baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

NanoValid

Developing Reference Methods for Nanomaterials

Safety Management and Nanomaterial

Supplementary item No 1

Imprint

This report is a final product of the project NanoValid - project F2268 - and was generated under the lead responsibility of Miriam Baron (Federal Institute for Occupational Safety and Health).
The research leading to these results has received funding from the European Union Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 263147 (NanoValid – Development of reference methods for hazard identification, risk assessment and LCA of engineered nanomaterials).
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First published: July 2015

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1 Nanomaterials and other chemicals

It is important to realize that although Nanomaterials have only recently be recognized as a group of materials that merits extra attention, the fundamental safety procedures to handle such materials are not different from the procedures that have been developed for handling "traditional" chemicals. A company or laboratory that has already implemented good safety procedures for traditional chemicals will find it easy to extend these to incorporate specific instructions for nanomaterials. The following sections will discuss important aspects of such safety management systems, with an emphasis on practical aspects.

2 Management Systems

In many cases more or less ready-made frameworks for occupational safety systems are offered by management systems like ISO 14001 or OSHAS 18001. Setting up a structure as required by those systems will in many cases already take case of many of the aspects discussed below.

3 Safety intentions and reality

All companies and institutes are bound by a national legal framework that requires that they have to operate in a safe way and avoid adverse effects of their activities for the employees and for the environment. However, even if this obligation has been incorporated in some kind of mission statement, this does not automatically ensure that the safety organisation in a company or institute will operate in an optimum way. In many cases the set of external requirements (if known at all) is felt as a cumbersome strait-jacket and in daily routine some "shortcuts" may develop. Because in many cases nothing negative will happen if the rules are interpreted somewhat more loosely, over time common practices may develop that carry risks. People that may criticise such practices (like safety experts) are perceived as outsiders, who do not understand how things function in reality, and whose advice is therefore largely ignored. Only after incidents or accidents happen, critical reviews or investigations are performed that reveal preceding errors. Subsequently, improvements in procedures or equipment are introduced to make things "safer" However, if time goes by, routine again sets in and the cycle is likely to repeat itself.

It has to be realized that safety management systems can only reach lasting and significant improvements if they are part of the company culture on all levels. Only if management and employees on all levels shows an active involvement in introducing new procedures and in supporting and checking their implementation and their effectiveness, success may be expected. In order to reach such a situation, it is necessary for all employees to have an active involvement in the safety culture of an organisation by regular trainings, participating in regular audits (or being audited by others) and discussions of potential improvements, even in case no incidents have occurred yet.

4 Responsibility and Organisation

Though the details may depend on the national legislation, in most cases the owner/manager of a company or the scientific leader of a research institute will be the ultimate legal responsible person for the safety environment of a department. This also means such a person will be held responsible if a major accident happens. Because the involvement of such a person with the daily work practices may be low, it is common to delegate part of his legal responsibilities to specific managers/ department leaders at a lower level. If necessary, responsibility may be delegated through two or more levels. In such a case, the following aspects should be considered:

1. A written delegation of responsibility should be in place. This should contain the specific areas and responsibilities that are delegated and should be signed by the person delegating and the one being delegated to.
2. The person being delegated to, should have the authority to be able to independently perform actions and/or give instructions within the framework of his responsibilities.
3. If the person being delegated to, needs specific training to be able to carry out his duties, this training should be organized and offered.

