The contents of this document will be discussed at the open Commission Meeting (briefing) scheduled for September 19, 2012.

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

DATE: August 31, 2012

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: October 3, 2012

TO: The Commission
Todd A. Stevenson, Secretary

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

FROM: Patricia M. Pollitzer, Acting Assistant General Counsel
Barbara E. Little, Attorney, OGC

SUBJECT: Notice of Proposed Rulemaking: Safety Standard for Bassinets and Cradles

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 bassinets and cradles, pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008.

Please indicate your vote on the following options:

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

_____ _____
(Signature) (Date)

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

_____

_____

_____

_____ _____
(Signature) (Date)

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

_____ _____
(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

Attachment: *Federal Register* Supplemental Notice of Proposed Rulemaking to Establish a Safety Standard for Bassinets and Cradles

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1218

CPSC Docket No. CPSC-2000-0028

RIN 3041

Safety Standard for Bassinets and Cradles

AGENCY: Consumer Product Safety Commission.

ACTION: Supplemental Notice of Proposed Rulemaking.

SUMMARY: Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), part of the Danny Keysar Child Product Safety Notification Act, 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 bassinets and cradles in response to the direction under Section 104(b) of the CPSIA. This constitutes a second round of notice and comment, or supplemental notice of proposed rulemaking, for bassinets and cradles.

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-2010-0028, 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 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 2010-0028, into the "Search" box and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Patricia Edwards, Project Manager, Directorate for EngineeringSciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone 301-987-2244; e-mail pedwards@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. Bassinets and cradles are specifically identified in section 104(f)(2)(L) as a durable infant or toddler product.

In April 2010, the Commission issued a notice of proposed rulemaking (NPR) for bassinets and cradles. (75 Fed. Reg. 22303, April 28, 2010). Through ongoing consultation and assessment of the standard, both the ASTM standard and the Commission's proposals have evolved since publication of the April 2010 NPR, such that the Commission believes a supplemental notice and opportunity for the public to comment would be beneficial. Thus, in

this document, the Commission is proposing a safety standard for bassinets and cradles in a supplemental notice of proposed rulemaking. 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 F2194-12, "Standard Consumer Safety Specification for Bassinets and Cradles" (ASTM F2194-12), with additions and modifications to strengthen the standard. The ASTM standard is copyrighted but 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 F2194-12 defines a "bassinet/cradle" as a "small bed designed exclusively to provide sleeping accommodations for infants supported by free standing legs, a wheeled base, a rocking base, or which can swing relative to a stationary base" and provides that a bassinet/cradle is "intended to provide sleeping accommodations only for an infant up to approximately 5 months in age or when the child begins to push up on hands and knees, whichever comes first." 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." The Commission is proposing modifications to the scope and definition of a bassinet/cradle and bassinet/cradle accessory, as further discussed herein.

C. The Voluntary Standard--ASTM F2194

The voluntary standard for bassinets and cradles was first approved and published by ASTM in 2002, as ASTM 2194, *Standard Consumer Safety Specification for Bassinets and Cradles.* The standard has been revised a number of times since then. The Commission's April 2010 NPR assessed the effectiveness of ASTM F2194-07a$^{\varepsilon 1}$. Since publication of the 2010 NPR, the standard has been revised three times: in 2010, 2011, and, most recently, in 2012. The 2012 version, ASTM F2914-12, was approved on June 1, 2012. The 2012 voluntary standard contains requirements addressing a number of hazards. The requirements include:

1. Compliance with CPSC's regulations at 16 CFR part 1303 (ban of lead in paint), 16 CFR 1500.48 and 16 CFR 1500.49 (sharp points and sharp edges), and 16 CFR part 1501 (small parts), both before and after the product is tested according to the standard.
2. Exposed wood parts on bassinet/cradles, prior to testing, must be smooth and free of splinters.
3. Bassinets/cradles must not present scissoring, shearing, or pinching hazards.
4. Requirements and test method to prevent unintentional folding.
5. Requirements for the permanency of labels and warnings.
6. Prohibition against using wood screws in the assembly of any components that must be removed by the consumer in the normal disassembly of a bassinet/cradle.
7. Limits on how far a corner post assembly may extend.
8. Prohibition against containing an occupant restraint system when the product is used in the bassinet/cradle mode.
9. Performance requirements for the spacing of rigid sided bassinet/cradle components.

10. Performance requirements for the openings of mesh/fabric sided bassinet/cradles to prevent entrapment.
11. Performance requirements and test methods for static load and stability of the bassinet/cradle.
12. Requirements regarding the thickness and dimensions of the sleeping pad.
13. Requirements for the side height of the bassinet/cradle.
14. Requirements and test method for protective components of bassinet/cradle.
15. Fabric-sided enclosed openings requirement and test method involving a torso probe to protect against entrapment in bounded openings in the bassinet/cradle.
16. Performance requirements and test methods for the rock/swing feature of bassinets or cradles.
17. Marking, labeling, and instructional literature requirements.

D. Incident Data

The CPSC's Directorate for Epidemiology reports that there have been 335 incidents reported to the Commission regarding bassinets/cradles from November 2007 through December 2011. The data is drawn from the CPSC's "Early Warning System" (EWS), a pilot project initiated in 2007, which draws all data entered into the CPSC's epidemiology databases on a weekly basis. The 335 incidents involved 94 fatalities and 241 nonfatal incidents. (Because the number of emergency department-treated injuries associated with bassinets and cradles was insufficient to derive any reportable national estimates, injury estimates are not presented separately but are instead included within the category "nonfatal incidents.").

1. Fatalities

A total of 94 bassinet-related fatalities have been reported from early November 2007 through December 2011. Eight of the 94 deaths are associated with the design aspects of the product. Three of these 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 convertible bassinets/bedside sleeper that was subsequently recalled for this defect. Two of these three infants were 6 months old, while the third infant was a 4-month-old. Three of the eight deaths are associated with problems dealing with the flatness of the mattress pads used in a bassinet accessory of a play yard. All three of these decedents were 5 months old or younger. One of the three decedents suffocated in the corner of the bassinet when he rolled into that position due to the unlevel mattress pad; the other two decedents were found face down in a dip in the center of the unlevel mattress pad. The rocking feature of a bassinet, which contributed to its non-level resting position, was associated with an additional suffocation death of a 1-month-old infant. The remaining fatality associated with the design of the product occurred when the bassinet bed fell off its stand and allowed the 3-month-old decedent to get pinned between the bassinet and a nearby dresser.

Eighty two of the deaths were asphyxiations due to the presence of soft or extra bedding in the bassinet, prone placement of the infant, and/or the infant getting wedged between the side of the bassinet and an added mattress or pillow. All but two of the 82 decedents were 5 months old or younger in age; one infant was 7 months old and another was 8 months old. There were four fatalities with not enough information to allow the CPSC to determine the hazard scenario.

2. Nonfatal Injuries

A total of 241 bassinet-related, nonfatal incidents were reported from November 2007 through December 2011. Fifty-two of these incidents reported an injury to an infant using the

bassinet or cradle. The majority of the injuries, (30 out of 52), were identified as resulting from falls out of the bassinets. Because 28 of the 30 falls were reported through the emergency department-treated injury surveillance system, little or no circumstantial information is available on how the fall occurred. However, the reports do indicate that 76 percent of the injured infants who fell out of bassinets were older than the ASTM-recommended maximum age limit of 5 months, with four infants as old as 9 months of age falling out of bassinets. All of the falls resulted in head and facial injuries.

Overall, there were six bassinet-related injuries that reportedly required hospitalization. Four of them, all serious head injuries, resulted from a fall out of the bassinet. One injury, a leg fracture, resulted from a caregiver unknowingly attempting to lift an infant out of the bassinet while the infant's leg was caught in a structural opening. The remaining hospitalized injury was due to a moldy bassinet pad that caused respiratory illness to the infant.

Two additional serious injuries were reported, but neither of these infants was hospitalized. There was a report of a second-degree burn suffered by an infant from the bassinet's overheated mobile and a report of an arm fracture from an infant's arm getting caught in the bassinet. The remaining injuries were limited mostly to contusions and abrasions.

The remaining 189 reports either indicated 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.

3. Hazard Analysis

Based on the incident data, the Commission identified hazard patterns associated with bassinet and cradle incidents. The incidents were grouped into four broad categories:

- Product-related issues;

- Non-product-related issues;
- Recalled product-related issues; and
- Miscellaneous other issues.

1) Product-related issues: The hazard scenarios in 209 of the 335 incidents (62 percent) reported were attributed to some sort of failure/defect or a potential design flaw in the product itself. This category includes five fatalities and 46 injuries, five of which involved hospitalization. Listed below are the reported problems, beginning with the most frequently reported concerns:

- Lack of ***structural integrity***, which includes issues such as instability, loose hardware, collapse of the product, and loose wheels. This issue was reported in 64 (about 19 percent) of the incidents. One death is associated with this issue.
- Reports of infants ***falling or climbing out*** of bassinets/cradles. This category accounted for most of the bassinet-related injury reports that were received from emergency departments around the United States. While little product-/scenario-specific information was available in these reports, a majority indicated that the victims were over the ASTM-recommended upper age limit of 5 months. This issue was reported in 32 (about 10 percent) of the incidents.
- Problems with ***mattress flatness*** in bassinet attachments to play yards. Examples include mattresses that would not remain level horizontally because of poorly designed metal rods/other structures that are meant to be positioned underneath the mattress; lack of rigid mattress support; and failure of straps/hooks/bars designed to hold the bassinet attachment inside the play yard. This issue was reported in 31 (about 9 percent) of the incidents and was associated with three deaths.

- Problems with ***rocking*** bassinets and cradles, with locking or tilting issues that caused the infant to roll/press up against the side/corner of the product and posed a suffocation hazard. This issue was reported in 23 (about 7 percent) of the incidents, including one death.
- Problems with ***packaging*** of the product that resulted in broken/damaged products during delivery. This issue was reported in 19 (about 6 percent) of the incidents.
- Problems with bassinet ***mobiles***, where components overheated, smoked, or sparked. This issue was reported in 13 (about 4 percent) of the incidents.
- ***Miscellaneous*** other product-related problems, ranging from a tear in the bassinet fabric, to odors, to product assembly/quality issues. Twenty-seven (about 8 percent) of the incidents reported these issues.

2) Non-product-related issues: Eighty-three of the 335 reports (25 percent) were about incidents that involved no product defect or failure. This category consisted of 82 fatalities, most of which were associated with the use of soft/extra bedding or prone positioning. There was also one nonfatal injury incident that did not involve any product-related issues.

3) Recalled product-related issues: There were 26 reports (8 percent) that involved recalled products. Some of the reports were received by CPSC staff prior to the recalls being published. There were three fatalities and two injuries due to entrapment and/or hanging of an infant between structural components of the bassinet. Most of the remaining reports were complaints or inquiries from consumers regarding a recalled product.

4) Miscellaneous other issues: The remaining 17 (5 percent) incident reports were related to miscellaneous other or unspecified issues. Some of these reported concerns from consumers about perceived safety hazards; others described incidents with insufficient specificity for CPSC

staff to identify the hazard scenario. There were four fatalities (unknown circumstances) and three injuries, including a hospitalized injury, reported in this category.

In summary, there are five product-related issues associated with incident deaths and/or significant injuries:

- structural integrity/instability,
- mattress flatness,
- rocking,
- falling or climbing out, and
- entrapment in fabric sided products (recalled product-related).

In addition, there are multiple deaths associated with the use of soft/extra bedding or prone positioning of the child that are considered non-product related.

4. Recalls.

There have been a total of five consumer-level recalls involving bassinets from October 2006 through June 2012.

One recall, involving 46,000 bassinets manufactured from July 2008 through May 2010, pertained to the latching system between the bassinet bed and the frame/stand. The latches that attach the bassinet bed onto the metal frame/stand could appear to be locked in place but still remain unlocked. This allowed the bassinet bed to become detached from the metal frame/stand, causing the bassinet bed to fall and the infant to be injured. There were seven incidents reported to CPSC and the manufacturer. One infant received a bruised cheek when the bassinet bed detached from the metal frame/stand and landed sideways on the floor with the infant inside. (The proposed Removable Bassinet Bed Attachment test, discussed in Sections F and G, would address this hazard.)

Another recall, conducted on February 16, 2011, involved all bassinets manufactured by the company before June 2010. The cross-bracing rails on the bassinet stands were misinstalled, and thus, were not fully locked into position, resulting in the bassinet collapsing, which caused the infant to fall to the floor or fall within the bassinet and suffer injuries. The manufacturer received 10 reports of incidents in which two infants received minor injuries as a result of the collapses, including bruises to the head and shoulder. Consumers were supplied with better instructions and guidance on how to install the cross-braces properly. This was a very design-specific hazard, and CPSC staff has not seen similar incidents from other manufacturers.

The third recall was conducted in December 2009 and involved five models that were bassinet accessories to play yards. This recall involved metal bars used to support the floorboard of the bassinet accessory that came out of the fabric sleeves and created an uneven sleeping surface, posing a risk of suffocation or positional asphyxiation. The manufacturer received no reports of injuries. (The proposed mattress flatness requirement, discussed in Sections F and G, would address this hazard.)

A fourth recall, conducted in May 2009 by the same manufacturer as in the third recall, also involved portable play yards. The convertible play yard included a bassinet accessory and changing station feature and was manufactured before December 1, 2008. This recall involved the play yard's rocking bassinet accessory that was tilting, even when secured by straps in the non-rocking mode, or that stayed tilted without returning to a level sleeping surface while in the rocking mode. These conditions could cause an infant to roll to the corner or side of the bassinet and become wedged in the corner or pressed against the side or bottom of the bassinet, posing a risk of suffocation or positional asphyxiation. The manufacturer and CPSC received 10 reports of infants rolling to one side, including six that had their faces pressed against the side or the

bottom of the bassinet. One child reportedly was turning purple and was out of breath when discovered. No other injuries were reported. (The rock/swing angle test, proposed in the 2010 NPR and added to the ASTM standard in its 2012 iteration, would address this hazard.)

The fifth recall, conducted in September 2008, involved 3-in-1 and 4-in-1 convertible bassinets that contained metal bars covered by an adjustable fabric flap attached with Velcro.® The fabric was folded down when the bassinet was converted into a bedside sleeper position. If the Velcro® was not resecured properly when the flap is adjusted, an infant could slip through the opening and become entrapped in the metal bars and suffocate. CPSC learned that on August 21, 2008, a 6½-month-old girl died when she became entrapped and strangled between the bassinet's metal bars. This is the second strangulation death that the CPSC learned of involving the co-sleeper bassinets. On September 29, 2007, a 4-month-old girl became entrapped in the metal bars of the bassinet and died. (The fabric-sided openings test, proposed in the 2010 NPR and added to the ASTM standard in its 2012 iteration, would address this hazard.)

E. April 2010 NPR and Subsequent Changes to the ASTM Voluntary Standard

In April 2010, the Commission approved a proposed rule on bassinets/cradles that referenced the requirements specified in ASTM F2194-07a$^{\varepsilon 1}$ as a mandatory standard for bassinets and cradles, with several modifications to further reduce injuries and deaths. The modifications and edits included the following:

- Updated warnings;
- Stability requirements;
- Performance requirements for fabric-sided products to address entrapment incidents;
- Performance requirements to limit the rocking/swinging angle to 20 degrees and the rest angle of certain rocking/swinging cradles to 5 degrees;

- Requirement to eliminate active restraints;
- Changes to scope and terminology; and
- Performance requirements specifying a mattress flatness angle of 5 degrees to address suffocation incidents on segmented mattresses.

The April 2010 NPR also proposed to include hammocks within in the scope of the standard.

Many of the changes proposed in the April 2010 NPR have been incorporated in some capacity into ASTM F2194-12. Other changes to ASTM F 2194-12 have come about in response to comments to the April 2010 NPR. The Commission proposes to revise two of the proposed changes to the 2010 NPR (involving hammocks and the mattress-flatness requirement), based on review of public comments, further testing and analysis, and discussions with the ASTM task group on bassinets.

1. Proposed Changes in April 2010 NPR Incorporated into ASME F2194-12.

Restraints

The 2010 NPR proposed to prohibit bassinets with restraints that require action on the part of the caregiver to secure the restraint. A commenter requested that bassinets be allowed to have restraints and provided several reasons why they should be allowed. The primary reason that the Commission believes restraints should not be allowed in bassinets is that most bassinet uses do not require a restraint, so consumers have a strong motivation to avoid using restraints, if they are provided. When unused, restraints have been known to entrap and strangle children in similar products, like swings, handheld infant carriers, and bouncers. While none of the bassinet incidents was associated with restraint harness strangulation, this is probably due to the fact that restraints are rare on bassinets and not because they would not pose a hazard if they were present.

The 2012 version of F2194 contains a stronger requirement than that proposed in the April 2010 NPR that prohibits *all* restraints in bassinets. The Commission supports this change to the standard, and notes that it is more conservative than the restraints requirement proposed in the 2010 NPR.

The Prominence of Warnings about Soft Bedding

The 2010 NPR proposed a stronger warning label to address suffocation hazards. The current ASTM standard for bassinets, F2194-12, includes an enhancement of the soft bedding warnings by: (1) increasing the font size for the suffocation warning label to 0.4 inches or higher; and (2) adding emphasis by stating that "Infants have suffocated . . .," rather than stating "Infants can suffocate . . .."

Maximum Rock/Swing and Rest Angles

The Commission's 2010 NPR proposed a maximum rock/swing angle of 20 degrees and a maximum rest angle of 5 degrees for rocking cradles. Several commenters recommended a maximum rock/swing angle of 20 degrees and a maximum rest angle of 7 degrees for rocking cradles. The 5-degree angle was based on the Australian standard for rocking cradles. In the Australian standard, the angle is measured with the CAMI infant dummy placed in the center of the cradle. The intent is to ensure that the rocking cradle returns to a level position and provides a flat sleeping surface for the infant. In ASTM F2194-12, the angle is measured with the CAMI dummy placed to one side of the cradle. The Commission believes that the placement of the CAMI to one side results in a more stringent requirement than the Australian standard. For this reason, a 7-degree rest angle is a reasonable and achievable requirement for bassinets that will address suffocation hazards associated with an angled sleep surface. Therefore, the Commission is not making any recommendations with respect to this issue.

Fabric-Sided Enclosed Openings Test

The performance requirements for fabric-sided products included in F2194-12 to address entrapment incidents are the same as in the 2010 NPR, except for editorial changes made to clarify the requirement and test procedure.

Stability

The stability requirements are intended to ensure that the product does not tip over when pulled on by a 2-year-old male. The 2010 NPR clarified that the stability requirement applies to all manufacturer-recommended use positions, including the position where the locks are engaged to prevent rocking/swinging motion. ASTM incorporated this change in ASTM F2194-11; therefore, it is included in the latest version, ASTM F2194-12.

2. Changes to ASTM F2194 that arose out of a response to comments received on the April 2010 NPR.

Baby Size Limits

In response to the 2010 NPR, one commenter noted that because "bassinets provide an important tool for parents to monitor premature babies," a target age range for infant occupants may be necessary to enhance the understanding of the developmental milestones used in the warnings. They also suggested that if there is "a size at which a bassinet becomes unsafe for a baby," then that factor should be listed in the product's instructions and warnings.

The 2012 version of the ASTM standard includes a reference to the maximum recommended weight in the FALL HAZARD warning label. The Commission supports this addition to the standard.

Static Load

The static load test is intended to ensure structural integrity even when a child three times the recommended (or 95th percentile) weight uses it. This has been modified following publication of the April 2010 NPR to also test play yard bassinet accessories at all four corners to ensure structural integrity of the product.

Side Height Requirement

This requirement, which is intended to prevent falls, was added to F2194-12 in response to comments to the 2010 NPR. The side height requirement in F2914-12 requires that the bassinet/cradle side height be at least 7 ½ inches from the top of the uncompressed mattress surface.

3. **Revisions to proposed changes in 2010 NPR.**

Hammocks

The Commission's 2010 NPR proposed to include infant hammocks in the scope of the standard. The voluntary standard for bassinets and cradles does not state explicitly whether infant hammocks are included within the scope of the standard. However, the Juvenile Products Manufacturers Association (JPMA) historically has certified some infant hammocks to the bassinet standard because there was not a separate standard for infant hammocks and other inclined sleep products. Including infant hammocks in the scope would effectively ban most infant hammocks currently on the market because, by their nature, they would be unable to meet the performance criteria in the bassinet standard addressing rest angle, segmented mattress flatness angle, and rock/swing angle.

Several comments were received regarding the inclusion of infant hammocks and other inclined sleeping products in the scope of the 2010 NPR. The comments were universally against such inclusion, asserting that this would effectively ban a product that has utility. The

comments also opined that banning them might increase hazardous sleeping arrangements, causing consumers to resort to a substitute product such as a car seat or makeshift soft bedding to prop up an infant. The Commission agrees that alternative products or makeshift products would present additional hazards if consumers chose to use them instead of cribs, bassinets, or other common juvenile products intended for sleep.

An inclined sleeper differs from a bassinet in that it is intended to have an inclined sleep surface and it conforms to the contour of the occupant. Most hammocks have mattresses that are also inclined in a manner that elevates the head, as well as conforming to the body contours of the infant. They are also intended to allow swinging or bouncing motions. These special features, especially elevating the head, are sometimes intended to help prevent reflux. Features that allow head elevation, swinging, and bouncing motions distinguish these products from common bassinets and cradles, which generally have flat mattresses with solid or fabric-covered framed sides. The Commission believes that a separate standard targeted specifically to these products will more effectively address any hazards associated with them. Due to the significant progress in the development of a separate voluntary standard to address hammocks and inclined sleeping products, the Commission is not including them within the scope of this proposed rule.

Mattress Flatness

In the 2010 NPR, a mattress flatness performance test for all types of bassinets and cradles was included. The performance requirement specified a mattress flatness angle of 5 degrees to address suffocation incidents on mattresses. The mattress flatness performance requirement that the Commission is proposing in this document only applies to segmented mattresses because the CPSC's review of the data showed that only segmented mattresses used in play yards were involved in incidents. In addition, the Commission determined that an angle

of 10 degrees or less would still provide protection; allow for testing variances; and also address design and manufacturability concerns with segmented mattress pads. The Commission's new proposal has additional requirements for two-occupant bassinets. The test method now uses a rigid cylinder to simulate the infant, rather than a soft/deformable CAMI dummy. This change provides more consistent test results. The mattress flatness test is discussed in more detail in Section F.

F. Assessment of ASTM Voluntary Standard and International Standards

The Commission believes that ASTM F2194-12 addresses many of the general hazards associated with durable nursery products, such as lead in paints, sharp edges/sharp points, small parts, wood part splinters, scissoring/shearing/pinching, openings/entrapments, warning labels, and toys. The standard also includes specific requirements for tip stability, unintentional folding of the product, and static load.

