gas explosion hazard is some four times that of a standard electrical installation. Therefore, one can quickly start to see that it is worthwhile spending the time and money to get the sealing technology right.

This is being facilitated by another driver, that of reducing emissions of Volatile Organic Compounds (VOCs). The EU's Best Available Techniques Reference Document (BREF) and associated legally binding "Best Available Techniques Conclusions" for the "Common Waste Water and Waste Gas Treatment/ Management Systems in the Chemical Sector" adopted in June 2016, stress the requirement for high integrity equipment, such as valves, pumps and gaskets, to reduce fugitive emissions of VOCs. Indeed, manufacturers have responded by producing a range of certified low leakage valves, gaskets, etc. It has also been recognised that the biggest source of leakage in flanged joints is due to them being improperly torqued, which is why a specific standard has been introduced in relation to the competency of bolting technicians, namely EN 1591-4:2013: "Flanges and their joints Part 4: Qualification of personnel competency in the assembly of the bolted connections of critical service pressurised systems".

The whole domestic and commercial gas industry is based on the fact that such gas supplies occur through durably technically tight piping systems, with as a result no or negligible zoning applied; see for example the previously mentioned IGEM code from the UK. Yet the PharmaChem and Food & Drink sectors have somewhat of a mental block that the same could apply to them. Yet if one thinks about it, a gas leak is an immediate explosive cloud; while a leak in a low pressure solvent transfer line will first lead to a pool on the floor, which will slowly evaporate, resulting in a local low level explosive atmosphere. Which one is the lower risk? Then there is also the aspect of ventilation, production areas being generally better ventilated than domestic and commercial buildings.

8. Do we need all that Ventilation?

The earlier 2005 edition of the Model Code 15 (Energy Institute, 2015) defined 'adequate ventilation' as *"the achievement of a uniform ventilation rate of at least 12 air changes/hr, with no stagnant area".* While this may have been applicable in the past to the oil and gas sector, it does not necessarily apply to other sectors. Indeed NFPA 497:17 defines 'adequate ventilation as: *"A ventilation rate that affords six air changes per hour, 0.3 m^3 /min/m^2 of floor area, or other similar criterion that prevents the accumulation of significant quantities of vapor-air concentrations from exceeding 25 percent of the lower flammable limit (LFL)".* In reality, the appropriate air change rate can only be determined by risk assessment and depends largely on the degree of sealing of the plant; a highly sealed plant will require less ventilation to prevent explosive atmospheres from occurring. It is also important when actually designing air flow systems, to ensure that they are effective at the appropriate height and 'dead zones' with inefficient ventilation do not occur.

In the PharmaChem sector for GMP reasons it is often necessary to have high volumetric flows of conditioned filtered air, 15 air changes per hour not being uncommon, although GMP requirements in the food sector can also be quite stringent. The energy costs of utilising this air on a once through basis are very high, which raises the issue of recirculation. In the German TRBS 2152 Part 2 "Avoidance or reduction of hazardous potentially explosive atmospheres" in the section on technical (room) ventilation, it is clarified that "*the extraction of supply air out of explosion hazardous areas cannot raise the hazard. If make-up air is extracted from explosion hazardous areas, then additional measures (e.g. the application of gas warning equipment) are necessary".* Indeed, personal experience of the author Pat Swords is that the German pharmaceutical regulator is very concerned with the high energy requirements for air treatment in this sector and that appropriate measures be taken to minimise it. Recirculation of some of this high GMP related air flow, even in areas designated with hazardous zones, is an effective and worthwhile measure and will quickly pay back the additional investment required in gas monitoring.

9. Where the Hazard really lies – inside the Equipment

In a properly designed PharmaChem and Food & Drink facility, if external zones are present, then they should be predominately Zone 2 and / or a very limited Zone 22. Hence the external explosion risk profile is low, which is not always the case with the internals of equipment, where higher risk zones frequently occur. As the EU Commission's ATEX 2014/34/EU guidelines of December 2017 clarify; *""Zoning" is not a concept to be found in Directive 2014/34/EU but in Directive 1999/92/EC dealing with employer's obligations with respect to employees operating in hazardous atmospheres. It is not the responsibility of the manufacturer to "zone" but evidently this it is helpful to give an example of the area of intended use".* Strictly speaking one assigns an ATEX equipment category or an equivalent IECEx Equipment Protection Level (EPL) to the internals of equipment, but the zone concept is still useful in this regard. Regardless, in the higher risk Zone 0/20 the equipment protection must consider "*potential ignition sources that are effective or may become effective during normal operation, expected malfunction and rare malfunction*". It is this rare malfunction, which is the technical challenge, as this is defined in the IEC and ISO standards for explosion protection as a "*type of malfunction, which may happen, but only in rare instances*". Note: No indication is given as to when a malfunction is so rare, that it no longer has to be considered.

