

# **EFFICIENCY TESTING AND IMPLEMENTATION OF RISK MANAGEMENT MEASURES TO MITIGATE EXPOSURE TO NMS**

**HENK GOEDE, TOM LIGTHART, JODY SCHINKEL, WOUTER  
FRANSMAN**

# › INTRODUCTION



With increasing use of NMs, considerable effort needed to ensure safe use in occupational settings



To mitigate or reduce worker exposure & health effects, Risk Management Measures (RMM) should be introduced



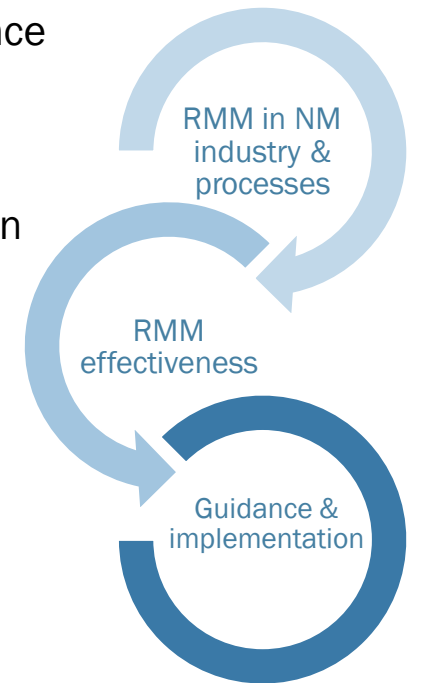
For risk assessment & modelling purposes, (i) RMM design criteria for NM applications and (ii) quantitative effectiveness values are required to recommend and implement RMM in the workplace



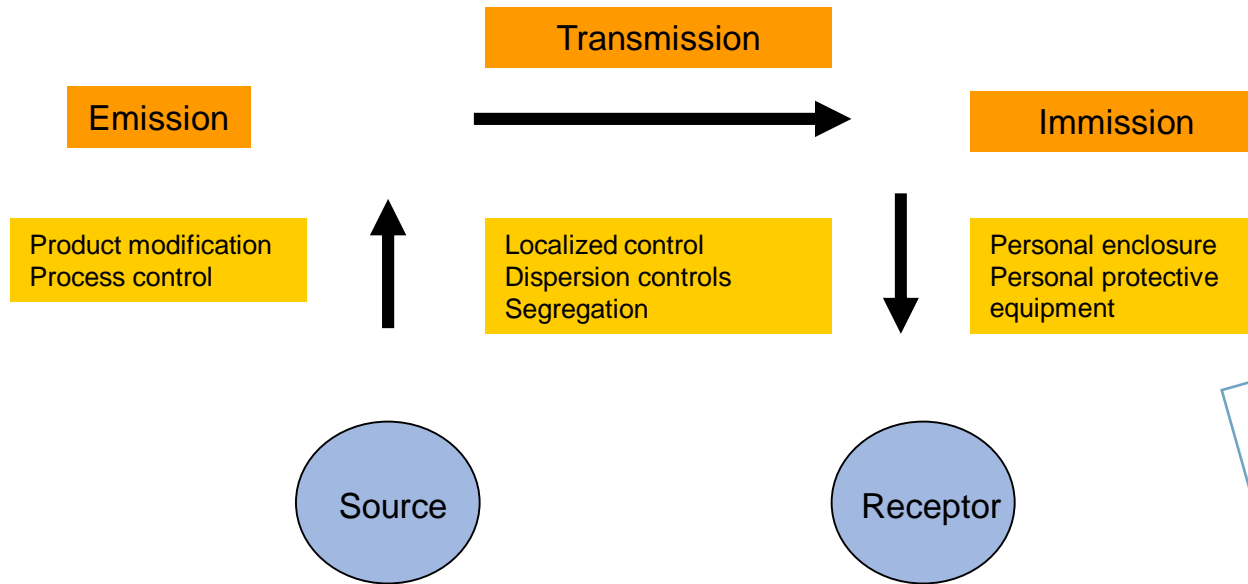
Valuable information is already available from recent projects & guidelines focusing on RMMs for NMs, e.g. NIOSH, OECD, LIFE NanoRISK, SUN, NANoREG and GUIDEnano



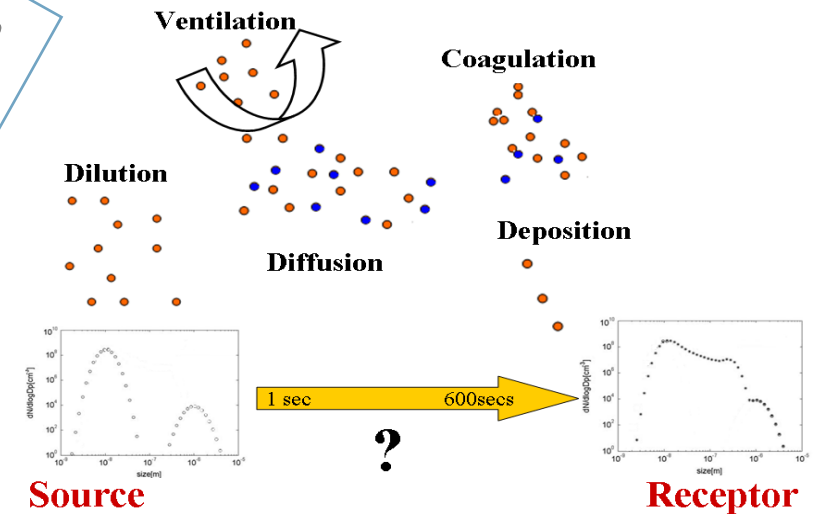
There is a need to integrate evidence to develop guidance and support implementation



