



Review of Safety Practices in the Nanotechnology Industry

Phase One Report: Current Knowledge and Practices Regarding Environmental Health and Safety in the Nanotechnology Workplace

Prepared for the International Council on Nanotechnology
by the University of California, Santa Barbara

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Introduction

Nanotechnology is the understanding and control of engineered materials at dimensions of 1 to 100 nanometers, i.e. at the “nanoscale.”¹ Nanomaterials are designed to exhibit novel or enhanced properties that affect their physical and chemical behavior, in effect presenting opportunities to create new and better products. Consequently, nanotechnology has the potential to make significant contributions in many fields, from semiconductors to biotechnology to energy, transportation, agriculture and consumer products. Nanomaterials are currently being used in the manufacture of cosmetics, clothing, sports equipment, coatings, and electronics. It is estimated that global sales of nanomaterials could exceed \$1 trillion by 2015.² Jih Chang Yang, Executive Director of Taiwan's Industrial Technology Research Institute, has stated, “We believe the marketplace is already the focal point for nanotechnology today.”³

However, nanotechnology also presents new challenges for measuring, monitoring, managing, and minimizing contaminants in the workplace and the environment. The properties for which novel nanoscale materials are designed may generate new risks to workers, consumers, the public, and the environment. While some of these risks can be anticipated from experiences with other synthetic chemicals and with existing knowledge of ambient and manufactured fine particles, novel risks associated with new properties cannot be easily anticipated based on existing data. In the absence of specific information concerning risks and hazards associated with new nanomaterials, nanotechnological manufacturing industries may be implementing workplace safety and product stewardship practices that are both inspired by existing knowledge and, in some cases, are in response to anticipated hazards. Such practices could lay the foundation for industry standards, either voluntary or regulated. A survey and compendium of current practices will be critical for both assessing the maturity of practice development and for communicating practices throughout the many nanotechnological sectors.

In response to the absence of a consolidated understanding of current health, environmental, and stewardship practices in nanomaterial manufacturing, the International Council on Nanotechnology (ICON) issued a request for proposals (RFP) in December 2005 for the performance of a survey of current practices. Subsequently, an interdisciplinary team of researchers at the University of California at Santa Barbara (UCSB) was selected to perform this study which is occurring in two phases. In the first phase, which is the subject of this report, the charge is to describe *existing and planned* efforts to discover and summarize current industrial practices in workplace safety, environment and product stewardship. This first phase of research is thus intended to reveal ongoing or planned efforts that are similar to the second phase of this project: i.e. to directly survey nanotechnological organizations regarding their current practices in the workplace, environment and with product stewardship.

In this Phase One report, global efforts to document current practices (e.g., “best practices”) and to establish risk assessment frameworks are compiled and summarized. The reviewed efforts are critically evaluated for their approaches, completeness and foci. They are

¹ National Nanotechnology Initiative (NNI). “What is Nanotechnology?”
<<http://www.nano.gov/html/facts/whatIsNano.html>>. June 21, 2006.

² Roco, M.C. “Overview of the National Nanotechnology Initiative.” Presentation to the National Research Council on March 23, 2005. <http://www.nsf.gov/crssprgm/nano/reports/nni_05-0323_nset@nrc.pdf>. June 11, 2006.

³ Mokhoff, Nicolas. 2003. “Nanotech Forum Reflects On Technology's Mission.” *Techweb.com*. (September 12).

then compared to the efforts planned by the UCSB team for Phase Two of this project, and recommendations are made, where necessary, for the latter.

Summary of Findings and Organization of this Report

In Phase One, recent and ongoing efforts to examine current health and safety practices in the nanotechnology workplace, as well as efforts to assess product stewardship issues are documented and summarized. Each of the reviewed efforts differ on several fronts including scope and type of study, regional focus, method, and the manner in which the findings are disseminated. The scope of the efforts vary according to what and who was surveyed (e.g., industry, research labs or universities), with most efforts documenting current practices focusing on manufacturers and commercial users of nanomaterials. Research labs and academic settings have not constituted a significant focus in the efforts reviewed. Overall, research efforts to date were found to have generally focused on specific national contexts, although some did evaluate practices internationally. Only the German Federal Institute for Occupational Safety and Health (BAuA) conducted large-scale surveys of industry. Three other projects utilized interviews and on-site observations to document current practices in the nanotechnology workplace, while two forthcoming projects will rely on voluntary submissions from industry to gather information about current practices. In addition, an array of novel risk management plans and guidelines were evaluated, some of which are still in development, as well as efforts to establish standard nomenclature and databases on nanomaterials. Overall, it was observed that few research efforts have produced significant information documenting current environmental health and safety (EH&S) practices in nanotechnology sectors. Most of the findings generated by the research efforts to date were publicly disseminated, but some research groups intend for their findings to be used only by their clients.

In researching past, ongoing and planned efforts to document current practices, the following regions were of particular interest: North America, the European Union, Asia, and Australia. Within North America, efforts to both compile and develop current practices in the United States were identified. Similar work in Canada is evolving. Voluntary reporting programs in Germany and the United Kingdom are beginning to gather current practices information. There are also efforts by the EU to identify occupational safety and environmental risks related to nanotechnology and to develop regulatory standards. While it appears that there are relatively fewer similar, current efforts in Asia, there are existing efforts to gather information regarding current practices in Japan, Taiwan, and China. There were no similar efforts discovered for Australian organizations.

This report is organized to first describe the methods used, results found, and interpretations of the results. The results are organized into four categories based on the type of research effort. These categories are: I) Cataloging of current practices, II) Voluntary Reporting Programs, III) Recommended “Best Practices” and Frameworks, IV) Databases and Other Activities. Efforts that are most similar to those planned in Phase Two of this project are emphasized, although less similar, albeit related, studies are also discussed. The findings are summarized in tabular form in Appendix A.

Methods

Internet searches and telephone interviews were used to identify ongoing or recently completed research on current practices worldwide. Internet searches were performed using Google, and search terms/phrases included: “nanotechnology workplace safety,” “nanotechnology best practices,” and “nanotechnology occupational health and safety.” These searches generated both initial data and contact information, including the following sources:

- *Government websites and documents.* We initially focused our search on US government agency sites, such as the US Environmental Protection Agency⁴ and the National Institute of Occupational Safety and Health (NIOSH).⁵ Google searches using key phrases such as “occupational health and safety” and “environmental protection ministry” led us to similar agency websites in Europe⁶,⁷, Asia⁸ and Australia.⁹¹⁰ Some of these websites listed documents pertinent to Phase One research, which are addressed in the following sections. Further, various government-funded programs were investigated (mostly found by Google searches), such as the National Nanotechnology Initiative¹¹ (US), and the National Science and Technology Program for Nanoscience and Nanotechnology¹² (Taiwan),
- *Industry trade association websites.* These websites were located mainly by referrals from our industry contacts, and were used primarily to generate additional contacts as well as potential Phase Two survey respondents. In particular, ASTM International¹³ and The Association of German Engineers (VDI)¹⁴ websites uncovered documents useful to this research.
- *Nanotechnology organization websites.* These include the Project on Emerging Nanotechnologies¹⁵ (the Wilson Center), the Foresight Nanotech Institute¹⁶ and the

⁴ U.S. Environmental Protection Agency. 2006. <<http://www.epa.gov/>>

⁵ National Institute of Occupational Safety and Health. 2006. <<http://www.cdc.gov/niosh/homepage.html>>

⁶ BAuA. 2006. <http://www.baua.de/nn_5568/en/Homepage.html__nnn=true>

⁷ UK Department for Environment Food and Rural Affairs. 2006. <<http://www.defra.gov.uk/>>

⁸ Environmental Protection Administration. 2006. Environmental Implications and Applications of Nanotechnology. <http://ivy2.epa.gov.tw/out_web/cooperation/nanotech/ch_db/index_cn.html>

⁹ Australian Department of Employment and Workplace Relations. 2006. <<http://www.dewr.gov.au/>>

¹⁰ Australian Safety and Compensation Council. 2006. <<http://www.nohsc.gov.au/>>

¹¹ National Nanotechnology Initiative. 2006. <<http://www.nano.gov/>>

¹² National Science and Technology Program for Nanoscience and Nanotechnology. 2006. <<http://nano-taiwan.sinica.edu.tw/NewsBig5.asp>>

¹³ ASTM International. 2006. <<http://www.astm.org/>>

¹⁴ The Association of German Engineers (VDI). 2006. <<http://www.vdi.de/vdi/english/index.php>>

¹⁵ Project on Emerging Nanotechnologies. 2006. <<http://www.nanotechproject.org/>>

Institute of Nanotechnology¹⁷ (UK), which maintains NanoChina¹⁸ and served as a source of information in Phase One.