From the incident data and hazard patterns associated with bassinets and cradles (as discussed in Section C), the Commission identified six addressable hazards: (1) suffocation due to the addition of soft bedding; (2) suffocation/positional asphyxia due to excess mattress pad angle; (3) entrapments in fabric-sided openings; (4) suffocation due to excess rock/swing angles; (5) misassembly of removable bassinet beds; and (6) falls and climb-outs. Following is an analysis of the adequacy of ASTM F2194-12 in addressing these hazards.

1. Suffocation due to the addition of soft bedding.

The majority of the deaths associated with bassinets and cradles were asphyxiations due to the presence of soft or extra bedding in the bassinet, prone placement of the infant, and/or the infant getting wedged between the side of the bassinet and an added mattress or pillow.

As mentioned in Section E of this preamble, since publication of the 2010 NPR, ASTM F2194 has been revised to strengthen the suffocation warning. Specifically, ASTM F2194-12, includes an enhancement of the soft bedding warnings by: (1) increasing the font size for the suffocation warning label to 0.4 inches or higher; and (2) adding emphasis by stating: "Infants have suffocated . . .," rather than indicating: "Infants can suffocate…."

The Commission supports the strengthening of the suffocation warning label as included in the latest revision of the ASTM voluntary standard and does not believe that there are additional requirements that can be put in place in the standard to address unsafe sleep environments and unsafe sleep practices. The Commission will continue information and education efforts, such as the Safe Sleep campaign, to address suffocation and other serious sleep hazards.

2. Suffocation/positional asphyxia due to excess mattress pad angle.

Bassinets that are commonly sold as accessories to play yards use the floor of the play yard (a segmented mattress pad) as the floor of the bassinet. Seams between segments of folding play yard bassinet accessory mattress pads have been known to create a valley shape in a bassinet sleeping surface in the crease between adjoining segments of the mattress.

An inclined sleeping surface (on a product not intended to provide a contour or other means to contain the child) can contribute to an infant rolling, increasing the likelihood that they will be found face down and become trapped in a significant V-shaped crease. When lying prone in a valley (or V-shaped crease), infants may have more difficulty keeping their airways unobstructed than they would on a flat surface because their faces are trapped in the juncture between adjacent surfaces. Their heads cannot rotate to the side as much as when the sleeping surface is flat. Immature head control and weak neck muscles may not allow them to free their

airways. Thus, infant sleeping surfaces need to be as firm, flat, and level as possible because soft, uneven and non-level surfaces may create a higher risk of suffocation than a level surface.

The Commission has identified incidents associated with a sleeping surface (segmented mattress) that is not level or flat. The data include fatal and nonfatal incidents involving play yard attachment bassinets with insufficient mattress support.

In one in-depth investigation (IDI), the product was apparently assembled without two key structural support bars beneath the mattress pad of a bassinet accessory that was intended by the manufacturer to be mounted from the top rails of the play yard. The incident summary states:

> *A 3 month and 26 day old male victim was found deceased inside a play yard. The ME determined that the cause of the death was asphyxia. The victim was found face down in a crease produced by the mattress. He was pronounced deceased at the hospital.*

The Commission notes that requirements to ensure that key structural supports are properly installed by consumers would have helped prevent this incident from occurring. The Bassinet Misassembly Provision NPR, published on August 29, 2012, is a Commission-directed NPR to amend the play yard mandatory standard to include a provision to address the hazards associated with play yard bassinet accessories that can be misassembled. (77 *FR* 52272). However, there has never been a requirement for sleeping surfaces to be flat or even nearly flat, which is the critical feature of the product that constitutes a hazard. A play yard could be designed to position the occupant in a valley, and it would still pass the play yard standard and the misassembly provision. The Commission believes both requirements are necessary to address these hazards: (1) a missing component requirement to prevent installation/use of a bassinet accessory that has a key component missing; and (2) a flatness requirement to ensure segmented mattresses, like

those found in bassinet accessories, are flat when assembled according to manufacturer's instructions.

In another IDI, the victim was in a bassinet accessory to a play yard that was also misassembled. The incident summary states:

> *A two month old male was found unresponsive in his . . . play yard with no signs of trauma. The child had rolled in the bassinet section causing his face to be placed in the corner of the bassinet. He was lying on a blanket with another blanket on top of him. Investigators who initially measured the bassinet at the scene reported that one side was five inches higher than the other. I observed during my investigation that depending on weight and movement that there will be a variance in height within the unit.*

Other risk factors also may have contributed to the incident (*e.g.*, the placement of the infant to sleep in the prone position and the presence of a blanket under the infant), but the case nonetheless illustrates the potential for non-level sleeping surfaces to contribute to bassinet occupants getting into fatal positions from which they may not be able to remove themselves.

A third fatality involved a victim with serious physical challenges who was placed face down to sleep (both of these are additional risk factors) and was found in a sagging bassinet accessory to a play yard. The incident report states:

> *The mother was using the elevated playpen platform for her 5 month old male baby's sleeping area. He was born with multiple physical complications including the inability to swallow and would drool constantly. The parents placed the infant in the playpen at night face down and awoke to find he had expired in the middle of the night. The playpen elevated platform showed sagging in the center possibly due to incorrect assembly of the playpen.*

In the fourth incident involving a fatality, a baby died in the corner of a tilted bassinet accessory on a play yard. A rod intended to be placed in a pocket at the end of the accessory was left out. When a clip on the corner of the bassinet came off for unknown reasons, the sleeping surface tilted downward, allowing the infant's head to become entrapped. While the incident was included in data used for the final rule briefing package for play yards, it is included here because the manner of death is related to a non-level, segmented mattress.

In addition to the fatal incidents, a nonfatal incident was found to be associated with the same hazard. In this incident, a child in a bassinet accessory of a play yard was observed rolling into seams on the sleep surface, but the child was not injured. The incident report states:

> *No injury occurred to a five-month-old female, who while asleep in the bassinet section of a portable and collapsible play yard rolled into a seam of the removable changing pad used with the bassinet. The mother of the five-month old noticed that the five month old had a tendency to roll into seams of the mattress pad when it was used with the bassinet.*

There is no requirement for mattress flatness in ASTM 2194. The 2010 NPR proposed a mattress flatness requirement that specified a 5-degree maximum tilt angle for segmented sleeping surfaces, like those found in play yard bassinet accessories. The ASTM subcommittee for bassinets believed that the 5-degree maximum angle was not achievable within the tolerances necessary to manufacture play yard bassinet accessories; accordingly, they considered alternative test methods and requirements for sleeping surface flatness in products with segmented mattresses.

In lieu of the 5 degrees proposed in the 2010 NPR for segmented mattresses, the ASTM subcommittee sent out to ballot a requirement that allowed up to 14 degrees on either side of a valley formed at a seam, with higher inclines possible if the sum of the two angles on either side

of the valley did not exceed 28 degrees in total. The 14-degree angle was based on an extrapolation of angles formed by dimensions of *average* infant faces. By combining an infant's mandible width with dimensions of nasal protrusion, an isosceles triangle can be created that represents a cross-section of the volume of space beneath the nose. From this cross-section, one can extrapolate both the angle of the valley and the angle of the incline of the surface that would contact a prone infant's face. The angle resulting from the combination of the *average* facial dimensions is 15 degrees, from which the ASTM subcommittee subtracted a single degree for a factor of safety. This ASTM ballot item received many negative votes and was not approved for the standard.

The Commission is uncomfortable using the *average* infant facial dimension as the basis for this requirement. A product that has a 14-degree angle in the valley formed at the seam of the mattress would leave about one-half of the potential occupant population unprotected from suffocation. While the ASTM Committee used an angle resulting from the combination of *average* facial dimensions, the Commission generally recommends using the smallest users' anthropometrics for justifying requirements of this nature. If the facial measurements of the smallest (5^{th} percentile) infants are used to form the isosceles triangle, the resulting valley is 158 degrees, which yields an 11-degree angle of sleep surface incline from the horizontal on each side. If a single degree is subtracted from this incline angle for a minor factor of safety, the requirement becomes a 10-degree maximum incline from the horizontal. In the Commission's proposed test, each seam of a folding bassinet sleeping surface is tested with a pass/fail criterion of 10 degrees maximum for either side of the valley formed by a weighted cylinder.

In August 2012, ASTM reballoted the mattress flatness test. Several modifications were made to the test procedure, and CPSC staff was involved throughout the development of this

requirement. The actual test procedure that was reballotted by ASTM is identical to the Commission's recommendation. However, the test requirement (the pass/fail criteria) is different. In the test procedure, a measurement is taken on each side of each seam of the mattress (for a total of 6 or 8 measurements per bassinet). As mentioned, the Commission is proposing a test requirement of 10 degrees maximum for each measurement taken. Under the ASTM ballot, 10 degrees or less for all measurements would pass, more than 14 degrees for one or more measurements would fail, and any angle measurements between 10 and 14 degrees would require a two-step process where the test lab would take two additional measurements, average them, and then use 10 degrees as the final pass/fail delineator.

With regard to the test method itself, the 2010 NPR's method for testing flatness used a CAMI dummy to weight the surface prior to measuring the side angles of the valley formed in the sleeping surface. However, the CPSC and the ASTM subcommittee prefer a rigid cylinder to help increase the reliability of the test across test laboratories. This is because CAMI dummies tend to vary slightly with age because of the nature of their construction. CPSC staff tested a variety of cylinder diameters and lengths and found that small differences in the footprint of the test cylinder were not critical to differentiating hazardous from nonhazardous products. The most critical factor was the design of the mattress support structure. An exact replica of the human form is not necessary for this type of screening, and the benefits of using standardized, readily available test methods are appreciated by industry. As previously mentioned, the test procedure that the Commission is proposing is identical to what ASTM recently balloted.

3. Entrapments in fabric-sided openings.

Three deaths associated with bassinets and cradles 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 convertible bassinets/bedside sleepers of a particular brand of convertible bassinets/bedside sleepers. These incidents occurred in one manufacturer's bassinet that was recalled on August 28, 2008.

As discussed in Section E, since publication of the 2010 NPR, ASTM has revised the bassinet standard to include a fabric-sided enclosed openings test. The test, as added to the 2012 version of the standard, is very close to what was included in the 2010 NPR. Thus, the Commission is not recommending any further changes relating to this hazard.

4. Suffocation due to excess rock/swing angles.

Bassinets and cradles with locking or tilting issues that caused the infant to roll/press up against the side/corner of the product pose a suffocation hazard. There have been several nonfatal incidents and one fatality associated with a rocking bassinet. In the fatal incident, a 1-month-old was found pressed up against the fabric side of a bassinet. It is not known whether the lock, which was designed to prevent rocking, was engaged properly, or wasn't functioning correctly.

As discussed in Section E, since publication of the Commission's 2010 NPR, ASTM has included a rock/swing angle requirement in its standard. The requirement specifies a maximum of 20 degrees for the swing angle and 7 degrees for the rest angle. The Commission believes that this requirement adequately addresses the hazard. Thus, the Commission is not proposing any further changes to the standard relating to this hazard.

5. False latching/stability of removable bassinet beds. The Commission is aware of several incidents involving bassinets beds that were designed to be removed from their stand, four of which have IDIs. During the incidents, the bed portion of the unit was not completely locked or properly attached to its stand. The bed portion of the unit appeared to be stable, giving the

caregivers a false sense of security. For various reasons, the bed portion fell or tilted off of its stand. In one case, a 3-month-old infant was killed. The Commission was also informed by Health Canada of a second death. In e-mail correspondence from Health Canada staff, the following was reported:

> *It strongly appears the bassinet was not attached to the base when the infant was put down for a nap. When the infant was found, the bassinet was perpendicular to the base and had fallen into the base opening at an angle suspending the infant. The straps and hooks attaching the bassinet to the base were not snapped in.*

There have also been nonfatal incidents involving bassinet beds that tipped over or fell off their base/stand when they were not properly locked/latched to their base/stand, or the latch failed to engage as intended. In May 2012, there was a recall of 46,000 bassinets that could appear to latch to the stand when they actually had not latched. (http://www.cpsc.gov/cpscpub/prerel/prhtml12/12173.html).

The reason that removable bassinet designs need inherent stability (or obvious instability) is consumers will sometimes avoid activating lock or latch mechanisms if it appears that the bassinet bed is stable when placed on its stand/base. Consumers may do this because the locks or latches seem redundant or because they are worried about making noise when activating locks or latches around a sleeping infant. Locks and latches also accidentally may give feedback that they are locked when they are not. This constitutes a "false latching" situation. Because of these foreseeable use patterns, this requirement will make bassinets with a removable bed portion inherently stable or have visible indicators to show when the bassinet bed is not properly attached to the stand.

Commission staff has been actively involved in an ASTM task group that is currently developing requirements to address the hazards associated with bassinets with removable bed portions. To date, the language that the task group drafted has yet to be balloted. The Commission proposes recommends adding a new requirement for the NPR, based on what the ASTM task group has developed to date. The proposed recommended requirement allows multiple options to pass. These options will either ensure that the bed portion of the unit is inherently stable when it is placed on the stand unlatched, or it will give obvious feedback that the unit is not latched or stable. One option allows the unit to give an extreme appearance of instability by being tilted 20 degrees or more. The 20-degree minimum is twice the allowable deviation from horizontal that staff recommends for sleeping surface flatness. This angle was extrapolated from an IDI report involving a caregiver who noticed that a bassinet was tilted. From photographs of the incident product, the ASTM task group assigned to examine the problem estimated that the unit produced about a 17-degree angle, which they felt would be reasonable to round up to 20 degrees for the standard. A sleeping surface at 20 degrees from the horizontal seems severe enough that consumers would notice that it was not level. This proposed requirement is slightly less than the angle proposed to address similar hazards in the play yard standard (*i.e.,* 30 degrees from the horizontal), but the ASTM subcommittee reasoned that bassinets are different in structural design and materials and will appear to be misassembled more easily than the suspended and segmented mattress supports used in play yards.

In addition to the aforementioned options, a bassinet that has a removable bed would also pass the requirement if it has a visual indicator to alert a caregiver that the bassinet bed is not properly locked onto the stand. Or, the bassinet would also pass the requirement if it can pass the standard's stability test while in an unlocked position.

6. Falls and Climb-Outs

The majority of the nonfatal injuries (30 out of 52, or 58 percent) were identified as falls from the bassinets. Because 28 of the 30 falls were reported through the emergency department-treated injury surveillance system, little or no information is available on how the falls occurred. However, the reports do indicate that 76 percent of the injured infants who fell out of bassinets were older than the ASTM-recommended maximum age limit of 5 months, with four infants as old as 9 months of age. All of the falls resulted in head and facial injuries.

The Commission believes the new side height requirement in ASTM F2194-12, which requires a bassinet side to be at least 7.5 inches above the mattress surface, as well as the proposed removable bassinet requirements, will help address fall hazards.

In addition to the requirements for mattress flatness and removable bassinet bed attachments, the Commission is proposing changes to the scope of the standard and a revised test method for stability.

Scope.

In order to clarify which products are covered under the scope of the proposed standard and to ensure more complete coverage of sleep products, the Commission is proposing the following with respect to the scope of the ASTM standard. The scope would encompass products with an incline of 10 degrees or less, but not products with a greater than 10-degree angle. This would include cradle swings within the scope, which, by definition, recline less than 10 degrees. The Commission proposes including products that can be supported by a stationary frame/standard, such as carriage attachments to strollers and Moses baskets, only when they are used with a stationary or rocking stand. (A Moses basket is a portable cradle, typically made from wicker or cloth, with no legs or a stand.) Finally, the Commission proposes to specify that

the standard covers products *primarily* used to provide sleeping accommodations. This would expand the scope beyond products *only* used to provide sleeping accommodations. This would ensure, for example, that a bassinet sold with a toy mobile that is meant to entertain an infant who is lying in the bassinet would still fall within the scope of the standard.

Stability Test Dummy.

During evaluations of the test methods for removable bassinet beds, Commission staff made comparisons of the stability of products weighted with the newborn CAMI dummy (7.45 lbs) as opposed to the infant CAMI dummy (17.4 lbs). ASTM F2194-12 contains a stability requirement that uses the heavier infant CAMI dummy. There is no rationale included in the ASTM standard for why the heavier dummy was specified in the stability requirement. 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. For these reasons, the Commission is proposing a revised test procedure for bassinet stability, which uses a newborn CAMI instead of an infant CAMI.

International Standards.

The Commission reviewed Canadian, European, and Australian standards for bassinets and/or cradles. Many of the requirements found in the 2012 ASTM standard can also be found in some of these international standards.

The European Standard, EN 1130-1: 1996, "Furniture – Cribs and Cradles for Domestic Use," has several requirements not found in ASTM F2194-12. Most of these additional requirements address hazards associated with cribs intended for use with older children (in excess of the 5-month recommended maximum age for bassinets). Thus, they are not applicable to bassinets.

The scope of the European Standard, EN 12790-2009, "Child Use and Care Articles - Reclined Cradles," includes inclined bassinets/cradles, car seat carriers, hammocks, and bouncers. Some of the general requirements could apply, but because the scope of the product is not the same, most of the requirements are not applicable to bassinets.

The Australian/New Zealand standard (AS/NZS 4385:1996) contains requirements for rocking and swinging angles that were used to develop some of the requirements in ASTM F2194. The ASTM rock/swing rest angle performance requirement, while based on AS/NZS 4385:1996, contains a more severe test method than that in AS/NZS 4385:1996, due to the placement of the CAMI dummy. This is discussed more fully in Section E.

The Canadian standard (SOR 86-962: 2010) includes requirements for cribs and non-full-size cribs. This standard does not distinguish between a bassinet and non-full-size cribs. As a result, many of the requirements are not applicable for this NPR. However, the Canadian standard was used to develop the ASTM requirement for bassinet side height.

The Commission believes that the current ASTM F2194-12 standard is the most comprehensive of the standards to address the incident hazards. There are some individual requirements in various foreign standards that are more stringent than ASTM; however, many of these requirements do not address the identified hazards in the incident data reported to the CPSC.

G. Description of Proposed Changes to ASTM Standard

The proposed rule would create a new part 1218 titled, "Safety Standard for Bassinets and Cradles." The proposal would establish ASTM F2194-12, "Standard Consumer Safety Specification for Bassinets and Cradles," as a consumer product safety standard, but with certain changes. These proposed changes include a revision to an existing test method (the bassinet

stability test method), two additional new requirements and associated test methods (for mattress flatness and removable bassinet bed attachments), and a revised scope and associated definitions or references to support these additions. They are detailed herein.

1. Clarifying the scope of the standard and associated definitions (Sections 1.3, 3.1.1, and 3.1.2)

The Commission is proposing to revise the scope of ASTM F2194-12 and corresponding terminology to better define which products fall within or outside the scope of the standard. The current text of ASTM F2194-12 provides that the "consumer safety performance specification covers products intended to provide sleeping accommodations only for an infant up to approximately 5 months in age, or when the child begins to push up on hands and knees, whichever comes first." The Commission is proposing to change the scope and definition of a "bassinet/cradle"—from products meant exclusively for sleeping—to those intended *primarily* for sleeping. This would ensure that a bassinet sold with a toy mobile that is meant to entertain an infant who is lying in the bassinet, for instance, would still fall within the scope of the standard.

The Commission is also proposing to amend the definitions of "bassinet/cradle" and "bassinet/cradle accessories" to specify that the sleeping surface of these products, while in a rest (non-rocking or swinging) position, is intended to be less than or equal to 10 degrees from horizontal. This change would complement the definition of "inclined sleeper" in the draft ASTM inclined sleeper standard, which defines the "inclined sleeper" as having more than a 10-degree sleep surface incline. Thus, the following are covered under the standard: cradle swings with inclines less than or equal to 10 degrees from horizontal while in rest position; carriage baskets/bassinets that are removable from the stroller base, when the carriage basket/bassinet meets the definition of "bassinet/cradle" found in the standard; bassinet/cradle attachments to

cribs or play yards, when in bassinet/cradle-use mode. The following would not fall under the scope of the bassinet/cradle standard: products used in conjunction with an inclined infant swing or stroller and products that are intended to provide an inclined sleep surface (defined as greater than 10 degrees from horizontal while in the rest (non-rocking) position).

2. Segmented Mattress Flatness Requirement and Test Method (Sections 6.9 and 7.10)

In order to address the hazard of suffocation/positional asphyxia due to an excess mattress pad angle, the Commission is recommending performance requirements and a test method for the minimum flatness of segmented mattress surfaces. This requirement applies only to segmented mattresses, such as those seen in a bassinet accessory to a play yard. The Commission recommends 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.

3. 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)

In order to address hazards associated with misassembly of removable bassinet bed and falls, the Commission is recommending performance requirements and a test method for products that have bassinet beds that attach to an elevated stand. The requirements apply to removable bassinet beds that are designed to separate from the stand/base without the use of tools. The Commission is proposing 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.

4. Revised Test Procedure for Bassinet Stability (Sections 2.3 and 7.4.4)

For the reasons described in the previous Section, the Commission is proposing a revised test procedure for bassinet stability that uses a newborn CAMI instead of an infant CAMI.

H. 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 bassinets and cradles 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 bassinet and cradle manufacturers to come into compliance with the rule.

I. Regulatory Flexibility Act

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 (IRFA) must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the IRFA 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 IRFA 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.

The Market

Bassinets and cradles are typically produced and/or marketed by juvenile product manufacturers and distributors, or by furniture manufacturers and distributors, some of which have separate divisions for juvenile products. The Commission believes that there are currently at least 55 suppliers of bassinets and/or cradles to the U.S. market; 24 are domestic manufacturers, and 11 are domestic importers. An additional 14 domestic firms have unknown

bassinet/cradle supply sources; three of those firms are retailers and nine specialize in bedding, some of which is sold with bassinets or cradles. There are also six foreign firms supplying the U.S. market: five manufacturers and one importer who imports from foreign companies and distributes from outside of the United States.

Bassinets and cradles from 12 of the 55 firms have been certified as compliant by the JPMA, the major U.S. trade association that represents juvenile product manufacturers and importers. Firms supplying bassinets or cradles would be certified to the ASTM voluntary standard F2194-10, while firms supplying play yards with bassinet/cradle attachments would also have to meet F406-11b. Nine additional firms claim compliance with the relevant ASTM standard for at least some of their bassinets and cradles.

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), 64 percent of new mothers own bassinets; 18 percent own cradles; and 39 percent own play yards with bassinet attachments. Approximately 50 percent of bassinets, 56 percent of cradles, and 18 percent of play yards were handed down or purchased second-hand. Thus, about 50 percent of bassinets, 44 percent of cradles, and 82 percent of play yards were acquired new. This suggests annual sales of about 1.3 million bassinets (.5 x .64 x 4.1 million births per year); 325,000 cradles (.44 x .18 x 4.1 million); and 1.3 million play yards with bassinet attachments (.82 x .39 x. 4.1 million). This yields a total of approximately 3 million units sold per year that could be affected by the proposed bassinet/cradle standard.

