The contents of this document will be discussed at the Commission Briefing scheduled for February 8, 2012.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

This document has been electronically approved and signed.

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: FEBRUARY 22, 2012

February 1, 2012

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM: Philip L. Chao, Assistant General Counsel
Hyun S. Kim, Attorney, OGC

SUBJECT: Final Rule: Safety Standard for Portable Bed Rails

The Office of the General Counsel is providing for Commission consideration the attached draft final rule on a safety standard for portable bed rails.

Please indicate your vote on the following options:

I. Approve publication of the draft final rule in the *Federal Register*, without changes.

_____ _____
(Signature) (Date)

II. Approve publication of the draft final rule in the *Federal Register*, with changes. (Please specify.)

_____

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_____ _____
(Signature) (Date)

III. Do not approve publication of the draft final rule in the *Federal Register.*

_____ _____
(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

Attachments:

Draft *Federal Register* Safety Standard for Portable Bed Rails: Final Rule

Staff Briefing Package: Draft Final Rule for Portable Bed Rails, from Rohit Khanna, dated February 2012.

[Billing Code 6355-01-P]

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.

DATES: The rule will become effective **[insert date six months after date of publication in the *Federal Register*]** 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 **[insert date six months after date of publication in the *Federal Register*]**.

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, Pub. Law 110-314 ("CPSIA") was enacted on August 14, 2008. Section 104(b) of the CPSIA requires the Commission 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. 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 website at

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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 at 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 at 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 at 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 at 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 F208-12 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

(Com*ment 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 bedrail that is specifically designed to attach the bedrail 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 bedrail 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 ½-inch protrusion out of the plane of the rail**.**

Under ASTM F2085-12, the following new sections and figures have been added:

- 6.9 Bedrail 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 bedrail shall be considered a misassembled bed rail if it appears to be a functional bedrail 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 bedrail'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 bedrail 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 bedrail 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 bedrail. 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 Bedrails 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).

FIG. 5 Example of Fail Condition

FIG. 6 Examples of Fail Conditions

FIG. 7 Example of Condition Not To Be Tested

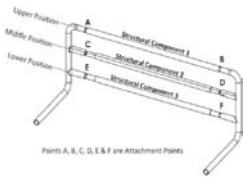

FIG. 8 Example of Tube Inverted or Interchanged

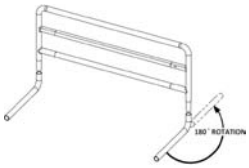

FIG. 9 Example of Test for Unidirectional Arm

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. 6 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 I* 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 1.89m ± 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 1.89m ± 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 *Determining Misassembled/Functional Portable Bed Rail*:
- 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 ½-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). Apply the force over a period of 5 seconds; hold the force for 10 seconds, and release.
- 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 *Determining Misassembled/Functional Portable Bed Rail*.
- 8.8.2 Gradually apply a force of 1 lb, using a ½-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.

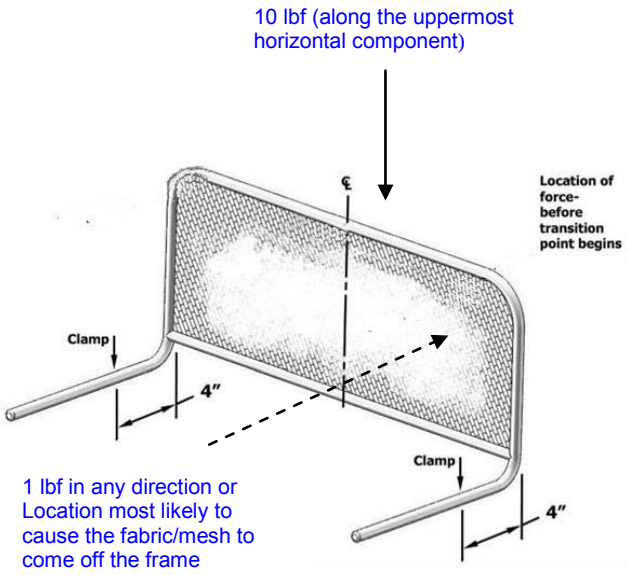

Figure 8: Determining misassembly/functional bed rail test setup

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 publically 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 compliant 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 at 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 x 17 firms x 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 x 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 [**insert date 6 months after date of publication in the FEDERAL REGISTER**].

§ 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, PO 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:_____

_____
Todd A. Stevenson, Secretary
U.S. Consumer Product Safety Commission

Staff Briefing Package

Draft Final Rule for Portable Bed Rails
February 2012

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EXECUTIVE SUMMARY

Section 104 of the Consumer Product Safety Improvement Act (CPSIA), *Standards and Consumer Registration of Durable Nursery Products*, requires the U.S. Consumer Product Safety Commission (CPSC) to promulgate consumer product safety standards for certain durable infant and toddler products. These product standards should be identical to applicable voluntary standards or more stringent, if the Commission determines that additional requirements would further reduce the risk of injury associated with the product.

This briefing package assesses the effectiveness of the voluntary standard for portable bed rails and presents staff's recommendations for a draft final rule to address potential hazards to children associated with these products.