- *Conference abstracts.* The 2006 Annual Meeting¹⁹ of the American Institute of Chemical Engineers included a session on Health and Environmental Effects of Nanoparticles, where the preliminary program uncovered Environ International Corporation, which had submitted a paper on “Managing Uncertainty: a Best Management Practices Approach to Nanoscale Materials and Occupational Health Concerns.”²⁰ The team secured abstract listings of the 2nd International Symposium on Nanotechnology and Occupational Health.²¹ Contacts located include Keith Swain (DuPont), Chuck Geraci (NIOSH), and Steven Brown (Intel). Notes from the ICON meeting at Rice University in May 2006 also generated leads, including database information (e.g., NIOSH’s Nanoparticle Information Library²²).
- *Industry newsletters.* A newsletter published jointly by NIOSH and the Center for Disease Control was consulted during the beginning of the Phase One research process.²³ Newsletters regularly searched include the Meridian Nanotechnology and Development News (from the Meridian Institute²⁴), the Wilson Center Update, the Foresight Nanotech Weekly News Digest, ICON News, Asia Pacific Nanotech Weekly²⁵ (within the National Institute of Advanced Industrial Science and Technology), the Research Projects on Nanotechnology and Materials in Japan Update²⁶, and the CBEN Interest Group Digest (from Rice University’s Center for Biological and Environmental Nanotechnology²⁷).
- *Scientific articles.* Research tools such as Web of Science were utilized to run an initial search of “best practices” in the nanomaterial industry, with little success. However, bibliographical sections produced leads, specifically names of authors affiliated with

¹⁶ The Foresight Institute. 2006. <<http://foresight.org/>>

¹⁷ Institute of Nanotechnology. 2006. <<http://www.nano.org.uk/>>

¹⁸ NanoChina. 2006. <<http://www.nanochina.cn/english/>>

¹⁹ AIChE. 2006 Annual Meeting. 2006. <<http://www.aiche.org/Conferences/AnnualMeeting/index.aspx>>

²⁰ AIChE. 2006 Annual Meeting. Health and Environmental Effects of Nanoparticles: Preliminary Program. 2006. <http://aiche.confex.com/aiche/2006/preliminaryprogram/session_2330.htm>

²¹ 2nd International Symposium on Nanotechnology and Occupational Health. Proceedings and Final Program. 2006. <http://www.cce.umn.edu/pdfs/cpe/conferences/nanotech_abstracts.pdf>

²² NIOSH. Nanoparticle Information Library. 2006. <<http://www2a.cdc.gov/niosh-nil/>>

²³ National Institute of Occupational Safety and Health / Center for Disease Control. 2005. *Focus on Nanotechnology*. <<http://www.cdc.gov/niosh/topics/nanotech/newsarchive.html#fieldteam>>

²⁴ The Meridian Institute. 2006. <<http://www.merid.org/nanodev/>>

²⁵ Nanoworld. 2006. *Asia Pacific Nanotech Weekly*. <<http://www.nanoworld.jp/apnw/>>

²⁶ Nanotechnology Researchers Network Center of Japan. 2006. *Research Projects on Nanotechnology and Materials in Japan*. <<http://www.nanonet.go.jp/english/info/nanoproject.html>>

²⁷ Rice University’s Center for Biological and Environmental Nanotechnology. 2006. <<http://cben.rice.edu/>>

various government agencies, industry trade organizations and nanotechnology organizations. Scientific articles were also forwarded to the UCSB research team by industry contacts throughout the Phase One research process. Although none of these papers were directly relevant to the research, again leads were extracted from the text and primarily the bibliography sections in these papers.

In addition to drawing from these internet-based sources, extensive personal networking was used to further extract data. Some contacts were provided directly by ICON. Many were obtained from professional networking beginning with ICON and other direct contacts; this, in turn, led to numerous referrals to government officials, concerned industry professionals, EH&S specialists at academic and industry labs, EH&S consultants, and members of international standards organizations. Approximately 50 individuals in as many organizations were contacted to identify recent and ongoing efforts to document current practices.

In the following sections the findings of the Phase One research are organized into four categories based upon the similarity of the research efforts to those planned for Phase Two. These categories are “Cataloging Current Practices,” “Voluntary Reporting Programs,” “Recommended ‘Best Practices’ and Frameworks,” and “Nomenclature, Databases and Other Activities.” Each section begins with a description of the rationale behind the category. This, in turn, is followed by a brief summary of the key facets of each research effort, including scope, target industry and region, methods and findings related to current or ‘best’ practices.

I. Cataloging Current Practices

The ICON request for proposals (RFP) of December 2005 requested the identification of existing “best practices” development efforts directly relevant to nanomaterial risk management occurring worldwide. In the following section, five research efforts are identified and their approaches to developing best practices are described. Each is actively engaged in surveying and observing industry to ascertain current practices in the handling of nanomaterials. While each has a particular scope and substantive orientation, they are grouped together because they are actively researching the state of current practices through surveys, site observation, and evaluation. This is in distinction to efforts like voluntary programs or the articulation of “best practices” and management frameworks (each of which is discussed separately below). As such, research efforts discussed in this section are the most similar to the ICON RFP. Nonetheless, as will be demonstrated by this report, the UCSB research effort will fill important gaps in scope and method not addressed by these ongoing research efforts.

I.a. Descriptions of Cataloging Current Practices

National Institute for Occupational Safety and Health

The National Institute for Occupational Safety and Health (NIOSH) in the US began in early 2006 a program of onsite field evaluations of US nanotechnology companies. A broad range of companies were evaluated, from small research and development firms to large scale manufacturing facilities. Companies volunteer to be evaluated in response to advertisements and public solicitations for participation.

Teams of NIOSH scientists visit companies and evaluate processes on several fronts. A screening team will make a general assessment of the nanomaterial handling practices. This team will determine which of the remaining teams should also participate in the evaluation. Another group, a controls team, determines what is being done with regards to engineering controls and personal protective equipment (PPE). The focus is on airborne particulate matter, but also identifies what PPE are selected and in particular, the reason for these choices. In addition to evaluating practices, the team offers suggestions for improvements. A third team, an analytical measurements team, is mainly concerned with monitoring ambient levels of nanoparticles. This information is obtained with two different handheld particle counters and collected air samples to be examined with Transmission Electron Microscopy (TEM). A medical monitoring team is in development and will monitor the health of workers exposed to nanomaterials over time.²⁸

Ultimately, NIOSH aims to use the evaluations to develop case studies and recommendations of best practices for public dissemination. The project will continue until NIOSH is satisfied with their findings, or until funding is no longer available. The findings will be used to periodically update the NIOSH website and the working document, "Approaches to Safe Nanotechnology: An Information Exchange with NIOSH."²⁹ With this document, initially released in October 2005 and updated in July of 2006, NIOSH provides guidelines for the safe handling of nanomaterials, but does not describe the practices as "best" due to the lack of available knowledge regarding best practices.³⁰ NIOSH's efforts aim to provide interim precautionary recommendations, based upon the best available knowledge, and to describe gaps in existing information. The intent is that this working document and the NIOSH website will be periodically updated with the most current practices.

Included in this document³¹ are descriptions of various techniques for monitoring workplace exposure. There is no national or international consensus for measurement standards, but NIOSH proposes a multi-pronged approach to characterizing workplace exposure to airborne nanoparticles. This method would use:

- A condensation particle counter (CPC) should be used to determine particle concentrations. Crucial to using this device is to collect information on the background concentrations, as well as the concentrations during handling of the nanomaterials.
- Nanoparticle surface area measurements should be taken with a portable diffusion charger.
- Aerosol size distributions should be determined using either a Scanning Mobility Particle Sizer or an Electrical Low Pressure Impactor.

²⁸ Phone interview with Chuck Geraci, NIOSH on April 25, 2006.

²⁹ National Institute of Occupational Safety and Health/ Center for Disease Control. 2006. "Approaches to Safe Nanotechnology: An Information Exchange with NIOSH." Unpublished manuscript. <http://www.cdc.gov/niosh/topics/nanotech/pdfs/Approaches_to_Safe_Nanotechnology.pdf>. August 15, 2006.

³⁰ Phone interview with Chuck Geraci, NIOSH on April 25, 2006.

³¹ National Institute of Occupational Safety and Health/ Center for Disease Control. 2005. "NIOSH to Form Field Research Team for Partnerships in Studying, Assessing Nanotechnology Processes." *Focus on Nanotechnology*. <<http://www.cdc.gov/niosh/topics/nanotech/newsarchive.html#fieldteam>>. June 22, 2006.

- Personal sampling should be performed, using either a filter or grid to capture particulates within the worker's immediate environment. The sample would be examined by electron microscopy and possible chemical analysis.

The use of a combination of measurement techniques provides a reasonable assessment of worker exposure to nanoparticles. In addition, the document also provides interim recommendations for exposure controls procedures.