Reason for Agency Action and Legal Basis for Proposed Rule.

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate a mandatory standard for bassinets/cradles that is substantially the same as, or more stringent than, the voluntary standard. CPSC worked closely with ASTM to develop

the new requirements and test procedures that have been added to the voluntary standard since 2010. These new requirements address several known hazard patterns that will help to reduce injuries and deaths in bassinets and cradles, and they have resulted in the current voluntary standard, F2194-12, upon which the proposed rule is based.

However, the Commission proposes adding two new requirements to F2194-12, as well as modifying the scope and the test CAMI dummy used in the existing stability test. The first new requirement would address suffocation and positional asphyxia hazards that have occurred as a result of problems with segmented mattress flatness in play yard bassinet accessories. The second would address the stability of bassinets with removable bassinet beds, particularly the attachment mechanisms. The Commission also proposes modifying the scope (and some of the terminology) to ensure that inclined sleepers (including infant hammocks) would no longer be covered under the bassinet/cradle standard, unless they recline to 10 degrees or less. The expanded scope would also include Moses baskets and stroller carriage accessories when used in conjunction with a stationary stand. These modifications would also help eliminate gaps in product coverage (*i.e.*, most products that may be used for infant sleep will be included under at least one durable nursery product standard). Finally, the Commission proposes that the CAMI newborn dummy be used for stability testing because it more closely resembles the characteristics of bassinet users than the CAMI infant dummy in F2194-12.

4. Requirements of the Proposed Rule

The Commission proposes adopting the voluntary ASTM standard for bassinets and cradles (F2194-12) with a new mattress flatness requirement, a new stability requirement for bassinets with removable beds, a revised scope, and a modified CAMI dummy for the existing stability requirement. Some of the more significant requirements of the current voluntary standard for

bassinets and cradles (ASTM F2194-12) are listed below. The requirements that were added to the ASTM voluntary standard or modified since the 2010 NPR are italicized.

- Spacing of rigid-side components—intended to prevent child entrapment between both uniformly and non-uniformly spaced components, such as slats. *This has been modified for clarity to remove duplicative test references.*
- Openings for mesh/fabric—intended to prevent the entrapment of children's fingers and toes, as well as button ensnarement.
- Static load test—intended to ensure structural integrity even when a child three times the recommended (or 95th percentile) weight uses it. *This has been modified to also test play yard bassinets in all four corners.*
- Stability requirements—intended to ensure that the product does not tip over when pulled on by a 2-year-old male. *ASTM adopted the revised test requirements included in the 2010 NPR (includes testing with locks/latches engaged).*
- Sleeping pad thickness and dimensions—intended to minimize gaps and the possibility of suffocation due to excessive padding. *F2194-12 allows thicker mattresses for rigid-sided products because a thicker mattress does not pose the same suffocation hazard when used in rigid-sided, rather than soft-sided, products.*
- Tests of locking and latching mechanisms—these are intended to prevent unintentional folding while in use.
- Suffocation warning label—intended to help prevent soft bedding incidents. *F2194-12 requires the warning to use a larger font than the 2010 NPR.*
- *Fabric-sided openings test—intended to prevent entrapments. This test was included in the 2010 NPR and has been adopted in F2194-12 with a few editorial changes.*

- *Rock/swing angle requirement—intended to address suffocation hazards that can occur when latch/lock problems and excessive rocking or swinging angles press children into the side of the bassinet/cradle. The 2010 NPR recommended a maximum rocking angle of 20 degrees and a maximum rest angle of 5 degrees. ASTM F2194-12 adopts the maximum deflection angle of 20 degrees, but includes a maximum rest angle of 7 degrees with a more severe test condition where the CAMI doll is positioned at the side, rather than the center, of the bassinet/cradle.*
- *Occupant restraints—intended to prevent incidents where unused restraints have entrapped and strangled children. The 2010 NPR proposed that only passive restraints be allowed. ASTM F2194-12 is even stricter, allowing no restraints to be used in a bassinet/cradle configuration.*
- *Side height requirement—intended to prevent falls. This requirement, which is new to F2194-12, arose from the comments to the 2010 NPR. A bassinet/cradle side height of 7½ inches from the top of the uncompressed mattress is now required.*

The voluntary standard also includes: (1) torque and tension tests to ensure that components cannot be removed; (2) requirements for several bassinet/cradle features to prevent entrapment and cuts (minimum and maximum opening size, small parts, hazardous sharp edges or points, and edges that can scissor, shear, or pinch); (3) requirements for the permanency and adhesion of labels; (4) requirements for instructional literature; and (5) corner post extension requirements intended to prevent pacifier cords, ribbons, necklaces, or clothing that a child may be wearing from catching on a projection.

The Commission proposes modifying the scope, using the more appropriate infant CAMI dummy for stability testing, and adding new mattress flatness and attachment of removable

bassinet bed requirements to ASTM F2194-12. As part of these changes, there would also be several new or revised definitions, including "bassinet/cradle," "bassinet/cradle accessory," and "bassinet bed." Following is a discussion of the impact of each of these changes.

a. Scope.

There are three major proposed changes to the scope of the bassinet/cradle standard:

1. Specification that it is to cover products primarily used to provide sleeping accommodations. This expands the scope beyond products only used to provide sleeping accommodations.
2. Products with an incline of 10 degrees or less would be included, while products with a greater than 10 degree incline would not. ASTM and CPSC have developed this demarcation across product standards to help ensure complete coverage of sleep products. This would include cradle swings which, by definition, recline less than 10 degrees from horizontal.
3. Specification that it includes products that can be supported by a stationary frame/stand. This would bring in carriage attachments to strollers and Moses baskets *only* when used with a stationary or rocking stand.

These scope changes may affect suppliers in several ways. First, they would provide additional clarity to suppliers regarding which products would be covered under what standards. Reduced confusion means less time reviewing, testing, and making necessary modifications. Second, "cradle swings," defined by the infant swings standard, F2088-11a, as an infant swing intended for use by a child lying flat (*i.e.,* horizontal), would be covered under both the bassinet standard and the infant swings standard. The Commission believes that cradle swings currently on the market should be able to meet the proposed standard for bassinets without additional

modifications. Third, Moses baskets and carriage attachments to strollers would now be subject to the bassinet/cradle standard when used in conjunction with a separate stand. However, this would apply only to Moses baskets and carriages that are produced and sold by the same company that makes the stand, and therefore, are intended to be used together. Firms that supply bassinet/cradle stands, as well as either Moses baskets or carriage attachments for strollers, would need to ensure that their Moses baskets and/or carriage attachments meet the bassinet/cradle standard when attached to the stand(s). This would likely require some redesign, most notably to meet the side height and stability requirements, and it would affect 10 known firms. Alternatively, they could stop supplying the stands.

b. Stability Testing with Newborn CAMI Dummy

Because bassinets and cradles are intended to be used by very young children, it is appropriate that the smaller newborn CAMI dummy be used for stability testing. The heavier (17.5 pound) infant CAMI currently used for stability testing in F2194-12 could make these products more stable when tested than they actually would be in a real-world situation. Based on preliminary Commission testing, it appears that most bassinet/cradles will be able to pass this revised test procedure without modification. However, at least one product failed stability testing with the newborn CAMI and passed with the infant CAMI. It is possible that a few products may require modifications to meet the revised stability test procedure. It is likely to affect only a few manufacturers, but it is unlikely to require product redesign. Affected firms would most likely increase the stability of their product by widening the structure, making the bassinet bed deeper, or making the base heavier. If meeting the modified requirement necessitates a change to the hard tools used to manufacture the bassinet, the cost could be more significant.

c. Mattress Flatness

The Commission is proposing the addition of a mattress flatness requirement and test method to the standard, as well. The mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented mattresses. These incidents suggest that products with mattresses that have multiple seams could pose a suffocation hazard. Based on Commission testing, it appears that the play yard bassinet attachments of many suppliers (both compliant and noncompliant with F2194-10) would pass this requirement without any modifications. Those that do require modifications would need to increase the mattress support in their bassinets. This could be accomplished, for example, by retrofitting their play yard bassinets to use longer rods or a better-fitting mattress shell. The cost of such a retrofit is unknown and would likely vary from product to product; however, it should be less expensive than a product redesign. Based on this information, it appears that at least a few play yard bassinets may require modifications, which could include product redesign. However, it is believed that most firms would opt for the less expensive option of retrofitting their existing designs.

d. Removable Bassinet Beds

Finally, the Commission proposes adding a new requirement and test method to address the attachment of removable bassinet beds. There are several manufacturers with bassinet designs that allow for the bassinet bed to be removed from the stand easily (*i.e.,* without the use of tools) and used separately. In many cases, the bassinet bed sits securely on the stand without any attachment mechanism. In other cases, clips or locks may be used to ensure that the stand retains the bassinet bed during use. Incidents have arisen where the attachments have either failed or have not been used, rendering the bassinet bed unstable. Therefore, CPSC, in conjunction with

an ASTM task group, has developed a requirement and test methods to address the potential instability of some removable bassinet beds when used with a stand.

There are several firms supplying bassinets with removable bassinet beds to the U.S. market. The majority will not need modifications to meet the proposed requirement. However, at least four firms will need to make changes to one or more of their bassinets. Essentially, the products will need to be modified so that they are either inherently stable (automatically lock or stable even without the locks) or obviously unstable (unsupportable or obviously tilted without locks or a visual indicator that locks not in use). There are numerous ways that firms could meet this new requirement if their product(s) required modification, including redesigning the product entirely. However, it seems likely that many firms would opt for less expensive alternatives, such as more sensitive locks that activate with little pressure (*i.e.,* with just the weight of the bassinet).

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 bassinets/cradles 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.

Impact on Small Businesses

There are approximately 55 firms currently known to be marketing bassinets and/or cradles in the United States. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of bassinets or cradles is small if it has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, 38 are small firms—19 domestic manufacturers, 8 domestic importers, and 11 firms with unknown supply sources (including 9 specializing in bedding). The remaining firms are five large domestic manufacturers, three large domestic importers, three large retailers with unknown supply sources, and six foreign firms. There may be additional unknown small bassinet/cradle suppliers operating in the U.S. market.

Small manufacturers. The expected impact of the proposed standard on small manufacturers will differ based on whether their bassinets/cradles are already compliant with F2194-10. Firms whose bassinets and cradles meet the requirements of F2194-10 are likely to continue to comply with the voluntary standard as new versions are published. In addition, they are likely to meet any new standard within 6 months because this is the amount of time JPMA allows for products in their certification program to shift to a new standard. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice. Therefore, it is likely that firms supplying bassinets and cradles that comply with ASTM F2194-10 (which went into effect for JPMA certification purposes in

November 2010) would also likely comply with F2194-12 by January 2013, even in the absence of a mandatory standard.

It is possible that the direct impact for manufacturers whose products are likely to meet the requirements of ASTM F2194-12 (10 of 19 firms) could be significant for one or more firms if they must redesign their bassinets to meet the proposed rule. While none of these manufacturers would be newly covered due to the proposed change in scope, seven would be affected by the mattress flatness requirement (*i.e.,* they produce play yards with bassinet attachments), and at least two (and possibly four) may be affected by the removable bassinet bed stability requirement. For the most part, the bassinets/cradles and bassinet cradle attachments supplied by these firms will be able to meet the staff-recommended changes to ASTM F2194-12, without modification. In cases where modifications are necessary, they would most likely opt to retrofit their products, rather than undertake an expensive redesign. However, it is possible that some products may require redesign, particularly to meet the new removable bassinet bed stability requirement; therefore, costs could be significant in some cases.

Meeting ASTM F2194-12's requirements could necessitate product redesign for at least some bassinets/cradles that are believed not to be compliant with F2194-10 (9 of 19 firms). Two of these firms produce either Moses baskets or carriage stroller attachments along with separate stands, and therefore, they are included only because of the proposed change in scope. (Since no Moses baskets or carriage attachments for strollers are currently tested to the ASTM bassinets/cradles standard, it is assumed that none would meet ASTM F2194-12 without modifications). The remaining seven firms could require redesign, regardless of the staff-recommended modifications. A redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric, but it could be more significant if changes

to the frame are required, including changes to side height. One manufacturer estimated that a complete play yard redesign, including engineering time, prototype development, tooling, and other incidental costs, would cost approximately $500,000. The Commission believes that a bassinet redesign would tend to be comparable. Consequently, the proposed rule could potentially have a significant direct impact on small manufacturers whose products do not conform to F2194-10. However, any direct impact might be mitigated if costs are treated as new product expenses that can be amortized.

It is possible that some firms supply bassinets/cradles that are compliant with F2194-10, even though they are not certified or marketed as compliant. The Commission has identified many such cases with other products. To the extent that some of these firms may supply compliant bassinets/cradles and have developed a pattern of compliance with the voluntary standard, the direct impact of the proposed standard will be less significant than described above. There are also two small firms with unknown supply sources, none of which appear to comply with F2194-10 (one is covered by the proposed rule due to the expanded scope). If these firms are manufacturers, they may also require redesign to meet the proposed standard.

In addition to the direct impact of the proposed standard described above, there are indirect impacts. These impacts are considered indirect because they do not arise directly as a consequence of the bassinet/cradle rule's requirements. Nonetheless, they could be significant. Once the rule becomes final and the notice of requirements is in effect, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements. This will include any physical and mechanical test requirements specified in the final rule; lead and phthalates testing is already required, and hence, not included here.[1]

[1] Bassinet and cradle suppliers already must third party test their products to the lead and phthalate requirements. Therefore, these costs are left out of the analysis above.

One manufacturer estimated that testing to the ASTM voluntary standard runs around $1,000 per model sample, although they noted that the costs could be lower for some models where the primary difference is fabric rather than structure. Testing overseas could potentially reduce some testing costs, but this may not always be practical.

On average, each small domestic manufacturer supplies eight different models of bassinets/cradles and/or play yards with bassinet/cradle accessories to the U.S. market annually. Therefore, if third party testing were conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about $8,000 annually. Based on a review of firm revenues, the impact of third party testing to ASTM F2194-12 is unlikely to be significant if only one bassinet/cradle sample per model is required. However, if more than one sample would be needed to meet the testing requirements, third party testing costs could have a significant impact on a few of the small manufacturers.

Small Importers.

As with manufacturers of compliant bassinets/cradles, the four small importers of bassinets/cradles currently in compliance with F2194-10 could experience significant direct impacts as a result of the proposed rule, if product redesign is necessary. In the absence of regulation, these firms would likely continue to comply with the voluntary standard as it evolves and likely the final mandatory standard as well. Any increase in production costs experienced by their suppliers may be passed on to them.

Importers of bassinets/cradles would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the proposed rule, which may be the case with the four importers of bassinets/cradles believed not to be in compliance with F2194-10 (two of which are covered by the proposed rule due to the expanded scope). Some could respond

to the rule by discontinuing the import of their noncompliant bassinets/cradles, possibly discontinuing the product line altogether. However, the impact of such a decision could be mitigated by replacing the noncompliant bassinets/cradles with compliant bassinets/cradles. Deciding to import an alternative product would be a reasonable and realistic way to offset any lost revenue.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, they will experience costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers who must perform the testing themselves if more than one sample per model were required.

Bedding Suppliers. There are nine known small firms specializing in the supply of bedding, including bedding for bassinets and cradles. Each firm sells basic bassinet or cradle shells, covered with their bassinet and cradle bedding. While it is clear that these firms do not manufacture the structural parts of the bassinets or cradles themselves, it is unclear whether they purchase them domestically or overseas. Regardless, these firms will be affected by the proposed rule in a manner similar to importers.

Because none of these firms is believed to supply bassinets or cradles in compliance with F2194-10, they would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the proposed rule. Unlike most importers, however, they would not have the option of replacing a noncompliant bassinet/cradle with another product. While they could opt to sell the bedding without the associated bassinet/cradle, this is the standard method of sale, and it might make it more difficult to compete in the bassinet/cradle market.

As with manufacturers and importers, these firms will also be subject to third party testing and certification requirements, and they will experience costs similar to those for manufacturers if their supplying firm(s) does not perform third party testing. The resulting costs could have a significant impact on some of these small bassinet/cradle suppliers who must perform the testing themselves.

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. Doing so would eliminate the impact on the six small firms that would be newly covered under the bassinet/cradle standard due to the proposed change in scope. These firms all supply Moses baskets or carriages, along with stationary stands; the Commission believes that these products require additional safety features when used for sleeping purposes. Adopting the voluntary standard without modifications could also reduce the impact on other small manufacturers and importers whose ASTM-compliant bassinets/cradles would require modifications due to the proposed changes. However, because of the severity of the incidents associated with instability and mattress tilt, the Commission does not recommend this alternative.

A second alternative would be to set an effective date later than the proposed 6 months that is generally considered sufficient time for suppliers to come into compliance with a proposed rule. Setting a later effective date would allow suppliers additional time to modify and/or develop compliant bassinets/cradles and spread the associated costs over a longer period of time.

The Commission invites comments describing the possible impact of this rule on manufacturers and importers, as well as comments containing other information describing how this rule will affect small businesses.

J. 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.

K. 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 Bassinets and Cradles

Description: The proposed rule would require each bassinet and cradle to comply with ASTM F 2194-12, "Standard Consumer Safety Specification for Bassinets and Cradles." Sections 8 and 9 of ASTM F 2194-12 contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of "collection of information," as defined in 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import bassinets/cradles.

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
1218	55	5	275	1	275

Our estimates are based on the following:

Section 8.1.1 of ASTM F 2194-12 requires that the name of the manufacturer, distributor, or seller and either the place of business (city, state, and mailing address, including zip code) or telephone number, or both, be marked clearly and legibly on each product and its retail package. Section 8.1.2 of ASTM F 2194-12 requires a code mark or other means that identifies the date (month and year, as a minimum) of manufacture.

There are 55 known entities supplying bassinets to the U.S. market. All 55 firms are assumed to use labels already on both their products and their packaging, 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 entity supplies an average of eight different models of bassinets; therefore, the estimated burden associated with labels is 1 hour per model x 55 entities x 5 models per entity = 275 hours. We estimate the hourly compensation for the time

required to create and update labels is $27.55 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," March 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 to industry associated with the labeling requirements is $2,041.92 ($27.55 per hour x 275 hours = $7,576.25). There are no operating, maintenance, or capital costs associated with the collection.

Section 9.1 of ASTM F2194-12 requires instructions to be supplied with the product. Bassinets and cradles are products that generally require assembly, and products sold without such information would not be able to compete successfully with products supplying this information. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the "normal course of their activities" are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are "usual and customary." Therefore, because we are unaware of bassinets or cradles that generally require some installation, but lack any instructions to the user about such installation, we tentatively estimate that there are no burden hours associated with section 9.1 of ASTM F2194-12 because any burden associated with supplying instructions with bassinets and cradles would be "usual and customary" and not within the definition of "burden" under the OMB's regulations.

Based on this analysis, the proposed standard for bassinets would impose a burden to industry of 275 hours at a cost of $7,576.25 annually.

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.

L. 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.

M. 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 1218, "Safety Standard for Bassinets and Cradles," 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 in the *Federal Register* the proposed rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies,* 77 FR 331086, which, when finalized, would establish the general requirements and criteria concerning testing laboratories. 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 at 16 CFR part 1112, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 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 bassinet

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 bassinets and cradles 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 1218, Safety Standard for Bassinets and Cradles included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at www.cpsc.gov/labsearch.

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 bassinets and cradles and the test methods incorporated within that standard. The Commission may recognize limited circumstances in which the Commission will accept certification based on product testing conducted before the Commission's acceptance of accreditation of laboratories for testing bassinets and cradles (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 bassinets and cradles and the accompanying proposed NOR.

N. Request for Comments

This proposed rule is part of a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for bassinets and cradles. 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 1218

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 chapter II 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. Add §Part 1112.15(b)(33) 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)

(33) 16 CFR part 1218, Safety Standard for Bassinets and Cradles.

3. Add part 1218 to read as follows:

PART 1218-SAFETY STANDARD FOR BASSINETS AND CRADLES

Sec.

1218.1 Scope.

1218.2 Requirements for bassinets and cradles.

Authority: The Consumer Product Safety Improvement Act of 2008, Pub. L. 110-314, § 104, 122 Stat. 3016 (August 14, 2008).

§ 1218.1 Scope.

This part establishes a consumer product safety standard for bassinets and cradles.

§ 1218.2 Requirements for bassinets and cradles.

(a) Except as provided in paragraph (b) of this section, each bassinet and cradle must comply with all applicable provisions of ASTM F 2194-12, Standard Consumer Safety Specification for Bassinets and Cradles, 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 F 2194-12 standard with the following additions or exclusions:

(1) Instead of complying with section 1.3 of ASTM F 2194-12, comply with the following:

(i) 1.3 This consumer safety performance specification covers products primarily intended to provide sleeping accommodations for an infant up to approximately 5 months in age, or when the child begins to push up on hands and knees, whichever comes first. Products used in conjunction with an inclined infant swing or stroller, or products that are intended to provide an inclined sleep surface (head-to-toe direction) of greater than 10° from horizontal, while in the rest (non-rocking) position, are not covered by this specification.

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.

(ii) [Reserved]

(2) Add "CAMI Newborn Dummy (see Fig. 1A). Drawing numbers 126-0000 through 126-0015 (sheets 1 through 3), 126-0017 through 126—0027, a parts list entitled "Parts List for CAMI Newborn Dummy," and a construction manual entitled "Construction of the Newborn Infant Dummy" (July 1992). Copies of the materials may be inspected at NHTSA's Docket Section, 400 Seventh Street, S.W., Room 5109, Washington DC, or at the Office of the Federal

Register, 800 North Capitol Street, NW., suite 700, Washington, DC." to "2.3 Other References" and use the following figure:

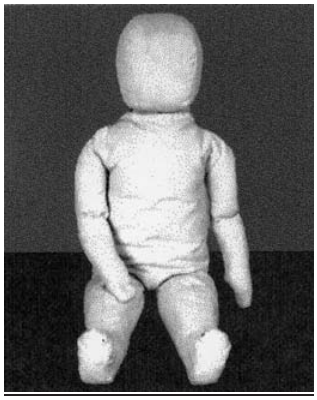


FIG. 1A CAMI Newborn Dummy

(3) Instead of complying with section 3.1.1 of ASTM F 2194-12, comply with the following:

(i) 3.1.1 *Bassinet/cradle*, n – small bed designed primarily to provide sleeping accommodations for infants, supported by free-standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which 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.

(ii) [Reserved]

(4) Instead of complying with section 3.1.2 of ASTM F 2194-12, comply with the following:

(i) *Bassinet/cradle accessory*, n –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 sleep surface less than or equal to 10° from horizontal while in a rest (non-rocking or swinging) position.

(ii) [Reserved]

(5) Instead of complying with section 3.1.3 of ASTM F 2194-12, comply with the following:

(i) 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.

