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Project Partners:

1. LEITAT
2. IOM
3. CEA
4. TECNALIA
5. UKCEH
6. CNRS
7. RIVM
8. GAIKER
9. FIOH
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11. THINKWORKS
12. ALLIOS
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15. SYMLOG
16. DUKE UNIVERSITY

SAbyNA

H2020-NMBP-15-2020

Simple, robust and cost-effective approaches to guide industry in the development of safer nanomaterials and nano-enabled products

Start date of the project: 01/03/2020

Duration 48 months

WP5 D5.2 – Adaptations made to the existing resources for SbD of nanoprocesses, improving their usability

WP	5	Towards SAFER nanoPROCESSES: Managing risks of nanoprocesses along the NF/NEP life cycle applying SbD strategies and other RMM		
Dissemination level[1]	PU		Due delivery date	31/12/2021 (M22)
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Contributing beneficiaries	WP5 partners

[1] Dissemination level: **PU** = Public, **PP** = Restricted to other programme participants (including the JU), **RE** = Restricted to a group specified by the consortium (including the JU), **CO** = Confidential, only for members of the consortium (including the JU)

[2] Nature of the deliverable: **R** = Report, **P** = Prototype, **D** = Demonstrator, **O** = Other

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Deliverable abstract

The first step in the SAbyNA project within WP5 was the compilation, analysis and mapping of existing resources (strategies, models, tools, frameworks, databases, as well as previous outcomes from EU funded projects e.g. NanoReg2, caLIBRAte and GUIDEnano) for the Safety by Design of nanoprocesses. The second step (i.e. T5.2) was to improve the usability of the resources identified and specified previously to facilitate their use and practical implementation by the industry. The activities related to task 5.2 have focused on the improvement of the usability of the most suitable resources from the WP5 Resource Library based on three main criteria:

- Applicability
- User-friendliness
- Robustness

Based on the ranking of the resources according to the assessment by the WP5 experts a selection of 32 documents that were described and for which Usability Cards were prepared for further use in WP6. These gathered resources and the associated guidance provided via the Usability Cards will enable the designer/manufacturer and/or user to perform activities in the field of SbD in nanoprocesses,

1. Identify potential "hot spots" in processes/nanoprocesses
2. Conduct risk assessment of the process/nanoprocess in all stages of the life cycle
3. Identify and select the most appropriate control measures to be implemented by the designer/manufacturer as well as the criteria for its selection:
    a. Inherently safe design measures
    b. safeguarding and complementary protective measures
    c. information for use
4. Identify and select the most appropriate control measures to be implemented and/or by the user as well as the criteria for its selection:
    a. additional safeguards
    b. organization
    c. use of PPEs
    d. training
    e. Health surveillance and other
5. Define the procedures to be used for the validation of the design and operation stages of the nanoprocesses, as well as the procedures for the measurement of impacts:
    a. Environment
    b. OHS, e.g. nanometric aerosol emissions, derived exposures, etc.

It is important to realise that there are many existing standards, guidelines etc that enable the design/modification of processes (using a SbD method) that are not nano-specific but are still fully relevant for a process that includes nanomaterials. These standards can be used as the “backbone” for any nano specific guidelines.

Table of Content

0. Abbreviations

AFNOR	Association Française de Normalisation
BSI	British Standards Institute
CEN	The European Committee for Standardisation
DoW	Description of Work
ECHA	European Chemical Agency
EHS	Environment, Health and Safety
ENM	Engineered Nanomaterial
FAIR	Findable, Accessible, Interoperable and Reusable
FF	Far field
INRS	French National Research and Safety Institute for the Prevention of Occupational Accidents and Diseases
IRSST	Institut de recherche Robert Sauvé en santé et sécurité au Travail
INSST	Instituto Nacional de Seguridad y Salud en el Trabajo
ISO	International Standardization Organization
NEA	Nano-Enabled Article
NEP	Nano-Enabled Product
NEM	Nano-Enabled Material
NF	Nanoform
NIOSH	The National Institute for Occupational Safety and Health
NM	Nanomaterial
NOAA	Nano-objects and their aggregates and agglomerates
NP	Nanoparticle
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
OHS	Occupational Health and Safety
PSbD	nanoProcess Safety by Design
RA	Risk Assessment
RMM	Risk Mitigation Measure
SbD	Safety or Safe by Design
SME	Small and Medium Enterprise
SOP	Standard Operation Procedure
UNE	Spanish Association for Standardisation
WP	Work Package

1. Introduction and scope

The first step in the SAbyNA project within WP5 was the compilation, analysis and mapping of existing resources (strategies, models, tools, frameworks, databases, as well as previous outcomes from EU funded projects e.g. NanoReg2, caLIBRAte and GUIDEnano) for the Safety by Design (SbD) of nanoprocesses. The second step is to improve the usability of existing resources for the Safety by Design (SbD) of ***nanoprocesses***.

The work set out within Task 5.2 is based on the resources identified and specified in T5.1. It aims at adapting and improving the usability of these resources to facilitate their use and practical implementation by industry thanks to the SAbyNA platform.

This document is focused on the "Adaptation made in the existing resources for SbD of nanoprocesses improving their usability" and will be made available for the SAbyNA guidance platform.

2. Description of the tasks

The objective of WP5 is to develop and customize a SAbyNA strategy and a set of associated resources, aimed at achieving safer nanoprocesses along the NF/ NEP life cycle, including end-of-life processes.

WP5 has created a resource library of key documents related to the safe-by-design for nanoprocesses by analyzing more than 50 documents. This analysis is described in Deliverable 5.1 as well as the WP5 Resource Library excel file. The deliverable D5.1 focused on defining the "Map of available resources for strategies towards SbD nanoprocesses, including end-of-life processes, and specifications for improving their usability".

The full design of a process/nanoprocess cannot be completed in just a single step – i.e. just from implementing the measures of inherently Safe by Design (SbD) – which would otherwise leave the process design unfinished. Therefore, the compilation of resources (P-SbD Resource Library) has not only included resources associated with SbD but also includes other available resources that are needed to implement complementary strategies (i.e. protection, information, etc.) more associated to the user. This analysis has been done considering both the designer and user level.

Activities conducted in T5.2 were focused on the development of a method to assess and improve the usability of the mapped resources from T5.1. The necessary steps behind the work was to create a consensus on terminology and criteria to eventually improve the usability for the selected resources which later will be integrated in the SAbyNA platform (WP6).

The usability assessment was conducted on all of the available resources identified in T5.1 using different sets of criteria as depicted in Figure 1. The different criteria were categorised into "relevance", "cost-effectiveness", "applicability", "user friendliness", "nanospecificity" and "robustness". For each category, different questions were proposed with sub-criteria in order to finely evaluate them using three main levels (high, medium or low). Tecnalia, LEITAT, IOM and CEA contributed to the analysis of the 52 resources. Details and examples were given in the Excel spreadsheet to facilitate the evaluation by the different partners involved.

Based on the partners inputs, CEA proposed to sort the different resources using three main criteria. "Applicability", "user-friendliness" and "robustness" were defined by the contributing partners as the three key parameters to select the relevant resources to be further adapted. The other criteria (i.e. "relevance",

"cost effectiveness" and "nano-specificity") were used to bring additional relevant resources that were not selected initially and to finely classify the selected resources.

From this sorting, some of the 'most usable' resources were selected for further adaptations to achieve robust and user-friendly versions for practical implementation by the industry. Moreover, usability cards were prepared for each of the selected resources to facilitate their identification and use through the SAbyNA guidance platform. An interactive tool will allow users, with a predefined profile based on expertise, to sort and select appropriate resources such as a market place (WP6).

Relevance (i.e. credibility of the organization developing the resource)	Is the objective of the PSbD approach clearly defined?	Does "Safe(r) by Design" explicitly mentionned?	Does the PSbD comply with current Regulatory Requirements?	
Cost effectiveness (i.e. time and ressource needed to apply PSbD strategy)	Are there any information on **cost/benefit** of the PSbD approach?	Is the PSbD strategy **"Effective"**? Considering risk management and risk mitigation	If effective, how would be the impact in terms of risk mitigation ?	
Applicability (i.e. direct use of the ressource by the designer/user)	At which **"scale"** is the SbD strategy applied/implemented?	Is it possible to **scale-up** the PSbD strategy?	Has the PSbD strategy been **tested sufficiently and across different applications**?	Is the PSbD strategy bear sufficient information for applicability / implementation ?
User friendliness (i.e. degree of ease of use of the ressource by the designer)	Does the ressource requires a translation into english for broader diffusion ?	Is the PSbD strategy **easy to understand** for an ordinary user?	Is the PSbD strategy **easy to apply in a real case**?	Is the PSbD strategy easy to acces (is it publicly available) and sufficiently high on a search criteria (e.g., "google etc.")?
Nano-specificity (i.e. degree of specificity of the resource to cover the nano-requirement concerned categories)	Is the PSbD too general that makes it not applicable or its outputs not useful?	Is the PSbD too specific that makes it not applicable or its outputs not useful?	Is the PSbD sector specific ?	If yes, is the PSbD targeting SAbyNA case studies (i.e. paints & 3D printing) ?
Robustness (i.e. influence of the user/designer on the results)	What is the required level of expertise of the targeted ressource user ?	General remarks - free text		

Figure 1. Proposed sets of criteria to assess the usability of the selected resources

This task was conducted in close collaboration with T4.2 in order to provide a comprehensive and global strategy towards the design of safer NFs, NEPs and nanoprocesses as early as possible in the industrial innovation process. Both D4.2 and D5.2 promote the use of usability cards for a more straightforward implementation in the SAbyNA guidance platform.

3. Analysis of criteria

As indicated earlier in the task description, three main criteria were defined and implemented in the Excel spreadsheet to conduct the resource analysis. Experts from Tecnalia, LEITAT, IOM and CEA were asked to provide a level for the 3 selected criteria as "low", "medium" or "high" based on their educated opinion. The results of the analysis of the 52 identified documents is detailed below.

3.1. Applicability

The applicability criterion aims to define if the users could directly use the resource. A "High" level would be linked to a straightforward use whilst a "Low" level would indicate major obstacles. A "low" answer to this criterion is considered as a warning against the resource selection. Four additional questions (sub-criteria) detail the "applicability":

- At which "scale" is the SbD strategy applied/implemented? *[Production, Pilot scale, Lab scale, Any, NA]*

- Is it possible to scale-up the PSbD strategy? *[Yes, No]*
- Has the PSbD strategy been tested sufficiently and across different applications? *[High i.e. extensively tested, Medium i.e. moderately tested, Low i.e. single use]*
- Does the PSbD strategy bear sufficient information for applicability / implementation? *[Yes, No]*

Figure 2 shows that three quarter of the resources mapped in T5.1 were reported by the consulted experts as highly applicable. Only one resource is not directly applicable by the users: RPSbD0043 "Occupational safety and health in nanotechnology and Organisation for Economic Cooperation and Development". This article describes OECD activities around occupational safety and health of nanotechnology and provides state-of the science overview resulting from an OECD workshop on exposure assessment and mitigation for nanotechnology workplace and was published by the Journal of Nanoparticle Research.

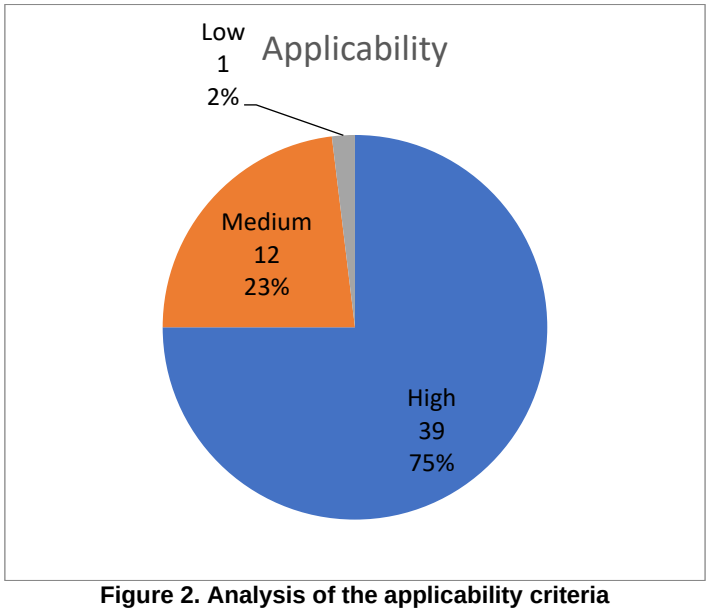


Figure 2. Analysis of the applicability criteria

Figure 3 details the sub-criteria related to "applicability" for all the resources. The PSbD strategies have mostly been tested sufficiently and across different applications and bear sufficient information for their applicability and implementation. For only one resource, the PSbD strategy could not be scaled up. More than 75% of the resources present SbD strategies that could be applied at any scale. This analysis of the sub-criteria is in line with the 75% of resources highly applicable.

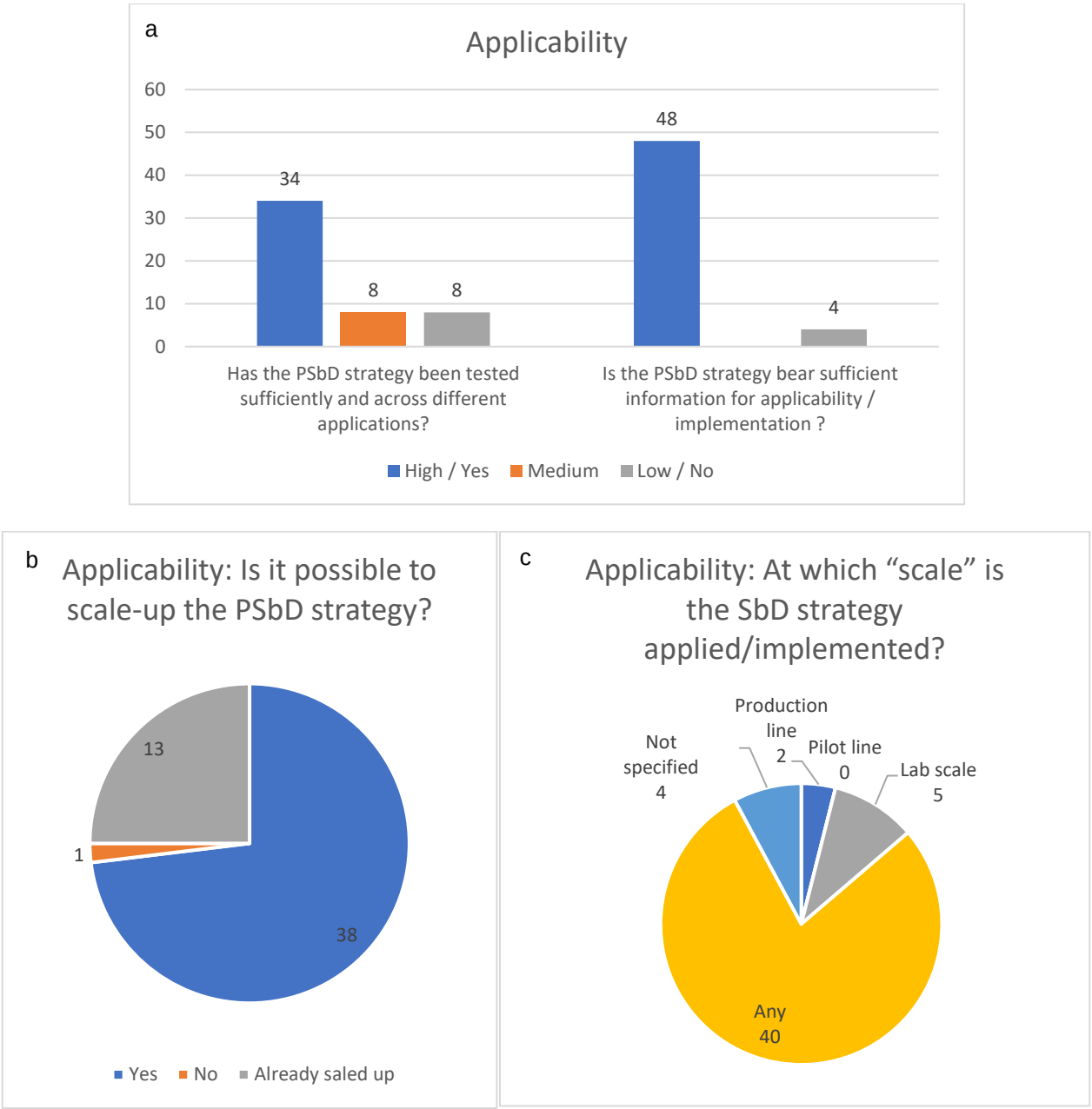


Figure 3. Detailed analysis of the 'applicability' sub-criteria

3.2. User-friendliness

The user-friendliness criterion aims to define how easy the use of the resource is for the designer. A "low" answer to this criterion would be considered as a warning for the resource selection. Four additional questions (sub-criteria) detail the "user-friendliness":

- Does the resource require a translation into English for broader diffusion? *[Yes, No]*
- Is the PSbD strategy easy to understand for an ordinary user? *[Yes, No]*
- Is the PSbD strategy easy to apply in a real case? *[High i.e. easy to apply, Medium i.e. moderately easy, Low i.e. hard to apply]*
- Is the PSbD strategy easy to access (is it publicly available) and sufficiently high on a search criterion (e.g., "google etc.")? *[Yes, No]*

Figure 4 shows that more than three quarters of the resources mapped in T5.1 were reported by the experts as highly user-friendly. Only one resource is not easy to use by the designers: RPSbD0043 "Occupational safety and health in nanotechnology and Organisation for Economic Cooperation and Development". The same resource is not directly applicable by the users (section 3.1 Applicability).

