The contents of this document will be discussed at the open Commission Meeting (Briefing) scheduled for October 31, 2012.

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

This document has been electronically approved and signed.

DATE: October 17, 2012

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: November 7, 2012

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Mary T. Boyle, Acting General Counsel
Kenneth R. Hinson, Executive Director

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

SUBJECT: Notice of Proposed Rulemaking: Safety Standard for Bedside Sleepers

The Office of the General Counsel is providing for Commission consideration the attached draft proposed rule for publication in the *Federal Register*. The proposed 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.)

_____

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_____

_____ _____
(Signature) (Date)

Attachment: Draft *Federal Register* Notice of Proposed Rulemaking - Safety Standard for Bedside Sleepers

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1222

Docket No. CPSC-2012-

Safety Standard for Bedside Sleepers

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Proposed Rulemaking.

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 proposing a safety standard for bedside sleepers in response to the direction under Section 104(b) of the CPSIA.

DATES: Submit comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**]**.

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2012- , may be submitted electronically or in writing:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: http://www.regulations.gov. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer directly accepting comments submitted by electronic mail (e-mail), except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions in the following way: Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to http://www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov, and insert the docket number, CPSC-2012- , into the "Search" box and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Douglas A. Lee, Project Manager, Directorate for Engineering Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone 301-987-2073; e-mail dlee@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008, (CPSIA, Pub Law 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.

In this document, the Commission is proposing a safety standard for bedside sleepers. 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 beside sleepers are accessories to play yards/non-full-size baby cribs. On October 3, 2012, the Commission approved a notice of proposed rulemaking (NPR) for a Safety Standard for Bassinets and Cradles (http://www.cpsc.gov/library/foia/foia12/brief/bassinetnpr.pdf). The Commission has issued a Safety Standard for Play Yards, codified at 16 CFR part 1221. Recently the Commission has proposed specific language to address hazards due to misassembly of play yard bassinet

accessories in a notice of proposed rulemaking (77 FR 52272, August 29, 2012). This proposed rule, if finalized, would amend the Safety Standard for Play Yards. The proposed rule for beside sleepers would adopt many of the requirements in the proposed NPR for bassinets, as well as address the hazards associated with the use of bassinet play yard accessories that can be assembled with missing key structural requirements for bedside sleeper play yard accessories.

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 proposed standard is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2906-12, "Standard Consumer Safety Specification for Bedside Sleepers" (ASTM F2906-12), with additions to make the standard more stringent. The ASTM standard is copyrighted, but it can be viewed as a read-only document, only during the comment period on this proposal, at: http://www.astm.org/cpsc.htm, by permission of ASTM.

B. The Product

ASTM F2906-12 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 that permits newborns and infants to sleep close by an adult without being in the adult bed. In current products, the horizontal sleep surface is typically 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 lowered, thereby differentiating bedside sleepers from bassinets, where all four sides of a bassinet are the same height. 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. Current bedside sleepers range in size from about 35″ x 20″ to 40″ x 30.″ They may have rigid sides, but they are most commonly constructed with a tube frame covered by mesh or fabric.

Freestanding bassinets are not covered under the proposed standard for bedside sleepers. They are covered under ASTM F2194-12a, "Standard Consumer Safety Specification for Bassinets and Cradles."

Several manufacturers produce multiuse (or multimode) bedside sleeper products that convert into bassinets and/or play yards. Most bedside sleeper products can be converted into a bassinet by raising the lowered side to have four equal-height sides, and a few also convert into 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 have been evaluated by CPSC staff 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 product that converts into a play yard and a bassinet would have to meet: ASTM F2906 bedside sleeper requirements, ASTM F2194 bassinet requirements (except for height of the fourth lowered side for bedside sleepers) and sections of the ASTM F406 play yard requirements applicable to bassinets when in the bedside sleeper mode; ASTM F406 play yard requirements when in play

yard use mode; and ASTM F2194 bassinet requirements and applicable sections of ASTM F406 play yard requirements when in bassinet mode.

To ensure consistency with the existing and proposed standards for bassinets and play yards, the Commission is proposing additions to the scope and performance requirements of a bedside sleeper, as discussed below.

C. The Voluntary Standard--ASTM F2906

ASTM first published a voluntary standard for bedside sleepers, ASTM F2906-11, in December 2011. It required bedside sleepers to meet the voluntary standard requirements of the product upon which it was based, either a play yard/non-full-size baby cribs, ASTM F406 (play yard standard) or a bassinet, ASTM F2194 (bassinet standard). The standard also addressed hazards specific to bedside sleeper products. It 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 ensured 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 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. And, 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 served to mitigate the foreseeable head and neck entrapment hazards posed by bedside sleepers. The standard requires a minimum 4-inch lowered side height over which a child is unlikely to be able to roll. In addition, latching and locking devices are evaluated to prevent unintentional movement of the side that lowers and to ensure overall product integrity.

In 2012, the standard for bedside sleepers was changed from meeting either ASTM F406 (play yard standard) or ASTM F2194 (bassinet standard), to require all products to meet ASTM F2194 only. The bassinet minimum side-height requirement (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) is also required for beside sleepers, with the exception of a 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 they are used by children with the same developmental abilities and for the same purpose. Many bedside sleepers also function as bassinets. By requiring beside sleepers to be tested to ASTM F2194 (bassinets) rather than to ASTM F406 (play yards), ASTM made the bedside sleeper standard more stringent because there are bedside sleeper hazards covered by the bassinet standard but that are not covered by the play yard standard. Additionally, ASTM F406 requires a bassinet accessory on a play yard structure to meet the applicable sections of the play yard voluntary standard. These changes were incorporated into ASTM F2906-12, "Standard Consumer Safety Specification for Bedside Sleepers," in July 2012.

CPSC staff also reviewed mandatory and voluntary international standards in Canada, the European Union, Australia, and New Zealand. There are some international standards governing safe sleep products for infants; however, there are no specific requirements that address the hazards unique to bedside sleeper products. Canada has a mandatory standard for cribs, cradles, and bassinets, SOR/2010-26; the European Union uses *EN 1130 Cribs and Cradles* and *EN 12790 Child Care Articles – Reclined Cradles* to assess and market various design elements and

structures in bedside sleeper products. In Australia and New Zealand, several standards exist for safe sleep products– AS/NZS 2172:2003 *Cots* (full-size and non-full-size cribs that do not fold); AS/NZS 2195:1999 *Folding Cots* (play yards and folding cribs of any size); AS/NZS 4385:1996 *Infants' Rocking Cradles* (cradles and bassinets that tilt.)

The Juvenile Products Manufacturers Association (JPMA) has a certification program for a variety of juvenile products, including bassinets and play yards. Manufacturers that voluntarily obtain JPMA certification submit products to an independent test laboratory for conformance testing to the most recent version of the voluntary standard. Manufacturers have 6 months after publication of a new or revised standard to certify products to the new requirements. Currently, JPMA does not have a certification program for bedside sleepers, and no firm claims to meet the ASTM voluntary standard, ASTM F2906-12. However, three firms supply multimode products, where one mode is 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.

D. Incident Data

CPSC staff identified 40 cases of bedside sleeper-related incidents from 2001 to 2011. The CPSC databases searched were the In-Depth Investigation database, the Injury or Potential Injury Incident database, and the Death Certificate file. 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. Therefore, the risk of injury associated with the number of products in use cannot be calculated.

CPSC staff is aware of four fatalities and 36 nonfatal incidents (with and without injuries) related to bedside sleepers that were reported from January 2001 through December 2011. Bedside sleepers have been on the market since 1997. During this time, there have been two recalls for product defects that created a substantial product hazard. One recall involved four deaths, three from head entrapment and one from suffocation, and several complaints on the same entrapment hazard from a bedside sleeper with a bassinet base. This recall involved 3-in-1 and 4-in-1 convertible bassinets that contained metal bars covered by an adjustable fabric flap, attached with Velcro,® that folded down when the bassinet was converted into a bedside sleeper. If the Velcro® was not resecured properly when the flap was adjusted, an infant could slip through the opening and become entrapped in the metal bars and suffocate. Because of additional incidents, this recall was re-announced three times. There were 900,000 units recalled. The second recall involved a bedside sleeper with a play yard base. There were 10 reports of infants falling from the mattress into the bottom of a bedside sleeper or becoming entrapped between the edge of the mattress and the side of the bedside sleeper. There were 76,000 units recalled. Details of the recalls can be found on the cpsc.gov website.

1. Fatalities

All four reported fatalities involved the same brand of recalled bedside sleeper/bassinet. In all four cases, the product was being used in the bassinet mode, with the adjustable side raised at the time of the incident. Three of the deaths were due to entrapment and/or hanging, which resulted after an infant's body, but not head, slipped through the fabric covering and underlying structural components of a particular brand of bedside sleeper. In two of these three fatalities involving a 4-month-old and a 6-month-old decedent, the infant's head was entrapped between the lower horizontal bars (of the adjustable side) and the top of the mattress. The fabric flap

designed to cover the metal bars was not in place. In the third fatality, the fabric flap covering the adjustable side was not secured to the permanent fabric siding, and the horizontal bars of the adjustable side were broken/missing. As a result, the 6-month-old decedent's body slipped out through an opening in the fabric siding, but her chin/throat got caught on a lower crossbar. The fourth death occurred when an infant moved into a corner where the fabric covering the adjustable side was not secured by the Velcro® strip and the bassinet was also missing the lower rail. This created a pocket between the side and bassinet floor. The infant was found with their head in the pocket and face against the side of the bassinet, resulting in suffocation.

2. Nonfatal Incidents

Of the 36 nonfatal incidents, there were three reported injuries involving infants, none hospitalized, during the use of a bedside sleeper. All of the injured infants were under 5 months of age, which is within the ASTM recommended user age range. Two of the infants suffered bruising when they were entrapped between the metal rungs of the same product that had caused three of the fatalities described in the previous section. The third injury occurred when the infant rolled into a position where his neck was hyperextended into a non-breathable corner of the product, and he suffered respiratory difficulties. In all three cases, the caregiver was nearby to prevent any serious consequences.

The remaining 33 reports indicated that no injury occurred or provided no information about any injury. However, many of the descriptions in the reports indicated the potential for a serious injury, or even death, in bedside sleepers. In cases where victim age was reported, six reported ages between 6 months and 8 months old; the other infants were under 5 months of age.

3. Hazard Pattern Analysis

CPSC staff considered all 40 incident reports to identify the hazard patterns associated with bedside sleeper-related incidents. The hazard scenarios in 24 of the 40 incidents (60 percent) reported were attributed to some sort of failure/defect or a potential design flaw in the product. This category includes the four fatalities and three non-hospitalized injuries. Listed below are the reported problems, beginning with the most frequently reported concerns:

- A problem with the adjustable fabric cover over the horizontal metal bars on the side that lowers in the bedside sleeper mode was responsible for nine of the reported incidents. These included all four fatalities and two of the injuries. All of these incidents involved one particular manufacturer's bedside sleeper/convertible bassinet product, which was recalled in 2008. Two of the fatalities occurred before the CPSC recall; the third, which involved a secondhand product in poor condition, occurred after the 2008 recall, but prior to the 2009 recall (which was an expansion of the 2008 recall). Between the two injuries, one occurred prior to the 2008 recall, while the other occurred after that recall. Neither of the post-recall incident reports indicated whether the consumers were aware of the recall.
- Issues with assembly instructions were identified in six reported incidents. In all of these reports, the consumer had misassembled the product but reported the product as being faulty. None of the incidents resulted in any injury or fatality. All but one of these incidents involved one particular manufacturer's bedside sleeper, which was recalled in 2011.
- Miscellaneous other product-related issues**,** such as non-levelness of the product (two reports), instability of leg extensions (two reports), poor design (two reports), broken component (one report), failure of the attachment (to adult bed) mechanism (one

report), and unclear age labeling (one report) were reported in the remaining incident reports. One incident reported an injury associated with poor product design.

- In response to CPSC recall notices, there were 16 non-incident reports of concerns or complaints. In these reports, the consumer either sought advice on options regarding a bedside sleeper product they owned that had been recalled, or they inquired about whether the product they owned was within the scope of the recall.

E. Proposed Changes to ASTM F2906-12

CPSC staff identified 24 incidents due to defect or potential design flaws in the product. 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 proposes 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. Section 5 (Performance Requirements) of ASTM F2906-12 requires that in addition to the tests provided in ASTM F2906-12, the bedside sleeper must be tested to the bassinet standard (ASTM F2194). Specifically, section 5.1 provides that:

> Prior to or immediately after testing to this consumer safety specification, the bedside sleeper must be tested to Consumer Safety Specification F2194. Multi-mode products must also be tested to each applicable standard. When testing to Consumer Safety Specification F2194 the unit shall be free standing, and not be secured to the test platform as dictated elsewhere in this standard.

Because bedside sleepers already are required to be tested to the applicable bassinet standard requirements, and multimode products, to each applicable standard, the Commission proposes in this rule to add clarifying language to ensure that the requirements that are not yet included in an

existing standard or proposed in an NPR (*i.e.*, ASTM F406-12a (play yards) and ASTM F2194-12 (bassinets)) are also included in ASTM F2906-12 (bedside sleepers).

1. Fabric-Sided Enclosed Openings

The current version of ASTM F2194-12a (bassinets) contains a *Fabric-Sided Enclosed Openings'* performance requirement for bassinets. This requirement prohibits completely bounded openings large enough to permit passage of an infant's torso. The hazard scenarios addressed by this requirement encompass the three strangulation deaths described above and a related, foreseeable suffocation hazard. These hazards occur when a child passes through an opening, either becomes trapped between the liner and mattress pad and suffocates, or becomes suspended by the neck, and then strangles. This hazard, associated with a recall of 900,000 units, led to three of the four fatalities on a bassinet that converts to a bedside sleeper. The bassinet test procedure (ASTM F2194-12a, section 7.8) attempts to push a torso probe the size of a 5th percentile infant through bounded openings with 20 lbs of force. The test is first performed with product assembled per the manufacturer's instructions. If the product has a removable cover, it is performed a second time after all fasteners or snaps are unfastened, but the removable cover left in place. In doing so, the test intentionally replicates the incorrectly secured fabric liner hazard scenario of the fatal incidents.

A manufacturer's bedside sleeper accessory exhibited this hazard, which led to its recall in 2011. The recall was initiated in response to incident reports in which the bedside sleeper accessory's removable cover (liner or shell) was either not used, or was present but not secured to the play yard frame. This bedside sleeper accessory can also be used as a play yard, or a bassinet accessory to a play yard. When in the bassinet accessory position, the front side of the product can be lowered, transforming it into the beside sleeper mode. A 1 ½-year-old unused sample of this

product was recently retested by CPSC staff, confirming that it fails the ASTM F2194 fabric-sided enclosed opening requirement. However, a new sample of a similar model from the same manufacturer passed this test. Staff identified two possible reasons for testing variances. One explanation is that the fit of the shell to the play yard frame becomes looser with repeated assembly and disassembly. The other reason is that the seam joining the mesh and fabric part of the liner may be in a slightly different location on some models. The seam may cause sufficient friction on the torso test probe during force testing on some models. Accordingly, minor changes in materials or construction may not be sufficient to remedy the hazard presented by the fabric-sided, bounded opening hazard.

Under section 6.7 of ASTM F2194-12, for bassinets/cradles with fabric sides, a completely 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 bassinets or play yard accessories. Bassinets 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; test labs would likely consider that a failure. However, for bassinets that convert to a bedside sleeper with a lowered side, CPSC staff determined that all bedside sleeper play yard accessories should be subject to the requirements of the ASTM F2194-12 bassinet standard's section 6.7 *Fabric-Sided Enclosed Opening* without the exemption for bassinet play yard accessories, given the demonstrated hazards presented when a bedside sleeper's removable cover (liner or shell) is either not used, or not secured properly.

The Commission proposes additional language for the ASTM F2906 bedside sleeper standard 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. Unlike bassinet play yard accessories, bedside sleeper (or a bassinet that is converted into a bedside sleeper) play yard accessories could have fasteners left unclipped (through the detachment of snaps/Velcro) where the bedside sleeper with the lowered side does not completely collapse. Because the bedside sleeper could still appear functional, the Commission proposes to add language under Section 3 (Terminology) of ASTM F2906-12. The new proposed section 3.1.8 would state: "*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." The Commission also proposes to add a new proposed section 5.7, stating: "a *Bedside Sleeper Accessory Fabric-Sided Enclosed Openings*—A bedside sleeper accessory shall meet the F2194 performance requirement "*Fabric-Sided Enclosed Openings."* Under new proposed section 5.7.1, bedside sleeper accessories would be exempt from this requirement if either of the following two conditions were met after disengaging all fasteners between the accessory and the non-full-size crib or play yard base to which it is assembled: (1) the bedside sleeper accessory collapses under its own weight, such that any part of the mattress pad contacts the bottom floor of the non-full-size crib or play yard (5.7.1.1); or (2) the bedside sleeper accessory's sleep surface tilts by more 30 degrees (5.7.1.2). These requirements are also consistent with the proposed requirements in the NPR for the Safety Standard for Play Yards for play yard bassinet accessory misassembly provisions, which require all key structural elements to be attached permanently to the bassinet shell. The second method of

compliance is to meet a catastrophic failure test, where a missing key structural element makes the product collapse completely or tilt more than 30 degrees. 77 FR 52273.

2. Consumer Misassembly with Missing Components.

The Commission proposed a requirement to address consumer misassembly of key structural elements for bassinet accessories to play yards in the NPR for the Safety Standard for Play Yards, 77 FR 52272. However, the NPR for play yards did not include specific language for bedside sleeper play yard accessories. Although section 5 (Performance Requirements) of ASTM 2906-12 provides that bedside sleepers must be tested to ASTM F2194 (bassinets), and multimode products must also be tested to each applicable standard, the Commission proposes to add language to ASTM 2906-12 (bedside sleepers) to make explicit that the requirements for addressing consumer misassembly of key structural elements is required for bedside sleeper play yard accessories in addition to bassinet play yard accessories.

