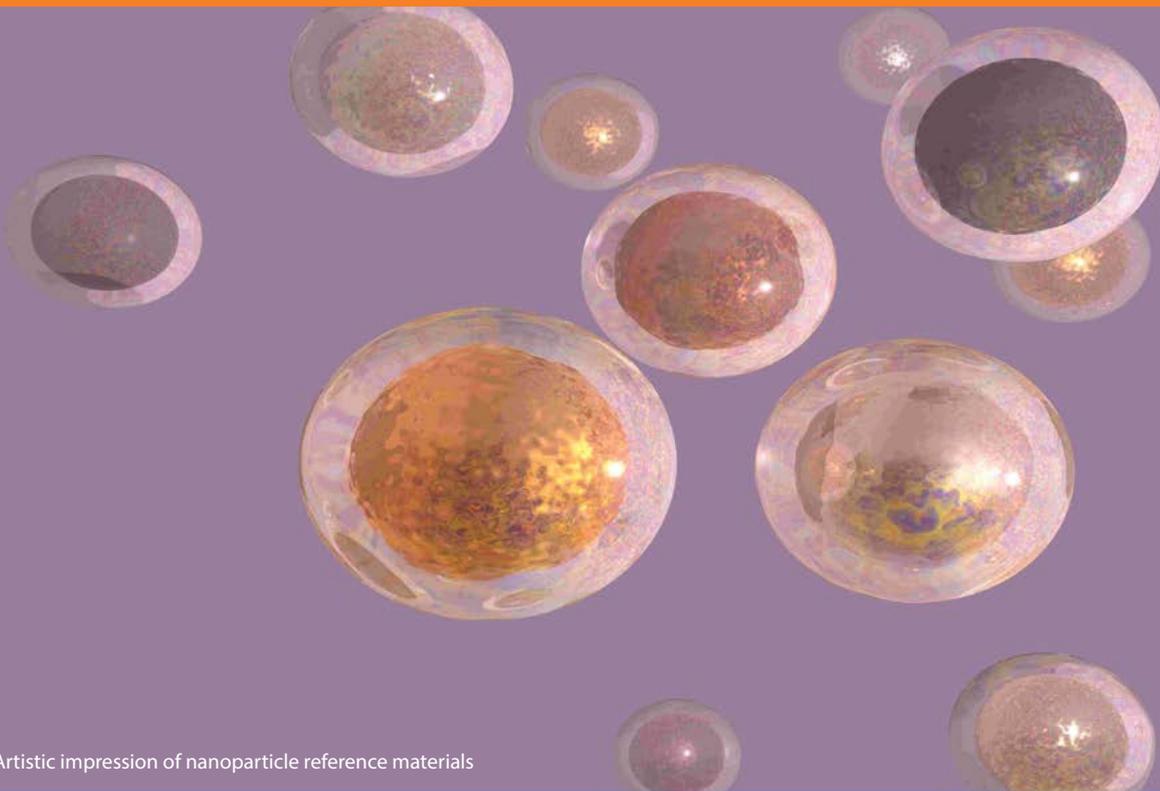


# European Metrology Programme for Innovation and Research

Delivering Impact



Credit: NPL, UK

Artistic impression of nanoparticle reference materials

## The first ISO Technical Standard for nanoparticle concentration

The use of nanomaterials in society is increasing due to their unique properties. Nanomaterials are used for advanced medical technology and consumer products such as medical imaging, drug delivery, sunscreen and advanced coatings for solar cells. However, the rapid pace of product innovation is outstripping regulatory standards– which must be developed to support innovation and address safety concerns.

### Europe's National Measurement Institutes working together

The European Metrology Programme for Innovation and Research (EMPIR) has been developed as part of Horizon 2020, the EU Framework Programme for Research and Innovation. EMPIR funding is drawn from 28 participating EURAMET member states to support collaborative research between Measurement Institutes, academia and industry both within and outside Europe to address key metrology challenges and ensure that measurement science meets the future.

