Report of Review Panel Meetings on

Preventive Measures for Worker Exposure to Chemical Substances Posing Unknown Risks to Human Health

(Nanomaterials)

November 2008

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Part 1 Foreword

1 Background

"Nano" in "nanomaterials" denotes one-billionth (10^{-9}) and "one nanometer" is equivalent to one-thousandth of a micrometer. A nanomaterial is a material with nano-scale dimensions. It is well known that nanomaterials possess unique chemical and physical properties when the compositional structure size decreases. This raises expectations of new materials having more excellent properties than existing materials. As a result, many international researches and developments on nanomaterials have been actively undertaken. Engineered nanomaterials have been produced as carbon black, silica, titanium oxides, and zinc oxides, and so on. The materials already have been applied for various purposes, for example, tires, silicone rubbers, cosmetics, and pharmaceuticals, and so on. In recent years, research and development, mainly on carbon nanotubes, have been actively pursued; therefore, in the future, more new nanomaterials are expected to be further developed and used for a wide range of applications.

Meanwhile, although many studies on the health effects of nanomaterials have been conducted around the world, the necessary degree of knowledge has not been gathered yet. Recently, some academic papers reported that nanomaterial caused adverse effects to mice under certain conditions, but there has been no report that those nanomaterials may cause adverse effects to human health.

As the production and application of nanomaterials expands, workers engaged in their manufacturing and handling are expected to increase rapidly in the near future. From the view of proactively preventing the health impairment of such workers, the Ministry of Health, Labour and Welfare(MHLW) has issued interim preventive measures against exposure to nanomaterials in workplaces on February 7th of 2008, as a "Notification on Present Preventive Measures for the Prevention of Exposure at Workplaces Manufacturing and Handling Nanomaterials" based on an internationally, well-known basic concept, "precautionary approach", and the MHLW is promoting extensive dissemination of the Notification.

In order to increase the efficiency of countermeasures for the control of nanomaterials, a more specific management approach based on the status of workplaces should be presented and also, the current situation of and future challenges on exposure preventive measures need to be considered. This time, review panel meetings entitled " Review Panel on Preventive Measures for Worker Exposure to Chemical Substances Posing Unknown Risks" (Panel Chair: Shoji Fukushima, Director of Japan Bioassay Research Center, Japan

Industrial Safety and Health Association (JISHA)) were held with participation of academic experts where they discussed preventive measures against exposure to nanomaterials. As a result of these meetings, this report was released.

2 Attendee List of "Review Panel on Preventive Measures for Worker Exposure to Chemical Substances Posing Unknown Risks" (dispensed with Mr./Mrs.)

Kazuyuki Omae	Prof. of Department of Preventive Medicine and Public Health, School of Medicine, Keio University
Yasutaka Ogawa	Manager of Department of Research Planning and Coordination, Japan National Institute of Occupational Safety and Health JNIOSH
Masayoshi Karasawa	Licensed Occupational Health Consultant
Yoshihito Konishi	Manager of Investigation & Research Department, Japan Association of Working Environment (JAWE)
Fumiaki Shono	General Manager of Chemical Management Department/Vice Secretary-General of REACH Task Force, Japanese Chemical Industry Association (JCIA)
Shigeru Tanaka	Prof. of School of Human Life Sciences, Department of Food & Nutrition of the Faculty of Human Life, Jumonji University
Toshio Nagoya	Prof. of Waseda University Faculty of Science and Engineering
○ Shoji Fukushima	Director of Japan Bioassay Research Center, JISHA

(Special Attendees Related to the Field of Nanotechnology)

Jun Ogawa	Member of Standardization & Social Implications Committee, Nanotechnology Business Creation Initiative (NBCI)
Masashi Gamo	Head of Risk Management Strategy Team, Research Center for Chemical Risk Management, Advanced Institute of Science and Technology (AIST)
Jun Kanno	Head of Division of Toxicology, Biological Safety Research Center, National Institute of Health Sciences (NIHS)
Shigeki Koda	Senior Research Fellow of Hazard Evaluation and Epidemiology Research Group, JNIOSH
Ayako Takata	Lecturer of Department of Preventive Medicine, St. Marianna University School of Medicine
Toshihiko Myojo	Associate Prof. of Department of Environmental Health Engineering, University of Occupational and Environmental Health, Institute of Industrial Ecological Sciences

○ : Panel Chair

* The above affiliation and titles of attendees were provided at the time when the first review panel meeting was held.

3 Chronology of Review Panel Meetings

The 1st Meeting (March 3rd, 2008 (Mon))
- Holding of Review Panel Meetings
- Nanomaterials
- Past Efforts Taken by the MHLW, etc.
- Future Plan for the Subsequent Review Panel Meetings

The 2nd Meeting (April 4th, 2008 (Fri))
- Scope of Nanomaterials
- Status on the Development of Nanomaterials
- Development of Measurement Technology for Nanomaterials

The 3rd Meeting (May 2nd, 2008 (Fri))
- Health Effects Caused by Nanomaterials

The 4th Meeting (May 30th, 2008 (Fri))
- Current Status and Countermeasures of Occupational Hygiene in Handling Nanomaterials; Results of a Questionnaire Survey to Related Enterprises
- Response to Notifications
- Future Agenda

The 5th Meeting (July 9th, 2008 (Wed))
- Preventive Measures for Avoiding Exposure to Nanomaterials

The 6th Meeting (July 30th, 2008 (Wed))
- Preventive Measures for Avoiding Exposure to Nanomaterials

The 7th Meeting (August 28th, 2008 (Thur))
- Preventive Measures for Avoiding Exposure to Nanomaterials

The 8th Meeting (Oct. 1st, 2008 (Wed))

・ (Proposed) Reports

The 9th Meeting (Oct. 31st, 2008 (Fri))

・ (Proposed) Reports

Part2 Applications, Production Volume and Nature of Nanomaterials

1 Applications and Production Volume of Nanomaterials in Japan

According to the MHLW-sponsored research conducted in 2007, applications and production volume of nanomaterials are as shown in Table 1 and Table 2, respectively.

This research was performed among 21 types of nanomaterials, some of which are already in practical use, others of which are at an advanced development stage.

For particle diameters, carbon-based nanomaterials are the smallest, diameter of fullerene particles was 1nm or smaller, and that of single-walled carbon nanotube (SWCNT) was roughly 1nm.

The applications of most nanomaterials include home appliances and electrical/electronic products, cosmetics, or paint and inks. When looking at the results by category, silica, silver, silver ion deposited onto inorganic microparticles (silica, alumina, etc), titanium oxides, nanoclay, and zinc oxides are used in various fields (See Table 1).

For production volumes (i.e., usage), carbon black, silica, titanium oxides, and zinc oxides account for the major part of the total (See Table 2).

The usage status of major nanomaterials is summarized in the following paragraphs.

(1) Carbon Black

The domestic usage in 2006 is 1 million tons. Carbon black is usually used by mixing into rubbers or resins, and/or by adding to solvents. 80% of the total usage is used for tires, 15% is for other rubber products and 5% is used for coloring such as inks or paints. Advantages in use include reinforcement of rubbers, enhancement in electrical conductivity and colorability of rubbers/resins, and improvement of tinting strength as a pigment.

(2) Silica (crystalline and amorphous)

The domestic usage in 2006 is approximately 13,500 tons. Silica is used in silicone rubber, FRP, and paints. Advantages in use include improvement in strength and the enhancement of insulation properties and water resistance.

(3) Titanium Oxide (rutile-type and anatase-type)

Titanium oxide exists in different crystal structure, “rutile and anatase type”. The rutile crystaline has larger production volume. The domestic usage in 2006 is approximately 1,250 tons. Titanium oxide is used in cosmetics, toners, and car paints. Advantages in use include ultraviolet protection, charge adjustment, and photocatalytic action.

(4) Zinc Oxide

The domestic usage in 2006 is approximately 480 tons. Zinc oxide is mainly used for cosmetics. Advantages in use include ultraviolet protection over a wide range of wavelength and enhancement in transparency.

(5) SWCNT

The domestic usage in 2006 is approximately 100 kilograms. Although SWCNT is used by mixing with resins and/or ceramics, its useful application is currently being researched and developed. Advantages in use include reduction in weight and assignment of electrical conductivity.

(6) Multi-walled Carbon Nanotube (MWCNT)

The domestic usage in 2006 is approximately 60 tons. MWCNT is used for semiconductor trays. Advantages in use include assignment of electrical conductivity, improvement in strength, and electromagnetic shielding properties.

