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NMI

Written Statement for Inquiry into Nanotechnology in NSW

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Opening Statement

Nanotechnology promises to be the next significant new technology, with diverse benefits and considerable economic potential. Technology at the nanoscale is not simply a matter of applying established classical physics to smaller dimensions. The nanoscale is the arena of quantum physics, and new engineering and manufacturing techniques will need to be developed. Consequently, new methods of measuring and testing will be required to demonstrate that a product or manufacturing process meets specified demand or conforms to environmental and safety standards.

A metrological infrastructure has underpinned all industrial revolutions and nanotechnology will be no exception. Nanometrology is the science of measurement at the nanoscale. Accurate and reliable measurements of physical, chemical and biological quantities will be required at all stages of the nanotechnology value chain to truly understand and control the manufacturing process and ensure and demonstrate product quality.

All major economic nations have a National Measurement Institute (NMI), whose main role is to establish, maintain and disseminate physical standards of measurement. International comparisons and agreements establish international and national traceability of measurements, making measurements quantitatively comparable and enhancing trade. In response to improvements in science, technology and manufacturing processes, NMIs continuously develop and improve standards to fulfill the needs of their national industry and society. Australia's NMI has the critically important role of establishing an internationally accepted measurement infrastructure for nanotechnology in this country.

A documentary standard is a published document that sets out specifications and procedures designed to ensure that a material, product, method or service is fit for purpose and consistently performs in the way intended. They establish a common language that defines quality and establishes criteria. The responsibility for developing Australian documentary standards lies with Standards Australia.

International standardization will play a critical role in ensuring that the full potential of nanotechnology is realised and safely integrated into society. Documentary standards help create a smooth transition from the laboratory to the marketplace, promote progress along the nanotechnology value chain – from nanoscale materials that form the building blocks for components and

devices to the integration of these devices into functional systems – and facilitate global trade.
Standardisation aids growth in productivity by supporting innovation, value generation, compliance and regulation. The production of well characterised and controlled nanotechnology-applied products depends on the availability of documentary standards for terminology and nomenclature and measurement and characterisation. International Standards also provide the technological and scientific bases underpinning health, safety and environmental legislation.

1). Can you please provide an update on the current status of the International Organisation for Standardisation's (ISO) Technical Committee 229, and the progress towards an agreed definition of nanotechnology? What is the role of Standards Australia and the National Measurement Institute in relation to that Committee?

Status of TC229:

The scope of TC229 is standardization in the field of nanotechnologies that includes either or both of the following:

"Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications,

Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties."

Specific tasks include developing standards for: terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; and science-based health, safety, and environmental practices.

The Chairman and Secretariat are both from the UK. There are now 29 participating countries and 10 observing countries, with 23 formal liaisons with other ISO committees and organisations, including the OECD and the European Commission.

There are 4 working groups: Terminology and nomenclature; Measurement and Characterisation; Health, Safety and Environment; and Materials Specification.

Roadmaps have been prepared for each working group and a Work Programme involving some 25 individual Work Items is underway.

The first TC229 technical draft standard "Nanotechnologies-Terminology and definitions for nanoparticles" was formally approved by ballot in February 2008. Nevertheless, the passage of this DTS through to an official ISO

standard is expected to take several years. The draft Technical Report "Health and safety practises in occupational settings relevant to nanotechnologies" is currently out for ballot, closing in May. It is expected that his will be published faster than the nanoparticle terminology standard.

The next plenary meeting (the 6th) of TC229 will be in Bordeaux, France in May 2008.

Definition of nanotechnology

The definition of nanotechnology is dependent on the definition of nanoscale. Thus, it would be expected that nanotechnology will be defined as technology, that is, the engineering of functional systems, at the nanoscale.

The problem within TC229 has been agreeing on a definition of nanoscale, with two main sticking points. The first was to agree on the size range and the second to agree on whether or not the definition should include the unique properties that often emerge at nanometre lengths.

It has now been accepted, but perhaps not yet formally agreed to, that the size range should be "from approximately 1 to 100 nm". This appears in the recently agreed to "Terminology and definitions for nanoparticles" draft standard. The use of "approximately" was the subject of considerable debate. Those for it argued that the size range should not be so restrictive that it would exclude objects lying just outside the range. Those against argued that the users of standards, such as regulators, required clear cut-off points.

It has also been accepted that the emergence of unique, novel or unusual phenomena should not be incorporated into the definition of nanoscale, but should appear as a note such as:

Emergent phenomena associated with size quantization and potentially other properties that are not regular extrapolations from larger size ranges will typically, but not exclusively, be exhibited at the nanoscale.

