Laboratory Medicine Standards:
An update and how you can contribute
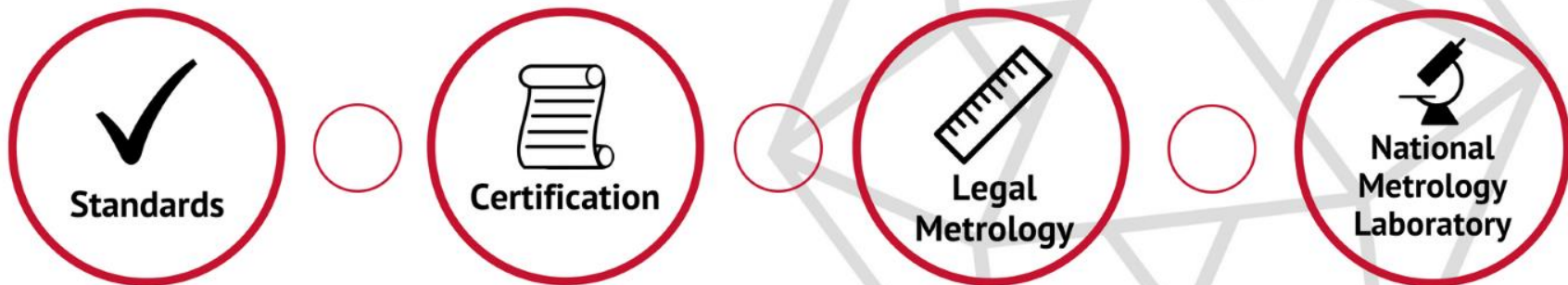## IEQAS Annual conference

