กันไว้ดีกว่าแก้

Prevention is better than cure:

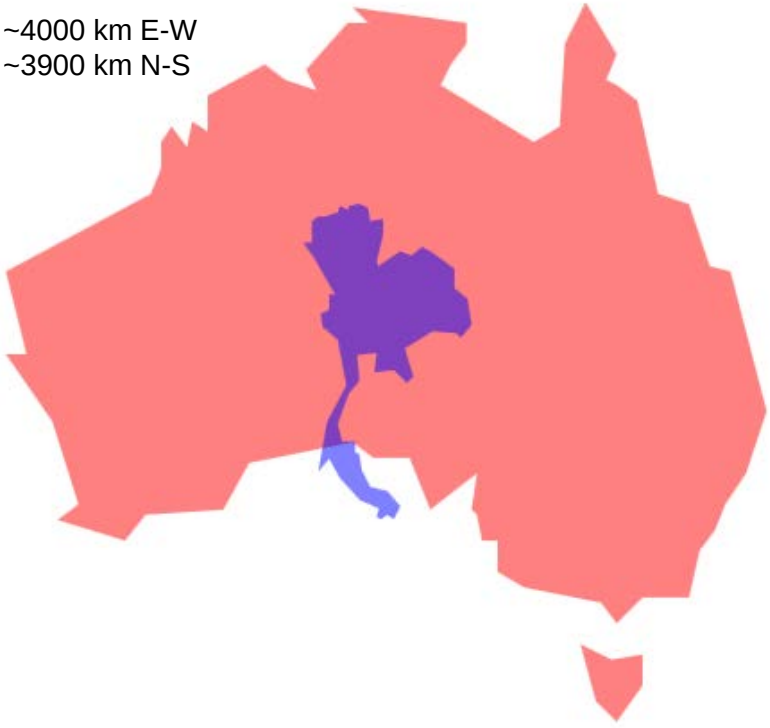
How reliable measurement supports medical, food and water safety in Australia

V. A. Coleman, M. Ballico, R. Iavetz, M. Croft, G. Stevenson, L. Mackay, C. Lim, A. E. Samuel and P. T. H. Fisk

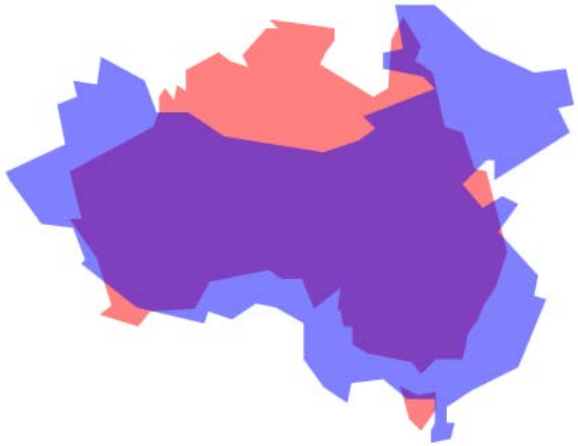
National Measurement Institute Australia

Some Facts about Australia

~4000 km E-W
~3900 km N-S

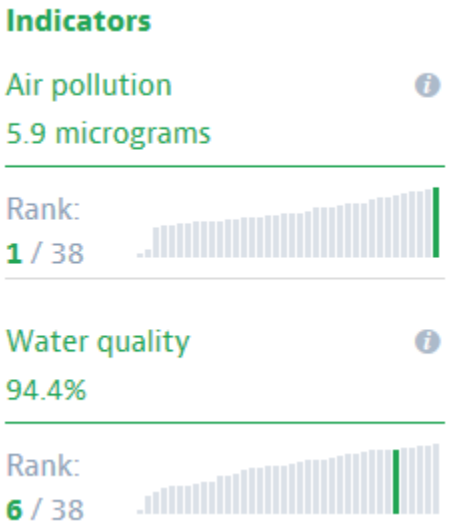


Australia (7,692,024 km²) is **14.99** times as big as Thailand (513,120 km²).



Australia (7,692,024 km²) is **0.8** times as big as China (9,596,961 km²).

Population: 24 million people
Life expectancy: 82.10 years
Median age: 37.3 years
2011-12 health $140.2 billion (9.5% of GDP)
Health expenditure growing faster than population growth.



OECD Better Life Index

mapfight.appspot.comv

NMIA's Role

NMIA is responsible under the *National Measurement Act (1960)* for Australia's top-level infrastructure for physical, chemical, biological and legal measurement.

Ensure that measurements in Australia can be fit-for-purpose, accurate and accepted internationally
Represent Australia under international measurement treaties intercomparisons, mutual recognition
Contribute measurement expertise to policy development
Manage Australia's national trade measurement system (value ~$400B p.a.)
Support the adoption of measurement technologies in real-world situations