- A risk management plan should be implemented which includes: installing and evaluating engineering controls, training of employees regarding handling nanomaterials, and procedures for the selection and use of personal protective equipment.
- To reduce worker exposure to airborne particulates, engineering controls such as source enclosures or local exhaust ventilation systems should be used.
- High-efficiency particulate air (HEPA) filters should be used in exhaust ventilation systems. NIOSH believes these filters to be adequate in removing nanoparticles. NIOSH is testing HEPA filters in respirators and environmental control systems to determine filter efficiency.
- At the end of each work shift (or more frequently), work areas should be cleaned using a HEPA-filtered vacuum system or wet wipe techniques. Sweeping of dry material or use of air hoses should not be used.
- Workers should wash their hands before eating, smoking, or leaving the work place.
- NIOSH rates the efficiency of various respirator types for use in situations where engineering controls do not adequately reduce worker exposure to nanoparticles. The document, NIOSH Respirator Selection Logic,³² guides users to select an appropriate respirator.
- Spills containing nanomaterials should be cleaned with a HEPA-filtered vacuum cleaner and dry nanomaterials should be wetted with soapy solutions or cleaning oils to prevent dispersion. Absorbent traps should be used to isolate spills.
- No guidelines for personal protective clothing or gloves are currently provided by NIOSH.

The recommendations provided by NIOSH are described as interim and research is currently being undertaken by the organization to further refine these guidelines. As information becomes available, it will be disseminated through the NIOSH website and working document.³³

Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA)

Affiliated with the German Federal Ministry of Economics and Labour, BAuA was established on July 1, 1996 through the merger of the former Federal Institute for Occupational Safety and Health and the former Federal Institute for Occupational Medicine. BAuA runs a

³² National Institute of Occupational Safety and Health/ Center for Disease Control. 2004. "NIOSH Respirator Selection Logic." <www.cdc.gov/niosh/docs/2005-100/default.html>

³³ National Institute of Occupational Safety and Health/ Center for Disease Control. 2006. "Approaches to Safe Nanotechnology: An Information Exchange with NIOSH." Unpublished manuscript. <http://www.cdc.gov/niosh/topics/nanotech/pdfs/Approaches_to_Safe_Nanotechnology.pdf>. August 15, 2006.

department of occupational safety in Dortmund and a department of occupational health in Berlin.³⁴

BAuA is concerned with worker safety in the nanotechnology industry. In the first quarter of 2006, the BAuA collaborated with VCI (Verband der Chemischen Industrie, i.e. Association of the German Chemical Industry), to conduct a written survey of German nanotechnology companies with the goal of further understanding worker exposure in the workplace. The VCI membership includes over 1,600 chemical companies, which is 90% of the chemical industry in Germany.³⁵ BAuA distributed the survey by mail to VCI members that work with nanomaterials, but the response rate was not published. The final report will focus on companies which handle nanomaterials in the form of a powder. Survey data are being collected in the second quarter of 2006 and BAuA anticipates evaluating the results in the third quarter of 2006.³⁶

“As result of the survey we expect a quantitative description of aspects of the occupational safety in production and handling of nano-materials in Germany as well as statements about the character and the handling of the materials. We will publish the results as a research report in cooperation with the VCI”.³⁷

The survey was prepared by scientists at the BAuA with the VCI and representatives of the participating companies. It solicits information regarding quantity of material handled, size of company, worker health, as well as asks for volunteers for a baseline exposure evaluation. The survey is most specific in its attention to nanomaterial structure and size, engineering controls and PPE, and ambient monitoring of particulates. A copy of the survey instrument is attached in Appendix B.

The BAuA is planning to perform field evaluations of nanotech companies in the future.

Lux Research Inc.

Lux Research is a research and advisory firm on nanotechnology based in New York, NY. It provides information on market analysis and strategic advice to its clients, which include large corporations, start-up CEOs, investment professionals, and policy makers. Lux Research conducts written research, including framework reports and weekly turnouts to its clients. The firm also organizes conferences and is working on a Nanotechnology Index for investors.

Lux Research recently completed a survey on EH&S practices in the nanotechnology workplace.³⁸ The survey was conducted for the purpose of generating a report for Lux Research

³⁴ Health & Safety Executive. May 5, 2006. “Organizations concerned with health & safety: Germany.” <<http://www.hse-databases.co.uk/org/germany.htm>>. June 25, 2006.

³⁵ Verband der Chemischen Industrie e. V. (VCI). 2006. “Portrait of VCI in English.” <<http://www.chemische-industrie.de/default.asp?rub=0&tma=0&cmd=shd&docnr=74311&nd={0}&ond=&snd=&shmode=>>>. June 22, 2006.

³⁶ Email exchange with Erhardt Gierke and Sabine Plitzko, BAuA between May 5, 2006 and June 2, 2006.

³⁷ Ibid.

³⁸ Phone interview with Michael Holman, Lux Research, Inc. on May 12, 2006.

clients that addresses risk management issues. This final report, "Taking Action on Nanotech Environmental, Health, and Safety Risks," follows an earlier report published by Lux Research, which included a general introduction to potential EH&S risks of nanomaterials throughout a product life-cycle, a basic framework for risk management, and addressed general policy and public perception issues. The second report is more prescriptive on how to manage EH&S risk across the whole product life-cycle. It includes "best practices" to address product stewardship issues. It also offers regulatory insight to keep Lux Research clients abreast of regulatory developments in the field. Thus, the report is preparatory in nature with regards to risk management. In general, both reports are meant to provide advice to industry decision-makers and health and safety officers.

The survey consisted of general open-ended questions that address perceptions of risk and regulation. Lux Research considered their interview schedule confidential and would not release it when requested by this UCSB research team. The surveys were conducted by telephone, and contacts were generated through Lux Research's extensive network. Confidential interviews took place with 17 experts from industry, academia, and non-governmental organizations, and 10 officials at regulatory agencies. Managers, and specifically experts, in the nanotechnology field were interviewed, not necessarily the EH&S personnel or workers. Nanotechnology companies of various sizes were targeted due to their ample experience in the EH&S area, and the likelihood that they have already developed their "best practices." Most of the companies reside in the US, although some are located in the EU and even fewer in Asia, mainly due to the time difference and language barrier.

Surveys began in April 2006 and ended late May. The final report on survey findings was released to clients mid-June 2006. The full 39-page report is available only to clients of Lux Research's Nanotechnology Strategies advisory service; otherwise the results will not be disseminated or sold. However, a statement of findings was made available in June 2006.

National Institute of Advanced Industrial Science and Technology, Japan

A research team working at the Research Center for Chemical Risk Management at the National Institute of Advanced Industrial Science and Technology (AIST) recently conducted ten case studies of risk management as currently practiced by Japanese nanomaterial companies.³⁹ These case studies were based on two days of roundtable meetings held in early 2006 with ten Japanese companies, all of which are currently manufacturers and/or users of nanomaterials. Each company was asked to make a presentation on risk management within their company. The concept of "risk management," as defined in the meeting, included not only countermeasures for occupational health but also for product safety and public acceptance.

A report summarizing the meeting has just been published in Japanese in March 2006. Because nano-risk is a sensitive topic for these companies, the research team did not describe the presentations from each company in the report, but instead summarized the discussion for each topic. The English version is being written and will be finalized in early July 2006; however, it will only include the section on Research and Studies on Risk Management of Nanomaterials

³⁹ Email exchange with Dr. Masashi Gamo of AIST Japan between May 24, 2006 and June 23, 2006.

(Section 1.2.2 in the original report). In this section, a summary of the following practices and topics are presented by the participating companies⁴⁰:

- Precautions in the work environment. The majority of participants are exercising precautions when working with nanomaterials. Personal protective equipment and engineering controls are used to protect workers' safety.
- Measurement in the work environment. The metrology is not yet well established in Japan; therefore, some companies do monitor their ambient environment but not specifically for nanoparticles.
- Condition of nanomaterials at the time of shipment and purchase. The condition of nanomaterials at shipment and purchase may present the possibility of exposure, but not every company is managing this for the purpose of risk management. Thus, nanomaterials are handled in various conditions during shipping and purchasing.
- Exhaust and waste. Many companies use HEPA filters and scrubbers. Some incinerate waste.
- Product life-cycle consideration. Some companies prefer not to use nanomaterials when not necessary as a precautionary measure because there is not sufficient evidence for the safety of these materials.
- Implementation of hazard testing. Some companies perform in-house testing while others rely on external organization, or public research institutes. Testing is conducted for both raw materials and products.
- Implementation of research. Many companies collaborate with university labs or research institutes although some may have their own research and development department.
- Data or information gathering. In addition to conducting their own tests, companies also gather and exchange information regarding EH&S practices through Japanese and international governments, academia, industry, literature, and conferences.
- Information provision. Most companies provide their product information through Material Safety Data Sheets. The properties of many nanomaterials are unknown, therefore companies recommend to their customers to treat them as hazardous.
- Organizational department responsible. Companies don't create special departments for nanomaterial safe handling, but address the safety issues within their existing in-house systems.