As described at length in the NPR for the Safety Standard for Play Yards, 77 FR 52272, omission of key structural elements of a bassinet assembly (such as rods, tubes, bars, and hooks that keep the sleep surface flat and level) could result in a tilt in the sleeping surface and put the infant in a position where he or she is unable to breathe and is at risk of suffocation. This hazard is magnified should these misassembled products be used as an unsupervised sleep environment, another reasonably foreseeable scenario. Similarly, a misassembled bedside sleeper play yard accessory may not be readily apparent or obvious to the consumer. If the misassembled accessory supports an infant without a catastrophic and obvious change to the sleep surface, a consumer may continue to use the misassembled accessory and inadvertently place a child in danger. Bedside sleeper accessories and bassinet accessories incorporate very similar designs and manufacturing processes (because many bedside sleepers also function as bassinets), and many of

the same performance requirements are applicable to both products. Accordingly, in order to ensure that all of the hazards associated with bedside sleeper play yard accessories and bassinet play yard accessories that can be assembled missing key structural elements are addressed, the Commission proposes to add under section 5 (Performance Requirements) to ASTM F2906-12, new proposed section 5.8 *Bedside Sleeper Play Yard Accessories Missing Key Structural Elements.* The new section 5.8 will provide: A bedside sleeper accessory shall meet the F406 general requirement, "Bassinet/Cradle Accessories Missing Key Structural Elements."

3. New Requirements for Bassinets

ASTM F2906-12 already requires bedside sleepers to meet the requirements of the bassinet standard, ASTM F2194 "Standard Consumer Product Safety Specification for Bassinets and Cradles," 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. The Commission's proposed modifications to address bassinet hazards in ASTM F2194-12 have been discussed in great detail in the NPR and in the Bassinet NPR staff briefing package. Specifically, the Commission proposed four changes to the ASTM bassinet standard. Three of those proposed changes to the bassinet standard would also be applicable to bedside sleepers. The fourth proposed change would update the scope and corresponding terminology specific to bassinets under ASTM F2194, and it is not applicable to bedside sleepers. Three of the proposed requirements that would apply to bedside sleepers include: (1) Segmented Mattress Flatness Requirement and Test Method; (2) Removable Bassinet Bed Stability; and (3) Stability Test Dummy. Because bedside sleepers are already required to be tested to the bassinet standard, ASTM F2194, there is no need to add language to the bedside sleeper standard proposing these requirements and test methods. Accordingly, if the proposed changes to ASTM

F2194 are finalized, bedside sleepers will also be required to meet the following requirements and test methods in addition to all other applicable requirements in ASTM F2194. The following proposed changes to the bassinet standard would also be applicable to bedside sleepers:

A. Proposed Segmented Mattress Flatness Requirement and Test Method (Sections 6.9 and 7.10 of ASTM F2194-12a)

In order to address the hazard of suffocation/positional asphyxia due to an excess mattress pad angle, the Commission proposed performance requirements and a test method for the minimum flatness of mattress surfaces. This requirement would apply to segmented mattresses, such as those seen in a bassinet accessory to a play yard. The Commission proposed that the segmented mattresses commonly used in play yards shall not create an angle greater than 10 degrees when tested using a 17-pound cylinder to simulate the weight of a 6-month-old infant. This performance requirement and test method would also apply to a segmented mattress used in a bedside sleeper accessory to a play yard.

B. Proposed New Performance Requirement and Associated Definitions to Address Hazards Associated with the Stability of Removable Bassinet Beds (Sections 3.1.3, 3.1.17, 3.1.18, 3.1.19, 3.1.20, 6.10, 7.11 of ASTM F2194-12a)

In order to address hazards associated with misassembly of removable bassinet beds, the Commission proposed performance requirements and a test method for products that have bassinet beds that attach to an elevated stand. The requirements would apply to removable bassinet beds that are designed to separate from the stand/base without the use of tools. The Commission proposed that if a removable bassinet bed is not properly attached or assembled to its base, it must meet one of the following requirements:

- The base/stand shall not support the bassinet (*i.e.,* the bassinet bed falls from the stand so that it is in contact with the floor); or
- The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action); or
- The stand/base shall not be capable of supporting the bassinet bed within 20 degrees of horizontal; or
- The bassinet shall contain a visual indicator mechanism that shall be visible on both sides of the product; or
- The bassinet bed shall not tip over and shall retain the CAMI newborn dummy when subjected to the stability test outlined in the standard.

These requirements are equally applicable to removable bedside sleepers that are designed to separate from the stand/base without the use of tools.

C. Proposed Revised Test Procedure for Bassinet Stability (Sections 2.3 and 7.4.4 of ASTM F2194-12a)

During evaluations of the test methods for removable bassinet beds, CPSC staff made comparisons of the stability of products weighted with the newborn CAMI dummy (7.45 lbs) as opposed to the infant CAMI dummy (17.5 lbs). ASTM F 2194-12 contains a stability requirement that uses the heavier infant CAMI dummy. Use of the newborn CAMI, which is readily available to test labs and represents the 50th percentile newborn, would result in a more conservative stability test. In addition, bassinets are intended for use with newborns. Accordingly, the Commission proposed a revised test procedure for bassinet stability that uses a newborn CAMI instead of an infant CAMI. This test procedure is equally applicable to

removable beside sleepers that are designed to separate from the stand/base without the use of tools because they too are intended for use with newborns.

F. 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). To allow time for bedside sleepers to come into compliance, the Commission proposes that the standard would become effective 6 months after publication of a final rule in the *Federal Register*. The Commission invites comment on how long it will take bedside sleeper manufacturers to come into compliance with the rule.

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 rules on small entities, including small businesses. Section 603 of the RFA requires that the Commission prepare an initial regulatory flexibility analysis and make it available to the public for comment when the notice of proposed rulemaking is published. The initial 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 initial regulatory flexibility analysis must contain:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of the reasons why action by the agency is being considered;
- A succinct statement of the objectives of, and legal basis for, the proposed rule;

- A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed 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
- An identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

In addition, the initial regulatory flexibility analysis must contain a description of any significant alternatives to the proposed rule that would accomplish the stated objectives of the proposed rule and, at the same time, reduce the economic impact on small businesses.

2. The Market

Typically, bedside sleepers are 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.

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of bedside sleepers is small if it has 500 or fewer employees, and an importer is considered small if it has 100 or fewer employees. Based on these guidelines, all four domestic manufacturers known to be supplying the U.S. market are small.

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 bedside sleeper voluntary standard. However, three firms supply multimode products where one mode is 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.

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. Therefore, the risk of injury associated with the number of products in use cannot be calculated.

3. Compliance Requirements of the Proposed Rule

Although all bedside sleepers currently on the market will require some modification in order to meet the voluntary standard, several of these requirements would impose little to no burden on manufacturers because firms also must comply with similar requirements in existing voluntary standards.

Several modifications of the product may be required. The lowered side of the bedside sleeper must be 4 inches. The height requirement for sides that cannot be lowered is identical to that of bassinets, 7½ inches. This requirement is not expected to pose a substantial cost for firms. However, 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 4-inch side height.

ASTM F2906-12 requires that the gap between the bedside sleeper and adult bed should not be more than a ½ 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. Alternatively, firms may opt to redesign their attachment system. Cost should be minimal if no new materials are used.

Some products will require some modification in order to meet the two proposed bedside sleeper accessory requirements. The Commission proposes that the bedside sleeper accessory would be required to meet the (1) fabric sided opening requirement and (2) consumer misassembly requirement. In order to comply with the fabric opening requirement, the bedside sleeper accessory must pass the torso probe test. Alternatively, when the fabric-sided liner is unsecured, the bedside sleeper accessory should either collapse under its own weight or the sleep surface should tilt by more than 30 degrees. The proposed consumer misassembly requirement is identical to the play yard bassinet misassembly requirement proposed in the NPR for the Safety Standard for Play Yards. The Commission proposes that a bedside sleeper accessory that can be assembled and attached to the play yard with any of the key structural elements missing must either: (1) have all key structural components permanently attached or (2) be obviously unusable when attached to the play yard with any key structural element removed. The bedside sleeper accessory, if misassembled, should provide visual cues, such as the mattress pad contacts the bottom floor of the non-full-size crib or play yard, or the sleep surface angle tilts by more than 30 degrees to indicate misassembly. The actual cost of meeting these proposed requirements to manufacturers is unknown, but it could be minimal, primarily involving

additional stitching, rivets, and other methods of attachment. However, if product redesign is required, the costs could be significant.

The proposed bassinet requirements that are also applicable to bedside sleepers—mattress and stability requirements—are expected to have little to no incremental impact on firms. These requirements are identical to requirements in the bassinet NPR for Safety Standard for Bassinets and Cradles and the cost of meeting those requirements was accounted for in the bassinet NPR. If these requirements are finalized as proposed, a manufacturer who produces a bedside sleeper and a bassinet combination product would already need to meet these requirements and would have incurred the associated costs under the bassinet standard. As a consequence, meeting the same requirements under a bedside sleeper standard would impose no additional burden. Most bedside sleeper manufacturers produce such a combination product. In addition, firms would need to revise current warning labels to include a description of correct assembly and conversion modes. This represents a minor modification.

4. Other Federal or State Rules

The Commission is in the process of implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA. Section 14(a)(2) of the CPSA requires every manufacturer of a children's product that is subject to a children's product safety rule to certify, based on third party testing, that the product complies with all applicable safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards (i) for ensuring that a children's product is tested periodically and when there has been a material change in the product, (ii) for the testing of representative samples to ensure continued compliance, (iii) for verifying that a product tested by a conformity assessment body complies

with applicable safety rules, and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler.

Because bedside sleepers will be subject to a mandatory standard, they will also be subject to the third party testing requirements of section 14(a)(2) of the CPSA when the mandatory standard and the notice of requirements become effective.

5. Impact on Small Businesses

There are five firms known to be marketing bedside sleepers in the United States. One is a foreign manufacturer. The analysis applies to the four domestic firms, all of which are small. The impact of the standard on manufacturers depends on two factors: (1) whether their products are multiuse products and are already in compliance with one or more existing voluntary (or mandatory) 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 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 manufacturers will need to make only slight, if any, modifications to comply with the bedside sleeper standard. The three producers of multiuse products are unlikely to experience a significant impact.

Two of the domestic manufactures rely almost solely on the sales of bedside sleepers as their revenue source. One of the firms produces a multiuse product that is in compliance with an existing voluntary standard, as described above, and should not experience a significant impact. The other firm, however, produces a product that serves only as a bedside sleeper. The costs of compliance for this firm are unknown but could be significant if a complete product redesign is

required. In addition, the impact could be magnified because most of this firm's revenues are due to the sales of bedside sleepers.

All manufacturers will need to modify existing warning labels. A new warning label poses a small burden because it represents a minor modification. Costs associated with the new warning label would be low because no new materials are used. Once the final rule and notice of requirements are in effect, all manufacturers will be subject to third party testing and certification requirements.

6. Alternatives

Under the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, one alternative that would reduce the impact on small entities is to make the voluntary standard mandatory with no modifications. Adopting the current voluntary standard without any changes potentially would reduce costs for manufacturers. Three of the four small manufacturers who are already compliant with a voluntary standard would have a reduced burden. However, all firms still require some product changes in order to meet the voluntary standard. Because the staff's proposed changes add little to the overall burden, adopting the voluntary standard with no changes will not significantly offset the burden.

A second alternative would be to set an effective date later than the staff-recommended 6 months. This would allow suppliers additional time to modify and/or develop compliant bedside sleepers and spread the associated costs over a longer period of time.

H. Environmental Considerations

The Commission's regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. If our rule has "little or no potential for affecting the human environment," it will be categorically exempted

from this requirement. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exemption.

I. Paperwork Reduction Act

This proposed 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). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

Title: Safety Standard for Bedside Sleepers

Description: The proposed rule would require each bedside sleeper to comply with ASTM F2906-12, Standard Consumer Safety Specification for Bedside Sleepers. Sections 7.1, 8.1, and 8.2 of ASTM F2906-12 contain requirements for marking, labeling, and instructional literature that are disclosure requirements, thus falling within the definition of "collections of information" at 5 C.F.R. 1320.3(c). Section 7.1 of ASTM F2906-12 requires that all bedside sleeper products meet with the marking and labeling instructions of ASTM F2194, *Standard Consumer Safety Specification for Bassinets and Cradles*. Section 8.1 of ASTM F2194-12 requires:

- the name and the place of business (city, state, mailing address including zip code) or telephone number of the manufacturer, importer distributor, or seller; and
- a code mark or other means that identifies the date (month and year as a minimum) of manufacture.

Section 8.1 of ASTM F2906-12 requires that all bedside sleeper products comply with the instructional literature requirements of ASTM F2194, Standard Consumer Safety Specification for Bassinets and Cradles. Section 9.1 of ASTM F2194-12a requires all firms supplying bedside sleepers to provide easy-to-read and understand instructions regarding assembly, maintenance, cleaning, operating, and adjustments, where applicable. Section 8 of ASTM F2906-12 also requires that the instructions cover correct assembly of product and use of attachment system, and conversion, as well as alert consumers that they should read all instructions and keep the instructions for future use. These requirements fall within the definition of "collection of information," as defined in 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import bedside sleepers.

Estimated Burden: 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

Our estimates are based on the following:

There are five known firms supplying bedside sleepers to the U.S. market. All five firms are assumed to use labels on both their products and their packaging already, but they might need to make some modifications to their existing labels. The estimated time required to make these

modifications is about 1 hour per model. Each of these firms supplies an average of two different models of bedside sleepers; therefore, the estimated burden hours associated with labels is 1 hour x 5 firms x 2 models per firm = 10 annual hours.

Sections 8.1 and 8.2 of ASTM F2906-12 require instructions to be supplied with the product. This is a practice that is customary with bedside sleepers. Bedside sleepers are products that generally require some installation and maintenance instructions, and any products sold without such information would not be able to compete successfully with products that provide this information. Therefore, because the CPSC is unaware of bedside sleepers that: (a) generally require some installation, but (b) lack any instructions to the user about such installation, there are no burden hours associated with the instruction requirement in sections 8.1 and 8.2 because any burden associated with supplying instructions with bedside sleepers would be "usual and customary" and not within the definition of "burden" under the OMB's regulations.

We estimate that hourly compensation for the time required to create and update labels is $27.64 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," June 2012, Table 9, total compensation for all sales and office workers in goods-producing private industries: http://www.bls.gov/ncs/). Therefore, the estimated annual cost associated with the proposed requirements is $276 ($27.64 per hour x 10 hours = $276).

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, to the

Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this notice).

Pursuant to 44 U.S.C. 3506(c)(2)(A), we invite comments on:

- whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility;
- the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

J. 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.

K. 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 proposed rule for 16 CFR part 1222, "Safety Standard for Bedside Sleepers," when issued as a final rule, will be a children's product safety rule that requires the issuance of an NOR.

On May 24, 2012, the Commission published a proposed rule in the *Federal Register* titled, "Requirements Pertaining to Third Party Conformity Assessment Bodies," 77 FR 31086, which, when finalized, would establish the general requirements and criteria concerning testing laboratories under 16 CFR part 1112. These include the requirements and procedures for CPSC acceptance of the accreditation of a laboratory to test children's products in support of the certification required by section 14(a)(2) of the CPSA. The proposed rule lists the children's product safety rules for which the CPSC has published NORs for laboratories. In this document, the Commission is proposing to amend the list in 16 CFR part 1112, once that rule becomes

final, to include the bedside sleeper standard, once finalized, along 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* once that rule becomes final. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, it 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 prepared an Initial Regulatory Flexibility Analysis (IRFA). *Requirements Pertaining to Third Party Conformity Assessment Bodies.* 77 FR 31086, 31123-26. The IRFA concluded that the requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements are imposed on laboratories that do not intend to provide third party testing services under Section 14(a)(2) of the CPSA. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from providing the mandated testing to justify accepting the requirements as a business decision. Laboratories that do not expect to receive sufficient revenue from these services to justify accepting these requirements would likely not pursue accreditation for this purpose. Similarly, amending the rule to include the NOR for the bedside sleeper standard would not have a significant adverse impact on small laboratories. Moreover, 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, perhaps fewer than 6, 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 could certify that the proposed NOR for the bedside sleeper standard will not have a significant impact on a substantial number of small entities.

The final NOR will base the CPSC laboratory accreditation requirements on the performance standard set forth in the final rule for the safety standard for bedside sleepers and the test methods incorporated within that standard. The Commission may recognize limited circumstances in which it will accept certification based on product testing conducted before the Commission's acceptance of accreditation of laboratories for testing bedside sleepers (also known as retrospective testing) in the final NOR. The Commission seeks comments on any issues regarding the testing requirements of the proposed rule for bedside sleepers and the accompanying proposed NOR.

L. Request for Comments

This proposed rule begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for bedside sleepers. We invite all interested persons to submit comments on any aspect of the proposed rule. Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

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 proposes to amend Title 16 of the Code of Federal Regulations by amending Part 1112 and adding a new Part 1222, 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: Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

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 and/or test method?

*** * * * ***

(b) The CPSC has published previously, or in the cases of 16 CFR parts 1221, 1223, and 1224, and ASTM F 963-11 for the first time, the requirements for accreditation for third party conformity assessment bodies to assess conformity with the following CPSC rules and/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 F2906-12, Standard Consumer Safety Specification for Bedside Sleepers, approved on June 1, 2012. 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 the ASTM F2906-12 standard with the following additions:

(1) In addition to complying with section 3.1.7 of ASTM F2906-12, comply with the following:

(i) 3.1.8 "*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."

(ii) [Reserved]

(2) In addition to complying with section 5.6 of ASTM F2906-12, comply with the following:

(i) 5.7 *Bedside Sleeper Accessory Fabric-Sided Enclosed Openings*—A bedside sleeper accessory shall meet the F2194 performance requirement, "*Fabric-Sided Enclosed Openings."*

(A) 5.7.1 Bedside sleeper accessories are exempt from this requirement if either of the following two conditions is met after disengaging all fasteners between the accessory and the non-full-size crib or play yard base to which it is assembled:

(B) 5.7.1.1 The bedside sleeper accessory collapses under its own weight, such that any part of the mattress pad contacts the bottom floor of the non-full-size crib or play yard.

(C) 5.7.1.2 The bedside sleeper accessory's sleep surface tilts by more than 30 degrees.

(ii) 5.8 *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."

Dated: _____.

