

# ISO 80369 series & Contributing to standard development

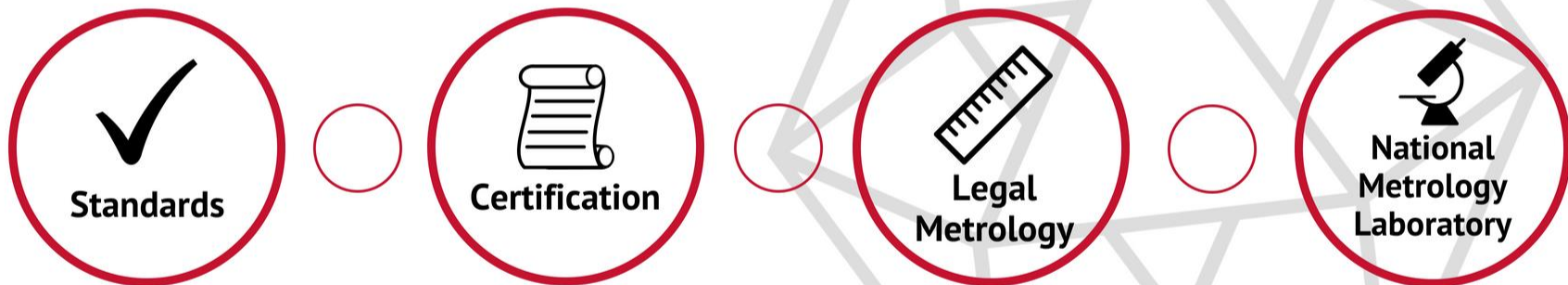
## NSAI Workshop

Linda Hendy  
Standard Officer  
NSAI Standard development.  
26<sup>th</sup> March, 2019.



