

respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Fort Worth ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(m) Related Information

For more information about this AD, contact Andrew McAnaul, Aerospace Engineer, ASW-150 (c/o MIDO-43), 10100 Reunion Place, Suite 650, San Antonio, Texas 78216; telephone: (210) 308-3365; facsimile: (210) 308-3370; email: andrew.mcanaul@faa.gov.

(n) Material Incorporated by Reference

(1) You must use Mooney Aviation Company, Inc. Service Bulletin No. M20-313, dated February 7, 2012, to do the actions required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference (IBR) under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Mooney Aviation Company, Inc., 165 Al Mooney Road North, Kerrville, Texas 78028; telephone: (830) 896-6000; email: technicalsupport@mooney.com; Internet: www.mooney.com.

(3) You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal-register/cfr/ibr_locations.html.

Issued in Kansas City, Missouri, on February 16, 2012.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1224

[CPSC Docket No. CPSC-2011-0019]

Safety Standard for Portable Bed Rails: Final Rule

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”) requires the U.S. Consumer Product Safety Commission (“CPSC,” “Commission,” or “we”) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. In this rule, the Commission is issuing a safety standard for portable bed rails in response to the CPSIA.¹

DATES: The rule will become effective August 29, 2012 and apply to product manufactured or imported on or after that date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of August 29, 2012.

FOR FURTHER INFORMATION CONTACT: Rohit Khanna, Project Manager, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone (301) 987-2508; rkhanna@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background: Section 104(b) of the Consumer Product Safety Improvement Act

The Consumer Product Safety Improvement Act of 2008, Public Law 110-314 (“CPSIA”) was enacted on August 14, 2008. Section 104(b) of the CPSIA requires the Commission to

¹ The Commission voted 4-0 to approve publication of this final rule.

promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The term “durable infant or toddler product” is defined in section 104(f) of the CPSIA as a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years. Portable bed rails (also referred to as “bed rail” or “bedrail”) are one of the products identified by the Commission under section 104(f) of the CPSIA as durable infant or toddler products. On December 29, 2009, the Commission issued requirements for consumer registration of durable infant or toddler products and a bed rail was identified as a durable infant or toddler products that needed to comply with the registration card requirements. 76 FR 68668.

In the **Federal Register** of April 11, 2011 (76 FR 19914), we published a proposed rule that would incorporate by reference ASTM F2085-10a, “Standard Consumer Safety Specification for Portable Bed Rails” but with several modifications that strengthen the standard. In response to the proposed rule and based on comments to the proposed rule, the ASTM Subcommittee on Portable Bed Rails, in collaboration with CPSC staff, developed a newer edition of the standard, ASTM F2085-12, “Standard Consumer Safety Specification for Portable Bed Rails,” which incorporates many of the proposed modifications in the proposed rule, with a few clarifications and modifications that strengthen the standard. ASTM F2085-12 contains more stringent requirements than its predecessor, ASTM F2085-10a, and would further reduce the risk of injury associated with portable bed rails. In this document, we are issuing a safety standard for portable bed rails, which incorporates by reference, the new voluntary safety standard developed by ASTM International (formerly known as the American Society for Testing and Materials), ASTM F2085-12, “Standard Consumer Safety Specification for Portable Bed Rails.” We summarize the proposed rule and discuss the final rule (including differences between the proposal and the final rule) in section F of this preamble. The information discussed in this preamble comes from CPSC staff’s briefing package for the portable bed rails final rule, which is

available on the CPSC's Web site at <http://www.cpsc.gov/library/foia/foia12/brief/briefing.html>.

B. The Product

ASTM F2085–12, and its predecessor ASTM F2085–10a, define a “portable bed rail” as a “portable railing installed on the side of an adult bed and/or on the mattress surface which is intended to keep a child from falling out of bed.” The scope of ASTM F2085–12, and its predecessor, ASTM F2085–10a, also states that a portable bed rail “is as a device intended to be installed on an adult bed to prevent children from falling out of bed.” Portable bed rails are intended for children (typically from 2 to 5 years of age) who can get in and out of an adult bed unassisted. They include bed rails that only have a vertical plane that presses against the side of the mattress but does not extend over it (referred to as “adjacent type bed rails”), as well as bed rails that extend over the sleeping surface of the mattress (called “mattress-top bed rails”).

As discussed in the preamble to the proposed rule, a review of market information showed that there are products that differ from traditional, rigid portable bed rails in that they are constructed of nonrigid (also referred to as “non-rigid”) materials, such as foam or inflatable materials. (76 FR 19915 through 19916). Although these foam and inflatable products do not use the term “bed rails” in their packaging or labeling, we stated that such products meet the definition of a portable bed rail and should be included in the scope of the standard. However, most of the performance requirements in the ASTM standard, which pertain to traditional, rigid portable bed rails, did not apply to these products because the standard was developed to address the hazards from portable bed rails constructed from rigid (wood/metal) materials. Accordingly, the revised ASTM F2085–12 standard now covers foam and inflatable products but would require that only certain relevant provisions of the standard apply to such bed rails.

Both portable bed rails made for a specific manufacturer's adult-size beds and “universal” bed rails that can attach to any *adult-size bed* are included in the scope of ASTM F2085–12 and its predecessor, ASTM F2085–10a. However, as we stated in the preamble to the proposed rule (76 FR 19916), guard rails that are used with crib mattresses on toddler beds are not covered under this voluntary standard. They are addressed under the Consumer Safety Specification for Toddler Beds. Other products that are not covered include: side rails that connect the

headboard to the footboard and may or may not have any barrier purposes; conversion rails intended to convert a crib to a full-size bed; and adult-size beds, where the rail is permanently attached to the bed (*i.e.*, bunk beds). ASTM F2085–12 now makes it clear that such products are not covered under the standard.

Additionally, the U.S. Food and Drug Administration (“FDA”) has several regulations pertaining to hospital beds, including a regulation for pediatric hospital beds (21 CFR 880.5140). The FDA regulations, in general, identify a hospital bed as having (among other things) movable and latchable side rails. If a pediatric hospital bed is subject to regulation by the FDA as a medical device, then the bed rails on that pediatric hospital bed are outside the scope of this final rule.

C. Incident Data

The preamble to the proposed rule (76 FR 19916 through 19917) summarized the data for incidents from January 1, 2000 through March 31, 2010, related to portable bed rails. For that period, we received reports of a total of 132 incidents related to portable bed rails. Among the 132 reported incidents, there were 13 fatalities, 40 nonfatal injuries, and 79 noninjury incidents. Of the 13 child fatalities reported involving portable bed rails, most children (9 out of 13) were under 1 year old; two were between 1 and 2 years old; and two children, both physically handicapped, were 6 years old. Of the 13 fatalities, there were two deaths that resulted from portable bed rail displacement, when the portable bed rail partially pushed away from beneath the mattress and allowed the child to fall into the opening and get trapped. There were three cases of portable bed rail misassembly. In three additional fatal incidents, not enough information was available to determine the contributing factor(s) that led to the hazardous entrapment scenario. The beds used in the eight cases mentioned previously were adult-size beds. More information concerning these incidents is provided in the preamble to the proposed rule (76 FR 19916 through 19917).

On the remaining five fatalities (out of 13), after publication of the proposed rule, we received additional information, through in-depth follow-up investigations on 4 deaths out of the 5 remaining fatalities that were listed as having insufficient information at the time of publication of the proposed rule. One of the 4 fatalities included among the incident data in the portable bed rail proposed rule is now known to have occurred from partial displacement of

the bed rail, which led to the entrapment of the decedent. A second fatality listed previously as lacking sufficient information, still remains in that status. The third fatality is now known not to involve any portable bed rail; what was originally reported as a bed rail has now been confirmed to be a crib rail. Finally, it seems unlikely that the fourth fatality was associated with a portable bed rail. The decedent, co-sleeping with a sibling and a parent, suffocated. The role, if any, of a portable bed rail, now seems questionable. A fifth fatality could not be investigated because the victim's name was not released.

While preparing a final rule, CPSC staff also conducted a new search of the CPSC's epidemiological databases and found that there were 23 new portable bed rail-related incidents reported between April 1, 2010 and November 9, 2011. These incidents are reported to have occurred between 2009 and 2011. Four of the 23 incidents were fatal, and 19 were nonfatal incidents, 8 of which reported an injury. Among the 23 newly reported incidents that specified age (18 out of 23), three reported a child younger than 15 months old. The majority of the incidents (15 out of 18) reported the child's age to be between 15 months and 4 years.

Among the newly reported incidents, there were 4 fatalities. One resulted from a misinstalled bed rail, where the decedent was strangled by the straps of the reinforced anchor system. The second fatality occurred when the infant slipped through the torn section of the mesh and got caught when the bed rail flipped down and caught him at the neck. The remaining 2 fatalities lacked any information on the product or scenario-specific details.