Linda Hendy
Standard Officer
NSAI Standard development.
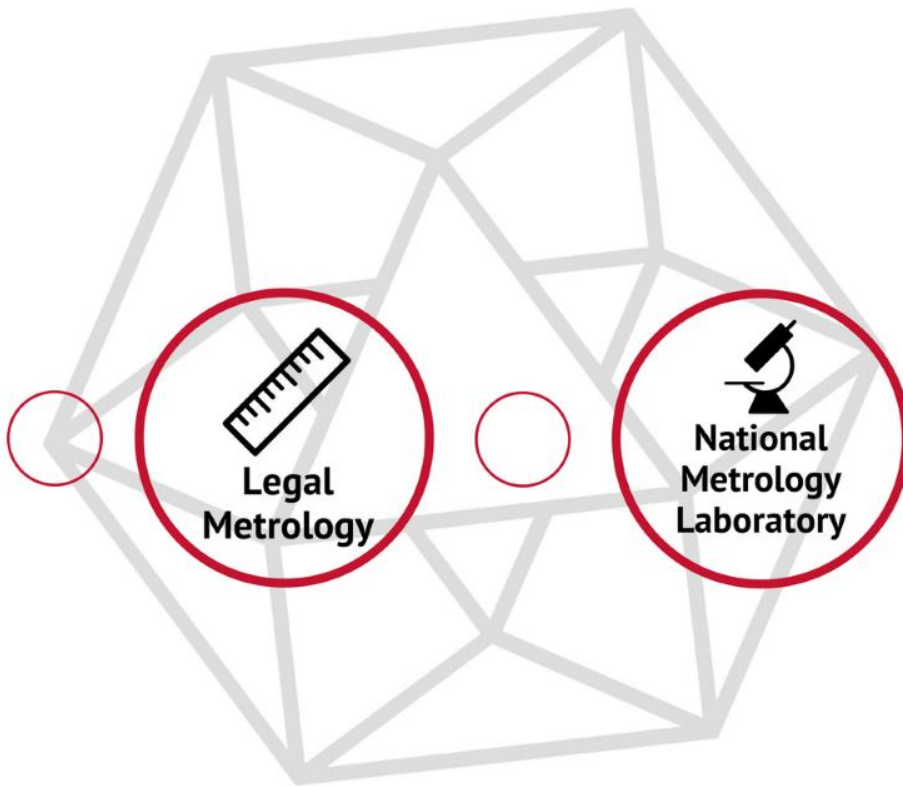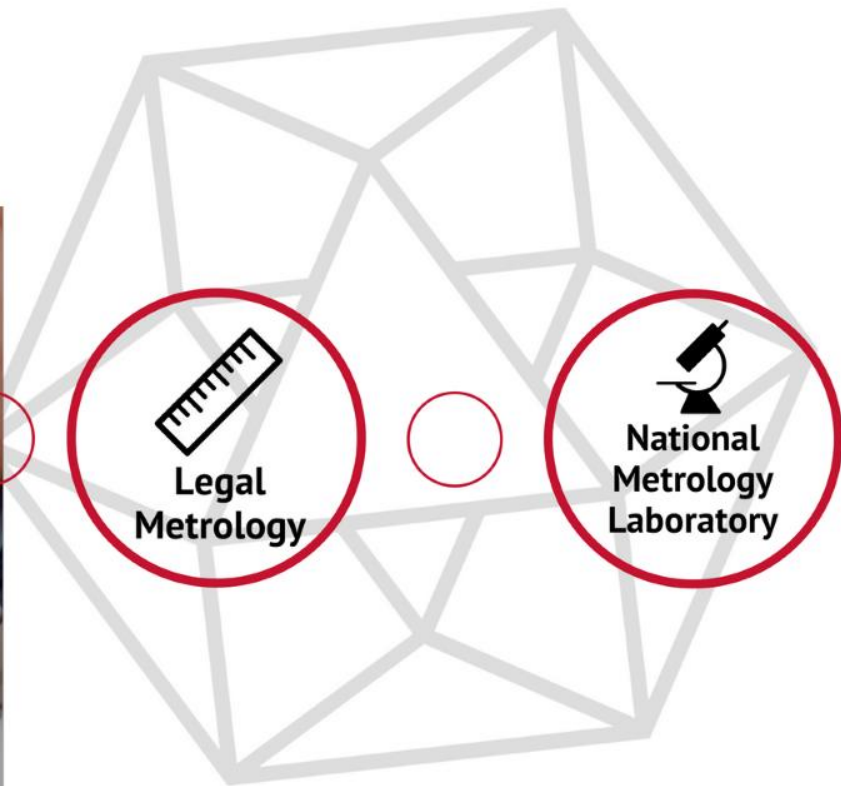4th Oct, 2018.

