

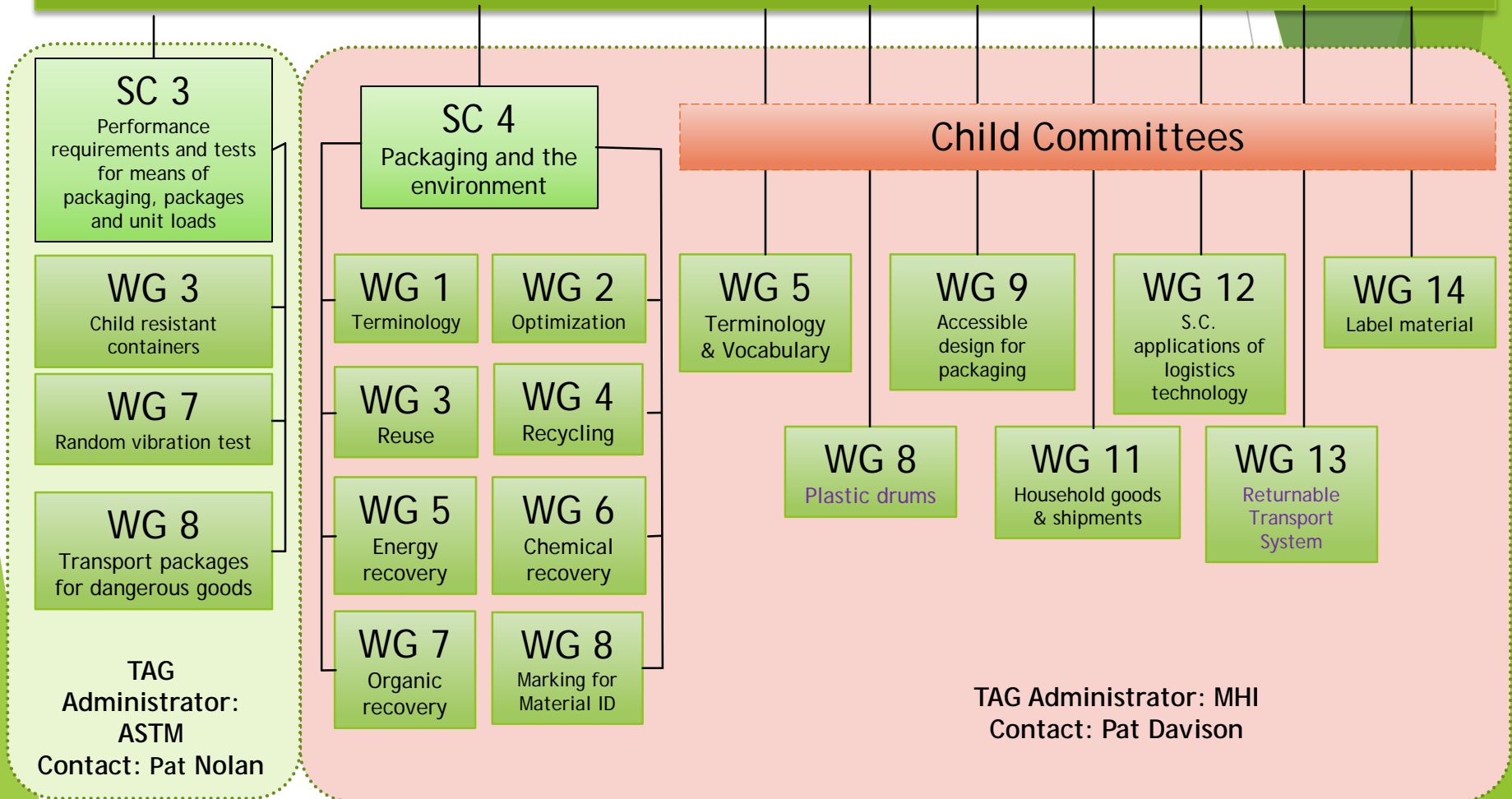
ISO/TC 122 and ANSI/MH 10 Committee Structure

