Draft Document
Revised: February 2015 by A Lamba

Draft Inhalation Monitoring Data Collection Guidelines

Developed by the U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
Risk Assessment Division[1]

INTRODUCTION

At times, OPPT might request inhalation monitoring or sampling data to help evaluate the health risk to employees from exposure to new or existing substances covered under the Toxic Substances Control Act (TSCA).

To help ensure that the appropriate data is received to allow OPPT/RAD to conduct its review and to minimize the need for additional efforts on the part of the submitter, the following guidance provides information on developing an inhalation monitoring study protocol prior to conducting monitoring. This document provides general guidance to environmental, safety, and health professionals for conducting monitoring studies to assess inhalation exposure concerns in the workplace. It does not cover all individual situations or special circumstances. Monitoring studies should be undertaken by a qualified individuals like industrial hygienists who have been trained in the evaluation and control of workplace exposures.

If monitoring has already been completed, improvements or additions may need to be made to the final monitoring report so that all necessary aspects are addressed before OPPT/RAD can evaluate the study. Incomplete protocols and/or results may not be adequate for OPPT/RAD to fully evaluate exposures or exposure potential, and may require additional work on the part of the submitter. Although comprehensive exposure assessment is not needed or required by OPPT/RAD, all monitoring studies should ideally fit within the structure of a larger exposure assessment plan and implementation of a complete industrial hygiene program at the worksites.

MONITORING PROTOCOL

Use the following outline and questions to assist in the development of the inhalation monitoring study protocol. Your monitoring report should provide pertinent information for Sections A-F below.

[1] A 2002 draft of these guidelines was developed by the Chemical Engineering Branch (CEB). CEB was integrated with the Risk Assessment Division in 2014.

A. Objective of the Monitoring Study:

Consider the following questions to determine and identify the objective of the monitoring study. Clearly describe the objective of the monitoring study in the monitoring report you

- What are the final data results sought through this study?
- What are the exposures of concern?
- What is the target population of workers?
- Is the study designed to assess acute or chronic exposures? This will affect the pattern and duration of sampling, and also possibly the media used to collect the samples.
- Is the objective to determine average or worst-case exposures to the substance?
- If the data are from a previous study, the purpose of the original data collection or study may have been different than the current objective.
- Was personal monitoring conducted in a way that will give an accurate picture regarding exposure to the substance of concern, particularly if the original purpose of the monitoring study was different?
- If the purpose of monitoring was different, such as prompted by a specific, unrelated incident, was the monitoring method one which will accurately characterize the exposures currently under evaluation? For example, are long-term exposures (months or years), shift-long exposures, or short-term exposure (15 minutes or less) of the greatest interest in evaluating exposures?
- Although not necessary for OPPT purposes, it may be useful to consider how the objective of this monitoring study fits logically into a larger exposure assessment framework for the workplace. As noted in the introduction, any individual sampling plan or objective should be part of a larger exposure assessment strategy for the entire workplace. This exposure assessment should include identifying all workplace hazards, developing similar employee exposure groups, conducting baseline exposure monitoring and/or modeling studies where necessary to characterize the hazards, using follow-up monitoring and/or modeling as needed to confirm compliance with relevant exposure thresholds, and evaluating exposures using both the results and professional judgment.

B. Sampling Strategy/Sampling Methods:

Describe the sampling plan and methodology.

- A large number of sampling protocols and methods exist for conducting field industrial hygiene monitoring. These are generally substance-specific methods or methods that are specific to the physical properties of the chemical being sampled (for example, many airborne solids and dusts can be sampled in very similar manner). Both the National Institute of Occupational Safety and Health (NIOSH), see

http://www.cdc.gov/niosh/docs/2003-154/, and the Occupational Safety and Health Administration (OSHA), see http://www.osha.gov/dts/sltc/methods/index.html, have lists of analytical sampling methods that have already been developed. If the substance is a new chemical without an established sampling method, contact an industrial hygiene laboratory or any professional analytical laboratory to get information on developing a new sampling method or adapting an existing method for sampling the new chemical substance. In some cases, analog sampling data (i.e., for a similar substance used in an identical operation) may also be acceptable data.

- Has the sampling method been validated by an independent organization (i.e, NIOSH, OSHA, the American Society for Testing and Materials (ASTM), the International Standards Organization (ISO) etc.)?
- What sampling media or direct reading instrument will be used? What is the strategy that will be used for sample collection, including sample location, flow rates, sampling time, and sample replication?
- Will enough samples be taken to ensure that the results are statistically significant for the population of concern?
- Will a worst-probable or a random sampling strategy be employed?
- Will be samples collected be representative of the the desired fractions, e.g., for particulates, are both inhalable and respirable fractions needed or just one.

