



# Ballot Vote Sheet

**TO:** The Commission  
 Alberta E. Mills, Secretary **DATE:** March 9, 2022

**THROUGH:** Austin C. Schlick, General Counsel  
 Mary T. Boyle, Executive Director

**FROM:** Daniel R. Vice, Assistant General Counsel,  
 Regulatory Affairs  
 Hyun S. Kim, Attorney, Regulatory Affairs

**SUBJECT:** Petition Requesting a Ban or Standard on Adult  
 Portable Bed Rails (Petition CP 13-1)

**BALLOT VOTE DUE:** Tuesday, March 15, 2022

In 2013, the CPSC received two requests to initiate proceedings under the Consumer Product Safety Act (CPSA) to address an unreasonable risk of injury associated with adult portable bed rails (APBRs). Gloria Black, the National Consumer Voice for Quality Long-Term Care, Consumer Federation of America, and 60 other organizations (the Consumer Group) made one request; Public Citizen Health Research Group (Public Citizen) made the other request. The Consumer Group and Public Citizen collectively are referred to as petitioners. The CPSC has docketed the requests as a single petition under Petition CP 13-1. On June 4, 2013, the Commission published notice of the petition (78 Fed. Reg. 33393). The Commission deferred decision on the petition in 2014 and 2015 to allow development of the ASTM voluntary standard on APBRs. In August 2017, ASTM published the voluntary standard, ASTM F3186-17, *Standard Specification for Adult Portable Bed Rails and Related Products*. On July 15, 2020, staff provided its assessment of ASTM F3186-17 (2020 Briefing Package) to the Commission. This briefing package supplements the 2020 Briefing Package and provides staff's recommendation to grant the petition.

Please indicate your vote on the following options:

- I. Grant the petition.

\_\_\_\_\_  
 (Signature)

\_\_\_\_\_  
 (Date)



# Ballot Vote Sheet

(a) Direct staff to draft an advance notice of proposed rulemaking.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

(b) Direct staff to draft a notice of proposed rulemaking.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

II. Defer the petition.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

III. Deny the petition.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

IV. Take other action specified below.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Attachment: *Staff Briefing Package on Petition CP 13-1*



United States

**Consumer Product Safety Commission**

## Staff Briefing Package

### Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails

March 09, 2022

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*This report was prepared by the CPSC staff.  
It has not been reviewed or approved by,  
and may not necessarily reflect the views of,  
the Commission.*



# Executive Summary

Staff's briefing package addresses the petition, CP 13-1, *Petition Requesting a Ban or Standard for Adult Portable Bed Rails*, and whether the U.S. Consumer Product Safety Commission (CPSC or Commission) can propose regulations under the Consumer Product Safety Act (CPSA), requiring adult portable bed rails (APBRs) to comply with certain requirements to address hazards associated with APBRs, including entrapment and strangulation hazards.

## Background

On April 25, 2013, and on May 9, 2013, the CPSC received requests from two groups to initiate rulemaking under sections 8 and 9 of the CPSA to address reported hazards associated with APBRs. The requests were docketed in a single petition, CP 13-1.

In 2013, ASTM International (ASTM) formed the F15.70 subcommittee for Adult Safety Products and began developing a voluntary standard for APBRs. On April 23, 2014, staff delivered a briefing package to the Commission, recommending that the Commission defer a decision on the petition, to allow the voluntary standard process to continue until the APBR voluntary standard had been developed and evaluated by staff. On April 29, 2014, the Commission voted to defer the petition.

Staff updated the Commission on the progress of the ASTM voluntary standard development process on April 17, 2015, and on April 28, 2015, the Commission voted again to defer the decision on the petition to allow the ASTM voluntary standard development process to continue. Staff updated the Commission on the progress on January 20, 2016, and again on September 27, 2016.

CPSC staff worked with ASTM throughout the voluntary standard development process for APBRs. In August 2017, ASTM published the voluntary standard ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. Staff updated the Commission on July 18, 2018 regarding the progress in responding to petition CP 13-1. Staff stated that because the standard was new, the market had not been assessed to determine the level of compliance with ASTM F3186 – 17. However, staff planned to test 35 randomly selected APBRs to determine whether they conformed to the new standard.

On July 15, 2020, staff provided a briefing package to the Commission on its review of ASTM F3186 – 17 (2020 briefing package). Staff's assessment indicated that ASTM F3186 – 17, with minor modifications, adequately addresses the hazards identified in the known incident reports. Despite the effectiveness of the standard, staff found little-to-no evidence of market compliance with the voluntary standard. Accordingly, staff concluded that manufacturers may need additional time to adopt the standard and to increase compliance with the standard. Considering

the pressing need for market compliance, CPSC's Office of Compliance and Field Operations sent a letter to industry, urging those involved with APBRs to meet the requirements of the voluntary standard and reduce the risks associated with the products.

Since the 2020 briefing package, staff has continued to monitor industry compliance with the voluntary standard. Staff's incident data analysis now includes all known APBR incidents between January 2003 through September 2021.

In this update, staff's review indicates that there is little evidence of market compliance changes since publication of ASTM F3186 – 17. On average, 16 fatal incidents related to APBRs are reported to CPSC each year. Of these incidents, 92 percent are related to entrapments, which staff has found would likely be eliminated in products that comply with ASTM F3186 – 17.

### Staff Recommendation

Although CPSC staff's evaluation of ASTM F3186 – 17 indicates that the performance and test requirements in the voluntary standard, with minor modifications, would adequately reduce the risk of injury and death from known hazards associated with APBRs, staff's review also indicates that there is little-to-no market compliance with the voluntary standard. Despite staff's outreach efforts, several product recalls, and the additional time allowed manufacturers to comply with the voluntary standard, fatal entrapment incidents continue to occur, as demonstrated by incident data. Staff recommends that the Commission grant the petition and direct staff to prepare a briefing package and a draft NPR, proposing requirements to address the safety hazards associated with APBRs.

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# Briefing Memorandum



## Briefing Memorandum

**TO:** The Commission  
Alberta Mills, Secretary

**DATE:** March 09, 2022

**THROUGH:** Austin C. Schlick, General Counsel  
  
Mary T. Boyle, Executive Director  
  
DeWane Ray, Deputy Executive Director for Operations

**FROM:** Duane Boniface, Assistant Executive Director,  
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Vineed K. Dayal, Project Manager,  
Division of Mechanical Engineering  
Directorate for Laboratory Sciences

**SUBJECT:** Staff's Recommendation for Petition CP 13-1, Requesting a  
Ban or Mandatory Standard on Adult Portable Bed Rails

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### Introduction

On April 25, 2013, and on May 9, 2013, the U.S. Consumer Product Safety Commission (CPSC) received requests from two groups (Petitioners) to initiate rulemaking under sections 8 and 9 of the Consumer Product Safety Act (CPSA) to address reported hazards associated with adult portable bed rails (APBRs). The requests were docketed in a single petition, CP 13-1, *Petition Requesting a Ban or Standard for Adult Portable Bed Rails*.<sup>1</sup> After evaluating the factors to be considered in deciding whether to grant or deny a petition, described at 16 CFR § 1501.9, staff recommends that the Commission grant the petition.

In 2013, ASTM International (ASTM) formed the F15.70 subcommittee for Adult Safety Products and began developing a voluntary standard for APBRs.<sup>2,3</sup> On April 23, 2014, staff delivered a briefing package to the Commission, recommending that the Commission defer a decision on

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<sup>1</sup> Petition CP 13-1, *Petition Requesting a Ban or Standard on Adult Portable Bed Rails*, Public Citizen, Gloria Black, Consumer Federation of America, Consumer Voice, et al., June 4, 2013. Retrieved from: <https://www.regulations.gov/document?D=CPSC-2013-0022-0001>.

<sup>2</sup> The CPSC has a consumer product safety standard for children's portable bed rails, which incorporates ASTM F2085-19, and is codified at 16 CFR § 1224. (85 Fed. Reg. 10565).

<sup>3</sup> Staff's 2014 Briefing Package discussed the distinction between bed rails that are considered medical "devices" under the FDA's authority, and other bed rails that fall under CPSC's jurisdiction. Bed rails that are an accessory or an appurtenance to regulated hospital beds generally are considered by FDA to have a medical purpose and are devices under FDA. Bed rails intended for use with a non-FDA-regulated bed, and that are not considered by the FDA to have a medical purpose, and are not medical devices, generally would fall under the CPSC's jurisdiction, irrespective of where the bed is used (i.e., nursing home, long-term care facility, or residence).

the petition to allow the voluntary standard process to continue until the APBR voluntary standard had been developed and evaluated by staff.<sup>4</sup> On April 29, 2014, and again, on April 28, 2015, the Commission voted to defer the petition.

CPSC staff has worked with ASTM throughout the voluntary standard development process for APBRs. In August 2017, ASTM published the voluntary standard ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*.<sup>5</sup> Staff updated the Commission on July 18, 2018, regarding the progress responding to petition CP 13-1. Staff updated the Commission on July 15, 2020 (2020 briefing package).<sup>6</sup> Staff assessed ASTM F3186 – 17 regarding the factors the Commission considers when granting or denying a petition. Under section 9(i) of the CPSA, 15 U.S.C. § 2058(i), the Commission may not deny a petition based on a voluntary standard, unless:

- the voluntary standard is in existence at the time of the denial of the petition,
- the Commission has determined that the voluntary standard is likely to result in the elimination or adequate reduction of the risk of injury identified in the petition, and
- it is likely that there will be substantial compliance with the standard.

Staff evaluated whether ASTM F3186 – 17 would likely eliminate or adequately reduce the risk of injury identified in the petition and whether there would be substantial market compliance with the standard. Although staff determined that the standard, with minor modifications, would adequately address the associated hazards, staff did not find substantial compliance with the standard. Staff concluded that an additional round of testing would be required to assess whether substantial market compliance would be likely in the future, as required by the CPSA.<sup>7</sup> To promote compliance during this time, staff continued market outreach efforts, and CPSC's Office of Compliance and Field Operations (Compliance) sent a letter to industry, urging

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<sup>4</sup> Staff Briefing Package, *Petition CP-13-1 Requesting a Ban or Standard for Adult Portable Bed Rails*, April 23, 2014. Retrieved from: [https://www.cpsc.gov/s3fs-public/pdfs/foia\\_PetitionCP131RequestforBanorStandardforAdultPortableBedRail.pdf](https://www.cpsc.gov/s3fs-public/pdfs/foia_PetitionCP131RequestforBanorStandardforAdultPortableBedRail.pdf)

<sup>5</sup> ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, ASTM International, West Conshohocken, PA, 2017, [www.astm.org](http://www.astm.org).

<sup>6</sup> Staff Briefing Package, *Update on Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails*, July 15, 2020. Retrieved from: <https://www.cpsc.gov/s3fs-public/Update%20on%20Peititon%20CP%2013-1%20-%20Requesting%20a%20Ban%20or%20Mandatory%20Standard%20on%20Adult%20Portable%20Bed%20Rails.pdf?kiDixW5Z7x9xcOqjxSeS3QpvspdfQMBY>

<sup>7</sup> 15 U.S.C. § 2058(i).

compliance with ASTM F3186 – 17 to reduce the risks of entrapment and strangulation associated with APBR products.

This briefing package updates the work reported in staff’s 2020 briefing package, to identify any changes in the market since it was last reviewed in 2018. Staff has evaluated the most up-to-date incident data and available market data as of 2021. Specifically, staff:

- analyzed new incident data to identify common hazard patterns;
- compared hazard patterns identified through the incident data analysis with those addressed in ASTM F3186 – 17, to evaluate whether the standard adequately reduces the risk of injury;
- conducted a second APBR market analysis to identify the number of unique product models and number of manufacturers;
- acquired a market sample of 17 APBR products, based on the number of new and unique models on the market; and
- tested the samples to determine compliance with ASTM F3186 – 17 and compared the results to first round of compliance testing completed in 2019.<sup>8</sup>

### Incident Data & Hazard Analysis<sup>9,10,11</sup>

The Petitioners asserted that APBRs on the market at the time of the petition were responsible for many injuries and deaths among users, particularly the elderly and frail. The Petitioners stated that many of these deaths resulted from asphyxiation caused by entrapment within openings of the rail, or between the rail and the mattress or bed frame. Adding to the analysis submitted with the 2020 briefing package, staff completed an updated review of death and injury

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<sup>8</sup> Staff observed that several APBR models that were essentially the same model (e.g., same supplier and specifications) could be marketed across multiple channels, but under different names. Staff considered all APBRs that appeared to have the same supplier and same specifications to constitute one unique model, even though the model might be offered under multiple names or brands.

<sup>9</sup> Tab A, Qin, A. Memorandum by The Directorate for Epidemiology, Division of Hazard Analysis, *Adult Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries*, 2022.

<sup>10</sup> Tab B, Row R. Memorandum by The Directorate for Economic Analysis, *Adult Portable Bed Rail Market and Societal Cost of Associated Injuries*, 2022.

<sup>11</sup> Tab C, Wanna-Nakamura, S. Memorandum by The Directorate for Health Sciences, Division of Pharmacology and Physiology Assessment, *Health Sciences Assessment for Petition CP 13-1, Requesting a Ban or Standard for Adult Portable Bed Rails*, 2022.

incidents to evaluate the nature and extent of the hazards associated with APBRs currently on the market.

### **Incident Data**

In the 2020 briefing package, staff of the CPSC’s Directorate for Epidemiology, Division of Hazard Analysis (EPHA), reviewed incident data from January 2003 through December 2019, finding a total of 260 incidents, including 247 fatalities and 13 nonfatality or “injury not reported” cases. For this briefing package, EPHA reviewed incident data received from January 2003 through September 2021, involving bed rails. The updated incident data showed a total of 320 incidents involved APBRs, including 300 fatalities and 20 nonfatality or “injury not reported” cases. CPSC staff’s analysis found that most of the reported decedents were age 70 or older. In addition, most incidents involved victims with underlying medical conditions.

### **NEISS Data Summary<sup>12</sup>**

In the 2020 briefing package, EPHA reviewed National Electronic Injury Surveillance System (NEISS) data from January 2003 through December 2019, finding approximately 69,300 possible APBR injuries. EPHA’s most recent review of NEISS data, including reports between 2003 and 2020, found approximately 74,000 possible APBR injuries treated at hospital emergency departments (ED). Using the CPSC’s Injury Cost Model (ICM), CPSC’s Directorate for Economic Analysis (EC) staff estimates that there were another 136,230 non-ED-treated injuries associated with APBR use from 2003 through 2020. This includes an estimated 133,871 injuries treated at outpatient facilities, such as doctors’ offices or clinics, as well as another 2,359 victims treated through direct admission to hospitals. The total estimate of injured victims treated is 210,569, or approximately 11,698 per year over the 18 years examined.<sup>13</sup>

EC staff estimates that between 40,000 and 182,000 APBRs are sold annually, and that the preliminary estimate of annual societal costs of fatal and nonfatal APBR injuries could be as high as \$525 million per year (\$163 million due to fatalities + \$363 million due to nonfatal injuries). However, in many cases, the NEISS record did not include enough information to determine whether the bed rail in question was an APBR, or whether the incident involved an injury that could be addressed by a standard.

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<sup>12</sup> The source of the injury estimates is the NEISS, a statistically valid injury surveillance system.

<sup>13</sup> The ICM is fully integrated with NEISS and uses empirical relationships between the characteristics of injuries and victims initially treated in hospital EDs and those treated elsewhere, to estimate the number of medically attended injuries treated outside of hospital EDs.

## Hazard Pattern Analysis

Directorate for Engineering Sciences Division of Human Factors (ESHF), along with Health (HS) and EPHA staff, reviewed the 320 incidents (300 fatal and 20 nonfatal or “injury not reported”) reported to the CPSC that occurred from January 2003 through September 2021, to identify hazard patterns associated with APBRs. Staff identified two main hazard types: rail entrapments and falls.

### Rail Entrapments

There were 276 incidents related to rail entrapment; all but one incident resulted in a fatality. This hazard pattern accounts for 92 percent of all reported fatal incidents, and it includes incidents in which the victim was caught, stuck, wedged, or trapped between the mattress/bed and the bed rail; between the bed rail bars; between a commode and rail; and between the floor and rail. Based on the incident narratives provided, the neck and head were the most frequently injured body parts.

### Falls

There were 24 incidents related to falls; 22 were fatal, and two were nonfatal. This hazard pattern includes incidents in which the victim fell and hit the bed rail, fell after climbing over the bed rail, and similar scenarios.

### Staff’s Assessment of ASTM F3186 – 17 Adequacy to Address the Identified Hazard Patterns<sup>14</sup>

This section provides staff’s analysis of the requirements in ASTM F3186 – 17 and how the requirements are expected to reduce the risk of injury from APBRs.

#### Scope and Definition

ASTM F3186 – 17 establishes performance requirements for APBRs, including requirements for resistance to entrapment, marking and labeling, instructional literature, and advertising.

Section 3.1.1 of ASTM F3186 – 17 defines “adult portable bed rail” as:

[A]n adjacent type bed rail, grab bar, assistive bar, transfer aid, cane or rail (henceforth identified as the product or products) intended by the manufacturer to be installed on, against, or adjacent to an adult bed. The product may vary in lengths (for example, full,

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<sup>14</sup> Tab D, Foster, Z. Memorandum by The Directorate for Engineering Sciences, Division of Human Factors, *Human Factors Assessment of ASTM – 17, Standard Specification for Adult Portable Bed Rails and Related Products, and the Likelihood of Industry Compliance to Certain Requirements of the Voluntary Standard, 2022.*

half, or partial rails, grab bar or handle or transfer post or pole), and is intended by the manufacturer to aid the bed occupant in moving on the bed surface, in entering or exiting the bed, to minimize the possibility of falling out of bed, or for other similar purposes. This includes similar products that are likely to be used for these purposes even if this is not explicitly stated by the manufacturer. However, the standard does not address all products that might be so used, for example, a chair.

ASTM F3186 – 17 (Section 3.1.2) defines “adjacent type bed rail” as:

[A] portable bed rail or related product in which the guard portion (portion that an adult would contact when rolling toward the mattress edge) is essentially a vertical plane or pole that is positioned against the side of the mattress.

Staff worked with the ASTM subcommittee to develop these definitions based on the scope of the petition and the types of portable bed rails that are not covered by CPSC’s existing regulations for children’s bed rails. CPSC staff reviewed bed rails under CPSC’s jurisdiction, including products that are installed or used along the side of a bed that are intended to:

- reduce the risk of falling from the bed,
- assist the consumer in repositioning in the bed, or
- assist the consumer in transitioning into or out of the bed.

These ABPRs were described in detail in staff’s 2014 briefing package. Figure 1 shows typical examples of APBR products.





Figure 1: General examples of APBR types – (1) Full-Length Bed Rail, (2) Bed Cane, (3) Bed Handle, and (4) Half-Length Bed Rail

## General Requirements

ASTM F3186 – 17 includes general requirements in Section 5. Section 5.1 requires that there will be no hazardous sharp points or edges. Section 5.2 states that any exposed parts shall be smooth and free from rough edges. Section 5.3 requires that products covered by the standard that are installed on a bed that articulates (*i.e.*, is adjustable) must meet the performance requirements when the bed is in the flat and articulated positions.

General requirements mandating smooth edges on exposed parts improve safety by preventing potential lacerations or skin injuries from APBRs. In addition, staff finds that testing APBR products on articulating beds is essential to assess openings that could potentially lead to entrapment when the bed is adjusted from the flat position to the articulated position.

## Performance Requirements

Several performance requirements in ASTM F3186 – 17 are intended to address the risk of injury associated with APBRs. These include requirements for assembly, structural integrity, retention system performance, and fall and entrapment prevention.

## Misassembly and Misinstallation

Staff identified 275 fatal incidents related to rail entrapment. This hazard pattern is the most prevalent among the incidents, accounting for 92 percent of all fatal incidents. Effectively addressing the entrapment hazard associated with APBRs depends on, among other things, consumers assembling and installing the product properly. ASTM F3186 – 17 includes performance requirements intended to improve the likelihood that the APBR will be assembled and installed properly. For example:

- Section 6.1 sets forth a requirement for products to include a retention system, which maintains the installed product in position without requiring readjustment of the components. This retention system must be permanently attached to the APBR once it has been assembled and must not be removable without the use of a tool.
- Section 6.2 includes structural integrity requirements that call for the product to be tested without changing dimensions.
- Section 6.5 requires that structural components and retention system components must not be capable of being misassembled, which the standard defines as the APBR being assembled in a way that appears functional but would not meet the retention system (Section 6.1), structural integrity (6.2), entrapment (6.3), or openings (6.4) requirements.

Staff concluded that the requirement that retention systems be permanently attached to the APBR once it has been assembled, and removable only with a tool, reduces the likelihood that consumers will misplace the retention system, and increases the likelihood that consumers, including secondary users, will continue to use the retention system. The requirement that structural and retention system components not be misassembled reduces the risk of injury or death that could arise from the consumer omitting key parts of the APBR (e.g., a center rail) during assembly, in ways that could result in entrapment or other hazards.

