THE NANOSAFER V1.1 RISK ASSESSMENT AND MANAGEMENT TOOL

–

OVERALL SENSITIVITY ANALYSIS AND ASSESSMENT OF THE MODEL PERFORMANCE

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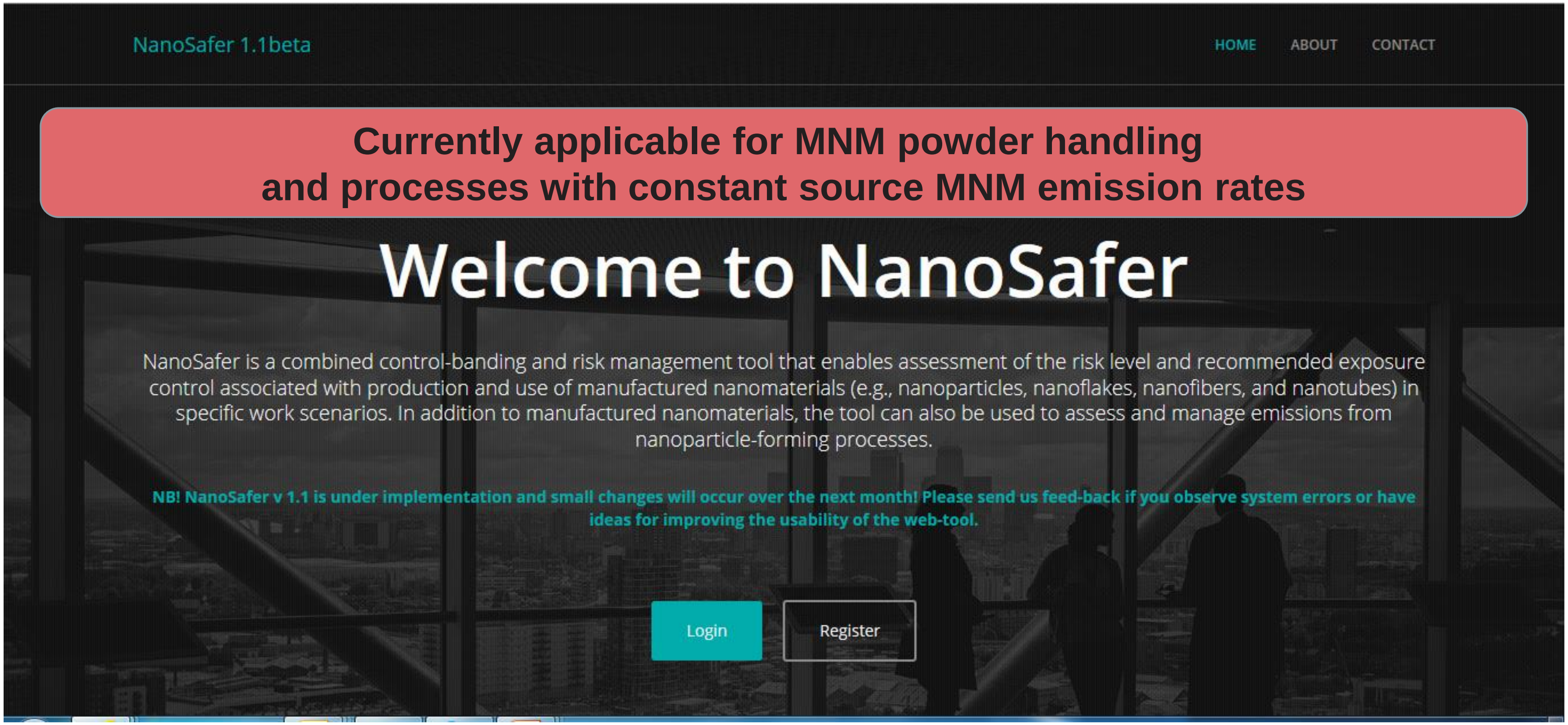
NanoSafer 1.1beta (www.nanosafer.org)







Key elements and information requirements in the Control Banding models

Method	Number of Input parameters asked for	Number of input parameters used			Number of control bands		
		Nano-relevance	Hazard scaling	Expo. scaling	Haz.	Exp.	Risk
ANSES CB Tool ¤	9	1	5	3	5	4	5
NanoSafer 1.0 #	25	5	5	13	4	5	5
IVAM Guidance ¤	28	-	2	1	3	3	3
Swiss Precautionary Matrix	28	7	6	6	n.a.	n.a.	2
CB Nanotool	53	-	15	5	4	4	4
Stoffenmanager Nano #	47	-	2	26	5	4	3