If one can design out the Zone 0/20 internals, then not only is there a high degree of inherent safety, but the complexity of the necessary protection is greatly reduced, as for Zone 1/21 the equipment protection must only consider; "*all potential ignition sources that are effective or may become effective during normal operation and expected malfunction*". This is a far reduced technical challenge, as an expected malfunction is defined as "*disturbance or equipment malfunction which normally occurs in practice*". For example, the ISSA guidance on mills referenced already in relation to Switzerland explains: "*The intended use of mills is operation at full capacity. In such conditions the product concentration is very high and an explosion is not possible. During start-up or shutdown explosive atmospheres may arise occasionally and therefore at least a zone 21 is present".* On the other hand if frequent start/stops occur, then a Zone 20 is applicable, with both a greater inherent explosion risk and a more complex and costly compliance requirement.

Another example would be the tangential filling of silos, which greatly reduces the degree of dust cloud formed versus axial filling. For vapour hazards, the use of inerting or vacuum processing can be a simple and effective means of reducing the applicable zoning and hence the complexity of the equipment compliance required. The same principle applies, instead of assigning zones, one should first try and reduce them, this not only has benefits with respect to inherent safety, but it also has the potential to significantly reduce costs.

10. Conclusions

What the above shows is that there are useful 'acknowledge rules of technology' available for the PharmaChem and Food & Drink sectors in the area of hazardous area classification, although much of these remain to date in the German language. While these sectors might well consider having some of these rules formally translated, the main opportunity for gain is to be achieved with a change of mind-set, namely that there now exists very good possibilities to design out a lot of these external zones and reduce the degree of zoning within equipment. It is accepted that greater attention to detail is therefore required at the design phase and potentially some increased initial equipment investment costs. However, this is easily offset by the reduced requirements for Ex compliance and facility housekeeping, plus the benefit that the facility is inherently safer. EU legislation, like many other jurisdictions, has a general requirement to update existing risk assessments to improvements in technical knowledge and as current hazardous area classifications are reviewed, these factors can be considered.

11. References

AGS (Committee for Hazardous Substances of the German Ministry for Labour): TRGS 510 "Storage of hazardous substances in non-stationary containers", latest amendment November, 2015**

AGS: TRGS 509 "Storage of liquid and solid hazardous substances in stationary vessels as well as filling and empting systems for non-stationary containers", latest amendment November, 2015**

Dyrba, B: "Praxishandbuch Zoneneinteilung" (Practical handbook on zoning), 2nd Edition, 2012, Carl Heymanns Verlag

Energy Institute: Model Code of Safe Practice 15 "Area classification for installations handling flammable fluids" 4th Edition, June 2015.

EU Commission: "Non-binding guide to good practice for implementing Directive 1999/92/EC (ATEX)", April 2003*.

EU Commission: "The 'Blue Guide' on the implementation of EU products rules 2016". 2016/C 272/01*

Haddon Cave, QC: "The Nimrod Review". The Stationery Office, October 2009*

Swords P: "In a globalised world is process safety becoming harmonised?" IChemE, Hazards 27, May 2017.

Wenzel, M: "Alkohol-Konzentrationsmessungen in Brennereien und Spirtuosenbetrieben" (alcohol concentration measurements in distilleries and spirits operations): Technische Sicherheit, Bd. 7 (2017) Nr. 01/02.

Available on-line. ** *All TRBS and TRGS are available on line at the website of the BAuA.*

"The author thanks the International Electrotechnical Commission (IEC) for permission to reproduce Information from its International Standards. All such extracts are copyright of IEC, Geneva, Switzerland. All rights reserved. Further information on the IEC is available from www.iec.ch. IEC has no responsibility for the placement and context in which the extracts and contents are reproduced by the author, nor is IEC in any way responsible for the other content or accuracy therein".

The author in a similar manner also thanks the International Organization for Standardization (ISO) for permission to reproduce Information from its International Standards. All such extracts are copyright of the ISO, Geneva, Switzerland. All rights reserved.