## Challenge

Nanoparticles (NPs) are extremely small – less than 100 nm in size. Due to their high surface area, nanoparticles often have increased activity. This has led to their use in a wide range of modern products, including sunscreen, fuel cells, semiconductors, drug and gene delivery vehicles, or as contrast agents for Magnetic Resonance Imaging.

However, a common issue is batch-to-batch variability, with over half of NPs produced for high performance applications failing to meet specifications. Numerous cycles of production and measurement are required to develop reproducible processes.

The nanotechnology sector is also an area where product innovation is developing faster than the techniques required to ensure compliance with regulatory frameworks. This is especially the case for determining the concentration of nanoparticles in suspension – the knowledge of which is required to optimise and reproduce formulations and products. In most cases, this number concentration is not known but is calculated upon the basis of assumptions and mass-balance considerations.

The direct determination of number concentration for nanoscale particles is challenging. Documentary standards need to be developed within the International Organization for Standardisation (ISO) to measure this parameter. A lack of validated measurement protocols, reference materials for calibration or quality control has hindered the establishment of metrological traceability.

## Solution

The [Innanopart](#) project developed and validated a wide range of techniques for accurately measuring nanoparticle number concentrations. In addition, as a world first, gold colloidal nanoparticle reference materials were characterised and validated.

Based upon these results, a VAMAS intercomparison (TWA34, Project 10) was launched using the reference material and the techniques developed. A total of 50 laboratories delivered results for the number concentration of 30 nm gold colloidal nanoparticles. The study identified best practice to improve accuracy by a factor of five. As the need for standardisation in nanoparticle characterisation was marked as an area of high priority, the chair of ISO/TC 229 'Nanotechnologies' asked that the underlying metrology developed in the project be adapted and published as an ISO Technical Report in order to meet ongoing industry and legislative needs.

## Impact

Based upon the work performed in the Innanopart project, in 2019 a new EURAMET project was launched, [ISOCONCur](#), in order to adapt these results into a working ISO Technical Specification.

This was successful, and in November 2023 the new ISO standard was published: "ISO/TS 24672:2023 Nanotechnologies — Guidance on the measurement of nanoparticle number concentration". This document provides an overview of the methods used to determine nanoparticle number concentration in liquid dispersions and aerosols.

Much of the data it contains was derived from the methods

developed in Innanopart including DCS, SAXS, UV-vis, PTA, CPC and spICP-MS, providing information on the use of each technique, along with considerations on sample preparation, advantages and limitations.

The standardised and validated measurements it details will enable the industrial and pharmaceutical industries utilising these particles to demonstrate compliance with EU regulations linked to the definition of nanomaterials (2011/696/EU). It will also help allow the European Chemical Agency (ECHA) to more accurately evaluate the properties of new nanomaterials submitted for authorisation under 'Registration, Evaluation, Authorisation and Restriction of Chemicals' (REACH) legislation (Regulation (EC) 1907/2006).

In addition, the new Technical Report will help contribute to an improved acceptance of nanotechnology and nanotechnology-based products by society and provide a basis for more reliable, efficient and new products with higher performance.

### Developing an ISO technical specification on nanoparticle concentration

In 2019 an outline of an ISO standard on methods to accurately determine nanoparticle concentration was produced and agreed by ISO/TC 229. A second draft was then written and circulated to the ISOCONCur project consortium, ISO TC24/SC4, and experts from the wider stakeholder community. In July 2020 a ballot was held for a new work item on nanoparticle concentration, with 27 countries voting positively with zero "no votes".

In April 2021, after addressing 35 pages of comments, it was re-circulated to experts and an updated version produced and circulated to ISO TC229 JWG2.

In May 2021 it was again updated and circulated to ISO experts, and in June permission was granted by the ISO TC229 JWG2 committee to send the document out for committee draft ballot.

After a final ballot in July 2023 the new ISO Technical specification: "ISO/TS 24672:2023 Nanotechnologies — Guidance on the measurement of nanoparticle number concentration" was published.

As a direct output from Innanopart the BIPM CCQM also launched a key comparison for particle number concentration – the first ever direct comparison of NMI capabilities across the globe in this area.



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[www.euramet.org/18SIP01](http://www.euramet.org/18SIP01)

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