Institute of Environmental Sciences and Technology

IEST-RP-NANO205.1

Contamination Control Division, Nanotechnology Committee
Recommended Practice 205.1

Nanotechnology Safety: Application of *Prevention through Design* Principles to Nanotechnology Facilities

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Contamination Control Division
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1 SCOPE AND LIMITATIONS

1.1 Scope

This Recommended Practice (RP) provides facility design information intended to minimize risks for personnel associated with nanotechnology research and production. Using "Prevention through Design" principles disseminated by the National Institute for Occupational Safety and Health (NIOSH), issues related to incoming materials, products, processes, and byproducts are addressed and methods of risk mitigation suggested [NIOSH (2011a)]. Facility design and response systems for conditions including normal operation, external emergency, and internal emergency are described. Information is provided to assist in the development of an effective nanotechnology environmental health and safety program. This document is useful to all those involved in facilities that develop or use nanomaterials.

This Recommended Practice (RP) is intended to complement IEST-RP-NANO200: *Planning of Nanoscale Science and Technologies Facilities: Guidelines for Design, Construction, and Start-up.*

1.2 Limitations

CAUTION: Use of this RP is voluntary. It is the responsibility of the user to establish appropriate safety, security, and health practices and to determine the applicability of regulatory limitations prior to use of this RP. It is beyond the scope of this RP to cover all of the potential safety issues associated with the design and operation of nanotechnology facilities. Relevant safety standards, national and local regulations, and building codes must be consulted in designing facilities and developing safety plans and training programs.

Additionally, the following limitations apply:

1. This RP does NOT address toxicity and other hazards of specific nanomaterials. Use of this RP is limited to the design principles that prevent exposure to hazardous and potentially hazardous materials. This RP is intended to work in parallel with guidance documents for determining hazard levels for nanomaterials.
2. This RP is limited to operational issues as they apply to the design of the facility. A subsequent document will address specific operational safety practices.
3. This RP does not address animal facilities.
4. Fugitive emissions from a process or a delivery system of airborne molecular contaminants (AMCs) and surface molecular contaminants (SMCs) are not addressed within this RP. This RP does not address safety implications of AMCs and SMCs. However, such emissions and safety implications should be considered in any facility.
5. This RP does not address ambient nanomaterials. However, ambient nanomaterials may need to be considered in the overall internal environment of the facility and in the overall risk assessment of the facility operation.

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6. This RP does not address general energy sources such as high voltage, high amperage, laser, and radio frequency (RF) magnetic and electric fields.
7. All guidelines for radiolabeled nanomaterials are superseded by—and supplemented by—the Nuclear Regulatory Commission (NRC) and other applicable state and governmental regulations.

Information in this RP was the best available at the time of development and does not purport to encompass all current information or resources on topics contained herein. Also, an effort was made to provide information and principles that are generally applicable. However, the understanding of the effects of nanomaterials is increasing rapidly, and current considerations should be explored and updated through the review of current resources, publications, and websites such as NIOSH (see section 2).

2 REFERENCES

The cited editions of the following documents are incorporated into this RP to the extent specified herein. Subsequent revisions of these publications do not automatically supersede the cited editions. Users should investigate the applicability of revised editions of the references.

2.1 Documentation

2.1.1 American Glovebox Society (AGS)

AGS-G001-2007: Guideline for Gloveboxes

AGS-G002-1998: Standard of Practice for the Design and Fabrication of Glovebags

AGS-G003-1998: Standard of Practice for the Application of Linings to Gloveboxes

AGS-G004-2014: Standard of Practice for Leak Test Methodologies for Gloveboxes and Other Enclosures

AGS-G005-2014: Standard of Practice for the Specifications of Gloves for Gloveboxes

AGS-G006-2005: Standard of Practice for the Design and Fabrication of Nuclear Application Gloveboxes

AGS-G010-2011: Standard of Practice for Glovebox Fire Protection

AGS-G013-2011: Guideline for Glovebox Ergonomics

2.1.2 American National Standards Institute

ANSI/ISEA (International Safety Equipment Association) Z87.1-2015: American National Standard for Occupational and Educational Personal Eye and Face Protection Devices

2.1.3 American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE)

Standard 41.2-1987 (RA 92)—Standard Methods for Laboratory Airflow Measurement

Standard 62.1-2013—Ventilation for Acceptable Indoor Air Quality

Standard 110-1995—Method of Testing Performance of Laboratory Fume Hoods

2.1.4 American Society for Testing and Materials (ASTM)

ASTM E2535-07(2013) Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings

2.1.5 European Committee for Standardization (CEN)

EN 15051:2006 Workplace atmospheres – measurement of the dustiness of bulk materials – requirements and test methods

