Wheelchair Flammability Standard ISO 16840-10
Overview of the Risk and Evidence-Based Approach

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Wheelchair Seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method

ISO 16840-10 Executive Overview October 19, 2020
Wheelchairs -- Resistance to ignition of non-integrated seat and back support cushions

The aim of this ISO standard is to provide appropriate alternatives to using furniture-based flammability standards, to reflect the uses and purposes of wheelchairs and their accessories.

From the original release of ISO 16840-10 in 2014, through its extensive evolution to the current standard, the function of wheelchair seating, and the needs of seated client, have been carefully considered and researched. The approach has followed the guidance of the new medical device regulations in Europe (MDR) as well as the medical device risk management approach of ISO 14971. Key to this analysis was an understanding and emphasis on what benefits wheelchair seating provide the user, what risks the users may be exposed to, and what the potential, unintended harms may be. In performing this review, standards committee members from the US RESNA, international ISO, and European CEN committees have provided input, challenged thinking, and led to the conclusions that drove the publication of this newly evolved standard for flammability.

As noted in the standard “given the minimal risks of flammability as a hazard in wheelchair seating, and the significant potentially adverse health effects of flame retardants, strong consideration should be given to utilizing ISO 16840-10 as the ignition resistance standard for all wheelchair seating textiles/soft components which interface with the human body. Eliminating the more severe flame resistance required by furniture standards and ISO 7176-16:2012 compliance allows more clinically appropriate textiles to be used, for the health and comfort of the wheelchair user.”

I. The Problem

Although ISO 16840-10 was first published in 2014, specifically for clinical wheelchair seat and back cushion technologies, tender and registration bodies continue to request furniture flammability standards such as EN 1021-1 and EN 1021-2 in 2018, particularly through the more general requirements of EN 12182, EN 12183, and EN 12184.
As a result, wheelchair users have not benefited from the work of this WG11 committee. Our recommendation is that ISO 16840-10 be adopted by statutory and regulatory authorities. Furniture standards should apply only to consumer products, since they do not consider the unique clinical benefits that proper, medical wheelchair cushion surfaces provide to individuals. [1]

II. Risk Considerations

The intended clinical benefits of wheelchair seating, the associated risk from ignition sources, and potential unintended risks and harms were considered:

A. Intended Use / Intended Function

- Wheelchair seat and back cushion design is critical to providing skin/soft tissue protection as well as postural support. ISO 16840-10 states: “The intent of this document is primarily to cover cushions whose described purpose is that of protecting skin tissue against pressure, shear, and maceration related damage, as well as textile based postural support devices, all of which are ‘soft components’ which interface with the human body.”
- Immersion and envelopment are key design strategies to provide tissue protection. Per the International Clinical Practice Guideline (CPG), “Cushion construction achieves pressure redistribution in one of two basic methods: immersion/envelopment or redirection/off-loading” [2]
- Cover design is critical, as the CPG notes “select a stretchable/breathable cushion cover that fits loosely on the top of cushion surface and is capable of conforming to the body contours” [2]
- Biocompatibility is important for the end user, with ISO 16840-10 stating “Materials chosen are to comply with biocompatibility requirements and risk management guidance of ISO 10993–1”

B. Unintended Risks from Flame Retardants

- Stiffer Materials are typically employed to achieve the flammability resistance of open flame, furniture standards, which can limit the necessary immersion and envelopment of the body in the cushion, thereby reducing the intended skin/soft tissue protection.
- Stiffer Cover Materials may not allow for the recommended stretching, breathability, and conformance to body contours.
- Toxic chemicals, as recognized in the European Union and/or other regions of the world, are often employed to provide the flame resistance.
  - In 2018 The State of California issued a regulatory amendment to eliminate the use of open flame standards for furniture in public buildings, because compliance to current open flame test TB 133 presents “unnecessary health risks”, further stating “by reducing the need for flame retardant chemicals, this action is anticipated to improve public health by reducing exposure to carcinogenic organohalogen flame retardants” [3]
  - Jan 22, 2019 California’s Bureau of Electronic and Appliance Repair, Home Furnishings and Thermal Insulation (Bearftht) repealed Technical Bulletin (TB) 133 – The Flammability Test Procedure for Seating Furniture for Use in Public
Occupancies. Bearhthi said TB 133 has become “obsolete” in most areas, as it overlaps with the recently updated TB 117-2013. Furthermore, it said, the use of organohalogen flame retardants typically used to meet TB 133 “present significant health risks to consumers, as established by overwhelming scientific research. [4]

- In 2015 Minnesota legislators passed into law the “Firefighter and Children Health Protection Act” which prohibits the sale and distribution of children’s products and upholstered residential furniture that contain more than a certain amount of one or more flame retardant chemicals named within the bill. [5]

- The Minnesota research examined numerous flame retardant chemicals, all of which are banned in the Cal Prop 65 list, and many are banned in the REACH Substances of Very High Concern (SVHC) list. The report cites evidence that flame retardants may present exposure and health concerns, including:
  - Crossing the placenta and passing through breast milk
  - Altering the endocrine system, causing fluctuations in thyroid production.
  - Altering sex hormones
  - Affecting the nervous system
  - Causing uterine tumors
  - Affecting reproductive health
  - Affecting early development
  - Causing cancer

- Harmful chemicals can be released by ignition itself. ISO 16840-10 states “Good practice is also to use materials which minimize the risk of release of toxic substances as a result of ignition, and which do not pose a biocompatibility risk to the wheelchair user.”

