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**Industrial Gases Council (IGC)
Andrea Mariotti, 2016-2017 Chair**

The analysis to identify gaps in the EIGA library, to discover areas where potential safety issues are not yet properly addressed in the existing documentation, is mainly based on identification of the various hazards for the different types of production process, systems and equipment and a comparison with the recommendations of our technical documents. This analysis has been already performed by our experts in a number of areas including air separation plants, acetylene production, specialty gases, and industrial cylinder operations. This approach is an alternative to the traditional development of new documents or the implementation of the existing ones, as a reaction to incidents.

In many cases, the conservation of mechanical integrity during the life of equipment has been identified as an area of concern, either by the gap analysis or by the study of incidents in ours and in other industries. The mechanical integrity of vessels, pipe work and other equipment containing hazardous substances is the primary barrier against a loss of containment where the effects of an integrity failure may have serious consequences. The successful management of plant integrity requires a clear strategy for the whole plant lifecycle that is frequently extended much further than expected in the design phase. We always wish to operate equipment well beyond its original design life, if a design life was even defined, or to repair or re-use equipment almost indefinitely.

Additionally the ageing of process plants affects not only the vessels and the piping that contain the hazardous substances but also, and often more frequently, their primary protection devices, like pressure or temperature control safety systems, local instruments, control systems and even supports and foundations. But the ageing of the plants is not always related to the year of the first installation but is more related to what we know about its history, its current condition and how that is changing over time. If equipment is poorly designed, manufactured, maintained or undergoes changes in its service conditions, it can start to age from day one. The culture of a company can affect the equipment it operates: a positive culture can be created by engagement, motivation and appreciation throughout company staff. Providing good opportunities for communication among plant operators, maintenance people, supervisors and management and sharing experience among the company and with the industry associations, can be very effective to implement a successful programme of mechanical integrity.

EIGA has already published some documents about this issue: Doc 190: Plant Integrity Management” gives generic guidance to designers, manufacturers and operators on how to implement a plant integrity management system to ensure the safety of equipment containing hazardous substances. The publication includes guidance for inspection policy, organisational arrangements, inspection schemes and reporting,



possible degradation mechanisms and procedures and methods for the detection and sizing of defects and damages. In the appendices of this document some specific information for pressure equipment located inside the cold box of air separation plants and for bulk storage tanks can be found.

A more specific document is the harmonised publication Doc 202: *Mechanical Integrity of Syngas Outlet Systems* that provides a baseline for the safe operation of reformer header systems by identifying the possible failure modes, the monitoring and inspection needed during plant operation, on-line possible remedial action and off-line maintenance and inspection.

Another harmonised document under preparation and that is expected to be published in 2017 is the document *Hydrogen Pressure Swing Absorber Mechanical Integrity Requirements*.

Following the acetylene gap analysis our experts will start work in the near future on two other harmonised documents: *Mechanical Integrity of Acetylene Plants* and *Industrial Gas Pipeline Integrity Management*.

EIGA has, in the past year, published Doc 200: *Safe Design, Manufacture, Installation, Operation and Maintenance of Valves Used in Liquid Oxygen and Cold Gaseous Oxygen Systems* and EIGA Doc 202: *Mechanical Integrity of Syngas Outlet Systems*. Implementation of both documents will contribute to increased safety and reliability of our installations.

For more details please contact the IGC chair: Mr Andrea Mariotti at SOL Group (I) Tel.: +39.039.2396.361 Fax: +39.039.2396.377 - E-mail: a.mariotti@sol.it

Medical Gases Council (MGC) Kent Drott, 2016-2017 Chair

In the previous EIGAZette I described the critical role medical gases play in modern society and also highlighted that the regulatory environment is becoming increasingly complex. During the joint EIGA Working Group and National Associations meeting in Bratislava in April 2016 this fact was interestingly further confirmed. For most EIGA members medical gases represent a relatively small share of their business. In the meeting I noted however, especially during the presentations from the National Associations, that healthcare represented a disproportionately large share of the topics being discussed. With the healthcare business being impacted not only by traditional technical gas regulation, but also by the complex pharmaceutical and medical device regulations, it is increasingly challenging for EIGA members. With this in mind it is very important to continuously build competencies in said areas in order to be able to not only monitor but also influence the development of healthcare in Europe. MGC is here playing a vital role to gather the best expertise, develop standards and position papers, align the member companies and countries to strengthen argumentation and finally to communicate timely, consistently and appropriately to relevant stakeholders.

For more details please contact the MGC chair: Mr Kent Drott at Linde, Tel: +49 173 159 5589, E-mail: kenth.drott@linde.com

Regulatory Environment Council (REC) Chris Szweda, 2015–2016 Chair

This report covers the period since December 2015. In our last report we noted the work of the REC had been focussed on analysing the draft EU ETS proposal text and evaluating potential consequences. The work of the REC in 2016 has

now moved to focus on the development of its thinking to develop position statements and position papers to be used to influence the text of the proposal and to highlight inconsistencies between two articles – Articles 10a (benchmarks) and Article 10b (carbon leakage criteria) - of the text which could lead to distortion of competition between insourced and outsourced production of hydrogen, oxygen, nitrogen and syngas.

EIGA had its Position Papers approved by the EIGA Board in February and has set about a targeted phase of advocacy.

In late February, EIGA held a number of meetings with EU policymakers on the topic of ETS reform currently under discussion in the European Parliament and Council of the EU. The meetings allowed EIGA representatives to meet with seven members of the European Parliament and their advisors, plus three representatives of the Member States, namely UK, the Netherlands and Slovakia.

In the European Parliament, EIGA met with representatives from the EPP group, the Liberals, the Greens and Conservatives. MEPs and advisors were all receptive and potentially favourable towards EIGA's concern on the carbon leakage status of hydrogen and syngas. The Green representative was particularly keen to know what the environmental consequences would be should the level playing field approach not be maintained. Of note, nobody openly opposed EIGA's issue or rejected the proposed solution. There was a general sense that our concern could be solved and some of the policy makers noted they were willing to question the Commission about the proposal's inconsistency.

In the Council, EIGA met with representatives from the UK, Netherlands and Slovakia. All three attachés seemed to believe that the issue of hydrogen and syngas production could be dealt with in line with EIGA proposals. All three indicated that they would certainly not oppose EIGA's proposed amendments. However, with the possible exception of the UK, neither the Netherlands (as rotating Presidency, they need to maintain a neutral stance and not propose amendments) nor Slovakia (the issue is not a priority in the ETS reform for them) were prepared to push this issue at the Council.

