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APFs & the new ISO Standards
The way forward

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Background

RPD Selection

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Respiratory Protective Devices (RPD) must be correctly selected to achieve optimum wearer protection

- RPD must be:
  - *Suitable* for environment, the task and the wearer
  - *Adequate* for the concentration of contaminant
- Selection has been based on Nominal Protection Factors (NPF)

Nominal Protection Factor

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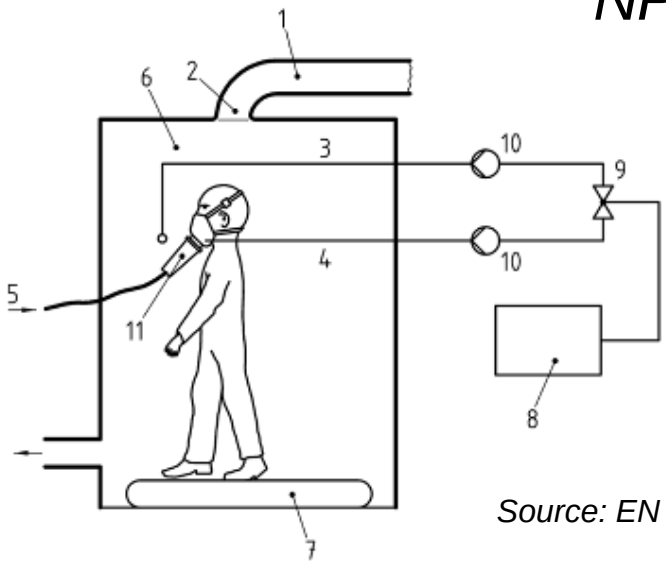
NPFs are calculated from the max permitted total inward leakage values specified in CEN standards

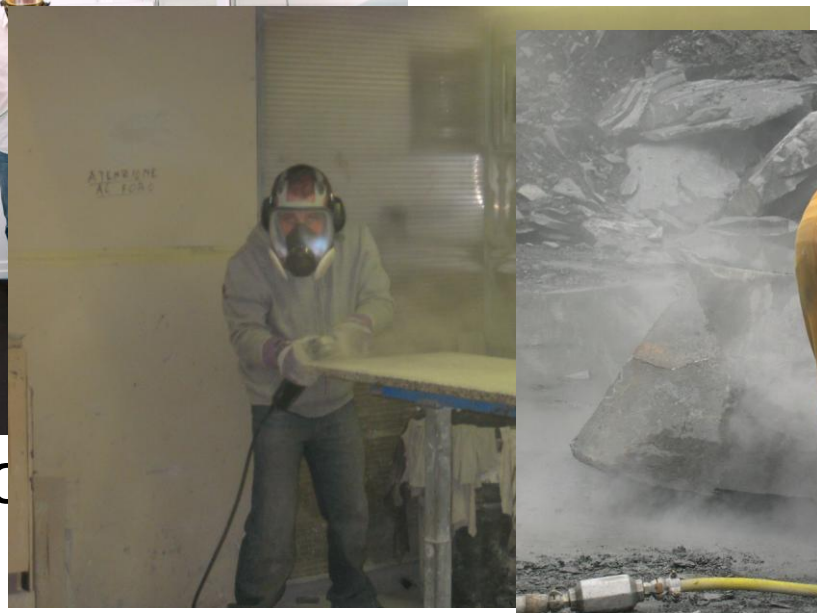
$$NPF = \frac{c_{outsideRPD}}{c_{insideRPD}}$$



Source: EN 13274-1

Are NPF appropriate for selection?

