NSAI Standards Development

Welcome
PPE RPD

NSAI Standards

PPE Directive – general overview

Categories of PPE

Link between the directive and standards

How standards are developed and changed

How to get involved…

Current Standards in the field of PPE

RPPE – guidance and standards

Occupational Hygiene Conference – PPE & RPD

Purpose of PPE Directive (89/686 EC)

- Provide a legal framework for regulation
- Ensure user safety
- Ensure open and equal market
- Ensure effectiveness of products

Legal document….. Legal language…..

PPE Directive & Application (89/686 EC)

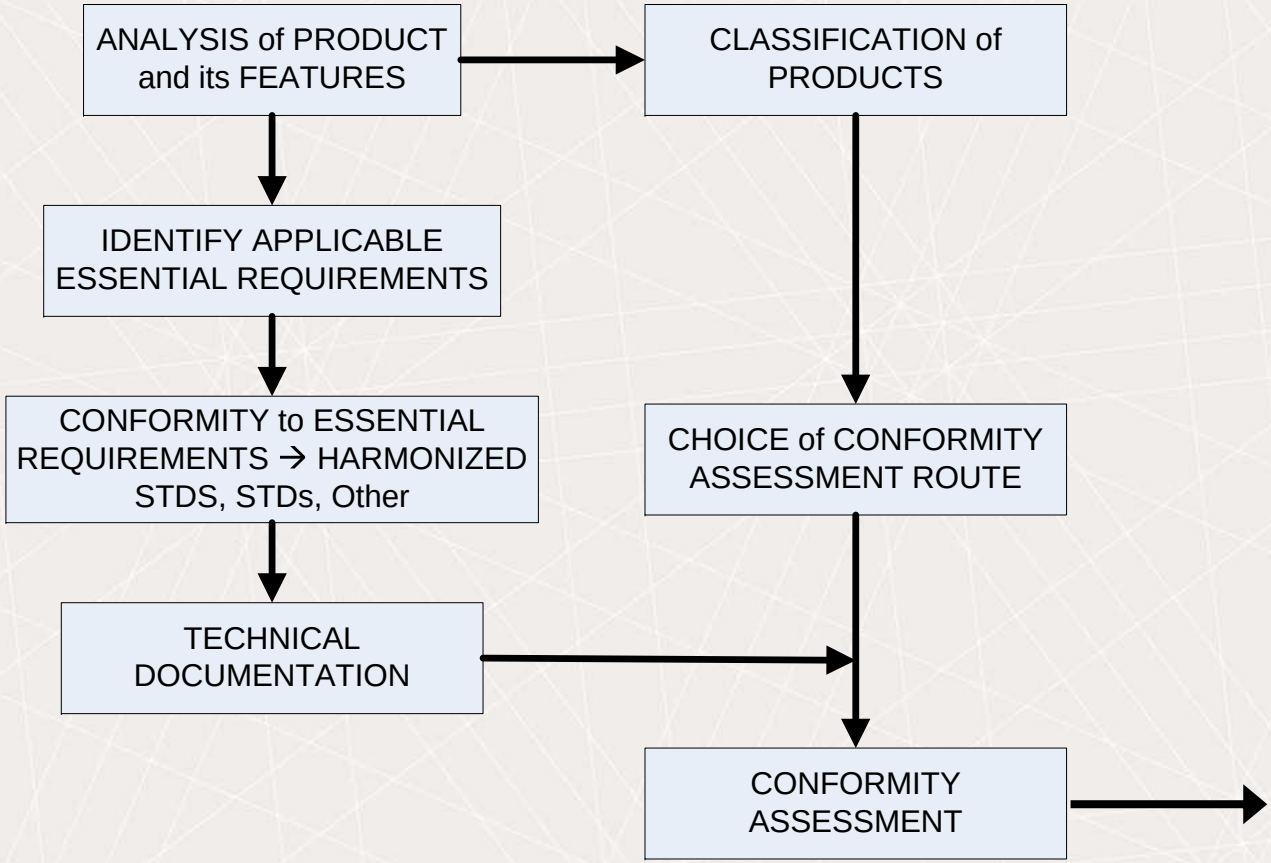
- PPE shall mean any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.