NSAI

About NSAI

Four main divisions

Standards

Certification

Legal Metrology

National Metrology Laboratory

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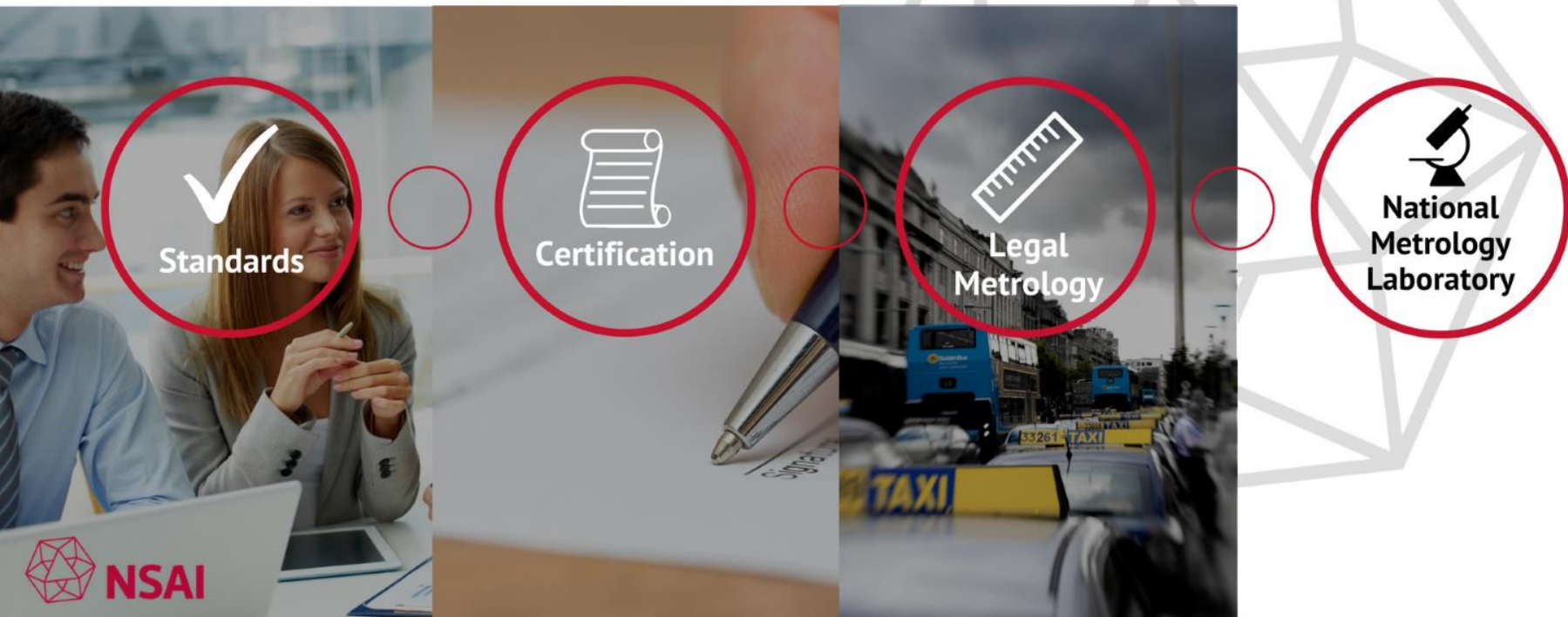
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What is a Standard

A Standard:

- Specifies   requirements
- Prescribes   methods
- Gives   recommendations
- Offers   guidance

What is a Standard

- voluntary in application
- established by all interest parties
- approved by a recognized body
- intended for common and repeated use

Irish Standard
I.S. EN ISO 15189:2012

Medical laboratories - Requirements for quality and competence (ISO 15189:2012, Corrected version 2014-08-15)

International Standard Organizations

ISO - International Organization for Standardization

Technical, Services, Energy, Healthcare, Food…

IEC - International Electrotechnical Commission

Electricity and Electrotechnical

ITU - International Telecommunications Union

Electronic Communications

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European Standard Organizations (ESO's)

CEN - European Committee for Standardization

Technical, Services, Energy, Healthcare, Food…

CENELEC - European Committee for Electrotechnical Standardization

Electricity and Electrotechnical

ETSI - European Telecommunications Standards Institute

Electronic Communications

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Types of Deliverables

| Type of Deliverable	Objective/content
European Standard	Standard adopted by CEN-CENELEC with an obligation of implementation as an identical national standard and withdrawal of conflicting national standards "Harmonised Standard" is a term used in Regulation (EU) No 1025/2012 of the European Parliament and of the Council, meaning a European Standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation
Technical Specification	Document adopted by CEN-CENELEC for which there is the future possibility of agreement on a European Standard, but for which at present: • the required support for approval as a European Standard cannot be obtained, • there is doubt on whether consensus has been achieved, • the subject matter is still under technical development, or
Technical Report	Document adopted by CEN-CENELEC containing informative material not suitable to be published as a European Standard or a Technical Specification e.g. data on the "state-of-the art" in relation to national standards on a particular subject, data obtained from a survey carried out among the CEN-CENELEC, members, data on work in other organizations.
CEN-CENELEC Workshop Agreement	CEN-CENELEC document, developed by a Workshop, which reflects an agreement between identified individuals and organizations responsible for its contents

