

# **NSAI & the Promotion of Health Information Standards**

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**NSAI**  
Standards

# Standards ... are useful



## Which of the 'un/knowns' below applies to us?

**Known knowns** - these are things we know that we know.

**Known unknowns** - these are things that we now know we don't know.

**Unknown unknowns** – these are things we do not know we don't know.

**Unknown knowns** – these are things we choose to ignore!!

# HI Standards Development Organisations (SDOs)

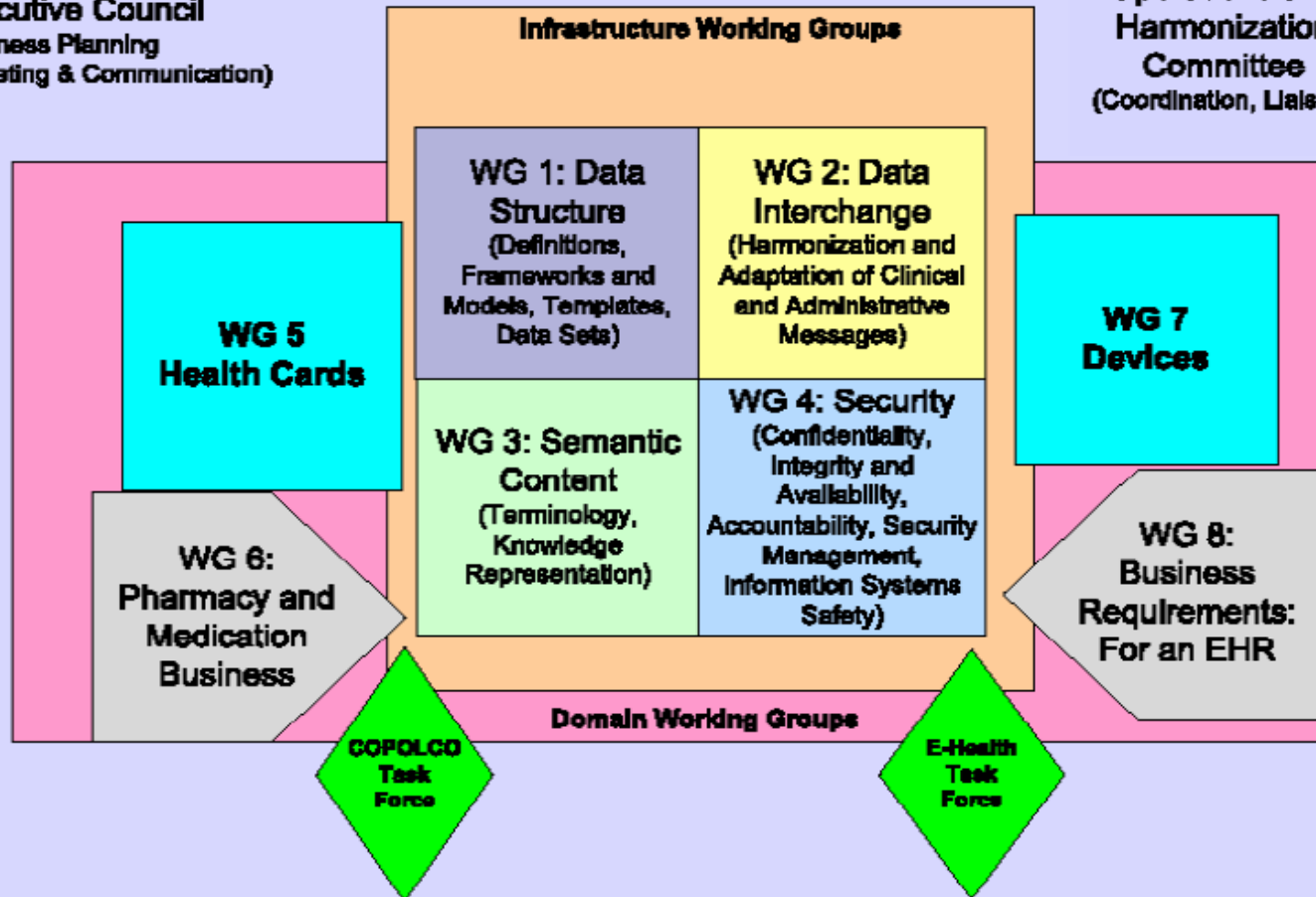
- ISO (TC251) (EHR, identity, security,...)
- HL7 (via ANSI) (EHR, health messaging,..)
- CEN (TC215) (EHR, identity, device interfacing)
- IHTSDO (terminology, ontologies)
- WHO (terminology,...)
- OpenEHR (EHR,...)
- DICOM (Medical imaging)
- OMG (UML, CORBA, identity...)
- IEEE (Medical device interfacing)