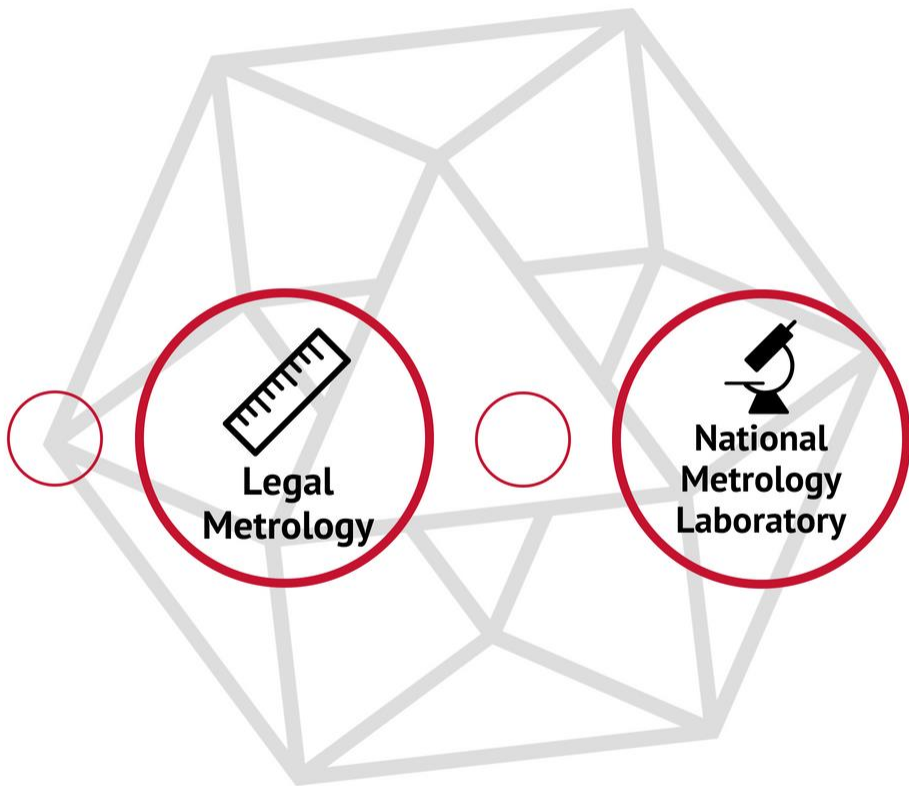
# About NSAI

## Four main divisions



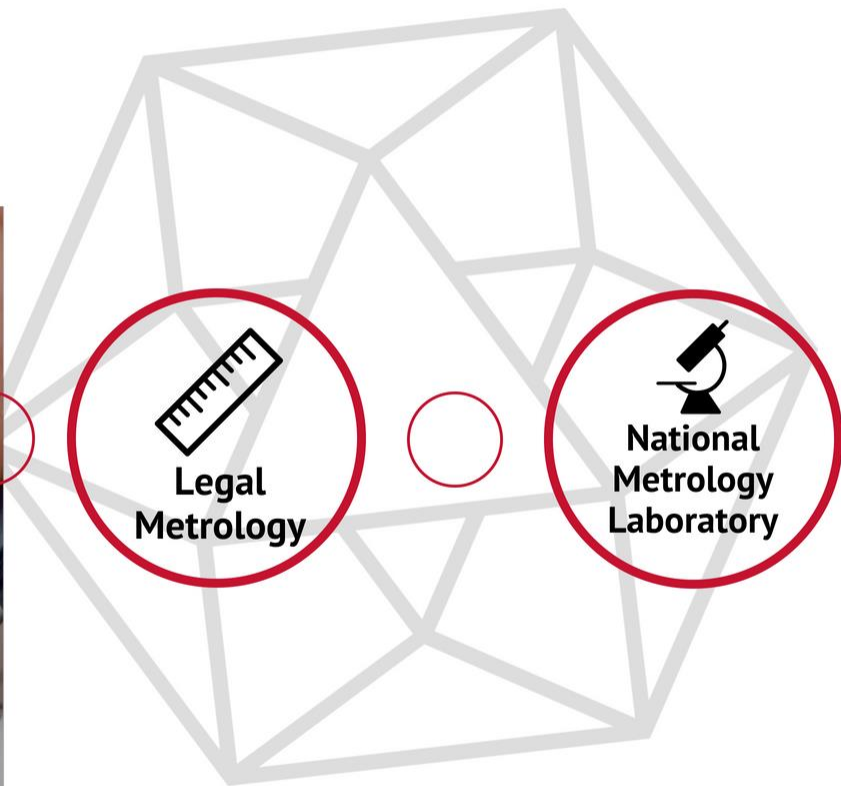
# About NSAI

## Four main divisions



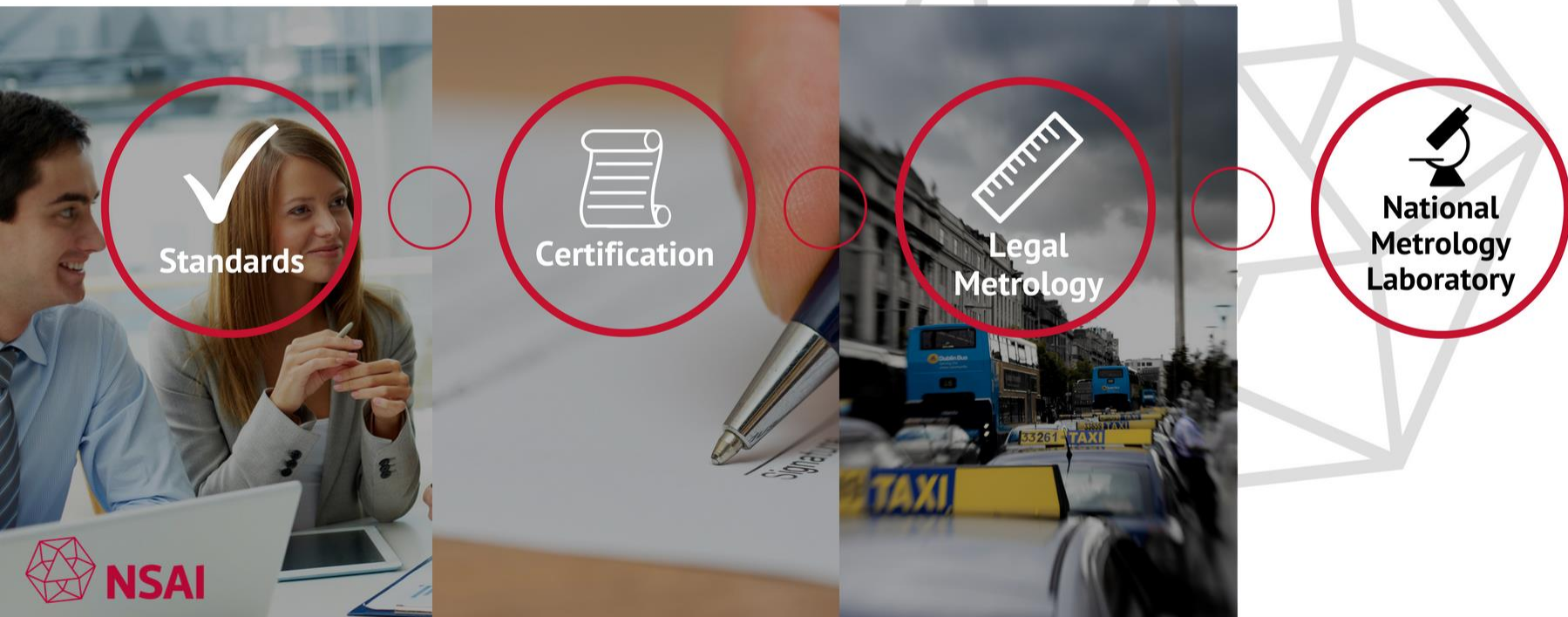
# About NSAI

## Four main divisions



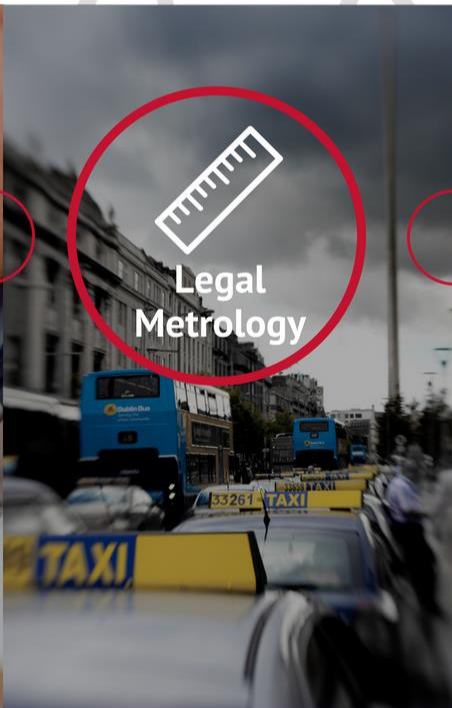
# About NSAI

## Four main divisions



# About NSAI

## Four main divisions



# 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



**NSAI**  
Standards

Irish Standard  
I.S. EN ISO 80369-1:2018

Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO 80369-1:2018)



# 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** 9001:2015 an International Standard published by ISO, adopted as a European Standard and therefore adopted by Ireland.
- NSAI Published standard catalogue available – [www.standards.ie](http://www.standards.ie)

# 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

# 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

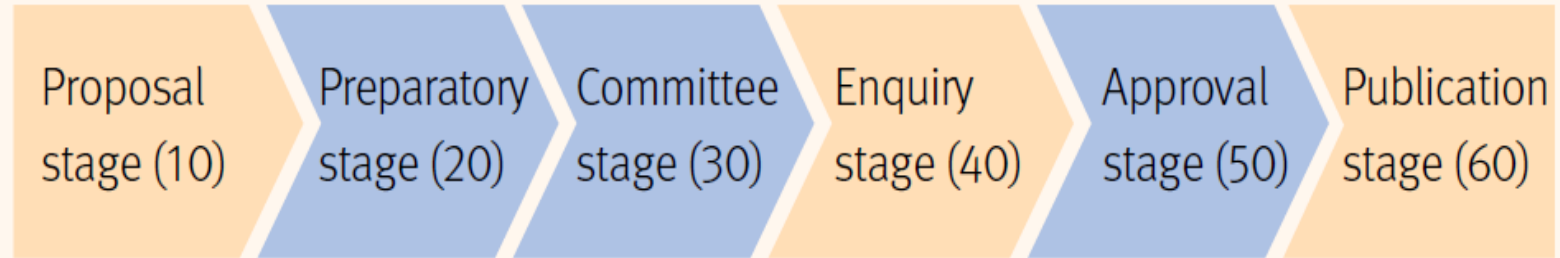
# Types of Deliverables

<b>Deliverable</b>	<b>Objective</b>
Standards – ISO EN	Rules, guidelines for activities or results/performance to be achieve
Technical Specifications	Used when work is still under technical development – possible future standard
Technical Report	Data or results produced in an informative report.
Workshop agreement	Developed in “open workshop” approach. Used to disseminate information e.g. outcome of research project or other agreed approach among participants.