Occupational Hygiene Conference – PPE & RPD

- **Personal Protective Equipment Council Directive 89/686**

- Article 8 of Council Directive 89/686/EEC(a) sets out the procedures for assessing the conformity of PPE to the essential health and safety requirements
- Four different conformity assessment procedures are defined for the whole range of PPE products (see article 1 and Annex I of the PPE-D.).
- It is solely the **manufacturer's** or his authorised representative's responsibility to select the correct conformity assessment procedure to be applied.

Product Approval
– Basic Approach



CE 0xxx

NSAI Standards

Occupational Hygiene Conference – PPE & RPD

Personal Protective Equipment Council Directive 89/686

- PPE protects its intended user against one or more hazards. Exposure to hazards may lead to injury

- Risk based approach: The seriousness of these injuries has been categorised as follows:
- Category I (less serious injuries),
- Category II summarising the remaining degrees of seriousness of injuries..).
- Category III (very serious injuries leading to irreversible harm to health and/or death)

Occupational Hygiene Conference – PPE & RPD

Categories of Products……
Responsibilities and actions are commensurate with product risk

- Category I" : declaration of conformity by the manufacturer on his own responsibility (Article 8, paragraph 3) (a) OJ. L 399 of 30.12.1989, p.18 amended by Directives 93/68/EEC (OJ. L 220, 30.08.1993, p.1) and 93/95/EEC (OJ. L 276, 9.11.1993, p.11) 2

- (b) "Category II" : declaration of conformity by the manufacturer after a notified body has drawn up an EC type-examination certificate for a PPE model (Article 8, paragraph 2)

- (c) "Category III": declaration of conformity by the manufacturer after a notified body has drawn up an EC type-examination certificate for a PPE model and after a notified body (either the same one that drew up the EC type-examination certificate or another one) has carried out the quality control of the PPE manufactured (Article 8, paragraph 4).

Occupational Hygiene Conference – PPE & RPD

- *For example*

  - All eye protections and filters are Category II , but there are exceptions e.g. Eye protection and filters providing protection against ionising radiation is Category III

  - All protective equipment for protections against falls from a height are Category III

  - All equipment for part or whole face protection is either Category II or III

  - All respiratory protective devices are Category III

  - All hearing protection are Category III

The Directive requires that a Technical file showing compliance is prepared and for higher categories, a notified body review and provide EC type examination of the product, and for highest category, review the QMS, before the product can be CE marked and placed on the market.

Occupational Hygiene Conference – PPE & RPD

ANNEX II - *BASIC HEALTH AND SAFETY REQUIREMENTS*

- *Basic Health and Safety Requirements (BHSRs) at Annex II are drafted to ensure the highest possible level of protection.*
- *These requirements are to be applied in accordance with the foreseeable conditions of use for which the PPE is intended.*
- *They either lay down the possible protection objectives and/ or refer to the performance of the product itself.*
- *BHSRs define the results to be attained, or the hazards to be dealt with, but do not specify or predict the technical solutions for doing so.*

Occupational Hygiene Conference – PPE & RPD

- **BHSRs set out in Annex II include all that is necessary to achieve the objective of the Directive.**

- **PPE may be placed on the market and put into service only if they are in compliance with all applicable BHSRs.**

Occupational Hygiene Conference – PPE & RPD

PPE Directive (89/686 /EEC) & Other European Product Directives

- It is possible that a respiratory protective device may also fall under other European Product Directives, e.g. Low Voltage Equipment Directive (73/23/EEC), the EMC Directive (89/336/EEC) or PED Directive (97/23/EC). In such cases it is possible that some parts of the respiratory protective device may require to be assessed under another directive

Some product can be classed as both PPE and MDD.

- For example, a mask to be used by a surgeon is a medical device as it protects the patient.
- Hand equipment worn by health care personnel to protect themselves against infectious agents falls under the PPE Directive

NOTE: Where a device is intended by the manufacturer to be used in accordance with both the provisions on personal protective equipment in Council Directive 89/686/EEC and the MDD, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled." (Article 2 (I)f of Directive 2007/47/EC).

