Scaffold Public Documents - SPD17

Innovative strategies, methods and tools for occupational risks management of manufactured nanomaterials (MNMs) in the construction industry

BEST PRACTICE GUIDE FOR RISK MANAGEMENT OF MANUFACTURED NANOMATERIALS (MNMs) IN THE CONSTRUCTION SECTOR

Scaffold Public Documents - Ref.: Scaffold SPD17

Soledad Contreras Malavé, Lucía Ortiz Arroyo, Sonia Fernández González, Jesús López de Ipiña

30.04.2015

The Scaffold research has received funding from the European Community's Seventh Framework Programme (FP7/20072013) under grant agreement number 280535.

Disclaimer

This document was prepared following extensive consultation with a range of stakeholders (via workshops, meetings, surveys, interviews and document reviews):

- Representatives of the construction sector, including:
  - European Construction Industry Federation (FIEC);
  - European Federation of Building and Wood Workers (EFBWW);
  - OHS Managers from several construction companies.
- Manufacturers of construction products;
- European and Spanish agencies for occupational safety;
- Manufacturers of personal protection equipment;
- Experts in nanosafety;
- Policy makers at European and national (Spain) levels.

The authors would like to place on record their thanks all those who contributed. In particular the authors would like to thank Domenico Campogrande (FIEC) and Rolf Gehring (EFBWW) for their advice and assistance throughout the Scaffold project.

The views expressed herein are solely those of the authors.

Presentation of the guide

This Best Practice Guide produced as MNMs Risk Management guide is one of the results from the AENOR collaboration as partner in SCAFFOLD Project. This Best Practice Guide for risk management is aimed to help Occupational Health and Safety coordinators managing the potential risks derived from the use of nanomaterials in the construction sector. It provides a useful model based on the PDCA cycle that could be easily integrated into an OSHAS 18001 management system or be taken into account independently for those companies that have not a systematic approach in OH&S management.

This reference guide helps to implement of the Model developed inside the SCAFFOLD project: Risk Management Model (RMM) and includes recommendations to implement in companies from construction sector, regardless of the size or type of organization, in all its areas and levels. Every subsector involved in construction cycle could apply the MNMs RMM but with different necessities, perceptions and criteria (manufacture, building and civil construction and demolition).

Index

List of tables and figures

Executive Summary

The MNMs Risk Management Model (RMM) developed helps the construction sector companies to manage the specific risk derived from the use of MNMs in the construction sector. The MNNs RMM model has the following characteristics:

- OHSAS 18001 particularization for construction sector companies and MNMs risks;
- derive and include requirements for the model based on the guideline and best practices or risk management include in ISO 31000;
- establish the basis for the integration of innovative solution and conclusions of SCAFFOLD's work on product design, risk assessment and protection measures;

This guide provides a reference document also for the implementation of the MNMs RMM in construction sector companies and includes specific recommendations to SME companies.

For more detailed information regarding the RMM and the implementation: the *Guide for RMM implementation in construction* (SPD14), the *Guide for RMM initial review, monitoring and audit* (SPD15) and the *Guide for RMM implementation and audit in SMEs* (SPD16), should be consulted.

This guide is linked with an outstanding result of SCAFFOLD: a software toolkit that will be used for training, as library and also as a management tool (see the technical report, SPD 18). The brief explanation of this software functionality is included as an annex 4 to this guide.

Introduction

Through the MNMs Risk Management Model (RMM), all type of organizations in construction sector could take into account MNMs risks in occupational health and safety systems, in case of previous implementation of OHSAS 18001 or not, as a systematic model to manage MNMs Risk.

The MNMs RMM has been designed using requirements of OHSAS 18001 (structure, elements, etc.) with additional requirements derived from the guidelines established in ISO 31000. It will be an effective tool for the construction sector to consider in a systematic approach the incorporation on MNMs risk management in the organization by the consideration of NMMs risk management elements (MNMs risk assessment, PPEs for control MNMs exposure, workers training or emergencies).

The scope of Best Practice Guide on risk management is to define specific and useful recommendations on the implementation of the requirements include as RMM that should be applied in any type of organization irrespective of size and type, in all its areas and levels. Every subsector involved in construction cycle could apply the MNMs RMM but with different necessities, perceptions and criteria (manufacture, building and civil construction and demolition).

1. Mapping the construction sector & exposure scenarios to NOAAs.

NOAA and nano-enabled products are being considered for various uses in the construction industry and related infrastructure industries, not only for enhancing material properties and functions but also in the context of energy conservation.

So far, only a limited number of nano-products make it to today's construction sites, the main ones are based on silicon and titanium oxides. The key areas of application are in: cement based materials, insulation materials, infrastructure coatings and coatings and paints for wood, glass and other materials as well as for self-cleaning purposes.

In Scaffold project we have selected five nano-objects: clay nanoparticles, carbon nanofibers, cellulose nanofibers, nano-SiO2 and nano-TiO2; each of the above mentioned NOAAs are being studied in one particular application, due to the properties that they give to the matrix in which they are added (see next table).

Table 1- NOAAs and applications selected in the SCAFFOLD project.

NOAA	Application/matrix	Expected benefit
n-SiO_2	Concrete	Improvement of rheology and mechanical properties
n-TiO_2	Mortar	Self-cleaning and decontamination
n-TiO_2	Self-cleaning coating	Self-cleaning and decontamination
Nano-clay	Fire resistance panels	Improvement of creep resistance and thermal stability
Cellulose NFs	Insulations	Improvement of mechanical and thermal properties
Carbon NFs	Coating/paint	Improvement of mechanical, thermal and electrical properties

Cementitious materials such as concrete experience changes in their properties by the incorporation of nano-SiO2; nano-particles of SiO_2 can fill the spaces between particles of gel of C– S–H, acting as a nano-filler and basically improving the strength and durability of the materials. In contrast to the bulk TiO2 (>100 nm) that is considered chemically inert, nano-scale TiO2 can act as a photo-catalyst, and can generate reactive oxygen species upon illumination. A wide range of applications exist, exploiting the various properties of TiO2 nanomaterials. For instance, in coating paints nano-sized TiO2 is used as a photocatalyst producing reactive oxygen that may degrade other organics. The addition of TiO2 to the common mortar implies the improvement of barrier properties of the material. These NOAAs add to the mortar the capacity to maintain the surface of the product clean more time than the common mortar, therefore the maintenance tasks of the product will be reduced during the use of the product. Nanoclays are usually incorporated into polymeric matrixes in order to improve or modify one or more characteristics of the material: improve their mechanical properties, increase their resistance to thermo-oxidative processes, modify their surface properties, increase their crystallinity, improve their creep behavior, reduce the gas permeability, give antibacterial properties, etc. This nano-filler is industrially used in the

automotive and packaging sectors as well as in the construction for the preparation of materials and elements with improved fire resistance, since the clay layers reduce the gas permeation and act as protection to the polymeric matrix. Cellulose fibers are extensively used in paper production, cotton textiles, and as insulation and structural strengtheners in construction products. Finally, carbon nanofibers (CNF) are used in construction, for example, in composite materials to improve strength, stiffness, electrical conductivity, or heat resistance.

Although the use of NOAAs in the construction sector is growing, they have found some barriers; the main ones have been identified:

- the expensiveness of NOAAs compared to traditional solutions,
- the conservative profile of the sector and the lack of awareness about emerging technologies,
- the general uncertainty with respect to health and safety risks and how to properly manage them in order to protect the workers and be in compliance with the existing OHS legislation.

Workers exposure to NOAA may occur over the life cycle of nano-enabled products: during the nano-objects manufacturing process, in the manufacturing of products containing NOAAs, their application and installation, during their use (e.g. maintenance tasks) and finally in the products end of the life including demolition/disposal and recycling processes. In all these steps, many enterprises from the sector with different profiles are implied.

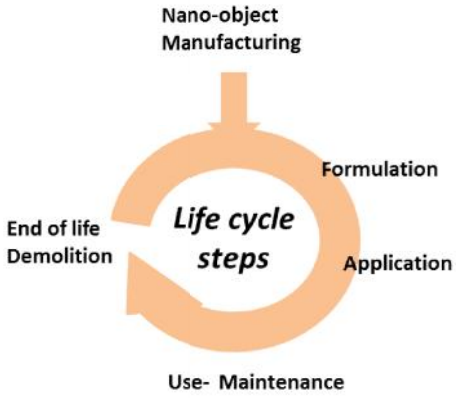


Figure 1-Life cycle steps of nano-enabled products and applications.

Exposure predominantly can occur via inhalation, dermal, oral and ocular routes. The major possible portals of NOAAs entry are lung, skin, gastrointestinal tract, nasal cavity and eyes. Exposure through inhalation of dust is the scenarios most likely to pose health risks. Skin penetration may in theory play a role as well, but most studies have shown little to no transdermal absorption through healthy skin. However, the uptake via damaged skin cannot be ruled out. Oral exposure can occur from intentional ingestion and from unintentional hand-to-mouth transfer. Swallowing inhaled particles that are cleared via the mucociliary escalator, and of drainage from the eye socket via the nasal cavity following ocular exposure are less important ways of exposure.

Critical factors affecting exposure to NOAAs include the amount of material being used, the ability of the material to be dispersed (in the case of a powder) or form airborne sprays or droplets (in the case of suspensions), the degree of containment, and duration of use.

Jobs and operations that may increase the likelihood of exposure to nanoparticles include for example:

- Generating nanoparticles in the gas phase in non-enclosed systems.
- Handling nanostructured powders.
- Working with nanomaterials in liquid media without adequate protection (e.g., gloves).

- Working with nanomaterials in liquid during pouring or mixing operations or where a high degree of agitation is involved.
- Machining, sanding, drilling, or other mechanical disruptions of materials containing nanoparticles (e.g. during the installation of materials, in demolition/recycling processes).
- Conducting maintenance on equipment and processes used to produce or fabricate nanomaterials, or the clean-up of spills or waste material.
- Cleaning of dust collection systems used to capture nanoparticles.

In Scaffold the occupational exposure to the five selected NOAAs has been measured in scenarios covering the life cycle of the six applications; see next matrix summarizing the scope of the scenarios investigated in the project (table 2).

	Nano-object and application					
Life cycle step	**nano-TiO2** depollutant mortar	**nano-TiO2** self-cleaning coating	**nano-SiO2** self-compacting concrete	**nano-Clay**(fire retardant panels	**carbon nano-fibers** coating laminates	**nano-cellulose** insulations
Nano-object manufacturing	X	X	◯			
Manufacturing nano-enabled products and application	X	X◯	◯	◯	X	X
Use/maintenance: Machining	X	X	X	X◯	X	X
Demolition	X	X	X	X◯	X	X
Accidental fires	X	X	X	X	X	X

Table 2-Scope of the scenarios investigated in Scaffold project.
Note: cells marked with X have been investigated at lab/pilot scale; cells marked with the red circle have been investigated in the case studies.

The results found are encouraging and in general workers performing the tasks measured were not overexposed to NOAAs in the scenarios investigated. Data of occupational exposure were below the limits proposed for the NOAAs by Scaffold (Stockmann-Juvala H. et al, 2014), NIOSH (NIOSH 2011) and the nano-reference values proposed by IFA (IFA, 2014, SER 2012); the limits used are showed later in this document. For that reason, the scenarios in the matrix are showed in green color although some remarks have been marked for some of them.

(1) Considering the metric of mass concentration (mg/m3), the occupational exposure measured in all scenarios was below proposed limits by NIOSH and SCAFFOLD. As expected, the highest mass concentration measured was found in tasks where nano-objects were handled directly and in significant quantities as for example, during cleaning

operations in the nano-TiO2 manufacturing process or during the spraying of a self-cleaning coating in a wall (marked with (1) in table 2).