Slides 1 to 4 from Patrick Davison
Remaining slides by Jan Gates
9 April 2016

ISO/TC 122 Committees

ISO/TC 122 - Packaging

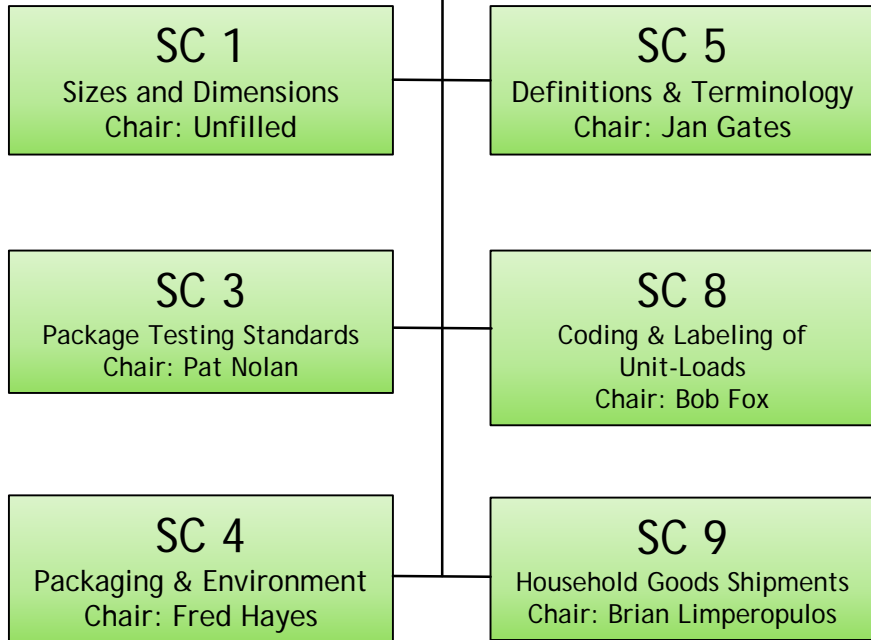
US TAG Chair: Dan Kimball



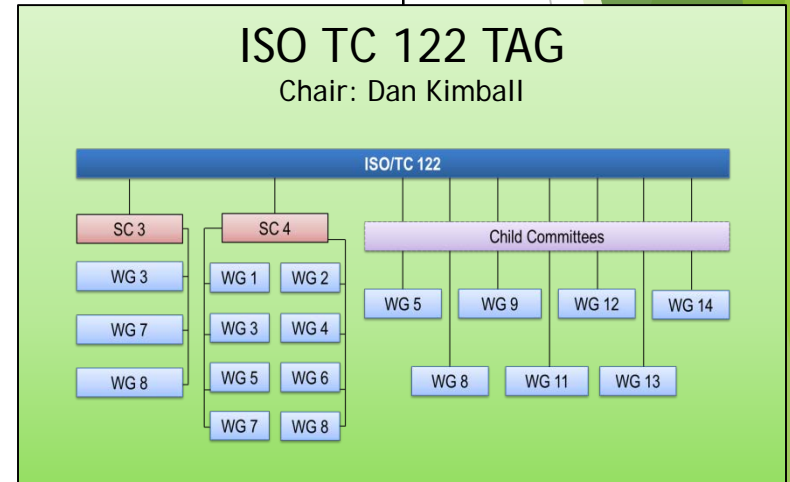
ANSI/MH 10 Committees

ANSI/MH10
Chair: Dan Kimball

ANSI Committees



ISO TAG Committee



ISO/TC122 Packaging

Secretariat: [JISC](#)

Twinned secretariat: [ISIRI](#)

Secretary: [Mr. Akira Shirakura](#)

Twinned secretary: [Ms. Manijeh Abdi](#)

Chairperson: Dr Takeo Shiina until end 2020

ISO Technical Programme Manager: [Mme Maho Takahashi](#)

ISO Editorial Programme Manager: [Mr Francesco Dadaglio](#)

Creation date: 1966

Scope:

Standardization in the field of packaging with regard to terminology and definitions, packaging dimensions, performance requirements and tests.

Excluded : matters falling within the scopes of particular committees (e.g. TC 6, 52 and 104).

Total number of published ISO standards related to the TC and its SCs
(number includes updates): 76

Number of published ISO standards under the direct responsibility of
ISO/TC 122 (number includes updates): 41

Participating countries: 34

Observing countries: 44

ISO/TC 122

- ▶ Standards and projects under the direct responsibility of ISO/TC 122 Secretariat = 54
- ▶ Standards and projects under the direct responsibility of ISO/TC 122/SC 3 Secretariat = 27
- ▶ Standards and projects under the direct responsibility of ISO/TC 122/SC 4 Secretariat = 10

ISO/TC 198 Sterilization of Health Care Products

•Secretariat: [ANSI](#)

Secretary: [Ms Amanda Benedict](#)

Chairperson: Dr. Eamonn V. Hoxey until end 2016

ISO Technical Programme Manager: [Dr Mary Lou Pelaprat](#)

ISO Editorial Programme Manager: [Mrs. Laura Mathew](#)

Creation date: 1990

Scope:

Standardization of processes and equipment for sterilization of health care products.