Standard development CEN

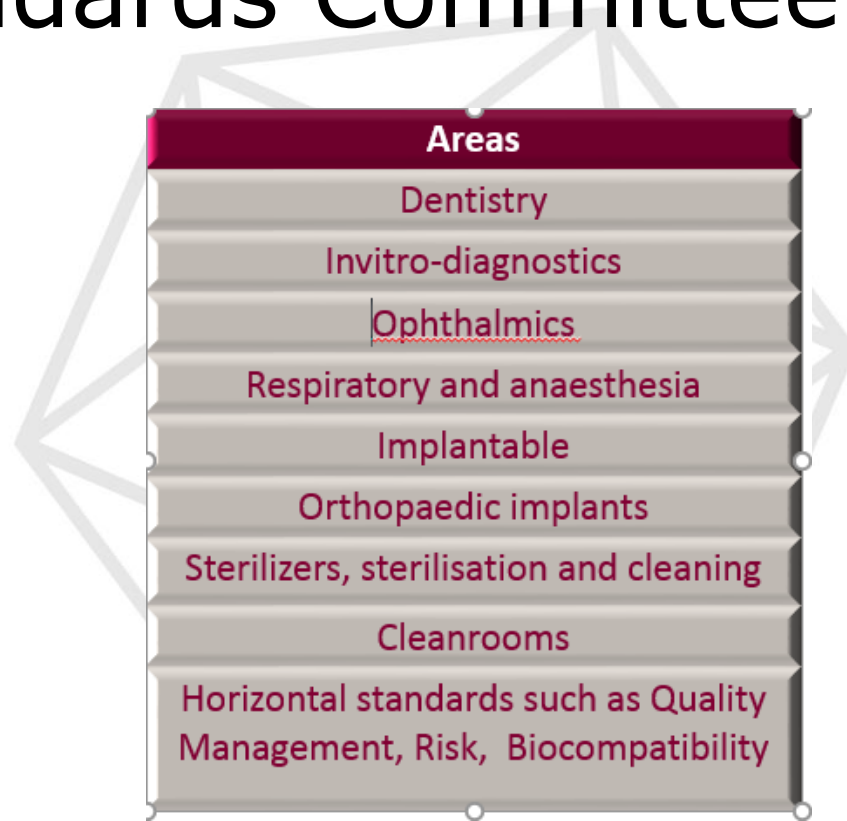Development of a European Standard (EN)