EN 61000-6-1:2007 (WI=16092) Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity for residential, commercial and light-industrial environments

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2.1.6 Institute of Environmental Sciences and Technology (IEST)

IEST-RP-CC001.5: HEPA and ULPA Filters

IEST-RP-CC007: Testing ULPA Filters

IEST-RP-CC012.2: Considerations in Cleanroom Design

IEST-RP-CC021.3: Testing HEPA and ULPA Filter Media

IEST-RP-CC024.1: Measuring and Reporting Vibration in Microelectronics Facilities

IEST-RP-CC026.2: Cleanroom Operations

IEST-RP-CC027.2: Personnel Practices and Procedures in Cleanrooms and Controlled Environments

IEST-RP-CC028.1: Minienvironments

IEST-RP-CC034.3: HEPA and ULPA Filter Leak Tests

IEST-RP-NANO200: Planning of Nanoscale Science and Technologies Facilities: Guidelines for Design, Construction and Start-up

2.1.7 International Code Council (ICC)

International Building Code (IBC)

2.1.8 International Organization for Standardization (ISO)

ISO 10648-1:1997 Containment enclosures—Part 1: Design principles

ISO 10648-2:1994 Containment enclosures—Part 2: Classification according to leak tightness and associated checking methods

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ISO/TS 10868:2011 Nanotechnologies—Characterization of single-wall carbon nanotubes using ultraviolet-visible-near infrared (UV-Vis-NIR) absorption spectroscopy

ISO/TR 10929:2012 Nanotechnologies—Characterization of multiwall carbon nanotube (MWCNT) samples

ISO/TS 11251:2010 Nanotechnologies—Characterization of volatile components in single-wall carbon nanotube samples using evolved gas analysis/gas chromatograph-mass spectrometry

ISO/TS 11308:2011 Nanotechnologies—Characterization of single-wall carbon nanotubes using thermogravimetric analysis

ISO/TS 11888:2011 Nanotechnologies—Characterization of multiwall carbon nanotubes—Mesoscopic shape factors

ISO/TS 12025:2012 Nanomaterials—Quantification of nano-object release from powders by generation of aerosols

ISO/TR 12885:2008 Nanotechnologies—Health and safety practices in occupational settings relevant to nanotechnologies

ISO/TS 12901-1:2012 Nanotechnologies—Occupational risk management applied to engineered nanomaterials—Part 1: Principles and approaches

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

ISO/TR 13121:2011 Nanotechnologies—Nanomaterial risk evaluation

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ISO/TS 13278:2011 Nanotechnologies—Determination of elemental impurities in samples of carbon nanotubes using inductively coupled plasma mass spectrometry

ISO/TR 13329:2012 Nanomaterials—Preparation of material safety data sheet (MSDS)

ISO 14644-1:1999 Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness

ISO 14644-2:2000 Cleanrooms and associated controlled environments—Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

ISO 14644-3:2005 Cleanrooms and associated controlled environments—Part 3: Test methods

ISO 14644-4:2001 Cleanrooms and associated controlled environments—Part 4: Design, construction and start-up

ISO 14644-5:2004 Cleanrooms and associated controlled environments—Part 5: Operations

ISO 14644-7:2004 Cleanrooms and associated controlled environments—Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)

ISO 14644-8:2013 Cleanrooms and associated controlled environments—Part 8: Classification of air cleanliness by chemical concentration (ACC)

ISO 14644-9:2012 Cleanrooms and associated controlled environments—Part 9: Classification of surface cleanliness by particle concentration

ISO 14644-10:2013 Cleanrooms and associated controlled environments—Part 10: Classification of surface cleanliness by chemical concentration

ISO/DIS 14644-12 Cleanrooms and associated controlled environments—Part 12: Classification of air cleanliness by nanoscale particle concentration

ISO 15900:2009 Determination of particle size distribution—Differential electrical mobility analysis for aerosol particles

ISO/TS 17200:2013 Nanotechnology—Nanoparticles in powder form—Characteristics and measurements

ISO 21501-1:2009 Determination of particle size distribution—Single particle light interaction methods—Part 1: Light scattering aerosol spectrometer

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ISO 22412:2008 Particle size analysis—Dynamic light scattering (DLS)

ISO/TR 27628:2007 Workplace atmospheres—Ultrafine, nanoparticles, and nano-structured aerosols—inhalation exposure characterization and assessment

