

The contents of this document will be discussed at a Commission Meeting (Briefing) scheduled for December 18, 2013.



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

This document has been electronically approved and signed.

DATE: December 4, 2013

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: **January 8, 2014**

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Elliot F. Kaye, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
Hyun S. Kim, Attorney, OGC

SUBJECT: Final Rule: Safety Standard for Bedside Sleepers

The Office of the General Counsel is providing for Commission consideration the attached draft final rule for publication in the *Federal Register*. The final rule would establish a safety standard for bedside sleepers pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008.

Please indicate your vote on the following options:

- I. Approve publication of the attached document in the *Federal Register*, as drafted.

(Signature)

(Date)

II. Approve publication of the attached document in the *Federal Register*, with changes.
(Please specify.)

(Signature)

(Date)

III. Do not approve publication of the attached document in the *Federal Register*.

(Signature)

(Date)

IV. Take other action. (Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice: Safety Standard for Bedside Sleepers

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1222

Docket No. CPSC-2012-0067

Safety Standard for Bedside Sleepers

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) 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 Commission is issuing a safety standard for bedside sleepers in response to the direction under Section 104(b) of the CPSIA.

DATES: The rule will become effective on [INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER.] The incorporation by reference of the publication listed in this rule is approved by the Director of the *Federal Register* as of [INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Daniel Dunlap, Compliance Officer, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301-504-7733; e-mail: ddunlap@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008, (CPSIA, Pub. L. 110-314), was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, and (2) promulgate consumer product safety standards for durable infant and 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)(1) 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. Bassinets and cradles are specifically identified in section 104(f)(2)(L) as durable infant or toddler products. Bedside sleepers are similar to bassinets, and many bedside sleepers also function as bassinets. In addition, some bedside sleepers are accessories to play yards, which are explicitly identified in section 104(f)(2)(F).

On December 10, 2012, the Commission issued a notice of proposed rulemaking (NPR) for bedside sleepers (77 FR 73345). The NPR proposed to incorporate by reference the voluntary standard, ASTM F2906-12, “Standard Consumer Safety Specification for Bedside Sleepers,” with certain changes to provisions in the voluntary standard to strengthen the ASTM standard.

In this document, the Commission is issuing a safety standard for bedside sleepers. Pursuant to Section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this proposed standard, largely through the ASTM process. The rule incorporates the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2906-13, “Standard Consumer Safety Specification for Bedside Sleepers” (ASTM F2906-13), by reference, and requires bedside sleepers to be tested to 16 CFR part 1218, the Safety Standard for Bassinets and Cradles (bassinet standard).

B. The Product

ASTM F2906-13 defines “bedside sleeper” as “a rigid frame assembly that may be combined with a fabric or mesh assembly, or both, used to function as sides, ends, or floor or a combination thereof, and that is intended to provide a sleeping environment for infants and is secured to an adult bed.” A “multi-mode product” is “a unit that is designed and intended to be used in more than one mode (for example, a play yard, bassinet, changing table, hand held carrier, or bedside sleeper).” A bedside sleeper is intended to be secured to an adult bed to permit newborns and infants to sleep close by an adult without being in the adult bed. Bedside sleepers currently on the market have a horizontal sleep surface that typically is 1 inch to 4 inches below the level of the adult bed’s mattress. The side of the bedside sleeper that is adjacent to the adult bed can usually be adjusted to a lower position, a feature that differentiates bedside sleepers from bassinets, where all four sides of a bassinet are the same height. Current bedside sleepers range in size from about 35” x 20” to 40” x 30.” Bedside sleepers may have rigid sides, but they are most commonly constructed with a tube frame covered by mesh or fabric. Bedside sleepers are intended for use with children up to the developmental stage where

they can push up on hands and knees (about 5 months). This is the same developmental range for the intended users of bassinets.

Several manufacturers produce multiuse (or multimode) bedside sleeper products that can convert into bassinets and/or play yards. Most bedside sleeper products can be converted into a bassinet by raising the lowered side to create four equal-height sides, and a few also convert into both a bassinet and play yard. Some play yards include bedside sleeper accessories, which when attached, convert the play yard into a bedside sleeper; and some bassinets convert into bedside sleepers. All of the tube-framed products that CPSC staff has evaluated may be collapsed for storage and transport. A bedside sleeper that can be used in additional modes would need to meet each applicable standard. For example, a bedside sleeper that converts to a bassinet must meet the bedside sleeper standard and the bassinet standard.

C. Incident Data

The preamble to the NPR summarized the incident data involving bedside sleepers reported to the Commission from January 2001 through December 2011. 77 FR 73345 (December 10, 2012). The data was extracted on January 24, 2012. CPSC's Directorate for Epidemiology staff identified 40 cases of bedside sleeper-related incidents from 2001 to 2011, including four fatalities and 36 nonfatal incidents (with and without injuries). Since the NPR, the incident data have been updated to include bedside sleeper-related incident data reported to the Commission between January 24, 2012 and May 15, 2013.

Since the extraction of the data presented in the NPR, CPSC staff has received four new reports involving bedside sleepers. One of the reports was a consumer query regarding a recalled product and did not involve an actual incident. The rest of the reports involved no fatalities or injuries. The infants identified in the incident reports ranged in age from 1 to 6 months.

The hazards reported in the new incidents were consistent with the hazard patterns identified among the 40 incidents presented in the NPR briefing package. The hazard scenarios reported in 24 of the 40 incidents (60 percent) were attributed to some sort of failure/defect or a potential design flaw in the product.

Among the four new reports, two incidents were classified under *miscellaneous product-related issues* concerning the *poor design* and a *broken/detached component* of the product. In the incident reporting poor design, the consumer expressed concern that the fabric side could create a suffocation hazard when the child's face is against the fabric; the consumer reportedly stopped using the product. The second incident involved a six-month-old who fell onto the floor from a recalled, multimode product when the horizontal bar that converts the product from a bedside sleeper to a bassinet, broke off or detached. No injury was reported, and it is unclear whether the consumer was aware of the recalled status of the product. The third incident is categorized as an *assembly instruction issue*, where it appears that the consumer did not properly follow the assembly instructions. The last report was a *CPSC recall-related consumer query*; no actual incident was involved.

D. Overview of ASTM F2906

ASTM first published a voluntary standard for bedside sleepers, ASTM F2906-11, in December 2011. ASTM F2906 specifically addressed hazards associated with bedside sleepers, including incidents involving the creation of a hazardous gap between the product and an adult mattress, by requiring the successful completion of three disengagement tests. The tests help ensure that the securing components can withstand forces that may be exerted on the product by either the child or an adult, while sleeping. The gap must be no more than 0.5 in. when the product is installed onto the adult bed, per each manufacturer's directions. When a 25-lb.

horizontal force is applied near the attachment system or corners, the gap may not exceed 1.0 in. To simulate an adult rolling into a bedside sleeper while sleeping, a gap greater than 1.0 in. may not be created after the application and release of a 50-lb. horizontal force to the bedside sleeper's corners. The inclusion of these anti-gap requirements serve to mitigate the foreseeable head and neck entrapment hazards posed by bedside sleepers. In addition, bedside sleepers must also satisfy the minimum side-height requirement for bassinets (the upper surface of the non-compressed mattress of a bassinet/cradle must be at least 7.5 inches lower than the upper surface of the lowest side in all intended bassinet/cradle use positions), with the exception of the lowered side rail (the height of the side rail in the lowest position shall be no less than 4 inches when measured from the top of the uncompressed bedside sleeper mattress to the top of the lowered side rail, when the mattress support is in its highest position).

Bedside sleepers and bassinets share a significant number of hazard patterns because both products are intended to be used by children with the same developmental abilities and for the same purpose. Many bedside sleepers also function as bassinets. Accordingly, the bedside sleepers voluntary standard requires bedside sleepers to be tested to the bassinet standard (ASTM F2194).

1. Proposed Rule

In the NPR, CPSC identified 24 incidents attributed to defect or potential design flaws in bedside sleepers. The hazards associated with these incidents included: issues with the adjustable fabric cover over the metal bars on the side that lowered in the bedside sleeper mode (9 incidents); poor assembly instruction (6 incidents); and miscellaneous other product-related issues (9 incidents). To address these incidents, the Commission proposed in the NPR to adopt by reference, ASTM International's voluntary standard, ASTM F2906-12, *Standard Consumer*

Safety Specification for Bedside Sleepers, with a few additions to strengthen the standard. ASTM F2906-12 also required that, in addition to the tests provided in ASTM F2906-12, the bedside sleeper must be tested to the bassinet standard (ASTM F2194). Additionally, multimode products must also be tested to each applicable standard associated with the product's use modes.

In the NPR, the Commission proposed adding clarifying language to ASTM F2906-12 so that the hazards associated with play yard bassinet misassembly and fabric-sided enclosed openings would also be addressed in bedside sleepers for bedside sleeper accessories. As discussed in the preamble to the NPR, for bassinets/cribels with fabric sides, a fully bounded opening may not be created that allows the complete passage of the torso probe (based on a torso diameter of a 5th percentile, 0 to 2-month-old infant) when tested in accordance with the fabric release test methods for enclosed openings. However, the test does not apply to play yard bassinet accessories. Bassinet accessories to play yards (that cannot be converted to bedside sleepers) are usually held in place by fasteners that clip to the top of the play yard's railing. If the fasteners were left unclipped, the bassinet would fall, rendering the product untestable, due to the complete collapse of the bassinet attachment. Unlike bassinet play yard accessories, a bedside sleeper play yard accessory could have fasteners left unclipped (through the detachment of snaps/Velcro[®]) where the bedside sleeper with the lowered side does not completely collapse and appears functional. As a result, the Commission determined that all bedside sleeper play yard accessories should be subject to the requirements of the bassinet standard's fabric-sided enclosed openings test (without the exemption for bassinet play yard accessories), given the entrapment and suffocation hazards presented when a bedside sleeper's removable cover (liner or shell) is either not used or not secured properly.

To address this hazard, the Commission proposed to add a new definition for “bedside sleeper accessory” and eliminate the fabric-sided, bounded-opening performance requirement exemption currently granted to play yard bassinet accessories. The definition proposed was: “bedside sleeper accessory, n – an elevated sleep surface that attaches to a non-full-size crib or play yard, designed to convert the product into a bedside sleeper intended to have a horizontal sleep surface while in a rest (non-rocking) position.” In addition, the Commission proposed to add a new section: “Bedside Sleeper Accessory Fabric-Sided Enclosed Openings—A bedside sleeper accessory shall meet the F2194 performance requirement “Fabric-Sided Enclosed Openings.” However, a bedside sleeper would be exempt from this requirement if the bedside sleeper collapsed under its own weight or the sleep surface tilts by more than 30 degrees.

The Commission also proposed additional language to address play yard bedside accessory misassembly. The Commission had already proposed a requirement to address consumer misassembly of key structural elements for bassinet accessories to play yards in the play yard standard, ASTM F406. However, the proposed play yard standard did not include specific language for a misassembled bedside sleeper accessory. Accordingly, the Commission proposed to add a new section to include bedside sleepers: “Bedside Sleeper Play Yard Accessories Missing Key Structural Elements: A bedside sleeper accessory shall meet the F406 general requirement “Bassinet/Cradle Accessories Missing Key Structural Elements.”

2. Recent Developments in the Play Yard Standard and Bassinet Standard

After the the Commission published the NPR for bedside sleepers in the *Federal Register*, the ASTM play yard subcommittee worked closely with the ASTM bassinet subcommittee to address hazards related to bassinet accessory misassembly. The subcommittees decided to address the hazards associated with bassinet accessory misassembly in two different

ASTM standards: (1) the play yard standard, ASTM F406-13, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*, now addresses safety issues related to bassinet accessory attachment components (*i.e.*, structures that attach the bassinet accessory to the play yard); and (2) the bassinet standard, ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles*, addresses safety issues related to mattress support rods (and all other structures that ensure that the bassinet accessory mattress is flat and stable) through the segmented mattress-flatness test contained in the bassinet standard. These requirements are now part of the current ASTM standards for play yards, ASTM F406-13, and for bassinets/cradles, ASTM F2194-13.

On August 19, 2013, the Commission issued an amendment to the *Safety Standard for Play Yards*, to incorporate by reference the most recent version of ASTM's play yard standard, ASTM F406-13, to address the hazards associated with misassembly of play yard bassinet accessories. 78 FR 50328. The play yard standard, ASTM F406-13, now addresses safety issues related to bassinet accessory attachment components (*i.e.*, structures that attach the bassinet accessory to the play yard).

On October 23, 2013, the Commission issued a final rule for bassinets, *Safety Standard for Bassinets and Cradles*, to incorporate by reference the most recent version of ASTM's bassinet standard, ASTM F2194-13, to address safety issues related to mattress support rods (and all other structures that ensure that the bassinet accessory mattress is flat and stable) through the segmented mattress-flatness test contained in the bassinet standard. 78 FR 63019. In addition, the Commission's bassinet rule required several modifications to ASTM F2194-13. These modifications:

- added new definitions, a test requirement, and test procedure for a new performance requirement pertaining to the stability of bassinets with removable bassinet beds;
- revised the current stability test procedure by specifying the use of a newborn CAMI dummy, rather than the six-month infant CAMI dummy;
- revised the pass/fail criterion for the segmented mattresses flatness test to make it more stringent;
- excluded segmented mattress flatness test bassinets that are less than 15 inches wide along the width of the mattress; and
- revised the scope to clarify that a multimode or combination product must meet the requirements of all standards associated with its use modes.

These additional requirements are codified at 16 CFR part 1218, *Safety Standard for Bassinets and Cradles*.

3. Current ASTM Bedside Sleeper Standard (ASTM F2906-13)

The current version of the voluntary standard for bedside sleepers adopts the same performance requirement and test method in ASTM's play yard standard, ASTM F406-13, which addresses the hazards associated with misassembly of play yard bassinet accessories, for bedside sleeper accessories. To provide clearer definitions of a "bedside sleeper accessory," ASTM F2906-13 now provides definitions for "bedside sleeper accessory" and "bedside sleeper accessory attachment components." ASTM F2906-13 provides that a bedside sleeper accessory is an elevated sleep surface that attaches to a play yard designed to convert the product into a bedside sleeper and is intended to have a horizontal sleep surface while in a rest (non-rocking)

position. Bedside sleeper accessory attachment components are defined as components that provide the means of attachment for a bedside sleeper accessory to a play yard.

ASTM F2906-13 also adds a definition of a “bedside sleeper shell.” As explained in the NPR, there are demonstrated hazards presented when a bedside sleeper’s removable cover, including a liner or shell, is either not used or not secured properly. 77 FR 73348-49.

Accordingly, “bedside sleeper shell” is defined as a textile cover for bedside sleeper accessory that incorporates structural elements such as tubing, permanently attached clips or hooks, or other elements that allow it to be suspended from the play yard frame.

In addition, ASTM F2906-13 addresses the hazards associated with misassembly of play yard bedside sleeper accessories. The standard adopts the same requirements set forth in ASTM F406-13 for bassinet/cradle accessories missing accessory attachment components, and an associated test method for misassembly failure under the bassinet/cradle accessory sleep surface collapse/tilt test. Under the current ASTM F2906-13 standard, bedside sleeper accessories must have all accessory attachment components permanently attached to the bedside sleeper accessory. If bedside sleeper accessories that require consumer assembly of accessory attachment components can be assembled and attached to the product with any accessory attachment component missing, the accessory must either: (1) collapse such that any part of the mattress pad contacts the bottom floor of the play yard or is not able to support 4.0 lbm test mass tested; or (2) the bedside sleeper accessory sleep surface must tilt by more than 30 degrees when tested to the bedside sleeper accessory sleep surface collapse/tilt test.

