November 10, 2020

Flammability standards relating to wheelchair seating

Dear Sir or Madam,

As the ISO TC 173 subcommittee (SC1) responsible for wheelchair related standards, and its Working Group (WG 11) focused on Wheelchair Seating, it is our mission to develop wheelchair testing and characterization standards with the goal of minimizing the risk of harm to the individual while protecting and enhancing their health, mobility, independence, and quality of life.

TC173 SC1 and its working groups aim to educate and inform prescribers, regulatory bodies, manufacturers, and clinicians about the intentions of the standards under their oversight, and how they can benefit individuals who use wheelchairs. Through this communication, we wish to address the flammability standard for wheelchair cushions ISO 16840-10:2020 Wheelchairs — Resistance to ignition of postural support devices – Requirements and test method [1]

The committee developed ISO 16840-10 after careful assessment of the potential risks and benefits that wheelchair seat and back support cushions, custom seating solutions, and postural support devices including positioning belts and harnesses can provide an individual. The current state of flammability requirements relies upon varying furniture standards, such as EN 1021-1 [2] and EN 1021-2 [3] in Europe, and ISO 8191-1 [4] and ISO 8191-2 [5] internationally. Furniture standards apply to consumer products, with no consideration of the unique clinical benefits that proper, medical wheelchair seating surfaces provide to individuals. In addition, they have been written on the assumption that the back support and the seat element can be tested at a junction between the two – and are thus not applicable for testing components on their own. The aim of ISO 16840-10 is to provide appropriate alternatives to using furniture-based flammability standards, to reflect the uses and purposes of wheelchairs and their accessories.

The primary function of wheelchair seating is to protect the skin and soft tissues of seated individuals, who are particularly prone to pressure ulcers/injuries, which in turn may lead to death. The prevalence of pressure ulcers in health care facilities is increasing. Pressure ulcer incidence rates vary considerably by clinical setting, ranging from 0.4% to 38% in acute care, from 2.2% to 23.9% in long-term care, and from 0% to 17% in home care [6]. Seat and back cushions help protect the tissues by immersing and enveloping the body, to reduce tissue stresses and strains. The additional function of wheelchair seating is to help position the individual appropriately for functional activities, and to protect against the development of skeletal abnormalities.

To provide the level of flame resistance required by furniture standards, the resulting cover material typically has a reduced ability to stretch and yield, which thereby impedes the individual’s ability to immerse into the cushion. Additionally, the flame retardants employed to provide additional protection often include “substances of very high concern”
(SVHC) by both the EU Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) and OEKO-TEX textile standards. These potential increased risks were considered in the coverage of ISO 16840-10.

As noted in the scope of ISO 16840-10:

“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”

And in the Introduction:

“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.”

We encourage all registration bodies and manufacturers to take the same risk-management based approach when considering solutions for individuals with disabilities, and we recommend the use of ISO 16840-10:2020 as a flammability standard for the assessment of removable wheelchair seat and back cushions and other positioning and postural supports.

Please do not hesitate to contact the committee if there are any questions.

With best wishes,

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See also: "Wheelchair Flammability Standard ISO 16840-10: Overview of the Risk and Evidence-Based Approach" available to read on Public Documents section of ISO TC171 SC1 WG11 ISO ecommittees site. Topics covered are: The problem; Risk considerations; Probability of occurrence; Overall risk management