- Workplace studies have shown that NPF do not reflect the true protection achieved in the workplace
  - Big difference between laboratory and workplace conditions



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Assigned Protection Factor

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- Level of respiratory protection that can realistically be expected to be achieved in the workplace by 95 % of adequately trained and supervised wearers using a properly functioning and correctly fitted RPD and is based on the 5th percentile of the Workplace Protection Factor (WPF) data

Examples of current APFs

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RPD type and class	RPD class	APF Sweden	APF Germany	APF UK	APF US
Filtering facepiece	FFP2	10	10	10	10
Filtering facepiece	FFP3	20	30	20	10
Full face mask & P3	**[FFM] P3**	**500**	**400**	**40**	**50**
Powered hood	TH3	200	100	40	25/1000
Powered Full face mask	TM3	1000	500	40	1000

- Why the large difference?
- Difference methods used to determine the APF
  - Workplace data (WPF/As-Is)
  - Safety factors applied to NPF
  - Professional judgement

Discordant APFs

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Why is the discord between APFs a problem?

- Confusing for multi-national companies
  - different control measures in different countries
- Unnecessarily complex RPD programmes
  - more expensive, difficult operational challenges
- Are high APFs putting the wearer at risk?
- Lack of harmonisation
  - CEN/ISO harmonised performance requirements

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ISO RPD Standards

ISO RPD Selection

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- NPF not applicable to the workplace
- Can we use APFs?
  - Vast difference across the globe
  - Some countries don't have any APFs
  - Currently no global harmonisation
- Protection Levels (PL)
  - A means of ranking the RPD performance based on lab tests

CEN Classification Scheme

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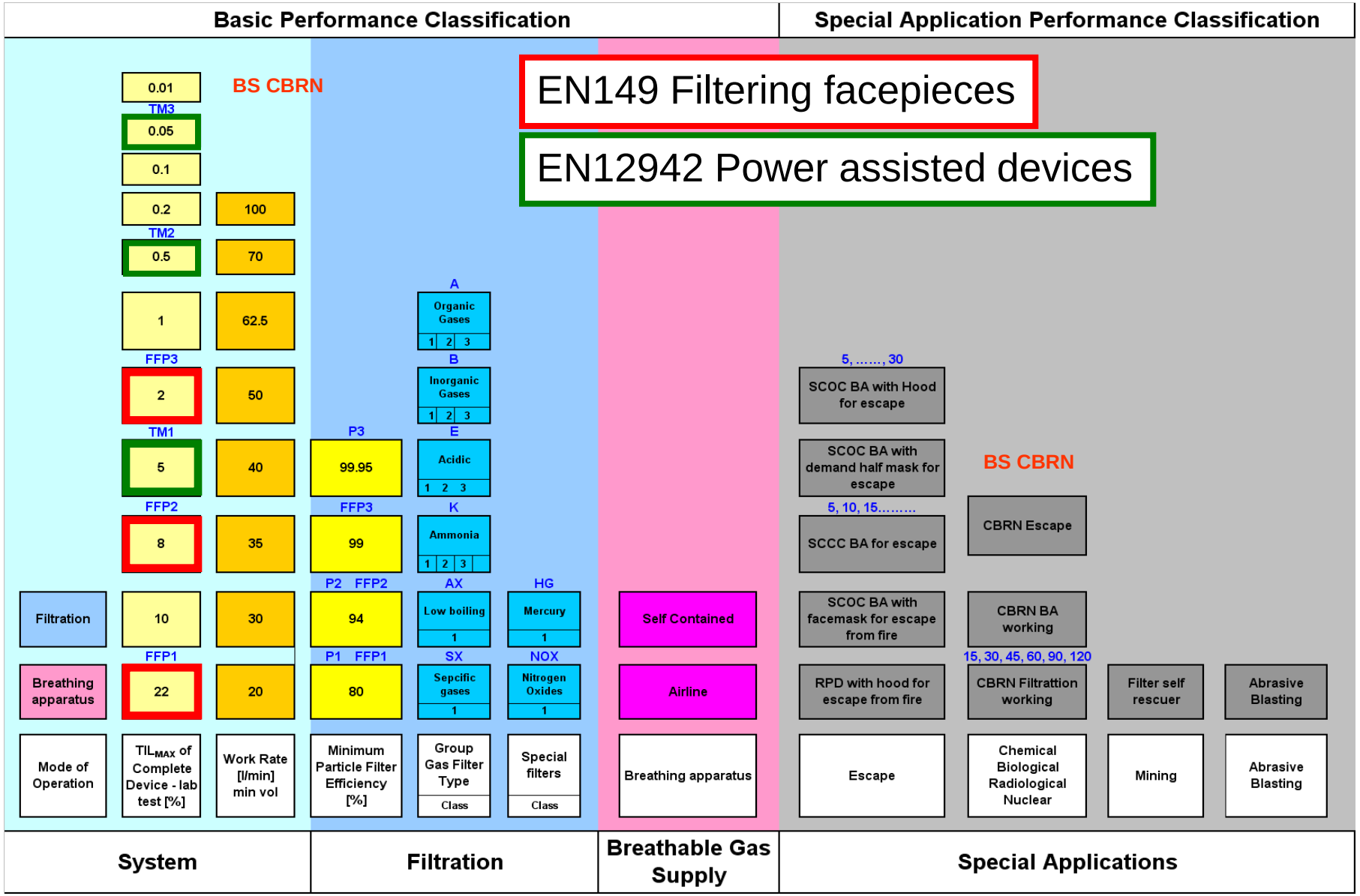

