Respiratory Protective Equipment Against Airborne Infectious Agents

UK Regulatory Perspectives

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HSE
Health & Safety Executive

An agency of the Health and Safety Executive

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Personal Protective Equipment

- Legislation
  - HSE Regulations
  - EU Directives, ‘CE’ marking and CEN Standards
- Guidance
  - UK Health Care guidance
    - Dept of Health (DoH)
    - Health Protection Agency (HPA)
  - HSE guidance
- Fit testing
- Future actions

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Regulations concerning use of PPE

- PPE at Work Regulations 1992
- PPE Regulations 2002
- COSHH 2002
- Control of Asbestos at Work Regulations
- Control of Lead at Work Regulations
- Ionising Radiations Regulations

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Legal requirements

All include general duties:

- Carry out a risk assessment
- Prevent exposure to risk where possible

or if not possible

- Control risks to acceptable levels
  - Use of PPE ‘last resort’

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Legal requirements - COSHH

The law says that PPE used at work must:

- be **adequate** and provide the wearer with effective protection
- be **suitable** for the intended use
- be "CE" marked (PPE Directive)
- be correctly selected, used, maintained, examined & tested by properly trained people
- Be correctly stored and records kept

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RPE Programme

- Hazard identification
- Risk assessment
- Selection of *adequate* and *suitable* RPE
- Training
- Cleaning & Maintenance
- Record keeping
- Review
- Management systems for implementing the programme

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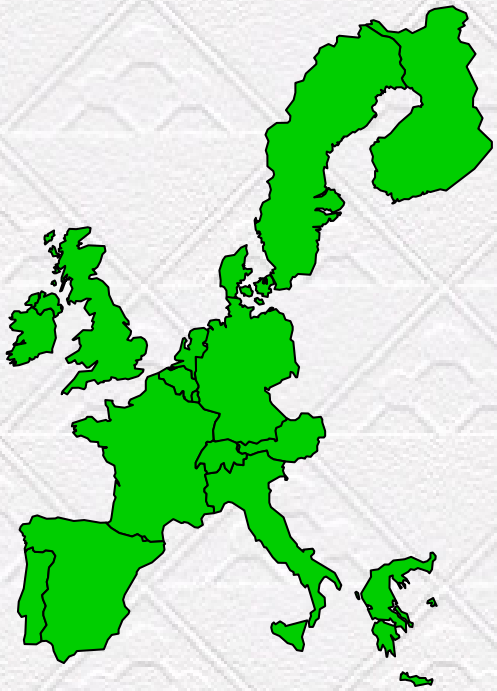
European Directive 89/686/EEC
(the PPE Directive)

- subsequently amended by Directives 93/68/EEC, 93/95/EEC and 96/58/EEC

- 'Article 100a' Directive, i.e. to eliminate barriers to trade within Europe, while safeguarding health and safety



- essential health and safety requirements for different types of PPE (the EHSRs)

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PPE Directive

Compliance with EHSRs demonstrated by:

- Conformance with European Standard
  - e.g. EN136, EN149, EN137
- Other technical specification (eg ISO, BS) assessed as meeting the EHSRs by a Notified Body ('Technical File' route)

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PPE Directive - Exemptions

Equipment for use solely by the armed forces, or for use in maintenance of law and order

Equipment solely for escape from ships and aircraft, not worn all the time

Equipment covered by another Directive (e.g. Medical Devices)

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Medical Devices Directive 93/42/EEC - Exemptions

..does not apply to PPE covered by Directive 89/686/EEC - PPE Directive

Which directive applies to devices used in health care?

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EU Directives

- Devices should comply with the Directive(s) that covers the *'principle intended purpose'* of the device
- Protecting the **patient** – Medical Devices Directive
- Protecting the **wearer** – Personal Protective Equipment Directive
- PPE should not be ***used*** or placed on the (EU) market unless it conforms to the PPE Directive

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Correct selection of RPE?

Tecnol PFR95 -NIOSH N95 class respirator - mask type commonly used for infection control (SARS and TB)

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‘CE’ marking

- ‘CE’ mark – so OK??
- NO – ‘CE’ mark for compliance with the Medical Devices Directive and NOT to the PPE Directive!!
- Should not be used as PPE

Confusing!!

