## Occupational Hygiene Risk Management (OHRM) System

## Summary

## This guidance document provides a tool to assess and manage the risks imposed on employees and contractors on site from inhalation exposure to chemicals. This guidance specifically covers the subject of preventing ill health by limiting long-term inhalation exposure to hazardous substances.

This guidance relates to the implementation of the REACH legislation in Europe. This legislation is intended to prevent and limit human and environmental exposure to hazardous substances. The results from many REACH studies carried out delivered essential toxicological information, needed to establish safe occupational exposure limits. However, for many substances (especially low tonnage substances) limited data are present. The current guidance helps in setting internal exposure limits for these substances by using hazard classes and occupational exposure banding methods.

Apart from setting internal exposure limits, the guidance also provides a method to estimate the potential degree of inhalation exposure, resulting from activities related to handling hazardous substances. Together with the hazard class, substances (and mixtures) can be rated by risk (low, moderate or high) and focus can be placed on safely executing activities involving substances with risk. The tool also helps to define the appropriate technical and procedural occupational hygiene control strategies to be put in place or helps to verify existing strategies in place to be effective.

1. **Purpose**

This guidance document provides a tool to assess and manage the risks imposed on employees and contractors at work on sites, related to the inhalation exposure to hazardous substances. Its purpose is to create and maintain a safe and healthy working environment.

1. **Scope**

This tool is meant to assess and manage inhalation exposure to substances (and mixtures), at distribution centers, warehouses and production sites, where exposure to (hazardous) substances may occur. It is not intended for use by RD&I facilities (except for setting internal exposure limits) because the quantities handled are considered small. Specific guidance is available for RD&I environments.

1. **Synonyms and definitions**

The following terms and definitions are applicable:

|  |  |
| --- | --- |
| Term | Definition |
| AD | Aerosol Dispersion |
| CAS | Chemical Abstracts Service |
| CB | Control Banding |
| CE | Control Effectiveness |
| COSHH | Control of Substances Hazardous to Health |
| CMR | Carcinogenic Mutagenic and Reproductive toxic |
| DD | Degree of Dilution |
| DMEL | Derived Minimum Effect Level |
| DNEL | Derived No Effect Level |
| DT | Duration of Task |
| GHS | Globally Harmonized System |
| HC | Hazard Class |
| IEL | Internal Exposure Limit |
| IH-stat | Industrial Hygiene statistics |
| LEV | Local Exhaust Ventilation |
| LoM | Detection Limit of the Method |
| LoQ | Limit of Quantification |
| LV | Limit Value |
| kPa | kilo Pascal (vapor pressure) |
| MAC | Maximum Allowable Concentration (8-h mean value) |
| MC | Material Characteristics |
| MSDS | Material Safety Data Sheet |
| mg/m3 | milligram per cubic meter |
| MI | Material Interaction |
| mm Hg | Millimeter Mercury (vapor pressure) |
| MW | Molecular Weight |
| OEB | Occupational Exposure Band |
| OEC | Occupational Exposure Concentration |
| OEL | Occupational Exposure Limit |
| OHCS | Occupational Hygiene Control Strategy |
| OHRM | Occupational Hygiene Risk Management |
| PEL | Permissible exposure limit |
| PDE | Potential Degree of Exposure |
| a-PDE | adjusted Potential Degree of Exposure |
| i-PDE | Initial Potential Degree of Exposure |
| PPE | Personal Protective Equipment |
| Ppm | parts per million |
| QH | Quantity Handling |
| REL | Recommended Exposure Limit |
| RMM | Risk Management Measure |
| SEG | Similar Exposure Group |
| RTP | Rapid Transfer Point |
| SBV | Split Butterfly Valve |
| SMART | Specific Measurable Attainable Realistic /relevant Time bound |
| STEL | Short Term Exposure Limit (15 min mean value) |
| TLV | Threshold Limit Value |
| TRR | Task Risk Ranking |

1. **Recommended procedure**

Substances (registered with a *CAS* and/or EC number) are used to produce other substances and products (mixtures etc.). This means that workers can potentially be exposed to those substances and mixtures at the workplace. An up to date list of all substances or chemicals (including associated hazards) used and produced shall be available at each site.

The hazard (intrinsic toxic properties) of a substance together with the degree of occupational exposure to this substance determines the health risk potential of that substance or mixture. It also requires the selection of an appropriate control strategy.

Hazard + Exposure potential → Health risk assessment → Control strategy

The Occupational Hygiene Risk Management (*OHRM*) system is a structured tool that helps to prioritize risks and ranks controls based on the known or assumed toxic properties of a substance. The four different steps of this approach are described in this document.

*Step 1: Hazard assessment*

To identify the hazard of a substance, toxicity data are required. Only for certain substances (e.g. high tonnage substances) a full toxicity data set is available allowing a complete hazard assessment and derivation of an Occupational Exposure Limit (*OEL*).

In various countries these values have different names such as Threshold Limit Value (*TLV*), Permissible Exposure Limit (*PEL*), Recommended Exposure Limit (*REL*), or Maximum Allowable Concentration (*MAC*) and the values may vary from country to country or organization to organization establishing these limits. Some chemical manufacturers also may issue a recommended exposure limit based on data they may have related to the specific chemical.

These values are normally indicated as an 8-h TWA value (time weighted average) and are applied for exposure during lifetime (e.g. 40 years). For substances with serious acute effects, besides a *TLV* or another 8-h value, also Short Term Exposure Limit (*STEL*) 15-min values or ceiling values (values that never should be exceeded) may have been established.

Due to the REACH legislation, requiring testing and subsequent registration of substances in 2010 (> 1000 ton per year), 2013 (100-1000 ton per year) and 2018 (1-100 ton per year), more occupational exposure limits were established with time. These limits are called Derived No Effect Levels (*DNELs*). Derived Minimum Effect Levels (*DMELs*) are established in case of e.g. carcinogenic substances that show a genotoxic, non-threshold, mode of action.

For those chemicals with currently no or hardly any toxicity data available, methods have been described in literature to derive Occupational Exposure Bands (*OEB*), i.e. levels below which safe working would be guarantee]d. A variety of such methods has been published. One of these, the ‘Control of Substances Hazardous to Health’ (*COSHH*) Essentials, has been published by the UK Health and Safety Executive.

The Nouryon Occupational Hygiene Risk Management (*OHRM*) system is largely based on principles of the *COSHH* Essentials and has been worked out in this guidance note.

*Step 2: Exposure assessment*

In this document, the approach to assess exposure to substances in the workplace is based on control banding. Control Banding (*CB*) is grouping of chemicals according to similar physical and chemical characteristics, intended processes/handling, and (anticipated) exposure scenarios (e.g. amount used, duration).

The control banding in the Nouryon *OHRM* system is based on occupational exposure values (see further below).

*Step 3: Risk assessment and risk management (control strategy)*

As indicated above, the risk assessment is based on the hazard of the substance and the exposure to this substance. Based on the factors mentioned under ‘Exposure assessment’, appropriate control strategies (= risk management measures) are determined for each of these groupings depending on the hazard of the substance. The control strategies are defined on hierarchical levels. These are containment, engineering controls, ventilation, use of personal protective equipment and working practices.