## Falls

Falls were the second most common hazard pattern in the incident data, accounting for 24 incidents (8 percent). Staff found that most falls associated with APBRs involve the victim falling against or striking the APBR, but these incident reports usually have limited details. Therefore, the APBRs might have played an incidental role in some of these cases. If the fall was triggered by the APBR becoming dislodged, or its position shifted, then these incidents would likely be addressed by the voluntary standard's structural integrity testing and the requirement of a permanently attached retention system to maintain the installed product in position.

A minority of fall-related incidents, according to staff's review, involved the victim deliberately climbing over the APBR. Section 6.2 of ASTM F3186 – 17 also includes a "structural integrity"

requirement that calls for the installed APBR to extend at least 4 inches above the top of the thickest recommended mattress. The minimum height requirement for APBRs may address fall incidents by limiting the ability of consumers to climb over these products. However, this requirement may not prevent consumers from falling, particularly consumers who deliberately climb over APBRs.

### Entrapment Testing

As stated, staff identified entrapment as the most prevalent hazard pattern among the incidents. In accordance with the entrapment test methods specified in Section 8 of the standard, Section 6.3 of ASTM F3186 – 17 requires products to be tested to assess the potential for entrapment in four different zones. These zones represent four of the seven sectors identified by the U.S. Food and Drug Administration (FDA) in its 2006 guidance document, *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment* (FDA, 2006),<sup>15</sup> as potential areas of entrapment in hospital bed systems. The FDA’s guidance is based on recommendations from the Hospital Bed Safety Workgroup (HBSW), which was formed in 1999, to address reports of patient entrapment.<sup>16</sup>


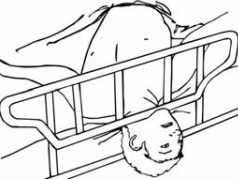


Section 8.4 defines the four entrapment zones tested under ASTM F3186 – 17, which are (1) within the product; (2) between rail support(s) and the bed mattress, when applicable, under the product; (3) between the product and the mattress; and (4) between the underside of the end of the product and the mattress. Entrapment testing to ASTM F3186 – 17 is performed using an “entrapment test probe,” which is the cone and cylinder tool described in the 2006 FDA guidance document (Section 7.2). In addition, some entrapment zones require using a force gauge to test the force applied on the test probe (Section 7.3). Table 1, below, describes the four entrapment zones, with illustrations from the 2006 FDA guidance document of sample entrapments within each of these zones.

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<sup>15</sup> The FDA guidance document is available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment>. (FDA, 2016). Three of the zones identified in the FDA guidance (Zone 5, Zone 6, and Zone 7) were not applicable to APBRs, or could not be tested for entrapment under ASTM F3186 – 17, and therefore, they are excluded from the standard.

<sup>16</sup> The HBSW was formed by the FDA, in partnership with the U.S. Department of Veterans Affairs, Health Canada’s Medical Devices Bureau, and representatives of national health care organizations and provider groups, patient advocacy groups, and medical bed and equipment manufacturers. The 2006 document includes a full list of HBSW participating organizations. The HBSW also worked in cooperation with the Joint Commission on Accreditation of Healthcare Organizations, the U.S. Centers for Medicare and Medicaid Services, and the U.S. Consumer Product Safety Commission to improve patient safety associated with the use of hospital beds.

**Table 1: ASTM F3186 – 17 Entrapment Zones<sup>17</sup>**

<p><i>Zone 1: Within the Product</i> Entrapment in any open space within the perimeter of the APBR</p>	
<p><i>Zone 2: Between Rail Support(s) and the Bed Mattress, When Applicable, Under the Product</i> Entrapment under the bottom edge of the APBR, between the rail supports or next to a single rail support, against the mattress</p>	
<p><i>Zone 3: Between the Product and the Mattress</i> Entrapment in the space between the inside surface of the APBR and the side of the mattress</p>	
<p><i>Zone 4: Between the Underside of the End of the Product and the Mattress</i> Entrapment under the lowermost portion of the end of the APBR, against the mattress</p>	

Staff’s review of the rail entrapment incidents, test requirements, and test methods showed that the majority of the reported entrapment fatalities involved one of the four zones listed above. Specifically, staff could determine the entrapment location of 207 of the 275 incidents, and all but six of these cases occurred in one of the four zones of entrapment tested in ASTM F3186 – 17, as shown in Table 2 below. Based on this analysis, it is likely that most of the 68 incidents for which there was insufficient information to identify the location of the entrapment also involved one of these four zones.

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<sup>17</sup> The zone names in this table are taken directly from ASTM F3186 – 17.

**Table 2: Fatalities by Entrapment Location**

Reported Rail Entrapment Location	Entrapment Test Location	No. of Fatalities
Between APBR and mattress	Zones 2, 3, or 4	195
Within APBR itself	Zone 1	6
Against outside of APBR	None	5
Between APBR and headboard	None (Zone 6)	1
Unknown location	Unknown	68
Total		275

Staff’s finding that rail entrapments predominantly occur in Zones 1 through 4 is consistent with the FDA’s finding that these four zones accounted for about 80 percent of hospital bed rail entrapment events reported to the FDA. This finding was the basis for the FDA’s recommended dimensional limits for these zones.

**Labeling, Warning, and Instructional Literature Requirements**

Section 9.1 specifies that the labeling on the APBR and its retail packaging must be marked with the type and size of beds and mattresses, including the mattress thickness range for which the APBR is intended. In addition, the labeling and retail packaging on the APBR must state the appropriate distance between an installed APBR and the headboard or footboard of the bed. This section also specifies that all on-product labels must be permanent.

Section 9.2 establishes requirements for warning statements that must appear on the APBR and its retail packaging, instructions, and digital or print advertising. The warning statements must be easy to understand, and any other labels or written instructions provided along with the required statements cannot contradict or confuse the meaning of the required warnings or otherwise be misleading.

Section 11 specifies requirements for instructional literature that must accompany APBRs. The instructions provided must be easy to read and understand; include assembly, installation, maintenance, cleaning, operation, and adjustment instructions and warnings, where applicable; include drawings or diagrams to provide a better understanding of set up and operation of the product; include drawings that depict all the entrapment zones; and include all warning statements specified in Section 9.2, including warnings about product damage or misalignment.

Although staff believes that relying on labeling, warning, and instructional requirements is less effective at reducing hazards than product designs that directly address known hazards, staff

found that these requirements in the standard act as a substantial supplementary safety measure for risks that may be eliminated through design.

### **Adequacy of ASTM F3186 – 17**

Staff's previous briefing package concluded that compliance with the requirements of the standard would adequately reduce the risk of injury of hazards associated with APBR products. Although staff found the standard to be adequate, staff also identified some areas of the standard that could be improved upon, such as minor corrections to the requirements for labels and warnings, and clarification of certain test procedures.<sup>18</sup> Staff has continued to work with ASTM to refine these parts of the standard. Staff's updated incident data, included in this briefing package, indicate that the previously identified hazard patterns have not been addressed despite additional time to adopt the voluntary standard. Based on the known levels of market compliance, described in the last briefing package and discussed in the next sections below, staff concludes, again, that compliance to ASTM F3186 – 17 would adequately reduce the risk of injury.

### **Staff's Assessment of Market Compliance to ASTM F3186 – 17<sup>19,20,21</sup>**

Staff conducted two rounds of market compliance testing to ASTM F3186 – 17. The first round during 2018 to 2019; the second was completed in 2021. In both rounds of market compliance testing, no products met all requirements of ASTM F3186 – 17. Furthermore, all products failed the labeling, warning, and instructional requirements, and all products failed at least one mechanical requirement of the standard. In this section we summarize:

- 1) Staff's 2018 Market Compliance Testing;
- 2) Staff's market outreach activities following the results of the 2018 Market Compliance Testing; and

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<sup>18</sup> Refer to Tab D of this document, as well as Tabs D & E of the 2020 Briefing Package, for additional information regarding staff's suggested improvements to the standard.

<sup>19</sup> Tab E, Howie, A. Memorandum by The Directorate for Laboratory Sciences, Division of Mechanical Engineering, *Engineering Analysis of Petition CP 13-1, Requests for Ban or Standard on Adult Portable Bed Rails*, 2022.

<sup>20</sup> Tab F, Dayal, V. Memorandum by CPSC's Designated Representative for Voluntary Standards - ASTM F15.70, *CPSC Voluntary Standards Involvement for Petition CP 13-1, Requests for Ban or Standard on Adult Portable Bed Rails*, 2022.

<sup>21</sup> Tab G, O'Donnell, C. Memorandum by The Office of Compliance and Field Operations, Division of Enforcement and Litigation, *Update on Petition CP 13-1, Requesting a Ban or Mandatory Standard on Adult Portable Bed Rails*, 2022.

3) Staff's 2021 Market Compliance Testing.

**2018 APBR Market Compliance Testing**

From 2018 through 2019, CPSC staff tested 35 randomly selected APBR models for compliance to ASTM F3186 – 17, which became effective in August 2017; APBRs were purchased in fiscal year 2018 (FY 2018); CPSC’s Directorate for Laboratory Sciences Division of Mechanical Engineering (LSM) staff tested the products to determine conformance with the general requirements and the performance requirements of the standard. ESHF staff tested conformance with the labeling, warning, and instructional literature requirements. Staff found that none of the 35 sampled products conformed to the voluntary standard. These results indicated to staff that market compliance with the standard was likely low when staff purchased the samples in 2018, after the standard had become effective. However, due to the lack of proper labeling, staff could not confirm all the manufacture dates for the products to compare them to the standard’s effective date. As shown in Table 3 below, compliance varied by section of the standard. Overall, 33 APBR models did not meet the entrapment performance requirements, and none of the 35 models met the labeling, warnings, or instructional literature requirements.

**Table 3: ASTM F3186 – 17, 2018 APBR Market Compliance Testing Result Summary**

Section		Title	# of Failed Samples	Failure Rate
			(of 35 Total Samples Tested)	
General Requirements	5.1	Hazardous Points/Edges	0	0%
	5.2	Jagged Surfaces	0	0%
	5.3	Articulated Beds	0	0%
Performance Requirements	6.1	Retention Systems	28	80%
	6.2	Structural Integrity	15	43%
	6.3	Entrapment	33	94%
	6.4	Openings	0	0%
	6.5	Misassembled Products	8	23%
Labels and Warnings Requirements	9.1	Labeling	35	100%
	9.2	Warning Statements	35	100%
Instructional Literature	11	Instructional Literature	35	100%



The entrapment hazard pattern was the most prevalent among the reported incidents identified in the 2020 briefing package, accounting for 226 of the 260 incidents. Of the 35 APBR models staff tested to assess the potential for entrapment in the four different zones in and around the APBR: 14 failed the Zone 1 entrapment requirement; 27 failed Zone 2; 11 failed Zone 3; and 6 failed Zone 4.

Staff's testing also revealed high failure rates in several other sections, including the retention system requirements (28 of 35 samples), and structural integrity requirements (15 of 35 samples).

Retention system failures occurred when components were not permanently attached to the product, the retention strap permanently deflected or detached during the free end pull test, or the retention system did not restrain the product during entrapment testing.

Structural integrity failures occurred when the APBR did not extend at least 4 inches over the top of the thickest recommended mattress, or when fasteners loosened or detached during testing, causing the product to change dimensions.<sup>22</sup>

All 35 models failed the labeling, warning, and instructional literature requirements. None of the 35 models fully met the following requirements: Section 9.1 for retail packaging and product labels; Section 9.2, which specifies that warning statements must appear on the product, its retail package, and its instructions; and Section 11 to include instructional literature with required warning statements.

### **Market Outreach (2020 to 2021)**

To ensure market awareness of the standard and associated hazards, staff conducted outreach through CPSC's Office of Compliance and Field Operations (Compliance). In June 2020, Compliance sent a letter to 19 known APBR manufacturers, urging industry members to stop manufacturing, distributing, and selling APBRs that do not comply with ASTM F3186 – 17. The letter also reminded firms of the dangers of entrapment and strangulation hazards, and it warned that CPSC “may regard [non-compliant] products as having a defect which could present a substantial product hazard under section 15(a) of the Consumer Product Safety Act.”

In addition, since completing the 2018 market compliance testing, staff has continued to engage actively with the ASTM F15.70 subcommittee. Staff has since presented and explained the 2018

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<sup>22</sup> Most products did not include a maximum recommended mattress height. In those cases, staff considered any mattress readily available to the public. In addition, the voluntary standard requires all products to be tested fully assembled in accordance with the manufacturer's instructions. However, several APBR manufacturers did not specify or instruct the user how to set the product's adjustable features. In the absence of direction from the manufacturer, CPSC staff adjusted the product's height to the height least likely to pass.



testing results to the subcommittee members, provided the subcommittee with Compliance’s letter to industry for all its members to review and disseminate, supplied updated incident data for the subcommittee’s review, and participated as technical experts at all subcommittee task groups.

### **2021 APBR Market Compliance Testing**

In 2021, staff conducted a second round of product testing to ASTM F3186 – 17 to determine if the additional time and outreach was sufficient for manufacturers to increase their overall level of compliance to the standard. A representative total of 17 APBR products were selected and procured for testing: these included all eight APBR models that staff identified as new to the market since the 2018 analysis, and nine additional, randomly selected models from the remaining available market, which were previously identified in the 2018 analysis. The 2021 testing, like the 2018 analysis, was designed to gauge overall compliance to the voluntary standard, with a focus on certain sections, including Retention Systems, Structural Integrity, Entrapment, Openings, Misassembled Products, Warning Statements, and Instructional Literature. All samples were tested until at least one of the performance requirements for Retention Systems, Structural Integrity, or Entrapment were not met. All 17 samples failed at least one of these requirements. Detailed testing results are provided in Appendix A.<sup>23</sup>

Additionally, all 17 models did not meet the labeling, warnings, and instructional literature requirements. As shown in Table 4 below, the failure modes of this analysis are also similar to the results of the 2018 analysis, indicating little-to-no changes in the market over this time.

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<sup>23</sup> Because testing of a sample stopped upon a failure, full testing to the standard was not completed in 2021, and the data collected may not account for all the potential failure modes per product.

**Table 4: ASTM F3186 – 17, 2021 APBR Market Compliance Testing Result Summary**

Section		Title	# of Failed Samples	# of Samples Tested
General Requirements	5.1	Hazardous Points/Edges	0	17
	5.2	Jagged Surfaces	0	17
	5.3	Articulated Beds	-	0
Performance Requirements	6.1	Retention Systems	13	17
	6.2	Structural Integrity	7	7
	6.3	Entrapment	14	16
	6.4	Openings	-	0
	6.5	Misassembled Products	1	1
Labels and Warnings Requirements	9.1	Labeling	17	17
	9.2	Warning Statements	17	17
Instructional Literature	11	Instructional Literature	17	17

**Section 15 Compliance Actions**

CPSC has issued four public notices regarding APBRs that did not comply with ASTM F3186 – 17. In April 2021, CPSC warned consumers to stop using three models of APBRs manufactured by Bed Handles, Inc., because the products pose an entrapment hazard. The firm is now out of business. Bed Handles, Inc., manufactured approximately 193,000 units of the bed rails, and CPSC is aware of four entrapment deaths associated with them.

In December 2021, CPSC announced voluntary recalls of APBRs manufactured by three firms, due to the entrapment hazard and risk of death by asphyxia posed by their products:

- Drive DeVilbiss Healthcare (496,100 units, 2 deaths);
- Compass Health Brands (104,900 units, 3 deaths); and
- Essential Medical Supply, Inc. (272,000 units, 1 death).

**Staff’s Conclusion and Recommendation**

The Commission considers several factors in granting or denying petitions under 16 C.F.R. § 1051.9, including whether the product presents an unreasonable risk of injury, whether a rule is reasonably necessary to eliminate or reduce the risk of injury, and whether failure to initiate rulemaking would unreasonably expose consumers to the risk of injury.

Staff found reports of 300 fatal incidents that occurred within January 2003 to September 2021, with rail entrapments resulting in the highest number of fatalities, among several significant hazard patterns. More than 75 percent of these incidents occurred to adults over 70 years of age. Although staff's evaluation of ASTM F3186 – 17 indicates that the performance and test requirements in the voluntary standard, with minor modifications, would adequately reduce the risk of injury from known hazards associated with APBRs, staff's review indicates that there continues to be little-to-no market compliance with the voluntary standard. Despite the additional time afforded to manufacturers to adopt the voluntary standard, and staff's outreach efforts since publication of ASTM F3186 – 17, fatal entrapment incidents continue to occur. Staff now recommends that the Commission grant the petition and direct staff to prepare a briefing package and a draft NPR, to propose requirements to address the safety hazards associated with APBRs.

**Tab A: Memorandum by The Directorate for  
Epidemiology, Division of Hazard Analysis**



# Memorandum

**TO:** Vineed K. Dayal,  
Adult Portable Bed Rails Project Manager,  
Division of Mechanical Engineering,  
Directorate for Laboratory Sciences

**THROUGH:** Stephen Hanway,  
Associate Executive Director,  
Directorate for Epidemiology

Risana Chowdhury,  
Director, Division of Hazard Analysis,  
Directorate for Epidemiology

**FROM:** Angie Qin,  
Division of Hazard Analysis,  
Directorate for Epidemiology

**SUBJECT:** Adult Portable Bed Rail-Related Deaths, Injuries, and  
Potential Injuries<sup>1</sup>

**DATE:** March 09, 2022

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## Introduction

This memorandum provides statistics on deaths and injuries and characterizes the hazard patterns related to adult portable bed rails (NEISS product code 4075). The counts are based on reports received by U.S. Consumer Product Safety Commission (CPSC) staff for incidents that occurred from January 2003 to March 2021, and that were reported from January 2003 to September 2021. The memorandum also includes the estimated number of emergency department-treated injuries from January 2003 to December 2020.

The ASTM International (ASTM) voluntary standard for adult portable bed rails is F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. According to the ASTM's definition, an "adult portable bed rail" is a product that is not designed as part of the bed by the bed manufacturer, and is installed on, against or adjacent to the side of an adult bed and is for use by adults to reduce the risk of falling from the bed, assist in repositioning in the bed, assist in transitioning into or out of the bed, or other similar purposes as stated by the manufacturer. Bed rails that meet the definition of a medical device are under the jurisdiction of the U.S. Food and Drug Administration (FDA), and adult portable bed rails that are not medical

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<sup>1</sup> This analysis was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission. Not all these incidents are addressable by an action the CPSC could take; however, it was not the purpose of this memorandum to evaluate the addressability of the incidents, but rather to quantify the number of fatalities and injuries reported to CPSC staff.

devices fall under the jurisdiction of CPSC. In this memorandum, CPSC staff limited the data to non-medical devices and incidents reporting user age to be 13 years or older. Incidents in which the user's age is unknown or unreported are also included.

### Incident Data<sup>2</sup>

CPSC staff received reports of 320 incidents, which included 300 fatalities and 20 nonfatalities related to adult portable bed rails that occurred from January 2003 to March 2021 and were reported from January 2003 to September 2021. Most of the reports were derived from death certificates and medical examiner/coroner reports. The remaining reports were submitted through various sources, such as newspaper clippings, consumer reports, and retailers or manufacturer reports. Staff removed possible duplicate reports. Because incident reporting is ongoing, the number of reported incidents may change in the future, especially for the period 2019 to 2021. Table 1 presents the breakdown of the incidents by year.

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<sup>2</sup> The CPSC database searched is the Consumer Product Safety Risk Management System (CPSRMS). These reported deaths and incidents are not a complete count of all that occurred during this time period. However, they do provide a minimum number of deaths and incidents occurring during this time and illustrate the circumstances involved in the incidents related to adult portable bed rails.

All data coded under product code 4075, for patients ages 13 years or older, were extracted. Upon careful team review, some cases were considered out of scope for the purposes of this memo. Cases specifying hospital bed or bed with fixed railings were excluded. Medical condition and injury location categories were also reviewed jointly.

**Table 1: Distribution of Reported Adult Portable Bed Rail-Related Incidents by Year, 1/1/2003 to 9/30/2021**

Year of Incident*	Fatalities	Non-Fatalities
2003	14	0
2004	23	0
2005	19	0
2006	25	1
2007	19	1
2008	16	0
2009	8	1
2010	10	1
2011	11	1
2012	9	1
2013	17	1
2014	10	3
2015	12	1
2016	14	3
2017	32	1
2018	13	3
2019	28	2
2020	18	0
2021	2	0
Total	300	20

Source: Consumer Product Safety Risk Management System (CPSRMS).  
 \*If the date of incident is not reported, the date reported to CPSC is used.

The victims' ages ranged from 14 to 103 years old. Seventy-five percent of the victims were age 70 and over. The age distribution was like that presented in the July 2020 briefing package. Table 2 presents the distribution of the incidents by age.