(7) Fullerene

The domestic usage in 2006 is approximately 2 tons. Fullerenes are widely used for sporting goods. Advantages in use include the enhancement of repulsion, reduction in weight, and improvement in strength.

(8) Dendrimer

Dendrimer is a dendritic macromolecule with a structure symmetrically branched out from its center, which consists of the center portion (core) and the peripheral side chains (dendron). It has been elucidated that the core surrounded by dendrons resides in an environment isolated from the outside, which results in the unique luminescence behavior and reactivities of dendrimers. Currently, Dendrimer is expected as a new functional material as a new functional material.

The domestic usage in 2006 is approximately 50 tons for papermaking and several tons for cosmetic use, showing that consumption for papermaking outweighs that for other purposes. One of the applications of dendrimers for papermaking is a paper coating agent. Advantages in use include rheology (flow characteristics) control for papermaking and water/oil repellency for cosmetics' application.

(These data are sourced from Toray Research Center, Inc. (TRC)/Toray Corporate Business Research, Inc. (TBR), and partially revised)

Table 1. Nanomaterial's Applications Classified by Type

	Pharmaceuticals, etc.	Food & Packages	Cosmetics	Fiber	Household & Sporting Goods	Home Appliances & Electrical/Electronic Products	Paints & Inks	Other Paper-making
Fullerene	△		○		○	△		
SWCNT						○△		
MWCNT	△			△		○	○	
Silver	△					○△		△ Catalyst
Silver + Inorganic Microparticles		○	○	○	○	○	○	
Steel						○		
Carbon Black			○			○△	○	○ Tires
Titanium Oxide			○	○	○	○	○△	○
Alumina			○			○△	△	
Cerium Oxide			△			○		
Zinc Oxide	○		○	○	○	△	○	
Silica	○	○	○	○		○	○	○
Polystyrene			○			○	○△	
Dendrimer	△		○△			△		○
Nanoclay	○	○△	○			○	○	○ Agrochemicals
Carbon Nanofiber					○	○△		△ Propellers for Wind Generators
Pigment Microparticles							○	
Acrylic Microparticles			○			○	○△	
Liposome	○	△	○					
Platinum Nanocolloid		○	○			△		○ Catalyst
Quantum Dot	△					△		○ Reagents for Laboratories
Nickel						○		

Note) Signs ○, △, and ○△ in the above represents as follows:

○ : current application, △ : potential application in the future, ○△ : predominant application areas expected in the future

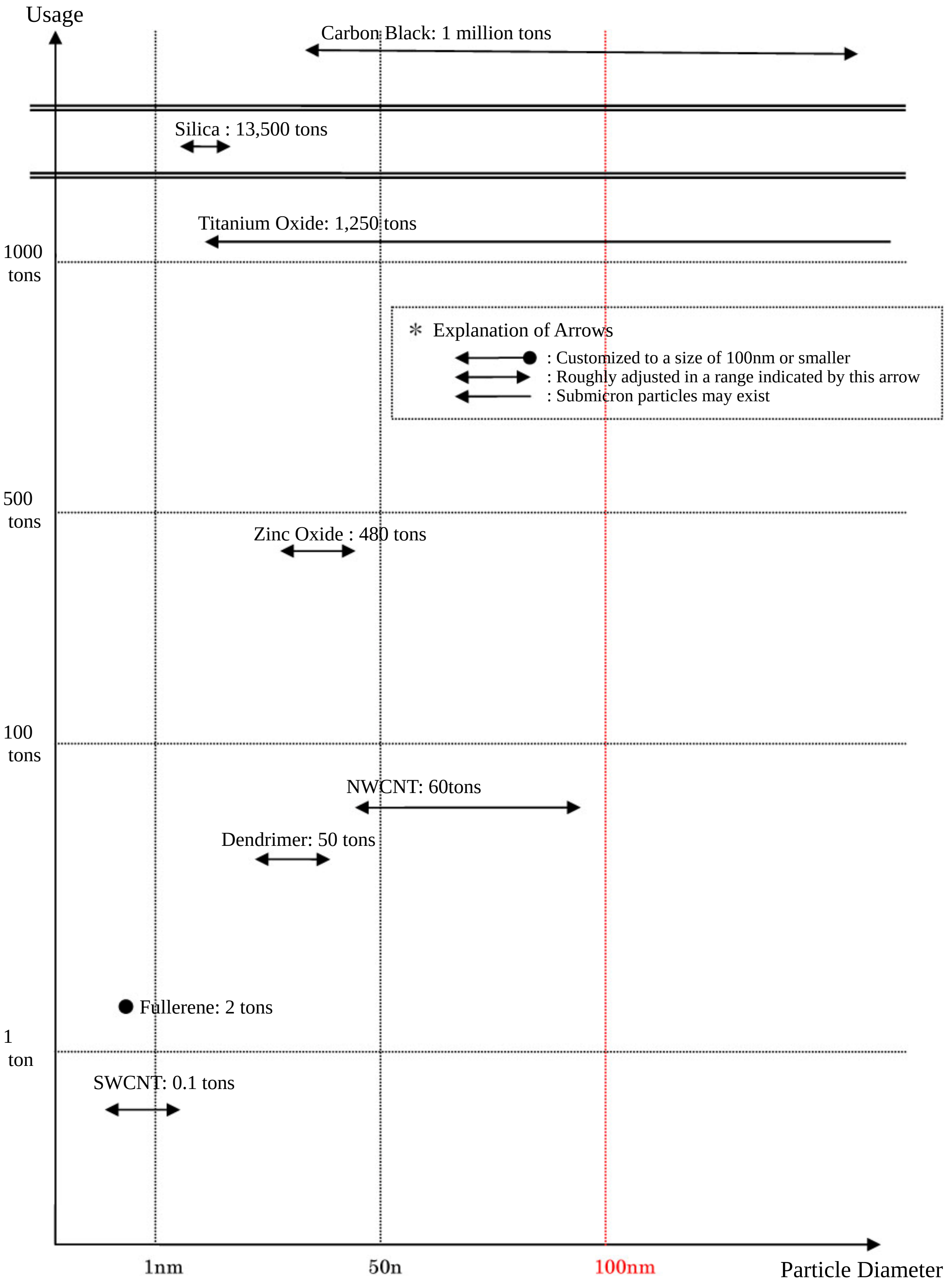
SWCNT：Single-walled Carbon Nanotube
MWCNT：Multi-walled Carbon Nanotube

Liposome：has a spherical shell structure composed of lipid bilayer membrane. Although the size depends upon production methods and/or conditions, the diameter ranges approximately from 20nm to 100nm. Liposome has a basic structure of bio membranes, which triggers the research and development for its application to drug delivery system, biosensors, etc.

Quantum dot：An virtual molecule obtained from the coupling of two “artificial atoms” that are artificially formed through a semiconductor microprocessing technology. Quantum dots are expected to be applied to quantum computers, which can provide ultrafast calculations. Some study considers whether its fluorochrome can be used as a label in body tissues/cells.

(The above information was provided by Toray Research Center, Inc. (TRC)/Toray Corporate Business Research, Inc. (TBR), and partially revised)

Table 2. Annual Japanese Usage and Particle Diameters of Major Nanomaterials (Overall Overhead View)



(The above information was provided by Toray Research Center, Inc. (TRC)/Toray Corporate Business Research, Inc. (TBR), and partially revised)

2 Nature of Nanomaterials

(1) Properties of Nanomaterials

Many properties of materials (such as electric, optical, and/or magnetic properties) depend on the electron states in the material. For nanomaterials, the reduction of the structure size induces alterations in the state of their electrons, which creates unique phenomenon that cannot be observed in ordinary macroscale materials.

Most nanomaterials have higher chemical reactivities due to their relatively large surface area. The specific surface area (surface area per unit mass) of particle becomes larger by reducing the size of it; this means the surface where chemical reaction occurs becomes larger.

In many cases, nanoscale particles have high strength because the size reduction of a material leads to the decrease defects in the material. For example, SWCNT is approximately five to twenty times stronger than steel wires and has about a twenty times higher elastic module than that of steel wires. For metal materials, it is known that the smaller the diameter of the crystal particle, the higher the hardness of the material.

The electrical property of nanomaterials is as follows. When a voltage is applied to macroscale matter, the electrical current is proportional to the voltage and changes continuously. However, as the size of matter approaches the nanoscale range, electrical current values become discrete.

The magnetic property is as follows. A ordinary-use magnet is composed of an assembly of small magnetic domains. However, when the magnet is scaled down to nanometer size, the nanomaterial, itself, corresponds to one magnetic domain and exhibits very high retention.