(2) Considering the metric of particles concentration (particles/cm3), the occupational exposure measured in all scenarios was also below the recommended nano-reference value of 40000 particles/cm3 (IFA, 2014). As expected, common activities in this sector produced a high release of particles. For instance, the highest values measured were during the machining of quite hard materials such as the self-compacting concrete and the laminates filled with CNF marked with (2) in table 2. However two issues should be underlined here. On the one hand, the release of particles is intrinsic to the machining process and in fact, no sticking differences have been found for processes performed with control materials (without NOAAs) and materials filled with NOAAs. On the other hand, the machining processes were performed during short times and, consequently, the concentrations averaged to the 8 h-day did not exceed the OELs; however, other working conditions with longer processes may lead to higher exposures.

(3) Fire tests performed with the materials from the six applications did not observe the release of the NOAAs added to the materials with the exception of the fire retardant panels where there may be indications of possible release of nano-clays during the combustion of the materials.

Nowadays there are still very few data available on workers exposure to NOAAs in the construction sector. The data achieved in Scaffold contributes to clarify if the use of new nano-enabled products may increase the risk of workers handling these materials. It should be noted that most of the measurements have been taken at pilot scale, so short times and small quantities have been handled. More data from real scenario would help to incorporate in a safe way these new materials in the sector. Finally, it should be underlined that construction work environments are rather complicated, typically handling different activities and chemicals, and where other hygienic risks may be more relevant than exposure to NOAAs.

2. Management systems

A management system is the framework of processes and procedures used to ensure that an organization can fulfill all tasks required to achieve its objectives.

The RMM has been designed using requirements of OHSAS 18001 (structure, elements, etc.) with additional requirements derived from the guidelines established in ISO 31000. It will also include other SCAFFOLD results to be an effective tool for the construction sector to consider in a systematic approach the incorporation on MNMs management risk in the organization by the consideration of NMMs risk management elements (MNMs risk assessment, PPEs for control MNMs exposure, workers training or emergencies).

From the 'management' point of view, the RMM is developed in consistency with de PDCA (Plan-Do-Check-Act) cycle for continual improvement as other management standards but tailored for the special case of MNMs risk management.

Then, therefore, the management system model MNMs RMM has been designed with 3 important points:

- PDCA Cycle: 'continual improvement' concept from management systems.
- Scheme: specifications/architecture developing of the model, including tracking with OHSAS 18001 and ISO 31000.
- Outline and brief development of most important points: principal requirements develop and inclusion of requirements related with ISO 31000.

The main conclusion is that the MNMs Risk Management Model will allow all type of organizations in construction sector to take into account MNMs risks in occupational health a safety systems (in case of previous implementation of OSHAS) or model.

2.1. PDCA cycle

Good practice in MNMs risk management requires a systematic approach, including appropriate capacity for the key management functions and processes needed to deliver effective action to achieve desired risk controls.

Successful implementation of a MNMs risk management model depends upon commitment from all persons working for the organization or on its behalf, from strategic management to operational delivery staff.

This commitment begins at the highest levels of management.

The RMM is based on the Plan-Do-Check-Act methodology, which is a cyclical approach requiring strong leadership and commitment from top management.

The rate, extent and timescale of this continual improvement process are determined by the organization in the light of economic and other circumstances.

a) **Step 1: Plan**

- ✓ Identify the impact the organization can have on MNMs risk management model, map that impact across interested parties, and determine the organizational scope of a management model, with reference to the identified needs throughout the planning process.
- ✓ Establish leadership commitment by, amongst other actions, adopting a long-term vision to eliminate the risks to be achieved by incremental MNMs risk management model targets and a strategy or approach to realizing these and providing resources to establish, implement, maintain and continually improve the MNMs risk management model, towards these ends. Establish, document and communicate policy, assign organizational roles, responsibilities and authorities.
- ✓ Determine risks and opportunities through assessment of current performance wherever possible and work through each factors to establish those which are relevant to the organization, and most important to MNMs risk management model improvement. Set MNMs risk management system objectives (measurable, if practicable) and measurable targets for each priority factor, taking into account management capacity needs and develop action plans.

b) Step 2: Do

- ✓ Implement and operate the MNMs risk management model and ensure that sufficient capacity is provided for the delivery of the key system functions to allow the identified actions to be carried out and to ensure that objectives and targets are met.

c) Step 3: Check

- ✓ Monitor and evaluate MNMs risk management model performance, conduct internal audits and periodic reviews of the management model to identify opportunities for continual improvement, achieving results and necessary changes in the MNMs risk management model.

d) Step 4: Act

- ✓ Improve the MNMs risk management model on a continual basis following review of performance against objectives and targets, MNMs risk management model performance, deficiencies and non-conformities and identification of corrective action and opportunities for preventive action aimed at reducing the incidence and risk.

2.2. OHSAS 18001 Standard and future ISO 45001 reference

In the management systems related to Occupational health and Safety, OHSAS 18001 is the most recognize reference. It was developed by BSI (British Standards Institute) for helping the organizations to improve occupational health and safety First version of OSHAS 18001 was published in 1999.

The OSHAS objective is to control OHS risks and improve the performance of health and safety at workplaces. It specifies the requirements for a management system that allows an organization to develop and implement a policy and objectives taking into account legal requirements and information regarding occupational health and safety risks.

The overall aim of this OSHAS 18001 is to support and promote good occupational health and safety practices allowing:

- identify and control any risk related with occupational safe and safety,
- reduce accidents and incidents,
- legal and regulatory compliance,
- improvement of process inside the organization,
- reduce costs and increase organization profitability,
- the alignment and integration with other management standards as ISO 9001 and ISO 14001.

At the beginning of 2013, BSI with the support of both the national stakeholders and the OHSAS Project Group submit to ISO members a new work item proposal on Occupational health and safety management for the development of an International Standard on '*Occupational health and safety management systems – Requirements'*.

This proposal finally approved by ISO members is now being developed by the recently constituted ISO/PC 236 *OH&S Management Systems – Requirements*

So there are many public or private actions, guidance, requirements and regulations that seek to address the identify need, such as technical papers, proven practices, academic or professional studies, or any other body of knowledge (e.g. a key document ILO's OSH Guidelines).

The purpose of the ISO 45001 future international standard would be to harmonize such documents and activities and to share the best practices at worldwide level.

ISO 45001 will support new areas of management systems to ensure better compatibility and systems governance, making the implementation within an organization a lot smoother. Once published, the standard will apply to any organization wishing to:

- ✓ Establish and implement an internationally recognized occupational health and safety management system to reduce or minimize risks to personnel and other relevant parties
- ✓ Maintain and constantly improve their health and safety performance
- ✓ Keep all operations in line with their stated health and safety policies to an internationally recognized standard.

ISO 45001has been tracked to ensure future compatibility of the RMM model with this worldwide used future agreed reference for reduce de risk of harm in OH&S context. In annex 1 could evidence the traceability to the future ISO 45001 standard and the future HLS standards.

ISO 45001 will also have a direct impact on society. With more internationally recognized occupational health and safety systems in place, the number of incidents and accidents will decrease, with less disruption to operational processes. This means fewer emergency treatments at the workplace and hospitals, less people being removed from sites and reduced long term care for those who are unable to return to work following an accident.

2.3. ISO 31000 - Risk management-Principles and guidelines

Risks affecting organizations can have consequences in terms of economic performance and professional reputation, as well as environmental, safety and societal outcomes. Therefore, managing risk effectively helps organizations to perform well in an environment full of uncertainty.

ISO 31000:2009, *Risk management – Principles and guidelines* was published in 2009. It provides principles, framework and a process for managing risk. It can be used by any organization regardless of its size, activity or sector. Using ISO 31000 can help organizations increase the likelihood of achieving objectives, improve the identification of opportunities and threats and effectively allocate and use resources for risk treatment.

However, ISO 31000 cannot be used for certification purposes, but does provide guidance for internal or external audit programmes. Organizations using it can compare their risk management practices with an internationally recognised benchmark, providing sound principles for effective management and corporate governance. It recommends that organizations develop, implement and continuously improve a risk management framework as an integral component of their management system.

Risk assessment provides decision-makers and responsible parties with an improved

understanding of risks that could affect achievement of objectives, as well as of the adequacy and effectiveness of controls already in place. The standard provides a basis for decision about the most appropriate approach to treat particular risks and select between options. ISO/IEC 31010 will assist organizations in implementing the risk management principles and guidelines provided in ISO 31000. ISO/IEC 31010 reflects current good practice and answers the following questions:

- What can happen and why?
- What are the consequences?
- What is the probability of their future occurrence?
- Are there any factors that mitigate the consequences of the risk or that reduce the probability of the risk?

All technical committees developing management system standards have to follow Annex SL in the new consolidated ISO Supplement. Annex SL harmonizes structure, text and terms and definitions, while leaving the standards developers with the flexibility to integrate their specific technical topics and requirements. ISO has over the years published many management system standards for topics ranging from quality and environment to information security, business continuity management and records management. Despite sharing common elements, ISO management system standards come in many different shapes and structures. This, in turn, results in some confusion and difficulties at the implementation stage.

Annex SL shown in annex 1 now elevates the preventive and corrective action concept into a more encompassing risk assessment process. It proactively wants risks to be anticipated and addressed in the planning phase, not as something to which one reacts. Essentially, it asks the organization to use the inputs it has gained, add its experience and provide a reasonable analysis of risks and successful responses to them. It also asks for a more measurable approach to planning, using metrics of what will be attained that are meaningful to support implementation.

After the publication of ISO 31000, ISO has just completed work to provide identical structure, text and common terms and definitions for management system standards of the future. This will ensure consistency among future and revised management system standards and make integrated use simpler. It will also make the standards easier to read and, in so doing, be understood by users.

3. Risk management model for MNMs (RMM)

The SCAFFOLD RMM has been designed using requirements of OHSAS 18001 (structure, elements, etc.) with additional requirements derived from the guidelines established in ISO 31000. The correspondence with OSHAS and ISO 31000 is included for reference.

From the 'management' point of view, the RMM is developed in consistency with the PDCA (Plan-Do-Check-Act) cycle for continual improvement as other management standards but tailored for the special case of MNMs risk management.

One organization that proves the successful implementation of this model should ensure all interested parties that has an appropriate MNMs risk management. The future OH&S standards (like ISO 45001) should be tracked to ensure future compatibility of the model with this worldwide used future agreed reference for reduce de risk of harm in OH&S context.

This designed RMM will allow any construction sector organization to find a systematic approach to manage its risk associated with MNMs. Figure 1 below, shows the different stages where worker might be exposed to MNMs:

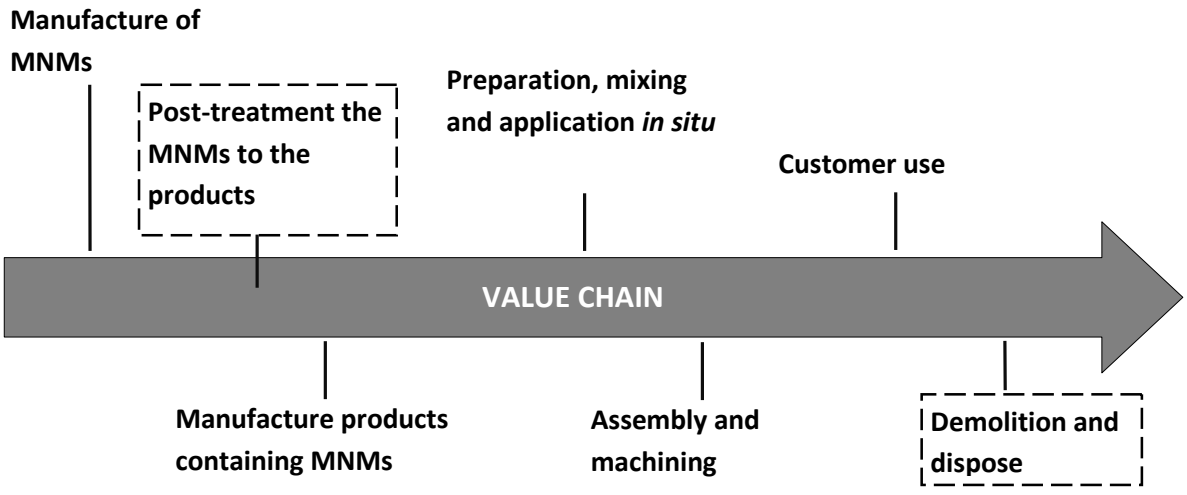


Figure 2- Construction Sector life cycle (from SCAFFOLD's Roadmap on Occupational Exposure to MNMs in the Construction sector – SPD3)

The systematic approach of management system standards and other management reference are the basis to implement a Risk Management Model (RMM) that can help the construction sector to take into account MNMs risks.