ASTM F2906-13 also continues to require bedside sleepers to meet the requirements of the bassinet standard, ASTM F2194, with the exception of the height of the lowered fourth side. Most bedside sleepers also function as bassinets. The intended users are identical, and the

majority of the hazards are identical. Because bedside sleepers are already required to be tested to the bassinet standard, ASTM F2194, all of the requirements and test methods in ASTM 2194 are not restated in the bedside sleeper standard ASTM F2906-13. However, ASTM F2906-13 specifically adds a new section on fabric release test methods for enclosed openings for bedside sleeper accessories. As stated above, although the bassinet standard, ASTM F2194, contains a requirement for fabric-sided enclosed openings, the test does not apply to play yard bassinet accessories. Bassinet accessories to play yards (that cannot be converted to bedside sleepers) are usually held in place by fasteners that clip to the top of the play yard's railing. If the fasteners were left unclipped, the bassinet would fall, rendering the product untestable, resulting in test failure. However, the unique hazard associated with bedside sleepers requires testing for fabric-sided enclosed openings because bedside sleepers have a lowered fourth side that can create a hazard when the removable cover or shell is either not used or not secured properly. ASTM F2906-13 addresses this hazard by making explicit that the fabric release test methods for enclosed openings apply to all bedside sleepers and bedside sleeper accessories.

In this rule, the CPSC incorporates by reference ASTM F2906-13 because the Commission's proposed modifications in the NPR have been adopted in ASTM F2906-13, including the requirements and test methods for bedside sleeper accessories missing accessory attachment components and bedside sleeper accessory fabric-sided enclosed openings. In addition, because bedside sleepers are required to be tested to the bassinet standard, and because the Commission recently issued a mandatory standard for bassinets (incorporating the ASTM bassinet standard with modifications), which was codified at 16 CFR part 1218, the Commission adopts ASTM F2906-13 with revisions to change the references to the voluntary bassinet

standard, ASTM F2194, in the standard with references to the mandatory bassinet standard, 16 CFR part 1218.

E. Response to Comments

The Commission received five comments in response to the NPR from consumers, industry, consumer advocacy groups, and trade associations. A summary of each comment topic and response is provided.

1. General comments

Comment: One commenter generally supported the proposed rule. Another commenter stated that the responsibility for the safe use of products lies with the parent of the young child.

Response: Section 104 of the CPSIA requires the Commission to examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products and to promulgate mandatory standards. The Commission has identified bedside sleepers as a durable infant or toddler product. Bedside sleepers are similar to bassinets and function also, in many instances, as bassinets. The Commission has concluded that more stringent requirements would further reduce the risk of injury associated with the product. Accordingly, the Commission is issuing a safety standard for bedside sleepers in response to the direction under section 104 of the CPSIA.

2. Mandatory standards should be finalized

Comment: Several commenters stated that the standards for play yards and bassinets should be finalized, including the issues related to fabric-sided enclosed openings and consumer misassembly with missing components before they are applied to bedside sleepers. In addition, two commenters stated that to avoid confusion, the specific requirements of ASTM F406 and

ASTM F2194 should be inserted into ASTM F2906, rather than simply referencing those standards.

Response: ASTM has finalized both the play yard standard, ASTM F406-13, and the bassinet standard, ASTM F2914-13. The Commission has made some additional modifications to ASTM F2194-13. The requirements for fabric-sided enclosed openings have been adopted in ASTM F2906-13 for bedside sleeper accessories. The requirements for misassembly of play yard bassinet accessories have also been adopted in ASTM F2906-13 for bedside sleeper accessories. Those provisions have been included in ASTM F2906-13.

ASTM's bedside sleeper standard, ASTM F2906-13 did not include all the modifications that the Commission subsequently made to the CPSC bassinet standard. Therefore, the final rule for bedside sleepers requires reference to 16 CFR part 1218 to reflect those modifications.

3. Redundant product safety feature

Comment: One commenter stated that the play yard bassinet accessory misassembly requirement may compel manufacturers to eliminate redundant safety features that are already a component of the product. The commenter stated that removal of the mattress pad support bars does not replicate or address the misassembly incident or result in a safer product.

Response: This comment has been addressed in the Commission's final safety standards for play yards and for bassinets and cradles. The play yard standard, ASTM F406-13, addressed safety issues related to bassinet accessory attachment components (*i.e.*, structures that attach the bassinet accessory to the play yard). The bassinet standard, ASTM F2194-13, addressed the issue of mattress pad support rods (and all other structures that keep the bassinet accessory mattress flat and stable) through the segmented mattress flatness test. ASTM F2194-13 now requires that bassinets with removable mattress support rods be tested both with and without the

mattress support rods. In addition, the Commission's modifications to ASTM F2194 in the final rule for the safety standard for bassinets included a change to the pass/fail criterion for the mattress flatness test and revisions to the stability test procedures for bassinets. These safety features are not redundant because each product must meet the standards associated with the product's use mode. 78 FR 50332 and 63025.

4. Intellectual property

Comment: One commenter stated that there may be patents that restrict options for manufacturers. For example, the commenter stated that there is a patent application pending, detailing 10 different methods to “stiffen a play yard mattress pad before the mattress is used in a play yard bassinet accessory.”

Response: This comment has been addressed in the final rule on the safety standard for play yards. The Commission stated that the concern regarding the means of stiffening a mattress pad is no longer an issue for the play yard rule because the play yard bassinet accessory misassembly requirement no longer applies to mattress support rods or any other methods that might be used to stiffen a mattress pad. Instead, the play yard rule focuses only on accessory attachment components that attach the bassinet accessory to the play yard. Moreover, the bassinet standard, which addresses mattress flatness, does not require a specific design to pass the standard, and a bassinet can meet the mattress-flatness test in a variety of ways without necessarily implicating patented technology. 78 FR 50333.

5. Requirements for Stability of Removable Bassinet Beds

Comment: One commenter stated that adding the removable bassinet bed stability requirement is premature. The commenter stated the belief that the requirement should be removed from the regulation and that ASTM should be allowed to continue work on this issue.

Response: This comment has already been addressed in the Commission’s final consumer product safety standard for bassinets and cradles, which likewise would apply to bedside sleepers with a removable bed.

Specifically, the Commission has provided manufacturers with options to meet the removable bassinet bed requirements. The Commission stated that any product containing a removable bassinet bed with a latching or locking device intended to secure the bassinet bed to the base/stand shall comply with at least one of the following: (1) the base/stand shall not support the bassinet bed (*i.e.*, the bassinet bed falls from the stand and contacts the floor or the base/stand collapses when the bassinet bed is not locked on the base/stand); (2) the lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action) in all lateral positions; (3) the sleep surface of the bassinet bed shall be at an angle of at least 20 degrees from a horizontal plane when the bassinet bed is in an unlocked position; (4) the bassinet/cradle shall provide a false latch/lock visual indicator(s). At a minimum, an indicator shall be visible to a person standing near both of the two longest sides of the product; or, (5) the bassinet bed shall not tip over and shall retain the CAMI newborn dummy. 78 FR 63022.

6. Ambiguity in catastrophic failure evaluation

Comment: One commenter objected to the 30°-tilt requirement in the catastrophic failure test. The commenter stated that the requirement is not adequately supported by scientific data and expressed the belief that this test is counterintuitive to the typical design approach by manufacturers of building in redundancies that prevent catastrophic failure.

Response: This comment has been addressed in the Commission’s final rule on the safety standard for play yards. Bedside sleepers that are used in the play yard mode must also meet the play yard requirements. In the play yard context, the Commission explained that the catastrophic

failure test is an alternative to the permanent affixture test. The Commission stated that the angle of 30 degrees represents a safety factor of three times the 10 degrees maximum safe sleep surface angle of incline. The Commission noted that CPSC staff, as well as ASTM members, can reconsider the tilt angle requirement during future revisions should evidence be presented indicating that the angle is too small or large. 78 FR 50332.

In addition any built in redundancies in testing have been resolved because bassinet accessory attachment components are addressed in the play yard standard, and because bassinet accessory mattress support rods are addressed in the bassinet standard. The play yard bassinet accessory misassembly requirement in F406-13 now applies to accessory attachment components. Misassembly issues related to mattress support rods are now addressed in the standard for bassinets and cradles. Bassinets with removable mattress support rods are required to be tested both with and without the mattress support rods. The bassinet also must pass the segmented mattress flatness test, with and without the mattress support rods. Accordingly, all known misassembly issues are addressed in either the play yard or the bassinet final standards.

6. Proposed Segmented Mattress Flatness

Comment: One commenter urged the CPSC to adopt the ASTM pass/fail criteria for the surface mattress flatness requirement proposed in the Bassinet NPR. The commenter further asserted that the repeated testing to ASTM F2194 surface flatness requirements has shown a tendency toward a lack of repeatability and that an established principle of looking at the mean of several trials should be used.

Response: This comment has been addressed in the final rule on the safety standard for bassinets. The Commission determined that mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented

mattresses, where seams could pose a suffocation and positional asphyxiation hazard. Under the Commission's pass/fail criteria, a bassinet attachment with a segmented mattress will fail if any tested seam creates an angle greater than 10 degrees. ASTM F2194-13 allowed measured angles between 10 degrees and 14 degrees to pass, as long as the mean of three measurements on that seam is less than 10 degrees. The 14-degree angle was based on an extrapolation of angles formed by dimensions of average infant faces. However, the Commission declined to use the average infant facial dimension as the basis for this requirement. Instead, in the final rule on bassinets, the Commission adopted the smallest users' anthropometrics to set the test requirement of 10 degrees maximum for each measurement taken. In addition, the bassinet final rule exempts from the mattress flatness requirement bassinets that are less than 15 inches across. The Commission found that these products do not pose the hazard the requirement is intended to address, and they are also not wide enough to test using the required procedures and equipment. 78 FR 63023.

7. Assembly and Instructions

Comment: One commenter requested that consistency be maintained with previously adopted mandatory regulations regarding assembly instructions and visual indicators as are demonstrated, for example, in the full-size crib requirement (16 CFR part 1219).

Response: Although the language in the full-size crib standard (16 CFR part 1219) and the ASTM F2906-13 and ASTM F2194-13 standards is not identical, the Commission finds that the content is sufficiently consistent among the standards regarding assembly instructions and visual indicators to convey the necessary information.

8. Attachment Mechanism

Comment: One commenter stated that a gap between the bedside sleeper and an adult bed creates a risk of injury to an infant in both the bedside sleeper and the adult bed. The commenter

recommended that CPSC include an attachment mechanism to be composed of only one part that is then attached to the bedside sleeper, as required in the portable children's bed rail standard, ASTM F2085-12. The commenter stated that the attachment mechanism would not need to be permanently attached to bedside sleepers that are also used in other modes without the attachment, but all necessary parts for attachment should be connected to each other, reducing the chance that caregivers will leave key elements out of the attachment process.

Response: The CPSC is not aware of any incidents in which an infant became entrapped in a gap between a bedside sleeper and an adult bed with or without missing key elements of the attachment mechanism. There are very few single-mode bedside sleeper products. Most bedside sleepers are multiuse with other modes, such as bassinets and play yards. Although the commenter indicated the attachment would not need to be connected permanently when used in other modes that do not require the attachment, CPSC staff is concerned that the attachment could present a risk of injury, such as strangulation or entrapment with the attachment cord or strap, when not in use. The addition of requirements to prevent entrapment in a gap between the bedside sleeper and the adult bed on very few single-mode bedside sleeper products at the expense of adding potential strangulation or entrapment risks does not appear warranted. At this time, the Commission does not support the inclusion of a requirement for a one-piece attachment device that would need to be installed permanently on single-mode bedside sleepers and also would need to be removable on bedside sleepers with free standing bassinet or play yard use modes.

9. Pictograms and Warnings

Comment: One commenter suggested that adding pictograms to the warnings would effectively convey the hazard and avoid language barriers that minimize comprehension of these warning

labels. The commenter also stated that the CPSC should add a warning that would advise the caregiver of the danger adult bedding can pose if bedding is allowed to fall into the bedside sleeper.

Response: Currently, all bedside sleeper products are required to comply with the marking and labeling requirements of the bassinet standard. Although a well-developed and tested pictogram could increase comprehension, designing effective, well-understood graphics can be difficult. Poor understanding of graphics may cause consumer confusion, the most severe of which is a critical confusion, where the graphic is interpreted to mean the opposite of the intention. Therefore, any warning pictogram should be developed with empirical study and well tested on the target audience. In addition, there are a number of products for which a soft bedding pictogram could be useful, such as bedside sleepers, bassinets, cribs, play yards, inclined sleep products, and others. Because of the increasing number of multimode products, the Commission believes a cross-product ad hoc working group may be the best place to develop such a pictogram and would allow testing and validation of the pictogram. Subject to budgetary and staff resources, CPSC staff would support participation in any such group, and should the need arise, staff will consider future action once such a graphic is developed.

10. Effective Date Marking

Comment: One commenter stated that the CPSC should add a marking on products that are manufactured after the effective date so that consumers can clearly identify products that meet the mandatory standard.

Response: On February 13, 2013, a final rule implementing *Testing and Labeling Pertaining to Product Certification*, 16 C.F.R. part 1107 (the 1107 rule), became effective. Under the 1107 rule, a manufacturer or importer may label a certified compliant product as “Meets CPSC Safety

Requirements.” Because producers are already allowed to label compliant products as such under the 1107 rule, including this option in the bedside sleeper standard would be redundant. Accordingly, the Commission will not require additional markings at this time.

F. Final Rule

The CPSC is incorporating by reference ASTM F2906-13 because the Commission’s proposed modifications in the NPR have been adopted in ASTM F2906-13, including the requirements and test methods for bedside sleeper accessories missing accessory attachment components and bedside sleeper accessory fabric-sided enclosed openings. In addition, because bedside sleepers are required to be tested to the bassinet standard, and because the Commission recently issued a final rule incorporating the ASTM standard for bassinets with some modifications, codified at 16 CFR part 1218, the references to the voluntary bassinet standard (ASTM F2194) are revised to reflect the current mandatory bassinet standard, 16 CFR part 1218.

Specifically, ASTM F2194 is referenced in sections 5.1, 5.1.1, 7.1 and 8.1. All of the references to ASTM F2194 are replaced with 16 CFR part 1218 as follows:

- 5.1 Prior to or immediately after testing to this consumer safety specification, the bedside sleeper must be tested to 16 CFR part 1218. Multimode products must also be tested to each applicable standard. When testing to 16 CFR part 1218, the unit shall be freestanding, and not be secured to the test platform, as dictated elsewhere in this standard.
- 5.1.1 The bassinet minimum side height shall be as required in 16 CFR part 1218, with the exception of a lowered side rail as permitted in 5.4.
- 7.1 All bedside sleeper products shall comply with the marking and labeling requirements of 16 CFR part 1218.

- 8.1 All bedside sleeper products shall comply with the instructional literature requirements of 16 CFR part 1218.

G. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of the rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). Only one commenter addressed the effective date and supported the 6-month effective date proposed in the NPR. To allow time for bedside sleepers to come into compliance with the standard, the bedside sleeper standard will become effective 6 months after publication of a final rule in the *Federal Register*.

G. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires agencies to consider the impact of proposed and final rules on small entities, including small businesses. Section 604 of the RFA requires that the Commission prepare a final regulatory flexibility analysis when promulgating final rules, unless the head of the agency certifies that the rule will not have a significant impact on a substantial number of small entities. The final regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

- a succinct statement of the objectives of, and legal basis for, the rule;
- 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;

- a description of, and, where feasible, an estimate of, the number of small entities to which the rule will apply;
- 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
- 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

Bedside sleepers are typically produced and/or marketed by juvenile product manufacturers and distributors. Currently, there are at least five known manufacturers supplying bedside sleepers to the U.S. market. Four are domestic manufacturers, including one manufacturer that dominates the market. The fifth is a foreign manufacturer who ships products directly to the United States. 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. Under this program, products voluntarily submitted by manufacturers are tested against the appropriate ASTM standard, and only passing products are allowed to display JPMA's Certification Seal.

Currently, JPMA does not have a Certification Program for bedside sleepers, and no firm claims to meet the ASTM voluntary standard. However, three firms supply multimode products, which in one mode, are compliant with the associated ASTM voluntary standard. Two firms claim compliance with the ASTM standard for bassinets; one firm is JPMA-certified as compliant, and the other claims compliance with the ASTM bassinet standard. A third firm supplies play yards that are JPMA-certified as compliant with the ASTM play yard/non-full-size crib standard.

3. Other Federal or State Rules

There are two federal rules that impact the bedside sleeper standard: (1) *Testing and Labeling Pertaining to Product Certification* (16 CFR part 1107); and (2) *Requirements Pertaining to Third Party Conformity Assessment Bodies* (16 CFR part 1112).

