NanoMag European Consortium Survey #3 Standardisation of MNPs

Response statistics

Questions written by Uwe Steinhoff and Oliver Posth, PTB based on Standardisation Work Package Closed on October 30th, 2015

- Had 97 responses but 32 were incomplete
- Can't do response rate because survey sent by consortium members to their contacts
- RadioMag project also made the survey available to its members

Of 65 responses:

75% External contacts18% Consortium members8% Stakeholders

New Contacts (Details from Question 1)

New contacts at universities in: **Brazil, Argentina, Turkey, Norway, Serbia & Portugal**New contacts from two universities from the **USA** and three universities EACH from **France, Belgium & Spain**

Three commercial MNP companies

(Q2) What is the role of your company/institution when you work with MNPs? (Could choose more than one)

81%	Researcher	24%	Applications of MNPs in Technical
44%	Application of MNPs in bio-diagnostics		devices
27%	Manufacturer of MNPs	8%	Environmental protection
27%	Investigation of toxicity	4%	MNP trader
24%	Applications of MNPs in other	3%	End consumer
	research		

(Q3) If your company works with national standards specify the standard title or in-house quality management document.

Choice seems to be ISO standards:

- ISO9001; ISO 14001; ISO 13485; ISO for DLS measurements
- SoPs developed under several EU Projects, including NANoREG guidelines

Or in-house procedures:

- Lab is regularly controlled for the fumehoods/benches & electrical equipment for characterisation of MNPs
- Full characterisation of materials prepared including colloid titulation, specific absorption rate performance under RF fields within a wide frequency and amplitude range
- Use standard magnetometry techniques, magnetogravimetry and Mössbauer effect spectroscopy
- Have to declare the quantities of nanomaterials synthesized and/or handled
- In-house quality management is quite rough; only laboratory procedures and calibration of apparatus against standards are used regularly
- Use requirements and investments for GLP compliancy when offering services for biodistribution studies with MNP labelled cells

(Q4) If your organisation has internal facilities for particle characterisation specify what is defined in your standard (open answer):

- 79% Method of sample preparation for analysis
- 76% Measurement
- 64% Data Evaluation
- 33% Analysis Reporting

(Q5) Are standards playing a role in your communications between manufacturers & customers?

- 42% Yes
- 58% No

(Q6) Do you think that standards can be a valuable argument in a product placement strategy?

96% said "absolutely!"

Summary:

- The use of standards ensures the traceability of the samples and the reproducibility and repeatability of the final products
- Method to compare different types of nanoparticles from different producers
- ❖ Important for security issues when dealing with nanomaterials for health
- Essential in order to make advancements in the field

Quotes:

"Magnetic properties, size distribution, long-term stability should be provided and guaranteed..."
"...save time by supressing sources of experimental error and lack of reproducibility sometimes found with scientific publications where protocols are too vague."

"If an aqueous suspension of NPs, is going to be stored for using in a biomedical application, such things as, standards of concentration, stability, SAR, saturation magnetisation as well as date of expiry must be specified."

One of the negative answers:

"There has to be an added value to us as a producer in addition to such things as reduced scrap or lower cost...Physical characterisation is very seldom a reason for any failure."

(Q7) - (Q9) Availability of standards

- (Q7) 74% would prefer to order MNPs based on standards.
- (Q8) 71% would invest in new techniques based on standards.
- (Q9) 66% are **NOT** aware of national or international standards for MNPs.

(Q10) Which of the following properties of MNPs are good candidates for standardisation? (Could choose more than one)

75%	Iron Content	64%	Chemical Composition
74%	Saturation Magnetisation	61%	Core Size Distribution
66%	M(H) Measurements	60%	AC-susceptibility Measurements
66%	Hydrodynamic Size Distribution	59%	X-Ray Diffraction Patterns

(Q11) What are the three most important properties of MNPs (suspensions) that could be defined in an international standard? (Open answer - these are the most common categories in 172 replies)

- Size & distribution (41 mentions)Saturation magnetisation (20)
- 9% Chemical Composition (16)
- 7% Iron Concentration (12)
- 5% M(H) Measurement (9)
- 4% AC Susceptibility (4)
- 1% Colloidal Stability (2)

(Q12) The current proposal for an ISO norm focuses on the following properties. Please rate each one in order of importance:

Stability is the most important at 82%; Solid Content, Coercivity and Remanence were equally of secondary importance.

(Q13) In which area would you see the highest advantage of a standard for MNPs? (Could choose more than one)

- 70% Manufacturing
- 61% Physical Research
- 56% In-vitro Diagnostics
- 56% Quality Control
- 48% Toxicity Evaluation
- 42% Trade of MNPs
- 18% Environmental Distribution

General Comments on future international standards for MNPs:

- "The application of the ISO standard in the daily practice should be possible without the use of highly sophisticated measurement techniques."
- "RADIOMAG should contribute to the ISO standard in particular regarding the standardization of protocols."
- "If this is done one should have a very clear correlation with the application that is being addressed for such well controlled samples."
- "I think it is important to specify single domain state. I think some denominations like SPIONS are misleading and non-convenient."
- "Global composition is very important, iron content is not sufficient."
- "Distinguish between the overall properties of the suspension (e.g. AC susceptibility and M(H) curve) and the properties of the individual nanoparticles (e.g. size distribution)."
- "Knowing the real shelf life (in terms of preserving the best colloidal stability and magnetic properties) will be a plus."
- "The standard needs to be put together by a wide audience of disciplines."