1. Guidance on Developing a Sampling Strategy

Once a sampling and analytical protocol has been identified, a sampling strategy must be developed. A number of strategies and methodologies have been proposed to determine the appropriate number of samples that will be necessary to estimate exposure profiles for specific tasks. Although models have been developed to assist with this task, professional judgment is also important in determining the appropriate number of samples to be taken. Before considering the number of samples needed, identify and categorize the major types of processes to be evaluated and the different types of job tasks associated with each of these processes. Worker groupings by specific job tasks are commonly referred to as similar exposure groups (SEGs).[2] Once the major processes, job tasks, and similar exposure groups have been outlined, specific sampling can be planned.

Four sample groups or types should be identified and considered for the sampling strategy:

1. Identify the employees at the greatest risk of exposure to the chemical within the exposure group or job task to be evaluated and collect samples from this subgroup to assess likely maximum exposures.
2. Identify locations in which to conduct process sampling (sometimes referred to as area

[2] Ignacio J. S. & Bullock W. H. (Editors). A Strategy for Assessing and Managing Occupational Exposures. 3rd Ed. AIHA Press. 2006.

sampling) to map possible worker exposures in and around relevant process equipment. This may help to identify one or more job tasks or SEGs where maximum exposures are likely to occur.

3. In addition to sampling for maximum exposures within a job task, it is also prudent to randomly select workers for personal monitoring within the defined job task or SEG in order to determine typical or average exposures in this group (please see section below, "***The Importance of Random Sampling***", for more information on random sample selection).
4. Where relevant, be sure to identify and select workers in non-routine (i.e., maintenance activities) for personal monitoring to determine likely worst-case and typical exposures for these activities, particularly if these non-routine tasks are integral to the identified daily or routine job tasks.

Note: Sometimes it is not possible to determine a maximum risk exposure group. If this is the case, random sampling techniques should be used for sample selection in all similar exposure groups and for process sampling.

2. Determining the Number of Samples to Collect

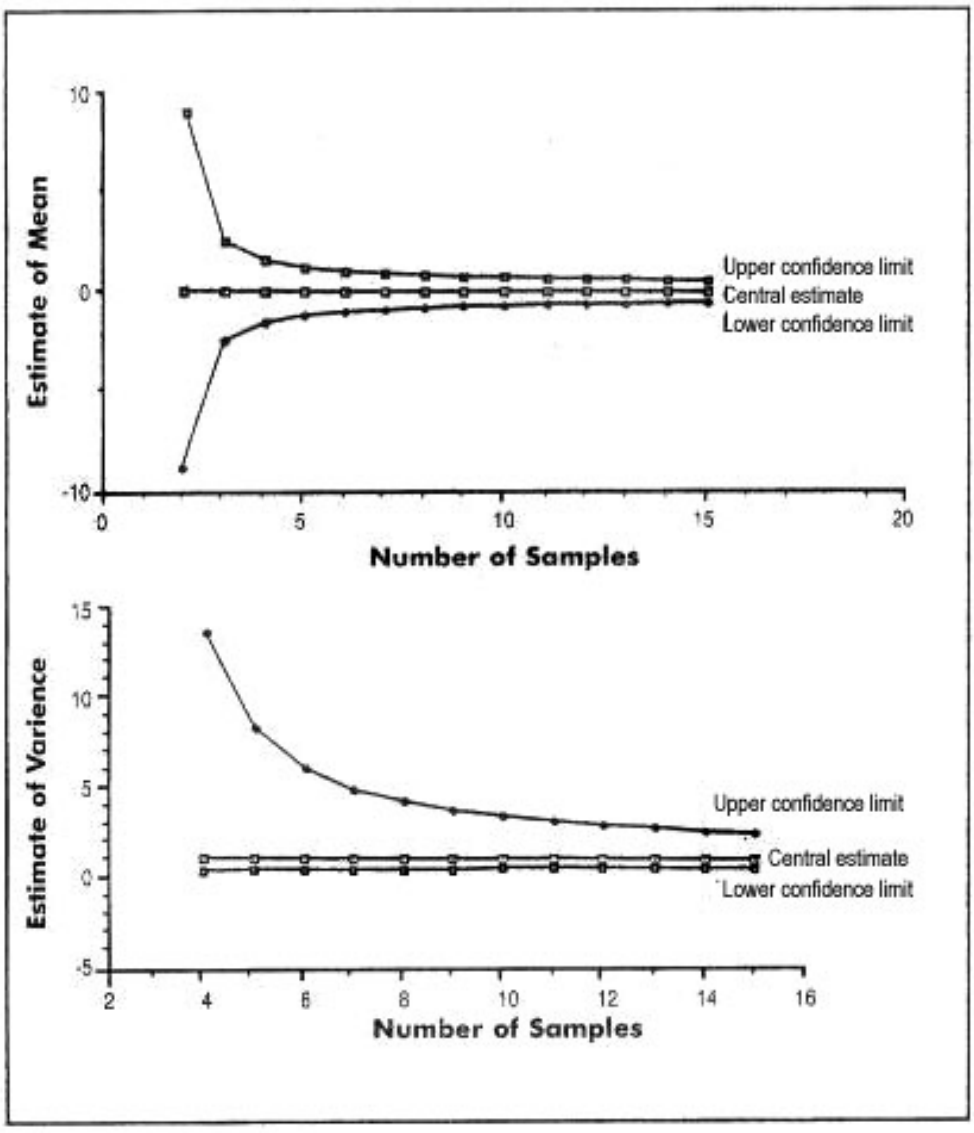
It is important to determine the appropriate number of samples needed to get statistically significant results from a sampling study. The number of samples needed will depend on a number of different factors, including the objective of the monitoring study, the characteristics of the SEG (e.g. degree of homogeneity), and the actual measured levels of exposure relative to an occupational exposure limit (OEL) or threshold of concern.