In April 2011, the Commission published a notice of proposed rulemaking (NPR) for portable bed rails to adopt the ASTM International (formerly known as the American Society for Testing and Materials) ("ASTM") voluntary standard, ASTM F2085-10a, *Standard Consumer Safety Specification for Portable Bed Rails*, with additional requirements to strengthen the standard to reduce the risk of injury associated with portable bed rails. The NPR solicited information and comments concerning all aspects of the proposed rule. The CPSC received 16 comments on the NPR. Eight comments expressed general support for the proposed rule and eight comments raised other issues.

In November 2011, ASTM balloted a revision to the standard that contained the additional requirements contained in the NPR, with a few clarifications and modifications, and addressed the comments received on the NPR. The revised ASTM standard was approved and published in January 2012. The staff's draft final rule to address hazards associated with portable bed rails incorporates the newly published ASTM F2085-12 *Standard Consumer Safety Specification for Portable Bed Rails*, which is more stringent than the previous standard.

The impact of the draft final rule on small manufacturers will vary depending on whether they were compliant with the previous version of the voluntary standard. The firms that were not in compliance with the previous version may require substantial modifications to meet the current voluntary standard. The actual costs associated with these changes are unknown but could be significant for some firms. The impact on firms that were in compliance with the previous voluntary standard may be less significant. However, even portable bed rails compliant with the previous voluntary standard will require some modifications.

CPSC staff recommends that the Commission proceed with publication of the final rule for portable bed rails under section 104(b) of the CPSIA, as drafted by the Office of the General Counsel. CPSC staff also recommends an effective date of 6 months after publication of the final rule.

BRIEFING MEMORANDUM

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

This document has been electronically approved and signed.

Memorandum

DATE: February 1, 2012

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM: DeWane Ray, Assistant Executive Director
Office of Hazard Identification and Reduction
Rohit Khanna, Project Manager
Office of Hazard Identification and Reduction

SUBJECT: Staff's Draft Final Rule for Portable Bed Rails

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act (CPSIA), *Standards and Consumer Registration of Durable Nursery Products*, requires the U.S. Consumer Product Safety Commission (CPSC) to study and develop safety standards for certain infant and toddler products. 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 product that needed to comply with the registration card requirements. 76 FR 68668.

Section 104 of the CPSIA also requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the voluntary standards. For portable bed rails, this consultation process commenced in August 2010, at an ASTM International (formerly known as the American Society for Testing and Materials) ("ASTM") subcommittee meeting regarding the ASTM portable bed rail voluntary standard. Staff participates in the ASTM meetings on an ongoing basis.

This briefing package assesses the effectiveness of the portable bed rail voluntary standard and presents staff's recommendations for a final rule to address potential hazards associated with portable bed rails.

II. BACKGROUND

A. Pre-NPR Standard Activity

A "portable bed rail" is a device intended to be installed on an adult bed to prevent children from falling out. Portable bed rails are intended for children who can get in and out of bed unassisted (typically from 2 to 5 years of age).

On October 3, 2000, an advance notice of proposed rulemaking (ANPR) was published in the *Federal Register* (65 FR 58968) to address hazards associated with portable bed rails. The most common hazard pattern involving child fatalities was entrapment, which can occur when the bed rail moves outward partially (away from the mattress) and the child rolls into the gap between the mattress and the bed rail. Once entrapped, the child can asphyxiate.

ASTM F2085, *Standard Consumer Safety Specification for Portable Bed Rails*, is the voluntary standard that was developed to address the identified hazard patterns associated with the use of portable bed rails. The ASTM standard was first published in May 2001. The first edition of the standard included labeling requirements but did not contain performance requirements to address entrapment hazards. In October 2001, the Commission voted to direct staff to prepare a notice of proposed rulemaking (NPR) based on staff's draft proposed standard, which included performance requirements to address entrapment hazards. Subsequently, the ASTM Portable Bed Rail Subcommittee agreed to ballot a revision to the ASTM standard that was substantially the same as staff's draft proposed standard; accordingly, the NPR was deferred. The revised ASTM standard was approved and published in June 2003. In 2008, ASTM published another standard revision that included a structural integrity test to address incidents involving hinge lock mechanism failures. From 2009 to 2010, minor revisions to the standard were published (ASTM F 2085-10a).

B. NPR Standard Activity

On April 11, 2011, an NPR for portable bed rails was published in the *Federal Register* (76 FR 19914) to adopt ASTM F2085-10a, with additional requirements to strengthen the standard to reduce the risk of injury associated with portable bed rails. (On the same date, a withdrawal of the October 3, 2000, ANPR was published in the *Federal Register* (76 FR 19926)). The proposed additional requirements in the NPR included: (1) revisions to the scope to include inflatable and foam-type bed rail products; (2) new performance requirements and associated test methods to address fatal entrapment incidents related to misassembly; (3) a new performance requirement and warning label requirement to address the potential for fatal entrapment incidents related to misinstallation; and (4) a revised warning label to specify the intended user age for portable bed rails. These additional requirements were developed by staff, in collaboration with the ASTM Portable Bed Rail Subcommittee and balloted on February 10, 2011. On November 7, 2011, ASTM balloted a revision to the standard that contained the additional requirements and that was approved by the committee; a revised standard was published in January 2012 (ASTM F2085-12). Staff's draft final rule incorporates by reference the new portable bed rail standard ASTM F2085-12.