Support Australian productivity and innovation

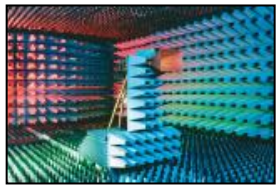













Some Facts about NMIA

Part of Commonwealth Department of Industry Innovation and Science

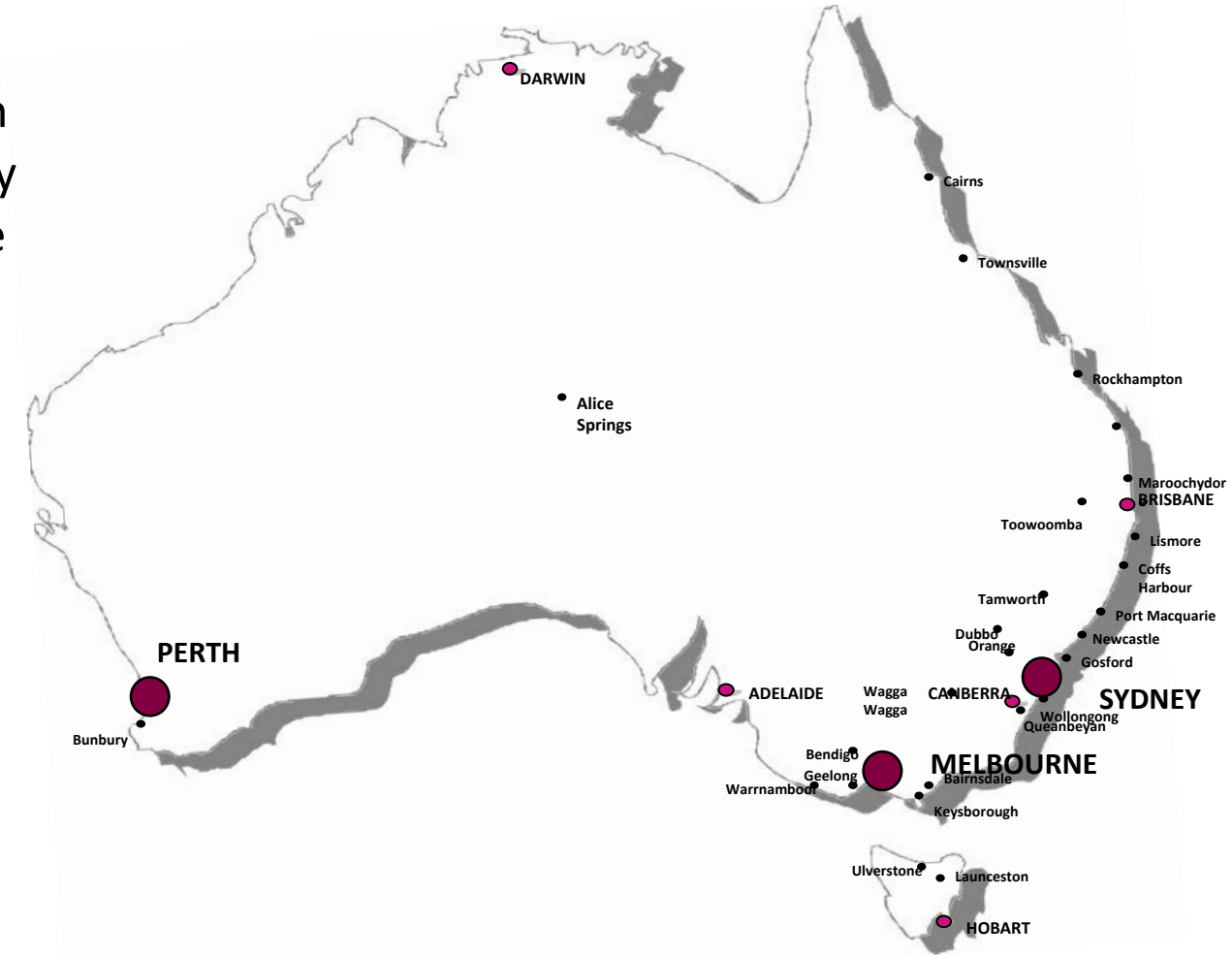
~350 Staff

~$80M Expenditure

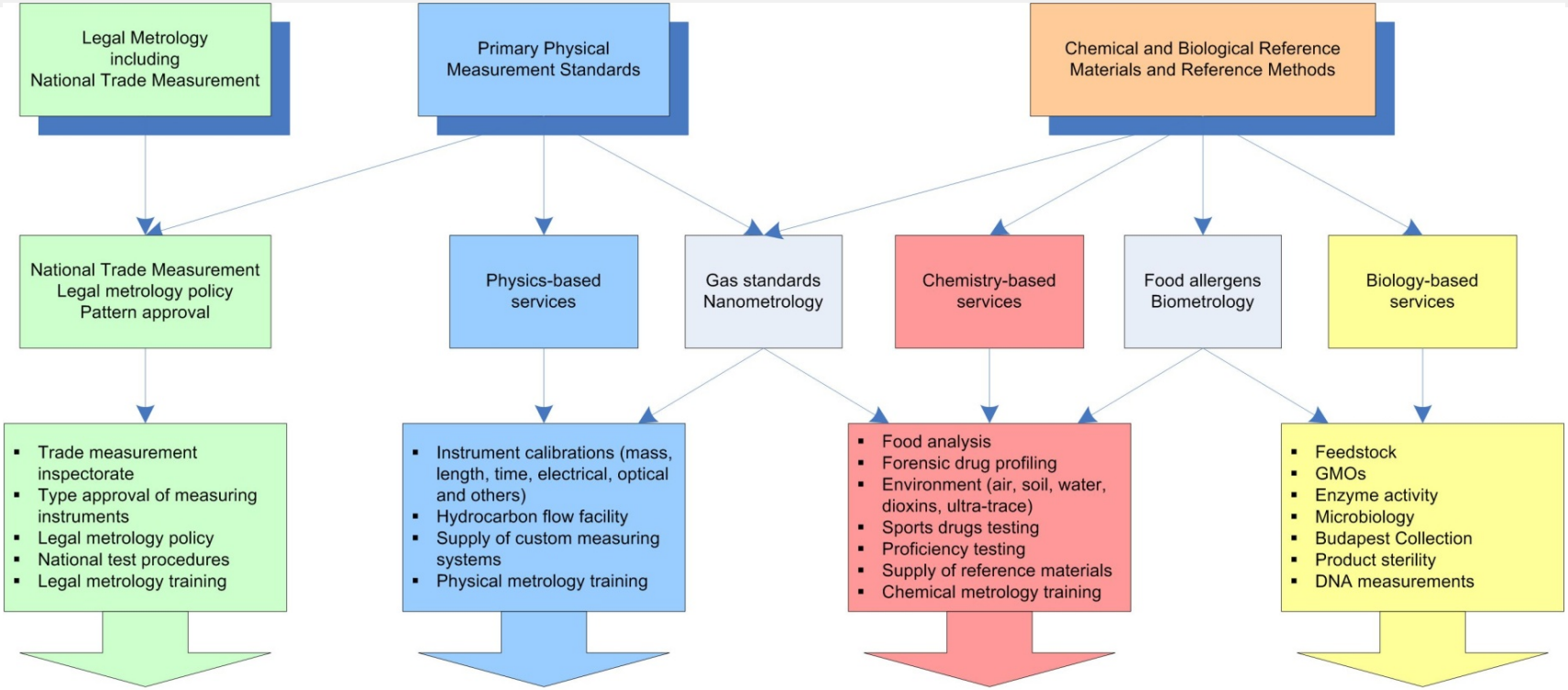
~$35M Revenue
(fee for service)

~$45M Appropriation

~25 Sites



Focussing NMI to address Australia's Grand Challenges – the Sector Approach



NMIA's sector approach - Looking from the outside in

- Small cross-technical project teams research an industry sector in depth.
- Think about issues from the perspective of stakeholders, rather than from the traditional metrology approach.
- Develop an understanding of drivers, regulation, other providers, cost structures etc. ……
- Use this knowledge to "break-through" barriers to engage with industry.
- Build "NMI" brand recognition.

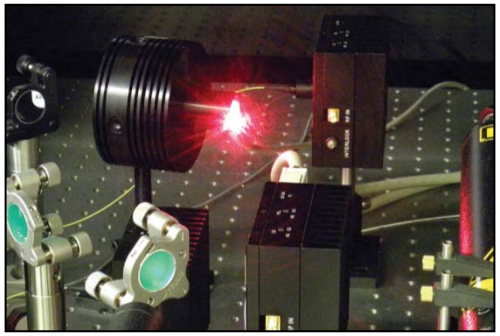
Sectors:

Health, Energy, Environment, Food

NMIA supporting safety – 3 examples

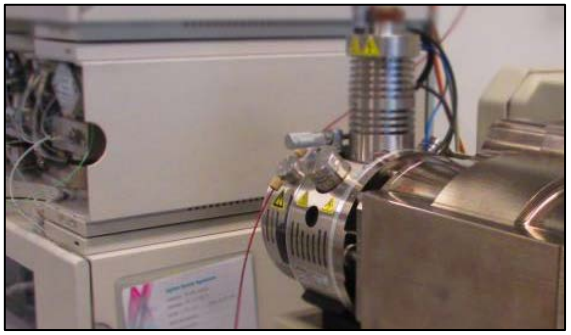
Metrology for…

…medical devices



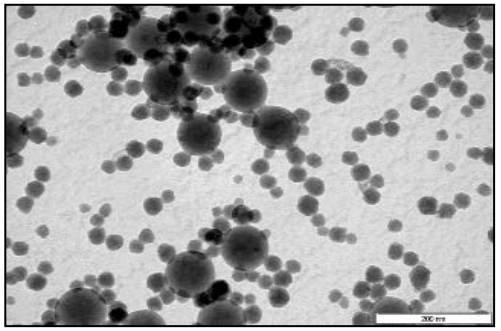
Laser power calibration for medical lasers

…addressing public health issues



Development of methods for PFOS/PFOA testing

…the future



Nanometrology to support nanotechnology

NMIA supporting safety – Medical Devices

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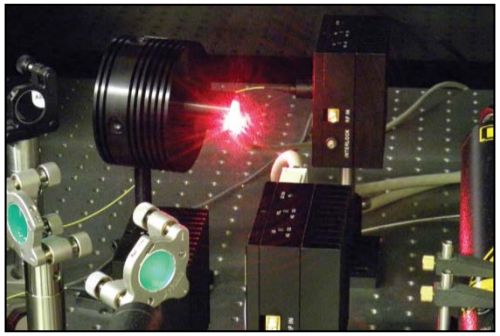

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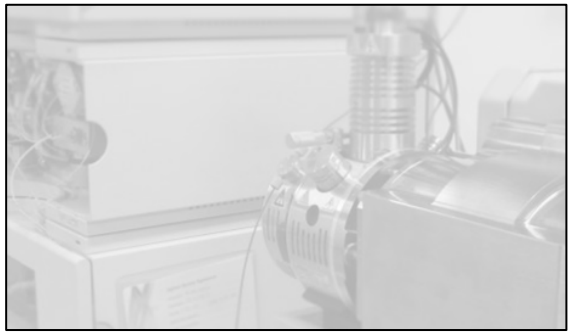

