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Corporate members :

ACHOBEL Belgium

Editorial

After a well-deserved vacation, we are back at the control panels ! In this issue, you will read an article that may not seem very exciting but whose subject is very important for a better understanding of the effects Europe can have on our activities. What is a European standard ? What is it used for ? In what aspects are we concerned ? It is not possible to keep saying "that has nothing to do with me" or "I am not interested" - Europe catches up with us, it is up to us to know !

Furthermore, you will find the summary of an article that one of our members will present at the next EUBS congress (Ajaccio, September). This paper is the result of a long work, completed with patience and rigor. I thank our members who complete this studies for their courage and perseverance. In addition, I make a point of stimulating each one among you to work together on common subjects.

EBAss is directed by a Board of Directors which meets regularly. In our preoccupation for transparency, you will find henceforth, a summarized report of the meetings and decisions in this newspaper.

At our last meeting, we decided, on proposal of its president to end the activities of the scientific committee and to start immediately a new committee more in line with our objectives: the Safety Committee.

If you wish to know some more, then visit your Web site "www.ebass.org" where space is reserved for you as a member.

I wish you good reading !

Robert Houman
President

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 Registered office : 9, Sainte Anne - B 7880 FLOBECQ - BELGIUM
 Secretariat : EBAss - 267 Avenue des Croix de Guerre - B 1120 BRUXELLES - BELGIUM
 E-mail : cosette.mannens@skynet.be Website : www.EBASS.org

Normalisation of hyperbaric systems for medical purpose: the essential requirements of European Directive CE 93/42 and their consequences in terms of EN standards

HOUMAN Robert - CHT - HBO safety manager

Centre for Hyperbaric Oxygen Therapy - Military Hospital - Brussels (Belgium)

Introduction

The European Directive CE 93/42 is based on the concept of a new and global approach. The mechanisms in place to achieve this aim are based on prevention of new barriers to trade, mutual recognition and technical harmonisation.

In short, harmonised European legislation has been limited to the essential requirements (equipment in the field of safety or of general interest) in order to ensure the free movement and fabrication of the product for the entire community.

The manufacturer has, indeed, the obligation to prove that his products are in conformity with the essential requirements of the concerned directive. The European standards (EN) are recognised as being in conformity with the essential requirements of the concerned directive. Different standards would therefore represent guarantee with regard to the essential requirements of the directive.

By the medical hyperbaric chambers, it doesn't actually exist any specific standard.

How the manufacturer can prove the conformity of his product ?

Method

The reference document is the annex 1 of the directive: for each article, it must be defined if the chamber and the systems are concerned by this article.

Structure of the Annex¹:

Article 1 to 6: General requirements

Article 7. Chemical, physical and biological properties

Article 8. Infection and microbial contamination

Article 9. Construction and environmental properties

Article 10. Devices with a measuring function

Article 11. Protection against radiation (not concerned)

Article 12. Requirements for medical devices connected to or equipped with an energy source

Article 13. Information supplied by the manufacturer

For each article, the manufacturer shall research existing EN standards.

Example of article 1:

" 1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. "

Therefore, a risk management process based on the EN ISO 14971 will verify each generated hazards of the device. The manufacturer shall establish a process for identifying hazards associated with a medical device, estimating and evaluating the associated risks, controlling these risks and monitoring the effectiveness of the control. This process shall be documented and shall include the following elementsⁱⁱ:

- Risk analysis,
- Risk evaluation,
- Risk control and post production information.

Application of relevant standards as part of the medical device design might constitute risk control activities. For the medical hyperbaric chambers systems, more than 60 EN standards can be pointed !

Examples:

EN 737 - Medical gas pipeline systems

EN 738 - Pressure regulators for use with medical gases

EN 1041 - Information supplied by the manufacturer with medical devices

EN ISO 8185 - Humidifiers for medical use - General requirements for humidification systems

EN ISO 10993 - Biological evaluation of medical devices

EN 12218 - Rail systems for supporting medical equipment

EN 13220 - Flow-metering devices for connection to terminal units of medical gas pipeline systems

EN 60601 - Medical electrical equipment

The applications of EN standards give a presumption of conformity. But they are specific hazards non-covered by standards. Hyperbaric medical systems are specific and complicated.

In fact, our community was not totally deprived. Germany owns since 1984, a DINⁱⁱⁱ standards for "pressure vessels for human occupancy – multi place pressure chamber for hyperbaric therapy – performance, safety requirements and testing".

The only problem was, that these standards have been edited by a committee of a national normalisation institution (DIN), which regroups, among others, the manufacturers and institutions of national certifications^{iv}

It's here that the group TF 127 intervenes. The CEN (European Committee for Normalisation) has been created in 2001, a task force 127 to propose a European standard on hyperbaric chambers (pr EN 14931). The process of normalisation of hyperbaric systems for therapeutic use is currently under way. The initial document used is standard DIN 13256 2.

Via the intergovernmental framework for European Co-operation in the field of Scientific and Technical Research - COST Action B14 Hyperbaric Oxygen Therapy - the Working Group Technical aspects (WGT) took shape on March 2000. The WGT^v decided to aim for the initiation of a harmonization process in Europe and to produce a document to be presented to the CEN. The work method applied will consist of the identification of risks in accordance with the Ex EN 1441^{vi} and ISO Guide 51^{vii}. These results have been published and are available on the website www.oxynet.org

Moreover, the author went over each essential requirement of European Directive 93/42 in order to determine whether it responds to the specificity of a therapeutic hyperbaric system.

Each article taken into consideration has thus been checked against the specific standards, guidelines and recommendations of each European country.

The following documents were examined:

Germany: standard DIN 13256 2;

British Hyperbaric Association (BHA): Health & safety for therapeutic hyperbaric facilities: a code of practice^{viii},

ISPESL (Italy): safety supervision of multiplace hyperbaric chambers in a clinical environment^{ix};

French regulations^x: Decree N 90-277 of March 28, 1990 concerning the protection of the workers in hyperbaric environment.

Discussion

Study of the essential requirements:

The essential requirements are general. However, each article must have an answer, generated by one or multiple risks pointed out in the risk analysis.

Study of the EN 14971:

Each new medical device must be analysed before its launch on the Market. It's no more a question of pointing out or estimating the risks, but being able to deal with them. It's a long and meticulous work which requires everyone's competence. Therefore, it could be judicious for the manufacturers to listen to the users.