Among the newly reported incidents, there were 19 nonfatal incidents resulting in 8 injuries. The 8 injuries sustained were mostly bumps and bruises; one case reported a laceration that was severe enough to require multiple stitches, and another reported a fractured collar-bone. None of the injuries required hospitalization. The hazard patterns identified among the 23 incident reports were similar to the hazard patterns identified in the data included in the proposed rule, including hinge-lock failure (8 incidents including 4 injuries and 1 fatality). The fatality was attributable, in part, to the hinge-lock failure of the bed rail and, in part, to the torn mesh panel. Other hazard patterns showed displacement of the bed rail (7 incidents, including 3 injuries, where the bed rail pushed out from underneath the mattress and created an opening between the mattress

and the rail); sharp surface (3 incidents, including 1 injury, due to sharp surfaces on the bed rail); misinstallation (1 strangulation fatality on the straps of the reinforced anchor system of the bed rail was reported to have been due to the improper misinstallation of the bed rail); and miscellaneous issues that included 4 incidents and 2 fatalities with insufficient information on the product or scenario and 2 non-fatal incidents (1 reporting hazards from broken screws and the other reporting design issues with the bed rail).

D. The ASTM Voluntary Standard

Section 104(b) of the CPSIA requires the Commission to assess the effectiveness of the voluntary standard in consultation with representatives of consumer groups, juvenile product manufacturers, and other experts. We have consulted with these groups regarding the ASTM voluntary standard, "Standard Consumer Safety Specification for Portable Bed Rails," throughout its development. In response to the proposed rule, and in comments to the proposed rule, the ASTM Subcommittee on Portable Bed Rails, in collaboration with the CPSC staff, developed a new ASTM standard on portable bed rails, ASTM F2085-12, "Standard Consumer Safety Specification for Portable Bed Rails," which incorporates many of the proposed modifications in the proposed rule, with a few clarifications and modifications that strengthen the standard. ASTM F2085-12 contains more stringent requirements than its predecessor, ASTM F2085-10a, and it would further reduce the risk of injury associated with portable bed rails.

E. Response to Comments on the Proposed Rule

The preamble to the proposed rule invited comments concerning all aspects of the proposed rule. We received 16 comments. Eight commenters stated general support for the proposed rule. Eight commenters raised specific issues that are addressed by topic below.

We describe and respond to the comments in section E of this document and also describe the final rule. To make it easier to identify the comments and our responses, the word "Comment," in parentheses, will appear before the comment's description, and the word "Response," in parentheses, will appear before our response. We also have numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the

comment's value or importance, or the order in which it was received.

1. Proposed Misassembly and Misinstallation Requirements

(*Comment 1*) One commenter questioned the need for a revised standard. Two commenters expressed concerns about the proposed requirements to address portable bed rail misassembly and misinstallation. The commenters stated that the proposed language is vague, arbitrary, and invites unacceptable variability in test conditions because there are too many possible misassembly options.

(*Response 1*) We believe that requirements are necessary to address the entrapment hazards that may result from the misassembly and misinstallation of portable bed rails based on our incident data. However, we agree that the proposed requirements of the proposed rule could be clarified and improved. After publication of the proposed rule, the ASTM Portable Bed Rail Subcommittee working group developed alternate performance requirements to address the commenters' concerns about testing and limited the misassembly possibilities to configurations most likely to present entrapment hazards. These requirements have been added to ASTM F2085-12, "Standard Consumer Safety Specification for Portable Bed Rails," which improves upon the proposed test requirements in the proposed rule. In order to improve the misassembly requirements, ASTM F2085-12 requires captive hardware to ensure that fasteners remain attached to their respective components before normal assembly and after normal disassembly. The addition of Figure 1 depicts types of captive hardware, including bolts that are free floating and that can retract but are not completely removable, as well as a pin that is retractable but is not removable without tools. Installation components are required to be fully assembled, inseparable, and permanently attached to a component requiring consumer assembly.

ASTM F2085-12 also addresses the issue regarding the potential for variability in misassembly test conditions. A significant difference between the proposed rule and ASTM F2085-12 is that there are no longer any test requirements or procedures to determine if a misassembled bed rail lacks sufficient vertical structure or provides sufficient visual cues that would notify a consumer that the bed rail is not assembled properly. Instead, the new standard focuses the testing on components that were identified in the incident data. The addition of figures

and illustrations clarifies the pass and fail criteria of the requirements. Figure 5 in ASTM F2085-12 shows an example of a center horizontal structural component that is omitted; consequently, the bed rail's mesh fabric does not engage the center structural component. Figure 6 in ASTM F2085-12 shows additional examples of fail conditions, including a bed rail fabric with the bottom zipper misassembled, where the fabric cover can be zipped up without engaging the bottom horizontal bar. There also is an illustration of how the bottom bar can be omitted from insertion into the fabric sleeve or channel located at the base of the fabric component. Figure 7 in ASTM F2085-12 gives an example of a condition that is not to be tested; Figure 8 in ASTM F2085-12 gives an example of a tube that is inverted or interchanged; and Figure 9 shows an example of a test for unidirectional arm. Test personnel will conduct visual assessments of a bed rail after attempting to misassemble the bed rail. This will require some judgment to determine whether a bed rail can be misassembled using reasonable engineering judgment. We believe that the addition of such illustrations and figures will identify the misassembly combinations that actually would occur and that will prevent unnecessary testing of an unlimited variety of test configurations.

2. Foam and Inflatable (Nonrigid) Bed Rails

(*Comment 2*) Several commenters requested that inflatable and foam bed rails be included in the scope. A few commenters stated that these types of bed rails should meet all of the requirements in the standard and/or have requirements to address a potential suffocation hazard.

(*Response 2*) Nonrigid portable bed rails are included in the scope of ASTM F2085-12 and will need to meet the general requirements to address sharp edges or point, small parts, and permanency of labels, as well as requirements for a new warning label. However, the standard was developed for rigid portable bed rails, and many of the test requirements would not be applicable to these products. Although we are not imposing additional requirements at this time, we expect the ASTM Subcommittee on Portable Bed Rails to continue to monitor these types of nonrigid portable bed rails and pursue the development of additional requirements, as necessary.

3. Test Equipment: Mattress Platform and Sheeting Material

(Comment 3) One commenter stated that the specifications for the Mattress Test Platform 2 and the bed sheeting requirements in ASTM F2085–10a—Section 7.1.2.1 (and 7.1.1.1 for sheeting) *Mattress Construction* are too restrictive and difficult to obtain.

(Response 3) We agree that the Mattress Test Platform 2 and the bed sheeting specification in ASTM F2085–10a are unnecessarily restrictive. ASTM F2085–12 removes the Intention Load Deflection (“ILD”) test that is designed to test the firmness of a foam material and is relevant for Test Platform 1, which is a 4”-thick foam mattress. Test Platform 1 was selected to use on a thin and not very firm mattress. Test Platform 2 is an inner spring mattress, and thus, not solid foam. It was selected for use on a thick mattress (10–11”). However, there is no concern about the foam firmness of Test Platform 2 because the inner spring design gives the mattress rigidity. Therefore, there is no need to have an ILD requirement and test for Test Platform 2. In addition, there is no practical way to test the foam in an inner spring mattress to the ILD test. ASTM F2085–12 also allows greater flexibility for available bed sheet types for use in testing. The change in the sheet specifications was based on our finding that sheets that provide the weight-per-ounce were not practical. We believe that a 50/50 cotton-poly sheet over the mattress is a basic requirement for the test and that the range in thread count would not otherwise affect the results. Accordingly, ASTM F2085–12 allows greater flexibility for available mattress and bed sheet types for use in testing.

4. Double-Sided Bed Rails

(Comment 4) Several commenters recommended that portable bed rails be sold in sets of two (double-sided) only, to reduce entrapment between the wall and a piece of furniture.

(Response 4) Double-sided bed rails currently, are available to consumers. However, we believe that the potential for entrapment between the bed and the wall is not related to, or limited by, the use of a single-sided bed rail, and there is no evidence to support the assertion that requiring double-sided bed rails will address this hazard. We believe that consumers should continue to be educated regarding a safe sleep environment for children, including being aware of and eliminating hazards that are caused by gaps between a mattress and a wall.

5. Bed Sheet Changing

(Comment 5) One commenter stated that the proposed standard does not address issues such as daily changing of bed sheets or other routine use that can cause movement or stress on the components of a bed rail and lead to an unsafe product.

(Response 5) A review of the incident data did not indicate that changing of bedding or other routine behavior contributed to fatal or nonfatal incidents due to additional stress on the component parts of a bed rail. The standard contains requirements that test the strength of the bed rail. We believe that these requirements are adequate to address potential stress-related failures.