(ii) [Reserved]

(6) In addition to complying with section 3.1.16 of ASTM F 2194-12, comply with the following:

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

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

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

(iv) 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.

(7) In addition to complying with section 6.8 of ASTM F 2194-12, comply with the following:

(i) 6.9 *Segmented Mattress 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.

(ii) 6.10 *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 6.10.1, 6.10.2, 6.10.3, 6.10.4 or 6.10.5 when tested in accordance with 7.11.

(A) 6.10.1 The base/stand shall not support the bassinet bed (*i.e.,* the bassinet bed collapses from the stand and contacts the floor).

(B) 6.10.2 The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action).

(C) 6.10.3 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.

(D) 6.10.4 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.

(E) 6.10.5 The bassinet bed shall not tip over and shall retain the CAMI newborn dummy.

(8) Instead of complying with section 7.4.4 of ASTM F 2194-12, comply with the following:

(i) 7.4.4 Place the CAMI Newborn Dummy 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 50th percentile 6-month-old infant.

(ii) [Reserved]

(9) In addition to complying with section 7.9 of ASTM F 2194-12, comply with the following:

(i) 7.10 *Segmented Mattress Flatness Test*

(A) 7.10.1 Angle measurement for bassinets intended for a single occupant:

(B) 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.

(C) 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.

(D) 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.

(E) Figure 13. Infant Test Cylinder

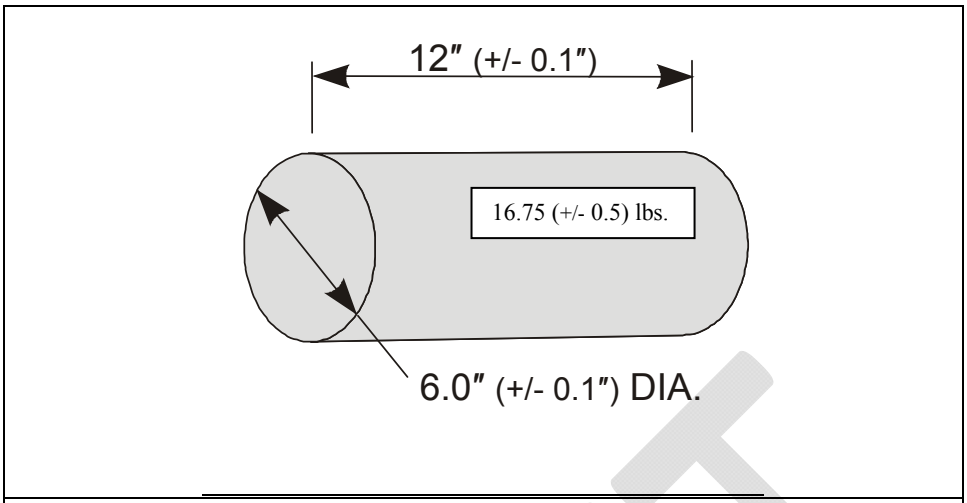


FIG. 13. Infant Test Cylinder

(F) Figure 14. Cylinder placement on mattress seam.

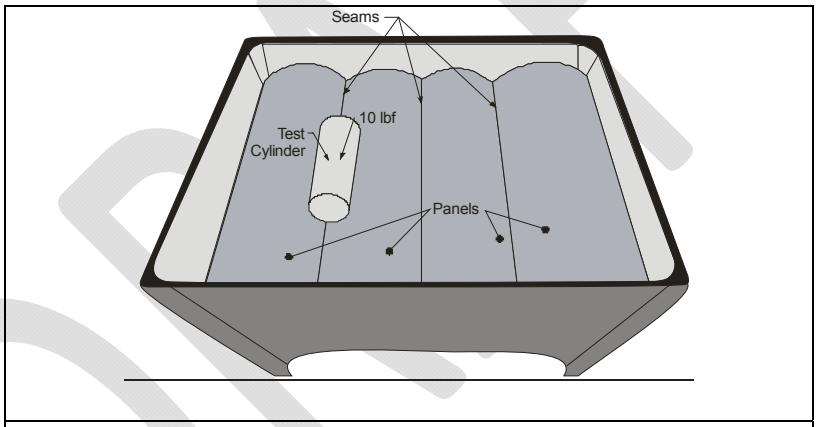


FIG. 14. Cylinder placement on mattress seam

(G) 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.

(H) 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.

(I) 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.

(J) Figure 15. Steel block in front of the cylinder for a single occupant bassinet

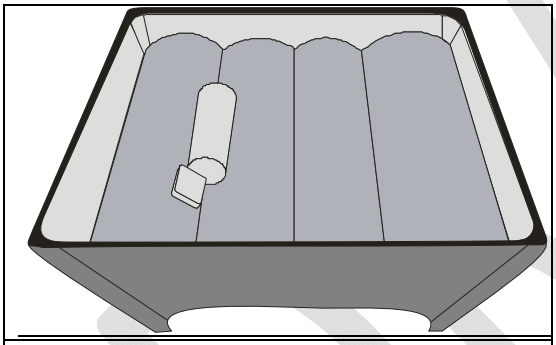


FIG. 15. Steel block in front of the cylinder for a single occupant bassinet

(K) Figure 16. Inclinometer on steel block in front of the cylinder for a single occupant bassinet

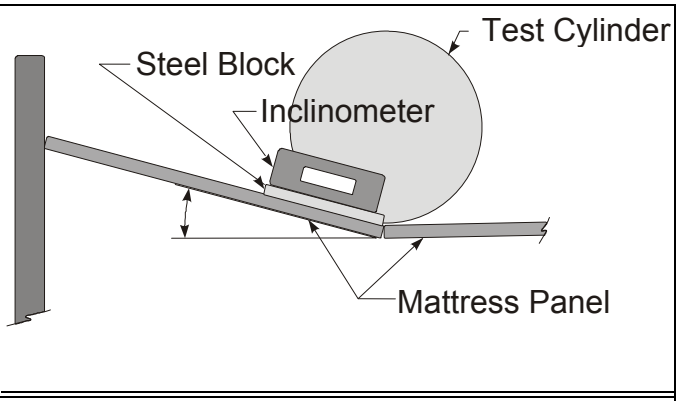


FIG.16. Inclinometer on steel block in front of the cylinder for a single occupant bassinet

(L) 7.10.1.6 Record the angle measurement.

(M) 7.10.1.7 Repeat 7.10.1.4–7.10.1.5 on the opposite side of the seam and record the measurement.

(N) 7.10.1.8 Remove the cylinder from the bassinet.

(O) 7.10.1.9 Repeat 7.10.1.3–7.10.1.8 on each remaining seam of the mattress and record the angles.

(P) 7.10.2 Angle measurement for bassinets intended for two occupants:

(Q) 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.

(R) 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.

(S) Figure 17. Newborn Test Cylinder

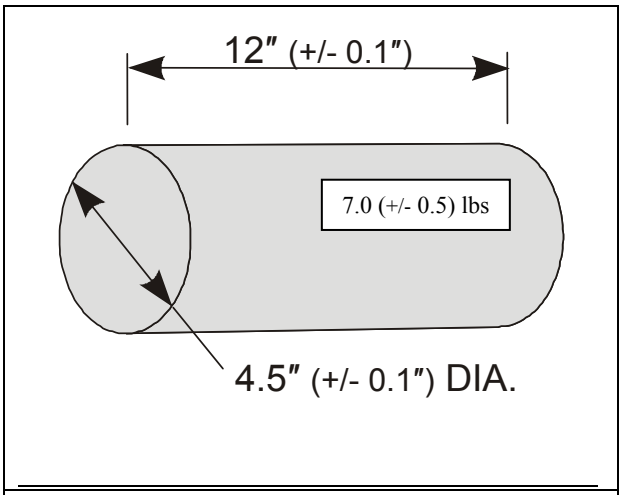


FIG. 17. Newborn Test Cylinder

(T) Figure 18. Placement of cylinders for a 2 occupant bassinet

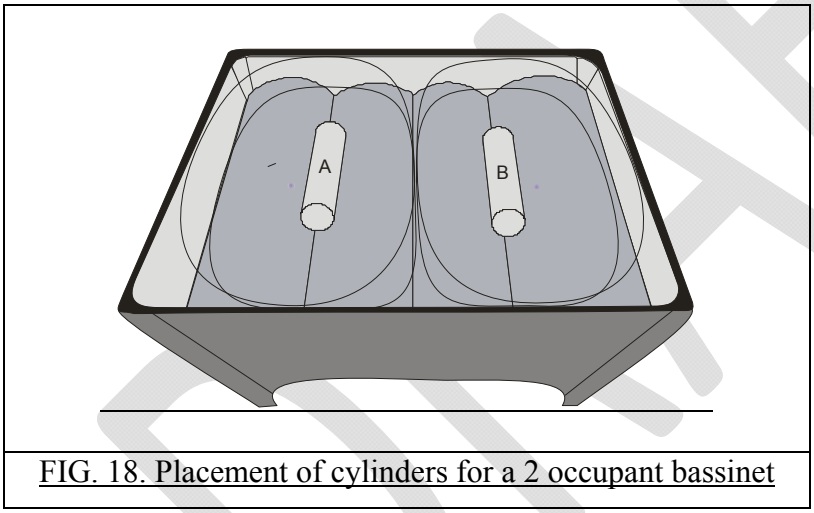


FIG. 18. Placement of cylinders for a 2 occupant bassinet

(U) 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.

(V) 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.

(W) 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.

(X) 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.

(Y) Figure 19. Steel block in front of the cylinder for a 2-occupant bassinet

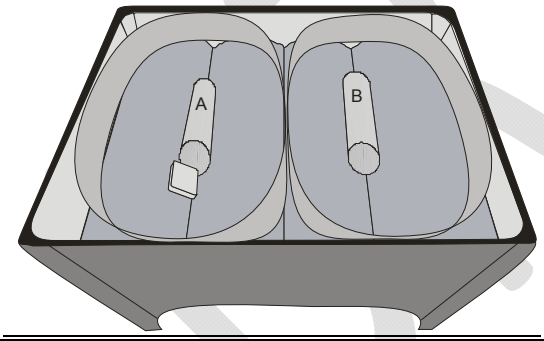


FIG. 19. Steel block in front of the cylinder for a 2-occupant bassinet

(Z) Figure 20. Inclinometer on Steel block in front of the cylinder for a 2-occupant bassinet

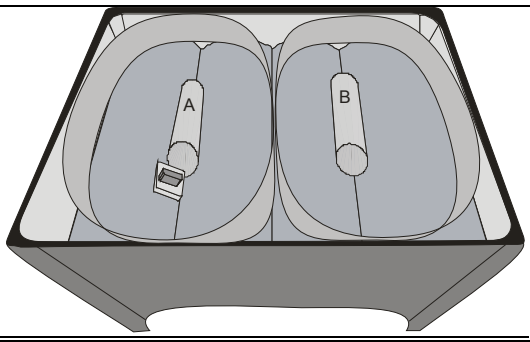


FIG. 20. Inclinometer on Steel block in front of the cylinder for a 2-occupant bassinet

(AA) 7.10.2.6 Record the angle measurement.

(BB) 7.10.2.7 Repeat 7.10.2.4–7.10.2.5 on the opposite side of the cylinder and record the measurement.

(CC) 7.10.2.8 Repeat the angle measurements 7.10.2.4–7.10.2.7 for cylinder B and record the measurement.

(DD) 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.

(EE) 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.

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

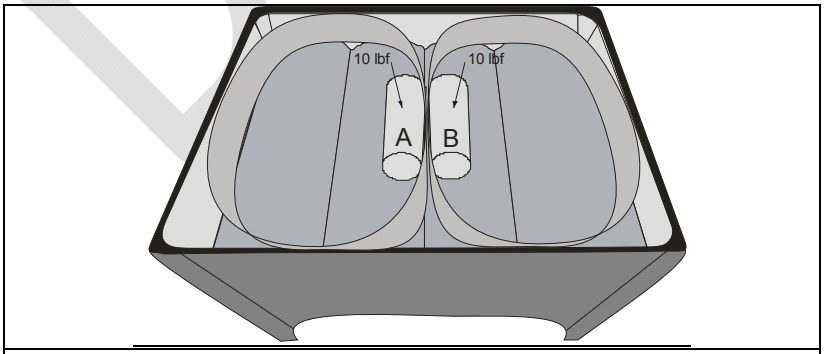


FIG. 21. Two cylinders (A and B) in contact with the inside wall

(GG) 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.

(HH) 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.

(II) 7.10.2.13 Record the angle measurement.

(JJ) 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.

(KK) 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.

(LL) 7.10.2.16 Record the angle measurement.

(MM) Figure 22. Angle measure in front of Cylinder A

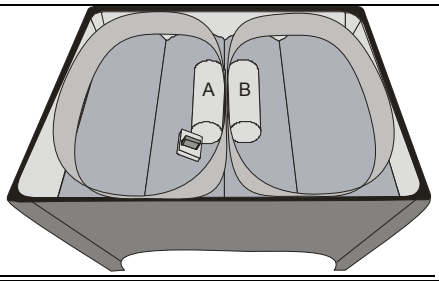


FIG.22 Angle measure in front of Cylinder A

(NN) Figure 23. Angle measure in front of Cylinder B

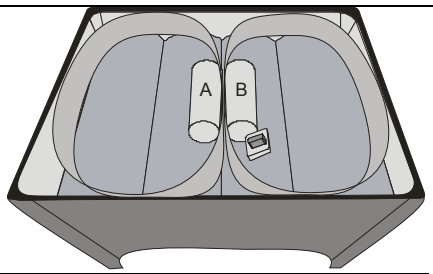


FIG. 23. Angle measure in front of Cylinder B

(OO) *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.

(ii) [Reserved]

(10) In addition to the changes to ASTM F 2194-12 in paragraph (b)(10) of this section comply with the following:

(i) 7.11 *Removable Bassinet Bed Attachment Tests*

(A) 7.11.1 Assemble the bassinet/cradle base/stand only, in accordance with manufacturer's instructions.

(B) 7.11.2 Place the base/stand in one of the manufacturer's recommended use positions.

(C) 7.11.3 Place the base/stand and the inclinometer on a flat level horizontal surface (0 +/- 0.5°) to establish a test plane. Zero the inclinometer.

(D) 7.11.4 Remove the mattress pad from the bassinet bed.

NOTE —For mattresses that are integral with the mattress support, do not remove the mattress and perform all angle measurements for 7.11 on a 6 by 6 by 3⁄8-in. nominal aluminum block placed on the center of the mattress.

(E) 7.11.5 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 (see Figure 24), the unit shall be evaluated in the lateral position most likely to fail the requirements outlined in 6.10.

(F) Figure 24: Bassinet Bed Resting on Stand, Showing Possible Alternate Lateral Positions.

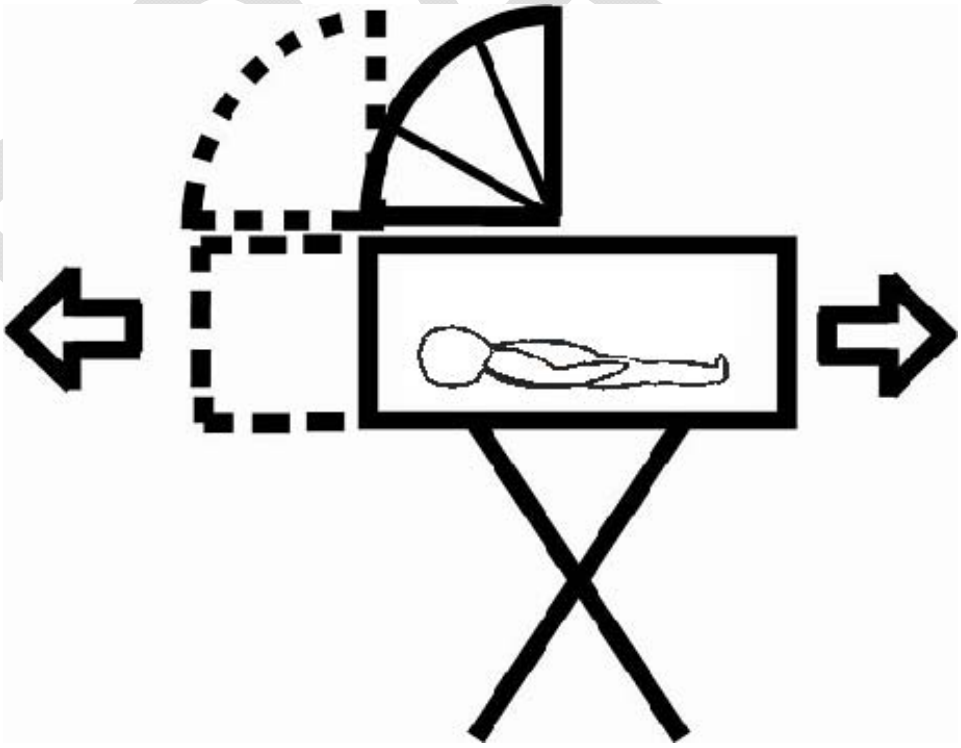


Figure 24: Bassinet Bed Resting on Stand,
Showing Possible Alternate Lateral Positions

(G) 7.11.5.1 If the base/stand supports the bassinet bed, place the inclinometer on the mattress support at the approximate center of the mattress support. Care should be taken to avoid seams, snap fasteners, or other items that may affect the measurement reading. Record the angle measurement.

(H) 7.11.5.2 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 6.10.4.

(I) 7.11.5.3 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 7.4.2-7.4.7.

(J) 7.11.6 Repeat 7.11.3 through 7.11.5.3 for all of the manufacturer's base/stand positions.

(K) 7.11.7 If the product design allows, repeat 7.11.2 through 7.11.6 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 properly locked/latched 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 properly engaged can create a false sense of security by appearing to be stable. Unsecured or mis-aligned lock/latch systems are a hidden hazard because they not easily seen by consumers due to being located beneath the bassinet or 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 properly secured.

Section 6.10 allows bassinet bed designs that:

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

2) automatically lock 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 properly locked onto the stand/base, or

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

(ii) [Reserved]

Dated: _____.

_____

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission

Staff Briefing Package

Notice of Proposed Rulemaking (NPR) for Bassinets and Cradles
Consumer Product Safety Improvement Act of 2008

August 31, 2012

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

Table of Contents

Briefing Memo

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

This document has been electronically approved and signed.

Memorandum

August 31, 2012

TO: The Commission
Todd Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

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

Patricia Edwards, Project Manager
Directorate for Engineering Sciences

SUBJECT: Consumer Product Safety Improvement Act of 2008 (CPSIA): Notice of Proposed Rulemaking (NPR) for Bassinets and Cradles

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) is the Danny Keysar Child Product Safety Notification Act. This act requires the U.S. Consumer Product Safety Commission (CPSC) to: (1) examine and assess voluntary safety standards for certain infant and toddler products, and (2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. The list of products in section 104 includes bassinets and cradles.

In April 2010, the Commission issued a notice of proposed rulemaking (NPR) for bassinets and cradles (75 Fed. Reg. 22303, April 28, 2010). The proposed rule incorporated by reference the voluntary standard, ASTM F2194-07a$^{\varepsilon 1}$, *Standard Consumer Safety Specification for Bassinets and Cradles,* with certain changes to specific provisions in the voluntary standard in order to strengthen the proposed rule.

Due to the substantial differences between the 2010 NPR and staff's current recommendations, which resulted from additional analysis performed by staff and the ASTM subcommittee on bassinets and cradles subsequent to the publication of the 2010 NPR, staff is recommending a supplemental notice of proposed rulemaking of the 2010 proposed bassinet rule.

This briefing package reviews the incident data and assesses the effectiveness of the current bassinets and cradles voluntary standard and how it compares with the 2010 NPR. The package also discusses the impact of staff's recommendations on small businesses, reviews recent recalls associated with bassinets, presents an overview of the comments received for the 2010 NPR that modified the staff recommendations, and provides staff recommendations to the Commission.

Specifically, staff is recommending that the Commission publish an NPR that incorporates by reference the voluntary standard ASTM F2194-12, *Standard Consumer Safety Specification for Bassinets and Cradles,* with two additional requirements and associated test methods, one modification to an existing test method, and a revised scope and associated definitions.

II. BACKGROUND

A. Product Review

Bassinets are intended to provide sleeping accommodations for infants up to approximately 5 months of age. Figures 1–4 show some typical bassinets or cradles.

			
Figure 1. Stationary Bassinet	Figure 2. Bassinet With Rocking Base	Figure 3. Swinging Rigid-Sided Cradle	Figure 4. Play Yard Bassinet Combination

Figure 4, it should be noted, is also a play yard product. A play yard that contains a bassinet accessory, as seen in Figure 4, falls within the scope of two different standards, the play yard standard and the bassinet standard. Both standards have requirements for these accessories, and thus, in order to be in compliance, products must meet the applicable requirements in both standards. The final rule for the play yard standard was approved by the Commission on June 27, 2012 and published in the Federal Register on August 29, 2012.

There are two other product categories that are closely associated with a bassinet: (1) a bedside sleeper, and (2) an inclined sleeper/hammock (see Figures 5–7).

Figure 5: Bedside Sleeper

Figure 6: Inclined Sleeper

Figure 7: Infant Hammock

A bedside sleeper (see Figure 5) is a multiuse product with its own standard. A bedside sleeper is a subset of a bassinet, one intended to be attached to the side of an adult bed so that the caregiver is in close proximity to the sleeping infant. Because it is a subset, all bedside sleepers fall under the scope of the bassinet standard, and, in addition, bedside sleepers have their own standard to address characteristics specific to them. Some bedside sleepers are actually three products in one: a play yard, a bassinet, and a bedside sleeper. Therefore, those bedside sleepers should meet the requirements of all three standards. Shortly, staff will provide the Commission with a briefing package outlining the recommendations for a proposed rule on bedside sleepers.

An inclined sleeper (Figure 6) is also a sleeping product intended for infants. It differs from a bassinet in that it is intended to have an inclined sleep surface and it conforms to the contour of the occupant. Most hammocks (Figure 7) have mattresses that are also inclined in a manner that elevates the head, and also conform to the body contours of the infant. They are also intended to allow swinging or bouncing motions. These special features, especially elevating the head, are sometimes intended to help prevent reflux. Features that allow head elevation, swinging, and bouncing motions distinguish these products from common bassinets and cradles which generally have flat mattresses with solid or fabric-covered framed sides. Such specialized design features would prevent hammocks and other inclined sleepers from meeting some of the performance requirements in the bassinet standard.

Because of the differences in the intended sleep position for the occupant, these products require different safety requirements, such as side-to-side containment requirements. Within the next year, an ASTM standard for inclined sleepers is expected to be balloted by ASTM. Following publication of the ASTM standard, staff will provide the Commission with a briefing package outlining recommendations for a proposed rule for inclined sleepers and hammocks.