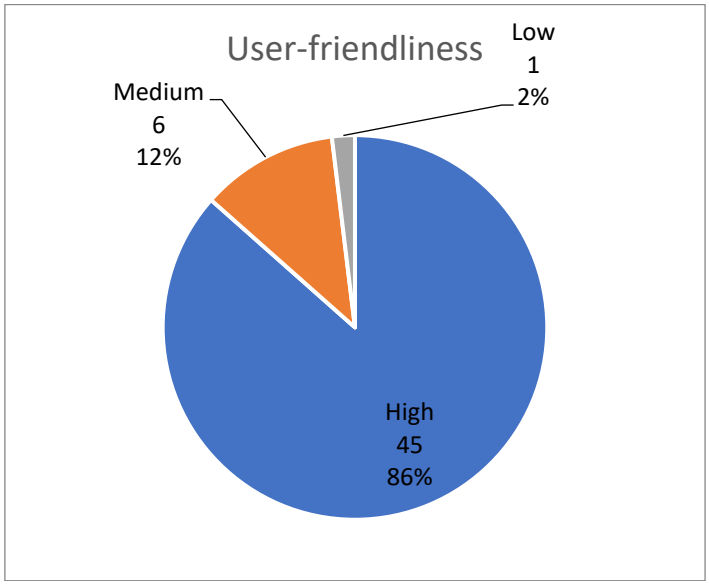


Figure 4. Analysis of the user-friendliness criteria

Figure 5 details the "user-friendliness" sub-criteria for all the resources. Only four resources require a translation into English. These resources are currently available in French and were published by the INRS (French national institute for occupation safety). They are thus not selected for further adaptions. All the PSbD strategies were reported as easy to understand for an ordinary user. Most of the PSbD strategies appear to be easy to apply in real cases and easy to access. This analysis of the sub-criteria is in line with the 86% of resources being highly user-friendly.

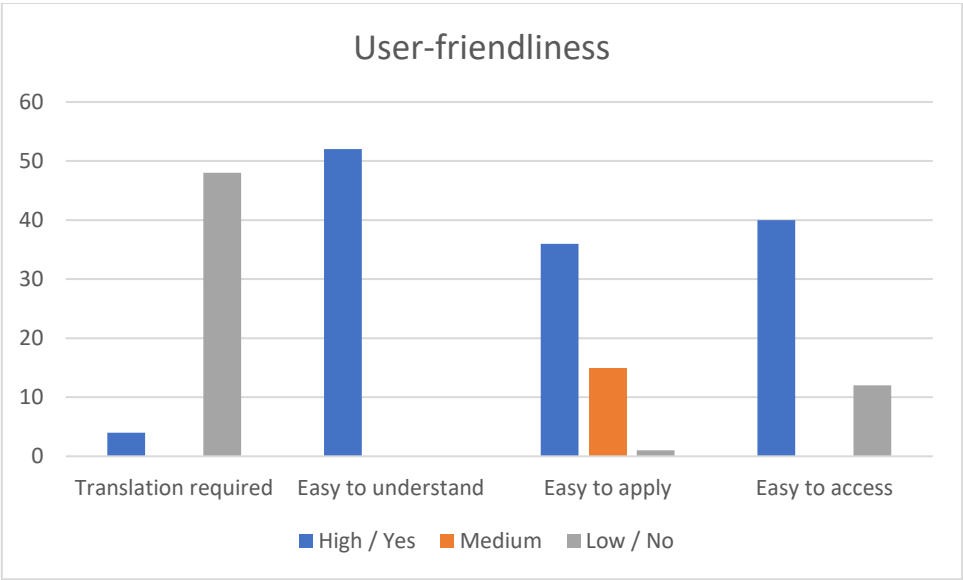


Figure 5. Detailed analysis of the user-friendliness sub-criteria

3.3. Robustness

The robustness criterion aims to define if the users have an influence on the results when implementing the PSbD strategy. A "low" answer to this criterion would be considered as a warning for the resource selection.

Figure 6 shows that the half of the resources mapped in T5.1 appear to be highly robust. Only three resources were reported with a potential influence from the user:

- RPSbD0031 "General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories". This document provides guidance to those working with ENMs in research/pilot scale laboratories on risk management, hazard identification and exposure control.
- RPSbD0034 "Working Safely with Manufactured Nanomaterials Guidance for Workers". This document provides guidance for general use of manufactured nanomaterials in occupational settings for workers. The document includes a description of what nanomaterials and nano-enabled products are, basis for current concerns, treating manufactured nanomaterials, exposure and safe working actions.
- RPSbD051 "Perspectives on the design of safer nanomaterials and manufacturing processes". This document introduces the user to Prevention through Design (PtD) principles and discuss their applicability to design of safer nano-enabled products; approached from the material side and from the facility, tool, and task side; and how the outcomes of a prevention approach will support an environmental, health, and safety management system approach.

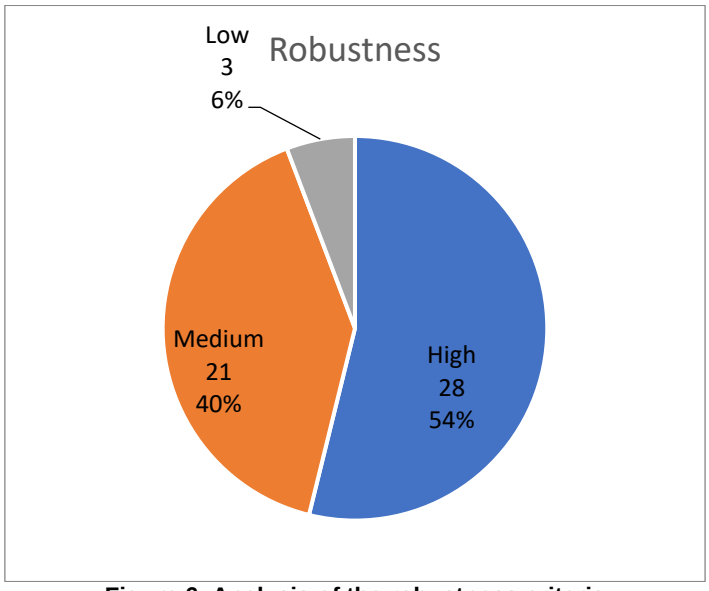


Figure 6. Analysis of the robustness criteria

3.4. Applicability, User-friendliness and robustness

Applicability, user-friendliness and robustness have been defined in the section "Description of the task" as the key parameters to be used for the selection of the relevant resources. Figure 7 shows that 58% of the resources mapped in T5.1 have 'mixed' level regarding these three criteria (i.e. different H, M or L levels for the three criteria). Twenty resources (38%) are highly applicable, user friendly and robust (i.e. H level for the three indicators).

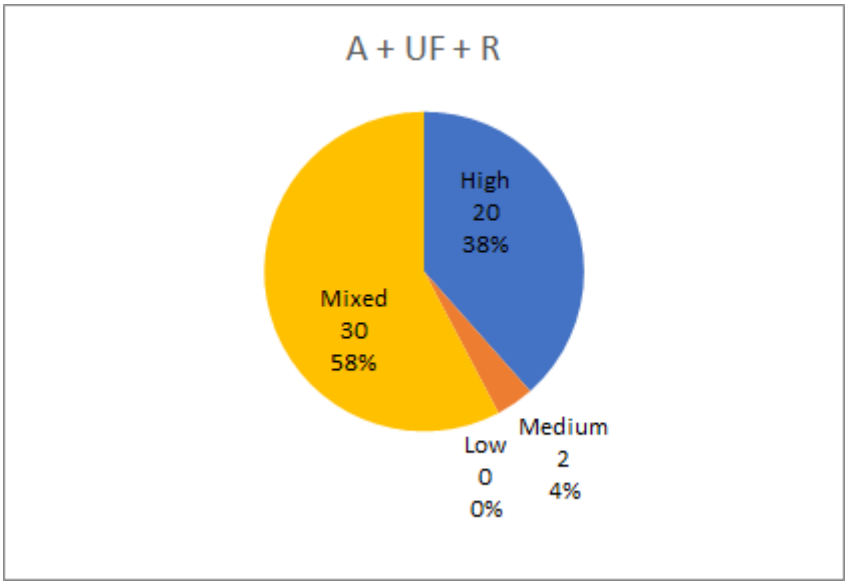


Figure 7. Analysis of the three criteria: applicability, user-friendliness and robustness

4. Selection of the relevant resources to be adapted

4.1. List of the relevant resources

The classified resources listed in Table 1 have been selected for further adaptation. Table 1 also presents the level of each non-crucial criteria ("cost effectiveness", "nano-specificity" and "relevance").

Table 1. Selected resources based on the analysis of the three key criteria

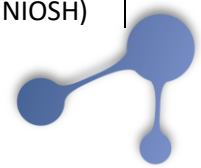
Resource names and codes		Owners of the resources	Description	Cost effectiveness	Nano-specificity	Relevance
RPSbD 001	EN 689:2018 + AC:2019 Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values.	European Committee for Standardization (CEN)	RPSbD001 is the European Standard EN 689 and deals with measurement strategy for comparing workers' exposure by inhalation with occupational exposure limit values (OELVs). The strategy gives a procedure to overcome the problem of variability and to use a relatively small number of measurements to demonstrate, with a high degree of confidence, that workers are unlikely to be exposed to concentrations exceeding the OELVs. The strategy shall be conducted by an appraiser and consists of 1) an Initial Workplace Exposure Assessment and then 2) Periodic Reassessment. A summary of the standard is available at the link in the usability card but a payment is required for access to the full standard.	H	M	H
RPSbD 002	EN 1093-1:2008 Safety of machinery - Evaluation of the emission of airborne hazardous substances - Part 1: Selection of test methods	European Committe for Standardization (CEN)	RPSbD002 is the European Standard EN 1093-1:2008 related to the Safety of machinery - Evaluation of the emission of airborne hazardous substances - Part 1: Selection of test methods. This European Standard specifies parameters which can be used for the assessment of the emission of pollutants from machines or the performance of the pollutant control systems integrated in machines. It gives guidance on the selection of appropriate test methods according to their various fields of application and types of machines including the effects of measures to reduce exposures to pollutants. The test methods are given in additional parts of this European Standard.	H	M	H

RPSbD 003	EN 1093-11:2001+A1:2008 Safety of machinery - Evaluation of the emission of airborne hazardous substances - Part 11: Decontamination index	European Committe for Standardization (CEN)	RPSbD003 is EN 1093-11:2001+A1:2008 Safety of machinery - Evaluation of the emission of airborne hazardous substances - Part 11: Decontamination index. This standard describes a method for the measurement of the decontamination index of pollution control systems e. g. capture devices including local exhaust ventilation, water spray systems and, when appropriate, separation equipment installed on a machine. This method uses the real pollutant (EN 1093-1: 1998) and can be operated in room or field environments.	M	M	H
RPSbD 006	EN ISO 13849-1:2015 Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design (ISO 13849-1:2015)	European Committe for Standardization (CEN)	RPSbD006 is European Standard EN ISO 13849-1:2015 Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design. This document provides safety requirements and guidance on the principles for the design and integration of safety-related parts of control systems (SRP/CS), including the design of software. For these parts of SRP/CS, it specifies characteristics that include the performance level required for carrying out safety functions.	H	L	H
RPSbD 007	EN ISO 14123-1:2015 Safety of machinery — Reduction of risks to health resulting from hazardous substances emitted by machinery — Part 1: Principles and specifications for machinery manufacturers	European Committe for Standardization (CEN)	RPSbD007 is European Standard EN ISO 14123-1:2015 Safety of machinery — Reduction of risks to health resulting from hazardous substances emitted by machinery — Part 1: Principles and specifications for machinery manufacturers. This part of ISO 14123 establishes principles for the control of risks to health resulting from hazardous substances emitted by machinery. The standard is not applicable to substances that are a hazard to health solely because of their explosive, flammable or radioactive properties or their behaviour at extremes of temperature or pressure. This resource is linked with RPSbD008.	M	L	H

RPSbD 008	EN ISO 14123-2:2015 Safety of machinery - Reduction of risks to health resulting from hazardous substances emitted by machinery - Part 2: Methodology leading to verification procedures	European Committe for Standardization (CEN)	RPSbD008 is European Standard EN ISO 14123-2:2015 Safety of machinery - Reduction of risks to health resulting from hazardous substances emitted by machinery - Part 2: Methodology leading to verification procedures. This standard establishes a methodology that leads to the selection of critical factors relating to emissions of hazardous substances for the purpose of specifying suitable verification procedures. This part of ISO 14123 can also be used to assist designers and manufacturers to identify sources of emission that can subsequently affect the exposure of operators and others. ISO 14123-2:2015 is intended to be used in conjunction with ISO 14123-1 (resource RPSbD007).	H	L	H
RPSbD 009	EN 16966:2018 Workplace exposure - Measurement of exposure by inhalation of nano-objects and their aggregates and agglomerates - Metrics to be used such as number concentration, surface area concentration and mass concentration	European Committe for Standardization (CEN)	RPSbD009 is EN 16966:2018 Workplace exposure and is nano-specific. This European Standard specifies the use of different metrics for the measurement of exposure by inhalation of NOAA during a basic assessment and a comprehensive assessment, respectively, as described in EN 17058. This document is intended for those responsible for selecting measurement methods for occupational exposure to airborne NOAA.	M	H	H
RPSbD 010	EN 17058:2018 Workplace exposure - Assessment of exposure by inhalation of nano-objects and their aggregates and agglomerates	European Committe for Standardization (CEN)	RPSbD010 is a nano-specific European Standard EN 17058:2018 Workplace exposure - Assessment of exposure by inhalation of nano-objects and their aggregates and agglomerates. It provides guidelines to assess workplace exposure by inhalation of nano-objects and their aggregates and agglomerates (NOAA). It contains guidance on the sampling and measurement strategies to adopt and methods for data evaluation. It is linked to the OECD Harmonized tiered approach (2015). While the focus of this document is on the assessment of nano-objects, the approach is also applicable for exposure to the associated aggregates and agglomerates, i.e. NOAA, and particles released from nanocomposites and nano-enabled products.	M	H	H

RPSbD 011	ISO/TR 12885:2018 Nanotechnologies — Health and safety practices in occupational settings	International Organization for Standardization (ISO)	RPSbD011 is nano-specific ISO Technical Report ISO/TR 12885:2018 Nanotechnologies — Health and safety practices in occupational settings. This document describes health and safety practices in occupational settings relevant to nanotechnologies. This document focuses on the occupational manufacture and use of manufactured nano-objects, and their aggregates and agglomerates greater than 100 nm (NOAAs). It does not address health and safety issues or practices associated with NOAAs generated by natural processes, hot processes and other standard operations which unintentionally generate NOAAs, or potential consumer exposures or uses, though some of the information in this document can be relevant to those areas.	M	H	H
RPSbD 012	ISO/TS 12901-2:2014 Nanotechnologies — Occupational risk management applied to engineered nanomaterials — Part 2: Use of the control banding approach	International Organization for Standardization (ISO)	RPSbD012 is a nano-specific ISO Technical Specification entitled ISO/TS 12901-2:2014 Nanotechnologies — Occupational risk management applied to engineered nanomaterials — Part 2: Use of the control banding approach. The resource describes the use of a control banding approach for controlling the risks associated with occupational exposures to nano-objects, and their aggregates and agglomerates greater than 100 nm (NOAA), even if knowledge regarding their toxicity and quantitative exposure estimations is limited or lacking. It is focused on intentionally produced nano-objects such as nanoparticles, nanopowders, nanofibres, nanotubes, nanowires, as well as of aggregates and agglomerates of the same materials. This covers whether in their original form or incorporated in materials or preparations from which they could be released during their lifecycle. The resource is intended to help businesses and others, including research organizations engaged in the manufacturing, processing or handling of NOAA, by providing an easy-to-understand, pragmatic approach for the control of occupational exposures.	H	H	H

RPSbD 013	ISO/TR 14121-2:2012 Safety of machinery — Risk assessment — Part 2: Practical guidance and examples of methods	International Organization for Standardization (ISO)	RPSbD013 is an ISO Technical Report entitled ISO/TR 14121-2:2012 Safety of machinery — Risk assessment — Part 2: Practical guidance and examples of methods. It gives practical guidance on conducting risk assessment for machinery in accordance with ISO 12100 (RPSbD004) and describes various methods and tools for each step in the process. This resource gives examples of different measures that can be used to reduce risk and is intended to be used for risk assessment on a wide variety of machinery in terms of complexity and potential for harm. Its intended users are those involved in the design, installation or modification of machinery (for example, designers, technicians or safety specialists).	H	H	H
RPSbD 014	ISO/TR 18637:2016 Nanotechnologies — Overview of available frameworks for the development of occupational exposure limits and bands for nano-objects and their aggregates and agglomerates (NOAAs)	International Organization for Standardization (ISO)	RPSbD014 is a nano-specific ISO Technical Report entitled ISO/TR 18637:2016 Nanotechnologies — Overview of available frameworks for the development of occupational exposure limits and bands for nano-objects and their aggregates and agglomerates (NOAAs). It provides an overview of available methods and procedures for the development of occupational exposure limits (OELs) and occupational exposure bands (OEBs) for manufactured nano-objects and their aggregates and agglomerates (NOAAs) for use in occupational health risk management decision-making.	H	H	H
RPSbD 015	EN ISO 19353:2019 Safety of machinery - Fire prevention and fire protection	European Committe for Standardization (CEN)	RPSbD015 is ISO Standard EN ISO 19353:2019 Safety of machinery - Fire prevention and fire protection . This document specifies methods for identifying fire hazards resulting from machinery and for performing a risk assessment. It gives the basic concepts and methodology of protective measures for fire prevention and protection to be taken during the design and construction of machinery. The resource describes inherently safe design measures, safeguarding, complementary protective measures, integrated fire-fighting and fire detecting measures as well as further complementary protective measures.	H	H	H
RPSbD 017	Workplace Design Solutions: Protecting Workers during Nanomaterial Reactor Operations	National Institute for Occupational Safety and Health (NIOSH)	RPSbD017 as the RPSbD018 is a nanospecific NIOSH guidance document specially designed to address risks arising during nanomaterials processes in occupational settings. This Workplace Design Solutions document provides guidance on	H	H	M