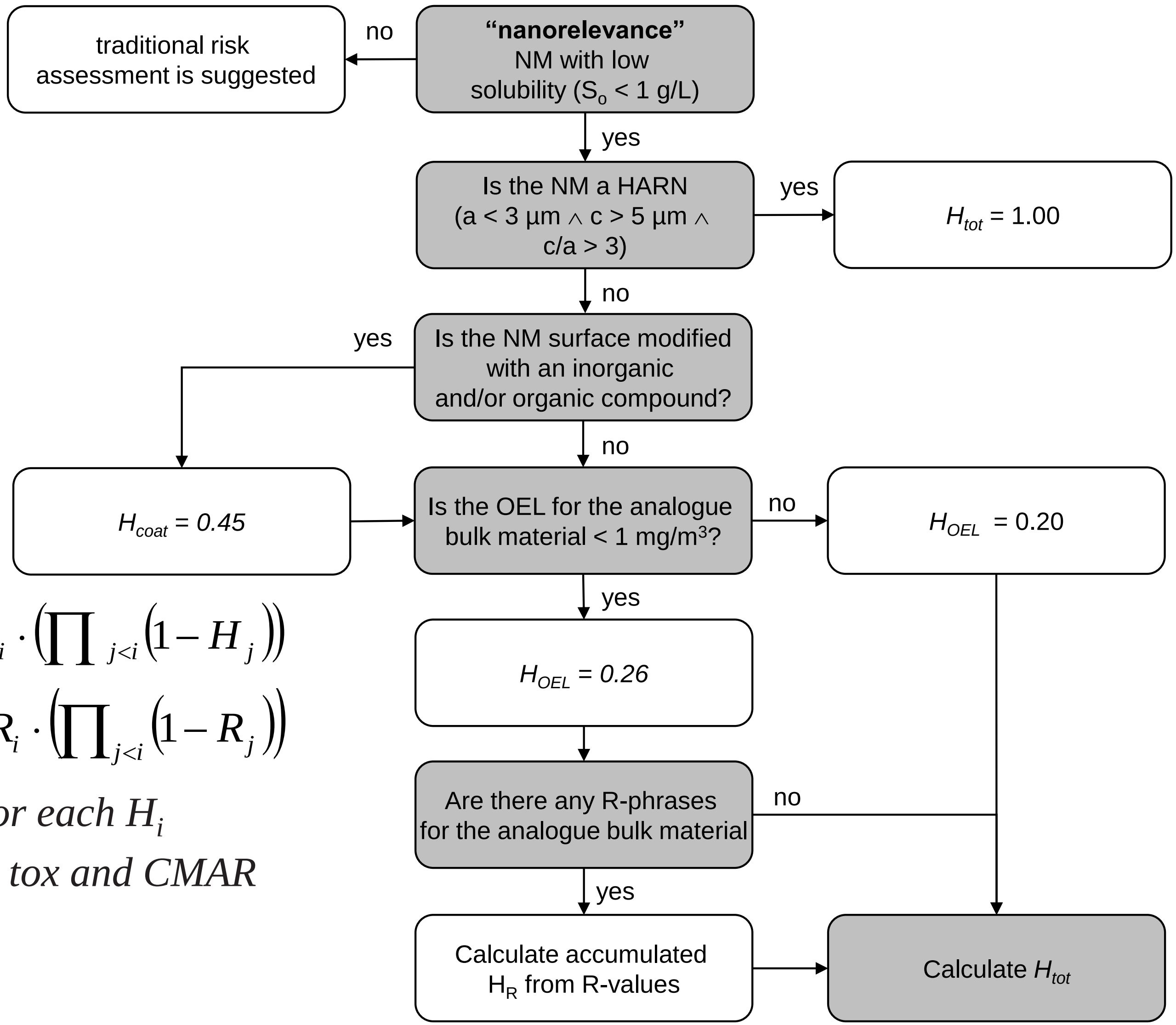
¤ The technically simplest model
The technically most advanced models

Modified from Liguori et al. (2016)

Four Assessments in "One Go"
(Near-Field and Far-Field – Acute and Daily)