Many of these topics overlap with the UCSB Phase Two survey objectives. Further, the following key issues are addressed, which pertain to the difficulties that the companies confront when working to improve their EH&S practices:

- These issues are too big for one company to address by working alone. Although having R&D departments is useful, what one company can accomplish is limited. Therefore collaborations with governmental organizations and public research institutes are conducted, but still, example models and methodologies are needed. Participants also expressed their desire to have mechanisms to obtain and share information with other companies or even other industries involved in dealing with nanomaterials.

⁴⁰ AIST, Japan. 2006. "Report of Findings: Research Project on Facilitation of Public Acceptance of Nanotechnology." Unpublished draft document.

- Available information is limited. While there is sparse evidence of risks and no consensus on assessment methods, companies can only work on EH&S practices by being precautionary and using the expertise of in-house researchers.
- Questions about dealing with nanomaterials as a materials issue or as a product issue. When conducting hazardous properties testing, product properties may differ even if they are made of the same materials. Some companies considered hazardous properties as associated with the material, and that exposure should be associated with the products.
- Comments on a (hypothetical) system to communicate a corporation's approach to deal with safety of products that use nanomaterials. Generally, participants did not think this hypothetical system will alleviate consumers' concern. Moreover, the issues of liability may arise and corporations will have to respond to demands for more information. This is not what a company can accommodate now.
- The need to create a new discussion group to follow up the risk and safety issues in the nanomaterial industry. Participating companies did not think there is a need for this now.

The AIST research team does not have a specific plan for public availability of this report, but will work out a way in the future to make the report available to the public.

Contrary to the face-to-face meetings held with companies in Japan, an email-based survey was administered to companies in the US and the EU. This survey addressed risk management of nano-products. The questionnaire was sent out to 21 US companies and 11 European companies. The research team contacted selected companies via the email address obtained on their respective websites. However, this effort was unsuccessful, possibly because the emails did not go to the appropriate people. Only four companies replied to express their interest in participating but none of these respondents completed the survey.

Center for High-Rate Nanomanufacturing

In October, 2004, the University of Massachusetts Lowell, Northeastern University, and the University of New Hampshire were jointly awarded a National Science Foundation grant of \$12.4 million over five years for research in nanotechnology.⁴¹ Between the three campuses, approximately ten laboratories are working on various aspects of new nanomanufacturing processes. To ensure safe practices in their own labs, they developed a questionnaire to survey what processes, nanomaterials, and protective equipment are used in the lab.⁴² Using the questionnaire, one graduate student conducted comprehensive face to face interviews and walk-throughs with at least one researcher in each lab. They found that practices in the nanomanufacturing labs were not different from practices in other university labs. The researchers are conducting toxicological tests on dermal exposure because they found that exposure to air particles is not significant. They plan to continue monitoring and evolving the safety practices throughout their five year research grant.

⁴¹ Center for High-Rate Nanomanufacturing (CHN). 2006. "About Us." <<http://www.nano.neu.edu/aboutus.html>>. June 22, 2006.

⁴² Phone interview with Kwangseog Ahn, University of Massachusetts, Lowell on May 24, 2006.

I.b. Summary of Cataloging Current Practices

The research efforts described in the section above are all engaged in identifying and documenting current environmental health and safety practices related to nanomaterials. These efforts actively seek and acquire information on current practices through interviews, surveys or field evaluations. Of the five efforts, one is located in Europe, one in Japan and the other three are based in the United States. While the Center for High-Rate Nanomanufacturing focuses its efforts on identifying and coordinating safety practices in their multiple labs, the efforts of NIOSH, BAuA, and AIST focus on industry-wide safety practices within their own national contexts. Only the Lux Research effort is international in scope and even still, this effort is primarily focused on the United States. In the following section, efforts to identify and document current practices that rely on public-private partnerships and industry's voluntary submission of current practices information are described.

II. Voluntary Reporting Programs

The research efforts identified in this section base the collection of information about current practices on voluntary submissions by manufacturers and users of nanomaterials. These two projects are coordinated by government agencies responsible for monitoring the use of hazardous substances and focus on the United States and the United Kingdom, respectively. Each project relies on the cultivation by government of voluntary private sector participation. Neither of the two programs is operational.

II.a. Descriptions of Voluntary Reporting Programs

US Environmental Protection Agency -- Nanoscale Materials Voluntary Program

The US Environmental Protection Agency (EPA) is currently discussing the development of a voluntary reporting program for nanotechnology companies and researchers, the Nanoscale Materials Voluntary Program (NVP). The framework of this plan is being discussed by the National Pollution Prevention and Toxics Advisory Committee. Discussion of the plan began in the 2nd half of 2005, with the goal of initiating the program in 2006.⁴³

Under the Toxic Substances Control Act (TSCA), the EPA is provided with the framework to oversee the manufacture and risk assessment of new materials. The voluntary program will enable the EPA to better understand the properties of nanomaterials, prior to creating nano-specific regulation.

The proposed plan would allow companies to become involved at two levels of participation, a "basic" level and a more involved "in-depth" level. The participating organization would volunteer one or more engineered nanomaterials and submit all relevant existing data regarding material characteristics, hazard data, exposure potential, and risk management practices. Organizations involved at the basic level would also fill in the

⁴³ United States Environmental Protection Agency. "National Pollution Prevention and Toxics Advisory Committee: Overview Document on Nanoscale Materials." November, 22 2005.
<<http://www.epa.gov/oppt/npptac/pubs/nanowgoverviewdocument20051125.pdf>>. June 11, 2006.

knowledge gaps regarding material characterization and implement basic risk management practices.

Organizations involved at the in-depth level would provide all the information of the basic level, as well as work to develop additional data to fill existing knowledge gaps, beyond those of the basic level. In addition, these organizations would institute protective risk management practices throughout their supply chain, monitor air particulates in the workplace, environmental releases, and monitor worker health.

The NVP is intended to be an initial voluntary data reporting program that will aid in the development of regulations of nanomaterials under TSCA. Information collected in the NVP would be publicly available, except in cases of confidential business information.

The EPA wishes to include scientific peer consultation during the design and implementation of the program, in particular from NIOSH and the National Toxicology Program.⁴⁴

UK Department for Environment, Food and Rural Affairs

The United Kingdom Department for Environment, Food and Rural Affairs (DEFRA) has proposed a voluntary reporting scheme for engineered nanoscale materials. This program aims to build evidence upon which to develop appropriate controls and regulations to address risks posed by nanomaterial manufacturing and use.

Currently, there is a proposal for the voluntary reporting program on the DEFRA website.⁴⁵ It invites industry to submit feedback by June 23, 2006 to help develop the voluntary reporting scheme. DEFRA aims to publish a summary of the consultation responses by the end of July 2006. Respondents' feedback will be used to develop the final proposal and implement the voluntary scheme in the summer of 2006. The program will continue for two years. A program review at the end of the two year period will decide if there is sufficient information or if the program should continue in some form.

Initially the focus of the program will be on the manufacturing, use and disposal of freely mobile engineered nanomaterials. Companies with commercial products, as opposed to research labs, would be targeted. Information on material characterization, hazard, use and exposure potential, and risk management practices will be solicited. The intention is to encourage submission of existing data, not future plans or intentions. Participants may indicate which pieces of information can be shared through a publicly available database, and which they would prefer to remain confidential. Parallel to the voluntary reporting program, an information campaign will be launched to encourage company submissions. Later in the lifetime of the program, the information campaign may focus on dissemination of good practice guidance.

II.b. Summary of Voluntary Reporting Programs

Both voluntary submission programs will culminate in the articulation of “best practices” guidelines and, in the case of the EPA, possibly regulation of nanomaterials under the TSCA. Both projects are anticipated to begin operation by the end of 2006. In the following

⁴⁴ Ibid., p. 10

⁴⁵ UK DEFRA. “Consultation on a proposed Voluntary Reporting Scheme for engineered nanoscale materials.” <<http://www.defra.gov.uk/corporate/consult/nanotech-vrs/consultation.pdf>>. June 11, 2006.

section, recent and ongoing attempts to articulate best practices guidelines and nanomaterial risk management frameworks are identified and described.

III. Recommended “Best Practices” and Frameworks

Nine distinct efforts were identified to promote risk identification, assessment and management frameworks. These “best practices” frameworks draw on relevant scientific literature and established best practices in closely related scientific fields to construct management frameworks for identifying and controlling any potential hazards that may stem from nanotechnology and the industrial production of nanomaterials. Unlike the efforts described above, these projects do not seek to acquire new information on current practices. Instead, they rely on scientific literature, established best practices frameworks, consulting firms, and, in one case, assessments of current practices documented by the research projects described above in category one. Four of these framework development efforts have been lead by private consulting firms, in one case (Canadian Stewardship) in close cooperation with the Canadian government. The European Union and Taiwan have also been active in developing risk assessment and management frameworks.