RPSbD 018	Workplace Design Solutions: Protecting Workers during the Handling of Nanomaterials		exposure control approaches for protecting workers during the handling of nanomaterials.	M	H	M
RPSbD 019	Workplace Design Solutions: Protecting Workers during Intermediate and Downstream Processing of Nanomaterials	National Institute for Occupational Safety and Health (NIOSH)	RPSbD019 is a nano-specific resource from NIOSH entitled Workplace Design Solutions: Protecting Workers during Intermediate and Downstream Processing of Nanomaterials. A qualified industrial hygienist can help assess process-related risks and make recommendations to minimize exposure. Control measures for ENMs and other hazards should be implemented within the context of a comprehensive occupational safety and health management system [ANSI/AIHA 2012]. Engineering controls used during post-production processing of nanomaterials may include local exhaust ventilation (LEV) such as annular exhaust hoods, enclosures around the emission points, or even down flow booths for larger scale processes. Each of these controls should be carefully designed for the process, tested, and properly operated to be effective. Below is a description of exposure sources (i.e., points of potential release of ENMs during processing) and control approaches for a range of common processes used with nanomaterials.	M	H	M
RPSbD 020	Curent Intelligence Bulletin 65. Occupational Exposure to Carbon Nanotubes and Nanofibers	National Institute for Occupational Safety and Health (NIOSH)	RPSbD020 and RPSbD021 are guidance documents provided by NIOSH to prevent the development of adverse respiratory health effects in workers exposed to respectively carbon nanotubes (CNT), carbon nanofibers (CNT) and Titanium Dioxide (TiO_2). They provide information and recommendations about these nanomaterials, the assessment of the health risk and recommended Exposure Limit and the exposure measurement and controls.	H	H	M
RPSbD 021	Current Intelligence Bulletin 63: Occupational Exposure to Titanium Dioxide			H	H	M

RPSbD 039	The Exposure Control Efficacy Library (ECEL v3.0)	TNO	RPSbD039, the Exposure Control Efficacy Library (ECEL) is a web-based, open source and user-friendly library. It is a very broad resource and provides specific examples that might be necessary to specifically evaluate one SbD strategy. It offers a database structure to search for different types of RMM for different exposure or emission scenarios and to compare their effectiveness. This information is required in the context of the European Chemicals policy (REACH - Registration, Evaluation and Authorization of Chemicals) and other European regulations to demonstrate and document safe use of substances based on quantitative exposures and exposure reduction by Risk Management Measures (RMM).	M	M	L
RPSbD 041	Effectiveness of nanoparticle exposure mitigation measures in industrial settings	International Journal of Hygiene and Environmental Health	The resource “RPSbD041- Effectiveness of nanoparticle exposure mitigation measures in industrial settings” is not further developed, since the relevant data and information are essentially included in “RPSbD039- The Exposure Control Efficacy Library (ECEL v3.0)”.	M	H	L

Furthermore, the resources in Table 2 are also selected even if one of their criteria (applicability, user-friendliness and robustness) is not the higher. The following resources were proposed by contributing experts. Indeed, most of the selected resources in Table 1 are standards that are not open sources.

Table 2. Additional selected resources based on the experience of WP5 partners

Resource names and codes		Owners of the resources	Reason for inclusion	Applicability level	User-friendliness level	Robustness level
RPSbD 004	EN ISO 12100:2010 Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)		RPSbD004 is European Standard EN ISO 12100:2010 Safety of machinery - General principles for design - Risk assessment and risk reduction . The standard specifies basic terminology, principles and a methodology for achieving safety in the design of machinery. It specifies principles of risk assessment and risk reduction to help designers in achieving this objective. These principles are based on knowledge and experience of the design, use, incidents, accidents and risks associated with machinery. Procedures are described for identifying hazards and estimating and evaluating risks during relevant phases of the machine life cycle, and for the elimination of hazards or sufficient risk reduction. Guidance is given on the documentation and verification of the risk assessment and risk reduction process.	M	H	H
RPSbD 023	Best practices guidance for nanomaterial risk management in workplace	IRSST	Resources RPSbD023 and 24 provide a medium level of applicability. Indeed, the PSbD strategies developed in these documents are generic and should be used with additional information to be implemented (e.g. the advice of a ventilation expert is needed to choose the right equipment). However, both are highly user-friendly and highly robust. These documents should be used as a starting point for beginners.	M	H	H
RPSbD 024	Using Nanomaterials at work including CNT and other bio persistent HARNs	Health and Safety Executive		M	H	H
RPSbD 027	Safe handling and use of carbon nanotubes	Safe Work Australia	In general, for source RPSbD027 it focuses on the safe use of carbon nano tubes but this information is also covered in sources RPSbD020 and 024 which are both freely accessible and from more credible sources which are likely to be updated.	H	H	M

RPSbD 028	Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials	CDC/NIOSH	For sources RPSbD028 to 035 these generally focus on the safe handling of nanomaterials to control risks that are applicable to any setting, where all of these sources in summary present risk management measures. These documents contain similar information to that available in sources RPSbD011, 018 and 041 specifically noted in table 1 with only RPSbD018 available freely to all users. Although sources RPSbD027 to RPSbD35 can be represented by sources noted in table 1, some of these are not freely available and accessible to all future users of the platform. RPSbD027 to RPSbD35 are all freely available and present good general guidance; RPSbD029 summarised in appendix 1 is the best example of these, but the others still present good ideas that could be useful in presenting future flow diagram etc that the SAbyNA platform may wish to adopt.	H	H	M
RPSbD 029	Building a Safety Program to Protect the Nanotechnology Workforce: A Guide for Small to Medium Enterprises	CDC/NIOSH		H	H	M
RPSbD 030	Controlling Health Hazards when Working with Nanomaterials: Questions to Ask Before You Start?	CDC/NIOSH		H	H	M
RPSbD 031	General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories	CDC/NIOSH		H	H	L
RPSbD 032	Safe handling of nanomaterials and other advanced materials at workplaces	Nanovalid		H	H	M
RPSbD 033	WHO Guidelines on Protecting Workers from Potential Risks of Manufactured Nanomaterials	WHO		H	H	M

RPSbD 034	Working Safely with Manufactured Nanomaterials Guidance for Workers	EC		H	H	L
RPSbD 035	Guidance on the protection of the health and safety of workers from the potential risks related to nanomaterials at work - Guidance for employers and health and safety practitioners	EC		H	H	M

These two tables (Table 1 and Table 2) raise a list of relevant resources for the selection of the relevant resources to be adapted.

4.2. Adaptation of the resources

In order to find these resources, SAbyNA will develop, as part of WP6 activities, an interactive tool allowing to sort resources through expected needs such as a market place. The first step will be to select the level of expertise and then the design strategy, the design topic and the type of actions. Once expected resources are found, it is possible to identify the main outcomes of the resources including links with other resources in order to create a tailor-made library. Figure 7 exposes the sorting system for each category (e.g. Level of expertise) and the possible choices that will be proposed to the SAbyNA guidance platform user (e.g. expert, advanced and beginners).

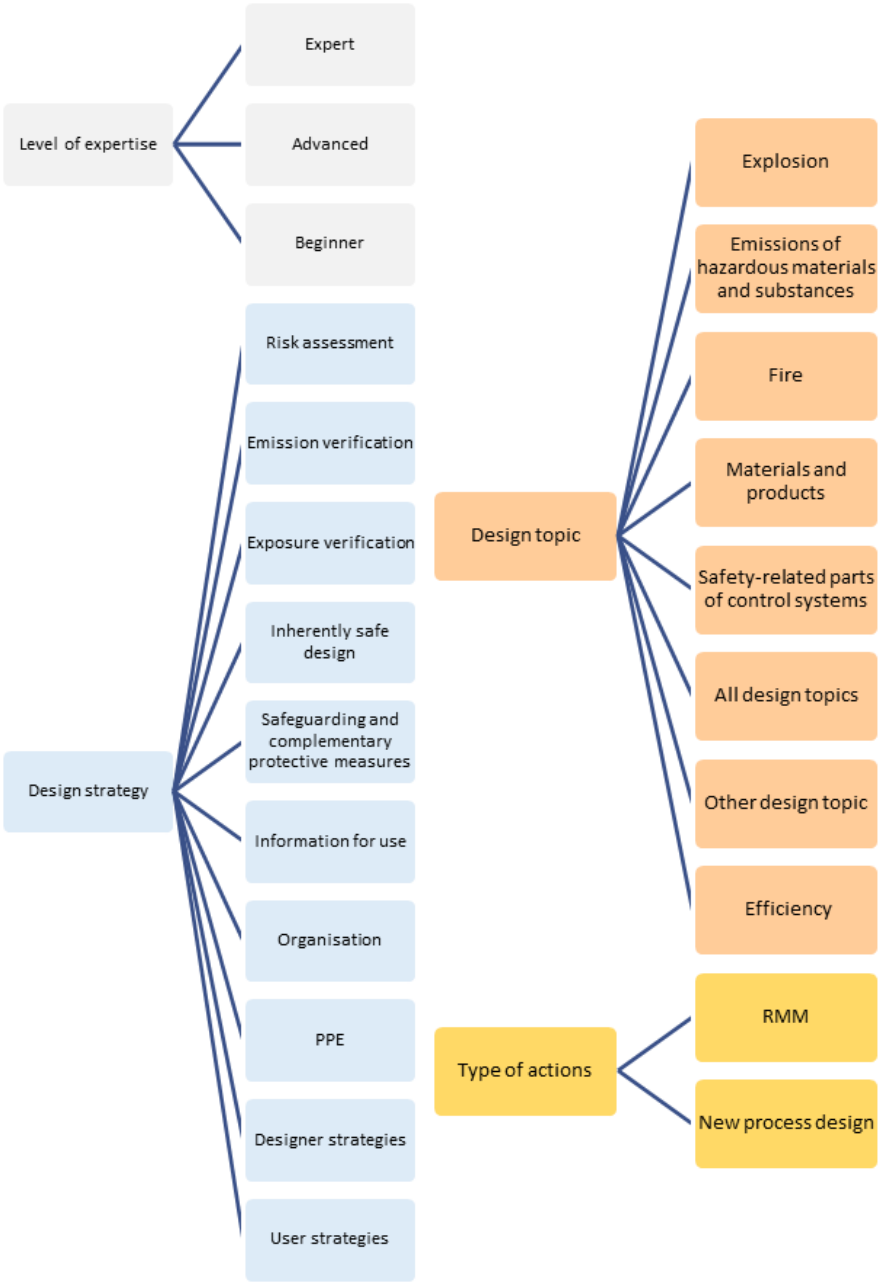


Figure 7. Proposed resources sorting system

The level of expertise is considered as a key parameter for this sorting system. This category is divided in three sub-categories:

- "Expert": the document is aimed at people with several years of experience in nanosafety

- “Advanced’: the document is aimed at people with few notions on nanosafety
- “Beginner”: the document is aimed at people without any experience in nanosafety

The design strategy and the design topic are developed in “D5.1: Map of available resources for strategies towards SbD nanoprocesses, including end-of-life processes, and specifications for improving their usability”.

The category “Type of action” is related to the risk management of the process and will allow to sort resources based on their potential use by process designer and/or safety engineers. We proposed two subcategories for adaptations on existing process (i.e. implementation of risk management measures “RMM”) or the design of a new process (i.e. “new process design”) where the freedom to implement controls measures is larger.

5. Improvement of the usability

5.1. Usability card

Once expected resources are identified, it is possible to find the main outcomes of the resources. The following usability card template (A4 sheet) is used to present each resource using the same format. All the usability cards are available in appendix.

This warning sentence pop up when a user is opening the usability cards: “The following cards summarized complex documents containing a lot of additional information. If you are interested in, it is advisable to follow the link to access the full document.”

Resource code « RPSbDxxx»	**NAME OF THE RESSOURCE**
Scope / abstract	

Design topic	*Design strategy*	*Type of actions*	*Level of expertise*
Main content:			

Recommendations for use: (e.g. link to other resources)	*Resource type* *Nano-specificity*
Source	**Owner of the resource**

5.1. Level 1: Beginner

The resources selected for “beginners” are:

RPSbD015	EN ISO 19353:2019 Safety of machinery - Fire prevention and fire protection (ISO 19353:2019)	European Committe for Standardization (CEN)
RPSbD017	Workplace Design Solutions: Protecting Workers during Nanomaterial Reactor Operations	National Institute for Occupational Safety and Health (NIOSH)
RPSbD018	Workplace Design Solutions: Protecting Workers during the Handling of Nanomaterials	National Institute for Occupational Safety and Health (NIOSH)
RPSbD023	Best practices guidance for nanomaterial risk management in workplace	IRSST
RPSbD024	Using Nanomaterials at work including CNT and other bio persistent HARNs	Health and Safety executive
RPSbD027	Safe handling and use of carbon nanotubes	Safe Work Australia
RPSbD028	Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials	National Institute for Occupational Safety and Health (NIOSH)
RPSbD029	Building a Safety Program to Protect the Nanotechnology Workforce: A Guide for Small to Medium Enterprises	National Institute for Occupational Safety and Health (NIOSH)
RPSbD030	Controlling Health Hazards when Working with Nanomaterials: Questions to Ask Before You Start?	National Institute for Occupational Safety and Health (NIOSH)
RPSbD031	General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories	National Institute for Occupational Safety and Health (NIOSH)
RPSbD032	Safe handling of nanomaterials and other advanced materials at workplaces	NanoValid
RPSbD034	Working Safely with Manufactured Nanomaterials Guidance for Workers	European Commission (EC)
RPSbD035	Guidance on the protection of the health and safety of workers from the potential risks related to nanomaterials at work - Guidance for employers and health and safety practitioners	European Commission (EC)
RPSbD039	The Exposure Control Efficacy Library (ECEL v3.0)	TNO

The usability cards of all these resources are available in the Appendix.

5.2. Level 2: Advanced

The resources selected for “advanced” users are:

RPSbD001	EN 689:2018+AC:2019 Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values.	European Committe for Standardization (CEN)
RPSbD002	EN 1093-1:2008 Safety of machinery - Evaluation of the emission of airborne hazardous substances - Part 1: Selection of test methods	European Committe for Standardization (CEN)

RPSbD003	EN 1093-11:2001+A1:2008 Safety of machinery - Evaluation of the emission of airborne hazardous substances - Part 11: Decontamination index	European Committe for Standardization (CEN)
RPSbD004	EN ISO 12100:2010 Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)	European Committe for Standardization (CEN)
RPSbD006	EN ISO 13849-1:2015 Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design (ISO 13849-1:2015)	European Committe for Standardization (CEN)
RPSbD007	EN ISO 14123-1:2015 Safety of machinery — Reduction of risks to health resulting from hazardous substances emitted by machinery — Part 1: Principles and specifications for machinery manufacturers	European Committe for Standardization (CEN)
RPSbD008	EN ISO 14123-2:2015 Safety of machinery - Reduction of risks to health resulting from hazardous substances emitted by machinery - Part 2: Methodology leading to verification procedures (ISO 14123-2:2015)	European Committe for Standardization (CEN)
RPSbD013	ISO/TR 14121-2:2012 Safety of machinery — Risk assessment — Part 2: Practical guidance and examples of methods	International Organization for Standardization (ISO)
RPSbD019	Workplace Design Solutions: Protecting Workers during Intermediate and Downstream Processing of Nanomaterials	National Institute for Occupational Safety and Health (NIOSH)
RPSbD033	WHO Guidelines on Protecting Workers from Potential Risks of Manufactured Nanomaterials	World health Organisation (WHO)

The usability cards of all these resources are available in Appendix.

5.3. Level 3: Expert

The resources selected for “experts” in nanosafety are:

RPSbD009	EN 16966:2018 Workplace exposure - Measurement of exposure by inhalation of nano-objects and their aggregates and agglomerates - Metrics to be used such as number concentration, surface area concentration and mass concentration	European Committe for Standardization (CEN)
RPSbD010	EN 17058:2018 Workplace exposure - Assessment of exposure by inhalation of nano-objects and their aggregates and agglomerates	European Committe for Standardization (CEN)
RPSbD011	ISO/TR 12885:2018 Nanotechnologies — Health and safety practices in occupational settings	International Organization for Standardization (ISO)
RPSbD012	ISO/TS 12901-2:2014 Nanotechnologies — Occupational risk management applied to engineered nanomaterials — Part 2: Use of the control banding approach	International Organization for Standardization (ISO)
RPSbD014	ISO/TR 18637:2016 Nanotechnologies — Overview of available frameworks for the development of occupational exposure limits and bands for nano-objects and their aggregates and agglomerates (NOAAs)	International Organization for Standardization (ISO)
RPSbD020	Current Intelligence Bulletin 65. Occupational Exposure to Carbon Nanotubes and Nanofibers	National Institute for Occupational Safety and Health (NIOSH)
RPSbD021	Current Intelligence Bulletin 63: Occupational Exposure to Titanium Dioxide	National Institute for Occupational Safety and Health (NIOSH)

RPSbD041	Effectiveness of nanoparticle exposure mitigation measures in industrial settings	International Journal of Hygiene and Environmental Health

The usability cards of all these resources are available in Appendix.

6. Deviations from the workplan

No deviations to be reported. The outputs of this task will be further expanded and updated over the course of the SAbyNA project.