On 17 March, the members of the European Parliament Industry & Energy (ITRE) Committee held an exchange of views with Director-General for Climate Action Jos Delbeke on the EU ETS Reform. Of most interest to EIGA, MEP Ashley Fox (ECR, UK) referred to the outsourced production of industrial gases in his speech on behalf of the ECR group. "These sectors are often more efficient than their global competitors and outsourcing – for example gas producers – makes sense from an environmental point of view" he noted. Mr Fox spoke on behalf of German MEP Hans Olaf Henkel, who is a leading MEP for the Conservatives in the Industry Committee, and whom EIGA has met as part of its outreach activity to the Parliament. During the meeting, Mr Henkel (ECR, DE) was very supportive of EIGA's insourcing and outsourcing distortion issue. The fact that the outsourcing model was in the ECR speaking points at the first ITRE Committee meeting on the ETS is a positive sign, showing that EIGA's engagement with policy makers is gradually beginning to bear fruit in the European Parliament.

The next six months will be key to see how well our advocacy sticks in the minds and the texts being discussed.

The timetable and activity are quite intense but give us many opportunities to reinforce our messages. For those of you who like political thrillers and intrigue then keep these dates in your diary and watch the press and media channels – it is sure to be fascinating. Key dates for the players and actors will be:

In the Council: 20 June, Environment Council to adopt “political guidelines” on the ETS reform. Early 2017: Council likely to adopt general approach (i.e. the first informal agreement by Member States). Second half 2016: a first agreement on the file is likely during the Slovakia EU Presidency. Second half 2017: the final agreement on the file is most likely under the UK EU Presidency. REC has already been meeting with UK officials before they enter their purdah in the run up to their Presidency.

In the European Parliament:

Industry (ITRE) Committee. Mid to end of May: ITRE will finalise its opinion. 23rd May: consideration of Draft Opinion in ITRE Committee. 31st May: amendments deadline in ITRE Committee. 12th July: consideration of amendments. 13th October: expected vote on the ITRE Committee draft opinion.

Environment (ENVI) Committee. Mr Duncan (rapporteur for ENVI Committee) started drafting his report on the reform of the EU ETS in April. 15th June: consideration of Draft Report in ENVI Committee. 21st June: amendments deadline in ENVI Committee. September: consideration of amendments. 8th December: expected vote in the ENVI Committee. Early 2017: expected vote in Plenary.

As we go to print Mr Duncan was seen to be in favour of a collegial approach for the preparation of his report to key stakeholders to gauge preferences and said “the first draft will be a ‘skeleton’ report setting out a series of options for the key issues”. EIGA saw an early draft of this report that set out a number of high level structural options. One such option was aligned with an EIGA amendment.

Again, as we go to print EIGA had just finished a second phase of advocacy meetings with Permanent Representatives in Brussels for key Member States and meetings with technical officials in Member States. Our Ad Hoc team is doing a great job.

In April, I had the chance again to present to the Working Group Chairs and the National Associations in Slovakia to promote the work of the REC and also discuss with some of the associations more deeply our work on EU ETS and opportunities they could take to promote our positions in their Member States.

Another key topic that the REC has been supporting and working closely alongside WG-5 came to fruition in March. EIGA met with the lead policy officer for the Packaging and Packaging Waste Directive in the European Commission’s DG Environment. The purpose of the meeting was for EIGA to get a better understanding of the context of the Commission’s proposal and its thinking about Annex I and EIGA’s concerns regarding the current inclusion of gas cylinders. Refillable steel cylinders used for various kinds of gas are included in Annex I. Even though the items listed are for guidance on decisions on how to treat packaging the items in the list become treated “de facto” as packaging! EIGA therefore wanted to better understand any intentions to review and adapt Annex I in the future.

EIGA is very aware of the current difference of treatment in some Member States where placing on the market new or for the first time triggers “packaging taxes”. At the meeting, the Commission official was positive about EIGA’s explanation of the gas cylinder supply chain process and considered it a good example in the context of the circular economy – a topic that is very relevant in the Commission. EIGA emphasised that the cylinders do not become waste and that industry remains the owner throughout the process. The Commission official said that this process is “what the Commission wants” within the context of the circular economy. It was confirmed that there would be no review of Annex I in the current waste proposal in the short-term. However, it seems that there could be opportunities in terms of more long-term solutions as the Commission seemed very interested in including stronger provisions and possible exemptions on packaging re-use in a future review of the Directive. In the meantime, the Commission policy officer also committed to discuss the current discrepancies and issues with Member States.

In January, EIGA submitted its response to the European Commission Public Consultation on the review of Directive 2012/27/EU on Energy Efficiency. This new proposal to review the directive will not target directly the industrial sector and is expected in September 2016.

Responding to consultation documents has become a key task for the work of the REC in order to raise legitimate concerns and re-inforce common positions that are important to our industry on energy and climate topics. Responding to consultations also provides EIGA with a legitimate seat at the discussion table as a piece of policy and regulation progresses.

In its response to the consultation EIGA, pointed out two main messages, which can be summarised as follows:

- EED and ETS: On the question about how energy efficiency legislation has worked with ETS, EIGA expressed some concerns on the current ETS proposal. The current ETS proposal, in fact, calls for a 1% annual decrease in the benchmarks, which implies a 1% energy efficiency improvement a year for industry. Sharing concerns with many industrial stakeholders, EIGA noted that the 1% yearly improvement is disconnected from the industrial reality.

- 2030 target: On the question regarding the EU energy efficiency target for 2030, EIGA highlighted that 1) any goal for energy efficiency must be tailored to the unique situation in each sector and 2) encouraging cross sectoral efficiency in gains: the industrial gases sector exists to enhance energy, environmental and production efficiency and the health and safety of its customer sectors. Process developments by the industrial gases sector in support of other energy intensive sectors are key to improvements in energy efficiency overall.

Our advocacy consultants (Fleishman Hillard) also provide additional support at events where proposals are discussed and debated. This helps provide EIGA with early intelligence on key issues that may be important and raises any possibilities of the need to act and influence or remain passive while the debate is being waged. One such event was the Stakeholders’ Forum on the upcoming reviews of energy efficiency legislation on 14th March, where Commission officials said that the package is still expected to be released in mid-September but could be combined with the effort-sharing decision proposal. The impact assessment is ongoing

and should be ready by June. By attending such an event we were able to learn that, the legislation is not expected to impose any additional penalties on the energy intensive sector. Instead the focus will be on the buildings sector.

The REC continued to monitor and keep an eye on the publication of the European Commission's roadmap on the evaluation of the Environmental Liability Directive (ELD). It was expected that the Commission would publish the long-awaited ELD evaluation report in Q3 2015 (it was originally due in April 2014). In February, the REC learnt from our consultants that the European Commission official in charge of the file reported that the publication and evaluation report on the Environmental Liability Directive was again delayed but will be expected "soon". The official could not give any further indication about the exact timing. According to the Commission official, there were no objections from other DGs during the inter-service consultation but final changes still need to be made to the report, which will require political approval.