# Standard development process

## Stages for developing ISO standards

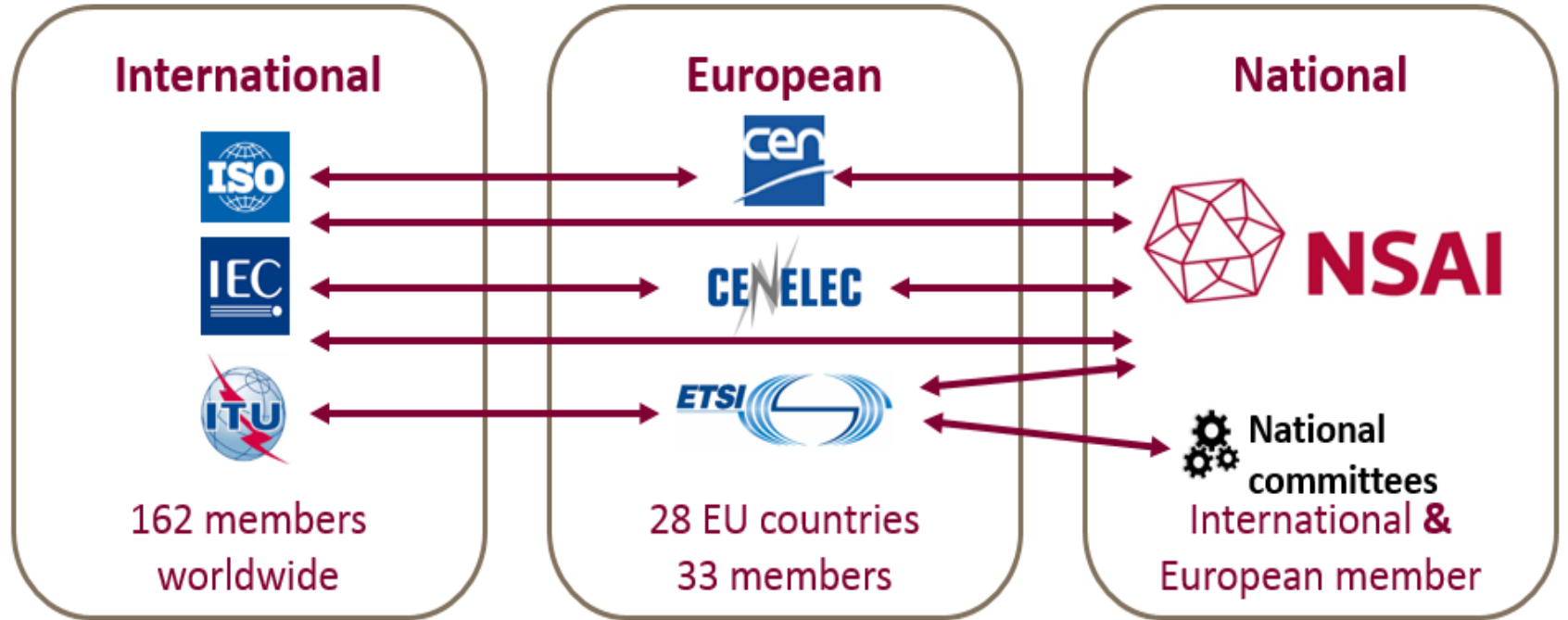


obligatory



optional

# Role of NSAI



# Healthcare Standards Committee

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



# ISO 80369 Series

Small bore connectors for liquid and gases in healthcare applications

- ISO TC 210 – Quality management and corresponding aspects for medical devices
  - JWG 4 – Small bore connectors.
- CEN/CLC/JTC 3 – Quality management and corresponding general aspects for medical devices



# ISO 80369 Series

Standard	Scope	Current Version
I.S.EN.ISO 80369-1	General requirements for small bore connectors	2018
*NP ISO 80369-2	Connectors for breathing systems and diving applications	WI registered on TC WP
I.S.EN.ISO 80379-3	Connectors for enteral applications	2016/ Amd1:2019

# ISO 80369 Series

Standard	Scope	Current Version
IEC.ISO 80369-5 +Cor1:2017	Connectors for limb cuff inflation applications	2016
I.S.EN.ISO. 80369-6	Connectors for neuraxial applications	2016
I.S.EN.ISO 80369-7	Connectors for intravascular or hypodermic applications	2017
ISO 80367-20	Common test methods	2015

# Access – NSAI Website

REGISTER YOUR INTEREST HERE

- Get involved in committee work
- “Register your interest”

Name

 \*

Company Name

 \*

Current Role In Company

 \*

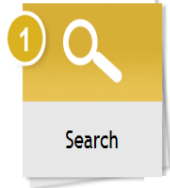
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## Your Standards, Your Say



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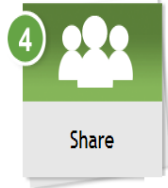
Read

Read and review the current standard and think about how it would affect you and your business



Comment

Comment on the draft standard and help shape its future



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NSAI - furthering the social and economic interests of the consumer and industry through the development and promotion of

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# Thank you.

**WWW.NSAI.IE**

[linda.hendy@nsai.ie](mailto:linda.hendy@nsai.ie)



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**NSAI**

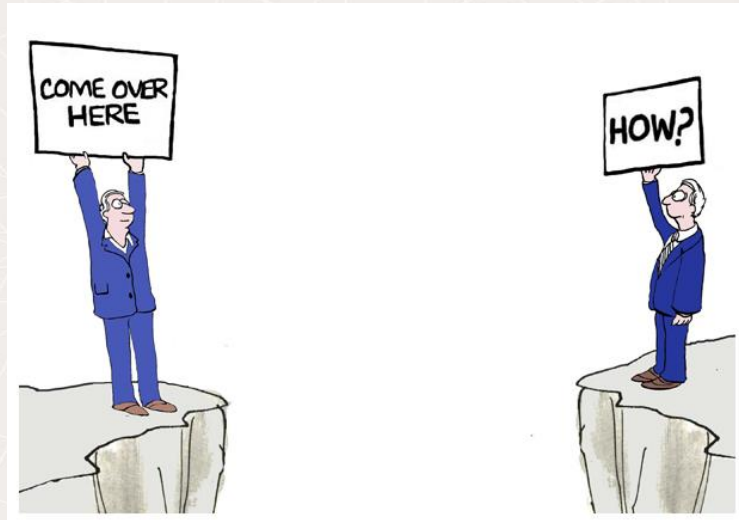
# **NSAI – Requirements & guidelines**

Eilís Hogan

Certification and Inspection Officer

# NSAI

Clarification  
for engineers





# NSAI

- Updating to ISO80369
- Harmonized standards
- Documentation connections
- General tips

# NSAI- ISO80369-7:2016 & ISO80369-1:2018

- Date to switch:  
Each company to discuss with their own suppliers and own notified bodies for any plans to upgrade. NBOG 2014-3
- Currently not a list for harmonization to the MDR.



