NSAI Committee Training
Module 2b: National Experts Level

Slide 1

Hello, this is Annette and welcome to another module in the NSAI Expert training series. In this module we will cover the standard development process and how you as an expert can contribute and influence the content of standards. Next Slide.

Slide 2

In this module we will be addressing a number of learning outcomes starting with the structure or content of a standard. The standard development process will also be covered as well as the different types of standard deliverables.

We will cover how standards are named and the importance of standard dates.

We will take a brief look at a very specific type of standard called a "harmonized standard" and how these support regulations.

Finally, the functions of the national committee will be reviewed. Understanding the development process is important to know when you can make technical changes to standards and contribute to their development. Next Slide.

Slide 3

We will start with the typical content of a standard. The main standard development organizations have sets of rules or Directives that set out how standards are developed and also the structure and content. Each standard will have a unique number and title which should be clear and concise.

A Foreword to the standard provides information about the Standard development organization and the technical committee involved. It provides information on the rules and voting processes applied and can include dates of implementation for members, applicable for European standards. This section is mandatory but informative meaning it does not contain any requirements. An introduction is optional and can set out the background to the development of the standard.

Next is the scope, this is a mandatory section and should clearly and concisely set out what is covered by the document, for example …. specifies or establishes requirements for…. Normative references is also a mandatory section even if no references are used. The documents listed here are normatively referenced, either in total or in part, within the body of the standard. It is important to note that if you wish to claim compliance with the standard you also must comply with the normative references as referred to in a standard.

Terms and definitions set out the terms that apply for the purpose and use of the document.

The main body of the standard sets out the clauses and subclauses of what the user needs to do to meet the standard. Notes and examples can be included for additional information. Annexes can be included to provide additional information, and these can be normative or informative. The language used in a standard is important and has particular meaning. Next Slide**.**

Slide 4

Verb usage is particularly important to the intent and meaning of the clauses in a standard. As outlined in this slide "shall" is a requirement, while "should" is a recommendation. This is an important distinction in the interpretation of a standard and means that in order to claim compliance with a standard you need to meet all the "shall" statements. Other verbs used include "may" which indicates something is allowed or permitted and "can" indicating possibility and capability.

We previously noted that Annexes are normative or informative. Normative means you have to comply, informative is guidance of good practice. So, if an annex is normative it also needs to be complied with in order to comply with the standard. The rules or Directives for standard development sets out how standards should be drafted including verb usage. We will now look at the standard development process. Next slide**..**

Slide 5

What is the standard development process? In the next few slides, we will look at processes for developing standards and how, as a national expert, you can contribute to and keep up to date on standards. Next slide**..**

Slide 6

Key principles are core to the development of standards. Standards are developed based on market need and are based and developed with global expert inputs. Technical committees are set up to develop standards and all Standard development organizations maintain list of all committees and their work programmes on their websites. Anyone can check the current work programme from the relevant website or have access through their National Standard Body or member. Therefore, the process is transparent and open for anyone to get involved.

Standards are developed based on consensus, which in standard world is defined as the "lack of sustained opposition" or can be generally considered as "you can live with it". Impartiality is maintained by structures and roles for committees such as Committee Chairs and Secretaries. Next slide**..**

Slide 7

This slide shows the main International standard development organizations and how NSAI fits in with all these international Standard Development Organizations. We have covered the different types of standards developed by the different standard development organizations in a previous module.

What is important to know is that NSAI being a member of these international bodies has access to standard development documents. It is through your participation in an NSAI standards committee, that you can keep up to date and contribute to standard developments. Next slide.

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Typically, there are three types of deliverables produced by Technical Committees: A Standard, a Technical Specification, and a Technical Report. These differ in the level of consensus and the process required for their development. Technical Specifications and Technical reports are a lesser consensus document and have a shorter development timeline. It should be noted that TS's or TR's may become full standards at some point in the future. European standards are a particular area of focus for NSAI.

Because Ireland is a member of the EU, we are obliged to adopt all European standards as national standard and to withdraw national conflicting standards. This is the case ONLY for standards, not for European TS's or TR's. There is no such obligation for International standards. Next slide.

Slide 9

Here is the development process for ISO Standards. The different stage codes or numbers indicate different steps of the development process. Some of the stages are obligatory and must be completed by the Technical committee. These include the proposal stage – all new proposals require support by at least 5 members in order to be approved.

The Enquiry stage is an important part of the process where the draft is made available to the public for comment. This is done in each country through the member body or the National Standard Body.

The final stage is publication where the standard is approved before final publication. Other stages may be skipped based on the committee's decisions, the level of maturity of the document and the level of consensus. Next slide.

Slide 10

This is the development process for CEN/CENELEC and is similar to the process in ISO with options to skip some of the stages. There is also flexibility given to committees as to how long they spend on drafting stages. New Work Items or NWI's need to be approved to appear on the work programme and require up to 5 members to approve.

There is also an enquiry or Public comment stage in this process, allowing those who are not involved in the process a chance to view and comment of the draft. In this process there is time built in for translation of the draft into different languages. It typically takes up to 3 years for a standard to be developed with Technical Reports and Technical Specifications developed in a shorter timeframe, requiring only one ballot before publication. Next slide.

Slide 11

Here we see the different project stages, names and abbreviations used at both International and European level for the standard development process. This is important to know as the abbreviation is generally included in any ballot document and indicates how far in the process the draft is. You should become familiar with these.