The optical property is as follows. A material showing metallic luster can give off colors, when the size of the material is decreased to nanoscale. These colors will vary depending on the size of nanomaterials.

(2) Health effects of Nanomaterials

In vitro test results are reported that some nanomaterial show cytotoxic suppression and or cytostatic properties.

Meanwhile, *in vivo* test results show that under specific conditions, exposure to some nanomaterial induces an inflammation response in the lungs, etc. of mice and rats. Also, recent studies indicate that the instillation of MWCNT into the peritoneal cavity of mice and into the scrotal cavity of rats induced peritoneal mesotheliomas. However, with regard to inhalation through the respiratory tract, which is considered as main exposure route in workplaces, long-term exposure tests with small laboratory animals have not yet been conducted. Furthermore, there has been no report whether MWCNT may give rise to adverse effects on human health.

As mentioned above, the use of nanomaterials, excluding some types, has been rapidly growing; while many studies about health effects of nanomaterials have been moving forward simultaneously. However, their mechanisms still remain to be fully elucidated.

Part3 Perspective and Scope for Considering Exposure Preventive Measures

1 Current Status of Legal Regulations and Safety Measures

Nanomaterials are present as nano sized particles or nano sized fibrous matter. They usually have a powdery appearance. For some nanomaterials, such as carbon blacks and/or titanium oxides, manufacturing and handling of them may correspond to "operations in a dusty environment". In that case, the employers have to enforce facilitical measures, working management, and occupational health management based on the Pneumoconiosis Law, the Industrial Safety and Health Law (ISHL), the Enforcement Ordinance of the Pneumoconiosis Law, the Ordinance on Prevention of Hazards Due to Dust, and other related regulations. These legislative regulations will be applied to the case not because the matter corresponds to nanomaterials but because both the relevant material and its manufacturing and handling correspond to the "operations in a dusty environment" specified in the legislative regulations.

Additionally, a provision specified in Article 28-2 of the ISHL entitled, "Investigation, etc. to be Carried Out by Employer" states that: "The employer shall endeavor to investigate the danger or harm, etc. due to raw materials, gases, vapors, dust, etc. and to take necessary measures for preventing dangers or health impairment to workers, in addition to taking the measures provided for by the provisions pursuant to this Act or the orders based on the results of the said investigations." Therefore, it is essential that any employer who is engaged in, for example, manufacturing, handling, or importing/exporting nanomaterials must conduct research on the dangers and harmful effects of nanomaterials based on the above provision and take necessary measures based on the research results.

In recent years, the research and development of and the applications of nanomaterials have been in progress. Therefore, it is expected that, from now on, the number of workers who are engaged in manufacturing and handling nanomaterials will increase. Meanwhile, although the actual exposure status and adverse health effects of nanomaterials on humans are not still completely elucidated, experiments with small laboratory animals suggest potential health effects of nanomaterials. Thus, from the view point of "precautionary approach", the MHLW issued, as a notification from the Director General of Labour Standards Bureau, LSB Notifications No. 0207003 and No. 0207004, entitled "Notification on Present Preventive Measures for the Prevention of Exposure at Workplaces Manufacturing and Handling Nanomaterials" (hereinafter referred to as "Notification") and has been urging employers of the relevant workplaces to implement appropriate exposure preventive measures.

2 Scope of Considering

Although the above-mentioned Director's Notification has been issued as an interim measure from the MHLW, in order to increase the efficiency of countermeasures for the control of nanomaterials, a more specific management approach should be presented and further, the current situation and future challenges on exposure preventive measures need to be considered. Therefore, this review panel decided to consider the following subjects:

(1) Scope of nanomaterials to be targeted for the preventive measures;
(2) Interim exposure preventive measures associated with nanomaterials; and
(3) Future occupational health and safety problems associated with nanomaterials.

3 Perspectives for Considering Preventive Measures

(1) Because there are no exposure control values for nanomaterials such as allowable concentration, it is impossible to adopt the conventional methodology of management practices for nanomaterials that is performed based on the exposure level and concentration of a substance. Therefore, for preventive measures, we have determined to take a recently, worldwide well-known approach, so-called "precautionary approach"[1].

(2) In considering measures for nanomaterial exposure, we decided to seek the best feasible solution by taking into consideration overseas trends, the latest scientific knowledge, the status of control practices taken in workplaces, and the progress of relevant technology, etc.

(3) In general, nanomaterials exist in powder form under ordinary conditions and exhibit particular electrical, chemical, and physical properties that arise from their size reduction to

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[1] Precautionary Approach

The basic concept of the preventive approach is as specified in Principle 15 of Rio Declaration on Environment and Development (The United Nations Conference on Environment and Development held in 1992) stating "･･･, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cast-effective measures to prevent environmental degradation."

In addition, the 2002 Johannesburg Summit agreed upon the goal of achieving sound chemicals management based on an international commitment, "By 2020, chemicals should be used and produced in ways that lead to minimization of adverse effects on humans and the environment". As a measure for achieving this commitment, SAICM (Strategic Approach to International Chemicals Management process), which was adopted in 2006, recommends the adoption of the precautionary approach.

the nano-scale range. Moreover, at present, the harmful effects of each nanomaterial still remain unclear. Therefore, we decided to consider interim preventive measures against exposure to nanomaterials, not based on each type of nanomaterials but on the whole group of nanomaterials.

Part 4 Results of Considerations Associated with Exposure Preventive Measures

1 Basic Points

(1) Scope of Nanomaterials to be Targeted for Exposure Preventive Measures

In the Notification, targeted nanomaterials are defined as “solid state materials manufactured using chemical elements and so on as a raw material”. The Notification limits the target scope of nanomaterials exclusively to manmade materials. Other than engineered nanomaterials, various nano-sized particles occur in nature. Currently, any occupational health concerns do not arise from these nanoparticles; therefore, it can be said that nano-size particles present in nature fall beyond the target range. Additionally, although there still remains the possibility that nano-sized materials may occur unexpectedly during ordinary processes such as a manufacturing process, at present, no occupational health concerns arise from such nano-sized materials. Therefore, it can be again said that they fall beyond the target range.

The Notification defines only the upper size limit of nanomaterials. In most of other countries, the lower size limit is usually defined as 1nm, but unless the lower limit is defined, even an atom will be targeted. Therefore, it would be appropriate that the present definition should be restated as follows: ”nano-objects[2] with at least one of three dimensions of approximately 1nm – 100nm and a nano-structured material composed of such nano-objects (including objects containing nano-scale structure and aggregate of nano-objects)”

Additionally, in the Notification, the aggregation of nano-objects is also targeted for preventive measures. Results of *in vitro* tests showed that aggregated nano-structured materials cannot be easily separated; in other tests for fullerenes, it was reported that, once they enter into the body, nano-structured materials are subjected to strong biological effects, including effects by macrophages and biological redox effects, and are likely to be separated. Even if the size of an aggregated nano-structured material is beyond 100nm and if the size of nano-objects is less than 100nm, it is proper for the aggregated

[2] Descriptions are provided according to the definition of ISO/TC229 TS27687 Nanotechnologies－Terminology and definitions for nano-objects－nanoparticles, nanofibre and nanoplate. Nano-objects include three types: nanoparticles; nanofibre; and nanoplate. However, Japanese translation of these terms remains tentative.

nano-structured material to be involved in the target range.

(2) Workers to be Targeted for Exposure Preventive Measures

The workers with the chance of exposure to nanomaterials are those who are engaged in manufacturing or handling nanomaterials or formulations containing nanomaterials (including repairs and inspections of equipment or instruments as well as manufacturing and handling for scientific purposes, etc.) in a workplace and those who are engaged in supervising these operations in the same workplace. Therefore, here it is appropriate to redefine the definition as ”the scope of workers include those(including supervisors) who are engaged in manufacturing or handling nanomaterials or formulations containing nanomaterials in a workplace”.

In handling products in which nanomaterials are used, only when the nanomaterials are embedded in the products or otherwise, they exist in a stable state and cannot be expected to break free, it may be considered that there is little chance of exposure to those nanomaterials. However, for instance, when these products are disposed of, the possibility cannot be denied that nanomaterials may be released from inside the product, causing occupational exposure for workers who are engaged in the disposal operations. Therefore, it is appropriate that the scope of workers should include not only workers who are engaged in manufacturing and handling nanomaterials, but also workers who are engaged in disposing of and recycling products containing nanomaterials.