The main conclusion is that the MNMs Risk Management Model will allow all type of organizations in construction sector to take into account MNMs risks in occupational health and

safety systems (in case of previous implementation of OSHAS) or use the model itself in case the company does not have a formal management system based in OSHAS.

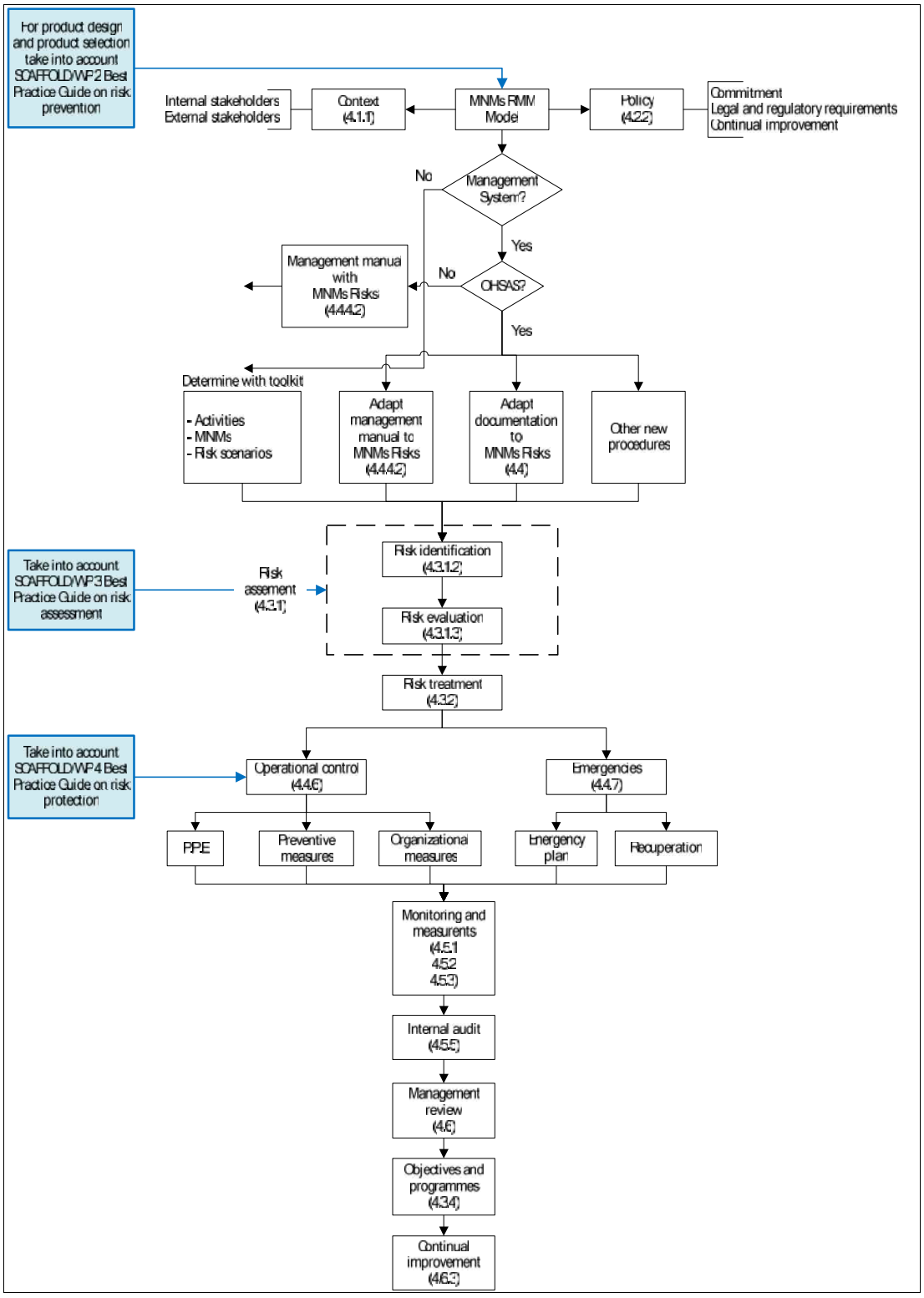
The conceptual work of develop a new model based on OSHAS 18001 and ISO 31000 is a really new approach that needs the participation of different AENOR perspectives: standardization, certification technical management and also audit experiences in both areas.

The principal difficulties in the model design are related with:

- the fact that ISO 31000 is not a requirement standard but a guideline, then does not include specific rules it is made on recommendations;
- the conversion of recommendations from ISO 31000 into specific requirements;
- the analysis of this requirements that should be added to complete OSHAS 18001;
- the decisions on the risk assessment approach in the model taking into account that both references have different definitions;
- the model is design to be applied to all type, size and context organization (as all other management systems) and this is a difficult approach to consider also the detailed information needed taking into account nanorisks. The specificity for MNMs risk is not simple to find in this general model. The present Guide includes all the innovative results from SCAFFOLD's other guidelines and other works that will 'shape' this general model to a more adapted guideline for MNM risks.

AENOR have worked in a multidisciplinary team to deal with the specific task of the MNMs RMM design that has the overview of a 'standard' taking into account the easy understanding of SCAFFOLD partners and especially for the final audit work of the RMM in SCAFFOLD's case studies. It is necessary to remark that besides the formal appearance of a common standard there is an **innovative point of view** for nanorisks OH&S issues.

The next figure presents a flow chart that includes the decision making process to face MNM RMM and SCAFFOLD's Best Practice Guide on risk prevention, risk protection and risk assessment. The numbers are related to clauses and subclauses in the Guide SPD14 attending to requirements to the RMM and the information in the SCAFFOLD Toolkit (see Annex 4).



WP: Work Package

Figure 3-Flow chart on MNMs RMM with the relation with other SCAFFOLD's Best Practice Guides and Toolkit

3.1. RMM Requirements

The RMM complete OHSAS 18001 requirements with other requirements derived from ISO 31000 guidelines, that allows the improving the MNMs risk management.

Following the trend of many companies from different countries if the organization have started OHSAS 18001 implementation, with the goal of obtaining occupational health and safety management system certification, the implementation of this RMM allows the organization to consider MNMs risk into OHSAS model. On the other hand, if the organization has no experience on a systematic approach for managing its occupational health and safety risks, the MNMs RMM implementation could be the first step for a more complete and organized perspective of OHS risks.

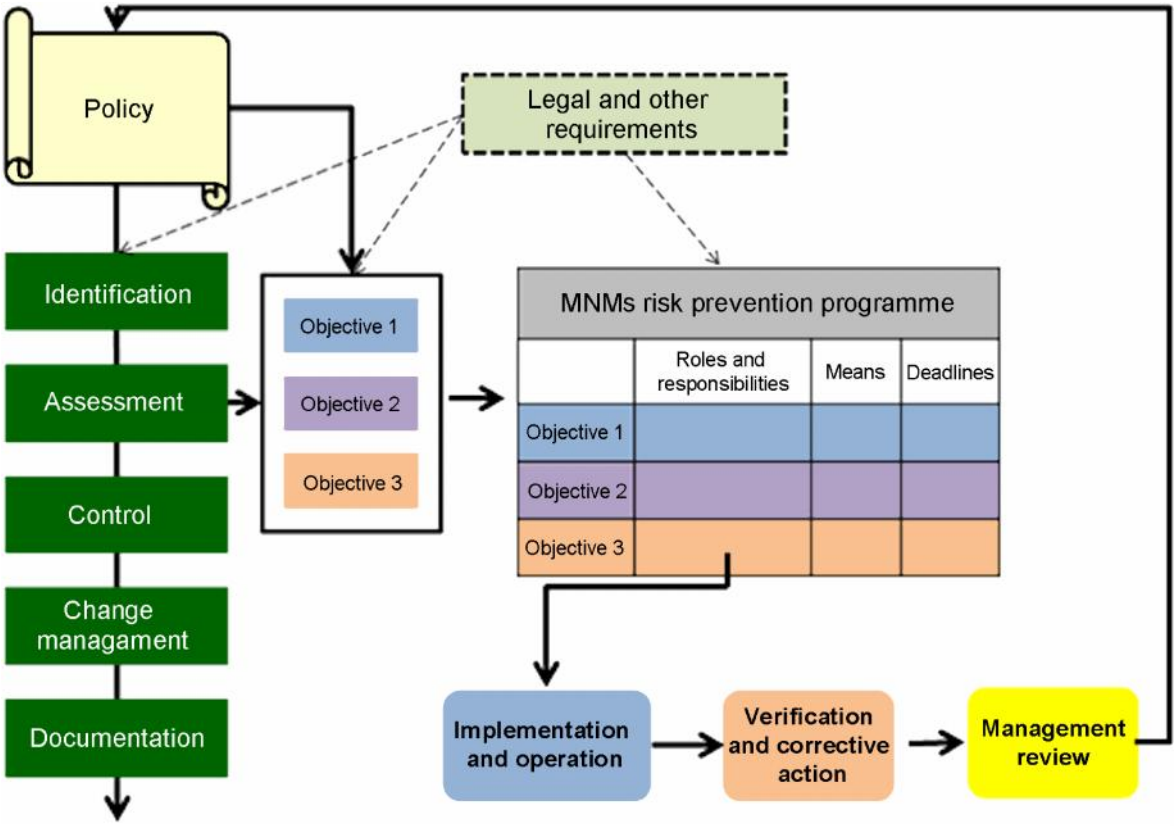


Figure 4-Diagram for RMM Model's implementation (from SCAFFOLD report D5.5. Specifications, implementation & audit plans from Industrial Use Cases, AENOR)

General Requirements

As a first step towards the MNMs risks management, the organization shall define both the external and the internal context in which the organization shall manage those risks. During the definition of the context, the organization shall take into account the necessities and expectations of stakeholders (shareholders directives and expectations, clients' requirements, contractor or suppliers' demands, final users' necessities, etc.) as interested parties in the risk management.

Once the previous information has been gathered, the organization shall determine the scope, as well as the level and extent of the pertinent risk management activities. Scope explicit definition, identifying inclusions and exclusions is convenient.

MNMs risk management policy and management commitment

Top management shall demonstrate its leadership and commitment to the success of the MNMs RMM and to achieve a better performance of the risk management, through the continual improvement and the fulfillment of the legal requirements and other requirements to which the organization subscribes. This commitment will be embodied into the MNMs risk management policy.