Total number of published ISO standards related to the TC and its SCs 54

(number includes updates):

Number of published ISO standards under the direct responsibility of 54

ISO/TC 198 (number includes updates):

Participating countries: 27

Observing countries: 24

TC 198 Standards

[ISO 11135:2014](#) Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
[ISO 11137-1:2006](#) & Amd 1:2015 Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
[ISO 11137-2:2013](#) Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
[ISO 11137-3:2006](#) Sterilization of health care products -- Radiation -- Part 3: Guidance on dosimetric aspects
[ISO 11138-1:2006](#) Sterilization of health care products -- Biological indicators -- Part 1: General requirements
[ISO 11138-2:2006](#) Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization processes
[ISO 11138-3:2006](#) Sterilization of health care products -- Biological indicators -- Part 3: Biological indicators for moist heat sterilization processes
[ISO 11138-4:2006](#) Sterilization of health care products -- Biological indicators -- Part 4: Biological indicators for dry heat sterilization processes
[ISO 11138-5:2006](#) Sterilization of health care products -- Biological indicators -- Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes
[ISO/TS 11139:2006](#) Sterilization of health care products -- Vocabulary
[ISO 11140-1:2011](#) Sterilization of health care products -- Chemical indicators -- Part 1: General requirements
[ISO 11140-2:2007](#) & Cor 1:2007 Sterilization of health care products -- Chemical indicators -- Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
[ISO 11140-4:2007](#) Sterilization of health care products -- Chemical indicators -- Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration
[ISO 11140-5:2007](#) Sterilization of health care products -- Chemical indicators -- Part 5: Class 2 indicators for Bowie and Dick-type air removal tests

[ISO 11607-1:2006](#) & Amd 1:2014 Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems

[ISO 11607-2:2006](#) & Amd 1:2014 Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes

[ISO 11737-1:2006](#) & Cor 1:2007 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
[ISO 11737-2:2009](#) Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
[ISO/TS 13004:2013](#) & Amd 1:2013 Sterilization of health care products -- Radiation -- Substantiation of selected sterilization dose: Method VDMA5D
[ISO 13408-1:2008](#) & Amd 1:2013 Aseptic processing of health care products -- Part 1: General requirements
[ISO 13408-2:2001](#) Aseptic processing of health care products -- Part 2: Filtration
[ISO 13408-3:2006](#) Aseptic processing of health care products -- Part 3: Lyophilization
[ISO 13408-4:2006](#) Aseptic processing of health care products -- Part 4: Clean-in-place technologies
[ISO 13408-5:2006](#) Aseptic processing of health care products -- Part 5: Sterilization in place
[ISO 13408-6:2006](#) & Amd 1:2013 Aseptic processing of health care products -- Part 6: Isolator systems
[ISO 13408-7:2014](#) Aseptic processing of health care products -- Part 7: Alternative processes for medical devices and combination products
[ISO 14160:2011](#) Sterilization of health care products -- Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives -- Requirements for characterization, development, validation and routine control of a sterilization process for medical devices
[ISO 14161:2009](#) Sterilization of health care products -- Biological indicators -- Guidance for the selection, use and interpretation of results
[ISO 14997:2009](#) Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
[ISO 15287:2008](#) Sterilization of health care products -- Chemical indicators -- Guidance for selection, use and interpretation of results
[ISO 15288-1:2006](#) & Amd 1:2014 Washer-disinfectors -- Part 1: General requirements, terms and definitions and tests
[ISO 15288-2:2006](#) Washer-disinfectors -- Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
[ISO 15288-3:2006](#) Washer-disinfectors -- Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers
[ISO 15288-4:2008](#) Washer-disinfectors -- Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
[ISO/TS 15288-5:2003](#) Washer-disinfectors -- Part 5: Test soils and methods for demonstrating cleaning efficacy
[ISO 15288-6:2011](#) Washer-disinfectors -- Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment
[ISO 15288-7:2016](#) Washer-disinfectors -- Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment

[ISO/TS 16775:2014](#) Packaging for terminally sterilized medical devices -- Guidance on the application of ISO 11607-1 and ISO 11607-2

[ISO 17664:2004](#) Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices
[ISO 17666-1:2006](#) Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
[ISO/TS 17665-2:2003](#) Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1
[ISO/TS 17665-3:2011](#) Sterilization of health care products -- Moist heat -- Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization
[ISO 18262:2016](#) Manufacture of cell-based health care products -- Control of microbial risks during processing
[ISO 18417:2006](#) Sterilization of health care products -- Biological and chemical indicators -- Test equipment
[ISO 20087:2010](#) Sterilization of health care products -- Dry heat -- Requirements for the development, validation and routine control of a sterilization process for medical devices
[ISO 25424:2009](#) Sterilization of medical devices -- Low temperature steam and formaldehyde -- Requirements for development, validation and routine control of a sterilization process for medical devices

MHI General Meeting

- 1 April 2016

- ▶ Reorganizing structure to match ISO committees
- ▶ Pat Davison is working to reorganize the MHI/MH10 structure and communications
- ▶ Dan Kimball is the ANSI/MH10 - US Tag for TC122
 - ▶ Currently traveling until June
- ▶ Two WG need leaders:
 - ▶ **WG 13 Returnable Transport Systems**
 - ▶ **WG 8 Plastic Drums**

MHI/MH10 Openings - Contacts

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