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

Staff Briefing Package

Section 104(b) of the Consumer Product Safety Improvement Act of 2008:
Safety Standard for Bedside Sleepers
Notice of Proposed Rulemaking

October 17, 2012

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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: October 17, 2012

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Kenneth R. Hinson, Executive Director
Mary T. Boyle, Acting General Counsel

FROM : DeWane J. Ray, Assistant Executive Director
Office of Hazard Identification and Reduction

Douglas A. Lee, Project Manager
Directorate for Engineering Sciences

SUBJECT : Consumer Product Safety Improvement Act of 2008 (CPSIA): Notice of Proposed Rulemaking (NPR) for Bedside Sleepers

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) staff 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 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 of the CPSIA 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 (formerly known as the American Society for Testing and Materials) 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.

This briefing package assesses the effectiveness of the voluntary standard and presents CPSC staff's recommendation for a draft proposed rule to address potential hazards associated with bedside sleeper products.

II. BACKGROUND

A. Product Review

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. 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.

Figures 1–9 show examples of various types of bedside sleepers and base configurations.

		
Figure 1: Bedside Sleeper (Bedside Sleeper Accessory on Play Yard Base)	Figure 2: Bassinet (Bassinet Accessory on Play Yard Base Converts from Figure 1)	Figure 3: Play Yard Base

		
Figure 4: Bedside Sleeper (Removable Bedside Sleeper Accessory on Play Yard Base)	Figure 5: Bedside Sleeper Accessory on Floor (No Bassinet Accessory Conversion)	Figure 6: Bedside Sleeper (Removable Bedside Sleeper/Bassinet, No Lower Side)

		
Figure 7: Bedside Sleeper (Converted on a Bassinet Base)	Figure 8: Bedside Sleeper (No Bassinet Conversion)	Figure 9: Bedside Sleeper (Converts to Bassinet)

Current bedside sleepers range in size from about 35″ x 20″ to 40″ x 30″ and are usually mounted on a bassinet base or play yard base. Commonly, they are constructed of a tube frame, covered by mesh and fabric, as shown in Figures 1-7, but they may be rigid sided (like cribs or as in Figures 8 and 9). Most of the products are designed to be converted to a bassinet by raising or lowering the one side and are also designed to collapse for easy transport.

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. These multimode products may convert the base product or add accessories to function as an additional product. For example, the bedside sleeper in Figure 1 can convert into a bassinet (Figure 2).

This product uses a bedside sleeper accessory[1] or a bassinet accessory[2] to convert the play yard base (Figure 3). The bedside sleeper on a play yard base (Figure 4) has a removable bedside sleeper accessory (Figure 5) and can also convert to a bassinet by using a bassinet accessory (not shown).

The bassinet in Figure 6 can be attached to an adult bed to become a bedside sleeper, or the bassinet can be removed to become a handheld carrier. The bedside sleeper in Figure 7 was converted from a bassinet by adjusting the fabric side and removing the top rail. Figure 8 is a bedside sleeper only and does not convert to another mode. The bedside sleeper in Figure 9 was converted from a bassinet by lowering one side.

Figures 10 through 13 show various attachment methods used by bedside sleeper manufacturers to secure their product to the adult bed. The bedside sleeper attachments in Figures 10 and 11 are intended to be inserted between the mattress and box spring. The strap in Figure 12 is intended to wrap around the top and bottom of the box spring. The strap in Figure 13 is placed between the mattress and box spring while the plate is held by the mattress and box spring on the side opposite the bedside sleeper.

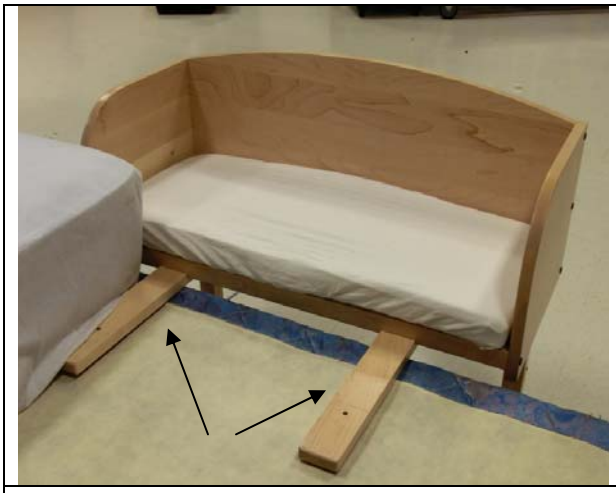

Figure 10 - Wood Attachment

Figure 11 – Pillow/Friction Attachment

[1] ASTM Ballot F15 (12-07) Item 9, published on September 14, 2012, proposes to define a "bedside sleeper accessory" as 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.
[2] ASTM F2194-12 defines a "bassinet cradle/accessory" as a supported sleep surface that attaches to a crib or play yard designed to convert the product into a bassinet/cradle intended to have a horizontal sleep surface while in a rest (non-rocking) position.

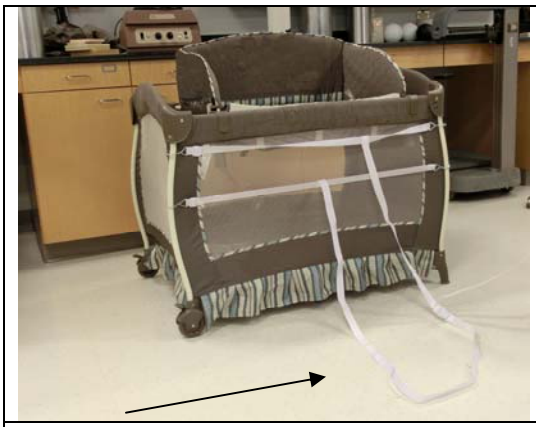

Figure 12 – Strap Attachment

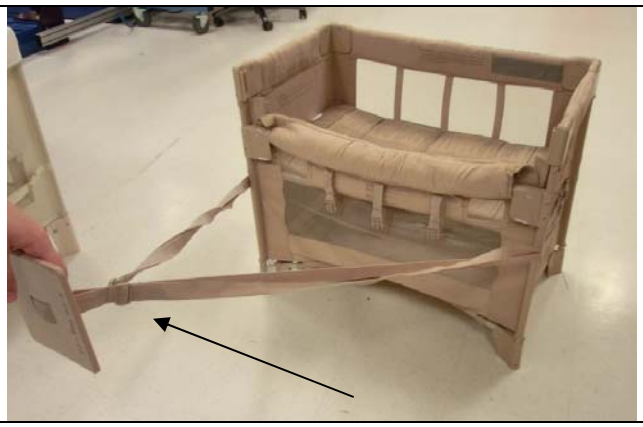

Figure 13 – Strap and Plate Attachment

B. Voluntary and International Standards Overview

1) Bedside Sleeper Voluntary Standard ASTM F2906

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

The standard then addressed hazards specific to bedside sleeper products. It 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 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 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 indentified a 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. [1] Lastly, latching and locking security and child resistance is

[1] ASTM F2906-12, Standard Consumer Safety Specification for Bedside Sleepers, Section 5.4.1, Four-Inch Nest Rationale.

evaluated to help prevent unintentional movement of the side that lowers and to ensure overall product integrity.

In early 2012, sufficient evidence had been gathered by CPSC staff and the ASTM Bedside Sleeper Subcommittee (F15.18) to change the primary requirement from meeting either F406 (play yard voluntary standard) or F2194 (bassinet voluntary standard), to require all products to meet F2194 only. Bedside sleepers and bassinets share a significant number of hazard patterns because they are 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 standard more stringent because it expanded the range of hazards that are addressed by including hazards not covered by the play yard standard. 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 (F406). 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.

2) Other Bedside Sleeper Standards

CPSC staff reviewed mandatory and voluntary international standards in Canada, the European Union, Australia, and New Zealand.

Canada – There are no specific bedside sleeper standards in Canada. Health Canada considers bedside sleepers to be too heavy to be portable and classifies them as cribs. Canada has a mandatory standard for cribs, cradles, and bassinets, SOR/2010-261, which contains a specific requirement for a bounded sleeping surface on all sides. All sides must be at least 230 mm (9 inches) above the upper surface of the mattress support. This requirement essentially bans most bedside sleeper products from sale in Canada.

European Union – There are no specific bedside sleeper standards in Europe. Selected portions of *EN 1130 Cribs and Cradles* and *EN 12790 Child Care Articles – Reclined Cradles* are used by manufacturers to assess and market various design elements and structures in bedside sleeper products. However, there are no specific requirements that address the hazards unique to bedside sleeper products.

Australia and New Zealand – There are no specific bedside sleeper standards in Australia and New Zealand. However, there are three mandatory standards governing safe sleep products for children in Australia and New Zealand:

a) AS/NZS 2172:2003 *Cots* (full size and non-full size cribs that do not fold)
b) AS/NZS 2195:1999 *Folding Cots* (play yards and folding cribs of any size)
c) AS/NZS 4385:1996 *Infants' Rocking Cradles* (cradles and bassinets that tilt)

These standards have specific minimum side height requirements based on the height from the top of the mattress support. Based on their typical mattress thickness 76 mm (3 inches), they equate to similar ASTM requirements of 190 mm (7.5 inches) above the top of the mattress.

C. Juvenile Products Manufacturers Association Certification

The Juvenile Products Manufacturers Association (JPMA) has a certification program for a variety of juvenile products including bassinets and play yards. Manufacturers who voluntarily obtain JPMA certification submit products to an independent test laboratory for conformance testing to the most recent version of the voluntary standard. Manufacturers have 6 months after publication of a new or revised standard to certify products to the new requirements.

Currently, JPMA does not have a certification program for bedside sleepers and no firm claims to meet the ASTM voluntary standard, ASTM F2906-12. However, three firms supply multi-mode products where one mode is 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 multi-mode play yards which are JPMA certified as compliant with the ASTM play yard/non full size crib standard.

III. DISCUSSION

A. Incident Data (Tab A)

CPSC staff from the Directorate for Epidemiology characterized the number of deaths and injuries and the types of hazards related to bedside sleepers. CPSC staff is aware of four fatalities and 36 non-fatal incidents (with and without injuries) related to bedside sleepers that were reported to have occurred from January 2001 through December 2011. Table 1 indicates the breakdown of the incidents by the incident year. See Tab A for more details regarding the data and its limitations.

Table 1: Bedside Sleeper-Related Reported Incidents
2001 through 2011

Incident Year	***Number of Reported Incidents***		
	Total	Fatal	Non-fatal
2001	2	--	2
2005	1	--	1
2006	3	--	3
2007	5	1	4
2008	14	2	12
2009*	*3*	*1*	*2*
2010*	*5*	--	*5*
2011*	*1*	--	*1*
Unknown	6	--	6
Total	***40***	***4***	***36***

Source: Consumer Product Safety Commission's epidemiological databases.
Note: * indicates data collection is ongoing.

1) Fatalities

All four reported fatalities involved the same brand of bedside sleeper/bassinet. In all four cases, the product was being used in the bassinet mode, with the adjustable side raised at the time of the incident. Three of the deaths were due to entrapment and/or hanging that resulted after an infant's body, but not head, slipped through the fabric covering and underlying structural components of a particular brand of bedside sleepers. In two of these three fatalities involving a 4-month-old and a 6-month-old decedent, the infant's head was entrapped between the lower horizontal bars (of the adjustable side) and the top of the mattress. The fabric flap designed to cover the metal bars was not in place. In the third fatality, the fabric flap covering the adjustable side was not secured to the permanent fabric siding, and the horizontal bars of the adjustable side were broken/missing. This allowed the 6-month-old decedent's body to slip out through an opening in the fabric siding, but her body got caught at the chin/throat on a lower crossbar. The fourth fatality involved a 2-month-old decedent who had rolled into a corner where the loose fabric flap covering the adjustable fourth side had created a pocket, and the infant suffocated.

2) Nonfatal Incidents

There were three reported injuries involving infants, none hospitalized, during the use of a bedside sleeper. All of the injured infants were under 5-months of age, which is in the ASTM recommended user age range. Two of the infants suffered bruising when they were entrapped between the metal rungs of the same product that had caused three of the fatalities described in the previous section. The third injury occurred when the infant rolled into a position where his neck was hyperextended into a non-breathable corner of the product, and he suffered respiratory difficulties. In all three cases, the caregiver was nearby to prevent any serious consequences.

The remaining 33 cases reported that no injury had occurred or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death in bedside sleepers. In cases where victim age was reported, six reported ages to be between 6 and 8 months old; the remaining infants were under 5 months of age.

B. Hazard Pattern Analysis (Tab A)

CPSC staff considered all 40 incident reports to identify the hazard patterns associated with bedside sleeper-related incidents. The reports were grouped into two broad categories: product-related and recall-related complaints.

1) *Product-related issues*: The hazard scenarios in 24 of the 40 incidents (60 percent) reported were attributed to some sort of failure/defect or a potential design flaw in the product itself. This category includes four fatalities and three non-hospitalized injuries. Listed below are the reported problems, beginning with the most frequently reported concerns:

- A problem with the ***adjustable fabric cover over the horizontal metal bars*** on the side that lowers in the bedside sleeper mode was responsible for nine of the reported incidents. These included all four fatalities and two of the injuries. All of these incidents involved one particular brand of a bedside sleeper/convertible bassinet product which was recalled by the CPSC in 2008. Two of the fatalities occurred before the CPSC recall; the third, which involved a secondhand product in poor condition, occurred after the 2008 recall, but prior to a 2009 recall (which was an expansion of the 2008 recall). Between the two injuries, one occurred prior to the 2008 recall, while the other occurred after that recall. Neither of the post-recall incident reports indicate whether the consumers were aware of the recall.

- Issues with ***assembly instructions*** were identified in six reported incidents. In all of these reports, the consumer had misassembled the product but reported the product as being faulty. None of the incidents resulted in any injury or fatality. All but one of these incidents involved products of one particular manufacturer, which was recalled by the CPSC in 2011.

- Miscellaneous other product-related issues***,*** such as ***non-levelness*** of the product (two reports), ***instability of leg extensions*** (two reports), ***poor design*** (two reports), ***broken component*** (one report), ***failure of the attachment (to adult bed) mechanism*** (one report), and ***unclear age labeling*** (one report) were reported in the remaining incident reports. One incident reported an injury associated with poor product design.

2) *Recall-related consumer complaints*: In response to ***CPSC recall*** notices, there were 16 non-incident reports of concerns or complaints. In these reports, the consumer either sought advice on options regarding a bedside sleeper product they owned that

had been recalled, or they inquired about whether the product they owned was within the scope of the recall.

The distribution of the 40 reported incidents by the hazard patterns described above is shown in Table 2.

Table 2: Distribution of Reported Incidents by Hazard Patterns Associated with Bedside Sleepers Date of Incident: 2001–2011

Issues	***Total Reports***		***Reported Deaths***		***Reported Injuries***	
	Count	*Percentage*	*Count*	*Percentage*	*Count*	*Percentage*
Product-related	**24**	**60**	**4**	**100**	**3**	**100**
Fabric flap/cover over horizontal bars	9	23	4	100	2	67
Assembly instruction	6	15	--		--	
Other	9	23	--		1	33
Non-Level	*2*		--		--	
Unstable Leg Extensions	*2*		--		--	
Poor Design	*2*		--		*1*	
Broken Component	*1*		--		--	
Attachment Failure	*1*		--		--	
Age Labeling	*1*		--		--	
Recall-related consumer complaints	**16**	**40**	--		--	
Total	**40**	**100**	**4**	**100**	**3**	**100**

Source: Consumer Product Safety Commission's epidemiological databases IPII, INDP, DTHS, and NEISS.
Note: The percentages have been rounded to the nearest integer and shown for totals and subtotals only. Subtotals do not necessarily add to heading totals.

C. Recent Compliance Activity

Bedside sleepers have been on the market since 1997. During this time there have been two recalls for product defects that created a substantial product hazard.

One recall of a bedside sleeper with a bassinet base involved 4 deaths, three from head entrapment and one from suffocation, and several complaints on the same entrapment hazard. Because of additional incidents, this recall was expanded or re-announced three times. There were 900,000 units recalled.

The other recall of a bedside sleeper with a play yard base involved 10 reports of infants falling from the raised bedside sleeper mattress into the bottom of a play yard base or becoming entrapped between the edge of the mattress and the side of the base. There were 76,000 units recalled.

Details of the recalls can be found on the cpsc.gov website or provided links.
Bedside Sleeper Recalls:

Simplicity Recalls Convertible "Close-Sleeper" Due to Entrapment Hazard, CPSC Release #08-378(August 27, 2008) http://www.cpsc.gov/cpscpub/prerel/prhtml08/08378.html

Simplicity Expanded Recall to Graco and "Winnie the Pooh" models, CPSC Release #08-396 (Expanded September 25, 2008) http://www.cpsc.gov/cpscpub/prerel/prhtml08/08396.html

Six Retailers Stop Sale and Recall Simplicity Bassinets, CPSC Release #08-381 (Revised April 27, 2009) http://www.cpsc.gov/cpscpub/prerel/prhtml08/08381.html

Six Retailers Stop Sale and Recall Simplicity Bassinets, CPSC Release #09-319 (Re-annnounced August 20, 2009) http://www.cpsc.gov/cpscpub/prerel/prhtml09/09319.html

Arms' Reach Recalls Older Model Bedside Sleepers, CPSC Release #11-187 (April 5, 2011) http://www.cpsc.gov/cpscpub/prerel/prhtml11/11187.html

D. CPSC Staff Recommendations for Bedside Sleepers (Tab B)

CPSC staff conducted an assessment of the current voluntary standard by reviewing the incident data for the performance requirements and conducting testing and evaluation of current products in the market. Based on CPSC staff's review, the requirements in the voluntary standard are not adequate to address some of the known hazards associated with bedside sleepers. Therefore, CPSC staff recommends two changes to ASTM F2906 and inclusion of recommended changes to ASTM F2194 in the September 19, 2012 Bassinet Notice of Proposed Rulemaking for its draft proposed rule for bedside sleepers. CPSC staff recommends:

1) Fabric-Sided Enclosed Openings

The current version of the bassinet/cradle voluntary standard, ASTM F2194-12a, contains a *Fabric-Sided Enclosed Openings'* performance requirement. Although the ASTM standard for bedside sleepers requires that bedside sleepers must be tested to the requirements of ASTM F2194 (for bassinets), bassinet accessories to play yards (including those that convert to bedside sleepers) are currently exempt from the fabric –sided enclosed openings requirement of ASTM F2194. As discussed below, the staff recommends that this requirement apply to such bedside sleepers. This requirement prohibits completely bounded openings large enough to permit passage of an infant's torso. The hazard scenarios addressed by this requirement encompass the three strangulation deaths described above and a related, foreseeable suffocation hazard. These hazards occur when a child passes through an opening, either becomes trapped between the liner and mattress pad of the bassinet and suffocates or becomes suspended by the neck and then strangles.