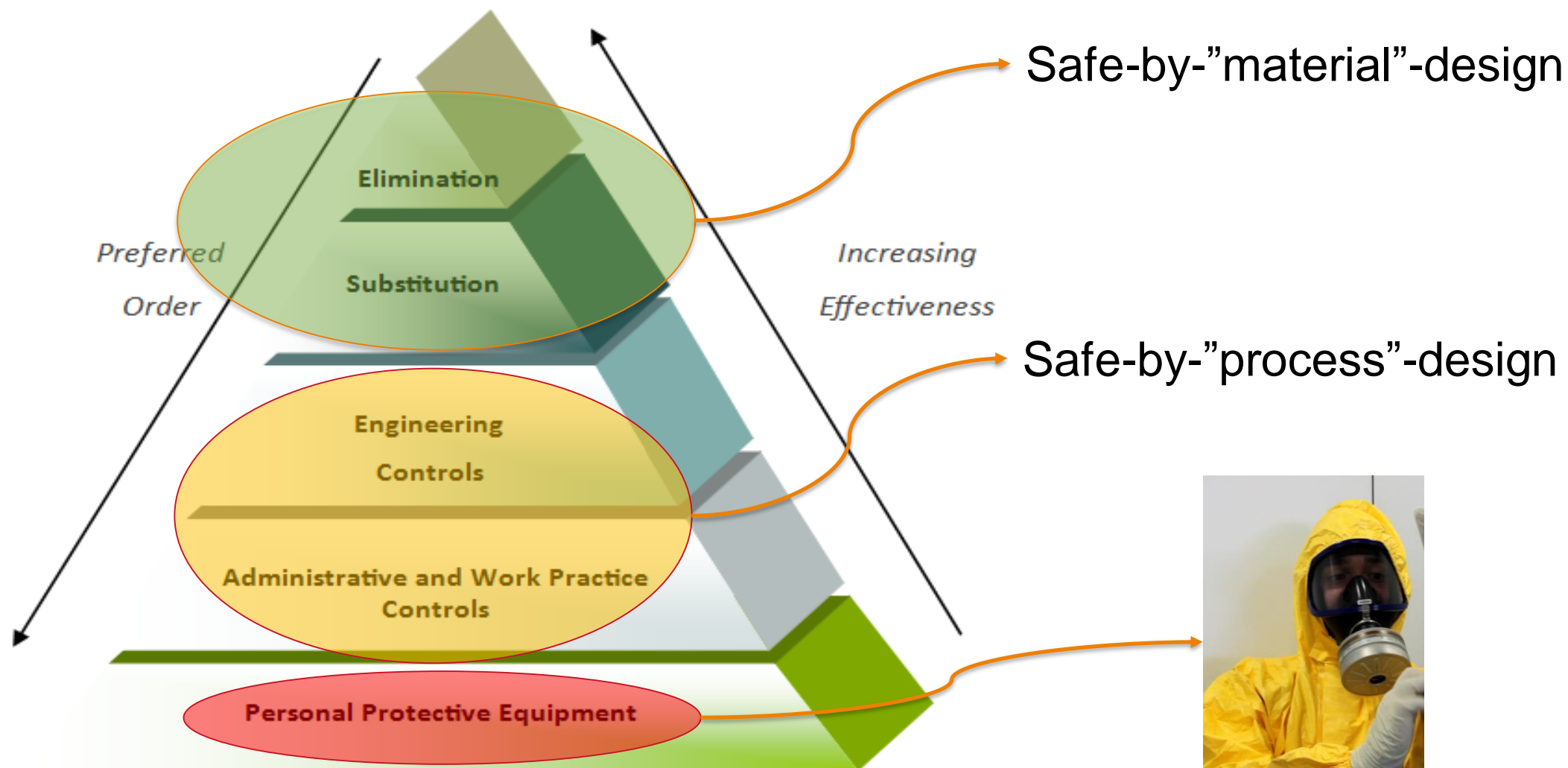
# EXPOSURE TO NANOMATERIALS VS CONTROL



How effective are RMMs for nanomaterials?



# PRIORITIZATION & MANAGING THE RISKS OF EXPOSURE



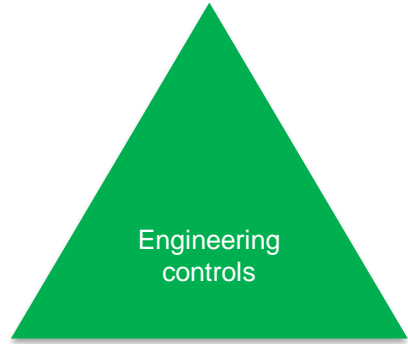
Safe-by-''material''-design



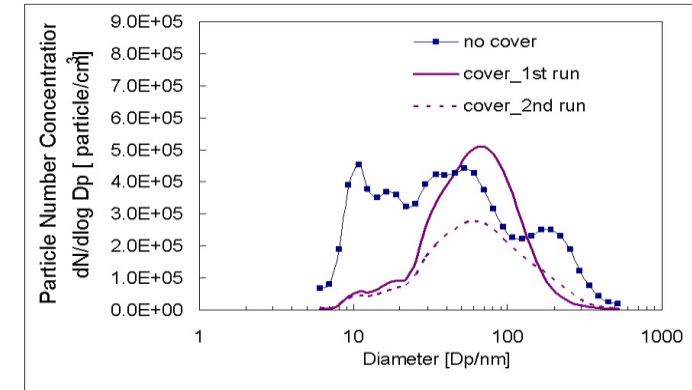
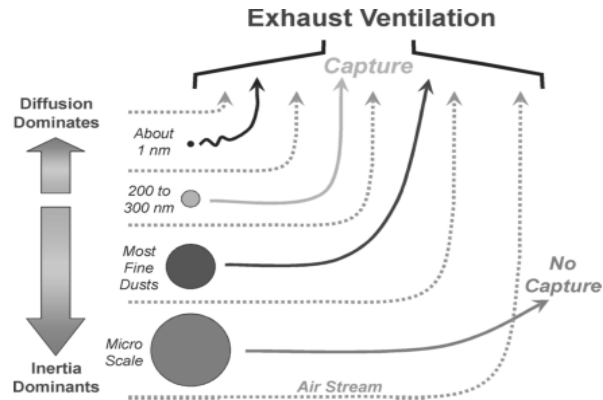
Safe-by-''process''-design



# RMM EFFICIENCY: THEORY VS PRACTICE

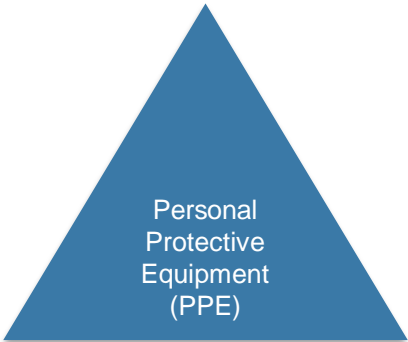


Diffusion vs inertia

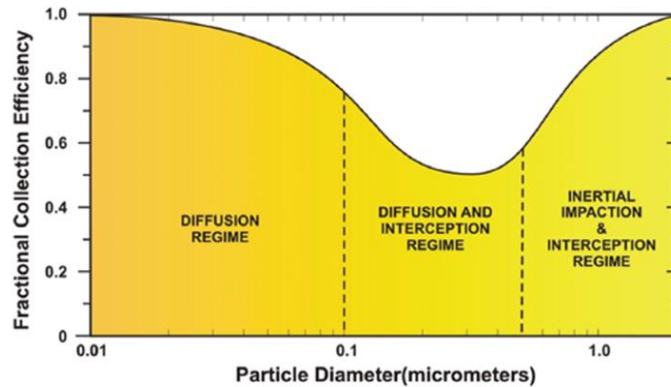


Particle capture efficiency in a ventilation system (Schulte et al., 2008)