Hazard Assessment

- Example with R-sentences



$$H_{tot} = \sum_{i=1}^{n} H_i \cdot \left(\prod_{j<i} (1 - H_j) \right)$$

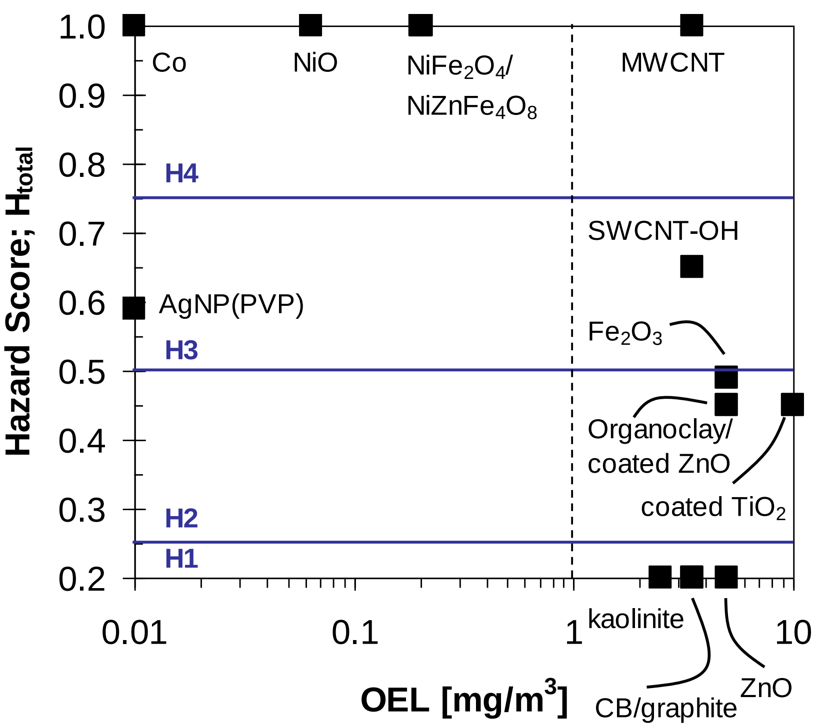
$$H_{carc} = \sum_{i=1}^{n} R_i \cdot \left(\prod_{j<i} (1 - R_j) \right)$$

$R_j \in [0.1;1]$ *for each* H_i

H_i *= General tox and CMAR*

Examples of MNM Hazard Ranking Compared to OELs of analogue bulk materials

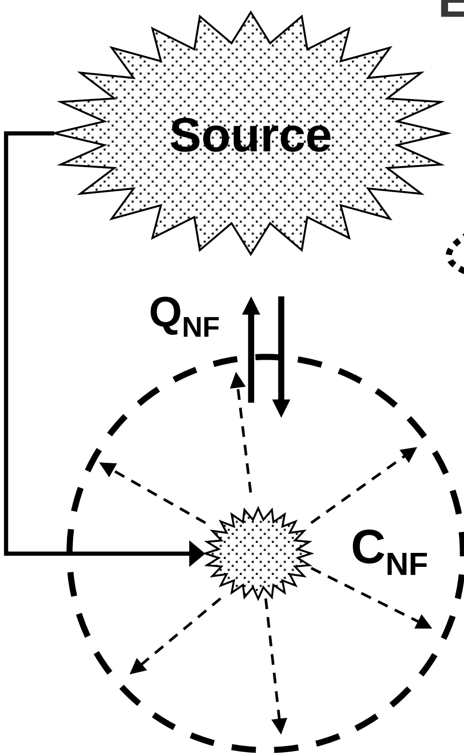
Material	SSA [m²/g]	HARN	Coated	OEL [mg/m³]	R_i
TiO_2	21	-	0.45	10.0	-
TiO_2	107	-	0.45	10.0	-
ZnO	12.4	-	-	4.98	-
ZnO	15.1	-	0.45	4.98	-
graphite	225	-	-	3.50	-
carbon black	23.8	-	-	3.50	-
carbon black	295	-	-	3.50	-
Kaolin	23.1	-	-	2.50	-
nanoclay	8.44	-	0.45	5.00	-
SWCNT-OH	407	-	0.45	3.50	R36/R37
MWCNT	233	1	-	3.50	R36/R37
Fe_2O_3	27.4	-	-	5.00	R36/R37/R8
Fe_2O_3	27.7	-	-	5.00	R36/R37/R8
$NiFe_2O_4$	87.7	-	-	0.200	R43/R49
$Ni_{0.5}Zn_{0.5}Fe_2O_4$	104	-	-	0.203	R43/R49
NiO	6	-	-	0.064	R49/R43/R53
Co(10% O passivated)	60	-	-	0.010	R11/R42/R43/R53
Ag	0.03	-	0.45	0.010	-



Exposure Assessment and Scaling
- Example of using Powders

Emission rate:

$E_i = E_o \times A_i \times dM/dt$

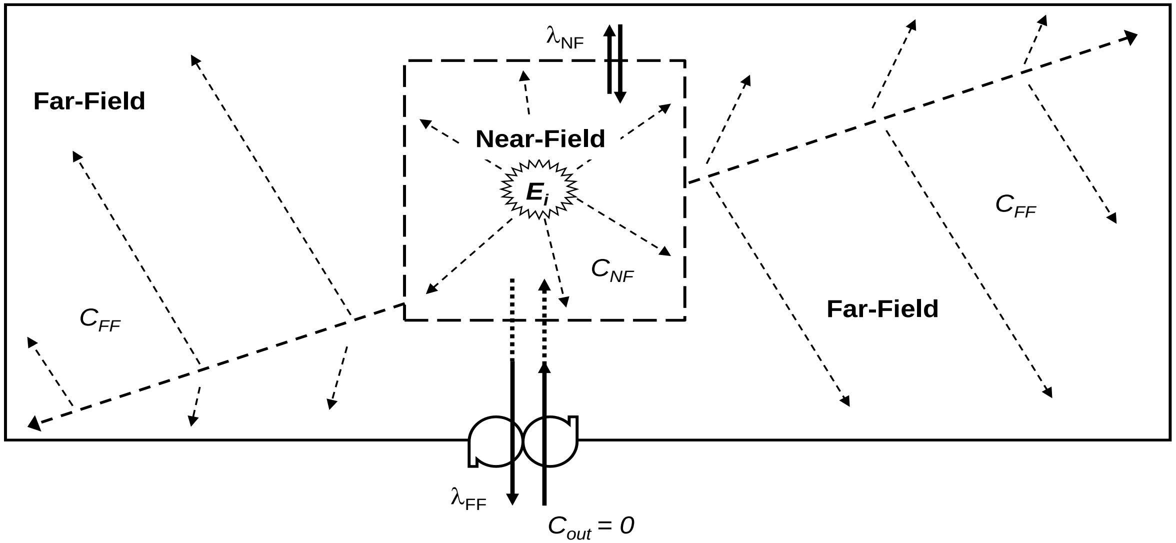


E_i = release rate

E_o = dustiness index
A_i = activity energy factor
A_o: ”zero” (clean transport)
A_1: very low (weighing mg’s)
A_2: low (< 5 cm drop)
A_3 : moderate (5-30 cm drop)
A_4 : high (30-100 cm drop)
A_5 : very high (> 100 cm drop)

dM/dt = mass flow rate

Exposure Assessment and Scaling
- Example of using Powders



Exposure scaling

NF Acute (15 min): Upper limit is 2 xOEL_{nano}
NF Daily (8-hour): Upper limit is OEL_{nano}
FF Acute (15 min) : Upper limit is 2 xOEL_{nano}
FF Daily (8-hour) : Upper limit is OEL_{nano}

NF volume = 12.17m³ (2.3³ m³)

Exposure scale: C_i / OEL_{nano}

OEL_{nano} = OEL_{bulk} x ($VSSA_{nano}$ / $VSSA_{bulk}$)

Dispersion model:

$$C_{NF,t} = \frac{E_i}{V_{NF}} \cdot \Delta t + \left[\frac{M_{FF\to NF} - M_{NF\to FF}}{V_{NF}}\right] + R_{NF,t-1}$$

$$C_{FF,t} = \left[\frac{M_{NF\to FF} - M_{FF\to NF}}{V_{FF}}\right] + R_{FF,t-1}$$

Where *M* and *R* are:

$$M_{FF\to NF} = \left[\frac{\lambda_{NF} \cdot C_{FF} \cdot V_{NF}}{\Delta t \cdot (\lambda_{NF})^2}\right] \cdot \left[\lambda_{NF} \cdot \Delta t + e^{(-\lambda_{NF} \cdot \Delta t)} - 1\right]$$

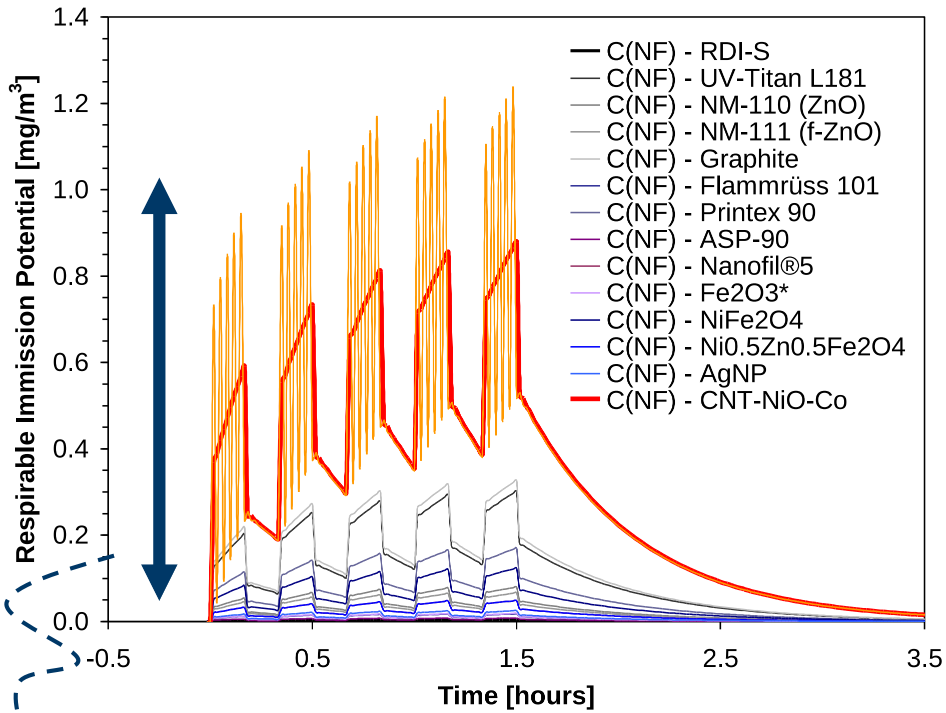
$$M_{NF\to FF} = \left[\frac{\lambda_{NF} \cdot C_{NF} \cdot V_{NF}}{\Delta t \cdot (\lambda_{NF})^2}\right] \cdot \left[\lambda_{NF} \cdot \Delta t + e^{(-\lambda_{NF} \cdot \Delta t)} - 1\right]$$

