

Title: Towards an ISO standard for magnetic nanoparticles

Abstract

Magnetic nanoparticles (MNPs) find wide application in biomedicine, mechanical engineering and environmental remediation. However, international standards defining terminology, characteristics and necessary measurement procedures for MNPs are missing. In 2015, the International Organization for Standardization (ISO) began the implementation of a material specification for liquid suspensions of magnetic nanoparticles, registered as ISO 19807. Proposals in response to this SRT should provide scientific input into the preparation of ISO 19807, ensure uptake of state of the art results into the international standardisation process, summarise metrological knowledge on MNPs according to ISO/TC 229 N 673 and secure the representation of European NMIs and stakeholder interests in the development of the new ISO standard on MNPs.

Keywords

Magnetic nanoparticles, ISO 19807, co-normative standardisation

Background to the Metrological Challenges

The global market for nanoparticles in biotechnology and pharmaceuticals is expected to grow from \$30 billion in 2014 to \$70 billion in 2019, with European industry having a share of 35 %. Several large companies and an impressive number of small or medium sized enterprises work on magnetic nanoparticles in Europe.

Currently there are some European initiatives towards the standardisation of MNPs:

- European roadmap documents, including the “Integrated Research and Industrial Roadmap for European Nanotechnology” (Nanofutures 2012), underline the need for standardisation of all nanomaterials.
- EU FP7 project NanoMag “Nanometrology Standardization Methods for Magnetic Nanoparticles” (2013-2017) aims to improve and redefine existing MNPs analysis methods, and to develop new analysis methods for MNPs. As a pre-normative project, it generates scientific knowledge needed in the implementation of a standardisation document.
- EU TD COST Action 1402 “Multifunctional Nanoparticles for Magnetic Hyperthermia and Indirect Radiation Therapy (RADIOMAG)” (2014-2018) has a research branch on standardising magnetic hyperthermia. It is expected that this project will result in a compendium of best practices for magnetic hyperthermia and parts of it may be incorporated into an international standard document.

However so far there are no international or European standards defining the properties of MNPs or explaining the methods to obtain characteristic MNP parameters in a reproducible way.

Independently from European initiatives, a large number of ISO standards exist that cover the determination and description of geometric and structural properties of different nanomaterials. However, the description and the measurement of magnetic properties of nanomaterials are not yet standardised.

In July 2015 ISO approved a new project in the work programme of ISO/TC229 WG4 for ISO 19807 “Nanotechnology -- Liquid suspension of magnetic nanoparticles -- Characteristics and measurements”. The aim is to develop a guideline for a material specification of MNP suspensions providing a common definition of terms and characteristic properties for suppliers, customers and other interested parties. It is anticipated that the ISO standard development process will take up to 3 years, i.e. until 2018. European stakeholders are represented in the ISO committees by their national standardisation organisations (SDOs).

Objectives

Proposers should address the objectives stated below, which are based on the PRT submissions. Proposers may identify amendments to the objectives or choose to address a subset of them in order to maximise the overall impact, or address budgetary or scientific / technical constraints, but the reasons for this should be clearly stated in the protocol.

The JRP shall focus on metrology research necessary to support standardisation related to magnetic nanoparticles.

The specific objectives are

1. To develop measurement methods and techniques to ensure highly qualified scientific input into the preparation of the new international standard document ISO 19807 “Liquid suspension of magnetic nanoparticles”. Specifically, this shall include:
 - collection and preparation of existing pre-normative knowledge on identification and definition of relevant physical parameters of MNPs such as i) saturation magnetisation, ii) crystallite size composition and distribution, iii) hydrodynamic size distribution and iv) magnetic interaction between MNPs;
 - definition and description of appropriate measurement methods for MNPs properties by static and dynamic magnetisation measurements;
 - coherent application of existing standards for X-ray and neutron diffraction techniques for determination of crystallite structure and application of transmission electron microscopy (TEM) and dynamic light scattering (DLS) for MNPs size characterisation;
2. To summarise metrological knowledge on MNPs gained in this project according to the “Metrological Checklist” ISO/TC 229 N 673, so that further normative documents covering measurement techniques for MNPs can be prepared.
3. To ensure the take up of results from finalised and ongoing FP7 and Horizon 2020 EU research projects on MNPs e.g. “NanoMag” and “RADIOMAG” into the international standardisation process.
4. To ensure coordinated participation of European NMIs and stakeholders in ISO’s standardisation process on MNPs to provide highest impact and fastest development of the standard. To facilitate the take up of methods and technology developed in the project by technical committees e.g. ISO/TC 229 and end-users e.g. biomedicine, mechanical engineering and environmental remediation sectors

The proposed research shall be justified by clear reference to the measurement needs within strategic documents published by the relevant Standards Developing Organisation or by a letter signed by the convenor of the respective TC/WG. EURAMET encourages proposals that include representatives from industry, regulators and standardisation bodies actively participating in the projects.

Proposers should establish the current state of the art, and explain how their proposed research goes beyond this. In particular, proposers should outline the achievements of the EU FP7 project NanoMag and EU TD COST Action 1402 RADIOMAG and how their proposal will build on those.

EURAMET expects the average EU Contribution for the selected JRPs in this TP to be 0.6 M€, and has defined an upper limit of 0.8 M€ for this project.

EURAMET also expects the EU Contribution to the external funded partners to not exceed 30 % of the total EU Contribution to the project.

Any industrial partners that will receive significant benefit from the results of the proposed project are expected to be unfunded partners.

Potential Impact

Proposals must demonstrate adequate and appropriate participation/links to the “end user” community, describing how the project partners will engage with relevant communities during the project to facilitate knowledge transfer and accelerate the uptake of project outputs. Evidence of support from the “end user” community (e.g. letters of support) is also encouraged.

You should detail how your JRP results are going to:

- Address the SRT objectives and deliver solutions to the documented needs,
- Feed into the development of urgent documentary standards through appropriate standards bodies,
- Transfer knowledge to the biomedicine, mechanical engineering and environmental remediation sectors.

You should detail other impacts of your proposed JRP as specified in the document “Guide 4: Writing Joint Research Projects (JRPs)”.

You should also detail how your approach to realising the objectives will further the aim of EMPIR to develop a coherent approach at the European level in the field of metrology and include the best available contributions from across the metrology community. Specifically the opportunities for:

- improvement of the efficiency of use of available resources to better meet metrological needs and to assure the traceability of national standards
- the metrology capacity of EURAMET Member States whose metrology programmes are at an early stage of development to be increased
- organisations other than NMIs and DIs to be involved in the work

Time-scale

The project should be of up to 3 years duration.