Planning

The following figure is developed to systematically MNMs risk assessment risks:

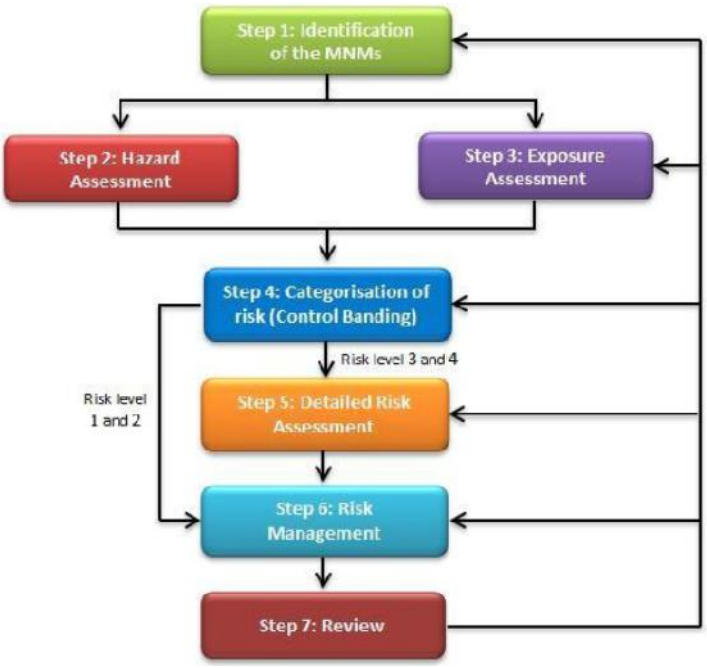


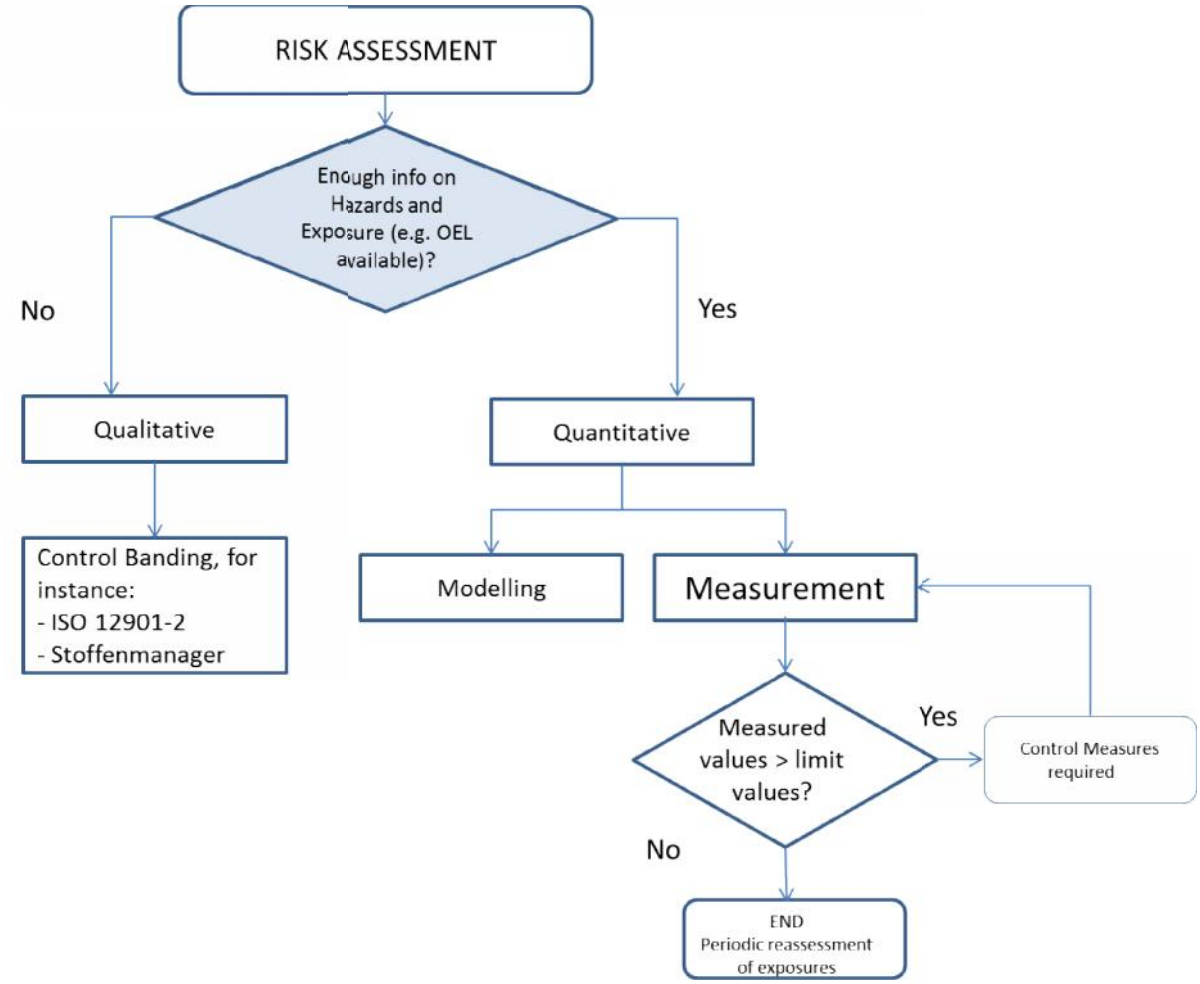
Figure 5- Diagram for the Risk Assessment (EC Guidance on the Protection of Health and Safety of Workers from the potential Risks related to Nanomaterials, January 2015)

- **MNMs risk assessment**

  In order to give a proper management of the health and safety risks in the workplace is essential to assess the risks. The risk assessment is the process which covers identification of risks, analysis and risk evaluation, this will lead to eliminate, or reduce them to an acceptable risk level.

  When thinking about risk assessment, must be taken into account the difference between hazard and risk. According to the definition given by the OSHAS 18001, risk is the combination of an occurrence of hazardous event or exposure(s) and the severity of injury or ill health that can be caused by the event or exposure(s), while hazard is defined as the source, situation, or act with a potential for harm in terms of human injury or ill heath, or a combination of these.

  In order to identify the risks due to the use of products that content MNM, the identification of the MNM present in the material is requested, gathering as much as information is available related to physicochemical, toxicity and ecotoxicity characteristics; potential routes for human exposure; human dose response and safety aspects. Some MNMs and their application, according to SCAFFOLD's Best practice guide for risk assessment **(SPD9**, April 2015), are given below:



NOAA	Risk Assessment		Application in the scope of Scaffold
	Qualitative (a)	Quantitative (b)	
Nano-TiO2	CB	number/mass	Depollutant mortar/self-cleaning coatings
Nano-SiO2	CB	number/mass	Self-compacting concrete
Nano-clay	CB	number/mass	Fire retardant panels
CNF	CB	fibers	Laminate coatings
Nano-cellulose	CB	fibers	Insulations

Figure 6 - Flow chart and decision making matrix with the general approach for risk assessment of NOAA (Best practice guide for risk assessment, SCAFFOLD SPD9, April 2015)

- **MNMs risk treatment**

As the result of the MNM risk evaluation, certain risk levels will be deemed by the organization as acceptable and will require a monitoring of the existing controls. In other cases, risks levels will be considered as unacceptable, they will require a risk treatment in order to eliminate or reduce the level of risk to an acceptable one. So a MNM risk treatment plan must be prepared and implemented. This treatment plan shall be documented and subjected to ongoing monitoring and review.

The following table are identified the most adequate controls:

Box 2. Hierarchy of Risk Management Controls Options

Isolate or Enclose

Operations which involve the likely release of MNMs into the air should be performed in contained installations or in facilities that can be operated remotely from a protected area

Engineering Control

Processes where there is a potential for creating dusts or aerosols of MNMs should be carried out in areas with efficient local exhaust or extraction ventilation.

Wet cutting is recommended for cutting solid articles (e.g. nano-enabled products) containing MNMs.

Administrative Control

Working procedures and staff assignment to tasks should be developed so as to ensure safe handling of MNMs;

Adequate training and information should be provided to individual workers;

. An Emergency Management Plan should be established.

Personal Protective Equipment (PPE)

PPE should be regarded as a 'last resort' control measure or a supplemental option to be used in conjunction with other measures.

Figure 7- Hierarchy of Risk Management Controls Options (European Commission document on Working Safety with Manufactured Nanomaterials, January 2015)

- **Legal and other requirements**

The legal and other requirements identification pursues, the promotion of the knowledge and comprehension of legal responsibilities and the permanent updating of the legal and other requirements related to the MNM risks.

So far, no regulatory occupational exposure limit values (OELs) have been given for any OEL-setting authority. Scaffold proposed the following ones for the NOAAs in the scope of Scaffold project (Best practice guide for risk assessment, April 2015):

Nano-object	OEL (mg/m3) or fibers/cm3 (1)	Reference Values particles/cm3 or fibers/cm3(1)
nano-TiO2	0.1	40.000
nano-SiO2	0.3	40.000
nano-clay	0.3 (respirable) & 4 (inhalable)	40.000
Low toxicity dust	0.3 (respirable) & 4 (inhalable)	
nano-cellulose	0.01 (1)	0.01 (1)
Carbon nano-fiber	0.01 (1)	0.01 (1)

Table 3 - OELs and reference values recommended by Scaffold project (Best practice guide for risk assessment, SCAFFOLD SPD9, April 2015)

- **Objectives and programmes**

Aligned to the commitment to prevention of injury and ill health, and continuous improvement, the organization must establish objectives that satisfy these commitments. These objectives must be documented at relevant functions and levels in the organization.

Implementation and operation

- **Roles, responsibility and authority**

In order to achieve the requirements of the MNMs RMM top management must provide the necessary resources for the effectiveness of the Occupational, Health and Safety system and the MNMs RMM, defining and establishing roles, responsibilities, accountabilities and authorities. The model effectiveness can be evaluate with the provided data as the compliance degree for the objectives that permit to assure if the resources have been sufficient for the different action development.

- **Competence, training and awareness**

The organization must ensure the competence of employees in those tasks which may involve MNM risk, taking as basis, education, training or adequate experience. The organization is responsible for the assurance of the correct competence and awareness of employees.

- **Communication, participation and consultation**

  The organization must define the mechanisms and procedures for internal, external and contractors and visitors communication, participation and consultation in order to encourage and guarantee the participation in good practices, the support of the MNM RMM policy and objectives.

- **Documentation**

  The organization must establish, and maintain updated, a series of documents to ensure consistent application of the MNMs RMM. These documents must establish the responsibilities, authorities, roles, Scope o of the MNMs RMM, Policy, etc.

  The MNMs RMM documentation shall be as specific as possible and suitable for the complexity of the organization.