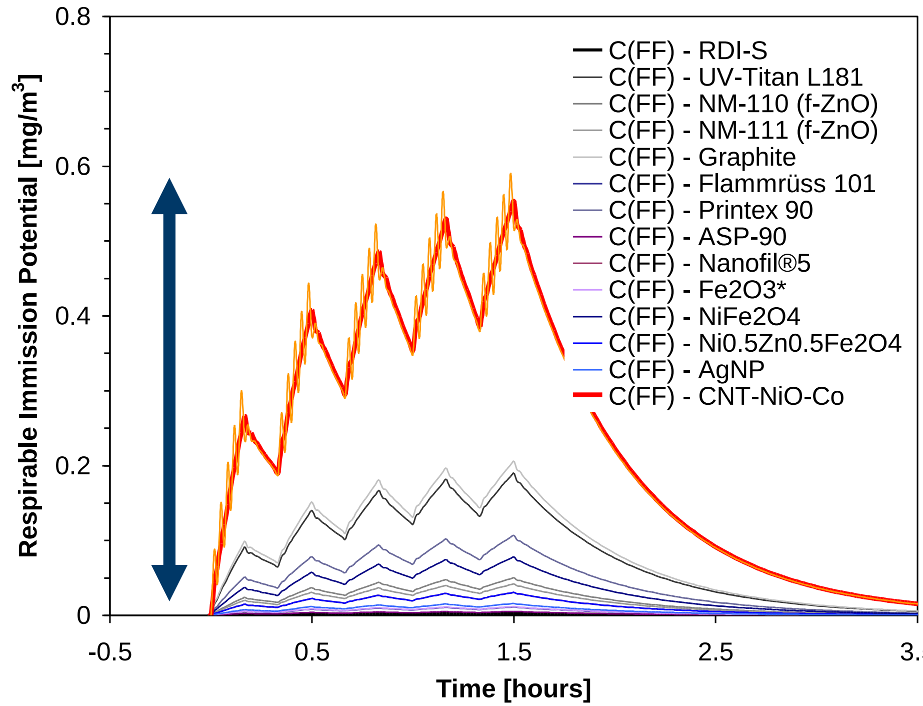
$$R_{NF,t-1} = \left[\frac{C_{NF,t-1}}{(\lambda_{FF} \cdot \Delta t)}\right] \cdot \left[1 - e^{(-\lambda_{FF} \cdot \Delta t)}\right]$$

$$R_{FF,t-1} = \left[\frac{C_{FF,t-1}}{(\lambda_{FF} \cdot \Delta t)}\right] \cdot \left[1 - e^{(-\lambda_{FF} \cdot \Delta t)}\right]$$

Aerosol decay functions after Schneider et al. (2004)

Exposure Assessment and Scaling
- Example of using Powders





Variation reflects variation in dustiness

NM not one category

Scooping/filling 5 x 500 g bags in small scale production:
Total mass: 500 g
Mass per transfer (spoonful): 50 g/scoop.
H_i = 0.3
Duration per filling: 10 minutes
Duration per transfer: 0.5 minute
Pause between each filling: 5 minutes
Work area: 3.5 m x 5 m long x 2.9 m high
ventilation rate of 5 h^{-1}

