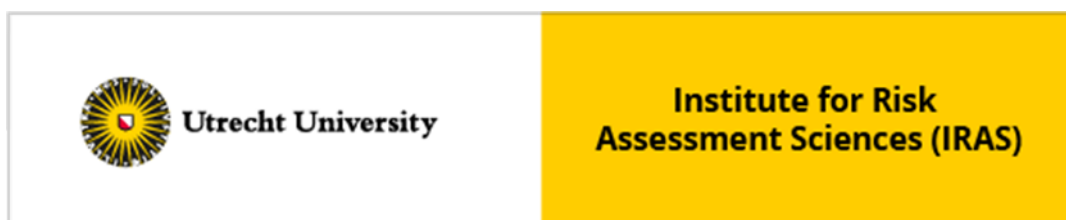# European Network for Silica (NEPSI)

Respirable Crystalline Silica Monitoring Protocol

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Chapter 1 Context

On 25 October 2006 the NEPSI signatories[1] (European Network for Silica) signed an 'Agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products containing it', further referred to in this document as the NEPSI agreement (https://www.nepsi.eu/agreement). Dust exposure monitoring is one of the elements of this agreement, and a dust monitoring protocol was included as Annex 2 of the 2006 NEPSI agreement.

The recent debate on the new European Binding Occupational Exposure Limit has highlighted the need to further discuss monitoring of the exposure to respirable crystalline silica (RCS) within the NEPSI industrial sectors. The signatories of the NEPSI agreement have expressed the need for a NEPSI harmonised methodology to monitor the exposure to RCS among their members. The existing Annex 2 on Dust Monitoring within the NEPSI Agreement was considered to be too general and more specific and updated guidance for a common methodology to monitor respirable crystalline silica at their workplaces was needed.

On 26 February 2019 the newly established NEPSI roadmap was launched by the signatories of the NEPSI agreement. Several projects within the roadmap were defined, one of them being the 'Development of a NEPSI standardized RCS measurement methodology'.

For this purpose, the NEPSI partners commissioned in 2019 the Institute for Risk Assessment Sciences (IRAS) of Utrecht University in cooperation with the Netherlands Expertise Centre for Occupational Respiratory Disorders (NECORD) to prepare such a common basic methodology, which would enable the NEPSI partners to collect RCS exposure data in a harmonised way.

At the start of the project an inventory was made of existing sampling programs and/or protocols among all 18 NEPSI signatories by a short questionnaire via E-mail ('Does your organization have a dust monitoring program and/or a written protocol on sector level to perform representative exposure measurements of respirable dust and its crystalline silica content?'). Fifteen sectors (83%) responded to this inventory. Of the respondents four sectors (27%) indicated that a dust monitoring program at sector level existed. The other 11 sectors (73%) did not have a common protocol at sector level, however, within several of the sectors dust monitoring programs had been implemented at individual members (company) level.

Sectors that had monitoring protocols available (either at sector or at company level) were interviewed in more detail. In total, seven interviews were held with sector and/or company representatives: CEMBUREAU (sector), EXCA (sector), EUROMINES (one company), FEVE (2 companies), Glass Fibre Europe (one company), Glass for Europe (one company). In addition, detailed information was already available from IMA-Europe, since both IRAS and NECORD have been involved in the IMA Dust Monitoring Programme since 2006.

A standardized interview protocol was used with the following core items:

- What are the main aims of the dust monitoring program or protocol?
- What is the year of implementation of this program or protocol?
- What are the potentially exposed groups of workers covered by the program?

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[1] Employers: ASTA Worldwide (engineered stones); BIBM (Precast Concrete), CAEF (Foundry), CEEMET (Metal, Engineering and Technology-Based Industries), CEMBUREAU (Cement), CERAME-UNIE (Ceramics), ECSPA (calcium silicate), EMO (Mortar), ERMCO (Ready-mixed concrete), EUROMINES (Mining), EUROROC (Natural Stones), EURIMA (Insulation Mineral Wool), EXCA (Expanded Clay), FEVE (Container Glass), Glass for Europe (Flat Glass), Glass Fibre Europe (Glass Fibre), IMA-Europe (Industrial Minerals), UEPG (Aggregates)
Trade Union: IndustriALL European Trade Union

- What were the sampling strategy and sampling methodology being used?
- What is described for data management (data handling, storage & confidentiality)?
- What are the main elements that should be covered in the new NEPSI harmonized protocol?

The results of this survey were presented and discussed during a NEPSI Technical Committee Meeting in Brussels on 3 December 2019. In addition, a short complementary two-question survey was held by E-mail among the participants just prior to the meeting:

- What are the most important reasons for your organization to have a NEPSI standardized RCS measurement methodology?
- From the perspective of your sector, what main elements need to be covered by the standardized protocol to meet these goals within your organization?

During the meeting an open discussion was held on the goals of the common NEPSI RCS Monitoring Protocol, and the particular guidance needed for specific elements. All respondents mentioned compliance testing with Occupational Exposure Limit Values (OELVs) as their first need of the protocol. In addition, the need to lower exposure levels and being able to compare exposure levels between members were seen as important.

The current RCS protocol has been developed with the input of NEPSI partners as described above and will answer the following questions:

- Why collect measurement data on dust and RCS? (Chapter 2 Objectives)
- What measurement strategy should be followed? (Chapter 3 Measurement Strategy)
- How should the monitoring take place? (Chapter 4 Metrology)
- How should measurement results be used and what format could be used to store and handle measurement data? (Chapter 5 Data management)
- What tools exist for statistical evaluation of measurement data? (Chapter 6 Statistical evaluation)

Although NEPSI partners have a mutual goal for a common RCS monitoring protocol, it is important to realize that the exact obligations for each sector or company may vary due to national legislation and or specific sector/company policies. The new protocol should therefore be seen as guidance on the basic principles of RCS monitoring, but at the same time it does allow for flexibility on many aspects to be able to comply with other existing obligations.

Chapter 2 Objectives

The main objective of this monitoring protocol is to provide a harmonized methodology to measure exposure to respirable crystalline silica (RCS) of workers employed at member companies of the NEPSI signatories.

The project aims to provide a common basic methodology to help those sectors who do not have a standardized monitoring methodology in place and enable these sectors to collect RCS exposure data in a harmonized and representative way. Guidance is provided on measurement strategy, appropriate sampling and analytical methods, and data management.

The implementation of the protocol is not mandatory, but should be considered as guidance for the development of a dust and quartz monitoring programme within all NEPSI partners.

Chapter 3 Measurement strategy

This chapter will focus on all aspects of the measurement strategy. More technical aspects (pumps, dust fraction, sampling heads, sampling flow, filters, analytical methods for RCS and blanks) will be covered in Chapter 4 Metrology.

Some companies will make use of external contractors for sampling and analysis of the samples. Annex 1 provides an instruction sheet for external contractors which summarizes relevant items of measurement strategy, practical sampling instructions end sampling- and analytical methods. All aspects are described in more detail in the following chapters.

Testing of Compliance with Occupational Exposure Limit Values (OELVs) was identified by the NEPSI partners as the main aim of this protocol. In Europe, the technical standard EN-689 "Workplace exposure – Measurement of exposure by inhalation to chemical agents – Strategy for testing compliance with occupational exposure limit values" provides guidance on how to evaluate exposure measurement data in relation to an OELV, and was recently updated in 2018.

It should be kept in mind, that the approach outlined in EN-689 is not a mandatory approach, but should be seen as mere guidance. EN-689 was therefore used as the starting point of this protocol.

In this chapter the following topics will be covered:

- Similar Exposure Groups (SEGs)
- Type of sampling (personal sampling versus static sampling)
- Sampling duration
- Number of samples needed
- Number of workers per SEG to be sampled and number of samples per worker
- Periodicity of sampling

Similar Exposure Groups (SEGs)

As it will not be feasible to sample each individual worker in a company, all workers have to be classified into groups of workers with an assumed similar exposure, so-called Similar Exposure Groups (SEGs). Those SEGs are defined before the actual sampling takes place and will form the sampling frame from which workers to be sampled should be chosen at random. SEGs need to be defined based on the exposure profile of the workers, in this case their RCS exposure profile:

- Similar location or phase within the production process
- Similar tasks and work patterns
- Similar exposure profile (frequency and duration of tasks with RCS exposure)
- Similar exposure conditions (operational conditions, control measures)

As the sectors within NEPSI have distinctly different production processes, it is not possible to define one standardized set of job functions or SEGs for all NEPSI partners as part of this protocol. The list of SEGs will be specific for each industrial sector although some job functions like for instance maintenance/engineering and transport workers might appear in multiple sectors. For some sectors it might even be difficult to define a list of SEGs that will be applicable for all member companies within that specific sector. However, if comparison of exposure data between companies is desirable within a sector, it is highly recommended to use a standardized list of SEGs, which at company level could even be subdivided

for local purposes. An example of the SEG definition from one of the NEPSI sectors (IMA Europe) has been included in Annex 2.

The analysis of the production process will define which SEGs will potentially be exposed to RCS. It is recommended to take RCS measurements in each of these SEGs and not to limit measurements to the highest exposed SEGs. After the initial sampling campaign it is possible to differentiate follow-up based on the exposure concentrations and variability of exposure, and put more focus on highest exposed SEGs and less on SEGs with RCS exposures well below the OELV (see also 'Periodicity' below).