# ISO – the most influential SDO

Annex C

**Executive Council**  
(Business Planning  
Marketing & Communication)

**Operations and  
Harmonization  
Committee**  
(Coordination, Liaison)





# Standard: a definition - ISO

*"...A document established by consensus and approved by a recognised body, that provides for common or repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context..."*

# Types of standards

## A MIX OF...

- **Official Standards** – developed by SDOs and made obligatory by government organisations. (fee)
- **Voluntary standards** developed by SDOs but compliance is not (yet?) enforced. (fee)
- **Industry** (market driven) **standards** defined by single company or group of companies (e.g. Microsoft office doc formats)
- **Open standards** - everyone can help to define them – don't have to be part of an SDO. It also means that the final specification is available to all and can be used on a royalty free basis

# Why adopt standards?

- Standards can promote:
  - Better communications (interoperability)
  - Increased homogeneity / harmony
  - Increased cooperation
  - Reduced replication
  - Safety
  - Reduced cost and increased efficiency



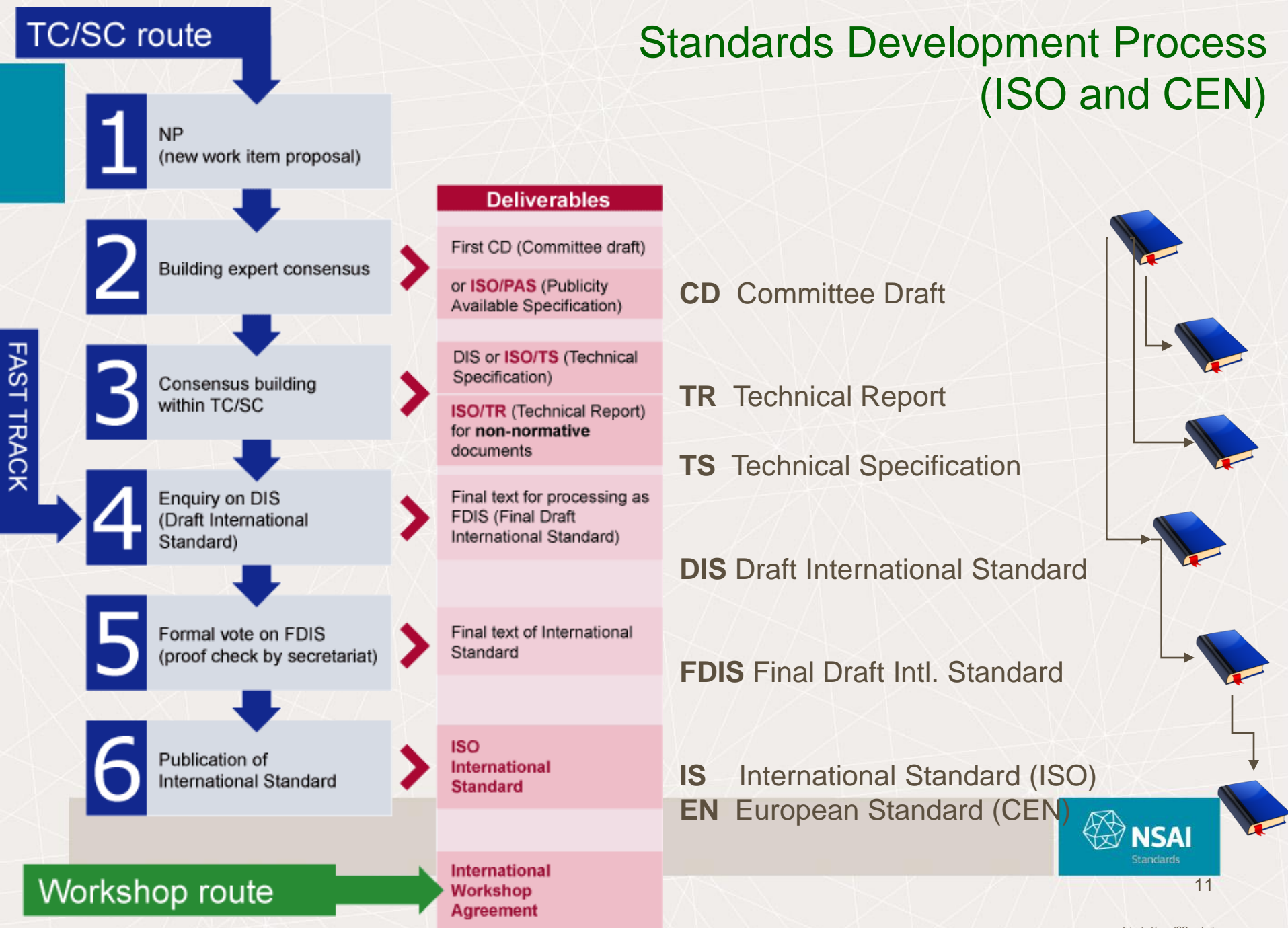
# Why adopt standards? - trust

- Ultimately users are more likely to trust information and information systems that comply with a standard
- Trust is absolutely essential if healthcare information is being shared between organisations.
  - Health information that is used for purposes of care must be absolutely trusted
  - Users will not be familiar with the context of data collection in original site: in their own site they are generally aware of certain context information.
  - Only the application of appropriate standards to information that is being exchanged will help receiving users to trust the data.

# NOTES: Why standards are important for Health Informatics in Ireland

- Standards and standardised approaches are the glue that links health information systems together
- Adoption of a standardised approach reduces the effort of system integration.
- We are a small country – significant critical mass required to do it all ourselves is not justifiable
- Standards based reuse - reusing the results of other countries successful efforts
- Standardised 'best of breed'