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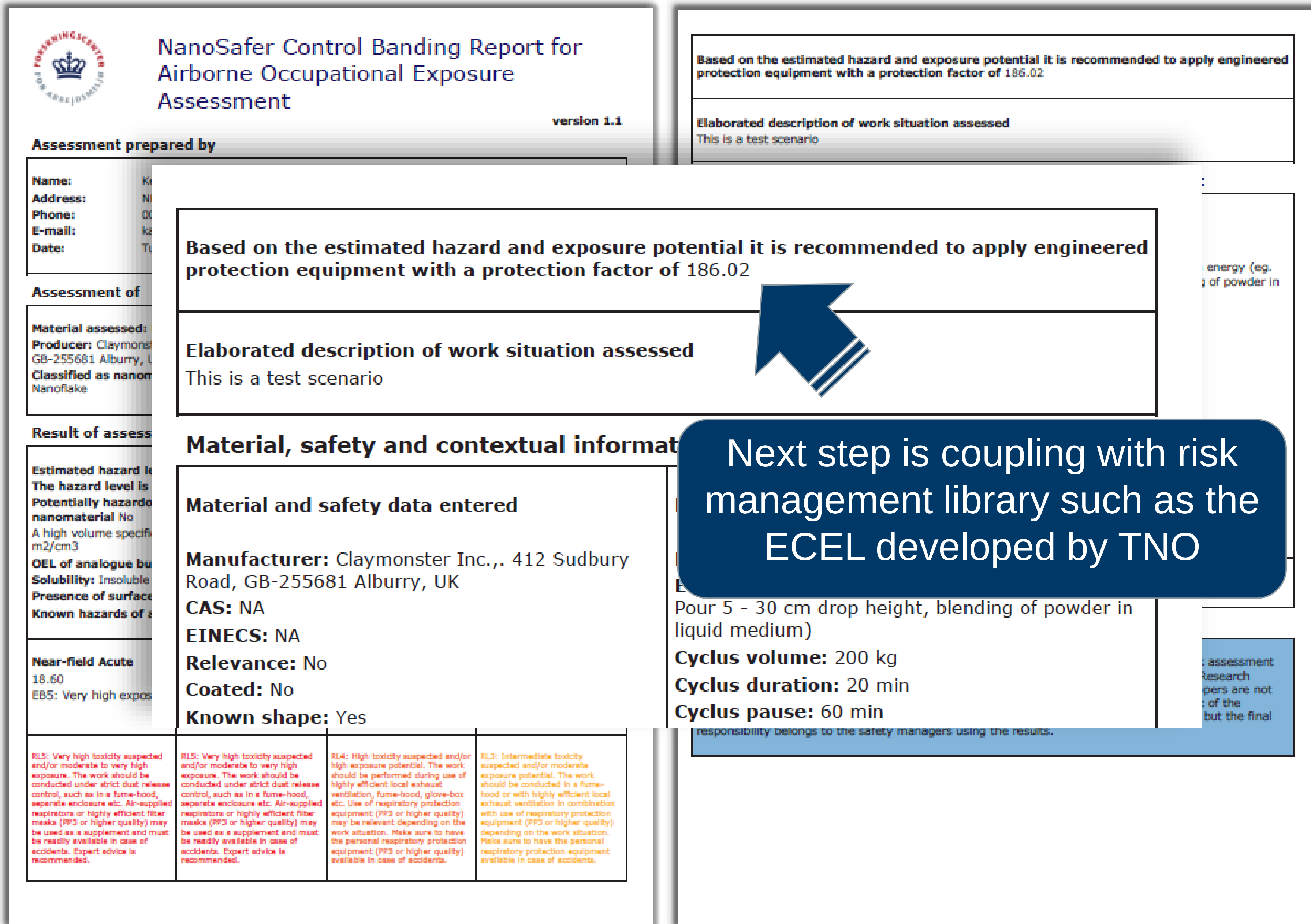
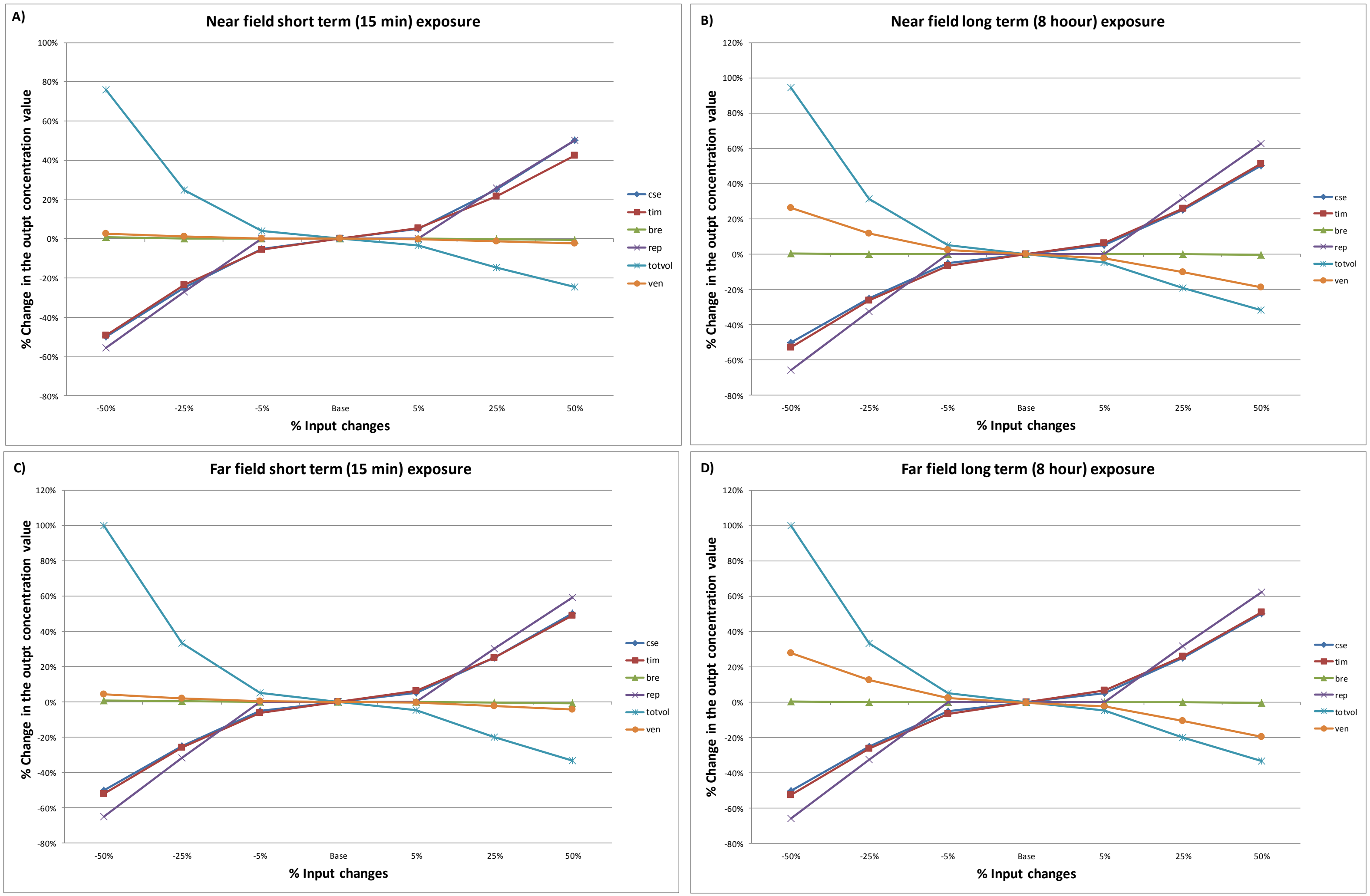