III. DISCUSSION

A. NPR Comments

In the NPR, the Commission solicited information and comments concerning all aspects of the proposed rule. Staff received 16 comments on the NPR. Eight comments stated general support for the proposed rule and the other eight comments raised other issues that are addressed, by topic, below. All of the NPR comments can be found in Tab A. Staff has addressed these comments, in detail, in the attached memos at Tabs B, C, and E. Following is a summary of the comments and staff's responses.

PROPOSED MISASSEMBLY AND MISINSTALLATION REQUIREMENTS

Comments: One commenter questioned the need for a revised standard noting that misassembly of a portable bed rail does not present a significant hazard. In addition, there were two comments that expressed concerns that the proposed language related to misassembly and misinstallation is vague, arbitrary, and invites unacceptable variability in test conditions.

Staff Response: Staff disagrees with the comment that misassembly of portable bed rails does not need to be addressed. As stated in the NPR, most bed rails currently in the market are difficult for the consumer to assemble correctly due to the number of components and complexity of the fastening hardware. Staff identified fatal incidents involving misassembled bed rails and concluded that requirements were needed to address this hazard pattern. Staff agrees, in part, with the other comments. After publication of the NPR, 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 the new edition of the ASTM standard that is incorporated in staff's draft final rule. The requirements in ASTM F2085-12 are simpler and clearer, compared to the proposed NPR test requirements. ASTM F2085-12 addresses public comments and concerns regarding the NPR including issues such as the potential for numerous test configurations, the complexity of testing zippered products, the difficulty in determining misassembly of adjustable components, and the lack of repeatability of testing between testing laboratories.

A significant difference between the NPR and ASTM F2085-12 is the removal of proposed test methods in the latter to determine whether 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. This approach should reduce the number of misassembly combinations and prevent unnecessary testing, as compared to the proposed requirements in the NPR. The addition of figures and illustrations clarifies the pass and fail criteria of the requirements. 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. Test personnel are trained to understand the intent of the standards for which they provide testing services, and competent laboratories should be capable of making reasonable engineering judgments.

FOAM AND INFLATABLE (NON-RIGID) BED RAILS

Comments: There were several comments supporting the inclusion of inflatable and foam bed rails 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.

Staff Response: Non-rigid portable bed rails are included in the scope of ASTM F2085-12 and are required to meet the general requirements to address sharp edges or points, small parts, and permanency of labels, as well as a requirement 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. Staff requested that ASTM evaluate these types of products including the potential risk of strangulation associated with straps used to secure the bed rail on to the bed. The ASTM subcommittee agreed to continue to monitor these types of non-rigid, portable bed rails and pursue development of additional requirements, as necessary.

TEST EQUIPMENT: PLATFORM AND SHEETING MATERIAL

Comment: 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.

Staff Response: CPSC staff agrees that the Mattress Test Platform 2 and the bed sheeting specification are unnecessarily restrictive. ASTM F2085-12 removes the Indentation 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 represent a mattress that was both thin and not very firm. Test Platform 2 is an inner spring mattress, and thus not solid foam. It was selected to be thick (10-11"). 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, thus in order to ensure a mattress meets this requirement, it would be necessary to track down the supplier of the foam in the mattress to obtain a suitable test piece. ASTM F2085-12 was also revised to allow greater flexibility for available bed sheet types for use in testing. Finding sheets that provide the previously specified weight per ounce is not practical. The subcommittee believes that having 50/50 cotton poly sheets over the mattress should be the basic requirement. A slight difference in thread count should not affect the results.

DOUBLE-SIDED BED RAILS

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

Staff Response: Double-sided bed rails currently are available to consumers. Staff is not aware of entrapment incidents between the wall and the bed that have occurred because of the use of either a single or double portable bed rail. An entrapment between the bed and the wall can occur without the use of any type of portable bed rail and there is no evidence to support the contention that requiring double-sided bed rails will address this hazard. However, consumers

should continue to be educated regarding safe sleep environments to address the hazard of entrapment between the wall and the mattress.

BED SHEET CHANGING

Comment: One commenter stated that the CPSC does not address issues like daily changing of bed sheets or other routine use that will result in movement or stress on the portable bed rail components which may make the product unsafe.

Staff Response: 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 components of the portable bed rails. The ASTM standard contains requirements that test the strength of the bed rail. CPSC staff believes that these requirements are adequate to address stress-related failures.

MATTRESS SYSTEMS

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

Staff Response: Staff's review of bed rail products showed that most bed rails are adjustable to fit various mattress sizes. The ASTM standard 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.

WARNING LANGUAGE REVISIONS

Comment: 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 is done in the current voluntary standard. One commenter stated that the NPR revision to the primary warning provides a false sense of security for the caregiver of children who can get in and out of an adult bed without help; and the commenter further asserted that the proposed wording of the entrapment hazard warning for critical installation components is misleading because correct installations can also result in entrapment and death.