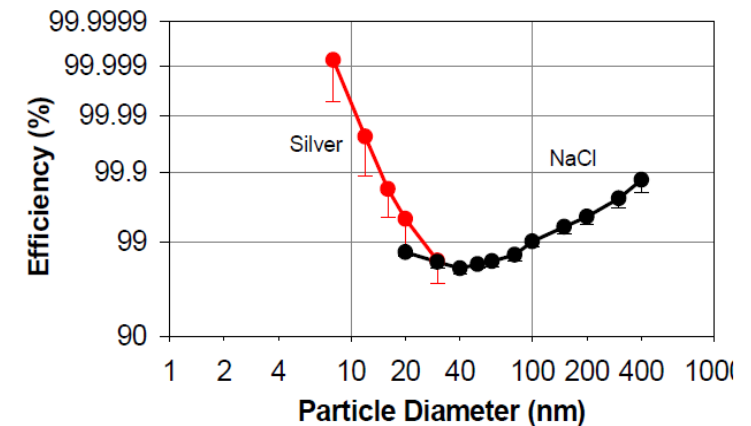
Example of engineering controls on particle number concentrations w/o cover (from Tsai et al, 2008)



Diffusion vs interception



Collection efficiency curve of the fractional collection efficiency versus particle diameter for a typical filter (from Lee and Liu, 1980)



Filtration Performance of a Typical N95 Filtering Facepiece Respirator (FFR) (from Rengasamy et al., 2008)

# RMM TESTING

- › RMM effectiveness (or efficiency) refers to the reduction in an (exposure) concentration, expressed as a percentage (%)
  - › Calculated from control on/off, efficacy factor, protection factor (PF) or Total Inward Leakage (TIL)
  
- › Obtained from a wide range of studies, for example:
  - › Pre-/post- tests from field & intervention studies
  - › Model estimates from large datasets / cross-sectional studies
  - › Upstream/downstream tests from field / experimental studies

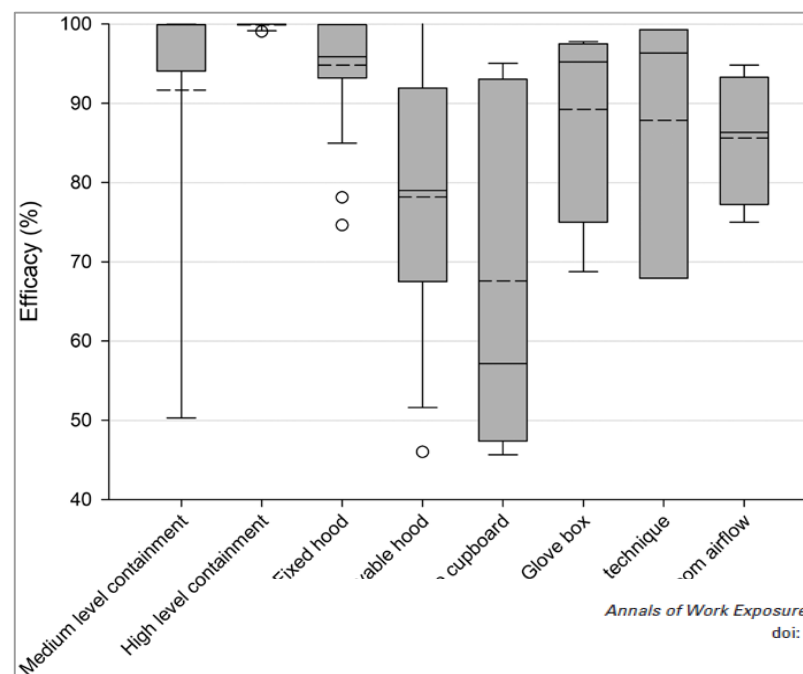
**nanom/CEX**

**NANOREG**

**Scaffold**

## LITERATURE REVIEWS & ANALYSIS

- › Literature review & analysis RMMs for NMs (2005–2016)
- › Key finding: (too) limited data available to derive RMM effectiveness values
- › **Engineering controls**: effectiveness appears in same order of magnitude to that of conventional RMMs
  - Specific attention proposed for containment, fume cupboards, and glove boxes
- › **Respiratory Protective Equipment (RPE)**: mostly experimental data, but also field studies indicate high effectiveness
  - Filtering face respirators less effective - indicated the lowest PFs for particles between 80 and 200 nm



*Annals of Work Exposures and Health*, 2018, 1–16  
doi: 10.1093/annweh/wxy032  
Review

**BOHS**  
The Chartered Society for  
Worker Health Protection

OXFORD

Review

### **A Review of Workplace Risk Management Measures for Nanomaterials to Mitigate Inhalation and Dermal Exposure**

**Henk Goede\***, Yvette Christopher-de Vries, Eelco Kuijpers and Wouter Fransman

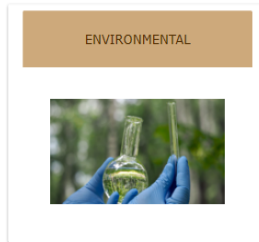
TNO, Risk Analysis for Products in Development (RAPID), PO Box 360, 3700 AJ Zeist, the Netherlands

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# EXPOSURE CONTROL EFFICACY LIBRARY (ECEL)

Risk Management



The Exposure Control Efficacy Library (ECEL v3.0) provides information on the effectiveness of occupational and environmental Risk Management Measures (RMM). ECEL v3.0 was developed by TNO in a project funded by the CEFIC LRI programme (LRI-B15). The library is available on the TNO DIAMONDS platform and brings together various information sources that is supportive to industry for a wide range of Risk Management Measure (RMM) applications. It offers a database structure to search for different types of RMM and exposure or emission scenarios and to compare their effectiveness. This information is required in the context of the European Chemicals policy (REACH - Registration, Evaluation and Authorization of Chemicals) and other European regulations to demonstrate and document safe use of substances based on quantitative exposures and exposure reduction by Risk