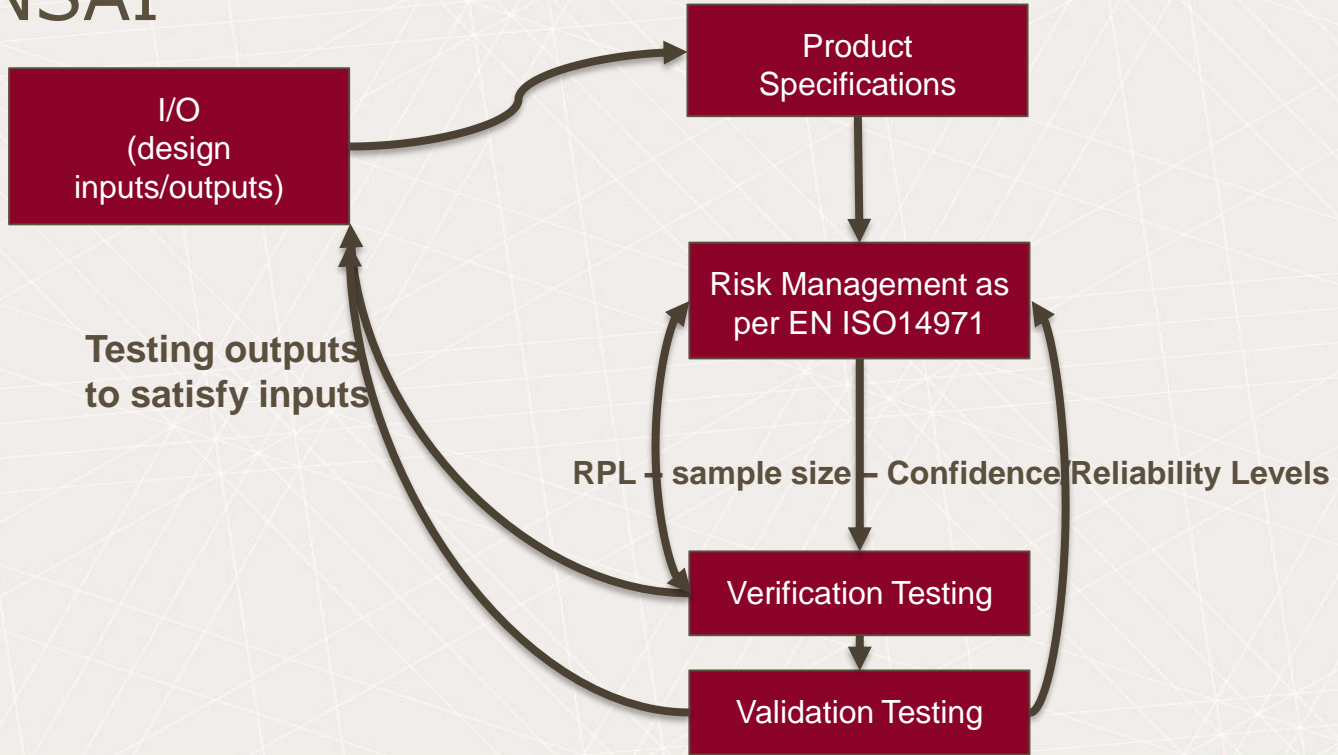
# NSAI

Official journal of the European Commission provides list of harmonized standards

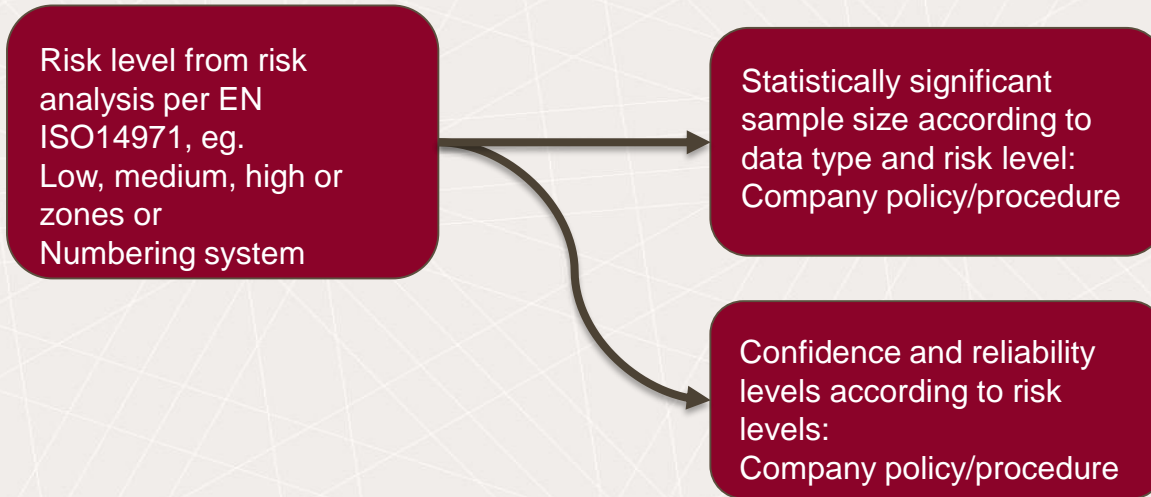
Harmonized Standard

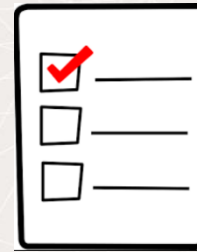
State of the art  
(New revised standard)

# NSAI



- Risk level, Sample Size & Confidence/reliability levels





## General tips\*:

- Provide well defined device and test description
- If using a standard, state the sections that apply and insert all relevant setting, conditions etc from the standard
- Provide clear linkage between all documentation
- State sample size selection and provide a rationale
- Present testing results in a concise manner, providing all raw data and statistically approach/calculations
- R&D engineers should make themselves aware of applicable standards during the early development stages
- External test reports should be approved by legal manufacturer

NSAI – Thank you!!!