The main advantage of using the concept of SEGs as the basis of a measurement strategy is that only a selection of the workers within a SEG need to be measured. If the exposure of a representative selection of workers is below the OELV, it is considered that all workers within a SEG will be in compliance with the OELV. As SEGs are defined *a priori* (before the start of the measurements), it is important to evaluate homogeneity of exposure within a SEG after the measurement results have become available and if necessary redefine the SEG. 'Representative sampling' within a SEG (choosing a random worker on a random working day) is preferred over 'worst-case sampling' (selecting the assumed worst sampling conditions or select a worker with the potentially highest exposed tasks during the day of sampling). First, the EN-689 and comparable standards do consider random sampling necessary for statistical evaluation of measurement data. Statistical evaluation will not be informative with worst-case sampling strategies. Second, worst-case sampling will limit the possibilities of comparing measurement data with other companies or between sectors.

Most workers will be part of just one SEG during a working day (all tasks performed during a sampling day will be part of the regular tasks of that specific SEG). In many sectors, however, a small proportion workers may perform multiple tasks over a shift, that have been assigned to more than one SEG. If so, a multi-skilled job function can be included in the list of SEGs to cover workers for which none of the *a priori* SEGs will fully apply. Measurements should be assigned to a multi-skilled job function when for instance less than 50% of a worker's working time belongs to just one SEG.

Type of sampling (personal sampling versus static sampling)

The main goal of the monitoring will be to get a valid and unbiased estimate of workers' exposure within a SEG. This will require personal sampling, using samplers or personal sampling pumps with sampling heads positioned in the workers' breathing zone. Static sampling (with a sampler or a pump and a sampling head at a certain location within the workplace during the entire sampling time) will hardly ever provide a valid estimate of workers' exposure. Often the worker's activity is the main source of exposure (for instance emptying a bag or sweeping a floor) and static sampling will in that case likely underestimate the worker's exposure, as there will be no optimal (close enough to the breathing zone) position for the static sampler. When however the static sampler is close to the source of exposure, but the workers spend most of the time in a control room the static measurement will result in overestimated exposure concentrations. Therefore in this protocol, personal monitoring is required.

Sampling duration

The OELV for RCS is set as an 8-hour time weighted average (8-hr TWA). No Short Term Exposure Limit (STEL) has been set for RCS. Full-shift sampling is therefore required to evaluate compliance with the OELV. It is recommended to aim for 6-8 hours of sampling. If shifts of workers are different from regular 8-hour shifts (e.g. 12 hour shifts) it is recommended to sample for at least 75% of the duration of the shift. For measurements with shorter sampling duration the sampling result will not represent a full work shift of a

worker within a SEG. Measurements of shorter duration can be useful for other purposes, for instance to study the sources of high exposures within a SEG. Task-based sampling or real-time sampling can help identifying the sources of exposure and provide valuable information for risk mitigation measures. However, these types of measurement are not part of the NEPSI RCS monitoring protocol. Within this protocol, full shift sampling is required.

Number of samples needed

Within a SEG, RCS exposure will vary considerably from day to day, as process conditions, activities and tasks performed, environmental conditions, etc. will not be constant from day to day. The average 8-h TWA exposure estimate for a SEG will therefore be more precise and more stable when samples are being collected over multiple days. Importantly, compliance with an 8-h TWA OELV can never be evaluated based on one sample within a group. To be in line with the EN-689 guidance a minimum of three samples should be collected for basic compliance testing with the OELV. Preferably up to six samples per SEG collected over multiple days would be needed for statistical evaluation (see Chapter 6). Also, when comparing exposure levels between SEGs within a company, or when comparing SEGs between different companies within a sector, measurements of multiple workers on multiple days per SEG are needed for meaningful comparisons.

Number of workers per SEG and number of samples per worker

Within each SEG, RCS exposure will slightly vary from worker to worker and for each worker from day to day. To evaluate exposure and check compliance with an OELV, it is vital to take into account the variability of exposure. It is therefore important to take some multiple measurements over several days from the same workers, whenever possible. In addition, if we have multiple measurements from workers in a SEG, it will be possible to better evaluate day-to-day variability in exposure and to evaluate (a-posteriori) the similarity of workers' average exposures within a pre-defined SEG. Of course, the possibilities for repeated sampling will largely depend on the total number of samples being taken in each SEG and the number of workers in a SEG. To provide some guidance:

- When taking only the minimum 3 samples per SEG:
    - Sample on multiple days
    - Sample multiple workers
- When taking up to 6 samples per SEG:
    - try to collect repeated samples per individual, e.g.:
        - 4 workers sampled just once and 1 repeated sample for an additional worker
        - 3 workers, each measured two times
        - 2 workers, each measured two times and two additional workers sampled once
        - avoid sampling one person six times or six people once

Periodicity of sampling

Situations vary over time, e.g. changes in production process, changes in production volumes, the probability of process disturbances with aging equipment, and hygiene policies. Therefore, RCS sampling cannot be limited to just one sampling campaign and exposure needs to be re-evaluated regularly. If exposure levels exceed the OELV, control measures need to be taken to reduce the workers' RCS exposure. After risk mitigation measures have been put in place, new measurements need to be taken to evaluate the

effectiveness of the control measures and to define a new RCS exposure level for the SEG. If RCS exposure within a SEG is below the OELV (based on the evaluation according to EN-689), the main goal of repeated sampling is to ensure that RCS exposure has not changed, or to detect changes in exposure in time. The periodicity of the sampling can depend on the exposure level, sampling more often in SEGs with exposure closer to the OELV, and fewer sampling in SEGs who are under control and well below the OELV. It is recommended to follow the scheme as mentioned in EN-689:

- Geometric mean exposure of a SEG above 50% of the OELV: sample every 12 months
- Geometric mean exposure of a SEG between 25-50% of the OELV: sample every 18 months
- Geometric mean exposure of a SEG between 10-25% of the OELV: sample every 24 months
- Geometric mean exposure of a SEG below 10% of the OELV: sample every 36 months

The above scheme is relevant if the initial evaluation is based on six samples. If the initial evaluation is based on less than six samples (preliminary testing phase according to EN-689), at least three additional samples need to be taken after one year. If process conditions have not been changed, these results can be pooled with the earlier ones in order to test compliance and to determine the period for the next reassessment. In case significant modifications in the workplace have occurred (e.g. change in process, significant change in process volumes, implementation of control methods), all previous sampling results will no longer be relevant for compliance testing. In such cases, start again with the basic characterization and evaluation.

Outliers

Exposure levels can vary considerably from day to day. As exposure within a SEG will follow a lognormal distribution, incidental high exposure levels can happen when several determinants of high exposure occur on a given day (e.g. excessive cleaning with compressed air). In principle, therefore, all available measurements should be part of the statistical evaluation, even high values. Only if there are clear indications of tampering with the measurement or if technical failure is apparent, outliers should be deleted.

Summary of basic elements of the measurement strategy:

	Recommendations (Dos)	Discouragements (Don'ts)
Similar Exposure Groups (SEGs)	- Classify your workforce into groups with assumed similar exposure - Preferably use a standardized set of job functions or SEGs within each sector to be able to compare exposure data across companies - Sample all SEGs with potential RCS exposure - Sample a representative selection of workers within each group on multiple days (random sampling)	- Worst-case sampling within a SEG as this will hamper both compliance testing according to EN-689 and will not allow comparisons exposure data across companies within a sector
Type of sampling	- Personal sampling	- Static sampling
Sampling duration	- Full-shift sampling (6-8 hour sampling) - If longer than an 8-hour shift, sample at least 75% of the duration of the shift	- Task-based sampling or real-time sampling (useful for identifying sources of exposure but not part of this protocol)

Number of samples	- A minimum of 3 samples per SEG - Preferably 6 samples per SEG	- Less than 3 samples per SEG
Number of workers per SEG & number of samples per worker	- Sample multiple workers over multiple days - Try to collect repeated samples per individual for each job title	- Take all samples within a SEG on one single day
Periodicity of sampling	- Re-evaluate after major changes in production process or implementation of control measures - Re-evaluate SEG exposures from time to time to detect relevant changes in exposure - Periodicity of sampling depends on exposure level within a SEG	- Limit RCS sampling to just one sampling campaign

Chapter 4 Metrology

Dust fraction

Dust that can be inhaled by humans can have a wide range of particle sizes. Bigger particles will be deposited in the nose, mouth or upper airways. Smaller particles can reach the alveoli of the lungs. For dust measurements in occupational settings different dust fractions are distinguished, most importantly the inhalable dust fraction (all dust particles that can be inhaled) and the respirable dust fraction (smaller dust particles that can reach the alveoli) (see Figure 1). For health effects of respirable crystalline silica only small particles that can reach the alveoli are relevant. Respirable dust consists of particles that are generally smaller than 10 µm, with a 50% cut-off aerodynamic diameter (d_{50}) of 4.00 µm. More information can be found in EN-481 "Workplace atmospheres – Size fraction definitions for measurement of airborne particles" (CEN 1993). When sampling for respirable crystalline silica it is important to use sampling equipment that measure the respirable dust fraction.
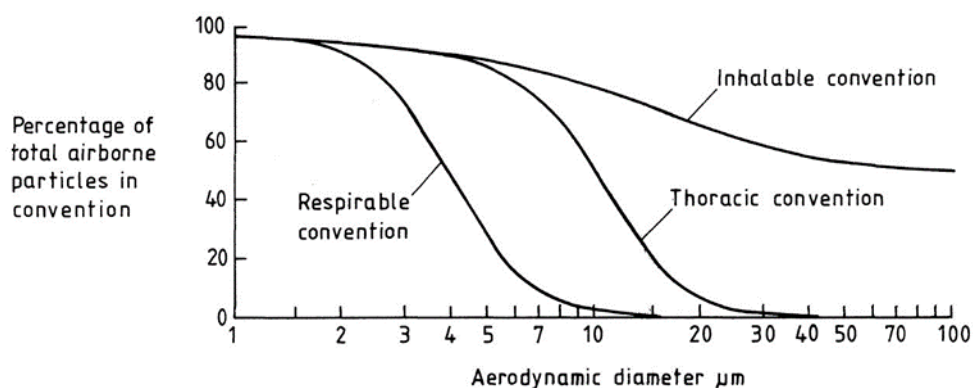
Figure 1. Inhalable, thoracic and respirable conventions as percentage of total airborne particles (CEN 1993)

General guidance for the measurement of respirable crystalline silica can be found in the international standard ISO 24095 (ISO 2009), which is currently being revised.