Next step is coupling with risk management library such as the ECEL developed by TNO

Sensitivity Analysis (Exposure Algorithm)
- One At Time

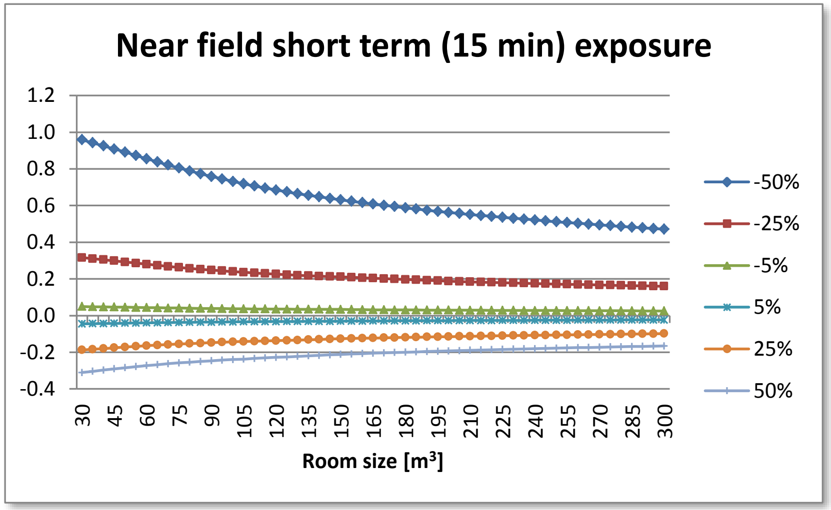


Liguori et al. (in prep.)

