PAUL SCHERRER INSTITUT		Registration AW-96-09-04e
Title	General directive for **Activities involving Nanomaterials at PSI**	Replaces
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Overview:

This general directive outlines the most important statutory and operational instructions regarding activities involving nanomaterials at the Paul Scherrer Institute (PSI), and governs the relevant areas of responsibility. It also refers to basic codes of conduct adopted in order to protect personnel from the hazards presented by nanomaterials and regulates the responsibilities.

This directive is binding on every person working at the Paul Scherrer Institute.

Following the practice used in the statutory texts, this document often uses only the masculine personal form. All designations always apply to women on an equal basis

These instructions were approved at Meeting 10/05 of the Directorate on 25.05.2010.

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1 Introduction

PSI's research activities extend to the use of nanomaterials. By law, line managers bear the responsibility for ensuring adherence to the statutory directives relating to the protection of employees handling hazardous materials. At PSI, the line managers are supported in this duty by the Nanomaterials Expert.
At present, there is still some uncertainty with regard to the hazard posed by nanomaterials, and no special regulations have been introduced in Swiss or European law. The "Action plan for synthetic nanomaterials" released by the Swiss Federal Council provides for a precautionary matrix for products and applications involving synthetic nanomaterials (see 6.2). This directive contains a concept and regulations for dealing with nanomaterials within the institute, and is based on this precautionary matrix. Its aim is to ensure the safe handling of nanomaterials at PSI and to guarantee fulfilment of the general statutory provisions.

2 Scope

This directive only applies to synthetic nanomaterials.

3 General principles

3.1 Definitions[1]

Nanotechnology:

1 Nanotechnology is concerned with structures that typically measure between 1 and 500 nm (also known as nanoscale).

2 Nanotechnology exploits characteristic effects and phenomena that appear in the transition zone between the atomic and mesoscopic scales.

3 Nanotechnology is aiming for complete control of the material down to the molecular scale, in terms of chemistry, structure and morphology.

Nanomaterials:

Nanomaterials, or nano-objects, are materials with structural components (e.g. crystallites, fibres or particles) that are on the nanoscale in at least one of their dimensions. The International Organization for Standardization (ISO) defines nano-objects in its technical specification ISO-TS-27687 as follows:

- Nanoparticles: Nano-objects in which all three dimensions are on the nanoscale,
- Nanofibres: Nano-objects where two of the three dimensions are on the nanoscale, but the third is much larger.
- Nanoplates: Nano-objects where one of the three dimensions is on the nanoscale, but the other two are much larger.
- Nanorod: solid nanofibre
- Nanotube: hollow nanofibre
- Nanowire: electrically-conducting or semiconducting nanofibre

[1] Definition from the report: "Meili C., Widmer M., Hussmann F., Gehr P., Blank F., Riediekre M., Schmid K., Stark W., Limbach L. 2007: Synthetische Nanomaterialien. Risikobeurteilung und Risikomanagement. Grundlagenbericht zum Aktionsplan. Umwelt-Wissen Nr. 0721. Bundesamt für Umwelt und Bundesamt für Gesundheit"

- Quantum Dot: Crystalline nanoparticle with dimension-dependent optical or electronic properties based on the limited ability of the charge carrier to move.

Nanomaterials are made of inorganic or organic materials, or a mixture of both. Nanoparticles, nanofibres and nanoplates are components of objects known as nanocomposites and nanocoatings.

Synthetic nanoparticles:

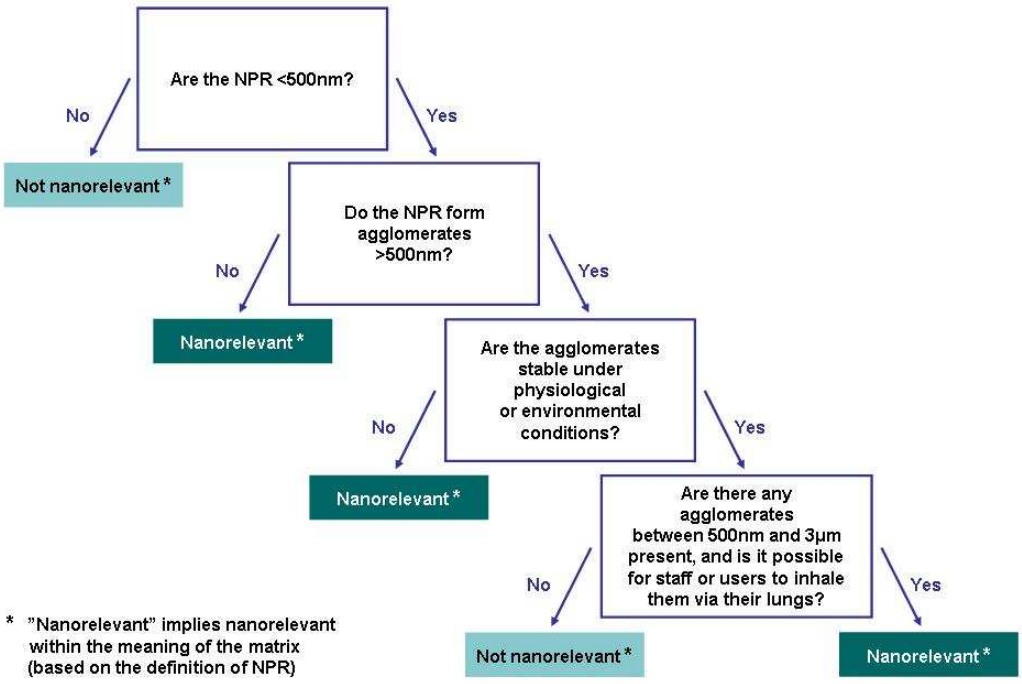
Synthetic nanoparticles (often also simply called Nanoparticles) are synthetically manufactured nanoscale solid particles.

Nanoparticles and nanorods, NPR:

In the table of precautions, it is assumed that nanospecific risks only arise if it is possible to release particles that are nanoscale in 2 dimensions (such as nanorods) or 3 dimensions (nanoparticles). These two types of particle are therefore consistently grouped and abbreviated together as nanoparticles and nanorods or NPR.

Nanorelevant materials:

Materials that could involve a risk potential as a result of their nanoscale or properties. The question of whether a risk might be arise in handling materials (nanorelevance) can be clarified with the help of the following diagram:



Flow chart for the clarification of nanorelevance

Materials recognised as nanorelevant are then further evaluated for their risk potential with the help of the precautionary matrix.

3.2 Types of hazard

The extent to which the hazard potential of nanoparticles differs from that of their chemical constituents is largely unclear. It is hardly possible to estimate the long-term risk for in-

soluble or almost-insoluble nanoparticles; an outcome – such as that discovered with asbestos – can therefore not be excluded. Toxicologists regard inhalation through the lungs as the main risk. It has been proven that nanoparticles can catalyse the creation of oxygen radicals. This may result in cell damage that can initiate inflammation and cause consequential damage.

3.3 The law relating to nanomaterials

Switzerland does not yet have any special law on nanomaterials. A list of the laws relating to chemicals applicable in Switzerland and to PSI is provided in Appendix 6.1.1.

3.4 Classification of nanomaterials

The precautionary matrix for synthetic nanomaterials divides nanorelevant materials into classes. The material is eventually assigned to Class A or Class B.
Class A indicates that the risk potential of the material is zero or negligible.
Class B indicates that there is a risk potential. A special risk analysis must be carried out for this class, followed by precautionary protective measures.

3.5 Safety data sheets

A safety data sheet (*Sicherheitsdatenblatt* or SDB) contains, like the insert in medication packages, a concise and clear description of the most important information.
The purpose of the safety data sheet (SDB) is to inform the occupational users of materials or preparations of the necessary physical/chemical, safety-related, toxicological and eco-toxicological details. These are required for correct handling, so that the necessary health and environmental protection measures and safety at work precautions can be arranged.
At present, only a few safety data sheets containing specific advice on the risk potential and associated precautionary measures for nanomaterials are available.