Finally, the REC ad hoc working group on ozone agreed and is about to publish a Briefing Note *Compliance with the Biocidal Products Regulation of Oxygen as a Precursor for In-Situ Production of Ozone*. The team also provided more detailed technical work during 2016 in order to maintain a sensible approach on the required technical dossier that is needed to authorise ozone when oxygen is used as a biocidal pre-cursor under the regulation in order to meet the requirements provided by the Commission to the Competent Authorities under the regulation.

This will be my last EIGAZette report as Chair and I wish to thank the work of the REC and in particular provide words of courage to our Ad Hoc Group ETS that is now in the thick of the battle on ETS "the power of your story may not lie in its drama, but in its absolutely perfect relationship to your cause."

For more information, please contact the REC chair: Mr Chris Szweda at The Linde Group (UK). Tel: +44-1483-57 98 57
E-mail: chris.szweda@hoc.com

Safety Advisory Council (SAC) Rainer Wysotzki, 2016-2017 Chair

EIGA Safety Performance:

Part of SAC's mission is to maintain EIGA accident databases and accident statistics, with the aim of monitoring EIGA safety performance. To improve the analysis of the incidents SAC introduced flags for:

- SEVESO relevant incidents
- PSIF (Incidents with actual or Potential for Severe Injury or Fatality)

Let's take a look at how the gas industry has been doing recently:

Safety figures for 2015 showed almost the same figures as past years. There seems to be a magical "recessive statistical plateau".

The Lost Time Frequency Rate (number of injuries per million working hours) stayed at the plateau of 1.8.

An increase is observed in the case of the Recordable Working Injuries (RWI) from 3.1 to 3.49 RWIs per million working hours. SAC is not sure if this is really an increase or a consequence of more complete reporting of RWIs by EIGA members. The number of RWIs (279) is twice the amount of

LTIs (140). Theoretically the value should be higher. Therefore we might assume that the reporting of RWI by EIGA members is still incomplete.

Human error is still seen as a major cause of injuries, the same story every year. Can we fight against this type of cause by only issuing new documents and sharing best practices? I believe we can do more by tackling human factors, human behaviour or human reliability (for employees and contractors) and of course, closely related to this, leadership is the main industry's challenge for improving safety performance. This is the reason why we selected "Human Factors" as the topic for the next EIGA Winter Seminar in 2017.

In 2015 several fatalities were reported by the member companies. Safety in transport of gases, which closely relates to contractors, is the industry's second safety challenge.

SAC work at a glance:

SAC meetings are a place to exchange information and experience on recent gas industry-related incidents, as well as to analyse their causes and preparing incident resume reports. I would like to draw your attention again to the publications titled *Training Package – Recent Incidents* which are issued quarterly. SAC's ambition is that these provoke discussion and new ideas on how to improve safety in our industry.

There is now a separate folder of these incident related Training Packages on the EIGA website in order to be able to find them more easily.

In 2015 a new award was created, the Safety Innovation Award. Each year a special topic will be selected. In 2015 this was Acetylene. The winner will be announced at the summer meeting in June 2016.

The topics for the next two Safety Innovations Awards are already defined and they will cover the main areas of concern: 'Transport Safety' in 2016 and 'Human Factors' in 2017.

Life-Saving Rules - these rules, developed by SAC's Ad-Hoc Group, are intended to remind workers of the hazards and to refer to their local risk assessments. All relevant documentation is now available for the member companies for use.

You can find reports of the SAC working groups in the later on in this EIGAZette.

Other ad-hoc working groups under SAC are busy developing materials to support improvement process safety, health and hygiene, product safety, worker safety. Additionally Ad-Hoc Group REACH closely monitors the development of the REACH Regulation in order to verify, influence or initiate changes.

As the transport of gases in private vehicles has been recognised as a widely underestimated hazard, SAC decided to create a new ad-hoc group that will work on developing new guidelines for the gas industry.

I want to thank all members of the SAC Working Groups and Ad-Hoc Groups for contributing a huge effort to develop and revise new and existing documents.

As already, mentioned, EIGA is preparing a Seminar on human factors and human reliability in January 2017. Be a part of this EIGA project and contribute to our common cause.

SAC challenges for 2016:

- In compliance with the new EIGA strategic priorities, to find a way to identify consistently bad performers and how to help these companies to improve their safety performance;
- Further developing guidance on transport safety;
- Improving contractor management;
- Further developing strategies on how to influence human behaviour;
- Encouraging National Associations to interact more closely with SAC.

For more information, please contact the SAC chair: Mr Rainer Wysotzki at Praxair (Germany) Tel. +49 211 2600 4131
Fax. +49 211 2600 55 131 E-mail: rainer_wysotzki@praxair.com

EIGA Office News

EIGA Staff News

There are a number of events to mark with respect to EIGA staff.

Firstly, Mien Mortier will be retiring at the end of June and leaving EIGA after 17 years with the Association. We would like to take this opportunity to thank her for her great contribution over this time, for welcoming and facilitating the visits of the hundreds of company experts that come to our offices for their work group meetings. We wish Mien good health and good fortune.

Secondly, Isabelle Rondeau and Patricia Vanderplasschen are both marking 25 years with EIGA in 2016. We congratulate them both and thank them for their invaluable contribution to the organisation.

Finally and sadly, we learnt earlier in the year of the death of Peter Bernard. Peter Bernard was Deputy General Secretary of EIGA from 1974 to 1989 and then became General Secretary of IGV in 1990.

EIGA Council Members

At their meeting in January, the EIGA Board of Directors Meeting approved the nominations of the Vice Chairmen of our Councils as follows:

- Frank Hopfenbach, Messer Group was nominated to complete the term of office of Tim Evison, Messer Group as Vice-chairman of REC for 2015/2016.
- Iñaki Uriarte, Praxair was nominated by IGC as Vice-chairman for 2016/2017.
- Stefania Mariani, SOL was nominated by MGC as Vice-chairman for 2016/2017.
- Jesus Gomez, Air Liquide was nominated by SAC as Vice-chairman for 2016/2017.

The Vice-Chairman will automatically become Chairman of the respective Councils at the end of these terms.

Following the election process in 2015 for EIGA's independent member companies to elect representatives of Category 2 and Category 3 Companies, there were some vacant positions open. Subsequently, Manuela Stöckl of Linde Austria has been nominated to the Safety Advisory Council and Giorgio Bisolotti of SIAD has been nominated to the Industrial Gases Council for the term of office 2016-2017.

EIGA Winter Session 2016

In January, EIGA welcomed delegates to the Carbon Dioxide Training Course. The event attracted 110 delegates with a very wide range of roles within our industry. They came from more than 25 countries, including visitors from Australia, Europe, the Middle East and the USA; both members and non-members.