As discussed above, responsibility for safety in a facility ultimately rests with management. However, in many cases safety rules are complex and not every manager may be sufficiently knowledgeable in this field. Therefore it is advisable to have in each working group of max. 30-40 people a safety contact who can function as a link between what actually happens at the workfloor and what management may be aware of. If done well, such a person will be the first point of contact for the employees on the workfloor, to ask questions, suggest improvements or to report unsatisfactory situations, before these develop into situations where people may actually be harmed. To fill such a position it is necessary that such a person has some basic knowledge of safety rules and how they are supposed to be implemented in the company, as well as a good understanding of what happens in daily practice. In many cases some extra training is necessary to acquire the necessary knowledge for this role. On top of that, it is advisable for each organisation to have some safety expert(s) available for more thorough professional analysis of more complex safety situations and for proposing improvements and evaluation methods. Depending on the size and complexity of an organisation, this can be an in-house expert or an outside professional who spends a certain number of hours in the organisation, based on a specific contract. Many countries have professional degrees to certify such experts and require each facility to have available a certain number of hours of professional safety assistance for their organisation. If more specialized assistance is needed that is not available within the organisation, additional external experts can be hired for certain tasks.
In cases severe accidents have to be investigated, it is advisable to set up investigation teams that also contain neutral experts not directly involved in the situation leading to the incident, in order to ensure an independent investigation.

5 Information on hazardous materials and inventory lists

In order to be in a position to perform a meaningful risk analysis for the use hazardous chemicals, including nano-materials, it is necessary to have a good overview of the kind of materials that are present and which may come into use. Therefore, even in those countries where if it may not be a legal obligation by itself, it is strongly recommended to prepare a directory of hazardous substances in a facility. As a minimum this directory should contain following information:

1. Identification of the compound (Name, CAS and/or EC Number)
2. Supplier
3. Physical state
4. Quantity (make sure to use a common unit)
5. CLP data (H phrases and labelling information)
6. Description of storage location
7. Owner
8. Link to a copy of the Material Safety Datasheet

It is recommended to have an off-line electronic copy available, or a hard copy, in order to be independent of a functioning internet connection.
It has to be ensured that the inventory is kept up to date, by either assigning a specific responsibility for this update, or to agree on a regular common review and update.

6 Risk Analysis

In order to prioritise activities and programs in order to work safely, it is important to have an idea in what situations the risk of accidents because of the use of specific materials or equipment may be particularly high. In this respect, it is important to realize that "risk" is not identical with "hazard". Hazard is an objective property of substances (e.g. the potential to initiate cancer), or equipment (e.g. presence of moving parts). A hazard will only produce an accident if it coincides with the presence of special conditions (be it because of external influences or by the behaviour of a human operator). In other words, the probability of an accident (the "risk") is a combined function of the objective hazard and the presence of one or more specific conditions.

If done properly, risk may be expressed in a (semi-)quantitative way (e.g. that 1 in so many events will result in an accident of a certain severity class), or in a more qualitative way (e.g. control-banding). Safety experts have available specific methods to perform such an analysis, using various estimation tools.

The results of an analysis performed for several procedures in a laboratory, will give important information on which procedures in a department carry the highest risk. Once this is known, efforts can be concentrated on either lowering the hazard, or in case this is not possible (which is often the case if projects deal with specific investigations of hazardous substances which cannot be replaced because they are at the heart of the project), how conditions that may lead to a high probability of accident may be eliminated, prevented, or at least reduced in their consequences. Apart from technical improvements on equipment (e.g. shielding of moving or hot parts), examples of such actions may be specific trainings to raise awareness, or improving procedures like filling or disposal. However, in many cases the knowledge on the frequency of occurrence of dangerous conditions may be limited and may only be given in relative terms. However, even in such cases the risk evaluation may still be helpful, because it will allow an initial risk priorisation already. If necessary the analysis may be refined with more specific data collection.

7 Measures

In order to monitor the performance of a safety system, it is advisable to set some parameters that can be monitored over time and are indicative of how well the safety culture develops. Such parameters may primarily be the

number of incidents of a certain kind (large or small), the number of small injuries (like cuts) as shown in a logbook at the first-aid box, or other parameters that can easily be checked during audits (e.g. percentage of people using correct PPE, availability of mandatory instruction cards, completeness of trainings, etc). If an organisation feels that it is necessary to set common goals for such parameters that should be achieved within a certain time frame, this should be communicated well. However, it should be realized that achievement of more administrative goals is only a secondary value, that should never replace the true protection of people.

