USAID'S HEALTH EVALUATION AND APPLIED RESEARCH DEVELOPMENT (HEARD) PROJECT

Standards Working Group Meeting Recap
December 14, 2022

The ISWP Standards Working Group met by conference call on Wednesday, December 14 12:00 – 1:30 pm U.S. Eastern Standard Time/17:00 – 18:30 GMT. This provides a meeting recap. Action items and individuals responsible are shown in bold/underline.

Next call: Wednesday March 8 , 2023 12:00 p.m. U.S. Eastern Standard Time/17:00 GMT.

1. **Introductions:** Welcome to Alex Kamadu, who joined ISWP as Executive Director, and brief introductions for attendees of the ISWP Standards Working Group and Wheelchair Testing Centers meeting.

2. **ISWP Update:** Alex attended two meetings in Geneva in late October. The first meeting was with AT Scale, an organization which provides pooled funding, and which has a focus on assistive technology and wheelchairs. Key stakeholders attended from the development part of the sector, in follow up from the stakeholder meeting in Bangalore in 2018, and a report will be available from that meeting. UNICEF is a global purchaser of assistive technology, and Dennis Sotoberg from UNICEF presented and talked about challenges to the wheelchair sector. Some challenges include market fragmentation, lack of harmonization of standards, and the need for further progress to operationalize standards for global purchasers. The second meeting at WHO was on Global Wheelchair Service Standards, which will be published in April, and are focused on the workforce delivering appropriate wheelchairs. Both meetings were opportunities for Alex to meet and network with stakeholders.

   In the near term, the current founding board will be expanded to a full board and include voting members to meet the governance requirements for a nonprofit. We are working through the final process of receiving another grant from USAID which will be awarded to the new entity, with an expected amount of $1.5 million, which will provide support for a few years of operations. In 2023, ISWP will contract with the University of Pittsburgh for time from needed personnel to support the transition and operations, but at a reduced level of effort.

3. Flammability Standard (ISO 16840) Kara Kopplin

The ISO Wheelchair Seating Standards Working Group has been looking into the flammability standard, its appropriateness, and how it might be improved.

Background

There are a variety of flammability standards, most of which were developed for furniture but have been applied to wheelchairs, initially for cushions but later expanded for all contact and postural support surfaces. The ISO 7176-16 standard uses an open flame for testing, whereas ISO 16840 use a simulated cigarette. ISO 16840-10 is a relatively new standard for flammability, published about 8 years ago.

Incidence

First, the group looked into how often this is a problem, and found the incidence rate was less than 4 persons per million. The incidence rate is low compared with pressure injuries, which kills 60,000 people per year. It was reiterated that seating is a medical device (not furniture) and should not focus on mitigating an issue with a very low incidence rate.

Standards

ISO 7176-16 was replaced with ISO 16840-10 in 2021. The major difference between standards is that ISO 7176-16 evaluates the time for a flame to extinguish compared with ISO 16840-10, which evaluates resistance to ignition and flaming. The flammability standards should be applied to all wheelchair support surfaces. The European standards EN12183 and EN12184 were updated adding ISO 16840-10 as the preferred flammability test method. These standards have to be adopted as part of the medical device requirements in Europe before becoming a legal requirement. In the US, the FDA currently recognizes ISO 7176-16 even though the 16840 replaced it, although manufacturers can use 16840 for testing.

Alternative ignition source

The purpose of evaluating alternative ignition sources was to expand opportunities for labs to use a more cost effective ignition source. Multiple laboratories evaluated the proposed alternative nickel chromium (NiCR) coil as an ignition source in place of the electronic cartridge. The standard requires verifying the ignition temperature, and temperature sensitive paints are often used to accomplish this, but it is complicated. A simpler and more streamlined test measuring ignition time for paper was developed and validated across labs, correlating coil amperage (2.0 to 2.5 amps) with time for paper ignition. Measuring paper ignition time replaced temperature sensitive paints to determine coil temperature, and simplified testing.

Addendum to ISO 16840-10 to add hot wire

The working group formally proposed this draft (addition of an alternative NiCR coil as ignition source) to the standard at the Berlin ISO meeting in October 2022. The group approved proceeding with the Annex to ISO 16840-10, and it was submitted in December 2022 for balloting.

4. ISO TC 173 Lab Certification Perspective – Kara Kopplin
The working group looked into good laboratory practices (GLP), which specify what is required for a lab to verify they are following good laboratory practices. GLP are general and broad, and are used by many different industries. There are both GLP guidelines and formal standards (ISO 17025:2017).

