INDIRECT EXPOSURE OF MAN TO NICKEL VIA THE ENVIRONMENT: ASSESSMENT OF INHALATION EXPOSURE TO THE GENERAL POPULATION

I. Introduction

This is a nickel specific guidance document for performing a site-specific assessment and risk characterisation for indirect exposures to populations that neighbour your site. This guidance follows the approach known as indirect exposure to man via the environment (MvE). The most critical endpoints and drivers are local respiratory effects, thus the inhalation exposure route is the only route of exposure addressed in this document. Systemic effects due to integrated exposure via the oral pathway (food, dust/soil, water) and via inhalation are also relevant for MvE; however, it is demonstrated in the Ni REACH Dossiers that protecting from local respiratory effects via inhalation is sufficiently protective for systemic effects.

The GES for MvE has been developed differently than the other environmental compartments due to the complexity of estimating local air concentrations to neighbouring populations. Instead of one set of operational conditions and risk management measures, summary statistics were provided for each sector including minimum, median, 90th percentile and max values for the relevant parameters (see example in Table 1 below).

Table 1: Overview statistics of operational conditions and risk management measures for a downstream use sector for estimating indirect exposure to MvE.

<table>
<thead>
<tr>
<th></th>
<th>tonnage (T/year)</th>
<th>daily emissions to air (kg/d)</th>
<th>release factor to air (g/T)</th>
<th>Emission days to air per site (d/y)</th>
<th>$C_{\text{local, air}}$ (ng Ni/m³)</th>
<th>PEC air$^2$ (ng Ni/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>min</td>
<td>175</td>
<td>&lt;0.01</td>
<td>2</td>
<td>247</td>
<td>&lt; 1</td>
<td>1</td>
</tr>
<tr>
<td>max</td>
<td>796</td>
<td>0.06</td>
<td>25</td>
<td>360</td>
<td>11</td>
<td>19</td>
</tr>
<tr>
<td>median</td>
<td>715</td>
<td>0.04</td>
<td>14</td>
<td>276</td>
<td>7</td>
<td>12</td>
</tr>
</tbody>
</table>

$^*$: based on air model EUSES
$^2$: based on measured values and $C_{\text{local, predicted}}$ + regional background and monitoring data depending on available information

As in the example of Table 1, this only provides a general overview of the sector and it cannot be considered as an assessment of compliance for your own individual site. Thus, it is recommended that each company completes an exposure assessment to MvE (documented in-house) to demonstrate compliance for this critical compartment.

The next section in this guidance presents the derived no effect level for local air concentrations ($\text{DNEL}_{\text{local-air}}$) that protects against local respiratory effects to the general population. Guidance for performing the risk characterisation is also presented in this section. The third section presents a tiered approach for determining predicted local air concentrations ($\text{PEC}_{\text{local-air}}$), starting from the application of a generic tool (DU scaling Tool) and progressing to increasingly more site-specific refined tool such as the Gaussian Plume Model (GPM) and steady-state bi-Gaussian Plume Model (IFDM).

II. Nickel DNEL for long-term local respiratory effects

The ambient air guidance value for nickel in the EU of 20 ng Ni/m³ is used as the DNEL for long-term local respiratory effects after inhalation. This is considered a conservative value to protect against local respiratory effects of all nickel substances.

To confirm that you are working out of risk for the MvE compartment, the local predicted exposure concentration in the air ($\text{PEC}_{\text{local-air}}$) must be below the DNEL. In other words, the risk characterisation ratio (RCR) must be less than 1 ($\text{PEC} < 20$ ng Ni/m³). Please see below the following formula for calculating RCR.

Equation 1:

$$R\text{CR} = \frac{\text{PEC}_{\text{local-air}}}{\text{DNEL}}$$
If $RCR < 1$ → **NO RISK**

If $RCR > 1$ → **RISK**

If the PEC\textsubscript{local, air} is based on monitoring data (provided that monitoring is performed at relevant location for the nearby population) for air, the annual-average Ni concentration in air should not exceed 20 ng/m$^3$.