6. Mattress Systems

(Comment 6) One commenter stated that the rulemaking proceeding does not address the fact that portable bed rails can be used in various mattress systems.

(Response 6) Our review of portable bed rail products showed that most portable bed rails are adjustable to fit various size mattresses. ASTM F2085–12 contains test requirements that evaluate the safety of portable bed rails on test platforms intended to represent the different types of adult beds available in the market.

7. Warning Language

In general, all eight comments that addressed the warning requirements appear to support the general approach to improving the warning language that was in ASTM F2085–10a. However, some comments raised specific issues and suggested that additional revisions to these requirements would be helpful.

(Comment 7) Several commenters requested more specificity in the warning language. One commenter stated that warning labels should include age limits because bed rails should not be used with children younger than 2 years old. Another commenter noted the importance of describing the hazard more concisely than the warning in the current voluntary standard. One commenter stated that the proposed rule suggested that the revision to the entrapment hazard warning for critical installation components misleads consumers because it provides a false sense of security for those with children who can get in and out of an adult bed without help.

(Response 7) We agree that the primary bed rail warning label on the product and its retail packaging should include explicit age guidance and that the warning statements in the previous edition of the voluntary standard,

ASTM F2085–10a, lacked this specificity. We believe that the new ASTM F2085–12 warning requirements address the public comments and are an improvement to the requirements in both the prior version of the voluntary standard and the proposed rule. The age at which children should not be using a bed rail has been made more explicit with the statement: “NEVER use with children younger than 2 years old”; and the statement immediately following: “Use ONLY with older children who can get in and out of adult bed without help,” clarifies that children must meet both criteria. Additional revisions to the language, such as “Gaps in and around bed rails have entrapped young children and killed infants” clarify the mechanism by which children are dying or becoming injured.

The new warning requirements in ASTM F2085–12 also result in a more concise warning, which may increase the likelihood that consumers will take the time to read the warning and understand the information. For example, the proposed rule’s warning requirements would result in a warning approximately 148 words long; whereas, the warning requirements in ASTM F2085–12 result in a much shorter warning of 102 words long. The revised warning language is now written at a slightly lower grade level than the proposed rule warning language, so that more people who read the warning may be more likely to understand it.

We disagree that the entrapment hazard warning for critical installation components misleads consumers. The purpose of the entrapment hazard warning is to alert consumers to the importance of installing the bed rail correctly. The statement in question—“Incorrect installation can allow the portable bed rail to move away from the mattress, which can lead to entrapment and death”—refers specifically to incorrect installation as the mechanism by which the bed rail can move away from the mattress. Nothing in the warning suggests that other mechanisms of entrapment exist that do not involve movement of the bed rail. Moreover, the bed rail itself includes a more comprehensive warning that discusses other sources of entrapment, such as the placement of the bed rail relative to the headboard or footboard of the adult bed, which clearly shows that other hazards and entrapment scenarios exist.

(Comment 8) One commenter stated that the warning labels should describe the materials used when producing the bed rails.

(Response 8) We disagree that the warning requirements should specify the materials used in the product.

Warnings are intended to be used only to identify a significant hazard. The commenter has not identified what materials present a hazard or what a warning requirement would address. The consequences of exposure to the hazard and appropriate avoidance behavior in response to the hazard also are key pieces of information that should be present in a warning, unless this information can be inferred readily. The commenter did not specify any of this information. Thus, including in a warning label a description of the materials used when the bed rail is produced is not appropriate at this time.

(*Comment 9*) Another commenter stated that there should be a strict warning about modification of the bed rail and the bed rail components.

(*Response 9*) We disagree that warning requirements should include provisions regarding modification of the bed rail and its components. We interpret this comment to indicate that the commenter seeks the addition of warning language to address the scenario of consumers intentionally altering the bed rail components. Our review of incident data does not support that consumers' intentional alteration of bed rail components leads to injury. Thus, mandating such warning language is not supported by the data.

8. Adult Bed Rails

(*Comment 10*) Two commenters stated that the scope of the rule should guarantee more stringent safety standards for all portable bed rails, including adult bed rails. These commenters note that bed rails are used routinely in nursing facilities, hospitals, and private homes. According to the commenters' data, between 1985 and 2009, the FDA received reports of 803 incidents of patients caught, trapped, entangled, or strangled in hospital beds, including 408 deaths, 138 non-fatal injuries, and 185 near-misses due to staff intervention. To address these types of incidents, the commenters requested that the Commission take action on adult bed rails, including mandating warning labels, enforcing reporting requirements, recalls, and civil penalties, and engaging in greater collaboration with the FDA.

(*Response 10*) Section 104(b) of the Consumer Product Safety Improvement Act requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. Accordingly, this rulemaking is limited to bed rails intended for use with children (typically from 2 to 5 years of age) to keep them from falling out of an adult bed. Comments pertaining to other bed rail products

intended for use by older children or adults are outside the scope of this proceeding. With respect to bed rails intended for use by adults or older children, we are aware that some bed rails may be considered "devices" under the Federal Food, Drug, and Cosmetic Act ("FDCA"); therefore, they are subject to regulation by the FDA. The FDA has several regulations pertaining to hospital beds, including a regulation for pediatric hospital beds (21 CFR 880.5140). The FDA regulations, in general, identify a hospital bed as having (among other things) movable and latchable side rails. However, the commenters raised important issues regarding incidents with bed rails that were not intended to be either a part of, or an accessory to, a hospital bed or FDA-regulated pediatric bed. To the extent that there may be such bed rails that are not regarded as medical devices regulated by the FDA, but that are considered, instead, to be "consumer products" under the CPSA or otherwise subject to our jurisdiction, we will continue to review this issue and consider what actions are appropriate, if any.

9. Shipment Costs and Product Size

(*Comment 11*) One commenter stated that shipping costs are a significant portion of the product's total cost and increasing the box size to contain a preassembled product could potentially increase the cost to ship the product by 50 percent. This commenter also stated that the proposed rule may result in adverse retail response to stocking bulkier packages on shelves or in inventory, or retailers dropping products, or refusing to accept a price increase, thus, placing the cost burden on manufacturers.

(*Response 11*) Not all products would need to be preassembled or put in larger boxes. Retooled and redesigned components may allow manufacturers to use existing boxes. To the extent that a manufacturer decides to preassemble parts, or the portable bed rail, we agree that preassembling portable bed rails may require larger boxes and that shipping larger boxes is likely to increase shipping costs. It is possible that the increased shipping costs could be significant for some small firms. We also agree that if larger boxes for bed rails were required, they would need additional storage and shelving space. As a result, some retailers might choose to decrease the number or type of bed rail models they offer to the public, which, in turn, could result in decrease in product demand for some manufacturers.

F. Summary of ASTM F2085–12, "Standard Consumer Safety Specification for Portable Bed Rails"

When the Commission issued its proposed rule in April 2011, the Commission proposed incorporating by reference ASTM F2085–10a, *Standard Consumer Safety Specification for Portable Bed Rails*, with certain modifications, under a new 16 CFR part 1224, *Safety Specification for Portable Bed Rails*. The requirements for portable bed rails in ASTM F2085–12 incorporate many of the proposed changes in the proposed rule, with additional clarifications and improvements. Accordingly, 16 CFR part 1224 will incorporate by reference, without modification, ASTM F2085–12, which includes more stringent requirements that would further reduce the risk of injury associated with portable bed rails.

1. Scope

ASTM F2085–10a provided that under section 1, *Scope*, 1.1: "This consumer safety specification establishes requirements for the performance of portable bed rails. It also contains requirements for labeling and instructional literature."

The proposed rule would not make any change to section 1.1. However the preamble to the proposed rule made clear that the standard did not cover guardrails that fall under the scope of the "Consumer Safety Specification for Toddler Beds", ASTM F1821; or side rails that connect the headboard to the footboard; conversion rails that convert a crib to a full-size bed; and adult-size beds, on which the rail is permanently attached to the bed. 76 FR 19916. Accordingly, to make the scope of portable bed rails explicit so that it does not include such products, ASTM F2085–12 now provides under section 1.1: "This consumer safety specification establishes requirements for the performance of portable bed rails. It also contains requirements for labeling and instructional literature. This consumer safety specification does not cover guardrails that fall under the scope of the Consumer Safety Specification for Toddler Beds, F1821 or guardrails that are designed for a specific model of bed and which attaches at the headboard or footboard."

The proposed rule also would revise section 1.4 of ASTM F2085–10a to state: "In addition to complying with section 1.4 of ASTM F2085–10a, comply with the following: (i) 1.4.1 Foam and inflatable bed rails need meet only the General Requirements of section 5, the performance requirement of 6.3.

Enclosed Openings, and the warning requirement of section 9.3.1.” This section is addressed below in section 3, “Terminology,” and section 5, “General Requirement.”