8 Training

Specific tasks that carry a certain risk can only be carried out if certain knowledge and handling experience is present among the people carrying out such tasks. Usually this is considered no problem for long term experienced employees, but nevertheless also in such cases regular review may be helpful to correct wrong habits that may have developed. Moreover, for newcomers it is important to be trained in such a way that they will learn to operate safely already from the start, using the lessons acquired by others in the past. Therefore, standardized trainings/ instructions materials need to be developed for tasks that carry a risk. Examples of such areas/tasks where trainings may be necessary are: Setting up and operation of experimental installations, cleaning of experimental installations, use of hazardous chemicals, use of equipment with hazardous characteristics, how to handle in case of emergency, be it in a personal accident or in the building in general.

A training schedule needs to be set up. It may be differentiated for each employee, depending on the type of activities he/she is involved in, indicating which type of training he/she has to go through and how often this has to be repeated, and who is authorized to give the training. Training documents related to day to day work need to be easily available for reference on the work-floor. A special mentioning deserve the operating instructions (like the ones used in Germany, see the supplementary item no 3 “Operating instruction Example”) Also in the case of Nanomaterials these can serve to summarize the critical aspects of how to handle such compounds in a safe way and what to do if something goes wrong.

9 Auditing / Checks

Each system requires steady checks to see if in real life the rules that have been defined are being followed. External safety management systems require periodic audits by external inspectors in order to judge the functioning of such a system. Even without such an external obligation, it is recommended to set up small regular internal audits that focus on one or more aspects of the safety system. Examples of aspects that can be checked are the correct use of PPE or the relevance of training materials or training schedules.

10 Updates / Review

Each system, how good it may be initially, will gradually become out of date. Therefore it is recommended to set periods of major review of all available documents and methods. Such a review may become necessary after major restructuring in equipment or space – but in general it should be considered to plan such a review at least each second year.

11 Near-Misses reports

Major accidents usually are the result of an unlikely combination of events. In a well-run facility, the number of major incidents or accidents will be low. This may create a false sense of safety. The fact that a major event did not take place, may be caused by sheer luck, if not all elements in such an unlikely combination of events did materialize. However, it may very well be possible that significant unsafe situations are present that next time will produce a real accident. In such a case, it is important to develop a view for such unsafe situations. Corrections of such situations will decrease the probability of major incidents in the future. Therefore, it is recommended to introduce a reporting system where all employees can enter observations of situations that may have the potential to lead to serious incidents and also to propose corrective actions or report actions that have been taken in order to remove such situations. It is important to use such a system in a spirit of "amnesty", where each employee feels free to report small and large incidents without having to fear personal repercussions, even if personal errors were made. A successful "near miss system" may help to improve the safety performance in an organisation. Communication of such experiences (anynonimised if needed) may help to learn from errors that were made by others and avoid a repeat.

12 Document Management / Management of change

An effective and transparent safety management system is only possible if the rules are defined in a clear and transparent way and are easily accessible for everyone. This makes it necessary to have a set of valid guidances and rules available to everyone. This can be in the form of hard copies or in the form of an electronic document. Moreover, most management systems have specific requirements on how documents (be it hard copies or electronic) have to be maintained and updated. For realizing a good and reliable documentation system the following aspects need to be considered:

1. Naming the documents should follow clear rules. It is helpful if the document name already conveys some kind of idea of its content.
2. In order to improve easy readability it is recommended to use standard formats (e.g. lay-out or colour) for each type of document (e.g. instruction sheets, organograms, description of policies, technical methods). This makes it easy to allocate a document to a specific category and helps to find the most important information rather quickly, because it will appear in the same place for various documents.
3. For electronic documents, a well thought-out folder structure will allow quick and easy retrieval of a relevant document.
4. For good maintenance, each document should clearly indicate who the owner of the document is, what its area of validity, approval by management, the latest revision date as well as the expiry date.
5. There should be a well-defined procedure for making changes to documents, including who initiates changes and who needs to approve. In order to prevent unplanned, unauthorised changes, it is recommended to keep most documents as a read-only version, where only a selected group of people can make changes.