It is important to note that technical changes are no longer accepted once the draft has reached the Final Draft stage or Formal vote stage. This is shown in this table of the different stages with green text for the earlier stages – Proposal or stage 10, Working draft of stage 20, Committee draft or stage 30 and Enquiry or stage 40. Red text indicates no more technical changes and applies for stages 50 – final approval and Publication or stage 60. Next slide.

Slide 12

Once a standard is published it does undergo review every 3 to 5 years. A Systematic Review is a periodic review of a standard which occurs every 5 years for a standard and every 3 years for a Technical Specification. Members are asked to confirm the standard or seek to revise a standard. Technical committees may update a standard based on feedback from the Systematic Review.

A published standard can be corrected by the addition of Corrigenda's, usually added after publication to correct an error or typo. Amendments can also be added post publication to include important new information needed for safety reasons etc. These additions are included in the name and numbering of the standard, so the user is aware of the most recent additions, we have an example of this in a later slide. Next slide.

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This slide addresses the obligation of members of CEN/CENELEC regarding the adoption of all published European standards as national standards. NSAI being a member of CEN and CENELEC is obliged to publish all European standards as National or Irish Standards, or I.S. Therefore, all EN or European standards become de facto I.S. or Irish Standards. Once a standard is made available by the CEN, this is the D-A-V or Date of Availability. Members have up to 6 months to publish the standard as a national standard.

In general, NSAI publishes standards withing 2-3 weeks from the DAV. Other members may have to translate documents hence the timeframe is 6 months. The D-O-P or Date of Publication is the latest date for publication as a national standard and the D-O-W or Date of Withdrawal is the latest date for withdrawal of conflicting national standards that members need to comply with. If you are using standards it is important to ensure you have the most up to date version of the standard. Next slide.

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Here is an example showing D.A.V. dates including two updates, an amendment (update) and a corrigendum (correction). The standard is ISO 13485 – Medical devices – Quality management systems – requirements for regulatory purposes. It was made available by CEN in March 2016. This new edition supersedes the 2012 edition. A correction was issued as a corrigendum in March 2018, and this shown in the standard name by the addition of AC:2018 at the end of the standard number. There is a new amendment being worked on, with the DAV expected in October 2021. All published versions have been published as Irish Standards or I.S. All versions are mandated by the European Commission which means this standard can be used to support compliance with European Medical devices regulations. These are known as Harmonised standards but more on Harmonised Standards later. Next slide.

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There is co-operation between International and European standard development organizations. The overall aim is to eliminate duplication of work and to ensure there is one standard accepted worldwide. The Vienna Agreement is between CEN and ISO with ISO generally taking the lead in the development work. It results in parallel votes at both CEN and ISO and the adoption of ISO standards by CEN. Similarly, there is the Frankfurt agreement between IEC and CENELEC that supports planning of joint work with IEC generally taking the lead. It results in parallel votes and European adoption of international standard. This will result in national adoption of such standards. All developments are based on consensus. Next slide.

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Here we have a table showing examples of how the standard number can show where the standard originated. For example, the first three, I.S. 123, S.R. 123 and SWiFT 123 cover the three different of national deliverables that NSAI can develop and are shown in Green.

The next example, EN 12345 is a European example that could have been developed by CEN or CENELEC and this is shown in Blue. The next two examples, ISO 12345 and IEC 60125 are international standards published by ISO and IEC respectively, just back text.

The next example, I.S. EN ISO 12345 is a European standard that is published as an Irish standard hence the I.S. is shown in green with EN 12345 shown in blue. In the next two examples, EN ISO 12345 is the European adoption of an ISO standard that would have been developed under the Vienna agreement, the EN is shown in blue. I.S. EN ISO 12345 is the National adoption of the European and international standard with the I.S. shown in green and the EN in blue, which we are obliged to do being a member of CEN.

In the next example, I.S. ISO 12345 it is the Irish adoption of an international standard which can be done on a voluntary basis, there is no obligation to do so

but if a standard is particularly useful nationally it may be adopted. The I.S. here is shown in green to highlight the national adoption.

The final example, ISO/IEC shows a joint work between ISO & IEC. Next slide.

Slide 17

We had previously mentioned a particular group of standards called "Harmonised Standards". This slide shows a quote taken directly from the Commission website that defines what a Harmonised standard is. It is important to note that harmonised standards are only generated following a request from the European Commission. They are developed by European Standard organizations and can be used to demonstrate that products, services or processes comply with relevant EU legislation.

It is important to note that NOT ALL EN or EUROPEAN STANDARD ARE HARMONISED STANDARDS – Only those mandated by the Commission. Harmonised standards are issued by the Commission and are listed in the Official Journal of the EU. Many different sectors use harmonised standard for example chemicals, construction, transport and healthcare. Next slide.

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Finally, as an NSAI expert it is important to be aware of national mirror committee functions. These are set out in NSAI procedure NSAI P-ST 01which covers the operation and review of NSAI Technical bodies. Appendices to this procedure set out functions of NSAI.

Some of the functions as listed here include advising NSAI on standard, monitoring international committee activities, agree international participation and attending international plenary meetings, drafting national forewords and national annexes as necessary and also developing national standard where needed as well as providing advice and supporting promotion and awareness of standards.

All standards work is based on code of conduct that include respect and professionalism. A key function of national mirror committees is to advise NSAI on the development of standards including international standards in the area. The national balloting system facilitates this, and experts are encouraged to use this platform to provide their comments and feedback on standards. The next module will cover how to use this system. Next slide.

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Thank you for your attention. For more information on standards and for other modules on standardization please see our Learning Centre on the NSAI website NSAI.ie.

End of Module 2B