Staff Response: Staff agrees 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. The proposed revision to the warning language in the NPR did not make this explicit. Staff believes 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 NPR. 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, including the warning: "Gaps in and around bed rails have entrapped young children

and killed infants" clarify for consumers 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 NPR warning requirements result in a warning of approximately 148 words; whereas, the warning requirements in ASTM F2085–12 result in a much shorter warning of 102 words. The revised warning language also is written at a slightly lower grade level than the NPR warning language, which means that people who read the warning may be more likely to understand it better.

Staff disagrees that "the entrapment hazard warning for critical installation components misleads consumers, because correct installations can also result in entrapment and death." The purpose of the entrapment hazard warning is to alert consumers to the importance of installing the bed rail correctly. The statement: "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: One commenter stated that the warning labels should describe the materials used to produce the bed rails. Another commenter stated that there should be a strict warning about modification of the bed rail and the bed rail components.

Staff Response: Staff disagrees that the warning requirements should specify the materials used in the product. Warnings should be used only to identify a significant hazard. The commenter has not identified what hazard such a warning requirement would be intended to 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 readily inferred. The commenter does not specify any of this information. Thus, including a description in a warning label of the materials used to produce the bed rail is not appropriate at this time.

Staff also disagrees that warning requirements should include provisions regarding the modification of the bed rail and its components. Staff interprets the commenter's statements as seeking the addition of warning language to address intentional alteration of the bed rail components by consumers. Staff's review of the incident data does not support the premise that intentional modification of bed rail components by consumers led to injury. Thus, mandating such warning language is not supported by the data.

ADULT BED RAILS

Comments: 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 U.S. Food and Drug Administration ("FDA") received reports of 803 incidents of patients caught, trapped, entangled, or strangled in hospital beds, including 408 deaths, 138 nonfatal injuries, and 185 near-misses, where injuries were prevented 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.

Staff Response: 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, CPSC staff is aware that some bed rails may be considered "devices" under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and therefore, they are subject to regulation by the FDA. As stated in the preamble to the NPR, 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 associated with bed rails that are 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 are considered instead to be "consumer products" under the CPSA or otherwise subject to CPSC's jurisdiction, staff will continue to review this issue and consider what actions, if any, are appropriate.

SHIPMENT COSTS AND PRODUCT SIZE

Comment: 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.

Staff Response: Staff agrees 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 higher shipping costs could be significant for some manufacturers.

Comment: The same commenter stated that the proposed rule may result in adverse retail response to stocking bulkier packages on shelves or in inventory, or may result in retailers dropping products or refusing to accept price increases, thus, placing the cost burden on manufacturers.

Staff Response: Staff agrees that, all else equal, larger boxes for bed rails would need additional storage and shelving space. As a result, some retailers might choose to decrease the number or model of bed rails they offer to the public, which could, in turn, have the effect of reducing sales by manufacturers.

B. *Incident Data (Tab E)*

NPR Incident Data

The NPR summarized the data for incidents related to portable bed rails from January 1, 2000 through March 31, 2010. For that period, CPSC 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 which resulted from portable bed rail displacement, when the portable bed rail partially pushed away from underneath the mattress and allowed the child to fall into the opening and get trapped. There were 3 cases of portable bed rail misassembly. In 3 additional fatal incidents, the contributing factor(s) that led to the hazardous entrapment scenario could not be determined. The beds involved in all eight cases were adult-size. The remaining 5 (of the 13) fatal incidents had no product or scenario-specific information.

Follow-up on NPR Reported Fatal Incidents

Since the publication of the NPR, staff received additional information through in-depth, follow-up investigations on 4 of the 5 fatal incidents that had been categorized as having insufficient information in the NPR. One of the four fatalities (document number 0427019066) that was included among the incident data in the portable bed rail NPR is now known to have occurred from partial displacement of the bed rail, leading to the entrapment of the decedent. Another fatality, (document number 0406130408), listed earlier as lacking sufficient information, remains in that status; CPSC field investigators were unable to establish contact with anyone with firsthand knowledge of the product or the scenario of the incident. The third fatality (document number 0717000449) is now known not to have involved any portable bed rail; what originally was reported as a bed rail has been confirmed to be a crib rail. Finally, it seems unlikely that the fourth fatality (reported in document number 0442078182) was associated with a portable bed rail. The decedent, co-sleeping with a sibling and a parent, died from suffocation. The role, if any, of a portable bed rail, now seems questionable.

New Incident Data

The Directorate for Epidemiology, Division of Hazard Analysis (EPHA) conducted a new search on November 9, 2011 of the CPSC's epidemiological databases[1] to determine the number of new incidents reported since the data presented in the NPR (Tab E). The new search

[1] CPSC databases that were searched included the In-Depth Investigations (INDP) file, the Injury or Potential Injury Incidents (IPII) file, and the Death Certificates (DTHS) file. These reported deaths and incidents are neither a complete count of all that occurred during this time period, nor are they a sample of known probability of selection. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to portable bed rails. The date of extraction for reported incident data on portable bed rails was 11/09/2011. All data coded under product code 4075 and age as 6 years or younger (to accommodate any physically disabled children) was extracted. Upon careful joint review with the CPSC's Directorate for Engineering Sciences staff, some cases was considered out of scope (for example, adult bed rails).

showed that there were 23 portable bed rail-related incidents reported between April 1, 2010 and November 9, 2011. Four of the 23 incidents were fatal, and 19 were nonfatal, 8 of which reported an injury. Among the fatalities, one resulted from a misinstalled bed rail (X1190536A), where the child was strangled by the straps of the reinforced anchor system. The second fatality (I1170672A) occurred when an 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 two fatalities (0906085374 and 0948097318) lack any product information or scenario-specific details. Eight of the 19 nonfatal incidents resulted in injuries. Most of the injuries were bumps and bruises; one incident reported a severe laceration and another reported a fractured collarbone. None of the nonfatal injuries required hospitalization.