7. Summary of work and recommendations for Task 5.3 and WP6

The work carried out in T5.2 and described in this deliverable report has been based on the resources identified and specified in the T5.1 Resource Library. Task 5.2 has had the aim to adapt and improve the usability of these resources to facilitate their use and their practical implementation by the industry. However, after analysing the implications of "adapting" or "improving" existing resources – especially resources that are European standards (ISO, CEN etc) – it was decided that this terminology was not suitable. It is not possible to "adapt" or "improve" an existing standard without considerable effort that would require European-, or even World- wide approval. Therefore, it is important to state that the activities have focused on "*improving the usability of the resources*". This improvement of usability has focused on the following:

- Identifying the most suitable resources within the WP5 Resource Library based on:
  - Applicability
  - User-friendliness
  - Robustness

Based on the ranking of the resources according to the assessment by the WP5 experts, the first of two tables of resources was generated based on the analysis of the three key criteria shown above (Table 1). Additional selected resources based on the experience of WP5 partners were identified in a second table (Table 2). The resources in the second table were selected even if one of their three main criteria was not the higher. The resources have still been judged to be sufficiently relevant for inclusion in the list of resources with Usability Cards. These gathered resources and the associated guidance provided via the Usability Cards will enable the designer/manufacturer and/or user to perform activities in the field of SbD in nanoprocesses,

A. Identify potential "hot spots" in processes/nanoprocesses
B. Conduct risk assessment of the process/nanoprocess in all stages of the life cycle
C. Identify and select the most appropriate control measures to be implemented by the designer/manufacturer as well as the criteria for its selection:
   a. Inherently safe design measures
   b. safeguarding and complementary protective measures
   c. information for use
D. Identify and select the most appropriate control measures to be implemented and/or by the user as well as the criteria for its selection:
   a. additional safeguards
   b. organization
   c. use of PPEs
   d. training

    e. Health surveillance and other

E. Define the procedures to be used for the validation of the design and operation stages of the nanoprocesses, as well as the procedures for the measurement of impacts:
    a. Environment
    b. OHS, e.g. nanometric aerosol emissions, derived exposures, etc.

It is important to realise that there are many existing standards, guidelines etc that enable the design/modification of processes (using a SbD method) that are not nano-specific but are still fully relevant for a process that includes nanomaterials. These standards can be used as the "backbone" for any nano specific guidelines.

A strong standard, in terms of existing structure and industry wide acceptance, is EN ISO 12100:2010 (RPSbD004), in the framework of the Directive 2006/42/EC on Machinery . The primary purpose of this harmonized Standard is to provide designers with an overall framework and guidance for decisions during the development of machinery to enable them to design machines that are safe for their intended use. It also provides a strategy for standards developers.

The concept of safety of machinery considers the ability of a machine to perform its intended function(s) during its life cycle where risk has been adequately reduced. To implement risk assessment and risk reduction the designer shall take the following actions, in the order given (see Figure 1 in Usability Card RPSbD004):

a. determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof;
b. identify the hazards and associated hazardous situations;
c. estimate the risk for each identified hazard and hazardous situation;
d. evaluate the risk and take decisions about the need for risk reduction;
e. eliminate the hazard or reduce the risk associated with the hazard by means of protective measures.

Actions a) to d) are related to risk assessment and e) to risk reduction. Many of the other resources in the WP5 Resource Library can be linked directly into this structure at each of these steps, to support and expand the resources typically used by a process designer at this point of the design process.

Risk assessment is a series of logical steps to enable, in a systematic way, the analysis and evaluation of the risks associated with machinery. Risk assessment is followed, whenever necessary, by risk reduction. Iterations of this process can be necessary to eliminate hazards as far as practicable and to adequately reduce risks by the implementation of protective measures. It is assumed that, when present on machinery, a hazard will sooner or later lead to harm if no protective measure or measures have been implemented.

Protective measures are the combination of the measures implemented by the designer and the user in accordance with Figure 2 (see Figure 2 in Usability Card RPSbD004). Measures which can be incorporated at the design stage are preferable to those implemented by the user and usually prove more effective.

The objective to be met is the greatest practicable risk reduction, taking into account the four factors below. The process itself is iterative and several successive applications can be necessary to reduce the risk, making the best use of available technology. In carrying out this process, it is necessary to take into account:

- the safety of the machine during all the phases of its life cycle;
- the ability of the machine to perform its function;
- the usability of the machine;
- the manufacturing, operational and dismantling costs of the machine.

The ideal application of these principles requires knowledge of the use of the machine, the accident history and health records, available risk reduction techniques, and the legal framework in which the machine is to be used.

N.B. A machine design which is acceptable at a particular time could be no longer justifiable when technological development allows the design of an equivalent machine with lower risk.

Providing proper information for use is part of the designer's contribution to risk reduction, but the protective measures concerned are only effective when implemented by the user. The user input is that information received by the designer from either the user community, regarding the intended use of the machine in general, or from a specific user.

The structure defined in resource RPSbD004 is an ideal starting point for the activities in Task 5.3. Although this SbD approach is applicable to the design of nanoprocesses, RPSbD004 does not automatically provide specific requirements for nano-risks, and currently no specific supporting standards are available. However, with the identified resources from T5.1 the main focus in T5.3 will be to customize the general approach of RPSbD004 (EN ISO 12100:2010) to the design of nanoprocesses throughout their life cycle. The most appropriate of the identified resources in this deliverable will be used to support the design process structure from this resource.

Next steps: recommendations for Task 5.3

Task 5.3 will develop the SbD strategy to be followed by SAbyNA (and particularly in support of the activities in WP6) to achieve a structure, based on existing resources, for the safe design of nanoprocesses (for NFs and NEPs), including end-of-life processes. The strategy will integrate the key resources identified in T5.2 to create a design strategy procedure that will guide the identification and selection of the most suitable resource(s) and the most appropriate use in each case. The strategy will include an iterative and hierarchical procedure for the selection of protection measures, until reaching the maximum risk reduction and the safest feasible design for the nanoprocesses (RPSbD004 - EN ISO 12100:2010).

The SbD strategies for nanoprocesses will integrate the prevention, mitigation and control of the expected impacts on the human and environmental health and safety for workers, as well as the procedures for verifying such impacts (e.g. measurement, inspection, balance).

The results of T5.3 will be compiled in the D5.3 deliverable, which will describe the SbD strategy to ensure the safe design and operation of the nanoprocesses along their life cycle, including end-of-life processes, describing at the same time, when, how and what resources (T5.2) will be necessary to involve in each case.

8. Appendix - Usability cards

This appendix contains all the usability cards of the selected resources for the Safety by Design of nanoprocesses.

RPSbD001	**EN 689:2018+AC:2019 Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values.**

This European Standard specifies a strategy to perform representative measurements of exposure by inhalation to chemical agents, in order to demonstrate the compliance with occupational exposure limit values (OELVs). Within EN 689, compliance means that workers' time weighted average workplace exposure is below an OELV with a corresponding reference period. OELVs include legal values and other numerical criteria. This standard is the European reference for the assessment of exposure within the framework of the EU directive on chemical agents at work 98/24/EC.

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*Exposure verification*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content (extracted from EN 689):

EN 689 deals with measurement strategy for comparing workers' exposure by inhalation with occupational exposure limit values (OELVs). The strategy gives a procedure to overcome the problem of variability and to use a relatively small number of measurements to demonstrate, with a high degree of confidence, that workers are unlikely to be exposed to concentrations exceeding the OELVs. The strategy shall be conducted by an appraiser and consists of an 1) Initial Workplace Exposure Assessment and then 2) Periodic Reassessment (Figure 1).

1) INITIAL WORKPLACE EXPOSURE ASSESSMENT

The initial workplace exposure assessment consists of two phases:

a) Basic characterization of the workplaces. Prior to conducting exposure measurements, the workplace and the related exposure profile under consideration shall be considered. The basic characterization of exposure determinants is in three steps: identification of chemical agents and other information required, review of workplace factors and estimation of exposure. All the information collected during the basic characterization shall be used to decide a) whether measurements are necessary or not, and b) constitute the different SEGs. If the basic characterization shows that exposure is probably higher than the OELV, then it is recommended to reduce exposure by risk management measures (RMM) before measurements are planned for compliance testing.

b) Exposure measurements. This phase deploys the following steps:

- Constitution of similar exposure groups (SEGs). The SEG concept is developed to simplify the exposure assessment if several workers have the same exposure profile. Where exposure measurements on some workers of the SEG indicate that the OELVs are met (compliance), then it is considered that this is so for all workers in the SEG.
- Selection of a suitable measuring procedure. The aim of the measuring procedure and sampling strategy is to obtain **valid and representative measurements** of the exposure of the workers for comparison with the OELVs, taking into account all possible conditions which can reasonably expected to be present throughout time. Measuring procedures shall comply with the requirements of EN 482. If this is not technically feasible, the reasons shall be given in the report. Additional indications on samples location, sampling duration and minimum number of measurements, among others are also provided by EN 689.
- Performing exposure measurements. Measurements will be carried out according to the measuring procedure established in the previous step. The employer should ensure that workers are informed about the objectives of exposure measurements.
- Validation of exposure measurements results and SEGs. Before testing compliance with the OELV it is necessary to consider the validity of each measurement and to use the measurements to evaluate the constitution of the SEG for testing compliance
- Comparison of results with OELVs. EN 689 describes the comparison with OELVs, both for a single chemical agent and for several hazardous chemical agents in combination. For this last situation an **exposure index** can be calculated, and this value shall be compared with 1, instead of comparing the exposure with the OELV. Preliminary and statistical tests and criteria are established to verify the compliance.
- Reporting of results.

If the initial workplace exposure assessment indicates non-compliance with OELVs for some SEGs, control measures shall be implemented, and a new initial workplace exposure assessment shall be conducted.

2) PERIODIC REASSESSMENT

Workplace exposure assessment shall be updated periodically to keep it current and ensure that worker's exposure remains in compliance with the OELV. Following the initial workplace exposure assessment, periodic reassessments shall be conducted. When significant changes occur at the workplaces that may affect exposure conditions, the appraiser shall decide whether a new initial workplace exposure assessment shall be conducted. Periodic intervals for measurements are proposed by EN 689.

In addition, several informative annexes containing relevant information are also provide by EN 689: A)Assessment of exposure under different working conditions, B) Occupational exposure limit values for compliance testing, C) Simultaneous workplace exposure to several chemical agents, D) Exposure profile and sampling duration, E) Check of exposure measurements distribution, and identification of exceptional exposure within the SEG, F) Testing compliance with OELVs, G) Exposure calculation with a work shift longer than 8h, H) Exposure below the limit of quantification and I) Interval for periodic measurements.

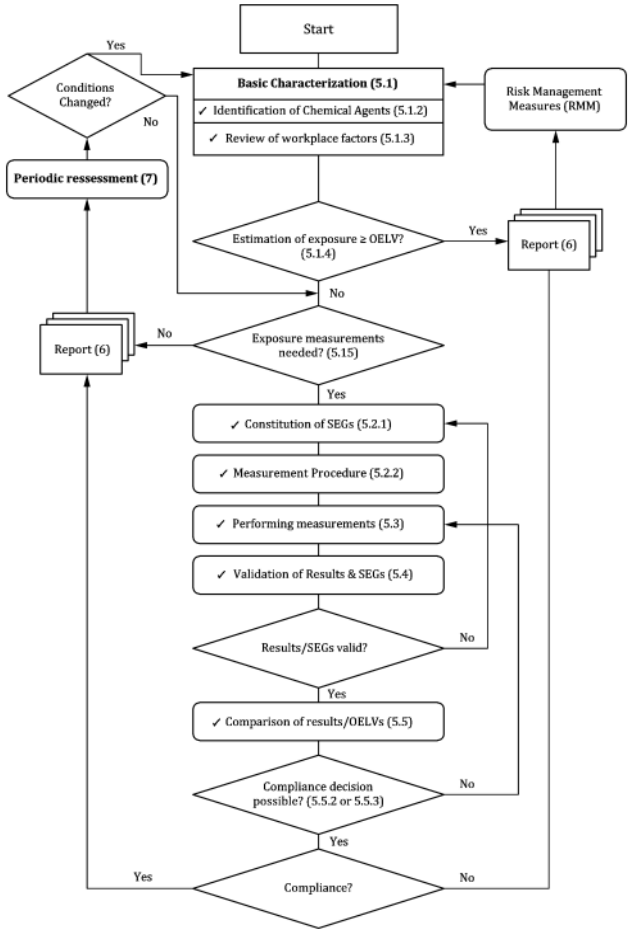


Figure 1. Schematic overview of the strategy deployed by EN 689:2018+AC:2019

If available, an OEL for a specific NOAA can be selected for risk management and exposure control decision-making. In this case, this document could be used as a guide to make representative measurements of inhalation exposure to NOAAs, to demonstrate compliance with selected Occupational Exposure Limit Values (OELVs).	*Standard* *Not nano-specific*
Source:https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:67662,6119&cs=14AF6DBAB8597419DB537B242544A737F	**CEN**

RPSbD002	**EN 1093-1:2008 Safety of machinery - Evaluation of the emission of airborne hazardous substances - Part 1: Selection of test methods**

This European Standard specifies parameters which can be used for the assessment of the emission of pollutants from machines or the performance of the pollutant control systems integrated in machines. It gives guidance on the selection of appropriate test methods according to their various fields of application and types of machines including the effects of measures to reduce exposures to pollutants. The test methods are given in additional parts of this European Standard.

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*Emission verification*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content (extracted from EN 1093-1):

This document provides general guidance on test methods to be used for the evaluation of the emission of airborne hazardous substances in machinery: a) types of test, according to the nature of pollutant used and the test environment (Laboratory methods and Field methods); b) selection of test, regarding the assessment parameter, the test environment and the nature of the pollutant, and finally, 3) statistical evaluation. The informative Annex A also provides the list of standards suitable for the measurement of fluid flow rates.

Table 1 presents the different methods dealt with in the different parts of this European Standard. Each identified method is described in detail in the part of this European Standard indicated in Table 1. Additional information about more specific test conditions will be provided in each new type-C standard dealing with a specific category of machinery.

Table 1. Summary of test methods

Assessment parameters		**Nature of pollutant**	**Chosen method**		
			Test bench method	**Room method**	**Field method**
Emission	**Emission rate**	Tracer and pollutant	–	EN 1093-2	
		Pollutant	EN 1093-3	–	–
	Pollutant concentration	Pollutant	EN 1093-8	EN 1093-9	–
Capture	**Efficiency**	Tracer	EN 1093-4		
		Pollutant	–	–	–
	Decontamination index	Pollutant	–	EN 1093-11	
Separation	**Efficiency**	Pollutant	EN 1093-6 and EN 1093-7	–	–

Harmonized standard. Compliance with the normative clauses of this standard - within the limits of the scope - confers a presumption of conformity with the corresponding essential requirement 1.5.13.- Emissions of hazardous materials and substances of the EU Directive 2006/42/EC on Machinery, and associated EFTA regulations. Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union.	*Standard* *Not nano-specific*
Source: https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:27868,6096&cs=19D334F0E8895E9D0395F640737099B14	**CEN**

RPSbD003	**EN 1093-11:2001+A1:2008 Safety of machinery - Evaluation of the emission of airborne hazardous substances - Part 11: Decontamination index**

This standard describes a method for the measurement of the decontamination index of pollution control systems e. g. capture devices including local exhaust ventilation, water spray systems and, when appropriate, separation equipment installed on a machine. This method uses the real pollutant (EN 1093-1: 1998) and can be operated in room or field environments.

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*Emissions verification*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content (extracted from EN 1093-11):

The **decontamination index** is defined as the average of the ratios, obtained at a number of specified locations in the surroundings, of the ambient air quality improvement to the real pollutant mean concentration with the pollution control system not in operation.

The principle of this measurement method consists in determining the **decontamination index**, the concentrations being measured at predetermined points around the machinery under inspection and in interpreting the value of this index, taking into account its range of variation and the influencing factors.

Corrections can be necessary to take into account of air pollution caused by other operations ("the background level").

When particle size distribution is determined at the same time as pollutant concentration, a decontamination index for each size fraction can be determined (see for example EN 481 “Workplace atmospheres - Size fraction definitions for measurement of airborne particles”).

The document provides guidance on the principle of the method, the determination of the concentration measurement points, the test method, the application to a specific group of machines, the influencing factors, the expression of results and the test report.

Harmonized standard. Compliance with the normative clauses of this standard - within the limits of the scope - confers a presumption of conformity with the corresponding essential requirement 1.5.13.- Emissions of hazardous materials and substances of the EU Directive 2006/42/EC on Machinery, and associated EFTA regulations. Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union.	*Standard* *Not nano-specific*
Source: https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:31115,6096&cs=1E6A640EA68CB94627A18B800863AEBDC	**CEN**

RPSbD004	**EN ISO 12100:2010 Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)**

EN ISO 12100:2010 specifies basic terminology, principles and a methodology for achieving safety in the design of machinery. It specifies principles of risk assessment and risk reduction to help designers in achieving this objective. These principles are based on knowledge and experience of the design, use, incidents, accidents and risks associated with machinery. Procedures are described for identifying hazards and estimating and evaluating risks during relevant phases of the machine life cycle, and for the elimination of hazards or sufficient risk reduction. Guidance is given on the documentation and verification of the risk assessment and risk reduction process.

Design topic	***Design strategy***	***Type of action***	***Level***
Explosion *Emissions of hazardous materials and substances* *Fire* *Materials and products* *Safety-related parts of control systems*	*Risk assessment*	*New process design (i.e. risk elimination by conception)*	*Advanced*

Main content (extracted from EN ISO 12100):

Basically, EN ISO 12100 provides and displays a general methodology for the safe design of a machine, based on risk assessment and risk reduction, supported by the principle of prevention by design (SbD). In this sense, it should be noted that the term machine encompasses not only unitary machines but also assemblies of machines (for example, a manufacturing line). The informative Annex B (informative) provides examples of hazards, hazardous situations and hazardous events.