(3) Exposure Routes of Nanomaterials

Possible exposure routes of nanomaterials can be considered as follows:

a Inhalation exposure through the respiratory tract such as lung, etc., which is the most common exposure pathway of suspended particles in working environment;

b Entry into the body from nerve endings in the nasal cavity, which is another exposure pathway by inhalation;

c Entry into the body through skin contact

d Entry into the body through the mucous membrane of the eyes; and

e Entry into the body by oral ingestion

(4) Manufacturing and Handling Operations Associated with Nanomaterials and their Chance of Exposure

Examples of manufacturing and handling operations associated with nanomaterials include the following:

- Production
- Receiving
- Weighing
- Inputting into equipment（such as kneading with resins or inputting of raw materials）
- Collecting from production/processing equipment, and translocation of containers (such as translocation of intermediate products)
- Cleaning and maintenance of equipment/containers
- Other operations (such as disposition and recycling of products containing nanomaterials)

The possibility cannot be denied that workers engaged in any of these operations may suffer from exposure to nanomaterials. According to the results of questionnaire research, which was, from September 2007 through to February 2008, jointly conducted by the Japan National Institute of Occupational Safety and Health (JNIOSH) and the National Institute of Advanced Industrial Science and Technology (AIST) (hereinafter referred to as “questionnaire results”), more than 50% of occupational health supervisors in workplaces thought, almost all of working processes, both the possibility of leakage of nanomaterials into the outside of the workplace during each production process and of worker’s exposure to nanomaterials, although the percentage in a receiving process is relatively lower than in other processes.

The chance of human exposure to nanomaterials varies depending on the morphology of nanomaterials, the state of nanomaterials, or operation methods for nanomaterials. When particles of nanomaterials are being dispersed in liquid and the possibility of emissions to air (caused by evaporation of liquid) can be reduced, or when nanomaterials are being embedded in resins, etc. or immobilized in a bulk material, it can be thought that, in handling such nanomaterials, the chance of exposure will be greatly reduced.

Conversely, in handling nanomaterial powders, it can be considered that the chance of exposure is significantly increased.

2 Items to Consider and the Results of Considerations (Associated with Each Measures)

By referring to the following measures, workplaces should strive to reduce exposure to nanomaterials on the basis of their actual conditions in terms of materials, processes, and transaction volume.

Enough basic data is not yet available to consider exposure prevention measures. Under such disadvantages, using currently available data and knowledge, the following separate measures have been provided which should be taken by relevant workplaces. Therefore, if workplaces have some referential knowledge for preventive measures to be taken and further if, based on such knowledge, it is possible to take effective measures for preventing exposure from the view of a precautionary approach, such workplaces may take their own response in spite of these measures shown below.

(1) Working Environment Management

a) Assessment on the Measurement of Exposure Conditions (Exposure Assessment)

In order to understand the conditions of nanomaterials released into the working environment or to confirm the efficiency of preventive measures against exposure to the nanomaterials, a quantitative analysis of nanomaterials in the working environment is necessary. However, the measurement method of nano-sized particles has not been established.

Measurement instruments used for nano sized particles include SMPS (Scanning Mobility Particle Sizer), ELPI (Electrical low pressure impactor) , these devices can measure concentration by particle size or other low pressure impactors, CPC (Condensation Particle Counter), which can be used for measuring the total number of particles, DC (Diffusion Charger-based Surface-Area Monitor), which can measure the total surface area of particles, or electron microscopes, which are used for the morphological observation of collected particles.

Most of measurement instruments for nano-sized particles are usually large in size and expensive. Therefore, in Europe and the United States, these instruments are not used for measuring personal exposure which is the ordinary manner of working environment assessment in those countries; oversea technical papers demonstrate that the measurement of particles has been executed by sampling air from the working environment. SMPS is expensive and does not have enough durability for measurements that are to be performed in the working environment. Recently, for CPC and DC, their small-sized equipment is available, which can be brought into a workplace, but the durability is unknown. When the durability of a measurement instrument is low, such instruments will require frequent maintenance as a result of the measurement operation, which is likely to become an obstacle for implementing measurements. Also, because the respective measuring device has limitations in performance, in some cases, only a single device may be insufficient.

The problem in measuring nano-sized particles is that various nano-sized particles exist in workplaces. For example, in a workplace into which the external air flows, nano-sized dust in the atmosphere may affect on the measurement results. Therefore, in such a case, it is impossible to discern whether measurement values (including the number, weight, and surface area of particles) are associated with the targeted nanomaterials. For the purpose of identifying nanomaterials, analysis of component needs to be made.

In the context of actual management of the working environment, it can be thought that the following four items need to be implemented: survey on raw materials; measurement of a working environment; measurement of personal exposure; and more detailed survey on nano-sized particles. Investigation of raw materials will require information provided by the manufacturer, such as electron micrographs, particle size, and specific surface area.

With regard to the working environment management in workplaces, for the present, it is necessary to conduct the measurement of working environment as well as investigation of raw materials and to try to improve the working environment. If the conditions of the working environment such as the location of or operations corresponding to a nano-sized particle emission source can be identified, these findings can serve as a reference in selecting a control measures and selecting/using protective equipment. For the measurement of nano-sized particles, SMPS, CPC (as a relative densitometer), DC, and other small, portable measurement device should be selected and used depending on the circumstances. If these devices are difficult to be used, a dust meter that can measure ordinary size particles, i.e., particle counters should be used. Generally, in a working environment, dust particles with a broad particle-size distribution exist, which are generated from the same source. Therefore, even with a device that is not designed for measuring nano-sized particles, the results of measurement in such working environment are somewhat effective for the control of nanomaterials. Some of these measuring devices are capable of automatically recording the concentration change over time, which may help to evaluate correlation between working operations and concentration changes.

In addition, more detailed research on nano-sized particles will require the use of－TEM (transmission electron microscope), SEM (scanning electron microscope), SMPS, ELPI, etc.

b　Location to be equipped with Enclosure needed

Definitions of terms for equipment and machinery are as follows. Any machinery used in one of manufacturing processes for nanomaterials, is called “production equipment”. A series of production equipment is called “production facility”. Also, a working facility associated with manufacturing, as well as the production facility, is called “facilities”. A structure in which facilities are located called “building”.

As an exposure preventive measure, except for cases where there is no possibility of exposure to nanomaterials, for example, a nanomaterial is embedded into solid materials such as resins or is suspended in liquids (in a liquid case, measures for droplets are necessary), in principle, manufacturing devices that emit nanomaterials must be enclosed.

Also, except in cases where there is no chance of exposure, in principle, enclosure, unmanning, and automation (hereinafter referred to as “enclosure, etc.”) must be applied to all processed that involve direct handling of nanomaterials by workers－such as accepting deliveries of raw materials; weighing raw materials and products; feeding into manufacturing/processing devices (including mixing process); collecting from manufacturing/processing devices; repacking into containers,etc.; cleaning, inspections, and repairing of manufacturing/processing devices; and cleaning of containers－in order to prevent workers from exposure to nanomaterials. In particular, mixing of nanomaterial powder with liquids or resins is highly likely to result in exposure to nanomaterials; therefore, either enclosing, etc. or operations in a glove box must be adopted.

Moreover, even in the disposal of wastes or in recycling operations, when exposure to nanomaterials is possible, in principle, necessary measures (such as enclosure, etc.) must be taken.

Additionally, when enclosure, etc. is difficult to be taken, a local exhaust ventilation system, etc. (including push-pull type ventilation system: the rest stays the same) is necessary to be installed to deal with this situation.

c　Location to be Equipped with Local Exhaust Ventilation System

In a location where devices manufacturing and handling nanomaterials cannot have a sealed structure, a local exhaust ventilation system, etc. must be installed to prevent dispersion of nanomaterials. The following specific processes are included in the processes of manufacturing and handling nanomaterials and expected to fail to achieve enclosing or automation; therefore, they must be equipped with a local exhaust ventilation system, etc. These processes are:

・ The following processes conducted at workplaces manufacturing nanomaterials where dry nanomaterials need to be directly handled by workers;

－ Processes of collecting synthesized nanomaterials (except for continuous and/or automated processes)

－Processes of weighing, packing, and packaging of produced nanomaterials

・ The following processes are conducted at workplaces handling nanomaterials in order to process and treat received, dry nanomaterials (including unpacking of containers and inputting into devices)

－Unpacking process (a process and operations of unpacking shipper-packed containers containing nanomaterials so as to facilitate the later feeding process)

－Dividing and weighing process (a process weighing and taking of a portion of nanomaterials for the next feeding process)

－Feeding process (a process of inputting nanomaterials into a hopper, etc.)