Under 16 CFR part 1107, every manufacturer of a children's product that is subject to a children's product safety rule is required to certify, based on third party testing by a CPSC-accepted conformity assessment body (or laboratory), that the product complies with all applicable safety rules. Because bedside sleepers will be subject to a mandatory children's product safety rule, the product will also be subject to the third party testing requirements of section 14(a)(2) of the CPSA.

Under 16 CFR part 1112, the Commission established requirements for the accreditation of third party conformity assessment bodies to test for conformance with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. This rule amends 16 CFR part 1112 to establish the requirements for accepting the accreditation of a conformity assessment body to test for compliance with the bedside sleeper standard.

4. Impact on Small Businesses

There are four domestic firms known to be marketing bedside sleepers in the United States. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of bedside sleepers is small if it has 500 or fewer employees. Based on these guidelines, all four domestic manufacturers are small. The economic impact on small domestic manufacturers depends on two factors: (1) whether their products are multiuse products and are already in compliance with one or more existing standards; and (2) the proportion of their total sales or revenue that bedside sleepers constitute.

Three of the four domestic manufacturers produce a multiuse product or a product that may be used as a bedside sleeper as well as a bassinet or play yard. These three multiuse products are required to comply with other existing standards, and there is significant overlap between standards. For example, firms that produce multimode bedside sleeper/play yards are already required to comply with the mandatory play yard standard. In addition, these three multiuse products also function as bassinets and will need to comply with the bassinet standard prior to the effective date for the bedside sleeper final rule. If the products comply with applicable standards pertaining to other use modes, these products will require only slight, incremental modifications. Thus, assuming that these multiuse bedside sleeper products comply or will comply with the standards applicable to other use modes, the three producers of multiuse products are unlikely to experience an economically significant impact due to the bedside sleeper draft final rule.

Two of the domestic manufactures rely almost solely on the sales of bedside sleepers, including a bedside sleeper accessory, as their revenue source. This includes one of the firms mentioned above which produces a multiuse product that will need to comply with an existing standard prior to any effective date for the bedside sleeper draft final rule. Again, based on the

assumption that this firm's products will comply with other existing standards, the bedside sleeper rule should not result in a significant economic impact on this firm. The second firm, however, produces a product that serves as a standalone bedside sleeper. Staff believes that this firm's standalone bedside sleeper would need several modifications to meet the requirements in the bedside sleeper standard. The firm will need at least two modifications (adding a lowered fourth side and complying with new stability requirements). However, the firm's plans for modifying the product and costs of compliance are unknown. Even if the cost of each modification taken individually is small, total costs of compliance could be modest or high. Because the majority of this firm's revenues is tied to bedside sleepers and assuming that several modifications may be needed to comply with the bedside sleeper standard, this firm is more likely experience an economically significant impact as a result of the bedside sleeper mandatory standard.

Under section 14 of the CPSA, bedside sleepers are also subject to third party testing and certification. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, *Testing and Labeling Pertaining to Product Certification* (16 C.F.R. part 1107). Third party testing will pertain to any physical and mechanical test requirements specified in the bedside sleeper final rule; lead and phthalates testing is already required. Third party testing costs are in addition to the direct costs of meeting the bedside sleeper standard.

Based on information from the durable nursery product industry and confidential business information supplied for the development of the third-party testing rule, testing to a single ASTM voluntary standard could cost around \$500–\$600 per model sample. On average, each small domestic manufacturer supplies two different models of bedside sleepers to the U.S.

market annually. Therefore, if third-party testing to the requirements in the bedside sleeper standard were conducted every year on a single sample for each model, third-party testing costs associated for each manufacturer would be about \$1,000-\$1,200 annually. Based on an examination of estimates of firms' revenues from recent Dun & Bradstreet reports, the impact of third-party testing to ASTM F2906-13 is not likely to be economically significant if only one bedside sleeper sample per model is required. However, if more than one sample would be needed to meet the testing requirements, third-party testing costs could have an economically significant impact on two of the small manufacturers (*i.e.*, based on SBA guidelines, staff typically uses 1 percent of gross revenue as the threshold for determining economic significance and testing costs could be 1 percent or more of gross revenue). The exact number of samples needed to meet the "high degree of assurance" criterion as required in 16 C.F.R. part 1107 is unknown.

5. Alternatives

An alternative to the rule would be to set an effective date later than 6 months, which is generally considered sufficient time for suppliers to come into compliance with a rule. Setting a later effective date would allow suppliers additional time to develop compliant bedside sleepers and spread the associated costs over a longer period of time. The Commission finds that a 6-month effective date is adequate for manufacturers to comply with the bedside sleeper standard because the changes necessary to comply with the standard are not substantial given that most bedside sleepers are also multi-mode products.

I. Environmental Considerations

The Commission's regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. These regulations provide a

categorical exclusion for certain CPSC actions that normally have “little or no potential for affecting the human environment.” Among those actions are rules or safety standards for consumer products. 16 CFR 1021.5(c)(1). The rule falls within the categorical exclusion.

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. 3501–3521). The preamble to the proposed rule (77 FR at 73352 through 73353) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. Sections 7 and 8 of ASTM F2906-13 contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

OMB has assigned control number 3041-0160 to this information collection. The Commission did not receive any comments regarding the information collection burden of this proposal. Accordingly, we estimate the burden of this collection of information 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
1222	5	2	10	1	10

K. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a consumer product safety standard 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 and Notice of Requirements (NOR)

Section 14(a) of the 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, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children’s products subject to a children’s product safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children’s product safety rule to which a children’s product is subject. The “Safety Standard for Bedside Sleepers,” to be codified at 16 CFR part 1222, is a children’s product safety rule that requires the issuance of an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), which is codified at 16 C.F.R. part 1112 (referred to here as part 1112). This rule became effective on June 10, 2013. Part 1112 establishes requirements for accreditation of third party conformity assessment bodies (or laboratories) to test for conformance with a children’s product safety rule in accordance with

Section 14(a)(2) of the CPSA. Part 1112 also codifies a list of all of the NORs that the CPSC had published at the time part 1112 was issued. All NORs issued after the Commission published part 1112, such as the bedside sleeper standard, require the Commission to amend part 1112. Accordingly, this rule amends part 1112 to include the bedside sleeper standard in the list with the other children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for bedside sleepers would be required to meet the third party conformity assessment body accreditation requirements in 16 CFR part 1112, *Requirements Pertaining to Third Party Conformity Assessment Bodies*. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1222, Safety Standard for Bedside Sleepers, included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: www.cpsc.gov/labsearch.

CPSC staff conducted an analysis of the potential impacts on small entities of the proposed rule establishing accreditation requirements, as required by the Regulatory Flexibility Act, and the agency prepared an Initial Regulatory Flexibility Analysis (IRFA). *Requirements Pertaining to Third Party Conformity Assessment Bodies*. 77 FR 31086, 31123-26. Specifically, the NOR for the bedside sleeper standard would not have a significant adverse impact on small laboratories. Based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the bedside sleeper standard. Most of these laboratories already will have been accredited to test for conformance to other juvenile product standards, and the only cost to

them would be the cost of adding the bedside sleeper standard to their scope of accreditation. As a consequence, the Commission certifies that the NOR for the bedside sleeper standard will not have a significant impact on a substantial number of small entities.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1222

Consumer protection, Imports, Incorporation by reference, Infants and Children, Labeling, Law Enforcement, and Toys.

For the reasons discussed in the preamble, the Commission amends Title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

Authority: 15 U.S.C. 2063; Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008).

2. Amend Part 1112.15 by adding paragraph (b)(34) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?

* * * * *

(b) The CPSC has published the requirements for accreditation for third party conformity assessment bodies to assess conformity for the following CPSC rules or test methods:

* * * * *

(34) 16 CFR part 1222, Safety Standard for Bedside Sleepers.

PART 1222-SAFETY STANDARD FOR BEDSIDE SLEEPERS

Sec.

1222.1 Scope.

1222.2 Requirements for bedside sleepers.

Authority: The Consumer Product Safety Improvement Act of 2008, Pub. L. 110-314, § 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112-28, 125 Stat. 273 (August 12, 2011).

§ 1222.1 Scope.

This part establishes a consumer product safety standard for bedside sleepers.

§ 1222.2 Requirements for bedside sleepers.

(a) Except as provided in paragraph (b) of this section, each bedside sleeper must comply with all applicable provisions of ASTM F2906-13, Standard Consumer Safety Specification for Bedside Sleepers, approved on November 18, 2013. 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 from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/cpsc.htm>. You may inspect a copy 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) Comply with ASTM F2906-13 with the following changes:

(1) Instead of complying with section 5.1 of ASTM F2906-13, comply with the following:

(i) Prior to or immediately after testing to this consumer safety specification, the bedside sleeper must be tested to 16 CFR part 1218. Multimode products must also be tested to each applicable standard. When testing to 16 CFR part 1218 the unit shall be freestanding, and not be secured to the test platform as dictated elsewhere in ASTM F2906-13.

(ii) 5.1.1 The bassinet minimum side height shall be as required in 16 CFR part 1218, with the exception of a lowered side rail as permitted in 5.4.

(2) Instead of complying with section 7.1 of ASTM F2906-13, comply with the following:

(i) All bedside sleeper products shall comply with the marking and labeling requirements of 16 CFR part 1218.

(ii) [Reserved]

(3) Instead of complying with section 8.1 of ASTM F2906-13, comply with the following:

(i) All bedside sleeper products shall comply with the instructional literature requirements of 16 CFR part 1218.

(ii) [Reserved]

Dated: _____

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission



Staff Briefing Package

Draft Final Rule for Bedside Sleepers Under the Danny
Keysar Child Product Safety Notification Act
December 4, 2013

CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: <http://www.cpsc.gov>

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Briefing Memo



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

This document has been electronically
approved and signed.

Memorandum

Date: December 3, 2013

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Elliot F. Kaye, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

FROM : George A. Borlase, Assistant Executive Director
Office of Hazard Identification and Reduction

Douglas A. Lee
Project Manager, Bedside Sleepers
Directorate for Engineering Sciences

SUBJECT : Staff's Draft Final Rule for Bedside Sleepers under the Danny Keysar Child
Product Safety Notification Act

I. INTRODUCTION

The Danny Keysar Child Product Safety Notification Act, Section 104 of the Consumer Product Safety Improvement Act (CPSIA), requires the U.S. Consumer Product Safety Commission (CPSC, Commission) to study and develop safety standards for certain infant and toddler products. The Commission is charged with: (1) examining and assessing applicable voluntary consumer product safety standards, and (2) promulgating mandatory consumer product safety standards that are substantially the same as or more stringent than the voluntary standards, if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. Bedside sleepers, which are very similar to bassinets, are under the purview of Section 104 of the CPSIA.

Section 104 also requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers to examine and assess the effectiveness of the voluntary standards. For bedside sleeper products, this consultation began in March 2010, with CPSC staff's participation in an ASTM International (ASTM) Task Group within Subcommittee F15.18 – Cribs, Toddler Beds, Play Yards, Bassinets, Cradles and Changing Tables. The Task Group, with CPSC staff's participation, completed drafting of the first edition of the ASTM voluntary standard for bedside sleepers in December 2011. CPSC staff continues to consult with the task group to make revisions, as necessary, to reduce incidents with bedside sleeper products, completing revisions in July 2012 (F2906 –12) and July 2013 (F2906-13).

This briefing package includes staff's responses to comments received in response to the notice of proposed rulemaking (NPR), which the Commission published on December 12, 2012, in the *Federal Register* (77 FR 73345). The briefing package also assesses changes made to the bedside sleeper voluntary standard since the publication of the NPR and presents staff's draft final rule to address potential hazards with bedside sleepers.

A bedside sleeper is a bassinet-type product, intended to provide a sleeping environment for an infant up to approximately 5 months of age, or when a child begins to push up on his or her hands and knees, whichever comes first. These products are designed to be secured to an adult bed, for the purpose of having a baby sleep in close proximity to an adult. A bedside sleeper can have a side adjacent to the adult bed that is lower or can be lowered. To protect a child from getting his or her neck caught on the lowered rail, the product is designed to attach securely to an adult bed. Many products are multimode or multiuse products that can also function as a play yard, bassinet, changing table, or handheld carrier, in addition to functioning as a bedside sleeper.

II. BACKGROUND

A. Pre-NPR Standard Activity

ASTM F2096-11

ASTM first published a voluntary consumer product safety standard for bedside sleepers, ASTM F2906-11, in December 2011. For starters, the standard required bedside sleepers to meet the voluntary standard requirements of the product upon which it is based for use, either a bassinet or play yard, to establish a basic level of overall product safety.

The standard additionally included requirements to address hazards specific to bedside sleeper products. The standard addressed incidents involving the creation of a hazardous gap between the product and an adult mattress by requiring the successful completion of three disengagement tests. The tests are intended to ensure that the securing components can withstand forces that may be exerted on the product by either the child or an adult, while sleeping. The gap must be no more than 0.5 in. when the product is installed to the adult bed, per each manufacturer's directions. When a 25-lb. horizontal force is applied near the attachment system or corners, the gap may not exceed 1.0 in. To simulate an adult rolling into a bedside sleeper while sleeping, a gap greater than 1.0 in. may not be created after the application and release of a 50-lb. horizontal force to the bedside sleeper's corners. The inclusion of these anti-gap requirements is crucial to mitigate the foreseeable head and neck entrapment hazards posed by bedside sleepers.

Human Factors staff identified a separate foreseeable hazard when the product is used by itself without being attached to the adult bed and the fourth side is lowered. The ASTM standard addresses this potential hazard by requiring a minimum 4-inch lowered side height over which a

child is unlikely to be able to roll. Lastly, latching and locking security and child resistance are evaluated to help prevent unintentional movement of the side that lowers (in the event there is one) and to ensure overall product integrity.

ASTM F2906-12

In early 2012, the ASTM Bedside Sleeper Subcommittee (F15.18), in consultation with CPSC staff, revised the ASTM standard to require that all bedside sleepers meet the requirements of the ASTM standard for bassinets (ASTM F2194). Bedside sleepers and bassinets share a significant number of hazard patterns because they are intended to be used by children with the same developmental abilities and for the same purpose. Ensuring that all bassinet hazards are addressed by the bedside sleeper standard made the bedside sleeper standard more stringent because this expanded the range of hazards that are addressed by including hazards not covered by the play yard voluntary standard (F406). Additionally, the ASTM subcommittee recognized that F2194 requires a bassinet accessory on a play yard structure to meet the applicable sections of the play yard voluntary standard. Changing the bedside sleeper standard (F2906) to require all bedside sleepers to meet the bassinet standard (F2194) makes the standard more stringent and at the same time ensures that no play yard-related hazards go unaddressed. This change was published in F2906-12 in July 2012.

B. NPR Overview

In December 2012, the Commission published an NPR in the *Federal Register* (77 FR 73345). The NPR incorporated by reference the voluntary standard for bedside sleepers (ASTM F2906-12), *Standard Consumer Safety Specification for Bedside Sleepers*, with a few modifications. In the NPR, the modifications to ASTM F2906-12 included:

- 1) *Language to address Fabric-Sided Enclosed Openings entrapment hazards.*
- 2) *Language to address Consumer Misassembly with Missing Components.*

The Commission's proposed modifications to ASTM F2194-12 to address bassinet hazards have been discussed in detail in the bedside sleeper NPR and the bassinet SNPR (Supplemental Notice of Proposed Rulemaking) staff briefing packages.¹ Specifically, the Commission proposed four changes to the ASTM bassinet standard in the bassinet SNPR. Three of those proposed changes to the bassinet standard are also applicable to bedside sleepers: (1) the pass/fail criterion for the segmented mattresses flatness test to make the criterion stricter than what is in the ASTM standard; (2) a new performance requirement for the stability of bassinets with removable

¹ Link to bedside sleeper NPR:

<http://www.cpsc.gov/PageFiles/140088/bedside.pdf>

Link to bassinet SNPR:

<http://www.cpsc.gov/library/foia/foia12/brief/bassinetsnpr.pdf>

bassinet beds (includes new definitions, a test requirement, and test procedure); and (3) a revision to the current stability test procedure specifying the use of a newborn CAMI dummy, rather than the six-month infant CAMI dummy.²

Since publication of the bassinet NPR, the Commission published a bassinet final rule that includes five modifications to the ASTM bassinet standard (F2194). Four of the modifications apply to bedside sleepers, including variations of the original three from the bassinet NPR package, plus a fourth: (4) Exemption of the Segmented Mattress Flatness Test for Narrow Mattresses. The fifth modification, a scope requirement for multimode products, is already in ASTM F2906-13. As of the submission of this briefing package to the Commission, ASTM has not included any of the four modifications in the current version of F2194. Thus, staff is also recommending that references to F2194 be revised to refer instead to 16 C.F.R. part 1218 (the mandatory bassinet standard) when bedside sleepers are tested to the bassinet standard.