During this research, also identified were several private companies, including DuPont and Luna Innovations, which have developed risk assessment frameworks. These frameworks are not included in this report because they are for internal use within the company. The Phase II report will more closely examine such internal risk assessment frameworks.

Due to the large number of programs in this area, they are listed in alphabetical order below.

III.a. Descriptions of Recommended “Best Practices” and Frameworks

ASTM International -- WK8985

ASTM International is a “voluntary standards organization” devoted to developing technical standards for materials, products, systems and services in a range of industries.⁴⁶ Standards are developed by technical committees whose staffing is drawn from the 30,000 members of ASTM International, including technical experts from government, non-governmental organizations, industries, and academia.

Committee E56 of ASTM International focuses on the issues related to nanotechnology and nanomaterials on a global scale.⁴⁷ This committee currently has representation from twelve countries. It is currently developing standards and guidance for health and safety in the nanotechnology industry. There are three primary working groups focusing on nomenclature,

⁴⁶ ASTM International. 2006. “About ASTM International.” <<http://www.astm.org/cgi-bin/SoftCart.exe/ABOUT/aboutASTM.html?L+mystore+twje6115+1151041247>>. June 22, 2006.

⁴⁷ Phone interview with Steven Brown, Intel Corporation on June 1, 2006.

metrology, and environmental safety. Committee E56 has six technical subcommittees that maintain jurisdiction over these standards.⁴⁸

- E56.01 Terminology & Nomenclature
- E56.02 Characterization: Physical, Chemical, and Toxicological Properties
- E56.03 Environment Health & Safety
- E56.04 International Law & Intellectual Property
- E56.05 Liaison & International Cooperation
- E56.06 Management of Environmental Occupational Health & Safety Risk and Product Stewardship

Subcommittee 03 and 06 have since been combined together to work on EH&S issues and the development of standards and guidance.

“WK8985,” which is currently under development, is a standards guide for handling unbound engineered nanoparticles in occupational settings for the purpose of preventing harmful employee exposures.⁴⁹ The guidelines will be a product of expert consultation amongst stakeholders within the E56 committee. This workbook will provide guidance on EH&S and engineering control and workplace administration to minimize human exposure to nano-scale materials during manufacturing processing or research and development activities in laboratories. Since there are no existing relevant standards and/or exposure information, “WK8985” will be developed based on the precautionary principle and intended to provide guidance in the absence of established standards. Through its website and press releases, committee E56 continues to actively solicit participation of experts on nanotechnology or health and safety plan development to contribute to the creation of “WK8985” guidelines.⁵⁰ The development work began one and a half years ago, and is almost complete. “WK8985” will be available to the public on the ASTM website.⁵¹

The Cadmus Group, Inc.

The Cadmus Group, a consulting firm providing research and analytical services, has developed an adaptive risk assessment framework for identifying approaches that clients can use to minimize nanomaterials-associated risks.⁵² The framework is towards protecting workers, consumers and the environment. The high level of uncertainty surrounding toxicity mechanisms and outcomes for a wide range of established and emerging nanomaterials is considered within

⁴⁸ ASTM International. “Technical Committees: Committee E56 on Nanotechnology.” <<http://www.astm.org/cgi-bin/SoftCart.exe/COMMIT/SUBCOMMIT/E56.htm?L+mystore+twje6115+1149830175>>. June 3, 2006.

⁴⁹ Nano Tsunami.com. “Nano Products in Depth.” <<http://www.voyle.net/Nano%20Products%202005/Products%202005-0085.htm>>. May 24, 2006.

⁵⁰ Technology Now. 2005. “Three New ASTM International Standards in the Works for Committee on Nanotechnology.” <http://www.nanotech-now.com/news.cgi?story_id=11956>. June 22, 2006.

⁵¹ ASTM International . “WK8985: Standard Guide for Handling Unbound Engineered Nanoparticles in Occupational Settings.” <<http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/WORKITEMS/WK8985.htm?L+mystore+twje6115+1149831695>>. June 8, 2006.

⁵² Shatkin, J.A. and B.E. Barry Approaching Risk Assessment of Nanoscale Materials. Technical Proceedings of the 2006 Nanotech 2006 Nanotechnology Conference and Trade Show, Volume 1. Pages: 553 – 556.

the framework. Uncertainty is addressed by applying established principles in hazard identification and risk assessment to the realm of nanomaterials. The adaptive nature of the framework incorporates new information as it becomes available. The framework is applied for all stages of nanomaterials including research and development, production, and use and disposal, thus providing risk minimization approaches throughout a product's lifecycle.

Cadmus applies its adaptive framework by conducting a stepwise screening level risk assessment throughout a nanomaterial's lifecycle. For each lifecycle step, hazards are assessed by analyzing the specific nanomaterials' properties, then exposures are assessed by evaluating field conditions including materials handling procedures, use of engineering controls, and use of personal protective equipment. Estimates of exposure levels are developed and recommendations are made for managing primary exposure pathways. At each step, risks and risk significances are identified, and related uncertainties are defined. Risks are prioritized for guiding client actions. Emerging toxicity information is incorporated into the risk assessment as it becomes available so that actions can be knowledge-adapted. The framework is fully adaptable to the needs of individual clients.

The adaptive risk framework was announced in Fall, 2005.⁵³ Examples of Cadmus clients include a start-up company where priority issues were discovered in the areas of workplace hygiene and ventilation. A second example was a client undergoing scale-up where product packaging operations were creating priority risks. In each case, a detailed analysis of specific risks and associated mitigation recommendations were facilitated by on-site evaluations of client practices and procedures.

Environ International Corporation

Environ is an international environmental consulting company developing corporate guidelines for best practices in nanomaterial manufacturing and use. Currently, they are working with one large, unnamed company and NIOSH to develop a flexible risk management framework that takes into account new scientific findings as they become available.⁵⁴ Environ consultants help companies develop EH&S controls, especially small and midsize companies who are less likely to have a developed, in-house EH&S program.

To develop their best practices recommendations, Environ gathered information from a variety of sources including professional meetings and scientific literature. They use the concept of Control Banding, which means working within companies' current control frameworks and modifying them to include nano-specific controls. Environ consultants advocate thinking about risks before the labs are built and including engineering controls such as appropriate ventilation in the design of research facilities. Similar banding approaches are used in radiation protection and protection from potentially deadly viruses when risks are unknown.

The research at Environ is ongoing. They have worked on occupational safety issues for five years, but are just beginning to understand the environmental concerns related to nanomaterial manufacturing and use.

⁵³ Shatkin, J.A. and B.E. Barry Approaching Risk Assessment of Nanoscale Materials. Technical Proceedings of the 2006 Nanotech 2006 Nanotechnology Conference and Trade Show, Volume 1. Pages: 553 – 556.

⁵⁴ Phone Interview with Diane Mundt, Environ International Corporation on June 2, 2006.

Environmental Defense and DuPont- Framework for Responsible Nanotechnology

Through a collaborative effort, Environmental Defense and DuPont are developing an expanded framework for responsible nanotechnology.⁵⁵ This framework will develop a systematic process to identify and manage risks, while providing a useful input for regulatory and product stewardship needs. It is intended that this framework could be broadly adopted by nanomaterial handlers worldwide; in industry, research, and university labs.

As currently envisioned, this framework is organized into six steps: 1-Describe material and use; 2-Profile life cycle(s) for material properties, hazards and exposure; 3-Evaluate risks; 4-Assess risk management; 5-Decide, document, and act; 6-Review and adapt. The entire process is designed to be iteratively applied, with each of the steps conducted at each major stage of product development. As new information about material properties and hazards, and health and safety practices becomes available, the action plan can be adapted and refined.

Throughout the process of developing the framework, Environmental Defense and DuPont are engaging a broad range of stakeholders. Stakeholders are engaged through the sharing of the current outline for the framework and feedback is encouraged.