Risk assessment is a series of logical steps to enable, in a systematic way, the analysis and evaluation of the risks associated with machinery. Risk assessment is followed, whenever necessary, by risk reduction. Iteration of this process can be necessary to eliminate hazards as far as practicable and to adequately reduce risks by the implementation of protective measures.

To implement a risk assessment and risk reduction design strategy, the designer shall take the following actions, in the order given (see Figure 1): a) determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof; b) identify the hazards and associated hazardous situations; c) estimate the risk for each identified hazard and hazardous situation; d) evaluate the risk and take decisions about the need for risk reduction; e) eliminate the hazard or reduce the risk associated with the hazard by means of protective measures. Actions a) to d) are related to risk assessment and e) to risk reduction.

The objective of risk reduction can be achieved by the elimination of hazards, or by separately or simultaneously reducing each of the two elements that determine the associated risk: severity of harm from the hazard under consideration and probability of occurrence of that harm. All protective measures intended for reaching this objective shall be applied in the following sequence, referred to as the three-step method (see also Figures 1 and 2).

Step 1: Inherently safe design measures. These measures eliminate hazards or reduce the associated risks by a suitable choice of design features of the machine itself and/or interaction between the exposed persons and the machine. This stage is the only one at which hazards can be eliminated, thus avoiding the need for additional protective measures such as safeguarding or complementary protective measures.

Step 2: Safeguarding and/or complementary protective measures. Taking into account the intended use and the reasonably foreseeable misuse, appropriately selected safeguarding and complementary protective measures can be used to reduce risk when it is not practicable to eliminate a hazard, or reduce its associated risk sufficiently, using inherently safe design measures.

Step 3: Information for use. Where risks remain despite inherently safe design measures, safeguarding and the adoption of complementary protective measures, the residual risks shall be identified in the information for use.

Information for use shall not be a substitute for the correct application of inherently safe design measures, safeguarding or complementary protective measures.

The process itself is iterative and several successive applications can be necessary to reduce the risk, making the best use of available technology
Protective measures are the combination of the measures implemented by the designer and the user in accordance with Figure 2. Measures which can be incorporated at the design stage are preferable to those implemented by the user and usually prove more effective. The final objective to be met is the greatest practicable risk reduction.

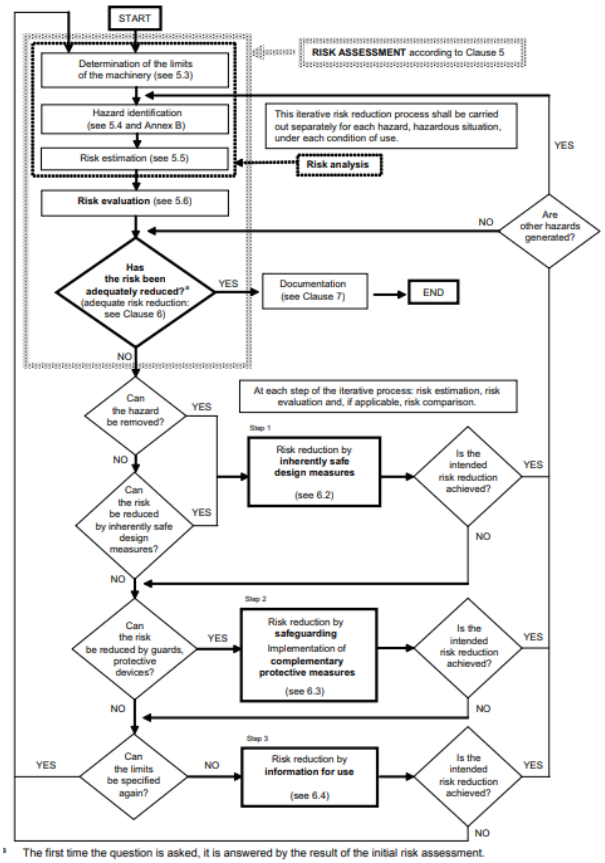


Figure 1. Schematic representation of risk reduction process including iterative three-step method

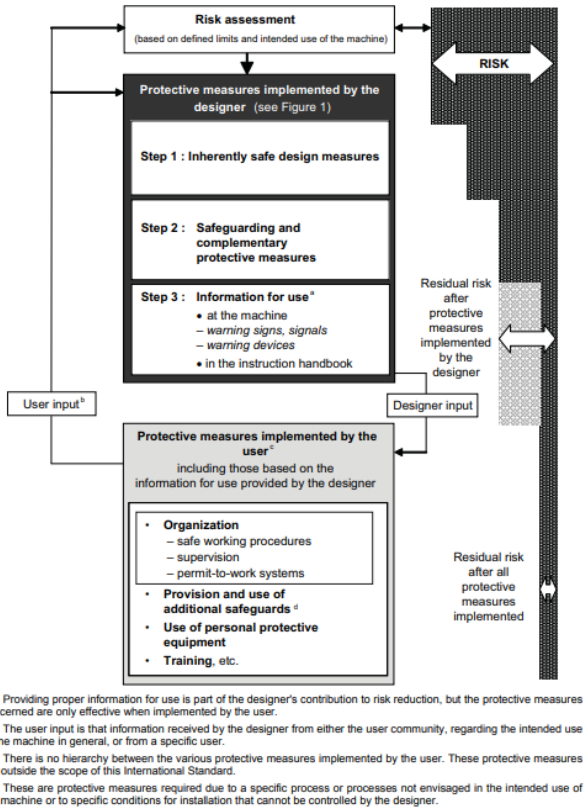


Figure 2 — Risk reduction process from point of view of designer

Harmonized standard. The approach deployed by EN ISO 12100 to integrate machine safety from design (prevention through design, SbD) can be applied to the design of the process as a whole. Compliance with the normative clauses of this standard - within the limits of the scope - confers a presumption of conformity with the corresponding essential requirements of the EU Directive 2006/42/EC on Machinery, and associated EFTA regulations. Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union.	*Standard* *Not nano-specific*
Source: https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:32299,6096&cs=14C6B274520C60586598CB63FE4732782	**CEN**

RPSbD006	**EN ISO 13849-1:2015 Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design (ISO 13849-1:2015)**

This standard provides safety requirements and guidance on the principles for the design and integration of safety-related parts of control systems (SRP/CS), including the design of software. For these parts of SRP/CS, it specifies characteristics that include the performance level required for carrying out safety functions.

Design topic	***Design strategy***	***Type of action***	***Level***
Safety-related parts of control systems	*Risk assessment*	*New process design (i.e. risk elimination by conception)*	*Advanced*

Main content (extracted from EN ISO 13849-1):

Parts of machinery control systems that are assigned to provide safety functions are called safety related parts of control systems (SRP/CS) and these can consist of hardware and software and can either be separate from the machine control system or an integral part of it. The ability of SRP/CS to perform a safety function under foreseeable conditions is allocated one of five levels, called performance levels (PL).

The strategy for risk reduction at the machine is given in EN ISO 12100. This strategy covers the whole life cycle of the machine. The design of the SRP/CS to provide the required risk reduction is an integral subset of the overall design procedure for the machine. The SRP/CS provides safety function(s) at a PL which achieves the required risk reduction. The greater the amount of risk reduction required to be provided by the SRP/CS, the higher the PL required shall be.

This part of EN ISO 13849 is intended to give guidance to those involved in the design and assessment of SRP/CS. In order to assist the designer and facilitate the assessment of achieved PL, this document employs a methodology based on the categorization of structures according to specific design criteria and specified behaviours under fault conditions. These categories are allocated one of five levels, termed Categories B, 1, 2, 3 and 4.

The document provides guidance on design considerations, safety functions, categories, fault consideration and fault exclusion, validation, maintenance, technical documentation and information for use.

A set of eleven annexes located at the end of the standard, provide additional content on determination of required performance level (PLr), block method and safety-related block diagram, calculating or evaluating MTTFD values for single components, simplified method for estimating MTTFD for each channel, estimates for diagnostic coverage (DC) for functions and modules, estimates for common cause failure (CCF), systematic failure, example of combination of several safety-related parts of the control system, examples, software and numerical representation.

The document is of relevance, in particular, for the market players with regard to machinery safety (machine manufacturers, health and safety bodies, machine users/employers, etc).

Harmonized standard. Compliance with the normative clauses of this standard - within the limits of the scope - confers a presumption of conformity with the essential requirement 1.2.1 of Annex I of the EU Directive 2006/42/EC on Machinery, and associated EFTA regulations. Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union.	*Standard* *Not nano-specific*
Source: https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:39285,6096&cs=1269268F03116BF7319D76D5A120E771A	**CEN**

RPSbD007	**EN ISO 14123-1:2015 Safety of machinery — Reduction of risks to health resulting from hazardous substances emitted by machinery — Part 1: Principles and specifications for machinery manufacturers**

<table>
<tr><td colspan="4">This part of ISO 14123 establishes principles for the control of risks to health resulting from hazardous substances emitted by machinery. This part of ISO 14123 is not applicable to substances that are a hazard to health solely because of their explosive, flammable or radioactive properties or their behaviour at extremes of temperature or pressure.</td></tr>
<tr><td>Design topic</td><td>Design strategy</td><td>Type of action</td><td>Level</td></tr>
<tr><td>Emissions of hazardous materials and substances</td><td>Designer strategies (D)</td><td>Risk management measures (i.e. implementation of control measures)</td><td>Advanced</td></tr>
<tr><td colspan="4">Main content (extracted from EN ISO 14123-1):

EN ISO 14123-1 provides a general framework for the design of the measures to be implemented in a new machine to ensure compliance with the requirements of the Machinery Directive in the field of dangerous substances emitted by machinery, taking into account human exposure to the machine at any stage of its life cycle.

The standard deploys the “three-step method” approach (EN ISO 12100: 2010) for the field of hazardous substances emitted by machinery. This approach, based on machine risk assessment, promotes a SbD approach to machinery design, where the designer must first attempt to eliminate or prevent risks resulting from exposure to hazardous substances using inherently safe design measures (Step 1), before implementing safeguarding and/or complementary protective measures (Step 2) or finally information for use for residual risks (Step 3).

The document provides general guidance on risk assessment, types of emissions (airborne emissions and non-airborne emissions), requirements and/or protective measures for elimination and/or reduction of risk and information for use and maintenance. Aspects related to the verification of safety requirements and/or protective measures are specified in EN ISO 14123-2.

Annex A lists examples of protective measures for reduction of exposure to hazardous substances, classified hierarchically according to the “three-step method”: elimination and prevention of risks, risk reduction (reduction of emission, reduction by ventilation, reduction of exposure by machinery operation or segregation) and information and other protective measures regarding residual risks.

This standard can be used as guidance in controlling the risk to health resulting from hazardous substances emitted by machinery where there is no type-C standard for a particular machine.

The document is of relevance, in particular, for the market players with regard to machinery safety (machine manufacturers, health and safety bodies, machine users/employers, etc).</td></tr>
<tr><td colspan="3">Harmonized standard. Compliance with the normative clauses of this standard - within the limits of the scope - confers a presumption of conformity with the corresponding essential requirement 1.5.13.- Emissions of hazardous materials and substances (Clauses 4 to 8) of the EU Directive 2006/42/EC on Machinery, and associated EFTA regulations. Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union.</td><td>Standard
Not nano-specific</td></tr>
<tr><td colspan="3">Source:
https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:59210,6096&cs=1D68899E03A3DA9C3315822EBCBCA8ADB</td><td>CEN</td></tr>
</table>

RPSbD008	**EN ISO 14123-2:2015 Safety of machinery - Reduction of risks to health resulting from hazardous substances emitted by machinery - Part 2: Methodology leading to verification procedures (ISO 14123-2:2015)**

EN ISO 14123-2:2015 establishes a methodology that leads to the selection of critical factors relating to emissions of hazardous substances for the purpose of specifying suitable verification procedures. Such procedures are required to take account of the health risks associated with the emission of hazardous substances in all phases of the machine life cycle.

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*Emission verification)*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content (extracted from EN ISO 14123-2):

The standard specifies the steps that shall be taken to develop a procedure for verifying the emission of hazardous substances in all phases of the machine's life cycle. In this sense, the document provides general guidance on: a) Identification of hazardous substances emitted during the intended use of the machine; b) Characterization of emissions (quantity or scale of the emission at all phases of the machine life cycle, location of the emission and the likely position of persons, physical characteristics of the emission, etc); c) Identification of critical factors on which the emission is most dependent; d) Specification of indicative parameters required to reduce emission (range of values, etc) and e) Verification, carried out by collection of data relating to the indicative parameters (it may include results from field testing, laboratory testing, measurements, examination or calculations).

The three Informative annexes at the end of the document provide additional information on the flow diagram of steps leading to verification procedure, examples of types of emission and how to assess them and examples of relevant factors and their indicative parameters.

This part of EN ISO 14123-2 can also be used to assist designers and manufacturers to identify sources of emission that can subsequently affect the exposure of operators and others. It can also be used as guidance in controlling the risk where there is no type-C standard for a particular machine.

The document is of relevance, in particular, for the market players with regard to machinery safety (machine manufacturers, health and safety bodies, machine users/employers, etc).

Harmonized standard. Linked with RPsbD007. EN ISO 14123-2:2015 is intended to be used in conjunction with EN ISO 14123-1. Compliance with the normative clauses of this standard - within the limits of the scope - confers a presumption of conformity with the corresponding essential requirement [1.5.13.- Emissions of hazardous materials and substances] of the EU Directive 2006/42/EC on Machinery, and associated EFTA regulations. Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union.	*Standard Not nano-specific*
Source: https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:59209,6096&cs=10DCA6333E1138F9EFDA4EDD50279BEBB	**CEN**

RPSbD009	**EN 16966:2018 Workplace exposure - Measurement of exposure by inhalation of nano-objects and their aggregates and agglomerates - Metrics to be used such as number concentration, surface area concentration and mass concentration**

This European Standard provides a guideline on the implications of choice of particle metric to express the exposure to airborne NOAAs e.g. released from nanomaterials and present the principles of operation, advantages and disadvantages of various techniques that measure the different aerosol metrics.

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*Exposure verification*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content (extracted from EN 16966):

For reason of evaluation it is recommended that the occupational exposure to airborne NOAAs is determined in parallel for more than one metric, as it is presently unknown which metric later will be considered as most relevant for the critical health effect.

The standard specifies which metrics should be measured during a basic assessment and a comprehensive assessment, respectively, as described in EN 17058.

EN 16966 provides specific information mainly for the following metrics/measurement techniques:

- Number/Condensation Particle Counters by optical detection;
- Number size distribution by electrical mobility;
- Surface area (electrical charge on available surface);
- Mass/chemical analyses (e.g. Inductively Coupled Plasma atomic Mass Spectrometry (ICP-MS), X-Ray Fluorescence (XRF)) on size-selective samples (e.g. by impaction or diffusion).

Potential problems and limitations are described and need to be addressed when occupational exposure limit values might be adopted in the future and compliance measurements will be carried out.

This document is intended for those responsible for selecting measurement methods for occupational exposure to airborne nano-objects.

Guideline on the choice of particle metric to express the exposure to airborne NOAAs and the principles of operation, advantages and disadvantages of various techniques that measure the different aerosol metrics.	*Nano--specific Standard*
Source: https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:40120,6119&cs=1D1AB202F7D3D4B8F73C514B0E7E65C69	**CEN**

RPSbD010	**EN 17058:2018 Workplace exposure - Assessment of exposure by inhalation of nano-objects and their aggregates and agglomerates**

This European Standard provides guidelines to assess workplace exposure by inhalation of nano-objects and their aggregates and agglomerates (NOAA). It contains guidance on the sampling and measurement strategies to adopt and methods for data evaluation. While the focus of this document is on the assessment of nano-objects, the approach is also applicable for exposure to the associated aggregates and agglomerates, i.e. NOAA, and particles released from nanocomposites and nano-enabled products. It is linked to the OECD Harmonized tiered approach (2015).

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*Exposure verification*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content (extracted from EN 17058):

The present document focuses on the assessment of occupational exposure by inhalation of nano-objects and their aggregates and agglomerates (NOAA). This document concerns the elements of exposure assessment and provides guidance for various applications.

The document provides general guidance on measurement strategy (objectives, source domains), measuring devices and measurement methods, levels of exposure assessment (initial, basic, comprehensive) and integration of levels of exposure assessment in a tiered-approach framework, including building blocks, evaluation criteria and decision rules.

The informative annexes at the end of the standard, provide additional guidance on instrumentation (real-time monitors, aerosol samplers and off-line analysis), checklist for minimum information required during the initial assessment, template for contextual information for comprehensive assessment (NECID), statistical analysis of time series, decision rules for basic assessment and an example for calculation of fraction deposited in the gas exchange region.

Three levels of assessment of exposure to NOAA will be distinguished, which differ with respect to their objectives, methodologies and accuracy of the outcome, as well as with the information input requirements and the level of expertise needed for application (Figure 1):

1) **Initial assessment (Tier 1),** to determine the potential for release and emission of NOAA into the workplace air resulting from processes and handling with nanomaterials. The gathered information in the initial assessment shall determine if the potential for release of NOAA into the occupational environment can be excluded or not.

2) **Basic assessment (Tier 2),** to get an indication of exposure to NOAA. Based on the results, the appraiser shall decide to use either a statistical method or the decision rule method to interpret the online monitoring (DRI) results to draw a conclusion on whether the level of exposure to the investigated NOAA is significant. Based on whether this is significant, and the results of the off-line analysis, the appraiser shall decide on the next step by using Table 1.