Among the incidents that reported age (18 out of 23), 3 involved a child younger than 15 months. The majority of the incidents (15 out of 18) reported the child's age to be between 15 months and 4 years.

The hazard patterns identified among the 23 incident reports were similar to the hazard patterns identified in the NPR, and they are as follows:

- *Hinge-lock failure:* There were 8 incidents, including 4 injuries and 1 fatality, where the hinge-lock mechanism failed to keep the side panel in an upright position. The hazard in the fatality was a combination of hinge-lock failure and torn mesh panel (see below).
- *Displacement of bed rail*: There were 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 surfaces:* There were 3 incidents, including 1 injury, due to sharp surfaces on the bed rail.
- *Worn or poor quality fabric on mesh panel:* There was 1 fatal incident, which was attributable, in part, to the torn mesh panel and, in part, to the hinge-lock failure of the bed rail (see above).
- *Misinstallation:* One strangulation fatality on the straps of the reinforced anchor system of the bed rail was reported to have been due to the improper installation of the bed rail.
- *Miscellaneous or unknown issues:* There were 4 incidents, including 2 fatalities with insufficient information on the product or scenario. Of the 2 nonfatal incidents, 1 reportedly involved hazards from broken screws, while the other reported design issues with the bed rail.

C. Staff's Draft Final Rule

The NPR for portable bed rails proposed to adopt ASTM F2085-10a, *Standard Consumer Safety Specification for Portable Bed Rails*, with the following modifications:

1. Revisions to scope to include inflatable and foam-type bed rail products;
2. New performance requirements and associated test methods to address fatal entrapment incidents related to misassembly of portable bed rails;
3. New performance requirement and warning label to address the potential for fatal entrapment incidents related to misinstallation of portable bed rails; and
4. Revised warning label to specify intended user age for portable bed rails.

Staff concluded that these additional requirements were necessary to further reduce the risk of injury associated with portable bed rails. The intent of the NPR was to provide coverage for newer bed rail products made of foam or inflatable materials; to address fatal incidents due to misassembly; to address potential fatal incidents due to misinstallation; and to emphasize warnings to specify intended user age.

Following publication of the NPR, the ASTM Portable Bed Rail Subcommittee collaborated with staff and held several meetings and webinars to develop similar requirements to address the additional requirements in the NPR and the issues that were raised in the NPR comments. These discussions focused on improving the NPR requirements, by simplifying test procedures, clarifying language, providing graphics and figures to illustrate acceptable and failing performance criteria and test configurations, and to clarify warning statements. The Directorate for Engineering Sciences, Mechanical Engineering Division (Tab B) and Human Factors Division (Tab C) provide detailed information on the rationale and supporting information for the draft final rule, as well as the changes from the NPR.

Misassembly Requirement Clarification

A significant difference between the NPR and the ASTM F2085-12 requirements is the removal of the proposed specific test methods associated with the misassembly performance requirements in the latter. The determination of whether there is the potential for bed rail misassembly will depend upon the judgment of qualified test personnel. The clarification of the misassembly performance requirements and examples of correct evaluation conditions in the new ASTM standard provide sufficient guidance for test personnel to make performance evaluations based upon sound engineering judgment. The requirements in the new ASTM standard are equivalent to the NPR's intent to reduce the potential for misassembly. Specifically, the new ASTM standard addresses the NPR's misassembly requirements with the following provisions:

1. Nuts and bolts are to be "captive" (*i.e.*, attached to the bed rail structure) to prevent the consumer from discarding or misplacing the fasteners. This requirement directly addresses fatal incidents where the exclusion of a fastener was a contributing factor.
2. A misassembled bed rail is identified as one that can be assembled without a supplied component or without engaging the entire frame as intended by the manufacturer. This requirement addresses directly fatal incidents where the horizontal bar was missing or where the mesh/fabric was not installed correctly over the bottom horizontal bar.
3. Components cannot be interchanged or inverted. This requirement will prevent the consumer from assembling the component in the backwards or upside down position, where the orientation impacts safety.

Warnings Clarification

Staff also engaged the ASTM Subcommittee on Portable Bed Rails to address issues on warnings that were raised in the comments and to clarify the warning statements.

The warning requirements in the new ASTM standard address the public comments received on the NPR and are superior to the requirements in the NPR. The age at which children should not be using a bed rail has been made explicit with the statement: "NEVER use with children younger than 2 years old," and the statement immediately following this: "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 "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 ASTM standard contains a more concise warning, which may increase the likelihood that consumers will take the time to read the warning and follow the information. For example, the NPR warning requirements result in a warning approximately 148 words long, whereas, the new ASTM standard warning is 102 words long. The new warning language also is written at a slightly lower grade level than the NPR warning language, meaning that people who read the warning may be more likely to understand it.

