



MEETING LOG

SUBJECT: ASTM F15.19 Wearable Infant Blankets Data Analysis and Performance Requirements Task Group Meeting Logs

FY 24 OP PLAN ENTRY: Wearable Infant Blankets

DATE OF MEETING: 8/26/2024

LOCATION OF MEETING: Hybrid (CPSC NPTEC, Rockville, MD)

CPSC STAFF FILING MEETING LOG: Khalisa Phillips, Ph.D.

FILING DATE: 9/12/2024

CPSC ATTENDEE(S): Khalisa Phillips, Ph.D., ESHF; Daniel Taxier, ESMC; Suad Wanna-Nakamura, Ph.D., HSPP; Paige Witzen, LSE; & Jacqueline Campbell, EXHR.

NON-CPSC ATTENDEE(S): Contact ASTM for the full attendee list.

Summary of Task Group Meeting on Data Analysis:

Task Group (TG) leads Dr. Carol Pollack-Nelson and Mr. Don Mays used the new ASTM Scientific Integrity Guidelines to identify hazard patterns in the July 1, 2024 CPSC-provided incident dataset for ASTM F15.19 wearable infant blankets. Dr. Pollack-Nelson presented the bulk of their findings. She stated the identification of hazard patterns is more important than focusing on frequency counts of incidents, and that it is not our role to debate cause of death in ASTM meetings. They skipped over “hearsay” complaints in the dataset entirely (example, “I heard XX product is dangerous”). They identified the primary hazard as suffocation or perceived strangulation due to bunching of fabric at the neck, mouth, nose, or face. They mentioned several ways the products result in fabric bunching at the neck and laying on the face including: 1) overly large neck holes, 2) swaddle bands riding up when baby raises their arms, and 3) product failures to retain occupant due to zipper and seam breakage. She mentioned several other hazard patterns such as toe injuries due to thread entanglement, fiber / batting shedding with a possible ingestion hazard, bruising due to tightness of swaddling, and lacerations / scratches due to sharp zipper edges and hook-and-loop fasteners. Their recommendation is to address the above hazard patterns by developing performance requirements.

By contrast, Dr. Pollack-Nelson stated that consumers’ unsafe sleep practices with their infants such as inclined surfaces, swaddling past the recommended motor milestones (ex. attempts at rolling), addition of soft bedding and other items in the sleep environment, and co-sleeping/overlay are better addressed through making improvements to instructions and warnings and consumer outreach safety efforts. They noted that multiple- unsafe (or unintended) sleep practices were present for at least three (3) of the five (5) fatalities associated with weighted infant sleep sacks and swaddles. Furthermore, they found no pattern among the 13 incidents (deaths + injuries) involving weighted sleep products. Mr. Mays stated that out of the 47 fatalities within the 160-incident dataset, 16 victims had been swaddled in a wearable product and had rolled-over and



suffocated on / under soft bedding. One cause appears to be continued use of swaddles past the recommended motor milestone (attempts to roll). He hypothesized that the cylindrical shape created by swaddling a very young infant may contribute to earlier rolling.

ASTM members also stated that specifying mode of use would be useful for transitional / convertible products to better understand how products were used during an incident. For example, if the subject product is a swaddle, was the consumer using it as a traditional swaddle (ex, both arms in) at the time of the incident? Next, ASTM asked CPSC staff what definition is being used for a “transition swaddle.” Staff agreed to look up how we defined transition products and report back. Finally, Mr. Mays asked for a status update on sharing IDs with ASTM, and staff responded that it is in progress.

Summary of Task Group Meeting on Performance Requirements:

Mr. Chris Gulbrandsen and Ms. Michelle Barry led the meeting. Mr. Gulbrandsen began by reading over the proposed test method for swaddle band migration and then trying out the procedure on a newborn CAMI dummy by: (1) repeatedly securing/adjusting the arm swaddle bands until a uniform gap is achieved (0.25in), and (2) securing swaddle bands to a dummy and then testing whether slippage exceeds the set amount in the standard (0.94in). The group considered measuring the vertical gap between the swaddle band and underlying sack using calipers as well as a set-diameter dowel. Questions were raised about using 0.25in as the measurement given that even an adult pinkie finger is nearly twice as wide. Members noticed that regardless of how tight a swaddle was secured to the dummy, it tended to be loose, especially with certain types of fabric. Members also discussed arm positioning under the swaddle (at sides, arms up, arms on chest) and how initial position may impact foreseeable arm movement when resisting / trying to escape the swaddle. Members eventually scrapped a gap test in favor of applying 10lbf via a force gauge to secure each of two swaddle bands onto the dummy. Members concluded that a better approach may be to simulate the full range of motion an infant would exert when trying to defeat a swaddle. They generated a new test sequence involving alternating forces of up and out and then checking for the extent of swaddle band slippage.

Next Steps for Wearable Infant Blankets:

Performance Requirements:

The Performance Requirements TG is considering hosting another hands-on testing TG meeting, perhaps during JPMA Committee Week in October. At the meeting, the TG plans to go over a revised swaddle band test and conduct testing on neck opening size.

Data Analysis:

Findings from the Data Analysis Task Group will be used by the Subcommittee to discuss whether there is a need for additional performance requirements, instructions, warnings, and consumer education efforts on safe sleep. As requested by the Data Analysis TG, CPSC staff will investigate and report back on:

- Staff’s definition of a “transition swaddle” and how products with sleeves are categorized.
- Identify whether mode of use was specified in any incident reports.
- Check on status of sharing IDs with ASTM.