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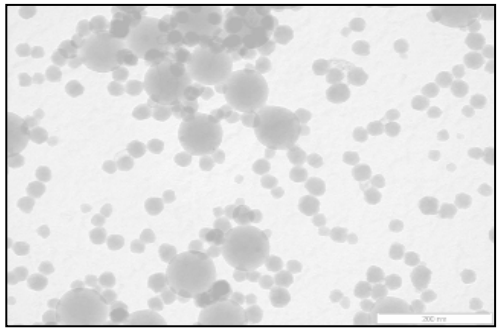
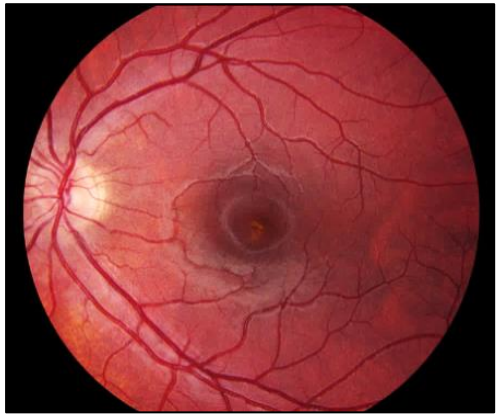


Nanometrology to support nanotechnology

Medical lasers - What's the problem?

- Lasers are used in a variety of applications in the medical industry (Surgery, eye surgery, dental, tattoo removal, hair growth, hair removal, skin/anti-aging treatments, aesthetics and therapeutics…).
- Rapidly growing area (economically) with fast developing/evolving technology.
- Laser power should be calibrated to ensure safe application on patients (i.e. so that ‘dose’ could be accuratley determined without patient harm.

The Australian Industry could benefit from metrology, and NMIA could potentially help…



Medical lasers – Tailoring a solution (the sector approach)

Key principles ("Marketing" Approach)

- Understand the customer: Anticipate their needs & develop only what they really need, not what we think they need.
- Understand the market.
- Offer a value proposition.

How:

- Coordinated and planned engagement strategy.
- Attended many industry trade shows and medical conferences.
- Speak to users, suppliers, manufacturers, regulators etc.

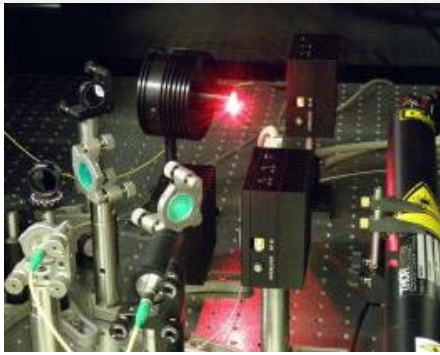
What did we find ?

- The regulatory environment is complicated.
- They have many competing issues to manage, most of which are more important than metrology.
- Different areas: different needs
  - Tattoo removal: (class-4 pulsed lasers!)
    - *Need advice on laser safety and classification*
  - Suppliers of Ophthalmic lasers
    - *Need fast turnaround laser calorimeter calibration.*

Medical lasers –
Tailoring a solution *- a fine tuned offering*

What did we offer

- Expanded our consultancy services e.g. laser classification
- Calibration service for field service engineer laser calorimeters:
  - Carefully chose wavelengths, power range to meet specific key users.
  - *Carefully structured NMI's services to offer 1 week turnaround.*
  - Developed the service around the expected price point.



However… more effort needed to ensure uptake

- Follow up calling of suppliers, users, regulators
- Attended same conferences again to ensure that NMI is seen as a reliable
- Make sure offering remains relevant

Medical lasers – a foot in the door

- Calibrations now rapidly growing
- Engagement with major equipment suppliers.
- "NMI brand" recognition in the area: now spreading … a lot more "I know of NMI, you were at……"
- Volume of non-calibration requests for advice, consultancy and non-standard R&D type testing now growing.

- The higher engagement and recognition of the value of metrology and of NMI now has the regulators and professional associations approaching NMI, rather than NMI asking to be "let in".
- Requests for testing in related areas now growing. =>> opportunities for growing NMI's R&D base: planning to expand to pulsed lasers, higher powers and other wavelengths

Medical lasers –
What went wrong, what we learned and what's next

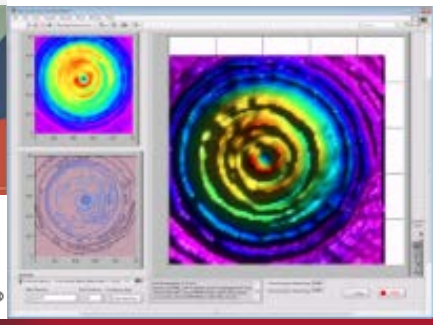
We had tried before (2000s) and failed, because:

- Unregulated market: *"calibration and testing is not compulsory so why do it*?"
- We didn't understand their "language" and "their" real needs.
- Global market: they found their own workaround "solutions"
- We really didn't understand who "they" were & who-did-what in the industry:
  each laser user field was siloed and with specific concerns and issues
  users, suppliers, agents, servicers, professional associations all have different roles

The key was really engagement and approaching the issue from the perspective of the stakeholder

Apply what we learned to break-through into other areas!

- Ultrasound area (another "false start" areas from the 2000's)
  physiotherapy, sonography
- Audiometry and Acoustic mastoids
- ….
- …



NMIA supporting safety – Public health issues

Metrology for…

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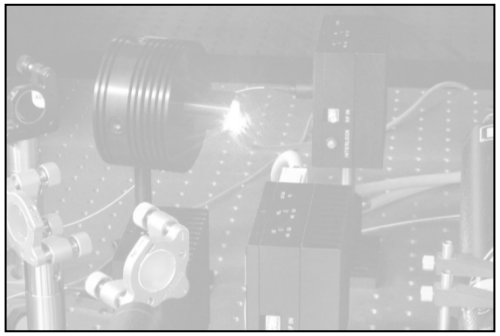

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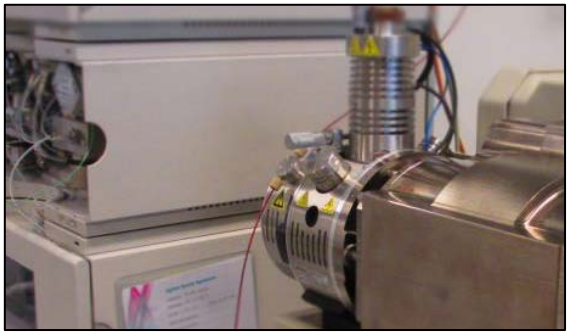

Development of methods for PFOS/PFOA testing

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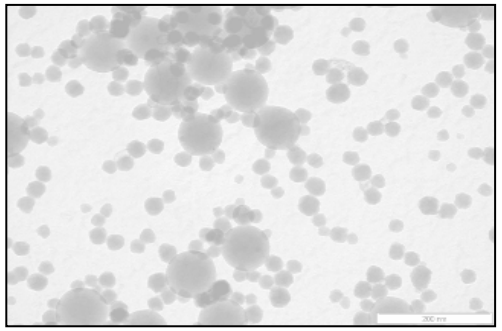
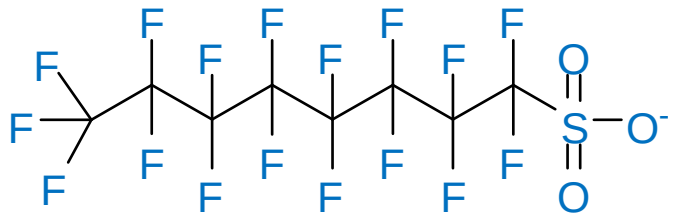
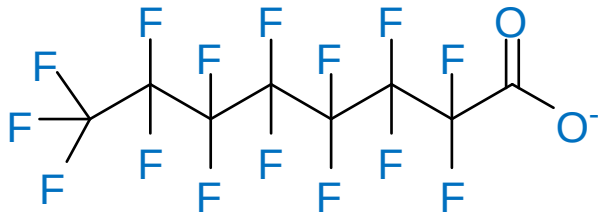