Choice of equipment

The choice of sampling equipment must be conform the international standard ISO 13137 (ISO 2013). The equipment either consists of a pump connected with a respirable dust sampling head or an integrated respirable dust sampler. The sampling takes place on a filter or in a foam. The performance of a large variety of samplers have been assessed in several experimental and field studies (Lidén 1993; Baron 1998; Görner et al. 2001; Lee et al. 2010; Verpaele and Jouret 2013; Stacey et al. 2016).

Examples of current respirable dust samplers are:

- FSP-10 high flow cyclone uses a 37 mm filter holder using a flow rate of 10 l/min, with a filter as the sample collection material
- CIP 10-R using a flow rate of 10 l/min, with polyurethane foam sponge as the sample collection material
- GS-3 using a flow rate of 2.75 l/min, with a filter as the sample collection material
- Respicon particle sampler using a flow rate of 3.11 l/min, with multiple filters as the sample collection material
- Dorr-Oliver 10mm nylon cyclone connected to a personal sampling pump using a flow rate of 1.7 l/min, with a filter as the sample collection material

- Higgins-Dewell cyclone connected to a personal sampling pump using a flow rate of 2.2 l/min, with a filter as the sample collection material
- IOM dual sampler includes a foam disc insert simultaneously collects respirable and inhalable dust using a flow rate of 2 l/min

For the cyclone sampling equipment the sample collection materials (filters) are placed in filter cassette. Examples are:

- Polyvinyl chloride (PVC) membrane filter, 25 or 37mm diameter, 5 µm pore size
- Silver membrane filter, 25mm diameter, 0.45µm pore size (cannot be used for FTIR analysis)
- Mixed cellulose ester (MCE) membrane filter, 25 or 37mm diameter, 0.8 µm pore size

Glass fibre filters should never be used for RCS sampling.

Currently two different analytical techniques can be used to determine the crystalline silica content of the collected dust: Fourier Transform Infrared spectroscopy (FTIR) and X-ray diffraction (XRD). FTIR is reported to have a lower detection limit than XRD and the samples require different handling procedures, but both methods are recommended and described in international standards and published methods (ISO 2009; ISO 2015a; ISO 2015b; ISO 2018; HSE 2005; NIOSH 2003a, 2003b). Cristobalite will require XRD analysis. Recent analysis of a large database of RCS measurements showed that no practical difference existed between laboratories using either XRD or FTIR methods (Harper et al. 2014).

The actual choice of sampling equipment and analytical method will be largely determined by the expected respirable dust concentration and its crystalline silica content. With a relatively high respirable dust concentration and high crystalline silica content a low volume pump with a traditional cyclone in combination with XRD analysis of the collected dust on the filter might be the choice of preference. However, when the respirable dust concentrations are expected to be low and have low crystalline silica content, a high volume sampler and FTIR analysis will be needed in order to collect informative concentrations above the limit of detection.

In the following scheme some guidance is being provided:

LoD

XRD 5-20 µg

8h 2 l/min (1.8-2.2) Higgins Dewell, Dorr-Oliver, IOM

% RCS	RCS ug/filter				
20%	19	38	96	192	960
10%	10	19	48	96	480
5%	5	10	24	48	240
1%	1	2	5	10	48
	0.1	0.2	0.5	1	5
	resp dust (mg/m3)				

8h 2.75-3.11 l/min GS-3, Respicon

% RCS	RCS ug/filter				
20%	29	58	144	288	1440
10%	14	29	72	144	720
5%	7	14	36	72	360
1%	1	3	7	14	72
	0.1	0.2	0.5	1	5
	resp dust (mg/m3)				

8h 10 l/min FSP-10, CIP10-R

% RCS	RCS ug/filter				
20%	96	192	202	960	4800
10%	48	96	101	480	2400
5%	24	48	50	240	1200
1%	5	10	10	48	240
	0.1	0.2	0.5	1	5
	resp dust (mg/m3)				

LoD

FTIR 1-5 µg

8h 2 l/min (1.8-2.2) Higgins Dewell, Dorr-Oliver, IOM

% RCS	RCS ug/filter				
20%	19	38	96	192	960
10%	10	19	48	96	480
5%	5	10	24	48	240
1%	1	2	5	10	48
	0.1	0.2	0.5	1	5
	resp dust (mg/m3)				

8h 2.75-3.11 l/min GS-3, Respicon

% RCS	RCS ug/filter				
20%	29	58	144	288	1440
10%	14	29	72	144	720
5%	7	14	36	72	360
1%	1	3	7	14	72
	0.1	0.2	0.5	1	5
	resp dust (mg/m3)				

8h 10 l/min FSP-10, CIP10-R

% RCS	RCS ug/filter				
20%	96	192	202	960	4800
10%	48	96	101	480	2400
5%	24	48	50	240	1200
1%	5	10	10	48	240
	0.1	0.2	0.5	1	5
	resp dust (mg/m3)				

For example when based on prior knowledge (or indicative measurements) the lowest expected respirable dust concentration will be 0.2 mg/m^3 and the percentage of respirable crystalline silica will be at least 5% a combination of a high volume sampler like FSP-10 and CIP10-R and XRD as analytical method will suffice, while when using FTIR, also more traditional sampling with low volume cyclones like Higgins-Dewell and Dorr-Oliver would also result in informative measurements. However, when in the same situation the percentage of respirable crystalline silica would be just 1% only FTIR and high volume cyclones (FSP-10, CIP10-R) would work.

Procedure

A calibrated analytical balance with a resolution of (at least) 0.1 mg for foam collection medium and (at least) 0.01 mg for a filter will be needed. The collection mediums should be conditioned in the weighing room for at least 12 hours before pre-weighing.

The collection equipment should have been thoroughly cleaned, conditioned and weighed. Before the actual sampling will be started make sure the pump batteries have been fully recharged so that it will be functional during an entire work shift. Calibrate the sampling pump according to manufacturer's instructions and the requirements for the used sampler. Load the collection medium (filter or foam whether or not in a cassette) in the sampler and connect to the sampling pump. Set and record the sampling flow rate before starting. Switch on the pump and record the start time. Place sampling equipment in the breathing zone of the worker (no more than 30 cm from the mouth) and record the actual place on the body.

During sampling, record all the important information (see sampling form in Annex 3) and, if the equipment allows it, check the sampling flow rate. During the sampling period record activities conducted, dust control measures in use, personal protective equipment used, etc.

At the end of the shift, remove the sampling equipment from the worker, check sampling equipment (pump, tubing and collection equipment connections) and measure the pump flow rate (over the loaded sampler). Consequently switch off the pump. Record the sampling end time. Remove the sampler from the sampling equipment. Take the collection equipment to the laboratory for the re-weighing procedure. If sampling has been carried out under humid conditions foams or filters should be placed in an oven at 50-60 °C for at least 4 hours. Consequently the foams in their cups or filters (cassettes) should be left next to the analytical balance for at least 12 hours before re-weighing. After re-weighing, the foams and filters should be analyzed for RCS by either FTIR or XRD. The analytes to be measured are at least quartz (also called α-quartz or free silica) and if relevant considering the production process, cristobalite or tridymite.

Field blanks

During each measurement day at least one field blank should be collected. Field blanks should follow the entire procedure, except active monitoring. Information on field blanks should be entered in the collection sheet as they will be used to estimate limits of detection for respirable dust and correct all samples for these field blanks. Furthermore, it is advised to send the field blanks for respirable crystalline silica analyses together with the regular samples. More detailed information on field blanks can be found in Annex 4.

Chapter 5 Data management

For the management of RCS exposure data, two phases needs to be distinguished. First, the phase of actual data collection at the time of the measurements. Second, the processing and storage of data for further evaluation and documentation.

Data recording during the measurements

During the measurement it is important to collect and document all relevant information for further processing of the information, but also for correct interpretation of the measurement results.

The following information is essential for calculation of the exposure concentrations:

- Start time of the sampling [hh:mm]
- Stop time of the sampling [hh:mm]
  - **D:** Sampling duration (stop time minus start time) [minutes]
- Flow-rate of the pump at start of sampling [litres/minute]
- Flow-rate of the pump at the end of sampling [litres/minute]
  - **F:** Mean flow-rate ((start flow + end flow)/2)) [litres/minute]
- Weight of filter or foam before sampling [mg]
- Weight of filter or foam after sampling [mg]
  - **W:** Weight gain (post-weight minus pre-weight) [mg]
- **RCS:** Result of RCS analysis (mass RCS) [mg]

With this information respirable dust and RCS exposure concentrations can be calculated as follows:

- **T:** Total flow rate $=$ (D [min] x F [l/min])/1000 [m^3]
- **Dust concentration** $=$ W [mg] / T [m^3] [mg/m^3]
- **RCS concentration** $=$ RCS [mg] / T [m^3] [mg/m^3]

Additional essential data to be recorded during sampling for tracking and identification of the measurement:

- Date of sampling
- Shift (day, morning, afternoon, night, weekend)
- Technician taking care of the sampling (name or code)
- Company and site (name or code)
- Job function or SEG (name or code)
- Worker being sampled (name or code)
- Pump (type and serial ID)
- Sampling head (type and number ID)
- Filter or foam (type and number ID)
- Technique for RCS analysis (XRD or FTIR)

Finally, contextual information may be recorded during the measurement to enable interpretation of the measurement results, e.g.:

- Use of respiratory protection during the sampling period
- Process disturbances on the day of measurement (if relevant)
- Specific tasks with high exposure potential carried out by the worker and duration of these tasks (e.g. cleaning activities)
- Process characteristics (are process conditions representative or does it significantly deviate from other days and if so, how)
- Control measures in place and/or correct use of these control measures by the worker (if relevant)
- Working behaviour of the worker during the measurement (normal or deviant from normal procedures)

As part of this protocol a sampling form has been developed (Annex 3). All items above appear on this form.