The Nouryon *OHRM* system is described below for:

* New substances and processes
* Existing substances and processes,
* New process design involving new substances

*Step 4: Monitor effectiveness of control strategies (closing the loop)*

Finally, the exposure can be checked quantitatively, to ensure that the containment strategy based on a qualitative exposure risk assessment is carried out properly or to check the effectiveness of the control strategies in place. This is not further elaborated in this guidance.

* 1. **Hazard Assessment**

To establish a proper hazard assessment, the sequence is as follows:  
- In case an occupational exposure limit is available refer to section 5.1.1  
- In case an occupational exposure limit is not available but there is sufficient toxicity data,  
 refer to section 5.1.2  
- In case of limited or insufficient toxicity data refer to section 5.1.3  
- In case of analyzing mixtures refer to section 5.1.4.

**5.1.1 In case an *OEL* or *DNEL* is available for the substance**

In the introduction, the meaning of *OEL* and *DNEL* (or *DMEL*) has been explained. In general, *OELs* have been established by (inter)national authorities, *DNELs* have been established by Industry (REACH). Due to differences in calculation methods, the *DNEL* may (slightly) differ from the currently existing *OEL* for those substances for which an *OEL* has been established. In addition, the *OEL* may also differ in various countries.

For those substances for which a well-documented *OEL* or *DNEL*/*DMEL* is available, the corresponding Hazard Class (*HC*) can be found in the Table below (Table 1). For a dust/solid/powder the values are indicated in *mg/m3*. For gases the values are indicated in *ppm*. In case of a liquid, please consider whether the substance should be categorized as a wet aerosol due to (very) low volatility (values in *mg/m3*) or as a vapor (gas) in case of high or medium volatility (values in *ppm*). Please refer for volatility to Table 2 and Figure 2.

For liquids(vapors)/gases: the corresponding value in mg/m3 can be calculated as follows:

1 *ppm* = *MW*/24.0 *mg/m3* (at 20ºC), *MW* = molecular weight.

Only substances with medium or high volatility (see Table 2 and Figure 2) belong to this category. Those with (very) low or non-volatility belong to the wet aerosol category and their *OEB* values are established in *mg/m3*. In general, these substances are only airborne following aerosolization.

Please note that on Material Safety Data Sheets (*MSDS*) for many substances especially for dusts/solids/powders (dry aerosols), the ‘general’ inert dust limits are used. In many countries these have been set at 10 mg/m3 for total (inhalable) dust and 3-5 mg/m3 for respirable dust. Inhalable dust (particles varying from ca. 10-100 micron aerodynamic size) consists of particles that can enter the nose and the main bronchi but these particles generally do not reach the lung alveoli; respirable dust (particles up to 10 micron aerodynamic size) consists of particles that at least partly can reach the lung alveoli. Therefore, if the material is a dust, solid or powder with an indicated *OEL* of 10 or 3-5 mg/m3 respectively, it should be concluded in most cases that this limit is just an estimate and not based on a large set of toxicological data. In such a case, a judgment should be made based on the existing data (see section 5.1.3).

Table 1 – Hazard classes (*HC*) and corresponding occupational exposure bands (*OEB*)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| HC | *OEB*  dust/solid/ powder/(very) low, non-volatile liquid  *(mg/m3* | *OEB*  medium/ high volatile liquids (vapors)/ gases (*ppm*)  *Note 1* | Hazard statements  *Note 2* | Remarks  *Note 3* |
| 1 | >1 | >50 | All others not otherwise listed |  |
| 2 | >0.1-1 | >5-50 | 302, 304, 312, 315, 319, 332, 335, 336, 360/361, 373 | H335: moderately irritating to airways  H373: significant toxic effects at 10-100 mg/kg bw  H360/361: significant toxic effects >30 mg/kg bw |
| 3 | >0.01-0.1 | >0.5-5 | 301, 311, 314, 317, 318, 331, 335, 360/361, 371, 372 | H335: strongly irritating to airways  H317: moderate skin sensitizer  H372: significant toxic effects at 1-10 mg/kg bw  H360/361: significant toxic effects at 3-30 mg/kg bw |
| 4 | >0.001-0.01 | >0.05-0.5 | 300, 310, 317, 330, 360/361, 370, 372 | H317: strong skin sensitizer  H372: significant toxic effects at 0.1-1 mg/kg bw  H360/361: significant toxic effects at 0.3-3 mg/kg bw |
| 5 | ≤ 0.001 | ≤0.05 | 334, 340/341, 350/351 | In case of mutagenic and/or  carcinogenic substances ask for expert advice to set exposure level |

*Note 1: Please refer for volatility to Table 2 and Figure 2*

*Note 2: See Annex 1 for the explanation of these hazard statements. PLEASE NOTE THAT THE OEL (or any other occupational limit value) ALWAYS TAKES PRECEDENCE OVER H STATEMENTS Note 3: Because CMR compounds are not classified based on potency but on the level of evidence only, in this table classification for repro (H360/361) is included based on potency; in case of classification for carcinogenicity (H350/351) one should look for either OEL/DNEL or for risk-based levels (e.g. DMEL); e.g. if the DNEL or DMEL for a non-volatile carcinogenic substance would be 0.4 mg/m3 it would be placed in hazard class 2, if it would be 0.2 ppm for a volatile liquid or gas it would be placed in hazard class 4.*

Examples

*Example 1: a substance (dust, solid, powder, non-volatile liquid) with a well-documented OEL or DNEL of 0.3 mg/m3 will fall in Hazard Class 2. In section 5.2 the corresponding risk management measures can be found.*

*Example 2: a substance (volatile liquid, vapor) with a well-documented OEL or DNEL of 3 ppm will fall in Hazard Class 3. In section 5.2 the corresponding risk management measures can be found.  
Note: for substances with a “Skin” notation, special safety measures, and in particular appropriate Personal Protection Equipment (PPE) should be advised.*

**5.1.2 In case an occupational exposure limit is not available but there is sufficient toxicity data**

In case no well documented Occupational Exposure Limit (*OEL*) or Derived No Effect Level (*DNEL*) is available for a certain substance, but sufficient toxicity data is available consult with a toxicologist to establish an *IEL* (Nouryon Internal Exposure Limit). Please be aware that in many instances the available data set will consist of ‘acute’ toxicity data only (such as acute oral, dermal or inhalation toxicity, skin and eye irritation, skin sensitization and a genotoxicity test in bacteria (i.e. Ames test)). Such an ‘acute’ data set does not provide any information on repeated (long-term) exposure and consequently, it should be considered a limited data set and as such one should refer to section 5.1.3.

The alternative, but less preferable, procedure is to evaluate all available toxicity data and corresponding classification and H statements, as described in the Global Harmonized System (*GHS*). In case of a sufficient number of tests performed (see note above), the presence or absence of H statements will give an indication of the toxic properties (hazard) of that substance.

If a certain substance is categorized, the mid value of the *OEB* will then be used to set the *IEL* for this substance.