Sensitivity Analysis (Exposure Algorithm) - One At Time

Main effects		
	[NF daily]	[FF daily]
CSE	50.9573	49.5076
TIM	42.8422	41.6568
REP	32.5480	31.4588
BRE	-27.0343	-26.4670
TOTVOL	-32.0269	-31.4291
VEN	-50.1953	-49.4954
	[NF Acute]	[FF Acute]
CSE	89.2789	86.3203
TIM	74.0052	72.8325
REP	65.0045	63.9056
BRE	-54.9602	-53.9095
TOTVOL	-64.2924	-63.8799
VEN	-85.7826	-86.2296

CSE	Constant Source Emission
TIM	Duration of work cycle
BRE	Pause between work cycles
REP	Frequency - Repetition of the workcycle
TOTVOL	Room size
VEN	Air Exchange rate



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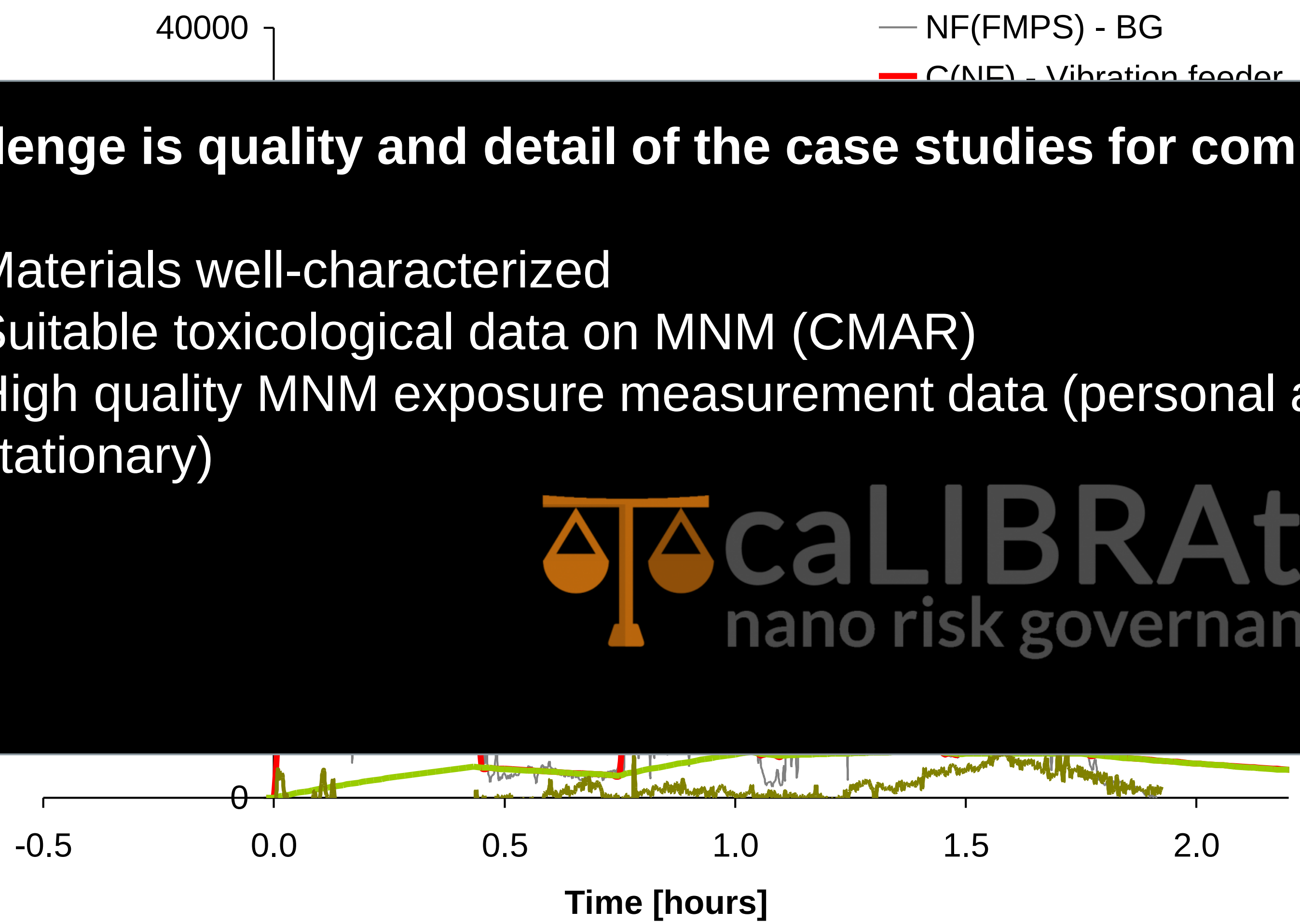
Next Step is Performance Assessment and Model Calibration



Challenge is quality and detail of the case studies for comparison

1. Materials well-characterized
2. Suitable toxicological data on MNM (CMAR)
3. High quality MNM exposure measurement data (personal and stationary)

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