Over the course of two half days, industry experts provided essential knowledge on carbon dioxide, its production and its applications; raised awareness of the applicable regulations and how to implement them effectively; reviewed the basic risks and basic safeguards; and reminded delegates of existing industry knowledge in the EIGA library. The Carbon Dioxide Training Course is now the third such product specific training course run by EIGA, following previous courses on oxygen and acetylene.

National Associations

The annual National Associations (NA) meeting was held in Bratislava, Slovakia, on 13th and 14th April 2016 and included a full day joint session with the Working Group Chairmen to discuss the activities of the Working Groups. The NA meeting, hosted by Dušan Driensky and the SAVDTP, was attended by 18 representatives from 15 out of EIGA's 23 National Association affiliates as well as the Council chairmen. The participants were able to join in active discussions on some of the key issues impacting our industry at a national level and to share experience from these issues and from incidents.

International Harmonisation Council (IHC)

The IHC and observers from the IOMA Global Committee companies met in Tokyo, Japan in March to review the progress on current projects and the resources required to complete projects in development.

In 2015, nine harmonisation projects have been closed, i.e. all the associations have published their version of the same document:

CGA and EIGA agreed and both published an additional 8 harmonised publications in 2015 and three to date in 2016.

EIGA Events

For your diaries:

EIGA Summer Session 2016, 2nd - 4th June 2016, Berlin, Germany

EIGA National Associations' Meeting, 18th November 2016, Brussels, Belgium

EIGA Winter Session 2017, 25th – 26th January 2017, Brussels – Human Factors Seminar.

EIGA National Associations' Meeting, 12th and 13th April 2017, Brussels, Belgium

E-mail EIGA office: info@eiga.eu

Publications

Please visit www.eiga.eu to download the following publications (new since the last issue of the EIGAZette):

EIGA Documents

- **Doc 86:** Gas Cylinders and Valves with Restricted Use in the EU (WG-2)
- **Doc 175:** Safe Practices for the Production of Nitrous Oxide from Ammonium Nitrate (WG-3)

- **Doc 176:** Safe Practices for Storage and Handling of Nitrous Oxide (WG-3)

Position Paper

- **PP 42:** EIGA High Level Contribution on the Proposal for Medical Devices Regulation - Revision of Directive 93/42/EEC (MGC)

Safety Information

- **Safety Info 22:** Potential Hazards of Quick Release Cylinder Valves Used with Firefighting Gases (WG-2)

Environmental Newsletter

- **ENL 29:** Key Aspects of Environmental Hazards Associated with Commissioning and Decommissioning of Installations on Customer Sites (WG-5)

Training Packages (for EIGA members only)

- **TP INC 22:** Recent Incidents in the Industrial and Medical Gases Industry - SAC 145 (SAC)

Technical Bulletin

- **TB 16:** “-40 °C” Mark on Cylinders/Valves (WG-2)

Briefing Notes

- **BN 18:** Connecting Packages to Customer Processes by Vehicle Crew Members (WG-1)

Campaigns

EIGA Life Saving Rules Campaign Website (SAC)

Working Group News

Transport (WG-1)

Briefing Note BN 16, mentioned in the previous EIGAZette and dealing with the connection of packages by drivers at customer sites is now available on the EIGA website.

In terms of international harmonisation, WG-1 will support the revision of the harmonised document Doc 41 dealing with sea transport of MEGC's.

The replacement of MLA 237 on import of DOT cylinders to Europe is still a major ongoing issue since its validity limit is June 2016. EIGA strongly supported the prolongation of this MLA during the last Joint Meeting in March in Bern. The UK authorities have volunteered to prepare a new draft which should be signed by most of the European countries. A proposal to include in this new MLA a list of the gases and mixtures able to be filled in the DOT cylinders was rejected by a majority. In parallel, work with CGA is still going on for mutual acceptance of European cylinders being imported and emptied in the US. Among the new proposed amendments, EIGA is working on the creation of a specific UN number for disilane, the use of metallic rings on drums and, in conjunction with Norway, clarifying the fastening of MEGC's in ADR. Since most of the amendments planned for the 2017 version of ADR have now been established, WG-1 is going to prepare a Training Package *ADR 2017: Changes for Class 2*.

For more information please contact Mr Christophe di Giulio, Chair of WG-1 at Air Liquide (France) - Tel: +33.1.58.07.86.02 Fax: +33.1.58.07.83.40 - E-mail: christophe.digiulio@airliquide.com

Gas Cylinders and Pressure Vessels (WG-2)

Highlight:

WG-2 is working together with WG-1 in the discussion with CGA on the mutual recognition of DOT and TPED cylinders. Several telephone conferences have taken place and others are planned to find a way for the acceptance of DOT cylinders in Europe and TPED in DOT areas.

Progress with Publications:

Harmonisation projects have included revision of the following documents:

- *Doc 64: Use of Residual Pressure Valves.* Revision done. Awaiting publication.
- *Info 22: Potential Hazards of Quick Opening Cylinder Valves used with Firefighting Gases.*

Following documents are in process of publication:

- TP xx: *Prefill Inspection of Gas Cylinders;*
- Doc 91: *Use of Pressure Relief Devices for Gas Cylinders;*
- TB xx: *Use of PRD's on Composite Tubes;*
- Doc 62: *Methods to Avoid and Detect Internal Gas Cylinder Corrosion;*
- TB xx: *Long term durability of steel gas cylinders;*
- Doc 138: *PTFE Used as a sealant for Cylinder/Valve Connections.*

Further activities:

ECMA: Particle tests for cylinders and special requirements for cylinders in medical and food service.

UN: participation in the informal working group on “Provisions on equipment for tanks and pressure receptacles” including proposals for revising the text of RID/ADR/ADN concerning pressure receptacles.

Outlook:

WG-2 has taken the initiative to produce an overview document for cylinder and valve parameters and equations plus an interpretation.

Special:

WG-2 would like to thank David Birch for his large contribution to the successful work of the group. He is, was and will always be a friend of the gas industry. We wish him all the best for the next years and that he will enjoy his time as a retired expert.

For more information, please contact Dr. Wolfgang Dörner, Chair of WG-2, at Linde AG Tel: +49 89 7446 1304 FAX: +49 89 7446 2599 E-Mail: wolfgang.doerner@linde.com

Atmospheric Gases Process and Equipment (WG-3)

Organisation:

Christian Weikinger was nominated as an additional member of the group, representing The Linde Group.

Recently published documents:

In the last period no new or revised documents were published.

Documents in progress:

We are currently in the approval process for the documents prepared by AHG-3.13 *Leak before break in flat bottom storage tanks* and AHG-3.14 *Cryogenic flat bottom storage tanks – risk assessment*. A few new comments have been

raised which need to be solved before the publication of the documents.

AHG-I.21, *Cleaning for oxygen service* held a first meeting and developed a large number of comments. This is a harmonised project and the next step will be a series of comment resolution meetings with the other Associations.