It is also important to realise that nanotechnology is actually a collective term for a wide range of technologies, in a similar way that Information Technology actually describes many different technologies.

I anticipate that nanotechnology will be defined as a collective term for a range of technologies, techniques and processes involving the manipulation of matter at the nanoscale, that is, in the size range from approximately 1 to 100 nanometres.

The role of Standards Australia and the National Measurement Institute

Standards Australia has been a full voting member of TC229 since its inception in 2005 and has had at least one delegate at all 5 plenary meetings. The role of SA is to represent Australia's interests, in particular the nanotechnology community, in relation to the development of ISO documentary standards. This includes participation in the development of standards, assistance with the operation of TC229 and providing a communication link between TC229 and NT-001, the Australian Technical Committee on Nanotechnologies. Australia has played an important and significant part in the work of TC229, particularly in planning, road mapping and the production of the TC229 business plan. The over-all aim is to significantly influence the content of TC229 Standards so as to make them more suitable for use in Australia.

The National Measurement Institute (NMI) is responsible for Australia's national infrastructure in physical, chemical, biological and legal measurements. Under the National Measurement Act 1960, NMI is responsible for coordinating Australia's national measurement system, and for establishing, maintaining and realising Australia's units and standards of measurement.

In relation to TC229 and NT-001, NMI has provided the chair of NT-001 and the Head of the Australian Delegation to TC229. Most of the national delegations to TC229 include at least one representative from their NMI due to the close relationship between physical and documentary standards. The measurement expertise that NMIs bring to the work of TC229 is vital if realistic and practical standards are to be produced.

2) Please briefly describe the process by which international standards are implemented at the national level in Australia. What action is required by NSW agencies in this process, and are there any particular challenges posed by the nature of nanotechnology?

I assume here that documentary standards are being referred to and so the process whereby Australia's physical measurement standards are aligned with the international community will not be discussed here. The procedure for the local adoption of ISO/IEC documentary standards by Standards Australia is fully described in their guide, "*SG-007 - Adoption of International Standards*". Implementation, whether for regulatory, commercial or scientific purposes, is generally left to the relevant user. An important action that the NSW government could take would be to adopt a policy of always using ISO/SA standards as the basis for regulation and legislation in nanotechnology.

The challenges posed by nanotechnology for documentary standards are many. Probably one of the most significant is that many of the standards developed by TC229 will be anticipatory since most nanotechnological development, and the resulting business, lies in the future. Much of the pre-

normative research required for these standards is still to be completed. Support for research in NSW in gaps identified by TC229 would be a valuable contribution.

3) In the submission of Standards Australia (p 5), there is a reference to the brokering role that Australia might play between European and North American perspectives on nanotechnology standards issues. What are the key differences between those perspectives?

The way the documentary standards systems are structured in Europe and the US is very different. Most nations have a single Standards Development Organisation (SDO) that develops national standards and represent their country on international bodies such as ISO. The US has over 400 SDOs based mainly in the private sector. They compete not only with each other but sometimes internationally. The main US SDO is the American National Standards Institute (ANSI) which is the US representative on TC229.

Europe has a much more centralised standards system. CEN, the European Committee for Standardization, was founded in 1961 by the national standards bodies in the European Economic Community and EFTA countries. CEN contributes to the objectives of the European Union and European Economic Area with voluntary technical standards which promote free trade, the safety of workers and consumers, interoperability of networks, environmental protection, exploitation of research and development programmes, and public procurement.

One result is that, in my opinion, the US standards development process is driven more by industry and defence needs than Europe, where more consideration is given to health, safety and environmental concerns. Input from community groups and NGOs is also encouraged more in Europe (and Australia) than in the US.

The US delegation to TC229 is thus more focussed on the particular commercial needs of their nanotechnology industries (as is Japan, China, and many of the Asian economies). This has resulted in an emphasis on bottom-up driven standards involving carbon nanotubes (CNTs) by these countries whereas Europe is more generally concerned with top-down driven standards designed more for regulatory purposes.

4) What are the current priorities of TC 229 for international standards development?

Each Working Group has developed a roadmap, setting out priorities for the future. Current priorities for WG1 are Terminology Standards for nanoparticles, carbon nanomaterials, measurement and instrumentation, a nomenclature for nanotechnology and a framework and core terms document.

Priorities for WG2 are standards for CNT characterisation (10 work items) and developing a general framework for determining nanoparticle content in nanomaterials by aerosol generation.