Nanometrology to support nanotechnology

Perfluoroalkyl compounds (PFCs) PFOS/PFOA
A public health issue

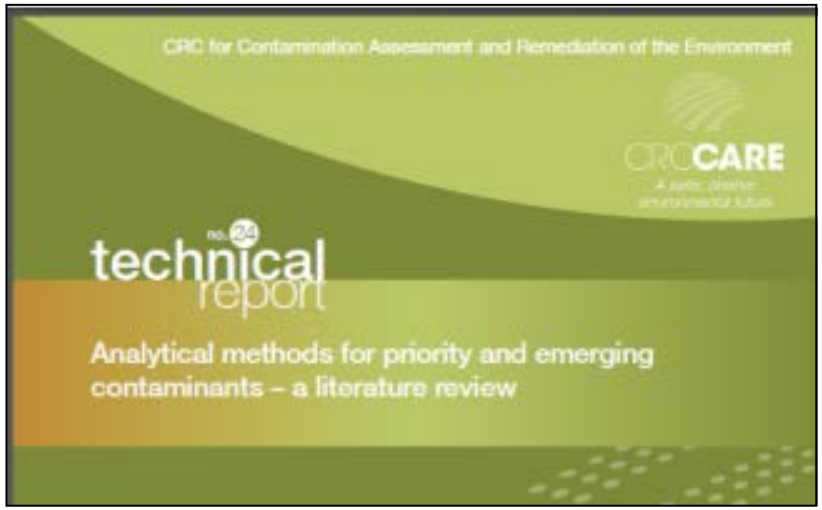
PFOS 

 PFOA

- Common synthetic fluorinated chemicals
- Highly resistant to degradation, persistent in environment, bio-accumulate, toxic to humans and wildlife, widely detected
- PFOS and its salts listed as Persistent Organic Pollutant (POP) under the Stockholm Convention (2010).
- PFOA proposed for listing by EU (Oct 2015)
- Information on PFOS/PFOA levels in Australia and their impact on the environment is limited
- PFC's not manufactured in Australia however a number of contaminated sites identified
  - legacy of the use of aqueous film-forming foams (AFFFs)
  - airports, emergency and training sites

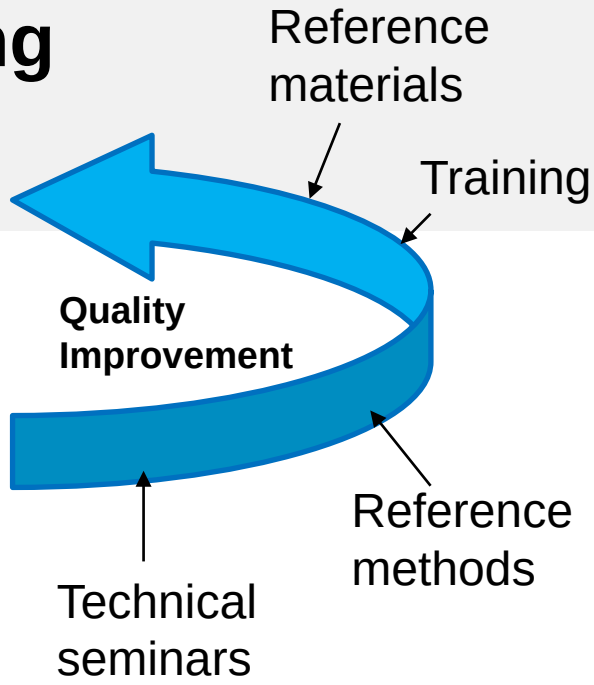
Understanding the PFOS/PFOA measurement capability in Australia

- Identified issues through literature review
- Suitable published analytical methods available for PFOS, PFOA in soil and water, standard methods for water only
- Limited commercial analytical capability in Australia
- BUT no Australian infrastructure to ensure quality and comparability of measurements (in particular no suitable matrix reference materials or Australian proficiency testing)



2013 CRC CARE literature review (NMI)

Development of Proficiency Testing to enhance Australia's capacity



- Allows 'snapshot' performance comparison of different labs performance at a particular time
- Educational emphasis vital - feedback to participants

Aim:

- 'Improved PFOS/PFOA Analysis through Proficiency Testing and Education'
  - 1st known Australian proficiency study for PFOS/PFOA
  - Collaboration between NMIA and EPA Victoria
  - Consensus values used rather than develop reference method and material
  - Informal discussion with participants held
  - Workshop for wider end-user feedback held

Well-designed Study Samples

Factors to consider in selecting levels:

- Consistent with real-world levels to have relevance for regulators
- Results from > 6 labs to be statistically significant, level must be above lab limit of reporting
- Practicality of dilution from initial concentrations

Analyte	Matrix	Level (µg/L)	Source
PFOS	Water	0.3	UK Public Health Guideline limits
PFOS	Marine Water	0.00053	Netherlands
PFOS	Fresh Water	0.00065	US, Netherlands
PFOS	Drinking Water	0.3	USA/Minnesota Department of Health
PFOA	Water	10	UK Public Health Guideline limits
PFOA	Drinking Water	0.5	USA/Minnesota Department of Health
PFOA	Drinking Water	0.04	USA/New Jersey
PFOA	Drinking Water	0.02	USA/Nth Carolina
Analyte	**Matrix**	**Level (µg/kg)**	**Source**
PFOS	Residential Soil	6000	USEPA
PFOA	Residential Soil	16000	USEPA

Study samples:

- 2 soil samples, 2 water samples
- 1 incurred (contaminated field sample) & 1 spiked (uncontaminated starting material) for each matrix
- Special packaging required to avoid Teflon contamination

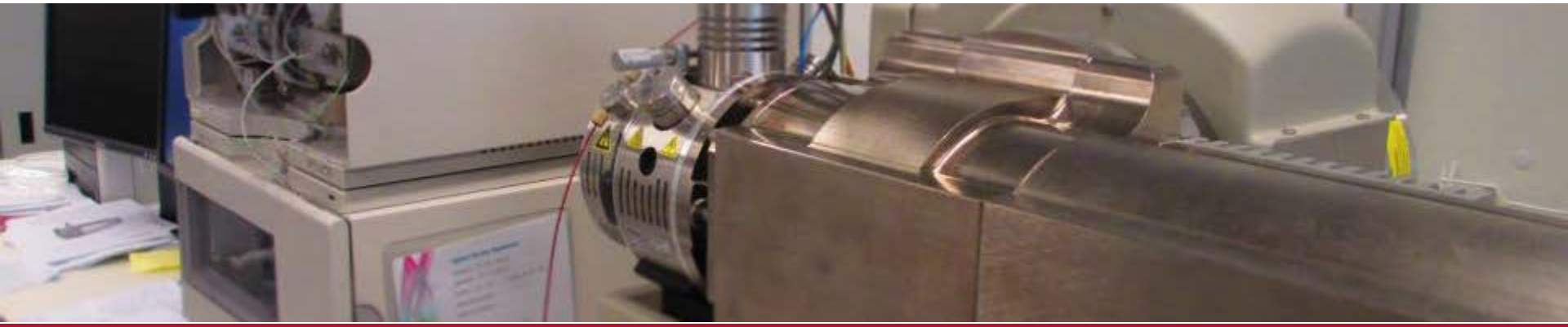
NMIA Analytical Methodology

Laboratory techniques

- ^{13}C labelled PFOS and PFOA added to sample before extraction to allow quantification
- PFOA and linear PFOS standards (Wellington Laboratories) used to create calibration standards
- Soils: solvent extraction and saponification, tumbling overnight
- Waters: extraction by solid phase extraction (SPE), elution with methanol