# Standards Development Process (ISO and CEN)



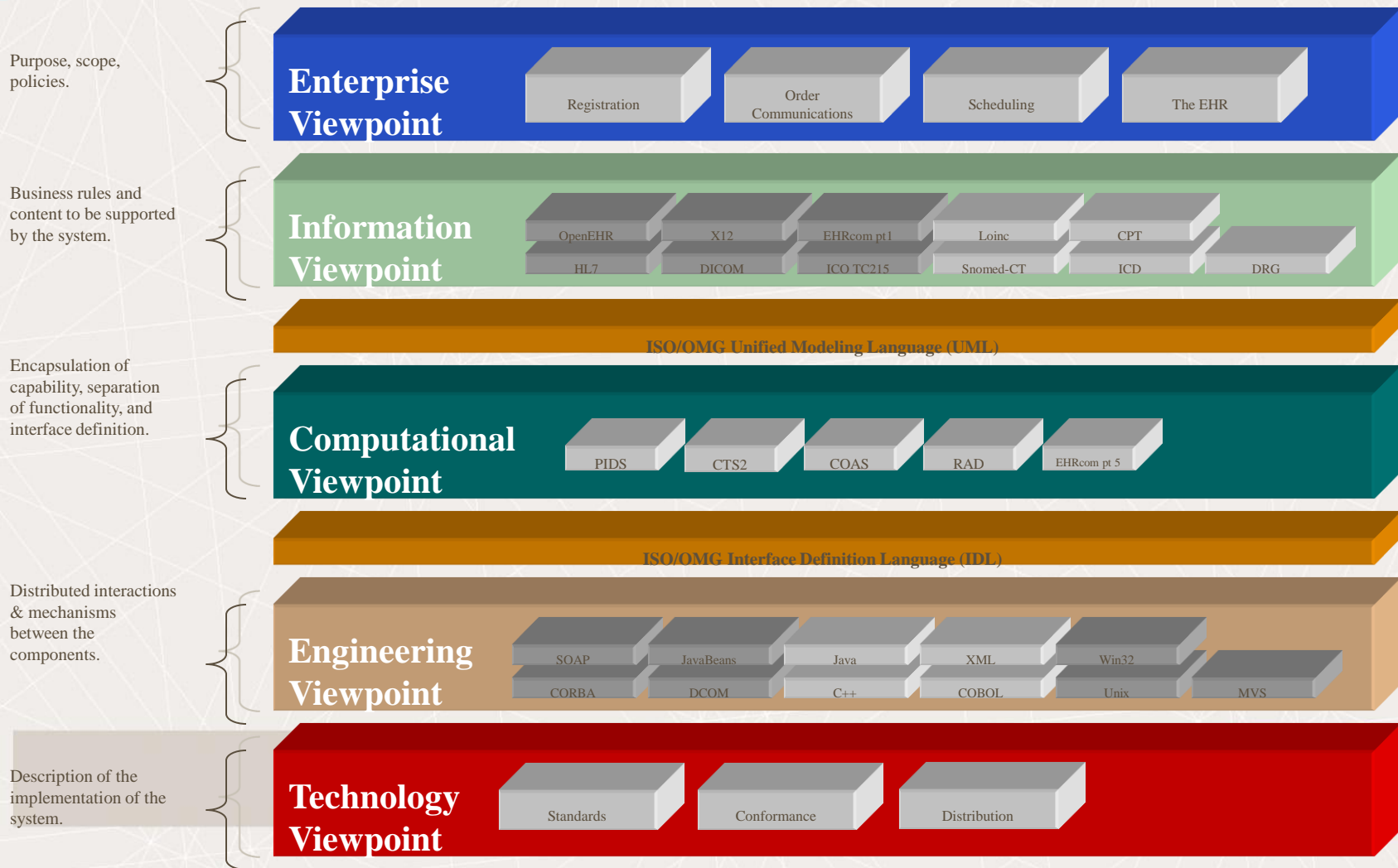
# Who should develop standards?

- **Vendor** agendas are often not ideal for standards development, as they can involve “lock in” and obfuscation (*e.g. Microsoft Java, HTML, XML, OpenDOC etc etc.*)
- On the other hand vendors (and all HI developers) have invaluable experience “at the coalface” which must be incorporated.
- **Health professionals** also have a valuable role to play – providing their domain knowledge and some realism (for example).
- **Academics** – among other things introduce valuable new approaches (*HTML, XML, UML, OWL, archetypes, OIDs, automated clinical guidelines*)
- **Government agencies** set priorities and influence roadmaps for standards development and adoption.



# Reference Model for Open Distributed Processing (RM-ODP)

*Standards exist at different levels and are aimed at different audiences*





# ISO Catalogue – Online standards store

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Address http://www.iso.org/iso/search.htm?qt=Electronic+Health+Record&published=on&active\_tab=standards Go Links

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




Standards (5) Publications & e-products (0) Site (0)

Electronic Health Record Search Sort results by: Relevance | ISO number | TC | ICS | Date | Stage code Advanced Search

Items to be displayed:

☒ Published standards ☐ Standards under development ☐ Withdrawn standards ☐ Projects deleted (last 12 months)