This hazard, associated with a recall of 900,000 units, led to three of the four fatalities on a bassinet that converts to a bedside sleeper and is the most serious class of incidents discussed above and in Section B, Incident Hazard Review. The test procedure (ASTM F2194-12a, section 7.8) attempts to push a torso probe the size of a 5th percentile 0 to 2-month-old infant (Tab B Fig. 5) through bounded openings with 20 lbs of force. The test is

first performed with the product assembled per the manufacturer's instructions. If the product has a removable cover, it is performed a second time after all fasteners or snaps are unfastened, but the removable cover left in place. In doing so, the test intentionally replicates the incorrectly secured fabric liner hazard scenario of the fatal incidents.

Another manufacturer's bedside sleeper product exhibited this hazard, which led to their recall in 2011.[3] The recall was initiated in response to incident reports in which the bedside sleeper accessory's removable cover (liner or shell) was either not used, or present but not secured to the play yard frame.[4] This product can also be used as a play yard, or a bassinet accessory to a play yard. When in the bassinet accessory position, the front side of the product can be lowered, transforming it to the beside sleeper mode.

A 1 ½-year-old unused sample of this product was recently retested by staff, confirming that it fails the ASTM F2194 fabric-sided enclosed opening requirement. However, a new sample of a similar model from the same manufacturer passed this test. Staff identified two possible reasons for testing variances. One explanation is that the fit of the shell to the play yard frame becomes looser with repeated assembly and disassembly. The other reason is that the seam joining the mesh and fabric part of the liner may be in a slightly different location on some models. The seam may cause friction on the torso test probe during force testing on some models. Regardless, when minor changes in materials or construction that can foreseeably occur during normal use have the potential to change this product from being a safe sleep environment to an unsafe sleep environment, the product is not safe with regard to the fabric-sided bounded opening hazard.

Play yard bassinet accessories are exempt from the fabric-sided openings requirement in the current bassinet standard, and thus this particular product would not have to meet the requirement. Therefore, staff recommends addressing the hazard of an unsecured shell on a play yard frame by requiring that all bedside sleeper products be subject to the requirements of the ASTM F2194-12a basinet standard's section 6.7 *Fabric-Sided Enclosed Opening* by reference, including those that could be considered a play yard bassinet accessory. Under section 6.7 of ASTM F2194-12a, for bassinets/cradles with fabric sides, a completely 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 bassinets or play yard accessories. The staff proposes additional language for the ASTM F2906 bedside sleeper standard 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. Unlike bassinet play yard accessories, bedside sleeper (or a bassinet that is

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[3] *Release #11-187, "Arm's Reach Concepts Recalls Infant Bedside Sleepers Due to Entrapment, Suffocation and Fall Hazards," Office of Information and Public Affairs, U.S. CPSC, April 5, 2011.*

[4] Misassembly of the bedside sleeper attachment by omitting the liner is addressed by staff recommendation #2, below.

converted into a bedside sleeper) play yard accessories could have fasteners left unclipped (through the detachment of snaps/Velcro) where the bedside sleeper with the lowered side does not completely collapse. Because the bedside sleeper could still appear functional, the staff proposes to add the following language:

(Underlined text is new):

3.1.X *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.

5.7 *Bedside Sleeper Accessory Fabric-Sided Enclosed Openings*—A bedside sleeper accessory shall meet the F2194 performance requirement "*Fabric-Sided Enclosed Openings."*

5.7.1 Bedside sleeper accessories are exempt from this requirement if either of the following two conditions is met after disengaging all fasteners between the accessory and the non-full-size crib or play yard base to which it is assembled.

5.7.1.1 The bedside sleeper accessory collapses under its own weight, such that any part of the mattress pad contacts the bottom floor of the non-full-size crib or play yard.

5.7.1.2 The bedside sleeper accessory's sleep surface tilts by more than 30 degrees.

2) Consumer Misassembly with Missing Components

Currently, there are no requirements in ASTM F2906 that directly address misassembly of bedside sleeper accessories to play yards. However, specific language to address this hazard for play yard bassinet accessories has been proposed in the notice of proposed rulemaking for Safety Standard for Play Yards (77 FR52272, August 29, 2012). This proposed rule, if finalized, would amend the Safety Standard for Play Yards, 16 CFR 1222 (see 77 FR 52220, August 29, 2012). Concurrently, the play yard bassinet attachment misassembly requirement is being balloted by the ASTM play yard subcommittee for inclusion in F406.[5]

During the course of ownership, or when the product is resold or handed down and placed in use by multiple, successive users, components that are not affixed permanently to one another can be lost. Therefore, staff believes that it is reasonably foreseeable that bedside sleepers with missing components, or makeshift repairs not approved by the manufacturer, could be placed in use with newborns and infants. This issue is not limited to structural elements such as bars, tubes, and clips. As discussed above in section I.B (2), the textile

[5] ASTM Ballot F15 (12-06) Item 3, published August 14, 2012.

shell of one multiuse product's bedside sleeper accessory has been omitted by consumers.[6] This was possible because the other structural elements supported the sleep surface without the shell, resulting in what appeared to be a safe environment. This hazard is magnified should these misassembled products be used as an unsupervised sleep environment, another reasonably foreseeable scenario. As the child shifts position while sleeping, the misassembled product may become unstable, causing the sleep surface to incline beyond 10 degrees.[7]

Staff also found this hazard in other products intended to provide a safe sleep environment (*i.e.*, one that does not require supervision, such as cribs and bassinets). In 2011, there was a product-related fatality of a 3-month-old child in the bassinet accessory of a play yard that had been assembled and used without an important structural component. Similarly, a bedside sleeper accessory misassembly may not be readily apparent or obvious to the consumer. If the misassembled accessory supports an infant without a catastrophic and obvious change to the sleep surface, a consumer may continue to use the misassembled accessory and inadvertently place a child in danger. Staff found that bedside sleeper accessories and bassinet accessories incorporate very similar designs and manufacturing processes, and therefore, many of the same performance requirements are applicable to both products.

Staff recommends that the following requirement be added to F 2906-12 (new language is underlined) that addresses misassembly to incorporate the same language proposed in the NPR for play yards in ASTM F406:

> 5.8 *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*."

3) Changes to F 2194-12 in the Bassinet Notice of Proposed Rulemaking

Most bedside sleepers also function as bassinets. The intended users are identical, and the majority of the hazards are identical. Staff recommendations to address bassinet hazards not addressed by the voluntary bassinet standard (F 2194-12) have been discussed in great detail in

[6] *"Arm's Reach Concepts Recalls Infant Bedside Sleepers Due to Entrapment, Suffocation and Fall Hazards," Release #11-187, U.S. CPSC, April 5 2011.*

[7] Ten degrees is the maximum sleep surface incline recommended by staff on the CPSC Bassinet Rulemaking Team. (See footnote 18, below.)

the Bassinet NPR staff briefing package.[8] Three of the four staff recommendations are applicable to bedside sleepers[9] and address foreseeable hazards:

a) Segmented Mattress Flatness Requirement and Test Method
   Hazard: Suffocation/positional asphyxia associated with excess mattress pad incline.
b) Removable Bassinet Bed Stability
   Hazard: Falls and entrapment under fallen product. The removable bed portion of the product is not completely latched or secured to the base, permitting it to fall off of its stand.
c) Stability Test Dummy
   Hazard: Falls and entrapment under fallen product. Staff recommends using the lighter 7.45 lbm. newborn CAMI dummy in the stability test instead of the 17.5 lbm. infant CAMI dummy to create a safer and stricter stability test requirement.

Staff recommends that these recommendations also be part of the bedside sleeper NPR. The language that addresses these proposed changes, in addition to the scope and definition changes they necessitate, are identical to the Bassinet NPR and are provided in the appendix to this memorandum.

E. Initial Regulatory Flexibility Analysis (Tab C)

Typically, bedside sleepers are 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 the firm that dominates the market. The fifth is a foreign manufacturer who ships products directly to the U.S. Based on U.S. Small Business Administration (SBA) guidelines, all four domestic manufacturers known to be supplying the U.S. market are small businesses.

CPSC staff believes that all bedside sleepers currently on the market will require some modification in order to meet the voluntary standard. Several of these requirements would impose little to no burden on manufacturers because firms must comply with similar requirements in existing voluntary standards. The impact of the standard on manufacturers depends on two factors: 1) whether their products are multiuse products and are already in compliance with one or more existing voluntary (or mandatory) standards; and 2) the proportion of their total sales or revenue that bedside sleepers constitute.

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

[8] Edwards P *et. al.*, Staff Briefing Package, "Consumer Product Safety Improvement Act of 2008 (CPSIA): Notice of Proposed Rulemaking (NPR) for Bassinets and Cradles," U.S. CPSC, September 19, 2012.
[9] The fourth recommendation made by Bassinet Rulemaking Team staff was to update the scope and corresponding terminology specific to the ASTM F2194.

likely that these manufacturers will only need to make small, if any, 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 complete product redesign is required.

F. Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Bedside Sleeper Standard: Small Business Impacts (Tab D)

Under section 14(a) of the CPSA, a manufacturer of a children's product, such as bedside sleepers, that is subject to a consumer product safety rule must certify that the product complies with applicable CPSC requirements. That certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body. 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 prepared an Initial Regulatory Flexibility Analysis (IRFA). See 77 Fed. Reg. 31074 (May 24, 2012). Briefly, the IRFA concluded that the requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements are imposed on laboratories that do not intend to provide third party testing services under Section 14(a)(2) of the CPSA. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from providing the mandated testing to justify accepting the requirements as a business decision. Laboratories that do not expect to receive sufficient revenue from these services to justify accepting these requirements would not likely pursue accreditation for this purpose. Similarly, amending the rule to include the notice of requirements (NOR) for the bedside sleeper standard would not have a significant adverse impact on small laboratories. Moreover, 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, perhaps fewer than 6, will seek CPSC acceptance of their accreditation to test for conformance with the bedside sleeper 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 their scope of accreditation. As a consequence, the Commission could certify that the proposed NOR for the bedside sleeper standard will not have a significant impact on a substantial number of small entities.

IV. CPSC STAFF RECOMMENDATION

CPSC staff recommends that the Commission incorporate by reference, ASTM F2906-12, *Standard Consumer Safety Specification for Bedside Sleepers*, with the following modifications:

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

CPSC staff also recommends incorporating the following performance requirements and associated test procedures, contained in the recommended changes to ASTM F2194-12 in the

Bassinet Notice of Public Rulemaking, to the bedside sleeper standard (ASTM F2906-12) to address hazards that bedside sleepers share with bassinets:

3) *Segmented Mattress Flatness Requirement and Test Method*
4) *Removable Bassinet Bed Stability Requirement and Test Method*
5) *Revised Stability Test to Use Smaller CAMI Dummy*

TAB A: [Bedside Sleeper-Related Deaths, Injuries, and Potential Injuries; 2001–2011]

TAB A

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

Memorandum

Date: September 19, 2012

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

THROUGH: Kathleen Stralka,
Associate Executive Director
Directorate for Epidemiology

Stephen Hanway
Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM : Risana T. Chowdhury
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Bedside Sleeper-Related Deaths, Injuries, and Potential Injuries; 2001–2011[11]

I. Introduction

This memorandum characterizes the number of deaths and injuries and the types of hazards associated with bedside sleepers over a period of over 11 years beginning in 2001.[12] These characterizations are based on reports received by CPSC staff. A "bedside sleeper" is defined in the ASTM voluntary standard F2906-12 as a product intended to provide sleeping space for an infant up to approximately 5 months of age (or when child begins to push up on hands and knees). These products are intended to be secured to the side of an adult bed for the purpose of having a baby sleep in close proximity to an adult. Some of these may be multimode products, in that the unit is designed and intended to be used in more than one mode, such as a stand-alone bassinet or play yard, as well as a bedside sleeper.

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

[11] 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.
[12] Not all of these incidents are addressable by an action the CPSC could take; however, it was not the purpose of this memorandum to evaluate the addressability of the incidents, but rather to quantify the number of fatalities and injuries reported to CPSC staff and to update estimates of emergency department treated injuries, whenever feasible.

department-treated injuries were identified as being associated with bedside sleepers; as such, the data analyzed in this memo include incident data only. In addition, incidents associated with bedside sleepers that are multi-mode products have been included in this analysis, as well as in the regulatory work for the other relevant product(s). ASTM F2906-12 is the first voluntary standard on bedside sleepers and was developed based on incident data, provided by CPSC staff, from the year 2001 forward. This memo also covers the data from the year 2001 forward.

II. Incident Data[13]

CPSC staff is aware of four fatalities and 36 nonfatal incidents (with and without injuries) related to bedside sleepers that were reported to have occurred since January 2001. Reporting is ongoing. The number of reported fatalities, nonfatal injuries, and noninjury incidents may change in the future. Table 1 indicates the breakdown of the incidents by the incident year. Given that these reports are anecdotal and that reporting is incomplete, CPSC staff strongly discourages the drawing of any inferences based on the year-to-year increase or decrease shown in the reported data.

Table 1: Bedside Sleeper-Related Reported Incidents
2001 through 2011

Incident Year	***Number of Reported Incidents***		
	Total	Fatal	Non-fatal
2001	2	--	2
2005	1	--	1
2006	3	--	3
2007	5	1	4
2008	14	2	12
2009*	*3*	*1*	*2*
2010*	*5*	--	*5*
2011*	*1*	--	*1*
Unknown	6	--	6
Total	***40***	***4***	***36***

Source: Consumer Product Safety Commission's epidemiological databases.
Note: * indicates data collection is ongoing.

A. Fatalities

[13] 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. These reported deaths and incidents are neither a complete count of all that occurred during this time period, nor a sample of known probability of selection. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to bedside sleepers.

Date of extraction for reported incident data was 01/24/12. 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. For example, a child was reported to have suffocated in soft bedding in a convertible bassinet/bedside sleeper. In this instance, the product was not being used as a bedside sleeper, and more importantly, the hazard was not related to any feature of the bedside sleeper. Therefore, it was excluded from the analysis.

All four reported fatalities involved the same brand of bedside sleeper/bassinet. In all four cases, the product was being used in the bassinet mode, with the adjustable side raised at the time of the incident. Three of the deaths were due to entrapment and/or hanging that resulted after an infant's body, but not head, slipped through the fabric covering and underlying structural components of a particular brand of bedside sleepers. In two of these three fatalities involving a 4-month-old and a 6-month-old decedent, the infant's head was entrapped between the lower horizontal bars (of the adjustable side) and the top of the mattress. The fabric flap designed to cover the metal bars was not in place. In the third fatality, the fabric flap covering the adjustable side was not secured to the permanent fabric siding, and the horizontal bars of the adjustable side were broken/missing. This allowed the 6-month-old decedent's body to slip out through an opening in the fabric siding, but her body got caught at the chin/throat on a lower crossbar. The fourth fatality involved a 2-month-old decedent who had rolled into a corner where the loose fabric flap covering the adjustable fourth side had created a pocket, and the infant suffocated.

B. Nonfatal Incidents

There were three reported injuries involving infants, none hospitalized, during the use of a bedside sleeper. All of the injured infants were under 5-months of age, which is in the ASTM recommended user age range.Two of the infants suffered bruising when they were entrapped between the metal rungs of the same product that had caused three of the fatalities described in the previous section. The third injury occurred when the infant rolled into a position where his neck was hyperextended into a non-breathable corner of the product, and he suffered respiratory difficulties. In all three cases, the caregiver was nearby to prevent any serious consequences.

The remaining 33 cases reported that no injury had occurred or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death in bedside sleepers. In cases where victim age was reported, six reported ages to be between 6 and 8 months old; the remaining infants were under 5 months of age.

III. Hazard Pattern Identification

CPSC staff considered all 40 incident reports to identify the hazard patterns associated with bedside sleeper-related incidents. The reports were grouped into two broad categories: product-related and recall-related consumer complaints.

A. Product-related issues: The hazard scenarios in 24 of the 40 incidents (60 percent) reported were attributed to some sort of failure/defect or a potential design flaw in the product itself. This category includes four fatalities and three non-hospitalized injuries. Listed below are the reported problems, beginning with the most frequently reported concerns:

- A problem with the ***adjustable fabric cover over the horizontal metal bars*** on the side that lowers in the bedside sleeper mode was responsible for nine of the reported incidents. These included all four fatalities and two of the injuries. All of these

incidents involved one particular brand of a bedside sleeper/convertible bassinet product which was recalled by the CPSC in 2008. Two of the fatalities occurred before the CPSC recall; the third, which involved a secondhand product in poor condition, occurred after the 2008 recall, but prior to a 2009 recall (which was an expansion of the 2008 recall). Between the two injuries, one occurred prior to the 2008 recall, while the other occurred after that recall. Neither of the post-recall incident reports indicate whether the consumers were aware of the recall.

- Issues with ***assembly instructions*** were identified in six reported incidents. In all of these reports, the consumer had misassembled the product but reported the product as being faulty. None of the incidents resulted in any injury or fatality. All but one of these incidents involved products of one particular manufacturer, which was recalled by the CPSC in 2011.

- Miscellaneous other product-related issues**,** such as ***non-levelness*** of the product (two reports), ***instability of leg extensions*** (two reports), ***poor design*** (two reports), ***broken component*** (one report), ***failure of the attachment (to adult bed) mechanism*** (one report), and ***unclear age labeling*** (one report) were reported in the remaining incident reports. One incident reported an injury associated with poor product design.

B. Recall-related consumer complaints: In response to ***CPSC recall*** notices, there were 16 non-incident reports of concerns or complaints. In these reports, the consumer either sought advice on options regarding a bedside sleeper product they owned that had been recalled, or they inquired about whether the product they owned was within the scope of the recall.

The distribution of the 40 reported incidents by the hazard patterns described in sections A and B above is shown in Table 2.