Standards and EU Regulations

- **EU Directives** specify the Essential Requirements, (BHSR) without specifying **how** it should be achieved
- **Conformity assessment policy:**
  - Products that conform to relevant **Harmonised Standards** must be **presumed** to conform to relevant legal directive requirements. (Article 5?)
- **Benefits**
  - Standards bring transparency and definition to the means of compliance.

How to Harmonise a Standards…..

- CEN, CENELEC or ETSI receive a mandate from the European Commission to develop harmonised standards.
- Standard is written and requirements of standard are mapped to requirements of the Directive, i.e. Annex Z.
- Published by European Commission and EFTA as a **harmonized** European Standard in the Official Journal of the European Union (OJEU)

Standards and EU Regulations

Annex Z **maps the clauses of the standard to the relevant Essential Requirements**

Standard		Essential Requirements
Clause 4.2	→	Ess Req 7.1
Clause 4.3	→	Ess Req 7.1
Clause 4.5	→	Ess Req 7.2
Clause 4.7	→	Ess Req 7.6
Clause 4.8	→	Ess Req 7.3
Clause 4.9	→	Ess Req 7.1

Harmonised Standards are the language of compliance with regulations, e.g. Directives

- Later, we'll see where to find these harmonised standards?

Standards and EU Regulations

Element of a Harmonised standard Annex Z, One-to-one Mapping…

Table ZA – Correspondence between this European Standard and Directive Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment

Clause(s)/sub-clause(s) of this EN	Essential Requirement (ERs) of Directive 97/23/EC	Qualifying remarks/Notes
Annex A, annex E	2.2.1, 2.2.3	Design for adequate strength
5.1, 10.2, 10.3, Annex I	2.6	Corrosion or other chemical attack
7	3.1	Manufacturing procedures
7.6, 7.7.5	3.1.1	Preparation of component parts
4.5, 7.5, 7.7	3.1.2	Permanent joining
9.5	3.1.3	Non-destructive tests
7.6.2, 7.8	3.1.4	Heat treatment
7.3	3.1.5	Traceability
9.8.2	3.2.1	Final inspection
9.8.1, Annex C	3.2.2	Proof test
11	3.3	Marking and labelling
12.2	3.4	Documentation

Standards and EU Regulations

- For Manufacturers…….
- Legal requirement is to comply with the Directive
- Only Harmonised standards presume compliance
- Read Annex Z carefully, (References, exceptions…)
- Read, use and comply with referenced standards
- Justify exceptions
- Maintain compliance up-to-date
- Requirement is for ALL products placed on market

Compliance…… How to show..

- Read the standard and guidance
- Read the referenced standards
- Prepare protocol according to Procedures
- Appropriate test methods
- Calibrated equipment
- Appropriate sample
- Analysis, Review and approval of results
- Maintenance of records
- Retest/revalidate/maintain files up-to-date with product/process/material/standard changes.

Range of Standards

- Product standards
- Material standards
- Biocompatibility standards
- Risk management
- Test method standards
- Packaging standards
- QMS standards.....

Occupational Hygiene Conference- PPE & RPD

- Summary
- **Compliance with the clause of the standard given in Table ZA.1 confers, within the limits of the scope of the standard, a presumption of conformity with the corresponding Essential Requirements of the Directive**