Development of the framework began in the fourth quarter of 2005. The framework is currently at the early stages of development. It is intended that a draft of the framework will be made available to the public during the first quarter of 2007. Environmental Defense and DuPont plan to demonstrate the framework on selected applications.⁵⁶

Foresight Nanotech Institute

The Foresight Nanotech Institute is a public policy research group founded in 1986 and based in Palo Alto, California that is dedicated to the beneficial implementation of nanotechnology. It recently published a document titled, "Foresight Guidelines for Responsible Nanotechnology Development."⁵⁷ The intent of the document is to provide guidelines for the responsible development of productive nanotechnology by practitioners and industry. Emphasis is placed on the importance of good judgment and ethical behavior of researchers to ensure human control over nanotechnology and to mitigate its abuse. The document specifically states that "a combination of moral and technical education, active industry and government cooperation, inherently safe system designs, legal frameworks, and R&D on secure immune systems for defense may be the best solutions available."⁵⁸

The document includes three self-assessment scorecards for voluntary use by nanotechnology practitioners, industry organizations, and government agencies to aid in developing guidelines and practices. It is the intent of Foresight that the resultant guidelines and practices be firmly grounded in the science and fundamental principles of nanotechnology, and

⁵⁵ Environmental Defense. 2005. "Environmental Defense and DuPont: Global Nanotechnology Standards of Care Partnership" <<http://www.environmentaldefense.org/article.cfm?contentID=4821>>. August 22, 2006.

⁵⁶ Information provided by Scott Walsh of Environmental Defense through a PowerPoint presentation. August 9, 2006.

⁵⁷ Jacobstein, Neil. "Foresight Guidelines for Responsible Nanotechnology Development." Foresight Nanotech Institute. Draft version 6. April, 2006.

⁵⁸ *Ibid.*, page 9.

serve as acknowledgement of the potential dangers to humans and the environment in its development. The first scorecard is most relevant to this UCSB research, as it pertains to the establishment of nanotechnology professional guidelines. There are eight guidelines for which practitioners self-score from 0 to 5, with 0 being 'no compliance' and 5 being 'high compliance.' In particular, guidelines 1 through 4 address product stewardship:

1. Nanotechnology developers adopt professional guidelines and ethical practices relevant to the responsible development of both near term and advanced nanotechnology.
2. Nanotechnologists attempt to consider proactively and systematically the environmental and health consequences of their specific technologies.
3. Nanotechnology research and development is conducted with due regard for the principles of environmental science and standard practices of public health, with the understanding that significant changes in physical, chemical, and physiological properties may occur when macro-scale materials are developed and utilized on the nanoscale.
4. Nanotechnology products are conceived and developed using total product lifecycle analysis.⁵⁹

German Society for Engineers (VDI)

The German non-profit organization VDI Technologiezentrum GmbH with the support of the European Commission published the Nanosafe I report in August, 2004, titled, "Risk assessment in production and use of nanoparticles with the development of preventive measures and practice codes."⁶⁰ Funded by the EU, The Nanosafe I project was carried out by nine companies and institutions. The participants included international corporations, medical laboratories, universities and research institutes from all over Europe. In addition to their own studies they compiled available research from scientific publications, worker protection organizations and national and EU legislation.

The Nanosafe I report, still a "working document," summarizes information drawn from scientific literature, internet sources, professional workshops and conferences, and expert interviews to evaluate potential hazards from industrial nanoparticle production. Based on this effort, a framework was developed for evaluating the risks to workers, consumers and the environment stemming from nanoparticle production. The report promotes a framework for hazard identification, characterization, exposure assessment and risk calculation and discusses specific preventive measures at the workplace and for the environment. The report concludes with a detailed discussion of worker and consumer safety legislation in each industry and proposes policy recommendations intended to attenuate risks in the nanotechnology workplace.

The EU is funding a follow-up project, "Nanosafe II," to expand the risk assessment and management recommendations for secure industrial production of nanoparticles.⁶¹ The project participants will examine case studies in the production and use of certain nanomaterials. These cases will be representative of the main groups of nanoparticles. The study will focus on particle

⁵⁹ Ibid., pp. 10-11.

⁶⁰ Luther, Wolfgang (ed.). 2004. "Industrial Application of Nanomaterials – Chances and Risks." VDI Technologiezentrum GmbH. <<http://www.nanosafe.org/node/277>>. May 11, 2006.

⁶¹ Nanosafe2. "Nanosafe: Safe Production and Use of Nanomaterials." <<http://www.nanosafe.org/node/265>>. May 11, 2006.

characteristics, primary production processes and related risks. The project started on April 1, 2005 and will continue for 4 yrs. No results are publicly available as of the date of this report.

Industrial Technology Research Institute, Taiwan

The Taiwanese Center for Environmental, Safety and Health Technology, within the Industrial Technology Research Institute (ITRI), completed a project on the Environmental Implications and Applications of Nanotechnology. The project was sponsored by Taiwan's Environmental Protection Administration. One of the foci of the project was to study the exposure level to nanopowders in the workplace, where a series of experiments were conducted to measure the exposure concentrations of nanoparticles in the working environment during the manufacturing process. Based on the findings of this research, ITRI developed a set of recommendations for the safe handling of nanomaterials. The research project included:

1. A review of past research on the impacts of nanoparticles to human health; and
2. experimental exposure evaluations for nanopowders.

The experiments were conducted during the manufacture of zinc oxide and tin oxide nanopowders. Exposure levels were measured at four sites: control system operating, nanopowder products collecting, raw material feeding, and waste emitting. They found that when workers are collecting small-diameter nanopowder products, the short-term, acute exposure concentration exceeded the recommended level. Over an eight hour work period however, the average exposure did not exceed the recommended level. Workers receive the most exposure –twice the average value – when cleaning machines used in the manufacturing process.

This empirical work formed the basis for a set of recommendations, including that Standard Operation Procedures be established, which require workers to wear proper protective equipment when operating, collecting products, and cleaning machinery. However the report did not indicate what equipment should be used. It recommended that the working area be defined and that access to the controlled area be limited to ensure workers' health and safety.⁶²

The follow-up research project will involve many government departments. The data collected at the operating area in the former experiments, including particle size and concentration, will be used to conduct animal tests. These tests will be conducted by the National Health Research Institute of Taiwan to define the impacts of nanomaterials to living organisms.⁶³

The Innovation Society Ltd

The Innovation Society, Ltd. is a Swiss consulting firm which facilitates a multi-stakeholder dialog on nano-regulation. Launched in Switzerland in 2005 in cooperation with

⁶² Environmental Protection Administration, R.O.C. "Environmental Implications and Applications of Nanotechnology." <http://ivy2.epa.gov.tw/out_web/cooperation/nanotech/ch_db/06_Technology.html>. May 29, 2006.

⁶³ Phone interview with Dr. TT Song, National Nanoscience and Nanotechnology Program Office on May 26, 2006.

international companies, governmental bodies, scientists and NGOs, it is focusing on safety, risk and regulation issues of nanotechnology. In particular it is concerned with:

- Occupational health safety (laboratory and large scale, manufacturing)
- Product and consumer safety (Life Cycle Analysis, waste, emissions)
- Environmental safety (Life Cycle Analysis, food-chain, waste, emissions)

A related report⁶⁴ was published in March 2006 to summarize the results of the dialog. Due to the already widespread application of nanomaterials in manufacturing and laboratories, the stakeholders decided that highest priority must be given to occupational health safety issues. The report therefore suggests that:

- Guidelines for safe and sustainable use and handling of nanomaterials should be developed.
- Technical measures for the protection of health and environment should be applied (e.g. filters, low pressure fume hoods, etc.).
- Voluntary labeling of potentially hazardous materials should be performed.
- Inventories of potentially critical nanoparticles and nano-applications should be made.
- Inventories of expositions and quantities of nano-sized particles should be issued.
- Threshold values for potentially hazardous nano-sized particles have to be established.
- Rules for declaration / self-declaration should be established.
- Requirements for Material Safety Data Sheets (MSDS) should be reviewed.
- Life Cycle Analysis studies of nanomaterials and nanoparticles must be conducted.
- A “Code of Conduct” regarding further product aspects should be established.⁶⁵

The stakeholders agreed that public policy needs to direct research towards the most pressing issues of health and safety and regulations should be based on research evidence about the hazards.

Science-Metrix Inc.

Environment Canada selected Science-Metrix, Inc. to identify best practices relevant to environmental nanotechnology-related issues. This study involved the examination of more than 500 documents on the topic of stewardship, in particular, current research in the environmental aspects of nanotechnology, and policies and strategies developed by the US, European and Asian countries to identify and resolve stewardship issues related to the development of nanotechnologies. A final report was completed in March 2005 titled, “Canadian Stewardship Practices for Environmental Nanotechnology.”⁶⁶ Results indicate that there are, to date, few

⁶⁴ Meili, Christoph. 2006. “Nano-Regulation: A Multi-Stakeholder-Dialogue-Approach Towards a Sustainable Regulatory Framework for Nanotechnologies and Nanosciences.” The Innovation Society Ltd. <http://www.innovationsgesellschaft.ch/images/publikationen/Nano_Regulation_final3.pdf>. May 1, 2006.

⁶⁵ Ibid., p. 26.