2. Referenced Documents

Consistent with the clarification in scope under section 1 (Scope)—that the new standard does not cover toddler beds—ASTM F2085–12 includes in section 2, (Referenced Documents) ASTM F1821, “Consumer Safety Specification for Toddler Beds.” In addition, ASTM F2085–12 includes Reference Document ASTM F1487, “Consumer Safety Performance Specification for Playground Equipment for Public Use” to specify the protusion gauge for entanglement used in the performance requirements.

3. Terminology

The proposed rule would revise the terminology in section 3 of ASTM F2085–10a, by creating the following new terms:

- 3.1.10 *foam bed rail*, n—portable bed rail constructed primarily of nonrigid materials such as fabric or foam.
- 3.1.11 *inflatable bed rail*, n—a portable bed rail constructed primarily of nonrigid material that requires air be inflated into the product to achieve structure.
- 3.1.12 *critical assembly component*, n—any component of the portable bed rail that requires consumer assembly in order to meet the performance requirements of 6.1 *Structural Integrity*, 6.3 *Enclosed Openings*, 6.4 *Openings Created by Portable Bed Rail Displacement of Adjacent Style Portable Bed Rails*, 6.5 *Openings Created by Displacement of Mattress-Top Portable Bed Rails* and 6.6 *Openings Created by Displacement of Portable Bed Rails Intended for Use on Specific Manufacturers’ Beds*.
- 3.1.13 *critical installation component*, n—any component of the portable bed rail that is used to attach the portable bed rail onto the bed.
- 3.1.14 *misassembled/functional portable bed rail*, n—a portable bed rail that has been assembled incorrectly but appears to function as a portable bed rail. Misassembly/functionality is determined by meeting one of the criteria listed in 6.9.

In ASTM F2085–12 the following terminology and figures have been included in section 3:

- 3.1.4 *captive hardware*, n—fasteners that remain attached to their respective components before normal assembly and after normal disassembly (see Fig. 1).

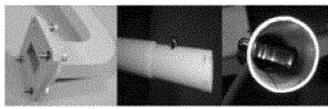


FIG. 1 Captive Hardware

- 3.1.6 *consumer adjustment*, n—those activities defined by the instructions to be taken by the consumer in order to properly fit and secure the bedrail to the mattress.

- 3.1.6.1 *Discussion*—Examples include sliding telescoping poles for proper fit, or initial adjustment for use, tightening of anchoring straps and positioning or changing of attachment components or locking pins.

- 3.1.7 *consumer assembly*, v—the fitting together of components of the bedrail according to manufacturer instructions.

- 3.1.8 *installation component*, n—component of the bed rail that is specifically designed to attach the bed rail to the bed and typically located under the mattress when in the manufacturer’s recommended use position.

- 3.1.10 *misassembled bed rail*, n—a bed rail that has been assembled incorrectly but appears to function as a bedrail.

- 3.1.12 *non-rigid bed rail*, n—portable bed rail constructed of non-rigid materials, including but not limited to fabric or foam, or that requires air be inflated into the product to achieve structure.

The new standard, ASTM F2085–12, contains some, but not all, of the proposed terminology. Proposed sections 3.1.10, *foam bed rail*, and 3.1.11, *inflatable bed rail*, are terms that are now incorporated as *non-rigid bed rail* under new section 3.1.12 in ASTM F2085–12. ASTM F2085–12 does not add proposed section 3.1.12, *critical assembly component*, because all of the bed rail components are critical to safety. Proposed section 3.1.13, *critical installation component*, has been modified to make clear the purpose of the *installation component* under new section 3.1.8 in ASTM F2085–12. Proposed section 3.1.14, *misassembled/functional portable bed rail*, also has been modified to make clear under new section 3.1.10 in ASTM F2085–12 what is meant by *misassembled bed rail*.

ASTM F2085–12 also adds additional terms for *captive hardware* under new section 3.1.4, *consumer assembly* under new section 3.1.7, *consumer adjustment* under new section 3.1.6, and new section 3.1.6.1 *Discussion*. These new sections create terminology to help testing laboratories differentiate between components that require consumer adjustment, such as straps

and telescoping rods, and components that are fitted or fastened together for the bed rails’ structure, and components that do not require consumer adjustment.

The basis for the new terminology is explained further under section 5 (General Requirements), section 6 (Performance Requirements), section 7 (Test Equipment), section 8 (Test Methods), section 9 (Marking and Labeling), and section 11 (Instructional Literature).

4. Calibration and Standardization

The proposed rule would not make any changes to section 4 of ASTM F2085–10a (Calibration and Standardization). This section is unchanged in ASTM F2085–12.

5. General Requirements

The proposed rule would add a section 1.4.1 stating, “1.4.1 *Foam and inflatable bed rails* need meet only the General Requirements of section 5, the performance requirement of 6.3 *Enclosed Openings*, and the warning requirement of section 9.3.1.”

New section 5.5 of ASTM F2085–12 provides that “Non-rigid bed rails need only meet the general requirements of Section 5, the performance requirement of 6.3, and the warning requirements of 9.3.” This section provides that both foam and inflatable bed rails are covered under the term “non-rigid” but are not limited to foam and inflatable products that are also used as bed rails.

In addition, the proposed rule would add the following sections to ASTM F2085–10a:

- 5.6 *Critical Installation Components* that are also *critical assembly* components and that meet the definition of a misassembled/functional portable bed rail must meet 5.6.1 or 5.6.2.

- 5.6.1 Critical installation components must be permanently affixed to a structural component(s) of the portable bed rail.

- 5.6.2 If a critical installation component(s) is also a critical assembly component and may result in a misassembled/functional portable bed rail, the portable bed rail must meet 6.10.1.

ASTM F2085–12 provides similar, but modified, language under new section 5.7 and section 5.8.

- 5.7 Installation components that are required to meet the performance requirements of 6.4, 6.5, and 6.6 shall be fully assembled, inseparable, and permanently attached to a component requiring consumer assembly (this excludes any consumer adjustment).

- 5.8 For products requiring consumer assembly, supplied hardware used for assembly of the bed rail such as screws, nuts or bolts shall be captive hardware to their respective components.

The proposed rule's critical installation components would prevent components (such as anchor plates and straps) that are used to attach the bed rail to the bed from being discarded or lost. All installation component(s) would be attached permanently to a structural component(s) of the bed rail. ASTM F2085–12 combines 5.6, 5.6.1, and 5.6.2 of the proposed rule into new section 5.7 and section 5.8. Like the proposed rule, these sections in ASTM F2085–12 require all installation components to be permanently attached to a structural component(s) that is required to make up the bed rail. This prevents installation components from being discarded or lost. The wording in ASTM F2085–12 clarifies the difference between installation components will require consumer adjustment and those components are part of consumer assembly. Test personnel will be able to identify components subject to the misinstallation requirement and it addresses the concern raised by commenters about the ambiguity of test requirements for installation components that are adjustable.

6. Performance Requirements

The proposed rule would add the following sections to ASTM F2085–10a:

- 6.9 *Determining Misassembled/Functional Portable Bed Rail*—a portable bed rail must be considered a misassembled/functional portable bed rail if it meets one of the criteria in 6.9.1, 6.9.2, 6.9.3, or 6.9.4.

- 6.9.1 The portable bed rail can be assembled without any critical assembly component.

- 6.9.2 The portable bed rail can be assembled without the supplied fasteners, such as screws, nuts, or bolts that are not captive to a critical assembly component such as the frame.

- 6.9.3 The portable bed rail's fabric cover or mesh can be placed over the rigid frame structure without engaging parts of the frame as intended in final assembly.

- 6.9.4 The portable bed rail can be assembled by improper placement of any critical assembly component, such as an inverted or an interchanged part, without permanent deformation or breakage.

- 6.10 *Determining Acceptability of Misassembled/Functional Portable Bed Rail*—Misassembled/Functional Portable Bed Rails must meet 6.10.1, 6.10.2, 6.10.3 or 6.10.4.

- 6.10.1 The portable bed rail must not remain upright or the vertical height must decrease by 6 inches at any point along the top rail when tested to 8.7.

- 6.10.2 The fabric cover or mesh must have a permanent sag a minimum of 3 inches after tested in accordance with 8.8.

- 6.10.3 The fabric cover will not fit over the frame without tearing.

- 6.10.4 Mating parts must clearly show misassembly by two parts overlapping and creating a minimum of a 1/2-inch protrusion out of the plane of the rail. Under ASTM F2085–12, the following new sections and figures have been added:

- 6.9 Bed rail components requiring consumer assembly shall not be able to be misassembled when evaluated to 6.9.1.

- 6.9.1 *Determining Misassembled Bed Rail*—A bed rail shall be considered

a misassembled bed rail if it appears to be a functional bed rail under any one of the conditions listed in 6.9.1.1, 6.9.1.2, or 6.9.1.3 and it does not meet the requirements of 6.4, 6.5, or 6.6.