Test Services  
a STERIS Company



# Designing Luer Connectors With Compliance in Mind

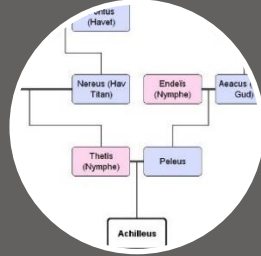
Philip Roxby,  
Technical Services Manager



# Overview of Presentation



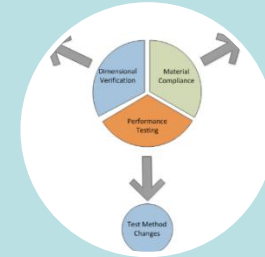
Luer basics



ISO 80369 family background and overview



“New” vs “Old” luer standards

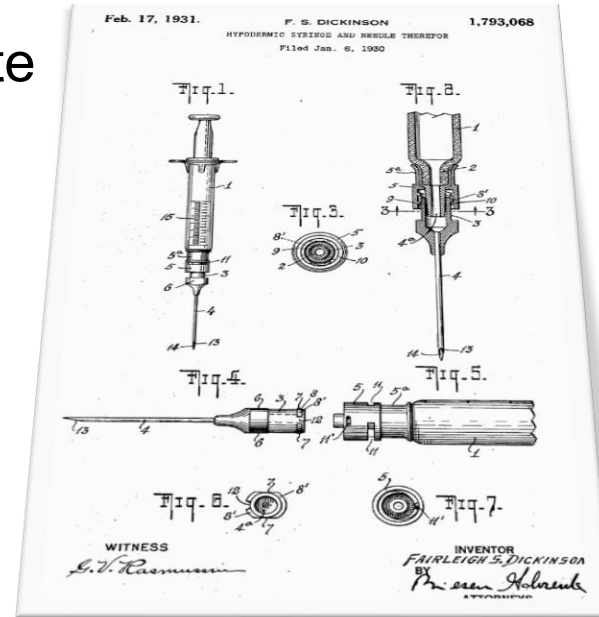


3 Steps to meeting requirements



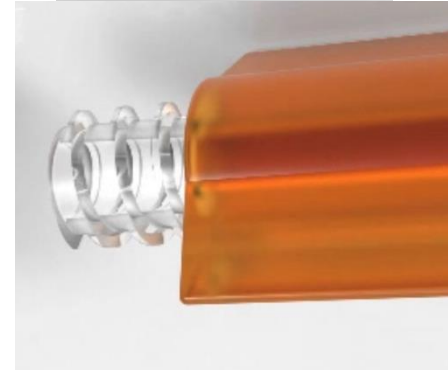
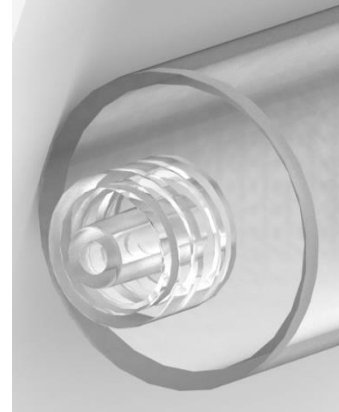
# What is a Luer?

- “Lüer syringe” invented in late 1860’s
- Becton Dickenson US distribution rights -1897
- Needle slippage problems
- Dickenson invented & patented “Luer-lok” connector



# Luer Types

- “Lock” - taper & thread
  - Male and Female
- Secure yet detachable
- Less common - “Slip” - taper only
  - Male and Female
- Standardised connection for intervascular or hypodermic applications
  - Fluid or gas handling



# Misconnection Risks

- 2007 – WHO recognised risk around “unintentional connections”
- FDA identified patient deaths:
  - Blood Pressure Monitor – IV Line – Fatal (air emboli)
  - Nasal gastric feed – IV Line - Fatal
  - Pneumatic compression device – needleless IV port – Fatal (air emboli)
  - Lithotripsy (kidney stone removal) suction line – air pump – Fatal



# ISO 80369 Family

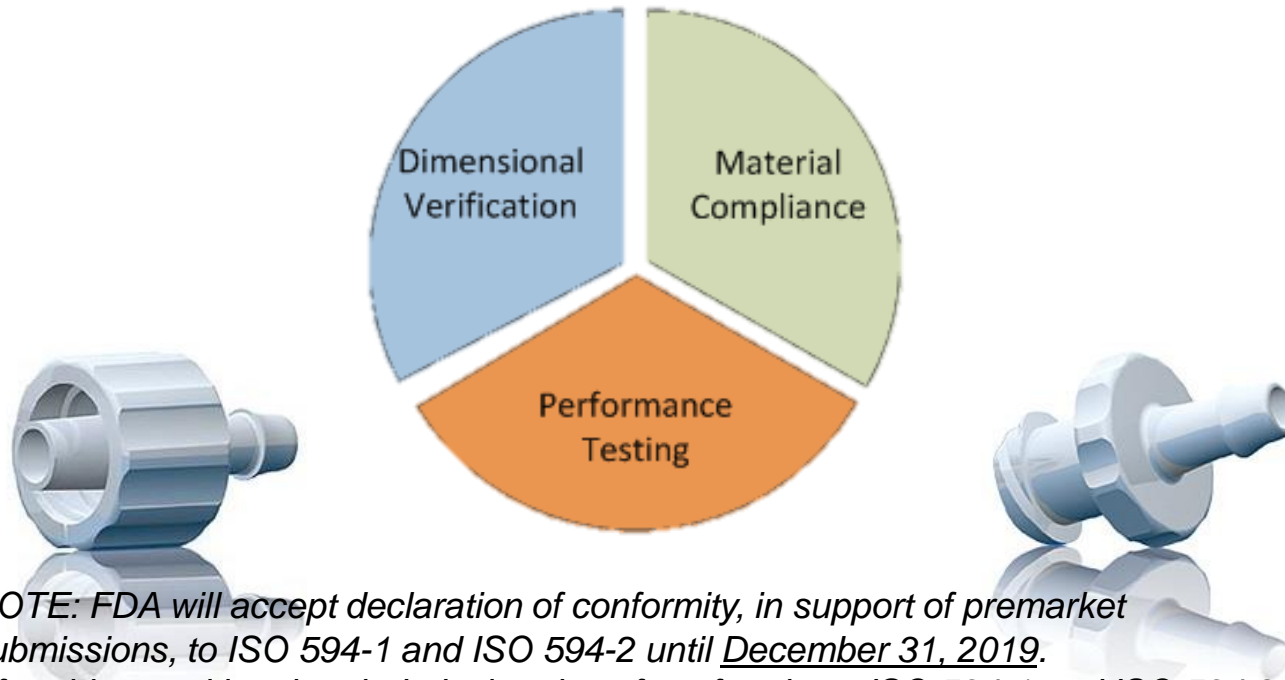


## ISO 80369

- 1: General requirements (2018)
- 20: Test Methods (2015)