C. Post-NPR ASTM Activity

The two bedside sleeper NPR modifications, the fabric-sided enclosed openings entrapment hazards and the consumer misassembly with missing components requirements, were balloted for inclusion in the ASTM F2906 standard in September 2012, and they received two negative votes. As a result of those votes, the two balloted items were revised and reballoted in May 2013. The items passed and were included in the subsequent version of the ASTM standard, F2906-13, which was published in July 2013.

III. DISCUSSION

A. Incident Data

In the NPR briefing package, staff reported 40 cases, including four fatalities and 36 nonfatal incidents (with and without injuries), related to bedside sleepers that occurred from January 2001 through December 2011. The reports were grouped into two broad categories: product-related incidents and recall-related comments. The product-related incidents included problems with the fabric cover over the adjustable fourth side, assembly instructions, product levelness, stability of leg extensions, design, component integrity, attachment mechanism, and age labeling. The recall-related comments expressed consumer concerns or queries related to CPSC recall notices on bedside sleepers.

Since the extraction of the data presented in the NPR briefing package, CPSC staff has received four new reports involving bedside sleepers. The reports did not include any fatalities or injuries, and CPSC staff has identified no new hazard pattern associated with these incidents.

² The CAMI (Civil Aeronautical Medical Institute) Newborn Infant and 6-month-old Infant test dummies are used in testing of many juvenile products by ASTM standards. These anthropomorphic test devices were originally developed by the Civil Aeronautical Medical Institute and have been used by the National Highway Traffic Safety Administration for the evaluation of child restraint systems (49 C. F. R. part 572 subparts D and K). The dummies consist of steel and aluminum blocks attached to leather skeletons wrapped in layers of foam padding and covered with a stitched cloth outer shell. The newborn CAMI dummy represents a 50th percentile newborn infant (7.5 lbs), which is a more appropriate user of a bassinet than the CAMI infant dummy, which represents a 50th percentile 6-month-old infant (17.5 lbs).

Three of the incidents reported product-related problems, such as design, component integrity, and assembly instructions; the fourth report was a consumer query regarding a recalled product and did not involve an actual incident. Because no new hazard was reported since the presentation of the NPR briefing package, staff is not recommending any additional requirements. Additional information on incident data can be found in Tab A.

B. Staff Response to Comments

The Commission received five comments in response to the NPR, including two from consumers, one from consumer advocacy groups, one from the voluntary standards working group chair, and one from a trade association. Two commenters made general statements about the proposed rule; one supported the NPR, and the other did not. Most of the comments were similar to the comments received for the bassinet and play yard NPRs because bedside sleepers are usually designed on a bassinet base or a play yard base, and most are multiuse or multimode products. Commenters generally requested that the requirements in the bassinet and play yard voluntary standards be finalized before completing a final rule on bedside sleepers.³ The comments for bedside sleepers can be viewed at: www.regulations.gov, by searching under the docket number CPSC-2012-0067.

For technical comments, the comment topic is presented, followed by staff’s response. See Table 1 below for the comment topic and the location of staff’s complete responses.

Table 1. Comment Topics and Location of Staff’s Response

Topic	Tab
Generally Supportive	B
Generally Unsupportive	B
Fabric Sided Enclosed Openings	B
Consumer Misassembly with Missing Components	B
Redundant Product Safety Feature	B
Intellectual Property	B
Assembly and Instructions (Harmonize Instructional and Graphical Requirements with Full-size Cribs)	C
Ambiguity in Catastrophic Failure Evaluation	B
Proposed Segmented Mattress Flatness and Pass Fail Rate Comparison w/CPSC Definition	B
Incorporating Another ASTM Standard by “Reference”	B
Attachment Mechanism	B
Pictograms	C
Suffocation Warning Language	C
Effective Date Marking	D

³ Staff’s responses for related bassinet and play yard comments are in their respective final rule briefing packages. The bassinet and play yard comments can be viewed at: www.regulations.gov, by searching under the docket number of the specific rulemaking CPSC-2010-0028 (bassinets and cradles), and CPSC-2011-0064 (play yards).

Fabric Sided Enclosed Openings

Comment:

Two comments stated that the fabric-sided enclosed openings requirement needs to be revised to test correctly for the entrapment hazard. The commenters suggested that the changes made to ASTM F2906 be finalized before moving forward with the bedside sleeper final rule.

Response:

Staff agrees. ASTM F2906-13 was recently published, and this revision contains a fabric-sided opening test that staff believes is adequate to address the entrapment hazards. Staff is recommending that the Commission incorporate by reference ASTM F2906-13 for the final rule. Thus, the fabric-sided openings test is already included in the draft final rule, and no further staff recommendations are needed with respect to this comment.

Consumer Misassembly with Missing Components

Comment:

One commenter stated that the hazards associated with misassembly of play yard bassinet accessories need to be vetted in the ASTM process and finalized in ASTM F406 before being addressed in the bedside sleeper standard.

Response:

Staff agrees. The hazards associated with play yard bassinet accessories that have missing or misassembled supporting rods on a play yard base were recently addressed in the latest version of the play yard standard, ASTM F406-13. The same language has been adopted to address bedside sleeper accessories on a play yard base in ASTM F2906-13. Thus, no additional recommendations from staff are needed with respect to this comment.

Redundant Product Safety Feature

Comment:

One commenter stated that the play yard bassinet accessory misassembly provision requirement in the NPR “may compel manufacturers [. . .] to eliminate redundant safety features that are already a component of the product.” The commenter used mattress support rods as an example of a structure that is not necessary to comply with the voluntary standard but does improve product safety by helping to create a “flatter and more stable sleeping position.” The commenter concluded that the added cost of being required to permanently affix redundant structures would lead to the structures being eliminated to avoid this cost, resulting in compliant, but less safe, products being sold.

Response:

Staff disagrees and notes that this comment has already been addressed in the final rules on the safety standards for play yards and for bassinets and cradles. ASTM stakeholders involved in both play yard and bassinet voluntary standard development have already addressed the issue of

mattress support rod misassembly in ASTM F406-13 and ASTM F2194-13; thus, the issue does not need to be addressed in the bedside sleeper final rule.

The ASTM play yard subcommittee and the ASTM bassinet/cradle subcommittee determined that (1) the play yard standard, ASTM F406-13, will address safety issues related to bassinet accessory attachment components (i.e., structures that attach the bassinet accessory to the play yard); and (2) the bassinet standard, ASTM F2194-13, will address mattress support rods (and all other structures that keep the bassinet accessory mattress flat and stable) by revising the segmented mattress flatness test contained in the bassinet standard. ASTM F2194-13 requires that bassinets with removable mattress support rods be tested for mattress flatness both with and without the mattress support rods installed. Since bedside sleepers must also be tested to ASTM F2194-13, the same testing requirements apply to bedside sleepers.

Intellectual property

Comment:

One commenter indicated that there is a patent application pending, detailing 10 different methods to “stiffen a play yard mattress pad before it is used in a play yard bassinet accessory.” The commenter acknowledged that “there may not be any products on the market today that would be impacted by this patent application” but indicated that the CPSC should “evaluate this issue and avoid design restrictions that limit marketplace competition.”

Response:

This comment has already been addressed in the Commission’s final rule for play yards. As the Commission stated, the concern regarding the means of stiffening a mattress pad is no longer an issue for the play yard rule because the play yard bassinet accessory misassembly requirement no longer applies to mattress support rods or any other methods that might be used to stiffen a mattress pad. Instead, the play yard rule focuses only on accessory attachment components that attach the bassinet accessory to the play yard.

Likewise, the bassinet rule, which does address mattress flatness, does not require that a specific design be used to pass the standard. As a result, the bassinet mattress flatness test can be met in a variety of ways without necessarily implicating patented technology.

Assembly and Instructions (Harmonize Instructional and Graphical Requirements with Full-size Cribs)

Comment:

The commenter requested that consistency be maintained with previously adopted mandatory regulations regarding assembly instructions and visual indicators as, for example, are demonstrated in the full-size crib requirement (16 C.F.R. part 1219).

Response:

Staff believes that this request is sufficiently addressed in the F2906-13 and F2194-13 voluntary standards. Although staff acknowledges the language is not uniform between the referenced standard (16 C.F.R. part 1219) and the two voluntary standards (F2906-12 and F2194-13), the instructional literature throughout the standards is consistent and provides the necessary information since all instructional literature for bedside sleepers must comply with F2194, the voluntary standard for bassinets.

Requirements for Stability of Removable Bassinet Beds

Comment:

One commenter stated that adding the removable bassinet bed stability requirement is premature. The commenter expressed the belief that the requirement should be removed from the regulation and that ASTM should be allowed to continue work on this.

Response:

This comment has already been addressed in the Commission's final rule for bassinets and cradles. In that rule, the Commission provided manufacturers with options to meet the removable bassinet bed requirements by stating that any product containing a removable bassinet bed with a latching or locking device intended to secure the bassinet bed to the base/stand, shall comply with at least one of the following: (1) the base/stand shall not support the bassinet bed (i.e., the bassinet bed falls from the stand and contacts the floor or the base/stand collapses when the bassinet bed is not locked on the base/stand); (2) the lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action) in all lateral positions; (3) the sleep surface of the bassinet bed shall be at an angle of at least 20 degrees from a horizontal plane when the bassinet bed is in an unlocked position; (4) the bassinet/cradle shall provide a false latch/lock visual indicator(s). At a minimum, an indicator shall be visible to a person standing near both of the two longest sides of the product; or, (5) the bassinet bed shall not tip over and shall retain the CAMI newborn dummy. As required by ASTM F2906-13, bedside sleepers are required to be tested to the voluntary bassinet standard (ASTM F2194).

Ambiguity in catastrophic failure evaluation

Comment:

One commenter objected to the 30° tilt requirement in the catastrophic failure test. The commenter expressed the belief that the requirement is not adequately supported by scientific data. The commenter also expressed the belief that the 30° tilt test is counterintuitive to the typical design approach by manufacturers of building in redundancies that prevent catastrophic failure.

Response:

This comment has already been addressed in the Commission's final rule for play yards. The Commission explained that the catastrophic failure test is an alternative to the permanent affixture test. The Commission stated that the angle of 30 degrees represents a safety factor of

three times the 10 degrees maximum safe sleep surface angle of incline. The Commission explained that CPSC staff concluded that an angle of 30 degrees would be sufficiently visually obvious to a consumer, such that the consumer would be discouraged from continuing to use the bassinet. In addition, ASTM stakeholders agreed with CPSC staff that 30 degrees was reasonable and would be considered by caregivers to be obviously hazardous. The Commission noted that CPSC staff, as well as ASTM members, can reconsider the tilt angle requirement as part of future revisions should evidence be presented indicating that the angle is too small or large. The Commission also stated that redundancies were resolved because bassinet accessory attachment components are addressed in the play yard standard, and because bassinet accessory mattress support rods are addressed in the bassinet standard. As a result, the play yard bassinet accessory misassembly requirement in F406-13 now only applies to accessory attachment components. Misassembly issues related to mattress support rods are now addressed in ASTM F2194-13, the voluntary standard for bassinets and cradles. ASTM F2194-13 requires that bassinets with removable mattress support rods be tested both with and without the mattress support rods. The bassinet must pass the segmented mattress flatness test contained in ASTM F2194-13 with and without the mattress support rods. In this way, all misassembly issues known to CPSC staff related to play yard bassinet accessories are addressed in either the Commission's play yard or bassinet final rules.

Proposed Segmented Mattress Flatness and Pass Fail Rate Comparison with CPSC Definition

Comment:

One commenter urged the CPSC to adopt, rather than rewrite, the ASTM pass/fail criteria for the surface mattress flatness requirement proposed in the bassinet SNPR. The commenter further asserted that the repeated testing to ASTM F2194 surface flatness requirements has shown a tendency toward a lack of repeatability and that an established principle of looking at the mean of several trials should be used.

Response:

This comment has already been addressed in the Commission's final rule for bassinets and cradles. The Commission stated that mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented mattresses, where seams could pose a suffocation and positional asphyxiation hazard. Under the Commission's pass/fail criteria, a bassinet attachment with a segmented mattress will fail if any tested seam creates an angle greater than 10 degrees. ASTM F2194-13 allows measured angles between 10 degrees and 14 degrees to pass, as long as the mean of three measurements on that seam is less than 10 degrees. The 14-degree angle was based on an extrapolation of angles formed by dimensions of average infant faces. However, the Commission declined to use the average infant facial dimension as the basis for this requirement. Instead of using the average infant anthropometrics as a basis for the pass/fail criteria, the Commission adopted the smallest users' anthropometrics to be protective of the majority of the user population. This set the test requirement of 10 degrees maximum. In addition, the Commission's bassinet final rule does

exempt bassinets that are less than 15 inches across from the mattress flatness requirement. The Commission found that these products do not pose the hazard the requirement is intended to address, and they are also not wide enough to test using the required procedures and equipment.

Incorporating another ASTM Standard by “Reference”

Comment:

Two comments suggested that the CPSC wait for the play yard and bedside sleeper voluntary standards to reach approval and publication and to incorporate the actual language of the requirement within the bedside sleeper standard, rather than reference the standard itself. One of these commenters expressed the belief that additional clarity is provided by not having to reference another standard and keep track of multiple revisions.

Response:

Staff agrees. ASTM F2906-13 now incorporates language from both ASTM F2194-13 and ASTM F406-13. The Bedside Sleeper Accessories -Missing Accessory Attachment Components (Section 5.8) requirement has been incorporated from ASTM F406-13. In addition, the Bedside Sleeper Accessory Fabric-Sided Enclosed Openings (Section 5.7) requirement has been incorporated from ASTM F2194-13, with the addition of the test methods for shells and removable covers. With the exception of the additional shell test requirement, the exact language in ASTM F2906-13 does not change the technical requirement from that recommended in the Bedside Sleeper NPR.

Attachment Mechanism

Comment:

One commenter indicated that a gap between the bedside sleeper and an adult bed creates a risk of injury to an infant in both the bedside sleeper and the adult bed. The commenter recommended that the CPSC consider including provisions that require the attachment mechanism to be comprised of only one part that is then attached to the bedside sleeper, as in the bedrail standard ASTM F2085-12, section 5.7. The commenter stated that the attachment mechanism would not need to be attached permanently to bedside sleepers that are also used in other modes without the attachment; but all necessary parts for attachment should be connected to each other, reducing the chance that caregivers will leave key elements out of the attachment process.

Response:

CPSC staff is not aware of any incidents in which an infant became entrapped in a gap between a bedside sleeper and an adult bed with or without missing key elements of the attachment mechanism. There are very few single-mode bedside sleeper products. Most bedside sleepers are multiuse with other modes, such as bassinets and play yards. Although the commenter indicated the attachment would not need to be connected permanently when used in other modes that do not require the attachment, CPSC staff is concerned that the attachment could present a risk of injury, such as strangulation or entrapment with the attachment cord or strap, when not in use. The addition of requirements to prevent entrapment in a gap between the bedside sleeper and the adult bed on very few single-mode bedside sleeper products at the expense of adding

potential strangulation or entrapment risks does not appear warranted. At this time, staff does not support the inclusion of a requirement for a one-piece attachment device that would need to be installed permanently on single-mode bedside sleepers and also would need to be removable on bedside sleepers with free standing bassinet or play yard use modes.