- 6.9.1.1 The bed rail's fabric cover or mesh can be placed over the rigid frame structure without engaging all structural components of the frame as intended in final assembly (Fig. 5 and Fig. 6). When the bed rail is evaluated, zippers and other means of attachment should be fully fastened. If possible to fasten the means of attachments without engaging said structural components, evaluation for misassembly should account for that (see Fig. 6).

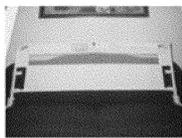
- **Note 1**—Any means of attachment, including, but not limited to, zippers, hooks and loops, and snaps, should be fully fastened. Fig. 7 represents a passing condition.

- 6.9.1.2 The bed rail can be consumer assembled with any horizontal structural components improperly positioned such as being inverted or interchanged, without permanent deformation or breakage of the component or bed rail. This excludes consumer adjustment or universal components that are designed to be interchangeable (Fig. 8). For example:

(1) Horizontal structural components shall be interchanged (Components 1, 2, 3).

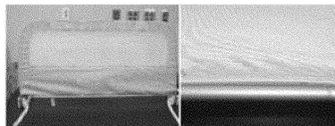
(2) Horizontal structural components shall be inverted (AB:BA); (CD:DC); (EF:FE).

- 6.9.1.3 Bed rails where the position of the arms are intended to be unidirectional are able to be assembled when the arms are rotated 180 degrees above the vertical axis (Fig. 9).



Center horizontal structural component is positioned consequently the fabric does not engage the center structural component.

FIG. 5 Example of Fail Condition

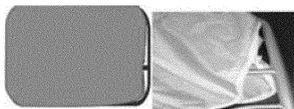


Bedrail fabric with bottom zipper misassembled, fabric cover can be slipped up without engaging the bottom horizontal bar.



Bottom bar can be omitted from insertion into fabric sleeve or channel located at the base of the fabric component.

FIG. 6 Examples of Fail Conditions



Bedrail fabric with a zipper that is not fully engaged. The zipper cannot be fully engaged due to interference with the middle bar.

FIG. 7 Example of Condition Not To Be Tested

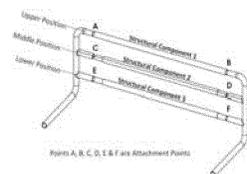


FIG. 8 Example of Tube Inverted or Interchanged

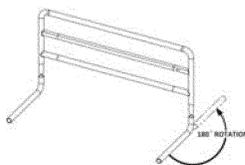


FIG. 9 Example of Test for Unidirectional Arm

The proposed rule contained performance requirements that did not exist in ASTM F2085–10a and were intended to address the risk of entrapment hazards associated with consumer misassembly of portable bed rails. The proposed rule contained test methods and performance criteria to

determine if a misassembled bed rail provided sufficient visual cues for a consumer to identify that the bed rail was misassembled. If the misassembled bed rail did not stay upright, or the top rail collapsed after testing, the misassembly was considered to have a sufficient visual cue for the consumer to

recognize that the product was not assembled correctly. This condition would be considered a passing result because the bed rail only could be misassembled in a way that was obvious to the consumer. Bed rails that are preassembled or designed to reduce the potential for consumer misassembly,

without deforming or breaking parts, also would meet these requirements. CPSC staff developed two prototype bed rails to demonstrate that products could be redesigned to meet the proposed requirement.

ASTM F2085–12 provides a means for determining misassembled portable bed rails that is similar to the proposed rule, but targets specific misassembled portable bed rail scenarios, such as missing horizontal components, fastening the fabric mesh without engaging a horizontal bar, and assembling parts to the wrong components or inverted components.

ASTM F2085–12 addresses misassembly by identifying criteria similar to the proposed rule, but it contains additional figures and illustrations showing examples of passing and failing bed rails that have been misassembled. ASTM F2085–12 section 5.8 is equivalent to section 6.9.2 of the proposed rule, and it requires that nuts and bolts be attached to the bed rail structure to prevent the consumer from discarding or misplacing the fasteners. ASTM F2085–12 section 6.9.1.1 is equivalent to sections 6.9.3 and 6.9.4 of the proposed rule. These requirements identify a misassembled bed rail as a bed rail that can be assembled without a part or without the fabric engaging the entire frame as intended by the manufacturer. These requirements directly address the fatal incidents where the horizontal bar was not used or where the fabric was not installed properly over the bottom horizontal bar. ASTM F2085–12 sections 6.9.1.2 and 6.9.1.3 are equivalent to section 6.9.4 of the proposed rule and require that bed rail components not be interchanged or inverted. This prevents the consumer from assembling a component in a backward or upside-down position.

The primary difference between ASTM F2085–12 and the proposed rule is that ASTM F2085–12 does not have a physical test that establishes pass and fail criteria to determine whether a misassembled bed rail appears to be functional as proposed in section 6.10.1 of the proposed rule. Determination of whether a misassembled bed rail appears to be functional (failing the standard) or appears *not* to be functional (passing the standard) is up to the judgment of the testing laboratory. The figures that show examples of passing and failing bed rails will provide guidance to testing laboratories in making the determination. The new requirements reduce the potential for numerous test configurations, eliminate the testing of zippered products for sag variability, reduce the possibility of misassembly of adjustable components

for installation, and improve repeatability of testing between labs.

7. Test Equipment

The proposed rule did not suggest any changes to the test platforms in ASTM F2085–10a. However, we received comments to the proposed rule that the specifications for the Mattress Test Platform and the bed sheeting requirements in ASTM F2085–10a under *Section 7.1.1.1 and 7.1.1.2* are too restrictive. In response to the comments, ASTM F2085–12 modifies the language to make it easier to test the mattresses and sheeting.

ASTM F2085–10a provided under section 7. Test Equipment, 7.1.1 *Test Platform 1, 7.1.1.1 Mattress Construction*:

- The mattress shall be of standard twin size, 38 by 74.5 in. ± 0.5 in. (0.97 by 1.89 m ± 13 mm). The mattress shall be made from open cell polyurethane foam padding and be 4 to 5 in. (102 to 127 mm) thick with a density of 1 lb/ft³ $+0.2$, -0 (16 kg/m³ $+3.2$, -0). The mattress shall weigh between 6.0 and 9.5 lb (2.7 to 4.3 kg). There shall be no surface texture features (for example, quilting) on the test mattress. The mattress shall be covered with a standard twin sized fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 180 threads per square inch and fabric weight of approximately 3.5 oz/yd² (161 g/m²). The sheet shall be laundered once before use in an automatic home washer, using hot water setting and longest normal cycle with the manufacturer's recommended quantity of a commercial detergent, and dried in an automatic home tumble dryer.

ASTM F2085–12 provides under new section 7:

- 7. Test Equipment, 7.1.1 *Test Platform 1, 7.1.1.1 Mattress Construction*—The mattress shall be of standard twin size, 38 by 74.5 in. ± 0.5 in. (0.97 by 1.89 m ± 13 mm). The mattress shall be made from open cell polyurethane foam padding and be 4 to 5 in. (102 to 127 mm) thick with a density of 1 lb/ft³ $+0.2$, -0 (16 kg/m³ $+3.2$, -0). The mattress shall weigh between 6.0 and 9.5 lb (2.7 to 4.3 kg). There shall be no surface texture features (for example, quilting) on the test mattress. The mattress shall be covered with a standard twin sized fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 100 to 300 threads per square inch.

ASTM F2085–10a provided under section 7. Test Equipment, 7.1.2 *Test Platform 2, 7.1.2.1 Mattress Construction*:

- The mattress shall be of standard twin size, 38 in. by 74.5 in. ± 0.5 in. (0.97 m by 1.89 m ± 13 mm). The mattress shall be of an innerspring design and be between 10.0 in. (0.25 m) and 11.0 in. (0.28 m) thick. The mattress shall weigh 50 ± 10 lb (22.7 ± 4.5 kg). The mattress shall be covered with a standard twin sized cotton fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 180 threads per square inch and fabric weight of approximately 3.5 oz/yd² (161 g/m²). The sheet shall be laundered once before use in an automatic home washer using hot water setting and longest normal cycle with the manufacturer's recommended quantity of a commercial detergent, and dried in an automatic home tumble dryer.

ASTM F2085–12 provides that under new section 7.1.2. *Test Platform 2*:

- 7.1.2.1 *Mattress Construction*—The mattress shall be of standard twin size, 38 in. by 74.5 in. ± 0.5 in. (0.97 m by 1.89 m ± 13 mm). The mattress shall be of an innerspring design and be between 10.0 in. (0.25 m) and 11.0 in. (0.28 m) thick. The mattress shall weigh 50 ± 10 lb (22.7 ± 4.5 kg). The mattress shall be covered with a standard twin sized cotton fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 100 to 300 threads per square inch.