*Example 3: Suppose a substance (dust, solid, powder, non-volatile liquid) has shown toxic effects to reproduction at a dose of 10 mg/kg bw; it will then be categorized in Hazard Class 3. Suppose this substance has also shown liver toxicity (systemic effects) at a dose of 1 mg/kg bw, then Hazard Class 4 would be required. The overall conclusion would be Hazard Class 4. The IEL will then be set at 0.005 mg/m3 (the middle of the OEB range). In section 5.2 the corresponding risk management measures can be found.*

*Example 4: a substance that has been classified as a respiratory sensitizer (H334) will fall in Hazard Class 5. In case no OEL/DNEL has been set, the internal exposure limit (IEL) will be set at 0.0005 mg/m3 (in case of a dust, solid, powder or non-volatile liquid) or 0.025 ppm (volatile liquid (vapor)/gas). In Chapter 5.2 the corresponding risk management measures can be found. The value of 0.025 ppm is 5 times higher than the TLV of toluene-diisocyanate (0.005 ppm), one of the most powerful respiratory sensitizers.*

### 5.1.3 In case of limited or insufficient toxicity data

In case no or a limited set of toxicity data is available, the substance should be tentatively placed in Hazard Class 3 (see Table 1). If the toxic degree of all chemicals is considered all together, a normal distribution of hazards will be obtained. The internal exposure limit (*IEL*) will then be set at 0.05 mg/m3 for dusts/solids/powders/wet aerosols and at 2.5 ppm for liquids(vapors)/gases (the middle of the *OEB* range). Refer to section 5.2 for respective risk management measures.

*Example 5: If based on the absence of sufficient data Hazard Class 3 is chosen for a certain volatile liquid/vapor, the corresponding limit would be 2.5 ppm (mid value of the OEB); this value will then be indicated as an IEL (Internal Exposure Limit). Suppose the MW of this substance is 96. Then the corresponding IEL value in mg/m3 would be 96/24 x 2.5 = 10 mg/m3 (20ºC).*

**5.1.4** **In case of analyzing mixtures**

For a mixture, each individual ingredient present in a reasonable amount (e.g. as a rule of thumb at 10% or more) will have to be evaluated and categorized in Table 1 indicated above. The ingredient in the highest hazard class, taking into account the amount present in the mixture, will determine the overall hazard class:

CCA (critical component assessment) = Ci / OEL (Ci = concentration in mixture (%))

If the mixture contains volatile chemicals, also the vapor pressure should be taken into account:

CCA (critical component assessment) = (vp \* Ci) / OEL (vp = vapor pressure)

*Note: OEL should be read as OEL/IEL/DNEL etc.*

In case no or a limited set of toxicity data is available for most/all of the ingredients, the mixture should be tentatively placed in Hazard Class 3. The internal exposure limit (*IEL*) will then be set at 0.05 mg/m3 for dusts/solids/powders/wet aerosols and at 2.5 *ppm* for liquids(vapors)/gases (the middle of the *OEB* range). Refer to section 5.2 for the respective risk management measures.

**5.2** **Exposure assessment, risk assessment/characterization and risk management**

The Nouryon *OHRM* system is an approach to derive a predictive exposure risk by using

qualitative exposure parameters. Apart from information on the hazard, *HC* or *IEL* of the

substance, also information on all variables that influence the degree of exposure (e.g. handling

activities, quantities handled, manual interaction, operational controls, etc.) play a role. Therefore,

the degree of exposure together with the hazard class of the substance determines the health-

based exposure risk of a given task (see Figure 1).

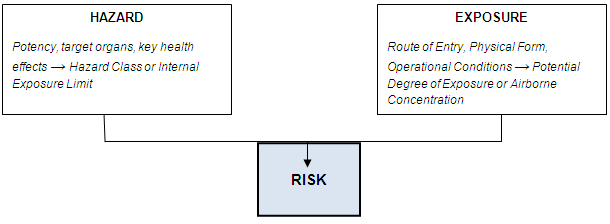
The assessment starts when the substance has been categorized in a hazard class and an *OEL* is available and/or an *IEL* determined (see previous section 5.1). Next, the Potential Degree of Exposure (*PDE*) is derived, based upon the evaluator’s knowledge of the process steps and tasks as well as the physical state of the substance. The *PDE* calculation is described in the next sections. The hazard class together with the *OEL* and/or derived *IEL* together with the *PDE* value then leads to the level of the Occupational Hygiene Control Strategy (*OHCS*) to be applied in order to ensure safe working conditions.

In section 5.2.1, the exposure risk assessment of new substances will be described, i.e. the process steps and tasks will be evaluated without taking into account any (present) control measures.

In section 5.2.2, the exposure risk assessment of known substances will be described for existing processes, i.e. including any control measures in place.

In section 5.2.3, information will be given on how to deal with these procedures, in case of new substances in a design stage of a new process.

Figure 1: Correlation between Hazard, Exposure and Risk



**5.2.1 Occupational hygiene risk management for new substances**

Before starting the *OHRM* procedure the industrial process has to be divided into Similar Exposure Groups (*SEG*) and related tasks.

In this section, the derivation of the initial Potential Degree of Exposure *(i-PDE*) ranking will be described*. i-PDE* is the *PDE* without taking into account any control measures. In part B, the set- up of the related exposure control strategy will be covered.

# Determine the initial potential degree of exposure *(i-PDE)*

Exposure is a function of the physical properties of a substance and the likelihood of the substance to become airborne. The qualitative exposure parameters or the determinants *of i-PDE* are:

* Material Characteristics (*MC*): volatility (vapor pressure) for liquids and dustiness for solids (4 levels)
* Manual Interaction (*MI*): the way the substance is handled, manually or by technical devices/engineering controls (3 levels)
* Quantity Handled (*QH*): quantity of the substance which is handled/used (physical actions, 3 levels)
* Aerosol Dispersion (*AD)*: visible and/or open process operations (3 levels)
* Duration of the task (*DT*): time blocs (4 levels)
* Degree of Dilution (*DD*): concentration of the substance in a mixture (4 levels)

The initial *PDE (i-PDE)* rating is the sum of the weighing factors of these parameters. The highest possible *i-PDE* rating is 18.

*i-PDE = [MC] + [MI] + [QH] + [AD] + [DT] + [DD]*

*Description of the six parameters of initial Potential Degree of Exposure:*

The rating criteria of the exposure parameters are:

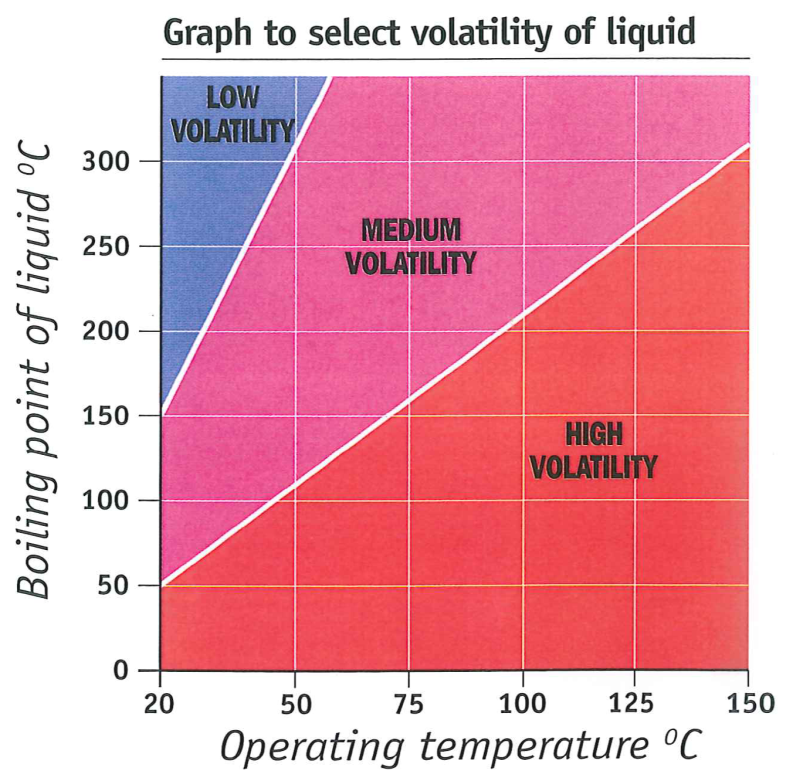
1. *Material Characteristics (MC)*

MC is based on the physical characteristics. These characteristics determine if the substance will become airborne or not. See *MC*-rating in Table 2. In case no information is available on the vapor pressure of the substance then the criteria of ‘Volatility levels of liquids’ will be used (Figure 2).

Table 2: Material Characteristics (*MC*) rating

|  |  |  |
| --- | --- | --- |
| **Weighing factor** | ***MC* Descriptions** | |
| 3 | Very/extremely dusty  e.g. micronized particulates, carbon black, cement, plaster, flour | High vapor pressure liquid (> 100 mm Hg or > 13.3 *kPa*), or high volatility range based on boiling temperature and operating temperature (Figure 3.2) |
| 2 | Dusty  e.g. light, fine particles, soap powder, talc, graphite | Moderate vapor pressure liquid (20-100 mm Hg or 2.7 – 13.3 *kPa*), or medium volatility range based on boiling temperature and operating temperature (Figure 3.2) |
| 1 | Slightly dusty  e.g. course particulates, soap granulates, sugar, salt | Low vapor pressure liquid (1-20 mm Hg or 0.13 – 2.7 *kPa),* or low volatility range based on boiling temperature and operating temperature (Figure 3.2) |
| 0 | Not dusty  e.g. solids, pellets, tablets, plastic granules | Very low vapor pressure liquid (< 1 mmHg or < 0.13 *kPa*) |

*Figure 2: Volatility levels based on operating temperature and boiling point of the liquid*



*Example 1: the use of xylene in a process*

*The vapour pressure of p-xylene at 20°C is 1.2 kPa which corresponds to an MC rating of 1 (Table 1). If the operating temperature would be 54°C then the vapor pressure will be 5.3 kPa. As such the MC rating becomes 2. If only the boiling point of p-xylene would be known (135°C), Figure 2 will be used instead. In case of an operating temperature of 54°C the volatility class will be Medium, or MC rating 2.*

*Example 2: the use of ethanol in a process*

*The vapor pressure of ethanol at 20°C is 50 mm Hg which corresponds to an MC rating of 2 (Table 1). If the operating temperature would be 40°C then the vapor pressure will be 134 mm Hg. As such the MC rating becomes 3. If only the boiling point of ethanol would be known (78°C), Figure 2 will be used instead. In case of an operating temperature of 40°C the volatility class will then be High, or MC rating 3.*

1. *Manual Interaction (MI)*

*MI* classifies the exposure of workers in relation to the kind of handling of the chemical agent and the worker’s position during that task. See *MI*-rating in Table 3.

Table 3: Manual Interaction (*MI*) rating

|  |  |
| --- | --- |
| **Weighing factor** | ***MI* Descriptions** |
| 3 | Direct handling |
| 1 | Indirect handling and continuous presence around the process task |
| 0 | No direct handling and little presence around the task |

*For example, weighing or emptying bags will correspond to an MI rating of 3. However, the MI rating will be 0 for a task when the worker, e.g. the process operator, is not present in the room during a reaction or blender procedure.*

1. *Aerosol Dispersion (AD)*

*AD* refers to the tendency of a material to become airborne through process or operator interaction (by mechanical processes). See *AD*-rating in Table 4.

An aerosol is defined as any system that disperses liquid droplets or solid particles in a stable airborne suspension. Liquid (wet) aerosols are generally classified as fogs or mist and solid particle (dry) aerosols as dusts, fumes or smokes.

Table 4: Aerosol Dispersion (*AD*) rating

|  |  |
| --- | --- |
| **Weighing factor** | ***AD* Descriptions** |
| 3 | High-continuous (visible) aerosol with long suspension, and/or significant amount of open mechanical interaction |
| 1 | Moderate-intermittent aerosol with short suspension, and/or small to moderate amount of open mechanical interaction |
| 0 | Low-no visible aerosol and minimum amount of mechanical interaction |

1. *Quantity Handled (QH)*

The quantity of the chemical agent involved in a process task is important when considering the potential for worker exposure. See *QH*-rating in Table 5.

Table 5: Quantity Handled (*QH*) rating

|  |  |
| --- | --- |
| **Weighing factor** | ***QH* Descriptions** |
| 3 | > 100 kg |
| 2 | 11- 100 kg |
| 1 | 1-10 kg |
| 0 | <1kg |

*Example: if 2 kg of a pure substance is handled, then the QH rating will be 1. But when this 2 kg is a part of a mixture of e.g. 100 kg then the latter amount determines the QH weighing factor which will be 2.*

1. *Duration of the task (DT)*

The determinant Duration of the Task is associated with the *OEL*, based on an 8-hour workday/shift. See the *DT* ranking in Table 6.

Table 6: Duration of the Task (*DT*) rating

|  |  |
| --- | --- |
| **Weighing factor** | ***DT* Descriptions** |
| 3 | > 4 hours |
| 2 | 2 – 4 hours |
| 1 | 15 min- 2 hours |
| 0 | < 15 minutes |

*Example: If the task is performed more than once during a shift, the duration of the task is multiplied accordingly. So when a task takes 1.5 hour and it will be done twice, the total duration of the task is 3 hours; the DT rating will then be 2.*

1. *Degree of Dilution (DD)*

This parameter refers to the concentration of the substance, expressed as a percentage of the total. The *DD* parameter accounts for this variable by scaling the rating. See Table 7.

Table 7: Degree of Dilution (*DD*) rating

|  |  |
| --- | --- |
| **Weighing factor** | ***DD* Descriptions (w/w %)** |
| 3 | >50% |
| 2 | >10 – 50% |
| 1 | >1 - 10% |
| 0 | ≤1% |

***An example calculating i-PDE:***

*Assume that:*

*MC= 2*

*MI= 3*

*AD= 1 i-PDE = 2 + 3 + 1 + 1 + 1 + 3 = 11*

*QH= 1*

*DT= 1*

*DD= 3*

Next, the Task Risk Ranking (*TRR*) is used to determine whether the *HC* and the *i-PDE* will result in a task with low, moderate or high risk (Table 8).