Characterization of such multiuse products presents a perennial challenge to standards developers. At present, products that provide a sleeping surface for infants include: carriages, strollers, play yards, swings, hammocks, bouncers, handheld carriers, bassinets, bedside sleepers, and inclined sleeping products. All of these product categories already have a standard or draft standard under development. As seen above, it is possible to design multiuse products that span two or more of these product categories. In general, industry members and consumer advocates recommend that a multiuse product conform to all of the applicable standards.

B. April 28, 2010 NPR Overview

The Commission published an NPR on April 28, 2010, for bassinets and cradles. The proposed rule referenced ASTM F2194-07a$^{\varepsilon 1}$ along with 14 modifications. These modifications were outlined in the NPR as follows:

(1) Revision to the scope of the standard;
(2) Addition of a new figure for testing purposes;
(3) Revision to the term "bassinet/cradle";
(4) Revision to the term "bassinet/cradle accessory";
(5) Five terminology additions (Maximum Deflection Angle, Rest Angle, Removable Cover, Double Action Release Mechanism, and Flatness Angle);
(6) Two additional requirements to the calibration and standardization section;
(7) New restraints requirement;
(8) Revision of the spacing test requirement;
(9) Revision of the stability test requirement;
(10) Addition of three new test requirements: rock/swing angle, bassinet/cradle surface (mattress flatness), and fabric-sided enclosed openings;
(11) Addition of three new test procedures to go with the three new requirements: rock/swing angle, bassinet/cradle surface (mattress flatness), and fabric-sided enclosed openings;
(12) Revision to the general warning statement descriptor;
(13) Revision to the wording of the suffocation warning;
(14) Addition of a new warning statement descriptor for the suffocation warning.[1]

The most significant proposed changes to the standard are encompassed in modifications #10 and 11, which are the three new performance requirements and their associated test methods. Since the NPR was published, considerable work has been done on these three performance tests by ASTM, CPSC staff, and various stakeholders. Two of the three requirements have been incorporated into the latest revision of the ASTM standard, F2194-12. The third requirement for segmented mattress flatness was recently reballoted by ASTM, but the results of the ballot are not yet known.

Another significant recommendation for the 2010 NPR dealt with the inclusion of infant hammocks in the scope of the standard. The voluntary standard, ASTM F2194-12, does not state explicitly whether infant hammocks are within the scope of the standard. However, the Juvenile Products Manufacturers Association (JPMA) historically has certified some infant hammocks to the bassinet standard because there was not a separate standard for infant hammocks and other inclined sleep products. For this reason, and because of the known hazard pattern associated with hammocks, the Commission included infant hammocks in the scope of the April 2010 NPR. Including infant hammocks and inclined sleepers in the scope in the bassinet standard would effectively ban most of these products currently on the market. ASTM is currently working on a separate standard for these products.

[1] 75 Fed. Reg. at 22305.

C. Incident Data

CPSC staff is aware of a total of 335 incidents involving 94 fatalities and 241 nonfatal incidents related to bassinets and cradles that were reported from November 2007 through December 2011. See Tab A[2] for more details regarding the data and its limitations.

1) Fatalities

A total of 94 bassinet-related fatalities have been reported from November 2007 through December 2011. Eighty-two of the 94 deaths (87 percent) were asphyxiations due to the presence of soft or extra bedding in the bassinet, prone placement of the infant, and/or the infant getting wedged between the side of the bassinet and an added mattress or pillow. There were four fatalities with little information to allow CPSC staff to determine the hazard scenario.

The remaining eight deaths are associated with a design aspect of the product. 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 convertible bassinets/bedside sleepers that was subsequently recalled for this defect. Three other deaths are associated with the non-flatness of the segmented mattress pads used in a bassinet accessory to a play yard. The rocking feature of a bassinet, which contributed to its non-level resting position, was associated with an additional suffocation death. The remaining fatality associated with the design of the product occurred when the bassinet tilted over and allowed the 3-month-old decedent to get pinned between the bassinet and a nearby dresser.

2) Nonfatal Incidents

A total of 241 bassinet-related nonfatal incidents were reported from November 2007 through December 2011. Of these, 52 incidents reported an injury to an infant using the bassinet or cradle at the time of the incident. Thirty of these injuries (58 percent) were identified as resulting from falls out of the bassinets. Because 28 of the 30 falls were reported through the emergency department-treated injury surveillance system, little or no circumstantial information is available on how the fall occurred. However, the reports indicate that 76 percent of the injured infants who fell out of bassinets were older than the ASTM-recommended maximum age limit of 5 months.

Overall, there were six bassinet-related injuries that were reported to have needed hospitalization. Four of them, all serious head injuries, resulted from a fall out of the bassinet. One injury, a leg fracture, resulted from a caregiver attempting to lift an infant out of the bassinet while, unknown to the caregiver, the infant's leg was caught in a structural opening. The remaining hospitalized injury was due to a moldy bassinet pad that caused respiratory illness in the infant.

Two additional serious injuries were reported, but neither of these infants was hospitalized. There was a report of a second-degree burn suffered by an infant from the bassinet's overheated

[2]Risana Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, April 10, 2012, "Bassinet- and Cradle-Related Deaths, Injuries, and Potential Injuries Reported Between November 2007–December 2011."

mobile, and a report of an arm fracture from an infant's arm getting caught in the bassinet. The remaining injuries were mostly limited to contusions and abrasions.

The remaining 189 incidents reported that no injury had occurred or they provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death.

D. Hazard Analysis

CPSC staff considered all 335 incidents to identify hazard patterns associated with bassinet and cradle incidents. The incidents were grouped into four broad categories:

- Product-related issues;
- Non-product-related issues;
- Recalled product-related issues; and
- Miscellaneous other issues.

1) Product-related issues: The hazard scenarios in 209 of the 335 incidents (62 percent) reported were attributed to some sort of failure/defect or a potential design flaw in the product itself. This category includes five fatalities and 46 injuries, five of which involved hospitalization. Listed below are the reported problems, beginning with the most frequently reported concerns:

- Lack of ***structural integrity***, which includes issues such as instability, loose hardware, collapse of the product, and loose wheels. This issue was reported in 64 (about 19 percent) of the incidents. One death is associated with this issue.
- Reports of infants ***falling or climbing out*** of bassinets/cradles. This category accounted for most of the bassinet-related injury reports that were received from emergency departments around the United States. While little product/scenario-specific information was available in these reports, a majority indicated that the victims were over the ASTM recommended upper age limit of 5 months. This issue was reported in 32 (about 10 percent) of the incidents.
- Problems with ***mattress flatness*** in bassinet accessories to play yards. Examples include mattresses that would not remain level horizontally because of: poorly designed metal rods/other structures that are meant to be positioned underneath the mattress; lack of rigid mattress support; and failure of straps/hooks/bars designed to hold the bassinet attachment inside the play yard. This issue was reported in 31 (about 9 percent) of the incidents and was associated with three deaths.
- Problems with ***rocking*** bassinets and cradles, with locking or tilting issues that caused the infant to roll/press up against the side/corner of the product and posed a suffocation hazard. This issue was reported in 23 (about 7 percent) of the incidents, including one death.
- Problems with ***packaging*** of the product that resulted in broken/damaged products during delivery. This issue was reported in 19 (about 6 percent) of the incidents.
- Problems with bassinet ***mobiles***, where components overheated, smoked, or sparked. This issue was reported in 13 (about 4 percent) of the incidents.
- ***Miscellaneous*** other product-related problems ranging from a tear in the bassinet fabric to odors to product assembly/quality issues. Twenty-seven (about 8 percent) of the incidents reported these issues.

2) Non-product-related issues: Eighty-three of the 335 reports (25 percent) were about incidents that involved no product defect or failure. This category consisted of 82 fatalities, most of which were associated with the use of soft/extra bedding or prone positioning. There was also one nonfatal injury incident that did not involve any product-related issues.

3) Recalled product-related issues: There were 26 reports (8 percent) that involved recalled products. Some of the reports were received by CPSC staff prior to the recalls being published. There were three fatalities and two injuries due to entrapment and/or hanging of an infant between structural components of the bassinet. Most of the remaining reports were complaints or inquiries from consumers regarding a recalled product.

4) Miscellaneous other issues: The remaining 17 (5 percent) incident reports were related to miscellaneous other or unspecified issues. Some of these reported concerns from consumers about perceived safety hazards; others described incidents with insufficient specificity for CPSC staff to identify the hazard scenario. There were four fatalities (unknown circumstances) and three injuries, including a hospitalized injury, reported in this category.

In summary, there were five product-related issues associated with incident deaths and/or significant injuries:

- structural integrity/instability,
- mattress flatness,
- rocking,
- falling or climbing out, and
- entrapment in fabric sided products.

In addition, there were multiple deaths associated with the use of soft/extra bedding or prone positioning of the child that were considered non-product related.

Staff looked at each of these issues when reviewing the adequacy of the current voluntary standard, ASTM F2194-12.

E. ASTM Voluntary Standard History

The voluntary standard for bassinets and cradles was first approved and published by ASTM in 2002, as ASTM F2194, *Standard Consumer Safety Specification for Bassinets and Cradles*. It has been revised a number of times since then, including versions in 2010 and 2011. The current version, ASTM F2194-12, was approved on June 1, 2012, and it contains requirements to address the following:

- Lead in Paints
- Hazardous Sharp Edges or Points
- Small Parts
- Wood Parts
- Scissoring, Shearing, Pinching
- Unintentional Folding

- Openings
- Labeling
- Fasteners
- Corner Posts
- Toy Accessories
- Restraints Requirement
- Bassinet/Cradle Accessories to Play Yard/Non-Full-Size Crib
- Spacing of Rigid Sided Bassinet/Cradle Components
- Static Load
- Stability
- Sleeping Pad Properties
- Protective Components
- Side Height Requirement
- Fabric Sided Enclosed Opening Requirements and Test Methods
- Rock/Swing Angle Requirements and Test Methods

Since publication of F2194-12, ASTM has issued two ballot items for consideration for future revisions to the standard. In July 2012, ASTM balloted a revised scope and associated definitions. That ballot item closed on August 8, 2012, with no negatives, and thus the new scope and definitions will be incorporated into the next revision of the standard. On August 14, 2012, ASTM balloted a segmented mattress flatness test requirement and procedure. The results of that ballot will not be known until mid-September.

F. International Standards Review

Tab B,[3] outlines various international standards from Canada, Europe, and Australia related to bassinets and/or cradles. Many of the requirements found in the 2012 ASTM standard can also be found in some of these international standards.

The European Standard, EN 1130-1, "Furniture – Cribs and Cradles for Domestic Use," has several requirements not found in ASTM F2194-12. Most of these additional requirements address hazards associated with cribs intended for use with older children (in excess of the 5 month recommended maximum age for bassinets), and thus, they are not applicable to bassinets.

The scope of the European Standard, EN 12790-2009, "Child use and care articles - Reclined cradles," includes car seat carriers, hammocks, and bouncers. Most of the requirements are not applicable to bassinets.

The Australian/New Zealand standard (AS/NZS 4385:1996) contains requirements for rock and swinging angles that were used to develop some of the ASTM F2194-12 requirements. The applicable ASTM performance requirement is more stringent because the CAMI placement results in higher swing angles.

[3] Mark Kumagai, Division of Mechanical Engineering, July 30, 2012, "ESME Recommendations for the Proposed Bassinet and Cradles Standard."

The Canadian Crib and Cradle regulation (SOR 86-962) also includes requirements for full-size cribs and non-full-size cribs. This standard does not distinguish between a bassinet and non-full-size cribs. As a result, many of the requirements are not applicable for this NPR. The Canadian standard was used to develop the ASTM requirement for bassinet side height.

Staff believes that the current ASTM standard, F2194-12, is the most comprehensive of the standards to address the incident hazards. There are some individual requirements in various other standards that are more stringent than ASTM; however, many of these requirements do not address the identified hazards in the CPSC incident data. Appendix 1 in Tab B summarizes and compares these requirements.

III. DISCUSSION

A. Adequacy of ASTM F2194-12 Requirements

CPSC staff believes that ASTM F2194-12 addresses many of the general hazards also associated with other durable nursery products, such as: lead in paints, sharp edges/sharp points, small parts, wood part splinters, scissoring/shearing/pinching, openings/entrapments, warning labels, and toys. Specific requirements for stability, unintentional folding of the product, static load, and a prohibition on occupant restraints are also included.

The most recent revision (ASTM F2194-12) also includes the following new or revised sections:

- **Marking and Labeling** – This revised section now requires that the "**SUFFOCATION HAZARD**" warning be in bold and at least 0.4 inches high. This requirement should help make the label more visible to address the suffocation hazard associated with soft bedding.
- **Side Height –** This new performance requirement states that a bassinet side be at least 7.5 inches above the mattress surface and is intended to help address fall hazards.
- **Fabric-Sided Enclosed Opening Requirements and Test Methods** – This new section requires that a fabric-sided bassinet not create an entrapment hazard if the fabric is <u>not</u> properly attached to the frame. This requirement is intended to address the fatal incidents associated with openings in fabric sided bassinets and is associated with a 2008 recall.
- **Rock/Swing Angle Requirements and Test Methods** – This new section requires that a rocking cradle come to rest at an angle of 7 degrees or less. This requirement is intended to address incidents where rocking bassinets remained tilted and caused the infant to roll/press up against the side/corner of the product, posing a suffocation hazard.

CPSC staff believes that ASTM F2194-12 will adequately address incidents associated with rocking and entrapments in the openings of fabric sided products. Staff also believes that the recent revisions to the standard will help address incidents associated with falls/climb-outs and suffocation due to the addition of soft bedding.

Staff believes that ASTM F2194-12 does <u>not</u> adequately address hazards associated with segmented mattress flatness issues, false latching of removable bassinet beds and/or stability.

B. Staff's Recommendations for the Proposed Safety Standard

1) Segmented Mattress Flatness Requirement and Test Method

CPSC staff recommends that the Commission propose to adopt ASTM F2194-12 as the mandatory safety standard for bassinets and cradles with a modification to add performance requirements and associated test methods for maximum mattress flatness angle on segmented mattresses. This would address suffocation/positional asphyxia incidents associated with excess mattress pad angle.

Figures 5 and 6 show play yard bassinets with a severe V-angle created by the segmented mattress panels.

Figure 5. Incident bassinet play yard – photo from in-depth investigation (arrow pointing to V-angle in the mattress pad)

Figure 6. Incident bassinet play yard – photo from in-depth investigation (arrow pointing to V-angle in the mattress pad)

It should be noted that any play yard that contains a bassinet accessory, as seen in the two figures above, falls within the scope of two different standards, the play yard standard and the bassinet standard. Both standards have requirements for these accessories, and thus, in order to be in compliance, products must meet the applicable requirements in both standards.

Seams between the segments of play yard bassinet accessory mattress pads have been known to create a valley, or incline, between adjoining segments of the mattress sleeping surface. Safe sleep messages tell caregivers that infants should be placed to sleep on their backs on a firm sleep surface. This is because in the prone position young infants are not able to remove themselves from positions that compromise their breathing and puts them at the risk for suffocation. However, an inclined sleeping surface (on a product not intended to provide a contour or other means to contain the child) can help an infant to roll, increasing the likelihood that they will be found face down and become trapped in a significant V-shaped crease which can obstruct the nose and mouth on both sides of the V. Furthermore, caregivers who are unaware of common safe sleep tenets may still opt to place their infants in the prone position. When lying prone in a valley (or V-shaped crease), infants may have more difficulty keeping their airways unobstructed than when on a flat surface because their faces are trapped in the

juncture between adjacent surfaces. Their heads cannot rotate to the side as much as when the sleeping surface is flat. Immature head control and weak neck muscles may not allow them to free their airways.

Such bassinets are commonly sold as accessories to play yards and use the floor of the play yard (a segmented mattress pad) as the floor of the bassinet. The play yard voluntary standard requires these accessories to meet the bassinet voluntary standard once assembled according to the manufacturer's instructions.

Fatal incidents involving play yard attachment bassinets (090213HCC1421, 090706CWE8347, 100421HCC1630, 110825CAA2853[4]) have influenced staff's understanding of such hazards. Infant sleeping surfaces need to be as level as possible because a non-level surface creates a higher risk of suffocation than a level surface.

In the in-depth investigation 090213HCC1421, the product was apparently assembled without two key structural support bars beneath the mattress pad of a bassinet accessory that was intended by the manufacturer to be mounted from the top rails of the play yard.

Staff notes that a requirement to ensure that key structural supports are properly installed by consumers would have helped prevent this incident from occurring. The Bassinet Misassembly Provision NPR, published on August 29, 2012, is a Commission-directed NPR to amend the play yard mandatory standard to include a provision to address the hazards associated with play yard bassinet accessories that can be misassembled.

However, even with the misassembly provision, there is no requirement for segmented sleeping surfaces to be flat or even nearly flat, which is the critical feature of this product that constitutes a hazard. A play yard bassinet accessory could be designed to meet the misassembly provision, but still have a non-flat mattress. Staff believes that both requirements are necessary to address these hazards: (1) a missing component requirement to prevent installation/use of a bassinet accessory that has a key component missing; and (2) a flatness requirement to ensure segmented mattresses, like those found in bassinet accessories, are flat when assembled according to manufacturer's instructions.

For the bassinet supplemental NPR, staff recommends requiring segmented mattresses to remain flat and not create a hazardous angle greater than 10 degrees when tested using a 17 lb cylinder to simulate the weight of a 6-month-old infant, which is the heaviest intended user and for this particular requirement, represents the worst case scenario. The 10-degree limit was developed based on anthropometrics of the smallest users of bassinets/cradles (5th percentile, 0–5 months old).

By using the weight of the oldest intended user and the anthropometrics of the youngest intended user, this requirement should be protective of all bassinet users. Details pertaining to the test

[4] Note: This IDI is not included in the Epidemiology memo (Chowdhury, 2012, Tab A) because it was included in the data used for the Final Rule briefing package for play yards. It has been included here for discussion purposes because the manner of death is related to a non-level segmented mattress.

procedure can be found in Tab B of this briefing package. Further explanation into the rationale for the failure threshold can be found in Tab C[5] of this briefing package.

An ASTM task group has been working on this performance requirement since before it was first proposed in the 2010 NPR and an early version was balloted in late 2010, but was not approved. Several modifications have been made to both the test procedure and the pass/fail criteria since then, and it was recently reballoted on August 14, 2012. The results of this latest ballot will not be known until after September 13, 2012.

The actual test procedure included in the ASTM ballot is identical to staff's recommendation. However, the test requirement (the pass/fail criteria) is different. In the test procedure, a measurement is taken on each side of each seam of the mattress (for a total of 6 or 8 measurements per bassinet). As mentioned above, staff is recommending a test requirement of 10 degrees maximum for each measurement taken. The requirement recently balloted by ASTM is a pass for 10 degrees or less for all measurements, and a fail for one or more measurements that is greater than 14 degrees. For angle measurements between 10 and 14 degrees, the test lab would take two additional measurements at that location and average them, and then use 10 degrees as the final pass/fail delineator.

CPSC staff has a rationale, based on the anthropometrics of the youngest intended users, for the 10 degree limit. The ASTM ballot does not contain a rationale for using the two-step pass/fail criteria for initial measurements above 10 degrees and below 14 degrees.

The exact language of staff's recommendation pertaining to segmented mattress flatness can be found in the appendix to this briefing memo.

2) Scope and Definitions

Staff is also recommending that the scope of the standard and some corresponding terminology in ASTM F2194-12 be revised to better define which products are considered bassinets (as opposed to other products, like swings, inclined sleepers, hammocks and stroller carriages).

The development of the bassinet standard affects other ASTM juvenile product standards, such as the draft inclined sleeper standard, the bedside sleeper standard, and the play yard standard, all of which either refer to the bassinet standard or have requirements meant to mirror those in the bassinet standard. Staff's recommendation is to not include inclined sleepers or hammocks in the scope of the bassinet standard, because they will be captured in the scope of the inclined sleeper standard, which is currently under development to specifically address hazards associated with those products. And also, as mentioned earlier, including inclined sleep products in the bassinet scope would effectively ban them.

The current draft ASTM inclined sleeper standard defines an "inclined sleeper" as having more than a 10 degree sleep surface incline. This 10-degree-minimum complements the definition(s) of a "bassinet/cradle" currently recommended by staff and also under consideration for ballot by

[5] Jonathan Midgett, Ph.D., Office of Hazard Identification and Reduction, June 4, 2012, "Bassinets and Cradles Standard: Human Factors Issues."

ASTM. Writing the scope of each standard and their corresponding definitions in this manner helps ensure that all infant sleep products will be covered under at least one of the standards.

In addition, CPSC staff recommends changing the scope and definition of a bassinet from products meant exclusively for sleeping, to those intended primarily for sleeping. This would ensure that a bassinet sold with a toy mobile—meant to entertain an infant who is lying in the bassinet—would still fall within the scope of this standard.

The changes in the scope, as recommended by staff, have already been balloted by ASTM and are expected to be included in the next revision of F2194.

The revised scope and the definitions can be found in the appendix to this briefing memo.

3) Removable Bassinet Bed Stability

Staff is aware of several incidents, including one death, involving bassinets that have beds designed to be portable, so that they can be removed from their stands without the use of tools. During the incidents, the bed portion of the product was not completely locked or attached to its stand, but it appeared to be stable, giving the caregivers a false sense of security. For various reasons, the bed portion fell, or tilted off of its stand in the incidents. In one case (IDI 110512HCC2531), a 3-month-old infant was killed when the bassinet bed fell over and allowed the 3-month-old decedent to get pinned between the bassinet and a nearby dresser. CPSC staff was also recently informed by Health Canada of a second death that occurred in Canada. In the e-mail correspondence from Health Canada staff, the following was reported:

> *It strongly appears the bassinet was not attached to the base when the infant was put down for a nap. When the infant was found, the bassinet was perpendicular to the base and had fallen into the base opening at an angle suspending the infant. The straps and hooks attaching the bassinet to the base were not snapped in.*

Staff first raised this issue and the related hazard to the ASTM bassinet subcommittee chairman in late May 2012, shortly after a related bassinet recall was announced by the CPSC. During staff's review of the incident data for the development of this briefing package, we were able to associate the death that occurred in 2011 with the recall that occurred in May 2012, and we identified this new hazard as a pattern that included more than one specific bassinet. Staff immediately performed testing on a variety of bassinets with removable beds to understand the hazard better and gain an understanding of how it occurs. On June 6, 2012, during an ASTM bassinet subcommittee meeting, the issue was discussed and a task group was formed to develop a requirement to address the hazard. The task group was very active, and within the next month, two meetings were held, and a draft of the new requirement and test method were developed. The task group continued to discuss and edit the draft via e-mail. To date, the language drafted by the task group has not been balloted, but it is expected to be discussed at the next subcommittee meeting in October 2012, and balloted shortly thereafter.