ISO Classification Scheme

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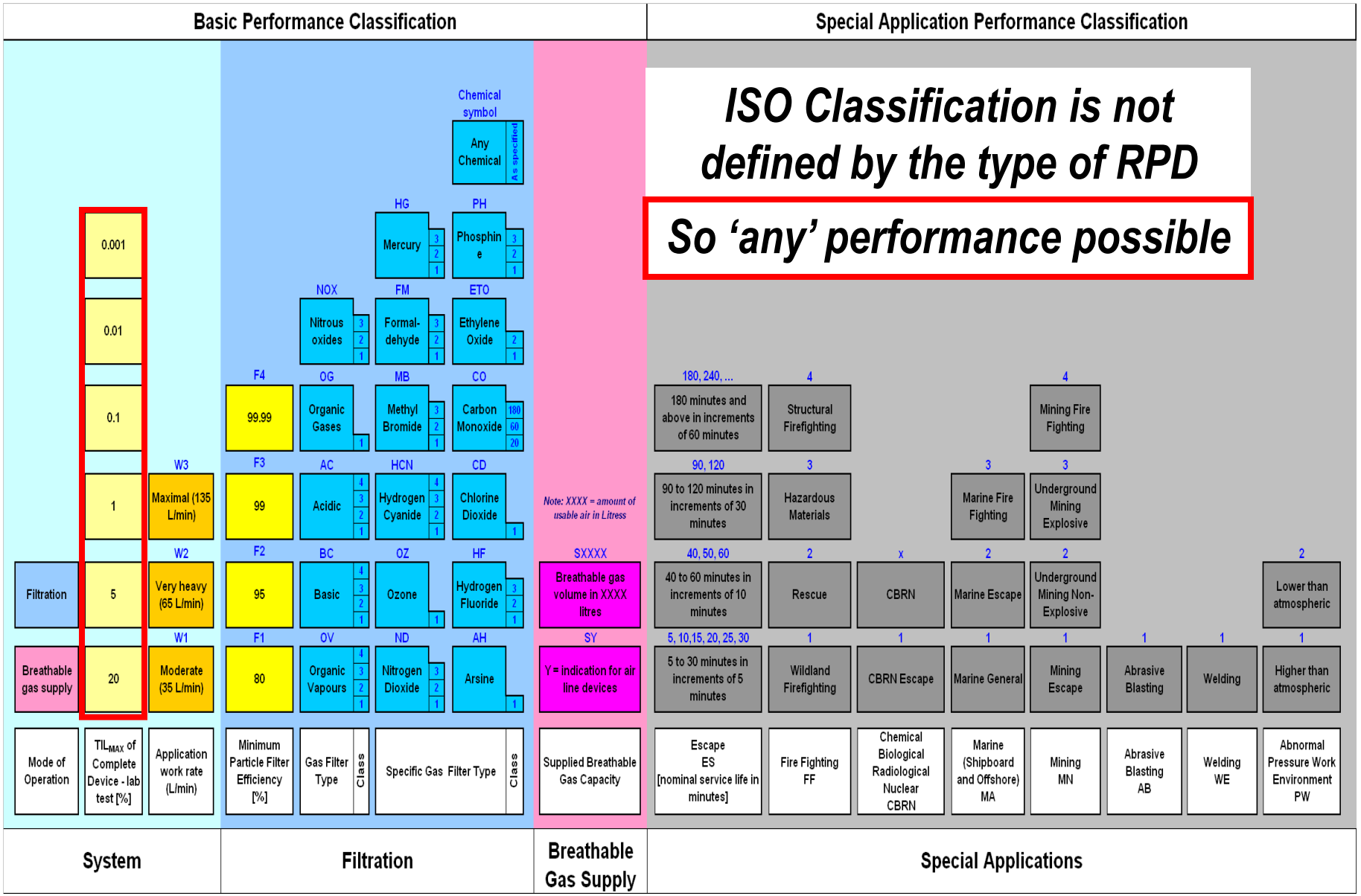