Table 8: The Task Risk Ranking (green= low risk; orange= moderate risk, red= high risk)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Hazard Class (HC)** | **5 *Note 1*** |  | | | | |
| **4** |  |  |  |  |  |
| **3** |  |  |  |  |  |
| **2** |  |  |  |  |  |
| **1** |  |  |  |  |  |
|  |  | **0-4** | **5-6** | **7-12** | **13-15** | **16-18** |
|  |  | **Initial Potential Degree of Exposure *(i-PDE)*** | | | | |

*Note 1 For substances in Hazard Class 5 special precautions are needed on a case-by-case basis (consult a professional certified occupational hygiene specialist).*

# Determine the Occupational Hygiene Control Strategy

The Occupational Hygiene Control Strategies (*OHCS*) categories describe the engineering controls, equipment design, personal protective equipment and give information on the workplace procedures which would result in a safe use of substances. *OHCS1*, *OCHS2* and *OHCS3* are explained in detail in Appendix 1.

How to select the proper Control Strategy?

The selection of proper controls is based on the hazard class and the initial Potential Degree of Exposure *(i-PDE)* for a certain substance. Therefore, information on the *i-PDE* and the *HC* is needed. See Table 9.

Table 9: Occupational hygiene control strategies (*OHCS*) selection table

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Initial PDE rating\* (i-PDE)  *Note 1* | Hazard class (HC) | | | | |
| 1 | 2 | 3 | 4 | 5 *Note 2* |
| 0-2 | OHCS1 | OHCS1 | OHCS1 | OHCS1 | special attention |
| 3-6 | OHCS2 | OHCS2 |
| 7-9 | OHCS2 |
| 10-12 | OHCS3 |
| 13-15 | OHCS2 | OHCS3 |
| 16-18 | OHCS3 |

*Note 1: The i-PDE rating is based on no use of control measures; a rating for control effectiveness is described in section 5.2.1.*

*Note 2: In case of exposure limits below 1 μg/m3 or 0.05 ppm (e.g. based on a relevant hazard like respiratory sensitization) special attention is required. E.g. full containment technology, full automated operations etc. In such cases contact a professional certified occupational hygienist.*

*For example, if the task has an i-PDE rating of 11 and the substance is categorized in Hazard Class 3, the Occupational Hygiene Control Strategy default would be OHCS2. In case the substance is categorized in Hazard Class 1, the OHCS would be 1.*

**5.2.2 Occupational hygiene risk assessment of substances in existing processes**

Compared to the exposure risk assessment of new substances, the risk assessment of substances which are used in existing processes needs one additional step when ranking the risks. The circumstances of existing processes are well known and there is a lot of information on the degree of containment, called ‘Control Effectiveness’ (*CE*). For existing processes the control effectiveness ranking (*CE*) is taken into account when the Potential Degree of Exposure (*PDE*) is calculated; now it is named the ‘adjusted *PDE’* *(a-PDE*). When the operational condition is safe, no further investigation is needed. To determine the adjusted *PDE* the initial *i-PDE* for the process earlier established is required.

For existing situations exposure risk is also ranked. This will be done by Task Risk Ranking (*TRR*) as explained before and the parameters involved are: hazard class and the adjusted Potential Degree of Exposure *(a-PDE*). The *TRR* predicts the overall occupational health risk as low, medium or high. This *TRR* is then used to derive follow-up quantitative exposure assessment and control strategies based on the assessed risk. See for the *TRR* process flow chart Figure 3.

Figure 3: Flow chart evaluation of the occupational health risk process



# Determine the adjusted potential degree of exposure *(a-PDE)*

In the case of a new process and/or new substance the term ‘initial *PDE’* is being used. In such cases the effectiveness of control measures has not been taken into account (initial *PDE* = gross *PDE*). To evaluate exposure risk of existing processes, the term ‘adjusted Potential Degree of Exposure‘ (a-*PDE*) is used This *a-PDE* is based on the evaluator’s observation, knowledge on the process tasks and systems as well as the physical state of the substance used and the knowledge on the effectiveness of the controls (*CE*). Based on this knowledge a correction is made on the *i-PDE,*

Below some suggestions are given for evaluating the effectiveness of the involved controls and activities of processes (which is mainly based on ventilation/exhaust):

Observations to be made:

* Note how the control is positioned in relation to the employee and the work being performed (e.g. positioning of a *LEV* hood),
* Look for signs of damage or malfunction (e.g. dust deposits or apparent loss of suction in front of a *LEV* hood),
* Conduct smoke testing to control the air stream direction or to check leakages,
* Check performance gauge readings located on the control (e.g. static pressure gauges across the outlet filter on isolators or velocity readings on safety cabinets),
* Confirm that periodic testing and maintenance is being performed,
* Note environmental conditions (e.g. settled powders on horizontal surfaces or evidence of leakages around seals or openings).

Based on the available information the control effectiveness rating can be carried out. See Table 10.

In general capture ventilation (e.g. local exhaust ventilation) warrants a minimal *CE* rating especially in case of dust capture. Ventilated partial enclosures (e.g. down flow booth) warrant a moderate *CE* rating and process equipment intervention controls (e.g. split butterfly valves (SBV), septum samplers) and full containment designs warrant a high *CE* rating.

Table 10: Control Effectiveness (*CE*)

| **CE rating** | **Description** | **Effect on Initial *PDE* rating** | **Examples** |
| --- | --- | --- | --- |
| A | High | Subtract with a value of ‘16’ from initial *PDE* | Bulk liquid transfer from a storage tank to a reactor vessel using a closed pipe system (a process control) |
| B | Moderate | Subtract with a value of ‘6’ from initial *PDE* | Using a laminar flow hood while discharging the contents of a dryer into unsealed 20 kg bags |
| C | Minimal | Subtract with a value of ‘2’ from initial *PDE* | Using a local exhaust ventilation hood to control dust generation while charging 20 kg bags into an intermediate bulk container |
| D | None | No modification action | General mechanical room ventilation to ‘control’ dust generation while charging 20 kg bags into an intermediate bulk container |

The *a-PDE* is finally calculated by subtracting the control effectiveness rating from the originally established *i-PDE*.

*a-PDE = [i-PDE] – [CE rating]*

Next, the Task Risk Ranking (*TRR*) is used to determine if there is a need to change the exposure containment strategy. In the case of orange or red, one should return to section 5.2.1 and check if the Occupational Hygiene Control Strategy is in line with the existing control measures. Take care of an appropriate containment performance.

Table 11: The Task Risk Ranking (green= low risk; orange= moderate risk, red= high risk)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Hazard Class (HC)** | **5 *Note 1*** |  | | | | |
| **4** |  |  |  |  |  |
| **3** |  |  |  |  |  |
| **2** |  |  |  |  |  |
| **1** |  |  |  |  |  |
|  |  | **<0-4** | **5-6** | **7-12** | **13-15** | **16-18** |
|  |  | **Adjusted Potential Degree of Exposure *(a-PDE)*** | | | | |

*Note 1 For substances in Hazard Class 5 special precautions are needed on a case-by-case basis (consult a professional certified occupational hygiene specialist).*

**5.2.3 Occupational hygiene risk assessment of substances used in processes in a design stage**

For processes in the design stage, knowledge on the effectiveness of an existing similar control measure may be useful in determining the effectiveness of a planned control measure. Control measurements of existing processes will provide this information. Another possibility is following the qualitative risk assessment described in Section 5.1.1. The Occupational Hygiene Control Strategies document (Appendix 1) can serve as a reference for judging whether a planned engineering control measure is appropriate or not.