ISO/TS 27687:2008 Nanotechnologies—Terminology and definitions for nano-objects—Nanoparticle, nanofibre and nanoplate

ISO 28439:2011 Workplace atmospheres—Characterization of ultrafine aerosols/nanoaerosols—Determination of the size distribution and number concentration using differential electrical mobility analysing systems

ISO/TS 80004-1:2010 Nanotechnologies—Vocabulary—Part 1: Core terms

ISO/TS 80004-1:2014 Nanotechnologies—Vocabulary—Part 1: Core terms-Amendment

ISO/TS 80004-2:2014 Nanotechnologies—Vocabulary—Part 2: Nano-objects:nanoparticle, nanofibre and nanoplate

ISO/TS 80004-3:2010 Nanotechnologies—Vocabulary—Part 3: Carbon nano-objects

ISO/TS 80004-4:2011 Nanotechnologies—Vocabulary—Part 4: Nanostructured materials

ISO/TS 80004-6:2013 Nanotechnologies—Vocabulary—Part 6: Nano-object characterization

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ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment (Second Edition)

Biopharmaceutical Manufacturing Facilities Baseline® Guide (2nd Ed.)

2.1.10 National Fire Protection Association (NFPA)

NFPA 45: Standard on Fire Protection for Laboratories Using Chemicals. www.nfpa.org/45

NFPA 70E: Standard for Electrical Safety in the Workplace.
www.nfpa.org/codes-and-standards/document-information-pages?mode=code&code=70E

NFPA 101: Life Safety Code.
www.nfpa.org/codes-and-standards/document-information-pages?mode=code&code=101

NFPA 318: Standard for the Protection of Semiconductor Fabrication Facilities.
www.nfpa.org/codes-and-standards/document-information-pages?mode=code&code=318

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OSHA (2011) Combustible Dust Expert Forum Meeting Summary Report.
http://www.osha.gov/dsg/combustibledust/expert_forum_summary_report.html

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www.sbaypipe.org/assets/pdf/TGO_Toxic_Brochure_single%20pages_0519.pdf

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CDC 21-1112: 2009 Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition

U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, HHS Publication No. (CDC) 21-1112.
http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

2.1.15 US Environmental Protection Agency (EPA)

Toxic Substances Control Act www.epw.senate.gov/tsca.pdf

2.1.16 US Nuclear Regulatory Commission (NRC)

NRC 10 CFR 30.15 www.nrc.gov/reading-rm/doc-collections/cfr/

2.2 Sources

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http://publicecodes.cyberregs.com/icod/index.htm

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ISPE
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Fax: 813-264-2816
www.ispe.org

NRC
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Phone: 301-415-7000
www.nrc.gov

NFPA
National Fire Protection Association
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Quincy, MA 02169-7471
Phone: 617-770-3000
Fax: 617-770-0700
www.nfpa.org

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National Institute for Occupational Safety and Health
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3 TERMS AND DEFINITIONS

See Appendix A for a glossary of terms used in this document and related terms.

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4 INTRODUCTION

4.1 Prevention through Design

Prevention through Design (PtD) is a National Institute for Occupational Safety and Health (NIOSH) initiative developed to improve workplace safety through the use of designed-in engineering controls. PtD is defined by NIOSH as "*addressing occupational safety and health needs in the design process to prevent or minimize the work-related hazards and risks associated with the construction, manufacture, use, maintenance, and disposal of facilities, materials, and equipment.*" [NIOSH (2011a)]. For further information, please see *The State of the National Initiative on Prevention through Design* [NIOSH (2013c)].

The IEST implementation of this initiative in regard to nanotechnology safety involves the documentation of facility, process, maintenance, and material-handling design choices to prevent or minimize hazards in nanotechnology research and manufacturing facilities.

The NIOSH PtD initiative provides the best solution to this complex set of challenges. In brief, the PtD initiative proposes the utilization of engineering controls rather than relying on operational controls to maintain safety. For example, fixed barriers would be designed into systems rather than relying on personal protective equipment (PPE). Another example would be the use of card-access security systems to restrict access to potentially hazardous locations.

Implementing such controls during the design phase of a building, a process, or a product is a key element of the PtD initiative. Early implementation allows for the use of more effective control methods, as the designer is not constrained by existing architecture, machinery, or processes. Additionally, it is more cost effective to implement controls early in the design cycle than to retrofit existing systems or place construction change orders.