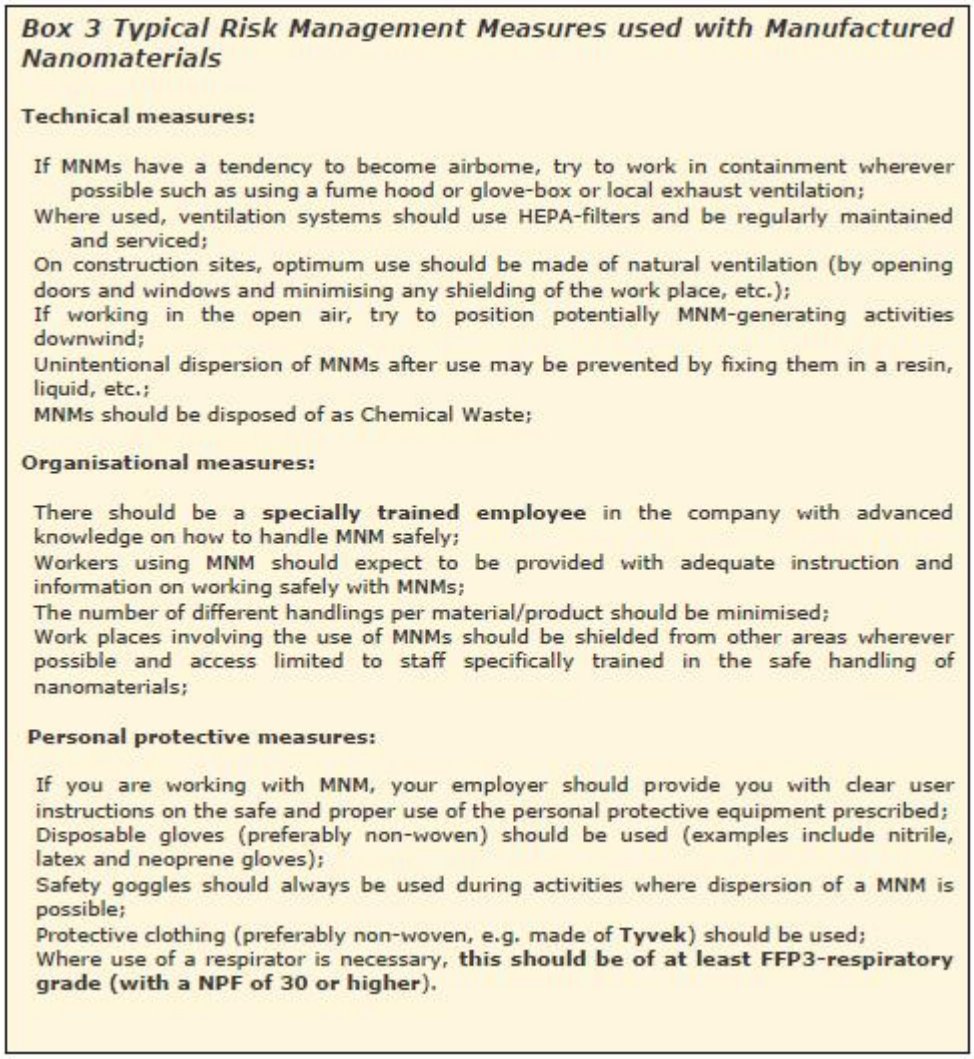
- **Control of documents**

  The MNMs RMM documentation shall be controlled by the organization, in order to guarantee their correct use by all members of the organization.

- **MNMs operational control**

  Once the risk assessment has been performed, operational measures must be implemented in order to manage the associated risk, leading them to the acceptable level, and fulfill the legal requirements and other. Summing up, the main objective of the operational controls is the risk management to comply with the MNMs RMM policy and objectives.

  The following table are identified the most adequate risk management activities for MNM:



Box 3 Typical Risk Management Measures used with Manufactured Nanomaterials

Technical measures:

If MNMs have a tendency to become airborne, try to work in containment wherever possible such as using a fume hood or glove-box or local exhaust ventilation;
Where used, ventilation systems should use HEPA-filters and be regularly maintained and serviced;
On construction sites, optimum use should be made of natural ventilation (by opening doors and windows and minimising any shielding of the work place, etc.);
If working in the open air, try to position potentially MNM-generating activities downwind;
Unintentional dispersion of MNMs after use may be prevented by fixing them in a resin, liquid, etc.;
MNMs should be disposed of as Chemical Waste;

Organisational measures:

There should be a **specially trained employee** in the company with advanced knowledge on how to handle MNM safely;
Workers using MNM should expect to be provided with adequate instruction and information on working safely with MNMs;
The number of different handlings per material/product should be minimised;
Work places involving the use of MNMs should be shielded from other areas wherever possible and access limited to staff specifically trained in the safe handling of nanomaterials;

Personal protective measures:

If you are working with MNM, your employer should provide you with clear user instructions on the safe and proper use of the personal protective equipment prescribed;
Disposable gloves (preferably non-woven) should be used (examples include nitrile, latex and neoprene gloves);
Safety goggles should always be used during activities where dispersion of a MNM is possible;
Protective clothing (preferably non-woven, e.g. made of **Tyvek**) should be used;
Where use of a respirator is necessary, **this should be of at least FFP3-respiratory grade (with a NPF of 30 or higher)**.

Figure 8 – Typical Risk Management Measures (European Commission document on Working Safety with Manufactured Nanomaterials, January 2015)

It is necessary to determine PPEs and clothes when they are in contact with MNMs in different states (liquid, powder, solid and aerosolized) during different steps of their life cycle (synthesis, handling, manufacturing, using and end of life). Exposure to MNMs may happen by ingestion, inhalation and dermal contact, so this decision tree (figure 7) has been organized in order to take a decision in according with SCAFFOLD's Best practice guide for risk protection (SPD13):

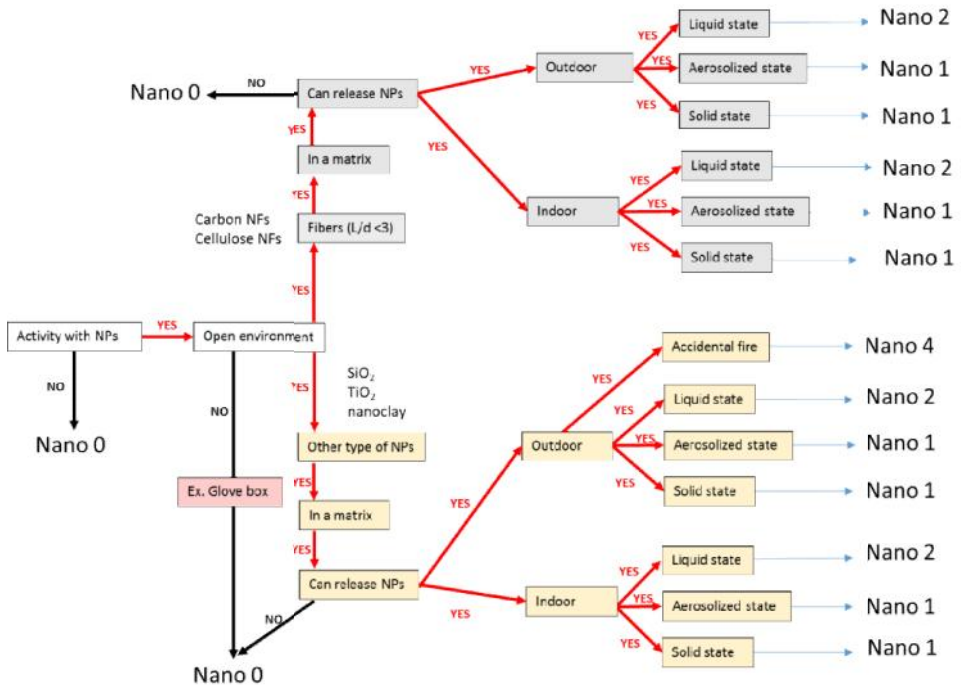


Figure 9 - Decision tree in the case of MNMs manipulation project (Best practice guide for risk protection, SCAFFOLD SPD13, April 2015)

- **MNMs emergencies preparedness and response**

  The primary objective of the MNMs emergencies preparedness and response is to ensure the ability of the organization for an effective response to emergency situations, preventing or mitigating adverse associated consequences.

Checking

- **Monitoring and measurements of MNMs risk management activities**

  MNMs risks management shall be monitored and measured to evaluate the effectiveness of the MNM RMM, to this end, the organization shall define key performance measurements.

- **Legal compliance evaluation**

  Once the organization has identified the legal and other requirements an evaluation of compliance must be performed as part of its commitment established on MNM RMM policy.

- **Incident investigation, nonconformity, corrective action and preventive action**

  The organization must investigate events and incidents in order to prevent further incidental situations by identifying root causes, analyzing these causes, and taking actions that will lead to a solution, and will prevent further occurrence. Effectiveness of action taken must be assessed.

- **Control of records**

  Records are the evidences for demonstrating the conformity of the MNMs RMM, so a procedure for assuring their integrity and correct conservation is required.

- **Internal audit**

  The internal audit is a tool that allows the organization to evaluate the implementation of the MNMs RMM.

- **Management review**

  The organization must perform management review the MNMs RMM at established intervals sufficient to ensure the adequacy and continua effectiveness of the model. This periodicity must be consistent with other cycles of the model. Usually this management review is made annually.

Following the trend of many companies from different countries if the organization have started OHSAS 18001 implementation, with the goal of obtaining occupational health and safety management system certification, the implementation of this RMM allows the organization to consider MNMs risk into OHSAS model. On the other hand, if the organization has no experience on a systematic approach for managing its occupational health and safety risks, the MNMs RMM implementation could be the first step for a more complete and organized perspective of OHS risks.

On the other hand, the MNMs RMM can be certificated. Globalization of the economy has prompted many organizations to implement standards that are demonstrable at international level, exemplified by the thousands with certified quality and environmental management systems, and this model is integrated with all these standards.

3.2. SME Recommendations

In SMEs companies the implementation of a management model/system is complex due to lack of resources, costs of establishment and maintenance of the model and sometimes the difficulty in understanding and applying the model.

Furthermore, the characteristics of SME influence the management philosophy taking into account the number of workers involved in general it could be state that communications are simple, each worker performs several tasks, and the decision making corresponds to very few.

SMEs practices usually attempt to minimize the cost of time and money into these businesses so that SME investment feasible in improving OSH management focused on MNM Risks.

Following recommendations has been developed to implement the SCAFFOLD MNMs RMM effectively and with fewer resources as possible. For the success in this implementation, the obvious first step is to understand the model and its requirements.

Since the purpose of the model is not to impose a new way of working in case the company has a previous management system implemented, the next step is to examine the current situation through an initial diagnosis. The SME should examine what is being done already, and if no documentation exists to change the activities of the organization and introduce more bureaucracy and management documents.

Taking into account AENOR experience in management systems audits, the main causes of possible failures are:

- The top management is not involved (for lack of will, time or means);
- Employees not actively participate due to lack of communication and motivation.

Following it establishes criteria for interpreting the MNMs RMM included to facilitate implementation in the SME construction companies in to the entire life cycle of the construction sector. Specifying the requirements that SMEs-organizations need to include (from SPD14) and how they should implement them in order to update their management systems or introduce a new systematic approach in the consideration of this risks if no previous management system is implemented.

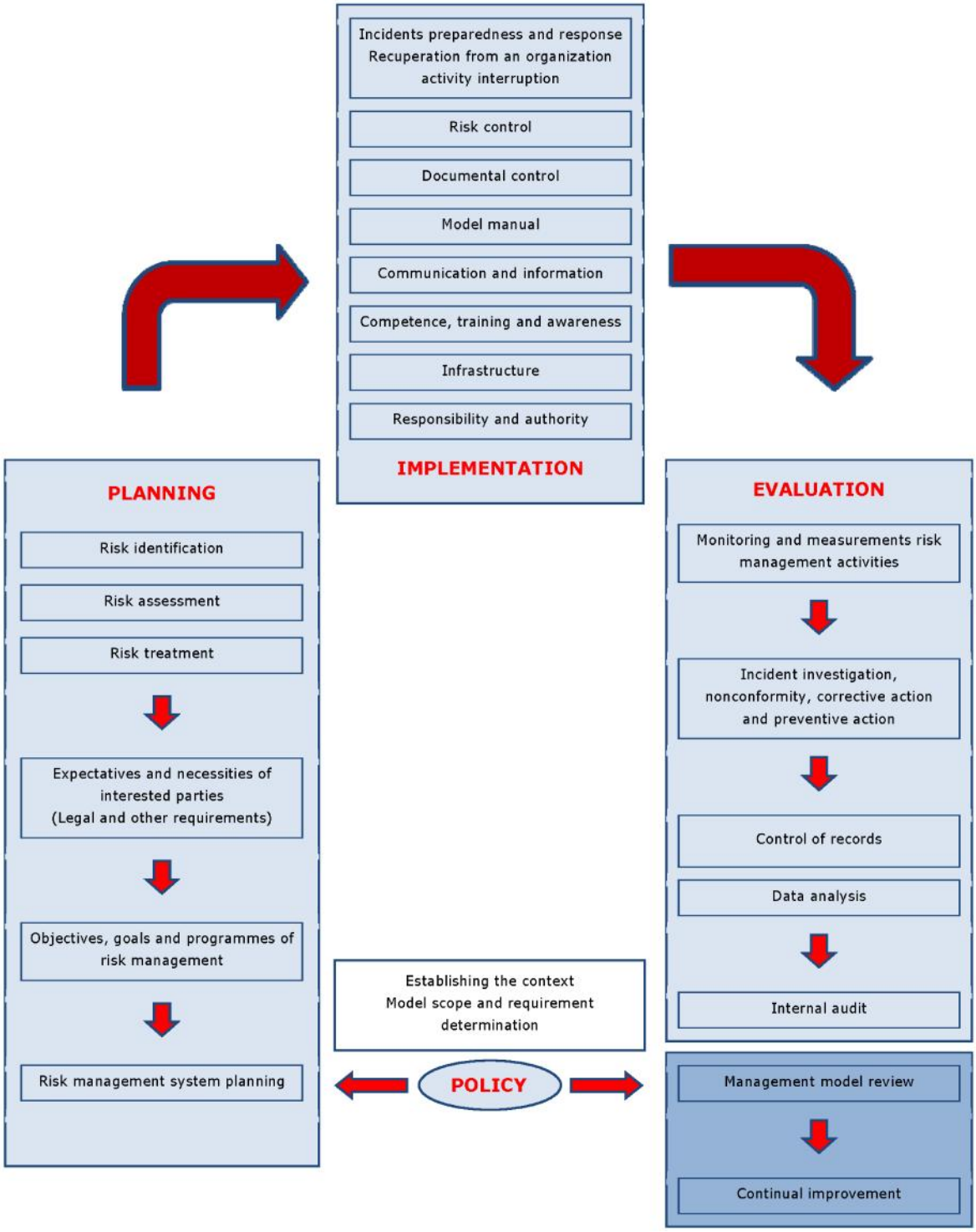


Figure 10-Diagram for RMM Model´s element. (from SCAFFOLD report D5.5. Specifications, implementation & audit plans from Industrial Use Cases, AENOR)