ASTM F2085–12 also deletes section 7.1.2.2 of ASTM F2085–10a, which provides:

- 7.1.2.2 *Mattress Performance*—The foam shall have an Indentation Load Deflection (ILD) of between 28 and 33 when tested in accordance with Test Methods D3574, Method B1.

In response to comments to the proposed rule that asserted that the specifications for the mattress platform and sheeting material were unduly restrictive (Comment 3 and Response 3), ASTM F2085–12 removed the Intention Load Deflection (“ILD”) test that is designed to test the firmness of a foam material because it was not appropriate for a rigid mattress under Test Platform 2. In addition, we agreed that purchasing sheets that provide the weight per ounce is not practical and that the range in thread count would not otherwise affect the results. Accordingly, we believe that the new requirements are an improvement over the existing standard.

The proposed rule would add the following section to ASTM F2085–10a on the force gauge:

- 7.6 *Force Gauge*—gauge must have a minimum range of 0 to 50 lb (222N) with a maximum tolerance of ± 0.25 lb (1.11N) to clarify the manner

in which the force will be applied under the proposed test method to determine acceptability of vertical structure of a misassembled/functional portable bed rail.

ASTM F2085-12 does not have a test to determine acceptability of the vertical structure of a misassembled/functional portable bed rail. Accordingly, under the new section, reference to the vertical structure of a misassembled/functional portable bed rail is omitted. However, because the force gauge is used for other tests in the standard, section 7.6 of ASTM F2085-12 states:

- 7.6 Force Gauge—gauge must have a minimum range of 0 to 50 lb (222N) with a maximum tolerance of ± 0.25 lb (1.11N).

8. Test Methods

The proposed rule would add the following sections to ASTM F-2085-10a:

- 8.7 Test Method for Determining Acceptability of Vertical Structure of a Misassembled/Functional Portable Bed Rail:

- 8.7.1 If possible, attempt to assemble the bed rail in a misassembled configuration(s), as defined in 6.9
- 8.7.2 Firmly secure the misassembled portable bed rail on a table top or other stationary flat surface, using clamps. The clamps should be located 4 to 6 inches from the intersection of the portable bed rail legs to the vertical plane (see figure 8).

- 8.7.3 Gradually apply a force of 10 lbs, using a 1/2-inch disc to the uppermost horizontal component of the rail in a downward direction at a location along the horizontal component that would most likely vertically deform the bed rail (see figure 8).

- 8.7.4 Repeat 8.7.1 through 8.7.3 for all misassembly configurations discovered in 6.9.
- 8.8 Test Method for Determining Fabric Sag Acceptability of a Misassembled/Functional Portable Bed Rail:
- 8.8.1 If possible, attempt to assemble the bed rail in a misassembled configuration(s), as defined in 6.9
- 8.8.2 Gradually apply a force of 1 lb, using a 1/2-inch disc on the fabric/mesh in any direction or location along the fabric/mesh that is most likely to cause it to come off of the frame (see Figure 8). Apply the force over a period of 5 seconds, hold for an additional 10 seconds, and release.
- 8.8.3 Repeat 8.8.1 through 8.8.2 for all misassembly configurations discovered in 6.9.

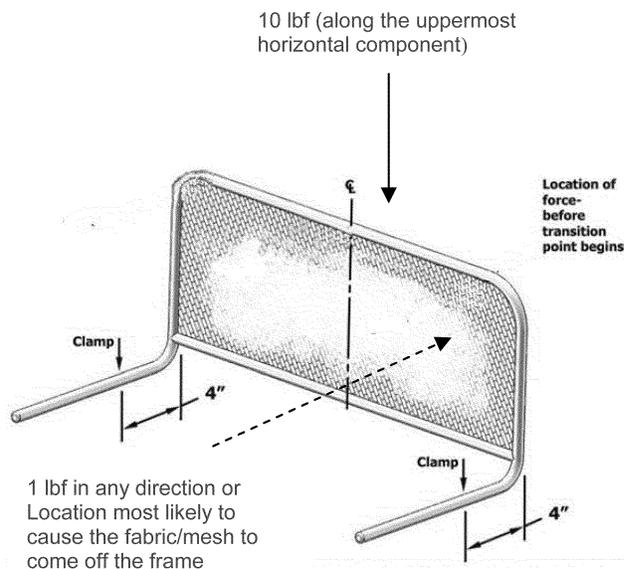


Figure 8: Determining misassembly/functional bed rail test setup

Section 6 in ASTM F2085-12 establishes requirements for determining misassembled portable bed rails, by targeting specific misassembled portable bed rail scenarios, such as missing horizontal components, fastening the fabric mesh without engaging a horizontal bar, and assembling parts to the wrong components or inverted components. ASTM F2085-12 does not have a test to

determine acceptability of the vertical structure of a misassembled/functional portable bed rail. The testing laboratories are in the best position to determine whether a misassembled bed rail appears to be functional (failing the standard) or appears *not* to be functional (passing the standard). Accordingly, we believe that the new requirements under sections 5 (General Requirements) and 6 (Performance Requirements) are an

improvement over the proposed rule's test requirements; accordingly, our proposed requirements in section 8 are not necessary.

9. Marking and Labeling

The proposed rule would make the following revisions to section 9, Marking and Labeling of ASTM F085-10a:

- 9.3.1.1  **WARNING:** Suffocation and Strangulation Hazard.

- 9.3.1.3 Children who cannot get in and out of an adult bed without help can be trapped between a mattress and a wall and suffocate. NEVER place children younger than 2 years old in adult beds with or without a portable bed rail.

- 9.4 Critical installation components must be labeled with the entrapment hazard warning in 9.4.1. The entrapment hazard warning must be in contrasting colors, permanent, conspicuous, and sans serif-style font. In the entrapment hazard warning statement the safety alert symbol "" and the words "WARNING - ENTRAPMENT HAZARD" must not be less than 0.20 in. (5 mm) high. The remainder of the text must be characters whose upper case must be at least 0.10 in. (2.5 mm) high.

- 9.4.1. The warning must including [sic] the following, exactly as stated below:

WARNING – ENTRAPMENT HAZARD



NEVER use portable bed rail without installing this part onto bed. Incorrect installation can allow bed rail to move away from mattress, which can lead to entrapment and death.

ASTM F2085–12 adopts some of the requirements in the proposed rule, but

clarifies the warning label. The new provisions state:

- 9.3.1 The warning statements shall include the following wording, exactly as stated below:

▲WARNING**SUFFOCATION AND STRANGULATION HAZARD**

Gaps in and around bed rails have entrapped young children and killed infants.

NEVER use with children younger than 2 years old. Use ONLY with older children who can get in and out of adult bed without help. NEVER use in place of crib.

NEVER use unless bed rail is tight against mattress, without gaps, and at least 9 inches from headboard and footboard. Do not fill gaps with pillows, blankets, or other items that can suffocate children.

NEVER use on toddler bed, bunk bed, water bed, or bed with inflatable mattress.

Use ONLY on adult bed.

- 9.3.2 For manufacturers' specific bed rails, the warning statements shall also address the following:

Use only on (*manufacturer insert applicable bed and mattress/platform information*).

- 9.4 At least one installation component must be labeled with the entrapment hazard warning in 9.4.1. The entrapment hazard warning shall be in contrasting colors, permanent, conspicuous, and sans serif style font. In the entrapment hazard warning statement the safety alert symbol “▲” and the words “WARNING – ENTRAPMENT HAZARD” shall not be less than 0.20 in. (5 mm) high. The remainder of the text shall be characters whose upper case shall be at least 0.10 in. (2.5 mm) high.

- 9.4.1 The following warning shall be addressed:

▲WARNING – ENTRAPMENT HAZARD

NEVER use bed rail without properly securing bed rail to bed. Incorrect installation can allow bed rail to move away from mattress, which can lead to entrapment and death.

Note 2—Addressed means that verbiage other than what is shown can be used as long as the intent is the same or information that is product-specific is presented.

We believe that the new ASTM F2085–12 warning requirements address the comments received on the proposed rule and improve the requirements in the prior version of the voluntary standard and the proposed rule. The age at which children should not be using a portable bed rail has been made explicit with the statement: “NEVER use with children younger than 2 years old.” Also, the statement immediately following that: “Use ONLY with older children who can get in and out of adult bed without help,” clarifies that children must meet both criteria: They must be at least 2 years old, and they must be able to get in and out of an adult bed without help. Additional revisions to the language, such as the statement: “Gaps in and around bed rails have entrapped young children and killed infants,” clarifies for consumers the mechanism by which children are dying or becoming injured.

The new warning requirements in ASTM F2085–12 also result in a considerably more concise warning, which may increase the likelihood that consumers will take the time to read the warning and encode the information. For example, the proposed rule’s warning requirements would have resulted in a warning approximately 148 words long; whereas, the warning requirements in ASTM F2085–12 result in a warning that is 102 words long. The revised warning language also is written at a slightly lower grade level than the proposed rule warning language, and people who read the warning may be more likely to understand it.