	Source	Content	N	Publication year
1	ECEL literature review 2019/2020~	• Broad scope of occupational RMM, except personal protective equipment (PPE)	102 <sup>a</sup> 1028 <sup>b</sup>	<2020 (mostly 2012-2020)
2	ECEL v2.0*~	• Mostly engineering controls	73 <sup>a</sup> 449 <sup>b</sup>	<2012
3	ECEL v1.0*	• Mostly engineering controls	81 <sup>a</sup> 361 <sup>b</sup>	<2008
4	TNO MEC RMM manufacturers' data~	• On-tool extraction systems • On-tool wetting systems	287 <sup>a,b</sup>	2003-2019
5	Nano-specific data*	• Engineering controls • Respiratory protective equipment (RPE) • Skin protective equipment (SPE)	43 <sup>a</sup> ~872 <sup>b</sup>	2005-2016
6	BROWSE PPE data*	• Skin protective equipment (SPE)	36 <sup>a</sup> 446 <sup>b</sup>	1994-2011

ders to share their knowledge on risk management measures in order to improve the user interface in the future. Are you interested to share



<https://diamonds.tno.nl/#ecel>

- › Open-source library developed in the CEFIC LRI B15-3 project
- › Scope: occupational and environmental RMM modules
- › Nano-specific data focusing on engineering controls, RPE, SPE
- › Content:
  - EC = 183 records / 18 studies
  - RPE = 430 records / 19 studies
  - SPE = 259 records / 11 studies

<sup>a</sup> Number of studies

<sup>b</sup> Number of records



# EXPOSURE CONTROL EFFICACY LIBRARY (ECEL)

- › Scenarios: apply filters for find relevant scenario, e.g.:
  - Type of RMM, agent, exposure/emission form, task, activity class, PROC, exposure route
  
- › Two outputs:
  - *Compare RMM*: plot showing different RMMs found and their effectiveness
  - *RMM analysis*: % effectiveness (reduction in exposure) >> median and a 95% credible interval

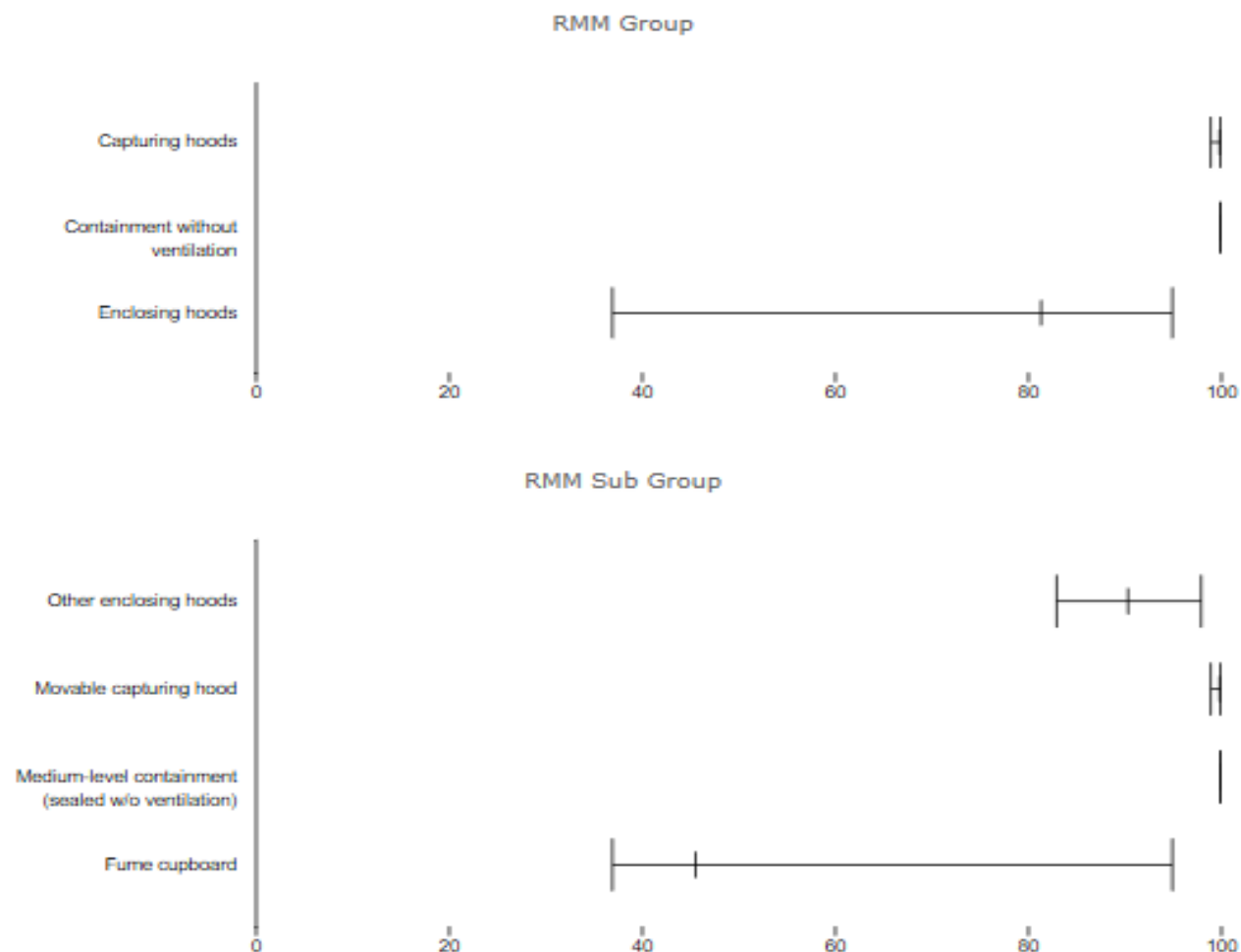
Selected filters	
Exposure Form	<ul style="list-style-type: none"> <li>• Nanoscale particles</li> </ul>
Activity Class	<ul style="list-style-type: none"> <li>• Movement and agitation of solids (powders, granules or pelletized material)</li> </ul>
RMM Type	<ul style="list-style-type: none"> <li>• Local ventilation systems</li> <li>• Containment / enclosure source</li> </ul>
RMM Group	<ul style="list-style-type: none"> <li>• Capturing hoods</li> <li>• Containment without ventilation</li> <li>• Enclosing hoods</li> </ul>

# EXPOSURE CONTROL EFFICACY LIBRARY (ECEL)

- › Scenarios: apply filters for find relevant scenario, e.g.:
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# EXPOSURE CONTROL EFFICACY LIBRARY (ECEL)