General Requirements

- **Context**

  The context defines the basic parameters in which MNMs Risk shall be managed.
  Key areas of internal context include: culture, Internal stakeholders, structure, resources, objectives and goals, etc…

  Whereas the external context involves: business environment, social concerns, threats to the organization, external stakeholder, technological progress, clients demands, regulations, etc.

- **Necessities and expectations for stakeholders**

  Once the stakeholders have been defined, they shall be categorized by their expectations and necessities, geographical areas, and their impact to the company. This helps to establish priorities to face, as well as that allows a global vision of other possible interactions.

- **Scope determination and requirements for the MNMs RMM**

  Defining the scope consist on the description of process, products (and/or services), facilities, departments, divisions, etc., of the company where the MNM is going to be applied, so it is important to document the exclusions of the model. Those exclusions shall not affect the ability of the organization to fulfill their objectives and comply with the legal and other requirements.

MNMs risk management policy and management commitment

- **Management commitment**

  Chairman, is key for the success of the MNMs RMM, thus, the allocation of human means, financial and technical resources. Roles, functions and responsibilities shall be defined, documented and communicated. An OHS responsible shall be appointed as chairman representative for the MNMs RMM.

- **MNM risk management policy**

  MNM risk management policy is the key element for the development of the MNMs RMM, and, therefore, shall be kept updated, in order to give a framework for establishing and reviewing MNMs RMM objectives and goals.

Due to its importance, must be documented and approved by the Chairman.

The full content of the policy shall be available to public and communicated to all employees.

Planning

- **MNMs risk assessment**

The risk assessment is the process which covers identification of risks, analysis and risk evaluation, this will lead to eliminate, or reduce them to an acceptable risk level.

Risk Identification

Risk identification is the process of finding, recognizing and recording risks.

The MNMs identification shall take into account:

- material (physicochemical, toxicity and ecotoxicity characteristics);
- potential routes for human exposure;
- human dose response and safety aspects
- routine and no routine situations
- works having access to the workplace, hazards originated out of the workplace, etc.

Risk Evaluation

The analysis of the information gathered during the identification of MNM risk, can be approached by quantitative or qualitative methods.
For the qualitative evaluation the organization must define a methodology that ensures to the analysis in terms of likelihood and consequences. The risk level must be determined and also the controls that will lead to the elimination or the acceptable level of risk.

In terms of risk evaluation, must be included also the consultation and proper participation of workers.

- **MNMs risk treatment**

MNM risk treatment plan must be prepared and implemented.

There are three basic options for the risk treatment:

- Avoidance of the MNM risk.
- Transfer the MNM risk (e.g. Outsourcing contract).
- Management of the MNM risk.

The MNM risk treatment plan shall be documented.

The organization must include these treatments in the management plans and regularly review the performance and establish, monitor and review the MNMs risk management processes.

- **Legal and other requirements**

The organization shall establish a procedure, that guarantees the access and the identification of the legal requirements, including those related to licenses and authorizations, contractual conditions, etc. as well as voluntary requirements which the organization subscribes.

Besides this identification, the organization shall ensure not only the continual update of the legal and other requirements, but the information to employees about the legal requirements related to the MNM risk of their concern.

- **Objectives and programmes**

Objectives and programs

Sources of information for defining objectives:

- MNM risk assessment,
- incident investigation,
- internal audits results,
- management review,
- workers opinions,
- technological options,
- financial, operational and business requirements,
- legal requirements and other requirements,
- internal and external context.

Objectives must be reasonable and reachable, measurable and if possible, quantified.

MNMs risk management planning

Objectives shall be described in a MNMs risk management program, establishing goals that will lead for the achievement of the objectives. For each both goals and objectives shall be provided clear accountability allocation, responsibility and authority for each task, resources and time-frames.

Implementation and operation

- **Roles, responsibility and authority**

The organization must make an effort and identify those functions relevant to the Occupational, Health and Safety and the MNMs Risk management. It is also important to establish responsibilities and accountabilities and the level of authority.

Responsibility and authority

Some roles will require organizational capability to make decision related to the management of the MNMs risk.

Management representative

The Chairman must designate an OHS MNMs RMM responsible, and has to be a member of the Top Management. The appointee OHS MNMs RMM responsible must be made available for all the employees.

Infrastructure

Infrastructure involves: workplaces, facilities, equipment (including hardware and software) and supporting services (Transport, communication, etc.).

- **Competence, training and awareness**

The required competence for the different functions (legal requirements shall be taken into account) shall be defined.

Once competence has been established, the organization shall identify the training needs and provide the necessary means to acquire it. The organization shall keep records of the effectiveness of this training.

Besides the training it is important to aware all employees about MNM risk and consequences of their behavior.

- **Communication, participation and consultation**

Communication and information

An effective internal communication shall be ascendant, descendant, and cross sectional, accordingly the employees should be consulted bout Occupational, Health and Safety related to MNMs risks issues at the work place, and related issues.

Regarding external communication and consultation this, shall involve not only contractors and visitors, but also State Members and other external interested parties.

OSH responsible shall ensure the information regarding to the identification of hazards, risk assessment, exposure control, etc.

Participation and consultation

Regarding to employees' participation usually is channeled through the Representative of Workers, and may include:

- New processes.
- New procedures.
- New preventive equipment, etc.

- **Documentation**

The MNMs RMM must include the following documents:

- MNM risk management Policy.
- MNM RMM Manual.
- Procedures.
- Objectives.
- MNMs risk criteria.
- Records.

The MNMs RMM documentation shall be as specific as possible and suitable for the complexity of the organization.

MNMs Risk Manual

The content of the MNM risk Manual shall include:

a) The scope of the MNMs RMM.

b) The description of the main elements of the MNMs RMM and their interaction, and reference to related documents.

c) The main types of MNMs risks and MNMs risk criteria.

d) The documented procedures established for the MNMs RMM, or reference to them.

- **Control of documents**

The procedure shall ensure the legibility and availability of all documents of the MNMs RMM.

The control of the documents must be extended to the external documentation, such as contractors procedures, etc.

- **MNMs operational control**

MNMs exposure control measures shall be technical, organizational and personal protection:

  - Technical measures: such as replacing substances, processes and equipment, process isolation or enclosure, changes of design, ventilation, etc.
  - Organizational measures implementing safe work practices.
  - Personal protection mainly respiratory and dermic protection.

- **MNMs emergencies preparedness and response**

MNMS incidents preparedness and response

The organization shall identify the potential emergency situations, and establish an Emergency Response Plan

For the development of this Plan applicable regulation and legislation must be considered, as well as external interested parties such as contractors, visitors, emergency services, etc…

All employees must know this Plan and be able to perform it in case of emergency, so it is important a periodical test involving, if it possible, all interested parties.

The Plan shall be review especially after an emergency situation or periodical testing.

Recuperation from an organization activity interruption

For an effective recuperation from an organization activity interruption, procedures for recovery of activity shall be established. These procedures must take into consideration, not only not only natural calamities but also in the event of smaller disruptions including illness or departure of key staffers, supply chain partner problems or other challenges.

These procedures shall periodically be reviewed in order to confirm its suitability.

Checking

- **Monitoring and measurements of MNMs risk management activities**

The organization must check the implementation of prevention measures derived MNMs risk assessment. Should be considered:

- Measurements:
  - Measurement of the occupational exposure to MNMs.
  - Health and Safety performance indicators (related to the exposure to MNMs).
  - Employees health surveillance.
  - Systematic workplace inspections.
  - Effectiveness of control measurements.
  - Effectiveness of awareness and training.
  - Compliance with legal and other requirements.
- Monitoring

Periodic inspections of workplaces to ensure the prevention of MnMs Risk and obtain data for continuous improvement.

- **Legal compliance evaluation**

  The organization must develop a procedure for the evaluation of the legal and other requirements. The periodicity of the legal compliance evaluation should be set up in agreement with the MNMs risk, size of the organization, interested parties concern, etc…

  It must be taken into account that the organization has express its commitment to fulfilling the legal and other requirements.

- **Incident investigation, nonconformity, corrective action and preventive action**

  Event and incident investigation

  The procedure for event and incident investigation, shall establish the person (s) responsible for incident notification and reporting, perform the investigation, cause analysis and result communication. The MNMs Risk assessment should be revised in several cases.

  Non-conformity, corrective action and preventive action

  Non-conformity is non fulfillment of a specified MNMs RMM or legal and other requirements.

  When non-conformities are detected, an analysis of causes is needed. As the result of the analysis of causes, corrective or preventive action shall be taken. All actions shall pursue the elimination of causes that leaded to the non-conformity.

- **Control of records**

  Records are evidence supporting of the fulfillment of the implementation of the MNMs RMM, so its integrity shall be protected.

  The procedure shall include the period of conservation of record. When defining this period, legal and other requirements should be taken into account.

- **Internal audit**

  Internal audits at planned intervals, to determine the compliance of the organization with the MNMs RMM, shall be performed.

When planning internal audits, the size of the organization, interested parties concern, and the results of MNMs risk assessments, and previous audits shall be taken into consideration.

Internal audit should cover all areas and activities included in the scope of the MNMs RMM.

Auditors must be competent, impartial and objective.

- **Management review**

  Management Model Review

  This management review should consist on the data analysis, and will end up into a report that will include opportunities of improvement, the need of changes in the MNMs RMM, need of resources, in order to fulfill with the commitments stated on the policy and demonstrate its commitment with the continual improvement.

  The results of this review must be communicated to employees.

  The periodicity of the management review shall be consistent with other cycles of the model.

  Data Analysis and Continual improvement

  During the stages of implementation and checking of the MNMs RMM, several data have been acquired. It is important the analysis of these data in order to evaluate the ability of the RMM to achieve the expected results and to establish action that will lead to the continual improvement.

This recommendation should be principally used as essential help by the SMEs, but it is not necessary to write up all the documentation if there is already a management system implemented (eg. OHSAS 18001, ISO 31000, etc.) and also that the formats/documents included in each requirement sheet should be produce in case of no management system implemented by the company.