10. Permanency of Label and Warnings

The proposed rule would not make any change to section 10 of ASTM F2085–10a “Permanency of Label and Warnings.” This section is unchanged in ASTM F2085–12.

11. Instructional Literature

We proposed to revise section 11.1 of ASTM F2085–10a to state:

- 11.1 Instructions must be provided with the portable bed rail and must be easy to read and understand. Assembly, installation, maintenance, cleaning, operating, and adjustment instructions and warnings, where applicable, must be included.

ASTM F2085–12 incorporates this provision but adds clarifying language in section 11.1.1. ASTM F2085–10a provided that:

- 11.1.1 The instructions shall contain the warning statements, required by 9.3.1 in the exact format, and shall address the statements in 9.3.2. In addition, instructions shall address the following: Discontinue use if damaged, broken or if parts are missing. ASTM 2085–12 section 11.1.1. now states:

- 11.1.1 The instructions shall contain the warning statements, required by 9.3.1 in the exact format, and where applicable, shall address the statement in 9.3.2. In addition, instructions shall address the following:
 - 11.1.1.1 Discontinue use if damaged, broken, or if parts are missing.

The revised requirement helps clarify that the instructions are appropriate for manufacturers’ specific bed rails, including the manufacturer’s applicable bed and mattress/platform information that was revised in section 7 (Test Equipment).

12. Keywords

The proposed rule would not change section 12 of ASTM F2085–10a “Keywords.” This section is unchanged in ASTM F2085–12.

13. Conforming Edits

ASTM F2085–12 provides conforming edits, including renumbering the figures to incorporate the addition of figures in section 3 (Terminology), and section 6 (Performance Requirements). ASTM F2085–12 also provides additional rationale for the changes in its appendix. The appendix is nonmandatory information and may be viewed in the ASTM F2085–12 standard under “Appendix (Nonmandatory Information); XI. Rationale.”

14. Additional Change to the Final Rule

On our own initiative, we revised § 1224.1, “Scope, application, and effective date,” by replacing “This part 1224 establishes * * *” with “This part establishes * * *.” This is a non-substantive change intended to simplify the sentence structure in § 1224.1.

G. Effective Date

The Administrative Procedure Act (“APA”) generally requires that the effective date of a rule be a least 30 days after publication of the final rule. 5 U.S.C. 553(d). The preamble to the proposed rule indicated that the standard would become effective 6 months after publication of a final rule. We sought comment on how long it would take manufacturers of portable bed rails to come into compliance with the rule. One commenter stated that 6 months allowed for too much delay of administrative enforcement of the new

requirements. One commenter stated that if a CPSC mandatory regulation differed from the ASTM standard, a minimum of 1 year is appropriate to allow adequate time for manufacturers to bring products into compliance with the new requirements. Because ASTM has published a new standard that was approved as of January 1, 2012, and because the final rule adopts the new standard as a CPSC mandatory regulation, we believe 6 months is an adequate length of time for manufacturers to comply with the new requirements. We believe that manufacturers would benefit from the additional 6 months after publication of a final rule to review the new requirements thoroughly and to ensure that new portable bed rails manufactured or imported after that date are in compliance with the new requirements, including the fabrication of new labels, as well as the retooling and redesign of products. Accordingly, the final rule provides that the rule will be effective 6 months after publication of the final rule in the **Federal Register**. A 6 month effective date should also enable the Commission to complete the required rulemaking with regard to the notice of requirements regarding the accreditation of laboratories to conduct the requisite third party testing to this new portable bed rails standard.

H. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act (“RFA”), 5 U.S.C. 601–612, requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that CPSC staff prepare a final regulatory flexibility analysis when the Commission promulgates a final rule. The final regulatory flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

1. A succinct statement of the objectives of, and legal basis for, the rule;
2. A summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis; a summary of the assessment of the agency of such issues; and a statement of any changes made in the proposed rule as a result of such comments;
3. A description of, and where feasible, an estimate of, the number of small entities to which the rule will apply;
4. A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities

subject to the requirements, and the type of professional skills necessary for the preparation of reports or records; and

5. A description of the steps the agency has taken to reduce the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

2. The Market

Typically, portable bed rails are produced and/or marketed by juvenile product manufacturers and distributors or by furniture manufacturers and distributors. When the proposed rule was published, we were aware of 14 manufacturers or importers supplying bed rails to the U.S. market. We are now aware of at least 17 known manufacturers or importers supplying bed rails to the U.S. market. Thirteen are domestic manufacturers (76 percent), and three are domestic importers (17 percent). The remaining firm has an unknown supply source, and there is no publicly available information regarding its size.

Under U.S. Small Business Administration (“SBA”) guidelines, a manufacturer of portable bed rails is small if it has 500 or fewer employees; an importer is considered small if it has 100 or fewer employees. Based on these guidelines, 12 of the domestic manufacturers and three of the domestic importers known to be supplying portable bed rails to the U.S. market are small. There may be additional unknown small manufacturers and importers operating in the U.S. market as well.

The Juvenile Products Manufacturers Association (“JPMA”), the major U.S. trade association that represents juvenile product manufacturers and importers, runs a voluntary Certification Program for several juvenile products. Five manufacturers supply bed rails to the U.S. market that are compliant with the ASTM standard F2085–10a (the previous voluntary standard). Among them, four are JPMA-certified as compliant with ASTM F2085–10a, and one firm claims compliance. Of the three importers, one firm is JPMA-certified as ASTM compliant with ASTM F2085–10a, and one firm claims to be in compliance. All seven firms, which are either JPMA-certified or claim compliance with ASTM F2085–10a, are small. However, none of these firms meets the requirements of the current voluntary standard, ASTM F2085–12.

JPMA estimates that current annual sales of portable bed rails are

approximately 750,000 units, and retail sales are approximately \$20 million. No information is available about the average product life of bed rails; but if, for example, bed rail sales are assumed to have remained constant in recent years, and bed rails remain in use for 3 to 5 years, then currently, there might be 2.25 million to 3.75 million bed rails in use. National estimates of bed rail product-related injuries are not available because the National Electronic Injury Surveillance System (“NEISS”) data do not allow for clear identification of youth bed rails. Therefore, the risk of injury associated with the number of products in use cannot be calculated.

3. Impact of the Standard on Small Business

There are 17 firms currently known to be producing or selling portable bed rails in the United States. Of these firms, 12 are small domestic manufacturers, and three are small domestic importers. The remainder of this analysis focuses on these 15 small domestic firms.

Small Domestic Manufacturers

The impact of the draft final rule on small manufacturers may differ, based on whether they comply with the preceding ASTM standard, ASTM F2085–10a. Of the 12 domestic manufacturers, five produce portable bed rails that are certified as compliant by JPMA or claim to be in compliance with ASTM F2085–10a.

The products of the firms that are not in compliance with ASTM F2085–10a may require substantial modifications to meet ASTM F2085–12. The costs associated with these modifications could include product redesign, development and marketing staff time, product testing, and focus group expenses. It is possible that some firms may change the type of materials used to make portable bed rails, resulting in some cost increase. Costs may also rise if additional materials are required, or the products need to be redesigned. The actual costs of product modifications are unknown, but they could be significant for some firms. However, the impact of these costs may be mitigated if they are treated as new product expenses and amortized.

The impact on the firms that produce portable bed rails that are compliant with ASTM F2085–10a may be less significant. Firms already in compliance with ASTM F2085–10a may require fewer modifications in order to bring their product into compliance with the current voluntary standard. Some firms may opt to preassemble component(s) rather than redesign their product. If

firms decide to preassemble products, then portable bed rails may require larger shipping boxes. Shipping larger boxes is likely to increase shipping costs, and increased shipping costs may be significant in some cases. Larger boxes will also require greater storage space and may cause some retailers to reduce portable bed rails from their shelves and inventories.

All manufacturers will need to modify existing warning labels. Costs associated with the new warning label would be low because no new materials are used. However, eliminating the specified test methods in the proposed rule and reducing the number of testing configurations as well as reducing the number of warnings may result in a small reduction in costs. At least four small manufacturers’ product lines consist primarily or entirely of nonrigid portable bed rails. These firms may need to alter the warning label and requirements for enclosed openings; but otherwise, these firms are not likely to be affected significantly by the voluntary standard.

Additionally, once the final rule and the notice of requirements is in effect, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements.