Challenge
For wheelchair testing, manufacturers need a lab which has 1) good lab practices (their own standards or 17025) and 2) expertise with these specific tests. The issue is there are a limited number of labs that conduct wheelchair testing, often small labs with limited resources, and meeting GLP certification or requirements may be a challenge to these small labs. Knowing how difficult it is to find labs that can do these tests, and that a lot of smaller labs can't afford to get ISO 17025 certification, was why the working group looked into this issue.

Requirements for GLP
The FDA requires GLP, which can be met either with 1) ISO 17025 or 2) test lab internal processes to demonstrate the lab meets FDA GLP requirements. In Europe, GLP requirements are stated, but does not specify ISO 17025, although certification to the ISO standard would meet the GLP requirement. It is the same situation with ISO and EU standards for wheelchairs and seating. Terms like "ISO 17025 or equivalent" are often used.

Proposal for clarifying statement
The working group came up with some proposed language to clarify the GLP requirement (that ISO 17025 certification is not required, and that GLP requirements can be met with internal lab standards. Although this was discussed at the ISO plenary session, it was concluded that no statement will be made by ISO. The primary concerns were that it would give a perception there is an issue with ISO 17025.

Questions and Comments
- Are GLP guidelines available to the public?
   Yes, the FDA outlines GLP requirements which are in line with ISO 17025.

- Could labs coordinate to work together to demonstrate proficiency in order to save cost? Proficiency requires performing the same test with three different testers, which could also be considered across labs. The cost of demonstrating proficiency with ISO 17025 is part of the high cost. A place where ISWP might help small labs is with the proficiency test. Instead of three different testers in one organization, multiple labs could demonstrate that one lab gets same result as another lab, thus reducing costs.

- One participant shared that although their wheelchair was tested to ISO 7176, certain countries (Kenya, Brazil) may require re-testing in their own specified labs, which means incurring additional significant cost. This creates another barrier to getting affordable wheelchairs to people who need them.

5. ISO updates – Bill Ammer

Bill Ammer provided a brief overview of ISO technical committees in the ISO portal on https://www.iso.org/technical-committees.html. There are many technical committees, TC173 is the technical committee for assistive products. Within TC173 SC1, there are four working groups and multiple subcommittees. Bill is the chair for WG1 Test methods working group. The other three working groups are WG6 (wheelchair restrain systems), WG10 (requirements and test methods for elect-technical systems for wheelchairs (power wheelchair testing requirements) and WG 11 (wheelchair seating). The current standards for each subcommittee are listed, along with the status/stage of the standard. Bill talked about the importance of standards, and encouraged individuals who are interested in standards to get involved. A benefit of involvement is learning more about what we are trying to do and the reasoning behind it.

6. Group Updates

Jack Fried: The paper is published "Accelerated wear testing shows that thermoplastic bushings could be a cost-effective and durable alternative to traditional bearings for wheelchair caster use" J. Fried, J. Pearlman, A. Mhatre. Journal of Rehabilitation and Assistive Technologies Engineering Dec 2022. https://doi.org/10.1177/20556683221144805

Holly Wilson-Jene: Work is progressing on a rolling resistance decision support tool. Clinician feedback is being used to guide development and revision, with multiple revisions completed. Clinician evaluations and feedback has been important for the tool's development.

7. Next Call: Wednesday March 8, 2023, 12:00 p.m. U.S. Eastern Standard Time/17:00 GMT.

✓	Bonnie Gonzalez, Free Wheelchair Mission	✓	Clive Brett, Kyaninga Child Development Centre
	Ben Judge, GRIT	✓	Nichole Ritchie Orton, UMTRI
✓	Keoke King, Participant Assistive Products	✓	Daniel Jefwa
	Dean Mubaiwa, ShonaquipSE		Marjelle Scheffers, BambooAbility
✓	Shona McDonald, ShonaquipSE	✓	Dave Brienza, University of Pittsburgh
✓	Matt McCambridge	✓	Jon Pearlman, University of Pittsburgh
✓	Norman Reese, LeTourneau University	✓	Nancy Augustine, University of Pittsburgh
✓	Bonnie Gonzalez, Free Wheelchair Mission	✓	Holly Wilson-Jene, University of Pittsburgh
✓	Don Schoendorfer, Free Wheelchair Mission	✓	Stephanie Vasquez, University of Pittsburgh
	Scott Walters, Mobility Worldwide	✓	Tricia Karg, University of Pittsburgh
✓	Kara Kopplin, Permobil, ISO, RESNA	✓	Daniel Umaña, CIREC
✓	Jack Fried, University of Pittsburgh		Elia Bernabeu Mira
✓	Bob Appleyard	✓	Jim Watson, CIC
✓	Evan Call, EC Service, Corp.		Mariana Castro Medina
✓	Alex Kamadu, ISWP	✓	Bill Ammer, Ammer Consulting

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