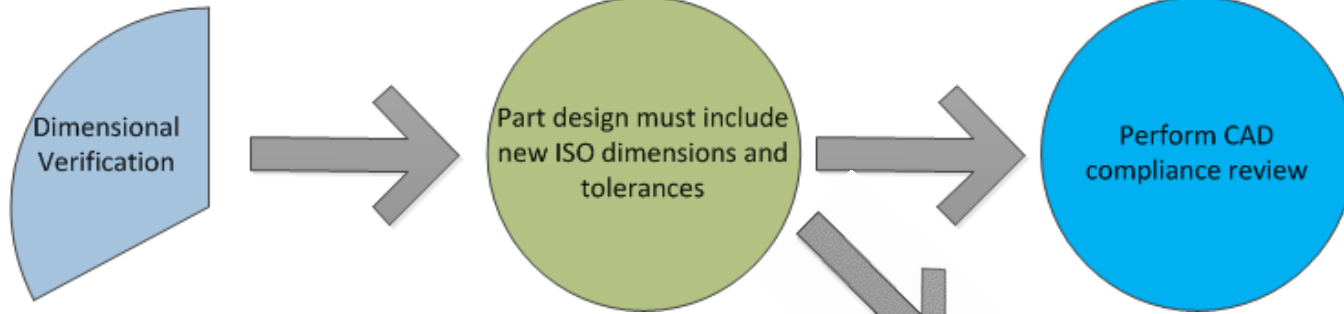


# ISO 594 vs ISO 80369-7

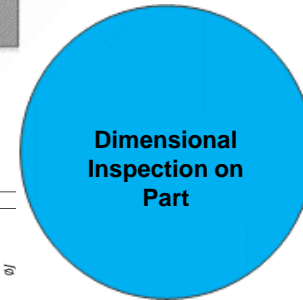
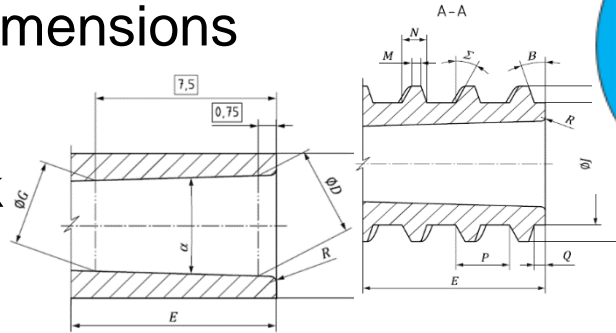


*NOTE: FDA will accept declaration of conformity, in support of premarket submissions, to ISO 594-1 and ISO 594-2 until December 31, 2019. After this transitional period, declaration of conformity to ISO 594-1 and ISO 594-2 will not be accepted*

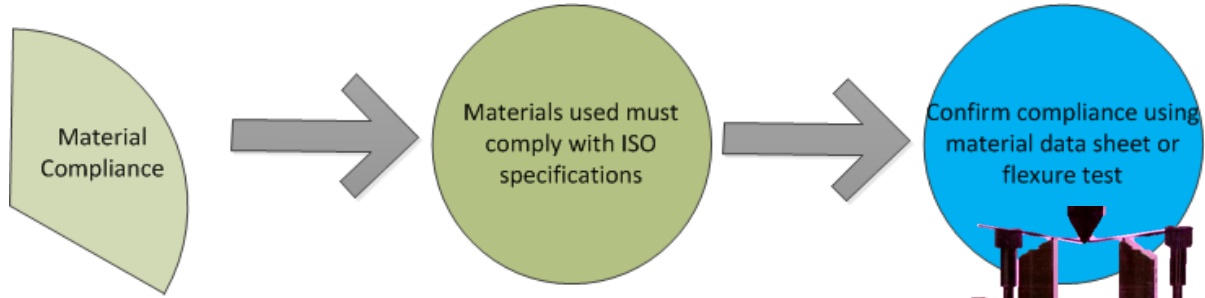
# Dimensional / Non Interconnectability Requirements



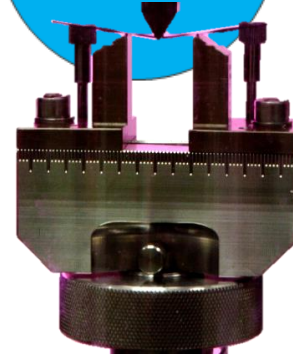
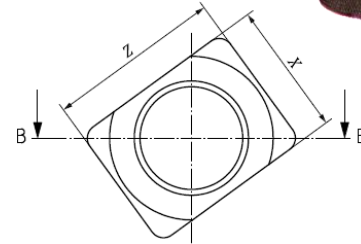
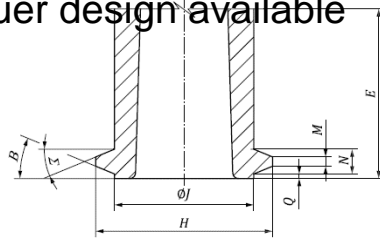
- Proof of Non Interconnectability
- ~15 angles/dimensions
- Taper check
- Thread check