Study of the existing EN standards:

A lot of harmonized standards are likely to be in accordance with one or the other article from the Annex 1 of the European Directive CE 93/42. However, the task force 127 has finished a specific proposal of EN standard for hyperbaric chamber for medical purpose. The publication is awaited for the end of 2004.

Study of the WGT work:

Following the structure of the annex C of the EN 1441 standard, five types of dangers have been studied :

- Energy Hazards (Electricity, heat, mechanical force, pressure, ...)
- Biological hazards (bio contamination, toxicity, pyrogenicity, ...)
- Environmental hazards (inadequate supply of power or coolant, incompatibility with other devices, ...)
- Hazards related to the use of the device (inadequate operating instructions, inadequate specification of accessories, use by unskilled/ untrained personnel, ...)
- Hazards arising from functional failure, maintenance and ageing (inadequacy of performance characteristics for the intended use, inadequate maintenance,...)

Within each type of danger, every element was identified with its kind of danger and its consequences for the patient, the accompanying personnel and the operators.

Each identified danger may have implications, follow-up into another type of danger.
This was a non exhaustive list of dangers.

In fact, it was a first step which should be continuing by the integration of the EN 14971 in cooperation with the manufacturers.

Study of different standards and guidelines:

From this study, it emerges that only the DIN standard is structured in such a way that most of articles of the essential requirements in the directive are dealt. For except, article 12.8 on "Protection against the risks posed to the patient by energy supplies or substances", which can pose a problem concerning the measurement of therapeutic gas administered to patients. This point was already mentioned by Méliet^{xi} in 1994.

In the same way, articles re protection against fire would have to be revised thoroughly.

Conclusions:

The reference document is the Annex 1 of the EC 93/42 directive.

It's of our best interest to stimulate and help the manufacturers to strictly apply the conditions of EN 14971, but to follow too the new harmonized standard, those which may apply to the medical hyperbaric systems.

Bibliography

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 - vi EN 1441 – Medical devices – Risk analysis _ European standard – European Committee for Standardization
 - vii ISO IEC Guide 51 – safety aspects – Guidelines for their inclusion in standards
 - viii Health and Safety for Therapeutic Hyperbaric Facilities: A Code of Practice - British Hyperbaric Association (BHA) - Published 2000
 - ix ISPEL – Guidelines – Safety Supervision of multiplace hyperbaric chambers in a clinic environment – Rev Oct 1999
 - x France – Arrêté du 28 janvier 1991 définissant les modalités de formation à la sécurité des personnels intervenant dans des opérations hyperbares (JO du 2 mars 1991)
 - xi Méliet JL - Normalisation des caissons hyperbares – 1ère Conférence Européenne de consensus sur la médecine hyperbare - Lille 1994 – p 231 - 242
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Regolamentazione degli impianti iperbarici a scopo clinico: requisiti essenziali delle Direttive Europee CE 93/42 e loro conseguenze in termini di Standards EN

HOUMAN Robert - CHT – HBO Responsabile della Sicurezza
Centro di Medicina Iperbarica – Ospedale Militare - Brussels (Belgium)

Resume in Italian by Miss Valeria Campanaro

Introduzione

La Direttiva Europea CE 93/42 è basata sul concetto di un nuovo approccio globale.

I meccanismi impiegati per realizzare questo scopo sono basati sulla prevenzione di nuovi ostacoli ad un libero scambio, riconoscimento reciproco ed armonizzazione tecnica.

In breve, la legislazione europea, di comune accordo, è stata limitata ai requisiti essenziali (apparecchiatura nel campo di sicurezza o di interesse generale) per assicurare la libera circolazione ed il montaggio del prodotto per l'intera Comunità.

Il fornitore ha, effettivamente, l'obbligo di dimostrare che i suoi prodotti sono conformi ai requisiti essenziali indirizzati dalle Direttive. Gli standards europei (EN) sono riconosciuti in conformità a questi requisiti essenziali.

I differenti standards quindi rappresenterebbero la garanzia riguardo ai requisiti essenziali richiesti.

In merito alle camere iperbariche in ambiente clinico, attualmente non esiste alcuno specifico standards. Come fa il fornitore a dimostrare la conformità del suo prodotto?

Metodo

Il documento di riferimento è l'allegato 1 delle Direttive: per ogni articolo, deve essere definito se la camera e sistemi sono conformi a questo articolo.

Struttura dell'allegato

Gli articoli da 1 a 6: Requisiti Generali

L'articolo 7: Proprietà chimiche, fisiche e biologiche;

L'articolo 8: Infezione e contaminazione microbica;

L'articolo 9: Costruzione e proprietà ambientali.

L'Articolo 10: Dispositivi di misurazione;

L'Articolo 11: Protezione contro le radiazioni (non attinente).

L'Articolo 12: Requisiti dei dispositivi medici collegati a fonti di energia.

L'Articolo 13: Informazioni che deve fornire il fornitore

Per ogni articolo, il fornitore si adeguerà agli standards esistenti dell'EN.

Esempio per l'Articolo 1:

1. I dispositivi devono essere progettati e prodotti in modo tale che, una volta usati nelle condizioni e per gli scopi previsti, non devono compromettere lo stato clinico o la sicurezza dei pazienti, o la sicurezza e salubrità degli utenti o, dove applicabili, di altre persone, si deve provvedere che tutti i rischi si riducano solo al rischio accettabile, necessita valutare i benefici per il paziente e la compatibilità con un livello elevato di protezione, di benessere e di sicurezza "

Di conseguenza, un controllo del rischio basato sull'ISO 14971 dell'EN verificherà ogni rischio generato dal dispositivo. Il fornitore stabilirà un procedimento per identificare i rischi connessi al dispositivo medico, e la valutazione dei rischi collegati, controllerà questi rischi e verificherà l'efficacia del controllo. Questo controllo sarà documentato ed includerà i seguenti elementi:

- Analisi di rischio
- Valutazione di rischio
- Controllo del rischio e informazioni di produzione.

L'applicazione dei relativi standards come parte del progetto del dispositivo medico ha permesso le attività di controllo del rischio. Per gli impianti iperbarici sono stati rilevati più di 60 campioni EN !