Pictograms and Warnings

Comment:

One commenter suggested that adding pictograms to the warnings would convey effectively the hazard and avoid language barriers that minimize comprehension of these warning labels. For example, the commenter suggested using the internationally recognized symbol of a red circle with a line through it, and the CPSC could draft pictograms showing a prone baby with his or her face on or near a pillow/padding. Because of the additional hazard of adult bedding nearby, the commenter also suggested that the CPSC should add a warning that would advise the caregiver of the danger adult bedding can pose if the bedding is allowed to fall into the bedside sleeper.

Response:

CPSC Human Factors (HF) staff acknowledges that a well-developed and tested pictogram could increase comprehension. However, the design of effective, well-understood graphics can be difficult. Poor understanding of graphics may cause consumer confusion, the most severe of which is a critical confusion, where the graphic is interpreted to mean the opposite of the intention. Therefore, any warning pictogram should be developed with empirical study and be well tested on the target audience. In addition, there are a number of products for which a soft bedding pictogram could be useful, such as bedside sleepers, bassinets, cribs, play yards, inclined sleep products, and others. Because of this, staff believes that a cross-product working group may be the best place to develop such a pictogram. This could ensure cross-product harmonization of such a pictogram and would allow testing and validation of the pictogram.

With respect to the comment to add a specific warning regarding adult bedding falling into the bedside sleeper, the bedside sleeper subcommittee decided to harmonize the suffocation warning with bassinets and chose to require the bassinet suffocation warning by reference (*i.e.*, 7.1 All bedside sleeper products shall comply with the marking and labeling requirements of Consumer Safety Specification F2194). This warning does contain information about *placing* adult bedding into the sleep environment, but does not contain information about adult bedding *falling* into the bedside sleeper. CPSC Human Factors (HF) staff was in agreement with this harmonization because there were no incidents suggesting that adult bedding products were accidentally entering the bedside sleeper environment and producing a hazard. However, staff does acknowledge this is a foreseeable hazard pattern. While staff disagrees with the commenter's request to add a soft bedding pictogram specifically for bedside sleepers, staff does recommend that the voluntary standard subcommittee consider adding language to the end of the referenced bassinet suffocation warning label, such as: "ALWAYS make sure adult bedding cannot fall into the bedside sleeper."

Effective Date Marking

Comment:

One commenter recommended that the CPSC add a marking on products that are manufactured after the effective date so that consumers can clearly identify products that meet the mandatory standard. The commenter also supported the six-month effective date proposed in the NPR.

Response:

A final rule implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA, *Testing and Labeling Pertaining to Product Certification*, 16 C.F.R. part 1107 (the 1107 rule), became effective on February 13, 2013. Under the 1107 rule, a manufacturer or importer may voluntarily label a certified compliant product as “Meets CPSC Safety Requirements.” CPSC staff believes there is sufficient incentive for compliant producers to label their products as such and recommends no change to the draft final rule based on this comment.

C. Comparison of the NPR and ASTM F2906-13

The NPR proposed to incorporate by reference ASTM F2906-12, *Standard Consumer Safety Specification for Bedside Sleepers*, with certain modifications to F2906 and F2194, which were proposed in the SNPR for bassinets and cradles.

The current voluntary standard for bedside sleepers, version ASTM F2906-13, differs from the NPR in the following ways:

- 1) **Fabric-Sided Enclosed Openings Performance Test:**
 - ASTM F2906-13 added specific language for the fabric-sided enclosed openings performance requirement to clarify that the referenced requirements in the NPR do apply to bedside sleeper accessories.
 - ASTM F2906-13 no longer has the NPR-proposed exemption for fabric-sided enclosed openings on bedside sleeper accessories that collapse during testing because it is no longer needed.
 - ASTM F2906-13 has a new “shell” definition and test requirements for the Bedside Sleeper Fabric-Sided Enclosed Openings requirement. The definition and test requirement were necessitated post-NPR when the consumer misassembly with missing components requirement was developed in F406.
- 2) **Bedside Sleeper Accessories – Missing Accessory Attachment Components performance requirement**
 - Post-NPR, the consumer misassembly with missing components performance requirement was broken into a play yard bassinets/cradles accessories missing accessory attachments requirement, which was subsequently adapted to a bedside

sleepers accessories missing accessory attachments requirement for F2906 and a bassinet mattress flatness requirement in F2194.

- ASTM F2906-13 added specific language for the bedside sleeper accessories missing accessory attachments performance requirement to ensure that bedside sleeper accessories were tested to this requirement, which was developed for bassinet accessories.

D. Staff-Recommended Changes from the NPR to the Final Rule

The ASTM F2906-13 additional requirements strengthen the voluntary standard and are consistent with the requirements in the NPR. Staff recommends that the Commission incorporate by reference, ASTM F2906-13, *Standard Consumer Safety Specification for Bedside Sleepers*, as the federal regulation for bedside sleepers, with modifications as discussed below.

ASTM F2906-13 requires that bedside sleepers are also tested to Consumer Safety Specification ASTM F2194 as the fundamental safety requirements for bedside sleepers. The Commission recently approved the Final Rule for Bassinets and Cradles on September 27, 2013 (16 C.F.R. part 1218), with additional modifications to ASTM F2194. The modifications:

- 1) Added new definitions, a test requirement, and test procedure for a new performance requirement pertaining to the stability of bassinets with removable bassinet beds.
- 2) Revised the current stability test procedure by specifying the use of a newborn CAMI dummy, rather than the six-month infant CAMI dummy.
- 3) Revised the pass/fail criterion for the segmented mattresses flatness test to make it stricter than what is in the ASTM standard.
- 4) Excluded from requiring compliance to the segmented mattress flatness test bassinets that are less than 15 inches wide along the width of the mattress.
- 5) Revised the scope to clarify the intent that multimode or combination products shall meet the requirements of all standards associated with its use modes.

Accordingly, staff recommends that the Commission adopt ASTM F2906-13, *Standard Consumer Safety Specification for Bedside Sleepers*, by reference, and require manufacturers to comply with 16 C.F.R. part 1218, the safety standard for bassinets and cradles when testing to ASTM F2194, as required by ASTM F2906-13, Section 5.1. Because the references to ASTM F2194 did not include the subsequent modifications made by the Commission in the bassinet final rule, staff recommends that bedside sleepers reference 16 C.F.R. part 1218, which includes the modifications to the bassinet standard.

E. Final Regulatory Flexibility Analysis for Bedside Sleepers

There are at least five known manufacturers supplying bedside sleepers to the U.S. market. Four are domestic manufacturers, and one is a foreign manufacturer that ships products directly to the United States. The analysis focuses on impacts to domestic firms. Based on U.S. Small Business Administration (SBA) guidelines, all four domestic manufacturers known to be supplying bedside sleepers to the U.S. market are small businesses.

Three domestic manufacturers supply a multiuse product or a product that may be used as a bedside sleeper as well as a play yard or bassinet. These multiuse products are already in compliance with an existing standard, and there is significant overlap between standards. It is likely that these manufacturers will need to make only small modifications to comply with the bedside sleeper standard. The fourth manufacturer produces a product that serves as a bedside sleeper only. The costs of compliance for this firm are unknown but could be significant if a substantial product redesign is required. In addition to possibly having higher compliance costs, the impacts to this firm could be further magnified because bedside sleepers constitute its entire product line.

F. Effective Date of Final Rule

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule (5 U.S.C. 553(d)). In the NPR, the Commission proposed a six-month effective date. CPSC staff believes that the Commission should set an effective date for the standard six months after publication for products manufactured or imported on or after that date.

IV. CPSC STAFF RECOMMENDATION

Staff recommends that the Commission incorporate by reference, ASTM F2906-13, *Standard Consumer Safety Specification for Bedside Sleepers*, and require bedside sleepers to comply with the recent modifications required for bassinets under 16 C.F.R. part 1218 when bedside sleepers are tested to ASTM F2194-13, as required by ASTM F2906-13, Section 5.1.

TAB A: Bedside Sleeper-Related Deaths, Injuries, and Potential Injuries Reported Between January 24, 2012 and May 15, 2013

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

Memorandum

Date: August 16, 2013

TO : Douglas Lee
Project Manager, Bedside Sleepers
Division of Electrical Engineering
Directorate for Engineering Sciences

THROUGH: Kathleen Stralka
Associate Executive Director
Directorate for Epidemiology

Stephen Hanway
Division Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM : Risana Chowdhury
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Bedside Sleeper-Related Deaths, Injuries, and Potential Injuries Reported
Between January 24, 2012 and May 15, 2013⁴

I. Introduction

This memorandum updates the data in the bedside sleepers notice of proposed rulemaking (NPR) briefing package presented to the Commission in November 2012. The date of extraction for the earlier data was January 24, 2012, and the time frame covered was January 1, 2001 to December 31, 2011. This memorandum includes bedside sleeper-related incident data reported to CPSC staff between January 24, 2012 and May 15, 2013.⁵

⁴ This analysis was prepared by CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

⁵ Not all of these incidents are addressable by an action the CPSC could take. It is not the purpose of this memorandum, however, to evaluate the addressability of the incidents, but rather, to quantify the number of fatalities and injuries reported to CPSC staff and to provide, when feasible, estimates of emergency department-treated injuries.

CPSC databases do not have a dedicated product code for identifying bedside sleepers. Instead, the bedside sleeper incidents were identified through keyword searches from a subset of products coded as 1537 (bassinets or cradles), 1529 (portable cribs), and 1513 (playpens). No emergency department-treated injuries were identified as being associated with bedside sleepers; as such, the data analyzed in this memorandum include incident data only. In addition, incidents associated with bedside sleepers that are multimode products have been included in this analysis, as well as in the regulatory work for the other relevant product(s).

II. Incident Data⁶

CPSC staff from the Directorate for Epidemiology characterized the number of incidents and the types of hazards related to bedside sleepers.

In the NPR briefing package, staff reported 40 cases, including four fatalities and 36 nonfatal incidents (with and without injuries), related to bedside sleepers that occurred from January 2001 through December 2011. Since the extraction of the data presented in the NPR briefing package, CPSC staff has received four new reports involving bedside sleepers. One of the reports was a consumer query regarding a recalled product and did not involve an actual incident. The rest of the reports involved no fatalities or injuries. The infants in the incident reports ranged in age from one to six months.

III. Hazard Pattern Identification

The hazards reported in the three new incidents were among the hazard patterns identified in the incidents presented in the NPR briefing package.

There were two incidents that are classified under *miscellaneous product-related issues* related to the *poor design* and a *broken/detached component* of the product. In the incident reporting poor design, the consumer expressed concern that the fabric side can create a suffocation hazard when their child's face is against it; the consumer reportedly stopped using the product. The second incident involved a six-month-old who fell onto the floor from a recalled, multimode product when the horizontal bar, which converts the product from a bedside sleeper to a bassinet, broke off or detached. No injury was reported, and it is unclear whether the consumer was aware of the recalled status—which addressed a different issue—of the product.

The third incident is categorized as an *assembly instruction issue*. While the consumer reported the product as faulty, it appears that the top rail collapsed because the consumer did not fully latch the bottom rail as indicated in the manufacturer's instructions.

⁶ The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, and the Death Certificate (DTHS) file. The reported deaths and incidents are not a complete count of all that occurred during this time period. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to bedside sleepers.

Date of extraction for reported incident data was 05/15/13. All data coded under product code 1537, 1513, and 1529 was extracted, and keyword searches were used to identify the potentially in-scope cases. Upon careful joint review with CPSC's Engineering Sciences (ES) staff, some cases were considered out-of-scope for the purposes of this memo. All incidents involving a hazardous environment in and around the bedside sleeper were retained. With the exception of incidents occurring on U.S. military bases, all incidents that occurred outside of the U.S. have been excluded. To prevent any double-counting, when multiple reports of the same incident were identified, they were consolidated and counted as one incident.

TAB B: ESME Recommendations for the Final Rule for Bedside Sleepers

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

Memorandum

Date: October 30, 2013

TO : Douglas Lee
Project Manager, Bedside Sleepers
Directorate for Engineering Sciences

THROUGH: Mark Kumagai, P.E.
Division Director
Division of Mechanical Engineering
Directorate for Engineering Sciences

FROM : John R. Murphy
Mechanical Engineer
Division of Mechanical Engineering
Directorate for Engineering Sciences

SUBJECT : ESME Recommendations for the Final Rule for Bedside Sleepers

I. Background/Overview

The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act (CPSIA), requires the Commission to: (1) examine and assess voluntary safety standards for durable infant and toddler products, and (2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. Bedside sleepers, which are very similar to bassinets, are under the purview of Section 104 of the CPSIA.

In December 2012, the Commission published a notice of proposed rulemaking (NPR) in the *Federal Register* (77 FR 73345). The NPR incorporated by reference the voluntary ASTM International (American Society for Testing and Materials) standard for Bedside Sleepers (F2906-12), *Standard Consumer Safety Specification for Bedside Sleepers*, with a few modifications. In the NPR, the modifications to ASTM F2906-12 included:

- 1) *Language to address Fabric-Sided Enclosed Openings entrapment hazards.*
- 2) *Language to address Consumer Misassembly with Missing Components.*

The Commission's proposed modifications to ASTM F2194-12 to address bassinet hazards have been discussed in detail in the bedside sleeper and bassinet NPR staff briefing packages.

Specifically, the Commission proposed four changes to the ASTM bassinet standard in the bassinet NPR. Three of those proposed changes to the bassinet standard are also applicable to bedside sleepers: (1) the pass/fail criterion for the segmented mattresses flatness test to make the criterion stricter than what is in the ASTM standard; (2) a new performance requirement for the stability of bassinets with removable bassinet beds (includes new definitions, a test requirement, and test procedure); and (3) a revision to the current stability test procedure specifying the use of a newborn CAMI dummy, rather than the six-month infant CAMI dummy.

Since publication of the bassinet NPR, the Commission published a bassinet final rule that includes five modifications to the ASTM bassinet standard (F2194). Four of the modifications apply to bedside sleepers, including variations of the original three from the NPR package, plus a fourth: (4) Exemption of the Segmented Mattress Flatness Test for Narrow Mattresses. The fifth modification, a scope requirement for multimode products, is already in ASTM F2906-13. As of the submission of this briefing package to the Commission, ASTM has not included any of the four modifications in the current version of F2194. Thus, staff is also recommending that references to F2194 be revised to refer instead to 16 C.F.R. part 1218 when bedside sleepers are tested to the bassinet standard.

This memorandum explains the major issues related to the proposed modifications in the NPR and the suggested changes to the current standard, ASTM F2906-13, *Standard Consumer Safety Specification for Bedside Sleepers*. Also included is a response to related comments submitted in response to the NPR.

II. Public Comments and Staff Responses

There were five comments received on the NPR, including two from consumers, one from the chairman of the ASTM F15 Bedside Sleeper subcommittee, one from a conglomerate of consumer groups (Kids in Danger, Consumer Federation of America, US Public Interest Research Group and Consumers Union), and one from the Juvenile Products Manufacturers Association (JPMA). Two commenters made general statements about the proposed rule; one was supportive, and the other was not supportive. Most of the comments were similar to the comments received for the bassinet and play yard NPRs because bedside sleepers are usually designed on a bassinet base or a play yard base, and most are multiuse or multimode products. Commenters generally requested that the requirements in the bassinet and play yard voluntary standards be finalized before completing a final rule on bedside sleepers.⁷

The comments can be viewed at: www.regulations.gov, by searching under the docket number CPSC-2012-0067.⁸

Generally Supportive

Comment:

⁷ Staff's responses for related bassinet and play yard comments are in their respective final rule briefing packages.

⁸ The bassinet and play yard comments can be viewed at: www.regulations.gov, by searching under the docket number of the specific rulemaking CPSC-2010-0028 (bassinets and cradles), and CPSC-2011-0064 (play yards).

One comment from a parent of three young children supported the proposed rule. The commenter stated that all parents should have “the security of knowing that the sleeper you place your child in has been reviewed for safety concerns.”

Response:

Section 104 of the Consumer Product Safety Improvement Act (CPSIA) requires the Commission to promulgate a consumer product safety standard that is substantially the same as the voluntary standard for bedside sleepers or more stringent than the voluntary standard if the Commission determines that a more stringent standard would further reduce the risk of injury associated with bedside sleepers.

Generally Unsupportive

Comment:

One comment from another parent of three young children supported the manufacturers of products. The commenter contended that the responsibility for the safe use of products lies with the parent of the young child.