⁶⁶ Bergeron, Stephane and Eric Archambault. 2005. “Canadian Stewardship Practices for Nanotechnology.” Science-Metrix.

stewardship practices and measures in place in the US, the EU or Asia that are linked to the environmental dimensions of nanotechnology. These countries are instead showing greater interest in developing the industrial and commercial applications of nanotechnology. Where stewardship is being explored, the emphasis is on the social and ethical implications of the science; very few strategies focus on the environmental aspects of nanotechnology. The report concludes that this lack provides an opportunity for Canada to assume international leadership in this specific area. Recommendations are provided to Environment Canada on how to best approach this role.

Science-Metrix, Inc. specializes in the measurement and evaluation of science and technology policy and in research and development.⁶⁷

III.b. Summary of Recommended “best practices” and Frameworks

Each of the efforts described above has or is currently working towards establishing guidelines for “best practices” and frameworks for nanomaterial risk management. In each case, developmental efforts have drawn on expert consultation, scientific literature reviews, and professional associations as the basis of their recommendations. Private research and consulting firms have been particularly active in these developmental efforts, though frequently in close collaboration with government and industry. Very few of these guidelines or frameworks are based on direct empirical research. Rather, each of these developmental efforts attempts to consolidate and synthesize current knowledge available from the scientific literature and expert consultation. The following section describes additional efforts to synthesize current knowledge and terminology about nanomaterials.

IV. Databases and Other Activities

This final category of recent and ongoing efforts to identify current EH&S and product stewardship practices in nanotechnology describes two programs. The first collects and systematizes vast quantities of relevant research about nanomaterial EH&S and standardizes nomenclature in the field. The second program describes Australia’s strategy for handling nanotechnology issues in the workplace. These are important elements in the process of determining best practices.

⁶⁷ Science-Metrix. “Science-Metrix – Évaluation S&T Evaluation.” <<http://www.science-metrix.com/index2.htm>>. May 20, 2006

IV.a. Descriptions of Databases and Other Activities

Integration of Nanomaterial EH&S Databases

Work is being done to integrate four existing nanomaterial EH&S databases. This is a cooperative effort between NIOSH, the Woodrow Wilson Center, and ICON.

- NIOSH maintains the Nanoparticle Information Library.⁶⁸ This database is intended to help organize and disseminate information on nanomaterials, including health and safety-associated properties. It also tracks what is being made and where. Users may search for a specific nanomaterial by structure or element.
- The Woodrow Wilson International Center for Scholars Project on Emerging Technologies is developing two databases. The Inventory of Nanotechnology Environment Health and Safety⁶⁹ maintains a catalog of global government-funded research into the human health, safety and environment implications of nanotechnology. It serves as a resource for researchers, policy makers and others involved in promoting nanotechnologies successfully through understanding and mitigating potential risks. Visitors to the site may run an advanced word search or browse entries. A second database, the Inventory of Nanotechnology Consumer Products catalogs consumer products that incorporate nanomaterials.
- ICON's database⁷⁰ contains summaries/abstracts and citations for research papers related to the EH&S implications of nanoscale materials. Links are provided to access some full papers. Users may browse by author or by year of publication, or they may perform an advanced search by using keywords or selecting categories.
- In December 2005 at the Nano EH&S workshop hosted by the US EPA in Washington D.C., David Rejeski offered the Organization for Economic Co-operation and Development to continue the operation of the Woodrow Wilson Project on Emerging Nanotechnology. The OECD has added this project to those being considered for the Chemical Committee's pending work group on nanotechnology.⁷¹

National Nanotechnology Strategy Taskforce

The Australian Government established a National Nanotechnology Strategy Taskforce to assess the issues that are important to the country's nanoscience community. This was accomplished by means of a survey designed by the Taskforce, which examined various issues including occupational health and safety. Most pertinent to the scope of the project herein is the

⁶⁸ National Institute for Occupational Safety and Health. "Nanoparticle Information Library." <<http://www2a.cdc.gov/niosh-nil/>>. June 1, 2006.

⁶⁹ Woodrow Wilson Center Project on Emerging Nanotechnologies. "Nanotechnology Health and Environmental Implications: An inventory on current research." <<http://www.nanotechproject.org/18/esh-inventory>>. June 1, 2006.

⁷⁰ International Council on Nanotechnology (ICON). "EHS Database." <<http://icon.rice.edu/research.cfm>>. June 1, 2006.

⁷¹ Information provided to us by Tracy Godfrey of Environmental Defense. August 7, 2006.

question: “Are there OH&S concerns related to your group’s research?” Eight percent of the respondents stated that formal guidelines are needed. Although the report did not investigate current EH&S practices, it did establish a need for such recommendations in Australia. The full report titled, “Report on Survey of Nanoscience Groups – Issues Affecting Nanoscience in Australia,”⁷² is publicly available for download on the Taskforce’s website.

Seventy Australian nanoscience research groups were contacted to complete the survey via the Australian Research Council’s National Nanotechnology Network, OzNano2Life, and Nanotechnology Victoria during October and November 2005. Twenty-nine responses were received.

IV.b. Summary of Databases and Other Activities

The two efforts described above, although very different in scope, are relevant to the developing of guidelines for best practices. The effort to integrate four existing nanomaterial EH&S databases will provide users with simplified access to important environmental health and safety information for working with nanomaterials. In the second effort, the survey conducted by the National Nanotechnology Strategy Taskforce demonstrates the need for the development of guidelines for best practices in Australia. The first effort will coalesce the dissemination of information regarding nanomaterial EH&S, while the second reveals a need for the UCSB project.

The Contribution of UCSB’s Phase Two Research

The research proposed for Phase Two of the ICON-funded UCSB study is unique from previous research based upon differences in several areas. First, the UCSB Phase Two research will gather current practice data from a worldwide pool of respondents. Geographical regions for the study focus have been selected based upon where it is perceived that the most intense nanotechnology manufacturing and research is underway. Second, this research will address health, safety, the environment and product stewardship in a single survey instrument. Third, this survey will not focus just on nanotechnology labs, but will cover a spectrum of nanotech companies, from small startup companies to large-scale manufacturing facilities, to research labs and university labs. Finally, this research will provide a catalogue of current practices that will eventually be publicly available. Few of the developmental efforts described above systematically document current practices. Those that do are based either on voluntary submissions from industry, to the exclusion of academic and research labs, or adopt methods which require a small sample size. This will make the research herein a valuable tool for guiding companies towards best practices. As new understanding of nanomaterial behavior and toxicology is developed, “best practices” may need to evolve. Furthermore, as new classes of nanomaterials emerge, new practices may need to be introduced.

⁷² Australian Government, Department of Industry, Tourism, and Resources. 2005. “Survey of Nanoscience Research Groups: Issues Affecting Nanoscience in Australia.” *Australian National Nanotechnology Strategic Taskforce*.
<http://www.industry.gov.au/assets/documents/itrinternet/survey_analysis_report20060308115528.pdf>. May 25, 2006.