A one-sentence summary of the goal of PtD is to "Make it easier to do it the safe way." If building, process, and product designs comprehend safety principles in their early-design stages, controls can be built in that lead people to safe operation. Conversely, if doing something safely is awkward or difficult, personnel may be tempted to perform the task in a less-safe manner. PtD tasks the designer with making the easiest way also the safest way.

The implementation of PtD in building design follows these principles:

1) Designers identify potential safety hazards in the early planning stages of the facility. A thorough hazard assessment of facilities, processes, raw materials, finished products, and byproducts is completed and updated as more information is obtained (see 5.2.2). The hazard assessment is a living document that is constantly updated during the design process.

2) Each potential hazard provides an opportunity to mitigate the risk by designing engineering controls into the facility. A control plan is developed which, like the hazard assessment, is updated as new information becomes available and as the design process continues.

3) The use of procedural controls should be specified when appropriate engineering controls cannot be designed into the facility, process, or product (see 5.2.3, hierarchy of controls).

4) Changes in the hazard assessment should always foster a review of the control plan [Manuele and Weaver (2009)].

4.2 Introduction to Nanotechnology

4.2.1 Technology development in the US

Nanotechnology as a unifying concept was initiated in the US as the National Nanotechnology Initiative (NNI) described by Roco et al. (1999). The NNI is administered by a subgroup of the National Science and Technology Council (NSTC), the Cabinet-level organization that coordinates science and technology policies across the Federal Government. Roots of nanotechnology include aerosol and colloidal science, powder technology, polymers, catalysts, and semiconductors.

The invention of the scanning tunneling microscope in 1981 by Binnig and Rohre [Binning and Rohre (1986)], which led to a Nobel Prize, made it possible to "image" and eventually manipulate individual atoms. One of the key concepts is that technology can be approached from either top-down or bottom-up points of view. The top-down approach is the traditional method of fabricating products by starting with a large block and removing unwanted material until the part has the desired function. The bottom-up approach is to build things from individual bits of matter to form the desired part. One concept of intense research is self-assembly, whereby molecules would arrange

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themselves into useful shapes and devices. This leads to the concept that products could be designed and fabricated at the most basic level. The three elements of nanotechnology as defined by the NNI include:

- To exploit the new phenomena and processes at the intermediate length scale between single atom or molecule and approximately 100 molecular diameters, the range of approximately 1 to 100 nanometers.
- Applying the same principles and tools used at the intermediate length scale, to establish a unifying platform for science and engineering at the nanoscale.
- To use atomic and molecular interactions to develop efficient manufacturing methods.

Nanotechnology is the continuation of a 300-year industrial trend to make products better, smaller, and faster. The research has led to intense activity and is beginning to show signs of maturing beyond the laboratory.

If the extraordinary properties at small scale can be understood and engineered, nanotechnology could lead to a new generation of high-performance products. A wide range of applications is envisioned, including communications, energy conversion, and medicine. The global standard of living could be improved. It is believed that nanotechnology would enable creation of global abundance and sustainable use of resources. In 1999 the NNI developed a well-designed roadmap anticipating research focus on several generations of products with the approximate initiation date indicated [Roco et al. (1999), Roco (2004)]:

- First generation (2001)—passive nanostructures. Examples are nanoparticles for catalysis, coatings, and advanced materials.
- Second generation (~2005)—active nanostructures. Examples are nanoelectronics, targeted drugs, and sensors.
- Third generation (~2010)—three-dimensional nanosystems and systems of nanosystems.
- Fourth generation (~2015)—heterogeneous molecular nanosystems. This concept envisions that each molecule in the nanosystem has a specific structure and plays a different role.

According to the Presidents Council (2005), however, the nanotechnology industry *per se* was quite small if defined very narrowly. On the other hand, when including the large number of industries already use nanotechnology to improve existing products (e.g., petrochemical, coatings, electronics, cosmetics, textiles, and pharmaceuticals), the nanotechnology is quite large and having an important impact on the world economy.

In 2010, the NNI program was reviewed with respect to progress in the first 10 years of operation and a vision developed for the next 10 years [Roco et al. (2010)]. It was concluded that progress had been rapid and the predictions made in 1999 were not far off. A fifth generation of converging technologies such as nanotechnology, biotechnology, and information technology will open even newer possibilities. The 2010 vision predicted that the field would grow to a $3 trillion segment of the global economy by 2020.

4.2.2 Nanomaterials

A geometrical based hierarchy has been developed to describe nanomaterials. (ISO/TS 80004-1:2010, ISO/TS:80004-2:2014) See section 7.