Even when the operation is to be performed with sealed production equipment or within an enclosed system, access openings for maintenance and inspection must be equipped with a local exhaust ventilation system, etc. or glovebags need to be used for such operation.

A booth-type hood is preferable for local exhaust ventilation systems. In a case where the size of the production equipment is large, the installation of a push-pull type ventilation system may be preferable for the convenience of workers.

In addition, after a local exhaust ventilation system, etc. is installed, it is critical to ensure that the periodic maintenance checks are performed.

d Method of Dust Removal from Exhaust Air

The outlet of a local exhaust ventilation system, etc. needs to be directly open to outside air. In that case, to prevent emission of nanomaterials along with exhaust air, a local exhaust ventilation system, etc. need to be equipped with high performance filters that are capable of collecting such nanomaterials.

In selecting filters to be used, in consideration of the aggregation nature of nanomaterials, the following points need to be investigated to select an appropriate filter capable of collecting targeted nanomaterials. These points are: the diameter of nanomaterial particles; the status of aggregation of nanomaterials; dust-catching performance of filters, etc.

When such an investigation is not to be conducted, a HEPA filter or the equivalent performance filter needs to be installed for exhaust filtration.

Performance of HEPA filters may vary depending on the diameter and aggregation nature of a nanomaterial; however, the dust-catching efficiency of HEPA filters is thought to be satisfactory for ordinary nanomaterials.

Also, prior to using HEPA filters, it should be noted that, regardless of the high performance, these filters have a high pressure loss and they are disposable. Therefore, when using HEPA filters in large-scale facility, it is necessary to raise the performance of electric generators/exhaust fans and to perform the replacement of HEPA filters in operations that may increase dust generation. In that case, it is important that prefilters are installed in front of the HEPA filter to reduce filter load and the frequency of replacement of HEPA filters.

Also, when a targeted substance can be adequately collected, use of electric dust collectors might be selected.

(2) Working Management

a Contents of Operation Rules

In order to ensure that working operations can be properly performed to prevent the occurrence of exposure to nanomaterials, it is essential that working specifications on handling of nanomaterials must be prepared and adequate instructions must be given to workers to allow them to follow the content of the specifications. Such working specifications must contain information on the harmful effects of nanomaterials to be handled as well as information and other findings associated with the working environment.

b Cleaning Method of Floors etc.

When cleaning floors and work benches in a workplace, the use of conventional vacuum cleaners and brooms may end up causing further dispersion of nanomaterials into the air. Therefore, it is required that cleaning operations should be performed by suctioning nanomaterials vacuum cleaners with a HEPA filter or, when this is difficult or unsuitable to be performed, by wiping with wet cloths. In this case, it may be effective to add moisture to accumulated nanomaterials firstly and to wipe off them; however, in a case of water-shedding powder, introducing water may disperse the powder. Therefore, cleaning operations need to be conducted in consideration of both the status of the workplace and properties of the nanomaterial. In addition, cloths used in wiping must be placed into an impervious and hard-to tear bag and disposed in a proper way.

c Prevention of Contamination in the Nanomaterial Workplaces and the Outside Environment

Facilities that manufacture, process, and/or handle nanomaterials must be segregated from the outside environment and also, a decontamination area in between to prevent nanomaterials from being transferred outside of workplaces on work clothing.

In addition, unauthorized persons must be kept away from facilities manufacturing, processing, and/or handling nanomaterials.

d When to Use RPE (Respiratory Protective Equipment)

Except in cases where there is no possibility of exposure to nanomaterials, when workers are engaged in the manufacturing and handling nanomaterials, effective RPE must be used by such workers. In implementing exposure preventive measures, enclosure of facilities, installation of a local exhaust ventilation system, and other facilitical measures should be prioritized. If appropriate, depending on the circumstances (such as facilitical measures), workers must select the most effective RPE.

In that case, in consideration of use in irregular or emergency situations, the required number of appropriate RPE used for preventing inhalation of nanomaterials must be stocked and kept clean and available.

e Performance Requirement for RPE and Precautions for Use

Effective RPE to be used by workers must be as follows: air-supply respirators such as supplied air-respirator; dust masks with a particle collection efficiency of 99.9% or higher, or face piece-, face shield- or hood-type PAPR (powered air-purifying respirator) with a particle collection efficiency of 99.9% or higher that is in compliance with JIS T8157. Among these respirators, dust masks to be used must have national certification. In selecting dust masks to be used, in consideration of the aggregation nature of nanomaterials, the following points need to be investigated to select an appropriate dust mask capable of collecting targeted nanomaterials. These points include: the diameter of nanomaterial particles; the status of the aggregation of nanomaterials; dust-catching performance of dust masks, etc.

Selections of RPE are given in the Appendix. In addition, RPE must be selected for each workplace, for example, a workplace that requires explosion-proof measures, a workplace that is in uncomfortable hot environment, or a narrow workplace, etc.

In selecting dust masks, after checking the adequacy of fit between a face piece and worker’s face, a face piece in good condition must be selected. Adequacy-of-fit tests need to be performed every time the face piece is worn. In addition to that, maintenance, inspection, cleaning, and appropriate storage of RPE are indispensable.

f Requirements for Protective Gloves and Precautions for Use

Where hand skin contact with nanomaterials is possible, protective gloves need to be used. Protective gloves to be used must be made of appropriate materials to prevent adherence of nanomaterials to the skin. Preferably, in order to maintain effective and clean conditions, protective gloves should be disposable but it is not the case only if clean conditions can be maintained by washing, etc. Also, if used protective gloves are disposed of, such gloves must be put into appropriate bags to be disposed of adequately.

When protective gloves are put on or taken off, if skin contact with nanomaterials is unavoidable or highly possible, it is necessary to wash hands with soap or wipe off the skin with a cleansing cream.

g　When to Use Goggle-type Protection Glasses

If eye contact with powder, spills, etc., of nanomaterials may occurs, it is necessary to use goggle-type protection glasses.

h　Use of Work Clothes and Precautions for Use

When nanomaterials are possibly adhere on work clothes, exclusive protective clothing needs to be put on. Preferably, protective clothing should be made of unwoven cloth; effective and clean conditions must be maintained by washing, etc.

Also, if protective clothing on which nanomaterials are deposited needs to be taken outside of the facility, such protective clothing must be put into, for example, impermeable, hard-to-tear bags to prevent the spread of exposure outside the facility.

i　Keeping of Operation Records

Operation records can serve as an information source to understand and improve the current status of exposure preventive measures. Therefore, it is very significant to store operation records on the manufacturing and handling of nanomaterials. Operation records must be prepared that indicate by whom, when, and how the operation was performed and also be retained for an extended period of time.

(3) Healthcare

Currently, little is known about the adverse effects of nanomaterials on human health. Healthcare is the basics of occupational health management. Employers must implement regular health examinations and recognize the present health conditions of the relevant workers.

(4) Occupational Safety and Health Education

In order to increase the efficiency of preventive measures against exposure to nanomaterials, it is critical to ensure that workers engaged in the related operations should understand the physical and chemical properties of nanomaterials, potential adverse health effects, control measures for the working environment, the use of PPE (personal protective equipment), etc., and also should abide by manuals such as operational procedures.

In particular, for RPE, it is important to select appropriate RPE fit for the conditions of the working environment and/or the duty of the operation. Additionally, in order to reduce leakage between the face piece of RPE and wearer's face, it is essential to ensure continued adequacy of fit. Therefore, the related workers must be given detailed instructions concerning the following: proper selection of RPE; a method on how to put on the RPE; the method of leakage rate measurement based on the adequacy of fit between face piece of respirators and face; method for checking adequacy of fit; and storage and management of RPE.

(5) Response to Waste Disposal

Among wastes generated from workplaces manufacturing and handling nanomaterials, those posing risks of nanomaterial dispersion must be placed into impermeable, hard-to-tear bags and properly disposed of to prevent the dispersion of such nanomaterials.

In a workplace where waste disposal is mainly undertaken or where recycling can be implemented, after consideration of the possibility of nanomaterial dispersion in the working environment and if there is any possibility of exposure, adequate measures (including facilitical measures, etc.) must be taken to prevent the workers from exposure to nanomaterials.

In addition, the treatment of nanomaterials needs to be performed in a manner or condition fitting their nature and properties. Carbon nanotubes, for example, are found to be pyrolytically decomposed at a temperature range from 750 °C to 850°C.

(6) Response to irregular Operations (repair of facilities, etc.)