C. Probability of Occurrence

- Ignition of wheelchair components is extremely low as evidenced by the FDA MAUDE database of reportable events [6]. There are an estimated 3.6 million US citizens who use wheelchairs [7], and events tagged as flammability occurrences accounted for less than one one-hundredth of a percent, with at least a third being unrelated/incorrectly tagged.

- Commercially available cigarettes now have a reduced ignition propensity (RIP). The WHO reports “adoption of the RIP standard by US appears to be the principal reason for a 30% decline in smoking material deaths from 2003 to 2011…All 50 US States, Australia, Canada, Iceland, South Africa, and all 28 European Union Member States have adopted policies enforcing RIP cigarettes” [8]

- Smoking as an ignition source has decreased. Per the Centers for Disease Control cigarette smoking among U.S. adults (aged ≥18 years) declined from 20.9 percent in 2005 to 15.5 percent in 2016 [9]

- As noted in ISO 16840-10, “In the United States, data collected in the 1990s showed that only a small number of individuals per million wheelchair users had died due to fire” [12].

- As noted in ISO 16840-10, “Public FDA records indicate most 21st century flammability incidents involving wheelchairs are from electrical faults” [6].

- Unlike a mattress or couch, in a wheelchair seating system, the amount of material that could be exposed to an ignition source is extremely low, and many of those areas are vertical surfaces on which a flame or match could not rest.
D. Overall Risk Management:

- Underwriters Laboratories commented upon the California regulations, which are used throughout the US: "environmental advocates, health professionals and academics, expressed concern about the use of FR chemicals in upholstered furniture. These concerns ultimately led to an executive order from the California Governor instructing the BHFTI to revise California TB 117 to eliminate the need for FR chemicals in furniture sold in California, while at the same time not reducing the level of safety to the public. [10]

- ISO 16840-10 “The day to day usage of a wheelchair may affect its materials’ resistance to ignition...Different environments commonly encountered by some wheelchair occupants may also affect the flammability of materials... Wheelchair manufacturers and occupants should be aware of these risks, and design and use wheelchairs accordingly as covered by ISO 14971”

- ISO 16840-10 “Requirements for the control of risks from sources of fire created by electrical and electronic components are included in ISO 7176–14” Per the MAUDE database search, electrical sources accounted for the vast majority of the (extremely limited) flammability incidents, [6] so this risk is managed through the ISO 7176-14 standard.

- MDR Regulation (EU) 2017/745 All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use. [11]

E. Committee Recommendation:

The requirements of this document have been set at a basic minimum level and are less severe than current requirements in some countries. However, given the minimal risks of flammability as a hazard in wheelchair seating, and the significant potentially adverse health effects of flame retardants, strong consideration should be given to utilizing ISO 16840-10 as the ignition resistance standard for all wheelchair seating textiles/soft components which interface with the human body. Eliminating the more severe flame resistance required by furniture standards and ISO 7176-16:2012 compliance allows more clinically appropriate textiles to be used, for the health and comfort of the wheelchair user.

Standards

EN 1021-1 Furniture – Assessment of the ignitability of upholstered furniture – Part 2: Ignition source smouldering cigarette

EN 1021-2 Furniture – Assessment of the ignitability of upholstered furniture – Part 2: Ignition source匹配 flame equivalent

EN 12182 Assistive products for persons with disability – general requirements and test methods

EN 12183 Manual Wheelchairs – Requirements and test methods

EN 12184 Electrically powered wheelchairs, scooters, and their chargers. Requirements and test methods

ISO 14971 Medical Devices – Application of risk management to medical devices
ISO 16840-10 Wheelchairs - Resistance to ignition of non-integrated seat and back support cushions — Part 10: Req. and test methods

ISO 7176-14 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters – Req. and test methods

Citations


[3] TB 133 has been repealed by California's Bureau of Electronic and Appliance Repair, Home Furnishings and Thermal Insulation, effective January 22, 2019


http://www.health.state.mn.us/divs/eh/risk/studies/retardantreport.pdf

[6] U.S. FDA MAUDE database frequency of occurrence – medical device reports submitted to the FDA by mandatory reporters – (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm


https://www.who.int/tobacco/industry/product_regulation/factsheetreducedignitionpropensitycigarettes/en/

[9] Centers for Disease Control and Prevention