Small Domestic Importers

All three small domestic importers would need to find an alternate source of portable bed rails if their existing supplier does not come into compliance with the current voluntary standard. The cost to importers may increase and in turn, they may pass on some of those increased costs to consumers. Some importers may respond to the rule by discontinuing the import of their portable bed rails. However, the impact of such a decision may be lessened by replacing the noncompliant portable bed rail with a complying product or another juvenile product. Deciding to import an alternative product would be a reasonable and realistic way for most importers to offset any lost revenue, given that most import a variety of products. However, for small importers whose product lines rely largely on bed rails, substituting another product may not be realistic. The impact on these small importers likely would be more significant.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, will experience additional costs.

4. Alternatives

Section 104 of the CPSIA requires the Commission to adopt a mandatory standard substantially the same as, or more stringent than, the voluntary standard, if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products. One alternative would be to set an effective date later than the staff-recommended 6 months. This would allow suppliers (and manufacturers) additional time to modify and/or develop compliant portable bed rails, thereby spreading the associated costs over a longer period of time.

I. Environmental Considerations

The Commission’s regulations provide a categorical exclusion for the

Commission’s rules from any requirement to prepare an environmental assessment or an environmental impact statement because they “have little or no potential for affecting the human environment.” 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

J. Paperwork Reduction Act

This rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (“OMB”) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The preamble to the proposed rule (76 FR 19922 through 19923)

discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. OMB has assigned control number 3041–0149 to this information collection. We did not receive any comment regarding the information collection burden of the proposal. However, the final rule makes modifications regarding the information collection burden because the number of estimated manufacturers subject to the information collection burden is now estimated at 17 manufacturers rather than the 14 manufacturers initially estimated in the proposed rule.

Accordingly, the estimated burden of this collection of information is modified as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

16 CFR Section	Number of respondents	Frequency of responses	Total annual responses	Hours per response	Total burden hours
1224.2(a)	17	2	34	1	34

There are no capital costs or operating and maintenance costs associated with this collection of information.

There are 17 known firms that supply portable bed rails to the U.S. market. All 17 firms are assumed to use labels on their products and their packaging, but they would need to make some modifications to their existing labels. The estimated time required to make these modifications is about 1 hour per model. Each firm supplies an average of two different models of portable bed rails; therefore, the estimated burden hours associated with labels is: 1 hour × 17 firms × 2 models per firm = 34 annual hours. We estimate that the hourly compensation for the time required to create and update labels is \$28.36 (Bureau of Labor Statistics, September 2011, all workers, goods-producing industries, sales, and office, Table 9). Therefore, the estimated annual cost to industry associated with the Commission-recommended labeling requirements is \$964 (\$28.36 per hour × 34 hours = \$964.24, which we have rounded down to \$964).

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this final rule to the OMB.

K. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a “consumer product safety standard under [the CPSA]” is in effect and

applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules,” thus, implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

L. Certification

Section 14(a) of the Consumer Product Safety Act (“CPSA”) imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product or on a reasonable testing program or, for children’s products, on tests on a sufficient number of samples by a third party conformity assessment body accredited by the Commission to test according to the applicable

requirements. As discussed in part K of this preamble, section 104(b)(1)(B) of the CPSIA refers to standards issued under that section, such as this final rule for portable bed rails, as “consumer product safety standards.” Furthermore, the designation of “consumer product safety standards” subjects such standards to certain sections of the CPSA, such as section 26(a) of the CPSA, regarding preemption. By the same reasoning, such standards also would be subject to section 14 of the CPSA, regarding testing and certification. Therefore, any such standard would be considered a consumer product safety rule to which products subject to the rule must be certified. We intend to issue a notice of requirements in the near future to explain how accredited laboratories can become recognized by CPSC as third party conformity assessments bodies to test to the new portable bed rails standard.

Additionally, because portable bed rails covered by this final rule are “children’s products,” they must comply with all other applicable CPSC requirements, such as the lead content and phthalates content requirements in sections 101 and 108 of the CPSIA; the tracking label requirement in section 14(a)(5) of the CPSA; and the consumer registration form requirements in section 104 of the CPSIA.

List of Subjects in 16 CFR Part 1224

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, and Law enforcement.

For the reasons stated in the preamble, the Commission amends Title 16 of the Code of Federal Regulations by adding a new part to read as follows:

PART 1224—SAFETY STANDARD FOR PORTABLE BED RAILS

Sec.

1224.1 Scope, application, and effective date.

1224.2 Requirements for portable bed rails.

Authority: Sections 3 and 104 of Pub. L. 110–314, 122 Stat. 3016 (August 14, 2008).

§ 1224.1 Scope, application, and effective date.

This part establishes a consumer product safety standard for portable bed rails manufactured or imported on or after August 29, 2012.

§ 1224.2 Requirements for portable bed rails.

(a) Each portable bed rail as defined in ASTM F2085–12, *Standard Consumer Safety Specification for Portable Bed Rails*, approved January 1, 2012, must comply with all applicable provisions of ASTM F2085–12. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of this ASTM standard from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA, phone: 610–832–9585; <http://www.astm.org/>. You may inspect copies at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) [Reserved]

Dated: February 22, 2012.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2012–4451 Filed 2–28–12; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION**16 CFR Part 1420**

[CPSC Docket No. CPSC–2011–0047]

Standard for All-Terrain Vehicles

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Improvement Act of 2008 (“CPSIA”) required the Consumer Product Safety Commission (“Commission,” “CPSC,” or “we”) to publish, as a mandatory consumer product safety standard, the American National Standard for Four-Wheel All-Terrain Vehicles Equipment Configuration, and Performance Requirements, developed by the Specialty Vehicle Institute of America (American National Standard ANSI/SVIA 1–2007). We did so on November 14, 2008. 73 FR 67385. ANSI/SVIA later issued a 2010 edition of its standard. In accordance with the CPSIA, we are amending the Commission’s mandatory ATV standard to reference the 2010 edition of the ANSI/SVIA standard.¹

DATES: The rule will become effective on April 30, 2012, and will apply to products manufactured or imported on or after that date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of April 30, 2012.

FOR FURTHER INFORMATION CONTACT: Justin Jirgl, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7814; jjirgl@cpsc.gov.

SUPPLEMENTARY INFORMATION:**A. Background**

The Consumer Product Safety Improvement Act of 2008 (“CPSIA”) directed the Commission to “publish in the **Federal Register** as a mandatory consumer product safety standard the American National Standard for Four Wheel All-Terrain Vehicles Equipment Configuration, and Performance Requirements developed by the Specialty Vehicle Institute of America (American National Standard ANSI/

¹The Commission voted 3–0–1 to approve publication of this rule. Chairman Inez M. Tenenbaum and Commissioners Nancy A. Nord and Robert S. Adler voted for the rule. Commissioner Ann M. Northup abstained from voting. Commissioner Adler filed a statement concerning this action which may be viewed on the Commission’s Web site at <http://www.cpsc.gov/pr/statements.html> or obtained from the Commission’s Office of the Secretary.

SVIA 1–2007).” 15 U.S.C. 2089(a)(1), as added by section 232 of the CPSIA. Accordingly, on November 14, 2008, we published a final rule mandating ANSI/SVIA 1–2007 as a consumer product safety standard. 73 FR 67385. The final rule is codified at 16 CFR part 1420.

B. The Amendment*1. Procedure*

Section 42(b) of the Consumer Product Safety Act (“CPSA”) provides that, if ANSI/SVIA 1–2007 is revised after we have published a **Federal Register** notice mandating the standard as a consumer product safety standard, ANSI must notify us of the revision, and we have 120 days after receiving that notification to issue a notice of proposed rulemaking to amend our mandatory ATV standard “to include any such revision that the Commission determines is reasonably related to the safe performance of [ATVs] and notify the Institute of any provision it has determined not to be so related.” 15 U.S.C. 2089(b)(1) and (2). Thereafter, we have 180 days after publication of the proposed amendment to publish a final amendment to revise the ATV standard. *Id.*

2. Changes From 2007 Edition

On March 16, 2011, ANSI notified us that, in December 2010, ANSI approved a revised version of the ANSI/SVIA standard for four-wheel ATVs, ANSI/SVIA 1–2010. We reviewed the changes from the 2007 version. Many changes are minor revisions to the wording in the standard. We considered the substantive changes to be: (1) Elimination from the scope section of a provision calling for expiration of the definition and requirements for the Y–12+ youth ATV age category on July 28, 2011; (2) a change in how to calculate the speed for the braking test of youth ATVs; (3) a change in the force applied to passenger handholds during testing; (4) the addition of a requirement that youth ATVs shall not have a power take-off mechanism; (5) the addition of a requirement that youth ATVs shall not have a foldable, removable, or retractable structure in the ATV foot environment; (6) additional specificity concerning the location and method of operation of the brake control; (7) tightening the parking brake performance requirement, by requiring the transmission to be in “neutral” during testing, rather than in “neutral” or “park”; and (8) the requirement that tire pressure information be on the label, when the previous requirement could be interpreted to allow tire pressure information to be on the label,