Potential exposure to nanomaterials may increase during irregular operations such as maintenance checks and/or refurbishment of production equipment that has been already used for manufacturing or processing nanomaterials, and the cleaning of production equipment or workplaces. Therefore, facilitical measures, such as local exhaust ventilation systems, etc. must be taken at first. If the measures are extremely difficult to be taken, PPE (personal protective equipment) such as RPE must be used to prevent exposure to nanomaterials.

Additionally, operation records in non-stationary operations need to be prepared and retained for an extended period of time.

(7) Others

a Measures of Preventing Fire and Explosion

As the size of a material approaches nanoscale, the specific surface area becomes larger and the minimum ignition energy becomes smaller, which can make a relatively inert material easily combustible. Dispersion of nanomaterials into the air may induce greater risks of explosion and fire than that of non-nanomaterials with the same components.

For preventive measures against explosion and fire caused by nanomaterials, the level of useful knowledge still remains unsatisfactory. The reduction of dust concentration, prevention of static charge generation, the reduction of oxygen concentration, etc. would be considered as general measures. These measures are necessary to be taken depending on the property of nanomaterials to be used, facility manufacturing and handling nanomaterials, related processes, contents of operations, etc.

b Response to Emergency Situations

For responses to emergency situations, it is important to establish criteria for determining emergency situations and to develop appropriate measures. For example, after criteria for small spill and/or large spill are specified, when such a situation takes place, warnings need to be provided to peripheral workers that an emergency has occurred. Also, in that case, some operational procedures must be established to prevent workers from exposure to the leaked nanomaterials.

Additionally, first aid measures to be taken in case of exposure are as follows:

Dust removal must be done in a clean-air environment;

If eye contact occurs, wash eyes thoroughly with water;

If inhaled, gargle or rinse mouth; and

If swallowed, (if possible) spit it out and then, gargle or rinse mouth

3 Further Advanced Study and Challenges to be Addressed

(1) Study on Possible Health Effects of Nanomaterials

For the potential health effects of nanomaterials, many research institutes in Japan and other countries as well as OECD and other international institutions are currently engaged in the elucidation of the mechanism, but, the useful scientific knowledge still remains insufficient. In particular, the long-term effects of nanomaterial inhalation (which is thought to be the primary exposure route in workplaces) on respiratory tracts and other organs have not been yet clarified. Therefore, along with international cooperation, long-term exposure tests with small laboratory animals and other necessary tests must be conducted to gather useful information on the harmful effects of nanomaterials. These tests will mainly focus on inhalation toxicity, which is assumed to be the actual route of exposure among workers, and dermal toxicity. However, due to the abundance of different types of nanomaterials to be studied, it is also important to promote research and development on convenient, hazard screening tests.

In addition, when conducting risk assessments to extrapolate from test results to human health effects, it is necessary to consider previously obtained data on other fibrous and/or particle materials.

Other than by the collection of information on harmful effects using laboratory animals, effects of nanomaterials on humans may be given by surveillance and analysis of the medical check-up results of workers engaged in manufacturing and handling of such nanomaterials. Therefore, if necessary, it is critical to establish a structure for effectively surveying and analyzing not only the medical records but also the work operation records of relevant workers, etc.

(2) Establishment of Occupational Exposure Limit Standards

In order to implement working environment management, occupational exposure limit standards must to be clarified. Therefore, it is important for the national government to surely follow up on the results of foreign and domestic research on the potential harmful effects of nanomaterials.

(3) Study on Engineering Measures for Preventing Exposure to Nanomaterials

a Study on Behaviors of Nanomaterials in the Working Environment

Although nanomaterials are known to be present in aggregated form, and studies on their behaviors are underway, little is known about the following matter in actual manufacturing and handling processes, that is size of nanomaterials aggregated and suspended in the working environment, size distribution of nanomaterials, concentration of nanomaterials and so on. Probably, these questions may have different answers depending on the type of nanomaterials, but clarifying these questions must be necessary to achieve both accurate measurement analysis and appropriate preventive measures for exposure to nanomaterials. Therefore, in-depth research must be moved forward through international cooperation. And also, obtained knowledge and information should be shared across the world and utilized for similar exposure prevention measures in other countries.

b Development of Measurement Methods, Measurement Equipment, and Estimation Technique for Nanomaterials

The most significant challenge for nanomaterial measurement is to develop measurement methods and measurement equipment, both of which are easy to implement in workplaces. Relevant authorities including private organizations should actively advance the development of highly durable, user-friendly small equipment that can be easily brought into operation sites.

Even if the development of such equipment succeeds, considering the fact that there still remain many obstacles for ordinary workplaces to measure nanomaterials, it could be important to develop, instead of actually measuring the concentration of nanomaterials, a practical methodology to estimate such concentrations in order to put forward exposure preventive measures.

c Engineering Measures for Preventing Dispersion and Exposure

As a preventive measure against exposure to nanomaterials that is associated with the manufacturing and handling of them, a local exhaust ventilation system, etc. plays an important role. Therefore, it is necessary to collect and organize practical information on the effectiveness of general exhaust ventilation systems as well as information on the effectiveness of other type ventilation systems in terms of the correlation between their type/performance and actual conditions of intended use in workplaces. Such information and findings need to be provided by each workplace in a timely and accessible manner.

d Collection of Information on the Performance of Dust Removal Devices

For filters and dust removal devices used for the removal of exhaust air from local exhaust ventilation systems, etc., more advanced studies seem to be required. Among the various types of filters, the performance of HEPA filters has been relatively elucidated. It is thought that nanomaterials can be captured with this HEPA filter, but the detailed knowledge about nanomaterials on type- and size-basis still remains unsatisfactory. The shortage of data on other type filters and dust removal devices is more pronounced. Nanomaterials vary in size and in electrical properties depending on the type and also, they often exist in aggregate form. Until collection of nanomaterials can be achieved using filters etc., there still remains many unknowns. Thus, for the purpose of easily selecting effective dust removal devices, it is necessary to gather and organize empirical knowledge for elucidating a dust removal device on the basis of the type and state of nanomaterials. Such knowledge and findings need to be provided by each workplace in a timely and accessible manner.

e Prevalence of Effective RPE

Currently, development of filters for dust masks has been underway. Preferably, in the future, necessary knowledge should be further gathered and also, more detailed information should be continue to be provided about the collection efficiency of a filter that is expected to be appropriate for each operation.

Also, the leakage rate of dust masks in wearing RPE might differ between nanomaterials and micro/macro-sized dust particles. Therefore, leakage rates for nanomaterials will need to be elucidated.

In this context, standard requirements to be met should be considered for respirators exclusively used for nanomaterials.

(4) Improvement of Structures for Transmitting Information to be Provided in Transferring/Providing Nanomaterials

In order to take preventive measures for exposure to nanomaterials in a relevant workplace, such a workplace must clearly understand what it is handling in relation to nanomaterials. To that end, it is indispensable to transmit and share information among relevant workplaces. Based on Article 57-2 of the ISHL, for some types of nanomaterials and formulations containing such nanomaterials, when they are transferred or provided, the shipment must be accompanied with a document stating the name, ingredients, etc. of the substance (MSDS). In this provision, however, not only information to be provided is not specific to nanomaterials, but also other type nanomaterials are not obliged to deliver the MSDS.

Among nanomaterials, with regard to a substance for which MSDS must be provided, it can be considered that, when the substance exists in nanoscale, the fact and precautions for handling should be reflected in its MSDS to transmit the relevant information. Similarly, even in a case where such an MSDS does not have to be provided, information transmission must be required. For nanomaterials, as well as voluntary countermeasures by manufactures, reliable information transmission models (including the reflection of information into MSDS) must be further developed.

(5) Considerations of Handling Nanomaterials Associated with Research into Chemical Substance Hazards

According to the ISHL, when a newly developed nanomaterial is composed of novel matter with nanoscale dimensions that cannot fit into any category of existing chemicals, such a nanomaterial must be notified as a new chemical substance and subject to the implementation of a health hazard survey under Article 57-3 of the Law. But, information submitted for the existing chemical notification system is not specific to nanomaterials.

In contrast, when newly developed nanomaterials are composed of existing chemical substance(s), under the current ISHL, such nanomaterials are, regardless of their nanoscale size, classified as “existing chemicals” and also, fail to fall within the category of notifiable substances. This is because the ISHL classification does not focus on the shape and size of a chemical substance.