Response:

Staff agrees parental responsibility is critical for the safe use of products for children. However, Section 104 requires staff to examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products and to promulgate mandatory standards. Bedside sleepers have been identified as a durable infant or toddler product. Bedside sleepers are similar to bassinets, and in many instances, they also function as bassinets. The Commission has concluded that more stringent requirements would further reduce the risk of injury associated with the product. Accordingly, the Commission is issuing a safety standard for bedside sleepers in response to the direction under section 104 of the CPSIA.

Fabric Sided Enclosed Openings

Comment:

Two comments stated that the fabric-sided enclosed openings requirement needs to be revised to test correctly for the entrapment hazard. The commenters suggested that the changes made to ASTM F2906 be finalized before moving forward with the bedside sleeper final rule.

Response:

Staff agrees. ASTM F2906-13 was recently published, and this revision contains a fabric-sided opening test that staff believes is adequate to address the entrapment hazards. Staff is recommending that the Commission incorporate by reference ASTM F2906-13 for the final rule. Thus, the fabric-sided openings test is already included in the draft final rule, and no further staff recommendations are needed with respect to this comment.

Consumer Misassembly w/Missing Components

Comment:

One commenter stated that the hazards associated with misassembly of play yard bassinet accessories need to be vetted in the ASTM process and finalized in ASTM F406 before being addressed in the bedside sleeper standard.

Response:

Staff agrees. The hazards associated with play yard bassinet accessories that have missing or misassembled supporting rods on a play yard base were recently addressed in the latest version of the play yard standard, ASTM F406-13. The same language has been adopted to address bedside sleeper accessories on a play yard base in ASTM F2906-13. Thus, no additional recommendations from staff are needed with respect to this comment.

Redundant Product Safety Feature

Comment:

One commenter stated that the play yard bassinet accessory misassembly provision requirement in the NPR “may compel manufacturers [. . .] to eliminate redundant safety features that are already a component of the product.” The commenter used mattress support rods as an example of a structure that is not necessary to comply with the voluntary standard but does improve product safety by helping to create a “flatter and more stable sleeping position.” The commenter concluded that the added cost of being required to permanently affix redundant structures would lead to the structures being eliminated to avoid this cost, resulting in compliant, but less safe, products being sold.

Response:

Staff disagrees and notes that this comment has already been addressed in the final rules on the safety standards for play yards and for bassinets and cradles. ASTM stakeholders involved in both play yard and bassinet voluntary standard development have already addressed the issue of mattress support rod misassembly in ASTM F406-13 and ASTM F2194-13; thus, the issue does not need to be addressed in the bedside sleeper final rule.

The ASTM play yard subcommittee and the ASTM bassinet/cradle subcommittee determined that (1) the play yard standard, ASTM F406-13, will address safety issues related to bassinet accessory attachment components (i.e., structures that attach the bassinet accessory to the play yard); and (2) the bassinet standard, ASTM F2194-13, will address mattress support rods (and all other structures that keep the bassinet accessory mattress flat and stable) by revising the segmented mattress flatness test contained in the bassinet standard. ASTM F2194-13 requires that bassinets with removable mattress support rods be tested for mattress flatness both with and without the mattress support rods installed. Since bedside sleepers must also be tested to ASTM F2194-13, the same testing requirements apply to bedside sleepers.

Intellectual property

Comment:

One commenter indicated that there is a patent application pending, detailing 10 different methods to “stiffen a play yard mattress pad before it is used in a play yard bassinet accessory.” The commenter acknowledged that “there may not be any products on the market today that would be impacted by this patent application” but indicated that the CPSC should “evaluate this issue and avoid design restrictions that limit marketplace competition.”

Response:

This comment has already been addressed in the product safety standard for play yards. As the Commission stated, the concern regarding the means of stiffening a mattress pad is no longer an issue for the play yard rule because the play yard bassinet accessory misassembly requirement no longer applies to mattress support rods or any other methods that might be used to stiffen a mattress pad. Instead, the play yard rule only focuses on accessory attachment components that attach the bassinet accessory to the play yard.

Likewise, the bassinet rule, which does address mattress flatness, does not require that a specific design be used to pass the standard. As a result, the bassinet mattress flatness test can be met in a variety of ways without necessarily implicating patented technology.

Requirements for Stability of Removable Bassinet Beds

Comment:

One commenter stated that adding the removable bassinet bed stability requirement is premature. The commenter expressed the belief that the requirement should be removed from the regulation and that ASTM should be allowed to continue work on this.

Response:

This comment has already been addressed in the final consumer product safety standard for bassinets and cradles. The Commission has provided manufacturers with options to meet the removable bassinet bed requirements. The Commission stated in the bassinet rule that any product containing a removable bassinet bed with a latching or locking device intended to secure the bassinet bed to the base/stand, shall comply with at least one of the following: the base/stand shall not support the bassinet bed (i.e., the bassinet bed falls from the stand and contacts the floor or the base/stand collapses when the bassinet bed is not locked on the base/stand); the lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action) in all lateral positions; the sleep surface of the bassinet bed shall be at an angle of at least 20 degrees from a horizontal plane when the bassinet bed is in an unlocked position; the bassinet/cradle shall provide a false latch/lock visual indicator(s). At a minimum, an indicator shall be visible to a person standing near both of the two longest sides of the product; the bassinet bed shall not tip over and shall retain the CAMI newborn dummy. Bedside sleepers are required to be tested to the bassinet standard.

Ambiguity in Catastrophic Failure Evaluation

Comment:

One commenter objected to the 30° tilt requirement in the catastrophic failure test. The commenter expressed the feeling that the requirement is not adequately supported by scientific data. The commenter also expressed the belief that the 30° tilt test is counterintuitive to the typical design approach by manufacturers of building in redundancies that prevent catastrophic failure.

Response:

This comment has already been addressed in the final rule on the consumer product safety standard for play yards. The Commission explained that the catastrophic failure test is an alternative to the permanent affixture test. The Commission stated that the angle of 30 degrees represents a safety factor of three times the 10 degrees maximum safe sleep surface angle of incline. The Commission explained that CPSC staff concluded that an angle of 30 degrees would be sufficiently visually obvious to a consumer, such that the consumer would be discouraged from continuing to use the bassinet. In addition, ASTM stakeholders agreed with CPSC staff that 30 degrees was reasonable and would be considered by caregivers to be obviously hazardous. The Commission noted that CPSC staff, as well as ASTM members, can reconsider the tilt angle requirement should evidence be presented indicating that the angle is too small or large. The Commission also stated that redundancies were resolved because bassinet accessory attachment components are addressed in the play yard standard, and because bassinet accessory mattress support rods are addressed in the bassinet standard. As a result, the play yard bassinet accessory misassembly requirement in F406-13 now only applies to accessory attachment components. Misassembly issues related to mattress support rods are now addressed in ASTM F2194-13, the voluntary standard for bassinets and cradles. ASTM F2194-13 requires that bassinets with removable mattress support rods be tested both with and without the mattress support rods. The bassinet must pass the segmented mattress flatness test contained in ASTM F2194-13 with and without the mattress support rods. In this way, all misassembly issues known to CPSC staff related to play yard bassinet accessories are addressed in either the play yard or the bassinet standard.

Proposed Segmented Mattress Flatness and Pass Fail Rate Comparison w/CPSC Definition

Comment:

One commenter urged CPSC to adopt, rather than rewrite, the ASTM pass/fail criteria for the surface mattress flatness requirement proposed in the bassinet SNPR. The commenter further asserted that the repeated testing to ASTM F2194 surface flatness requirements has shown a tendency toward a lack of repeatability and that an established principle of looking at the mean of several trials should be used.

Response:

This comment has already been addressed in the final rule on the safety standard for bassinets and cradles. The Commission stated that mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented mattresses, where seams could pose a suffocation and positional asphyxiation hazard. Under the Commission's pass/fail criteria, a bassinet attachment with a segmented mattress will fail if any tested seam creates an angle greater than 10 degrees. ASTM F2194-13 allows measured angles between 10 degrees and 14 degrees to pass, as long as the mean of three measurements on that seam is less than 10 degrees. The 14-degree angle was based on an extrapolation of angles formed by dimensions of average infant faces. However, the Commission declined to use the average infant facial dimension as the basis for this requirement. Therefore, instead of using the average infant anthropometrics as a basis for the pass/fail criteria, the Commission adopted the smallest users' anthropometrics to set the test requirement of 10 degrees maximum for each measurement taken. In addition, the bassinet final rule exempts from the mattress flatness requirement bassinets that are less than 15 inches across. The Commission found that these products do not pose the hazard the requirement is intended to address, and they are also not wide enough to test using the required procedures and equipment.

Incorporating Another ASTM Standard by “Reference”

Comment:

Two comments suggested that the CPSC wait for the play yard and bedside sleeper voluntary standards to reach approval and publication and to incorporate the actual language of the requirement within the bedside sleeper standard, rather than reference the standard itself. One of these commenters expressed the belief that additional clarity is provided by not having to reference another standard and keep track of multiple revisions.

Response:

Staff agrees. ASTM F2906-13 now incorporates language from both ASTM F2194-13 and ASTM F406-13. The Bedside Sleeper Accessories -Missing Accessory Attachment Components (Section 5.8) requirement has been incorporated from ASTM F406-13. In addition, the Bedside Sleeper Accessory Fabric-Sided Enclosed Openings (Section 5.7) requirement has been incorporated from ASTM F2194-13, with the addition of the test methods for shells and removable covers. With the exception of the additional shell test requirement, the exact language in ASTM F2906-13 does not change the technical requirement from that recommended in the Bedside Sleeper NPR.

Attachment Mechanism

Comment:

One commenter indicated that a gap between the bedside sleeper and an adult bed creates a risk of injury to an infant in both the bedside sleeper and the adult bed. The commenter recommended that CPSC consider including provisions that require the attachment mechanism to be composed of only one part that is then attached to the bedside sleeper as in the bedrail

standard ASTM F2085-12, section 5.7. The commenter stated that the attachment mechanism would not need to be permanently attached to bedside sleepers that are also used in other modes without the attachment, but all necessary parts for attachment should be connected to each other, reducing the chance that caregivers will leave key elements out of the attachment process.

Response:

CPSC staff is not aware of any incidents in which an infant became entrapped in a gap between a bedside sleeper and an adult bed with or without missing key elements of the attachment mechanism. There are very few single-mode bedside sleeper products. Most bedside sleepers are multiuse with other modes, such as bassinets and play yards. Although the commenter indicated the attachment would not need to be connected permanently when used in other modes that do not require the attachment, CPSC staff is concerned that the attachment could present a risk of injury, such as strangulation or entrapment with the attachment cord or strap, when not in use. The addition of requirements to prevent entrapment in a gap between the bedside sleeper and the adult bed on very few single-mode bedside sleeper products at the expense of adding potential strangulation or entrapment risks does not appear warranted. At this time, staff does not support the inclusion of a requirement for a one-piece attachment device that needs to be installed permanently on single-mode bedside sleepers and removable on bedside sleepers with free standing bassinet or play yard use modes.

IV. Staff-Recommended Changes from the NPR to the Final Rule

A. Post NPR Standard Activity

The two bedside sleeper NPR modifications, the fabric-sided enclosed openings entrapment hazards and the consumer misassembly with missing components requirements, were balloted for inclusion in the ASTM F2906 standard in September 2012, and received two negative votes. As a result of those votes, the two balloted items were revised and reballoted in May 2013. The items passed and were included in the next version of the ASTM standard, F2906-13, which was published in July 2013.

After the NPR for bedside sleepers was published in the Federal Register, the ASTM play yard subcommittee worked closely with the ASTM bassinet/cradle subcommittee to address hazards related to bassinet accessory misassembly. The subcommittees decided to address the hazards associated with bassinet accessory misassembly in two different ASTM standards: (1) the play yard standard, ASTM F406-13, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards, now addresses safety issues related to bassinet accessory attachment components (*i.e.*, structures that attach the bassinet accessory to the play yard); and (2) the bassinet standard, ASTM F2194-13, Standard Consumer Safety Specification for Bassinets and Cradles, addresses safety issues related to mattress support rods (and all other structures that ensure that the bassinet accessory mattress is flat and stable) through the segmented mattress flatness test contained in the bassinet standard. These requirements are now part of the current ASTM standard for play yards, ASTM F406-13, and for bassinets/cradles, ASTM F2194-13.

The balloted (F15(13-01)) misassembly requirement for play yards was revised by defining a “bedside sleeper accessory” and changing “bassinet accessory” to “bedside sleeper accessory.” The task group made additional clarifications to the definition of “accessory attachment components” and the full-size crib requirement (6.18) was removed because it was not necessary for bedside sleepers.

The bassinet fabric-sided opening requirement was revised to address hazards related to bedside sleeper accessories assembled on play yard bases with a lowered side. The revisions were required because some bedside sleepers have shells which, when fastened incorrectly, can lead to entrapment hazards. The language was taken from F2194-12b, Section 6.8 *Fabric-Sided Enclosed Openings* and 7.9 *Fabric Release Test Methods for Enclosed Openings*. The term “bassinet accessory” was changed to “bedside sleeper accessory.” A definition of a “shell” (see Appendix A of this memo) and an associated test were added to address hazardous conditions from sides lowering on a bedside sleeper. The test provides requirements for designs of bedside sleepers that include accessory attachment components attached to the fabric cover when the play yard misassembly requirements were balloted for inclusion in F406.

B. Comparison of the NPR and ASTM F2906-13

The NPR proposed to incorporate by reference ASTM F2906-12 *Standard Consumer Safety Specification for Bedside Sleepers*, with certain modifications to F2906 and F2194 that were proposed in the SNPR for bassinets and cradles.

The current voluntary standard for bedside sleepers, version ASTM F2906-13, differs from the NPR in the following ways:

- 1) *Fabric-Sided Enclosed Openings Performance Test*:
 - ASTM F2906-13 added specific language for the fabric-sided enclosed openings performance requirement to clarify that the referenced requirements in the NPR do apply to bedside sleeper accessories.
 - ASTM F2906-13 no longer has an exemption for fabric-sided enclosed openings on bedside sleeper accessories that collapsed during testing because the exemption is no longer needed.
 - ASTM F2906-13 has a new “shell” definition and test requirements for the Bedside Sleeper Fabric-Sided Enclosed Openings requirement. The definition and test requirement was necessitated post-NPR when the consumer misassembly with missing components requirement was developed in F406.
- 2) *Bedside Sleeper Accessories – Missing Accessory Attachment Components performance requirement*
 - Post-NPR, the consumer misassembly with missing components performance requirement was broken into a play yard bassinets/cradles accessories missing accessory attachments requirement, which was subsequently adapted to a bedside

sleeper accessories missing accessory attachments requirement for F2906 and a bassinet mattress flatness requirement in F2194.

- ASTM F2906-13 added specific language for the bedside sleeper accessories missing accessory attachments performance requirement to ensure that bedside sleeper accessories were tested to this requirement, which was developed for bassinet accessories.

V. ESME Staff-Recommended Changes from the NPR to the Final Rule

The ASTM F2906-13 additional requirements strengthen the voluntary standard and are consistent with the requirements in the NPR. ESME staff recommends that the Commission incorporate by reference, ASTM F2906-13, *Standard Consumer Safety Specification for Bedside Sleepers*, as the federal regulation for bedside sleepers, with modifications as discussed below.

ASTM F2906-13 requires that bedside sleepers are also tested to Consumer Safety Specification ASTM F2194 as the fundamental safety requirements for bedside sleepers. The Commission recently approved the Final Rule for Bassinets and Cradles on September 27, 2013 (16 C.F.R. part 1218) with additional modifications to ASTM F2194. The modifications:

- 1) Added new definitions, a test requirement, and test procedure for a new performance requirement pertaining to the stability of bassinets with removable bassinet beds.
- 2) Revised the current stability test procedure by specifying the use of a newborn CAMI dummy, rather than the six-month infant CAMI dummy.
- 3) Revised the pass/fail criterion for the segmented mattresses flatness test to make it stricter than what is in the ASTM standard.
- 4) Excluded from requiring compliance to the segmented mattress flatness test bassinets that are less than 15 inches wide along the width of the mattress.
- 5) Revised the scope to clarify the intent that multimode or combination products shall meet the requirements of all standards associated with its use modes.