**References**

Hirst N., Brockleband M. and Ryder M. (2002). Containment Systems. A Design Guide. Massachusetts, USA: Gulf Professional Publishing

HSE (2002). The Control of Substances Hazardous to Health (*COSHH*). Regulations and approved Codes of Practice. United Kingdom Health and Safety Executive, Suffolk, UK

Mulhausen J.R. and Damiano J (1988). A strategy for Assessing and Managing Occupational Exposures 2nd ed. Fairfax, USA: American Industrial Hygiene Association

### Appendix 1 Guidelines occupational control strategies

Within the Nouryon exposure control framework, emission sources can be managed by one of the Occupational Hygiene Control Strategies (*OHCS*), appropriate for the predicted health risk posed by inhalation. See next sections.

**Attention:**

Ensure that the introduction of control measures does not increase the overall risk to health and safety (e.g. ergonomically still feasible?).

### Appendix 1.1 – Occupational Hygiene Control Strategy 1 *(OHCS1)*

**General Ventilation**

**YES**

**Process Containment and Isolation**

Process containment and isolation are not applicable to the design basis for *OHCS1*

**Partial Containment and air-based Controls**

Partial containment and air-based control technologies (e.g. down-flow booth or laminar airflow table) are not applicable to the design basis for *OHCS1*

**General Ventilation**

*Design basis:*

Outdoor or general room ventilation eventually supplemented with simple Local Exhaust Ventilation (*LEV*) on conventional open equipment as described below.

* Filter general ventilation air prior to recirculation into the area
* Keep production area and non-production area ventilation systems separate
* Establish a negative differential air pressure relative to adjacent areas, if possible.
* Extract general ventilation air at the floor level behind the process equipment. Provide suitable air changes as appropriate for comfort
* Observe the following practices if simple local exhaust ventilation is used as the primary emission source reduction method:
  + Apply *LEV* (e.g. fixed or movable exhaust duct system with flanged hood) to open equipment or manual material handling activities
  + Relative location of the operations and *LEV* system should minimize escape of contaminants into the general work area and ensure airflow is directed away from the operator
  + Recirculation exhaust air from *LEV* systems handling powders through a suitable air-cleaning system
  + Direct exhaust air from *LEV* systems handling gases or solvent vapors through a suitable air-cleaning system (e.g. scrubber) prior to emission to the atmosphere in accordance with local regulations
  + Place all *LEV* systems ductwork located inside the building under negative pressure (e.g. achieved by a fan on the roof) whenever feasible
  + Place filter unit as close to the process equipment as feasible to prevent the contamination of exhaust ductwork.
  + Design *LEV* stacks to eliminate re-entrainment of contaminated exhaust air back into the facility.

**General Design Concepts**

Ensure work surfaces are easily cleanable and non-porous.

**Access and Egress/ Entrance and Passage**

Not applicable to the design basis for *OHCS1*. Generally limit entrance to (authorized) personnel only.

**Maintenance and Cleaning**

* Maintain cleanliness of the work area according to good housekeeping practices
* Design equipment for easy maintenance and cleaning
* The equipment need to be cleaned before maintenance
* Surfaces need to be cleaned using vacuum systems and wet methods. Implement a regular maintenance and cleaning schedule for equipment and surfaces.
* Prohibit use of compressed air for cleaning activities?
* Maintain alarms or performance indicators required for any control equipment in accordance with the recommended preventive maintenance schedule.
* *LEV* systems should be:
  + Visually checked periodically
  + Maintained in accordance with manufacturer’s specifications
  + Examined and tested at least annually in accordance with the site preventive maintenance program

**General controls achieved by good practices**

* Prohibit eating, drinking and smoking in the work area
* Prohibit potentially contaminated clothing from being worn outside the work area
* Implement procedures to minimize exposure of ancillary or contract workers (e.g. laundry workers, cleaners) to raw materials, intermediates and products.

**Personal protective equipment**

* Select Personal Protective Equipment (*PPE*) based on a documented *PPE* needs assessment
* Consider the need for respiratory protection during routine cleaning and maintenance activities
* Disposal of potentially contaminated *PPE* should be consistent with that of other contaminated waste in accordance with local site procedures
* Don’t reuse disposable *PPE*

In case of working with an irritating substance wear safety spectacles or goggles; in case of corrosives wear chemicals splash proof safety goggle or a face shield in conjunction with safety spectacles or goggles.

### Appendix 1.2 – Occupational Hygiene Control Strategy 2 *(OHCS2)*

**Partial Containment**

**+**

**Air-based Controls**

**YES**

**Process Containment and Isolation**

Process containment and isolation are not applicable to the design basis for *OHCS2*

**Partial Containment and air-based Controls**

*Design basis:*

Semi-enclosed material transfers, specially designed *LEV* systems and directional air-based controls as described below.

* Open handling is acceptable when specially designed local exhaust ventilation (*LEV*) is applied at the source to capture contaminants from open or partially contained operations.
* Partial containment and air-based control technologies include, but are not limited to:
  + Direction air-based controls such as down-flow booths
  + Laminar airflow booths or tables
  + Downdraft tables, ventilated drum or bag dumping station and chemical fume hoods
  + Enclosed discharge systems such as inflated drum packing seals or heads
  + Partially enclosed powder or liquid vacuum transfer system
  + Specially designed *LEV* systems
* Maintain enclosures, process vessels and containers under negative pressure to minimize leakage into the work area and into the operator’s breathing zone.
* Direct exhaust air from *LEV* systems handling powders through a High Efficiency Particulate Air (HEPA) filter fitted with an airflow alarm prior to emission to the atmosphere.

When recirculation of exhaust air contaminated with powders is unavoidable, direct the air through a double HEPA filter or a single HEPA filter fitted with a particle detector alarm.