3) **Comprehensive assessment (Tier 3),** to comprehensively characterize the airborne particles in the breathing zone for further evaluation.

The different levels of assessment can be used as ‘stand-alone’ modules to answer the specific objective of the measurements. For example an initial assessment can be sufficient to indicate whether a potential for release of NOAA exists for activities related to nanomaterials. A basic assessment as such can satisfy the objective of characterization of releases or the effectiveness of control measures, or ranking activities according to potential for exposure, or identify job titles that have potential for exposure. In addition, the basic assessment can give sufficient evidence to require risk mitigation actions. If the objective of the measurement is to further investigate

(comprehensive exposure assessment), a Tier 3 exposure assessment is required. The outcome of such an exposure assessment might be recommendations for risk management measures.

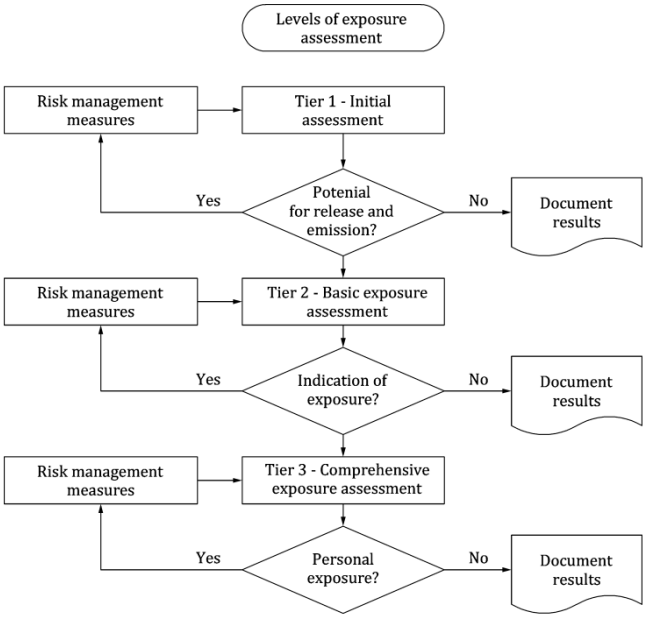


Figure 1. Building blocks and overview of a generic tiered approach

Table 1. Summary of decision logic (with presence of NOAA in background investigated)

Offline analyses results	**Offline analyses results in background**	**Online monitoring (DRI) results** (significance of activity-effect[a])	**Conclusion** (Likelihood of exposure induced by the nanomaterial-activity)
+	-	significant	likely[b]
+	+	significant	presumable [b]
+	-	non-significant	possible/not excluded
+	+	non-significant	
-	-	non-significant	unlikely
		significant[c]	

a Level of exposure = significant when activity-effect level (i.e. the average difference in concentration between background and activity) was significant ($p < 0,05$) as estimated with a 2nd-order MA-model.

b Likelihood becomes *possible/not excluded* when there were secondary sources present

c Indication of the presence of process-generated nanoparticles, but not the investigated NOAA (as determined with the off-line analysis).

This tiered approach in this European Standard applies to NOAA for which no nano-specific legal OEL exists. In case there is a nano-specific legal OEL, the associated measurement strategy and the measurement strategy according to national regulations/EN 689 shall be applied.	*Nano--specific Standard*
Source: https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:37668,6119&cs=15F75671B7475A592782A3200FDD096F5	**CEN**

RPSbD011	**ISO/TR 12885:2018 Nanotechnologies — Health and safety practices in occupational settings**

This document describes health and safety practices in occupational settings relevant to nanotechnologies. This document focuses on the occupational manufacture and use of manufactured nano-objects, and their aggregates and agglomerates greater than 100 nm (NOAAs). It does not address health and safety issues or practices associated with NOAAs generated by natural processes, hot processes and other standard operations which unintentionally generate NOAAs, or potential consumer exposures or uses, though some of the information in this document can be relevant to those areas.

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*User strategies (U)*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content (extracted from ISO/TR 12885):

This document is based on current information about nanotechnologies, including characterization, health effects, exposure assessments, and control practices.

It assembles useful knowledge on occupational safety and health practices in the context of nanotechnologies. Use of the information in this document could help companies, researchers, workers and other people to prevent potential adverse health and safety consequences during the production, handling, use and disposal of manufactured Nano-Objects, and their Aggregates and Agglomerates greater than 100 nm (NOAAs). This advice is broadly applicable across a range of NOAAs and applications.

The document provides practical information on nanomaterials description and production processes, hazard characterization, exposure assessment to nanomaterials, risk assessment in occupational settings and risk mitigation approaches.

Several informative annexes complement the document referring to: primary chemical composition of nanomaterials, nanomaterial-specific animal and cell culture toxicity studies, characteristics of selected instruments and techniques for monitoring nano-aerosol exposure, characteristics of biosafety cabinets, assigned protection factors for respirators and advantages and disadvantages of different types of air-purifying particulate respirators.

It is expected that this document will be revised and updated, and new safety standards will be developed as our knowledge increases and experience is gained in the course of technological advance.

This document collects information and describes health and safety practices applicable to work environments relevant to nanotechnologies.	*Nano—specific Standard*
Source: https://www.iso.org/standard/67446.html	**ISO**

RPSbD012	**ISO/TS 12901-2:2014 Nanotechnologies — Occupational risk management applied to engineered nanomaterials — Part 2: Use of the control banding approach**

ISO/TS 12901-2:2014 describes the use of a control banding approach for controlling the risks associated with occupational exposures to nano-objects, and their aggregates and agglomerates greater than 100 nm (NOAA), even if knowledge regarding their toxicity and quantitative exposure estimations is limited or lacking. The control banding tool described here is specifically designed for inhalation control. Some guidance for skin and eye protection is given in ISO/TS 12901-1.

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*Risk assessment*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content (extracted from ISO/TS 12901-2):

Control banding is a pragmatic approach which can be used for the control of workplace exposure to possible hazardous agents with unknown or uncertain toxicological properties and for which quantitative exposure estimations are lacking. It may complement the traditional quantitative methods based on air sampling and analysis with reference to OELs when they exist.

ISO/TS 12901-2 proposes guidelines for controlling and managing occupational risk based on a control banding approach specifically designed for intentionally produced NOAA. The term “NOAA” applies to such components, whether in their original form or incorporated in materials or preparations from which they could be released during their lifecycle.

Control banding can be particularly useful for the risk assessment and management of nanomaterials, given the level of uncertainty in work-related potential health risks from NOAA (Figure 1). It may be used for risk management in a proactive manner and in a retroactive manner. Both approaches are described in ISO/TS 12901-2. In the proactive manner existing control measures, if any, are not used as input variables in the potential exposure banding while in a retroactive manner existing control measures are used as input variables.

Control banding applies to issues related to occupational health in the development, manufacturing and use of NOAA under normal or reasonably predictable conditions, including maintenance and cleaning operations but excluding incidental or accidental situations.

ISO/TS 12901-2 emphasizes that the control banding method applied to manufactured NOAA requires assumptions to be formulated on information that is desirable but unavailable. Thus, the user of the control banding tool needs to have proven skills in chemical risk prevention and more specifically in risk issues known to be related to that type of material. The successful implementation of this approach requires a solid expertise combined with a capacity for critical evaluation of potential occupational exposures and training to use control banding tools to ensure appropriate control measures and an adequately conservative approach.

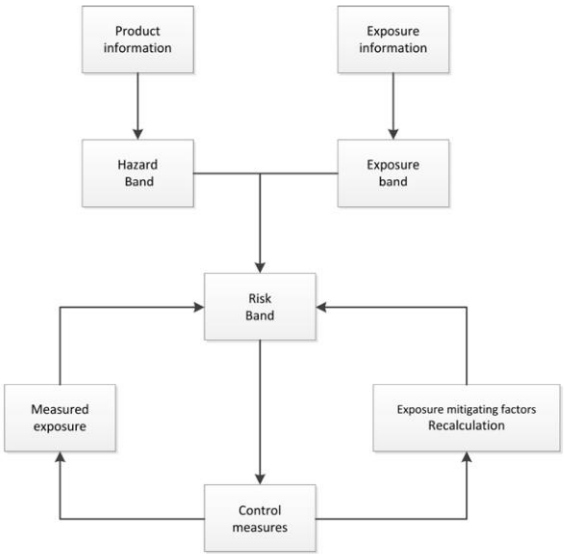


Figure 1. Evaluation and risk banding process according to ISO/TS 12901-2:2014

Control bands are obtained by matching the hazard band and the exposure potential band according to the following matrix (Table 1).

Table 1. Control band matrix as a result of hazard band and exposure potential band

		Emission potential band			
Hazard band		**EB 1**	**EB 2**	**EB 3**	**EB 4**
	A	CB 1	CB 1	CB 1	CB 2
	B	CB 1	CB 1	CB 2	CB 3
	C	CB 2	CB 3	CB 3	CB 4
	D	CB 3	CB 4	CB 4	CB 5
	E	CB 4	CB 5	CB 5	CB 5

Then, the five control approaches proposed by ISO/TS 12901-2 are:

- CB 1: Natural or mechanical general ventilation;
- CB 2: Local ventilation: extractor hood, slot hood, arm hood, table hood, etc.;
- CB 3: Enclosed ventilation: ventilated booth, fume hood, closed reactor with regular opening;
- CB 4: Full containment: glove box/bags, continuously closed systems;
- CB 5: Full containment and review by a specialist: seek expert advice.

ISO/TS 12901-2 is intended to help businesses and others, including research organizations engaged in the manufacturing, processing or handling of NOAA, by providing an easy-to-understand, pragmatic approach for the control of occupational exposures. In the absence of relevant regulatory specifications for NOAA, the control banding approach can be used as a first approach to controlling workplace exposure to NOAA. The ultimate purpose of control banding is to control exposure in order to prevent any possible adverse effects on workers' health.	*Nano-specific standard*
Source: https://www.iso.org/standard/53375.html	**ISO**

RPSbD013	**ISO/TR 14121-2:2012 Safety of machinery — Risk assessment — Part 2: Practical guidance and examples of methods**

ISO/TR 14121-2 gives practical guidance on conducting risk assessment for machinery in accordance with ISO 12100 and describes various methods and tools for each step in the process.

Design topic	***Design strategy***	***Type of action***	***Level***
All design topics	*Risk assessment*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content (extracted from ISO/TR 14121-2):

The purpose of risk assessment is to identify hazards, and to estimate and evaluate risks so that they can be reduced. There are many methods and tools available for this purpose and several are described in this document. The method or tool chosen will largely be a matter of industry, company or personal preference. The choice of a specific method or tool is less important than the process itself. The benefits of risk assessment come from the discipline of the process rather than the precision of the results. It can be useful to review the risk assessment when the design has been finalised, when a prototype exists and after experience of the use of the machinery.

Changes to machinery are generally less expensive and more effective at the design stage, so it is advantageous to perform risk assessment during machinery design. Adding protective/risk reduction measures to a design can increase costs and can restrict the facility of use of the machine if added after a design has been finalized or the machinery itself has already been built.

In this context, this document provides guidance on risk assessment process (hazard identification, risk estimation, risk evaluation, risk reduction), risk estimation tools (risk matrix, risk graph, numerical scoring, hybrid tool), risk reduction measures (inherently safe design, complementary protective/risk reduction measures, information for use, standard operating procedures), risk assessment iteration, and finally, documentation of risk assessment. In addition, Annex A provides a specific example for a risk assessment and a risk reduction process.

ISO/TR 14121-2 gives examples of different measures that can be used to reduce risk and is intended to be used for risk assessment on a wide variety of machinery in terms of complexity and potential for harm. Its intended users are those involved in the design, installation, or modification of machinery (for example, designers, technicians or safety specialists).

Apart from the risk assessment made at the design stage, during construction and commissioning, the principles and methods presented in this document can also be applied to existing machinery during revision or modification of machinery or at any time for the purpose of assessing existing machinery, for example, in the case of mishaps or malfunctions.

This resource gives examples of different measures that can be used to reduce risk and is intended to be used for risk assessment on a wide variety of machinery in terms of complexity and potential for harm. Its intended users are those involved in the design, installation or modification of machinery (for example, designers, technicians or safety specialists).	*Standard* *Not nano--specific*
Source: https://www.iso.org/standard/57180.html	**ISO**

RPSbD014	**ISO/TR 18637:2016 Nanotechnologies — Overview of available frameworks for the development of occupational exposure limits and bands for nano-objects and their aggregates and agglomerates (NOAAs)**

ISO/TR 16837:2016 provides an overview of available methods and procedures for the development of occupational exposure limits (OELs) and occupational exposure bands (OEBs) for manufactured nano-objects and their aggregates and agglomerates (NOAAs) for use in occupational health risk management decision-making.

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*User strategies (U)*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content (extracted from ISO/TR 18637):

This document presents an overview of the state-of-the-art in the development of OELs and OEBs for NOAAs. Current approaches for assigning default hazard bands in the absence of NOAA-specific toxicity data are described. These approaches build on current hazard and control banding strategies, such as those developed in ISO/TS 12901-2.

The document describes a general framework for the development of occupational exposure limits (OELs) or occupational exposure bands (OEBs) for individual NOAAs or categories of NOAAs with different levels of available data. OELs and OEBs are intended to provide occupational safety and health professionals with a health basis for assessing the effectiveness of exposure controls and other risk management practices.

Sufficient data to develop an OEL may not be available, especially for substances such as NOAAs used in emerging technologies. To date, few OELs and OEBs have been developed for specific NOAAs and none have been formally regulated by a government agency. To aid in hazard communication and exposure control decisions for substances without OELs, hazard banding has been used for many years. Hazard banding schemes typically consist of qualitative bands ranging from low to high severity of effects. Some hazard banding schemes include associated OEBs. In control banding, the hazard band and the exposure band are combined to determine the control band for any particular occupational scenario (e.g. ISO/TS 12901-2).

Standard OEL and OEB methodologies for NOAAs are needed to evaluate the evidence on the hazard potential of NOAAs in the workplace to provide a health basis for risk management decisions, including selection and evaluation of engineering control options. The current state of the methods and data to develop OELs and OEBs for NOAAs is described in this document, along with an evaluation of those methods used in developing the current OELs for NOAAs. Categorical approaches to derive OEBs for NOAAs with limited data are also discussed, such as those based on biological mode-of-action (MOA) and physico-chemical (PC) properties. In addition, the evidence-based approach described in this document may be useful in the evaluation and/or verification of current hazard and control banding schemes and for identifying the key data gaps.

The primary target audience of this document is occupational safety and health professionals in government, industry, and academia, who have the expertise to develop OELs or OEBs based on the guidance in this document.

This document can be considered complementary to ISO/TS 12901-2 on control banding for nanomaterials as it describes the state-of-the-art in the process of assigning nanomaterials to hazard bands/OEBs when the scientific evidence is not sufficient to develop an individual OEL.	*Nano--specific Standard*
Source: https://www.iso.org/standard/63096.html	**ISO**

RPSbD015	**EN ISO 19353:2019 Safety of machinery - Fire prevention and fire protection (ISO 19353:2019)**

This document specifies methods for identifying fire hazards resulting from machinery and for performing a risk assessment. It gives the basic concepts and methodology of protective measures for fire prevention and protection to be taken during the design and construction of machinery.

Design topic	***Design strategy***	***Type of action***	***Level***
Fire	*Designer strategies (D)*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content (extracted from EN ISO 19353):

Fire risk assessment comprises a series of logical steps that allow systematic examination of fire hazards according to the procedures outlined in EN ISO 12100. When deemed necessary, risk evaluation is followed by risk reduction. The fire risk assessment and risk reduction shall be repeated as an iterative process until the risk of a fire occurrence has been adequately reduced (see Figure 1, EN ISO 12100). Risk analysis judgements shall be supported by a qualitative or, where appropriate, quantitative estimate of the risk associated with the hazards present on the machinery.

The safety of machinery against fire involves fire prevention and fire protection and fire-fighting. In general, these include technical, structural, organizational and fire suppression measures. Effective fire safety of machinery can require the implementation of a single measure or a combination of measures. In this context, this document deals with the measures shown in Figure 1.

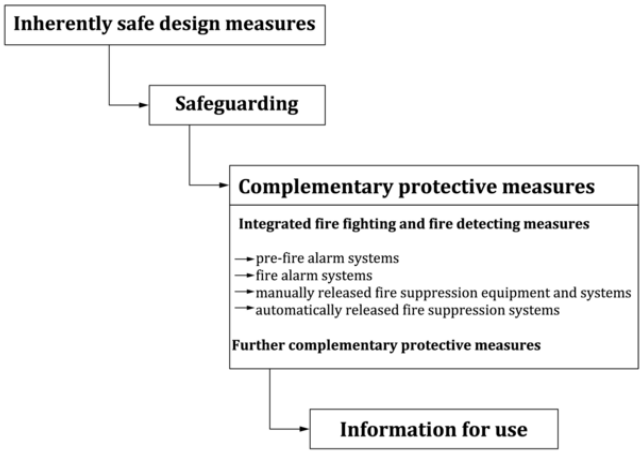


Figure 1. Protective measures dealt with in EN ISO 19353

EN ISO 19353 document provides guidelines for consideration in reducing the risk of machinery fires to acceptable levels through machine design, risk assessment and operator instructions. The measures consider the intended use and reasonably foreseeable misuse of the machine.

This standard specifies fire hazards (combustible materials, oxidizers, ignition sources), a strategy for fire risk assessment and risk reduction and a procedure for the selection of complementary protective measures.

The three Informative annexes at the end of the document provide examples of machines and their typical fire-related hazards, a methodology for selecting and qualifying a fire detection and fire suppression system, the design of a fire suppression system integrated in machinery, ignition sources and risk assessment and risk reduction of a machining centre for the machining of metallic materials.