Accordingly, ESME staff recommends that the Commission adopt ASTM F2906-13, *Standard Consumer Safety Specification for Bedside Sleepers by reference*, and require manufacturers to comply with 16 C.F.R. part 1218, the safety standard for bassinets and cradles when testing to ASTM F2194, as required by ASTM F2906-13, Section 5.1. Because the references to ASTM F2194 did not include the subsequent modifications made by the Commission in the bassinet final rule, staff recommends that bedside sleepers reference 16 C.F.R. part 1218, which includes the modifications to the bassinet standard.

Appendix A

Post NPR Revisions to ASTM F2906-13 Standard

Definitions

3.1.3 *bedside sleeper accessory, n*—an elevated sleep surface that attaches to a play yard designed to convert the product into a bedside sleeper and is intended to have a horizontal sleep surface while in a rest (nonrocking) position.

3.1.4 *bedside sleeper accessory attachment components, n*—the components that provide the means of attachment for a bedside sleeper accessory to a play yard (see Fig. 1).

3.1.4.1 *Discussion*—Fasteners used to permanently attach one or more components to each other such as but not limited to screws and rivets are not considered accessory attachment components.

3.1.10 *shell, n*—a textile cover for bedside sleeper accessory that incorporates structural elements such as tubing, permanently attached clips or hooks, or other elements which allow it to be suspended from the play yard frame.



FIG. 1 Example of Bedside Sleeper Accessory Attachment Component

Requirements

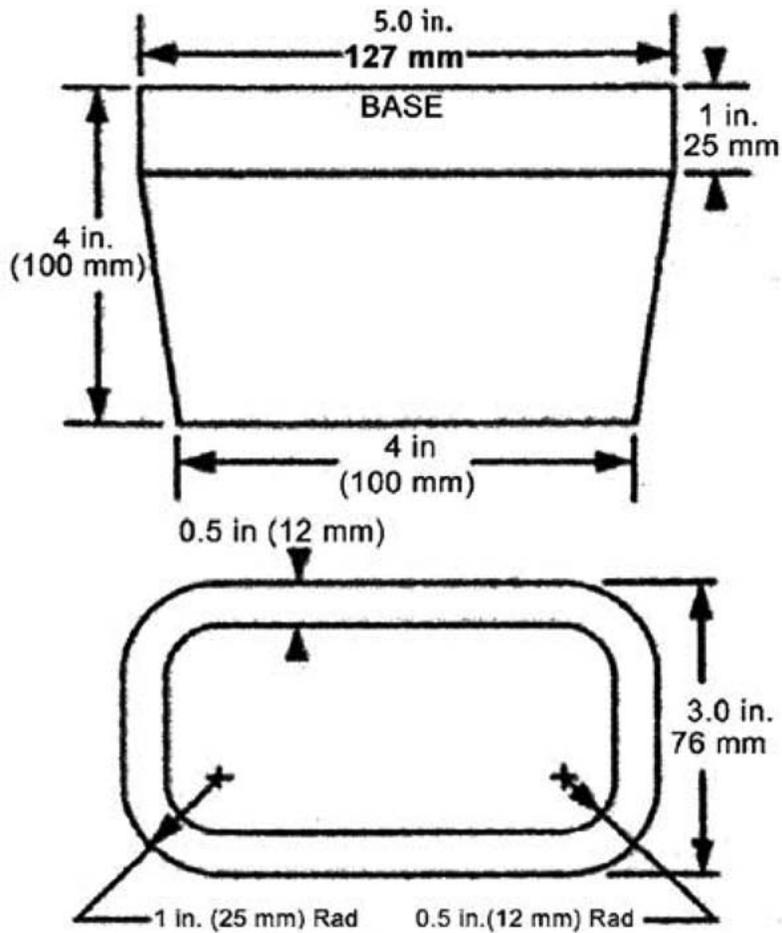
5.7 *Bedside Sleeper Accessory Fabric Sided Enclosed Openings*—For bedside sleeper accessories, a completely bounded opening shall not be created that allows the complete passage of the torso probe (Fig. 2) when tested in accordance with 6.3.

5.8 *Bedside Sleeper Accessories—Missing Accessory Attachment Components:*

5.8.1 Bedside sleeper accessories that have all accessory attachment components permanently attached to the bedside sleeper accessory, or by any permanent means prohibiting their removal from the bedside sleeper accessory, are exempt from the requirements in 5.8.2.

5.8.2 Bedside sleeper accessories which require consumer assembly of accessory attachment component(s), and that can be assembled and attached to the product with any accessory attachment component(s) missing, shall meet either 5.8.2.1 or 5.8.2.2 when each accessory attachment component not permanently attached is removed. 5.8.2.1 The bedside sleeper accessory shall collapse when any part of the mattress pad contacts the bottom floor of the play yard or is not able to support the 4.0 lbm test mass when tested to 6.4.

5.8.2.2 The bedside sleeper accessory sleep surface shall tilt more than 30° when tested to 6.4.



Material: Any rigid Material

NOTE 1—The probe dimensions represent the torso diameter of a 5th percentile 0 to 2-month-old infant.

FIG. 2 Torso Probe

Test Methods

6.3 Fabric Release Test Methods for Enclosed Openings:

6.3.1 Assemble and place the bedside sleeper in the manufacturer's recommended use position. If the bedside sleeper has a non-rocking locking mechanism, place the bedside sleeper in nonrocking mode. For this test, the unit shall be free standing, and not be secured to the test platform as dictated elsewhere in this standard.

6.3.2 With the torso test probe attached to a force gauge, place the small end of the probe against the fabric on the inside wall of the product and between any structural elements in any locations deemed most likely to fail without removing the mattress.

6.3.3 Apply a 20 lb (89 N) force to the probe over a period of 5 s and hold for an additional 10 s.

6.3.4 Upon completion of 6.3.3, without adjusting the fabric, evaluate any additional openings by repeating 6.3.2 and repeat 6.3.3 at these additional locations.

6.3.5 *Shell*—If the product has a shell, unfasten all fasteners, snaps, or both that are not required to suspend the shell to the play yard side (top) rails. Replace mattress in the product and repeat 6.3.2-6.3.4.

6.3.6 If the product has a removable cover, unfasten all fasteners or snaps, or both, but leave cover in place. Replace mattress in the product and repeat 6.3.2-6.3.4.

6.4 *Bedside Sleeper Accessory—Sleep Surface Collapse/Tilt:*

6.4.1 *Equipment*—One 4.0 lbm (1.8 kg) test mass made from an aluminum bar with dimensions 1 by 4 by 10.25 in. (25 by 101 by 260 mm).

6.4.2 Determine the number of removable (that is, not permanently attached to the accessory) accessory attachment components used in the assembly of the bedside sleeper accessory and number them 1 through n , until all removable elements are numbered.

6.4.3 Assemble the bedside sleeper accessory to the product according to manufacturer's instructions.

6.4.4 Establish a horizontal reference plane by placing an inclinometer on the floor of the testing area, and then zero the inclinometer.

6.4.5 Remove accessory attachment component #1 used in the assembly of the bedside sleeper accessory and attempt to assemble the accessory back onto the product.

6.4.5.1 If the accessory can be assembled onto the product without element #1, proceed to 6.4.6.

6.4.5.2 If the accessory cannot be assembled onto the product without element #1, the accessory shall be considered to meet 5.8.2. Proceed to 6.4.8.

6.4.6 Place the 4.0 lbm (1.8 kg) test mass in the center of the sleep surface, oriented parallel with the longest side of the bedside sleeper accessory (see Fig. 3). Visually determine if the bedside sleeper accessory collapses or it no longer supports the test mass within 2 s.

6.4.7 If collapse does not occur, measure the sleep surface's angle of incline relative to the horizontal plane established in 6.4.4 at the location(s) most likely to meet the angle requirement in 5.8.2.2. Record this angle (see Fig. 4).

6.4.8 Replace the removed accessory attachment component.

6.4.9 Repeat 6.4.5-6.4.8 removing and replacing each accessory attachment component (identified in 6.4.2) one at a time, starting with #2 through n and evaluating the resulting condition.

**TAB C: Human Factors Response to Public Comments
(Docket No. CPSC-2012-0067)**

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

Memorandum

Date: August 8, 2013

TO : Douglas Lee
Project Manager, Bedside Sleepers
Directorate for Engineering Sciences

THROUGH: Bonnie B. Novak, Director
Division of Human Factors

FROM : Hope E J. Nesteruk, Human Factors Engineer
Division of Human Factors
Directorate for Engineering Sciences

SUBJECT : Human Factors Response to Public Comments (Docket No. CPSC-2012-0067)

Introduction

The Consumer Product Safety Improvement Act of 2008, Public Law 110–314 (CPSIA) was enacted on August 14, 2008. Section 104 of the CPSIA, also known as the Danny Keysar Child Product Safety Notification Act, requires the Commission to promulgate mandatory 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 Commission proposed a safety standard for Bedside Sleepers in the *Federal Register*⁹ based on the voluntary standard, ASTM F2906-12, “Standard Consumer Safety Specification for Bedside Sleepers.” This notice of proposed rulemaking (NPR) requested comments from the public. Staff is recommending that the Commission incorporate F2906-13 by reference into the final rule, with a few modifications. This memorandum is a response to the human factors-related public comments submitted on docket number CPSC-2012-0067.

Comment: Pictogram

Add pictograms to the warnings to more effectively convey the hazard and avoid language barriers that minimize comprehension of these warning labels. Using the internationally recognized symbol of a red circle with a line through it, the CPSC could draft pictograms showing a prone baby with his or her face on or near a pillow/padding

Response

Human Factors (HF) staff acknowledges that a well-developed and tested pictogram could increase comprehension. However, the design of effective, well-understood graphics can be

⁹ 77 Fed. Reg. 73345 (Dec. 10, 2012).

difficult. Poor understanding of graphics may cause consumer confusion, the most severe of which is a critical confusion, where the graphic is interpreted to mean the opposite of the intention. Therefore, any warning pictogram should be developed with empirical study and well tested on the target audience. In addition, there are a number of products for which a soft bedding pictogram could be useful, such as bedside sleepers, bassinets, cribs, play yards, inclined sleep products, and others. Because of this, staff believes a cross-product working group may be the best place to develop such a pictogram. This could ensure cross-product harmonization of such a pictogram and would allow testing and validation of the pictogram. Staff will gladly participate in any such group, and should the need arise, staff will consider future action once such a graphic is developed.

Comment: Additional suffocation warning language

“In addition, because of the additional hazard of adult bedding nearby, CPSC should add a warning that would advise the caregiver of the danger adult bedding can pose if it is allowed to fall into the bedside sleeper.”

Response

Staff notes that the ASTM task group on bedside sleepers considered this statement. In fact, 2010 task group discussions included the discussions of language such as: “Never permit bedding from the adult bed to extend into the Bedside Sleeper” and “Never allow pillows, blankets, or other adult bedding to enter the Bedside Sleeper.” However, as noted above, the dangers of soft bedding extend to any infant sleeping product, not just bedside sleepers, and the Bassinet standard (ASTM F2194-12b) includes warnings about pillows, blankets, and other soft bedding. Specifically, F2194-12b section 8.4.2 contains the following warning:

8.4.2 SUFFOCATION HAZARD

8.4.2.1 Infants have suffocated:

- In gaps between extra padding and side of the bassinet/ cradle, and
- On soft bedding

Use only the pad provided by manufacturer. NEVER add a pillow, comforter, or another mattress for padding.

To avoid nonharmonized redundancy, in early 2011, the subcommittee decided to harmonize the suffocation warning with bassinets and chose to require the bassinet suffocation warning by reference (*i.e.*, 7.1 All bedside sleeper products shall comply with the marking and labeling requirements of Consumer Safety Specification F2194). HF staff agreed with this harmonization because there were no incidents suggesting that adult bedding products were falling into the bedside sleeper environment and producing a hazard. However, staff does acknowledge this is a foreseeable hazard pattern. HF staff recommends working with the ASTM bedside sleeper subcommittee to consider adding language to the end of the referenced bassinet suffocation warning label, such as: “ALWAYS make sure adult bedding cannot fall into the bedside sleeper” in a subsequent version of the bedside sleeper standard.

Comment: Harmonize instructional and graphical requirements with full-size cribs

We request that consistency be maintained with previously adopted mandatory regulations with regard to assembly instructions and visual indicators as, for example, are demonstrated in the full-size crib requirement (16 C.F.R. part 1219):

8.4.1.4 Check this product for damaged hardware, loose joints, loose bolts or other fasteners, missing parts, or sharp edges before and after assembly and frequently during use. Securely tighten loose bolts and other fasteners. DO NOT use crib if any parts are missing, damaged or broken. Contact (insert manufacturer's name) for replacement parts and instructional if needed. DO NOT substitute parts.

9.1 Instructions shall be provided with the crib and shall be easy to read and understand. These instructions shall include information on assembly, maintenance, cleaning, storage and use, an assembly drawing, a list and description of all parts and tools required for assembly, and a full-size diagram of the required bolts and other fasteners.

Response

HF staff believes that this request is sufficiently addressed in the F2906-12 voluntary standard. Specifically, F2906-12 section 8.2.3 states instructional literature must contain a:

List of all parts required for bedside sleeper mode and the statement: "DO NOT use bedside sleeper if any parts are missing, damaged, or broken. Contact (insert manufacturer's name) for replacement parts and instructional literature if needed. DO NOT substitute parts.

In addition, section 8.1 states that all instructional literature for bedside sleepers must comply with F2194, the voluntary standard for bassinets. Section 9.1 of F2194-12b states:

Instructions must be provided with the product and shall be easy to read and understand. Assembly, maintenance, cleaning, operating, and adjustment instructions, where applicable, must be included.

Therefore, all bedside sleeper instructional literature must follow these requirements. In addition, bedside sleeper on-product labels must have the following information:

7.4.1.3 Always use ALL required parts for each use mode. Check instruction manual for a list of required parts. Periodically check product for loose, damaged, or missing parts.

and

7.4.2.1 Clear instructions for proper assembly and use of the attachment system, including graphics, shall be printed on a permanent label attached to the mattress base or on the product base.

HF staff believes that elements of sections 7 and 8 of F2906-12, as quoted above, address the commenters concerns. Although staff acknowledges that the language is not uniform between the referenced standard (16 C.F.R. part 1219) and the two voluntary standards cited (F2906-13 and F2194-13), the content of the instructional literature throughout the standards is consistent and provides the necessary information.

TAB D: Final Regulatory Flexibility Analysis of the Staff-Recommended Final Rule for Bedside Sleepers; Regulatory Flexibility Analysis of the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Bedside Sleeper Standard

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**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814**

Memorandum

Date: November 14, 2013

TO : Douglas Lee
Project Manager, Bedside Sleepers
Directorate for Engineering Sciences

THROUGH: Gregory B. Rodgers, Ph.D.
Associate Executive Director
Directorate for Economic Analysis

Deborah V. Aiken, Ph.D.
Senior Staff Coordinator
Directorate for Economic Analysis

FROM : Samantha Li
Economist
Directorate for Economic Analysis

SUBJECT : Final Regulatory Flexibility Analysis of the Staff-Recommended Final Rule for Bedside Sleepers; Regulatory Flexibility Analysis of the Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Bedside Sleeper Standard

Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, section 104, the Danny Keysar Child Product Safety Notification Act, requires that the U.S. Consumer Product Safety Commission (CPSC) evaluate the current existing voluntary standards for durable infant or toddler products and promulgate a mandatory standard substantially the same as, or more stringent than, the applicable voluntary standard. While bedside sleepers are not mentioned explicitly in section 104, they are similar to bassinets, and many also function as bassinets which are explicitly mentioned in section 104.

On December 10, 2012, the Commission published a notice of proposed rulemaking (NPR) in the Federal Register (77 FR 73345). The NPR incorporated by reference the voluntary ASTM International (or ASTM, formerly known as the American Society for Testing and Materials) standard for Bedside Sleepers (F2906-12) *Standard Consumer Safety Specification for Bedside Sleepers*, with a few modifications. In April 2013, ASTM balloted a revision to the standard ASTM F2906-12 that contained additional requirements that are included in the NPR modifications. ASTM published a revised standard (ASTM F2906-13) in July 2013.