Table 2: Distribution of Reported Incidents by Hazard Patterns Associated with Bedside Sleepers Date of Incident: 2001–2011

Issues	***Total Reports***		***Reported Deaths***		***Reported Injuries***	
	Count	*Percentage*	*Count*	*Percentage*	*Count*	*Percentage*
Product-related	**24**	**60**	**4**	**100**	**3**	**100**
Fabric flap/cover over horizontal bars	9	23	4	100	2	67
Assembly instruction	6	15	--		--	
Other	9	23	--		1	33
Non-Level	*2*		--		--	
Unstable Leg Extensions	*2*		--		--	
Poor Design	*2*		--		*1*	
Broken Component	*1*		--		--	
Attachment Failure	*1*		--		--	
Age Labeling	*1*		--		--	
Recall-related consumer complaints	**16**	**40**	--		--	
Total	**40**	**100**	**4**	**100**	**3**	**100**

Source: Consumer Product Safety Commission's epidemiological databases IPII, INDP, DTHS, and NEISS.
Note: The percentages have been rounded to the nearest integer and shown for totals and subtotals only. Subtotals do not necessarily add to heading totals.

TAB B: [Proposed Changes to the Voluntary Standard for Bedside Sleepers (ASTM F2906-12) – Segue to a Mandatory CPSC Safety Standard for Bedside Sleepers]

TAB B

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

Memorandum

Date: September 18, 2012

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

THROUGH: James C. Hyatt, P.E., Director
Division of Mechanical Engineering
Directorate for Laboratory Sciences

Andrew G. Stadnik, P.E., Associate Executive Director
Directorate for Laboratory Sciences

FROM : Gregory K. Rea, Mechanical Engineer
Division of Mechanical Engineering
Directorate for Laboratory Sciences

SUBJECT : Proposed Changes to the Voluntary Standard for Bedside Sleepers (ASTM F2906-12) – Segue to a Mandatory CPSC Safety Standard for Bedside Sleepers

I. BACKGROUND AND OVERVIEW

On August 14, 2008, the Consumer Product Safety Improvement Act (hereafter referred to as the CPSIA) was signed into law [Public Law 110-314]. Section 104 of the CPSIA, the Danny Keysar Child Product Safety Notification Act, requires the U.S. Consumer Product Safety Commission (CPSC, or Commission) to develop safety standards for certain infant or toddler products, including bedside sleepers and many other children's products. The CPSIA requires the Commission to assess the effectiveness of the relevant voluntary safety standards and promulgate mandatory standards for these products. Section 104 (b)(1)(B) states that – "The Commission shall . . . promulgate consumer product safety standards that – (i) are substantially the same as voluntary standards; or (ii) are more stringent than such voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products."

The CPSC had not previously promulgated a mandatory standard for bedside sleepers. As discussed below, CPSC staff recommends adopting by reference ASTM International's voluntary standard F2906-12,[14] *Standard Consumer Safety Specification for Bedside Sleepers*, with two new requirements: Fabric-Sided Enclosed Openings and Consumer Misassembly with Missing Components.

In addition, because bedside sleeper products are closely related to bassinets, hey have many hazards in common. Therefore, Standard F2906-12 requires bedside sleeper products to first meet the requirements of the voluntary bassinet standard, ASTM F2194-12a, *Standard Consumer Product Safety Specification for Bassinets and Cradles*[15], with the exception of the height of the lowered fourth side. Recently, the CPSC's bassinet rulemaking team recommended four changes to the ASTM voluntary bassinet standard.[16] Three of those recommendations—one revised test method, and two new requirements and associated test methods—address the hazards bedside sleepers share with bassinets. (The fourth recommendation concerns the scope of, and definitions within, the bassinet standard, and it is not directly applicable to bedside sleeper products.) CPSC staff recommends that these proposed changes to the ASTM voluntary bassinet standard, likewise, be implemented in the bedside sleeper standard. These additional requirements will ensure that currently known and reasonably foreseeable hazards associated with bedside sleepers are addressed.

A. Product Description

A bedside sleeper is a safe sleep environment secured to an adult bed that permits newborns and infants to sleep close by an adult without being in the adult bed. In current products, the horizontal sleep surface is typically 1″to 4″ 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 lowered, thereby differentiating bedside sleepers from bassinets, where all four sides are the same height. 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.

[14] ASTM F2906-12, *Standard Consumer Safety Specification for Bedside Sleepers*, ASTM International, July 2012.
[15] ASTM F2194-12, *Standard Consumer Safety Specification for Bassinets and Cradles*, ASTM International, July 2012.
[16] Edwards P *et. al.*, Staff Briefing Package "Consumer Product Safety Improvement Act of 2008 (CPSIA): Notice of Proposed Rulemaking (NPR) for Bassinets and Cradles," U.S. CPSC, September 19, 2012.

Figure 1. Rigid-sided bedside sleeper.

Current bedside sleepers range in size from about 35″ x 20″ to 40″ x 30.″ They may have rigid sides (see Fig. 1), but they are most commonly constructed with a tube frame covered by mesh or fabric (see Fig 2(a) and 2(b)). Most products can be converted into a bassinet by raising the lowered side to have four equal-height sides, and many also convert into a play yard. All of the tube-framed products known to CPSC staff may be collapsed for storage and transport.

Several manufacturers produce multiuse (or multimode) bedside sleeper products that convert into bassinets and play yards. 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. Examples of these products are shown in Figure 2.

(a) Tube-framed bedside sleeper accessory and bassinet accessory on a play yard base (consumer assembly required).

(b) Bedside sleeper accessory on a play yard base and sitting on the floor (consumer assembly required).

(c) Combination bedside sleeper and bassinet product.

Figure 2. Examples of multiuse bedside sleeper products.

B. Incident Hazard Review

Over the past 11 years, 2001 through 2011 inclusive, 40 incidents related to bedside sleepers were reported to CPSC staff.[17] Of these, there were four fatalities, three nonfatal injuries (no hospitalizations), and 33 noninjury incidents. All four fatalities were attributable to design flaws in the same brand recalled on August 28, 2008.[18] These were multiuse products that could convert from a bassinet into a bedside sleeper. Two fatalities were caused when the infant's head/neck was trapped between a horizontal metal tubular bar and the sleeping surface when the product was being used as a bassinet. The product was not attached to an adult bed at the time of the incident, nor was the adjustable side lowered. In both of these incidents, the fabric flap that is supposed to cover the metal bars was not used. The third death occurred in a product, in which the fabric flap—designed to cover the metal bars of the adjustable side—was not secured to the permanent fabric siding. The child's torso slipped through the opening made by the unsecured fabric covering, the chin/throat caught on the edge of the lower crossbar, and the child strangled. The fourth death occurred when an infant moved into a corner where the fabric covering the adjustable side was not secured by the Velcro strip and the bassinet was also missing the lower rail. This created a pocket between the side and bassinet floor; the infant was found with the head in the pocket and face against the side of the bassinet, resulting in suffocation.

Of the three reported nonfatal injuries, two were the result of product-related head and neck entrapments identical to those that caused three of the fatalities described above, including the same product brand and model. The third injury, also product-related, was a respiratory difficulty due to a hyperextended neck, caused when the infant pushed its face into a cloth-covered corner of the sleep environment. Within the incident descriptions, CPSC staff found six other descriptions of near-strangulation or -suffocation events that did not cause injury.

More than 60 percent of the incidents (24 of 40) reported product-related issues. The remaining 16 were non-incident reports containing consumer concerns and/or complaints of products, or they were questions regarding CPSC recall notices. The 24 product-related incidents are the focus of this memorandum. They are discussed within the product-related issues listed below in order of severity and frequency:

1) Unsecured adjustable fabric cover

   This scenario led to all four fatalities and two of the three injuries. All six of these incidents occurred in the same brand and model multiuse product that could be converted

[17] Memorandum from Risana Chowdhury to Douglas Lee, "Bedside Sleeper-Related Deaths, Injuries, and Potential Injuries; 2001–2011," March 15, 2012.

[18] *"Six Retailers Agree to Stop Sale and Recall Simplicity Bassinets Due to Strangulation Hazard," Release #08-0381, U.S. CPSC, August 28, 2008 (revised April 9, 2009).*

from a bassinet to a bedside sleeper. This product was recalled on August 28, 2008. The sleep environment was constructed of a fabric-covered metal tube frame (see Fig. 3). On the side that lowered, the fabric wall could be separated from the rest of the covering. To lower the side, the fabric is unfastened from the upper rail, the upper rail is removed, and then the fabric is draped over the lower rail. The fabric is then intended to be secured over the lower rail. This procedure is to be reversed to restore the product to the bassinet mode. The vertical face of the fabric side is secured to the immobile fabric wall with a hook-and-loop fastener sewn into the edges.

If consumers fail to secure the fabric side over the upper rail and to the permanent fabric siding when restoring the product to the bassinet mode, an occupant could slide between the lower bar and the sleep surface. The reports of two deaths describe the infants being found hanging by the neck after their torsos slid through the lower opening through which their heads would not fit. The third death was similar. The child fell between the lower bar and sleep surface but was found with the chin on – and neck pushed against – the edge of the sleep surface, which led to strangulation. These reports also indicate that the product was in the bassinet mode at the time of the fatality, with the fabric side not secured over the top rail to the permanent fabric siding. Tests performed by CPSC staff indicate that the exact same fatal hazard scenario exists with the product in the bedside sleeper mode (Fig. 4). When the fabric side is also not secured correctly in the bedside sleeper mode, it presents the same fatally inadequate barrier to a child's torso.

These incidents would not have occurred if the product had been designed to meet the performance requirements of the current version of the voluntary bassinet standard, ASTM F2194-12a. Section 6.7 of the ASTM F2194-12a, *Fabric-Sided Enclosed Openings*, prohibits products from having a completely bounded opening that permits an infant-torso-size probe (Fig. 5) to pass through. The specific tests, described in section 7.8 of ASTM F2194-12a, force the tapered end of the probe against the interior fabric sides of the occupant space of a product assembled per the manufacturer's instructions.

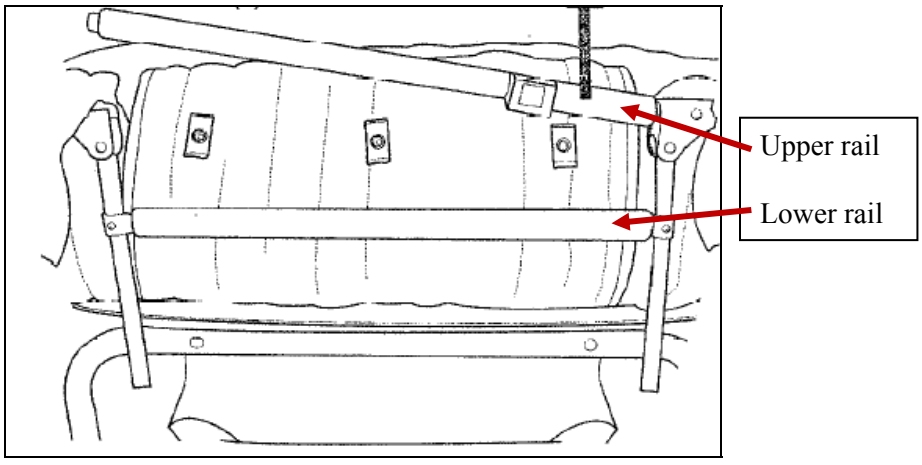

Figure 3. Construction of side lowered to convert product between bassinet and bedside sleeper modes.

Figure 4. Recalled product in bedside sleeper mode with fatal head/neck entrapment hazard.

Additionally, the bassinet voluntary standard addresses the scenario in which the fabric side is not secured properly. This is the scenario that led directly to all four deaths and the two injuries described above. Test section 7.8.5 in ASTM F2194-12a requires the product's fabric sides to be misassembled intentionally: "If the product has a removable cover, unfasten all fasteners and/or snaps but leave cover in place." The torso probe test is then repeated on the intentionally misassembled product. CPSC staff has performed this test on new samples of the recalled products. They fail this test because they allow the passage of the torso probe.

CPSC staff believes that the five hanging incidents (three fatalities and two injuries) would not have occurred if a performance requirement of section 6.7 in ASTM F2194-12a had existed in the bassinet standard, and the product was certified to the standard prior to manufacturing. The current voluntary bedside sleeper standard (ASTM F2906-12) addresses this hazard by requiring the ASTM F 2194-12 bassinet test to be performed on this product.

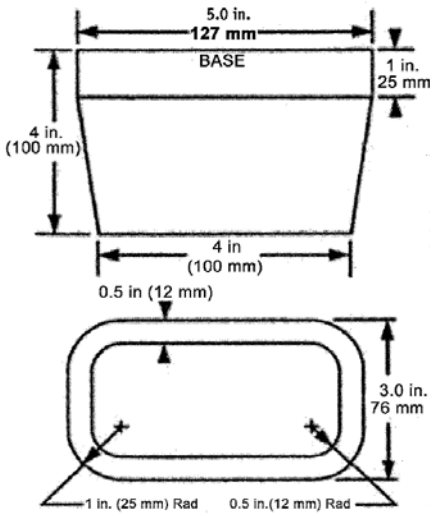

Figure 5. Infant torso probe used by ASTM F2194-12a.

The fourth death occurred when a two-month old child rolled against the unsecured fabric covering the adjustable side. The fabric was loose but the child did not fall through. When she rolled against the side, her face was covered by the fabric. Complete coverage the nose and mouth led to asphyxiation. The product was in the bassinet mode at the time of assembly. Staff believes that the torso probe test described above would have prevented this death. To pass this test, the manufacturer would have needed to have either secured the fabric to the underlying structure better, or limited the openings in the underlying structure itself. If the product had either of these modifications, the fabric side would no longer be loose enough to envelop a child's face.

2) Assembly instruction issues

There were six incidents involving assembly instructions in older products. In one incident, the consumer misassembled the product but presumed the product was defective and therefore, unsafe. The other five incidents were related to the use of a liner as an essential structural component. Some consumers believed it to be for decorative purposes only and either did not secure it to the product's play yard frame or omitted it entirely.

When the liner is omitted, it is possible for an infant to fall underneath the sleep surface onto the play yard floor support beams. The resulting injuries could forseeably include abrasions and contusions. Asphyxiation and strangulation are possible, depending on whether blankets, pillows, toys, diaper bags, or other soft or corded items are stored under the bedside sleeper accessory's mattress pad. When the liner is not secured to the play yard frame, an infant's torso could become entrapped between the lowered side rail

of the bedside sleeper and the mattress pad. This entrapment scenario could become fatal if the child's torso passes through but their head does not (Fig. 4).

This product was recalled in 2011 to include improvements in the instructions and labeling.[19] Newer units from the same manufacturer emphasize the necessity of the liner, and CPSC staff has no reports of this hazard scenario in the new units. CPSC Human Factors staff has evaluated the instruction manuals of recently manufactured product and believe they are appropriately detailed.[20] Additionally, CPSC staff participated in the ASTM task group that developed requirements for F2906. Section 8.1 of these requiremends states: "All bedside sleeper products shall comply with instructional literature requirements of Consumer Safety Specification F2194." The voluntary standard F2194 in section 9.1 requires: "Instructions must be provided with the product and shall be easy to read and understand." CPSC staff believes that the instructions meet this requirement and does not recommend changes or modifications to this language at this time.

3) Miscellaneous product-related issues (9 reports):

- *Product not level* (1 report)

  The consumer reported the sleep surface tilted down toward the lowered side, causing their swaddled 2-month-old child to roll into the bunched fabric, creating a suffocation risk. CPSC investigators visited the consumers and could not measure any discernible tilt to the product or the floor upon which it was placed during use.[21] The product was also evaluated in the CPSC National Product Testing and Evaluation Center (NPTEC) by LS and ES staff to the proposed bassinet NPR requirements, which it met.

  According to section 5.1 of the bedside sleeper ASTM standard, bedside sleeper products must comply with the requirements of the bassinet standard F2194 because they present the same hazards. For the bassinet , NPR, CPSC staff recently recommended modifications to the ASTM bassinet standard, ASTM F2194, to include a mattress flatness requirement that limits the allowable angle of a segmented mattress to 10 degrees. The CPSC Bassinet Rulemaking Team provided a detailed discussion of this change in the Commission's Bassinet Notice of Public Rulemaking briefing package.[22] Therefore, to address this

[19] Release #11-187, "Arm's Reach Concepts Recalls Infant Bedside Sleepers Due to Entrapment, Suffocation and Fall Hazards," Office of Information and Public Affairs, U.S. CPSC, April 5, 2011.
[20] Nesteruk, HEJ, Product Safety Assessment 0825.10, September 17, 2010.
[21] Epidemiologic Investigation Report 080721HCC3707, July 28, 2008.
[22] Edwards P *et. al.*, Staff Briefing Package "Consumer Product Safety Improvement Act of 2008 (CPSIA): Notice of Proposed Rulemaking (NPR) for Bassinets and Cradles," U.S. CPSC, September 19, 2012.

hazard with bedside sleepers, CPSC staff recommends adopting the mattress flatness requirements recommended by the Bassinet Rulemaking Team (see Appendix).

- *Unstable leg extensions* (2 reports)

  In two separate reports, consumers with the same brand bedside sleeper used manufacturer-recommended leg extensions to increase the height of the product. In doing so, they felt the product became unstable. The lowered side of bedside sleeper products is intended to be positioned at or just below the height of the adult bed's mattress. To adjust the height of their bedside sleeper products, one manufacturer sells leg extension segments that raise the product in 2-inch increments. Up to three of these 2-inch segments may be added to each leg.

  CPSC staff used the bassinet voluntary standard ASTM F2194-12a section 6.4 freestanding product stability requirement to test products from the same manufacturer that are substantially identical to those described in these incident reports. The products met the stability requirements. CPSC staff believes that these products are sufficiently stable to provide a safe sleep environment. Additionally, it is noted that bedside sleepers are intended to be secured to adult beds while in use. While secured to an adult bed, these products are extremely unlikely to tip or fall over. This hazard is addressed by F2906-12 because it requires bedside sleepers to meet the F2194-12a freestanding product stability requirement.

- *Poor design* (2 reports, 1 injury)

  Both of these reported incidents involved near suffocations. In one, a 90th percentile, 8-month-old boy moved himself perpendicular to the length of the bedside sleeper while it was used as a bassinet. Apparently, he lifted his head so that it got stuck on the side of the bassinet and could not remove it. CPSC staff notes that the age limit for children in bassinets and bedside sleepers is about 5 months; the user in this incident was 3 months over that limit. The side heights of bedside sleepers, bassinets, and cradles are designed for children who are not able to sit up or push to their hands and knees. This typically occurs by about 5 months of age. This incident highlights why a safe sleep product for a newborn is not necessarily safe for an older infant. No further action is recommended at this time.