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Three categories of PPE:

- Category 1 - 'Simple design' PPE
  - Self-certified by manufacturer
- Category 2 - 'Intermediate design' PPE
  - Type-tested and assessed by Notified Body
- Category 3 - 'Complex design' PPE
  - Type-tested and assessed by Notified Body
    - Conformity to EU Standard
  - Ongoing control of production

Medical Devices Directive

Class I – non-invasive devices

- Self-certified by manufacturer

Class II - surgically invasive devices

- Self-certified by manufacturer
- Limited quality assurance

Class III – medicinal product

- Type-tested and assessed by Notified Body
- Full quality assurance

Does not address inhalation exposure

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Filtering facepiece (BSEN149)

- Filtering efficiency – solid
- Filtering efficiency – liquid
- Measurement of inward leakage
- Breathing resistance
- Rebreathed CO_2
- Strength tests
- Vision
- Flammability
- Clogging

No bacterial filtration efficiency or fluid penetration

Surgical mask

- Bacterial filtration efficiency (staphylococcus aureus)
- Biocompatibility (EN10993-1)
- Fluid penetration (strike through test) 5.5psi blood
- Bioburden
- Breathing resistance
- Eye protection against fluid splash

Most requirements of EN149 not tested

Inhalation protection is not considered

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Total Inward Leakage – Respirator fit EN 149:2001

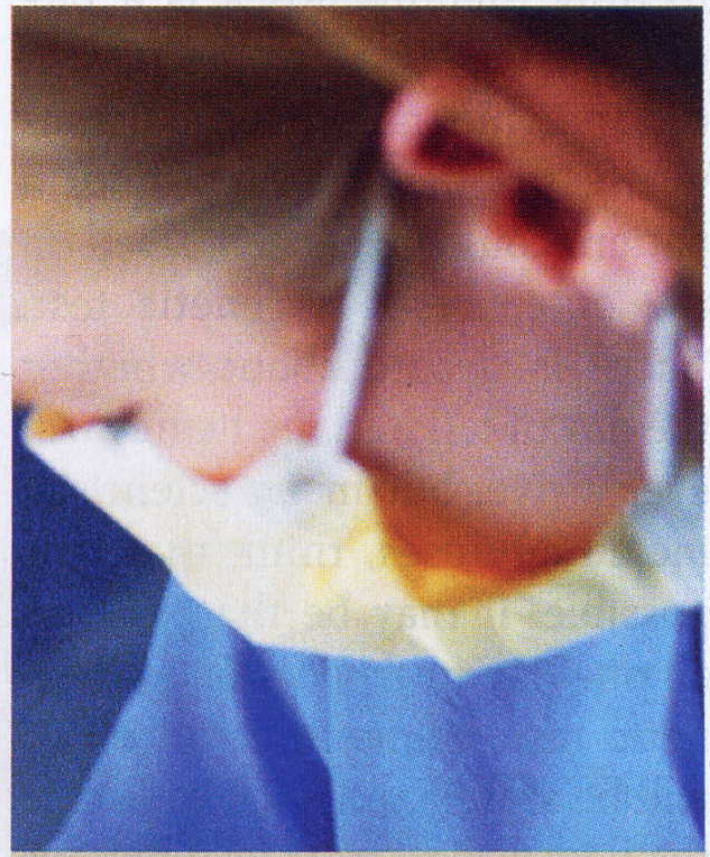
Requirements

Class (EN149)	TIL (%)	APF
FFP1	22	4
FFP2	8	10
FFP3	2	20

Measured

Surgical mask	TIL (%)	Respirator (EN149)	TIL (%)
Type 1 Type 2 Type 3	19 20 36	FFP1	6
		FFP2	6
		FFP3	0.11

Correct selection of RPE?