Data handling and storage after the measurements

For data storage a data collection sheet (a spreadsheet in MS-Excel$^{©}$) has been developed as part of this protocol. In this data collection sheet all essential and contextual information for the measurements can be entered. Exposure concentrations will be automatically calculated when entering the basic sampling information (start time, stop time, flow, filter weight & RCS analysis). In addition, all other relevant information for a measurement can be entered. Each record in the collection sheet will represent one measurement. In Annex 4 a more detailed instruction can be found for all items in the data collection sheet

Main purpose of the data collection sheet is a structured and uniformed storage of all RCS measurements. In addition, using the filter option in MS-Excel, specific data can be selected for entering into tools for statistical evaluation of the data (see Chapter 6).

When using the data collection sheet for entering and storing RCS exposure data, it will open the option of pooling and/or sharing data. Pooling of data can also be relevant within a company that has multiple sites. Importantly, data sharing is not a goal of this protocol. However, if in the future there might be a wish or need to pool or share data (between companies within a sector, or even between sectors within NEPSI), the use of this standardized data collection sheet will facilitate this.

Confidentiality

Confidentiality of information is relevant within the framework of the EU General Data Protection Regulation (EU-GDPR). In addition, confidentiality will be needed whenever data from multiple sites or companies will be pooled or shared. For this reason it is recommended to use codes instead of names for the following items in the collection sheet:

- Worker names (Worker ID)
- Technician names (Technician ID)
- Country names (Country code)
- Sector names (Sector code)
- Company names (Company code)
- Site names (Site code)

Part of the coding (country codes, sector codes) is specified for this protocol and can be found in Annex 4 and the Collection sheet. Coding of company and site names, worker IDs & technician IDs should be done at the level of each individual company. Importantly, coding will have to be harmonized between companies or sectors whenever measurement data will be shared.

Chapter 6 Statistical evaluation

Statistical evaluation conform EN-689 could be performed using an MS-Excel© tool developed by a concerted action of several National Occupational Hygiene Societies: BWStat (Geens et al 2005). In the text below guidance is provided for the statistical evaluation using EN-689 & BWStat.

Basic statistics

Occupational exposure measurements will almost always show a skewed distribution, with lower exposure concentrations more likely than higher exposure concentration. This is called a lognormal distribution (see Figure 2 below).

The arithmetic mean (AM) is the sum of all sampling results divided by the total number of samples. In the case of lognormal distributed data, the distribution of the measurement data can be described by just the geometric mean (GM) and the geometric standard deviation (GSD). The geometric mean (GM) is equal to the median of the distribution (50th percentile) and will always be lower than the arithmetic mean in case of a lognormal distribution. The geometric standard deviation (GSD) represents the variability of the measurement data. It is estimated by taking the exponential of the standard deviation of the logarithms of the measurement results. A GSD of 1 would imply no variability at all (all measurements taken from multiple days from multiple workers resulted in the same concentration). Analyses of a large database has indicated that on average a GSD of ~2.30 is to be expected for a group of workers with the same job in a location (Kromhout et al. 1995).

Occupational exposure measurement results can thus be described by just presenting the geometric mean (GM) and geometric standard deviation (GSD). Importantly, this needs to be done for each Similar Exposure Group (SEG).
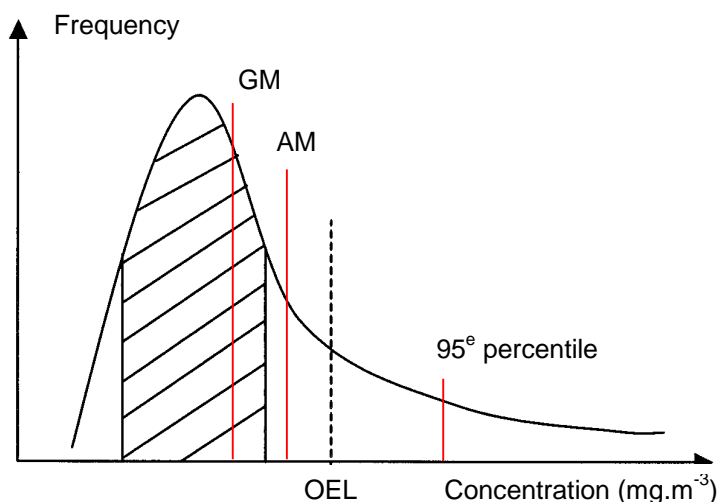

Figure 2 Lognormally distributed exposure measurements (as an example of the shape of a lognormal distribution).

Compliance in EN-689

To test compliance with an Occupational Exposure Limit value (OELV), you will have to show that exposure for a group of workers (SEG) is below the OELV. If you have one measurement result above the OELV, it will be an easy decision: non-compliance.

If all measurement results are below the OELV, this does not always imply that you will be in compliance with the OELV. Suppose the OELV is 0.1 mg/m^3 and you have a few measurement results that are close to this limit (e.g. 0.09 and 0.099 mg/m^3), how confident could you be that the observed SEG will be in compliance with the OELV? In this case, the probability that the next measurement result will exceed the OELV will be relatively high and you cannot be confident that this SEG is in compliance with the OELV. The question is how certain do you need to be and how can you consequently decide that the SEG will be in compliance with the OELV?

As an employer you need to be 95% certain that the SEG's exposure is below the OELV. For this purpose you can calculate the 95th percentile of the distribution (see Figure 2). In addition, you need to estimate the 95th percentile with a required amount of certainty (70% certainty). In other words you will have to estimate the Upper Tolerance Limit (UTL) of the distribution (the so-called UTL$_{95,70\%}$).

Although the statistical procedure to estimate the UTL is quite complex, the good news is that several free-of-charge tools are available on the Internet that will estimate the UTL. One of these tools is BWStat. The tool can be found on the website of the Belgian Society for Occupational Hygiene Society (BSOH): www.bsoh.be. The BWStat tool will be explained in this protocol. The collection sheet for data storage supports importation of measurement results into BWStat for statistical evaluation.

EN-689 compliance testing

Compliance testing can be performed as a preliminary test and as a formal statistical evaluation.

Preliminary test (if you have less than six exposure measurements)

The preliminary test requires three, four or five measurements. You will be in compliance with the OELV if:

- the three measurement results are all below 10% of the OELV. If any of the three samples is above 10% but below the OELV, no decision can be made and more samples are needed.
- the four measurements results are all below 15% of the OELV. If any of the four samples is above 15% but below the OELV, no decision can be made and more samples are needed.
- the five measurements results are all below 20% of the OELV. If any of the five samples is above 20% but below the OELV, no decision can be made and more samples are needed.

If one of the samples in the preliminary test is above the OELV, you will be in non-compliance with the OELV.

Statistical testing (if you have six or more exposure measurements)

As explained before (see Chapter 3) preferably six measurements over multiple days per SEG should be collected for statistical evaluation. If you have six or more measurement results you can estimate the Upper Tolerance Limit (UTL) of the distribution (UTL$_{95,70\%}$) and compare this value with the OELV:

- If for a SEG the UTL$_{95,70\%}$ is below the OELV, you will be in compliance with the OELV
- If for a SEG the UTL$_{95,70\%}$ is above the OELV, you will be in non-compliance with the OELV

If there is a situation of non-compliance in any of the SEGs, control measures need to be taken to further reduce RCS exposure. For potential control measures, please refer to the NEPSI Good Practice Guide (https://guide.nepsi.eu/).

Treatment of samples below the limit of detection

If one or more of the exposure measurements are below the limit of detection of the measurement procedure (LOD), these values need to be treated in a way which will not result in a biased evaluation of the exposure. There are several ways this can be done, but within the NEPSI RCS protocol we have chosen to use the 'Regression on Order Statistics (ROS)' method. In this method all samples below the LOD will be substituted by new values, based on the distribution of samples above the LOD. More detailed information on this method can be found in EN-689.

Importantly, a proper statistical evaluation can only be done if there are enough measurements available above the LOD. As a rule of thumb at least three measurements within a SEG must be above the LOD. If too many samples in a sampling campaign are below the LOD, it is strongly advised to consider more sensitive sampling methods (high volume samplers) and/or more sensitive analytical techniques (FTIR) (see Chapter 4). According to EN-482 (CEN, 2021) a method should at least be able to sample in the full range of 10% to 200% of the OELV.