Esempi:

EN 737 - Le linee guida dei gas medicali -

EN 738 - Regolatori di pressione per gas medicali-

EN 1041 - Requisiti generali medici forniti dal fornitore rispondenti alle direttive -

EN ISO 10993 - Valutazione biologica dei dispositivi medici -

EN 12218 - Linee guida per supportare il dispositivo medico -

EN 13220 - Dispositivi misuratori "Flow" da collegare alle unità terminali del sistema delle linee dei gas

EN 60601 - Materiale elettrico medico.

I dati degli Standards EN all'osservazione sono conformi. Ma ci sono particolari rischi che non sono coperti dai campioni. Gli impianti iperbarici clinici sono specifici e complicati.

Infatti, il nostro settore non è completamente privo di standard di controllo. La Germania possiede dal 1984, standards DIN per "i contenitori a pressione multiposto ad uso umano per la terapia iperbarica - prestazioni, con requisiti di sicurezza e prova".

L'unico problema è, che gli standards con regolamentazione (DIN) sono stati pubblicati da un comitato di un'istituzione nazionale che raggruppa, tra altre, i fornitori e le istituzioni di certificazioni nazionali

È qui che interviene il gruppo TF 127. Il CEN (comitato europeo per la regolamentazione) che è stato istituito nel 2001 è formato da un gruppo di 127 esperti per proporre un campione europeo sulle camere iperbariche (EN 14931). Il processo di regolamentazione dei sistemi iperbarici per uso terapeutico è attualmente in corso. Il documento iniziale usato è DIN standard 13256 2.

La struttura intergovernativa per la cooperazione europea nel campo di ricerca scientifica e tecnica - ossigenoterapia iperbarica "Azione Cost B14" - ha definito le funzioni tecniche del gruppo di lavoro (WGT) a marzo del 2000. Il WGT ha deciso di mirare ad un processo di armonizzazione in Europa e di redigere un documento da presentare al CEN. Il metodo del lavoro applicato consisterà nell'identificazione dei rischi in conformità con l'ex linee guida 51 dell'EN 1441 e delle ISO. Questi risultati sono stati pubblicati e sono disponibili sul Web site www.oxynet.org

Inoltre, l'autore è andato oltre ogni requisito essenziale delle Direttive europee 93/42 per determinare se rispondesse alla specificità di un sistema iperbarico terapeutico. Ha analizzato ogni articolo preso in considerazione con gli specifici campioni, le linee guida di riferimento e le raccomandazioni specifiche di ogni paese europeo.

I seguenti documenti sono stati esaminati:

- La Germania: DIN standard 13256 2;
- Associazione Iperbarica Britannica (BHA): Salubrità & sicurezza per le unità iperbariche terapeutiche: un codice di pratica professionale,
- I SPESL (1 talia): controllo e sicurezza degli impianti iperbarici multiposto in ambiente clinico;
- Regolazione francese: Decreto N 90-277 de 28 marzo 1990 riguardo alla protezione degli operai nell'ambiente iperbarico.

Discussione

Studio sui requisiti essenziali: I requisiti essenziali sono generali. Tuttavia, ogni articolo deve avere una risposta per uno o più rischi valutati dall'analisi di rischio.

Studio dell' EN 14971: Ogni nuovo dispositivo medico deve essere analizzato prima del relativo lancio sul mercato. Non è più una questione di stima o valutazione dei rischi, ma di conoscere questi dispositivi da parte di chi li deve usare. È un lungo e meticoloso lavoro che richiede competenza di ognuno. Di conseguenza, per i fornitori potrebbe essere buona consuetudine ascoltare gli utenti.

Studio sui campioni EN esistenti:

La maggior parte dei campioni probabilmente è conforme agli articoli dell'allegato 1 delle direttive CE europee 93/42. Tuttavia, il gruppo di 127 esperti ha proposto specifici standards EN per gli impianti iperbarici a scopo medico. La pubblicazione è attesa per la fine di 2004.

Studio sul lavoro di WGT:

Seguendo l'allegato C dell'EN 1441, sono stati studiati cinque tipi di pericoli:

- Rischi di energia (elettricità, calore, forza meccanica, pressione...)
- Rischi biologici (bio- contaminazione, tossicità, pirogenicità...)
- Rischi ambientali (rifornimento inadeguato di alimentazione o del refrigerante, incompatibilità con altri dispositivi...)
- Rischi relativi all'uso del dispositivo (istruzioni inadeguate di funzionamento, specifica inadeguata degli accessori, personale non addestrato e non qualificato...)
- Rischi in seguito al guasto, alla manutenzione e ad usura funzionale (inadeguatezza delle caratteristiche di prestazioni per l'uso progettato, la manutenzione inadeguata...)

In sito di ogni tipo di pericolo, è stato identificato ogni elemento del pericolo e le relative conseguenze per il paziente, il personale di assistenza e gli operatori. Ogni pericolo identificato può avere implicazioni, seguite da altro tipo di pericolo. Questa lista dei pericoli non è esauriente. Infatti, è solo un primo passo che dovrebbe essere seguito dall'integrazione dell'EN 14971 in collaborazione con i fornitori.

Studio dei differenti standards e delle linee guida di riferimento:

Da questo studio, emerge che soltanto il campione DIN è strutturato in modo tale che vengono trattati la maggior parte degli articoli sui requisiti essenziali delle direttive. Tranne, l'articolo 12.8 "Protezione contro i rischi al paziente provocati da energia o sostanze", che pone un problema riguardo alla somministrazione di gas terapeutico ai pazienti. Questo punto era già ricordato da Méliet nel 1994. Nella stessa direzione dovrebbero essere modificati completamente gli articoli con riferimento alla protezione antincendio

Conclusioni:

Il documento di riferimento è l'allegato 1 delle Direttive EC 93/42. È nel nostro interesse stimolare ed aiutare i fornitori ad applicare in conformità all' EN 14971, ma anche seguire il nuovo tentativo di armonizzare gli standards , che possono essere applicati agli impianti iperbarici medici.

Normalización de los sistemas médicos hiperbáricos. Requisitos esenciales de la Directiva Europea CE 93/42 y sus consecuencias respecto a las EN (Normas Europeas)

Roberto HOUMAN , Gerente de seguridad HBO - CHT ,
Centro para Oxigenoterapia Hiperbárica . Militar Hospital de Bruselas (Bélgica)

Traducción realizada por Oscar Mora

Introducción

La Directiva Europea CE 93/42 se basa en el concepto de un acercamiento nuevo y global.