Instrumental technique

- Liquid Chromatography Tandem Mass Spectrometry (LCMSMS)
- At least two mass transitions monitored for each compound



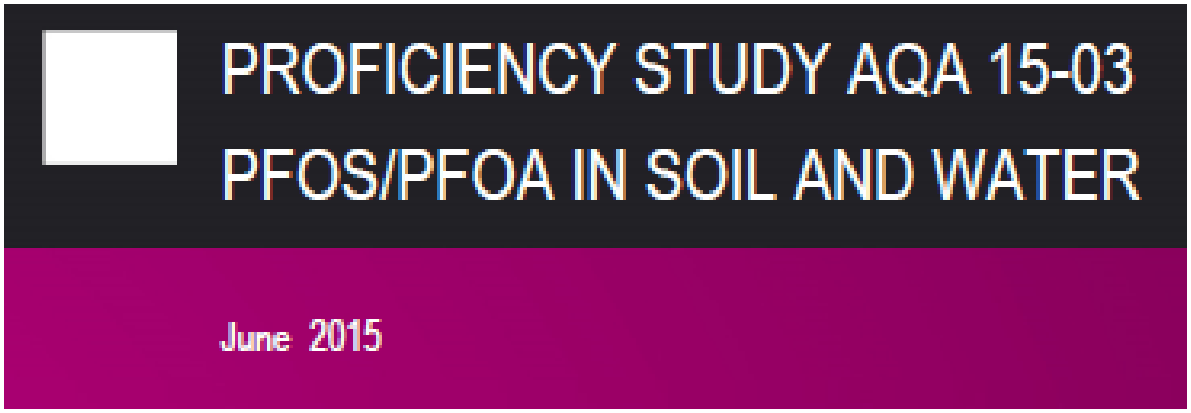
Study Report

Participants

- 11 laboratories registered, 10 submitted results
- Asked to report PFOA, linear PFOS, and total PFOS (quantified as linear)
- Issue: this instruction required some participants deviate from their normal test method and was not interpreted consistently

Overall performance

- Small number of participants meant that results could not be correlated with specific methods
- Similar spread of results compared to established pesticide proficiency studies that have been running for many years



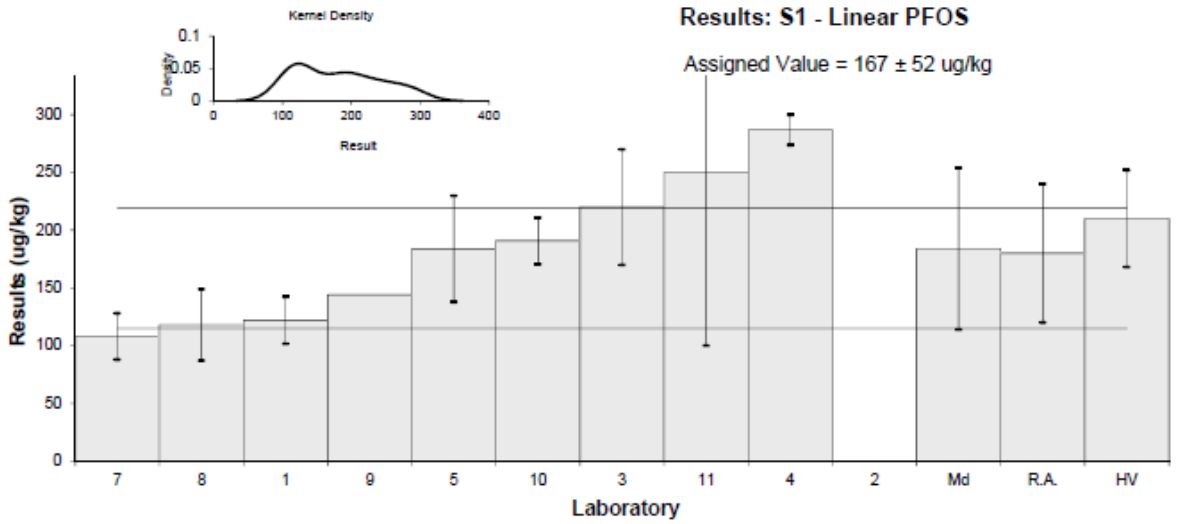
Study Report

PROFICIENCY STUDY AQA 15-03
PFOS/PFOA IN SOIL AND WATER

June 2015

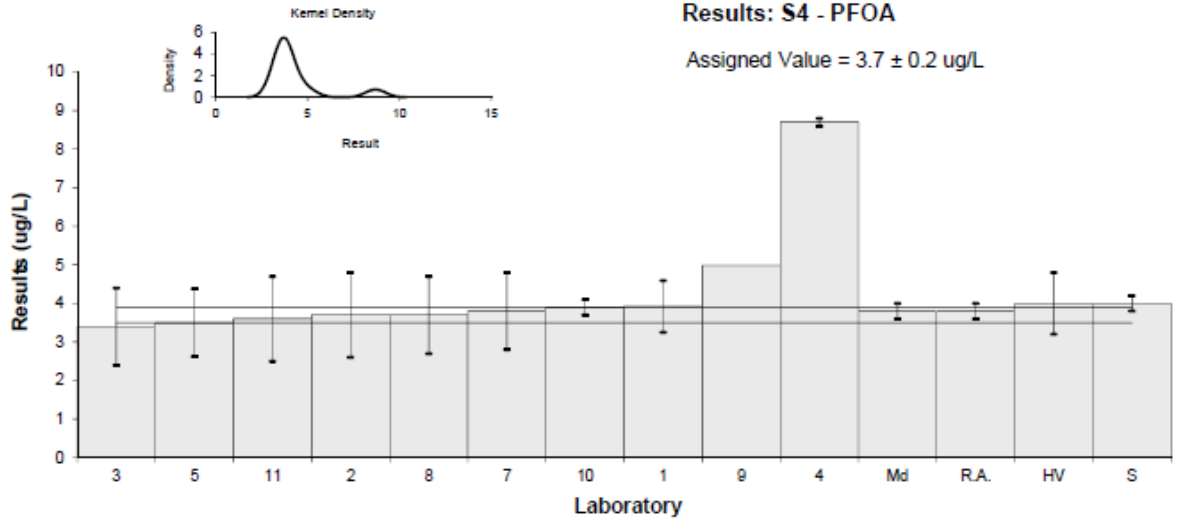
Linear PFOS in incurred soil

Assigned Value:
167 ± 52 ug/kg



PFOA in spiked water

Assigned Value:
3.7 ± 0.2 ug/L)



Participants and End User workshops

Participants Workshop July 2015

- Discussion of issues related study and raised some technical analysis points
- Concern about the level of PFOS/PFOA in the incurred water not representing contaminated site sample
- The use of linear vs mixed (linear + branched) PFOS was raised as this may cause differences in quantification
- Use of the term ‘isotope dilution’ and the use of ^{13}C labelled standards

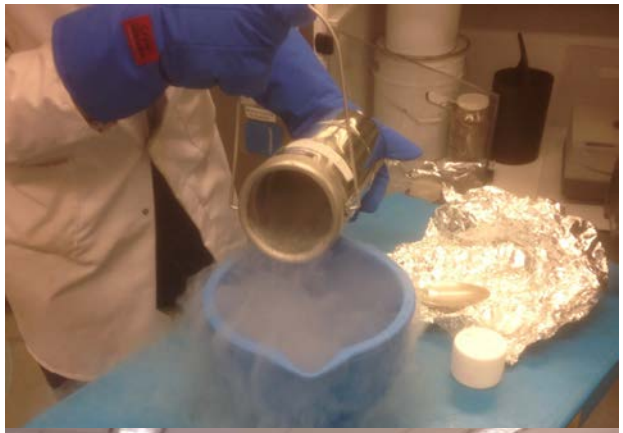
End User video conference workshop August 2015