A Strategy for Assessing and Managing Occupational Exposures,[3] published by the American Industrial Hygiene Association (AIHA), recommends that samples should be collected up to a statistical point of diminishing returns for each sample type or similar exposure group. According to this strategy, statistics show that there will be a point at which additional samples will not significantly improve confidence in the overall results. Assuming a normal population distribution and using a t-table, the maximum value derived from taking additional samples is reached after about 6 to 10 measurements within a defined SEG. **Typically, at least six measurements should be taken for each SEG to ensure with sufficient confidence that exposures for the SEG have been adequately characterized.** If initial measurements demonstrate that exposures are far less than 10% of the threshold of concern or higher than the actual threshold of concern, fewer measurements may be needed. For exposures very near the threshold of concern or OEL, more than six measurements will likely be needed to determine that exposures are, in fact, consistently below the threshold of concern (up to 10 or more measurements). Professional judgment should be used to make this determination,

[3] Ignacio J. S. & Bullock W. H. (Editors). A Strategy for Assessing and Managing Occupational Exposures. 3rd Ed. AIHA Press. 2006.

taking into account factors such as the cost of additional sampling relative to the cost of controls to limit exposures, and the level of statistical confidence in the results that is desired or needed.[4] The chart on the following page shows the increased confidence achieved by increasing the number of samples taken:

Effect of Sample Size on Estimating Population Mean and Standard Deviation[5]



[4] Ibid.

[5]Ignacio J. S. & Bullock W. H. (Editors). A Strategy for Assessing and Managing Occupational Exposures. 3rd Ed. AIHA Press. 2006.

3. If A Minimum Level of 90% Confidence in Sampling Results is Desired

If it is desired or necessary to obtain at least 90% confidence that maximum exposures are the results and may result in accurately characterized by the sampling results for a particular SEG, regardless of exposure monitoring or control costs, the following table can be used to estimate the minimum number of samples that will be necessary to achieve this level of statistical certainty. This table is published by NIOSH in their Occupational Exposure Sampling Strategy Manual, Chapter 3 (1977). If the number of workers in a SEG is known, the table provides the number of samples required to ensure with 90% confidence that at least one individual among those with the highest 10% of exposures for that SEG is contained in the sample set. As indicated above, however, additional samples over 10 within a single exposure group may not provide a great deal of additional confidence in significant additional sampling costs and time to complete the sampling study. Professional judgment should be used to determine cases where more than 10 samples are necessary to evaluate exposures.[6]

Size of Partial Sample for Top 10% Exposure at a Confidence Level of 0.90[7]

Size of Group N	Number of Required Samples
8	7
9	8
10	9
11-12	10
13-14	11
15-17	12
18-20	13
21-24	14
25-29	15
30-37	16

[6]National Institute of Occupational Safety and Health. Occupational Exposure Sampling Strategy Manual, Chapter 3: Exposure Measurement Sampling Strategy. pp. 34-35. DHHS (NIOSH) Publication No. 77-173, January 1977. http://www.cdc.gov/niosh/77-173.html

[7]National Institute of Occupational Safety and Health. Occupational Exposure Sampling Strategy Manual, Chapter 3: Exposure Measurement Sampling Strategy. pp. 35. DHHS (NIOSH) Publication No. 77-173, January 1977. http://www.cdc.gov/niosh/77-173.html

Size of Group N	Number of Required Samples
38-49	17
50	18

4. The Importance of Random Sampling

If it was not possible to determine an individual employee or group of employees with maximum risk for exposure, random sample selection techniques should be employed. Often, this can be difficult given real-world constraints, but in general, the use of certain sample selection techniques will improve the likelihood that the samples collected accurately characterize the exposure variability within an SEG.