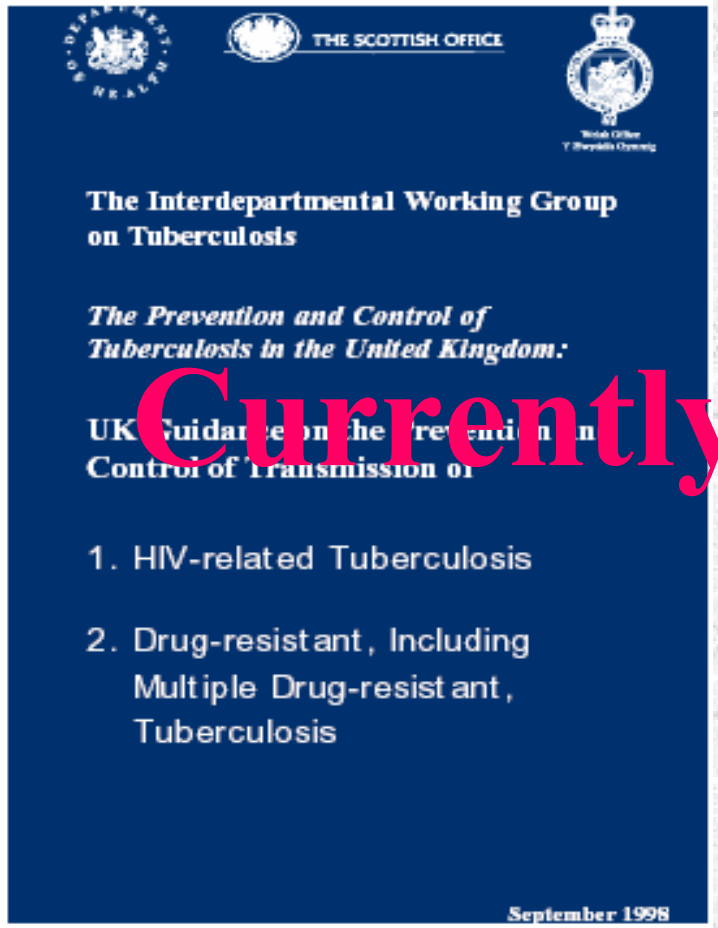


Breathe easy: Sars can be destroyed

Mask containing an enzyme claimed to kill the SARS virus !

But is it any good?

DoH guidance - TB



ANNEX E

RESPIRATORY PROTECTIVE DEVICES

.. the N95 series is the most appropriate for use in health care settings…..

Currently under revision

The document mentions FFP1 but infers that the N95 series is recommended

Also mentions use of medical devices (surgical masks) as providing sufficient protection

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Health Protection Agency guidance - SARS

- Original guidance 98% efficiency=FFP3
- Followed WHO guidance and recommended N95 respirators
  - EN149 class FFP2 added
- Revised (HSE) recommends EN149 class FFP3 respirator

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HSE Guidance for airborne infectious agents

In general, for HCWs -

- Thorough risk assessment
- Reduce exposure to ALARP
- FFP3 filtering masks conforming to EN 149:2001*
- Respirator must be fit tested
- Users to be adequately trained
- RPE 'CE' marked

(decision taken by the Pan-government Advisory Committee on Dangerous Pathogens)*

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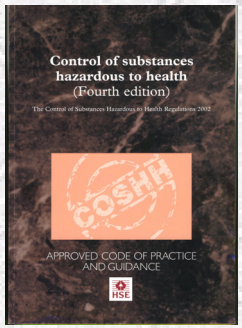
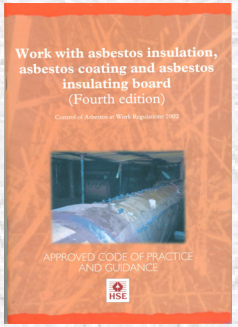
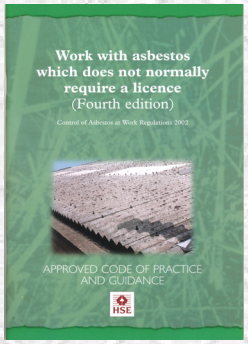
Why do you need to fit test ?

Required by Law:

- COSHH 2002 Reg. 7
- CLAW 2002 Reg. 6
- CAW 2002 Reg. 10







'Where adequate control of exposure cannot be achieved by other means, the provision of *suitable* personal protective equipment ……..'