Example compliance testing using BWStat

In this example we will use two sets of measurement results for two SEGs:

For Similar Exposure Group 1 (SEG1), the following six quartz measurement results are available:

- o 0.014 mg/m^3
- o 0.031 mg/m^3
- o 0.017 mg/m^3
- o 0.009 mg/m^3
- o 0.052 mg/m^3
- o 0.013 mg/m^3

For Similar Exposure Group 2 (SEG2), the following six quartz measurement results are available:

- o 0.040 mg/m^3
- o 0.008 mg/m^3
- o 0.052 mg/m^3
- o 0.011 mg/m^3
- o 0.025 mg/m^3
- o 0.073 mg/m^3

The actual statistical evaluation using BWStat can be performed as follows and requires seven steps.

STEP 1: Check if all information in the NEPSI RCS collection sheet is entered in the right format:

- Check if all information on LOD is available. In the worksheet 'LOD & Field blanks' the orange box in column L-O must be filled for the analytes that need statistical analysis
- Check if the information on field blanks is of good quality and if you want to use this blank information to correct your individual samples (for detailed information why this is necessary see Annex 4). If so, select 'yes' in field F3 in the worksheet 'LOD & Field blanks'
- Check if the information in the worksheet 'Collection sheet is complete', especially information on dust weight en -concentration, weight and concentration of analytes (quartz, cristobalite and/or tridymite), date, worker ID, and job function. If any of this information is missing, further statistical analysis is not possible.

STEP 2: Open the BWStat tool and enter the basic information

- Go to: https://www.bsoh.be/?q=nl/bwstat
- Enter the substance name (in this example respirable quartz)
- Enter the measurement unit (in this case mg/m^3)
- Enter the occupational exposure limit (in this example 0.1 mg/m^3, which is the current European OELV)

BWStat v3

BSOH
BELGIAN
SOCIETY FOR
OCCUPATIONAL
HYGIENE

Enter substance name:

> Respirable quartz

Enter measurement unit:

> mg/m³

Enter occupational exposure limit:

> 0,1

STEP 3: Select the data to be analysed in the NEPSI RCS collection sheet

- Go to one of the yellow coloured worksheets. In this example we want to analyse the data for respirable quartz. All relevant data from the collection sheet will appear in this worksheet:
  - Job function (SEG)
  - Type of measurement
  - Concentration respirable quartz (mg/m³)
  - Worker ID
  - Date
  - Information if the quartz result is above (TRUE) or below (FALSE) the detection limit
- Select the job function (SEG) that needs to be analysed, in this example we select the data for Similar Exposure Group 1 or Test SEG1. This how the data appear in the spreadsheet.:

	A Job function (SEG)	B Type of Measurement	C Concentration respirable quartz (mg/m3)	D Worker ID	E Date	F Quartz above (TRUE) OR below (FALSE) the limit of detection	G	H QUARTZ
2	Test SEG 1	Full-shift personal	0,014	101	1-Jun-21	TRUE		
3	Test SEG 1	Full-shift personal	0,031	101	2-Jun-21	TRUE		
4	Test SEG 1	Full-shift personal	0,017	102	3-Jun-21	TRUE		
5	Test SEG 1	Full-shift personal	0,009	103	5-May-21	TRUE		
6	Test SEG 1	Full-shift personal	0,052	104	6-May-21	TRUE		
7	Test SEG 1	Full-shift personal	0,013	104	7-May-21	TRUE		

- Make sure only full-shift personal measurements are analysed. If not, select in column B only the full-shift personal measurements. Other type of measurements cannot be used for compliance testing
- If relevant, make further selections for this SEG and select the period or dates to be analysed. Make sure that you end up with at least six samples for statistical analysis
- Select the data from the yellow marked columns. In our example this part of the collection sheet should be selected and copied:

0,014	101	1-Jun-21	TRUE
0,031	101	2-Jun-21	TRUE
0,017	102	3-Jun-21	TRUE
0,009	103	5-May-21	TRUE
0,052	104	6-May-21	TRUE
0,013	104	7-May-21	TRUE

STEP 4: Copy the selected data in the BWStat tool

- Go back to the BWStat webpage
- Select Past/Edit data
- Select Comma or Point for indication of decimals (default is Comma but it may depend on your version of Excel
- In the txtdata box delete all data currently in the tool
- Copy your data in this box
- Check the box 'Use dataset!' (this is an essential step and performs the actual selection of data to be analysed)
- The selected data will appear in BWStat as follows:

STEP 5: Start the analysis

- First, choose the imputation method to be used for samples below the limit of detection. Always select 'BWStat/EN689 (ROS)'. Within this method all samples below the limit of detection will be substituted by new values, based on the distribution of samples above the limit of detection by 'Regression on Order Statistics (ROS)'. More detailed information on this method can be found in EN-689.
- Check the box 'Analyse dataset!'
- Click on Numerical results
- This will appear in BWStat as follows:

- All data you will need for the evaluation of compliance with the OELV is available on this page

STEP 6: Select the information you need on from the "Numerical results" page

- You will need the following information to be added to summary page in the collection sheet. For each item a screenshot is taken where to find the information:
  - Number of quartz samples
  - Number of quartz samples above the OELV

```
Screening test:

Total number of samples: 6
OEL: 0.1
Number of samples below 10% OEL: 1
Number of samples between 10% OEL and OEL: 5
Number of samples above OEL: 0
Lognormal: Yes
Normal: Yes
```

  - Arithmetic mean respirable quartz (AM) [mg/m^3]
  - Geometric mean respirable quarts (GM) [mg/m^3]
  - Geometric standard deviation (GSD)

```
Group compliance test:

Geometric mean: 0.01885188
Geometric standard deviation: 1.900306
Arithmetic mean: 0.02266667
Arithmetic standard deviation: 0.01623166
Minimum: 0.009
Maximum: 0.052
Range: 0.043
Median: 0.0155
```

  - UTL$_{95,70\%}$ respirable quartz [mg/m^3]

```
UTL95,70 value: 0.077
Conclusion (utl): UTL95,70 < OEL:
statistical compliance
```

  - OELV respirable quartz [mg/m^3]

Enter occupational exposure limit:

0,1

STEP 7: Enter this information into the red coloured worksheet 'SEG list' and make decision on compliance or non-compliance based on BWStat parameters

This will appear in the in the worksheet "SEG list" as follows:

	A	B	K	L	M	N	O	P	Q	R
1	**Summary from statistical evaluation in BWStat (6 or more san**									
2						**Quartz exposure**				
3	**List SEG's**	Number of workers in this SEG	Number of quartz samples	Number of quartz samples above the OELV	Arithmetic mean respirable quartz (AM) [mg/m3]	Geometric mean respirable quartz (GM) [mg/m3]	Geometric Standard Deviation respirable quartz (GSD)	UTL95,70% respirable quartz [mg/m3]	OELV respirable quartz [mg/m3]	Respirable quartz compliant with OELV?
4	Test SEG 1		6	0	0,023	0,019	1,90	0,077	0,100	yes
5	Test SEG 2								0,100	

- More detailed information on the decision on compliance or non-compliance can be found as a comment in cell R3, and elsewhere in this protocol:
  - Non-compliant if:
    - one or more samples above the OELV
    - or UTL95,70% above the OELV
  - Compliant if:
    - all samples <OELV
    - and UTL95,70% below the OELV

Second example

In case we also analyse the second example as mentioned in the beginning of this chapter we will get the results below:

For Similar Exposure Group 2 (SEG2), the following six quartz measurement results are available:

- 0.040 mg/m^3
- 0.008 mg/m^3
- 0.052 mg/m^3
- 0.011 mg/m^3
- 0.025 mg/m^3
- 0.073 mg/m^3

	A	B	K	L	M	N	O	P	Q	R
1	**Summary from statistical evaluation in BWStat (6 or more san**									
2						**Quartz exposure**				
3	**List SEG's**	Number of workers in this SEG	Number of quartz samples	Number of quartz samples above the OELV	Arithmetic mean respirable quartz (AM) [mg/m3]	Geometric mean respirable quartz (GM) [mg/m3]	Geometric Standard Deviation respirable quartz (GSD)	UTL95,70% respirable quartz [mg/m3]	OELV respirable quartz [mg/m3]	Respirable quartz compliant with OELV?
4	Test SEG 1		6	0	0,023	0,019	1,90	0,077	0,100	yes
5	Test SEG 2		6	0	0,035	0,026	2,41	0,180	0,100	no
6	User Defined 3								0,100	

In the second example the SEG is non-compliant with the OELV, despite none of the actual samples exceeded the OELV. However, the exposure variability is high and therefore the Upper Tolarance Limit (UTL$_{95\%,70\%}$) is above the OELV.

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Glossary

AM	Arithmetic Mean
APF	Assigned Protection Factor (for respiratory protective devices)
BWStat	MS-Excel tool for evaluation of exposure data & compliance with the OELV
EU-GDPR	EU General Data Protection Regulation
FTIR	Fourier Transform Infrared Spectroscopy
GM	Geometric Mean
GSD	Geometric Standard Deviation
MCE	Mixed Cellulose Ester (filter)
NEPSI	European Network for Silica
OEL/OELV	Occupational Exposure Limit (Value)
PVC	PolyVinyl Chloride (filter
RCS	Respirable Crystalline Silica
ROS	Regression on Order Statistics
SEG	Similar Exposure Group
STEL	Short Term Exposure Limit
TWA	Time Weighted Average
UTL	Upper Tolerance Limit
XRD	X-ray diffraction

Annexes

Annex 1 Instructions and minimal requirements for external contractors

This sheet summarizes relevant items in case sampling and/or analysis is subcontracted to external parties. It will cover four items: (1) sampling- and analytical methods, (2) measurement strategy, (3) practical sampling instructions, and (4) data handling.