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Standards	Language	Format	Add to basket
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 <a href="#">ISO/TR 20514:2005</a> <b>Health informatics -- Electronic health record -- Definition, scope and context</b> Edition: 1   Stage: <a href="#">60.60</a>   <a href="#">TC 215</a> ICS: <a href="#">35.240.80</a> Document available as of: 2005-10-17	English	 Paper	CHF 118,00 
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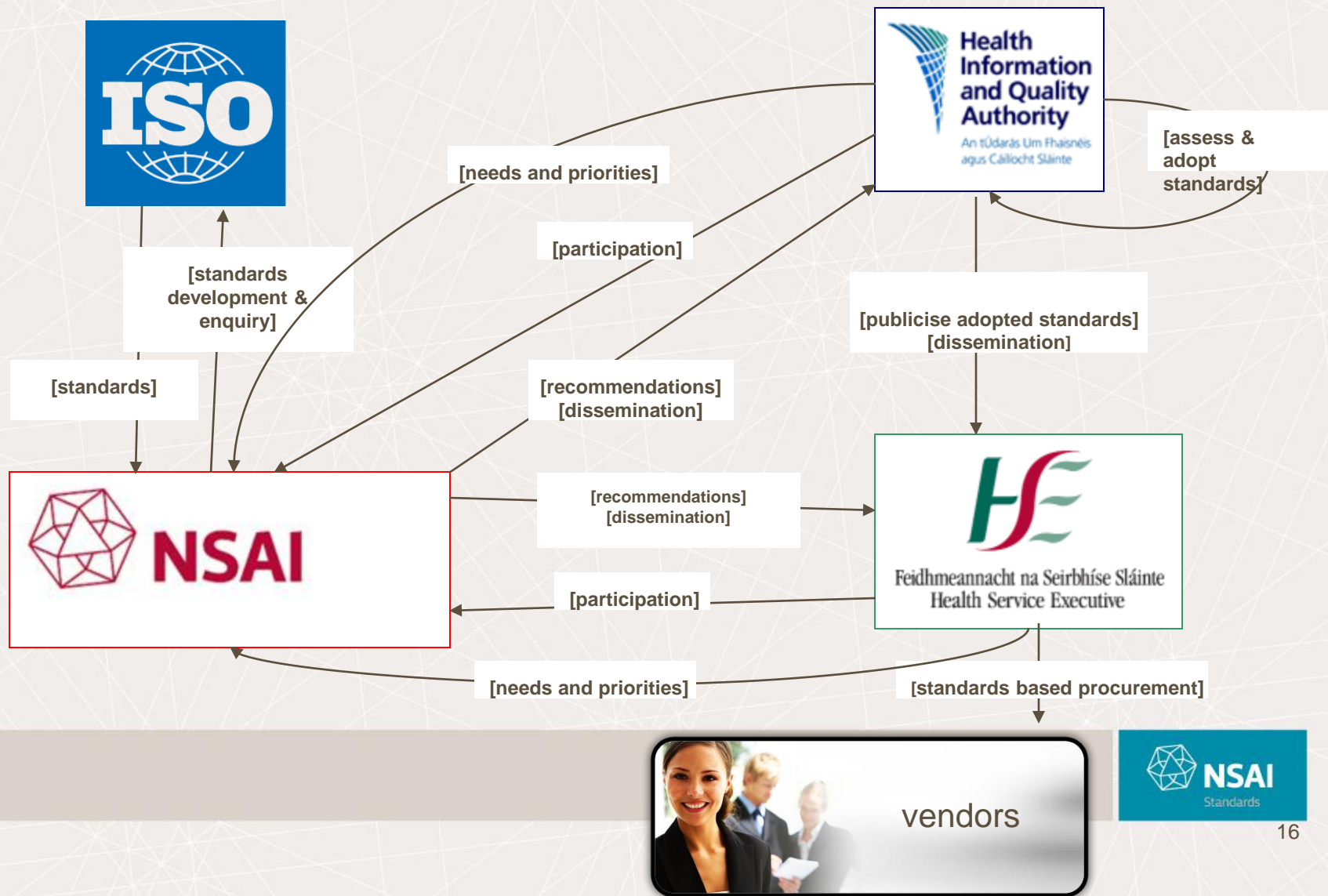
Browse by TC >>

Done Internet

# Role of NSAI in standards

- NSAI are the sole national interface to the two main SDOs - CEN TC251 and ISO TC215 (which provide a conduit for other orgs such as HL7, CDISC)
- NSAI activity is mostly voluntary – volunteers are experts – some come from the health service
- A conduit for standardisation feedback from the Irish community - and Irish led standards development.