Los mecanismos para lograr esta meta se fundamentan en la prevención de posibles nuevos problemas, en el reconocimiento mutuo y en la armonización especializada.

En resumen, la legislación europea ha estado limitada a requisitos esenciales, o sea a equipos en el campo de seguridad de interés general; para asegurar la fabricación y el libre movimiento del producto en la entera comunidad.

El fabricante tiene, ciertamente, la obligación de probar a quien va dirigido, que sus productos cumplen con ciertos requisitos esenciales. Por eso las normas europeas (EN) están pensadas como un signo objetivo del cumplimiento de una serie de requisitos esenciales.

Pero, ¿porque no existen normas estándar respecto a las cámaras hiperbáricas médicas?

¿Cómo puede probar el fabricante la conformidad de su producto?

Método

El documento de referencia sería el anexo 1º de la directiva, para cada artículo, debiera estar definido si a la cámara y a los sistemas les atañe este artículo.

La Estructura del Anexo:

- Artículo 1 al 6º. Requisitos generales
- Artículo 7. Propiedades químicas, físicas y biológicas
- Artículo 8. Infecciones y contaminación microbiana
- Artículo 9. Construcción y propiedades ambientales
- Artículo 10. Dispositivos con función de medición
- Artículo 11. Protección contra la radiación (no alarmante)
- Artículo 12. Requisitos de los dispositivos médicos conectados a una fuente de energía, o con fuente propia.
- Artículo 13. Información del fabricante

Para cada artículo, el fabricante deberá indagar, tomando como referencia las normas EN.

Ejemplo del artículo 1:

" 1. Todos los dispositivos han de ser diseñados y confeccionados de acuerdo con su fin, sin llegar a comprometer la, por supuesta, condición clínica de completa seguridad de los pacientes, o la seguridad y la salud de los usuarios u otras personas. Con tal que cualquier riesgo que pudiera ser asociado a su uso constituiría un riesgo estrictamente necesario con un beneficio claro para el paciente, y con un alto grado de protección de la salud y la seguridad. "

Por consiguiente, a través de un proceso de administración de riesgos basado en el EN ISO 14971 se verificarían los peligros generados por el dispositivo.

El fabricante establecerá un proceso para identificar peligros, que se asociarán con un acto médico, estimando y evaluar los riesgos asociados, controlando estos riesgos y registrando la efectividad del control establecido. Este proceso estará documentado e incluirá los siguientes elementos:

- Análisis del riesgo
- Evaluación del riesgo
- Control e información después de la producción.

La aplicación de normas pertinentes como parte del diseño médico del dispositivo, puede constituir una actividad de control de riesgos.

¡No olvidemos que en los sistemas médicos de cámaras hiperbáricas se podrían nombrar más de 60 normas EN!

Ejemplos:

EN 737 - Las tuberías de gas para sistemas medicinales

EN 738 - Los reguladores de presión para uso con gases medicinales

EN 1041 - Información abastecida por el fabricante de dispositivos médicos

EN ISO 8185 - los humidificadores para uso médico. Requisitos generales para los sistemas de humidificación

EN ISO 10993 - La evaluación biológica de los dispositivos médicos

EN 12218 - Los sistemas del riel para el anclaje de los equipos médicos

EN 13220 - Dispositivos medidores de flujo para la conexión de sistemas médicos de gas

EN 60601 - El equipo eléctrico médico

Las aplicaciones de las normas EN dan una presunción de conformidad, pero son bastante generales y hemos de tener en cuenta que los sistemas médicos hiperbáricos son de por sí, específicos y complicados.

De hecho, nuestra comunidad no estaba completamente desvalida, por ejemplo, Alemania posee desde 1984, unos estándares (**DIN**) de realización, de seguridad y de prueba para "Recipientes a presión para ocupación de humana (cámara multiplaza de terapia hiperbárica).

El problema fue que allí las normas son revisadas por un comité de una institución nacional (DIN) de normalización, lo cual reagrupa, entre los otros, a los fabricantes y a las instituciones que certifican a nivel nacional.

Aquí es donde interviene el grupo TF 127. El CEN (el Comité Europeo para la normativización) fue creado en 2001, un TF 127 para proponer un estándar europeo en cámaras hiperbáricas (pr EN 14931). El proceso de

normativización de sistemas hiperbáricos para el uso terapéutico está actualmente en proceso. El documento inicial usado como estándar es el DIN 13256 2.

A través de la vía intergubernamental para Cooperación Europea en el campo de Científico y Técnico - COST Action B14 Hyperbaric Oxygen Therapy - los aspectos del Grupo Técnico de Trabajo (WGT) tomaron forma en marzo del 2000. El WGT resolvió intentar la iniciación de un proceso de normativización en Europa y generar un documento para ser presentado para el CEN. El método de trabajo consistirá en la identificación de riesgos conformes con el EN Ex 1441 y el ISO Guide 51. Estos resultados han sido publicados y están disponibles en la siguiente página web www.oxy.net.org

Además, el autor repasó cada requisito esencial de la directiva europea 93/42 para determinar si corresponde a la especificidad de un sistema terapéutico hiperbárico.

Cada artículo tomado ha sido cotejado contra las normas específicas, las líneas directivas y las recomendaciones de cada país europeo.

Los siguientes documentos fueron examinados:

- Alemania: Standard DIN 13256 2;
- La Asociación Hiperbárica Británica (BHA): Salud y seguridad para instalaciones terapéuticas del hiperbárico: Un código de práctica
- I SPESL (Italia): Supervisión de la seguridad de cámaras hiperbáricas multiplaza en un ambiente clínico
- Las reglas francesas: El decreto N 90-277 del 28 de Marzo de 1990 que concierne a la protección de los trabajadores en ambiente hiperbárico.

Debate

- **El estudio de los requisitos esenciales:**

Los requisitos esenciales son generales. Sin embargo, cada artículo debe tener una respuesta, debido a los riesgos múltiples señalados en el análisis del riesgo.

- **Estudio del EN 14971:**

Cada dispositivo médico nuevo debe ser analizado antes de su lanzamiento al mercado. Sería una pregunta de orientación o estimación de los riesgos para poderlos manejar. Es un trabajo largo y meticuloso que exige la participación de personas competentes. Por consiguiente, podría ser juicioso para los fabricantes el escuchar a los usuarios.