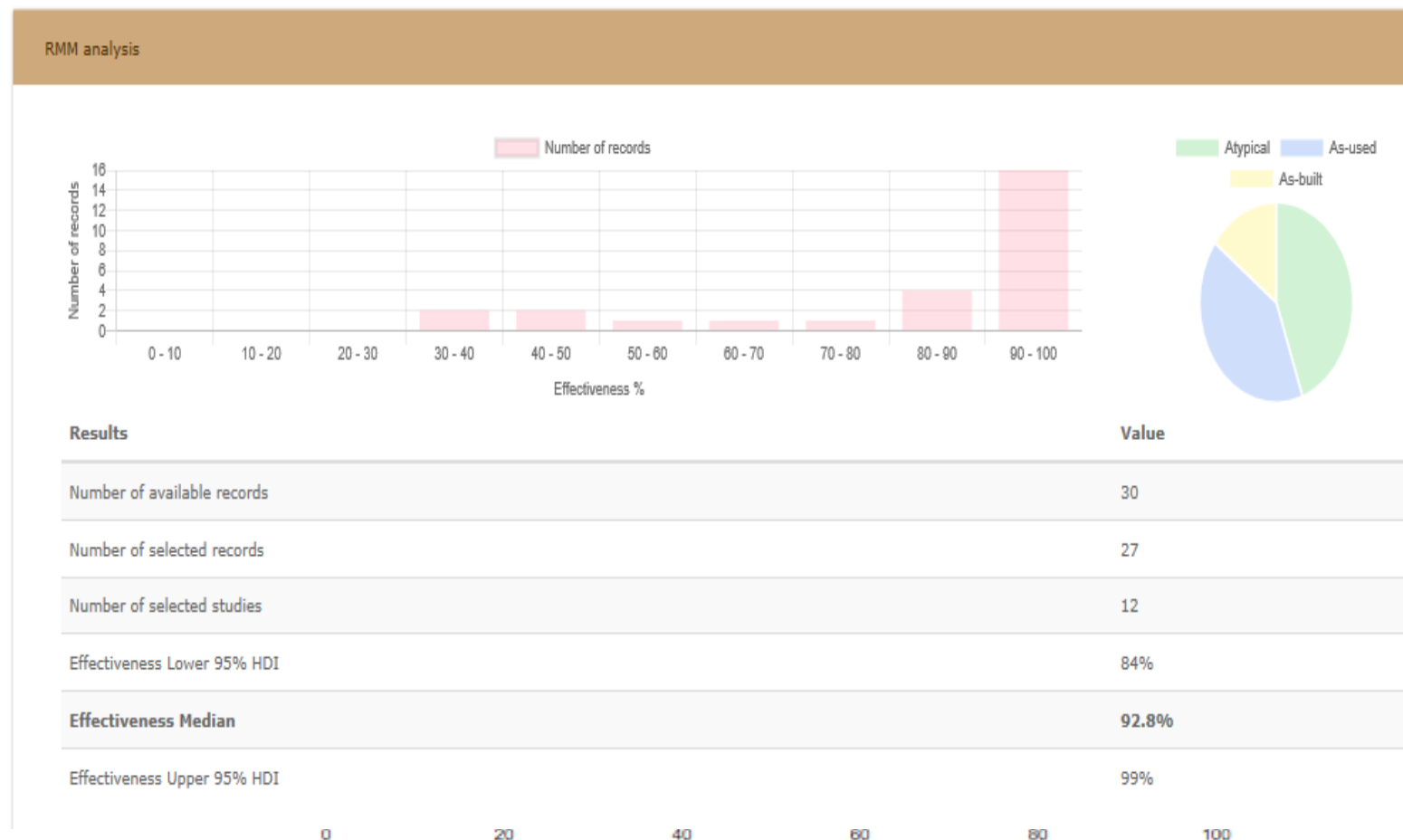
› Scenarios: apply filters for find relevant scenario, e.g.:

- Type of RMM, agent, exposure/emission form, task, activity class, PROC, exposure route

› Two outputs:

- *Compare RMM*: plot showing different RMMs found and their effectiveness
- *RMM analysis*: % effectiveness (reduction in exposure) >> median and a 95% credible interval

Results Selected records Compare RMMs RMM analysis



# › RMM EFFECTIVENESS

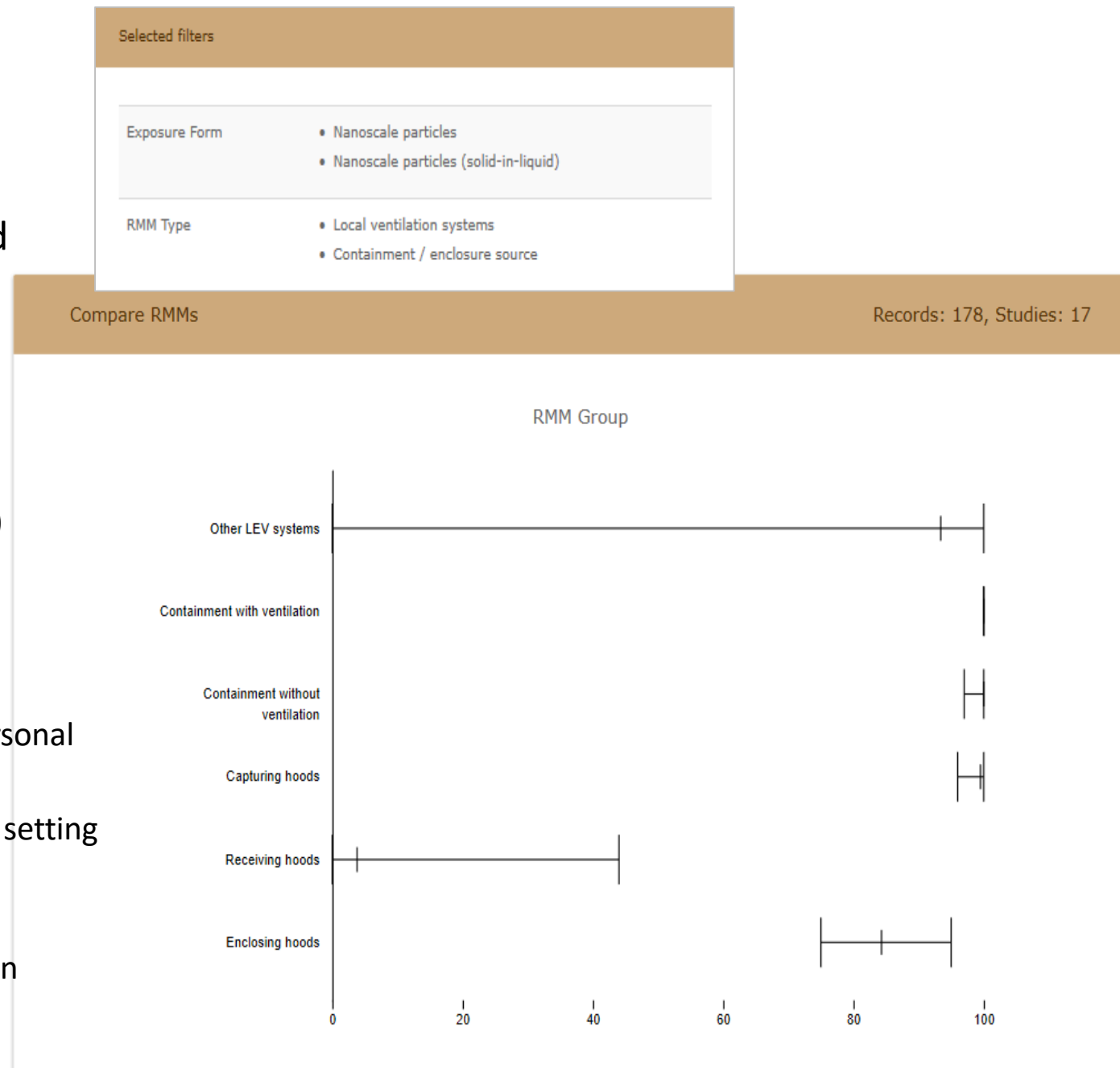
› Ongoing research to populate databases and analyse RMM effectiveness