AHG-3.17, *Liquid oxygen valves in customer stations* have already met four times and had some difficult discussions on how to adapt Doc 200: *Safe Design, Manufacture, Installation, Operation and Maintenance of Valves Used in Liquid Oxygen and Cold Gaseous Oxygen Systems* to customer stations. The next meeting is scheduled at the end of May.

Mechanical integrity of pipelines might become an issue in the gas industry after an incident occurred in France. A group of experts will meet to determine the scope of a possible document.

Currently WG-3 members are working on the revision of the following harmonised documents:

Doc 149: *Safe Installation and Operation of PSA and Membrane Oxygen and Nitrogen Generators*: a draft has been sent out for Association approval.

Doc 154: *Safe Location of Oxygen and Inert Gas Vents*: several tables were removed from the document where the accuracy had been questioned. The revised document will be sent out for Association approval. In a next step the tables will be re-calculated to complete the document again.

Development of a new document on *Vacuum Jacketed Piping in Cryogenic Service* has been on hold until now. Drafting of the document has now started, with CGA as the project lead.

For more information, please contact Mr Dirk Reuter, Chair of WG-3, at Messer Group (Germany) - Tel: + 49.2151.7811.141 – Fax: 49.2151.7811.511 E-mail: dirk.reuter@messergroup.com

Special Gases (WG-4)

International harmonisation:

WG-4 continues to work on the development of internationally harmonised documents with members of AIGA, CGA and JIMGA. A series of net-meetings have been held with CGA and AIGA/JIMGA to resolve comments received on the harmonised documents.

Current activities are focussed on the following documents:

Safe Handling of Hydrogen Selenide (A-1110), a new document and the revision of:

Doc 162: *Code of Practice: Phosphine*

Doc 163: *Code of Practice: Arsine*

Doc 140: *Code of Practice: Fluorine and Fluorine Mixtures*

The final technical reviews have all been completed and EIGA are waiting for the completion of final editing and approvals to publish the documents.

Doc 92: *Code of Practice: Nitrogen Tri-Fluoride* is currently being reviewed by a Joint Working Group.

EIGA documents:

A review of EIGA Doc 161: *Gas Compatibility with Aluminium Alloy Cylinders* has been completed and sent to IGC for approval to publish.

The five yearly reviews of Doc 129, *Pressure Receptacles with Blocked or Inoperable Valves* and Doc 130 *Principles*

for the Safe Handling and Distribution of Highly Toxic Gases and Gas Mixtures have been initiated.

International Standardisation – ISO Standards:

WG-4 continues to participate in the development and review of several ISO Standards, including:

ISO 11114-1:2012: *Gas cylinders - Compatibility of cylinder and valve materials with gas contents-Part 1: Metallic materials*. Following discussion and lobbying by EIGA the categorisation of nitric oxide (NO) as incompatible with aluminium alloy cylinders was rejected at the last meeting of ISO TC 58 WG-7.

ISO/FDIS 14456: *Gas cylinders – Gas properties and associated classification (FTSC) codes – Determination of properties of gases and gas mixtures* has been published in September 2015.

ISO 13338: 1995 (classification for corrosivity): *Determination of tissue corrosiveness of a gas or gas mixture* and **ISO 101298: 2010** *Determination of toxicity of a gas or gas mixture*. The standards were reviewed at the ISO TC58 SC2/WG-7 meeting in February 2016 and comments on the respective Committee Drafts (CD) addressed.

ISO 10156: 2010 (classification for flammability and oxidizing potential): *Gases and gas mixtures - Determination of fire potential and oxidizing ability for the selection of valve outlets*. The standard is currently undergoing revision and the revised draft is at the DIS stage.

Working group members and meetings:

The Working Group sends its best wishes to Giorgio Bissolotti who has left WG-4 after 16 years and becomes a Representative of the EIGA Category 2 and 3 members on the Industrial Gases Council (IGC). Giorgio is replaced on WG-4 by Laura Gagni from SIAD who participated in the working group meeting held in February 2016.

Pierluigi Radaelli, SAPIO has also left the group due to new responsibilities which do not allow him time to continue as a member. He will continue as a member of **AHG 4.10**, *ISO TC 158 'Analysis of Gases'*.

The AHG-4.10 continues to work on the development of a draft ISO 6142-2 standard which details the production of gravimetrically prepared calibration mixtures. An ISO TC158 WG-3 *Gravimetric Methods* meeting will review the latest draft during their July 2016 meeting.

For more information, please contact Dr Kevin Cleaver, Chair of WG-4, at BOC Gases (United Kingdom) Tel: + 44.1483.244.308 Fax+ 44.1483.45.07.41 E-mail: kevin.cleaver@boc.com

Environment (WG-5)

Legislation - Circular Economy

EIGA is seeking to influence the circular economy review concerning cylinders and packaging waste.

EIGA responded to the commission consultation on circular economy. We are pushing for an exemption from packaging legislation for re-usable gas cylinders on the basis that it supports the objectives of the circular economy. EIGA were able to have a meeting with the European Commission case officer in March 2016 with the objective of having cylinders recognised as a re-usable package and 'exempt'. The Commission was sympathetic but has no immediate plans to amend Annex 1 examples, and stated that their adjustments relate to a long-term objective (2-3 years) to have closed loop

re-usable packaging exempt (e.g. cylinders and re-usable pallets).

We are supporting REC in their work on EU Emissions Trading and are also monitoring implementation of the Fluorinated Gases Regulation (EU regulation no 517/2014). EIGA Doc 192/14 which contains guidance on the labelling provisions of regulation is now published and the CLP guide will be updated by WG-9.

EIGA Environmental Awards 2015

We received twelve good nominations which demonstrated the commitment of EIGA member companies to environmental improvements and the results will be announced at the summer meeting in June 2016.

Documents in progress

WG-5 continues to work on the acetylene BREF (Best available technique reference document). A new work item is a baseline reports guide for the industrial emissions directive (IED); three newsletters are planned as well as updating documents on noise (Doc 85), Environmental Auditing (with the Worker Safety Ad-Hoc Group), and revision of four environmental impacts documents for ASUs, transport, customer installations and hydrogen plants.

Doc 110 and Doc 111 on *Environmental Impacts of Cylinder Filling Plants* and *Environmental Impacts of Carbon Dioxide and Dry Ice Production* are ready for publication.

WG-5 has completed work on an extended document on *Management of Waste Gas Cylinders* and this is now going through the approval process and should be ready for publication shortly. This document builds on the advice in Doc 166 *Management of Waste Composite Cylinders*.

If you need any more information, or would like to make any comments; please contact your WG-5 representative, the WG-5 Chairman or the EIGA office. WG-5 typically meets 3-4 times per year and have reduced our carbon footprint by adopting the virtual meeting guidelines.