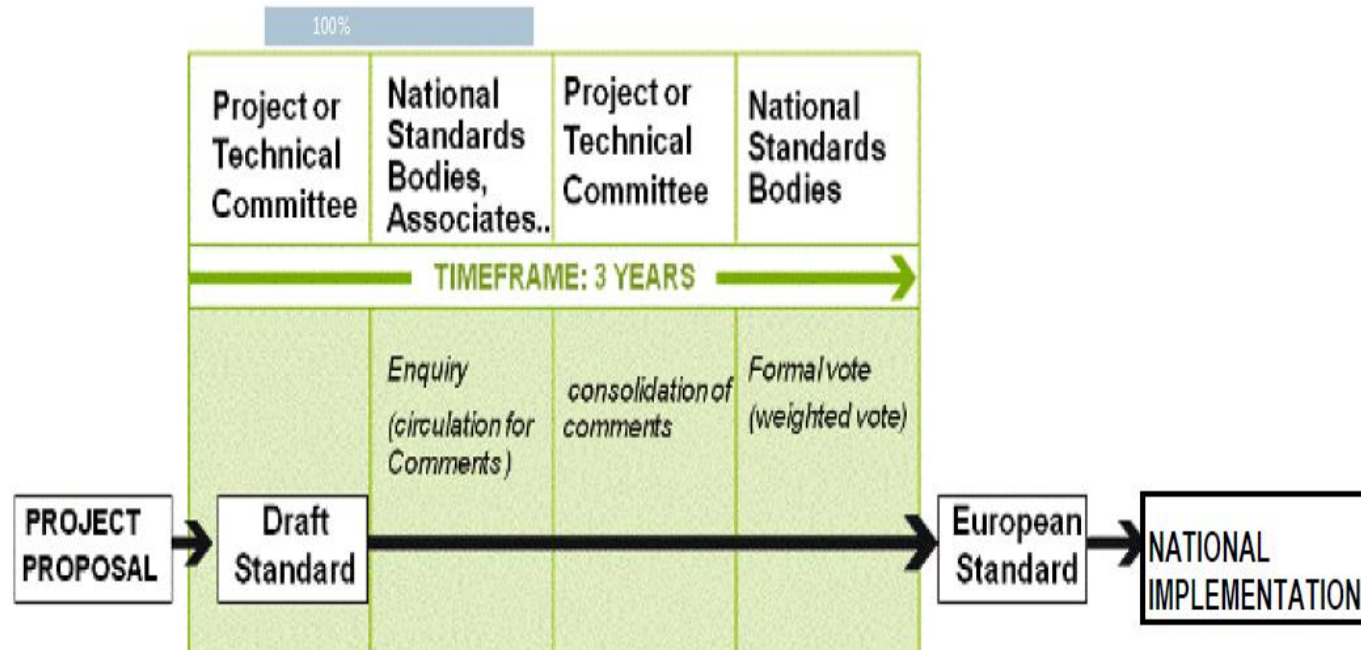
Role of NSAI
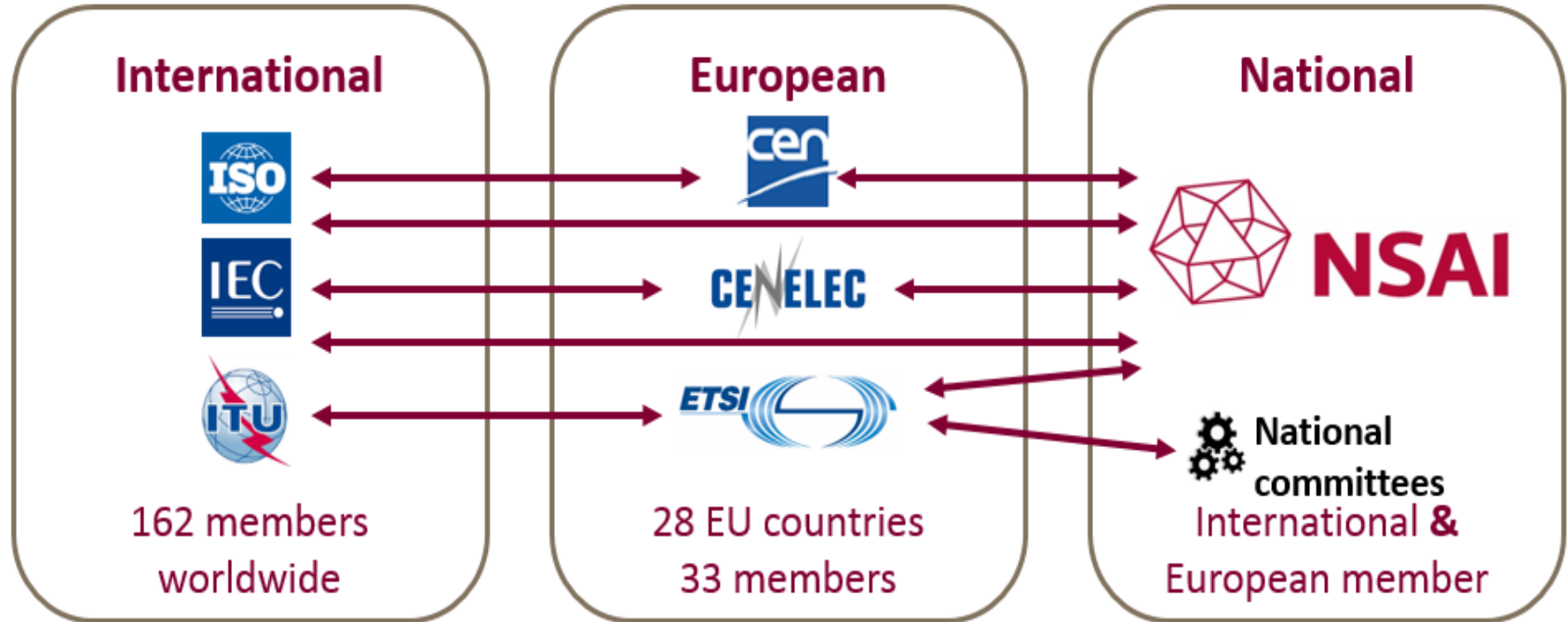
What's in a (Standard) Number