**Table 2: Distribution of Reported Adult Bed Rail-Related Incidents by Age, 1/1/2003 to 9/30/2021**

Age	Fatalities	Non-Fatalities
13 to 29 years	7	0
30 to 59 years	30	0
60 to 69 years	22	0
70 to 79 years	45	2
80 to 89 years	119	2
90 years and over	72	0
Not reported	5	16
Total	300	20

Source: Consumer Product Safety Risk Management System (CPSRMS).

Fifty percent of the incidents occurred at home. Table 3 presents the breakdown of the incidents by injury location.

**Table 3: Distribution of Reported Adult Portable Bed Rail-Related Incidents by Injury Location, 1/1/2003 to 9/30/2021**

Injury Location	Fatalities	Non-Fatalities
Home	155	5
Nursing home	48	0
Assisted living facility	39	2
Residential institution	14	0
Other*	21	0
Not reported	23	13
Total	300	20

Source: Consumer Product Safety Risk Management System (CPSRMS).

\*Other category included a care home/center, a foster home, a group home, a retirement center, an adult family home and a hospice.

Fifty-seven percent of the victims had a medical condition; about one-third of the victims had multiple medical conditions. Table 4 presents the breakdown of the incidents by the primary, or most severe, reported pre-existing medical condition.



**Table 4: Distribution of Reported Adult Portable Bed Rail-Related Incidents by Medical Conditions\*, 1/1/2003 to 9/30/2021**

Medical Conditions	Fatalities	Non-Fatalities
Cardiovascular disease	82	0
Alzheimer/dementia/mental	27	0
Mobility/paralysis/stroke	17	0
Parkinson	11	1
Pulmonary disease	9	0
Cerebral palsy	6	0
Cancer	5	0
Multiple sclerosis	5	0
Other**	20	0
Not reported	118	19
Total	300	20

Source: Consumer Product Safety Risk Management System (CPSRMS).

\* For patients with multiple medical conditions, the primary or the more severe condition was used.

\*\* Other category included tracheotomy and G-tube, severe burn, post-surgery, fracture, seizure, Lesch–Nyhan syndrome, amyotrophic lateral sclerosis, multiple drug ingestion, renal disease, agitation, diabetic, sepsis, leukemia, severe disabilities, and general weakness.

The hazard types were grouped into four categories based on the bed rail’s role in the incident. The hazard patterns found were like those identified in the July 2020 briefing package. The category list is ordered from the highest frequency to the lowest:

- **Rail entrapment:** There were 276 incidents of rail entrapment. This category included incidents in which the victim was caught, stuck, wedged, or trapped between the mattress/bed and the bed rail; between bed rail bars; between a commode and rail, between the floor and rail; between the night table and rail; or between a dresser and rail. Based on the incident narratives, the most frequently injured body parts were the neck and head. This category included 275 deaths and one nonfatal arm paralysis.
- **Falls:** There were 24 incidents related to falls. This category included incidents in which the victim fell off the bed, fell and hit the bed rail, or hit and fell near bed rail, and fell after climbing over the bed rail. This category included 22 deaths, one nonfatal knee fracture, and one non-injury incident.
- **Structural integrity:** There were 10 incidents related to structural component problems (e.g., weld of bed rail broke and bed rail not sturdy). This category included one laceration, one head bump, two unspecified injuries, and six non-injury incidents.

- **Miscellaneous:** There were 10 incidents reporting miscellaneous problems (*i.e.*, hanging on the bed rail after garment got caught, hand, arm, or leg laceration, pinched radial nerve against the bed rail, complaint about a misleading label, complaint about a bed rail that was noncompliant with the ASTM standard, and a claim against bed rail manufacturer about an unspecified issue). This category included three deaths, three lacerations, one pinched nerve, one unspecified injury, and two non-injury incidents.

**Table 5: Distribution of Reported Adult Portable Bed Rail-Related Incidents by Hazard Type, 1/1/2003 to 9/30/2021**

Hazards	Fatalities	Non-Fatalities
Rail entrapment	275	1
Falls	22	2
Structural integrity	0	10
Miscellaneous	3	7
Total	300	20

Source: Consumer Product Safety Risk Management System (CPSRMS).

### National Injury Estimates<sup>3</sup>

There were an estimated 74,000 adult bed rail-related injuries (sample size=1,815, coefficient of variation=0.06) treated in U.S. hospital emergency departments from January 2003 to December 2020. Partial data for 2021 are not available for calculation of estimates. There was no statistically significant trend observed from January 2003 to December 2020 ( $p$  value=0.19). In many NEISS cases, there was insufficient information available to determine whether the bed rail involved was an adult portable or fixed bed rail.

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<sup>3</sup> The data source of the injury estimates is the National Electronic Injury Surveillance System (NEISS), a statistically valid injury surveillance system. NEISS injury data are gathered from emergency departments of hospitals selected as a probability sample of all U.S. hospitals with emergency departments. The surveillance data gathered from the sample hospitals enable the CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products.

All data coded under product code 4075, for patients ages 13 years or older, were extracted. Upon careful team review, some cases were considered out of scope for the purposes of this memo. Cases specifying hospital and commercial bed were also excluded. These records were excluded prior to deriving the statistical injury estimates.

**Table 6: Adult Bed Rail-Related Injury Estimates by Year, 1/1/2003 to 12/31/2020**

Year	Cases	Estimates
2003	98	4,500
2004	82	3,400
2005	94	3,900
2006	72	3,400
2007	98	4,300
2008	102	4,200
2009	98	3,600
2010	100	4,000
2011	95	3,700
2012	81	3,100
2013	127	4,700
2014	108	4,400
2015	112	4,600
2016	91	3,700
2017	128	4,900
2018	104	4,300
2019	112	4,500
2020	113	5,100
Total*	1,815	74,000

Source: National Electronic Injury Surveillance System (NEISS)

\*Estimates column may not sum to total due to rounding.

No deaths were reported through NEISS. The data included an age range of 13 to 100 years old. Thirty percent were 80 years and older; 24 percent were between 60 and 79 years old; 30 percent were between 30 and 59 years old; and 16 percent were younger than 30 years old. Most of the injured (89 percent) were treated and released. The following injury characteristics occurred most frequently:

- Injured body part – head (18 percent), foot and toe (14 percent), lower leg (12 percent), upper trunk (9 percent)
- Injury type – contusions/abrasions (29 percent), laceration (26 percent), fracture (13 percent).

The injury pattern is like the pattern presented in the July 2020 briefing package.

## Compliance with the ASTM Standard

To assess the compliance of adult portable bed rails to the voluntary standard ASTM F3186 – 17, CPSC staff considered sampling and testing all known adult portable bed rail models (65 models currently in the market, per Directorate for EC<sup>4</sup>). This is the first sample compliance testing conducted by CPSC staff to be completed under the current voluntary standard. Given that no prior testing data are available regarding the compliance proportion, a range of possible compliance percentages were considered for 95 percent confidence intervals with two possible precision levels: 0.1 and 0.15.<sup>5</sup> Considering the resource limitations, EPHA staff recommended using a sample size of 35 and precision 0.15 to perform the compliance testing. Given the lack of market share information, a simple random sample was the best option for a representative sample.

Based on the Directorate for Laboratory Science’s test results, the proportion of fully compliant models in the market is zero. All 35 samples collected and tested and included in the 2020 briefing package failed the mechanical and label tests. All 17 additional samples collected after the last briefing package failed as well. EPHA concluded that there is no significant compliance<sup>6</sup> with the new voluntary standard of adult portable bed rails known to be in the market today. There is no compliance among models that have entered the market since the last round of testing. Moreover, there have been no changes to the models previously identified and tested and that are still available to increase compliance substantially.

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<sup>4</sup> The Amazon.com model listed as “not available” was excluded from this sampling evaluation. The original sample plan was based on 66 models; revised market analysis showed 65 models, but the original sample plan was not revised.

<sup>5</sup> Smaller sample sizes decrease the precision of the result.

<sup>6</sup> Using Binomial test, p-value was <0.05. The conclusion is limited to the list of bed rails that were provided by EC.

## **Tab B: Memorandum by The Directorate for Economic Analysis**



# Memorandum

**TO:** Vineed K. Dayal,  
Project Manager, Adult Portable Bed Rail Project  
Engineer, Directorate for Laboratory Sciences

**DATE:** March 09, 2022

**THROUGH:** Alex Moscoso, Associate Executive Director,  
Directorate for Economic Analysis

**FROM:** Rodney R. Row, Economist,  
Directorate for Economic Analysis

**SUBJECT:** Adult Portable Bed Rail Market and Societal Cost of  
Associated Injuries

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## Background

On April 25, 2013, and on May 9, 2013, the U.S. Consumer Product Safety Commission (CPSC) received requests from two groups to initiate rulemaking under sections 8 and 9 of the Consumer Product Safety Act (CPSA) to address reported hazards associated with adult portable bed rails (APBRs). The requests were docketed in a single petition, CP 13-1, *Petition Requesting a Ban or Standard for Adult Portable Bed Rails*.

In 2013, ASTM International (ASTM) formed the F15.70 subcommittee for Adult Safety Products and began developing a voluntary standard for APBR products. On April 23, 2014, staff delivered a briefing package to the Commission, recommending that the Commission defer a decision on the petition to allow the voluntary standard process to continue until the APBR voluntary standard had been developed and evaluated by staff. On April 29, 2014, the Commission voted unanimously (3–0) to defer the petition.

CPSC staff has worked with ASTM to develop a draft voluntary standard, and in August 2017, ASTM published the voluntary standard F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. The voluntary standard includes performance requirements, labeling and warning requirements, and instructional literature requirements intended to minimize entrapment and strangulation hazards associated with APBRs.

In 2018 and 2019, CPSC staff conducted market surveillance, collected a sample population of APBRs, and conducted ASTM F3186 – 17 market compliance testing. In 2020, CPSC staff submitted an informational briefing package to the Commission that included staff's findings from the initial round of market surveillance. The Directorate for Economic Analysis (EC) also used the findings from market surveillance to update information on the APBR market and societal costs of APBR-related injuries that EC originally collected for the 2014 briefing package.

In 2021, CPSC staff conducted a second iteration of market surveillance, collected a second sample population of APBRs, and completed a second round of ASTM F3186 – 17 market

compliance testing. In this memorandum, EC updates the information on the APBR market and the societal costs of associated injuries, using CPSC's second iteration of market surveillance.

### Market for Adult Portable Bed Rails

According to the Petitioners, the APBRs of concern include side rails, split rails, half rails, bed handles, full-length rails, bed canes, and similar products sold and marketed to the public and intended to be used with a home bed, rather than a hospital bed.<sup>1</sup> Generally, firms advertise and market these products as (1) rails intended to prevent consumers from falling out of bed, or (2) assistive devices intended to aid weak or unsteady consumers with getting in and out of bed or repositioning within the bed. Some APBRs claim to serve both functions.

In 2021, during September and October, EC staff conducted an online search that identified 11 firms supplying 58 distinct APBR models.<sup>2</sup> The retail prices of the 58 identified models ranged from \$38 to \$275, with a median price of \$99.<sup>3</sup> In February and March 2021, a similar search identified 13 firms and 63 distinct APBR models. In 2018, a similar CPSC online search identified 15 firms and 66 APBR models.<sup>4</sup> In 2014, CPSC staff identified a total of 16 suppliers and 74 unique models. These numbers reveal a decline of approximately 31 percent and 22 percent in APBR suppliers and models, respectively, between 2014 and 2021. It is unclear whether the decline in the number of firms and models resulted from a decrease in consumer demand for APBRs or simply firm consolidation (*i.e.*, companies merging with one another).

CPSC's correspondence with select APBR manufacturers indicates that several firms rely on foreign importers to supply products marketed under the manufacturers' brand names.<sup>5</sup> CPSC staff has not determined whether the relationships between these firms are exclusive or if any of these foreign importers also supplied APBRs to other firms identified in our most recent online search. Nor has staff determined if any of these importers provided APBRs to firms, identified in

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<sup>1</sup> Bed rails designed for use on hospital beds generally are considered medical devices and are under the jurisdiction of the U.S. Food and Drug Administration (FDA).

<sup>2</sup> CPSC staff conducted an internet search employing terms such as adult portable bed rail, bed rail, and portable bed rail in singular and plural forms. CPSC staff observed several APBR models that were essentially the same model (*e.g.*, same supplier and specifications) marketed across multiple channels, but under different names. Staff considered all APBRs that appeared to have the same supplier and specifications to constitute one unique model, even though the model might be offered under multiple names or brands.

<sup>3</sup> For the APBR models identified, the mean retail price is approximately \$112.

<sup>4</sup> Since 2018, one small firm is known to have ceased operations, and another appears to have done so, while three previously identified firms show no current evidence of APBR market activity.

<sup>5</sup> Correspondence subject to 6b limitations on information sharing.

our previous online searches, that have exited the market. In addition, one firm was found to be marketing under their own brand name at least four models manufactured or imported by other firms identified in our search.<sup>6</sup> Lastly, although EC conducted a targeted online search, it is possible that there are firms in the APBR market that EC did not identify.

In 2018, EC sent questionnaires to a non-statistical sample of six firms to obtain additional information about the market for APBRs. Based on the five firms that responded with estimates of their market share, and with information obtained from ReferenceUSAGov, EC developed estimates on the wholesale and direct-to-consumer APBR market in the United States. However, this estimate is heavily influenced by the data of one firm—the only firm of the five whose main line of business is APBRs. Additionally, EC observed a marked decrease in the firm’s revenue from 2018 to 2021, with no obvious explanation why.<sup>7</sup> Acknowledging these caveats, EC generated an estimate of the wholesale and direct-to-consumer APBR market in the United States to be between \$6 million and \$9 million. Using 2021 retail prices, this suggests firms sell between 40,000 and 182,000 APBRs annually.<sup>8</sup>

### Voluntary Standard

To find evidence of substantial industry compliance with the voluntary standard, ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. CPSC staff contacted five firms in January and February 2018. CPSC staff inquired whether the firms were familiar with the ASTM standard, whether they believed their products conformed to the standard, and whether they believed other suppliers would conform to the standard. Four firms indicated they were familiar with the standard; one indicated that their products currently conform, two indicated some modifications were required to bring their products into compliance, and two expressed uncertainty about whether they would put warning labels required by the voluntary standard on their product. One firm expressed concern that if they applied the required warnings to their product and competitors did not, consumers would believe their products were more hazardous than competing APBRs without warning labels causing the firm to lose market share. When asked if they believed most APBR manufacturers would

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<sup>6</sup> These products, as well as products from the firms no longer participating in the APBR market, were removed from the list of models.

<sup>7</sup> In 2018, this firm’s wholesale subsidiary accounted for approximately 85 percent of the firm’s revenues. In 2021, this subsidiary was no longer listed on ReferenceUSAGov. Meanwhile, ReferenceUSAGov reported an approximate threefold increase in this firm’s manufacturing entity revenue, to about 45 percent of the firm’s total 2018 revenue.

<sup>8</sup> If the firms’ decline in revenue is the result of a decline in market share, these numbers underestimate, perhaps significantly, the size of the APBR market and number of units sold.



conform to the voluntary standard, only one firm expressed the belief that at least 90 percent of the market would conform.

To assess industry compliance with the voluntary standard, CPSC staff collected sample populations of APBR models and tested them, first in 2018 through 2019, and then again in 2021.<sup>9,10</sup> In each instance, all APBRs examined by CPSC staff failed to comply with one or more substantive requirements of ASTM F3186 – 17. CPSC staff therefore assesses there is unlikely to be substantial industry compliance with the voluntary standard within a reasonable time. Staff discusses the results of this analysis in the Laboratory Sciences memo (Howie, 2022)(TAB E) and the Human Factors memo (Foster, 2022).

## Societal Costs of Injuries

### Fatalities

CPSC staff is aware of 300 fatal injuries associated with adult portable bed rails that occurred during January 2003 through September 2021, an average of about 16.6 fatalities per year (Qin, 2021).<sup>11</sup> Although some victims may have been as young as 13 years old, approximately 80 percent were over the age of 70.<sup>12</sup> EC estimates the societal costs associated with these fatalities by applying the value of a statistical life (VSL) to the number of deaths (OMB, 1993). The VSL is a measure of the amount people are willing to pay for a small reduction in risk of death; it is not a measure of the value of a particular life, or of an average life.<sup>13</sup> CPSC staff follows U.S. Environmental Protection Agency (EPA) recommendations regarding the value of a statistical life. EPA recommends using a default central VSL estimate of \$7.4 million (\$2006). EC adjusts the VSL for inflation, which results in an estimate of \$9.8 million in 2021 dollars.<sup>14</sup>

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<sup>9</sup> These sample populations are representative of the types of models offered for sale and are not statistical samples of APBRs sold.

<sup>10</sup> Models tested included those from firms which, in response to CPSC staff queries, indicated their products complied or partially complied with the voluntary standard.

<sup>11</sup> Because the reporting is still ongoing for the years 2019 through 2021, the average number of fatalities per year during this period could increase.

<sup>12</sup> In five incidents resulting in death, the age of the victim was not determined. The youngest identified fatality was 14 years of age; the oldest identified fatality was 103 years of age.

<sup>13</sup> For example, if 100,000 people are willing to pay an average of \$90 more for a product that, compared to a similar product, reduces the probability of death by 1 in 100,000 people, then the value those 100,000 people place on preventing 1 statistical death is \$9 million (\$90/person x 100,000 persons).

<sup>14</sup> The Bureau of Economic Analysis CPI-U inflation adjustment factor for the period 1/2006 to 1/2021 is 1.32; \$7.4 million x 1.32 = \$9.8 million. All subsequent dollar figures are given in 2021 dollars.

Consequently, EC estimates the societal cost of fatalities associated with adult portable bed rails to be \$2.91 billion (298 fatalities x \$9.8 million) from 2003 to 2020, or \$162 million annually (16.6 fatalities/year x \$9.8 million).<sup>15</sup>

### **Nonfatal Injuries**

EC used CPSC's Injury Cost Model (ICM) to estimate the societal costs of nonfatal injuries. The ICM is fully integrated with CPSC's National Electronic Injury Surveillance System (NEISS) and uses information in the NEISS case records to estimate the cost of injuries initially treated in hospital emergency departments (ED). In addition to injuries treated in EDs, the ICM uses empirical relationships between the characteristics of injuries and victims initially treated in hospital EDs and elsewhere, to estimate the number of medically attended injuries treated outside of hospital EDs, such as in physician's offices, urgent care centers, or that were admitted directly into a hospital bypassing the ED (Lawrence et al., 2018). The ICM produces comprehensive national estimates of both the number of injuries and the societal costs from medically attended injuries.

The ICM estimates three components to generate societal cost: medical costs, work losses, and the intangible costs associated with lost quality of life or pain and suffering. Medical costs include the short-term and long-term costs of medical services required to treat an injury victim. Work losses include earnings foregone by the victim due to the injury (including paid employment and household work), earnings foregone by friends and family members when caring for or visiting the injury victim, and costs to employers resulting from the need to rearrange schedules and/or recruit and train workers to replace injured employees (or those caring for injured friends and family members). Pain and suffering represent intangible costs like physical and emotional trauma of injury, as well as the mental anguish of victims and caregivers. The ICM bases estimates for pain and suffering on a regression analysis of jury awards for pain and suffering in nonfatal product liability cases. For greater detail on the methodology and databases used in the ICM, see Lawrence et al. (2018).

CPSC staff extracted all NEISS records for bed rail injuries in patients aged 13 years or older. CPSC staff then removed cases that, based on the case narrative, they determined were outside the scope of the product hazard. Cases removed included fixed bed rails, bed rails designed for use on hospital beds, bed rails designed for use on commercial hotel beds, and bed rail injury cases resulting from playing, running, and tripping. Even with these exclusions,

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<sup>15</sup> Of the 300 fatalities of which CPSC staff is aware, two occurred in 2021. To provide an estimate of the societal cost of fatal injuries consistent with that for nonfatal injuries, which is based on NEISS data from 2003-2020, the two fatalities occurring in 2021 were not used in the calculation of the estimate.

many of the remaining cases did not have sufficient information to determine if the bed rail was an APBR and/or if the injury was the result of, or incidental to, the presence of the bed rail. To present a risk-averse perspective, CPSC staff classified these ambiguous cases as in-scope. Consequently, the NEISS estimates of nonfatal injuries and the ICM estimates of societal costs potentially overestimate the actual costs.<sup>16</sup>

CPSC staff identified 1,815 possible (in-scope) APBR-related NEISS case records. Nonfatal injury victims identified in these cases were as young as 13 and as old as 103 years of age. In approximately 40 percent of cases, the victim was 70 years of age or older. Based on the 1,815 sample NEISS records, CPSC staff can extrapolate and estimate that 74,340 nonfatal, APBR-related injuries were initially treated at U.S. hospital emergency departments from 2003 through 2020. This estimate includes 66,243 injuries where the victim was released after treatment and another 8,097 injuries where the victim was subsequently admitted to the hospital. Using the ICM, EC estimates there were another 136,230 nonfatal, APBR-related injuries that were not treated in hospital emergency departments during the same period. This includes an estimated 133,871 injuries treated at outpatient facilities, such as doctors' offices or clinics, as well as another 2,359 victims treated through direct admission to the hospital. CPSC staff estimates that the number of all treated injuries over the 18-year period is 210,570<sup>17</sup> or 11,698 per year. The societal costs from these cases, on average, were \$31,057 per case.<sup>18</sup> This includes \$3,675 in medical costs, \$4,551 in costs from work losses, and \$22,831 in pain and suffering costs per incident. The total estimated societal cost of nonfatal injuries possibly related to APBR use for the period 2003 through 2020 is approximately \$6.54 billion (\$363 million per year on average).