Overview of the Standards Development process

- Standards are not written in Stone……

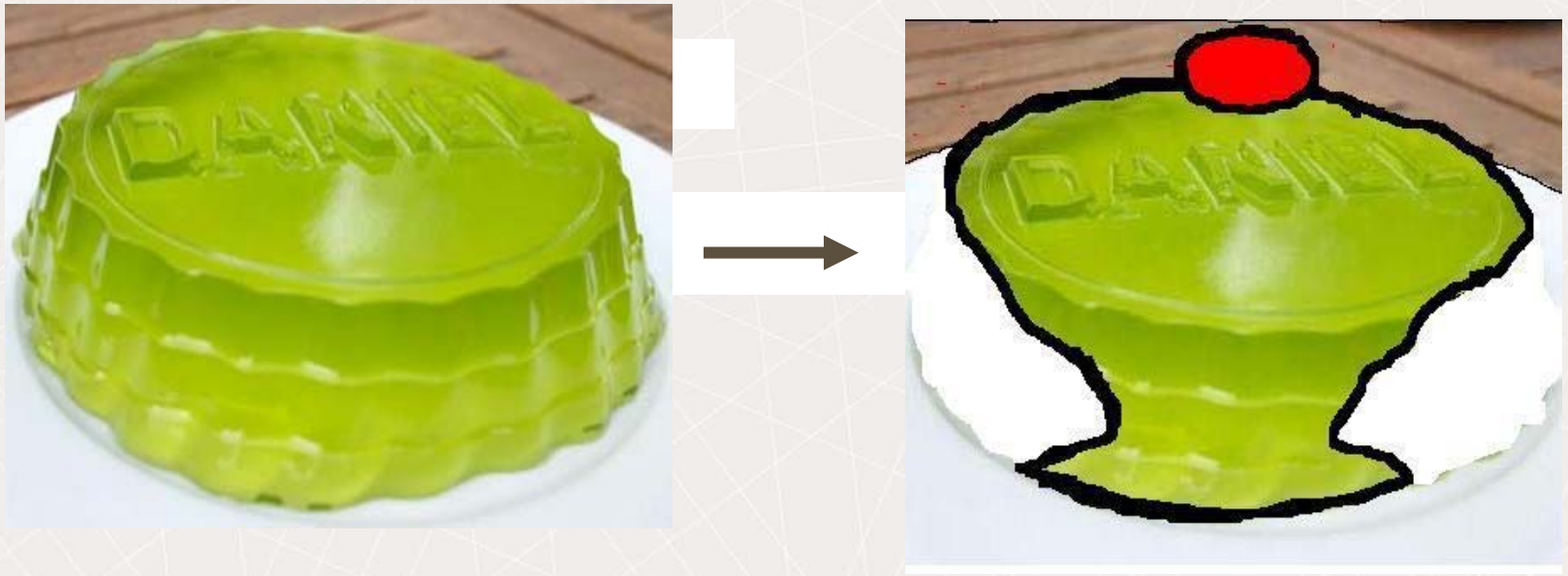
Overview of the Standards Development process

They are written in Jelly.....!

Overview of the Standards Development process

From time to time standards undergo review, or melt-down.
This is an opportunity to reshape and update the standard...

Standards can be ‘reshaped’ to ‘fit’ new technology



Overview of the Standards Development process

ISO Stages of a developing standard.

Document	Committee	Stage
NWIP	TC or SC	New work item proposal
CD	WG or SC	Committee Draft (Can be many)
DIS	SC or TC	Draft International Std
FDIS	SC or TC	Final Draft Int. Std.

PrEN: Provisional European Norm (Standard)

Overview of the Standards Development process

Frequently seen abbreviations …

Abb.	Document
EN/ISO	Standard originator
TS	Technical Specification
TR	Technical Report
CWA	Common Workshop Agreement
SR	Systematic Review (Melt down)

NSAI role in PPE Standards

CC structure

- **Chairman:**
  usually from industry
- **Secretary:**
  from NSAI
- **Membership:**
  broad representation from Industry, Consumers, Clinicians, Health & Safety interests, public bodies, technical expertise, educational bodies, as appropriate

Becoming involved, the pain and the gain

Standards are written by ‘Experts’ like you who contribute through the review and commenting process

Starting with a blank page, the headings are laid out on a template…..
Gradually the outline or framework emerges and
The document is ‘fleshed out’
Substantial changes are possible at the earliest stage.
As it grows in maturity, it becomes more focussed and rigid
Later changes are more focussed on ‘fine tuning’

Standard Development process is one of review and comment
Comments are the fundamental building blocks
It helps to be present to talk to and explain the rationale of the comment