# Material Requirements

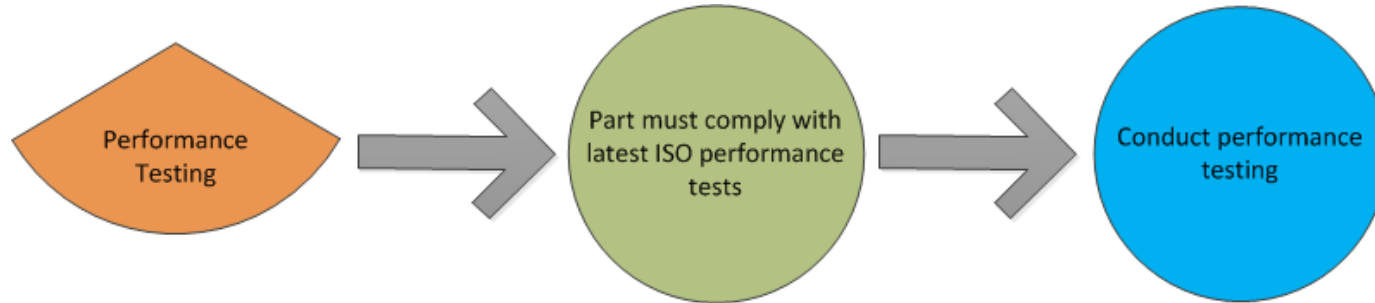


- $E_{FLEXURAL}$  or  $E_{ELASTIC} \geq 700$  MPa
- 700-3500 MPa (Semi-Rigid)
- >3500 MPa (Rigid)
  - additional luer design available





# Performance Requirements



- Mechanical tests
  - x6 for luer lock
  - x4 for luer slip
- Similar to ISO 594

# Performance Testing - What's New?

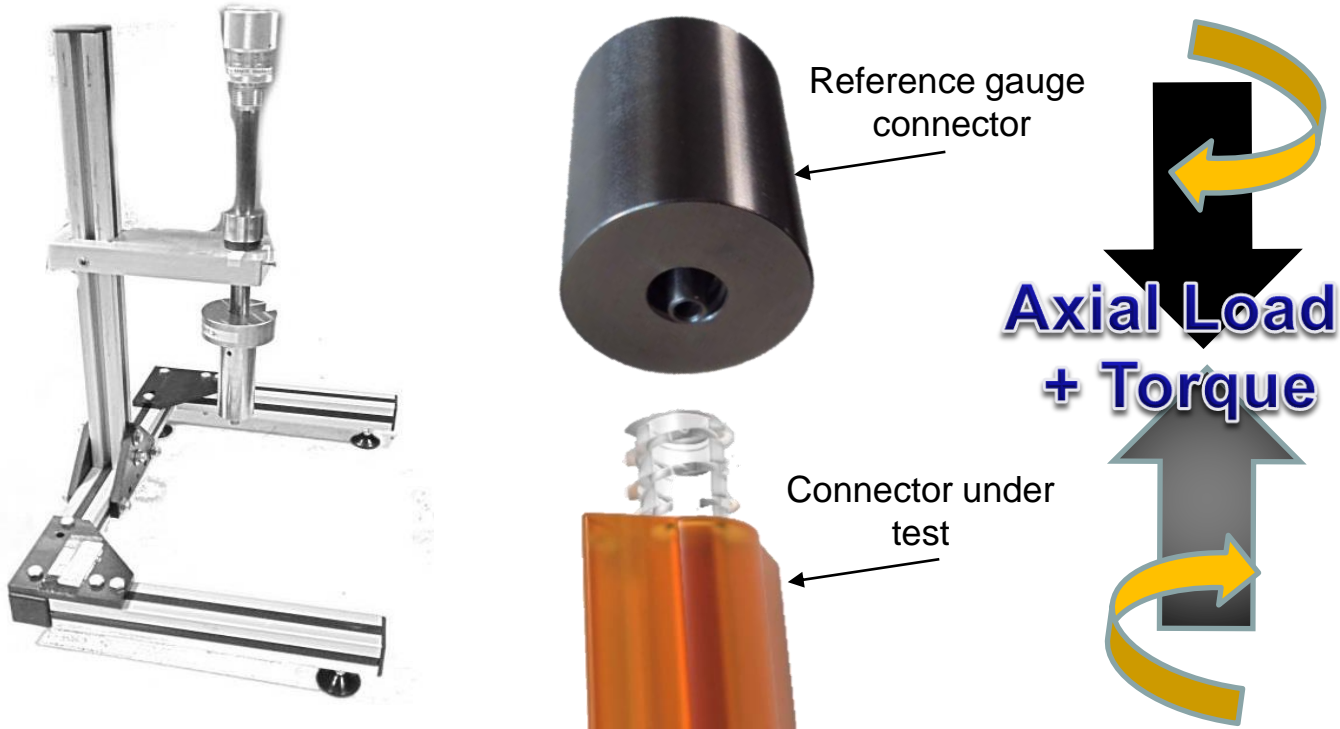
IN

- New Fluid & Air Leakage Test Techniques
- New Stress Cracking Evaluation Method
- Tighter test parameter tolerances across all tests