* Direct all exhaust air from *LEV* systems handling gases and solvent vapors through a suitable air cleaning system (e.g. scrubber) prior to emission to the atmosphere.
* Use ‘safe-change’ filters on:
  + *LEV* system dust collectors
  + Ventilated enclosures (e.g. down-flow booths)
  + Air handling systems integral to process equipment (e.g. fluid bed dryers)
  + Process equipment attached to house vacuum system
* Place all *LEV* system ductwork located inside the building under negative pressure (e.g. achieved by a fan on the roof) whenever feasible, unless protected by an air cleaning device upstream of the fan.
* Place *LEV* system air cleaning device as close to the process equipment as feasible to minimize the contamination of exhaust ductwork.
* Design *LEV* stacks to eliminate re-entrainment of contaminated exhaust air back into the facility
* Affix warning labels to contaminated ductwork that is not protected by HEPA filtration.
* Provide suppression or containment of dust collection system, as appropriate. Explosion venting may not be appropriate for certain *HC* 4 substances. If explosion venting is needed, control venting with catch tanks or vent scrubber/filter

**General Ventilation**

* Maintain a negative differential air pressure relative to adjacent areas. Monitor pressure differentiation to alert workers of air pressurization system failures
* Extract general ventilation air at the floor level behind the process equipment
* Provide adequate air changes per hour for operator comfort. Air changes needs are based on the size of the room, the activities to be performed, etc.
* Direct general ventilation air through a HEPA filter prior to emission to the atmosphere.
* When circulation of general ventilation air is unavoidable, direct the air through a HEPA filter fitted with a particle detector alarm or use two HPA filters.
* Use exhaust ‘safe change’ filters to prevent the contamination of exhaust ductwork.
* Direct all air contaminated with gases and solvent vapors through a suitable air-cleaning system (e.g. scrubber) prior to emission to the atmosphere.
* Keep production area and non-production area ventilation systems separate.
* Maintain contaminated exhaust ducts passing through the building under negative pressure. Equip exhaust duct with pressure alarms.
* Restrict access to general ventilation air discharges points to authorized persons.
* Design airflow distribution to minimize air currents in the room and minimize the entrainment of particles.
* Verify engineering control performance through acceptance testing (validation)

**General Design Concepts**

* Isolate the work area from unprotected areas like dressing rooms, observation rooms by means of separate airlocks (Prevent contamination).
* Locate washing facilities (e.g. sink for hand washing) adjacent to the work area.
* Architectural design should minimize ledges, sharp corners (floor-wall interface) and inaccessible areas where particulates may collect. Room surfaces should be non-porous and easily cleanable.
* Select surface materials that are resistant to the cleaning agents that will be used.
* Exclude non-essential equipment and piping from the work area. Incorporate design features so that utilities are accessible from outside the equipment or work area. Controls or instrumentation not requiring operator access should also be located outside the work area.
* Physically separate offices and other administrative areas from the production work area.

**Access and Egress/ Entrance and Passage**

* Limit entrance to (authorized) personnel only.
* Post work area with appropriate access and hazards warning
* Take only the equipment and supplies necessary for job activities into the working area.
* Consider doors with interlocks for materials airlocks and locker rooms

**Maintenance and Cleaning**

* Maintain cleanliness of the work area according to good housekeeping practices
* Design equipment for easy maintenance and cleaning
* The equipment need to be cleaned before maintenance
* Prohibit use of compressed air for cleaning activities?
* Surfaces need to be cleaned using HEPA vacuum systems and wet methods. Implement a regular maintenance and cleaning schedule for equipment and surfaces. HEPA vacuum and wet wipe outer surfaces of equipment and materials to be transported.
* Use ‘wash-in-place’ dust collectors.
* Maintain alarms or performance indicators required for any control equipment in accordance with the recommended preventive maintenance schedule.
* Engineering controls including *LEV* should be:
  + Visually checked weekly
  + Maintained in accordance with manufacturer’s specifications
  + Examined, tested at and certified at least annually. E.g. also filter integrity test like Di-octylphthalate (DOP) test or similar test.
* Contaminated liquid and solid wastes, including residuals, contaminated equipment and clothing, need to be categorized and disposed of according to local site environmental policy.
* Duct isolation may be needed during filter changes. But provide a safe-change system for filters when possible.
* Tools should be dedicated to the work area, where feasible. Clean all tools prior to removal from the work area.

**General Controls Achieved by Good Practices**

* Prohibit eating, drinking and smoking in the work area
* Prohibit potentially contaminated clothing from being worn outside the work area
* Implement procedures to minimize exposure of ancillary or contract workers (e.g. laundry workers, cleaners) to raw materials, intermediates and products.
* Use of disposable protective clothing is generally preferred to that of reusable clothing. Where reusable protective clothing is worn, it is important to have appropriate procedures in place to minimize exposure of laundry workers to contaminated clothing.
* Protect batch paperwork or other documentation from contamination
* Ensure that implications of any proposed process control changes are fully assessed and documented as part of site change management program before the change is implemented

**Personal Protective Equipment (*PPE*)**

* Select *PPE* based on a documented *PPE* needs assessment
* Respiratory protection may be needed under normal or special operating conditions and likely will be needed during changeovers, routine cleaning and maintenance activities
* Assess and implement *PPE* including Respiratory Protective Equipment (*RPE*) requirements for equipment maintenance and cleaning. The assessment should consider the type of cleaning required:
  + Easily soluble standard cleaning procedure
  + Product-specific cleaning with solvents and detergents
  + Specialized cleaning requiring high temperature or chemical deactivation
* Reference any quantitative exposure data to determine level of respiratory protection needed. See also chapter 2.2 of this document
* Reference *MSDS* for health hazard information and *PPE* recommendations
* Disposal of potentially contaminated *PPE* should be consistent with that of other contaminated waste in accordance with local site procedures
* Don’t reuse disposable *PPE*

In case of working with an irritating substance wear safety spectacles or goggles; in case of corrosives wear chemicals splash proof safety goggle or a face shield in conjunction with safety spectacles or goggles.

### Appendix 1.3 – Occupational Hygiene Control Strategy 3 (*OHCS3*)

**Full Process**

**Containment and**

**Isolation**

**YES**

**Process Containment and Isolation**

*Design basis:*

* Self-contained process equipment, totally enclosed processes and contained material transfers that serve as a barrier between the equipment, the room ad the operator.
* Special consideration of remote operations, full automation or redundant containment controls may be warranted under certain circumstances.
* The number and duration of breaches of containment should be limited during routine operations. Consider additional controls if breaches are unavoidable.
* Typical *OHCS2* control technologies include:
  + Self-contained process equipment
  + Ventilated, hard or soft-walled glove-boxes or isolators with split butterfly valve (*SBV*), rapid transfer ports (*RTPs*) or bag-in bag-out techniques
  + Closed transfer systems including specialized containment valve system like *SBV* or cone valves with or without *LEV* air wash, intermediate bulk containers, continuous flexible liners with inflated seals or closed vacuum or pneumatic powder transfer systems
  + Passive primary containment (e.g. glove-bag isolator) within a supplemental air-based control enclosure as a down-flow booth or laminar flow booth.
  + Sanitary valve connections supplemented by specially designed point *LEV* system
  + Closed handling or transfers within an isolator under circumstances
* Maintain enclosures, process vessels and containers under negative pressure to prevent leakage into the operating area and into worker’s breathing zone.
* Design process equipment and *LEV* dust collectors to be ‘wash-in-place’ or ‘cleaning-in-place’.
* Design in-process sampling with sample isolators, *RTP* or *SBV* samplers, iso-lock or closed in-line samplers
* Provide explosion suppression or containment of process and isolation equipment
* Assess ergonomic factors in the design of containment equipment
* Verify engineering control performance through acceptance testing.