Derivation of ISO Protection Levels

ISO %TIL (Max)	NPF	Safety Factor	Protection Level	Protection Level Class	Current APFs (CEN & OSHA)
0.001	100,000	10	10000	PL6	-
0.01	10,000	5	2000	PL5	40 - 10,000
0.1	1,000	4	250	PL4	20 – 1000
1	100	3.33	30	PL3	20 - 100
5	20	2	10	PL2	10 - 15
20	5	1.25	4	PL1	4

European APFs and ISO PLs

ISO TIL %	Current CEN Type/Class	Current CEN TIL %	APF CEN range	ISO PL
20	FFP1	22	4	4
	HM P1	2 + 20	4	
	FM P1	0.05 + 20	4	
	FFP2	8	10	
	HM P2	2 + 6	10	
	FM P2	0.05 + 6	10/15	
	TH1	10	5/10	
5	TM1	5	10	10
	FFP3	2	20/30	
	HMP3	2 + 0.05	20/30	
	TH2	2	20	
1	TM2	0.5	20/100	30
	TH3	0.2	40/200	
0.1	FM P3	0.05 + 0.05	40/500	250
	TM3	0.05	40/1000	
	BA (+ve)	0.05	1000/2000	

Why go back to NPF (TIL)?

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- No link with performance and RPD type
- TIL is the only RPD performance measure in common
- ISO TIL test is much more robust
  - 25 test subject instead of 10
  - 9 test exercises instead of 5
  - PL class determined from the TIL result

Protection Levels

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- Derivation of PLs **has not taken into account RPD design** – this may be necessary
- PLs need to be validated

Note added to the CD: *These protection levels have been derived from analysis of previous assigned protection factors, their associated nominal protection factors (NPF) and expert knowledge of differences between laboratory and workplace protection performance of current products. The values will be validated when RPD conforming to the requirements of ISO 17420 are available*

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How can the PLs be validated? The way ahead

PL Validation

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Options:

- *Do nothing!!*
  - *No validation, members countries use their own values – APF, NPF, safety factors, etc?*
- *Do something!!*
  - *What can we do NOW?*
  - *What can we do in the future?*

Validation - what can we do now?

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- Identify WPF data for current RPD
- Perform ISO TIL on that RPD
- Compare WPF data with ISO TIL & PL data

Problems

- Lack of suitable WPF data

Challenge

- Laboratories to offer to conduct TIL tests

Validation - what can we do in the future?

- Workplace protection factor studies

Challenge

- To obtain statistically valid WPF data is both economically and operationally challenging
  - Agreed WPF protocol, measurement techniques, etc.
- Requires input and support from the whole RPD community
  - Users, manufacturers, national standard bodies, regulators, etc.

Conclusion

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- Lack of harmonised APFs
- New performance requirements under ISO, but we also need to improved RPD selection
- Not only ISO, ISRP can take a large role
- Use the opportunity
- WPF are expensive **but** *can we 'afford' to do nothing*?

Questions?

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