Staff recommends adding the new requirement to the supplemental NPR, based on the work done, to date, by staff and the ASTM task group. The recommended requirement allows multiple options to pass. These options will either ensure that the bed portion of the bassinet is

inherently stable when it is placed on the stand unlatched, or it will give obvious feedback that the unit is not properly latched. One option allows the unit to give an extreme appearance of instability by being tilted 20 degrees or more. The 20 degree minimum is twice the allowable deviation from horizontal that staff recommends for sleeping surface flatness and was extrapolated from an in-depth investigation report in which a caregiver noticed that a bassinet was tilted. The ASTM task group deemed that a bassinet bed tilted 20 degrees or more from the horizontal was severe enough that consumers would notice that it was not attached properly.

In addition to the options listed above, a bassinet that has a removable bed can also pass the recommended requirement if it has a visual indicator to alert a caregiver when the bassinet bed is not locked properly onto the stand. For instance, when the bassinet is not properly locked, a red indicator would be visible on each side of the bassinet. Lastly, the bassinet can also comply if it can meet the standard's stability requirement when the bassinet bed is resting on, but not locked, on the stand/base.

The reason that such designs need inherent stability (or obvious instability) is because consumers will sometimes avoid activating lock or latch mechanisms if the bassinet bed appears stable when placed on its stand/base. Consumers may do this because the locks or latches seem redundant to them or because they are worried about making noise when activating locks or latches around a sleeping infant. Locks and latches may also give accidental feedback that they are locked when they are not, as was seen in some of the recall incidents. Because of these foreseeable use patterns, this requirement will make bassinets with a removable bed portion inherently stable or have visible indicators to show when it is not attached properly.

4) Stability Test Dummy

During evaluations of the test methods for removable bassinet beds, staff made comparisons of the stability of products weighted with either the newborn CAMI dummy (7.45 lbs) or the infant CAMI dummy (17.4 lbs). ASTM F2194-12 contains a stability requirement that uses the heavier infant CAMI dummy. For this particular performance requirement, a smaller, lighter occupant would be considered the worst case scenario. Thus, the question of why the infant (heavier) dummy was specified was posed to the ASTM task group, and no one could recall the original rationale, nor is there any rationale included in the ASTM standard. Because bassinets are intended for use with newborns, staff believes that bassinet stability should be tested with the newborn CAMI dummy. The newborn CAMI is readily available to test labs and represents the 50^{th} percentile newborn, which is about 10 pounds lighter than the infant CAMI dummy. Based on the intended user of a bassinet, and taking a safer and stricter approach, staff is recommending that the newborn CAMI dummy—instead of the infant dummy—be used for the stability testing requirement.

C. 2010 NPR Public Comments

Public comments to the 2010 NPR were received from 16 separate entities and processed under CPSC Docket 2010-0028. One commenter (JPMA) submitted two separate comments, one supplementing the other. Below is a table listing the commenters and their affiliation.

Name of Commenter	Affiliation
Nancy A. Cowles, Rachel Weintraub, Donald L. Mays	Consumer Union-KID-CFD
Judith S. Palfrey	American Academy of Pediatrics
Sharon Forshpan	Arms Reach
Wang Nini	China WTO/TBT National Notification & Enquiry Center
Dorothy Drago	Drago Expert Services
Kitty Pilarz	Fisher Price/Mattel
Tyler Goodier, Megan Fairfull, James Surowiak	Health Canada
Robert Waller	JPMA
Bob Coughlin	Kids II
Russ Butson	Kolcraft
Barry Cik	Naturepedic
Joseph Hei	Orbit Baby
John Menichelli	No Affiliation Given
Chelsey Hanson	No Affiliation Given
Ronald Morgan	No Affiliation Given
Jim Dodds	No Affiliation Given
Linwood Lee Rayford, III and Kate Aishton	Small Business Association

The comments received encompassed a variety of issues, mostly technical ones relating to the proposed modifications to ASTM F2194-07a$^{\varepsilon 1}$. Many of the comments are no longer valid, based on the work done by ASTM and changes to F2194 since then. An overview of the issues raised in the comments that pertained to the modifications outlined in the 2010 NPR and/or related to the staff-recommended proposed standard, and staff's responses are presented below. For a more detailed discussion of all the comments and staff's responses, see Tabs B and C.

Restraints

The 2010 NPR proposed to prohibit bassinets with restraints that require action on the part of the caregiver to secure the restraint. A commenter requested that bassinets be allowed to have restraints and provided several reasons why they should be allowed.

The primary reason that staff believes restraints should not be allowed in bassinets is that most bassinet uses do not require a restraint, so consumers have a strong motivation to avoid using restraints, if they are provided. When unused, restraints have been known to entrap and strangle children in similar products, like swings, handheld infant carriers, and bouncers. While none of the bassinet incidents outlined in Tab A were associated with restraint harness strangulation, this is probably due to the fact that restraints are rare on bassinets and not because they would not present a hazard if they were present.

The 2012 version of F2194 contains a requirement that prohibits all restraints in bassinets. Staff supports this change to the standard, and notes that it is more protective than the restraints

requirement proposed in the 2010 NPR. Therefore, staff does not believe any other changes with respect to restraints are warranted at this time.

The Prominence of Warnings about Soft Bedding

JPMA recommended some word changes and a font size of 0.2 inches or higher for the suffocation warnings.

The current ASTM standard for bassinets, F2194-12, includes an enhancement of the soft bedding warnings by: (1) increasing the font size for the Suffocation Warning label to 0.4 inches or higher; and (2) adding emphasis by stating that "Infants have suffocated . . .," rather than stating "Infants can suffocate . . .." Staff supports the strengthening of the suffocation warning label as included in the latest revision of the ASTM voluntary standard and does not believe any other changes to the standard are warranted to address this comment. Staff believes that information and education efforts by Commission staff, such as the Safe Sleep campaign, should be continued to address suffocation and other serious sleep hazards.

Baby Size Limits

Although not specifically addressed by the proposed standard, a commenter notes that because "bassinets provide an important tool for parents to monitor premature babies," a target age range for infant occupants may be necessary to enhance the understanding of the developmental milestones used in the warnings. They also suggested that if there is "a size at which a bassinet becomes unsafe for a baby," then that factor should be listed in the product's instructions and warnings. The 2012 version of the ASTM standard includes a reference to the maximum recommended weight, as set by the manufacturer, in the FALL HAZARD warning label. Staff supports this addition to the standard and does not feel anything else is warranted at this time to address this comment.

Scope

Several comments were received regarding the inclusion of infant hammocks and other inclined sleeping products in the scope of the 2010 NPR. The comments were universally against including them on the grounds that this would effectively ban a product that has some utility. The comments also opined that such a ban could increase hazards if parents use a substitute product. JPMA also recommended revising the scope to clarify that the standard covers products only intended for infants who have just started to push-up on their hands and knees, or for younger infants, and it includes products that are intended exclusively for sleeping.

CPSC staff agrees that the scope should clarify what products should and should not be included and is recommending a modified scope to F2194-12. CPSC staff also agrees that the scope of the standard should be limited to bassinets that are intended to provide a flat or nearly flat sleeping surface. Thus, most infant hammocks and all inclined sleepers would not be included in the scope of the staff-recommended proposed standard. ASTM is in the process of developing a new standard for inclined sleep products that should be published in the next year. CPSC staff is working with ASTM on this standard and shortly after publication of the ASTM standard, we intend to recommend an inclined sleeper products proposed rule for the Commission's consideration, under the authority of the CPSIA.

CPSC staff disagrees with the comment to limit the scope to products meant *exclusively* for sleeping. Instead, staff believes that the scope should cover products intended *primarily* for sleeping. This would ensure that a bassinet sold with a toy mobile, meant to entertain an infant who is lying in the bassinet, would still fall within the scope of this standard. A revised scope and associated definitions recommended by staff to address these comments are included in the appendix to this memo.

Bassinet Segmented Mattress Flatness Test

Several commenters provide recommendations or remarks on the mattress flatness requirement.

Since publication of the 2010 NPR, much work has been done on this performance requirement. Working together in an ASTM task group, CPSC staff, along with representatives from industry, testing laboratories, consumer advocate groups, and independent consultants have developed an improved test methodology/procedure to assess the flatness level of segmented mattresses.

As previously discussed, the staff recommended pass/fail criteria for mattress flatness is slightly more conservative than what ASTM recently balloted. Staff recommends a maximum of 10 degrees based on a single measurement, and ASTM balloted a two-step pass/fail criterion for any angle measurement between 10 and 14 degrees.

Maximum Rock/Swing and Rest Angles

Several commenters recommend a maximum rock/swing angle of 20 degrees and a maximum rest angle of 7 degrees for rocking cradles.

Since that comment was written, ASTM has included a rock/swing angle requirement that contains maximums of 20 degrees for the swing angle and 7 degrees for the rest angle in the 2012 version of the voluntary standard.

CPSC staff agrees with the comments regarding the rock/swing angle of 20 degrees. Staff also agrees with a 7 degree rest angle as published in ASTM F2194-12 rather than the 5 degree angle proposed in the 2010 NPR. The 5 degree angle was based on the Australian standard for rocking cradles. In the Australian standard, the angle is measured with the CAMI infant dummy placed in the center of the cradle. The intent is to ensure that the rocking cradle returns to a level position and provides a flat sleeping surface for the infant. In ASTM F2194-12, the angle is measured with the CAMI dummy placed to one side of the cradle. CPSC staff believes that the placement of the CAMI to one side results in a more stringent requirement than the Australian standard. For this reason a 7 degree rest angle is a reasonable and achievable requirement for bassinets that will address suffocation hazards associated with an angled sleep surface. Therefore, staff is not making any recommendations with respect to this issue.

Fabric-Sided Enclosed Openings Test

JPMA recommended testing openings on fabric-sided products using a torso probe and a head probe, rather than just the torso probe, as presented in the 2010 NPR. JPMA opined that if an opening allowed the passage of both probes, then the opening would also allow the infant to pass through completely and not result in an entrapment.

CPSC staff does not believe an opening in a bassinet that is large enough to pass the head probe is acceptable due to the potential for the infant to fall through the opening onto the floor. CPSC staff recognizes that it will be necessary to redesign some bassinets by closing up existing openings in the frames or making the fabric non-removable in order to meet this requirement. CPSC staff believes this is necessary to prevent entrapment incidents without creating a fall hazard.

Since that comment was written, ASTM has revised the bassinet standard to include a fabric-sided enclosed openings test that does **not** use the head probe, as recommended by JPMA. The test, as added to the 2012 version of the standard, is very close to what was included in the 2010 NPR. Thus, staff is not recommending any further changes relating to this hazard for this re-proposal.

Static Load and Stability

JPMA recommended adding a requirement to test play yard bassinet accessories at all four corners to ensure structural integrity of the product. JPMA also recommended adding a requirement to test bassinets for stability while the locks are engaged to prevent rocking/swinging.

CPSC staff agrees. The 2012 version of the ASTM standard included these static load and stability requirements. Thus, staff does not need to recommend them for this re-proposal.

Definition of a Double Action Release Mechanism

JPMA recommended adding a definition for a *double action release mechanism.*

CPSC staff agrees. The 2012 version of the standard includes this new definition. Thus, staff is not recommending anything for this re-proposal.

Spacing of Rigid Components

Commenters point out that the 2010 NPR contained a modification to the requirement for spacing of rigid components that was confusing because it relied on two different test methods.

CPSC staff agrees. Since that comment was written, ASTM revised this section in their 2012 standard to address the comments adequately. Staff does not recommend any additional modifications to address this issue for this re-proposal.

D. Comparison Between the 2010 NPR and Staff's Current Recommendation

In the 2010 NPR, the Commission approved a proposed rule that referenced the requirements specified in ASTM F2194-07a$^{\varepsilon 1}$ as a mandatory standard for bassinets and cradles, with several modifications and edits that could further reduce injuries and deaths. The modifications and edits included the following (and are discussed in more detail below):

a) updated warnings;
b) stability;
c) performance requirements for fabric-sided products to address entrapment incidents;

d) performance requirements to limit the rocking/swinging angle to 20 degrees and the rest angle of certain rocking/swinging cradles to 5 degrees;
e) requirement to eliminate active restraints;
f) scope and terminology; and
g) performance requirements for a mattress flatness angle of 5 degrees to address suffocation incidents on segmented mattresses.

The hazards outlined in Tab A of this briefing package and Section II (D) of this memo are similar to what was addressed in the 2010 NPR. Of the modifications above that are proposed in the 2010 NPR, all but the final two are, in some capacity, part of the recently revised voluntary standard ASTM F2194-12. These are outlined below:

a) Warnings: The 2010 NPR proposed a stronger warning label to address suffocation hazards. The 2012 ASTM standard requires that the warning: "SUFFOCATION HAZARD," be in bold and at least 0.4 inches high, which is twice the size proposed in the 2010 NPR.

b) Stability: The 2010 NPR clarified that the stability requirement applies to all manufacturer-recommended use positions, including the position where the locks are engaged to prevent rocking/swinging motion. ASTM incorporated this change in ASTM F2194-11; therefore, it was included in the latest version, ASTM F294-12.

c) Entrapment: The performance requirements for fabric-sided products included in F2194-12 to address entrapment incidents are the same as in the 2010 NPR, except for editorial changes made to clarify the requirement and test procedure.

d) Swing/Rest Angles: The performance requirements for a 20 degree maximum rock/swing deflection angle and a 7 degree rest angle found in F2194-12 are similar to what was in the 2010 NPR. The ASTM requirement allows up to 7 degrees but uses a more stringent test method for measuring the angle. Thus, staff believes it is comparable. The ASTM standard also has a simplified method of measuring the angle, which includes not requiring the test to be run using two different CAMI dummies, and running the test three times, rather than five.

e) Restraints: In the 2010 NPR, staff recommended a requirement to eliminate the use of restraint straps in bassinets that required action on the part of the caregiver. A stricter version of this requirement, which eliminates all restraints, was included as part of the 2012 version of the ASTM standard.

Staff is recommending that the last two modifications included in the 2010 NPR be revised based on staff's review of public comments in response to the 2010 NPR; further testing and analysis; and discussions with the ASTM task group on bassinets. Staff's recommended modifications to F2194-12 and how they compare to those modifications in the 2010 NPR are as follows:

f) Scope and Terminology: The scope of the 2010 NPR included infant hammocks. Staff has reevaluated that inclusion based on comments received in response to the

2010 NPR, and we no longer recommend including them. (See Tab C for more discussion on this matter.) The new recommendation, as presented in the appendix to this memo, specifically does not include inclined and infant hammock-style bassinets, but includes all flat (horizontal) and semi-inclined products (10 degrees or less incline from horizontal) and cradle swings. Staff's recommendation is virtually identical to what ASTM balloted in July 2012.

g) Mattress Flatness: In the 2010 NPR, a mattress flatness performance test for all types of bassinets and cradles was included. The current staff-recommended mattress flatness performance requirement only applies to segmented mattresses. CPSC staff's review of the data showed that only segmented mattresses used in play yards were involved in incidents. In addition, CPSC staff determined that an angle of 10 degrees or less would be as protective as the 5 degree angle set forth in the 2010 NPR; while allowing for testing variances and also addressing design and manufacturability concerns with segmented mattress pads. Staff's new recommendation has additional requirements for two occupant bassinets. The test method now uses a rigid cylinder to simulate the infant, rather than a soft/deformable CAMI dummy. This change provides more consistent test results. Tab C provides more discussion on the 10 degree test requirement.

In addition, staff is recommending two more modifications (and associated definitions) that were not part of the 2010 NPR. They are:

h) Removable Bassinet Bed Stability: This recommended requirement is for bassinets that have beds that can be removed without the use of tools. It would allow multiple options to pass. These options would either ensure that the bed portion of the unit is inherently stable when it is placed on the stand unlatched; or it would give obvious feedback that the unit is not latched properly. One option would allow the unit to give an extreme appearance of instability by being tilted 20 degrees or more. The 20 degree minimum is twice the allowable deviation from horizontal that staff recommends for sleeping surface flatness. In addition to the options listed above, a bassinet that has a removable bed could also pass the requirement if it has a visual indicator to alert a caregiver when the bassinet bed is not locked onto the stand properly. The bassinet could also pass the requirement if it can pass the standard's stability test while in an unlocked position.

i) Stability Test Procedure: Because bassinets are intended for use with newborns, staff believes that bassinet stability should be tested with the newborn CAMI dummy, rather than the infant CAMI dummy, which is in the current test method.

E. Compliance Recalls

As outlined in Tab D[6] of this briefing package, from October 2007 to June 2012, there have been a total of five consumer-level recalls involving bassinets. Two of the recalls are related to staff recommendations for this NPR (mattress flatness and removable bassinet bed false latching/stability). Two of the remaining recalls are associated with performance requirements that are new to F2194-12 (rock/swing rest angle and fabric opening test).

F. Initial Regulatory Flexibility Analysis

Bassinets and cradles are typically produced and/or marketed by juvenile product manufacturers and distributors, or by furniture manufacturers and distributors, some of which have separate divisions for juvenile products. CPSC staff estimates that there are currently at least 55 suppliers of bassinets and/or cradles to the U.S. market; 24 are domestic manufacturers, and 11 are domestic importers. An additional 14 domestic firms have unknown bassinet/cradle supply sources; three of those firms are retailers, and nine specialize in bedding, some of which is sold with bassinets or cradles. There are also six foreign firms supplying the U.S. market: five manufacturers and one importer that imports from foreign companies and distributes from outside of the United States. Based on U.S. Small Business Administration guidelines, 38 are small firms—19 domestic manufacturers, 8 domestic importers, 11 firms with unknown supply sources—likely to be affected by the staff-recommended proposed standard, as described in the Directorate for Economic Analysis memo (Tab E).

In most cases, the 10 small manufacturers and the four small importers whose products are likely to meet the requirements of ASTM F2194-12 should be able to modify their existing bassinet/cradle designs to meet the staff-recommended proposed rule. However, it is possible that the direct impact could be significant for one or more firms if they must redesign their bassinets. The direct impact on the nine small manufacturers whose bassinets and/or cradles are not compliant with the voluntary standard is likely to be more significant, as their products are more likely to require a substantial product redesign.

Importers of noncompliant bassinet/cradles may need to discontinue their import if their existing supplier does not come into compliance, possibly replacing the noncompliant bassinet/cradle with a compliant bassinet/cradle or another juvenile product. Firms specializing in bedding sold with bassinets and cradles might also need to find an alternative supply source if their existing supplier does not come into compliance.

In addition to the direct costs of the staff-recommended proposed bassinets/cradles standard, there are indirect costs that do not arise directly as a consequence of the rule's requirements. Rather, once the rule becomes final and the notice of requirements is in effect, bassinets and cradles will become subject to additional costs associated with the third party testing and certification requirements. These indirect costs could be significant for some small firms if more than one sample per model is required.

[6] Edward Williams, Jr., Office of Compliance, August 17, 2012, "Durable Nursery Products: Summary of Bassinets Recalls and Associated Injuries from October 2007 to June 2012."

III. STAFF RECOMMENDATIONS

CPSC staff recommends that the Commission publish a supplemental NPR that incorporates by reference the voluntary standard ASTM F2194-12, *Standard Consumer Safety Specification for Bassinets and Cradles,* with one revised test method, two additional new requirements and associated test methods, and a revised scope and associated definitions or references to support these additions, as written in the appendix to this memo. Staff also recommends that the Commission propose an effective date of 180 days following publication of the final rule but request comments on the impact of such an effective date.

Appendix
CPSC Staff-Recommended Revisions to ASTM F2194-12 Standard

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

A) Revised Scope and Associated Definitions

1.0 Scope

1.3 This consumer safety performance specification covers products primarily intended to provide sleeping accommodations ~~only~~ for an infant up to approximately 5 months in age, or when the child begins to push up on hands and knees, whichever comes first. Products used in conjunction with an inclined infant swing or stroller, or products that are intended to provide an inclined sleep surface (head-to-toe direction) of greater than 10° from horizontal, while in the rest (non-rocking) position, are not covered by this specification.

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 free standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which 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 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.

B) 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.

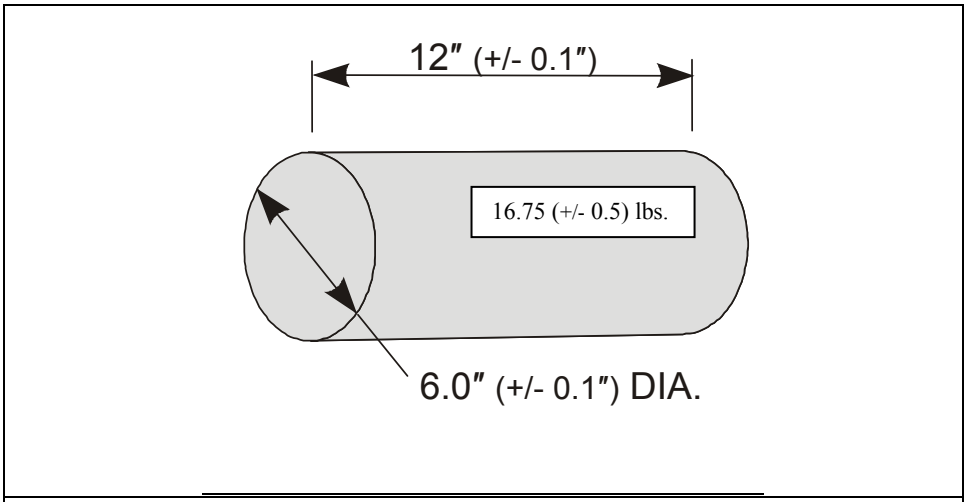


FIG. 13. Infant Test Cylinder

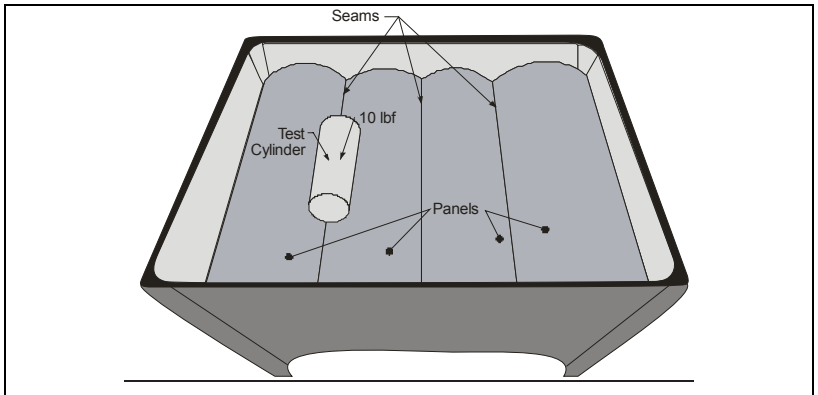


FIG. 14. Cylinder placement on mattress seam

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. 17. 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.