Becoming involved, the pain and the gain

Template for comments and secretariat observations

Date: 2005-06-23	Document: **prEN 14894**

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/Table/ Note** (e.g. Table 1)	**Type of com-ment**[2]	**Comment (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations** on each comment submitted
FR	6	Table 3	Te	Modify in accordance with ADR 6.2.1.7.1 c)	Column "Mark" : Identification of the inspection body Column "Specification" : The identity mark or stamp of the inspection body that is registered with the competent authority of the country authorizing the marking.	Accepted, text revised
IE	8	Table 4 A2	e	If the symbol "#" means the registered mark – indicate this.	The year (2 digits) followed by the month (2 digits) separated by a "slash" (i.e. "/") of the last periodic inspection followed by the registered mark (#) of the inspection body authorised by the Competent Authority of the country of use.	Text revised
IE	8	Table 4 A2	t	Is leaving out the month correct (see ADR 5.1.2.6 (c)). – see also P Wolfs reference to this issue in "Standards Working Group of the Joint Meeting ADR/RID 4th meeting, 13-15 September 2004, Geneva" What about the #?		Partially accepted, text revised
IE	8	Table 4 A2	e	The text does not match the example.	"TI" Mark followed by *identification number of the Inspection Body and* the date of reassessment ~~and the identification number of the Inspection Body~~.	Text revised
FR	6	Table 4 ref A2	Te	In "specification", - identification number or stamp of the inspection body shall be sufficient - modify the note and delete the last sentence, related to TPED.	…followed by the *registered mark or identification number* of the inspection body… NOTE The month need not be indicated for cylinders for which the interval between periodic inspections is ten years or more (e.g. : welded steel cylinders)	Text revised
PT	8	A2	te	In the stamp markings of steel cylinders, following the year shall be also indicated the registered mark of the inspection body.	Change "03" to "03 #" (second example).	Text revised
PT	8	A3	te	The sequence of the text (specification) and the example given are not in accordance with TPED. See article 10 (PI and Notification body number must be together).	Change the specification in accordance and the example to: "2003/12 PI 1234". Change also Annex A.	Text revised

1 **MB** = Member body (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)
2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial
NOTE Columns 1, 2, 4, 5 are compulsory.

Page 9 of 13

NSAI Standards

Becoming involved, the pain and the gain

- Benefits to participation
- Gives the participant a competitive edge..
  - Advance awareness of pending change
  - Awareness of latest innovations
  - Awareness of latest draft regulations
  - Networking within specific knowledge group
  - Facilitates the building of participants own knowledge base, i.e. participants may learn a great deal about the area in which they are engaged…..builds Expertise!

Standardisation – Technical Committees at European level (EN) CEN TC 79

- **CEN / TC 79 Active Respiratory protective devices**
- **CEN / TC 79 / SC 1 Terminology, definitions, classification and selection**
- **CEN / TC 79 / SC 2 Physiological requirements**
- **CEN / TC 79 / SC 3 Facepieces**
- **CEN / TC 79 / SC 4 Filters and absorption devices**
- **CEN / TC 79 / SC 5 Fresh air hose and compressed air line breathing apparatus**
- **CEN / TC 79 / SC 6 Self-contained breathing apparatus**
- **CEN / TC 79 / SC 7 Diving apparatus**
- **CEN / TC 79 / SC 8 Powered respirators**
- **CEN / TC 79 / SC 9 Test Methods and Interpretation of CEN / TC 79 standards**

- NOTE: All Committee SC's are dormant except for SC7 and SC8

CEN TC 79 Respiratory protective devices

Published & Developing Standards at CEN level

- **EN 529:2005** Respiratory protective devices - Recommendations for selection, use, care and maintenance - Guidance document
- **EN 405:** RESPIRATORY PROTECTIVE DEVICES - VALVED FILTERING HALF MASKS TO PROTECT AGAINST GASES OR GASES AND PARTICLES - REQUIREMENTS, TESTING, MARKING
- **EN 143:2000/AC:2005** Respiratory protective devices - Particle filters - Requirements, testing, marking
- **EN 14593-2:2005/AC:2005** Respiratory protective devices - Compressed air line breathing apparatus with demand valve - Part 2: Apparatus with a half mask at positive pressure - Requirements, testing, marking
- **EN 14594:2005/AC:2005** Respiratory protective devices - Continuous flow compressed air line breathing apparatus - Requirements, testing, marking
- **EN 15333-1:2008/AC:2009** Respiratory equipment - Open-circuit umbilical supplied compressed gas diving apparatus - Part 1: Demand apparatus
- **EN 14387:2004+A1:2008** Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking
- **EN 15333-2:2009** Respiratory equipment - Open-circuit umbilical supplied compressed gas diving apparatus - Part 2: Free flow apparatus