Sampling- and analytical methods

Sampling method	- Measurement of respirable dust conform the International standard ISO 13137 (2013). More guidance can be found in Chapter 4 of the protocol. - The choice of sampling method will depend national and/or company regulations, but also on the expected respirable dust concentration and its crystalline silica content. Guidance can be found in Chapter 4 of the protocol.
Dust weighing	- A calibrated analytical balance with a resolution of (at least) 0.1 mg for foam collection medium and (at least) 0.01 mg for a filter will be needed; - Both pre- and post-weight of filters should be documented, not weight difference only.
RCS analytical method	- Analysis of respirable crystalline silica conform the international standards and published methods. More guidance can be found in Chapter 4 of the protocol; - The choice of analytical method (Fourier Transform Infrared spectroscopy (FTIR) and X-ray diffraction (XRD)) will depend on the expected respirable dust concentration and its crystalline silica content. Guidance can be found in Chapter 4 of the protocol; - Analytical limit of detection for RCS should be specified; - External laboratories should be certified for RCS analyses.

Measurement strategy

Similar Exposure Groups (SEGs)	- Workforce should be classified into groups with assumed similar exposure (SEGs); - Sample all SEGs with potential RCS exposure; - Sample a representative selection of workers within each group on multiple days (random sampling).
Type of sampling	- Personal sampling only
Sampling duration	- Full-shift sampling (6-8 hour sampling); - If longer than an 8-hour shift, sample at least 75% of the duration of the shift.
Number of samples	- A minimum of 3 samples per SEG; - Preferably 6 samples per SEG
Number of workers per SEG & number of samples per worker	- Sample multiple workers over multiple days; - Try to collect repeated samples per individual for each job title

Practical sampling instructions

Flow measurement	- Record the sampling flow rate both at the start and at the end of sampling; - Measure the flow rate over the loaded sampler.
Field blanks	- During each measurement day at least one field blank should be collected. See Annex 3 of the protocol for detailed instructions on field blanks.

Data handling

Sampling form	- Make use of the sampling form in Annex 2 of the protocol and record for each sample all items as mentioned on the form.
Collection sheet	- Summarize and deliver all data in the format of the Collection sheet. Detailed instructions can be found in Annex 2 of the protocol; - Enter in the text fields all relevant information important for interpretation of the data.
Summary	- Evaluate all exposure data per SEG according to EN-689. Guidance can be found in Chapter 6 of the Protocol.

Annex 2 Example of SEG definition from one of the NEPSI sectors

Below the Similar Exposure Group as has been defined within the IMA Dust Monitoring Project within the NEPSI sector IMA-Europe

General category	Example of tasks/activities description
1. Quarry operator (outdoor)	Works in quarry Load dumper using an excavator Feed the crusher in quarry Transport raw materials to the unloading places using a dumper or wheel loader
2. Crusher operator (indoor)	Feed the crusher in plant Control of crusher in plant
3. Wet process operator	Supervise the process in a control room Sampling and control of sieve
4. Dry process operator	Supervise the process in a control room Sampling and control of screen or sieve
5. Miller operator	Supervise the process near the mill
6. Bagging operator	Supervise automatic bagging machines and bulk loading into 25/50kg bags Add bag to semi-automatic bagging machine Fill powder bags and cover pallets with plastic films Handle bags on pallets Stock the product in the storage building
7. Transport/bulk loading	Fill the hopper with end product using a wheel loader Supervise the conveyor belt feeding ship/train/truck Load goods in lorries and organize the storage operation
8. Foreman/plant management staff	General office work Supervise and organize plant activities Control of process and product
9. Maintenance	Control of plates in the crusher, new sieves, dust sealing, checking and cleaning inside enclosures In charge of mechanical and electrical maintenance in plant/office/quarry
10. Multi-skilled	The multi-skilled operator is an operator who does several job functions, none of which amounting to or exceeding 50 % of his working time.
11. Laboratory workers	Samples collection in the plant, analysis & quality control of the samples.
12. Research and Development	Development of new products in a pilot plant Running tests on an installation for technology or product improvement Applications of products on laboratory scale.
13. Plastification	Manufacture of prepared body from clay.

Annex 3 Sampling form (print on both sides)

NEPSI Sampling form for respirable crystalline silica (front side)	
General project information:	
Company	
Site	
Project coordinator	
Sampling method:	
Type of sampler	
Sample collection material	
Pump (type and ID)	
General sampling information:	
Date of sampling	
Weather conditions	Temperature(°C): Humidity(%): Wind speed(m/s):
Technician ID	
Sample ID	
Type of measurement	full-shift personal sampling
Department/sample location	
Job function (SEG)	
Worker ID	
Shift (circle the relevant shift)	Day/morning/afternoon/evening/night/weekend
Shift length (hrs)	

Sampling details:			
Start of sampling		End of sampling	
Filter weight (mg)		Filter weight (mg)	
Flow at start (l/min or rpm*)		Flow at end (l/min or rpm*)	
Start time (hr:min)		Start time (hr:min)	
Clock time on pump (min)		Clock time on pump (min)	

Quartz analytical information:	
Further analysis needed	O yes O no
Lab ID/name	
Analytical technique	O XRD O FT-IR

* Flow of a CIP-10 is checked by measuring rotational speed in rounds per minute (rpm)

		NEPSI Sampling form for respirable crystalline silica (back side)										
Tasks during sampling with relevance for the interpretation of sampling results												
		Control measures relevant for this sample (within the occupational hygiene strategy)										
Time (hr:min)	Short description of workers activity (type and place of work)	Duration of the task (min)	Enclosure of source	Local Exhaust Ventilation (LEV)	Area ventilation	Isolation/segregation of workers from the source	Increase distance from the source	Reduction of exposure time	Change in working methods	Maintenance & housekeeping	Education & training	Respiratory protective equipment (RPE)
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no
		O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no	O yes O no

When checked 'yes' on any of the above control measures, specify below the relevant details of the control measures (e.g. which type of RPE was used):

Annex 4 Data Collection Sheet instructions

When collecting dust sampling results as part of the NEPSI monitoring protocol, each participating company should use the collection sheet. In this instruction you will find all the information you will need when using the collection sheet.

The collection sheet and these instructions for using the collection sheet are linked to the NEPSI Respirable Crystalline Silica Monitoring Protocol. For details on procedures and background information please refer to that protocol.

The MS-excel file has in total 16 worksheets:

- Two grey colour tabbed works sheets
    o LOD & Field blanks
    o Collection sheet
- One red colour tabbed work sheet
    o SEG list
- Nine green colour tabbed work sheets
    o Analytical technique
    o RPE
    o Sample collection material
    o Samplers
    o Countries
    o NEPSI sectors
    o Shifts
    o Type of measurements
    o YesNo
- Four yellow colour tabbed work sheets

The green colour tabbed worksheets contain the drop-down lists for the variables in the collection sheets . Some of them don't need to be edited (Countries, NEPSI sectors, Shifts, Type of measurents & YesNo). Other drop-down lists can be modified and allow 'User defined' elements in the list. Below per variable instructions will be given when and how to make changes, if applicable.

The red colour tabbed worksheet is the list of Similar Exposed Groups (SEGs) for your NEPSI sector of company. In the protocol you can find information what a SEG is. Very likely, the definition of SEGs need to be done only once and the SEG list can be used in all subsequent sampling campaigns. The worksheet 'SEG list' can also be used for entering the results of the statistical evaluation using BWStat (see chapter 6 of the protocol).

The two grey colour tabbed worksheets must be filled with sampling information and need to be used in each sampling campaign.

First there are some general instructions, followed by more detailed instructions for each of the worksheets. Please read these instructions carefully when first using the collection sheet and keep these instructions as reference document afterwards.

General instructions

1. First define your SEGs (for instructions see the NEPSI Respirable Silica Monitoring Protocol) and enter the SEG names in column A of the worksheet 'SEG list'. Once entered here, the correct SEG names will show up in the collection sheet. Importantly, the worksheet 'SEG list' need to be filled with this information before entering the measurement data in the collection sheet.

2. Second, start with the worksheet 'LOD & Field blanks'. Information on analytical limits of detection and results of field blanks are important for proper interpretation and handling of the data. See the detailed instructions below for this particular worksheet. All cells to be filled out are marked with a yellow colour. White cells mostly contain a formula and most of these cells have a write protection. Importantly, do not enter data from field blanks in the regular collection sheet. Instead, enter this information in the worksheet 'LOD & Field blanks'.

3. Third, start entering information for each sample taken in the worksheet 'Collection sheet'. There is one line for each sample. See the detailed instructions below for this particular worksheet. All cells to be filled out are marked with a yellow colour. White cells mostly contain a formula and most of these cells have a write protection. Again, do not enter data from field blanks in the regular collection sheet.

4. Fourth, once all sampling information has been entered in the worksheets 'LOD & Field blanks' and 'Collection sheet', data is ready for statistical evaluation using BWStat. All information needed for input into BWStat is summarized into the four yellow worksheets, one for each type of analyte (dust, quartz, cristobalite, and tridymite). Most companies will only use the worksheets for dust and quartz, but in case cristobalite and/or tridymite will be relevant separate analysis can be done for these analytes as well. The yellow worksheets put all information in the exact format for analysis in BWStat. More detailed instruction for using these worksheets can be found in chapter 6 of this protocol. Output of BWStat can be entered in the worksheet 'SEG list', as is also explained in more detail in chapter 6.