### **Total Societal Costs from Fatal and Nonfatal Injuries**

EC estimates societal costs from fatal and nonfatal APBR-related injuries to be \$9.45 billion (\$2.91 billion from fatalities and \$6.54 billion in nonfatal injury costs) for the period 2003 through 2020. Staff estimates the societal costs of fatal and nonfatal APBR-related injuries at \$525 million per year over this period (\$163 million from fatalities and \$363 million in nonfatal injury costs).

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<sup>16</sup> This estimate can be thought of more accurately as an upper bound on the number and cost of APBR-related injuries.

<sup>17</sup> The ICM is fully integrated with NEISS and uses empirical relationships between the characteristics of injuries and victims initially treated in hospital emergency departments and those treated elsewhere, to estimate the number of medically attended injuries treated outside hospital emergency departments.

<sup>18</sup> The current version of the ICM returns injury cost estimates in 2018 dollars. Injury costs were adjusted to 2021 dollars using the Consumer Price Index, All Urban Consumers (CPI-U) for all goods and services.

## Summary

CPSC staff identified 11 firms supplying as many as 58 adult portable bed rail models. Based on market share information obtained from a few firms in 2018, and current revenue information from ReferenceUSAGov, CPSC staff estimates the adult portable bed rail market in the United States to be between \$6 million and \$9 million. At current observed retail prices, this suggests the number of adult portable bed rails sold annually is between 40,000 and 182,000 units.

Information solicited from a non-statistical sample of firms in 2018 was inconclusive regarding substantial industry compliance with the voluntary standard, ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. To assess industry compliance with the voluntary standard, CPSC staff tested sample populations of APBR models, first in 2018 through 2019, and again in 2021. In both instances, every tested APBR model failed at least one critical requirement of the voluntary standard. Therefore, CPSC staff assesses there is not likely to be substantial industry compliance with the voluntary standard within a reasonable period.

An average of 16.6 fatalities involving APBRs occurred annually between 2003 and 2020. Eighty percent of the victims, where age data was available, were more than 70 years of age. EC estimates the societal cost of fatal APBR-related injuries is approximately \$162 million annually. Using NEISS data and the ICM, staff estimates 11,698 nonfatal APBR-related injuries occurred annually between 2003 and 2020 at an estimated societal cost of \$363 million per year. EC estimates the societal cost of fatal and nonfatal APBR-related injuries combined at \$525 million per year. However, many of the NEISS cases used to estimate societal cost of APBR-related injuries did not have sufficient information to fully determine if the bed rail was an APBR and/or if the injury was incidental to the presence of the bed rail. Therefore, these estimates potentially overestimate actual nonfatal, APBR-related injuries and associated societal costs.

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Foster, Z. (2022) *Human Factors Assessment of ASTM F3186 – 17, Standard Specification for Adult Portable Bed Rails and Related Products, and Likely Industry Compliance to Certain Requirements of the Voluntary Standard*. CPSC Memorandum to Vineed K. Dayal, Project Manager, Adult Portable Bed Rails Petition, U.S. Consumer Product Safety Commission, Rockville, MD. (TAB D)

**Tab C: Memorandum by The Directorate for  
Health Sciences, Division of Pharmacology and  
Physiology Assessment**



# Memorandum

**TO:** Vineed K. Dayal,  
Adult Portable Bed Rails Project Manager,  
Division of Mechanical Engineering,  
Directorate for Laboratory Sciences

**THROUGH:** Mary Kelleher, Associate Executive Director,  
Directorate for Health Sciences

Stefanie Marques, Ph.D., Division Director,  
Pharmacology and Physiology Assessment

**FROM:** Suad Wanna-Nakamura, Ph.D., Physiologist,  
Division of Pharmacology and Physiology Assessment

**SUBJECT:** Health Sciences Assessment for Petition CP 13-1, Requesting  
a Ban or Standard for Adult Portable Bed Rails

**DATE:** March 09, 2022

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## Introduction

In the July 15, 2020, briefing package, CPSC's Health Sciences staff (HS) assessed the incident data on deaths and injuries associated with adult portable bed rails. This memorandum supplements the July 15, 2020, briefing package with HS's additional review of the incident data provided by staff of the Directorate for Epidemiology, Division of Hazard Analysis (EPHA) (Qin 2022, Tab A) for the period January 2003 to March 2021, and reported from January 2003 to September 2021.

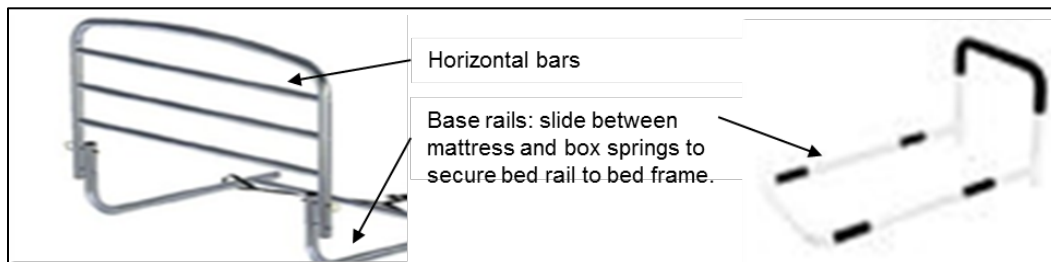
## Background and Product Description

On April 29, 2014, at CPSC's request, ASTM started a subcommittee of the F15 Committee on Consumer Products and began developing a voluntary standard for APBR products. In August 2017, ASTM International (ASTM) published a voluntary standard, ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. ASTM F3186 – 17 defines "portable bed rails and related products" as products installed by consumers that are "not designed as part of the bed by the bed manufacturer." These products are used to reduce the risk of falling from the bed, and to assist users in getting in or out of bed, as well as sitting and repositioning in the bed (Figure 1).



**Figure 1. Examples of adult bed rails and grab bar images copied from various retailer and manufacturer websites.**

Side rails and grab bars can be similar in design and overall shape. They are secured to the side of the bed primarily by two base rails, angled perpendicular to the main rail or bar, which slide between the mattress and box springs (Figure 2). Others have attachments that are product specific.



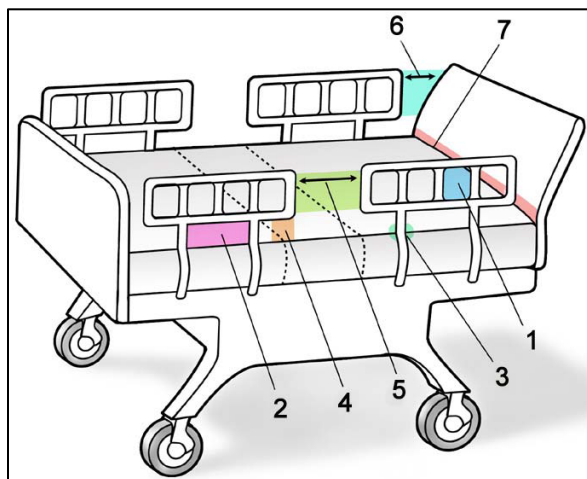
**Figure 2. Bed rail components**

Although similar in design, these products may have different functions. Some designs are meant to keep the occupant from rolling out of bed, and other designs are intended to assist an occupant in getting in and out of bed or repositioning on the bed surface. Some of these products can serve both functions. Because of the similarity in design and mechanism of attachment to the side of the bed, both types of products can have the same potential entrapment hazards.

Health Sciences (HS) staff has identified four sites within and around APBRs where entrapments have occurred, although staff was unable to determine the exact entrapment location for 70 of the 275 reported fatal entrapment incidents. Among the 205 incidents where that information was available, the vast majority of entrapments occurred in the space between the mattress and the inside surface of the APBR (Figure 3, Zone 3); followed by under the horizontal bars of the side rail and the mattress (Figure 3, Zones 2 and 4); and in openings



within the product (Figure 3, Zone 1); and in the space between the headboard/footboard and vertical end bar of the side rail (Figure 3, Zone 6).



**Figure 3. Zones 1-7 as identified by FDA. Image source: U.S. Food and Drug Administration (FDA).**

Upper body entrapment between the mattress and side rail, after sliding out of bed, can lead to positional asphyxia by neck flexion and chest compression between the rails or and suffocation or when the face is pressed against the mattress. Similar entrapments in hospital beds have been reported in the literature (US FDA, 2006 and Miles and Parker, 1998).

### Incident Data

The Directorate for Epidemiology, Division of Hazard Analysis (EPHA) staff conducted searches of CPSC databases in the Consumer Product Safety Risk Management System (CPSRMS) for the period January 2003 to September 2021 (Qin, 2022, Tab A) related to APBRs using NEISS product code (4075). EPHA staff identified a total of 320 incident reports for this period. Of these, 300 were reports of fatalities, and 20 were incidents reporting noninjuries or “injury not reported.” CPSC staff conducted 62 In-Depth Investigations (IDIs). Eleven were terminated after attempts to reach the consumer failed. All deaths were unwitnessed and appear to have occurred while the victim was in bed.

HS staff jointly reviewed and analyzed the incident data with EPHA staff for medical condition and injury location categories. EPHA staff extracted all data under product code 4075 for patients aged 13 years or older. Staff found that 275 of the fatal incidents and 1 nonfatal incident were related to body entrapment, including cases in which the victim was entrapped between the bed rail bars, and between the APBR and an adjacent product, and 22 fatal incidents were related to falls from the bed and not entrapment (Qin, 2022; Tab A, Table 5).

Based on the reported incident narratives, the most frequently injured body parts were the neck and head.

Of the 300 fatal incidents, 182 (61%) reported that the victims had one or more preexisting chronic medical conditions or disorders (Table 2). These conditions included Alzheimer’s disease, dementia, and other mental limitations; Parkinson’s disease; cerebral palsy; multiple sclerosis; Lesch-Nyhan syndrome;<sup>1</sup> amyotrophic lateral sclerosis; cancer; cardiovascular disease; and pulmonary disease. The list included victims with stroke, paralysis, seizures, heavy sedation, and drug ingestion, all factors that can limit mobility or mental acuity and contribute to the risk of death entrapment, because individuals with these conditions often cannot respond to the danger and free themselves.

**Table 2 5. Distribution of Reported Adult Portable Bed Rail-Related Incidents by Medical Conditions, 1/1/2003 to 3/17/2021**

Medical Conditions	Fatalities	Nonfatalities
Cardiovascular disease	82	0
Alzheimer/dementia/mental	27	0
Mobility/paralysis/stroke	17	0
Parkinson’s Disease	11	1
Pulmonary disease	9	0
Cerebral Palsy	6	0
Cancer	5	0
Multiple Sclerosis	5	0
Other**	20	0
Not reported	118	19
Total	300	20

Source: Consumer Product Safety Risk Management System (CPSRMS), Qin 2022 Table 4 Tab A

A review of the IDIs confirmed that product types like those shown in Figure 1 were involved in multiple incidents. The victim was typically found with their torso between the product and the mattress frame, with their neck resting on the lower bar (Figure 4, A and B). Three other hazard patterns were also reported: (1) chin resting on the bar (Figure 4, C and D); (2) patient slumped backwards, partially suspended with the thorax lodged and compressed in the gap between the rail and mattress (Figure 4, E); and (3) slumped through the bar opening (Figure 4, F). The medical examiners in these cases listed the causes of death as “positional asphyxia,” with an additional list of “underlying factors” or “contributory causes.”

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<sup>1</sup> A rare genetic disease characterized by neurological and behavioral abnormalities and occurs almost exclusively in males.



**Figure 4. Images showing victims and areas and manner of entrapment in different types of adult bed rails; Source: IDIs.**

HS staff's analysis of the data revealed that the head and neck were the body parts most frequently entrapped, with positional asphyxia (neck against rail) identified as the most common cause of death. Sustained external pressure on the neck can lead to "asphyxia," defined in medical literature as the failure of cells to thrive in the absence of oxygen. Neck compression, with or without airway blockage, can result in death, even when the body remains partially supported. Blood vessels taking blood to and from the brain and the carotid sinuses, located in soft tissues of the neck, are relatively unprotected. Compression of either the jugular veins or the carotid arteries can lead to death (Hoff, 1978; Iserson, 1984; and Polson, 1973). The amount of force required to cause mechanical vascular occlusion and blockage of blood flow can be as small as 2 kg (4.4 pounds) of force (Brouardel, 1897; Iserson, 1984). Oxygen deprivation can be partial (hypoxia), when there is inadequate oxygen supply to the lungs, or total (anoxia), when there is total impairment of oxygen transport to tissues, which is often accompanied by carbon dioxide retention. A reduction of oxygen delivery rate (per unit time) to the tissue can result in tissue injury and permanent, irreversible damage (Feldman, 1980). The brain is particularly sensitive to oxygen deprivation and is the most affected organ (DiMaio VJ, DiMaio D., 2001; Spitz, 2006; Oehmichen et al., 2005; Saukko, and Knight, 2004; Shapiro, G, 1982; McNie, 1980; Adams et al., 2006; and Saukko and Knight, 2004).

## Conclusion

HS staff evaluated the possible role that bed rails may have played in entrapment deaths. For most of the deaths, there is limited information available describing how the victims became entrapped, and most of the incidents appear to have been unwitnessed. The death certificates provided little detail. HS staff concludes that in most of these cases, the cause of death is asphyxia due to entrapment, as determined by the medical examiner or coroner.

There are several factors to be considered in this evaluation. Most of the fatalities involving APBR entrapment were adults 80 years and older (191 of 295, or 65 percent).<sup>2</sup> This is a potentially vulnerable population associated with an overall progressive decline in muscle strength, balance, and cognitive abilities. This population is also increasingly susceptible to a variety of ailments prevalent among the elderly. In addition to these age-related issues, more than half of the entrapment victims had other serious risk factors that were physical or neurological in nature. Conditions that limit mobility or reduce mental acuity can increase vulnerability and risk of entrapment and falls, because these conditions reduce the ability to self-rescue when entrapped.

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<sup>2</sup> In five of the fatal incidents, the age of the victim was not reported.

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**Tab D: Memorandum by The Directorate for  
Engineering Sciences, Division of Human  
Factors**



# Memorandum

**TO:** Vineed K. Dayal, Project Manager,  
Division of Mechanical Engineering,  
Directorate for Laboratory Sciences

**THROUGH:** Mark Kumagai, Associate Executive Director  
Directorate for Engineering Sciences

Rana Balci-Sinha, Ph.D., Division Director  
Division of Human Factors,  
Directorate for Engineering Sciences

**FROM:** Zachary Foster, Industrial Engineer,  
Division of Human Factors,  
Directorate for Engineering Sciences

**SUBJECT:** Human Factors Assessment of ASTM – 17, Standard  
Specification for Adult Portable Bed Rails and Related  
Products, and the Likelihood of Industry Compliance to  
Certain Requirements of the Voluntary Standard

**DATE:** March 09, 2022

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## Background

On July 15, 2020, CPSC staff submitted a briefing package to update the Commission on Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails. As part of the briefing package, staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF) assessed the adequacy of the ASTM F3186 – 17 requirements in addressing the APBR hazards relevant to the petition, and summarized staff's findings regarding likely industry compliance with the labeling, warning, and instructional literature requirements of the standard. This memorandum supplements the 2020 briefing package regarding the ASTM F3186-17 requirements, based on an assessment of the updated incident data on deaths and injuries associated with hazard patterns related to adult portable bed rails use. This memorandum also summarizes staff's findings regarding current industry compliance to the labeling, warning, and instructional literature requirements of the standard.

## The Products and Applicable Standards

According to the Petitioners, the APBRs of concern include side rails, split rails, half rails, bed handles, full-length rails, bed canes, and similar products sold and marketed directly to the public and intended to be used with a home bed, rather than a hospital bed.<sup>1</sup> Generally, these products are advertised and marketed in one of two ways: (1) rails intended to prevent consumers from falling out of bed, or (2) assistive devices intended to aid weak or unsteady

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<sup>1</sup> Bed rails designed for use on hospital beds are considered medical devices and are under the jurisdiction of the U.S. Food and Drug Administration (FDA).



consumers with getting in and out of bed, or repositioning within the bed. Some APBRs claim to serve both functions.

### Incident Data Review

Staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), has identified 320 incidents—300 fatalities and 20 nonfatal incidents and complaints—involving portable bed rails that occurred from January 2003 through March 2021 (Qin, 2022; see Tab A). These victims ranged in age from 14 to 103 years old. Many of the incident reports are death certificates and medical examiner or coroner reports, and therefore, they have limited details on the circumstances of the incidents.

Some additional details about the rail entrapment incidents are noteworthy:

- In 11 incidents, the APBR appeared to have been installed within about a foot of the headboard or footboard end of the bed. In many of these cases, staff could only estimate this distance based on available photographs of the scene. Even though this was not necessarily the entrapment location, an APBR that is secured so close to a headboard or footboard could lead to entrapment within this space.
- Two incidents involved the use of an APBR with an atypical bed. One incident involved a waterbed, and the other involved an air mattress.
- Some incidents are known to have involved APBRs that were not “secured” to the bed, and they only appeared to rely on the friction of the portion of the product that extends between the mattress and box spring (the “arms”) to hold the APBR in place. In one case, the product reportedly did not come with “safety straps” to secure the APBR, even though the product instructions showed them. In another case, the APBR was not secured to the bed with a “safety strap,” even though the product currently is sold with one. In another case, the person who installed the APBR reported difficulty in securing the retention strap due to its length. This person stated that the strap was “unclipped,” but they noted that the APBR was still secure.
- Two incidents report that the victims did not die during entrapment. Instead, the victims suffered injuries during their respective entrapments, developed complications from those injuries, and died later.

Previous ESHF staff memoranda regarding the petition have discussed adult aging issues that can contribute to entrapments, including age-related declines in muscular strength, muscular



power, motor control and coordination, and balance (Smith, 2014).<sup>2</sup> Consumers 80 years and older, who represent most fatalities, are especially vulnerable to such declines. About three-fifths of all fatalities involved a victim who had at least one underlying medical condition, and it is reasonable to conclude that some of these conditions contributed to the incidents. Also, given that consumers commonly purchase and use APBRs because they require help when getting in or out of bed—for example, some cases involved a consumer who was bedridden or used a wheelchair—APBR users would be less capable of escaping an entrapment scenario than the general population.

EPHA staff identified falls as the second most common hazard pattern associated with APBRs, accounting for 24 incidents (8 percent), 22 of which resulted in fatality. One fall involved the vertical rail of the APBR that had not been raised to an upright position. Another incident apparently involved a consumer who fell despite, rather than because of, the presence of the APBR. Fifteen incidents involved the victim falling against or otherwise striking the APBR; the product might have played more of an incidental role in these cases:

- Seven of these 15 cases occurred while the victim was in bed, getting out of bed, or trying to sit on the bed. However, the incident reports do not include any details suggesting that the APBR contributed to the fall. One separate incident occurred when the victim was being removed from her bed by long-term care facility staff.
- Three cases involved the victim falling from a standing position and striking the APBR.
- Six cases did not include any details about the circumstances of the incident.

Falls resulting from consumers trying to climb over APBRs are identified by the Petitioners as another reason, besides rail entrapment, for seeking Commission rulemaking. However, only five incidents reportedly involved the victim climbing over the APBR, and one of these five cases only reported that the victim “apparently” climbed over the product. In another one of the five climb-over cases, the victim climbed over the APBR because he was unable to lower the product.

### Staff Assessment of Voluntary Standard Requirements

Under the Consumer Product Safety Act (CPSA), the Commission may not deny a petition on the basis of an existing voluntary standard, unless the Commission has determined that the voluntary standard is likely to result in the elimination or adequate reduction of the risk of injury

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<sup>2</sup> See Smith (2005) for a detailed discussion of these and other age-related differences in the adult consumer population.

identified in the petition, and compliance with that standard is likely to be substantial.<sup>3</sup> In this section, ESHF staff assesses whether the current voluntary standard for APBRs, ASTM F3186 – 17, adequately addresses the hazards associated with these products.

### Performance Requirements

ASTM F3186 – 17 includes various performance requirements intended to address hazards associated with APBRs. These performance requirements include:

- entrapment testing in various entrapment zones in and around the installed APBR;
- permanently attached retention systems that must maintain the installed product in position without readjustment;
- a four-inch minimum height requirement for the APBR to extend over the top of the thickest recommended mattress; and
- the inability of structural components and retention system components to be “misassembled,” which the standard defines as being assembled in a way that appears functional but would fail the other performance requirements.