For more information, please contact Mr Stephen Bradley, WG-5 Chair, at Air Products Plc (UK) Tel: + 44 1932 249 992 Fax: + 44 2086.364.810 E-mail: bradlesc@airproducts.com

Cryogenic Vessels (WG-6)

Harmonised Doc 176: *Safe Practices for the Production of Nitrous Oxide for Ammonium Nitrate*, was published in March 2016.

WG-6 is working on a test programme to clarify if flame arrestors should be used or not and if it is necessary to avoid asphalt under nitrous oxide vessels.

Current activities are focused on the development and revision of the following documents:

Doc 06, *Safety in Storage, Handling and Distribution of Liquid Hydrogen*. The Working Group have finalised the revision of the document. After editorial review, the document will be circulated to IGC for technical review.

Doc 24, *Vacuum Insulated Cryogenic Storage Tank Systems Pressure Protection Devices*. WG-6 will review technical comments and continue to work on this revision.

A new document, on operation and inspection of static vacuum insulated cryogenic vessels, which is a compilation of Doc 114, *Operation of Static Cryogenic Vessels*, Doc 115, *Storage of Cryogenic Air Gases at User's Premises*, Doc 119, *Periodic Inspection of Static Insulated Vessels*, and takes into account ISO 21009-2, *Cryogenic vessels – static*

vacuum insulated vessels – Part 2: Operational requirements, is in preparation. The first draft was reviewed during the last meeting.

The harmonised document covering safe re-pressurisation of carbon dioxide vessels has been modified to include both EN and ASME design codes. Previously, EN design was an Annex. Some wording needs to be improved and discussed with other Associations.

The chairman of WG-6 has been invited to a CERN conference in September 2016 as chairman of ISO/TC 220. EIGA documents will also be presented.

ISO Standards:

The ISO Technical Committee formed to develop Cryogenic Vessel standards has published all the necessary standards. Standards which are available are the ones concerning materials, operational requirements and the design standards for small and large transportable vessels. Revision of standards is ongoing including the ones on operational requirements. A new standard on cryogenic pumps is being prepared. The standards for impact toughness are being revised. In particular, they will allow careful re-pressurisation of tanks where carbon dioxide has solidified. The next meeting will be held in Paris from 6th to 8th June, 2016.

CEN Standards:

The last CEN TC 268 meeting took place in Paris on 8th September, 2015.

The Formal Vote on EN ISO 24490, *Cryogenic vessels – pumps for cryogenic service*, ended on 12th February, 2016. The standard will be published soon.

The Formal Vote on EN ISO 21013-3, *Cryogenic vessels – pressure-relief accessories for cryogenic service – Part 3: Sizing and capacity determination*, ended on 14th March, 2016. The standard will be published soon.

The CEN/TC 268/WG 5 will meet in Paris on 5th July, 2016. The main item to be discussed is hydrogen quality for hydrogen fuelling stations.

For more information, please contact Mr H. Barthélémy, Chair of WG-6, at Air Liquide (France) Tel: +33 1 40 62 55 01 Fax: +33 (0) 1 40 62 57 95 E-mail: herve.barthelemy@airliquide.com

Medical Gases (WG-7)

Falsified Medicines:

Commission Delegated Regulation (EU) 2016/161 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use has been published.

As described in Annex 1 of the Regulation, Medicinal gases are excluded from the application of the safety features referred to in article 45(1) of the regulation.

WG-7 rationale had been provided to the EU Commission in order to achieve this result.

GMP Guidelines:

WG-7 is now working on GMP part II that covers the manufacturer of gases classified as Active Pharmaceutical Ingredients (API). An EIGA Technical Bulletin about the identification of the starting material and APIs in medicinal gases manufacturing has been prepared to be used with authorities and stakeholders.

Package Information Leaflet (PIL):

WG-7 is making a survey around Europe in order to check where it is possible to provide PIL just in electronic format. The objective would be to have the possibility to avoid paper PIL in all countries and make them available to patients and users in electronic format.

Pharmacovigilance:

WG-7 is finalising a Guideline on “*Typical post-marketing pharmacovigilance cases in the medical gases industry*” in order to have a harmonised approach in member companies and national associations on the classification of adverse drug reactions.

For more information, please contact Mrs Stefania Mariani, Chair of WG-7, at SOL Group (Italy) Tel: +39.039.239.63.90 Fax: +39.039.239.63.71 E-mail: s.mariani@sol.it

Food Gases (WG-8)

There have been several changes to the WG membership in recent months, for a number of reasons.

Jean-Claude Claeys (Messer) replaces James Hennequin.

Cristina Fernandez Muñoz (Carbueros) replaces Christian Pullen (AP).

Javier Campo Ortiz (Praxair) replaces Daniel Gonzalez.

The company Buse represented by Christof Gloger decided to no longer be a member of the WG.

We thank all of them for their great contribution over the past several years and extend a warm welcome to the new members.

The group is working on the basis of three face to face meetings a year at the EIGA office.

Work in progress:

A number of publications under WG-8 governance that were last published in the period 2008-2011 in relation to carbon dioxide are under revision:

Doc 56: *CO₂ Tanker Driver Manual*

Doc 66: *Refrigerated CO₂ Storage at Users' Premises*

Doc 67: *CO₂ Cylinders at Users' Premises*

Doc 68: *Prevention of CO₂ Back Feed Contamination*

Doc 70: *Carbon Dioxide Source Certification, Quality Standards and Verification*

Doc 83: *Recommendations for Safe Filling of CO₂ Cylinders and Bundles*

Doc 150: *Code of Practice - Dry Ice*

All members are reminded to review internally with their company for input, update and validation and other concerned WGs will be involved to review the draft documents when completed.

Compliance and standards:

1935/2004 EC Directive compliance:

Metals released from gas equipment materials making a typical complete food gas installation: After approving test protocols and AFGC (the French National Industrial Gas Association) ordering the study, we expect the first data collection from the Italian CNR by mid-year, to be shared and reviewed by the WG.

ISBT (International Society of Beverage Technologists):

It has been highly recommended that several WG-8 members should be a member of ISBT. Membership is based on an

individual subscription (not under company name). Some quality procedure details in the ISBT Nitrogen guideline document such as odour testing are still not clear as it still references inhalation of nitrogen gas as part of the test, while at the same time correctly referring to the risk of the asphyxia.

Security:

Some questions have been raised with gas companies regarding the security measures that are taken in our business, not only for customer bulk tanks and cylinders at customer premises and gas manufacturing plants but also along the complete supply chain and cycle of the gases containers including retests. In the US this subject, named ‘Food Defence’, has arisen from fears about food poisoning by terrorists. This issue will be covered in a revision of Doc 125 *Guide to the Supply of Gases for Use in Food*.