- **Estudio de las normas existentes EN:**

Una parte de las normas es probablemente para estar conforme con uno u otro artículo del Anexo 1 de la Directiva Europea CE 93/42. Sin embargo, la grupo de trabajo 127 tiene finalmente una propuesta específica de EN estándar para cámara hiperbáricas para fines médicos. La publicación se espera para finales del 2004.

- **Estudio del trabajo WGT:**

Siguiendo la estructura del anexo C de la EN 1441, cinco tipos de peligros ha sido estudiada:

- Los peligros de la energía (la electricidad, el calor, la fuerza mecánica, la presión, ...)
- Los peligros biológicos (la biocontaminación, la toxicidad, ...)
- Los peligros ambientales (el suministro inadecuado del líquido de refrigeración, la incompatibilidad con otros dispositivos, ...)
- Los peligros que guardan relación con el uso del dispositivo (las instrucciones operativas inadecuadas, la especificación inadecuada de accesorios, uso por personal no cualificado, ...)
- Los peligros procedentes del fracaso funcional, mantenimiento y envejecimiento (la falta de adecuación de las características de desempeño para el uso que se pretendía, el mantenimiento inadecuado, ...)

Dentro de cada tipo de peligro, cada elemento fue identificado con su tipo de peligro y sus consecuencias para el paciente, el personal acompañante y los operadores.

Cada peligro identificado puede tener consecuencias que impliquen a otro tipo de peligro. Así que, la lista anterior se podría considerar como una lista "poco exhaustiva" de peligros.

De hecho, sería un primer paso que debiera continuarse para la integración del EN 14971, con la colaboración de los fabricantes.

- **El estudio de las diferentes normas y líneas directivas:**

De este estudio, surge que sólo el estándar DIN está estructurado de tal manera que la mayor parte de artículos de los requisitos esenciales son distribuidos en la directiva. Exceptuando el artículo 12.8 referido a "la Protección en contra de los riesgos planteados para el paciente por suministros de energía o sustancias", lo cual podría plantear un problema respecto a la medición del gas terapéutico administrado a los pacientes. Este punto fue ya mencionado por Méliet en 1994.

Asimismo, los artículos de protección contra de fuego tendrían que estar revisados más a fondo.

Conclusiones:

El documento de referencia es el Anexo 1 de la directiva EC 93/42.

Es de nuestro mayor interés el estimular y ayudar a los fabricantes a seguir las condiciones de la EN 14971, para aplicarlos a los sistemas médicos hiperbáricos.

Normalisierung der hyperbaren Systeme zu medizinischen Zwecken: die wesentlichen Anforderungen der europäischen Direktive CE 93/42 und ihre Konsequenzen in EN Standard

Übersetzung von Daniel WINTERSDORFF

HOUMAN Robert - CHT - HBO safety manager

Centre for Hyperbaric Oxygen Therapy - Military Hospital - Brussels (Belgium)

Einleitung

Die europäische Direktive CE 93/42 basiert auf dem Konzept einer neuen und globalen Annäherung. Die Wege zum Erzielen dieses Zieles basieren auf Vorbeugung von neuen Handelsbehinderungen, gegenseitige Anerkennung und technische Harmonisierung.

Kurz gesagt ist die harmonisierte europäische Gesetzgebung auf die wesentlichen Anforderungen (Ausrüstung auf dem Gebiet der Sicherheit oder des allgemeinen Interesses) begrenzt worden um die freie Bewegung und die Herstellung des Produktes für die gesamte Gemeinschaft sicherzustellen.

Der Hersteller hat in der Tat die Verpflichtung, zu prüfen, daß seine Produkte in Übereinstimmung mit den wesentlichen Anforderungen der beteiligten Richtlinie sind. Die europäischen Standards (EN) sind übereinstimmend mit den wesentlichen Anforderungen der beteiligten Richtlinie. Verschiedene Standards würden folglich Garantie hinsichtlich der wesentlichen Anforderungen der Richtlinie darstellen.

Für die medizinischen hyperbaren Kammern bestehen momentan keine spezifischen Standards.

Wie kann der Hersteller die Übereinstimmung seines Produktes prüfen?

Methode:

Das Bezugsdokument ist der Anhang 1 der Richtlinie, für jeden Artikel muss definiert werden, ob die Kammer und die Systeme durch diesen Artikel betroffen sind.

Struktur des Anhanges (1):

- Artikel 1 bis 6: die allgemeinen Anforderungen
- Artikel 7. Chemische, physikalische und biologische Eigenschaften
- Artikel 8. Infektion und Mikrobenkontamination
- Artikel 9. Bauliche und Umwelteigenschaften
- Artikel 10. Vorrichtungen für Meßsysteme
- Artikel 11. Schutz gegen radioaktive Strahlungen
- Artikel 12. Anforderungen für die medizinischen Vorrichtungen angeschlossen an oder mit einer Energiequelle ausgerüstet
- Artikel 13. Herstellerinformationen

Für jeden Artikel erforscht der Hersteller bestehende EN-Standards.

Beispiel für Artikel 1:

„1. Die Vorrichtungen müssen entworfen werden und hergestellt werden, so dass, wenn sie unter den Bedingungen und zu den beabsichtigten Zwecken verwendet werden, sie nicht den klinischen Zustand oder die Sicherheit der Patienten beeinträchtigen. Oder die Sicherheit und die Gesundheit der Benutzer, wo anwendbar, anderer Personen, gefährden, vorausgesetzt alle mögliche Gefahren, die mit ihrer Benutzung verbunden sind annehmbar sind und sie den Nutzen für den Patienten unterliegen.

Folglich überprüft ein Risikomanagement, der auf der EN-ISO 14971 basiert, jede Gefahr der Vorrichtung. Der Hersteller erarbeitet eine Routine welche die Gefahren identifiziert, Dieser Prozess wird dokumentiert und die folgenden Elemente enthalten(2):

- Risikoanalyse,
- Risikoauswertung,
- Risikokontrolle und Produktionsinformationen.

Anwendung der relevanten Standards als Teil des medizinischen Vorrichtungsdesigns konnte die Risikokontrolle unterstützen.

Für die medizinischen hyperbaren Kammern können mehr als 60 EN-Standards zur Anwendung kommen.