### Entrapment Testing

Rail entrapments, which are entrapments in and around the APBR, comprise most fatalities associated with APBRs, accounting for 275 of the 300 reported fatalities. ASTM F3186 – 17 ‘s entrapment testing assesses the potential for entrapment in four different zones in and around the APBR.

These zones represent four of the seven entrapment zones identified by the U.S. Food and Drug Administration (FDA) in its 2006 document, *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment*,<sup>4</sup> as potential areas of entrapment in hospital bed systems. The guidance outlined in the document is based on recommendations from the

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<sup>3</sup> See section 9(i) of the CPSA, 15 U.S.C. 2058(i). In addition, the CPSA states that if the Commission were to grant the petition and begin rulemaking, the Commission could not issue a rule, unless the Commission finds that: (1) compliance with the voluntary standard is unlikely to eliminate or adequately reduce the risk of injury, or (2) substantial industry compliance with the voluntary standard is unlikely. See section 9(f)(3)(D) of the CPSA, 15 U.S.C. 2058(f)(3)(D).

<sup>4</sup> As of the date of this memorandum, this FDA document can be found online here: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment>. (FDA, 2016)

Hospital Bed Safety Workgroup (HBSW), which was formed in 1999, to address reports of patient entrapment (FDA, 2006).<sup>5</sup>

Table 1 identifies<sup>6</sup> and briefly describes the four entrapment zones tested in ASTM F3186 – 17 and includes illustrations from the 2006 FDA guidance document of sample entrapments within each of these zones.

**Table 1. Four Entrapment Zones of ASTM F3186 – 17**

<p><i>Zone 1: Within the Product</i></p> <p>Entrapment in any open space within the perimeter of the APBR</p>	
<p><i>Zone 2: Between Rail Support(s) and the Bed Mattress, When Applicable, Under the Product</i></p> <p>Entrapment under the bottom edge of the APBR, between the rail supports or next to a single rail support, against the mattress</p>	
<p><i>Zone 3: Between the Product and the Mattress</i></p> <p>Entrapment in the space between the inside surface of the APBR and the side of the mattress</p>	
<p><i>Zone 4: Between the Underside of the End of the Product and the Mattress</i></p> <p>Entrapment under the lowermost portion of the end of the APBR, against the mattress</p>	

<sup>5</sup> The HBSW was formed by the FDA, in partnership with the U.S. Department of Veterans Affairs, Health Canada's Medical Devices Bureau, and representatives from national health care organizations and provider groups, patient advocacy groups, and medical bed and equipment manufacturers. The 2006 document includes a full list of HBSW participating organizations. The HBSW also worked in cooperation with the Joint Commission on Accreditation of Healthcare Organizations, the U.S. Centers for Medicare and Medicaid Services, and the U.S. Consumer Product Safety Commission to improve patient safety associated with the use of hospital beds.

<sup>6</sup> The zone names are from section 8.4 of ASTM F3186 – 17.

The other three entrapment zones identified by the FDA are not applicable to APBRs or do not lend themselves to entrapment testing:

- Zone 5 is the area between two side rails on the same side of the bed. Generally, only a single APBR is installed on any given side of a bed. Although CPSC staff is aware of one APBR that contains two separate rails that are installed on the same side of the bed, currently, staff is not aware of any incidents that have been identified as Zone 5 entrapments.
- Zone 6 is the area between the end of the rail and side edge of the bed headboard or footboard. Although this location is relevant to APBRs, these products are installed by the consumer, so the potential for entrapment is dependent upon the consumer's placement of the APBR on the bed. This is addressed below in staff's discussion of the labeling and warning requirements.
- Zone 7 does not involve an APBR at all, and instead, it involves the space between the end of the mattress and the headboard or footboard. Thus, this zone is not applicable to APBRs.

Although the details surrounding many rail entrapment incidents are limited, the four zones of an installed APBR that are tested for entrapment (Zones 1 through 4) appear to cover virtually all the known entrapment-related fatalities. ESHF staff's review of the available incident data found that about 195 of the 300 reported fatalities involved entrapment between the APBR and the mattress/bed. Although staff was unable to determine the location of many of these 195 cases, at least 27 appear to have been between the inside surface of the APBR and the side of the mattress, or Zone 3; and four cases were entrapments "under" the APBR and against the mattress, meaning Zone 2 or 4. The remaining mattress-entrapment cases, staff surmises, most likely occurred within Zones 2, 3, or 4, which cover all known entrapment scenarios between the APBR and the mattress. Staff also concluded that at least 6 of the 275 reported fatalities involved entrapment within the APBR itself, or Zone 1.

At least five cases appear to involve entrapment against the exterior of the APBR by another object, such as a commode or dresser. This location is outside the four zones tested by the standard. One case, maybe two, involved entrapment between the APBR and a headboard. This area is identified as Zone 6 in the 2006 FDA guidance document; but this area is not tested for entrapment because it is dependent on where the consumer chooses to install the APBR on the bed. Staff was unable to identify the specific entrapment location in the remaining 68 cases. Table 2 briefly summarizes these conclusions.

**Table 2. Rail entrapment incident locations relative to ASTM F3186 – 17 entrapment zones**

Rail Entrapment Location	Entrapment Testing Location	No. of Fatalities
Between APBR and mattress	Zones 2, 3, or 4	195
Within APBR itself	Zone 1	6
Against outside of APBR	None	5
Between APBR and headboard	None (Zone 6)	1
Unknown location	Unknown	68
Total		275

These results illustrate that nearly all cases of rail entrapment for which ESHF staff could determine the entrapment location (201 of 207 incidents) occurred in one of the four zones of entrapment tested in ASTM F3186 – 17. So, most rail entrapment incidents that occurred in an unknown location probably also involved one of these four zones. Staff’s finding that the preponderance of rail entrapments occurred in Zones 1 through 4 is consistent with the FDA’s finding that these four zones accounted for about 80 percent of entrapment events reported to the FDA that were associated with hospital bed systems. Moreover, this finding was the basis for the FDA recommending dimensional limits for these zones (FDA, 2006).

Entrapment testing in ASTM F3186 – 17 is performed using an “entrapment test probe,” which is the cone and cylinder tool described in the 2006 FDA guidance document. An image of the probe appears in Figure 1. The probe design is based on the anthropometric dimensions of key body parts—the head, neck, and chest—of at-risk adults, and the probe design considers the effects of age, such as the loss of muscle mass in the neck:<sup>7</sup>

- The diameter of the large end of the cone represents the width of a small adult head.
- The diameter of the cylinder represents the size of a small adult neck.
- The cone and cylinder together weigh 15 pounds, which represents the combined weight of an adult head (12 pounds) and neck (3 pounds).
- The cylinder includes a red area that defines contact angles in which the neck could become wedged (up to 60 degrees).

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<sup>7</sup> FDA used international anthropometric data references (e.g., Peebles & Norris, 1998, as cited in FDA, 2006) to determine the relative sizes of the body parts for the population at greatest risk of entrapment. For example, the diameter of the large end of the cone is 120 mm (4¾ inches), which encompasses the 5th percentile female head breadth in all examined data sources. The diameter of the cylinder is 60 mm (2¾ inches), which reflects the 1st percentile female neck diameter, reduced by about 25 percent to account for the compressibility of neck tissue. FDA (2006) includes details about their selection of dimensional limits and a complete listing of the anthropometric references they consulted.



**Figure 1: Entrapment Test Probe. From FDA (2006).**

These dimensions appear to represent adequately the users of APBRs. Thus, ESHF staff concludes that entrapment testing in the four zones identified in ASTM F3186 – 17 using the entrapment test probe should effectively address the entrapment hazard posed by a properly installed APBR.

### **Misassembly and Misinstallation**

Eliminating the entrapment hazard associated with an APBR depends on the ability of the consumer to assemble and install the product properly. ASTM F3186 – 17 includes performance requirements intended to improve the likelihood that consumers will assemble and install the APBR properly. For example:

- Section 6.1 includes a requirement that retention systems—a method for maintaining the installed product in position—must be permanently attached to the APBR once it has been assembled, and the retention system must be removable only with a tool. Including this requirement reduces the likelihood that consumers will misplace this critical part of the APBR, and it also increases the likelihood that consumers, including secondary users, will continue to use the retention system.

- Section 6.5 includes a requirement that structural components and retention system components must not be capable of being “misassembled,” which the standard defines as the APBR being assembled in a way that appears functional but would not meet the retention system (Section 6.1), structural integrity (6.2), entrapment (6.3), or openings (6.4) requirements. This misassembly requirement reduces the risk of injury or death that could arise from the consumer omitting key parts of the APBR (e.g., a center rail) during assembly, in ways that could result in entrapment or other hazards.

In addition, some of the requirements and associated test methods depend upon information communicated to the consumer by the manufacturer. For example:

- Section 6.2.1 requires the top of the product to be at least 4 inches above the top surface of the thickest mattress recommended by the product manufacturer.
- Section 7.1.1 requires testing to be conducted on each mattress, mattress support, and bed type that the manufacturer specifies as suitable for use with their product.
- Section 8.4.6.3, related to Zone 4 entrapment, requires the product to be adjusted to the manufacturer’s recommended height or heights above the mattress if the height is consumer adjustable.
- Zone 3 entrapment testing depends on the lateral distance at which the product is installed from the mattress.

In these cases, the effectiveness of the performance requirements relies on consumers receiving and acting upon the pertinent information. The *Labeling, Warning, and Instructional Literature Requirements* section, below, discusses these types of issues.

## Falls

Falls are the second most common hazard pattern associated with APBRs, accounting for 24 reported incidents, nearly all fatalities. Although APBR-related incidents of falls are considerably less common than rail entrapments, these fall incidents also were identified by the Petitioners. Rail entrapments and falls, combined, account for virtually all reported fatalities associated with APBRs.

ESHF staff’s review of the incidents revealed that most falls associated with APBRs involve the victim falling against or striking the APBR. Reports regarding these incidents often include few details, and the APBR might have played an incidental role. For example, some incidents appear to involve the victim striking the APBR while falling from a standing position. Seven falls occurred while the victim was in bed, getting out of bed, or trying to sit on the bed. The incident reports for these seven cases do not include details suggesting that the APBR contributed to the fall. However, if the fall was triggered by the APBR becoming dislodged or shifting position, then



these incidents would likely be addressed by the entrapment testing and the performance requirement for a permanently attached retention system that maintains the installed product in position.

As many as five fall-related incidents involve the victim deliberately climbing over the APBR. Addressing these climbing incidents with a performance requirement is challenging. Section 6.2 of ASTM F3186 – 17 includes structural integrity requirements that include a requirement that the APBR extend at least 4 inches over the top of the thickest recommended mattress. This minimum height requirement for APBRs may address such incidents by limiting the ability of consumers to climb over these products. However, consumers who deliberately climb over APBRs might be motivated to do so, despite the height of the product. The most feasible approach to addressing this residual climbing-related fall hazard may be to warn potential APBR purchasers about this issue. ASTM F3186 – 17 includes fall-related warning requirements for retail packaging and instructions. These requirements are discussed briefly, later in this memorandum.

### Labeling, Warning, and Instructional Literature Requirements

As Smith (2014) discussed in detail in a previous ESHF staff memorandum regarding the petition, hazard-control measures that rely on consumers to alter their behavior to avoid the hazard are less effective than designing the hazard out of the product or guarding the consumer from the hazard. Therefore, hazard communication through labeling, warnings, and instructions should be viewed as a “last resort” measure that supplements, rather than replaces, redesign or guarding efforts, unless these higher-level hazard-control efforts are not feasible. This issue becomes especially important when older adults are at risk, because this group of consumers is a potentially vulnerable population. Smith (2014) provides additional details about the vulnerability of these consumers and the likely ineffectiveness of warnings aimed at these consumers. Smith also points out that APBR design changes or performance requirements that prevent entrapment in the first place would be a far more effective solution.

Although the primary hazard associated with APBRs, rail entrapment, is addressed by performance requirements in ASTM F3186 – 17, some of these requirements and associated test methods depend upon manufacturer-provided information about compatible beds and mattresses. This implies that for the performance requirements to be effective during real-life use, consumers must install the product based on this same information, which would appear in labeling, warnings, or instructions directed to the consumer.<sup>8</sup> In addition, labeling, warnings, and instructions might offer some benefit, as a supplemental safety measure, for risks that cannot be eliminated through design. Examples of these risks include entrapments in the space between

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<sup>8</sup> The “consumer” in this case might be the user of the product or caregiver of the product’s user.



an APBR and the headboard or footboard of the bed, and falls associated with climbing over APBRs.

The labeling, warning, and instructional requirements in ASTM F3186 – 17 are somewhat complicated, and there is a lot of overlap in the types of information that must appear on the product, on its retail packaging, and in the product instructions, or instructional literature. Staff has attempted to summarize these requirements below.

### **Labeling Requirements**

Section 9 of ASTM F3186 – 17 specifies requirements for APBR labeling and warnings. The labeling requirements, specified in Section 9.1, include requirements for the product and its retail packaging to be marked or labeled with:

- the type and size of beds and mattresses, including the mattress thickness range, for which the product is intended (*i.e.*, compatible beds and mattresses); and
- the appropriate distance between an installed APBR and the headboard or footboard of the bed.

This section also specifies that all on-product labels must be permanent.

ESHF staff supports the labeling requirements of ASTM F3186 – 17. Labeling about compatible beds and mattresses is important because the effectiveness of the performance requirements depends upon this information. Testing under the standard is performed on each mattress, mattress support, and bed type that the manufacturer specifies as suitable for use with their product. If the manufacturer fails to label the product properly with this information, consumers might choose to use the APBR with a bed or mattress that would cause the product to fail the performance requirements, and this would place consumers at risk of entrapment between the APBR and mattress (Zone 2, 3, or 4). Staff is aware of two rail-entrapment fatalities in which the product was used with an atypical bed type that might not have been suitable for the APBR. One incident involved a waterbed, and the other one involved an air mattress. Neither incident includes details about any relevant labeling on the APBR.

Section 9.1.1.3 requires labeling regarding the appropriate distance between an installed APBR and a bed headboard or footboard. This addresses the potential entrapment hazard in this space, which is a hazard recognized in the FDA's hospital bed rail guidance, as well as the child bed rail standard.<sup>9</sup> ESHF staff's review of the available incident data identified at least one

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<sup>9</sup> The mandatory standard for children's portable bed rails (16 C.F.R. § 1224) also includes a warning statement about entrapment in this location.

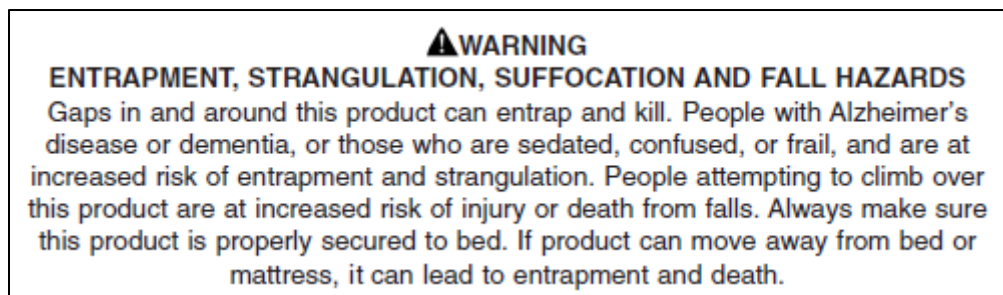
fatality, which appears to have involved entrapment between the APBR and a headboard.<sup>10</sup> The incident does not include details about labeling or warnings on the product that might have addressed this entrapment scenario.

As discussed below, Section 9.2.6 also requires the product warnings to include statements related to the distance between the bed rail and a headboard or footboard. Because the addition of a separate labeling requirement is redundant, staff considers a warning that includes this information to meet the labeling requirement, if the warning is placed in the required labeling location. However, these sections are contradictory: Section 9.1.1.3 states that the APBR shall be greater than 12 ½ inches or less than 2.4 inches from a headboard or footboard, but the warning required by Section 9.2.6 states that this distance must be at least 12 ½ inches. ESHF staff believes that this section of the voluntary standard should be revised to avoid possible confusion.

### Warning Requirements

Section 9.2 of ASTM F3186 – 17 specifies requirements for warnings that must appear on the APBR and its retail packaging, instructions, and Internet or print advertising. This section of the standard identifies three sets of warning statements. Although there is room for improvement in specific, individual warnings, ESHF staff concludes that the warning content, overall, is adequate.

The voluntary standard requires that the retail packaging, product instructions, and Internet or print advertising for the product include the warning statements below:



*Figure 2: Warning Statement for Packaging, Instructions, and Internet/Print Advertising*

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<sup>10</sup> ESHF staff identified a second incident that may have also involved entrapment between an APBR and a headboard, but staff was unable to confirm this.

This warning is intended primarily to communicate, at the point of purchase, the potential hazards associated with APBRs, to improve the likelihood that consumers will purchase the correct product for their needs. The warning identifies the entrapment-related hazards associated with gaps in and around the APBR, and emphasizes that consumers with Alzheimer’s disease, dementia, or similar conditions are at increased risk of entrapment and strangulation. The warning also acknowledges the risk of injury or death from climbing over the product and falling. ESHF staff’s review of the incidents revealed that few incidents involved the victim deliberately climbing over the APBR. However, staff agrees that alerting potential APBR purchasers about this potential hazard is valuable and may help consumers decide whether the users of this product might be prone to attempting this behavior.

ESHF staff acknowledges that certain aspects of this warning could be improved. For example, staff believes that the initial hazard statement, or heading could be reduced from, “ENTRAPMENT, STRANGULATION, SUFFOCATION AND FALL HAZARDS,” to the more concise, “ENTRAPMENT AND FALL HAZARD.” Additionally, there might be some benefit to rewording the warning to state explicitly that consumers should not purchase the product if the end user is likely to engage in behavior that could put them at risk, such as trying to climb over the product.

### Product Warning Statements

The voluntary standard also requires the following warning statements on the product, in the product instructions, and in Internet or print advertising for the product:

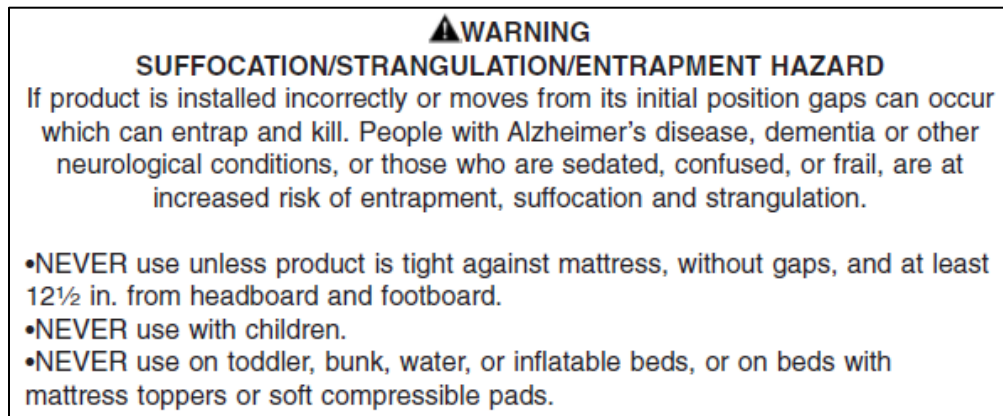


Figure 3: On-Product Warning

This warning focuses on the hazards associated with entrapment and the steps consumers should take to avoid the hazard. During ASTM subcommittee and task group meetings, the members discussed the possibility of including the fall hazard in this warning. However, the

consensus of the group was that the focus of the product warning should be on entrapment as the primary hazard. Staff agrees that it is reasonable to focus this warning on the entrapment hazard, including appropriate steps to avoiding the hazard.

The warning includes detailed descriptions of steps that consumers must take to avoid the hazard, including keeping the APBR tight against the mattress and at least 12 ½ inches from the headboard or footboard. ESHF staff has determined that these are important elements to address in the required warnings. Although the voluntary standard's performance requirements should effectively prevent most entrapments in and around a properly installed APBR, their effectiveness still depends on proper installation by the consumer. ESHF staff identified at least one rail entrapment fatality involving an APBR that was deliberately installed with a gap between the product and the mattress (Zone 3) to make it easier for the consumer to get out of bed. So, emphasizing the importance of installing the product tightly against the bed, without gaps, is essential to mitigating this entrapment hazard.

ESHF staff's review of the available incident data also identified at least one reported fatality associated with entrapment between the end of an APBR and a headboard. Entrapment in this location is a recognized hazard, identified as Zone 6 by the FDA (2006), and avoiding such entrapment depends on the consumer installing the APBR at the appropriate distance from the headboard and similar bed structures. Neither incident includes details about warnings on the product that might have addressed this entrapment potential. ESHF staff's review identified nine additional incidents in which the APBR appeared to have been installed within about a foot of the headboard or footboard.<sup>11</sup> These nine incident reports include photographs of the APBR, and none of the products appear to include warnings or labeling about the appropriate installation distance between the product and a headboard or footboard.