- Attended by 44 consultants, regulators and laboratory analysts across six NMIA locations
- Suggestions for further investigation
  - Conduct more PFOS/PFOA proficiency studies using concentrations typical of both environmental levels and contaminated sites
  - Introduce proficiency studies on other chemicals restricted by the Stockholm convention, e.g. PBDEs

Next Steps

Proficiency Test - Round two

- Currently in preparation
  - Water, soil, biota - 6 samples
  - one incurred sample and one spiked sample for each matrix
  - investigation of extraction efficiency using the different methodology
- Address issues raised in first study related to calibration standards
- 26 participants from at least 10 countries (Asia, Europe, North America)
  - Reporting limits vary depending on capability in the different countries:
    - Water: 0.0002 - 2 µg/L
    - Soil: 0.08 - 10 µg/kg
    - Fish: 0.009 - 100 µg/kg
- Sample dispatch imminent
- Study to be completed in August 2016



NMIA supporting safety – Future technologies

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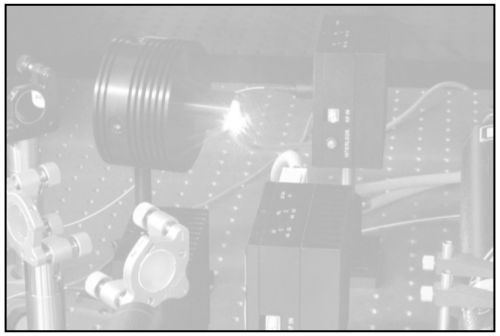

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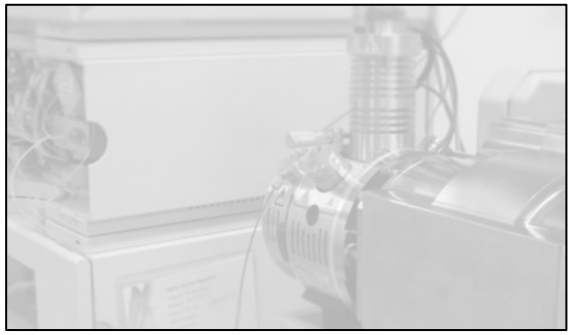

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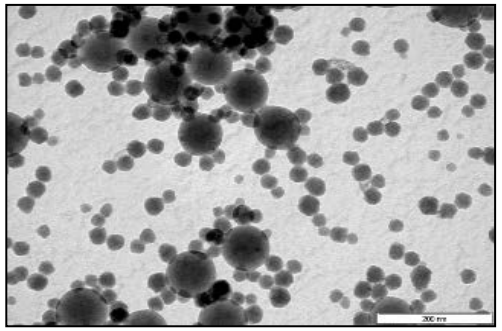
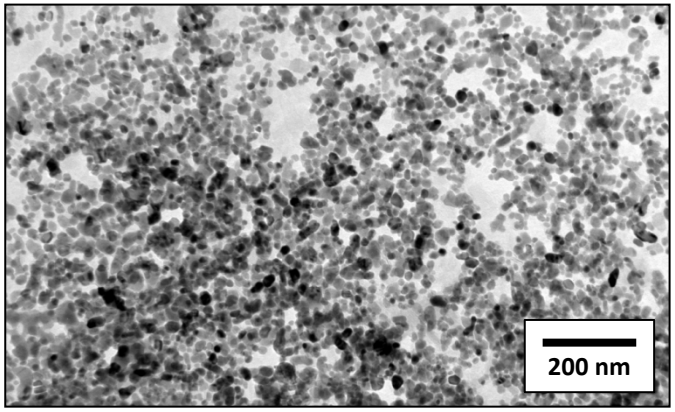


Nanometrology to support nanotechnology

Future technologies
Personalised medicine, new technologies

Example: Nanomedicine

Challenge: developing measurement methodology for characterisation of nanomaterials in matrices relevant to medical applications, i.e., body fluids, cells, tissue, and in nano-enabled medical products



Transmission electron micrograph of ZnO nanoparticles in a commercial sunscreen product

Why NMIA?
"One-stop shop" technical resource

Australian Government

Department of Health
National Industrial Chemicals
Notification and Assessment Scheme

NICNAS working definition for 'industrial nanomaterial'

At pres
for regu

The NIC

"...indus
compos
that is
surface

nally produced, manufactured or engineered to have unique p
that is a size range typically between 1 nm and 100 nm, and
r three dimensions at the nanoscale) or is nanostructured (i.e.
cale)"

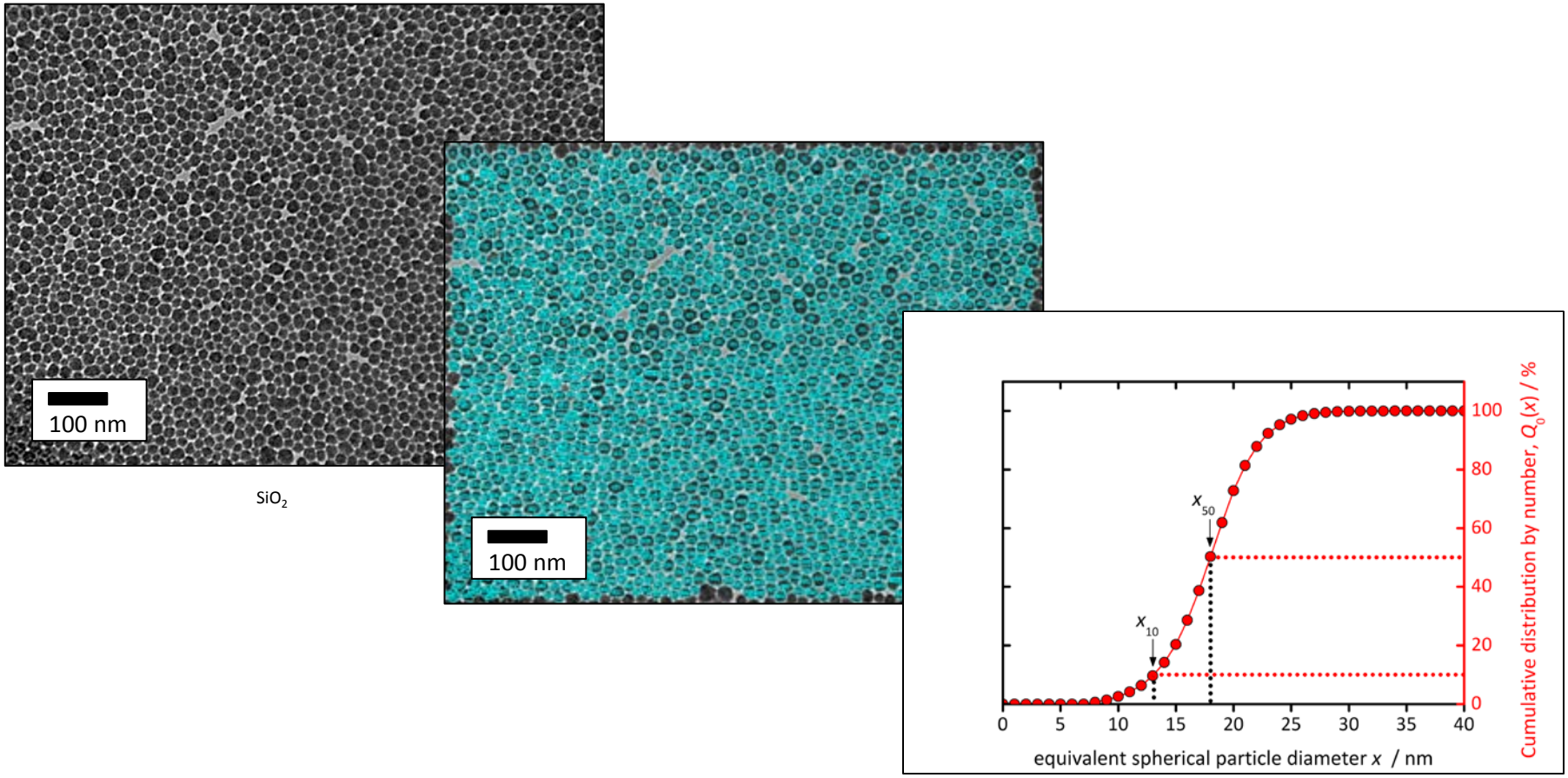
Notes t

- intentionally produced, manufactured or engineered materials are distinct from accidentally produced materials
-
-
-

material includes 10% or more number of particles that meet
es, intentionally produced) NICNAS will consider this to be a n

properties, intentionally produced) NICNAS will consider this to be a nanomaterial.