- **National prefix**; I.S. (Irish Standard), **DIN** (German Standard),**BS** (British Standard) etc.
- **European Prefix;** All European Standards (from CEN, CENELEC) use **EN**
- **International Prefix**; **ISO** or **IEC** for International Standards Organisation and International Electro technical Commission) **ITU** (International Telecommunications Union.

- **I.S. EN ISO** 9001:2000 an International Standard published by ISO, adopted as a European Standard and therefore adopted by Ireland.

- NSAI Published standard catalogue available – www.standards.ie

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Healthcare Standards Committee

- NSAI TC5
- Contribute to revisions
- Insight to the coming changes
- Planned compliance to new and revised standards

Areas

Dentistry

Invitro-diagnostics

Ophthalmics

Respiratory and anaesthesia

Implantable

Orthopaedic implants

Sterilizers, sterilisation and cleaning

Cleanrooms

Horizontal standards such as Quality Management, Risk, Biocompatibility

Areas of interest

- CEN TC 140

In-vitro diagnostic medical devices

- ISO TC 212

Clinical laboratory testing and in vitro diagnostic test systems

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Published Standards (CEN)

- **I.S. EN ISO 22870: 2016 -** Point-of-care testing (POCT) - Requirements for quality and competence (ISO 22870:2016)
- **I.S. EN ISO 15189:2012 -** Medical laboratories - Requirements for quality and competence (ISO 15189:2012, Corrected version 2014-08-15)
- **I.S. EN ISO 12322:1999** – In-vitro diagnostic medical devices – culture media for microbiology – performance criteria for culture media
- **I.S. EN ISO 6710:2017 -** Single-use containers for human venous blood specimen collection (ISO 6710:2017)

Draft standards (CEN)

- **FprEN ISO 20166-1** - Molecular in-vitro diagnostic examinations - Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 1: Isolated RNA (ISO/FDIS 20166-1:2018)
- **prEN ISO 15189** - Medical laboratories - Requirements for quality and competence
- **prEN ISO 23118** - Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for metabolomics in urine, venous blood serum and plasma

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Published Standards (ISO)

- **ISO TS 20658:2017** - Medical laboratories - Requirements for collection, transport, receipt, and handling of samples

- **ISO TS 22367:2008** - Medical laboratories - Reduction of error through risk management and continual improvement

- **ISO 15190:2003** - Medical laboratories - Requirements for safety

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Draft Standards (ISO)

- **ISO DIS 15290** – Medical laboratories – requirements for safety.
- **ISO FDIS 20166-2 -** Molecular in vitro diagnostic examinations -- Specifications for pre-examinations processes for formalin-fixed and paraffin-embedded (FFPE) tissue -- Part 2: Isolated proteins
- **ISO DIS 35001** - Biorisk management for laboratories and other related organisations

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Access – NSAI Website

REGISTER YOUR INTEREST HERE ──

- Get involved in committee work
- "Register your interest"

Name

*

Company Name

*

Current Role In Company

*

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Access – NSAI website
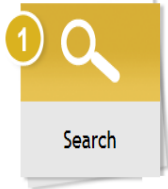
- "Your Standard your Say" – Draft standard access

Access – NSAI Website

- Search published standard catalogue

www.standards.ie

Thank you.

WWW.NSAI.IE

linda.hendy@nsai.ie

Search "NSAI"