However, it is well known that matter reduced to the nanoscale can exhibit unique properties compared to what they have on a micro/macroscale. In addition, there remains a possibility that nanomaterials may show different aspects of adverse health effects than micro- and macro-materials do. Apparently, current approaches for handling of nanomaterials need more consideration. In this context, we must understand how much scientific knowledge has been accumulated and take note of the progress of discussions among international institutions and keep up with regulatory trends on chemical substance management specified by other domestic regulations. With the exception of nanomaterials that have been already developed and currently manufactured and handled, when a novel nanomaterial is supposed to be developed in the future as a new chemical substance, and/or when a nanoscale material is expected to be newly developed from existing chemical substance(s), any of such cases must be separately considered on how to handle them under the ISHL.

(6) Collection and Provision of Information on Nanomaterials

Information gathering should focus on not only information provided from research and development on nanomaterials and research on the potential health effects of nanomaterials, but also various types of information provided from relevant workplaces, so as to allow such information to be utilized for preventive measures.

In addition, as provided for by Article28-2 of the ISHL, for nanomaterials as well as for other materials, employers must endeavor to investigate the danger or harm, etc. and take necessary measures based on the results of investigations. In order for this to be properly observed, the national government needs to strive to collect the best examples and publicly announce their findings to ensure extensive dissemination of the provision.

Although related information on nanomaterials has been already provided on the website of JNIOSH (National Institute of Occupational Safety and Health, Japan), it is essential that further improvement of the functionality and contents of JNIOSH’s website should be accomplished to ensure that their website becomes more accessible and helpful to users.

Other than information dissemination over the Internet, it is also important to provide information by utilizing leaflets, public relation magazines issued by relevant organizations, and a variety of other ways.

(7) Collaboration with the Relevant Ministries

As for collaboration with the relevant ministries, the Cabinet Office plays a central role in exchanging and sharing of information among the related ministries and agencies. In the future as well as at present, in collaboration with the relevant ministries and the related organizations, the government needs to continue promoting experiments and research on nanomaterials and sharing the useful related information.

Part 5 Afterword

Nanomaterials posing unknown risks to human health, including their properties, still do not reveal themselves. In this report, despite the lack of detailed knowledge about nanomaterials, by considering them from the viewpoint of a so called “precautionary approach” and organizing present knowledge on the applications, production volume, and nature of nanomaterials, these exposure preventive measures have been provided, which was considered to be the most appropriate solution at present.

As interim preventive measures against labour accidents associated with nanomaterials, solutions considered here should be applied to actual situations in workplaces. In addition to that, it is important that, with the understanding of actual measures taken in workplaces and of the current status of the workplaces, international support and cooperation should be a driving force not only to promote further investigations and R&D on matters that have not been yet elucidated and/or that have made less progress in technical development but also to reflect the obtained results in the present measures.

Appendix: Method for the Selection of Respiratory Protection Equipment

When using respiratory protection equipment (RPE), it is necessary to select RPE with an appropriate protection factor (PF) corresponding to the level of occupational safety measures at the facility or with assigned protection factors (APF). PF is a value that represents the protection performance of RPE and can be defined by the following equation:

$PF = Co/Ci$ *PF* : Protection Factor
Co : Dust concentration outside facepiece, etc.
Ci : Dust concentration inside facepiece, etc.

The above equation shows—the higher the PF, the less likely dust particles would leak into the respirator— such RPE can be considered to have a low potential for worker exposure. If it is impossible to make measurement of the PF in workplaces, assigned protection factors (APF) provided by the respective competent authority should be used. APF is a representative value of multiple protection factors measured within a laboratory.

APF is also a minimum expected value that would be obtained when trained wearers put on properly functioning RPE correctly. Table 1 shows assigned protection factors that have been publicly announced by the US and Japanese competent authorities.

When selecting RPE, in a case where, at industrial production sites, adequate facilitical measures cannot be taken on the basis of occupational health engineering and further, exposure to high concentration of nanomaterials can be expected, RPE with a higher APF should be selected. When it is possible to take appropriate measures such as the enclosing, automation, and remote-handling of production processes, RPE with a smaller APF can be selected. Also, when it is not possible to perform enclosure, etc. of production processes but possible to install local exhaust ventilation system, etc., this case falls in between the previous two cases and thus, RPE with an intermediate level of APF should be selected. When selecting RPE to be used for testing and research institutes, in a case where adequate facilitical measures cannot be taken on the basis of occupational health engineering and further, exposure to high concentration of nanomaterials can be expected, RPE with a higher APF should be selected. When it is possible to take measures (enclosure, etc.) and/or to install a local exhaust ventilation system, etc., RPE with smaller APF should be selected to respond to this event. Based on these concepts, information on the selection of RPE for common workplaces manufacturing/handling nanomaterials and testing/research institutes is provided, for reference purpose, in Fig.1 and Fig. 2 and in

Table 2.

In preparing these Figures and Table, the following matters were taken into consideration:

・If the results of working environment measurement, etc. cannot confirm whether there are no potential risk for worker exposure, even when handling nanomaterials in an enclosed system, it was determined that RPE should be put on.

・Recent literature indicate that, in some filter media used for RPE, a particle diameter of around 50nm results in lowering the collection efficiency of the filter media, and that even N95 (NIOSH standard：collection efficiency of 95% or higher) or S2 (National Standard for Dust Respirator Certification Test : collection efficiency of 95% or higher) filter media did fall short of the standard value of 95% in collection efficiency. Therefore, as filter media for dust masks, this document adopts filter media with a collection efficiency of 99.9% or higher, as specified in the previous notification (as of February 7th, 2008).

Meanwhile, these Table and Figures have been prepared based on currently available information and scientific knowledge. Therefore, the selection criteria for nanomaterials will have to be reviewed at all future stages where we can characterize: what hazards nanomaterials pose; what level the environmental concentration and/or worker exposure concentration of nanomaterials is present; and how much the collection efficiency changes depending on the particle diameter of filter media used for dust masks.

Fig. 1 RPE Selection Chart for
Common Workplaces Manufacturing or Handling Nanomaterials