  In the second incident, a 4-month-old child maneuvered into a position on his back with his head turned to the side and tilted backward, forcing his face against the cloth in a corner of the product. This position seemed to restrict the child's

ability to breathe. The consumer felt that the sides of the product should have been made of mesh. CPSC Health Sciences Directorate staff[23] reports that the vertical cloth wall on the incident product is not sufficient to cause suffocation because it does not completely envelop the child's nose and mouth. Soft mattresses, some toys, and voluminous blankets can pose a suffocation hazard because they can completely envelop an infant's face. In this incident, the victim was able to breathe from the side of his nose. CPSC staff also notes that the mattress fit properly; there were no objects in the product with the victim, such as pillows, toys, or blankets; nor was the sleep surfaced tilted; any of those things could have kept the child in place. No further regulatory action is recommended at this time. The CPSC continues to educate and warn parents and caregivers about the dangers of soft bedding in the infant sleep environment.

- *Broken component complaint* (1 report)

  One report was received of a rigid-sided product that broke after one month of use. The product was converted from a bassinet to bedside sleeper every evening and back to a bassinet every morning. After one month of use, the top rail of the side that lowers separated from the vertical slats. The consumer believed this to be a product failure. However, the manufacturer believed the product was damaged during shipping before the consumer received it.

  This incident occurred seven years ago (2006), and it is the only rigid-sided product incident out of the 40 total reports. CPSC staff is well aware of the hazards associated with the structural integrity of rigid-sided child sleep products (*i.e.*, full-size and non-full-size cribs). CPSC staff will continue to monitor incoming incident reports for rigid-sided products with structural integrity problems. No further action is recommended at this time.

- *Adult bed attachment mechanism failure* (1 report)

  The consumer reported that the straps that secure the product to the adult bed were routed incorrectly in the buckles, which permitted the strap to slip when tension was applied. Staff in the CPSC Engineering Sciences Directorate evaluated the incident description reported by the consumer and determined that the exemplar products were assembled correctly and should not slip. No further action is recommended at this time. The hazard posed by strap slippage is the creation of a gap between the bedside sleeper and adult bed, in which an infant could become entrapped. This hazard is addressed in F2906-12 with the section 5.3 Product Disengagement requirement and its associated test method in section 6.1.

[23] Personal communication with Suad Wanna-Nakamura, M.D., Ph.D., August 14, 2012.

- *Unclear age labeling* (1 report)

  The consumer reported that the convertible product, when used in play yard mode, has a weight limit of 30 lbm., but only an age limit is applied to its use in bassinet and bedside sleeper modes. The consumer felt that these use limitations were contradictory and confusing.

  This type of complaint is not unique to bedside sleepers. It is, therefore, very important that multiuse products are labeled clearly for each mode, in accordance with the marking and labeling requirements applicable to the particular mode (*e.g.*, bedside sleeper mode per F2906-12, play yard mode per F406-12a). When this incident occurred in 2006, there was no standard for bedside sleepers; however, Human Factors staff believes that the current standard will ensure that the bedside sleeper mode is identified more clearly in the marking, labeling, and instructions, and this will reduce possible confusion between the modes.

  In addition, CPSC staff believes that bedside sleepers should have the same developmental limits as bassinets, and that the developmental milestone is the most appropriate signifier for when to stop using a bedside sleeper. Section 7.3.1.3 of F2906-12 requires that the retail packaging for bedside sleepers be marked as follows: "A bedside sleeper is designed to provide a sleeping area for an infant until he or she begins to push up on hands and knees or approximately 5 months of age. Move your child to another sleeping product when your child reaches this stage." Section 7.2 requires marking the product with the same statement. No further action with regard to this incident report is recommended at this time.

C. Review of Mandatory and Consensus Standards

1. A Brief History of CPSC Rulemaking

   Currently, the CPSC does not have a specific regulation for bedside sleepers.

2. History of the Current Voluntary Standard ASTM F2906-12

   ASTM first published a consumer product standard for bedside sleepers, ASTM F2906-11, in December 2011. Initially, the standard required bedside sleepers to meet the

voluntary standard requirements of the product upon which it was based, either a bassinet or play yard, in order to establish a basic level of overall product safety.

The standard then addressed hazards specific to bedside sleeper products. It 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 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 alongside the adult bed, per 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. cannot 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 was crucial to mitigate the foreseeable head and neck entrapment hazards posed by bedside sleepers.

Human Factors staff indentified a 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.[25] Lastly, latching and locking security and child resistance is evaluated to help prevent unintentional movement of the side that lowers and to ensure overall product integrity.

In early 2012, sufficient evidence had been gathered by CPSC staff and the ASTM Bedside Sleeper Subcommittee (F15.18) to change the primary requirement from meeting either F406 or F2194, to require all products to meet F2194 only. Bedside sleepers and bassinets share a significant number of hazard patterns because they are used by children with the same developmental abilities and for the same purpose. Ensuring all bassinet hazards are addressed by bedside sleepers made the standard more stringent because there are bedside sleeper hazards not covered by the play yard standard. 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 (F406). Changing the bedside sleeper standard (F2906) to require all bedside sleepers to meet the bassinet standard (F2194 made the standard more stringent and at the same time ensured that no play yard-related hazards would go unaddressed. This change was published in F2906-12 in July 2012.

3. International Standards

[25] ASTM F2906-12, Standard Consumer Safety Specification for Bedside Sleepers, Section 5.4.1, Four-Inch Nest Rationale.

CPSC staff reviewed mandatory and voluntary standards promulgated by our colleagues in Canada, the European Union, Australia, and New Zealand.

Canada – In early 2011, Health Canada deemed standard size Arm's Reach Co-Sleeper products too heavy to be portable, and therefore, classified them as "cribs." As such, they did not comply with various requirements under their crib regulations. For example, Health Canada testing found that they do not meet the minimum side height requirement for cribs (230mm, about 9 inches above the upper surface of the mattress support).[26] In April 2011, Health Canada effectively banned full-size Arm's Reach products from sale in Canada.

The work leading to the Arm's Reach ban in April 2011 was expanded and incorporated into the June 20, 2011 mandatory standard for cribs, cradles and bassinets, SOR/2010-261.[27] This regulation, in essence, bans *all* bedside sleeper products from sale in Canada that are known to CPSC staff. All bedside sleeper products have one side that is permanently, or can be adjusted to be, lower than the other three. Health Canada requires all four sides around the sleeping surface to be at least 230 mm (about 9 inches) above the upper surface of the mattress support.

European Union – A bedside sleeper standard does not exist in Europe. Selected portions of EN 1130, *Cribs and Cradles,*[28] and EN 12790, *Child care articles – Reclined cradles,*[29] are used by manufacturers to assess and market various design elements and structures in their bedside sleeper products. For example, one manufacturer references the EN 1130 mattress pad support surface, hardware, and stability requirements on its website to promote their product's safety.

Australia and New Zealand – Australia and New Zealand also do not have a specific bedside sleeper standard. There are three mandatory standards governing child safe sleep products in Australia and New Zealand:

a. AS/NZS 2172:2003, *Cots* (full-size and non-full-size cribs that do not fold)
b. AS/NZS 2195:1999 *Folding cots* (play yards and folding cribs of any size)
c. AS/NZS 4385:1996 *Infants' rocking cradles* (cradles and bassinets that tilt)

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[26] Health Canada "Consumer Product Recalls" website: http://cpsr-rspc.hc-sc.gc.ca/PR-RP/recall-retrait-eng.jsp?re_id=1310, April 7, 2011.
[27] SOR/2010-261 Cribs, Cradles and Bassinets Regulations, Health Canada, June 10, 2012.
[28] EN 1130:1996 Furniture - Cribs and Cradles for domestic use - Part 1: Safety Requirements, - Part 2: Test Methods, European Committee for Standardization (CEN), March 1996.
[29] EN 12790:2009 Child care articles – Reclined cradles, European Committee for Standardization (CEN), May 31, 2009.

The first two require a minimum adjustable side height of 250 mm (about 10 inches) above the mattress base; the last requires a minimum side height of 300mm (about 12 inches) above the mattress base. With a typical 3-inch thick (76 mm) mattress, the effective side height for cots is reduced to about 7 inches (178 mm); and the effective side height for rocking cradles would be about 9 inches (229 mm). (Thinner mattresses would increase the effective side heights.) These values are similar to those required by the equivalent ASTM standards for cribs and non-full-size cribs (9 inches, 228 mm), and bassinets and cradles (7.5 inches, 191 mm). Bedside sleeper products have not been discussed by the Australian Standards Committee; therefore, no AS/NZS standard is expected in the foreseeable future.

D. Recent Changes to ASTM F2906

In March 2012, ASTM Section 15 Ballot 12-03 Item 26[30] proposed requiring that all bedside sleepers meet the bassinet standard (F2194) and eliminated the option of meeting the play yard standard's requirements (F406) instead. This recommendation was balloted, accepted, and published in July 2012, based in part on CPSC staff's recommendations to the ASTM subcommittee for bedside sleepers.[31] In effect, this made ASTM F2194, *Standard Consumer Product Safety Specification for Bassinets and Cradles* the fundamental consumer product safety requirement for all bedside sleepers whether or not they can be converted into a bassinet or cradle. Bassinets and bedside sleepers are intended for use by the children with the same developmental capabilities and recommended ages. By requiring the bassinet standard's requirements to be met, the bedside sleeper standard ensures hazards common to the same population of children are addressed.

Elimination of the play yard standard from the bedside sleeper standard as the fundamental requirement does not prohibit manufacturers from selling bedside sleeper products that may be converted into play yards. The bassinet standard (F2194 section 5.12) requires that:

> *A bassinet accessory intended to be attached to, removable from, sold with or separately from a play yard or non-full-sized crib shall comply with the requirements of this specification and Consumer Safety Specification F406 when attached in the manufacturer's recommended use position.*

In effect, bassinets that are based on play yard structures must meet the applicable sections of the play yard standard (F406). Because bedside sleeper products must meet the bassinet standard requirements (F2194), in turn, they also must meet applicable sections of the play yard standard

[30] ASTM Section 15 Ballot 12-02, Item 26, issued March 9, 2012.
[31] Letter from Doug Lee, CPSC Bedside Sleeper Project Manager to James Dodds, Chair ASTM workgroup for Bedside Sleepers dated September 8, 2011 providing CPSC staff comments.

(F406). Therefore, a bedside sleeper product that converts into a play yard and bassinet would have to meet:

1) the F406 play yard requirements when in the play yard mode;
2) F2194 bassinet requirements and applicable sections of the F406 play yard requirements when in the bassinet mode; and
3) F2906 bedside sleeper requirements, F2194 bassinet requirements (except for the height of the fourth side), and sections of the F406 play yard requirements applicable to bassinets when in the bedside sleeper mode.

II. STAFF-RECOMMENDED CHANGES FORTHE PROPOSED STANDARD

A. Changes Recommended to the Voluntary Bedside Sleeper Standard F 2906-12

1) Fabric-Sided Enclosed Openings

The current version of the bassinet/cradle voluntary standard, ASTM F2194-12a, contains a *Fabric-Sided Enclosed Openings'* performance requirement. This requirement prohibits completely bounded openings large enough to permit passage of an infant's torso. The hazard scenarios addressed by this requirement encompass the three strangulation deaths described above and a related, foreseeable suffocation hazard. These hazards occur when a child passes through an opening, either becomes trapped between the liner and mattress pad and suffocates, or becomes suspended by the neck and then strangles.

This hazard, associated with a recall of 900,000 units, led to three of the four fatalities on a bassinet that converts to a bedside sleeper and is the most severe class of incidents discussed above and in Section B, Incident Hazard Review. The test procedure (ASTM F2194-12a, section 7.8) attempts to push a torso probe the size of a 5^{th} percentile infant (Fig. 5) through bounded openings with 20 lbs of force. The test is first performed with product assembled per the manufacturer's instructions. If the product has a removable cover, it is performed a second time after all fasteners or snaps are unfastened, but the removable cover left in place. In doing so, the test intentionally replicates the incorrectly secured fabric liner hazard scenario of the fatal incidents.

Another manufacturer's bedside sleeper product exhibited this hazard, which led to their recall in 2011.[32] The recall was initiated in response to incident reports in which the bedside sleeper accessory's removable cover (liner or shell) was either not used, or present but not secured to the play yard frame.[33] This product can also be used as a play yard, or a bassinet accessory to a play yard. When in the bassinet accessory position, the front side of the product can be lowered, transforming it to the beside sleeper mode.

A 1 ½-year-old unused sample of this product was recently retested by staff, confirming that it fails the ASTM F2194 fabric-sided enclosed opening requirement. However, a new sample of a similar model from the same manufacturer passed this test. Staff identified two possible reasons for testing variances. One explanation is that the fit of the shell to the play yard frame becomes looser with repeated assembly and disassembly. The other reason is that the seam joining the mesh and fabric part of the liner may be in a slightly different location on some models. The seam may cause sufficient friction on the torso test probe during force testing on some models. Regardless, when minor changes in materials or construction could change this product from being a safe sleep environment to an unsafe sleep environment, the product is not safe with regard to the fabric-sided bounded opening hazard.

Play yard bassinet accessories are exempt from the fabric-sided openings requirement in the current bassinet standard, and thus this particular product would not have to meet the requirement. Therefore, staff recommends addressing the hazard of an unsecured shell on a play yard frame by requiring that all bedside sleeper products be subject to the requirements of the ASTM F2194-12a basinet standard's section 6.7 *Fabric-Sided Enclosed Opening* by reference, including those that could be considered a play yard bassinet accessory. Under section 6.7 of ASTM F2194-12a, for bassinets/cradles with fabric sides, a completely 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 bassinets or play yard accessories. The staff proposes additional language for the ASTM F2906 bedside sleeper standard 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. Unlike bassinet play yard accessories, bedside sleeper (or a bassinet that is converted into a bedside sleeper) play yard accessories could have fasteners left unclipped (through the detachment of snaps/Velcro) where the bedside sleeper with the lowered side does not completely collapse. Because the bedside sleeper could still appear functional, the staff proposes to add the following language:

(Underlined text is new):

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[32] *Release #11-187, "Arm's Reach Concepts Recalls Infant Bedside Sleepers Due to Entrapment, Suffocation and Fall Hazards," Office of Information and Public Affairs, U.S. CPSC, April 5, 2011.*

[33] Misassembly of the bedside sleeper attachment by omitting the liner is addressed by staff recommendation #2, below.

3.1.X *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.

5.7 *Bedside Sleeper Accessory Fabric-Sided Enclosed Openings*—A bedside sleeper accessory shall meet the F2194 performance requirement "*Fabric-Sided Enclosed Openings."*

5.7.1 Bedside sleeper accessories are exempt from this requirement if either of the following two conditions is met after disengaging all fasteners between the accessory and the non-full-size crib or play yard base to which it is assembled.

5.7.1.1 The bedside sleeper accessory collapses under its own weight, such that any part of the mattress pad contacts the bottom floor of the non-full-size crib or play yard.

5.7.1.2 The bedside sleeper accessory's sleep surface tilts by more 30 degrees.

2) Consumer Misassembly with Missing Components

Currently, there are no requirements in ASTM F2906 that directly address misassembly of bedside sleeper accessories to play yards. However, specific language to address this hazard for play yard bassinet accessories has been proposed in the notice of proposed rule for Safety Standard for Play Yards (77 FR52272, August 29, 2012). This proposed rule, if finalized, would amend the Safety Standard for Play Yards, 16 CFR 1222 (see 77 FR 52220, August 29, 2012). Concurrently, the play yard bassinet attachment misassembly requirement is being balloted by the ASTM play yard subcommittee for inclusion in F406.[34]

During the course of ownership, or when the product is resold or handed down and placed in use by multiple, successive users, components that are not affixed permanently to one another can be lost. Therefore, staff believes that it is reasonably foreseeable that bedside sleepers with missing components, or makeshift repairs not approved by the manufacturer, could be placed in use with newborns and infants. This issue is not limited to structural elements such as bars, tubes, and clips. As discussed above in section I.B (2), the textile shell of one multiuse product's bedside sleeper accessory has been omitted by consumers.[35] This was possible because the other structural elements supported the sleep surface without the shell, resulting in what appeared to be a safe environment. This hazard is magnified should these misassembled products be used as an unsupervised sleep environment, another

[34] ASTM Ballot F15 (12-06) Item 3, published August 14, 2012.

[35] *"Arm's Reach Concepts Recalls Infant Bedside Sleepers Due to Entrapment, Suffocation and Fall Hazards," Release #11-187, U.S. CPSC, April 5 2011.*

reasonably foreseeable scenario. As the child shifts position while sleeping, the misassembled product may become unstable, causing the sleep surface to incline beyond 10.°[36]

Staff also found this hazard in other products intended to provide a safe sleep environment (*i.e.*, one that does not require supervision, such as cribs and bassinets). In 2011, there was a product-related fatality of a 3-month-old child in the bassinet accessory of a play yard that had been assembled and used without an important structural component. Similarly, a bedside sleeper accessory misassembly may not be readily apparent or obvious to the consumer. If the misassembled accessory supports an infant without a catastrophic and obvious change to the sleep surface, a consumer may continue to use the misassembled accessory and inadvertently place a child in danger. Staff found that bedside sleeper accessories and bassinet accessories incorporate very similar designs and manufacturing processes, and therefore, many of the same performance requirements are applicable to both products.

Staff recommends that the following requirement be added to F 2906-12 (new language is underlined) that addresses misassembly to incorporate the same language proposed in the NPR for play yards in ASTM F406:

> 5.8 *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*."

B. Changes Recommended to F 2194-12 in the Bassinet Notice of Proposed Rulemaking

Most bedside sleepers also function as bassinets. The intended users are identical, and the majority of the hazards are identical. Staff recommendations to address bassinet hazards not addressed by the voluntary bassinet standard (F 2194-12) have been discussed in great detail in the Bassinet NPR staff briefing package.[37] Three of the four staff recommendations are applicable to bedside sleepers[38] and address foreseeable hazards:

3) Segmented Mattress Flatness Requirement and Test Method
   Hazard: Suffocation/positional asphyxia associated with excess mattress pad incline.