4 Organisation of the nanomaterials safety system and structure of responsibilities

4.1 Responsibility

The directive on safety, health protection and environmental protection at PSI (“Safety, Health, Protection and Environmental Protection at PSI”, AW-01-07-02e) regulates the overall responsibility for chemical safety at PSI’s facilities. This directive extends its provisions to nanomaterials.

4.2 Official nanomaterials expert

The line managers and Safety Officer are supported by the Official Nanomaterials Expert in relation to safety involving nanomaterials.

The Official Nanomaterials Expert is the PSI’s nanomaterials expert, appointed in accordance with Directive 6508, the directive governing the use of occupational physicians and other safety at work experts (the *Richtlinie über den Beizug von Arbeitsärzten und anderen Spezialisten der Arbeitssicherheit,* or ASA-Richtlinie) issued by the Swiss committee responsible for safety at work (the *Eidgenössische Kommission für Arbeitssicherheit*)).

4.2.1 Duties

- ☞ The Official Nanomaterials Expert is responsible for the production of regulations relating to the use of nanomaterials at PSI.

- ☞ In particular, this expert initiates the risk potential assessment relating to nanorelevant materials used and produced at PSI, in accordance with the applicable instructions (precautionary matrix as of 2009), and documents and checks the assessment and the measures undertaken.

- ☞ The expert also appoints advisers for nanorelevant materials at PSI, who will collaborate with the responsible experimenters to assess the risk potential according to the precautionary matrix, and organise measures for the tasks, for storage and for disposal. The expert is also responsible for the standard of their training.

- ☞ The expert also acts as subject consultant to the emergency response organisation.

4.2.2 Competences

The holder of this post is authorised to:

- ☞ Issue and update directives on the use of nanomaterials at PSI, in consultation with the Safety Officer.

- ☞ Regulate the use of nanomaterials at PSI, in consultation with the Safety Officer and the line managers, in accordance with the precautionary matrix. If the agreed safety measures have not been maintained, the Official Nanomaterials Expert is authorised to limit or prohibit activities without previous consultation with the Safety Officer, if there is any immediate danger.

- ☞ Delegate part of his/her responsibility in writing to suitable advisers on nanomaterials at PSI, in agreement with the Safety Officer, whereby the Safety Officer will bear the overall responsibility and the adviser will bear the responsibility for the tasks handed over to him/her.

- ☞ Request information from all the people dealing with nanomaterials at PSI.

- ☞ Communicate independently, verbally and in writing, with the authorities and other external offices, by agreement with the Safety Officer, as long as this does not result in any legal or financial obligations on the part of PSI.

5 Working with nanomaterials; storage and disposal

The primary goal is to prevent the ingestion of nanorelevant materials through inhalation by people at work. It is intended that this goal should be achieved by the use of measures similar to the regulations governing tasks involving other hazardous materials (ALARA principle[2]). Where possible and necessary, the effectiveness of the measures should be checked by using suitable testing instruments. Suitable measures will be discussed in advance with the participants, bringing other competent advisers in where necessary. They will also be put in writing. No risk potential assessment will be undertaken in the case of nanomaterials for which safety data sheets with specific advice about the risk potential are already available, and for which associated precautionary measures have been proposed. The safety measures suggested in the safety data sheets must be applied. The measures put in place will be checked by the Official Nanomaterials Expert.

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[2] ALARA: as low as reasonably achievable

5.1 Evaluation of the risk potential

The following procedure must be maintained:

1. The responsible experimenter (PSI employee or external guest) checks substances and materials that are to be used or produced for the first time for nanorelevance, according to the flow chart (2.4).

2. If this triage results in nanorelevance, the responsible experimenter contacts the Official Nanomaterials Expert.

3. The Official Nanomaterials Expert or his/her advisers assess the risk potential on the basis of the information supplied and with the help of the precautionary matrix.

4. The Official Nanomaterials Expert and the experimenter agree upon suitable measures.

5. The Official Nanomaterials Expert checks that the measures have been put in place.

6. The Official Nanomaterials Expert archives the documents (analyses, measures and checks).

5.2 Basic principles for working with nanorelevant materials from Class B

The responsible experimenter uses suitable protective measures (see Suva recommendation at http://www.suva.ch/home/suvapro/branchenfachthemen/nanopartikel_an_arbeitsplaetzen.htm),
and processes to prevent contamination of the workplace, and particularly the ingestion of nanorelevant materials into the lungs. The measures must be dependent on lung accessibility and the volume of the nanomaterials, and also take account of possible accident scenarios (explosion, etc.).