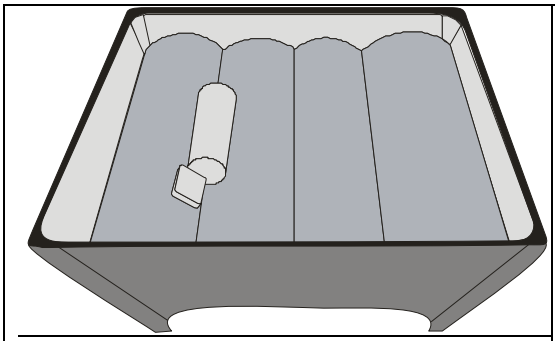


FIG. 15. Steel block in front of the cylinder for a single occupant bassinet

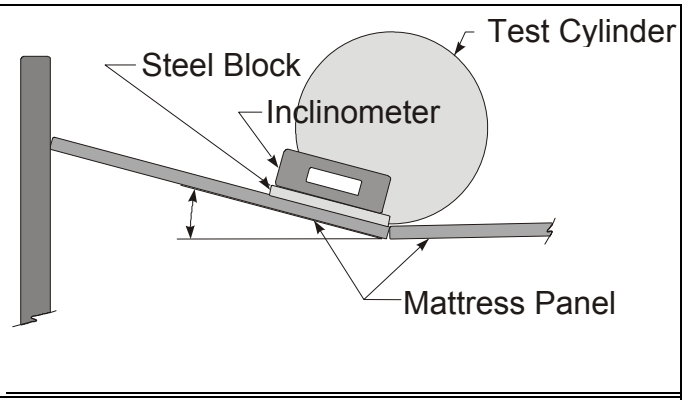


FIG.16. Inclinometer on steel block in front of the cylinder for a single occupant bassinet

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.

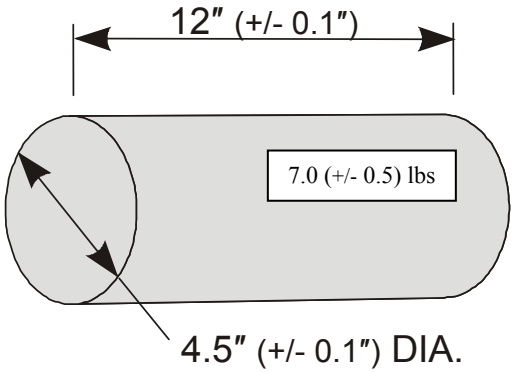


FIG. 17. Newborn Test Cylinder

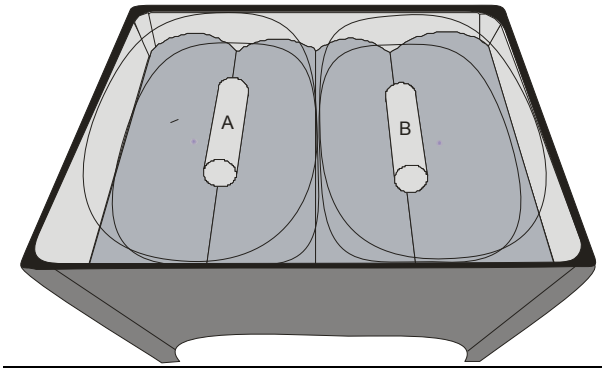


FIG. 18. Placement of cylinders for a 2 occupant bassinet

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.

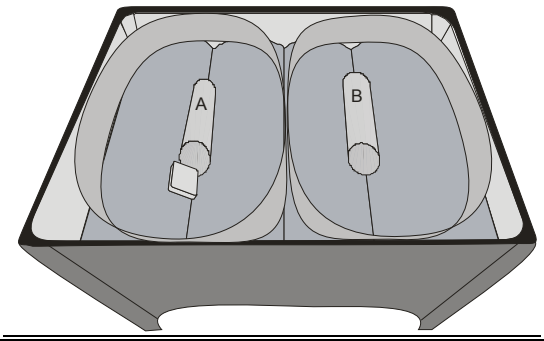


FIG. 19. Steel block in front of the cylinder for a 2-occupant bassinet

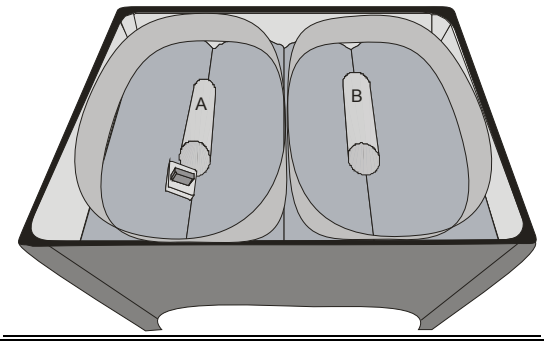


FIG. 20. Inclinometer on Steel block in front of the cylinder for a 2-occupant bassinet

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. 22.
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.

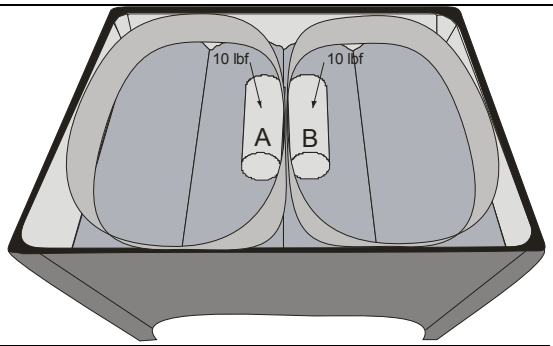


FIG. 21. Two cylinders (A and B) in contact with the inside wall

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.

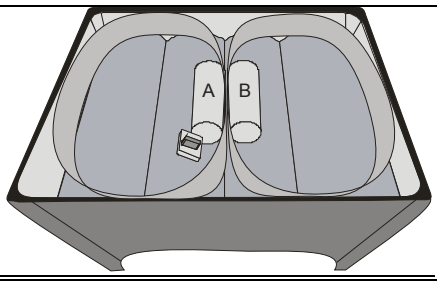


FIG.22 Angle measure in front of Cylinder A

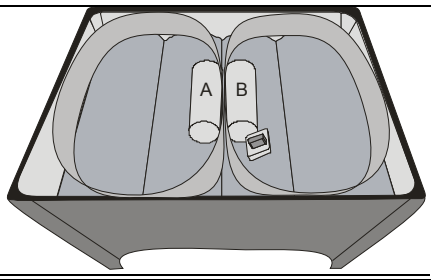


FIG. 23. Angle measure in front of Cylinder B

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.

C) Revised Test Procedure for Bassinet Stability

1) Add reference for the CAMI Newborn dummy.

2.3 CAMI Newborn Dummy (See Fig 1a)[7]

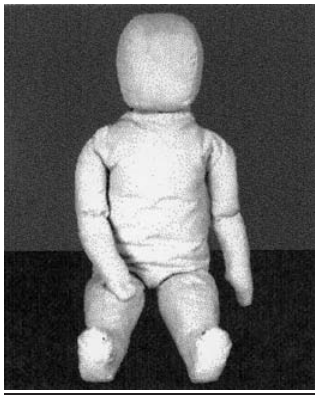


FIG. 1a CAMI Newborn Dummy

[7] Drawing numbers 126-0000 through 126-0015 (sheets 1 through 3), 126-0017 through 126-0027, a parts list entitled "Parts List for CAMI Newborn Dummy", and a construction manual entitled "Construction of the Newborn Infant Dummy" (July 1992). Copies of the materials may be inspected at NHTSA's Docket Section, 400 Seventh Street, S.W., Room 5109, Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

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

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 50th percentile 6-month-old infant.

D) 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 visually alert caregivers when a removable bassinet bed is not properly locked 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

6.10 *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 6.10.1, 6.10.2, 6.10.3, 6.10.4 or 6.10.5 when tested in accordance with 7.11.

6.10.1 The base/stand shall not support the bassinet bed (*i.e.,* the bassinet bed collapses from the stand and contacts the floor).
6.10.2 The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action).
6.10.3 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.

6.10.4 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.
6.10.5 The bassinet bed shall not tip over and shall retain the CAMI newborn dummy.

7.11 *Removable Bassinet Bed Attachment Tests*

7.11.1 Assemble the bassinet/cradle base/stand only, in accordance with manufacturer's instructions.
7.11.2 Place the base/stand in one of the manufacturer's recommended use positions.
7.11.3 Place the base/stand and the inclinometer on a flat level horizontal surface (0 +/- 0.5°) to establish a test plane. Zero the inclinometer.
7.11.4 Remove the mattress pad from the bassinet bed.

NOTE —For mattresses that are integral with the mattress support, do not remove the mattress and perform all angle measurements for 7.11 on a 6 by 6 by 3⁄8-in. nominal aluminum block placed on the center of the mattress.

7.11.5 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 (see Figure 24), the unit shall be evaluated in the lateral position most likely to fail the requirements outlined in 6.10.

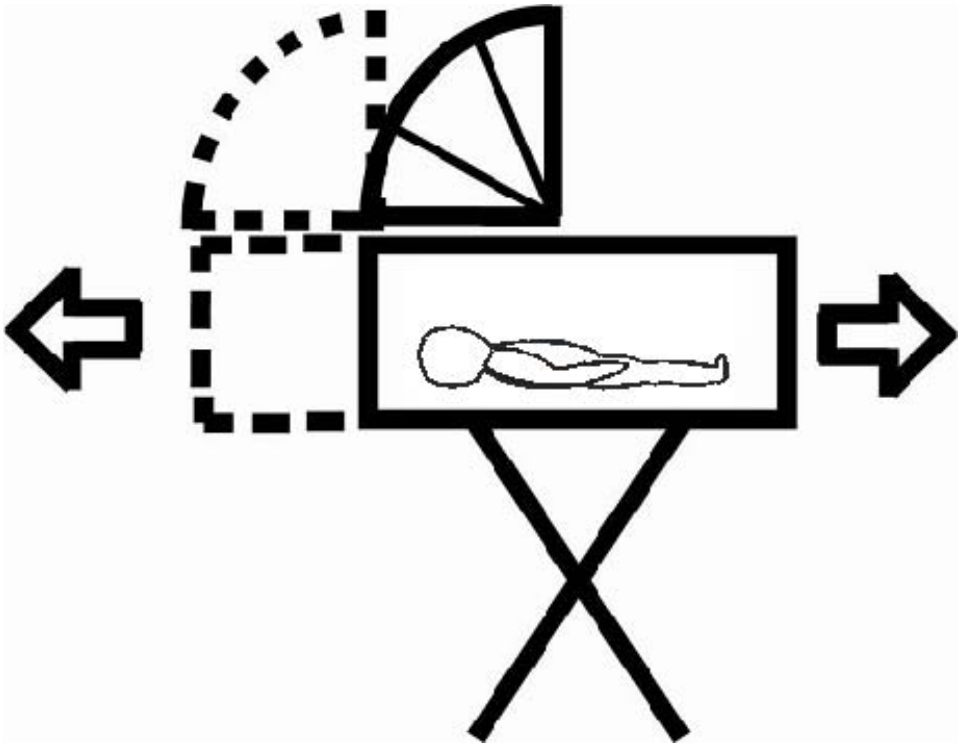


Figure 24: Bassinet Bed Resting on Stand,
Showing Possible Alternate Lateral Positions

7.11.5.1 If the base/stand supports the bassinet bed, place the inclinometer on the mattress support at the approximate center of the mattress support. Care should be taken to avoid

seams, snap fasteners, or other items that may affect the measurement reading. Record the angle measurement.

7.11.5.2 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 6.10.4.

7.11.5.3 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 visual indicator, test the unit in accordance with sections 7.4.2-7.4.7.

7.11.6 Repeat 7.11.3 through 7.11.5.3 for all of the manufacturer's base/stand positions.

7.11.7 If the product design allows, repeat 7.11.2 through 7.11.6 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 properly locked/latched 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 properly engaged can create a false sense of security by appearing to be stable. Unsecured or misaligned lock/latch systems are a hidden hazard because they not easily seen by consumers due to being located beneath the bassinet or 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 properly secured.

6.10. allows bassinet bed designs that:

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

2) automatically lock 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 properly locked onto the stand/base, or

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

TAB A:
Bassinet- and Cradle-Related Deaths, Injuries, and Potential Injuries Reported Between November 2007–December 2011

TAB A

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

Memorandum

Date: April 10, 2012

TO : Patricia Edwards
Bassinets Project Manager
Division of Mechanical Engineering
Directorate for Engineering Sciences

THROUGH: Kathleen Stralka
Associate Executive Director
Directorate for Epidemiology

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

FROM : Risana Chowdhury
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Bassinet- and Cradle-Related Deaths, Injuries, and Potential Injuries Reported Between November 2007–December 2011[8]

I. Introduction

This memorandum characterizes the number of deaths and injuries and the types of hazards related to bassinets and cradles (products coded as 1537) over a period of more than 4 years, beginning in November 2007.[9] These characterizations are based on incident reports received by CPSC staff.

The ASTM voluntary standard (F2194-12) addresses safety issues related to infant bassinets and cradles. According to the ASTM definition, a "bassinet" or "cradle" is a small bed designed exclusively to provide sleeping accommodations for infants supported by freestanding legs, a wheeled base, a rocking base, or which can swing relative to a stationary base. While in a rest (non-rocking or swinging) position, a bassinet or cradle is intended to have a horizontal sleep surface. Additionally, a bassinet or cradle

[8] 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.
[9] 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 provide, when feasible, estimates of emergency department-treated injuries.

attachment, which is a supported sleep surface that attaches to a crib or play yard to convert the product into a bassinet/cradle, is also considered in scope under the voluntary standard. These products are intended to provide sleeping accommodations for an infant up to approximately 5 months of age.

II. Incident Data[10]

CPSC staff has focused attention on incoming incident reports related to bassinets and cradles since late 2007, in a pilot project known as the Early Warning System (EWS). Each week, all data entered into the CPSC epidemiology databases during the previous week, is drawn into the EWS. It is important to note that the date of entry into the databases is different from the date of the actual incident. This analysis is based on all bassinet-related incident data in the EWS with a date of entry from November 1, 2007 through December 31, 2011. Incidents related to dual mode products that can function as bassinets, as well as bedside sleepers, have been included in this analysis and also in the analysis for the regulatory work for bedside sleepers. Similarly, incidents related to cradle swings, which are subject to both the infant swing standard and bassinet standard, have been included in the regulatory work for both products.

The number of emergency department-treated injuries associated with bassinets and cradles, for the timeframe covered, was insufficient to derive any reportable national estimates.[11] Hence, injury estimates are not presented separately in this memo. However, the emergency department-treated injuries are included in the total count of reported incidents presented here.

CPSC staff is aware of a total of 335 incidents involving 94 fatalities and 241 nonfatal incidents related to bassinets and cradles that were reported from November 2007 through December 2011. 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—currently in the EWS—by the incident year. Given that these reports are anecdotal and that reporting is incomplete, CPSC staff strongly discourages drawing any inferences based on the year-to-year increase or decrease shown in the reported data.

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

Date of extraction for reported incident data on bassinets and cradles was 01/18/12. All data coded under product code 1537 was extracted. Upon careful joint review with Engineering Sciences staff, some cases were considered out of scope for the purposes of this memo. Products such as sleep positioners, Moses baskets, and other sleeping aids were excluded. With the exception of incidents occurring at U.S. military bases in foreign countries, all incidents occurring outside of the United States have been excluded. Any case where the official report cited a natural cause of death, such as SIDS or pulmonary failure, was excluded. Incidents where the involvement of the bassinet was incidental (such as an incident where the infant was pulled out of a bassinet by a young sibling, or an infant was dropped while being placed in or retrieved from a bassinet by a caregiver, or an infant, outside the bassinet, fell from a bed on to the bassinet, for example) was considered out of scope as well. However, all incidents where hazardous environments in and around the bassinet resulted in fatalities, injuries, or near-injuries were retained.

[11] According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller.

Table 1: Bassinet- and Cradle-Related Incidents Reported From November 2007 through December 2011

Incident Year	***Number of Reported Incidents***
2007 and earlier	48
2008	83
2009*	74
2010*	71
2011*	41
Unknown	18
Total	***335***

Source: CPSC epidemiological databases.
Note: * indicates data collection is ongoing

A. Fatalities

A total of 94 bassinet-related fatalities have been reported since November 2007 through December 2011. Eight of the 94 deaths are associated with the design aspects of the product. 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 convertible bassinets/bedside sleepers that was subsequently recalled for this defect. Two of these three infants were 6-months old, while the third infant was a 4-month-old. Three other deaths were associated with problems dealing with the flatness of the mattress pads used in a bassinet accessory of a play yard. All three of these decedents were 5 months old or younger. One of the three decedents suffocated in the corner of the bassinet when he rolled into that position due to the unlevel mattress pad; the other two decedents were found face down in a dip in the center of the unlevel mattress pad. The rocking feature of a bassinet, which contributed to its non-level resting position, was associated with an additional suffocation death of a 1-month-old infant. The remaining fatality, which was associated with the design of the product, occurred when the bassinet tilted over and allowed the 3-month-old decedent to get pinned between the bassinet and a nearby dresser.

The majority of the deaths (82 out of 94, or 87 percent) were asphyxiations due to the presence of soft or extra bedding in the bassinet, prone placement of the infant, and/or the infant getting wedged between the side of the bassinet and an added mattress or pillow. There were four fatalities with too little information to allow CPSC staff to determine the hazard scenario. All but two of the 82 decedents were 5 months old or younger in age; one infant was a 7-month-old and another was an 8-month-old.

B. Nonfatal Incidents

A total of 241 bassinet-related, nonfatal incidents were reported from November 2007 through December 2011. Of these, 52 incidents reported an injury to an infant using the bassinet or cradle at the time of the incident. The majority of these injuries (30 out of 52, or 58 percent) were identified as resulting from falls out of the bassinets. Because 28 of the 30 falls were reported through the emergency department-treated injury surveillance system, little or no circumstantial information is available on how the fall occurred. However, the reports do indicate that 76 percent of the injured infants who fell out of bassinets were older than the ASTM-recommended maximum age limit of 5 months, with four infants as old as 9 months of age. All of the falls resulted in head and facial injuries.

Overall, there were six bassinet-related injuries that were reported to have needed hospitalization. Four of them, all serious head injuries, resulted from a fall out of the bassinet. One injury, a leg fracture, resulted from a caregiver unknowingly attempting to lift an infant out of the bassinet while the infant's leg was caught in a structural opening. The remaining hospitalized injury was due to a moldy bassinet pad that caused respiratory illness in the infant.

Two additional serious injuries were reported, but neither of these infants was hospitalized. There was a report of a second-degree burn suffered by an infant from the bassinet's overheated mobile and a report of an arm fracture from an infant's arm getting caught in the bassinet. The remaining injuries were limited mostly to contusions and abrasions.

The remaining 189 reports indicated that no injury had occurred, or else they provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death.

III. Hazard Patterns

CPSC staff considered all 335 incidents to identify hazard patterns associated with bassinet and cradle-related incidents. The incidents were grouped into four broad categories:

- Product-related issues
- Non-product-related issues
- Recalled product-related issues
- Miscellaneous other issues.

A. *Product-related issues:* The hazard scenarios in 209 of the 335 incidents (62 percent) reported were attributed to some sort of failure/defect or a potential design flaw in the product itself. This category includes five fatalities and 46 injuries, five of which required hospitalization. Listed below are the reported problems, beginning with the most frequently reported concerns:

   - Lack of ***structural integrity***, which includes issues such as: instability, loose hardware, collapse of the product, and loose wheels, among others. This problem was reported in 64 (about 19 percent) of the incidents.

   - Reports of infants ***falling or climbing out*** of bassinets/cradles. This category accounted for most of the bassinet-related injury reports that were received from emergency departments around the United States. While little product/scenario-specific information was available in these reports, a majority indicated that the victims were over the ASTM-recommended upper age limit of 5 months old. This problem was reported in 32 (about 10 percent) of the incidents.

   - Problems with ***mattress-flatness*** in bassinet attachments to play yards. Examples include mattresses that would not remain level horizontally because of poorly designed metal rods/other structures that are meant to be positioned underneath the mattress, lack of rigid mattress support, and failure of straps/hooks/bars designed to hold the bassinet attachment inside the play yard. This issue was reported in 31 (about 9 percent) of the incidents.

- Problems with ***rocking*** bassinets and cradles with locking or tilting issues that caused the infant to roll/press up against the side/corner of the product and posed a suffocation hazard. This issue was reported in 23 (about 7 percent) of the incidents.

- Problems with product ***packaging***. Poor packaging resulted in broken/damaged products during delivery of the product. This issue was reported in 19 (about 6 percent) of the incidents.

- Problems with bassinet ***mobiles*** that had components that overheated, smoked, or sparked. This issue was reported in 13 (about 4 percent) of the incidents.

- ***Miscellaneous*** other product-related problems, ranging from a tear in the bassinet fabric, to odors, as well as product assembly/quality issues. Twenty-seven (about 8 percent) of the incidents reported these issues.

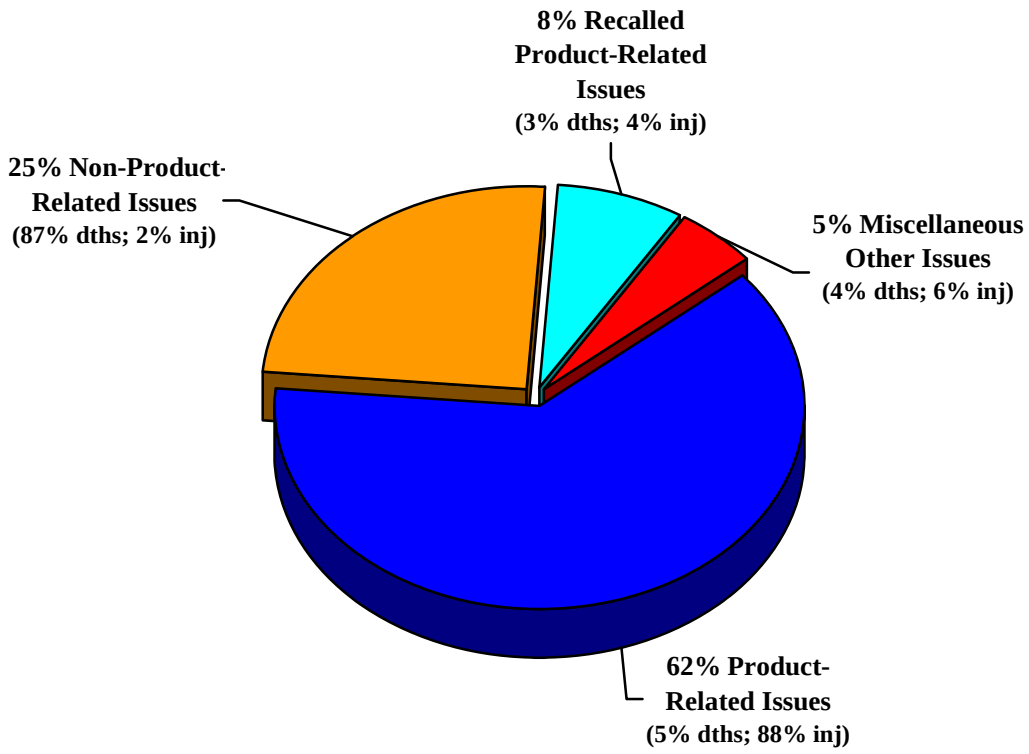
B. *Non-product-related issues:* Eighty-three of the 335 reports (25 percent) were about incidents that involved no product defect or failure. This category consisted of 82 fatalities, most of which were associated with the use of soft/extra bedding or prone positioning. There was also one nonfatal injury incident that did not involve any product-related issues.