Safety:

A number of fatal incidents were reported recently, not in relation to industrial gases companies’ involvement in supply but more in relation to near consumers’ misuses: asphyxia in an apple picker warehouse, asphyxia when breathing a whipping cream nitrous oxide cartridge. These reinforce the importance and necessity to inform related professional organisations by means of safety leaflets. National Industrial Gases Associations have been very active in this area.

For more information, please contact Mr Philippe Girardon, Chair of WG-8, at Air Liquide (France) - Tel: +33.1.39.07.69.68 Fax+33.1.39.07.65.53 E-mail: philippe.girardon@airliquide.com

Classification, Labelling, SDS (WG-9)

The mission of WG-9 is to monitor, and influence when needed, new and revised legislation on classification and labelling of pressure receptacles, the preparation of Safety Data Sheets (SDSs) and to publish recommendations on how to comply with the relevant legislation.

The mission of TF-9.1 is to develop with LISAM S.A. an SDS authoring tool that is compliant with legislation and the recommendations of EIGA.

Legislation at UN level:

- A new Chapter 2.18 “Chemicals under pressure” of GHS is presently under discussion. WG-9 determined the proposals to be acceptable for EIGA members and to be in line with current practices.

- Two proposals concerning new criteria for flammable gases are presently discussed.

The Joint Working Group TDG/GHS has adopted the criteria proposed by EIGA for splitting Cat.1. As an alternative, Germany is proposing to make use of the same criteria to differentiate Cat.2 (now empty) from Cat.1. The German proposal is supported by EIGA and Cefic.

Legislation at EU level:

Information to submit to Poison Centres

WG-9 is following closely the development of a new regulation to harmonise throughout the EU the information to be submitted to the National Poison Centres when new hazardous mixtures are placed on the market. WG-9 managed to have gas mixtures that have no hazard other than being “under pressure” to be excluded from the scope of the directive.

The new directive is expected to be approved by mid-2016 with a stepwise implementation period spread from July 2019 for consumer mixtures to July 2021 for industrial mixtures.

Adaptations to Technical Progress (ATPs) of the CLP

The 8th ATP that aligns CLP with the 5th revision of the GHS will be published shortly. The 9th ATP will be published later in 2016. Both ATPs have no major impact on gases. The 10th ATP will contain an Annex with all chemical names in all languages. The draft proposal of the 11th ATP for new/modified entries in Annex VI does not include any gas.

EIGA documents:

WG-9 is working on new updates for both CLP documents to be published at the same time in 2016. Doc 169 will be updated to incorporate the relevant changes from the ATPs to the CLP. Doc 919 will be updated with a new Annex that will outline the structure of the Exposure Scenario (ES) with the relevant library of phrases needed to generate ESs for gases.

SDS authoring tool:

TF-9.1 has created exposure scenarios (ES) for six gases. A database for phrases used in the ES has been created. A request for translations of new phrases will be sent to national associations shortly. ESs shall be made available by end of Q4 2016.

A new collaboration tool called WIKICHEMIA has been developed by LISAM. It will be used for maintenance in 23 languages of the set of EIGA phrases used in SDS and in ES. EIGA translators were trained on the new tool in April.

TF-9.1 is working on the update of ExESS v15 in order to improve some functionality and align the database with EIGA Doc 919/15. One of the major improvements will be the ability to publish the exposure scenarios that have been prepared and approved by WG-9 for several gases.

For more information, please contact Mr Joachim Barbe, Chair of WG-9, at joachim.barbe@messergroup.com or Mr Ewoud Beheydt, chair of TF-9.1 at ewoud.beheydt@praxair.com

Homecare (WG-10)

WG-10 has welcomed Harmen van Dijk as the new representative of Westfalen, Peter Van Draege representing Messer and Thomas Pfisterer from Linde; all have joined the group in recent months.

Since the last edition of the EIGAZette we met once in Brussels and organised two conference calls and have reviewed and updated the group's Scope and Terms of Reference. We remain focused on safety of our patients and staff in all our activities related to oxygen therapy, its services, gases and devices.

We recently analysed accidents with vehicles transporting homecare oxygen to patients and published an alert focusing on compliance with Doc 128: concerning *Design of Vehicles Used in Medical Oxygen Deliveries*. This document supports operators in implementing barriers to this kind of events.

We have finished the revision of Doc 89: *Medical Oxygen Systems for Homecare Supply*. The updates took into account the current trends in Homecare devices, which are increasingly portable, light and small and which did not exist a few years ago. You will soon find this revision on the EIGA website.

We are also, according to the strategic objectives of the EIGA Board and the priorities defined for the present year for our group, revising Doc 98, *Safe Supply of Transportable*

Medical Liquid Oxygen Systems by Healthcare Service Providers.

WG-10 is also preparing to work, for the first time, on the harmonisation of a document they have written and published in the past: a Technical Bulletin describing the *Handling and Cleaning of Externally Soiled Medicinal Gas Containers*.

And we are always attentive and receptive to information that may lead us to engage our efforts in the Safety prevention and management of risks.

For more information, please contact Mr Antonio Lima, Chair of WG-10, at Air Liquide Health Care (France) - Tel: +33.1.49.69.45.81 E-mail: antonio.lima@airliquide.com

Hydrogen Energy (WG-11)

Most of the WG-11 activity is moving towards building common positions within member companies and other players in the hydrogen infrastructure industry, in order to present common industry views to the various standardisation and regulation bodies.

In particular, WG-11 has provided supporting work to standardisation related to hydrogen refuelling stations, hydrogen quality and hydrogen quality assurance in conjunction with ongoing work at ISO TC197 WG24 and CEN TC 268 WG5.

Hydrogen refuelling risk assessment:

WG-11 has contributed to a refuelling risk assessment requested by the German government, TÜV and Shell in view of the mass deployment of Fuel Cell Electric Vehicles and hydrogen recharging stations. This exercise is to be finalised and will be used to define the safety requirements (SIL) to be applied to safety loops on recharging station dispensers and potential evolutions of standards for car on board high pressure storage. The result of the WG-11 work is to be transferred to ISO TC197 WG24 defining ISO TR19880-1.

Hydrogen quality and quality assurance for hydrogen energy applications:

WG-11 is requested by CEN TC268 WG5 to propose a draft document for a European standard for hydrogen quality. It has also been requested to participate in the development of a European standard with the car OEMs. A risk analysis approach has been developed within WG-11 to support the adaptation of the existing ISO 14687-2 dedicated to hydrogen quality specification for vehicles into a European standard and to propose the basis of a quality assurance approach for hydrogen. WG-11 has met with car manufacturers and three workshops took place in 2016. Since the beginning of 2016, two additional workshops have been organised in order to build a consensus on quality assurance.