Nanomaterials are usually classified as discrete items into two broad categories: nano-objects and nanostructured materials. Nano-objects have at least one dimension within the nanoscale. Nanoscale is defined as between 1 and 100 nm. Nano-objects are further divided into nanoparticles (three dimensions in the nanoscale), nanofibers (two dimensions in the nanoscale) and nanoplatelets (one dimension in the nanoscale). Nanostructured materials may have internal structures in the nanoscale. The desirable physical and chemical properties are obtained by controlling chemical composition in addition to size and shape. Nanoparticles and nanofibers (including nanotubes) have attracted the greatest interest from an environmental, health, and safety (EHS) standpoint. Nano-objects may be in the form of agglomerates and aggregates, complicating description of the materials. Within this classification are a wide range of materials and combination of materials intended to serve unique purposes.

Nanomaterials are used to manufacture, or are found in, a wide range of products. The implementation of nanotechnology depends on the particular industry. Facilities may represent the chemical process industry, semiconductor industry, or pharmaceutical industry, as examples. Some manufacturers of novel nanomaterials may be quite small and may be first generation scale-up of a bench operation. In all nanotechnology operations, common operations involving work with dry powder and liquid suspensions require careful consideration.

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4.3 Nanotechnology safety

4.3.1 Risks

Exposure to engineered nanomaterials poses potential risks. This RP addresses emerging information related to dealing with these potential risks solely in relation to the mitigation of risks as applied through facility design and construction. Any additional context is informational. The recognition of the potential or presumed presence of nanomaterials relates directly to this risk mitigation.

Interdisciplinary collaboration is a major strength of nanotechnology but also a significant concern regarding nanotechnology safety. While a significant portion of the material included in this RP is well established in particular industrial and research fields, these same safeguards are virtually unknown in other fields. This document attempts to bring together these safeguards to provide guidance to help prevent or minimize risk in this interdisciplinary environment.

EHS issues related to nanotechnology have been growing in importance as the field advances. The ability to invent new materials has significantly outpaced the understanding of related toxicity and risk factors. Oberdorster et al. (2005) reviewed highlights of what is known about the toxicology of nanomaterials and describes approaches for screening these materials. Nanomaterials when incorporated into products are often embedded in coatings and polymers, limiting accessibility to the environment. One concern is workplace safety at the intermediate stages of processing, involving syntheses of nanomaterials or handling of nanoscale powders containing nanoparticles and believed to have the greatest potential risk. NIOSH has issued a strategic plan for research to fill knowledge gaps with respect to safety of nanomaterials [NIOSH (2013b)].

4.3.2 Control methods

Ability to control nanoparticles is a critical component of nanotechnology safety. During the early development of nanotechnology, concern was expressed that air filtration might be ineffective for nanoparticles [Japutich et al. (2007)]. The mechanisms for removal of airborne particles in filters include impaction, interception, diffusion, and electrostatic attraction. Impaction and interception are effective for particles larger than approximately 300 nm. Diffusional collection by Brownian motion is effective below approximately 300 nm and increases in efficiency as the particle size is reduced. Studies indicated that air filters were effective for nanoparticle control due to diffusional collection [Kim et al. (2007), Rengasamy et al. (2008)]. These studies indicated commercial filters with required efficiency could be applied to gas stream cleanup, and appropriate commercial respirators could be safely applied for personnel protection.

4.3.3 Emerging materials

In certain cases, new materials created as a result of research and development efforts would not yet have Safety Data Sheets (SDSs). The generation of a safety plan for these materials generally involves a worst-case analysis using analogous materials. Reference NIOSH (2013a) and NIOSH (2012); also see section 5.2.1(d4) of this RP.

5 PLANNING FOR ENVIRONMENTAL HEALTH AND SAFETY

CAUTION: It is beyond the scope of this RP to provide planning for all of the potential safety issues associated with the design and operation of nanotechnology facilities. Relevant safety standards, national and local regulations, and building codes must be consulted when designing facilities and developing safety plans and training programs.

5.1 Contents of a safety plan

As with any technology facility, nanotechnology facilities require a systematic design process that considers applicable regulations as well as the best information available on the properties of the materials to be used on the premises and characteristics of the planned processes or operations.

A nanotechnology EHS program should address, at a minimum, the following elements:

Design considerations (see 5.2 for details)

- Identification of potential hazards
- Assessment of risks
- Design and hierarchy of appropriate controls
- Design, layout, and zoning considerations

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