Priorities for WG3 are the TR on "Safe practices in occupational settings relative to nanotechnologies", a series of standards on toxicological testing and assessment and producing a guidance document on physico-chemical characterisation of engineered nanoscale materials for toxicologic assessment.

5) How do TC 229 and the ISO contribute to the world-wide effort to evaluate health and environmental impacts associated with nanotechnologies?

By roadmapping future requirements for Standards, TC229 is working internationally to identify gaps in our knowledge and coordinate research activities.

6) Please explain the importance of measurement for nanotechnology research and development, and the commercialisation of nanotechnology. What particular challenges for measurement are posed by the nano scale?

"If you can't measure it, you can't make it and you can't regulate it".

Measurement is a fundamental part of science and industry and nanotechnology-based science and industry will be no exception. Accurate and reliable measurements of physical, chemical and biological quantities are required at all stages of the nanotechnology value chain to understand and control the manufacturing process and to ensure and demonstrate product quality.

The challenge is to anticipate and meet the ongoing demands of industry, defence, research and government organisations for ever increasing accuracy in measurement standards. The lead time for new measurement standards and protocols is usually at least several years, because the science involved is almost always at the leading edge of knowledge. The science must be fully developed, understood, documented and accepted by international peers before the resultant measurement standards can be accepted as correct.

The particular challenges posed by nanotechnology are that national physical standards for measurements at the nano-scale require new approaches. This is a science in which physics and chemistry both contribute because molecules – the stuff of chemistry – often fall within the nanoscale range.

7) Is there adequate metrology infrastructure in Australia and NSW to meet the challenges of nanotechnology measurement? What are the long term infrastructure requirements?

No. A survey of industry carried out by NMI in early 2006 showed that the most urgent nanometrology-related need in Australia is for a metrological infrastructure to support the dimensional measurement of nanoparticles.

This need was recognised in the 2006 Federal Government report on "Options for a National Nanotechnology Strategy" by the National Nanotechnology Strategy Taskforce, when it recommended that the NMI establish and coordinate a national nanometrology program covering physical standards and establish a laboratory for nanoparticle studies and measurement. This was accepted by the government as part of the National Nanotechnology Strategy in 2007, initially funded for $6.25M over four years, but subsequently reduced to $3.12M over 2 years.

The most important task is to establish physical standards and instruments capable of transferring Australia's realisation of the metre, using known optical wavelengths of light, down to nanometre measurements in the nanotechnology community via a chain of comparisons. This will enable measurements of dimensions at the nanoscale to be made with known accuracy, and to be recognised nationally and internationally. This will underpin all future nanometrology activities in NMI, and consequently in Australia.

Another very important task is to build on the outcomes of the first task and establish a facility for nanoparticle standards and measurement. The Nanoparticle Facility will disseminate nanoparticle standards via a cost-recovery testing and calibration service. It will also conduct proficiency testing, run training courses, publish standard operating procedures, participate in international comparisons and support regulatory frameworks.

An important objective is to recruit, train and develop staff of the highest international calibre to provide NMI's expertise in the proposed areas of nanometrology.

In the long term, the nanometrology program needs to extend to the provision of traceability, international acceptance and expertise to the entire spectrum of nanoscale measurements, including electrical, optical, magnetic, mechanical, chemical and biological measurements.

8) Once the ISO's Draft Technical Report on 'Health and safety practices in occupational settings relevant to nanotechnologies' is finalised and published, how will those practices be implemented in Australia? What audit processes need to be established and which agency is best placed to perform them?

It is likely to be used by regulatory authorities as a guidance document initially, perhaps in a stronger fashion by some jurisdictions and authorities. This document is a reflection of current best practices. As more is learned about the HSE aspects of nanotechnology, it is likely to evolve into a series of full standards within TC229 concerned with occupational health. At this stage, I would anticipate that Commonwealth and State regulators and departments would use these standards as the basis for formal laws and regulations.

9) How does the Australian nanotechnology technical committee, NT 001, address the health, safety and environmental concerns of the community and groups such as the Friends of the Earth?

The membership of NT-001 includes the Australian Council of Trade Unions and the Consumers' Federation of Australia. Friends of the Earth has been invited to join the committee but they declined. Nevertheless, we have maintained informal contact with representatives of FOE and encouraged them to participate. The membership of NT-001 includes government departments, regulators and agencies and the Australian Office of Nanotechnology. These organisations are all in close contact with the community and are well aware of community concerns involving nanotechnology.

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