› RMM testing

- › Single RMM (e.g. wetting system only)
- › Multiple RMM (combination of more than one RMM)
- › Improved RMM (or optimized RMM)

› Study types

- › **As-used:** field study data of single RMM based on personal exposures
- › **As-built:** manufacturer's data in (semi-) experimental setting during optimal conditions
- › **Atypical:** other relevant studies using 'atypical' test conditions (experimental) or work practices with often extreme outliers



# VARIABILITY IN RMM EFFECTIVENESS

› Dependent on:



(Technical) specifications & design



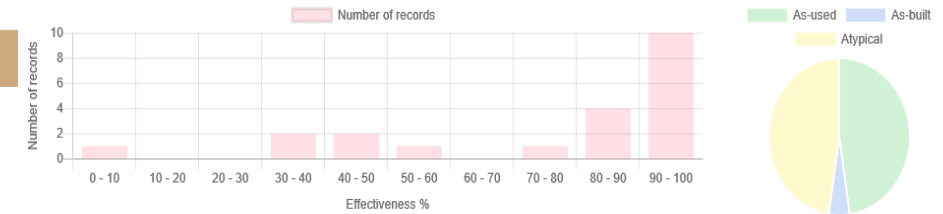
Maintenance (incl. periodic testing, repair, cleaning, storage)



Use in practice (how is the RMM used?, work practices, respirator fit, etc)

Selected filters	
Exposure Form	<ul style="list-style-type: none"> <li>Nanoscale particles</li> <li>Nanoscale particles (solid-in-liquid)</li> </ul>
RMM Type	<ul style="list-style-type: none"> <li>Local ventilation systems</li> </ul>
RMM Group	<ul style="list-style-type: none"> <li>Enclosing hoods</li> </ul>
RMM Sub Group	<ul style="list-style-type: none"> <li>Fume cupboard</li> </ul>

## RMM analysis



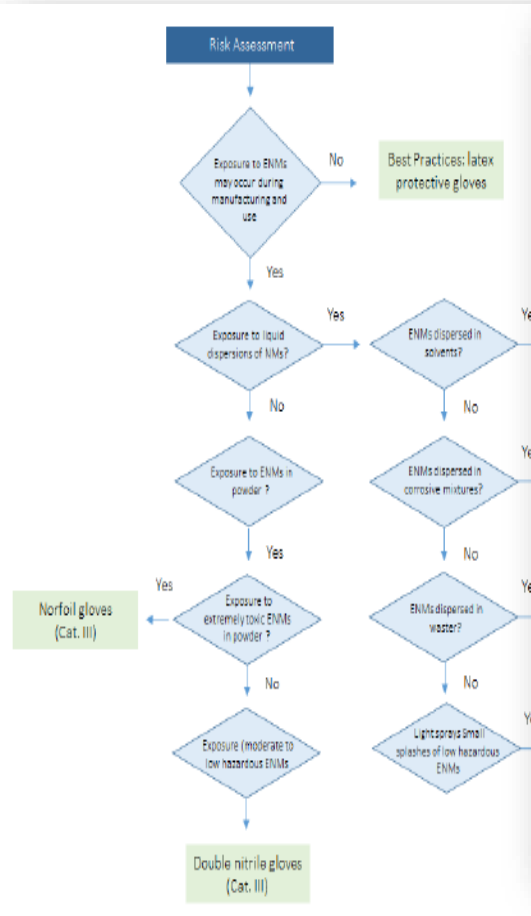
## Results

	Value
Number of available records	21
Number of selected records	21
Number of selected studies	8
Effectiveness Lower 95% HDI	79%
<b>Effectiveness Median</b>	<b>86.6%</b>
Effectiveness Upper 95% HDI	99%

› Manufactured nanoparticles are known to coagulate rapidly during emission from the source and transport to the receptor – affecting actual effectiveness of a PSD bin

› A wide range of determinants associated with the substance-, activity/process- and ambient/environmental conditions may contribute to variability in effectiveness

# RELEVANCE OF RMM FOR NANOMATERIALS



STAGE / PROCESS	LABORATORY	PILOT PLANTS	INDUSTRIAL SETTINGS (MEDIUM SCALE PRODUCTION)	INDUSTRIAL SETTINGS (LARGE SCALE PRODUCTION)
Material Unpacking (Dry Powder)	Ventilated Laboratory Hood (partial enclosure)	HEPA filtered down flow booth	Custom-fabricated enclosures	Custom-fabricated enclosures
Material Unpacking (Liquid dispersions)	Local exhaust enclosure (Glove Box)		HEPA filtered down flow booth	HEPA filtered down flow room
Material Unpacking (Dry Powder)	Ventilated Laboratory Hood (partial enclosure)	Ventilated Laboratory Hood (partial enclosure)	HEPA filtered down flow booth (or rooms) / Non ventilated enclosures for low Emissions Toxic ENMs	
Weighing (Dry Powder)	Ventilated Laboratory Hood (partial enclosure)	HEPA filtered down flow booth		
Weighing (Liquid dispersions)	Local exhaust enclosure (Glove Box)	Walk-in hood		
Transferring	Biological safety cabinet			
Sonicated	Ventilated Laboratory Hood (partial enclosure)	Ventilated Laboratory Hood (partial enclosure)		
Mixing (Dry Powder)	Ventilated Laboratory Hood (partial enclosure)	HEPA filtered down flow booth		
Mixing (Liquid dispersions)	Local exhaust enclosure (Glove Box)	Movable LEV systems (extendable arms)		
Production (physical and chemical synthesis)	Ventilated Laboratory Hood (partial enclosure)	Ventilated enclosure located inside a downflow room		
Packing / bag filling	Ventilated Laboratory Hood (partial enclosure)	HEPA filtered down flow booth Ventilated collar-type exhaust hoods Continuous liner product off-loading system		
Spraying	Ventilated Laboratory Hood + built-in water wash down systems	Walk-in hood		
Machining (sawing, grinding, etc)	Ventilated Laboratory Hood (partial enclosure) Movable LEV systems (extendable arms)	Custom-fabricated Movable LEV systems (extendable arms)		
Compounding / injection molding	Custom-fabricated Movable LEV systems	Canopy hood - Receiving hood (hot process)		