**Partial Containment and air-based Controls**

Application of air-based control is limited since total containment is the design basis for *OHCS3*. Specially designed *LEV* systems can be used to enhance the performance of *OHCS3* containment measures (by capturing incidental releases). Follow the practices below for specially designed *LEV* systems:

* Locate operations and *LEV* systems to minimize escape of contaminants into the general work area and ensure airflow is directed away from the operator
* Direct exhaust air from *LEV* systems handling powders through a suitable air-cleaning system prior to emission to the atmosphere. When circulation of exhaust air is unavoidable, direct the air through a safe-change HEPA filter fitted with a particle detector alarm.
* Direct all exhaust air from *LEV* systems handling solvent vapors through a suitable air-cleaning system prior to emission to the atmosphere.
* Place air-cleaning device as close to the process equipment as feasible to minimize the contamination of exhaust ductwork.
* Place All *LEV* system ductwork located inside the building under negative pressure (e.g. achieved by a fan on the roof) whenever feasible, unless protected by an air cleaning device upstream of the fan
* Design *LEV* stacks to eliminate re-entrainment of exhaust air back into the facility
* Affix warning labels to contaminated ductwork outside of work areas that is not protected by HEPA filtration
* Provide suppression or containment of dust collection system, as appropriate. Explosion venting may not be appropriate for certain *HC* 4 substances. If explosion venting is needed, control venting with catch tanks or vent scrubber/filter
* Use ‘safe-change’ filters on:
  + Pressurized isolators with visual and audible alarm (equipment with HEPA filters)
  + Air handling systems integral to process equipment (e.g. fluid bed dryers)
  + Process equipment attached to house vacuum system

**General Ventilation**

* Maintain a negative differential air pressure relative to adjacent areas. Monitor pressure differentiation to alert workers of air pressurization system failures
* Extract general ventilation air at the floor level behind the process equipment
* Provide adequate air changes per hour for operator comfort. Air changes needs are based on the size of the room, the activities to be performed, etc.
* Direct general ventilation air through a HEPA filter prior to emission to the atmosphere. Direct circulated general ventilation air through a suitable air-cleaning system. Circulation of *CMR* contaminated air is forbidden
* Use exhaust ‘safe change’ filters to prevent the contamination of exhaust ductwork.
* Direct all air contaminated with gases and solvent vapors through a suitable air-cleaning system (e.g. scrubber) prior to emission to the atmosphere.
* Keep production area and non-production area ventilation systems separate.
* Maintain contaminated exhaust ducts passing through the building under negative pressure. Equip exhaust duct with pressure alarms.
* Restrict access to general ventilation air discharges points to authorized persons.
* Design airflow distribution to minimize air currents in the room and minimize the entrainment of particles.

**General Design Concepts**

* Isolate the work area from adjacent areas by means of self-closing doors or airlocks/transition areas. If the process equipment is not completely contained or isolated then separate airlocks for materials and personnel may be needed.
* Ensure washing and changing facilities are easily accessible to the work area.
* Architectural design should minimize ledges, sharp corners (floor-wall) and inaccessible areas where particulates may collect. Room surfaces should be non-porous and easily cleanable.
* Select surface materials that are resistant to the cleaning agents that will be used.
* Exclude non-essential equipment and piping from the work area. Incorporate design features so that utilities are accessible from outside the equipment containment or work area. Controls or instrumentation not requiring operator access should also be located outside the work area.
* Physically separate offices and other administrative areas from the work area.

**Access and Egress/ Entrance and Passage**

* Limit entrance to (authorized) personnel only.
* Post work area with appropriate access and hazards warning
* Take only the equipment and supplies necessary for job activities into the working area.

**Maintenance and Cleaning**

* Use ‘wash-in-place’ or ‘cleaning-in-place’ process equipment and dust collectors.
* Maintain cleanliness of the work area according to good housekeeping practices
* The equipment need to be cleaned before maintenance
* Prohibit use of compressed air for cleaning activities
* Surfaces need to be cleaned using HEPA vacuum systems and wet methods. Implement a regular maintenance and cleaning schedule for equipment and surfaces. HEPA vacuum and wet wipe outer surfaces of equipment and materials to be transported
* Clean outer surfaces of equipment and materials to be transported
* Maintain alarms or performance indicators required for any control equipment in accordance with the recommended preventive maintenance schedule
* Engineering controls, including *LEV* and filters should be:
* Visually checked every week
* Maintenance in accordance with manufacturers’ specifications
* Examined and tested at least annually in accordance with the site preventive maintenance program

**General Controls Achieved by Good Practices**

* Prohibit eating, drinking and smoking in the work area
* Prohibit potentially contaminated clothing from being worn outside the work area
* Implement procedures to minimize exposure of ancillary or contract workers (e.g. laundry workers, cleaners) to raw materials, intermediates and products.
* Use of disposable protective clothing is generally preferred to that of reusable clothing. Where reusable protective clothing is worn, it is important to have appropriate procedures in place to minimize exposure of laundry workers to contaminated clothing.
* Prohibit eating, drinking and smoking in the work area
* Prohibit potentially contaminated clothing from being worn outside the work area
* Ensure that implications of any proposed process control changes are fully assessed and documented as part of site change management program before the change is implemented

**Personal Protective Equipment (PPE)**

* Select *PPE* based on a documented *PPE* needs assessment
* Respiratory protection may be needed under certain operating conditions to supplement primary *OHCS3* containment controls and likely will be needed during changeovers, routine cleaning and maintenance activities
* Assess and implement *PPE* including respiratory protective equipment requirements for equipment maintenance and cleaning. The assessment should consider the type of cleaning required:
  + Easily soluble standard cleaning procedure
  + Product-specific cleaning with solvents and detergents
  + Specialized cleaning requiring high temperature or chemical deactivation
* Reference any quantitative exposure data to determine level of respiratory protection needed. See also chapter 2.2 of this document
* Reference *MSDS* for health hazard information and *PPE* recommendations
* Disposal of potentially contaminated *PPE* should be consistent with that of other contaminated waste in accordance with local site procedures
* Don’t recycle disposable *PPE*

In case of working with an irritating substance wear safety spectacles or goggles; in case of corrosives wear chemicals splash proof safety goggle or a face shield in conjunction with safety spectacles or goggles.

### Annex 1 – List of applicable hazard statements

H300 – Fatal if swallowed

H301 – Toxic if swallowed

H302 – Harmful if swallowed

H304 – May be fatal if swallowed and enters airways

H310 – Fatal in contact with skin

H311 – Toxic in contact with skin

H312 – Harmful in contact with skin

H314 – Causes severe skin burns and eye damage

H315 – Causes skin irritation

H317 – May cause an allergic skin reaction

H318 – Causes serious eye damage

H319 – Causes serious eye irritation

H330 – Fatal if inhaled

H331 – Toxic if inhaled

H332 – Harmful if inhaled

H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled

H335 – May cause respiratory irritation

H336 – May cause drowsiness or dizziness

H340 – May cause genetic defects

H341 – Suspected of causing genetic defects

H350 – May cause cancer

H351 – Suspected of causing cancer

H360 – May damage fertility or the unborn child

H361 – Suspected of damaging fertility or the unborn child

H362 – May cause harm to breast-fed children

H370 – Causes damage to organs (single exposure)

H371 – May cause damage to organs (single exposure)

H372 – Causes damage to organs (repeated exposure)

H373 – May cause damage to organs (repeated exposure)