Instructions worksheet 'LOD & Field blanks'

The following information should be entered in this worksheet:

1. Choose in cell F3 yes or no if all samples should be corrected for the available field blanks. The default option in the worksheet is 'no'. We recommend to choose 'yes'. If you do, the numbers in line 54 will be used to correct all the samples entered in the collection sheet. For instance, if the mean weight difference of all field blanks will be 0,01 mg, the filter weight of all samples in the collection sheet will be subtracted with 0,01 mg. Importantly, first evaluate the information on field blanks before changing this option into 'yes'. Make sure that the information on field blanks is correct, as it will influence the final concentrations for respirable dust and respirable RCS of each individual sample.

3	Do you want to correct all you samples for field blanks	no

2. Enter in lines 8-10 the analytical limits of detection for weighing procedures and analytes. Again, this is important information as it will detect which samples in the collection sheet will be below or above the limit of detection. If needed, check with your (external) laboratory what the precision of the balance is, which type of analytical procedures have been used (FTIR or XRD), and what the exact limit of detection is for each relevant analyte (quartz, cristobalite, tridymite).

6	INFORMATION ON THE ANALYTICAL LIMIT OF DETECTION:				
7			Dust	Quartz	Cristobalite	Tridymite
8	Balance (mg)					
9	FTIR (mg)					
10	XRD (mg)					

3. Enter in lines 18-50 all relevant information on field blanks. See detailed instructions below what a field blank is and the exact procedures for field blanks. For each field blank, the following information should be entered:

   a. Date of the field blank
   b. Sample ID of the field blank
   c. Short free text for additional information or a short remark, if applicable
   d. Pre-weight of the filter
   e. Post-weight of the filter
   f. If relevant, the analytical results of the analytes (quartz, cristobalite and/or tridymite) if the field blank was sent to the laboratory for further analysis. **IMPORTANTLY**, if the analytical result of quartz, cristobalite or tridymite is below the limit of detection, **enter zero** in these cells. If you would enter the analytical limit of detection in these cells, all samples in the worksheet 'Collection sheet' will be corrected with this value and there will be an overcorrection of the actual samples.

13	FIELD BLANKS						ANALYSIS OF FIELD BLANKS		
14	For information on field blanks see instruction								
15									
16	Date	Field blank ID		Pre-weight (mg)	Post-weight (mg)	Amount (mg)	Quartz (mg)	Cristobalite (mg)	Tridymite (mg)
17	1-Dec-20	sample ID	additional info	2,000	2,200		0,001	0,002	0,003
18									
19									
20									
21									

Please do not enter information in the orange box in this worksheet. It automatically selects the relevant information needed for statistical evaluation in BWStat. Based on this information all actual measurements in the worksheet 'Collection sheet' will be identified as being below or above the limit of detection. More detailed information can be found in chapter 6 of this protocol.

	L	M	N	O
Input parameters LOD for calculations with BWStat				
Summary LOD for each analyte	mg			
Dust (mg)				
Quartz (mg)				
Cristobalite (mg)				
Tridymite (mg)				

<u>What is a field blank?</u>

A field blank is a filter handled in exactly the same way as a normal sample, **except** for the actual sampling itself.

<u>Why do we need field blanks?</u>

Information on the analytical limits of detection is only part of the information needed to calculate the limit of detection (LOD) for a dust sampling method. Irregularities in other steps of the sampling are not incorporated in the analytical limit of detection, for instance:

- Pollution of the filters when sampling heads are not properly cleaned after previous sampling, resulting in extra dust on the filters
- When removing filters out of the sampling head, slight damage of the filters might occur resulting in a small decrease in filter weight

When collecting and reporting field blanks in the excel sheet we will be able to detect problems **during sampling**, if any.

<u>How many field blanks should be taken:</u>

- During each measurement day at least one field blank should be collected
- When dust samples are further analysed in the lab at least 20% of all available (gravimetric) field blanks should be analysed for the relevant analytes for your company (quartz, cristobalite, etc), with a minimum of 1 per campaign. When taking 10 field banks within a sampling campaign, 2 field blanks should be analysed for each analyte.

<u>Handling field blanks when also using weighing blanks in the lab</u>

Some companies also use weighing blanks in their lab to account for differences in weighing conditions during pre- and post-weighing of the filters. Apparently, there has been some confusion how to handle field blanks when samples are also corrected for weighing blanks in the lab.

THE GOLDEN RULE IS AS FOLLOWS: FIELD BLANKS SHOULD BE TREATED AS ANY OTHER REGULAR SAMPLE.

Thus: if you use weighing blanks to correct your regular samples, also correct your field blanks in exactly the same way. The best thing to do is not to identify field blanks for the weighing personnel to avoid any confusion.

<u>Working procedure for field blanks:</u>

- Pre-weigh filter as other filters
- Put the filter in the sampling head as other filters
- Take the field blank with you to the field as other samples. Distribute the pumps and samples to the workers in a dust free environment on the production site, for instance an office room or coffee break room. Handling samples and field blanks on the actual dusty working environment may cause pollution on the samples <u>before</u> the actual sampling starts.
- Unpack the field blank in the field as other samples (if relevant). Do not connect the field blank to a running pump (no active sampling) and do not leave the field blank unpacked in the field during the sampling day (no passive sampling). After unpacking the field blank immediately treat the field blank as a sample which was just returned from the actual sampling (pack as other samples).
- Transport the field blank back to the lab in exactly the same way as all other samples
- Post-weigh filter as other filters (after reconditioning like all other samples)

- Enter all information in the collection sheet 'LOD and field blanks'
- Select field blanks for further analyses
- Send the filter of the field blank to the lab with all other filters to be analysed
- Enter the results of the analyses in the collection sheet 'LOD and field blanks'
    - Fill in the date of the field blank
    - Enter the sample ID for future identification and tracking
    - Add additional information if necessary (free text)
    - Enter pre- and post-weight of the filter. Make sure you receive actual weight information of the field blanks from the analytical laboratory or contractor in order to make any calculations on the LOD. Some laboratories only report a field blank as being below the limit of detection, without specifying information on pre- and post-filter weight. Such limited information is insufficient for estimating LOD.

When all information had been entered in the worksheet 'LOD & Field blanks' the information is summarized in lines 52-53:

- The limit of detection (LOD) is the lowest concentration of the analyte that can be reliably detected and distinguished from zero. It is calculated as the mean of the blanks + three times the standard deviation of the blanks. For dust this information will be used to identify which samples in the worksheet 'Collection sheet' are below or above the limit of detection (for RCS this will be done based on the analytical limit of detection in lines 9 and 10 of this worksheet.
- Blank correction: the mean value of all field blanks. This information will be used to correct all individual samples in the worksheet 'Collection Sheet'. Make sure that all field blank information is correct, as this will impact all individual sampling results.

52	Limif of Detection (LOD)							
53	Blank correction				0,000	0,000	0,000	0,000

Instructions worksheet 'Collection sheet'

General remark

One of the goals of the collection sheet is to record data for future use and optional to pool data from multiple sites and/or companies. Some of the information that is required in the collection sheet does not change within one campaign but still needs to be filled in for each individual sample (e.g. NEPSI sector, Country, Company, Site, and probably also Sampler, Sample collection material). In case data from multiple campaigns within a site, from multiple sites or even multiple companies need to be pooled, this information will be important contextual information of the data that needs to be available. Without this information, pooling of data will be hampered significantly.

NEPSI sector

Your NEPSI sector can be chosen from the drop-down menu. The drop-down list is defined in the green colour tabbed worksheet 'NEPSI sector'. As all the NEPSI sectors have been listed here, there won't be a need for editing this drop-down list. In column B a country code will appear as soon as you have chosen a country.

Country

The country can be chosen from the drop-down menu. All European sectors have been predefined in the green colour tabbed worksheet 'Countries'. As all European countries been listed here, there won't be a need for editing this drop-down list. In column D a country code will appear as soon as you have chosen a country.

Company and Site

For further identification of the samples, you can add the name (or a code) for a specific company and/or a specific site within a company. This can be entered as number or free text.

Sampler

In this column specify which type of sampler has been used, using the drop down menu. The drop-down list is defined in the green colour tabbed worksheet 'Samplers'. If your sampler is not specified in the drop-down menu, please go to the green colour tabbed worksheet 'Samplers' and change one of the 'User Defined' options in the name of your sampler. This is then added to the drop-down list as used by the Collection sheet.

Sample collection material

In this column specify which type of filter has been used, using the drop down menu. The drop-down list is defined in the green colour tabbed worksheet 'Sample collection material'. If your filter/foam is not specified in the drop-down menu, please go to the green colour tabbed worksheet 'Sample collection material' and change one of the 'User Defined' options in the name of your filter/foam. This is then added to the drop-down list as used by the Collection sheet.

Date

Enter the date for each sample using day – month – year format.

Technician ID

For reasons of traceability you may want to add the name (or code) of the technician involved in taking the sample.

Sample ID

Each sample should be given a unique sample ID. This sample ID can be used during the actual sampling and for identification of the sample for the laboratory.

Type of measurement

Only full-shift personal measurements will be relevant within the framework of the NEPSI RCS monitoring protocol. This can be chosen from the drop-down menu. There are two other options in the drop-down menu, in case some static or task-based sampling has been done and you want to document all samples within a campaign in the same collection sheet. Importantly, compliance testing conform EN-689 is only valid for personal samples and can be analyseD with BWStat.

Sample location

Is a free text field for more specific information on the exact department or location of the sampling, if needed.

Job Function (SEG)

In this column the job function or Similar Exposure Group (SEG) of the worker should be entered for the main task performed <u>during the sampling</u>. The name of the job function or SEG can be chosen from the drop-down menu. Importantly, each NEPSI sector needs to define their own SEGs. Once you have defined your SEGs, please go to the red colour tabbed worksheet 'SEG-list' and change the 'User Defined' options in the name of your SEGs. This is then added to the drop-down list as used by the Collection sheet. The worksheet 'SEG list' should therefore be filled before entering measurement data in the Collection sheet.