CEN TC 79 Respiratory protective devices

More Published & Developing Standards at CEN level…..

- **EN 269:1994** Respiratory protective devices - Powered fresh air hose breathing apparatus incorporating a hood - Requirements, testing, marking
- **EN 144-3:2003/AC:2003** Respiratory protective devices - Gas cylinder valves - Part 3: Outlet connections for diving gases Nitrox and oxygen
- **EN 12083:1998/AC:2000** Respiratory protective devices - Filters with breathing hoses, (Non-mask mounted filters) - Particle filters, gas filters, and combined filters - Requirements, testing, marking
- **EN 140:1998/AC:1999** Respiratory protective devices - Half masks and quarter masks - Requirements, testing, marking
- **EN 14387:2004+A1:2008** Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking
- **EN 13274-7:2008** Respiratory protective devices - Methods of test - Part 7: Determination of particle filter penetration

Standardisation – Technical Committees at International level (ISO)

- **TC94/SC1** Head protection
- **TC94/SC3** Foot protection
- **TC94/SC4** Personal equipment for protection
- against fall
- **TC94/SC6** Eye and face protection
- **TC94/SC12** Hearing protection
- **TC94/SC13** Protective clothing
- **TC94/SC14** Fire-fighters' personal equipment
- **TC94/SC15** Respiratory protective devices

ISO TC 94/SC15

Respiratory protective devices

- WG 1 General
- WG 2 Filtering devices
- WG 3 Supplied breathable gas devices

NSAI Standards

ISO TC94/SC15 Respiratory protective devices

Published & Developing Standards at ISO level

- ISO/TS 16976-1 Human factors -Part 1: Metabolic rates
- and respiratory flow rates
- ISO/CD 16900-1 Methods of test and test equipment –
- Part 1:Determination of inward leakage
- ISO/FDIS 16900-2. Part 2: Determination of breathing resistance
- ISO/DIS 16900-3. Part 3: Determination of particle filter penetration
- ISO/CD 16900-4. Part 4: Determination of gas filter capacity
- ISO/CD 16900-9. Part 9:Carbon dioxide content of the inhaled air
- ISO/CD 16900-11. Part 11: Determination of field of vision

ISO TC94/SC15 Respiratory protective devices

Standards currently under development in ISO TC 94

- ISO/DIS 16792 Terms, definitions, graphical symbols and units of measurement
- ISO/CD TR 16974 Marking and information
- ISO/CD 16975 Selection, use and maintenance
- ISO/CD TS 16976-2 Human factors – Part 2: Anthropometrics
- ISO/CD TS 16976-3 Human factors – Part 3: Physiological responses and limitations of oxygen and limitations of carbon dioxide in the breathing environment
- ISO/CD TS 16976-4 Human factors – Part 4:Work of breathing and breathing resistance.

ISO TC94/SC15 & CEN TC79 Respiratory protective devices Committees

Current activity at CEN & ISO level

- **Work at CEN (EN) level is dormant**
- **All active work is at international level (ISO level)**
- **Active work at ISO level to develop performance based standards.**
- **Once the standards are developed at ISO level , they will be adopted at European level (CEN)**
- **European Standards (EN 's) will be withdrawn**

Respiratory Protective Devices – I.S. EN 529

Current legal position in Ireland

- European harmonised standards for respiratory protective equipment have been developed as a means of demonstrating equipment conformity with the basic health and safety requirements of the EC Personal Protective Equipment Directive (89/686/EEC).
- This directive is implemented in Ireland as the European Communities (Personal Protective Equipment) Regulations, 1993