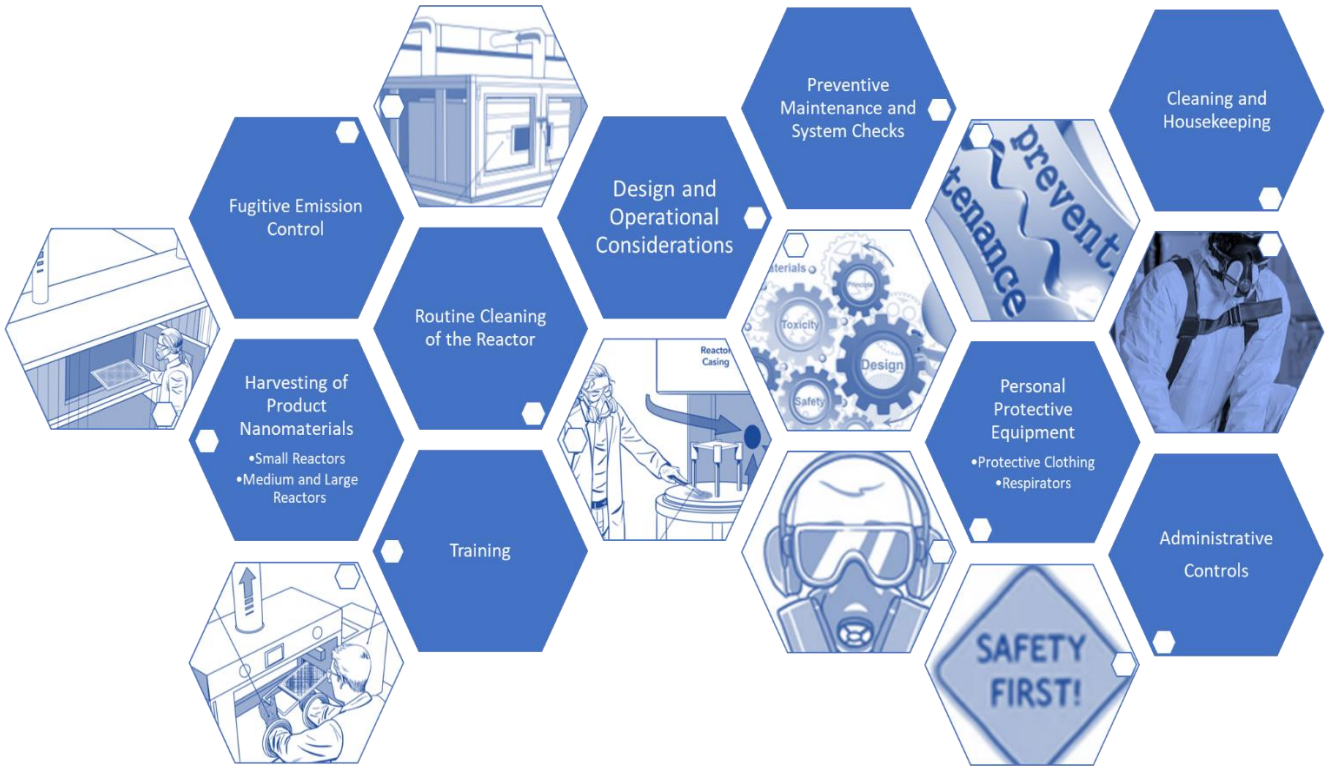
The document is of relevance, in particular, for the market players with regard to machinery safety (machine manufacturers, health and safety bodies, machine users/employers, etc).

Harmonized standard. Compliance with the normative clauses of this standard - within the limits of the scope - confers a presumption of conformity with the corresponding essential requirement 1.5.6 Fire, of the EU Directive 2006/42/EC on Machinery and associated EFTA regulations, with regard to identification of the protective measures available for risk reduction. Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union.	*Standard* *Not nano--specific*
Source:https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:64580,6096&cs=1D661405157B82946A7E37A895A7E9F39	**CEN**

RPSbD017	**Workplace Design Solutions: Protecting Workers during Nanomaterial Reactor Operations**

A compendium of control approaches for nanomaterial production and use processes. This Workplace Design Solutions document provides guidance on exposure control approaches for protecting workers during nanomaterial reactor operations. The mission is to reduce or prevent occupational injuries, illnesses, and fatalities by considering hazard prevention in the design, re-design, and retrofit of new and existing workplaces, tools, equipment, and work processes.

Design topic	***Design strategy***	***Type of action***	***Level***
Workplace Design Solutions / Safety part of control systems	*Inherently safe design, Information for use, Engineering controls, PPEs*	*Risk management measures (i.e., implementation of control measures)*	*Beginner*



The resources RPSbD018 Workplace Design Solutions: Protecting Workers during the Handling of Nanomaterials from the NIOSH and RPSbD023 Best practices guidance for nanomaterial risk management in workplace from the IRSST are complementary to this document.	*Guideline* *High Nano-specificity*
Source : https://doi.org/10.26616/NIOSHPUB2018120 Source of the complementary documents: https://www.cdc.gov/niosh/topics/nanotech/pubs.html http://www.irsst.qc.ca/media/documents/PubIRSST/R-899.pdf	**NIOSH**

RPSbD018	**Protecting Workers during the Handling of Nanomaterials**

Small-scale handling of nanopowders is a common task; examples include working with a quality assurance/control sample, weighing out a specific quantity for mixing/compounding, and processing smaller quantities in downstream industries. The tasks of weighing out nanomaterials can lead to worker exposure primarily through the scooping, pouring, and dumping of these materials. The identification and adoption of effective control technologies is an important first step in reducing the risk associated with worker exposure to ENMs and ENM-associated byproducts. This document provides information about hood and laboratory design and operation, administrative controls (such as good work practices), and the use of personal protective equipment.

Design topic	***Design strategy***	***Type of action***	***Level***
Workplace Design Solutions / Safety part of control systems	*Inherently safe design*	*Risk management measures (i.e., implementation of control measures)*	*Beginner*

Engineering control

- **Design and operational consideration**
- Locate the ventilated enclosure away from walkways
- Keep exhaust ducts short and simple
- Consider using Bag In/Bag Out filter change
- Conduct initial performance tests of the control as installed
- Restrict access to only those workers required
- Use of nano-powders that are pre-mixed in a liquid
- **Preventive Maintenance**
- Keep equipment in effective and efficient working order
- Look for signs of damage to the ducting and enclosure
- Regularly check

Administrative Controls

- **Good work practices**
- Avoid overcrowd or block the exhaust
- Clean up spills of liquids containing nanomaterials using absorbent materials
- Clean work surfaces with appropriate techniques
- **Cleaning and Housekeeping**
- Dailly clean of the working area and equipment
- Do not use dry methods such as a brush, broom
- Proper disposal of contaminant materials
- **Training**
- Provide safety and health training to workers
- Understand the nature of potential workplace exposures

Personal Protective Equipment

- **Personal Protective Clothing**
- Use nitrile or other chemically impervious gloves
- Never use compressed air to remove dust from clothing
- **Respirators**
- Employers should consult with an occupational safety and health professional to determine the respirator best suited for their specific application

The resource RPSbD023 Best practices guidance for nanomaterial risk management in workplace from the IRSST is complementary to this document.	*Guideline* *High Nano-specificity*
Source:https://www.cdc.gov/niosh/topics/nanotech/pubs.html Source of the complementary documents: http://www.irsst.qc.ca/media/documents/PubIRSST/R-899.pdf https://doi.org/10.26616/NIOSHPUB2018120	**NIOSH**

RPSbD019	**Workplace Design Solutions: Protecting Workers during Intermediate and Downstream Processing of Nanomaterials**

This Workplace Design Solutions document provides guidance on exposure control approaches for intermediate and downstream processes commonly used after the production of nanomaterials.

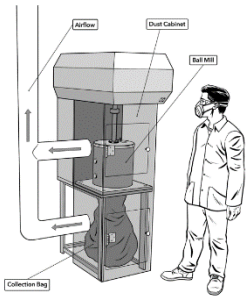
Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*User strategies (U)*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content:

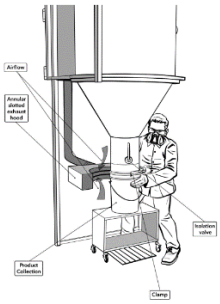
Description of Exposure

Engineering Controls

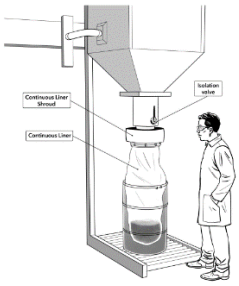
A qualified industrial hygienist can help assess process-related risks and make recommendations to minimize exposure. Control measures for ENMs and other hazards should be implemented within the context of a comprehensive occupational safety and health management system [ANSI/AIHA 2012].



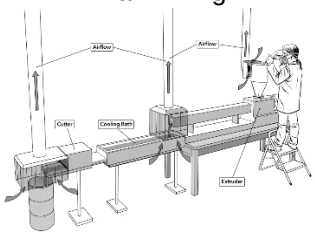
Ball milling



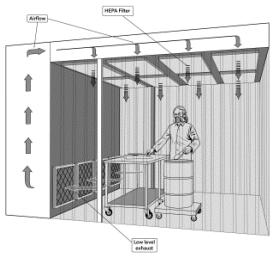
Spray dryer



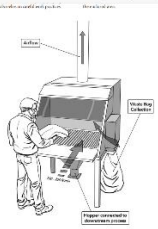
Product/discharge bag filling



Extrusion



Large-scale Material Handling/Packaging



Bag Dumping

- Design and Operational Considerations
- Preventative Maintenance and System Checks

Administrative Controls

- Cleaning and Housekeeping
- Training

Personal Protective Equipment

- Personal Protective Clothing
- Respirators

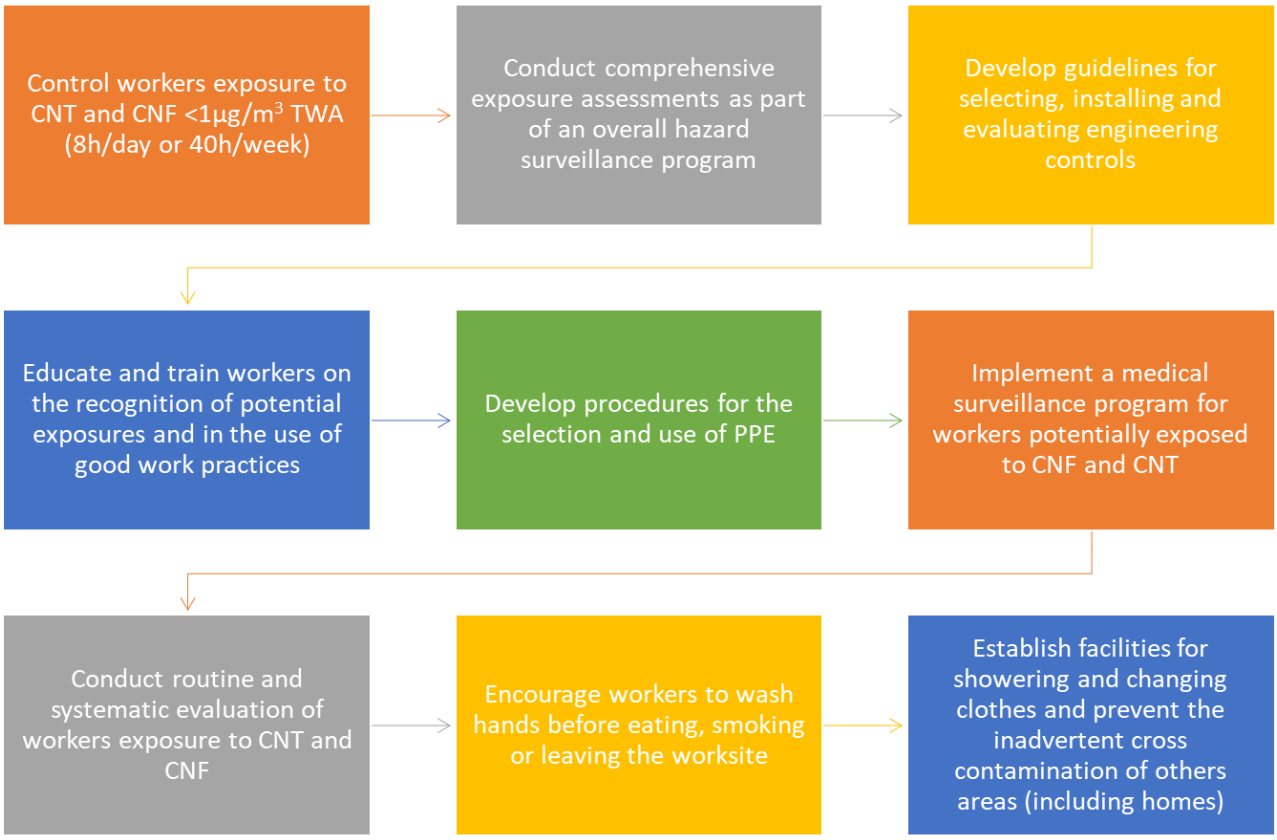
The controls described in this document include local exhaust ventilation (LEV) such as annular exhaust hoods, enclosures around the emission points, and down flow booths for larger scale processes.	*Standard Nano--specific*
Source: https://www.cdc.gov/niosh/topics/nanotech/pubs.html	**NIOSH**

RPSbD020	**Current Intelligence Bulletin 65. Occupational Exposure to Carbon Nanotubes and Nanofibers**

This document provides guidance to prevent the development of adverse respiratory health effects in workers exposed to carbon nanotubes (CNT) and carbon nanofibers (CNT). It provides information and recommendations about these nanomaterials, the assessment of the health risk and recommended Exposure Limit and the exposure measurement and controls.

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*User strategies*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content:
In light of current scientific evidence on the hazard potential of CNT and CNF, appropriate steps should be taken to minimise exposure worker exposure through the development of a risk management program.



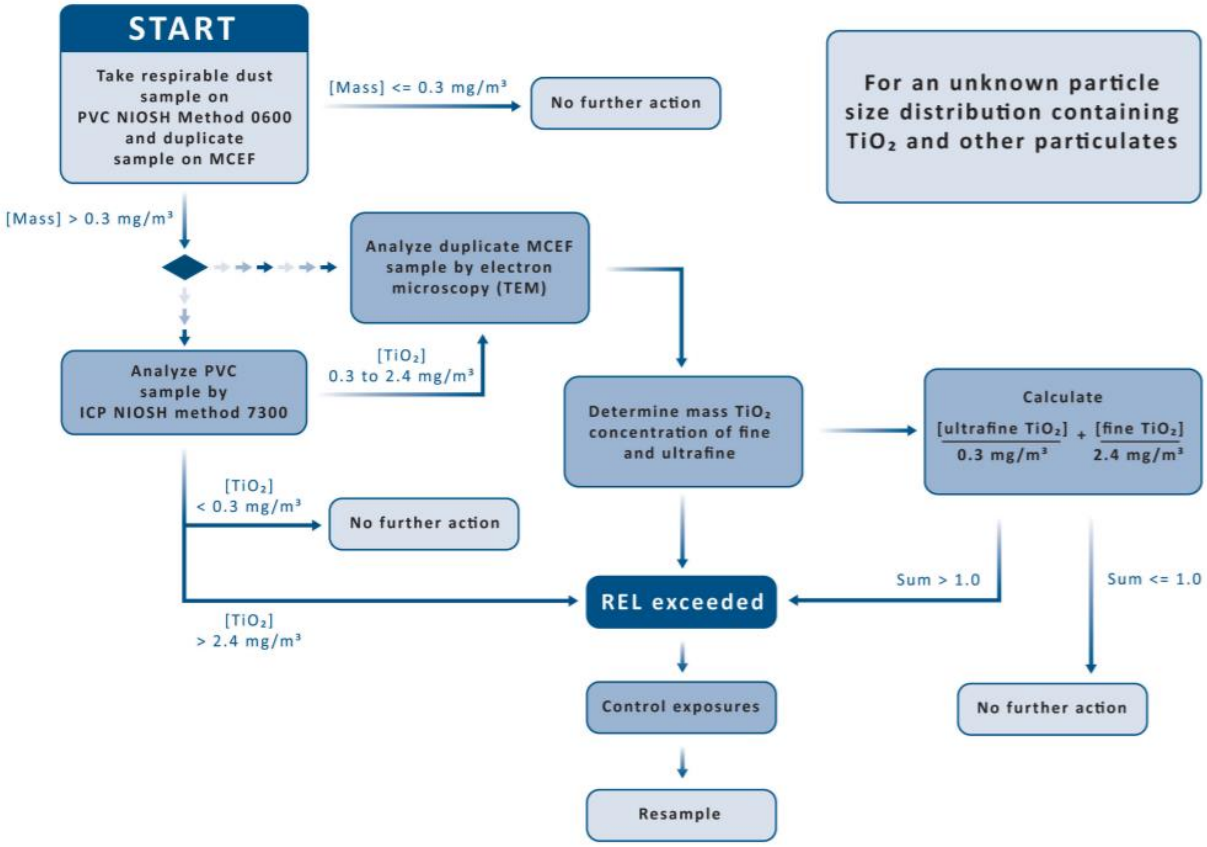
The following resources are complementary to this document: - RPSbD024- Using Nanomaterials at work including CNT and other bio persistent HARNs from the Health and Safety Executive - RPSbD027- Safe handling and use of carbon nanotubes from the Safe Work Australia	*Guideline* *Highly nano-specific*
Source: https://www.cdc.gov/niosh/docs/2013-145/default.html Source of the complementary documents: https://www.hse.gov.uk/pubns/books/hsg272.pdf http://www.safeworkaustralia.gov.au/doc/safe-handling-and-use-carbon-nanotubes.pdf	**NIOSH**

RPSbD021	**Current Intelligence Bulletin 63: Occupational Exposure to Titanium Dioxide**

This document provides guidance to prevent the development of adverse respiratory health effects in workers exposed to Titanium dioxide (TiO_2). It provides information and recommendations about these nanomaterials, the assessment of the health risk and recommended Exposure Limit and the exposure measurement and controls.