5.3 Personal protection measures

Suva (the Swiss accident and insurance fund) suggests protective measures for many risks. In any case, the appropriate procedure must be checked. The basic principle is to minimise exposure to nanorelevant materials. Prevention measures primarily involve collective protection (e.g. aspiration of particles), individual protection (protective equipment) and hygiene (washing and air showers).

5.4 Storage of nanorelevant materials

Nanomaterials must be kept in containers with an easily-legible, permanent label. The label must show the following minimum level of information:

- Description: “Nanorelevant, Class B”
- Name of material
- If possible, the exact chemical composition
- If possible, the dimensional scale of the particle (including unit)

- Volume (including unit)

- Name und internal address of the person responsible

Nanomaterials must be stored in a suitable location and notified to the Official Nanomaterials Expert, who will keep a stock inventory.

5.5 Disposal of nanorelevant materials

Nanorelevant materials from Class B will be subject to separate collection as far as possible, immobilised by agglomeration or embedding in a carrier material, and thus converted to Class A. Disposal of agglomerated nanomaterials is by the same methods as for other chemicals, subject to flammability and chemical toxicity.

6 Appendix

6.1 Statutory principles

The list includes all the most significant Swiss laws and ordinances relating to activities involving chemicals, environmental protection and safety at work that must also be observed when dealing with nanomaterials. The currently valid versions of the laws and ordinances can be consulted at any time at http://www.admin.ch/ch/d/sr/sr.html.
Advice on the “Precautionary matrix for synthetic nanomaterials” and the SUVA safety at work guidelines can be found under “Non-statutory recommandations” in Appendix 6.2:

6.1.1 Dealing with chemicals

- The Swiss law on protection against hazardous substances and preparations (the chemicals law, *ChemG*) SR 813.1
- The Swiss ordinance on hazardous substances and preparations (the chemicals ordinance, *ChemV*) SR 813.11
- The ordinance dated 18th May 2005 on the reduction of risks relating to activities involving certain particularly dangerous substances, preparations and items (the chemicals risk reduction ordinance, *ChemRRV*) SR814.81
- The EDI (Swiss department of home affairs) ordinance dated 28th June 2005 on the contact person for chemicals, SR 813.113

6.1.2 Environmental protection

- The Swiss law dated 7th October 1983 on environmental protection (the *Umweltschutzgesetz, USG*) SR 814.01
- The Swiss clean air ordinance dated 16th December 1985 (the *LRV*) SR 814.318.142.1
- The ordinance on ground pollution dated 1st July 1998 (the *VBBo*) SR 814.12
- The ordinance dated 27th February 1991 on protection against accidents (the *Störfallverordnung, StFV*) SR 814.012
- The law dated 24th January 1991 on water protection (the *Gewässerschutzgesetz, GSchG*) SR 814.20
- The water protection ordinance dated 28th October 1998 (the *GSchV*) SR 814.201

6.1.3 Safety at work

- The Swiss employment law dated 13th March 1964
  SR 822.11
- The accident insurance law dated 20th March 1981
  (the *UVG*) SR 832.20
- The ordinance on the prevention of accidents and occupational diseases dated 19th December 1983
  (the *VUV*) SR 832.30
- Various safety at work guidelines can be obtained from Suva at
  www.suva.ch/waswo.

6.2 Non-statutory recommendations

In view of the substantial uncertainty with regard to the risks associated with nanomaterials, there are currently no specific laws in this area. The recommendations made by the responsible authorities therefore assume major significance. We would refer in particular to the documents on the Intranet, which are continuously updated. The following important documents are available as of June 2009:

- ”Precautionary matrix for synthetic nanomaterials” dated 03 December 2008, issued by the Swiss Federal Office of Public Health (the *Bundesamt für Gesundheit,* BAG)

- ”Nanoparticles in the workplace”, July 2007, issued by Suva