4. Best practice

In the following paragraphs we have collected some recommendations for the construction sector when addressing the implementation of the MNMs RMM model developed:

1) RMM development: It will introduce the process or activities where the company will apply the MNMs RMM. In summary:

    - Identification of operations can be exposed to nanoparticles during the manufacture or in a particular construction.

    - Installations with general systems and manually equipment when staff are working

    - Selection of PPE (gloves, half face mask) that must be used by staff during possible contact with MNMs

    - Measurements done for the determination of potential exposure during the manufacture or in a particular construction.

2) RMM implementation. Depend on the organization has implemented a OHSAS 18001 or not, the companies have 2 options:

    - Organization without OHSAS management system: The organization will elaborate general documents (Manual, procedures and formats) based of the MNMs RMM and with the help of the SCAFFOLD Toolkit and taking as a model the documents and formats included in the Toolkit.

    - Organization with OHSAS management system. The organization will adapt this documentation for the new risk related to MNMs.

3) Risk Identification and Evaluation: The organization will identify operations in which staff can be exposed to MNM during the manufacture process or application en construction process. (see SCAFFOLD's Best Practice Guide for Risk Assessment – SPD9)

4) Operational Control: It will describe the providing protections measures of staff against MNM risks, both collection protection and suitable personal protection equipment (PPE). When there is MNMs risks identified, the preventive measures set out in other guides (see SCAFFOLD's Best Practice Guide for Risk Protection - SPD13).

5) Monitoring and measuring: The organization will define the monitoring and measuring of the activities in order to evidence the effectiveness of the management system implemented. It describes the necessary controls. It is also necessary to record non-compliances and incidents that are detected to assess the capacity response of the model, depending on systematic non conformity and incidents provided by the SCAFFOLD Toolkit. All this should be done ensuring communication to responsible workers.

References

- OHSAS 18001:2007, Occupational health and safety management systems — Requirements
- OHSAS 18002:2008, Occupational health and safety management systems — Guidelines for the implantation of OHSAS 18001
- ISO 31000:2009, Risk Management — Principles and guidelines
- ISO/PC-283 Distributed documentation and standard references.
- ISO 9000:2005, Quality management systems — Fundamentals and vocabulary
- ISO 9001:2008, Quality management systems — Requirements
- ISO 14001:2004, Environmental management systems — Requirements with guidance for use
- ISO 14004:2004, Environmental management systems — General guidelines on principles, systems and support techniques
- ISO 19011:2011, Guidelines for auditing management systems
- EC Guidance on the Protection of Health and Safety of Workers from the potential Risks related to Nanomaterials, CEN/TC 352, January 2015)
- European Commission document on Working Safety with Manufactured Nanomaterials, CEN/TC 352, January 2015
- OHSAS PROJECT GROUP-Results of 2009 Standards and Certificate Surveys)
- SCAFFOLD (2012). Life Cycle Analysis of nano-TiO2, nano-SiO2, carbon nanofibres, cellulose nanofibres and nanoclays in the construction sector. Scaffold Public Document SPD1.
- SCAFFOLD (2012). Background information on exposure, use, and hazard of manufactured nanomaterials in the construction sector. Scaffold Public Document SPD2.
- SCAFFOLD (2012-2015) Roadmap for occupational safety in relation with manufactured nanomaterials (MNMs) in the construction sector. Scaffold Public Document SPD3.
- SCAFFOLD (2012) Deliverable D.3.2. Design and plan of experimental campaigns for exposure measurement (inhalation, dermal and accidental)
- SCAFFOLD (2012) Deliverable D.4.1. Design and plan of the experimental campaign for testing efficiency of collective protection systems
- SCAFFOLD (2012) Deliverable D.4.3. Identification and selection of PPEs (respiratory protective devices) to be used in experimental tests
- SCAFFOLD (2012). Selection of representative PPEs used in the construction sector for efficiency tests. Scaffold Public Document SPD24.
- SCAFFOLD (2014). Guide for the implementation of a Risk Management Model in relation with manufactured nanomaterials (MNMs) in the construction sector. Scaffold Public Document SPD14 (AENOR).

- SCAFFOLD (2014). D Guide for the initial review, the monitoring and the audit of Scaffold's Risk Management Model in relation with manufactured nanomaterials (MNMs) in the construction sector. Scaffold Public Document SPD15. AENOR
- SCAFFOLD (2014). D.5.5. Specifications, implementation & audit plans from Industrial Use Cases, AENOR)
- SCAFFOLD (2014). Guide for the implementation and the audit of Scaffold's Risk Management Model for SMEs in relation with manufactured nanomaterials (MNMs) in the construction sector. Scaffold Public Document SPD16. AENOR.
- SCAFFOLD (2015). Best Practice Guide for Risk Assessment of manufactured nanomaterials (MNMs) in the construction sector. Scaffold Public Document SPD9.
- SCAFFOLD (2015). Best Practice Guide for Risk Protection in relation with manufactured nanomaterials (MNMs) in the construction sector. Scaffold Public Document SPD13.

ANNEX 1

ANNEX 1 Correspondences between RMM, OSHAS 18801, ISO 31000, HLS and proposed CEN/TC 352 TS

MNM RMM		OHSAS 18001		ISO 31000		HIGH LEVEL STRUCTURE Annex SL		TS - SCAFFOLD	
0	Introduction		Introduction		Introduction		Introduction		Introduction
0.1	General		Foreword						
0.2	General principles in MNMs risk management			3	Principles				
1	Scope	1	Scope	1	Scope	1	Scope	1	Scope
2	Normative references	2	Normative references			2	Normative references	2	Normative references
3	Terms and definitions	3	Terms and definitions	2	Terms and definitions	3	Terms and definitions	3	Reference publications
4	Requirements for the MNMs Risk Management Model (only title)	4	OH&S management system requirements	4.3	Design of framework for management risk	4	Context of the organization	4	OH&S management system requirements
						5	Leadership		
4.1	General requirements	4.1	General Requirements	4.4	Implementing the framework for managing risk	4.2	Understanding the needs and expectations of interested parties	4.1	General Requirements
4.1.1	Context			5.1	General	4.3	Determining the scope of the XXX management system		
4.1.2	Necessities and expectations for stakeholders			4.1	General	4.4	XXX management system		
4.1.3	Scope determination and requirements for the MNMs RMM			4.3.1	Understanding of the organization and its context	4.1	Understanding the organization and its context		
4.2	MNMs risk management policy and management commitment (only title)			4.1	General	4.4	XXX management system		
MNM RMM		OHSAS 18001		ISO 31000		HIGH LEVEL STRUCTURE Annex SL		TS - SCAFFOLD	

4.2.1	Management commitment	4.2	OH&S policy	4.2	Mandate and commitment	5.1	Leadership and commitment	4.2	OH&S policy
4.2.2	MNMs risk management policy			4.3.2	Establishing risk management policy	5.2	Policy		
4.3	Planning (only title)	4.3	Planning	5.4	Risk assessment (only title)	6.	Planning	4.3	Planning
4.3.1	MNMs risk assessment (only title)	4.3.1	Hazard identification, risk assessment and determining controls	5.4	Risk assessment (only title)			4.3.1	Hazard identification, risk assessment and determining controls
4.3.1.1	General			5.4.1	General				
4.3.1.2	MNMs risk identification			5.4.2	Risk identification				
4.3.1.3	MNMs risk evaluation			5.3	Establishing the context	6.1	Actions to address risks and opportunities		
				5.3.5	Defining risk criteria				
				5.4.3	Risk analysis				
				5.4.4	Risk evaluation				
4.3.2	MNMs risk treatment			5.5	Risk treatment				
4.3.3	Legal and other requirements	4.3.2	Legal and other requirements	4.2	Mandate and commitment	5.2	Policy	4.3.2	Legal and other requirements
				4.3.1	Understanding of the organization and its context				
4.3.4	Objectives and programs	4.3.4	Objectives and programme(s)	4.3.4	Integration into organizational processes	6.2	XXX objectives and planning to achieve them	4.3.4	Objectives and programme(s)
4.3.4.1	Objectives, goals and programs of risk management for MNMs			4.4.2	Implementing the risk management process				
4.3.4.2	MNMs risk management planning			4.2	Mandate and commitment				
4.4	Implementation and operation (only title)	4.4	Implementation and operation	4.4	Implementing risk management	7	Support	4.4	Implementation and operation
MNM RMM		**OHSAS 18001**		**ISO 31000**		**HIGH LEVEL STRUCTURE Annex SL**		**TS - SCAFFOLD**	
						8	Operation		

4.4.1	Resources, roles, responsibility, accountability and authority. General.	4.4.1	Resources, roles, responsibility, accountability and authority.	4.3.5	Resources	7.1	Resources	4.4.1	Resources, roles, responsibility, accountability and authority.
4.4.1.1	Responsibility and authority			4.3.3	Accountability	5.3	Organizational roles, responsibilities and authorities		
4.4.1.2	Management representative				-		-		
4.4.1.3	Infrastructure			5.3	Establishing the context	6.1	Actions to address risks and opportunities		
4.4.2	Competence, training and awareness	4.4.2	Competence, training and awareness	4.3.5	Resources	7.2	Competence	4.4.2	Competence, training and awareness
						7.3	Awareness		
4.4.3	Communication, participation and consultation	4.4.3	Communication, participation and consultation	4.3.6	Establishing internal communication and reporting mechanisms	7.4	Communication	4.4.3	Communication, participation and consultation
4.4.3.1	Communication and information			4.3.7	Establishing external communication and reporting mechanisms				
4.4.3.2	Participation and consultation			5.2	Communication and consultation				
4.4.4	Documentation	4.4.4	Documentation	5..5.2	Preparing and implementing risk treatment plans	7.5.1	General	4.4.4	Documentation
4.4.4.1	General					7.5.2	Creating and updating		
4.4.4.2	MNMs risk management manual								
4.4.5	Control of documents	4.4.5	Control of documents	5..5.2	Preparing and implementing risk treatment plans	7.5.3	Control of documented information	4.4.5	Control of documents
4.4.6	MNMs operational control	4.4.6	Operational control	4.4.1	Implementing the framework for managing risk	8.1	Operational planning and control	4.4.6	Operational control
MNM RMM		**OHSAS 18001**		**ISO 31000**		**HIGH LEVEL STRUCTURE Annex SL**		**TS - SCAFFOLD**	
4.4.7	MNMs emergencies preparedness and response			5.5	Risk treatment	8.1	Operational planning and control		
4.4.7.1	MNMs incidents preparedness and response	4.4.7	Emergency preparedness and response					4.4.7	Emergency preparedness and response

4.4.7.2	Recuperation from an organization activity interruption		-						-
4.5	Checking (only title). General	4.5	Checking					4.5	Checking
4.5.1	Monitoring and measurement of MNMs risk management activities	4.5.1	Performance measurement and monitoring	4.5	Monitoring and review of the framework	9.1	Monitoring, measurement, analysis and evaluation	4.5.1	Performance measurement and monitoring
				5.6	Monitoring and review	10.	Improvement		
				5.7	Recording the risk management process	9.	Performance evaluation		
4.5.2	Legal compliance evaluation	4.5.2	Evaluation of compliance	5.6	Monitoring and review	9.1	Monitoring, measurement, analysis and evaluation	4.5.2	Evaluation of compliance
4.5.3	Incidents investigation, non conformity, corrective action and preventive action (only title)	4.5.3	Incident investigation, nonconformity, corrective action and preventive action					4.5.3	Incident investigation, nonconformity, corrective action and preventive action
4.5.3.1	Event and incidents investigation	4.5.3.1	Investigación de incidentes	5.6	Monitoring and review	10.1	Nonconformity and corrective action		
4.5.3.2	Non conformity, corrective action and preventive action	4.5.3.2	No conformidad, acción correctiva y acción preventiva	5.6	Monitoring and review	10.1	Nonconformity and corrective action		
4.5.4	Control of records	4.5.4	Control of records	5.7	Recording the risk management process	7.5.3	Control of documented information	4.5.4	Control of records
4.5.5	Internal audit	4.5.5	Internal audit	5.6	Monitoring and review	9.2	Internal audit	4.5.5	Internal audit
4.6	Management review	4.6	Revisión por la dirección	4.2	Mandate and commitment	9.3	Management review	4.6	Management review
4.6.1	Management model review								
4.6.1.1	Outputs for the review								
4.6.1.2	Review results								
4.6.2	Data analysis								
MNM RMM		**OHSAS 18001**		**ISO 31000**		**HIGH LEVEL STRUCTURE Annex SL**		**TS - SCAFFOLD**	
4.6.3	Continual improvement			4.6	Continual improvement of the framework	10.2	Continual improvement		