Beispiele:

EN 737	Medizinische Gasleitungen
EN 738	Druckregelventile für Gebrauch mit medizinischem Gasen
EN 1041	Herstellerinformationen für medizinische Geräte
ISO 8185	allgemeine Anforderungen für medizinische Befeuchter
EN ISO 10993	biologische Kontrolle medizinischen Vorrichtungen
EN 12218	Schienensystem für die Befestigung medizinischer Apparate.
EN 13220	Flowmeter
EN 60601	elektrische medizinische Apparate

Die Anwendungen der EN-Standards geben eine Vermutung der Übereinstimmung. Aber die spezifischen Gefahren, sind durch Standards nicht gedeckt.

Aber unsere Gemeinschaft ist nicht total ungeschützt. Deutschland besitzt seit 1984, Standards einer DIN (3) für „Druckbehälter für menschliche Inanspruchnahme – mehrplatzkammern zur hyperbaren Therapie - Leistungen, Sicherheitsauflagen und Prüfung“.

Das einzige Problem ist dass diese Standards von einer nationalen Normalisierungsanstalt (DIN) redigiert worden sind. Einer Gruppierung, die, unter anderen, die Hersteller und beinhaltet (4).

Hier greift die Gruppe TF 127 ein. Die CEN (europäischer Ausschuss für Normalisierung) ist 2001 gegründet worden, eine Task Force 127 um einen europäischen Standard für hyperbare Kammern auszuarbeiten (EN 14931).

Der Prozess der Normalisierung der hyperbaren Systeme für therapeutischen Gebrauch ist zur Zeit in Arbeit. Das benutzte Ausgangsdokument ist die Standard DIN 13256 2.

Im Rahmen der europäischen Zusammenarbeit auf dem Gebiet der wissenschaftlichen und technischen Forschung - COST Action B14 Hyperbaric Oxygen Therapy – nahm die Arbeitsgruppe (WGT) im März 2000 Form an.

Die WGT (5) entschied sich für die Einführung eines Harmonisierungs-Prozess in Europa und dem CEN ein Dokument zu präsentieren. Die angewendete Arbeitsmethode besteht aus der Identifizierung der Gefahren in Übereinstimmung mit der EN 1441(6) und ISO Guide 51(7). Diese Resultate sind auf der Webseite (www.oxynet.org) veröffentlicht worden.

Außerdem ging der Autor über jede wesentliche Anforderung europäischer Richtlinie 93/42 hinaus, um festzustellen, ob sie auf die Besonderheit eines therapeutischen hyperbaren Systems entspricht.

Jeder Artikel, der in Erwägung gezogen wird, ist folglich gegen die spezifischen Standards, die Richtlinien und die Empfehlungen jedes europäischen Landes überprüft worden.

Die folgenden Dokumente wurden überprüft:

- Deutschland: Standard DIN 13256 2;
- Britische Hyperbar Verbindung (BHA): Gesundheit u. Sicherheit für therapeutische hyperbar Einrichtungen: eine allgemeine Vorschrift(8),
- I SPESL (Italien): Sicherheitsüberwachung der hyperbaren Mehrplatzkammern im klinischen Umfeld (9);
- Französische Regelungen(10): Verordnung N 90-277 von März 28, 1990 hinsichtlich des Schutzes der Arbeiter unter hyperbaren Bedingungen.

Diskussion

- **Studie der wesentlichen Anforderungen:**

Die wesentlichen Anforderungen sind allgemein. Die durch die Gefahrenanalyse ermittelten ein- oder mehrfache Gefahren müssen für jeden Artikel eine Antwort haben.

- **Studie des EN 14971:**

Jede neue medizinische Vorrichtung muß vor seiner Produkteinführung auf dem Markt analysiert werden. Es ist nicht mehr eine Frage des Unterstreichens oder des Schätzens der Gefahren, aber des in der Lage seins, mit ihnen umzugehen. Dies ist eine langwierige und gewissenhafte Arbeit welche die Kompetenzen eines jeden benötigt. Folglich könnte es für die Hersteller vernünftig sein, auf die Benutzer zu hören.

- **Studie der vorhandenen EN Standards:**

Eine Menge von harmonisiert Standards sind wahrscheinlich, mit dem einem oder anderen Artikel vom Anhang 1 des europäischen richtungweisenden CERS 93/42 übereinstimmend. Jedoch hat die Task Force 127 einen spezifischen Vorschlag eines EN-Standards für medizinische hyperbare Kammern finalisiert. Die Publikation wird für das Ende 2004 erwartet.

- **Studie der WGT-Arbeit:**

Nach der Struktur des Anhanges C des Standards en 1441, sind fünf Gefahrentypen studiert worden:

- Energiegefahren (Elektrizität, Hitze, mechanische Kraft, Druck...)
- Biologische Gefahren (Bioverschmutzung, Giftigkeit, Pyrogenizität...)
- Umfeldgefahren (unzulängliches Versorgungsmaterial für Energie oder Kühlmittel, Unverträglichkeit mit anderen Vorrichtungen...)
- Gefahren bezogen auf dem Gebrauch der Vorrichtung (unzulängliche Bedienungsanleitung, unzulängliche Spezifikation der Zusatzgeräte, Gebrauch durch unerfahrenes/ungeschultes Personal...)
- Gefahren, die aus Funktionsausfall, Wartung und dem Altern entstehen (Unzulänglichkeit der Leistungsmerkmale für den beabsichtigten Gebrauch, die unzulängliche Wartung...)

Innerhalb jeder Art Gefahr, wurde jedes Element mit seiner Art der Gefahr und seiner Konsequenzen für den Patienten, das Begleitpersonal und die Operatoren gekennzeichnet. Jede gekennzeichnete Gefahr kann Implikationen in eine andere Art Gefahr haben.

Dieses war eine nicht vollständige Liste von Gefahren.

Tatsächlich war es ein erster Schritt, der durch die Integration des EN 14971 in Zusammenarbeit mit den Herstellern fortgesetzt werden sollte.

- **Studie von unterschiedlichen Standards und Richtlinien:**

Diese Studie zeigt daß nur der DIN-Standard so strukturiert ist, so daß die meisten Artikeln der wesentlichen Anforderungen in der Richtlinie behandelt werden.