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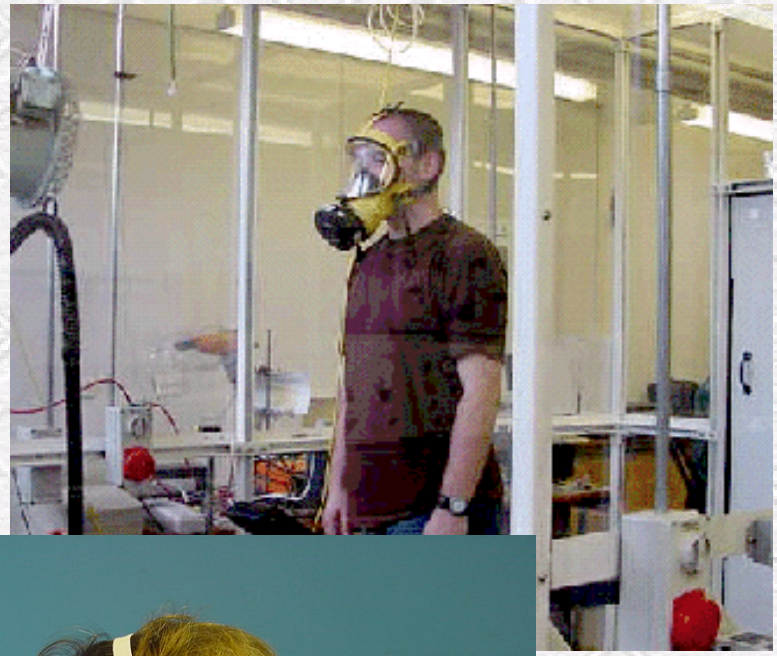
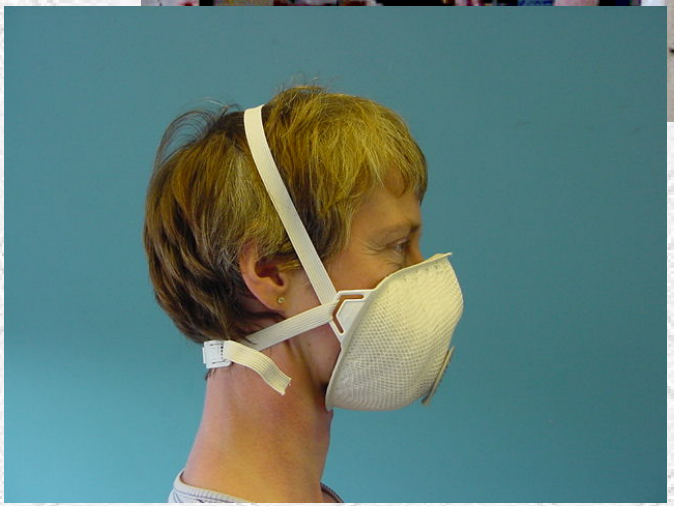
‘CE’ Testing

- Tested for inward leakage on a test panel of 10 subjects
- No guarantee that the facepiece is suitable for actual wearers
- Suitability by fit testing the actual wearer





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When to fit test ?

- Initial selection of RPE
- Facepiece not tested previously
- RPE change
- Facial characteristics changes
- H&S policy requires it

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Repeat fit testing?

- No requirement for general repeat fit testing
- Review planned 2005
  - Supporting evidence
  - Frequency based on risk assessment
    - Contaminant, frequency of use, etc.
- Training
- Competence of fit testers

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Future Actions

- Health care profession to review current guidance and use
  - Masks, protective clothing (gowns), gloves
  - What is the 'primary intended purpose' of the device?
  - Education
- Expansion of fit testing
  - Emergency services
    - Fire Service BA Qualitative fit test method
  - Repeat fit testing
- Develop guidance for testing and *safe parameters of use* for specific items of RPE for use in possible terrorist events
  - British Standard for CBRN RPE

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Clean air suits/Surgical helmets

Can look like PPE but are NOT

- reduce the dispersal of bacteria from the surgical team into the operating theatre air
- Do not meet respiratory protection performance levels
- Respiratory protection (RPE) should be used

- Not subjected to the same tests/req. as surgical gowns
  - should be used in addition to surgical gowns and not as a substitute
  - Provides an additional ‘protective’ barrier