Green/Low Carbon Hydrogen Guarantee of Origin:

A common position with regard to the consultation launched within the EU project CERTIFHY to define "Green Hydrogen" has been defined and transmitted to the project consortium. The request of WG-11 to include a definition of low carbon hydrogen has been adopted.

Safety distances - Evaluation of Sandia Lab HYRAM Tool:

WG-11 has defined a reference hydrogen refuelling station configuration. This configuration is used to evaluate the HYRAM probabilistic tool and compare its results with the

results obtained by the WG-11 members' own company tools.

Hydrogen vents for hydrogen energy applications:

Development of a hydrogen vent document based in particular on latest industry findings on hydrogen behaviour.

Liaisons with other organisations:

- A liaison has been established with the Clean Energy Partnership in Germany.
- A liaison has been established with ISO TC197.
- A liaison has been established with CEN TC268.

For more information, please contact Mr Guy de Réals, Chair of WG-11, at Air Liquide (France) Tel.:+ 33.1.39.07.69.05 e-mail: guy.dereals@airliquide.com

Acetylene (WG-12)

WG-12 activities in 2016 are focusing on new documents for which work item requests were approved in 2015.

The following documents are ready for publication:

- Safety Alert on *Hazards of Transport of Lime Slurry in Non-Dedicated Road Tankers*.
- Safety Alert on *Acetylene Compressors without Separation Pieces in the Crankcase*.
- Revision of Safety Leaflet 04: *The Safe Transport, Use and Storage of Acetylene Cylinders*.

The documents on calcium carbide specifications and acetylene installations at customer premises progressed significantly and should be ready before the end of the year.

WG-12 will contribute to comments on a new CGA document on safe operation of acetylene generators: the aim is to have a basis for a possible future harmonised document, as it is recognised that the draft document provided by CGA is a sound basis and that there are no critical discrepancies with the common best practices adopted in Europe.

The monitoring of the DMF restriction process continues.

Concerning participation in ISO standardisation committees, no significant recent activities have been reported by the WG-12 members.

WG-12 supports the revision of CEN/TR 14473 *Porous materials for acetylene cylinders* and, where possible, will be a data provider for the new or missing porous materials.

For more information, please contact Mr Lorenzo Beretta, Chair of WG-12, at SOL Group (Italy) - Tel: + 39.039.23.96.376 fax + 39.039.23.96.420 - E-mail: l.beretta@sol.it.

Security (WG-13)

Since the last EIGAZette, we have seen two terrorist attacks in Brussels. Fortunately there were no casualties amongst EIGA members or staff. Whilst these attacks were not directed towards the industrial gases industry, EIGA members need to continue to be vigilant and review and implement the recommendation in the EIGA publications covering security.

For the balance of 2016, WG-13 will be continuing to review if our security guidance publications cover the ever changing security environment.

EIGA office continues to maintain links with various bodies such as the European Commission on security issues.

Finally, WG-13 urges all EIGA members and their families to be vigilant with a busy summer of public events ahead of us.

For more information, please contact info@eiga.eu

Medical Equipment (WG-15)

Position Paper on reclassification of carbon dioxide:

The discussions on the new Medical Device Regulation (MDR) in the closed world of the European institutions are still ongoing and it is difficult to know in which direction they are evolving. This is particularly true concerning the controversial "Rule 21" used for the classification of medical devices.

Medical devices are to be classified in one of the four classes named I, IIa, IIb and III according to their level of risk for the patient, from low to high risk. For example, plasters are in class I, oxygen masks in class IIa, pressure regulators in class IIb and vascular stents are in class III. The class is determined by applying defined criteria (rules). Of course, the level of requirements for the conformity assessment procedure (CE marking) and involvement of the notified body increase significantly with the class of the device. Furthermore, the European Commission makes no secret that one of the goals of the new regulation is to strengthen the requirements for class III devices, such as clinical trials, scrutiny procedure and specialised notified bodies.

According to the current medical device directive, carbon dioxide (CO₂), when used as a medical device in procedures such as laparoscopy or virtual colonoscopy is classified as class IIb. But the new Medical Device Regulation has introduced a new classification rule, rule 21, which targets specifically *substance-based medical devices* – gases fall obviously in this category – introduced in the body via a body orifice. With this new rule, CO₂ for colonoscopy would be reclassified in class III, with attendant consequences, where CO₂ for laparoscopy remains in class IIb. A schizophrenic situation for the same product!

Carbon dioxide is a gas with a well-established use in medical practice where it has been safely used for decades. Clearly, it was not the aim of the regulators to reclassify CO₂. This gas is just a collateral victim of a rule targeting other products. As Mairead McGuinness, vice-president of the European Parliament, said at a conference on substance-based medical devices: "*In this sector, a word or two that gets through can have quite significant implications that are unintended*", recognising the need for "*very deep technical scrutiny of any text that is agreed*".

It is in this context that EIGA has issued a Position Paper (PP-42), written by WG-15 in the form of a high level contribution on the proposal for medical devices regulation, requesting that medical gases are excluded from rule 21, taking the example of carbon dioxide to demonstrate the irrelevance of this new rule for our products.

We hope that this Position Paper, pointing out an *unintended implication*, will give to the European regulators food for thought and help them to make an appropriate decision, such as the exclusion of medical gases or the pure and simple withdrawal of rule 21.

Standardisation

In May the annual plenary meeting of ISO TC 121, where many points on the agenda are of the highest interest for EIGA members, takes place in Chicago.

The now famous "fir-tree issue" should come to an end since the consensus proposal of the Advisory Group has been accepted by a vast majority of ISO members. It is recalled

that this proposal takes up the principle supported by EIGA, that is to say keeping the current corrugated nipple as the unique type of flow outlet for all medical devices directly supplying gas, such as VIPRs (Valve with Integrated Pressure Regulator) fitted on oxygen cylinders, and introducing the newly standardised small-bore connector on all patient interfaces such as oxygen masks and nasal cannulas, in view of preventing possible misconnection with other medical applications.

The revision of the ISO 10524 series on pressure regulators (10524-1: pressure regulators for cylinders, 10524-2: line and manifold regulators and 10524-3: VIPRs) continues and comments received from the national committees will be reviewed.

Regarding VIPRs, the overlapping areas between ISO 10524-3 and ISO 10297, the standard on cylinder valves which is referenced in ADR, should have been clarified after the work of an ad hoc group. The relationship with ISO 11117 on valve guard should be clarified as well. As an outcome of the meeting, the three standards will be sent out for comments as a DIS. Nevertheless, due to the number of significant changes made, it seems very likely that a second DIS will be necessary, which would mean a publication at the beginning of 2018 at the soonest.

*For more information, please contact Mr Benoît Marchal, Chair of WG-15, at Air Liquide (France) - Tel: + 33.1.49.69.83.60
E-mail: benoit.marchal@airliquide.com*

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