# The way it should work !!



# The Irish situation (1) NSAI HISC

- Voluntary Expert National Mirror Panel
- Roles
  - ❖ Raise awareness about standards
  - ❖ Represent Ireland at SDO meetings
  - ❖ Provide feedback and recommendations to other national bodies
  - ❖ Liaise with HIQA/HSE/vendors



# The Irish situation (2) HIQA

- Ensure that standards are fit for use
- Adopt Standards
- Disseminate proven standards
- Monitor compliance with standards





# The Irish situation – (3) HSE

- ... Implement standards.
- Engage in training
- Drive towards procurement of standards based solutions.
- Provide input to the standards development process.



# NSAI and National Integrated Services Framework

- NSAI provides a conduit for standards collaboration for standardisation bodies in other jurisdictions.
- Although it could be said that interaction is limited by direct affiliation to ISO and CEN only (i.e. no affiliation to HL7, IHE, IHTSDO, CDISC).
- Mature standards have typically already been defined by time they reach ISO.
- Evolution of an Irish HI standards adoption process through HSE and HIQA representation on NSAI HISC and on HIQA eSAG,
- Recent introduction of HL7 open specifications

# Future aims

- Increased direct involvement from health service experts / staff in standardisation
- Continued integration of standardisation process between NSAI, HIQA, HSE.
- Enhanced links with national standards organisations in other jurisdictions, e.g. British Standards.

# Future aims – most of all...

- Implementation of practical HI standards in Ireland

This requires

- Higher awareness of standards by stakeholders – training and dissemination.
- Enhanced and structured cooperation on standards between the main organisations in the field.
- Embed standards imperative into procurement process.



# ISO Principles for standards development

- **Consensus**  
The views of all interests are taken into account: manufacturers, vendors and users, consumer groups, testing laboratories, governments, engineering professions and research organisations.
- **Industry wide**  
Global solutions to satisfy industries and customers worldwide.
- **Voluntary**  
International standardization is market driven and therefore based on voluntary involvement of all interests in the market-place. It is up to nations and regions to enforce them.



# Main stages in standards development

1. **The need for a standard is expressed** by an industry sector, which communicates this need to a national member body.
2. **The member body** (e.g. NSAI) **proposes** the **new work item** to ISO as a whole.
3. **The WG defines the technical scope of the future standard** and a team leader / principal author is appointed.
4. **Member countries negotiate the detailed specifications** within the standard. (consensus-building).

# Main stages in standards development

## 5. **Formal approval of the resulting draft International Standard**

*Acceptance criteria stipulate approval by 2/3 of the ISO members that have participated actively in the standards development process, and approval by 75% of all members that vote),*

## 6. **The agreed text is published** as an ISO International Standard.

**CEN/ISO  
TC XXX**

Produce  
documents  
for review

**CEN/ISO  
TC XXX**

Compile  
votes and  
publishes  
new  
standard

**NSAI/HISC**  
Access documents  
on ISO/CEN  
Mirror Server

**Reviews Work  
Submits Vote**

Project Leader  
Balance of Experts  
Work on NSAI  
NMC

**How can I (you) contribute??**

## Conclusion

- CEN and ISO TCs need input from informed users of standards.
- Users of standards need to keep themselves informed of TC activities.
- NSAI welcomes all involvement.

And !!!



# Three fundamental issues to be resolved

1. Generals are always prepared (preparing) to fight the last war.
2. HIQA-HSE-NSAI-Dept of Health have yet to find a satisfactory *modus operandi* with respect to developing, adopting and utilising HI standards
3. CEN and ISO need to adopt some of the principles of OMG **e.g. proof of concept**



# ... looking to the future ...

*... do we agree we need standards?*



*Is there an acknowledgement that the current situation is unsatisfactory?*



*Do we understand how to proceed?*



**NSAI**  
Standards



When lost ... contact the following:

- [www.standards.ie](http://www.standards.ie) or
- [chrissie.keane@nsai.ie](mailto:chrissie.keane@nsai.ie)

**Thank you for your attention**



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