[36] Ten degrees is the maximum sleep surface incline recommended by staff on the CPSC Bassinet Rulemaking Team.
[37] Edwards P *et. al.*, Staff Briefing Package, "Consumer Product Safety Improvement Act of 2008 (CPSIA): Notice of Proposed Rulemaking (NPR) for Bassinets and Cradles," U.S. CPSC, September 19, 2012.
[38] The fourth recommendation made by Bassinet Rulemaking Team staff was to update the scope and corresponding terminology specific to the ASTM F2194.

d) Removable Bassinet Bed Stability

Hazard: Falls and entrapment under fallen product. The removable bed portion of the product is not completely latched or secured to the base, permitting it to fall off of its stand.

e) Stability Test Dummy

Hazard: Falls and entrapment under fallen product. Staff recommends using the lighter 7.5 lbm. newborn CAMI dummy in the stability test instead of the 17.5 lbm. infant CAMI dummy to create a safer and stricter stability test requirement.

Staff recommends these modifications should also be part of the bedside sleeper NPR. The language that addresses these proposed changes, in addition to the scope and definition changes they necessitate are identical to the Bassinet NPR and are provided in the appendix to this memorandum.

III. CONCLUSION

Staff recommends that the Commission propose to adopt by reference ASTM F2906-12 as the bedside sleeper mandatory rule, with the following substantive modifications:

1) Add language to address Fabric-Sided Enclosed Openings-related entrapment hazards.
2) Add language to address Consumer Misassembly with Missing Components.

CPSC staff also recommends proposing to incorporate the following performance requirements and associated test procedures contained in the bassinet standard (ASTM F2194-12a) to the bedside sleeper standard (ASTM F2906-12) to address hazards that bedside sleepers share with bassinets:

3) Segmented Mattress Flatness Requirement and Test Method
4) Removable Bassinet Bed Stability
5) Stability Test Dummy

Appendix
CPSC Staff-Recommended Revisions to ASTM F2194-12a Standard (for Bassinets)

(~~strikeouts~~ reflect deleted language, underline reflects added language)

Revised Definitions

NOTE:
Cradle swings, with an incline less than or equal to 10° from horizontal while in the rest (non-rocking) position, are covered under the scope of this standard. A sleep product that has an inclined sleeping surface (intended to be greater than 10° from horizontal while in the rest (non-rocking) position) does not fall under the scope of this standard. Strollers that have a carriage/bassinet feature are covered by the stroller/carriage standard when in the stroller use mode. Carriage baskets/bassinets that are removable from the stroller base are covered under the scope of this standard when the carriage basket/bassinet meets the definition of a bassinet/cradle found in 3.1.1. Bassinet/cradle attachments to cribs or play yards, as defined in 3.1.2 or 3.1.12, are included in the scope of the standard when in the bassinet/cradle use mode.

3.1.1 *Bassinet/cradle*, n – small bed designed ~~exclusively~~ primarily to provide sleeping accommodations for infants, supported by freestanding legs, a stationary frame/stand, a wheeled base, a rocking base, or that can swing relative to a stationary base; while in a rest (non-rocking or swinging) position, a bassinet/cradle is intended to have a sleep surface less than or equal to 10° from horizontal.

3.1.2 *Bassinet/cradle accessory*, n –a supported sleep surface that attaches to a crib or play yard designed for sleeping, to convert the product into a bassinet/cradle intended to have a ~~horizontal~~ sleep surface less than or equal to 10° from horizontal while in a rest (non-rocking or swinging) position.

New Performance Requirement for Mattress Flatness

6.9 Segmented Mattresses Flatness- If the bassinet or bassinet accessory has a folding and/or segmented mattress, any angle when measured in section 7.10 shall be less than or equal to 10 degrees.

7.10 *Segmented Mattress Flatness Test*

7.10.1 Angle measurement for bassinets intended for a single occupant:

7.10.1.1 Establish a horizontal reference plane by placing an inclinometer, with an accuracy capable of 0.5° minimum resolution, on the floor of the testing area and zeroing it.
7.10.1.2 Assemble the product according to the manufacturer's instructions. If the product has more than one mode, assemble in the bassinet mode(s). Disable the rocking/swinging feature if the product is equipped with such a feature.
7.10.1.3 Place the infant test cylinder, as shown in Fig. 13, in the center of the 1st seam (the seam between an end panel and its adjacent panel), as shown in Fig. 14, and allow the cylinder to come to rest in the seam.

NOTE: If the cylinder begins to roll out of the seam, place a stop(s) on the mattress surface against the cylinder to prevent movement. The stop(s) shall not influence the angle measurement and shall have a total weight no greater than 0.25 lbs.

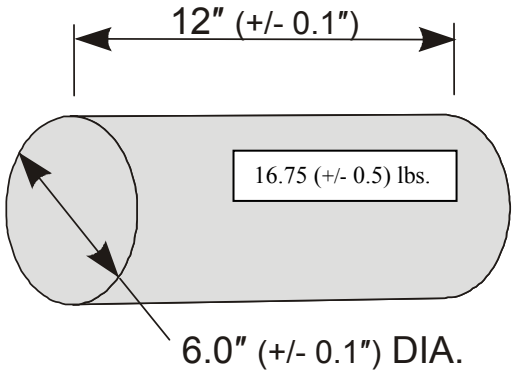

FIG. 13. Infant Test Cylinder

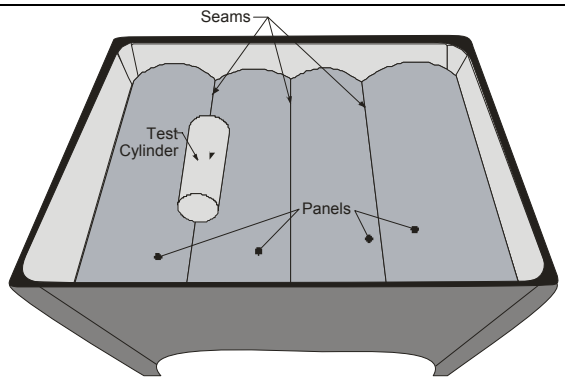

FIG. 14. Cylinder placement on mattress seam

7.10.1.4 Place a 6″x 4″ x 1/2″ (152 x 101.6 x 12.7 mm) nominal thickness steel block weighing 3.3 lbs. (+/- 0.2 pounds) on the mattress panel in front of the cylinder with the 6″ length of the block in line with the center line of the cylinder as shown in Fig. 15. Place the block within ½″ (12.7 mm) of the cylinder. If the block slides and touches the cylinder, this is allowable.

7.10.1.4.1 Where the play yard bassinet size constraints do not allow for placement of the steel block in front of the cylinder, move the cylinder off center, enough to allow placement of the block, as outlined above in 7.10.1.4.
7.10.1.5 Place the inclinometer in the center of the block, and measure the angle formed with the horizontal along the line that is perpendicular to the longitudinal axis of the cylinder, as shown in Fig. 16. Ensure the inclinometer does not touch the mattress surface.

Note: If needed, an additional level block of negligible mass, no greater than 0.2 lb, may be placed atop the steel block in order to elevate the inclinometer, such that it does not touch the mattress surface.

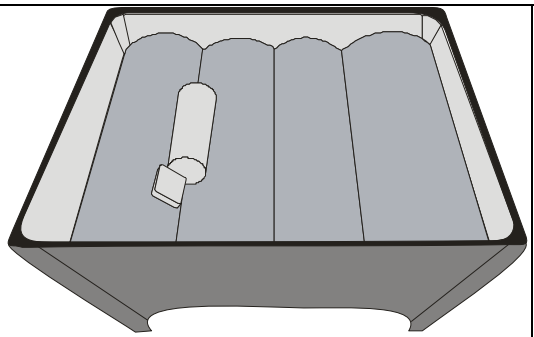

FIG. 15. Steel block in front of the cylinder for a single occupant bassinet

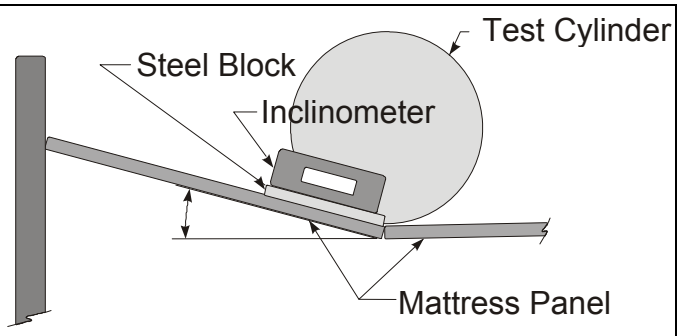

FIG.16. Inclinometer on steel block in front of the cylinder for a single occupant bassinet

7.10.1.6 Record the angle measurement.
7.10.1.7 Repeat 7.10.1.4–7.10.1.5 on the opposite side of the seam and record the measurement.
7.10.1.8 Remove the cylinder from the bassinet.
7.10.1.9 Repeat 7.10.1.3–7.10.1.8 on each remaining seam of the mattress and record the angles.

7.10.2 Angle measurement for bassinets intended for two occupants:

7.10.2.1 Establish a horizontal reference plane by placing an inclinometer, with an accuracy capable of 0.5° minimum resolution, on the floor of the testing area and zeroing it.
7.10.2.2 Place one at a time, two identical newborn test cylinders (A and B), as shown in Fig. 17 in the occupant retention areas, as shown in Fig. 18, and allow them to come to rest in the seam.

NOTE: If the cylinder begins to roll out of the seam place a stop(s) on the mattress surface against the cylinder to prevent movement. The stop(s) shall not influence the angle measurement and shall have a total weight no greater than 0.25 lbs.

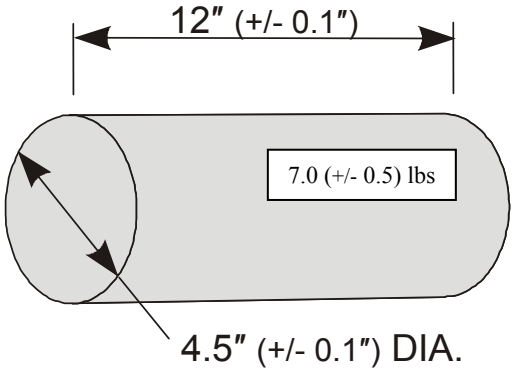

FIG. 17. Newborn Test Cylinder

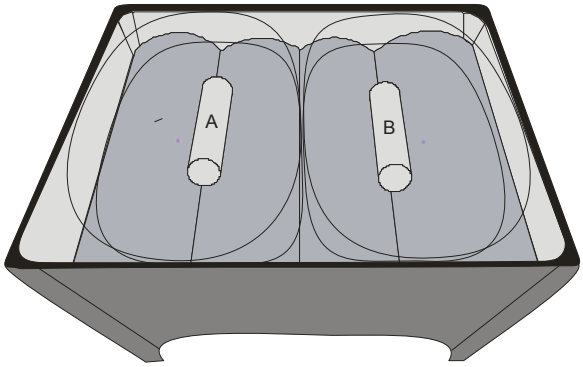

FIG. 18. Placement of cylinders for a 2 occupant bassinet

7.10.2.3 Apply a 10.0 ± 0.5 lb compression force simultaneously with a force gauge onto the center of each cylinder, and hold for 10 seconds.
7.10.2.4 Place a 6″x 4″ x 1/2″ (152 x 101.6 x 12.7 mm) nominal thickness steel block weighing 3.3 lbs. (+/- 0.2 pounds) on the mattress panel in front of cylinder A with the 6″ length of the block in line with the center line of the cylinder, as shown in Fig. 19. Place the block within ½″ (12.7 mm) of the cylinder. If the block slides and touches the cylinder, this is allowable.
7.10.2.4.1 Where the play yard bassinet size constraints do not allow for placement of the steel block in front of the cylinder, move the cylinder off center enough to allow placement of the block as outlined above in 7.10.2.4.
7.10.2.5 Place the inclinometer on the block, and measure the angle formed with the horizontal along the line that is perpendicular to the longitudinal axis of cylinder A, as shown in Fig. 20. Ensure that the inclinometer does not touch the mattress surface.

Note: If needed, an additional level block of negligible mass, no greater than 0.2 lb, may be placed atop the steel block in order to elevate the inclinometer, such that it does not touch the mattress surface.

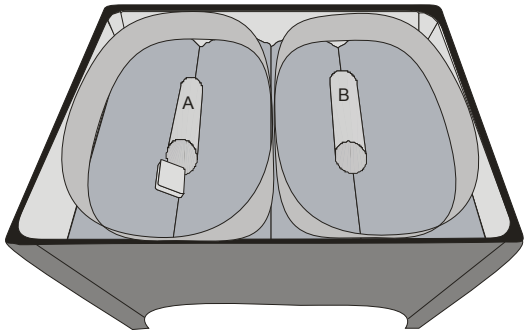

FIG. 19. Steel block in front of the cylinder for a 2-occupant bassinet

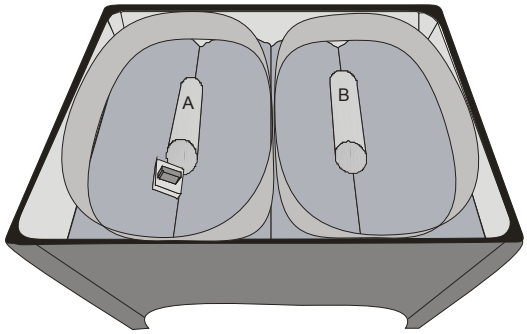

FIG. 20. Inclinometer on Steel block in front of the cylinder for a 2-occupant bassinet

7.10.2.6 Record the angle measurement.
7.10.2.7 Repeat 7.10.2.4–7.10.2.5 on the opposite side of the cylinder and record the measurement.
7.10.2.8 Repeat the angle measurements 7.10.2.4–7.10.2.7 for cylinder B and record the measurement.
7.10.2.9 Remove both cylinders and then place them in the occupant retention areas such that the side of the cylinders are in contact with the inside wall as shown in Fig. 21.
7.10.2.10 Apply a 10.0 ± 0.5 lb compression force simultaneously with a force gauge onto the center of each cylinder and hold for 10 seconds.

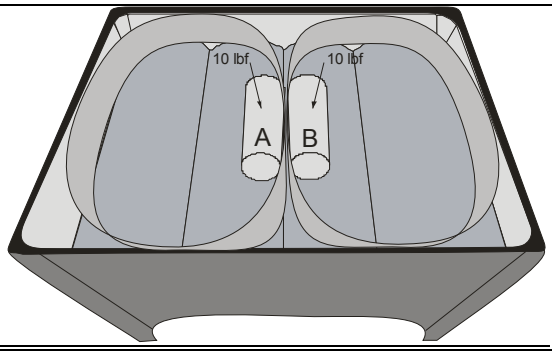

FIG. 21. Two cylinders (A and B) in contact with the inside wall

7.10.2.11 Place 6″x 4″ x 1/2″ (152 x 101.6 x 12.7 mm) nominal thickness steel block weighing 3.3 lbs. (+/- 0.2 pounds) on the mattress panel on one side perpendicular to the longitudinal axis of the cylinder, with the centerline of the block adjacent to the midpoint of the cylinder. Place the block within ½″ (12.7 mm) of the cylinder. If the block slides and touches either the inside wall or the cylinder, this is allowable.
7.10.2.12 Place the inclinometer in the center of the block, and measure the angle formed with the horizontal along the line that is perpendicular to the longitudinal axis of cylinder A as shown in Fig. 22.
7.10.2.13 Record the angle measurement.
7.10.12.14 Place a 6″x 4″ x 1/2″ (152 x 101.6 x 12.7 mm) nominal thickness steel block weighing 3.3 lbs. (+/- 0.2 pounds) on the mattress panel on one side perpendicular to the longitudinal axis of the cylinder, with the centerline of the block adjacent to the midpoint of the cylinder. Place the block within ½″ (12.7 mm) of the cylinder. If the block slides and touches the cylinder, this is allowable.
7.10.12.15 Place the inclinometer in the center of the block, and measure the angle formed with the horizontal along the line that is perpendicular to the longitudinal axis of cylinder B, as shown in Fig. 23.
7.10.2.16 Record the angle measurement.

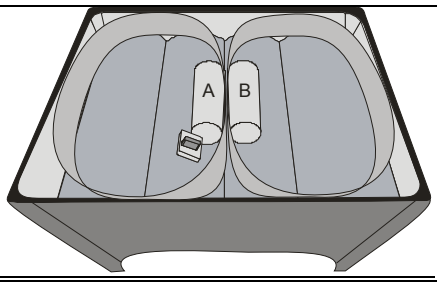	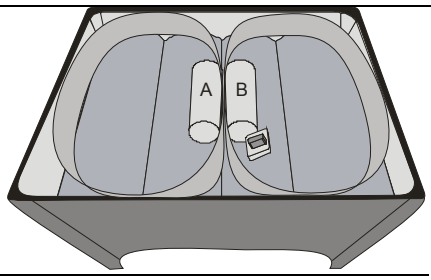
FIG.22 Angle measure in front of Cylinder A	FIG. 23. Angle measure in front of Cylinder B

Rationale:

The cylinder used in 7.10.1 was copied from a European standard for baby walkers (EN 1273:2005) and appears to be based on the weight and torso dimensions of a child between 6 and 8 months old. This represents the heaviest intended occupant, which will result in a more conservative test.

Because bassinet accessories intended for multiple births will have a shorter useful range of utility, the larger cylinder used in 7.10.2 was too heavy to represent the intended user population. The smaller cylinder used in 7.10.2 was based on the weight of an infant, matched to the height of the test cylinder in 7.10.1.

Revised Test Procedure for Bassinet Stability

1) Add reference for the CAMI Newborn dummy.

2.3 CAMI Newborn Dummy (See Fig X)[39]

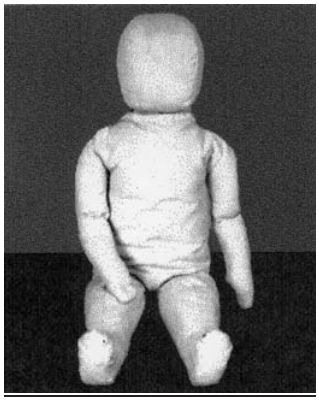

FIG. X CAMI Newborn Dummy

2) Change stability testing procedures to use CAMI Newborn dummy, rather than CAMI Infant dummy:

[40]A bassinet or cradle is a small bed for infants supported by freestanding legs, a wheeled base, a rocking base, or that can swing relative to a stationary base. ASTM International, *Standard Specification for Bassinets and Cradles* (F 2194-12).