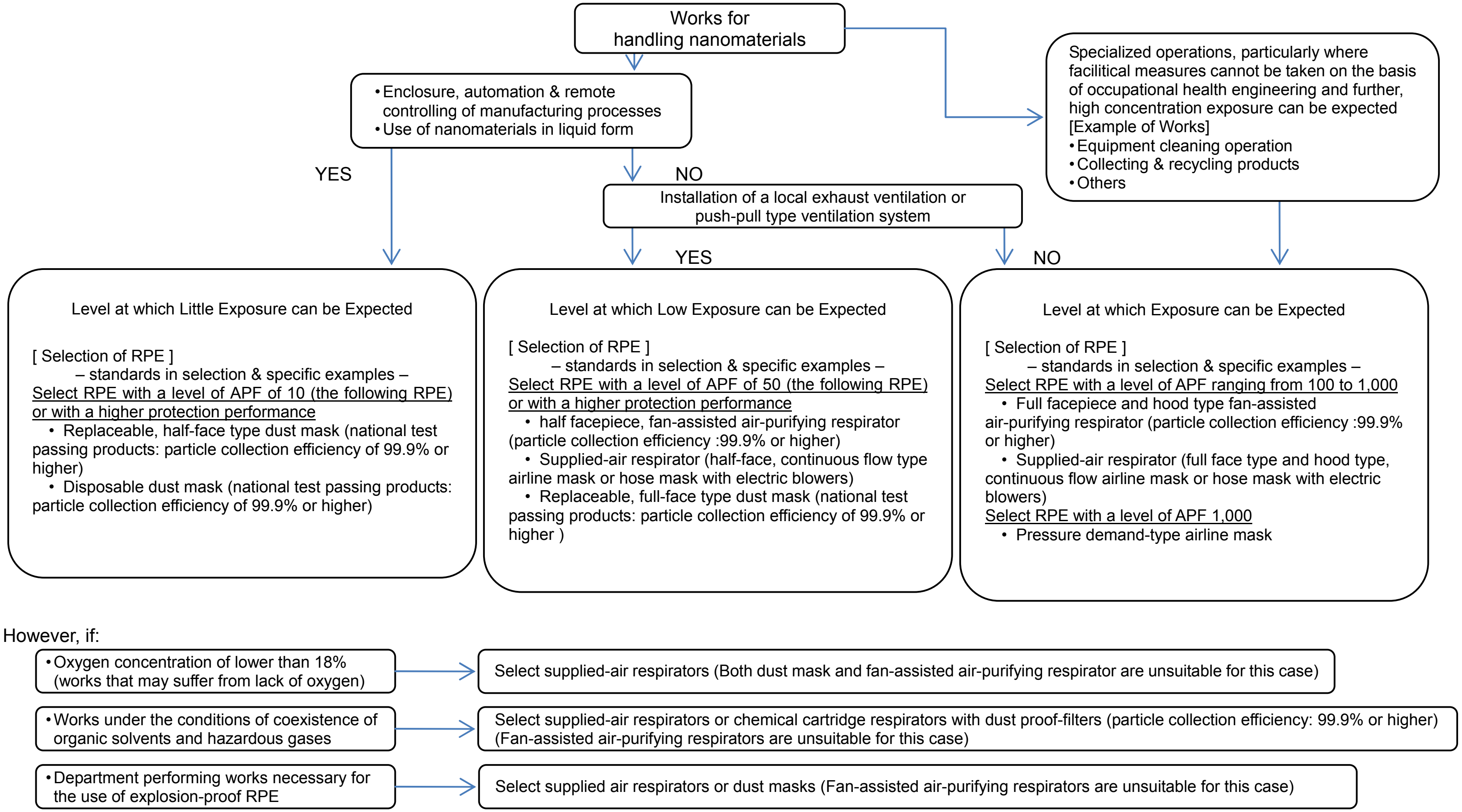

Fig. 2 RPE Selection Chart for Testing and Research Institutes

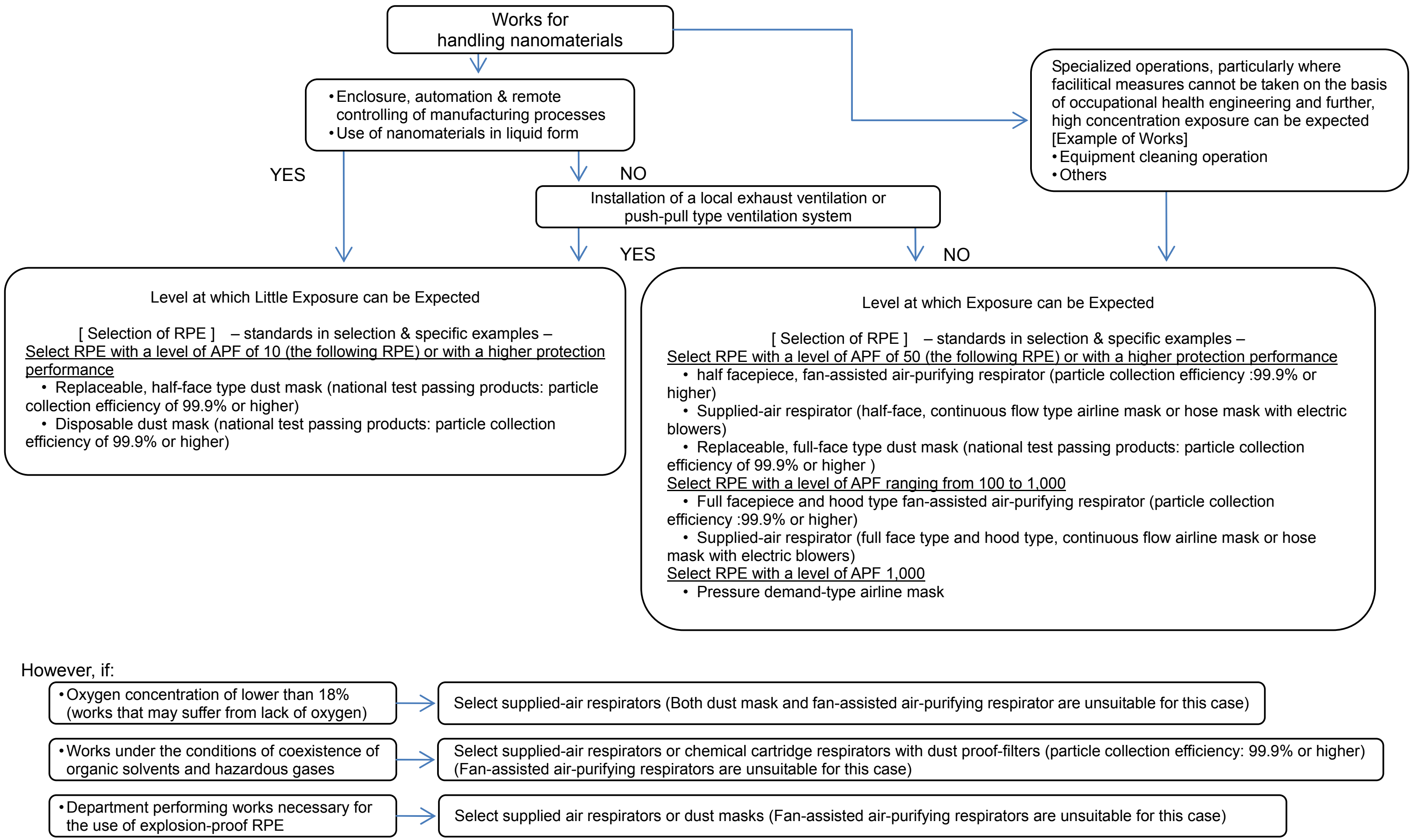

Table 1 : Assigned Protection Factor (APF) for Respiratory Protective Equipment (RPE)

Type of Respirators			OSHA 29 CFR 1910.134 (2006)	NIOSH Decision Logic (2004)	ANSI Z88.2 (1992)[e]	ANSI (Draft revision)	JIS T8150: 2006[f]
Air-purifying Respirator (APR)	Disposable type		10	10	10	5	3 - 10[g]
	Half face type mask		10	10	10	10	
	Full face type	With N/P/R 100 filter	50	10	100	50[d]	4 - 50[g]
		Without N/P/R 100 filter	50	50	100	50[d]	
Fan-assisted Air-purifying Respirator	Half face type		50	50	50	50	4 - 50
	Full face type		1000	50	1000[b]	1000	4 - 100
	Helmet/hood		25/1000[a]	25	1000[b]	1000	4 - 25
	Loose-fitting facepiece		25	25	25	25	4 - 25
Supplied-air Respirator	Demand type	Half face type	10	10	10	----	10
		Full face type	50	50	100	----	50
	Continuous flow type	Half face type	50	50	50	250	50
		Full face type	1000	50	1000	1000	100
		Helmet/hood	25/1000[a]	25	1000	1000	25
		Loose-fitting facepiece	25	25	25	25	25
	Pressure demand type	Half face type	50	1000	50	250	50
		Full face type	1000	2000	1000	1000	1000
Pressure demand, combination supplied-air/SCBA full-face respirator			----	10000	----	----	1000
Self-Contained Compressed Air Breathing Apparatus (SCBA)	Demand type	Half face type	10	----	10	----	10
		Full face type	50	50	100	----	50
		Helmet/hood	50	----	----	----	—
	Pressure demand type	Full face type	10000	10000	10000[c]	10000[c]	5000
		Helmet/hood	10000	----	----	10000[c]	—

[a] The employer must retain not only test results for these RPE but also the manufacturer's certificate indicating that the protection factor is 1000 or higher.

[b] HEPA should be used for protection from particles. Where the filter media is not HEPA: APF = 100

[c] Only for planning emergency measures.

[d] When a leakage rate is checked through quantitative fit test (using mask fitting testers), a PF of 50 is adopted, when through qualitative fit tests, the PF is to be regarded as 10.

[e] Declared invalid in 2003

[f] A minimum level of PF that is expected only when the RPE functions normally.

[g] Protection factors for APR can be calculated from the formula,"$100/ (L_m + L_f)$", where [L_m (%)] is the leakage rate of respiratory inlet covering and [L_f (%)] is the permeation rate of the filter of APR

Table 2. Selection of Respiratory Protective Equipment (RPE) in Handling Nanomaterials (Conclusion)

Place of Use	Enclosing, Automation, Remote Controlling, and Fluidization	Installation of a Local Exhaust Ventilation and Push-pull Ventilation System	Without Engineering Measures
Common Workplaces for manufacturing and Handling Nanomaterials	APF of 10 or Higher	APF of 50 or Higher	APF of 100 or Higher
Testing and Research Institutes	APF of 10 or Higher		APF of 50 or Higher

However, If:

Working Environment Conditions	Selection of RPE
Workplaces with Oxygen Concentration of Lower than 18%	Supplied-air Respirator
Works under the Conditions of Coexistence of Organic Solvents and Hazardous Gases	Supplied-air Respirator or Chemical Cartridge Respirator with Dust-proof Filter
Works Requiring the Use of Explosion-proof RPE	Supplied-air Respirator or Dust Mask