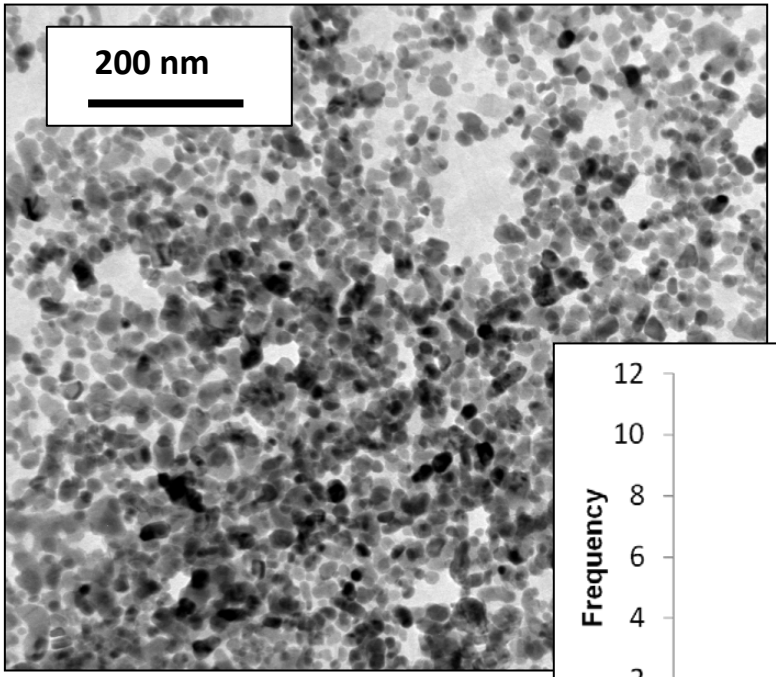
Why NMIA?
“One-stop shop” technical resource



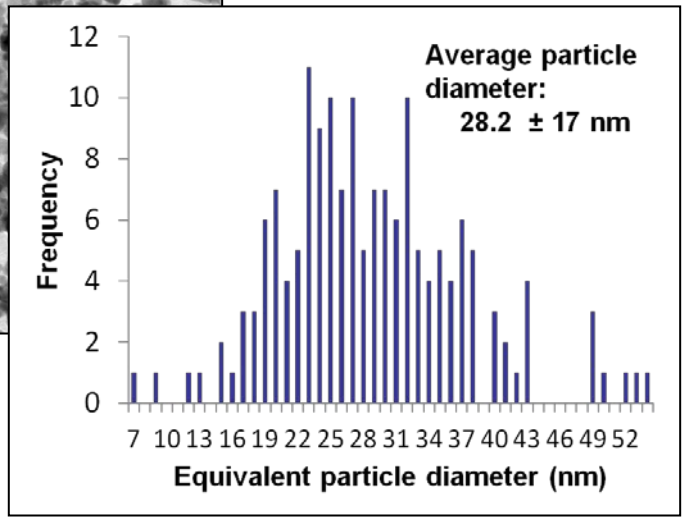
Example:
Nanomaterials in sunscreen

NMIA developed practical methods or nanoparticle sizing in sunscreen products and is working on complementing sizing with measurement of elemental composition.

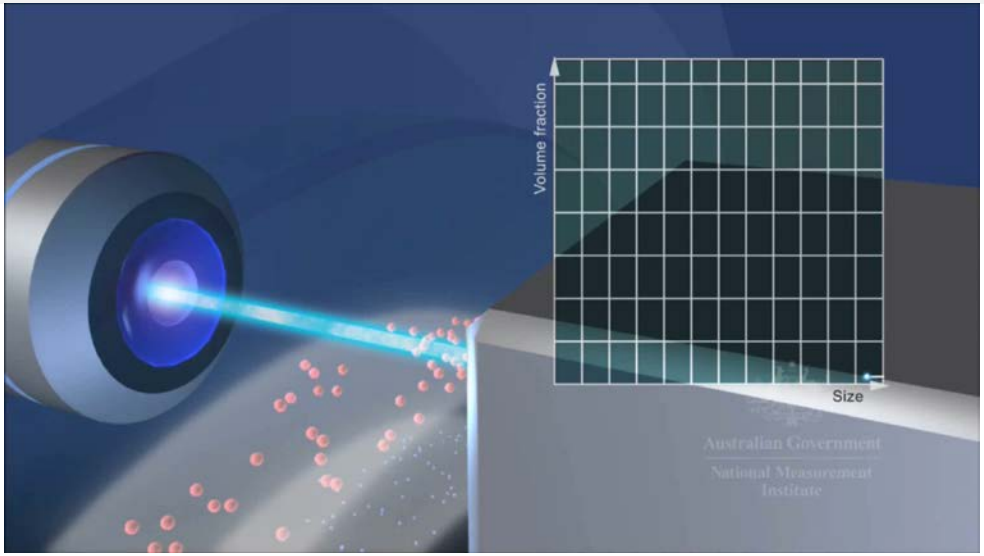
	Population 1 (Primaries) Mean
Sample A	25 nm
Sample B	24 nm
Sample C	31 nm
Sample D	32 nm
Sample E	35 nm
Sample F	259 nm



Sample C: ZnO (20 % by wt)

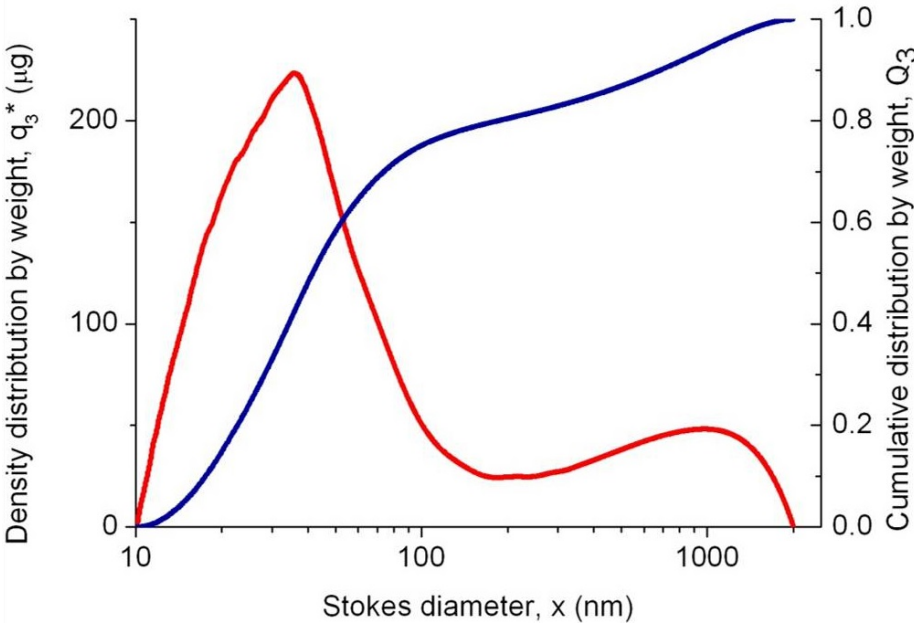


Example:
Nanomaterials in sunscreen – bench top methods



Separation of particles from formulation and measurement by bench top methods such as Differential centrifugal sedimentation.

Validate method by comparison with results From sunscreen.



Concluding thoughts

Measurement and metrology:

- Supports safety, regulation
- Underpins large number of documentary standards
- Helps ensure efficacy, safety and quality of tests and devices
- Assists in responsibly translating new technologies into industrial use.