Staff also agrees with the warning's recommendations never to use the product with children, for whom the product is not intended, or with certain types of beds. The voluntary standard allows manufacturers to modify the listing of incompatible beds, provided the manufacturer has "proven" that the product complies with the performance requirements when installed on the bed type that otherwise would have been prohibited.

Although staff concludes that the product warning is adequate, ASTM F3186 – 17 contains an error: the warning shown in Figure 4 of the voluntary standard does not match the required

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<sup>11</sup> These nine incidents, plus the two potential entrapments between the APBR and the headboard, account for the 11 incidents in total where the APBR appeared to be installed within about one foot of the headboard or the footboard end of the bed, as cited in ESHF staff's earlier review of the incidents.

warning statements.<sup>12</sup> An image of this figure appears below. To avoid confusion, the figure’s warning content and the required statements should match.

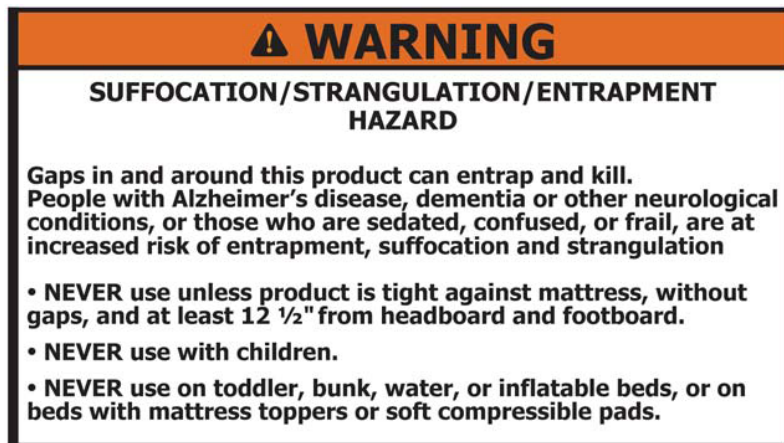


Figure 4: Example warning in ASTM F3186-17 that does not match required warning statements

### “Conspicuous Component” Warning Statements

Lastly, the voluntary standard requires that at least one “conspicuous component” of the product be labeled with the following warning statement:

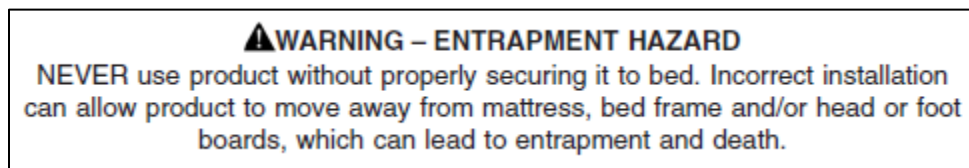


Figure 5: “Conspicuous Component” Entrapment Warning

The children’s portable bed rail standard (16 C.F.R. § 1224) includes a requirement for a similar warning to appear on at least one “installation component,” which is defined as a component of the bed rail that is designed specifically to attach the bed rail to the bed and that typically is located under the mattress when in the manufacturer’s recommended use position. The intent of the requirement was to improve the likelihood that consumers will use that component to install the product properly. ESHF staff recommended that a similar requirement be added to ASTM F3186 during its development, and a draft of the voluntary standard included such a requirement. However, before publication of the voluntary standard, the requirement for this

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<sup>12</sup> Figure 4 is supposed to be an example of the required warning statements, formatted according to the additional requirements of the standard.

warning to be on an installation component was changed to say that it must be located on a “conspicuous component.” The standard does not define this term, but it does define “conspicuous” in Section 3.1.3 as “visible, when the product is in the manufacturer’s recommended use position, to a person standing near the unit at any one position around the unit but not necessarily visible from all positions.” ESHF staff continues to believe that this warning should appear on an installation component, because:

- the warning is intended to draw attention to the installation component and to encourage its use;<sup>13</sup> and
- the installation component is commonly located under the mattress during use, and therefore, the warning would not be “conspicuous” when in the manufacturer’s recommended use position.<sup>14</sup>

### Other Warning Requirements

In addition to specifying the warning content, Section 9.2 includes other requirements related to warnings. For example, ASTM F3186 – 17 specifies the placement of warnings on the product, by requiring warnings to be “conspicuous,” which the voluntary standard defines in Section 3.1.3 (see above). Many ASTM standards include a similar “conspicuous” requirement for warnings and define this term to allow the consumer to assess conformance for that product. The definition of APBR requires the warnings to be visible to the consumer, even after the product has been installed (*i.e.*, the “manufacturer’s recommended use position”), which increases the likelihood that warnings are visible when needed.

ASTM F3186 – 17 also includes the following format requirements for warnings:

- The warnings must be in highly contrasting colors and in non-condensed sans serif type.
- Each group of warning statements must be preceded by a safety alert symbol (▲)<sup>15</sup> and the specified signal word (for example, “WARNING”).

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<sup>13</sup> Staff is aware of two rail entrapment fatalities involving APBRs that were not secured to the bed with a “safety strap,” even though the products currently are sold with one. However, for one of these fatalities, it is unknown whether the product was sold with a strap at the time of purchase.

<sup>14</sup> In other words, requiring the warning to be on a “conspicuous component” most likely would not permit the warning to be placed on an installation component. Yet, drawing attention to the installation component was the original purpose of the warning.

<sup>15</sup> The version of the safety alert symbol shown here is based on the default symbol used in the ANSI Z535 series of standards. For consistency, ESHF staff uses this version throughout the memorandum for all instances of the safety alert symbol.

- The safety alert symbol and signal word must be in letters at least 0.2 inches (5 mm) high, and the rest of the warning text must be characters whose upper case is at least 0.12 inches (3 mm) high.

Although the warning format requirements used in many ASTM juvenile product standards tend to be more stringent, ESHF staff concludes that these requirements are adequate. The type-size requirements are an improvement over similar requirements used in most other ASTM standards. For example, ASTM F3186 – 17 requires the text that appears in the message panel of each warning to be characters whose upper case is at least 0.12 inches tall. Most ASTM standards allow this type size to be as small as 0.1 inches; this is the type size recommended by the ASTM Ad Hoc Language Task Group, which was formed to develop standardized language across ASTM juvenile products standards, and has developed recommendations for warning format.<sup>16</sup> However, as ESHF staff pointed out in a prior memorandum related to this petition, age-related deficits in vision are likely to impair an older consumer’s ability to read a warning, and even the caregivers of older adults also might be older adults who suffer from similar age-related deficits (Smith, 2014). Smith (2005) includes a detailed discussion of age-related changes in vision and visual functioning, and Smith recommends at least 12-point type (about 0.12 inches) for information that must be read by older adults. For this reason, ESHF staff worked with the ASTM subcommittee to require warning message text for APBRs to be at least this size.

Lastly, ASTM F3186 – 17 requires that the warnings be permanent, easy to understand, in English, at least, and that any other labels or written instructions provided in addition to those required by the standard cannot contradict or confuse the meaning of the required warnings, or otherwise be misleading. Increasingly, this latter requirement appears in other ASTM standards, and thus, it reduces the likelihood that manufacturers will provide consumers with information that might mislead consumers or cause consumers to question the credibility of the warnings.

### **Instructional Literature Requirements**

Section 11 of ASTM F3186 – 17 specifies requirements for instructional literature, or “instructions,” that must accompany APBRs. These requirements include the following:

- The instructions must be easy to read and understand.

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<sup>16</sup> The ASTM Ad Hoc Language Task Group’s latest set of recommendations appear in the document, “Recommended Language Approved by Ad Hoc Task Group, Revision E,” dated May 28, 2019, and can be found here: [https://myastm.astm.org/KEY\\_DOCUMENTS/PDF\\_FILES/f150000adhoc7.pdf](https://myastm.astm.org/KEY_DOCUMENTS/PDF_FILES/f150000adhoc7.pdf). This link is accessible to Committee F15 members only.



- The instructional literature must include assembly, installation, maintenance, cleaning, operation, and adjustment instructions and warnings, where applicable.
- The instructions must include drawings or diagrams to provide a better understanding of set up and operation for use and must include drawings that depict all the entrapment zones.
- The instructions must include all warning statements specified in Section 9.2 of the standard (discussed earlier in this memorandum).
- The instructions must include the following additional warning statements:<sup>17</sup>
  - “Stop using immediately if damaged or broken, or if parts are missing.”
  - “Stop using immediately if product shifts out of its original position until it is readjusted into the correct position.”
  - “In addition to contacting the manufacturer directly, consumers should report problems to the CPSC at its [sic] website SaferProducts.gov or call 1-800-638-2772, or to the FDA at 1-800-332-1088.”
  - “For further information, see: [cpsc.gov/en/Safety-Education/Neighborhood-Safety-Network/Posters/Adult-Bed-Rails/](https://www.cpsc.gov/en/Safety-Education/Neighborhood-Safety-Network/Posters/Adult-Bed-Rails/) and [www.fda.gov/bedsafety](https://www.fda.gov/bedsafety).”
- Products that use straps to meet the requirements of the voluntary standard (for example, to secure the APBR), must include “WARNING: If the strap provided is not properly secured the product may move into an unsafe position which increases the danger of entrapment. See instructions for proper use of the straps.”
- All warnings in the instructions must meet the same design or formatting requirement as the product warnings.

As discussed, the real-life effectiveness of the performance requirements in ASTM F3186 – 17 depends upon proper assembly, installation, and adjustment of the APBR. The instructional literature requirements specify that the instructions must address these topics, among others. Furthermore, instructional literature must include drawings or diagrams to provide a better understanding of set-up and operation for use. ESHF staff concludes that APBRs that include this information, as well as the other information specified in Section 11, are more likely to be properly assembled and installed than APBRs without this information. These actions should

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<sup>17</sup> Some required statements refer consumers to both CPSC and FDA because ASTM F3186 – 17 covers APBRs that meet the definition of a “medical device,” and therefore, are under the jurisdiction of FDA, and covers other APBRs that are under the jurisdiction of CPSC.



reduce the incidence of fatal entrapments. Thus, ESHF staff supports these instructional literature requirements. However, as noted with “[sic]” in the bullet list above, the statement in Section 11.1.1.3 of ASTM F3186 – 17 includes a typographic error, with “is” used in place of “its.” Staff recommends correcting this error in the voluntary standard.

## Industry Compliance with Voluntary Standard Requirements

### 2018 APBR Market Compliance Testing

In 2018, to assess industry compliance with ASTM F3186 – 17, CPSC staff collected 35 sample APBRs that staff of CPSC’s Directorate for Economic Analysis (EC) determined to be representative of the market. ESHF staff examined the sample products to assess sample conformance to the labeling (Section 9.1), warning (Section 9.2), and instructional literature (Section 11) requirements. ESHF staff found that none of the 35 sample APBRs fully complied with these sections. A comprehensive discussion of ESHF staff findings can be found in the previous briefing package (Smith & Talcott, 2020).

### 2021 APBR Market Compliance Testing

In 2021, CPSC staff collected an additional 17 sample APBRs for evaluation and testing. ESHF staff examined the sample products to assess their conformance with the labeling (Section 9.1), warning (Section 9.2), and instructional literature (Section 11) requirements, applying the same methodology used on the 35 samples detailed in the 2020 briefing package.

None of the 17 sample APBRs conformed to all the ASTM F3186 – 17 labeling, warning, and instructional literature requirements. Specifically, ESHF staff found the following:

- none of the samples fully conformed to Section 9.1, *Labeling*;
- none of the samples fully conformed to Section 9.2, *Warning Statements*; and
- none of the samples fully conformed to Section 11, *Instructional Literature*.

The discussion below summarizes key findings from ESHF staff’s examination of the samples.

### Labeling Requirements

Section 9.1.1.3 requires the product and its retail packaging to specify that: (1) the APBR can be used only with certain types and sizes of beds and mattresses, including specifying the required mattress thickness, and (2) the distance between an installed APBR and the headboard or

footboard must be less than 2.4 inches or greater than 12.5 inches.<sup>18</sup> These requirements can directly impact whether the product presents an entrapment hazard.

None of the 17 sample APBRs fully met this labeling requirement, and 11 samples did not include *any* of the required labeling specified in Section 9.1.1.3 on the retail packaging or the product. ESHF staff's specific findings are summarized below.

### **Retail Package Labeling**

None of the 17 retail package samples included all the required information regarding the intended types and sizes of beds and mattresses.

- Five retail package samples specified the required mattress thickness. One retail package sample stated that the product is designed for use on any size, two-piece bed (box spring and mattress), and that the top of the box spring must be between 16.5" and 20.5" from the floor.
- One retail package sample stated that the product "fits any size home style bed," but did not specify what is a home-style bed.
- Ten retail package samples did not include any of this information.

None of the 17 retail package samples included information about the appropriate distance between an installed APBR and the headboard or footboard of the bed.

### **Product Labeling**

None of the 17 product samples included labels bearing all required information about the intended types and sizes of beds and mattresses.

- Twelve product samples had no labels specifying compatible beds and mattresses, or information about the appropriate distance between the APBR and a headboard or footboard.
- Of the remaining five samples, all produced by the same manufacturer:
  - All carried product warnings stating that the product must not be used on toddler, bunk, water, or inflatable beds;

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<sup>18</sup> As ESHF staff discussed earlier, a label that states that the APBR can be installed less than 2.4 inches from the headboard or footboard would contradict the required warnings, which state that this distance must be at least 12 ½ inches.

- None of included labeling identifying compatible bed sizes or mattress thicknesses;
- Four had warnings stating that the product should be installed “at least 12.5” from the headboard and footboard”; and
- One had warnings stating that the product should be installed “at least 125” from the headboard and footboard.” (This appears to be a typographical error.)

### **Warning Requirements**

None of the samples examined by ESHF staff fully conform to the warning requirements in Section 9.2 of ASTM F3186 – 17. Section 9.2 includes, among other requirements, specific warning statements that must appear on the product, its retail packaging, and its instructions. Staff’s review of the samples for conformance to the required warning statements is summarized below.

### **Retail Package Warnings**

Four of the 17 retail package samples include the required warning statements, specified in Section 9.2.5 of ASTM F3186 – 17. Additionally, one retail package sample includes part of the required warning statement; the rest appeared to have been cut off in a printing error. The remaining retail package samples contain no warning statements relevant to entrapment, strangulation, suffocation, or falls, which are the hazards identified in the standard’s required warning statements.

### **Product Warnings**

None of the 17 product samples included the required warning statements specified in Sections 9.2.6 and 9.2.7 of the voluntary standard. In addition, staff found the following:

- Five products included no warnings at all.
- One product included an entirely graphical warning, with no text. One of the pictograms appears to illustrate the potential for entrapment.
- The remaining 11 products included warnings related to at least one of the hazards identified in Sections 9.2.6 and 9.2.7 (*i.e.*, suffocation, strangulation, or entrapment), but the warnings included on these products do not match the required warning statements. For five of these products, the warnings begin with “Patient Entrapment Potential,” rather than the signal word, “WARNING,” and the products lack any additional description of the hazard or how to avoid it. Instead, these products refer the reader to unspecified “directions and warnings.” Five of the 11 products included warnings like the required

warning statements, but the warnings do not match in all respects. For example, the warnings use the wrong hazard statement or description, or they omit certain words from the required statements. All five are produced by the same manufacturer. One product included an entrapment warning, but the warning language did not match the required statements and did not specifically address suffocation or strangulation.

### **Instructional Literature Warnings**

None of the 17 samples included instructional literature containing the required warning statements, specified in Sections 9.2.5 and 9.2.6. ESHF staff found the following missing information among the sample instructions:

- One set of instructions did not include any warnings.
- Three sets of instructions did not include any warnings related to entrapment, strangulation, suffocation, or falls, which are the hazards identified in the required warning statements.
- The remaining 14 sets of instructions included warnings related to at least one of the hazards identified in Sections 9.2.5 and 9.2.6 of the voluntary standard (entrapment, strangulation, suffocation, or falls), but the warnings examined did not match the required warning statements. However, some of these 17 sets of instructions included warnings with content like what is required.

### **Instructional Literature Requirements**

Section 11 of ASTM F3186 – 17 includes requirements for instructional literature that must accompany APBRs. This instructional literature must include assembly, installation, maintenance, cleaning, operating, and adjustment instructions and warnings, where applicable. Because all APBRs must be installed on a bed, even a fully pre-assembled APBR that does not require or allow any adjustments would require installation instructions, at a minimum. All 17 of the sample products came with some form of instructional literature, the utility of which varied from product to product.

All 17 samples included instructional literature with the most basic instructional topics, such as installation and assembly instructions. However, all 17 instructional literature samples:

- Failed to include the warning statements in Section 9.2, as required by Section 11.1.1; and

- failed to include the additional warning statements specified in Sections 11.1.1.1 through 11.1.1.4, and in Section 11.1.2.<sup>19</sup>

Additionally, ESHF staff found that one sample's installation instructions were printed on the product itself, and those instructions did not include any drawings or diagrams, as specified in Section 11.1.

In addition to their general lack of conformance to the required warnings, the instructional literature included with the sample products often lacked information about the proper installation and adjustment of the APBR or provided conflicting information. LSM staff's testing revealed that this missing or conflicting information sometimes contributed to the inability of the APBR to meet the performance requirements. Examples of this issue, related to Zone 3 and Zone 4 entrapment testing, are discussed below.

### **Instructions Related to Zone 3 Entrapment**

Zone 3 entrapment testing, which tests for entrapment in the space between the inside surface of the APBR and the side of the mattress, depends on the lateral distance from the mattress at which the product is installed. APBRs should be installed against the mattress, and the voluntary standard requires the instructional literature to include warnings stating that APBRs should be "tight against mattress, without gaps."<sup>20</sup> Of the 17 instructional literature samples, nine instructional literature samples did *not* state explicitly that the APBR should be installed against the mattress. Five of these nine samples included recommendations suggesting that this lateral distance can be as large as 2 inches. One of the nine samples instructs readers to "situate the bed rail at a distance that is considerably smaller or larger than that which could result in entrapment."

The remaining eight instructional literature samples generally convey the appropriate distance, explicitly or implicitly, by stating<sup>21</sup> that there should be no space between the product and mattress; that the product should be tight against, or be firmly in contact with the mattress, with no gaps; or that the product should be inserted between the mattress and box spring "as far as possible." However, staff also found that four of these eight samples' instructions *also* contained entrapment zone information from the FDA, which included the FDA's recommendation that this

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<sup>19</sup> One set of instructional literature included the statements specified in sections 11.1.1.1 and 11.1.1.2 but did not include the other required statements.

<sup>20</sup> Recall that at least one rail entrapment fatality involved an APBR that was deliberately installed with a gap between the product and the mattress to make it easier for the consumer to get out of bed.

<sup>21</sup> This statement was sometimes presented as part of a warning within the instructions.

lateral distance not be more than 4 ¾ inches.<sup>22</sup> This information, taken as a whole, could lead consumers to conclude reasonably that a space as large as 4 ¾ inches is acceptable, particularly given that the instructions typically name the FDA as the source of this 4 ¾-inch recommendation.<sup>23</sup>

### **Instructions Related to Zone 4 Entrapment**

Zone 4 entrapment testing, which tests for entrapment against the mattress under the lowermost portion of the end of the APBR, requires the product to be adjusted to the manufacturer's recommended height or heights above the mattress if the height is consumer adjustable (Section 8.4.6.3). Eight of the 17 sample APBRs examined by staff are consumer-adjustable in height.<sup>24</sup> Four of these samples are adjustable only during assembly, meaning that the product would need to be at least partially disassembled to readjust the rail height.

Among the eight samples with consumer-adjustable heights, six do not provide any specific manufacturer's recommendation on the appropriate height of the APBR relative to the mattress. For three samples, the instructions merely tell consumers to adjust the product to their preferred or desired height; three others had instructions or descriptions of how to adjust the height, but these samples did not state why a consumer would want to do so. Some samples' instructions suggested that the mattress height is relevant to the height at which the APBR should be adjusted, but the instructions for these samples only referred to this ambiguously, stating simply that the ABPR is adjustable to accommodate a given range of mattress depths, without explaining the relationship between product height and mattress depth. One of these samples also included a separate document containing entrapment zone information. This document stated that the FDA recommends that the space between the mattress and the lowermost portion of the rail must not exceed 2.375" and recommends that the arm of the product be at least 12" away from the top surface of the mattress.<sup>25</sup>

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<sup>22</sup> Three of the five samples that suggest a maximum acceptable gap of 2 inches also include this information from the FDA. Thus, 7 of the 17 instructional literature samples suggest that the distance between the APBR and the mattress can be as large as 4¾ inches.