Worker ID

It is important that each worker participating in the sampling program is given a <u>*UNIQUE WORKER CODE!!*</u> A unique worker code will only be assigned to one and only one individual. Not only during one sampling campaign, but it has to be retained during the follow-up of all other campaigns. The same worker code has to be assigned to the same worker and not to any other worker. Worker codes should also be different between sites.

A personal registration number in the staff register of the company is a good example of such a unique worker code (if personal registration numbers are not reused when workers leave the company).

So it is very important that we can distinguish worker A and worker B, not only during one specific campaign, but we also need to be sure that worker B is the same worker B in all campaigns of that particular company even when a worker moves from site A to site B.

If unique worker codes have been assigned, the opportunities for the statistical analyses of the data will strongly increase.

Shift

Enter the relevant shift using the drop down menu: day, morning, afternoon, evening, night. The options in the drop-down list have been defined in the worksheet 'Shifts'. In general, there will be no need to modify this drop-down list, but it is possible when needed.

Shift length (hours)

For each sample the total regular shift length should be entered (do not enter the actual sampling time in this column!). So if a regular working day is 8 hours, please enter '8' in this column. If continental shift patterns are relevant for your site (3 x 12 hours or 4 x 12 hours), please enter '12' in this column.

Filter Weight before sampling (mg)

In this column enter the pre-weight of the filter. Make sure the weighing procedure is followed as described in the Protocol.

Filter Weight after sampling (mg)

In this column enter the post-weight of the filter. Make sure the weighing procedure is followed as described in the Protocol.

Weight collected dust (mg)

The weight collected dust will be calculated automatically. In case the laboratory does not report pre- and post-weight of the filter, but only weight difference, the calculation can be overruled by entering the reported weight difference in the column ('weight collected dust (mg)'). However, if pre- and post-weight of filters is available it is strongly advised to enter this more detailed information, as this will increase the possibilities for quality checks en control.

Weight collected dust corrected for blanks(mg)

If you choose the option to correct all samples for the field blanks in the worksheet 'LOD & Field blanks', the corrected weight collected dust will be calculated automatically (by subtracting the mean result of all field blanks from the sample weight).

Measured Flow rate at start sampling

In this column note down the <u>measured</u> flow rate in litres/minute at the start of the sampling. In case of a CIP10, note down the flow rate in litres/minute that correspond to the reading in rounds per minute (rpm).

Measured Flow rate at end sampling

In this column note down the <u>measured</u> flow rate in litres/minute at the end of the sampling. In case of a CIP10, note down the flow rate in litres/minute that correspond to the reading in rounds per minute (rpm).

Average Flow rate

The average flow rate during the sampling day will be calculated automatically. Please make sure that you enter the actual flow rate for each sample. The best practice for checking and estimating flow rate may differ, dependent on the sampler being used. Follow the best practice for your type of sampling equipment. In principle the calculation in the collection sheet can be overruled by entering a value in this column. However, it is strongly advised to enter the more detailed information and use the calculation option, as this will increase the possibilities for quality checks and control.

Sampling time on

In this column enter the exact time when the sampling was started using the time format, for instance 8:20 hours (do not type just 8 when you mean 8:00)

Sampling time off

In this column enter the exact time when the sampling was stopped using the time format, for instance 16:20 hours (do not type just 16 when you mean 16:00)

Sampling duration time (min)

The sampling duration will be calculated automatically. In principle the calculation in the collection sheet can be overruled by entering a value in the cell. However, it is strongly advised to enter the more detailed information and use the calculation option, as this will increase the possibilities for quality checks and control. If the sampling on a worker is stopped during lunch time you could choose for the option to enter the total sampling time here (sum of the sampling times before and after lunch break). However, it is preferred to continue sampling during lunch break (with the worker still carrying the pump in the lunch break area).

Sampled Volume (l)

The sampled volume will be calculated automatically. In principle the calculation in the collection sheet can be overruled by entering a value in the cell. However, it is strongly advised to enter the more detailed information and use the calculation option, as this will increase the possibilities for quality checks and control.

Calculated dust concentration (mg/m³)

The time weighted average (TWA) dust concentration will be calculated automatically. In principle the calculation in the collection sheet can be overruled by entering a value in the cell. However, it is strongly advised to enter the more detailed information and use the calculation option, as this will increase the possibilities for quality checks and control.

8-hour TWA dust concentration (mg/m³)

The 8-hour time weighted average dust concentration will be calculated automatically, by using the regular shift length. If a regular shift will be very different from a regular 8-hour shift, the 8-hour TWA dust concentration will be different from the calculated dust concentration. For instance, if your workers normally work on 12-hour shifts, the 8-hour TWA dust concentration will be higher, as the OELV has been set for an 8-hour exposure. If all your workers only work on regular 8-hour shifts, both concentrations will be the same.

Analyses

When samples are sent to the lab for further analysis, enter the relevant information in the appropriate columns:

- Quartz
- Cristobalite
- Tridymite

Quartz, Cristobalite or Tridymite Technique

In this columns enter the type of lab analyses, using the drop down menu. The drop-down list is defined in the green colour tabbed worksheet 'Analytical technique'. If your sampler is not specified in the drop-down menu, please go to the green colour tabbed worksheet 'Analytical technique' and change the 'User Defined' option in the name of your analysis. This is then added to the drop-down list as used by the Collection sheet.

Weight Quartz, Cristobalite or Tridymite (mg)

In this column enter the results of the lab analyses in milligrams. It is important that lab results below the analytical limit of the detection (LOD) are clearly marked in this column, preferably by entering the analytical limit of detection. When entering the analytical the analytical limit of detection in this field, samples will be treated in the statistical analysis as being below the LOD.

Weight collected dust corrected for blanks(mg)

If you choose the option to correct all samples for the field blanks in the worksheet 'LOD & Field blanks', the corrected weight collected RCS will be calculated automatically (by subtracting the mean result of all field blanks from the sample weight.

Concentration Quartz, Cristobalite or Tridymite (mg/m³)

The time weighted average (TWA) concentration of the analytes will be calculated automatically. In principle the calculation in the collection sheet can be overruled by entering a value in the cell. However, it is strongly advised to enter the more detailed information and use the calculation option, as this will increase the possibilities for quality checks and control.

Percentage Quartz, Cristobalite or Tridymite (%)

The percentage of analyte in the dust will be calculated automatically.

8-hour TWA concentration Quartz, Cristobalite or Tridymite (mg/m³)

The 8-hour time weighted average analyte concentration will be calculated automatically, by using the regular shift length. If a regular shift will be very different from a regular 8-hour shift, the 8-hour TWA dust concentration will be different from the calculated dust concentration. For instance, if your workers normally work on 12-hour shifts, the 8-hour TWA dust concentration will be higher, as the OELV has been set for an 8-hour exposure. If all your workers only work on regular 8-hour shifts, both concentrations will be the same.

Information on relevant tasks during sampling (free text)

Here you can summarize relevant information from the back of the sampling form in case specific tasks or activities have been performed that will be important for proper interpretation of the sampling result.

Respiratory protection worn during specific tasks

Select yes or no if the worker used respiratory protection during a specific task during the day of sampling. If so, further specify in the previous free text cell for which tasks this was relevant. As respiratory protection was only used during part of the day, no correction is possible of the measured exposure concentration, as they will reflect the mean exposure during the entire shift, and respiratory protection was only used during specific parts of the day.

Respiratory protection worn during the entire shift

Select yes or no if the worker used respiratory protection during the entire day of sampling. If so, it is possible to correct the measured concentration using the Assigned Protection Factor connected to the specific respiratory protection device that was used.

Type of respiratory protection worn and Assigned Protection Factor (APF)

In this column specify which type of respiratory protection that was used, using the drop down menu. The drop-down list is defined in the green colour tabbed worksheet 'RPE'. If your type of respiratory protection is not specified in the drop-down menu, please go to the green colour tabbed worksheet 'RPE' and change one of the 'User Defined' options in the name of your type of respiratory protective device. This is then added to the drop-down list as used by the Collection sheet.

The protection factor varies per type of respirator. In the worksheet 'RPE' the commonly used protection factor for each type of respirator has already been added, based on the 'Assigned Protection Factor (APF)' (the protection to be expected in actual field conditions). This protection factor is automatically added in the collection sheet if a respirator is selected. For the option Supplied Air Respirator no APF has been entered yet, as this largely depends on the exact type being used, and should be entered by the user. In case you enter a new type of respirator in one of the two 'User Defined' options in column A of this worksheet, you also should add the APF in column B.

Corrected concentrations (dust, quartz, cristobalite, tridymite)

If the respiratory protection was worn during the entire shift, the corrected concentrations for respirable dust, quartz, cristobalite and tridymite will be calculated by dividing the concentration with the Assigned Protection Factor (APF) for the selected type of respiratory protection. This is only done, however, if the option 'yes' was selected in the column 'Respiratory protection worn during the entire shift'. If not, no corrected concentrations will be calculated. If respiratory protection was only worn during specific tasks during the sampling day, it would be totally incorrect to correct a full-shift average concentration, as the protection factor was only relevant for the duration of that specific task.

Summarized information on control measures (free text)

Here you can summarize relevant information from the back of the sampling form with regard to the control measures in place that will be important for proper interpretation of the sampling result.

General comments (free text)

Here you can add any other information that will be important for proper interpretation of the sampling result, for instance if any process disturbance took place during the sampling day, specific process characteristics, etcetera.