NSAI Biotechnology Standards Consultative Committee Newsletter

The International Organization for Standardization, ISO develops international standards in many fields. In 2013 a Technical committee, TC was established to develop standards in the field of biotechnology – ISO TC 276. To mirror this, the NSAI established the NSAI Biotechnology Standards Consultative Committee (NSAI TC 62) in 2014.

The current scope of ISO TC 276 is as follows:

Scope

Standardization in the field of biotechnology processes that includes the following topics:
terms and definitions; biobanks and bioresources, analytical methods; bioprocessing,
data processing including annotation, analysis, validation, comparability and integration, metrology.

The current structure of ISO TC 276 is organised into working groups (WG) with responsibility for development of standards in the following areas:

ISO/TC 276/WG 1 Terminology
ISO/TC 276/WG 2 Biobanks and Bioresources
ISO/TC 276/WG 3 Analytical methods
ISO/TC 276/WG 4 Bioprocessing
ISO/TC 276/WG 5 Data processing and integration

Latest news from ISO TC 276 and NSAI TC 62:

Ireland has actively contributed to the work of WG2 to date. Emma Snapes of INFANT, UCC has been an active participant and contributor to the work of ISO TC 276 WG2. To date she has travelled to attend WG2 meetings in China, Japan, USA, Ireland, Korea and Italy. Her participation is supported by the Health Research Board (HRB) in Ireland.

One of the outputs of this group includes ISO Draft International Standard (DIS) 20387 – Biobanking – General requirements for biobanking. Emma has contributed greatly to the development of this new biobanking standard, having travelled to all
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meetings of WG2 to date and ensuring that Irish national interests are represented. The draft standard was available for public comment from the NSAI portal “Your Standard Your Say” from July-September, 2017. A workshop was organized for national stakeholders in St. James Hospital on the 14th of Sept. This event was well attended with a lot of interest shown in the new ISO biobanking standard. Comments were submitted to NSAI, reviewed by the mirror committee members NSAI TC 62 and submitted to ISO as Ireland’s contribution to the public commenting phase for ISO DIS 20387.

The most recent working group meetings of ISO TC 276 were held Nov 27-Dec 1st, 2017 in Rome. National experts including representatives from INFANT in UCC, TCD, Supertec box Ltd, participated in meetings of WG2 and WG5. The biobanking standard ISO 20387 is planned for publication in 2019.

Dr Suzanne Bracken (CRDI) and Linda Hendy (NSAI) – Chair and secretary of NSAI Biotec SCC at the Biobanking standards workshop.

Delegates attending the workshop on ISO DIS 20387 – Biobanking, General requirements for biobanking, in St James – Sept 2017.

Updates from the Working Groups

Working Group 1 “Terminology” have prepared a technical report (TR) based on a compendium of currently used terms and definitions, related to the work of ISO/TC 276 Biotechnology. The compendium provides information on different interpretations of terms and on the sources used to contribute to the definitions. WG1 will regularly review and update the TR. The draft international standard ISO TR 20186 – Inventory of biotechnology related terms has completed the public consultation stage.
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Working Group 2 “Biobanks and Bioresources” is working on several proposals in the field of biobanks. As described above, the draft document “Biotechnology – Biobanking – General requirements for Biobanks” which addresses general requirements for biobanks and aims to ensure consistent quality in sample collection, recently went through the public consultation phase and was approved with comments for the next phase.

Working Group 3 “Analytical methods” aims to develop standards for accurate, reproducible, robust measurement and analysis focusing on biologically relevant molecules and entities, including nucleic acids, proteins, and cells. Currently draft documents exist for cell counting, cell characterization and oligonucleotides. The draft international standard ISO 20391-1 – Biotechnology – Cell counting – Part 1: General guidance on cell counting methods, is at the final approval stage; while ISO/CD 20391-2 Biotechnology -- Cell Counting -- Part 2: Experimental design and statistical analysis to quantify counting method performance, is at the committee draft stage (before public consultation).

Working Group 4 “Bioprocessing” focuses on the development of biotechnology products, with emphasis on the processes rather than the products. It aims to develop standards for ensuring consistent, controlled and tracked processes to give confidence to suppliers and users of products. Draft documents include “Raw materials control for bioprocessing – Part 1: General definitions and requirements for quality control”, “Part 2: Best practice guide for suppliers” and “Part 3: Best practice guide for developers”. These are at the end of the working draft phase.

Working Group 5 “Data processing and integration” aims to develop standards for traceable, searchable and interoperable data together with integrated data processing for biotechnology and the life sciences. Its work focuses on the definition of data and metadata, model formats and their interfaces, and quality management of processed data and models. Documents are at the preparatory phase.

For further details and to access the current TC work programme use the link: https://www.iso.org/committee/4514241/x/catalogue/p/1/u/1/w/0/d/0

New proposals for standardization within ISO TCD 276 include:

ISO 20395-1 - Biotechnology -- Guidelines for evaluating the performance of targeted nucleic acid quantification methods -- Part 1: qPCR and dPCR

ISO 20397-2 - Biotechnology -- General requirements for massive parallel sequencing -- Part 2: Methods to evaluate the quality of sequencing data

ISO 20691 - Biotechnology -- Requirements for data formatting and description in the life sciences for downstream data processing and integration workflows
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ISO 21709 - Biotechnology -- Biobanking -- Process and quality requirements for establishment, maintenance and characterization of mammalian cell lines

ISO 21710 - Biotechnology -- Data management and publication in microbial biological resource centres

ISO 21899 - Biotechnology -- Biobanking -- General requirements for the validation and verification of processing methods in biobanks

ISO 21973 - Biotechnology -- General requirements to establish specification of cell transportation

ISO TR 22785 - Biotechnology -- Biobanking -- Implementation guide for ISO 20387

General Information on NSAI and the NSAI Biotechnology Standards Consultative Committee

The National Standards Authority of Ireland, NSAI is a member body of the International Organization for Standardization (ISO). Through this membership, national stakeholders can access information and draft developing standards. NSAI set up the Biotechnology Standards Consultative Committee, a national “mirror” group (NSAI TC 62) to facilitate national stakeholder involvement with standards being developed in the field of biotechnology. NSAI TC 62, chaired by Dr Suzanne bracken of Clinical Research Development Ireland, CRDI is the national forum for contribution to ISO TC 276 and addresses the following:

- Ensures national experts can access international working groups and working documents
- Nominates national experts to get involved in relevant international working groups
- Monitors output of ISO TC 276 to ensure national interests are addressed
- Provides comment and national input on the development of international standards to ensure national stakeholders are not disadvantaged
- Keeps national stakeholder informed of relevant international biotechnology standards information in the field

For more information on how to participate in this and other standard development, please register your interest with:

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