Ausgenommen, Artikel 12,8 über den Schutz des Patienten gegen die Gefahren durch Energiezufuhren oder Substanzen, welche ein Problem in der Messung der verabreichten medizinischen Gase darstellen können. Dieser Punkt war bereits durch Méliet(11) 1994 bearbeitet worden.

In der gleichen Weise würden Artikel bezüglich des Schutzes gegen Feuer gänzlich verbessert werden müssen.

Zusammenfassung:

Das Bezugsdokument ist der Anhang 1 der Richtlinie EC 93/42.

Es ist unser Interesse zu helfen und, die Hersteller anzuregen, die Vorgaben der EN 14971 strickt anzuwenden, aber einem neuen harmonisierten Standard entgegen zu gehen, welcher auf medizinische hyperbar Systeme zutrifft.

„NURSING WORK IN A TOP LEVEL HYPERBARIC FACILITY“

¹A.Schwarz; ¹A. Kemmer;

The level one traumacenter “BG-Unfallklinik Murnau” includes 425 beds. Our central aim is curing of casualties using all suitable methods. The hyperbaric facility belongs to the department of anaesthesia and ICU. We are treating all kinds of indications depending on the guidelines of the UHMS and GTUEM e.V.. Many of our patients are suffering from critical illness and are long term ventilated.

The scope of nursing duties in the hyperbaric facility of the BG-Unfallklinik Murnau includes following activities:

Technology

- Tag in and tag out of the hyperbaric chambers
- Steering and controlling of a hyperbaric chamber (Lock in and Lock out of personal etc.)
- Coping of small maintenance and repairing tasks

Nursing work

- Patient education
- Accompanying of Patients (Rules, proximity and keeping aloof in a professional client relationship etc.)
- Continuing of the critical ill patient care during the hyperbaric treatment
- Hygienics forwards, during and afterwards hyperbaric treatments, especially coping of problems with infectious Patients (for example MRSA Patients)
- Training of colleagues

Assistant work

- ENT investigation
- Lung function
- Planning of the daily schedule

For managing of this tasks in our hyperbaric facility it is very important, that each team member has to be fully educated as:

- Nurse (Diploma of nursing)
- Nurse of intensive care and anaesthesia

and especially trained as:

- Chamber operator (GTUEM e.V.)
- Hyperbaric medical assistant (GTUEM e.V.)
- Hyperbaric medicine Nurse for Intensive care (GTUEM e.V.)

We made the experience, that the best technology could not replace well trained staff. Many grateful in- and outpatients are our best recommendation.

¹Berufsgenossenschaftliche-Unfallklinik; Professor Küntscher Strasse 8; Germany 82414 Murnau

What's happen by the Board of Directors ?



The Board of Directors held a meeting on 15 May 2004. The local organizer was Campanaro, Valeria and the team of the Hyperbaric centre of Umberto I Hospital. It was a pleasure to meet the Team of the hyperbaric facility of Roma and ...the family Valeria's team . The organisation was excellent.

The meeting begon on 9 AM and finish (in theory) at 5 PM (in fact 7 PM...).

The agenda was "classic":

Presentation by the General Secretary - Miss Mannens in charge

(cosette.mannens@skynet.be)

On the suggestion of the General Secretary, the Board of Directors decided to stimulate using the website as the principal source of information. (In the next future, the website will be reorganised to facilitate your visits).

We noted that they are more and more Spams and for safety reasons, the Board of Directors decided to use a special format for the E Mails (ALWAYS a subject: Ebass + a Text and identification)

Presentation by the Treasurer - Mr van der Tol in charge

[M.H.vanderTol@amc.uva.nl]

A lot of hyperbaric centres ask to be members as a centre, but the fees is not adapted for.

The Board of Directors decided to ask on the General Treasurer to prepare for the next meeting (in September) a proposition of adaptation of fees for commercial companies and hyperbaric facilities as associate members. The staff members of the hyperbaric facilities will receive a discount on their membership.

Presentation by the Presidents of Committees:

(1) Education - Miss Condon in charge

Miss Condon presented the status of ongoing works of the Education Committee. Later and for circumstances beyond her control, Miss Condon, Catherine can not continue as President of the Committee Education. To help Catherine and this very important committee, the Board of Directors has decided to nominate Mr SCHWARZ, Armin from Murnau (Germany) as President a.i. of the Committee Education. (Armin.Schwarz@t-online.de)

The Board of Directors will stimulate the participation of the members inside this Committee.

(2) Communication - Mr Kelner in charge (b.kelner@amc.uva.nl)

Mr Atkey presented a proposal of recruitment campaign. The Board of Directors decided to create a new sub committee in charge of the recruitment campaign. Mr Atkey, Peter is in charge until January 2005. The mandate is the organization of a recruitment campaign for EBAss in Europe. (pete.atkey@ddrc.org).

(3) Scientific approaches -Mr Damiens in charge (dams263@free.fr)

Mr Damiens presented his intermediate report. During his work, it was discovered that the scientific and technological committee has no relationship with the hyperbaric field. As a consequence of this, he proposed to close this committee and start a new committee on safety. The Board of Directors decided to vote on the advice of Mr Damiens to close the scientific and technological Committee and to create the Safety Committee. The Board of Directors thanks Mr Damiens for his efforts and work on the scientific and technological committee.

(4) Safety committee (Mr Neiryck in charge) (Yoerik.Neiryck@mil.be)

The Board of Directors sets as mandate to develop the structure of this committee

The website: Mr van der Tol in charge [M.H.vanderTol@amc.uva.nl]

Mr van der tol present the website statistics. In 2004 (Jan - May), total visits 15.813. Concerning the links, the Board of Directors decided to generate links to others website, where a link exists to our website (Oxynet, Antei, BNA, BHA,...)

The Board of Directors asks the webmaster to make a proposal for a new website design, to be presented at the next meeting.

The Journal Mr Houman in charge (Rob.Houman@mil.be)

Mr Houman present the intermediate report. The Board of Directors decides to continue the publication of EBAss News within the same team. The Board of Directors has confirm the functions of the members of the Readers committee and redaction of the journal.

The next Board of Directors is planned on 16 Septembre in Ajaccio.

Safety Committee: Vision of the future.