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*User strategies*	*Risk management measures (i.e. implementation of control measures)*	*Advanced*

Main content:
This scheme illustrates an exposure assessment strategy that can be used to measure and identify particles so that exposure concentrations can be determine for fine and ultrafine TiO_2.



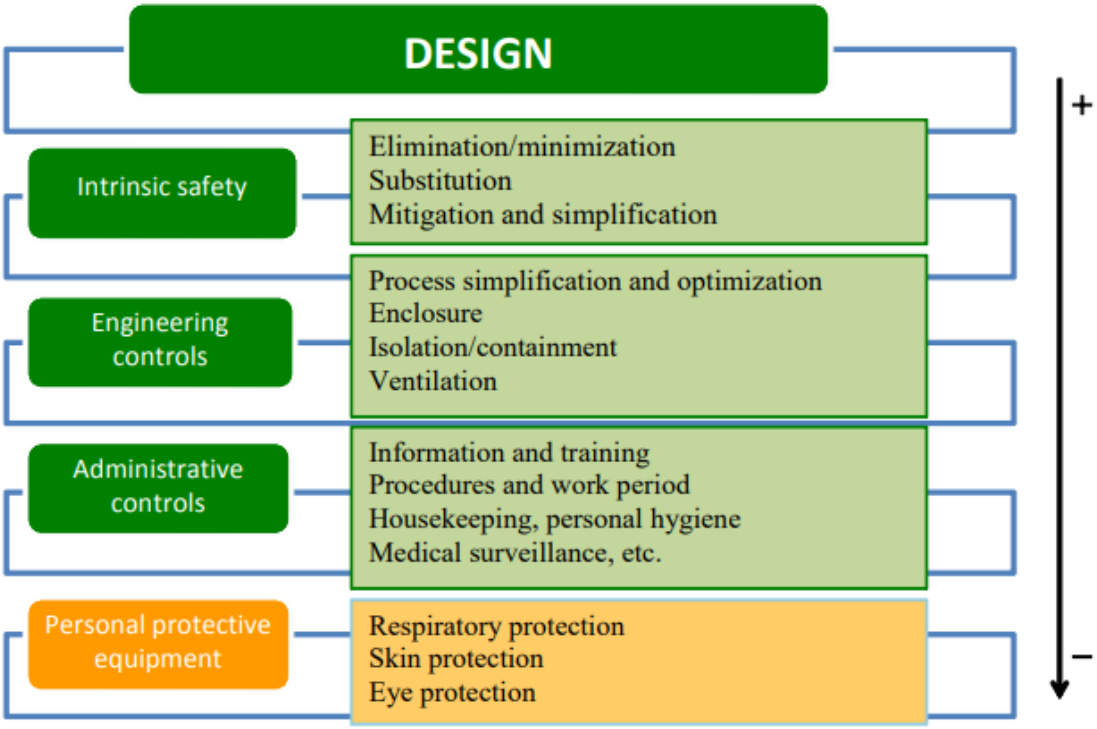
	Guideline *Highly nano-specific*
Source: https://www.cdc.gov/niosh/docs/2011-160/default.html	**NIOSH**

SAbyNA RPSbD023	**Best practices guidance for nanomaterial risk management in workplace**

This guide describes and suggests an approach, prevention advices and practical solutions for the safe handling of nanomaterials produced and used in work environment. The following topics are covered: variety of nanomaterials, nanomaterial synthesis, nanomaterial behavior and hazard identification, exposure characterization, risk assessment, laws, prevention and risk management.

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*Risk assessment* *Emission* *Inherently safe design* *Information for use* *Organization* *PPEs*	*Risk management measures (i.e. implementation of control measures)*	*Beginners*

Main content:
This document presents how to support the implementation of measures for controlling potentially toxic occupational exposure through a hierarchical risk reduction approach, from the design stage to the personal protective equipment by the intrinsic safety, the engineering controls and the administrative ones.



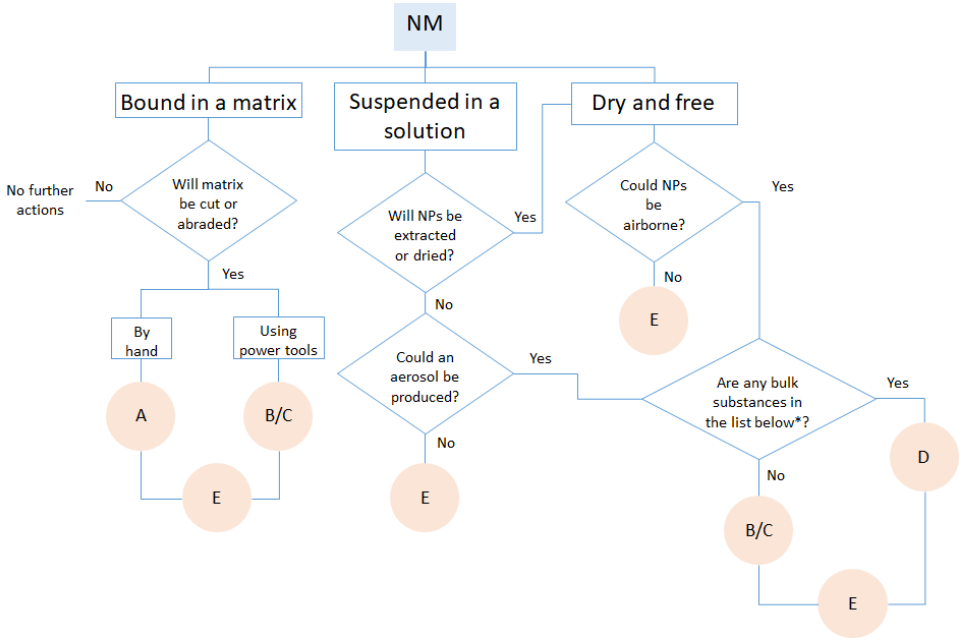
This document should be used as a first step to integrate SbD but a technical specialist is needed to choose at the end the relevant equipment. The resources RPSbD018 Workplace Design Solutions: Protecting Workers during the Handling of Nanomaterials from the NIOSH is complementary to this document.	*Guideline* *Highly nano-specific*
Source: http://www.irsst.qc.ca/media/documents/PubIRSST/R-899.pdf Source of the complementary documents: https://www.cdc.gov/niosh/topics/nanotech/pubs.html https://doi.org/10.26616/NIOSHPUB2018120	**IRSST**

RPSbD024	**Using Nanomaterials at work including CNT and other bio persistent HARNs**

This guidance describes how to control occupational exposure to manufactured nanomaterials in the workplace. The control principles described can be applied to all nanomaterials used in the workplace. Any differences between control of CNT and other high aspect ratio nanomaterials to any other type of nanomaterials are highlighted in this document. This document provides general control measures for occupational exposure to CNTs and HARNs, but it can be generalized to all type of manufactured nanomaterials.

Design topic	***Design strategy***	***Type of action***	***Level***
Safety part of control systems	*Risk assessment* *Safeguarding and complementary protective measures,* *Information for use,*	*Risk management measures (i.e. implementation of control measures)*	*Beginners*

Main content:
This document presents a nanomaterial control flow chart to help you decide on the most appropriate control measure.



*Toxic, corrosive, flammable, carcinogenic, mutagenic, toxic to reproduction, CNT, bio persistent HARN or a sensitiser?
Type A = Capture hood or receiving hood, ideally discharged to a safe place outside
Type B = Partial enclosure, discharged to a safe place outside e.g. fume cupboard or well-designed bespoke partial enclosure
Type C = Partial enclosure with HEPA filtration or Type D = Full enclosure with HEPA filtration and discharged in a safe place outside
Type E = Minimise exposure, PPE, Cleaning, Local exhaust ventilation, hazardous waste.

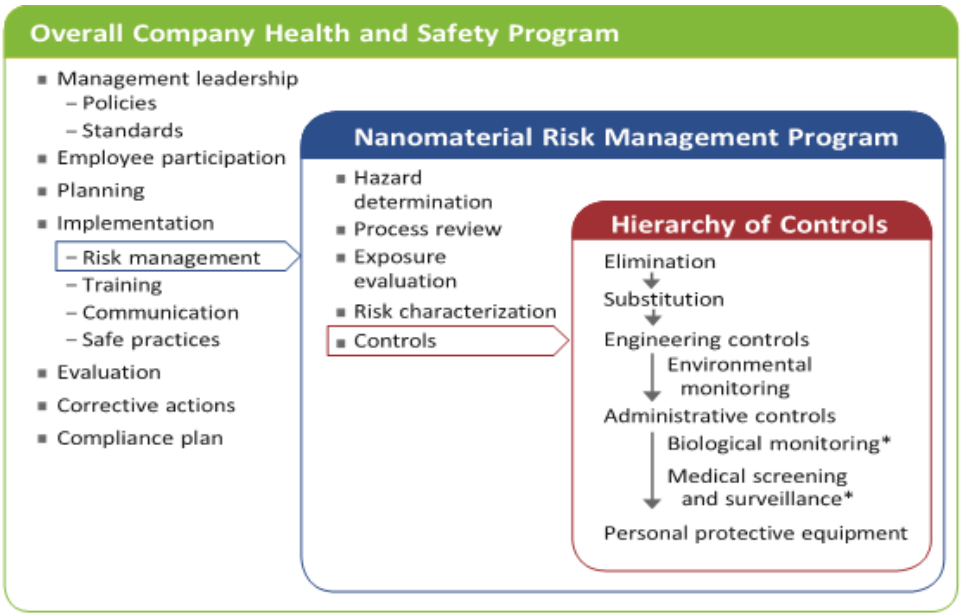
The following resources are complementary to this document: - RPSbD020- Current Intelligence Bulletin 65. Occupational Exposure to Carbon Nanotubes and Nanofibers from the NIOSH - RPSbD027- Safe handling and use of carbon nanotubes from the Safe Work Australia	*Guideline* *Highly nano-specific*
Source: https://www.hse.gov.uk/pubns/books/hsg272.pdf Source of the complementary documents: https://www.cdc.gov/niosh/docs/2013-145/default.html http://www.safeworkaustralia.gov.au/doc/safe-handling-and-use-carbon-nanotubes.pdf	**Health and safety executive**

RPSbD029	**Building a Safety Program to Protect the Nanotechnology Workforce: A Guide for Small to Medium Enterprises**

This resource aims to provide entrepreneurial business owners the tools necessary to develop and implement a written health and safety program, to protect workers. The aim is to help business owners recognize and control potential hazards and risks from their nanomaterial processes that may adversely impact the health, safety, and well-being of employees.
This resource discusses 'prevention through design PtD' and the advantages of integrating PtD early in the design of the facility. The document describes the hierarchy of controls and each strategy individually (i.e. elimination and substitution, engineering controls (with examples), administrative controls, PPE), then follows with a section on verification of controls. Additional sections include medical screening/surveillance, emergency preparedness, fire and explosion, product stewardship, federal regulatory compliance (useful only for US-based companies), and building and sustaining a successful program.

Design topic	***Design strategy***	***Type of action***	***Level***
Emissions of hazardous materials and substances	*Risk assessment*	*New process design (i.e. risk elimination by conception)*	*Beginner*

Components of an overall health and safety program as presented in SPSbD029.



The document additionally reviews biological and medical screening.

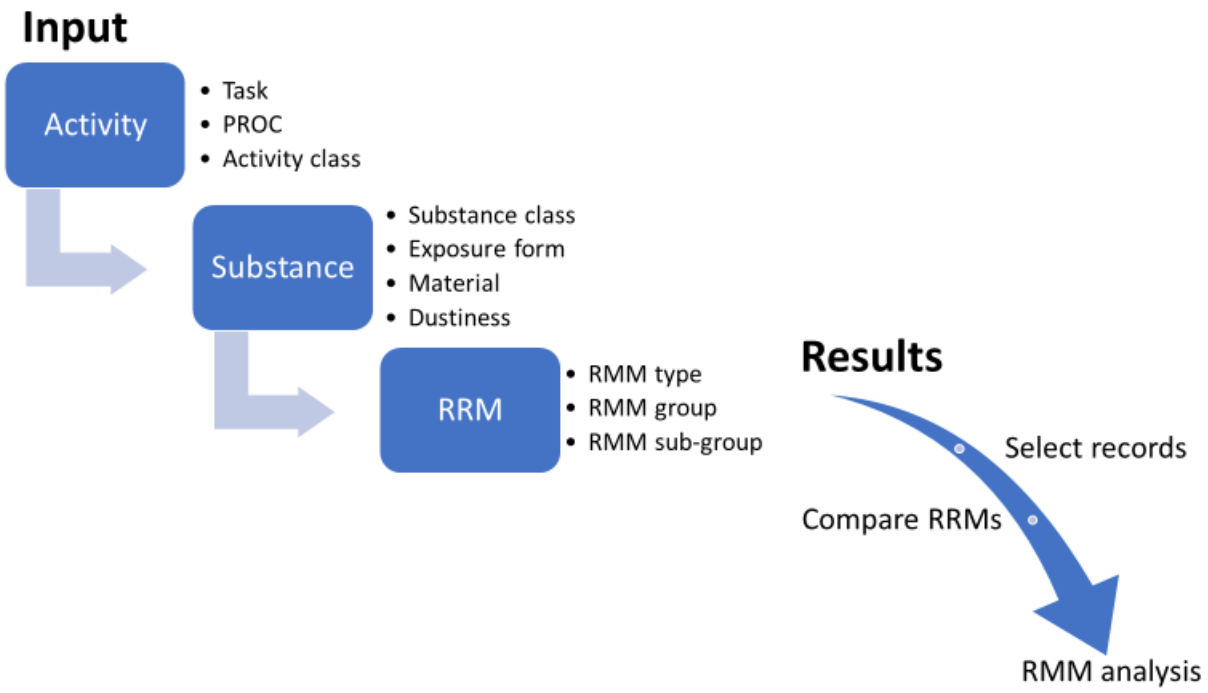
This document is deemed similar to resources RPSbD027-035 by reviewers which all focus on risk management advice and are freely available but may not be updated like comparable resources from more robust sources such as RPSbD011, 018 and 041 that have limited access. Sources RPSbD027-035 are all individual and may have some good process flow representations that could benefit the final SAbyNA platform although none are specific to the 3D printing or paint sectors. The document makes reference to other NIOSH guidance reports such as Current Strategies for Engineering Controls in Nanomaterial Production and Downstream such as Handling Processes (www.cdc.gov/niosh/docs/2014-102) and General Safe Practices for Working with Engineered Nanomaterials in Research Laboratories (www.cdc.gov/niosh/docs/2012-147/) for choosing engineering controls. This document is good for companies looking to create successful risk management programs and is representative of the information generally presented in RPSbD027-035.	*Guideline* *Nano-specific*
Source : https://www.cdc.gov/niosh/docs/2016-102/pdfs/2016-102.pdf Source of complementary documents: RPSbD027 - http://www.safeworkaustralia.gov.au/doc/safe-handling-and-use-carbon-nanotubes.pdf RPSbD028 - https://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf RPSbD030 - https://www.cdc.gov/niosh/docs/2018-103/pdfs/Nano_MP1_2018-103_508.pdf	**NIOSH**

RPSbD031 - https://www.cdc.gov/niosh/docs/2012-147/pdfs/2012-147.pdf?id=10.26616/NIOSHPUB2012147 RPSbD032 - http://www.nanovalid.eu/nanoToGo/Brochure/Safe%20handling%20of%20nanomaterials%20and%20other%20advanced%20materials%20at%20workplaces_v1-0.pdf RPSbD033 - http://apps.who.int/iris/bitstream/handle/10665/259671/9789241550048-eng.pdf;jsessionid=CBC7E114DAF887E3CE4F91C70DC85E5C?sequence=1 RPSbD034 - https://op.europa.eu/en/publication-detail/-/publication/4d51f5b2-545d-11ea-aece-01aa75ed71a1/language-en/format-PDF/source-184942294 RPSbD035 - https://op.europa.eu/en/publication-detail/-/publication/85064a82-56b6-11ea-aece-01aa75ed71a1/language-en/format-PDF/source-184945749	

RPSbD039	**Exposure Control Efficacy Library (ECEL v3.0)**

This resource provides information on the effectiveness of occupational and environmental Risk Management Measures (RMM). The library is available online and brings together various information sources that is supportive to industry for a wide range of Risk Management Measure (RMM) applications. It offers a database structure to search for different types of RMM and exposure or emission scenarios and to compare their effectiveness. This information is required in the context of the European Chemicals policy (REACH) and other European regulations to demonstrate and document safe use of substances based on quantitative exposures and exposure reduction by RMMs. Information available in this resource can also be applied by industry and downstream users to provide input for the development of control strategies.

Design topic	***Design strategy***	***Type of action***	***Level***
Selection of optimal-efficient exposure control measures	*Selection of optimal exposure mitigation strategies*	*Risk management measures (i.e., implementation of control measures)*	*Beginner*



This document could be used with the resource RPSbD041 Effectiveness of nanoparticle exposure mitigation measures in industrial settings published in International Journal of Hygiene and Environmental Health. This specific resource is not further developed, since the relevant data and information are essentially included in this usability card.	*Online library* *Nano-specific*
Source : https://diamonds.tno.nl/ecel/risk-managements	**TNO**