If the PEC\textsubscript{local, air} is based on air quality modelling tools the regional background must be added. The regional background for EU is 8.5 ng Ni/m$^3$ but country-specific backgrounds can be considered when data are available (Annex I).

### III. Tiered approach for performing a site-specific assessment for MvE

This section will describe all of the relevant steps recommended by the Nickel Consortia in determining your compliance with the DNEL for MvE. As you proceed further down the tiered approach more data is required by the site. Three models will be described, however only two of them are available as user-friendly models. You will need to provide information to the Nickel Consortia for the third model described below (IFDM model – tier III).
Figure 1: Schematic diagram of the tiered approach for checking compliance for the MvE compartment. Further details are given below on models and scaling.
Tier I Tool: DU Scaling Tool

The DU Scaling Tool (free to download from the ARCHE website: http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool) is a first screening tool that is easy to use, requires minimal site-specific input data; however, it is the most conservative since it is based on default assumptions. Figure 2 below illustrates an example of using the DU Scaling Tool for deriving local air concentrations (PEC_{local-air}). Please refer to Annex I of the Ni specific guidance for the environmental compartment for a more detailed overview on how to use the model.

Minimum required input parameters:

- Select the metal of choice, in this case Ni (Orange oval)
- Ni tonnage produced/use per day (annual average) (Red oval)
- One of: (Green oval)
  1. SpERC (Sector specific environmental release category);
  2. Release factor to air after on-site treatment (g/g) or;
  3. Local emission to air during episode after on-site treatment (kg/year). If daily emissions to air are >41.4 g/day or yearly emissions to air are >15 kg/year, then compliance will not be reached with Tier I tool. In this case, move on to the Tier II model.

Note: Several combinations of tonnage and release factors lead to GES compliance.

The output from the model is the PEC_{local-air} in ng Ni/m$^3$ (Blue oval). This value includes the EU regional background for air of 8.5 ng Ni/m$^3$. Thus, the model can be compared directly to the DNEL of 20 ng Ni/m$^3$.

if PEC_{local-air} is < 20 ng/m$^3$ → local risks are adequately controlled;
if PEC_{local-air} is > 20 ng/m$^3$ → proceed to Tier II below

Figure 2: Example of DU Scaling Tool for calculating PEC_{local-air}
Tier II Tool: GPM based compliance check Tool

The GPM (Gaussian Plume Model) is available to download at [http://www.arche-consulting.be/Metal-CSA-toolbox/Local-air-modeling-GPM-tool](http://www.arche-consulting.be/Metal-CSA-toolbox/Local-air-modeling-GPM-tool). This model is user friendly and has the advantage in comparison to the DU Scaling Tool in that site-specific parameters are used instead of defaults. In addition, the GPM model has the flexibility to model air concentrations at any distance from the point source (starting from distances of a few meters from the point source to up to 60km). However, limitations to the GPM are that it assumes constant emissions, temperature, wind speed and homogeneous turbulence. Figure 3 illustrates an example of using the GPM model for deriving PEC_{local-air}.

**Required input parameters (Yellow highlighted boxes in Figure 3):**
- Stack height (m)
- Stack diameter (m)
- Emission rate (g/s)
- Gas exit velocity (m/s)
- Gas exit temperature (°C)
- Ambient temperature (°C)

It is also required that you input the threshold value (DNEL; orange box). This model does not include the regional background in the PNEC_{local-air}. Therefore, 11.5 ng/m³ (20 – 8.5 [regional background] = 11.5 ng/m³) must be in this box.

**Output:**
The air pollution at ground level (ng Ni/m³) is given as a function of wind velocity (1-19 m/s) and selected distances from the source (0-60 km). Select the most accurate wind velocity and distance to the nearest population from your site. Anything highlighted in red indicates that the selected coordinates are at risk.

if PEC_{local-air} is < 11.5 ng/m³ → local risks are adequately controlled;
if PEC_{local-air} is > 11.5 ng/m³ → proceed to Tier III below

**Figure 3: Example using GPM model for calculating local air concentrations (PEC_{local-air})**
**Tier III Tool: IFDM based compliance check Tool**

The IFDM model was developed by VITO consulting. The IFDM model is a bi-gaussian model, with steady-state bi-Gaussian-plume for each hour. It simulates air quality and deposition and requires the following input information:

**Required input parameters:**
- Stack emissions to air (kg/day)
- Number of stacks
- Distance and orientation between the different stacks
- Stack heights (m)
- Gas velocity per stack
- Orifice temperature per stack
- Location (city) → in order to pick up site-specific meteorology
- Tonnage Ni production/use per day (year average)
- Emission factor to air (g/T)

Compared to the DU scaling Tool and the GPM model, the IFMD model takes into account site-specific, actual meteorological conditions (hourly records). However, due to the complexity of the model, it requires expert judgment and thus it is only available for use by VITO consulting. If this model is required to further evaluate local air concentrations, then please fill out the following questionnaire (right click to open hyperlink) and deliver it to the Nickel Consortia: reach@nickelconsortia.org. Evaluation and modeling of the data will depend on the available resources of the nickel consortia and availability of VITO to run the IFDM model.

The output of this model does not include the regional background, thus the PEC_{local-air} predicted must be compared to the threshold value of 11.5 ng/m³. Should the IFDM modeling still demonstrate non-compliance with the threshold value then please examine the other options below.

**Adjustment to Country specific background**

As previously mentioned, the EU regional background of 8.5 ng/m³ is included in the exposure and risk characterisation of indirect exposure to MvE. This results in an allowable C_{local-air} (Local Contribution of Ni from your site) of 11.5 ng/m³. Annex I list a number of country specific backgrounds where you can choose the country where you site is located. This will allow you to back-calculate a different C_{local-air} for your site.

For example, if you site is located in the Netherlands, you would use the country specific background of 4.31 ng/m³. This results in an allowable C_{local-air} of 15.69 ng/m³ (20 – 4.31 = 15.69).

**Collect monitoring data**

If all available models to estimate local air concentrations fail to demonstrate compliance with the DNEL of 20 ng/m³, then the next step is to collect monitoring data at the nearest populations to your site.

**Additional Risk Reduction Measures**

If monitoring data fails to demonstrate compliance with the DNEL, then you need to consider implementing new or additional risk reduction measures on site, and/or consider lowering production volumes. Discussions with the local authorities should be initiated.
Annex I:

Regional Ambient air Ni Concentration Levels

In order to determine PEC_{local-air} levels, the following PEC_{regional-air} values were selected as regional input values to add to the local environmental concentrations:

The values presented below are extracted from the Ni EU RAR (2008/2009).

Country-specific and EU mean measured PEC_{regional-air} (ng Ni mg^{-3}) value

<table>
<thead>
<tr>
<th>Member State</th>
<th>Regional Background* (ng Ni mg^{-3})</th>
</tr>
</thead>
<tbody>
<tr>
<td>AT</td>
<td>3.09</td>
</tr>
<tr>
<td>BE</td>
<td>15.59</td>
</tr>
<tr>
<td>BG</td>
<td>6.61</td>
</tr>
<tr>
<td>CY</td>
<td>4.51</td>
</tr>
<tr>
<td>CZ</td>
<td>1.69</td>
</tr>
<tr>
<td>DK</td>
<td>4.97</td>
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<tr>
<td>EE</td>
<td>14.08</td>
</tr>
<tr>
<td>ES</td>
<td>8.42</td>
</tr>
<tr>
<td>GB</td>
<td>5.15</td>
</tr>
<tr>
<td>IT</td>
<td>29.27</td>
</tr>
<tr>
<td>LV</td>
<td>6.01</td>
</tr>
<tr>
<td>MT</td>
<td>12.79</td>
</tr>
<tr>
<td>NL</td>
<td>4.31</td>
</tr>
<tr>
<td>SK</td>
<td>2.65</td>
</tr>
<tr>
<td><strong>Mean</strong></td>
<td><strong>8.51</strong></td>
</tr>
</tbody>
</table>

*90 percentile values based on log normal distribution

The mean of MS P90 Ni ambient concentrations (8.5 ng/m³) is taken forward as the EU average regional background Ni concentration in ambient air. As an additional step in the tiered approach for estimating local air concentrations, a company may use their country specific regional background in replacement of the EU regional background.