By Neiryck Yoerik, President Safety committee

The baromedical world is a particular world, a large number of physical, mechanical and physiological phenomena have an influence on our actions. Therefore one of the biggest challenges in our environment is safety. The chambers are hermetically closed, we use pressure, oxygen, etc on a daily basis, and these among other things do restrict us. Fire, barotraumas and decompression sickness are only some of the risks related to the environment that we work in. The consequences of an incident and certainly of an accident are mostly hard, and generally irreversible. The only way to create a safe environment is a well thought, preventive, safety policy.

The "Special Committee Safety" will work on this topic to increase the safety for patients, personnel and third parties. This by offering help to studies and publications concerning safety, developing guidelines and recommendations, creating a library, helping or referring those with questions and problems, offering support on safety education.

To do this we will work in three large categories:

- ◇ Studies and publications on safety
- ◇ Material resources
- ◇ Human resources

There still is a long way to go to accomplish all of the above. Those who are serious about safety and want to be active in this field can contact us; we have a large amount of work to do.

Candidatures, questions and suggestions are always welcome on safety@ebass.org

Review and comment on the some parts of the statutes and the intern rules

For each member, it is important to understand the statutes and the intern rules. We will review and comment some articles of the statutes and the intern rules...

TODAY: The general assembly

14. The General Assembly is the supreme power, which fulfils the objective of the association. It includes all the members of the association.

Only full and honorary members have the right to vote, each one accounts for one vote, the other members have the possibility to assist and participate to discussions, but cannot vote.

Comment: You decide and we comply!

15. The following points are of its competence :

- The modifications re the social status
- The election and exclusion of the administrators
- The approval of budgets and accounts
- The voluntary breaking-up of the association
- The exclusions of associates
- Any decision ultra vires, legally or statutory, assigned to the board of directors.

16. A general assembly must be held at least, once a year. As many times as the social interest of the registered office requires it, a special meeting will take place. This applies when at least, on fifth of the associates demands it.

Any assembly will be held on the day, at the hour, and place stipulated in the convening.

Comments: The first general assembly was in Brussels, second one in Amsterdam, and last one in Ajaccio... You visit Europe !

17. The General Assembly is convened by the Board of Directors by letter, fax or e.mail, at least thirty days before the date of the assembly, by letter signed by the president, the general secretary or by three administrators in the name of the board of directors.
The convening stipulates the place and the agenda.
The assembly can only deliberate about the subjects written down on the agenda.
 18. The president of the Board of Directors takes the chair, In his absence, it's the oldest administrator attending the meeting.
 19. A deputy of their choice, member or non-members of the association may represent the full and honorary members and who will be able to vote in their place. A deputy with a maximum of 5 procurations may represent the members for one attending member.
Comments: Very important ! If you can't come to the general assembly, use your procuration
 20. Unless opposite legal or statutory dispositions, the decisions of the general assembly are a majority decision; since as 25% of the members must attend or be represented at the meeting.
By derogation to the previous paragraph, the decisions of the assembly re the modifications about the status, exclusion of associates or voluntary breaking-up of the association, are only taken in return for three quarter of the given votes.
The modifications to the status will be effective, only after approbation by a royal decree and publication in the appendix of the "Moniteur Belge".
Comments: this article is to reduce the risk of decisions taked in "small committee"...
 21. The decisions of the general assembly are recorded in a special register, signed by the president and the secretary and the members who too asked for it. It's kept to the headquarters of the association where the concerned persons would be able to read it, but without moving or copying the registers. If the concerned persons aren't associates, but justify of their legitimate interest, this communication is dependent of the written authorization of the president of the Board of Directors.
The copies or abstracts of these minutes will be signed by the president or by two administrators.
-

Instructions for author's

Acceptance of a manuscript is based on originality and quality of the work as well as the clarity of presentation. All manuscripts will be evaluated for significance, soundness, and conformance to journal format by two or more members of the Editorial Board or guest referees.

After manuscripts have been accepted, authors are asked to submit the final version of the paper electronically or on computer diskette.

Preparation of Manuscripts

Title: A cover sheet which gives the title of the paper, the names and affiliations of the authors; a short title (running head); and the name, address, telephone and fax numbers, and e-mail address (if any) of the corresponding author must accompany the manuscript.

Text: Except in unusual situations, the manuscript should be divided into Introduction, Methods, Results, and Discussion. The overriding principles are that the composition is correct and unambiguous, clear, and concise. The active voice is usually preferable to the passive voice. Parallel construction of groups of like items or concepts aids in comprehension. Figures should be uncomplicated and legible. Abbreviations and acronyms should not be overused, should be clearly defined at their first appearance in the abstract and in the text, and should be avoided in the title. Specific items of information should appear only once in the manuscript; there should not be verbatim repetition in the text of material that appears in a table or figure, duplication of data in graphs and tables, or repetition in Discussion of information that appears in Results. All accepted manuscripts are subject to final editing in the Editorial Office to improve readability and to conserve space.

References: Authors are responsible for verifying references against the original documents. References must be numbered consecutively in the order in which they first appear in the text, and identified in the text by Arabic numerals in parentheses.

Example:

Mannens, C., Houman R. - A Hyperbaric Pan-European Technician, Operator and Nurses Association: a necessity ? Proceedings of the 28th Annual Scientific Meeting of the European Underwater and Baromedical Society. Germonpre P., Balestra C., Eds. Bruges, Belgium. 2002 p 115

Are you satisfied?

After 4 issues of the journal, we wish to know if you are satisfied by your journal.

Therefore you will find some affirmations, please answer by **YES** or **NOT** and send us your answers!

Affirmations	YES it is correct	NO it is not correct
1. I have no difficulties to read all the articles in english		
2. I can understand the main article only via the abstract in my own language		
3. The information published in the journal are high quality		
4. I appreciate to receive the journal via E mail		
5. I wish to receive other information via the journal		
List of others information: 1. 2. 3. 4. 5. ...		

Please send your answers to the editor on: rob.houman@mil.be or by Fax on + 32 2 264 48 61

Free participation !!!

EBAss News is a publication of The European Baromedical Association for Nurses, Operators and Technicians

Redaction: Daniel Leonard - 200 Rue Bruyn - B 1120 Brussels - Belgium

Editor: Robert Houman - 9 Sainte Anne - B 7880 Flobecq - Belgium

Readers committee:

Miss Valeria Campanaro (Italy),

Mr Daniel Wintersdorf (Luxemburg),

Mr Oscar Mora (Spain)