APPENDIX A

Summary of Research Efforts on Current Practices

Institution Name	Institution Category	Program Name	Funding Agency	Method	Type of Respondents	Geographic Data Pool	Safety / Product Stewardship	Status	Dissemination
Cataloging Current Practices									
University of California, Santa Barbara	US University	Review of Safety Practices in the Nanotechnology Industry	International Council on Nanotechnology	Phone Interviews, Written Surveys and Literature Review	Users/Manufacturers / Research Labs	US, EU, Asia	Both	In progress	public
National Institute of Occupational Safety and Health	US government			Site Visits	Users / Manufacturers	US	Safety	ongoing	public
BAuA	German government		German Federal Ministry of Economics and Labour	Written Survey	Users / Manufacturers of nanopowders	Germany	Safety	In progress	public
Lux Research Inc.	US consulting company			Phone Interview	Users / Manufacturers / NGOs / Government Agencies	US, some EU and Asia	Both	complete	available to clients only; press release
National Institute of Advanced Industrial Science and Technology	Japanese government			Expert Dialogue	Users / Manufacturers	Japan	Both	complete	public
Center for High-Rate Nanomanufacturing	US universities		National Science Foundation	Face-to-Face Interview and Site Visits	Research Labs	In-house	Safety	complete	internal; conference presentations
Voluntary Reporting Programs									
Environmental Protection Agency	US government	Nanoscale Materials Voluntary Program		Voluntary Program	Users / Manufacturers	US	Safety	In development	public
Department for Environment, Food and Rural Affairs	UK government			Voluntary Program	Users / Manufacturers	International, mainly UK	Both	In progress	public
Recommended "Best Practices" and Frameworks									
ASTM International	International standards development organization	Guide for Handling Unbound Engineered Nanoparticles in Occupational Settings	multistakeholder	Expert Dialogue	Membership	International	Safety	In progress	public
Cadmus	US consulting company	Adaptive Risk Assessment Framework		Risk Assessment Framework	Private Clients	developed in house	Both	complete	available to clients only; conference presentations
Environ International Corporation	US consulting company			Literature Review and Expert Dialogue	Users / Manufacturers	International	Safety	ongoing	available to clients only; conference presentations
Environmental Defense and DuPont	US NGO and Company	Framework for Responsible Nanotechnology		Risk Assessment Framework	multistakeholder	US	Both	In progress	public
Foresight Nanotech Institute	US think tank	Foresight Guidelines for Responsible Nanotechnology Development		Expert Dialogue	n/a	In-house	Product Stewardship	In progress	http://www.foresight.org/guidelines/
German Society for Engineers (VDI)	German trade association	Nanosafe III	European Commission	Literature Review and Expert Dialogue	Users / Manufacturers / Research Labs	EU and worldwide	Both	complete	public
Industrial Technology Research Institute (ITRI)	Taiwanese government			Lab Simulations	In-house	Taiwan	Safety	ongoing	public
Science-Metrix Inc.	Canadian consulting company		Environment Canada	Literature Review	n/a	International	Product Stewardship	complete	available for purchase
The Innovation Society Ltd	Swiss consulting company	Nano-Regulation	multistakeholder	Expert Dialogue	Users / Manufacturers	EU	Both	complete	public
Databases and Other Activities									
Integration of Nanomaterial EHS Databases	US government	Nanoparticle Information Library	NIOSH	Submissions	Users / Manufacturers / Research Labs / Government Agencies	International	Safety	ongoing	http://www2a.odc.gov/niosh-nl
	US think tank	Inventory on Nanotechnology EHS Research	Woodrow Wilson	Submissions and Collection from Publicly Available Sources	Users / Manufacturers / Research Labs / Government Agencies	International	Safety	ongoing	http://www.nanotechproject.org/18/esh-inventory
	multistakeholder	EHS Database	ICON	Submissions and Collection via Databases: TOXNET, MEDLINE, NTIS	Users / Manufacturers / Research Labs / Government Agencies	International	Safety	ongoing	http://icon.noe.edu/research.cfm
National Nanotechnology Strategy Taskforce	Australian government			Written Survey	Research Labs	Australia	Safety	complete	public

APPENDIX B

Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (German Federal Institute for Occupational Safety and Health) and VCI (German Chemical Industry Association) Survey Instrument

Questionnaire on aspects of worker protection during the production and handling of engineered nanomaterials

- General Part -

Lfd. Number ___A

For a quick and exact processing of this questionnaire that can be read by machine please fill the fields with a thick black or blue pen and avoid touching the margins.

Please use print letters and numbers following this pattern:

(Made anonymous through VCI)

In order to facilitate filling out the questionnaire it is divided into a general and specific part. The general part (e.g., no. 027A for company 27) includes questions relating to the company and only has to be filled out once. The specific part (e.g., no. 027S07 for material 7 in company 27) includes questions related to the material.

If your company / institution produces, uses, or processes several different products with nanomaterials, please fill in the specific part for each of these products (given a total annual use of more than 10 kg).

The definition of engineered nanoparticles in this questionnaire are particles produced as powder, which in at least two dimensions are smaller than 0.1 micrometers, as well as their aggregates and agglomerates (no fumes from soldering or metal and no diesel fumes).

1. What does your company/institution do with nanoparticles (nanomaterials)?
 - a. Produce Yes/No
 - b. Use Yes/No
 - c. Release by processing other products Yes/No
 - d. Unknown or not investigated

If your company/institution does not produce, use or release, you can finish the questionnaire here and return it to VCI.

2. To what extent are you handling nanomaterials?

(Indications of weight relate to the nanomaterials and not to the production process. The indications are independent of the size of the agglomerate and refer to the total amount produced, used or released nanomaterials in the company)

- a. 10 kg/year up to <100 kg/year
 - b. 100 kg/year up to < 1 ton/year
 - c. 1 ton/year up to <10 tons/year
 - d. 10 tons/year up to < 100 tons/year
 - e. 100 tons/year up to < 1,000 tons/year
 - f. 1,000 tons per year and more
3. How many employees are handling nanomaterials in your company/institution?
- a. 1 up to <10 employees
 - b. 10 up to < 50 employees
 - c. 50 up to < 250 employees
 - d. 250 and more employees
4. Are you or have you carried out measurements of exposure while handling nanomaterials?
- a. No
 - b. Yes, directed measures of A-dust (like a baseline or a one-time measurement to direct decisions going forward)
 - c. Yes, directed measures of E-dust
 - d. Yes, directing measures on the concentration of particle numbers (presently not standardized)
 - e. Yes, regular measures of A-dust
 - f. Yes, regular measures of E-dust
 - g. Yes, regular measures on the concentration of particle numbers (presently not standardized)
5. Would you be interested in participating in a BAuA supported research project intended to evaluate baseline exposure? Yes/No If yes, see contact for BAuA (below)
6. Do you have information about possible health effects about the nanomaterials produced or used by your company/institution? Yes/No
- a. Workplace medical monitoring
 - b. Epidemiological data
 - c. Other indications – if yes, which?
7. Do you know about complaints related to contact or handling particles from the employees in your company/institution? Yes/No If yes, which?
8. Are you interested in voluntary consultation by BAuA concerning the workplace medical aspects while in contact with nanomaterials? Yes/No If yes, please see contact at BAuA (below)

9. How are you transmitting, if this is the case, information to customers about possible dangers of nanomaterials?
- Material safety data sheet
 - Indications on technical instructions
 - Accompanying letter
 - Other indications – if yes, which?

Thank you for your cooperation!

Please fill in the specific part (if necessary, several times).

Contact at BAuA:

Questionnaire on aspects of worker protection during the production and handling of engineered nanomaterials

- Specific Part -

Lfd. Number __S__

Please fill in a copy of this questionnaire (3 pages) for each of your products and attribute an ongoing number to each sheet of the questionnaire, which should be filled in after the letter "S". The first three numbers before the S refer to the company and have to be identical to the number before the A on the first page of the general part.

11. Which nanomaterials (or dusts) are produced, used or released during the work processes?
- Tiny stone acid
 - TiO₂
 - ZiO₂
 - Chromium Oxide
 - NiO₂
 - AlO₂
 - FeO₂
 - Silicates
 - Carbon black / industry fumes
 - Other inorganic color pigments
 - Nano "ears" (horns?) (dendrimers?)
 - Metal powder
 - Organic color pigments
 - Vitamins
 - Polymers
 - Other product areas – if so, which

12. Are the sizes of the primary particles of the nanomaterials known (multiple names are possible)? Yes /No
If yes, how big are the primary particles (D50)?

- a. < 20 nm
 - b. 20 nm up to < 50 nm
 - c. 50 nm up to 100 nm
 - d. > 100 nm
13. How are nanomaterials being handled (brief bullet form description of activities (e.g., beschicken, filling in, mixing, polishing, etc.)?)
14. Is the extent of workplace exposure (average) known?
- a. No, not known
 - b. Yes, gravimetric concentration (E-dust) ___ mg/m³
 - c. Yes, gravimetric concentration (A-dust) ___ mg/m³

At present, there are no standardized measurement processes to investigate concentration of particles. Despite this, did you carry out measurements, e.g., as part of a study?

- d. Yes, concentration of numbers of particles $_ \times 10^{_} \text{ p/cm}^3$ (p = particles)

Do you know the distribution of particle sizes in the air at the workplace? Yes/No

If yes, at which particle size are the maximum?

- a. < 50 nm, etc.
- b. 50 up to < 100 nm
- c. 100 up to < 200 nm
- d. 200 up to < 500 nm
- e. 500 up to < 1,000 nm
- f. 1,000 up to < 5,000 nm
- g. > 5,000 nm
- h. No indication possible

15. Which measurement technique was used in your measurement of exposure?
- a. Gravimetric system (e.g., VC25, MPGII, PM4, PGP-System)
 - b. Impactors (e.g., Bern Impactor)
 - c. counter of core condensation (e.g., CPC, SMPS)
 - d. other measurement systems – if yes, which
 - e. not known

16. Are you using protection measures while handling nanomaterials? Yes/No

Engineering Measures

- a. No
- b. Closed system
- c. Automization of the manufacturing processes

- d. Wet processing
- e. Others – if yes, which?

Air circulation measures

- a. No
- b. Closed setting (e.g., capsule, box)
- c. Half open setting (e.g., cubicle, work table)
- d. Open setting (e.g., suction tube, vent)
- e. Air circulation by machine (mechanical ventilation?)
- f. Free air (outside air)
- g. Others – if yes, which?

Additional and accompanying Measures

- a. Personal protection (respiratory protection)
- b. No
- c. If yes, which?

17. If you are using mechanical ventilation:

- a. Do you have a way of reintroducing clean air? Yes/No – if yes, how is the filtering done (degree of separation – efficiency)?

Many thanks for your cooperation!