<sup>23</sup> Although the instructional literature requirements state that manufacturers must include drawings depicting all of the entrapment zones, "such as those available from the FDA" (section 11.1), it appears that many manufacturers are including not only FDA drawings, but also the FDA's spacing recommendations, despite conflicting with the required warnings. Product instructions that include seemingly contradictory recommendations such as these would not meet section 9.2.2 of ASTM F3186 – 17, which states that any labels or written instructions "shall not contradict or confuse the meaning of the required information, or be otherwise misleading to the consumer."

<sup>24</sup> ABPRs that had only raised/lowered positions were excluded from this count.

<sup>25</sup> ESHF staff notes that a specific product is named in this document, which differs from the name of the sample product included with this document.

Only two of the eight samples with consumer-adjustable heights included instructional literature with specific manufacturer's recommendations on the appropriate height of the APBR relative to the mattress. One sample instructs consumers to set the rail such that the top of the rail is between 4 to 7 inches above the top of the mattress. The other sample instructs consumers to set the "handle height" to 4 inches or more, to prevent users from climbing over the product, and includes a diagram showing that the vertical space between the top of the bed rail and top of the mattress must be 4 inches or more.

Nine of the 17 sample APBRs did not have consumer-adjustable heights, but some of these products' instructions still included information pertaining to the appropriate height of the APBR relative to the mattress. For example, one sample's instructions stated that the bottom horizontal rail of the APBR must be at least two inches below the top surface of the mattress. Five samples' instructions included the FDA recommendations for the maximum height between the mattress and the lowermost rail of the APBR (2.375"). Of these five, three contradicted this recommendation, by also specifying other heights for the product, relative to the mattress.

Because these products are not height adjustable, consumers presumably must have to select an appropriate mattress thickness to install the product at the recommended height. However, only three of these nine samples identified an appropriate range of recommended mattress thicknesses for the APBR.<sup>26</sup> As discussed, the voluntary standard requires testing to be conducted on each mattress, mattress support, and bed type that the manufacturer specifies as suitable for use with their product (Section 7.1.1); and the structural integrity requirements specify that the top of the product must be at least 4 inches above the top surface of the thickest mattress recommended by the product manufacturer (Section 6.2.1). So, specifying the appropriate mattress thickness is also important to meet these requirements.

## Conclusions

Most incidents associated with APBRs are rail entrapments, in which the victim becomes entrapped in or against the APBR, and these incidents most commonly involve entrapment between the APBR and the mattress, or bed. Consumers 80 years and older, who make up most fatalities, are especially vulnerable to age-related declines in muscular strength, muscular power, motor control and coordination, and balance. Adult aging issues such as these, as well as preexisting medical conditions, most likely contribute to entrapments, and these consumers are less capable of escaping an entrapment scenario than the general population.

The primary performance requirement in ASTM F3186 – 17 intended to address APBR hazards is entrapment testing, which assesses the entrapment potential in four zones in and around an

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<sup>26</sup> All three of these samples are from the same manufacturer. Additionally, ESHF staff examined two height-adjustable APBRs from this manufacturer that identify an appropriate range of recommended mattress thickness.



installed APBR. These zones account for virtually all known entrapment fatalities, and testing is performed using a probe that is based on key anthropometric dimensions of at-risk consumers. Thus, ESHF staff concludes that a properly installed APBR that passes this entrapment testing would effectively address the entrapment hazard. ASTM F3186 – 17 also includes performance requirements intended to address misassembly and misinstallation, as well as requirements for labeling, warnings, and instructional literature.

Although hazard control measures that rely on consumers to alter their behavior to avoid the hazard are less effective than designing the hazard out of the product or guarding the consumer from the hazard, particularly if the victims are older adults, ESHF staff concludes that labeling, warnings, and instructions offer some benefit as a supplemental safety measure for risks that cannot be eliminated through design. Examples of these risks include entrapments in the space between an APBR and the headboard or footboard of the bed, and falls associated with climbing over APBRs. Also, some requirements and test methods in ASTM F3186 – 17 depend on information provided by the manufacturer about compatible beds and mattresses. ESHF staff has identified some areas for improvement in the labeling and warning requirements, but concludes that compliance with these requirements, and compliance with the instructional literature requirements, should reduce the risk of injury and death associated with APBRs.

Even so, ESHF staff's examination of APBR samples, determined to be representative of the market, suggests that at this time, industry compliance with the labeling, warning, and instructional literature requirements of ASTM F3186 – 17 is very low. None of the samples fully conforms to the labeling requirements, warning requirements, or instructional literature requirements. Five of the samples contained no warnings relevant to the subject hazards. In addition, the instructional literature included with these samples often lacked key information about compatible mattresses and beds, and it contained conflicting information about how to install or adjust the APBR properly. This missing and conflicting information commonly contributed to the inability of the APBR to meet the performance requirements.

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**Tab E: Memorandum by The Directorate for  
Laboratory Sciences, Division of Mechanical  
Engineering**



# Memorandum

**TO:** Vineed K. Dayal, Project Manager,  
Division of Mechanical Engineering,  
Directorate for Laboratory Sciences

**THROUGH:** Andrew G. Stadnik, Associate Executive Director,  
Directorate for Laboratory Sciences

Michael Nelson, Division Director,  
Division of Mechanical Engineering,  
Directorate for Laboratory Sciences

**FROM:** Adam Howie, Mechanical Engineer,  
Division of Mechanical Engineering,  
Directorate for Laboratory Sciences

**SUBJECT:** Engineering Analysis of Petition CP 13-1, Requests for Ban or  
Standard on Adult Portable Bed Rails

**DATE:** March 09, 2022

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## Introduction

This memorandum, prepared by staff of CPSC's Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM), presents an analysis of adult portable bed rail (APBR) models and their compliance with the ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. Starting in fiscal year 2018 (FY 2018), LSM staff conducted compliance testing on 35 randomly selected APBR models available in the market. Staff determined that none of these APBR models met the safety requirements of the standard. In FY 2021, staff performed a second round of testing to determine if there was any change in the APBRs' compliance with the standard. This testing was performed on 17 new APBR models available in the market. Again, staff determined that none of the products met all the requirements of the standard. This memorandum summarizes the results of the mechanical testing from these market compliance studies, in conjunction with CPSC's Human Factors staff's (Tab D) analysis. Several of the issues related to product failures are associated with human behavior and user perception of the product.

## Studies of Market Compliance to ASTM F3186 – 17

To determine the level of APBR compliance with the ASTM F3186 – 17 standard, staff conducted two rounds of testing on APBR models available on the market. The first round of testing, conducted from 2018 through 2019, determined the baseline level of compliance in the market after the standard published in 2017. Staff conducted the second round of testing in 2021, to determine if firms had adopted the standard and made changes to APBRs to comply with ASTM F3186 – 17. Results from both rounds were used to determine if substantial compliance would be likely. For each round of testing, CPSC's Directorate for Economic

Analysis staff conducted a market analysis to identify all unique APBR models available on the market. Staff identified 66 models in 2018, and they identified 58 models in 2021.<sup>1</sup> In 2018, staff of the Directorate for Epidemiology, Division of Hazard Analysis determined a randomly selected sample of 35 unique APBR models would be adequate to represent statistically the market.<sup>2</sup> In 2021, staff determined that the eight new models that had entered the market since 2018, would all be tested, in addition to a random sampling of nine remaining models that had been previously identified in 2018, and were still available in 2021. Staff collected the sample set and tested all products to determine if they complied with ASTM F3186 – 17. This memo will summarize the results of the mechanical tests and will include testing from Section 9.1.2 Label Permanency. This memo will not cover other requirements addressing warnings, labels, or other informational literature, which are covered in Tab D.

### **2018 Market Compliance Study**

In 2018, LSM staff tested a sample set of APBR models available in the market, to evaluate compliance with the new standard. The test consisted of 35 APBR models, which, according to CPSC epidemiological and economic analyses, were representative of the entire APBR market at the time. The market samples included products from approximately 87 percent of all APBR manufacturer or importer firms known to staff, including products from the largest APBR manufacturers.

Upon completing testing, staff found that none of the samples tested met all the requirements in F3186 – 17, and most samples failed multiple sections, as seen in Figure 1. These results strongly indicate that APBRs on the market at that time did not comply with the voluntary standard.

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<sup>1</sup> Tab B, Row R. Memorandum by The Directorate for Economic Analysis, *Adult Portable Bed Rail Market and Societal Cost of Associated Injuries*, 2022.

<sup>2</sup> Tab A, Qin, A. Memorandum by The Directorate for Epidemiology, Division of Hazard Analysis, *Adult Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries*, 2022.

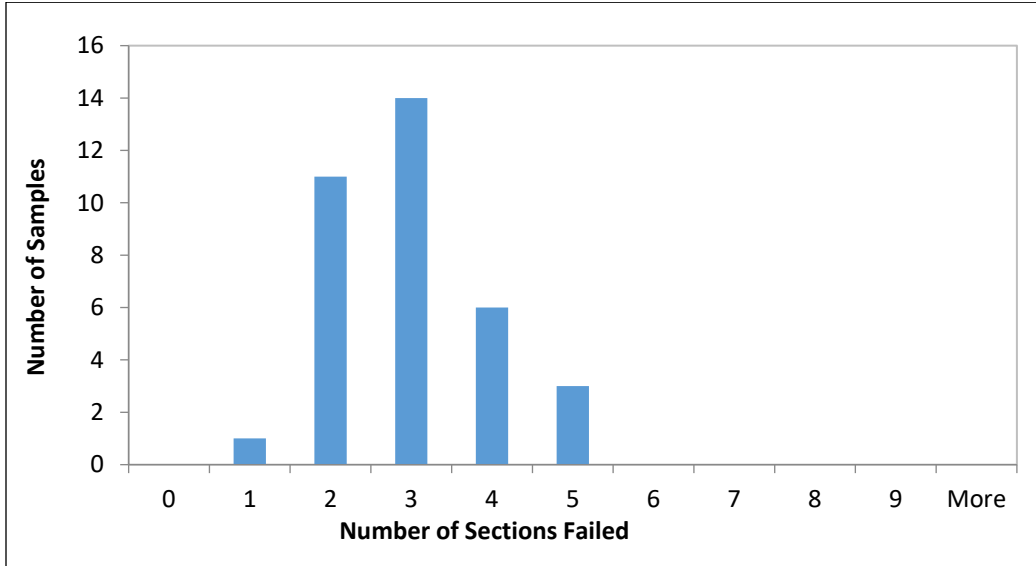


Figure 1: Number of Samples vs. Number of Sections Failed (2018)

As detailed in Table 1, the APBR models tested had a high number of failures when tested to the requirements for retention systems, structural integrity, entrapment, misassembled products, and label permanency. For each requirement, staff analyzed the major causes of failure.

**Table 1: Summary of Mechanical Testing Results for 2018 Samples.<sup>3</sup>**

Section	Title	Not Met (#)	Not Met (%)
5.1	Hazardous Points/Edges	0	0
5.2	Jagged Surfaces	0	0
5.3	Articulated Beds	0	0
6.1	Retention System	28	80
6.2	Structural Integrity	15	43
6.3	Entrapment	33	94
6.4	Openings	0	0
6.5	Misassembled Products	8	23
9.1.2	Label Permanency	19	54

## 2021 Market Compliance Study

In 2021, Staff conducted an additional round of product testing to see if additional time to adapt to the standard would allow manufacturers to increase the overall level of compliance. A total of 17 APBR products were selected; eight of these models covered all the identified APBRs

<sup>3</sup> Detailed testing results can be found in Appendix A: 2021 APBR Market Compliance Test Results

introduced to the market since 2018. The other 9 of the 17 were new APBR samples, previously identified and tested in the 2018 analysis. The 2021 testing, like the 2018 analysis, was designed to gauge overall compliance to the voluntary standard, with a focus on certain sections of the voluntary standard including Retention Systems, Structural Integrity, Entrapment, Openings, Misassembled Products, Warning Statements and Instructional Literature. All samples were tested until at least one of the performance requirements for Retention Systems, Structural Integrity or Entrapment were not met. All 17 samples failed at least one of these requirements. Detailed testing results are provided in Appendix A. The results in Table 2 below show that none of the new samples met all the requirements of the standard. Furthermore, the breakdown of the sections failed followed the same trend as the previous sample set. APBR models tested in the 2021 market compliance study demonstrated modes of failure like those found in the 2018 APBR compliance testing. These findings suggest that there has been very little change in the overall level of market compliance with the ASTM F3186 – 17 voluntary standard.

**Table 2: Summary of Mechanical Testing Results for 2021 Samples<sup>4</sup>**

Section	Title	Not Met (#)	# Tested
5.1	Hazardous Points/Edges	0	17
5.2	Jagged Surfaces	0	17
5.3	Articulated Beds	0	0
6.1	Retention System	13	17
6.2	Structural Integrity	7	7
6.3	Entrapment	14	16
6.4	Openings	0	0
6.5	Misassembled Products	1	1

### Common Product Compliance Failure Modes to ASTM F3186 – 17 Test Requirements

On August 30, 2017, ASTM International published ASTM F3186 – 17. The standard, intended to minimize entrapment and strangulation hazards, includes general and specific performance requirements. During both rounds of compliance testing, staff noticed common modes of failure for the products that did not meet the requirements of the standard. These are broken down by section below:

#### Section 6.1 - Retention Systems

Section 6.1 of the standard states that each product must meet three requirements: (1) it must have a method of maintaining the product’s position; (2) the retention system must be

<sup>4</sup> Detailed testing results can be found in Appendix A: 2021 APBR Market Compliance Test Results.

permanently attached to the product; and (3) the retention system shall not slip or permanently deform during testing.

The primary reason samples failed here was because the retention system components were not permanently attached to the product, an example of which can be seen in Figure 2 below. In other cases, the retention strap permanently deflected or detached during the free-end pull test, or the retention system did not restrain the product during entrapment testing.



*Figure 2: Example of a retention system that was not permanently attached to the product.*

## **Section 6.2 - Structural Integrity**

Section 6.2 has two main performance requirements: (1) during the static structural height test, the product shall extend at least 4 inches above the top surface of the thickest mattress recommended by the product manufacturer; and (2) the product shall not change dimensions or create a hazardous condition during or after cyclic testing.

Most APBR manufacturers did not specify a recommended mattress height or provide instructions on how to adjust product features for a specific mattress. When this was the case, LSM staff adjusted the product height and selected any mattress readily available to the public that would create the most difficult conditions for the product to meet the requirements. This was considered a reasonable approach to evaluating compliance to the standard, because no instructions were provided for adjusting the product features, and no mattress height was recommended by the manufacturer. The static height requirement, described in Section 6.2.1 of the standard, requires the product to extend a minimum of 4 inches above the top surface of the mattress. Adjusting the product to its lowest possible setting, and/or selecting the thickest recommended mattress, resulted in many products not meeting this requirement, as shown in Figure 3.<sup>5</sup>

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<sup>5</sup> Figures depicting test samples have been redacted to preserve sensitive model information. Dotted white outlines are used to indicate the product's relative geometry and structure to the failure mode.



Figure 3: Example of an APBR product failing the static height requirement in Section 6.2.1.

In many products tested, the fasteners loosened or detached during cyclic testing, which caused the product to change dimensions, as shown in Figure 4. This constitutes a failure under Section 6.2.2.

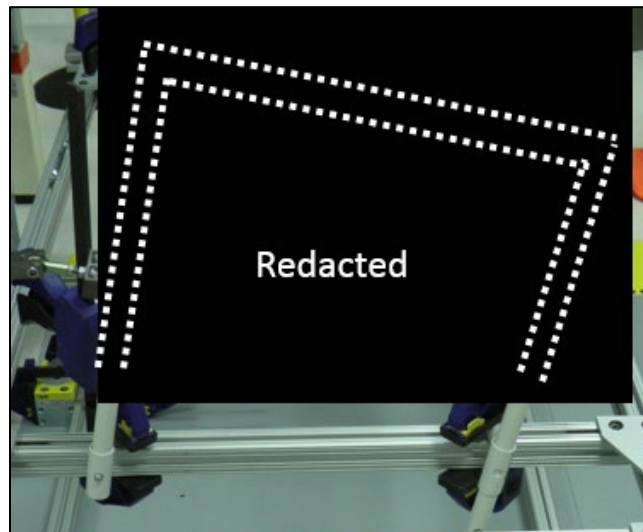






Figure 4: Example of APBR product deforming during cyclic testing, resulting in a failure of Section 6.2.2 of F3186 – 17.

### Section 6.3 - Entrapment

Section 6.3 requires that APBR products do not have one or more of the entrapment zones, as shown in Table 3 below. The zones are identified as follows: (1) Zone 1 - Within the rail; (2) Zone 2 - Under the rail between the rail supports, or under the rail next to a single rail support; (3) Zone 3 - Between the rail and the mattress; and (4) Zone 4 - Under the rail at the ends of the rail.



**Table 3 6: Entrapment Zones**

<p><i>Zone 1: Within the Product</i></p> <p>Entrapment in any open space within the perimeter of the APBR</p>	
<p><i>Zone 2: Between Rail Support(s) and the Bed Mattress, When Applicable, Under the Product</i></p> <p>Entrapment under the bottom edge of the APBR, between the rail supports or next to a single rail support, against the mattress</p>	
<p><i>Zone 3: Between the Product and the Mattress</i></p> <p>Entrapment in the space between the inside surface of the APBR and the side of the mattress</p>	
<p><i>Zone 4: Between the Underside of the End of the Product and the Mattress</i></p> <p>Entrapment under the lowermost portion of the end of the APBR, against the mattress</p>	

**Zone 1 Testing**

Many samples did not have adequate internal structure to prevent the head probe from passing through the Zone 1 opening, and these samples failed the Zone 1 entrapment requirements, as exemplified in Figure 5.

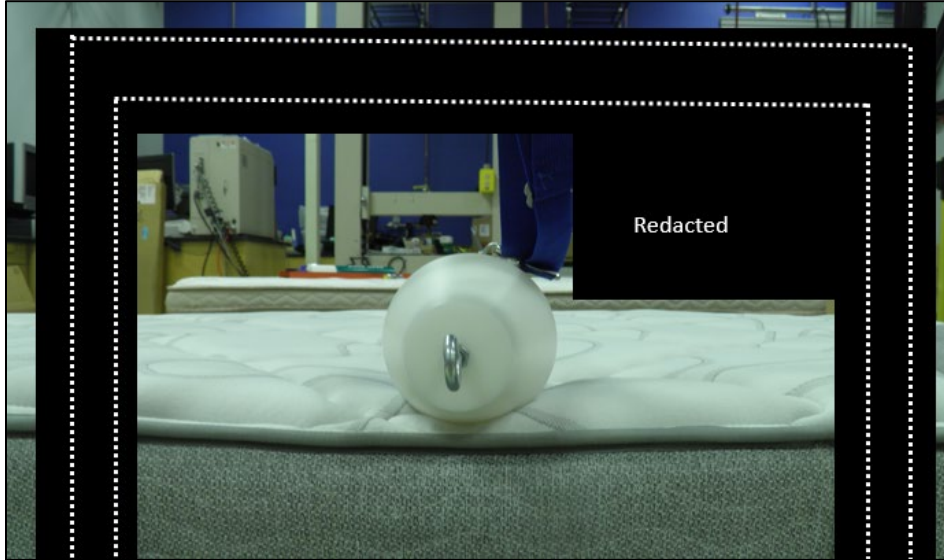


Figure 5: A product without sufficient Zone 1 internal structure.

### Zone 2 Testing

APBR models failed Zone 2 requirements due to two issues. The first issue concerned a lack of internal structure to prevent the probe from entering a Zone 2 opening between the rail and the mattress, as shown in Figure 6.