The ASTM bedside sleeper standard requires bedside sleepers to be tested to the ASTM bassinet standard. The Commission recently issued a mandatory standard for bassinets which is codified at 16 C.F.R. part 1218. Accordingly, for this bedside sleeper standard, the Commission incorporates by reference ASTM F2906-13 with modifications to replace the references to the voluntary bassinet standard (Consumer Safety Specification for Bassinets and Cradles F2194) with references to 16 C.F.R. part 1218.

The Regulatory Flexibility Act (RFA) 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.

The Product

Bedside sleepers are intended for an infant up to approximately 5 months of age (or when a child begins to push up on hands and knees). These products are secured to the side of an adult bed with an attachment system for the purpose of having a baby sleep in close proximity to an adult. One side, adjacent to the adult bed, is lower or can be lowered. Some bedside sleepers are designed to be used in more than one mode (referred to as a “multimode” or “multiuse” product). For example, some bassinet products can be converted to a bedside sleeper product by simply lowering one side.

The Market for Bedside Sleepers

Bedside sleepers are typically produced and/or marketed by juvenile product manufacturers and distributors. Currently, there are at least five known manufacturers supplying bedside sleepers to the U.S. market. Four are domestic manufacturers, including one manufacturer that dominates the market. The fifth is a foreign manufacturer that ships products directly to the United States.¹⁰ 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. Under this program, products voluntarily submitted by manufacturers are tested against the appropriate ASTM standard, and only passing products are allowed to display JPMA's Certification Seal.

Currently, JPMA does not have a Certification Program for bedside sleepers, and no firm claims to meet the ASTM voluntary standard. However, three firms supply multimode products which, in one mode, are compliant with the associated ASTM voluntary standard. Two of these firms claim compliance with the ASTM standard for bassinets; one firm is JPMA-certified as compliant and the other claims compliance with the ASTM bassinet standard. A third firm supplies play yards that are JPMA-certified as compliant with the ASTM play yard/non-full-size crib standard.

National estimates of bedside sleeper product-related injuries are not available because the National Electronic Injury Surveillance System (NEISS) data does not allow for clear identification of bedside sleepers. We also do not have an estimate of the number of bedside sleepers in use. Therefore, the risk of injury associated with the number of products in use cannot be calculated.

Reason for Agency Action and Legal Basis for the Draft Final Rule

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards for nursery products that are substantially the same as, or more stringent than, the voluntary standard. Staff recommends that the Commission incorporate by reference the voluntary standard (ASTM F2906-13) for the bedside sleeper final rule, as modified to reference 16 C.F.R. part 1218, where applicable.

CPSC staff identified 44 incident reports involving bedside sleepers from 2001 to 2013, including the 40 incidents reported in the NPR and four that have been reported since the extraction of data presented in the NPR.¹¹ The CPSC databases searched were the In-Depth

¹⁰ Staff made these determinations using information from Dun & Bradstreet and Reference USA Gov, as well as firms' websites.

¹¹ Memorandum from Risana Chowdhury, Directorate of Epidemiology, dated March 15, 2012, Subject: Bedside Sleeper-Related Deaths, Injuries, and Potential Injuries; 2001-2011 and Memorandum from Risana Chowdhury,

Investigation database, the Injury or Potential Injury Incident database, and the Death Certificate file. CPSC staff identified 27 incidents that may be due to defect or potential design flaws in the product itself. The hazards associated with these incidents included: problems with the adjustable fabric cover over the metal bars on the side that lowered in bedside sleeper model (9 incidents); poor assembly instruction (7 incidents); and miscellaneous other product-related problems (11 incidents). The remaining 17 incident reports were related to CPSC recall notices for bedside sleeper products, where the consumer either sought advice on options regarding a bedside sleeper product they owned that had been recalled, or they inquired whether the product they owned was within the scope of the recall. CPSC staff believes the draft final rule potentially would address the 27 incidents that may have involved a defect or product design hazard.

Compliance Requirements of the Staff-Recommended Final Rule

In the draft final rule, CPSC staff is recommending that the Commission incorporate by reference the current voluntary ASTM standard for bedside sleepers, ASTM F2906-13.¹² The bedside sleeper voluntary standard specifies that manufacturers must comply with the voluntary safety standard for bassinets and cradles (ASTM F2194) if their products are used as bassinets and cradles. The current version of this standard, ASTM F2194-13, was approved on April 1, 2013.

The Commission recently issued a mandatory standard for bassinets which will be codified at 16 C.F.R. part 1218. Accordingly the draft final bedside sleeper rule replaces references to ASTM F2194 with references to the mandatory bassinet rule (16 C.F.R. part 1218) in the current voluntary standard for bedside sleepers, ASTM F2906-13. Thus, because the bassinet rule included five modifications to ASTM F2194-13, bedside sleepers will also need to conform to the modifications contained in the bassinet rule.¹³

Directorate of Epidemiology, dated August 16, 2013, Subject: Bedside Sleeper-Related Deaths, Injuries, and Potential Injuries Reported Between January 24, 2012 and May 15, 2013.

¹² Key components of ASTM F2906-13 include:

- bassinet and cradle requirements – intended to ensure bedside sleepers meet the voluntary bassinet standard (ASTM F2194) requirements, except for the fourth side height requirement;
- multimode requirements – intended to ensure compliance with applicable standards when bedside sleepers are used in additional modes;
- four-inch side height requirement – intended to prevent the infant from rolling out of the side of the bedside sleeper that lowers;
- separation and product disengagement requirements – intended to prevent entrapment between the product and adult bed; and,
- bedside sleeper accessory requirements– intended to prevent entrapments and consumer misassembly.

¹³ The five modifications to F2194-13, contained in 16 C.F.R. part 1218, include:

- A clarification in scope for multimode products;
- An exemption from the mattress flatness requirement for bassinets that are less than 15 inches across;
- A modification to the stability test procedure to use a 7.5 lb newborn CAMI rather than an infant CAMI dummy specified in F2194-13;
- A modification in the mattress flatness performance requirement to allow 10° pass/fail criterion rather than measured angles between 10° and 14° to pass in F2194-13; and,
- A removable bed stability requirement to ensure the stability of bassinets with beds that can be removed from their stand/base without the use of tools.

Most bedside sleepers also function as bassinets and thus are expected to be in compliance with 16 C.F.R. part 1218 by the time the bedside sleeper final rule becomes effective. Hence, they will not be further affected by the requirement to comply with the mandatory bassinet standard. Companies that produce a standalone bedside sleeper or bedside sleeper accessory are not expected to be in compliance with 16 C.F.R. part 1218, but will need to be once the bedside sleeper rule becomes effective. Currently, there are two firms in the U.S. that produce such standalone products and could experience impacts due to the requirement to comply with the additional requirements in the mandatory bassinet standard.

A bedside sleeper that can be used in modes in addition to or other than the bassinet mode would also need to meet the applicable standards for the other modes. For example, a bedside sleeper product that converts into a play yard would have to meet the play yard standard (16 C.F.R. part 1212) when used in the play yard mode. Currently, all multi-mode bedside sleepers in the U.S. market include a bassinet mode and, as discussed above, are expected to be in compliance with the mandatory bassinet standard by the time the bedside sleeper final rule becomes effective. The mandatory bassinet standard already covers these multi-mode products, so the requirement to comply with the applicable standards for other modes is not expected to have any additional impact.

Under ASTM F2906–13, the lowered side of the bedside sleeper must be a minimum of four inches in height. The height requirement for sides that cannot be lowered is identical to that of bassinets, seven and one-half inches. It is possible that a few firms will need to modify their product in order to comply. Some products will need to add a permanent fourth side and some may need to raise the fourth side so that it meets the minimum four inch side height. However, based upon the nature of the product, the modifications represent only minor changes in product design. Therefore, staff believes the requirement should not pose a substantial cost to any of the firms supplying bedside sleepers to the U.S. market.

The standard also requires that the gap between the bedside sleeper and adult bed should not be more than one-half inch when the bedside sleeper is secured to the bed. Firms may need to modify the attachment system to meet the minimum requirement by adjusting the anchor and/or straps to reduce stretching and to limit slippage. If little or no additional materials are needed, then any increase in material costs due to the standard should be zero or small as well. Alternatively, firms may opt to redesign their attachment system, which could be more costly.

Bedside sleeper accessories must also meet the fabric sided enclosed opening and consumer misassembly requirements. These requirements are only slight variations from the “Fabric Sided Enclosed Openings” and “Bassinet/Cradle Accessories- Missing Accessory Attachment Components” requirements in the current bassinet and play yard mandatory standards, with which most manufacturers need to comply prior to any effective date for a final bedside sleeper standard. Any modifications to meet the two bedside sleeper accessory requirements are minor due to the similarities with the bassinet and play yard requirements and, therefore, staff believes the incremental costs would be small.

Issue Raised by Public Comment

There was one issue raised by public comment in response to the Initial Regulatory Flexibility Analysis prepared for the NPR. The commenter recommended that the CPSC add a marking on products that are manufactured after the effective date so that consumers can clearly identify products that meet the mandatory standard.

On February 13, 2013, a final rule implementing *Testing and Labeling Pertaining to Product Certification*, 16 C.F.R. part 1107 (the 1107 rule), became effective. Under the 1107 rule, a manufacturer or importer may label a certified compliant product as “Meets CPSC Safety Requirements.” Because producers are already allowed to label compliant products as such under the 1107 rule, including this option in the bedside sleeper standard would be redundant. Therefore, staff recommends no change to the draft final rule based on this comment.

Other Federal Rules

There are two federal rules that would interact with the bedside sleeper mandatory standard: (1) *Testing and Labeling Pertaining to Product Certification* (16 C.F.R. part 1107); and (2) *Requirements Pertaining to Third Party Conformity Assessment Bodies* (16 C.F.R. part 1112).

The testing and labeling rule (16 C.F.R. part 1107) requires that manufacturers of children’s products subject to product safety rules certify, based on third party testing, that their children’s products comply with all applicable safety rules. Because bedside sleepers will be subject to a mandatory rule, they will also be subject to the third party testing requirements when the bedside sleeper rule becomes effective.

In addition, the 1107 rule requires the third party testing of children’s products to be conducted by CPSC-accredited laboratories. Section 14(a)(3) of the CPSA required the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformance assessment bodies (*i.e.*, testing laboratories) to test for conformance with each children’s product safety rule. The NORs for existing rules are set forth in 16 C.F.R. part 1112. Consequently, staff is proposing an amendment to 16 C.F.R. part 1112 that would establish the requirements for the accreditation of testing laboratories to test for compliance with the bedside sleeper final rule.

Impact on Small Business

The regulatory flexibility analysis concerns the four domestic firms known to be marketing bedside sleepers in the United States. We limit our analysis to domestic firms because U.S. Small Business Administration (SBA) guidelines and definitions pertain to U.S.-based entities. Under SBA guidelines, a manufacturer of bedside sleepers is a small business if it has 500 or fewer employees. Based on SBA guidelines, all four domestic manufacturers known to be supplying the U.S. market are small.

One purpose of the regulatory flexibility analysis is to evaluate the impact of a regulatory action and determine whether the impact is economically significant. While the SBA gives considerable flexibility in defining economically significant, staff typically uses 1 percent of gross revenue as the threshold for determining economic significance. Any impact that is 1 percent or more of gross revenue is considered economically significant. The 1 percent of gross revenue threshold has been accepted by the SBA and is commonly used by agencies in determining economic significance.¹⁴

The impact of the draft final rule on small domestic manufacturers depends on two factors: (1) whether their products are multiuse products and are already in compliance with one or more existing standards; and (2) the proportion of their total sales or revenue that bedside sleepers constitute.

Three of the four domestic manufacturers produce a multiuse product or a product that may be used as a bedside sleeper as well as a bassinet or play yard. These three multiuse products are required to comply with other existing standards, and there is significant overlap between standards. For example, firms that produce multimode bedside sleeper/play yards are already required to comply with the mandatory play yard standard. In addition, these three multiuse products also function as bassinets and will need to be in compliance with bassinet standard prior the effective date for the bedside sleeper final rule. If the products comply with applicable standards pertaining to other use modes, the bedside sleeper draft final rule will only require slight, incremental modifications. Thus, the three producers of multiuse products are unlikely to experience an economically significant impact due to bedside sleeper draft final rule.

Two of the domestic manufactures rely almost solely on the sales of bedside sleepers, including a bedside sleeper accessory, as their revenue source. This includes one of the firms mentioned above who produces a multiuse product that will need to comply with an existing standard prior to any effective date for the bedside sleeper draft final rule. Again, this firm should not experience a significant economic impact.

The second firm, however, produces a product that serves as a standalone bedside sleeper which would not have been previously required to meet any standard. At the time of the NPR, this firm's standalone bedside sleeper would have needed several modifications to meet the draft final rule, and its plans for modifying its product are unknown as are its costs of compliance. Even if the cost of each modification taken individually is small, total costs of compliance could be relatively high. Because the majority of this firm's revenues is tied to bedside sleepers and because several modifications may be needed, it is more likely that this firm will experience an economically significant impact.

Under section 14 of the CPSA, bedside sleepers are also subject to third party testing and certification. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, *Testing and Labeling Pertaining to Product Certification* (16 C.F.R. part 1107).

¹⁴ Small Business Administration Office of Advocacy. A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act and Implementing the President's Small Business Agenda and Executive Order 13272. May 2012, pgs. 18-20. http://www.sba.gov/sites/default/files/rfaguide_0512_0.pdf

Third party testing will pertain to any physical and mechanical test requirements specified in the bedside sleeper final rule; lead and phthalates testing is already required. Third party testing costs are in addition to the direct costs of meeting the bedside sleeper standard.

Based on information from the durable nursery product industry and confidential business information supplied for the development of the third-party testing rule, staff estimates that testing to a single ASTM voluntary standard could cost around \$500–\$600 per model sample. On average, each small domestic manufacturer supplies two different models of bedside sleepers to the U.S. market annually. Therefore, if third-party testing to the requirements in the bedside sleeper standard were conducted every year on a single sample for each model, third-party testing costs associated for each manufacturer would be about \$1,000-\$1,200 annually. Based on an examination of estimates of firms’ revenues from recent Dun & Bradstreet reports, the impact of third-party testing to ASTM F2906–13 is not likely to be economically significant if only one bedside sleeper sample per model is required. However, if more than one sample would be needed to meet the testing requirements, third-party testing costs could have an economically significant impact on two of the small manufacturers (*i.e.*, testing costs could be 1 percent or more of gross revenue). It is unknown exactly how many samples will be needed to meet the “high degree of assurance” criterion as required in 16 C.F.R. part 1107.

Alternatives

One alternative would be to set an effective date later than the staff-recommended six months, which is generally considered sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule. Setting a later effective date would allow suppliers additional time to modify or develop compliant bedside sleepers and spread the associated costs over a longer period of time. However, given that the changes to meet the standard are not substantial, staff believes that six months is sufficient.

The 1112 Rule and the Impact on Small Conformity Assessment Bodies

In accordance with section 14 of the CPSA, children’s products that are subject to a children’s product safety rule must be tested by one of the accredited conformity assessment bodies (*i.e.*, testing laboratories) for compliance with applicable product safety rules. These accreditation requirements have been codified for existing rules at 16 C.F.R. part 1112. Consequently, staff is proposing an amendment to 16 C.F.R. part 1112 that would establish the accreditation requirements for these testing laboratories that want to test for compliance with the bedside sleeper final rule. This section assesses the impact of the amendment on the small laboratories.

A Final Regulatory Flexibility Analysis (FRFA) was conducted as part of the original 1112 rule (78 FR 15836, 15855-58), as required by the Regulatory Flexibility Act. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small testing laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that

were expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

Based on similar reasoning, amending the rule to include the NOR for the bedside sleeper standard would not have a significant adverse impact on small laboratories. Additionally, based on the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the bedside sleeper carrier standard. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards and the only costs to them would be the cost of adding the bedside sleeper standard to the scope of their accreditation. As a consequence, the Commission could certify that the NOR for the bedside sleeper standard will not have a significant impact on a substantial number of small entities.