To ensure our stakeholders are able to get the most benefit out of metrology, it is critical to see the problem through their eyes. (Engage , engage, engage…)

Ultimately, the whole economy benefits by raised awareness and increased capability

This leads to a safer environment for all Australians

Thank you for your attention!

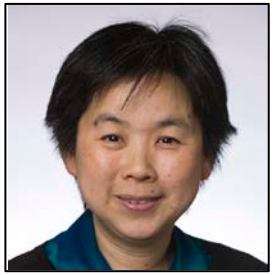

M.B.


R.I.


M.C.


G.S.


L.M.


C.L.

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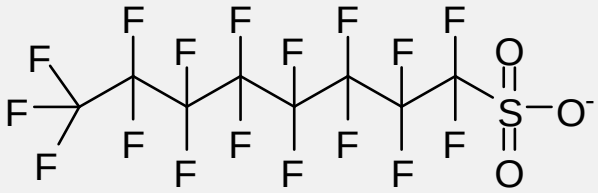
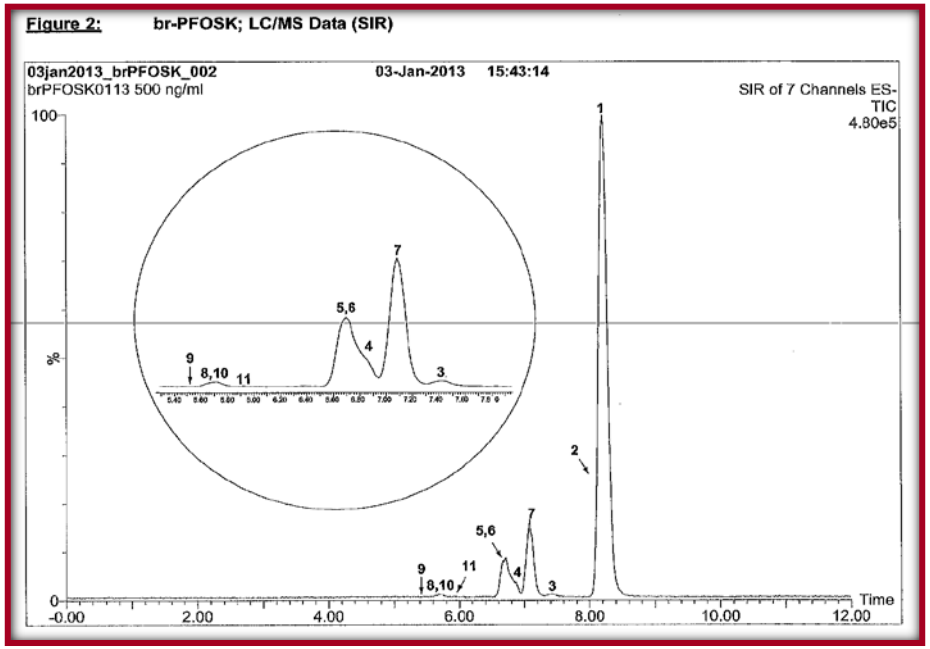
PFOS branched isomers



Calibration

- Commercial PFOS products contain a mixture of linear and branched PFOS, ratio dependent on the production process
- Branched isomers are therefore present in environmental samples
- To keep the first study simple, participants were requested to report linear PFOS and total PFOS (quantified as linear PFOS). This allows results obtained using different PFOS standards to be compared
- The different instrument response factors of the isomers can affect accuracy if only using linear PFOS standards, the magnitude depends on the composition of the isomers in the environmental sample



Production of Samples

Soil Samples

- Incurred soil collected from site contaminated with AFFF
- Clean soil analysed to confirm absence of PFOS/PFOA
- Air dried in fume cupboard for several days, foreign materials removed
- Tumbled, ground using cross beater mill. Ground material combined in V-blender
- Clean soil spiked with PFOS/PFOA standards diluted in solvent, solvent removed by evaporation
- Mixed again and dispensed into tubes for dispatch

Water Samples

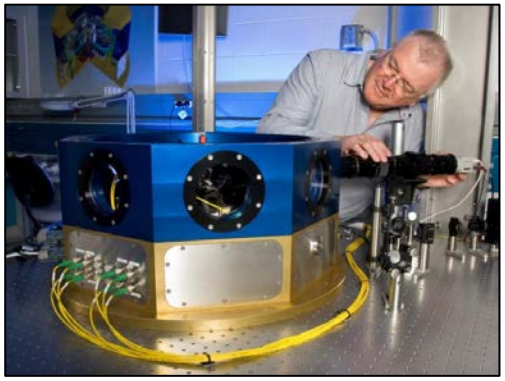
- Incurred water collected from Homebush Bay in Sydney, site of historical industrial contamination, but not known for PFOS production
- Clean water produced using Milli-Q de-ionisation and filtration system
- Clean water spiked with linear PFOS/PFOA standard solution in methanol
- Both thoroughly mixed by stirring then dispensed into HDPE bottles using automated system

End User workshop

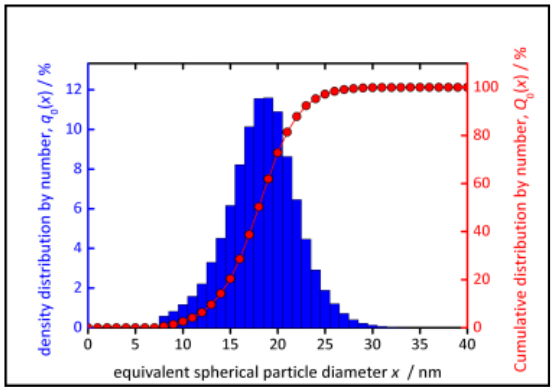
End User video conference workshop August 2015

- Suggestions for further investigation (cont)
  - Expand proficiency studies to consider related compounds, in particular potential degradation products and newer fluorochemicals developed as replacements for PFOS/PFOA. Eg PFBA and short-chain PFCs, the fluorotelomers, 6:2 FTS and 8:2 FTS
  - Investigate the impact of differences in field sampling methodologies and laboratory methods and equipment
  - Investigate the major contributors to the estimated measurement uncertainty by different laboratories for PFOS/PFOA
  - Investigate and quantify the impact of using linear vs. mixed (linear plus branched) standards for PFOS.
    - This investigation currently being undertaken at NMIA using individual branched standards and NIST reference materials

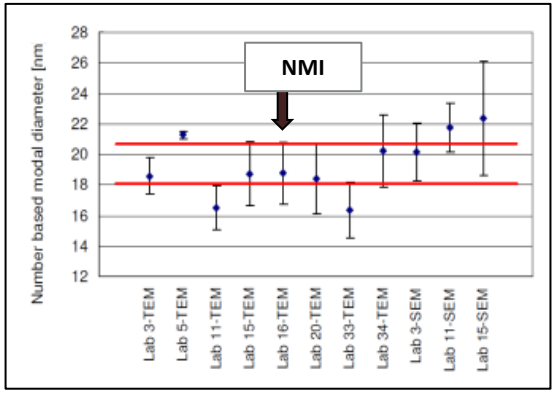
What we do:
Trusted measurements for nanotechnology



Primary standard development

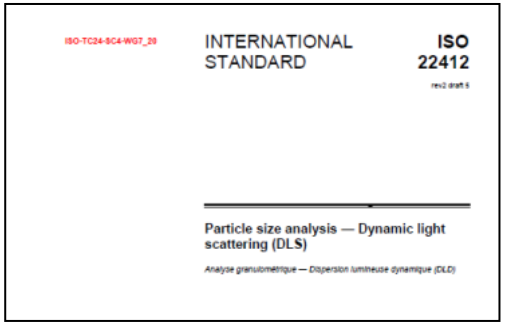


Measurement services/advice



Certification Report EUR 24620 EN for ERM®-FD100, EU (2011)

International acceptance



Standards development

R&D

Promote best practice