To conduct random sampling, sampling incidents should be chosen at random first by date, then by shift, and then by worker. During random sampling, samples should not be conducted in clusters (i.e., such as over a one-week period), but over a longer period of time. This period of time should be long enough to adequately capture exposure variability, but not so long that it affects the completion of the sampling study within a reasonable period of time. Multiple dates for sampling should be selected with no consideration for any particular conditions or events that could affect worker exposures. After multiple sampling dates are chosen, multiple work shifts, where applicable, and multiple workers must also be sampled to fully characterize exposure variability and reduce bias in the results.

Random sampling may be especially difficult for non-routine operations such as maintenance work. However, creative approaches can sometimes be used to conduct random sampling for these types of tasks. Examples include using a shorter sample time, or using a combination of full-shift sampling along with measurements from direct reading instruments.[8]

C. Laboratory Analysis/Analytical Method:

Describe where the laboratory analysis was conducted and what analytical chemistry method was used.

- Has the analytical method used been validated by a third party (e.g., was a specific NIOSH, OSHA, or ASTM method used)?

[8] Ignacio J. S. & Bullock W. H. (Editors). A Strategy for Assessing and Managing Occupational Exposures. 3rd Ed. AIHA Press. 2006.

- Has the laboratory that is selected for conducting analysis been accredited by a relevant industrial hygiene organization, such as the AIHA?
- What types of analytical methods are used by the laboratory to ensure accuracy and precision (e.g., how many analyses are conducted of the same extract of a collected sample)?
- If applicable, what type of specific direct reading instrument(s) were used for monitoring, and why? What is the level of detection, accuracy, and precision that can be obtained from this type of instrument?

D. Quality Assurance:

Discuss the number of samples collected, how many shifts and workers were sampled, how these shifts and workers were selected for inclusion, how the samples were stored after collection, and how they were transported to the laboratory for analysis.

- Were specific steps taken for quality assurance purposes (i.e., were blank samples or spiked samples sent to the laboratory along with the field samples collected)?
- Were the recommended sample storage and transport procedures followed prior to analysis?
- If used, were direct reading instruments properly calibrated? What error rate can be expected from the instrument measurements?
- How was the number of samples that were taken determined?
- If applicable, were individual workers and shifts randomly selected for sampling using appropriate methods?
- Were the samples properly collected to assess intended exposures (i.e., average or worst-case exposures)?

E. Sampling Results and Discussion:

Provide a summary of the results of the monitoring study. Include units, sampling time intervals, and limits of detection where applicable. Provide any necessary context or evaluation of the results.

- Describe any equations or calculations used to evaluate the results, including exposure assessment calculations, statistical calculations, or mathematical exposure modeling done using the data collected.
- Characterize the results in terms of the population targeted in the monitoring study (i.e., individual SEGs, etc.).
- Discuss the uncertainties in the results.

- Compare the results to previous monitoring studies.

F. Description of Industrial Hygiene Program:

Briefly describe the industrial hygiene program at the facility where the monitoring study was conducted.

- Is a written industrial hygiene program in place? What are the basic elements of the program?
- What types of controls (i.e., ventilation, work practices, respirators) are in place to prevent inhalation exposure, as well as other types of exposure?
- What types of employee training are conducted to inform workers of the hazards related to their jobs?
- What types of evaluation methods are used to assess the effectiveness of the program? How frequently is monitoring conducted? How often is the program evaluated?

If you have any questions regarding this guidance, please contact Anjali Lamba, RAD Industrial Hygienist, at (202) 564-0996; lamba.anjali@epa.gov or theOPPT/RAD engineer for your case.

References

Hewett, Paul. Past Chair, Exposure Assessment Strategies Committee, American Industrial Hygiene Association. Unpublished/Verbal communication: General Guidance on Developing an Exposure Assessment Strategy. April 2002.

Ignacio J. S. & Bullock W. H. (Editors). A Strategy for Assessing and Managing Occupational Exposures. 3rd Ed. AIHA Press. 2006.

National Institute of Occupational Safety and Health. Occupational Exposure Sampling Strategy Manual, Chapter 3: Exposure Measurement Sampling Strategy. pp. 34-35. DHHS (NIOSH) Publication No. 77-173, January 1977. http://www.cdc.gov/niosh/77-173.html

Plog, Barbara, ed. Fundamentals of Industrial Hygiene, Third Edition: Chapter 17, Methods of Evaluation, pp. 397-416. National Safety Council, 1988.

U.S. Environmental Protection Agency, *Technical Document for Characterizing and Presenting Summary Chemical Exposure Assessment Results (working draft)*, presented at the Voluntary Children's Chemical Evaluation Program Workshop, December 11-13, 2001. http://www.epa.gov/chemrtk/etechdoc.pdf.