7.4.4 Place the CAMI ~~Infant~~ Newborn Dummy, ~~Mark II,~~ on the sleeping pad in the center of the product face up with the arms and legs straightened.

Rationale

The newborn CAMI dummy represents a 50th percentile newborn infant, which is a more appropriate user of a bassinet than the CAMI infant dummy, which represents a 50 percent 6-month-old infant.

New Performance Requirement and Associated Definitions to Address Hazards Associated with the Stability of Removable Bassinet Beds

1) Associated definitions

3.1. 3 *conspicuous*, *adj*—describes a label or indicator that is visible, when the bassinet/cradle is in a manufacturer's recommended use position, to a person standing near the bassinet/cradle at any one position around the bassinet/cradle but not necessarily visible from all other positions.

3.1.17 *bassinet bed, n* – the sleeping area of the bassinet, containing the sleep surface and side walls.

3.1.18 *removable bassinet bed, n* – A bassinet bed that is designed to separate from the base/stand without the use of tools.

3.1.19 *false lock/latch visual indicator, n* – a warning system, using contrasting bright colors, lights, or other similar means, designed to alert caregivers visually when a removable bassinet bed is not locked properly onto its stand/base.

3.1.20 *intended use orientation,* n – The bassinet bed orientation (*i.e.*, the position where the head and foot ends of the bassinet bed are located), with respect to the base/stand, as recommended by the manufacturer for intended use.

2) Test Requirement and Procedure

6.X *Removable Bassinet Bed Attachment* - Any product containing a removable bassinet bed with a latching or locking device intended to secure the bassinet bed to the stand/base, shall comply with 6.x.1, 6.x.2, 6.x.3, 6.x.4 or 6.x.5 when tested in accordance with 7.X.

6.X.1 The base/stand shall not support the bassinet bed (*i.e.*, the bassinet bed collapses from the stand and contacts the floor).

6.X.2 The lock/latch shall engage automatically under the weight of the bassinet bed (without any other force or action).

6.X.3 The sleep surface of the bassinet bed shall be at least 20° off from a horizontal plane when the bassinet bed is in an unlocked position.

6.X.4 The bassinet shall provide a false latch/lock visual indicator(s) that is conspicuous, at a minimum, on the two longest sides of the product.

6.X.5 The bassinet bed shall not tip over and shall retain the CAMI newborn dummy when tested in accordance with 7.X.5.3.

7.X *Removable Bassinet Bed Attachment Tests*

7.X.1 Assemble the bassinet/cradle base/stand only, in accordance with manufacturer's instructions.

7.X.2 Place the base/stand in one of the manufacturer's recommended use positions.

7.X.3 Place the base/stand and the inclinometer on a flat level horizontal surface (0 +/- 0.5°) to establish a test plane. Zero the inclinometer.

7.X.4 Remove the mattress pad from the bassinet bed.

NOTE 2—For mattresses that are integral with the mattress support, do not remove the mattress, and perform all angle measurements for 7.X on a 6″ by 6″ by ⅜″ nominal aluminum block placed on the center of the mattress.

7.X.5, Place the bassinet bed on the base/stand in the intended use orientation without engaging any latch or lock mechanism. If the bassinet bed can rest on the base/stand in its intended use orientation in more than one lateral unlocked position, the unit shall be evaluated in the lateral position most likely to fail the requirements outlined in 6.X.

7.X.5.1 If the base/stand supports the bassinet bed, place the inclinometer on the mattress support at the approximate center of the mattress support or as close as possible. Care should be taken to avoid seams, snap fasteners, or other items that may affect the measurement reading. Record the angle measurement.

7.X.5.2 If the base/stand supports the bassinet bed and the angle of the mattress support surface is less than 20 degrees of horizontal, evaluate whether the bassinet has a visual indicator per 6.4.2.

7.X.5.3 If the base/stand supports the bassinet bed, and the angle of the mattress support surface is less than 20 degrees of horizontal, and the bassinet does not contain a false latch/lock indicator, test the unit in accordance with sections 7.4.2-7.4.6.

7.X.6 Repeat 7.X.3 through 7.X.5 for all of the manufacturer's base/stand positions.

7.X.7 Repeat 7.X.2 through 7.X.6 with the bassinet bed rotated 180° from the normal use orientation.

Rationale

This test requirement addresses fatal and nonfatal incidents involving bassinet beds that tipped over or fell off their base/stand when they were not locked/latched properly to their base/stand or the latch failed to engage as intended. Products that appear to be in an intended use position when the lock or latch is not engaged properly can create a false sense of security by appearing to be stable. Unsecured or misaligned lock/latch systems are a hidden hazard because they cannot easily seen by consumers due to their location beneath the bassinet or being covered by decorative skirts. In addition, consumers will avoid activating lock/latch mechanisms for numerous reasons if a bassinet bed appears stable when placed on a stand/base. Because of these foreseeable use conditions, this requirement has been added to ensure that bassinets with a removable bassinet bed feature will be inherently stable or it is obvious that they are not secured properly.

6.X. allows bassinet bed designs that:

1) cannot be supported by the base/stand in an unlocked configuration,

2) lock automatically and cannot be placed in an unlocked position on the base/stand,

3) are clearly and obviously unstable when the lock/latch is misaligned or unused,

4) provide a visual warning to consumers when the product is not locked properly onto the stand/base, or

5) have lock/latch mechanisms that are not necessary to provide needed stability.

TAB C: [Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Bedside Sleepers]

TAB C

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

Memorandum

Date: September 20, 2012

TO : Douglas Lee
Project Manager, Bedside Sleepers

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 : Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Bedside Sleepers

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 a durable toddler product of interest to the agency. Upon review, CPSC staff recommends that the Commission propose to adopt the voluntary ASTM International (or ASTM, formerly known as the American Society for Testing and Materials) standard for Bedside Sleepers (F 2906 – 12) *Standard for Consumer Specification for Bedside Sleepers*), with a few modifications.

The Regulatory Flexibility Act (RFA) requires that proposed rules be reviewed for their potential economic impact on small entities, including small businesses. Section 603 of the RFA requires that CPSC staff prepare an initial regulatory flexibility analysis and make it available to the public for comment when the general notice of proposed rulemaking is published. The initial 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 initial regulatory flexibility analysis must contain:

(1) a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
(2) a description of the reasons why action by the agency is being considered;
(3) a succinct statement of the objectives of, and legal basis for, the proposed rule;
(4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the types of professional skills necessary for the preparation of reports or records; and
(5) identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

Additionally, the initial regulatory flexibility analysis must contain a description of any significant alternatives to the proposed rule, which accomplish the stated objectives of the proposed rule, while reducing the economic impact on small entities.

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.

A unit that is designed to be used in more than one mode (referred to as a "multimode" or "multiuse" product) is included under the ASTM voluntary standard (F2906-12). Multimode products must comply with each applicable ASTM standard based on product use. A bassinet that can be converted to a bedside sleeper by lowering one side must comply with the bassinet standard, as well as the bedside sleeper standard.[40] A play yard that can be converted to a bedside sleeper must comply with the play yard standard, as well as the bedside sleeper standard.[41]

Freestanding bassinets are not covered under the proposed bedside sleeper standard. They are covered under the CPSC proposed rule for bassinets.

[40]A bassinet or cradle is a small bed for infants supported by freestanding legs, a wheeled base, a rocking base, or that can swing relative to a stationary base. ASTM International, *Standard Specification for Bassinets and Cradles* (F 2194-12).
[41] A play yard is a framed enclosure that includes a floor and has mesh- or fabric-sided panels primarily intended to provide a play or sleeping environment for children. It may fold for storage or travel. ASTM International, *Standard Specification for Non-Full-Size Baby Cribs/Play Yards* (F 406-12a).

The Market for Bedside Sleepers

Typically, bedside sleepers are 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.[42] There may be additional unknown small manufacturers and importers operating in the U.S. market as well.

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of bedside sleepers is small if it has 500 or fewer employees, and an importer is considered small if it has 100 or fewer employees. Based on these guidelines, all four domestic manufacturers known to be supplying the U.S. market are small.

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 (F 2906-12). However, three firms supply multimode products where one mode is 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.

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. 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 Proposed 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 adopting the voluntary standard (F 2906-12) with a few modifications.

[42] Staff made these determinations using information from Dun & Bradstreet and Reference USAGov, as well as firm websites.

CPSC staff identified 40 cases of bedside sleeper-related incidents from 2001 to 2011.[43] The CPSC databases searched were the In-Depth Investigation database, the Injury or Potential Injury Incident database, and the Death Certificate file. CPSC staff identified 24 incidents due to defect or potential design flaws in the product itself. The hazards associated with these incidents included: issues with the adjustable fabric cover over the metal bars on the side that lowered in bedside sleeper model (9 incidents); poor assembly instruction (6 incidents); and miscellaneous other product-related issues (9 incidents). The remaining 16 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 proposed rule potentially would address the 24 incidents involving product design.

Compliance Requirements of the Draft Proposed Rule

CPSC staff recommends that the Commission propose adopting the voluntary ASTM standard for bedside sleepers with a few modifications. Key components of the current ASTM standard for bedside sleepers (F 2906–12) include:

- bassinet and cradle requirements (F2194) – intended to ensure bedside sleepers meet the bassinet standard 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; and
- requirements for separation and product disengagement – intended to prevent entrapment between the product and adult bed.

CPSC staff recommends proposing to add to the existing ASTM standard the following requirements:[44]

- A requirement that a bedside sleeper accessory[45] be designed to meet the fabric-sided enclosed opening performance requirement, which prohibits openings large enough to permit the passage of an infant's torso.
- A requirement that a bedside sleeper accessory be designed to address consumer misassembly according to the F406 general requirement "Bassinet/Cradle Accessories Missing Key Structural Elements."

[43] Memorandum from Risana Chowdhury, Directorate of Epidemiology, dated March 15, 2012, Subject: Bedside Sleeper-Related Deaths, Injuries, and Potential Injuries; 2001–2011.
[44] Memorandum from Gregory K. Rea, Directorate for Laboratory Sciences, dated August 20, 2012, Subject: Proposed Changes to the Consensus Standard for Bedside Sleepers (ASTM F 2906-12) – Segue to a mandatory CPSC Standard for Bedside Sleepers.
[45] A bedside sleeper accessory is 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.

- A requirement that the bedside sleeper be designed to meet the mattress flatness performance requirement intended to minimize the possibility of suffocation due to an uneven mattress.
- A requirement that the bedside sleeper be designed to meet the removable bassinet bed stability requirement to ensure the product does not tip over.
- A requirement that the test procedure for stability be modified to use a 7.45 lbm newborn CAMI dummy in the stability test.

A bedside sleeper that can be used in additional modes would need to meet each applicable standard. A bedside sleeper product that converts into a play yard and a bassinet would have to meet:

- F2194 bassinet requirements (except for height of the fourth side) and sections of the F406 play yard requirements applicable to bassinets when in the bedside sleeper mode;
- F406 play yard requirements when in play yard use mode; and,
- F2194 bassinet requirements and applicable sections of F406 play yard requirements when in bassinet mode.

Staff believes that all bedside sleepers currently on the market will require some modification in order to meet the voluntary standard. Several of these requirements would impose little to no burden on manufacturers because firms also must comply with similar requirements in existing voluntary standards.

The bedside sleeper standard, ASTM F2906-12, requires the lowered side of the bedside sleeper must be 4 inches. The height requirement for sides that cannot be lowered is identical to that of bassinets, 7½ inches. This requirement is not expected to pose a substantial cost for firms. However, 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 4-inch side height.

The standard also requires the gap between the bedside sleeper and adult bed should not be more than ½ 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. Alternatively, firms may opt to redesign their attachment system. Cost should be minimal if no new materials are used.

Staff also believes products will require some modification in order to meet the two recommended bedside sleeper accessory requirements. These recommended modifications would require the bedside sleeper accessory to meet the (1) fabric sided opening requirement and (2) consumer misassembly requirement.

In order to comply with the fabric opening requirement, the bedside sleeper accessory must pass the torso probe test. Alternatively, when the fabric sided liner is unsecured, the bedside sleeper accessory should either collapse under its own weight or the sleep surface tilts by more than 30 degrees.

The second staff-recommended requirement is essentially identical to the play yard bassinet misassembly requirement being balloted by the ASTM play yard subcommittee.[46] A bedside sleeper accessory that can be assembled and attached to the play yard with any of the key structural elements missing must either: (1) have all key structural components permanently attached; or (2) are obviously unusable when attached to the play yard with any key structural element removed. The bedside sleeper accessory, if misassembled, should provide visual cues, such as the mattress pad contacts the bottom floor of the non-full-size crib or play yard, or the sleep surface angle tilts by more than 30 degrees, to indicate misassembly.

The actual cost of meeting both staff-recommended requirements to manufacturers is unknown, but it could be minimal, primarily involving additional stitching, rivets, and other methods of attachment. However, if product redesign is required, the costs could be significant.

The last three staff-recommended requirements—mattress requirement and stability requirements—are expected to have little to no incremental impact on firms. These requirements are identical to requirements in the bassinet NPR staff briefing package and the costs of meeting those requirements were accounted in the bassinet NPR. A manufacturer that produces a bedside sleeper and a bassinet combination product would already need to meet these requirements hand have incurred the associated costs under the bassinet standard. As a consequence, meeting the same requirements under a bedside sleeper standard would impose no additional burden. Most bedside sleeper manufacturers produce such a combination product.

In addition, firms would need to revise current warning labels to include a description of correct assembly and conversion modes. This represents a minor modification.

Other Federal Rules

The Commission is in the process of implementing Sections 14(a)(2) and 14(d)(2) of the Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA). Section 14(a)(2) requires every manufacturer of a children's product that is subject to a children's product safety rule to certify that the product complies with all applicable safety rules. Section 14(i)(2)(A) requires the Commission to establish protocols and standards: (i) for ensuring that a children's product is tested periodically and when there has been a material change in the product; (ii) for the testing of random samples to ensure continued compliance; (iii) for verifying that a product tested by a conformity assessment body complies with applicable safety rules; and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler.

Because bedside sleepers will be subject to a mandatory standard, they will be subject to the certification requirements of Section 14(a)(2) of the CPSA. Moreover, bedside sleepers are children's products and are subject to the third party testing requirements of Section 14(d)(2)(A) of the CPSA.

[46] ASTM Ballot F15 (12-06) Item 3, published August 14, 2012.

Bedside sleepers are already subject to the lead and phthalate limit requirements under Sections 101(a) and 108 of the CPSIA. Section 101(a) limits the amount of lead content in children's products. Section 108 of the CPSIA prohibits certain phthalates in concentration of more than 0.1% in children's toys and child care articles. "Child care articles" are defined as consumer products "designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking and teething."

Impact on Small Businesses

There are five firms known to be marketing bedside sleepers in the United States. One is a foreign manufacturer. The analysis applies to the four domestic firms, all of which are small.

The impact of the draft proposed standard on manufacturers depends on two factors: (1) whether their products are multiuse products and are already in compliance with one or more existing voluntary (or mandatory) 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 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 manufacturers will need to make only slight, if any, modifications to comply with the bedside sleeper standard. The three producers of multiuse products are unlikely to experience a significant impact.

Two of the domestic manufactures rely almost solely on the sales of bedside sleepers as their revenue source. One of the firms produces a multiuse product that is in compliance with an existing voluntary standard, as described above, and should not experience a significant impact. The other firm, however, produces a product that serves only as a bedside sleeper. The costs of compliance for this firm are unknown but could be significant if a complete product redesign is required. In addition, the impact could be magnified because most of this firm's revenues are due to the sales of bedside sleepers.

All manufacturers will need to modify existing warning labels. A new warning label poses a small burden because it represents a minor modification. Costs associated with the new warning label would be low because no new materials are used.

Once the final rule and notice of requirements are in effect, all manufacturers will be subject to third party testing and certification requirements.

Alternatives

Under the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, one alternative that would reduce the impact on small entities is to make the voluntary standard mandatory with no modifications. Adopting the current voluntary standard without any changes

potentially would reduce costs for manufacturers. Three of the four small manufacturers who are already compliant with a voluntary standard would have a reduced burden. However, all firms still require some product changes in order to meet the voluntary standard. Because the staff's proposed changes add little to the overall burden, adopting the voluntary standard with no changes will not significantly offset the burden.

A second alternative would be to set an effective date later than the staff-recommended 6 months. This would allow suppliers additional time to modify and/or develop compliant bedside sleepers and spread the associated costs over a longer period of time.

TAB D: [Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Bedside Sleeper Standard: Small Business Impacts]

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

Memorandum

Date: September 27, 2012

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

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

FROM : Robert Franklin
Economist
Directorate for Economic Analysis

SUBJECT : Accreditation Requirements for Conformity Assessment Bodies for Testing Conformance to the Proposed Bedside Sleeper Standard: Small Business Impacts

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 testing laboratories) to test for conformance with each children's product safety rule. On May 24, 2012, the Commission published a Notice of Proposed Rulemaking (NPR), to be codified at 16 CFR, Part 1112, to establish 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 Consumer Product Safety Act (CPSA). The proposed rule, among other things, would establish the requirements that must be met by conformity assessment bodies to test for conformance with children's product safety rules and for applying for CPSC recognition of their accreditation. The proposed rule would also codify all of the notice of requirements (NORs) that the CPSC had published to that date. Once finalized, all new NORs, such as for the bedside sleeper standard, will require an amendment to this rule.

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

prepared an Initial Regulatory Flexibility Analysis (IRFA).[47] Briefly, the IRFA concluded that the requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements are imposed on laboratories that do not intend to provide third party testing services under Section 14(a)(2) of the CPSA. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from providing the mandated testing to justify accepting the requirements as a business decision. Laboratories that do not expect to receive sufficient revenue from these services to justify accepting these requirements would not likely pursue accreditation for this purpose. Similarly, amending the rule to include the NOR for the bedside sleeper standard would not have a significant adverse impact on small laboratories. Moreover, 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, perhaps fewer than 6, will seek CPSC acceptance of their accreditation to test for conformance with the bedside sleeper 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 their scope of accreditation. As a consequence, the Commission could certify that the proposed NOR for the bedside sleeper standard will not have a significant impact on a substantial number of small entities.

[47] Consumer Product Safety Commission. Requirements pertaining to third party conformity assessment bodies. *Federal Register*. 2012;77(101):31123-31126. Available at: http://www.gpo.gov/fdsys/pkg/FR-2012-05-24/pdf/2012-10923.pdf