	VENTILATED TECHNICAL MEASURES								NON VENTILATED TECHNICAL MEASURES		
	Laboratory fume hood or cupboard	Local exhaust enclosure (Glove Box)	Receiving hood (hot process)	Movable LEV systems	Walk-in hood / booth	HEPA filtered down flow booth	Ventilated collar-type exhaust hoods	HEPA filtered down flow rooms	Custom-fabricated enclosures (fully - partial)	Continuous liner product off-loading system *	Inflatable seals
Material Unpacking	X	X				X		X	X		
Weighing (Dry Powder and liquid dispersions)	X	X			X	X	X	X			
Transferring	X				X				X		
Sonicated	X								X		
Mixing (Dry Powder and liquid dispersion)	X	X		X	X			X			
Synthesis (Dry/ liquid)	X		X						X		
Packing / bag filling	X					X	X	X	X	X	X
Spraying					X	X				X	
Machining	X			X	X				X		
Compounding / injection molding			X								

# GUIDANCE ON RISK MANAGEMENT MEASURES

Welcome to the NanoRISK Risk Management Measures Library

- Guidance 
- Open / Refine Study 
- Start New Study 
- Library of Individual Measures 
- Sector / Process related RMMs 
- References 

## GUIDANCE ON RECOMMENDED MEASURES AND CONTROLS FOR MITIGATING THE RISK POSED BY ENGINEERED NANOMATERIALS

### LIFE NanoRISK

Best practices effectiveness, prevention, protection measures for control of risk posed by engineered nanomaterials

### Instruction sheets

#### Respiratory protection equipment



#### TYPES

- FFR- Particulate Filtering Face piece Respirators (Filtering half mask)
- Half Mask Respirators (Filters: P1/P2/P3)
- Full Face Masks (Filters: P1/P2/P3)
- Particulate filters (Cartridges)

#### CERTIFICATION AND TESTING

- EN 13274-1:2001. Respiratory protective devices. Methods of test. Determination of total inward leakage
- EN 13274-7:2008 Respiratory protective devices. Methods of test. Determination of penetration
- EN 149 / EN 140 / EN 136 / EN 143

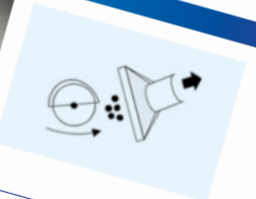
#### MAINTENANCE AND CLEANING

- Inspect respirators for cleanliness and damage before each use.
- Filtering face piece respirators can be reused by the same worker, but only if the properly, its shape remains unchanged, and the filter material is not physically damaged.
- A respirator inspection must include a check of the respirator's ability to work properly, and any connections; and the condition of the various parts, such as the face piece, hoses, and any cartridges, canisters, or filters.
- Store respirator in sealed bag in a clean, dry, non-contaminated area.
- Replace respirator and/or cartridge or filter if it is damaged, distorted, a proper breathing becomes difficult.
- If your respirator fails an inspection or is defective, your employer must remove either repair it or discard it.

#### RECOMMENDED RPE AGAINST ENMS

- Half Mask Respirators (Filters: P3)
- Full Face Masks (Filters: P3)
- Perform a negative or positive seal check each time before entering a contaminated area.

### Local Exhaustive Ventilation (LEV)



#### TYPES

- a) Enclosing Hoods
  - Laboratory Glove Box (complete enclosure)
  - Down-flow room (complete enclosure)
  - Horizontal/downward laminar flow booth
  - Laboratory Hood (partial enclosure)
  - Walk-in booths
  - Paint spray booth (partial enclosure)
- b) Capturing Hoods
  - Movable LEV systems (extendable arms)
  - HEPA Filtered down flow booth
  - Fixed Capturing Hoods
  - On tool extraction
- c) Receiving hoods

#### CERTIFICATION AND TESTING

- EN 14175-4:2005. Fume cupboards. Part 4. On-site test methods
- ASHRAE 52 2007. Method of testing general ventilation air-cleaning devices for removal efficiency by particle size.

#### MAINTENANCE AND CLEANING

- Maintenance Opening: The entire mechanical and electrical equipment of the ventilation system should be accessible via a secure and suitable opening.
- A fume cupboard function display should be installed to definitely indicate the correct functioning of the fume cupboard airflow.
- Routine checks on LEV systems must be undertaken by appropriately trained employees. The frequency of such checks will be determined by making reference to the manufacturer's recommendations, risk assessment findings, previous maintenance history, etc and should be recorded in the systems logbook.
- Before use: thorough visual examination to verify the LEV is in efficient working order, in good repair and in a clean condition.
- When installing LEV, use a reputable supplier, with experience of the type of control that is needed who can demonstrate that their system will adequately control potential contaminants.

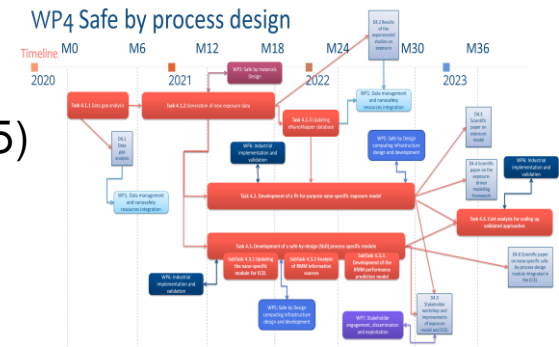
#### RECOMMENDED RPE AGAINST ENMS

- Local exhaust enclosure (Glove Box)
- Ventilated Laboratory Hood (partial enclosure)
- HEPA filtered down flow booth
- Ventilated Laboratory Hood + built-in water wash down systems (sprays)
- Movable LEV systems (extendable arms)
- Receiving hood (hot process)