ANNEX 2 Risk Assessment example

[Company Logo]	RISK ASSESSMENT	Pag.
		1/2
		FORMAT
		F-MNM 4.3.1-1

FACILITY:		ELABORATED BY:
WORKPLACE:		DATE:

HAZARD IDENTIFICATION		SEVERITY			PROBABILITY			RISK ESTIMATION					PROPOSED ACTION			CONTROL
		S	H	E	L	M	H	TR	TOL	MOD	IM	IN	ENGINEERING	ORGANIZATIONAL	VS	
PROFESIONAL DISEASE	Exposure to chemical agents															
	Exposure to biological agents															
	Ionizing dadiation															
	Non-ionizing radiation															
FATIGUE	Mental. Receiving information.															
	Mental. Reply															
	Chronic fatigue															
FIRE	Explosions															
	Fires. Trigger factors.															
	Fires. Propagation															
	Fires. Ways of fighting															
	Fires. Evacuation															
ACCIDENTS	Exposure to harmful or toxic substances															
	Contacts with caustic and / or corrosive															

[Company Logo]	RISK ASSESSMENT	Pag.

1.- SEVERITY

Slightly harmful	❑ Surface damage: fingers irritation and / or eyes. ❑ Discomfort and irritation headache.
Harmful	❑ Dermatitis, asthma, muscle and / or skeletal disorders. ❑ Disease that leads to less disability.
Extremely harmful	❑ Poisoning. ❑ Cancer and other chronic diseases that severely shorten life.

To estimate the severity of the risk, consider:
- ❑ The affected body parts.
- ❑ The nature of damage (slightly harmful, harmful, extremely harmful).

2.- PROBABILITY

Low	The damage will occur rarely.
Medium	The damage will occur occasionally.
High	The damage will occur always or almost always.

3.- RISK ESTIMATION - MNMs (Risk level = Severity x Probability)

SEVERIDAD		Slightly harmful	Harmful	Extremely harmful
PROBABILITY	Low	Trivial risk	Tolerable risk	Moderate risk
	Medium	Tolerable risk	Moderate risk	Important risk
	High	Moderate risk	Important risk	Intolerable risk

PROCEDURE

- ❑ Risk Assessment will be done by qualified personnel
- ❑ In the workplace, hazards will be identified and risk levels will be estimated based on the product Severity x Probability. For levels above Tolerable risk, actions will be established to reduce risk and their duration.
- ❑ Risk Assessment will be performed in the following cases:
  - •The risk assessment was not performed.
  - •New equipment and / or new technologies
  - •New chemical (e.g. MNMs and NEP)
  - •Changing in working conditions
  - •Damage to health
  - •Detection of failure on preventive measures
  - •Minimum frequency every 3 years
- ❑ Those risks not contemplated herein, will require specific assessments.

4.- RISK ASSESSMENT AND ACTION LEVEL

Trivial	A specific action is not required.
Tolerable	An improvement of preventive action is not required; however more profitable solutions or improvements that do not involve a significant economic burden should be considered.
	Periodic checks to ensure the effectiveness of control measures are required
Moderate	Efforts to reduce the risk, determining the necessary investments should be done. Measures to reduce the risk should be implemented in a given period.
	When the moderate risk is associated with extremely harmful consequences, further action will be needed to establish more precisely the likelihood of harm as a basis for determining the need for improved control measures.
Important	The work should not be started until reduce risk. It may require considerable resources to control risk.
	When the risk corresponds to a work that is being done, the problem must be remedied, in less than solving the moderate risks.
Intolerable	Work should not be started until reduce risk. If risk reduction is not possible, even with limited resources, work should be prohibited

ANNEX 3 Planning preventive activity example

[Company Logo]	PLANNING PREVENTIVE ACTIVITY	Pag. 1/1 FORMAT F-MNM 4.3.1-2

DEPARTAMENT		DATE:	
WORKPLACE		Nº WORKERS:	

CONTROLS / MEASURES			DATE		INTEREST GROUP	RESPONSIBLE	RESOURCES		MONITORING	VERIFICATION
Nº	PROPOSED ACTIONS	PRIORITY	START	END			HUMAN	ECONOMIC		

PROCEDURE	APROVAL
❑ The Director of OHS, based on the risk assessment for exposure to MNMs, will record in this document the actions necessary to control the risks. ❑ The monitoring of actions will be updated quarterly. ❑ The emergency measures, health surveillance, information and training will be included.	OHS Director Signature and date

ANNEX 4

The RMM-Toolkit represents the integration of all the solutions developed for risk management during the project in a software tool, friendly, easy to use and customizable for SMEs. It consists in a standalone desktop application for the Windows platform that follows the architecture and final skeleton on the SCAFFOLD RMM.

The Toolkit is structured into: 1) Five operational modules (Library, Customization, Risk management, Tools and Help) (Table 1), 2) two setups, a general setup for large or advanced companies in risk management, and a customized setup for SMEs and 3) Two operational modes (Table 2), learning and risk management. In tables 1 and 2 the main characteristics and content of the modules and operating modes are displayed.

Module	Description
1. Library	It provides a library with documentation to help the companies of the construction sector to deal with the risks arising from MNM.
2. Customization	It allows companies to customize the application to their processes, tasks, scenarios and size. It uses the Module 1 to facilitate data input and generate the company profile.
3. Risk Management	It enables the initial assessment, implementation and audit of RMM guided by a step-by-step dialog. This module deploys two different setups, depending on the company profile (Large company or SME).
4. Tools	It contains the toolbox for nanosafety management.
5. Help	It gives access to miscellaneous options: file management, configuration, and help (User manuals).

Table 5.1 SCAFFOLD Toolkit: Software modules

Operation mode	Description
Learning	The toolkit is used for training (e.g. toolbox), general information and communication (e.g. NOAA, hazards, control measures, good practices, etc). Only modules 1 and 4 are operating.
Risk Management	Customized mode. The toolkit is used for diagnosis, implementation, monitoring, auditing and improving the management of nanorisks in a specific construction company. All modules are operating.

Table 5.2 SCAFFOLD Toolkit: Operation modes

The main tools for risk management in the Toolkit are:

1) Risk management: opens the checklist for diagnostic, implementation or audit. The checklist enables the user to enter comments and generate bar charts. The Toolkit will include two check list depending on the set up decided by the company, the general check list (275 questions) is for general set up and the reduced check list (150 questions) is principally for SMEs set up.

2) Risk assessment: opens the risk evaluation tool. This window displays a list of processes, tasks and scenarios. Each scenario can be characterized with both quantitative and qualitative methods. The quantitative method allows the user to

enter the exposition and reference values. The tool will then calculate the exposure value and, according to the configured thresholds, the risk level. The qualitative method implements the control banding approach ISO 12901-2. The user can navigate through these charts to get a hazard band (A – E) and an exposure band (1 – 4). This characterization leads to another risk level. For each scenario, a set of control measures can be selected, allowing the user to specify whether they are already implemented or not.

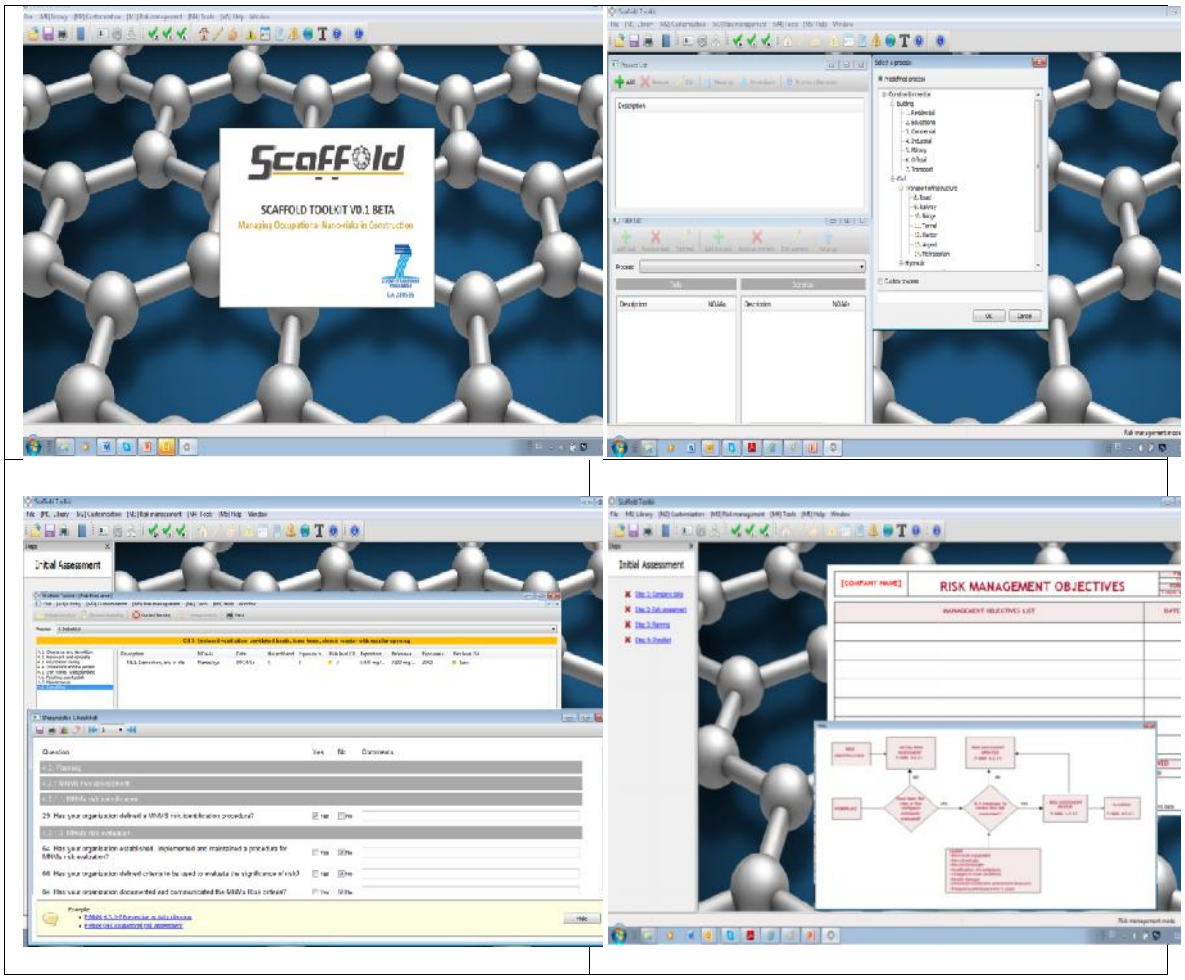


Figure 11-The Toolkit is a standalone desktop application for the Windows platform, friendly, easy to use and customizable for SMEs.

3) Planning: opens a tool to schedule the implementation of the control measures specified in the risk evaluation tool. For each control measure, the user can select the expected implementation date, the actual implementation date, the progress, the responsible and the associated cost. This planning can be exported to Excel.

4) KPIs: allows the definition, customization, calculation and visualization of Key Performance Indicators.

5) Documents and templates: gives access to a list of Word templates with procedures, instructions, registers and OHS manuals.