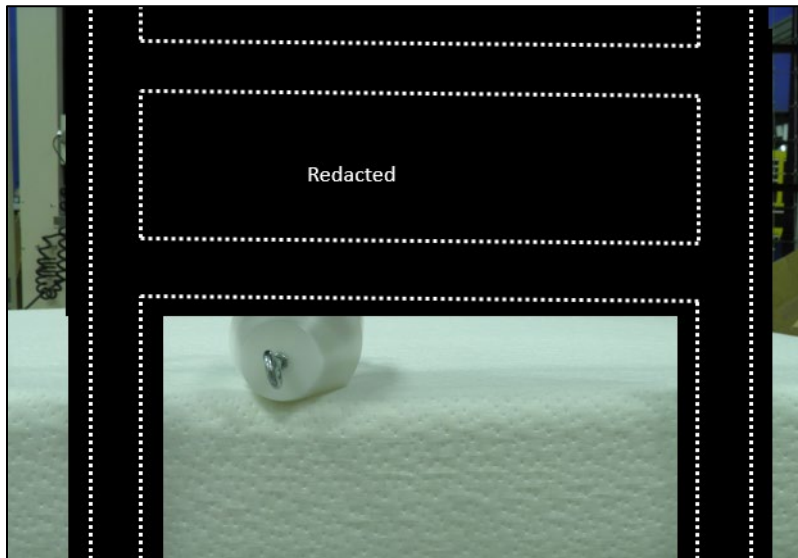
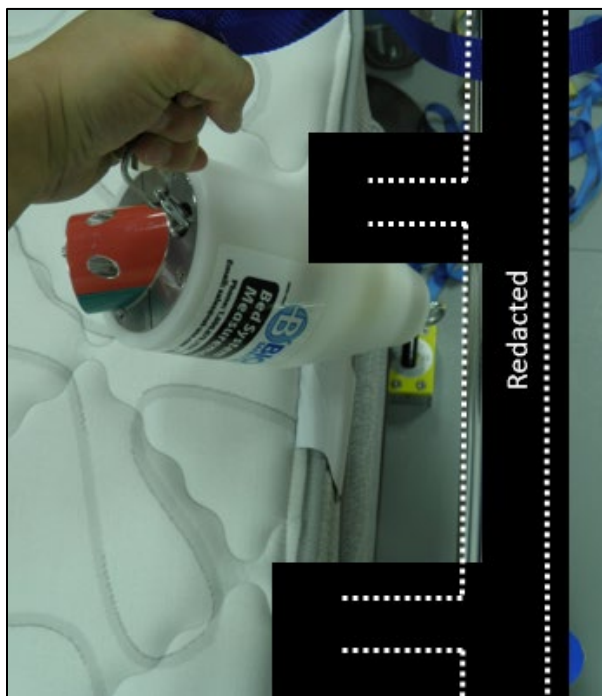


Figure 6: Example of a product without sufficient internal structure to cover the Zone 2 opening.

The second issue leading to the failure of Zone 2 requirements concerned the lack of specificity in the information manufacturers provided. Many manufacturers did not specify what mattress thickness to use with the product, nor did they describe how the consumer is to install and/or adjust the product to fit different size mattresses properly. Figure 7 shows an example of a product with installation instructions that allowed for a significant lateral gap between the mattress and the product.



*Figure 7: Example of a product with a considerable gap between the mattress and the product.*

### **Zone 3 Testing**

The causes of the Zone 3 entrapment failures were like those listed for Zone 2. Most failures occurred due to a lack of adequate structure and issues with the lack of instructions for mattress compatibility, as noted. In some cases, the gaps between the product's internal cross-beams were significant and allowed the probe to move laterally outward, partially into the gap between the cross-beams, which reduced the amount of support the probe would receive from the mattress, as seen in Figure 8. When the surface area supporting the probe decreases, the probe deflects more into the mattress, resulting in a failure related to the maximum allowable vertical deflection. One product used brackets that created a significant lateral offset between the bed frame, product, and the mattress. The gap between the product and the mattress allowed the probe to shift outward laterally, which reduced performance. As seen in Figure 9,

the user manual also contributed to the lack of compliance to the standard. Some user manuals do not explicitly state that the APBR should be installed against the mattress, and some of these include recommendations suggesting that this lateral gap can be as large as 2 inches. In addition, some user manuals that state that the APBR should be installed against the mattress, also suggest that the distance between the product and the mattress could be as large as 4 ¾ inches. This issue is discussed in more detail in the Human Factors memorandum (Tab D), as well as LSM staff's memorandum in the 2020 Briefing Package.

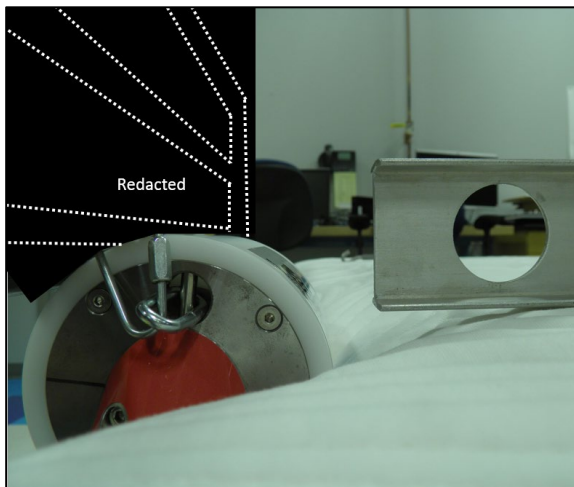


Figure 8: Example of large gap between cross beams permitting the probe to sink below the surface of the mattress.

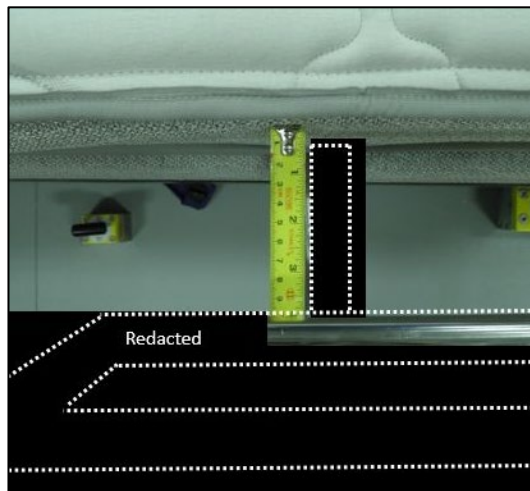


Figure 9: Example of large lateral gap between mattress and product allowed by the user manual.

### Zone 4 Testing

The Zone 4 entrapment failures were caused by overhanging structures at the ends of the rail resulting from the rail being positioned too high, relative to the mattress. Some products' geometry created large openings at the sides of the product, as seen in Figure 10. The test method for Zone 4 entrapment specifies that the product must be adjusted to the manufacturer's recommended height, or heights above the mattress, for products that allow consumer adjustment (see Section 8.4.6.3). In most cases, the manufacturer did not specify how to adjust or install the product for a given bed and mattress environment. As discussed in the Human Factors memorandum (Tab D), many instructions for products with consumer-adjustable heights simply tell consumers to adjust the product to their preferred or desired height; or, the instructions simply describe how to adjust the height, without saying why consumers should do so. In the absence of clear instructions from the manufacturer, CPSC's technical staff chose to use any mattress available to the public, with the product adjusted to any position, as seen in Figure 11.

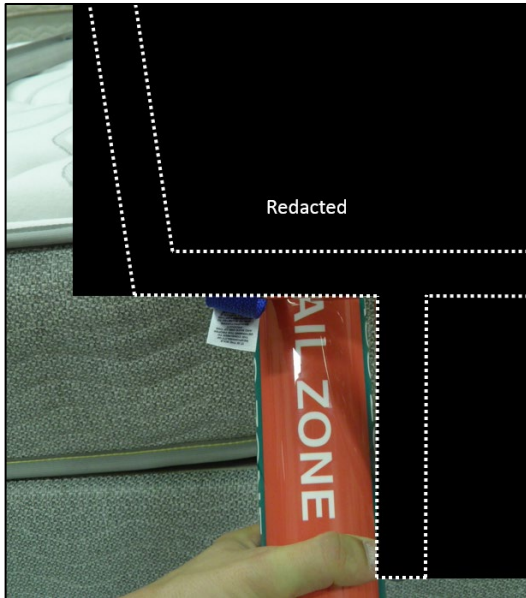


Figure 10: Example of a structure that created a large opening at the ends of the rail.



Figure 11: Example of overhanging structure that is too high relative to the mattress.

### Section 6.5 - Misassembled Products

Section 6.5 requires that APBR products that require consumer assembly meet the requirements of Sections 6.1-6.4 if it appears to be functional. For a more detailed description and interpretation of the requirements in this section see the Human Factors Memorandum (Tab D).

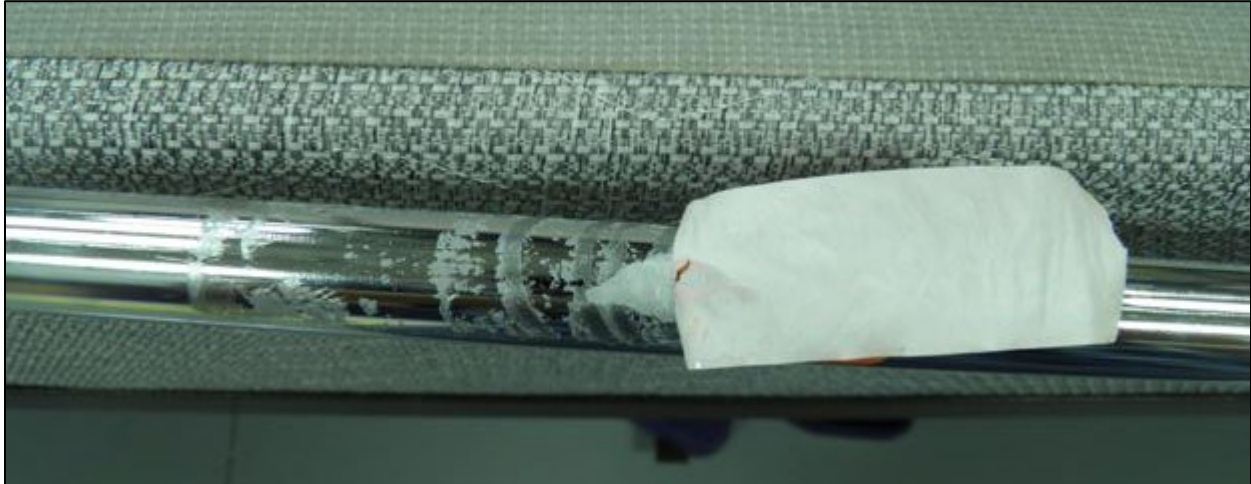
Most products that failed this section failed because the retention strap could not be installed and still appeared to be functional. Other products failed because they had user-installed structural beams, and when the beam was not installed, the entrapment hazard remained.

### Section 9.1.2 - Label Permanency

Section 9.1.2 establishes requirements for any warning labels present on the product, stating that the labels must be permanent, irremovable without the use of solvents, tools, or damaging the surface on which the label is affixed.

In many APBR samples tested, CPSC staff were able to remove the label without the use of any tools or solvents and without damaging the substrate causing these units to fail to meet the requirements of Section 9.1.2, *Label Permanency*. An example of this can be seen in Figure 12 below.





*Figure 12: Example of a label which was removed without damaging the substrate.*

## Conclusion

LSM staff conducted two rounds of APBR market compliance testing to ASTM F3186 – 17 and concluded there is likely little-to-no substantial market compliance with the voluntary standard.

In 2018, Staff evaluated 35 unique APBR models, randomly selected to represent the market, and staff found that none of the products tested complied with all requirements of the standard. In 2021, Staff conducted a second round of testing to determine if there was any change in compliance in the current APBR market. Staff tested 17 products, including all eight new and unique models that had entered the market since the 2018 analysis, and determined that none of them fully complied with the standard. In both rounds of testing, all products tested failed at least one requirement in the voluntary standard, with some failing as many as five different sub-sections of the standard.

**Tab F: Memorandum by CPSC's Designated  
Representative for Voluntary Standards - ASTM  
F15.70**



## Memorandum

**TO:** The Petition CP 13-1 File

**THROUGH:** Andrew G. Stadnik, Assistant Executive Director,  
Directorate for Laboratory Sciences

Michael Nelson, Division Director,  
Division of Mechanical Engineering,  
Directorate for Laboratory Sciences

**FROM:** Vineed K. Dayal, Designated Representative for Standards,  
Division of Mechanical Engineering,  
Directorate for Laboratory Sciences

**SUBJECT:** CPSC Voluntary Standards Involvement for Petition CP 13-1,  
Requests for Ban or Standard on Adult Portable Bed Rails

**DATE:** March 09, 2022

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This memorandum reviews CPSC staff's ongoing efforts with ASTM F15.70 since June 2020.<sup>1</sup>

### ASTM F15.70 Staff Involvement

ASTM F15.70 is the group responsible for the development and maintenance of ASTM F3186 – 17. Throughout this petition, staff has continued its involvement with ASTM F15.70, to develop the standard and continue outreach to stakeholders, such as manufacturers and consumer advocates, about their market compliance to the standard. Information on all public meetings involving staff and ASTM F15.70 can be found on CPSC's Public Calendar.<sup>2</sup> A general summary of these meetings is provided in the timeline below:

- 06/11/2020
  - CPSC staff presented a summary of the compliance test results of APBR models in the market and their compliance to F15.70. Staff informed the subcommittee that none of the models tested fully complied with the group's voluntary standard requirements, and staff provided general descriptions of the failure modes identified. The subcommittee was also reminded about CPSC's docketed petition on APBRs.
- 06/24/2020
  - ASTM staff distributed CPSC Director of Compliance's Letter to Industry to all F15.70 subcommittee members.
- 01/07/2021
  - CPSC staff provided updated APBR incident data to F15.70.

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<sup>1</sup> For additional information about the ASTM F15.70 subcommittee contact ASTM International, West Conshohocken, PA, 2017, [www.astm.org](http://www.astm.org).

<sup>2</sup> CPSC's Public Calendar: [Public Calendar | CPSC.gov](https://www.cpsc.gov/Public-Calendar).



- 03/26/2021
  - CPSC staff sent a letter to F15.70 requesting the next subcommittee meeting.
- 05/21/2021
  - CPSC staff attended the subcommittee meeting and participated in a Q&A session on CPSC's results presented at the last meeting and the previously provided incident data.
- 12/01/2021
  - CPSC Staff attended the subcommittee meeting, joined two task groups established at the meeting, and answered additional questions about the incident data and CPSC's actions/progress. One task group that staff joined was tasked with reviewing the incident data that staff had provided in a previous meeting. The other task group was tasked with reviewing proposed revisions to the standard relating to increasing clarity of the requirements.
- 01/20/2022
  - CPSC staff attended the task group meeting and facilitated the group's discussion on the previously provided incident data, as technical experts.

**Tab G: Memorandum by The Office of  
Compliance and Field Operations, Division of  
Enforcement and Litigation**



## Memorandum

**TO:** Vineed K. Dayal, Project Manager,  
Division of Mechanical Engineering,  
Directorate for Laboratory Sciences

**THROUGH:** Robert Kaye, Director,  
Office of Compliance and Field Operations

Jennifer Sultan, Deputy Director,  
Office of Compliance and Field Operations

Mary B. Murphy, Division Director,  
Division of Enforcement and Litigation

**FROM:** Caitlin O'Donnell, Trial Attorney,  
Division of Enforcement and Litigation

**SUBJECT:** Update on Petition CP 13-1, Requesting a Ban or Mandatory  
Standard on Adult Portable Bed Rails

**DATE:** March 09, 2022

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This memorandum describes enforcement activities involving adult portable bed rails (APBRs) by the Office of Compliance and Field Operations (Compliance) since June 2020.

### Industry Letter

In June 2020, Compliance sent letters to 19 APBR manufacturers, urging them to stop manufacturing, distributing, and selling APBRs that do not comply with ASTM F3186 – 17; reminding the firms of the deadly entrapment and strangulation hazard; and warning that the CPSC “may regard [non-compliant] products as having a defect which could present a substantial product hazard under Section 15(a) of the Consumer Product Safety Act.” Four firms responded; two stated that they only manufactured bed rails they considered to be within the FDA’s jurisdiction, and thus, exempt from ASTM F3186 – 17; one firm promised that it would undertake a review of its products for compliance to the standard; and one firm provided a general acknowledgment that it had received the letter.

### Section 15 Compliance Actions

Beginning in September 2020, Compliance contacted six bed rail manufacturers to initiate Section 15 investigations. To identify firms to assert Section 15 action against, we reviewed incident data to identify firms that had at least one known fatal entrapment incident associated with their APBRs, and whose products failed the entrapment performance requirements of ASTM F3186 – 17, according to testing performed by CPSC’s Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM).

As a result of these investigations, the CPSC has issued four public notices, described below. One notice warned the public about products manufactured by a firm no longer in business, and three other notices announced voluntary recalls.

In April 2021, CPSC warned consumers to stop using three models of APBRs manufactured by Bed Handles, Inc., a company that is out of business. Compliance determined that the products posed an entrapment hazard and risk of asphyxia to users, who could become entrapped within the rails of the products, or between the rails and mattress. The products failed to comply with the performance requirements of ASTM F3186 – 17.

Similar versions of the Bed Handles, Inc., bed rails were recalled in May 2014,<sup>1</sup> because the handles could shift out of place, creating a hazardous gap between the bed rail and mattress. At that time, consumers who participated in the recall were provided with retention straps that were not permanently attached. Subsequent analysis has revealed that consumers may not use retention straps if they are not permanently attached. Consequently, the ASTM standard requires that retention straps can be removed only with the use of a tool. Accordingly, upon reevaluating these products' retention systems, LSM concluded that the previously approved remedy was insufficient to protect consumers from entrapment. The 2021 press release warns consumers about the risks associated with all versions of these models and requests that consumers discard them.<sup>2</sup>

Bed Handles, Inc., distributed approximately 193,000 products, including those previously recalled. CPSC is aware of four entrapment deaths involving bed rails distributed by Bed Handles, Inc.

On December 6, 2021, CPSC and Medical Depot, Inc., d/b/a Drive DeVilbiss Healthcare (Drive), announced a voluntary recall of four models of APBRs, based on the products' entrapment hazard and risk of asphyxia.<sup>3</sup> Drive imported and distributed approximately 496,100 units of the recalled bed rails from October 2007 to June 2021. Two entrapment deaths were associated with two different models: one in California, in 2011, and one in Canada, in 2015. As a remedy, Drive is providing consumers with a full refund.

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<sup>1</sup> PR #14-185. The recall was re-announced twice: first on September 17, 2015 (PR #15-245), due to a low response rate, and again on October 7, 2015 (PR #16-005), after a fourth entrapment death was reported.

<sup>2</sup> PR #21-122, <https://www.cpsc.gov/Newsroom/News-Releases/2021/CPSC-Warns-Consumers-to-Stop-Use-of-Three-Models-of-Adult-Portable-Bed-Rails-Manufactured-by-Bed-Handles-Inc-Due-to-Entrapment-Asphyxia-Hazard>.

<sup>3</sup> PR #22-025, <https://www.cpsc.gov/Recalls/2022/Drive-DeVilbiss-Healthcare-Recalls-Adult-Portable-Bed-Rails-After-Two-Deaths-Entrapment-and-Asphyxiation-Hazards>.

On December 22, 2021, CPSC announced the voluntary recalls of APBRs manufactured by Compass Health Brands (Compass) and Essential Medical Supply, Inc. (Essential). Compass recalled two models of Carex-brand bed rails that presented an entrapment hazard and risk of asphyxia.<sup>4</sup> Compass distributed approximately 104,900 units of the recalled products from November 2012 to May 2021. Three entrapment deaths were associated with one of the models. They occurred between April 2014 and June 2020. As a remedy, consumers received either a CPSC-approved repair kit or a refund, depending on model.

Essential recalled four models of bed rails due to their entrapment hazard and risk of asphyxia.<sup>5</sup> Essential distributed approximately 272,000 units of the bed rails from October 2006 to March 2021. One entrapment death was reported; it occurred in December 2012. Essential is providing a refund to consumers who own bed rails sold or imported on or after November 1, 2015. The refunds are pro-rated based on the age of the bed rail. The news release warns consumers with older bed rails to stop use and dispose of them.

Compliance is continuing to review other APBRs for potential future enforcement action.

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<sup>4</sup> PR #22-040, <https://www.cpsc.gov/Recalls/2022/Compass-Health-Brands-Recalls-Carex-Adult-Portable-Bed-Rails-After-Three-Deaths-Entrapment-and-Asphyxiation-Hazards>.

<sup>5</sup> PR #22-039, <https://www.cpsc.gov/Recalls/2022/Essential-Medical-Supply-Recalls-Adult-Portable-Bed-Rails-Due-to-Entrapment-and-Asphyxia-Hazard-One-Death-Reported>.

# Appendix A: 2021 APBR Market Compliance Test Results

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Staff Briefing Package: Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed

Rails | March 09, 2022 | [cpsc.gov](http://cpsc.gov)

**Table A1: 2021 APBR Market Compliance ASTM F3186 – 17 Test Results**

Sample #	General Requirements			Performance Requirements					Labeling, Warning, and Instructional Requirements			Overall Result
	§5.1	§5.2	§5.3	§6.1	§6.2	§6.3	§6.4	§6.5	§9.1	§9.2	§11	
21-420-0010	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0011	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0012	M	M	NT	Not Met	NT	NT	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0013	M	M	NT	M	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0014	M	M	NT	Not Met	Not Met	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0015	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0016	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0017	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0018	M	M	NT	M	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0020	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0021	M	M	NT	Not Met	Not Met	M	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0022	M	M	NT	Not Met	Not Met	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0023	M	M	NT	Not Met	Not Met	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0024	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0025	M	M	NT	M	Not Met	M	NT	Not Met	Not Met	Not Met	Not Met	Fail
21-420-0026	M	M	NT	Not Met	Not Met	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0027	M	M	NT	M	Not Met	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail

*Table Key: M – The sample “Met” the requirement, NT – The sample was “Not Tested” to the requirement, Not Met – The sample did “not meet” the requirement, Fail – Sample “fails” to meet the requirements of ASTM F3186 – 17.*