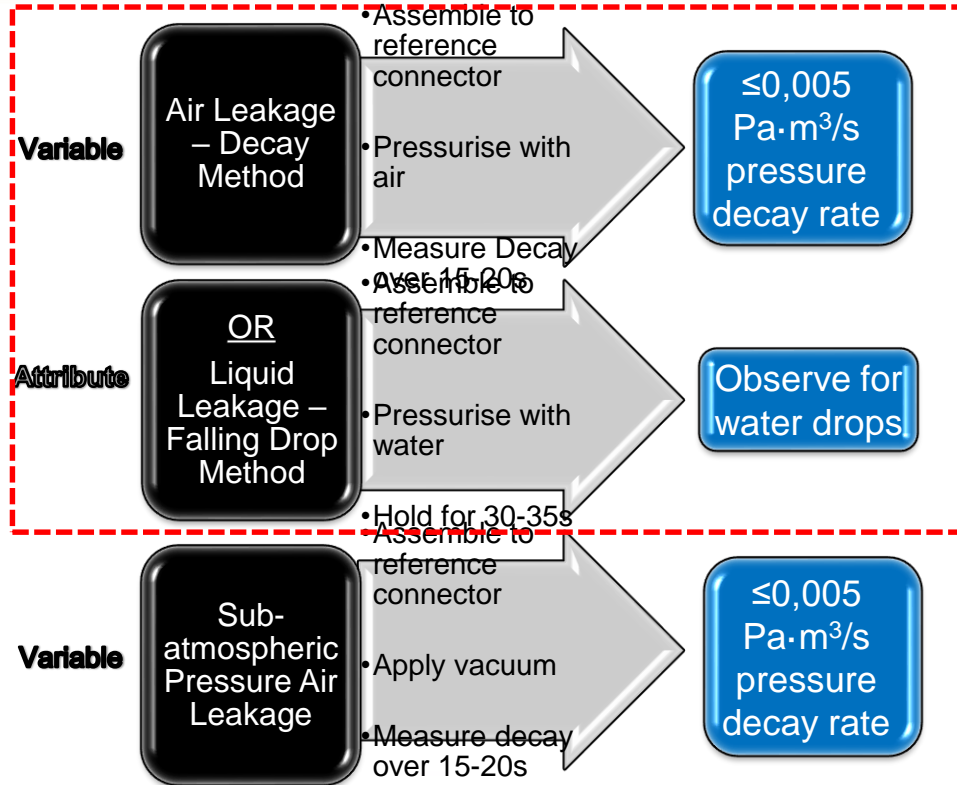
OUT

- Gauging Test
- Ease of Assembly Test

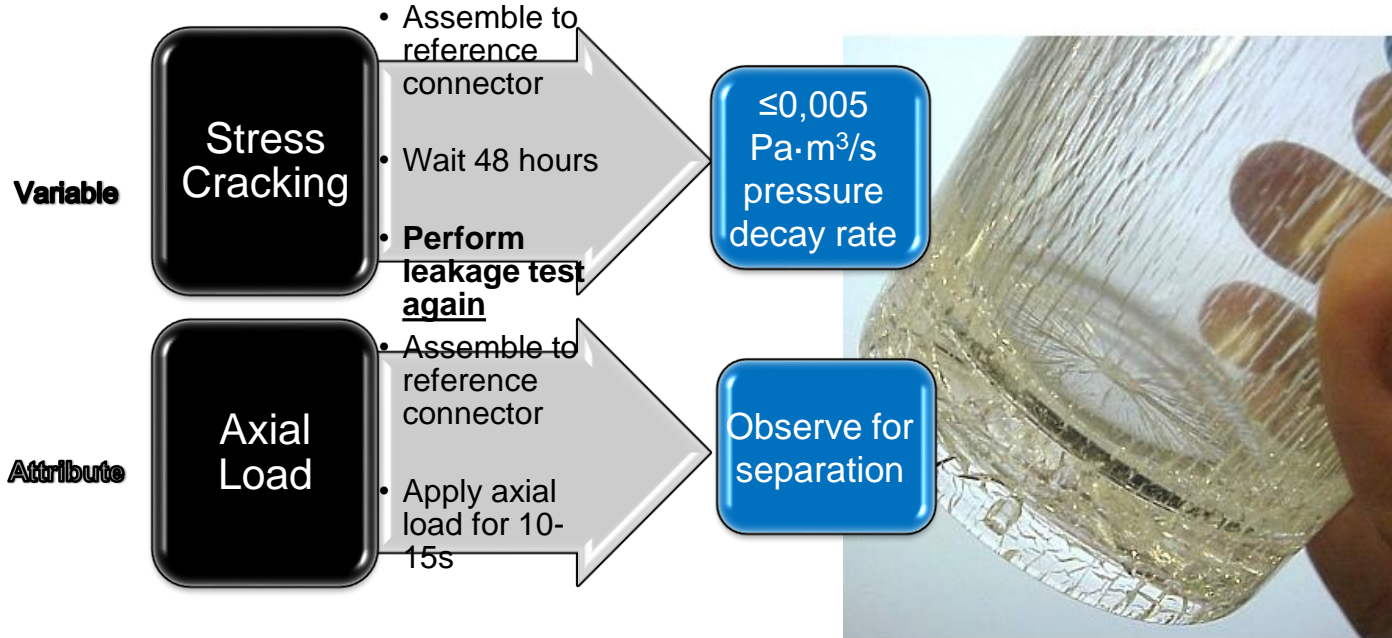
# Performance Testing - Assembly



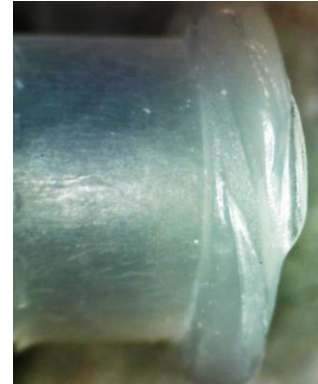
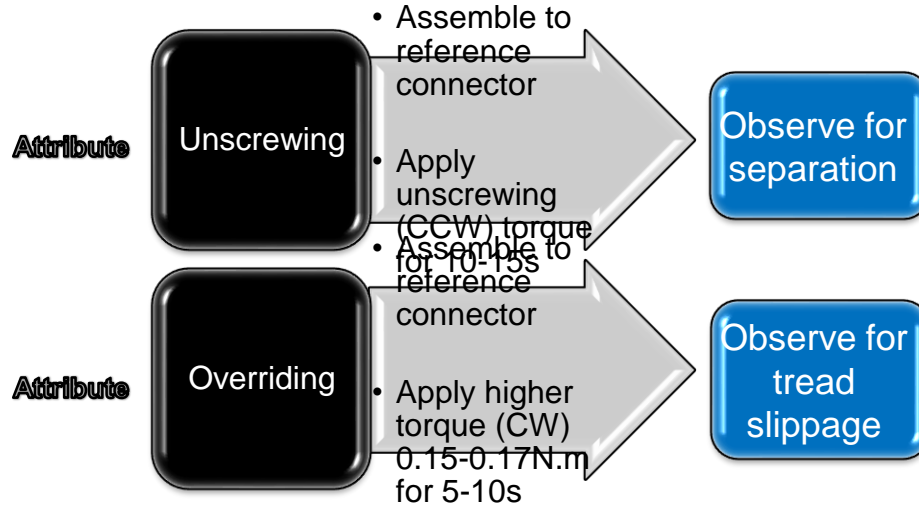
# Performance Testing - Methods



# Performance Testing - Methods



# Performance Testing - Methods



# Other Updates for ISO80369-7

Alternative Variable Results	Option for “Custom” Design	Application s / Usability
<p>methods discusse d</p> <ul style="list-style-type: none"><li>• Convert attribute test to variable</li><li>• Possible sample size reduction</li></ul>	<p>y to create custom designed fitting</p> <ul style="list-style-type: none"><li>• Substanti al workload to validate</li></ul>	<p>ve section</p> <ul style="list-style-type: none"><li>• Design applicatio ns</li><li>• Usability requirem ents</li></ul>

# Thank You

- **Thank You For Listening!**
- We look forward to more discussions on how we can solve challenges together.

## Questions



# Contact Us

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go to: [www.anecto-testservices.com](http://www.anecto-testservices.com)

For enquiries, please contact:  
[sales@anecto.com](mailto:sales@anecto.com)