- **RESPIRATORY PROTECTIVE DEVICES -**

RECOMMENDATIONS FOR SELECTION, USE, CARE AND MAINTENANCE –

GUIDANCE DOCUMENT

NSAI Standards

Respiratory Protective Devices – I.S. EN 529

Scope of this European Standard-

It provides :

- guidance on the best practice for establishing and implementing a suitable respiratory protective device programme
- a Europe-wide baseline for the **selection, use, care and maintenance** of respiratory protective devices.
- guidelines for preparing national guidance in this area

Respiratory Protective Devices – I.S. EN 529

Scope of this European Standard-

- is not intended to be exhaustive, but highlights important aspects to which attention should be given
- recommendations in this European Standard will help to comply with national legislation on this subject where it exists, or with European legislation

Respiratory Protective Devices – I.S. EN 529

Contents of this standard

- Classification
- Programmes process
- Risk Assessment process
- Criteria for using respiratory protective devices
- Risk assessment for respiratory protective device use
- Adequacy and suitability
- Use
- Operating information , instruction and training
- Maintenance / Storage / Record keeping
- Annex A – Types and components of respiratory protective devices
- Annex B- Atmospheres immediately dangerous to life or death
- Annex C – Protection factors
- Annex D- Suitability factors
- Annex E- Assessing the fit of tight fitting facepiece
- Annex F- Respiratory protection passport

Respiratory Protective Devices – Other Published I.S. EN Standards

IS EN 132 Definition of terms and pictograms

- **IS EN 133** Respiratory Protective Devices-Classification
- **IS EN 134** Nomenclature of Components
- **IS EN 136** Respiratory protective devices-full face masks-requirements, testing, marking
- **IS EN 140** Respiratory protective devices- half masks and quarter masks- requirements, testing, marking
- **IS EN 142** Respiratory protective devices- mouthpiece assemblies-requirements, testing, marking
- **IS EN 143** Respiratory protective devices- particle filters-requirements, testing, marking
- **IS EN 144** Respiratory protective devices-gas cylinder valves-Part 1/2/3
- **IS EN 149** Respiratory protective devices- filtering half masks to protect against particles-requirements, testing, marking
- **IS EN 13274** Respiratory Protective Devices-Methods of Test (Parts 1-8).

Occupational Hygiene Conference –PPE & RPD

- Published Documents on RPEs

  A Guide to Respiratory Protective Equipment- HSA , ISBN No: 978-1-84496-144-3

- **Websites of interest**

www.standards.ie

www.iso.org

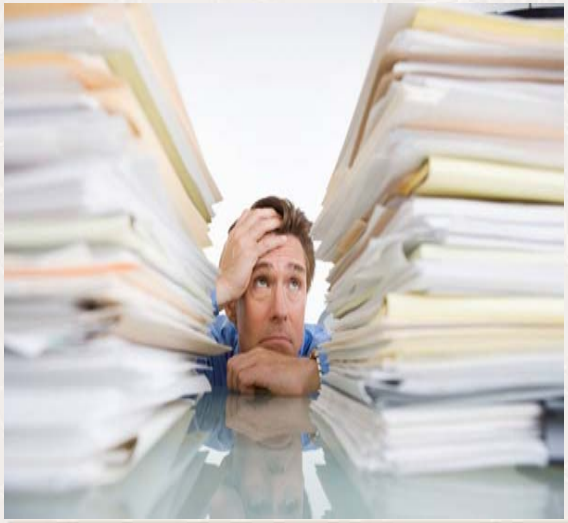
www.cen.eu

http://ec.europa.eu/enterprise/policies/european-standards

Conclusion

- Standards are a useful tool and methodology for compliance
- CEN TCs need input from informed users of standards.
- Users of standards need to keep themselves informed of TC activities.
- NSAI welcomes all Involvement

Becoming involved, the pain and the gain



NSAI Standards

NSAI and Standards…

When lost contact the following:

- www.standards.ie
- Elizabeth.oferrall@nsai.ie

NSAI
Standards

Thank you for your attention to Standards....