The following table summarizes the relevant sections of ASTM F2085-10a, the proposed modifications to ASTM F2085-10a, and the final standard, ASTM F2085-12.

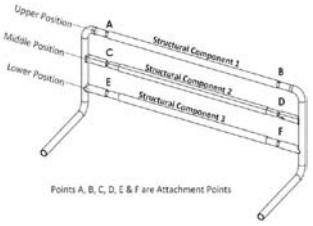
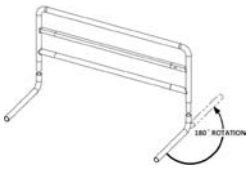
TABLE 1: CPSC Staff-Recommended Changes to the Proposed Rule for Portable Bed Rails – Underline Denotes Text Addition and Strikethrough Denotes Text Deletion

ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
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.	No change in NPR to address toddler beds.	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. <u>This consumer safety specification does not cover guardrails that fall under the scope of Consumer Safety Specification F1821 or guardrails that are designed for a specific model of bed and which attaches at the headboard or footboard.</u>
No section in ASTM	Proposed Section 1224.2(b) (1) *Foam* and *inflatable* bed rails need only meet the General Requirements of section 5, the performance requirement of 6.3 Enclosed Openings and the warning requirement of 9.3.1.	Addressed in Section 5 General Requirements
2. Referenced Documents	Same as ASTM F 2085-10a	F1487 <u>Consumer Safety Performance Specification for Playground Equipment for Public Use</u> <u>F1821 Consumer Safety Specification for Toddler Beds.</u>

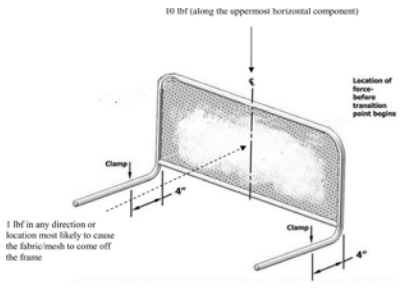
ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
3. Terminology	Proposed Section 1224.2 (b)(2) revised the terminology in section 3 of ASTM F 2085-10a by creating new terms as follows: *Foam bed rail* is a portable bed rail constructed primarily of nonrigid materials, such as fabric or foam; *Inflatable bed rail* is a portable bed rail constructed primarily of nonrigid material that requires air to be inflated into the product to achieve structure; *Critical assembly component* is any component of the portable bed rail that requires consumer assembly in order to meet the performance requirements of sections 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* of ASTM F 2085–10a; *Critical installation component* is any component of the portable bed rail that is used to attach the portable bed rail onto the bed; and *Misassembled/functional portable bed rail* is 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 proposed section 6.9, *Determining Misassembled/Functional Portable Bed Rail,* of ASTM F 2085–10a.	3.1.4 *captive hardware, n*—fasteners that remain attached to their respective components before normal assembly and after normal disassembly (see Fig. 1). 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 bedrail that is specifically designed to attach the bedrail 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.  **FIG. 1 Captive Hardware**
4. Calibration and Standardization	No Change	No change

ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
5. General Requirements Foam and inflatable bed rails are not covered. No requirements for installation components are in this edition of the standard.	Proposed section 1224 2(b)(1) stated that the foam and inflatable portable bed rails must meet only the General Requirements of section 5; the performance requirement of subsection 6.3, *Enclosed Openings;* and the warning statements of subsection 9.3.1 of ASTM F 2085–10a because those requirements can be applied to foam and inflatable portable bed rail products. Proposed section 1224.2(b)(3) would create a new section 5.6 of ASTM F 2085–10a, *Critical Installation Components.* This new section of ASTM F 2085–10a (new section 5.6.1) would provide that critical installation components that are also critical assembly components and meet the definition of a misassembled/functional portable bed rail must be permanently affixed to a structural component(s) of the portable bed rail. If a critical installation component(s) is also a critical assembly component and may result in a misassembled/functional portable bed rail, a new section 5.6.2 of ASTM F 2085–10a would require that a portable bed rail not remain upright or that the vertical height must decrease by 6 inches at any point along the top rail when tested to the method for determining the acceptability of the vertical structure of a misassembled/ functional portable bed rail. (The requirement regarding a portable bed rail not remaining upright or meeting certain vertical height requirements would be at a new section 6.10.1 of ASTM F 2085–10a.	5.5 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. 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.
6. Performance Requirements	Determining Misassembled/ Functional Portable Bed Rail (Proposed § 1224.2(b)(4)(i) and (ii)). Proposed § 1224.2(b)(4)(i) would create a new section 6.9 of ASTM F 2085–10a, Determining Misassmbled/ Functional Portable Bed Rail. It would consider a portable bed rail to be a misassembled/functional portable bed rail if: • The portable bed rail can be assembled without any critical assembly component (new section 6.9.1 of ASTMF 2085–10a); • 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 like the frame(new section 6.9.2 of ASTM F 2085 10a); • The portable bed rail's fabric cover or mesh can be placed over the rigid frame structure without engaging critical parts of the frame as intended in final assembly (new section 6.9.3 of ASTM F	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 bedrail shall be considered a misassembled bed rail if it appears to be a functional bedrail 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 bedrail 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

ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
	2085–10a), or • The portable bed rail can be assembled by improper placement of any critical component, such as an inverted or an interchanged part, without permanent deformation or breakage (new section 6.9.4 of ASTM F 2085–10a). To determine the acceptability of a misassembled/functional portable bed rail, proposed section 1224.2(b)(4)(ii) would set forth the requirements for a new section 6.10, Determining Acceptability of Misassmbled/ Functional Portable Bed Rail, of ASTM F 2085–10a. The new section would provide that misassembled/functional portable bed rails must meet sections 6.10.1, 6.10.2, 6.10.3, or 6.10.4 of ASTM F 2085–10a. Under the proposed rule, a new section 6.10.1 of ASTM F 2085–10a would provide that 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 new section 8.7 (Test Method for Determining Acceptability of Vertical Structure of a Misassembled/Functional Portable Bed Rail) of ASTM F 2085–10a. This section would provide criteria to determine whether a misassembled portable bed rail lacks sufficient vertical structure. A new section 6.10.2 of ASTM F 2085–10a would provide that the fabric cover or mesh attached to the bed rail must have a permanent sag that is a minimum of 3 inches after tested in accordance with new section 8.8 (Test Method for Determining Fabric Sag Acceptability of a Misassembled/ Functional Portable Bed Rail) of ASTM F 2085–10a. A new section 6.10.3 of ASTM F 2085–10a would provide that a product will not be considered acceptable if the fabric cover will not fit over the frame without tearing. A new section 6.10.4 of ASTM F 2085–10a would provide that 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. These new sections would provide the criteria for testing laboratories to determine the sufficiency of visual cues for fabric mesh misassembly.	(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 bedrail 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 bedrail. 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 positions of the arms are intended to be unidirectional are able to be assembled when the arms are rotated 180° about the vertical axis (Fig. 9).  FIG. 5 Example of Fail Condition  FIG. 6 Examples of Fail Conditions  FIG. 7 Example of Condition Not To Be Tested

ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
		 FIG. 8 Example of Tube Inverted or Interchanged  FIG. 9 Example of Test for Unidirectional Arm
7. Test Equipment 7.1.1 Platform 1 7.1.1.1 *Mattress Construction* The mattress shall be of standard twin size, 38 by 74.5 in. 6 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/ft^3 +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/yd^2 (161 g/m^2). 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.	No change	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/ft^3 +0.2, –0 (16 kg/m^3 +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 ~~180~~ threads per square inch. ~~and fabric weight of approximately 3.5 oz/yd^2 (161 g/m^2). 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 F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
7.1.2 Test Platform 2 7.1.2.1 Mattress Construction - The mattress[6] shall be of standard twin size, 38 in. by 74.5 in. ± 0.5 in. (0.97 m by 1.89m ± 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.[7] 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/yd^2 (161 g/m^2). 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.	No change	7.1.2 Test Platform 2 7.1.2.1 Mattress Construction - The mattress[6] shall be of standard twin size, 38 in. by 74.5 in. ± 0.5 in. (0.97 m by 1.89m ± 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.[7] 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~~ 100 to 300 threads per square inch~~. and fabric weight of approximately 3.5 oz/yd^2 (161 g/m^2). 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.~~
7.1.2.2 *Mattress Performance* - The foam shall have an Indentation Load Deflection (ILD)[4] of between 28 and 33 when tested in accordance with Test Methods D3574, Method B1.	No change	~~7.1.2.2 *Mattress Performance* - The foam shall have an Indentation Load Deflection (ILD)[4] of between 28 and 33 when tested in accordance with Test Methods D3574, Method B1.~~
No Section	Proposed section 1224.2(b)(5)(i) would state that a force gauge must have a minimum range of 0 to 50 lb (222N) with a maximum tolerance of ~~±~~0.25 lb (1.11N), as set forth under a new section 7.6 of ASTM F 2085–10a.	7.6 *Force Gauge*—Gauge shall have a minimum range of 0 to 50 lb (222 N) with a maximum tolerance of 60.25 lb (1.11 N).
No Section	(vii). Test Method for Determining Acceptability of Vertical Structure of a Misassembled/Functional Portable Bed Rail. (Proposed §§ 1224.2(b)(6)(i) and (ii)). Proposed §§ 1224.2(b)(6)(i) and (ii) would require new test methods to address misassembly of portable bed rails. These proposed requirements would include a test method for determining the acceptability of the vertical structure of a misassembled/ functional portable bed rail under a new section 8.7 of ASTM F 2085–10a, as well as a test method for determining fabric sag acceptability of a misassembled/functional portable bed rail under a new section 8.8 of ASTM F 2085–10a. These tests would provide a method for testing laboratories to determine if a misassembled portable bed rail lacks sufficient vertical	N/A - ASTM F2085-12 does not have test requirements to determine if a misassembled bed rail is acceptable.

ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
	structure and also determine the sufficiency of visual cues for portable bed rail misassembly. Under a new section 8.7 of ASTM F 2085–10a, the proposed test method for determining acceptability of vertical structure of a misassembled/functional bed would require, if possible, an attempt to assemble the portable bed rail in a misassembled configuration(s), as described in new section 6.9 of ASTM F 2085–10a. The proposed test method also would include: • Firmly securing the misassembled portable bed rail on a table top or other stationary flat surface using clamps (new section 8.7.2 of ASTM F 2085–10a). The clamps should be located 4 to6 inches from the intersection of the portable bed rail legs to the vertical plane. • Gradually applying a force of 10 lbs, using a ½ inch disc to the uppermost horizontal component of the rail in a downward direction at a location along the horizontal component most likely to vertically deform the portable bed rail; and applying the force over a period of 5 seconds, and holding the force for 10seconds and releasing (new section 8.7.3 of ASTM F 2085–10a); and • Repeating the steps in new sections 8.7.1 through 8.7.3 for all misassembly configurations (new section 8.7.4 of ASTM F 2085–10a). The proposed test method for determining fabric sag acceptability of a misassembled/functional portable bed rail (new section 8.8 of ASTM F 2085–10a) would require, if possible, an attempt to assemble the portable bed rail in a misassembled configuration(s), as described in new section 6.9 of ASTM F 2085–10a, and depicted in new Figure 8.  	

ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
	Figure 8: Determining missassembly/functional portable bed rail test setup. The proposed test method would include: • Gradually applying a force of 1 lb using a ½ 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; applying the force over a period of 5 seconds; and holding for an additional 10 seconds and releasing (new section 8.8.2 of ASTM F 2085–10a); and • Repeating these steps for all misassembly configurations discovered in new section 6.9 of ASTM F 2085–10a (new section 8.8.3 of ASTM F 2085– 10a).	
9. Marking and Labeling 9.3.1 The warning statements shall include the following, exactly as stated below: 9.3.1.1 Suffocation and Strangulation Hazard. 9.3.1.2 Death or Serious Injury Can Occur. 9.3.1.3 Infants 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 infants in adult beds with or without a bed rail. 9.3.1.4 **BED RAIL USE:** Bed rail can trap young children against mattress, headboard, or footboard. 9.3.2 The warning statements shall also address the following: 9.3.2.1 Use only for children who have outgrown a crib. NEVER use in place of crib. 9.3.2.2 Use only with children who can get in and out of adult bed without help (typically 2 years and up). 9.3.2.3 ALWAYS keep bed rail pushed firmly against mattress and at least 9 in. from headboard and footboard. 9.3.2.4 NEVER use on toddler bed, bunk bed, water bed, or bed with inflatable mattress. Use only on adult bed with mattress and mattress support as defined by the manufacturer.	(Proposed § 1224.2(b)(7), (8), and (9). Proposed section 1224.2(b)(7) would add a warning symbol and the word ''WARNING'' prior to ''Suffocation and Strangulation Hazard'' under section 9.3.1.1 of ASTM F 2085–10a. This proposed addition would give the warning more emphasis. Proposed section 1224.2(b)(8) would replace the existing marking under section 9.3.1.3 of ASTM F 2085–10a, which states: ''Infants 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 infants in adult beds with or without a portable bed rail.'' The proposed warning would state instead: ''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.'' Despite the current warning label cautioning against the use of this product with children under 2 years old, parents of infants continue to use this product with their infants. Accordingly, the revised language would emphasize the hazard presented to children younger than 2 years old when placed in adult beds. Proposed section 1224.2(b)(9) would require critical installation components to be labeled with the entrapment hazard warning for portable bed rail use to warn of issues related to misinstallation of portable bed rails	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*). In addition, ASTM 2085-12 created new sections that require labeling on installation components. This

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9.3.2.5 For manufacturers' specific bed rails: *(1)* Use only on (*manufacturer insert applicable bed and mattress/platform information*).	under a new section 9.4 of ASTM F 2085–10a. A new section 9.4 of ASTM F 2085–10a would require the entrapment hazard warning to be in contrasting colors, permanent, conspicuous, and sans serif-style font.	requirement is similar to the NPR. 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.
10. Permanency of Labels and Warnings	No change	No change
11. Instructional Literature	(ix). Instructional Literature (Proposed § 1224.2(b)(10)). This proposed section would revise the language in section 11.1 of ASTM F 2085–10a to add the word ''installation'' among the topics in instructional literature. This proposed section would read: ''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.'' This requirement would add clear instructional literature for installation components to provide consumers easy to understand information for securing portable bed rails on beds.	11.1 Instructions shall be provided with the bed rail and shall be easy to read and understand. Assembly, <u>installation</u>, maintenance, cleaning, operating and adjustment instruction and warnings, where applicable, shall be included. 11.1.1 The instructions shall contain the warning statements, required by 9.3.~~1in the same exact format, and shall address the statements in~~, <u>and, where applicable, shall address the statements in</u> 9.3.2. In addition, instructions shall address the following: <u>11.1.1.1</u> Discontinue use if damaged, broken, or if parts are missing. 11.2 Warning statements located within the instructional literature shall meet the same requirements as specified in 9.3.