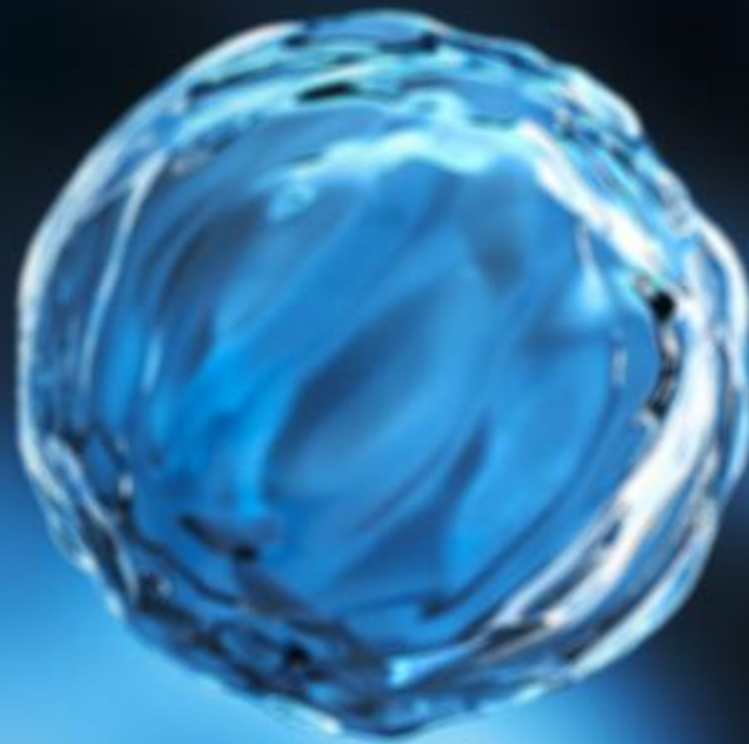
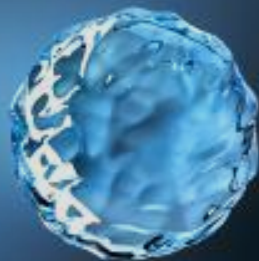
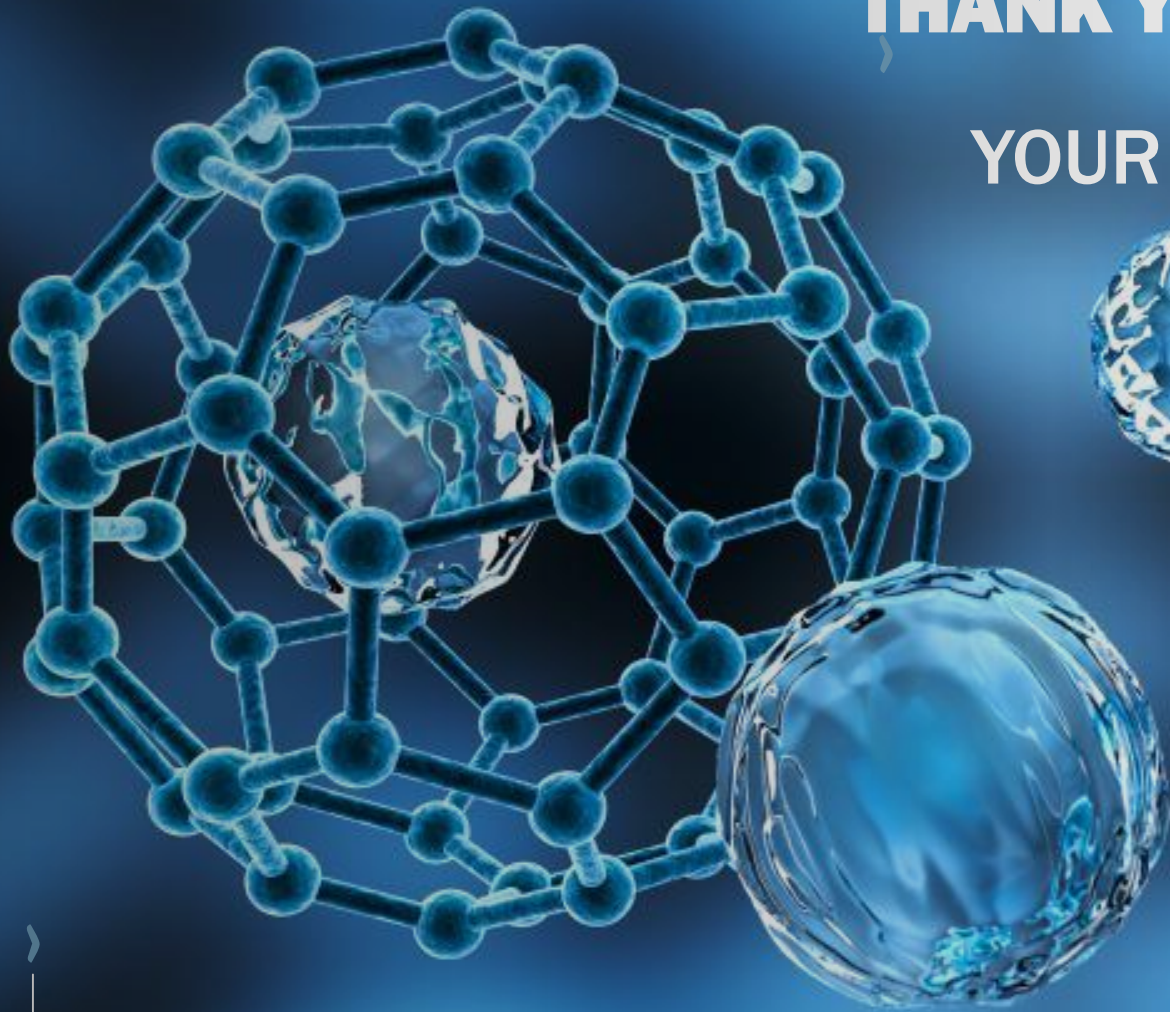
# WAY FORWARD?

- › Bring together information on RMM applications for NMs and their effectiveness – for improved guidance and implementation
- › Development of a safe-by-process design module in SbD4Nano (WP4)
  - › Integrate a safe-by-material design (WP3)
  - › Development of a RMM performance prediction model (WP4)
  - › Link will be made between RMM and exposure model (WP4) and e-infrastructure (WP5)
- › More nano-specific studies required that evaluate the effectiveness of RMMs
  - › Frequency analysis of ECEL and data gap analysis underway
- › Further population and analysis of libraries such as ECEL
  - › Examine the variability in RMM effectiveness values (to identify the drivers of effective & sustainable RMMs)
  - › Investigate ways to include PSD bins in extracting RMM effectiveness values



<https://diamonds.tno.nl/#ecel>

**THANK YOU FOR  
YOUR TIME**



**TNO** innovation  
for life