C. *Recalled product-related issues:* There were 26 reports (8 percent) that involved recalled products. Some of the reports were received by CPSC staff prior to the recalls being published. There were three fatalities and two injuries due to entrapment and/or hanging of an infant between structural components of the bassinet. Two of the fatalities occurred before the CPSC recall; the third occurred after the recall. Between the two injuries, one occurred prior to the recall, while the other occurred after the recall. Neither of the post-recall incident reports indicates whether the consumers were aware of the recall. Most of the remaining reports were complaints or inquiries from consumers regarding a recalled product.

D. *Miscellaneous other issues:* The remaining 17 (5 percent) incident reports were related to miscellaneous other or unspecified issues. Some of these reports expressed concerns from consumers about perceived safety hazards; others described incidents with insufficient specificity for CPSC staff to identify the hazard scenario. There were four fatalities and three injuries, including an injury requiring hospitalization, reported in this category.

The distribution of the 335 incidents by the hazard patterns described in Sections A through D above are shown in Fig. 1 below.

Fig 1: Distribution of Incident Reports Associated with Bassinets and Cradles by Hazard Pattern Characterizations Date Reported: 11/01/07-12/31/11



Source: CPSC epidemiological databases IPII, INDP, DTHS, and NEISS.

TAB B:

ESME Recommendations for the Proposed Bassinet and Cradles Standard

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

Memorandum

Date: July 30, 2012

TO : Patricia L. Edwards
Bassinets Project Manager
Division of Mechanical Engineering
Directorate for Engineering Sciences

THROUGH: George A. Borlase, Ph.D., P.E.
Associate Executive Director
Directorate for Engineering Sciences

FROM : Mark E. Kumagai, P.E.
Division Director, ESME

SUBJECT : ESME Recommendations for the Proposed Bassinets and Cradles Standard

I BACKGROUND/OVERVIEW

The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act (CPSIA), requires CPSC staff to: (1) examine and assess voluntary safety standards for certain infant and toddler products, and (2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. The list of products in section 104 includes bassinets and cradles.

ESME staff believes that a more stringent standard would further reduce the risk of injury associated with bassinets and cradles. Therefore, ESME staff recommends several changes to the current voluntary standard, ASTM F2194-12, *Standard Consumer Safety Specification for Bassinets and Cradles,* to be considered for the notice of proposed rulemaking (NPR).

This memorandum provides: a review of the hazard patterns associated with the use of bassinets, an overview of the current ASTM standard, a discussion and outline of the recommendations staff is making for the NPR, and a comparison of the current recommendations to the previous NPR that was published in April 2010 (2010 NPR).

Bassinets are intended to provide sleeping accommodations for infants up to approximately 5 months of age. Figures 1–4 show some typical bassinets.

			
Figure 1. Stationary Bassinet	Figure 2. Bassinet With Rocking Base	Figure 3. Swinging Rigid-Sided Cradle	Figure 4. Play Yard/ Bassinet Combination

II INCIDENT DATA/HAZARD PATTERN SUMMARY

A. Fatalities

A total of 94 bassinet-related fatalities have been reported from November 2007 to December 2011. The majority of the deaths (82 out of 94 or 87 percent) were asphyxiations due to the presence of soft or extra bedding in the bassinet, prone placement of the infant, and/or the infant getting wedged between the side of the bassinet and an added mattress or pillow.

Eight of the 94 deaths were associated with design aspects of the product.

- Three of the deaths (IDI 090709HBB3724, IDI 080827CWE0003, IDI 071002HWE7037) 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 convertible bassinets/bedside sleepers.
- Three other deaths (IDI 090706CWE8347, IDI 090213HCC1421, IDI 100421HCC1630) were associated with the flatness of the mattress pads used in a bassinet accessory of a play yard.
- The rocking feature of a bassinet, which contributed to its non-level resting position, was associated with an additional suffocation death of a 1-month-old infant (IDI 110304HCC1366).
- One fatality (IDI 110512HCC2531) occurred when the bed portion of the bassinet fell off its stand and allowed the 3-month-old decedent to get pinned between the bassinet and a nearby dresser. This may have been due to misassembly and a sibling pushing or pulling over the bassinet.[12]

[12] Jonathan Midgett, Ph.D., Office of Hazard Identification and Reduction, June 4, 2012, "Bassinets and Cradles Standard: Human Factors Issues."

B. Injuries

From November 2007 through December 2011, there were 52 reported injuries to infants using the bassinet or cradle at the time of the incident. The majority of these injuries (30 out of 52, or 58 percent) were identified as resulting from falls out of the bassinets. Since the majority of these injury incidents were reported through the National Electronic Injury Surveillance System (NEISS), details about the incidents are not available.

C. Addressable Hazards

ESME identified the following six hazards that were considered product-related hazards that could be addressed by a standard. These have been classified as Hazards #1–6, and they will be referred to throughout this memo as we discuss the adequacy of ASTM F2194-12 and staff's proposed requirements to address these hazards.

Hazard # 1 - *Suffocation due to addition of soft bedding*: The majority of the deaths were asphyxiations due to the presence of soft or extra bedding in the bassinet, prone placement of the infant, and/or the infant getting wedged between the side of the bassinet and an added mattress or pillow.

Hazard # 2 - *Suffocation/positional asphyxia due to excess mattress pad angle:* Three deaths (IDI 090706CWE8347, IDI090213HCC1421, IDI 100421HCC1630) resulted from problems with the flatness of the mattress pads used in a bassinet accessory of a play yard. All three of these decedents were 5 months old or younger in age. One of the decedents suffocated in the corner of the bassinet when he rolled into that position due to the unlevel mattress pad. The other two decedents were found face down in a dip in the center of the unlevel mattress pad.

Hazard # 3 - *Entrapments in fabric-sided openings:* Three of the deaths (IDI 090709HBB3724, IDI 080827CWE0003, IDI 071002HWE7037) were due to entrapment and/or hanging of the infant between structural components of a particular brand of convertible bassinets/bedside sleepers. These incidents occurred in one manufacturer's bassinet that was recalled on August 28, 2008.[13]

Hazard # 4 - *Suffocation due to excess rocking/swing angles:* Bassinets and cradles with locking or tilting issues that caused the infant to roll/press up against the side/corner of the product and that pose a suffocation hazard. There have been several nonfatal incidents and one fatality associated with a rocking bassinet (IDI 110304HCC1366). In the fatal incident a 1-month-old was found pressed up against the fabric side of the bassinet. It is not known whether the lock, which was designed to prevent rocking, was properly engaged or whether it was functioning correctly.

In 2009, a rocking bassinet/play yard was recalled due to many nonfatal incidents, in which the play yard's rocking bassinet attachment did not latch properly. The firm reported an incident in

[13] http://www.cpsc.gov/cpscpub/prerel/prhtml08/08381.html.

which the infant became wedged in the corner or pressed against the side or bottom of the bassinet, posing a risk of suffocation or positional asphyxiation.[14]

Hazard # 5 - *False latching/stability of removable bassinet beds:* Removable bassinet beds that are designed to separate from the stand/base have been involved in one fatality, several injury incidents, and a recall. The fatality occurred when the bassinet fell over and pinned the 3-month-old decedent between the bassinet and a nearby dresser (IDI 110512HCC2531). Health Canada staff also reported a death in a similar circumstance and provided CPSC staff with photographs and a short narrative, describing the product and the incident. There have also been nonfatal incidents involving bassinet beds that tipped over or fell off their base/stand when they were not properly locked/latched to their base/stand, or the latch failed to engage as intended. In May 2012, there was a recall of 46,000 bassinets that falsely could appear to latch to the stand when they had not.[15] Unsecured or misaligned lock/latch systems are a hidden hazard because they might not be seen easily by consumers it they are located beneath the bassinet or covered by decorative skirts.

Hazard # 6 - *Falls and climb-outs:* The majority of the nonfatal injuries (30 out of 52, or 58 percent) were identified as resulting from falls out of the bassinets. Because 28 of the 30 falls were reported through the emergency department-treated injury surveillance system, little or no information is available on how the falls occurred. However, the reports do indicate that 76 percent of the injured infants who fell out of bassinets were older than the ASTM-recommended maximum age limit of 5 months, with four infants as old as 9 months of age. All of the falls resulted in head and facial injuries[16].

III REVIEW OF STANDARDS

A. Summary of ASTM F2194-12

The voluntary standard for bassinets and cradles was first approved and published by ASTM in 2002, as ASTM F2194, *Standard Consumer Safety Specification for Bassinets and Cradles.* It has been revised a number of times since then, and the current version, ASTM F2194-12, was approved on June 1, 2012, and it contains requirements to address the following:

- Lead in Paints
- Hazardous Sharp Edges or Points
- Small Parts
- Wood Parts
- Scissoring, Shearing, Pinching
- Unintentional Folding
- Openings
- Labeling

[14] http://www.cpsc.gov/cpscpub/prerel/prhtml09/09219.html.

[15] http://www.cpsc.gov/cpscpub/prerel/prhtml12/12173.html.

[16] Risana Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, .April 10, 2012, "Bassinet and Cradle-Related Deaths, Injuries, and Potential Injuries Reported Between November 2007–December 2011."

- Fasteners
- Corner Posts
- Toy Accessories
- Restraints Requirement
- Bassinet/Cradle Attachment to Play Yard/Non-Full-Size Crib
- Spacing of Rigid-Sided Bassinet/Cradle Components
- Static Load
- Stability
- Sleeping Pad Properties
- Protective Components
- Side Height Requirement
- Fabric Sided Enclosed Opening Requirements and Test Methods
- Rock/Swing Angle Requirements and Test Methods

B. Review of Foreign Standards

ESME staff reviewed Canadian, European, and Australian foreign standards for bassinets and/or cradles. Many of the requirements found in the 2012 ASTM standard can also be found in some of these international standards. A detailed review of the standards can be found in Appendix A.

The European Standard, EN 1130-1: 1996, "Furniture – Cribs and Cradles for Domestic Use," has several requirements not found in ASTM F2194-12. Most of these additional requirements address hazards associated with cribs intended for use with older children (in excess of the 5-month recommended maximum age for bassinets), and thus, they are not applicable to bassinets.

The scope of the European Standard, EN 12790-2009, "Child use and care articles - Reclined cradles," includes inclined bassinets/cradles, car seat carriers, hammocks, and bouncers. Some of the general requirements could apply, but since the scope of the product is not the same, most of the requirements are not applicable to bassinets.

The Australian/New Zealand standard (AS/NZS 4385:1996) contains requirements for rocking and swinging angles that were used to develop some of the ASTM F2194-12 requirements. The ASTM rock/swing rest angle performance requirement is more stringent because the occupant surrogate, a CAMI dummy, is placed against the sidewall, and that results in higher rest angles.

The Canadian standard (SOR 86-962: 2010) includes requirements for cribs and non-full-size cribs. This standard does not distinguish between a bassinet and non-full-size cribs. As a result, many of the requirements are not applicable for this NPR. The Canadian standard was used to develop the ASTM requirement for bassinet side height.

Staff believes that the current ASTM F2194-12 standard is the most comprehensive of the standards to address the incident hazards. There are some individual requirements in various foreign standards that are more stringent than ASTM; however, many of these requirements do not address the identified hazards in the incident data reported to CPSC staff. Appendix A summarizes and compares these requirements. Table 1 below, summarizes the review of the international standards assessed for this memo.

TABLE 1: Review of Foreign Standards

Standard Number	Standard Name	Comments
AS/NZS 4385:1996	Australian/New Zealand Standard for Infant's Rocking Cradles – Safety Requirements	Requires all components to be permanently fixed or requires the use of a tool to enable partial or total disassembly. No other significant additional requirements contained in this standard over ASTM
SOR 86-962 (2010)	Canadian Standard for Cribs and Cradles	No significant additional requirements contained in this standard over ASTM (NOTE: this standard is intended for rigid-sided cribs in addition to cradles)
EN 12790:2009	European/British Standard for Child use and care articles – Reclined cradles	No significant additional requirements contained in this standard over ASTM (NOTE: this standard is intended for reclined bassinets and car seat carriers)
EN 1130 -1996	European Standard: Furniture-Cribs And Cradles for Domestic Use	This standard contains: locking and latching (for rocking cradles or drop sides); wheels/casters; mattress support openings; and slat strength requirements not found in the ASTM standard (NOTE: this standard is intended for rigid-sided cribs in addition to cradles)

IV ADEQUACY OF ASTM F2194-12 REQUIREMENTS

ESME staff believes that ASTM F2194-12 addresses many of the general hazards associated with durable nursery products, such as lead in paints, sharp edges/sharp points, small parts, wood part splinters, scissoring/shearing/pinching, openings/entrapments, warning labels, and toys. Specific requirements for tip stability, unintentional folding of the product, and static load are also included. ASTM F2194-12 also includes the following new or revised sections:

- **Marking and Labeling:** This revised section requires that the "**SUFFOCATION HAZARD**" warning be in bold and at least 0.4 inches high. This requirement should help make the label more visible to address the suffocation hazard associated with soft bedding.
- **Side Height:** This new requirement states that a bassinet side be at least 7.5 inches above the mattress surface and is intended to help address fall hazards.
- **Fabric-Sided Enclosed Opening Requirements and Test Methods:** This new section requires that a fabric-sided bassinet does not create an entrapment hazard if the fabric fasteners are not properly attached to the frame. This requirement is intended to address the fatal incidents associated with openings in fabric-sided bassinets.
- **Rock/Swing Angle Requirements and Test Methods:** This new section requires that a rocking cradle come to rest at an angle of 7 degrees or less. This requirement is intended

to address incidents when rocking bassinets remain tilted and cause the infant to roll/press up against the side/corner of the product, posing a suffocation hazard.

ESME believes these new or revised requirements will adequately address incidents associated with:

Hazard # 3 - *Entrapments in fabric-side openings*
Hazard # 4 - *Suffocation due to excess rocking/swing angles*

ESME also believes these new requirements will help address incidents associated with:

Hazard # 1 - *Suffocation due to addition of soft bedding*
Hazard # 6 - *Falls and climb-outs*

ESME believes that ASTM F2194-12 does **not** adequately address hazards associated with:

Hazard # 2 - *Suffocation/positional asphyxia due to excess mattress pad angle*
Hazard # 5 - *False Latching/Stability of removable bassinet beds*

V STAFF'S PROPOSED SAFETY STANDARD FOR BASSINETS AND CRADLES

Staff recommends that ASTM F2194-12 be proposed as the mandatory safety standard for bassinets and cradles, with a modification to add two new performance requirements and associated test methods to address: **Hazard # 2 - *Suffocation/positional asphyxia due to excess mattress pad angle;*** and **Hazard #5 – *False latching/stability of removable bassinet beds*** and potentially to help address ***Hazard #6 – Falls and climb-outs.***

A. Additional Performance Requirements to Address Hazard # 2 - Suffocation/positional asphyxia due to excess mattress pad angle

ESME staff is recommending performance requirements and a test method for the minimum flatness of mattress surfaces. This requirement applies to segmented mattresses, such as those seen in a bassinet accessory to a play yard. CPSC staff recommends requiring segmented mattresses to remain flat and not create an angle greater than 10 degrees (based on Human Factors staff evaluation of angles.)[17] Figures 5a and 5b show play yard bassinets with a severe v-angle created by segmented mattress panels.

[17] Tab C, Jonathan Midgett memorandum, "Bassinets and Cradles Standard: Human Factors Issues."

Figure 5a. Incident bassinet play yard – photo from IDI 090706CWE8347 (arrow pointing to v-angle in the mattress pad)

Figure 5b. Incident bassinet play yard – photo from IDI 090213HCC1421 (arrow pointing to v-angle in the mattress pad)

Staff recommends that a segmented mattress commonly used in play yards shall not create an angle greater than 10 degrees when tested using a 17 lb cylinder to simulate the weight of a 6 month old infant. Figures 6 and 7 show the test setup. The exact performance requirements and test procedures are included in Appendix B of this memo.

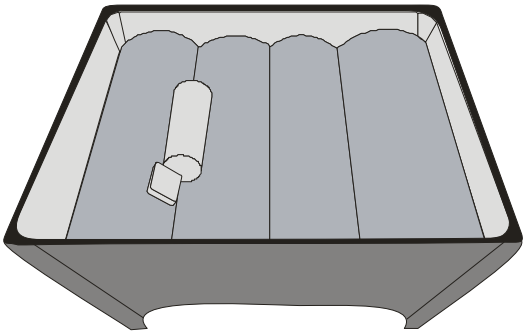


Figure 6. Mattress Flatness Test Set up

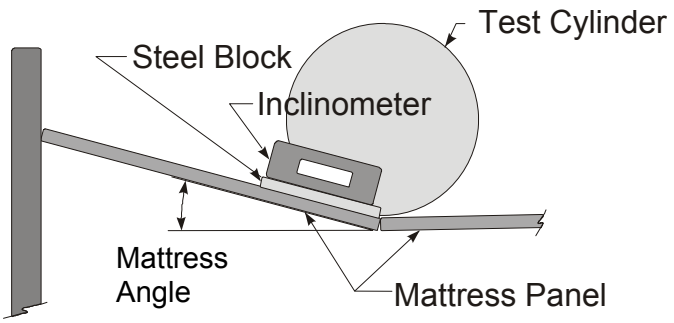


Figure 7. Mattress Flatness Angle Measurement

In addition to adding this new test requirement and corresponding test method, staff is also recommending that the standard's scope and corresponding terminology be revised to define better which products are considered bassinets (as opposed to other products, like swings, inclined sleepers, and stroller carriages).

The ASTM task group and the CPSC staff developed the mattress flatness requirements by testing several bassinet/play yards using various fixtures and different testing personnel, to determine the repeatability and reproducibility of the test method using the various test fixtures. Staff's recommended test method identified the poor performing mattress/bassinets compared to flat mattresses. It also provided the most repeatability between tests and testers. Variability of the angle measurements between testers are due to the construction of mattress and its support system. Some bassinet/play yard mattress angles varied 5-8 degrees between tests. Products with mattress angles consistently measured to be less than 10 degrees typically varied around 1 degree between tests. Staff believes that the proposed test method and performance requirement

for mattress flatness of less than or equal to 10 degrees is reasonable and achievable by bassinet/play yard manufacturers.

B. Additional Requirements to Address Hazards #5 – False latching of removable bassinet beds and #6 – Falls

ES staff is recommending performance requirements and a test method for products that have bassinet beds that attach to an elevated stand. This requirement applies to *removable bassinet beds* that are designed to separate from the stand/base without the use of tools. Staff is proposing that if a removable bassinet bed is not properly attached or assembled to its base, it must meet one of the following requirements:

1. 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
2. The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action); or
3. The stand/base shall not be capable of supporting the bassinet bed within 20 degrees of horizontal; or
4. The bassinet shall contain a visual indicator mechanism that shall be visible on both sides of the product to indicate if the bassinet is properly attached to the base; or
5. The bassinet bed shall not tip over and shall retain the CAMI newborn dummy when subjected to the stability test outlined in the standard.

This requirement addresses one fatal (IDI 110512HCC2531) and several nonfatal incidents involving bassinet beds that tipped over or fell off their stand/base when they were not properly locked/latched to their stand/base or the latch failed to work as intended. See Tab C for more details about the rationale and basis for this requirement.

During testing and ASTM task group meetings regarding this performance requirement, the existing stability test in the ASTM standard was discussed, because one of the options to meet this new requirement is to test the bassinet to the stability requirement when the bed is unlocked, on the stand. The stability test, which has been part of the standard for several years, uses a CAMI infant dummy (weighing approximately 17 pounds and representing the 50th percentile 6-month-old) as a surrogate occupant during the test procedure. A more conservative stability test would use the CAMI newborn dummy (weighting 7 pounds and representing a 50th percentile newborn). Staff believes that the use of the CAMI newborn in the stability test is not only more conservative, but it also represents better the users who are at risk; thus, staff is also recommending a change in the CAMI dummies for the stability test.

The exact performance requirements and test procedures for the removable bassinet bed attachment test are included in Appendix B of this memo.

VI DISCUSSION OF THE DIFFERENCES BETWEEN THE 2010 NPR AND STAFF'S RECOMMENDATIONS FOR THE SUPPLIMENTAL NPR

In the 2010 NPR, the Commission approved a proposed rule that referenced the requirements specified in ASTM F2194-07a$^{\varepsilon 1}$ as a mandatory standard for bassinets and cradles with several

modifications and edits that could reduce suffocations and entrapments further.[18] Since 2010, the ASTM subcommittee for bassinets has addressed many of staff's concerns, as outlined in the 2010 NPR. Staff believes that the recommendations in the 2010 NPR concerning: (a) Warnings, (b) Stability, (c) Fabric Attachment, (d) Rock/swing angle, and (e) Restraints are adequately addressed in voluntary standard ASTM F2194-12, as described below:

a) **Warnings**: The 2010 NPR proposed a stronger warning label to address suffocation hazards. The 2012 ASTM standard requires that the warning: "**SUFFOCATION HAZARD,**" be in bold and at least 0.4 inches high, which is twice the size proposed in the 2010 NPR. Staff believes that this adequately addresses the concerns identified in the 2010 NPR.

b) **Stability**: The 2010 NPR clarified that the stability requirement applies to all manufacturer-recommended use positions, including the position where the locks are engaged, to prevent rocking/swinging motion. ASTM F2194-07a$^{\varepsilon 1}$ was revised to incorporate this change, and the revision was approved in ASTM F2194-11, and is therefore, included in the latest version, ASTM F2194-12. Staff believes this adequately addresses the stability concerns identified in the 2010 NPR.

c) **Fabric-Sided Enclosed Openings:** The performance requirements for fabric sided products to address entrapment incidents included in F2194-12 are the same as in the 2010 NPR, except for editorial changes made to clarify the requirement and test procedure. Staff believes this adequately addresses the concerns identified in the 2010 NPR.

d) **Rock/Swing Angle:** The performance requirements for a 20 degree maximum rock/swing deflection angle and a 7 degree rest angle found in F2194-12 are similar to what was in the 2010 NPR. The ASTM test procedure has a simplified method of measuring the angle. This includes not requiring the test to be run using two different CAMI dummies, and running the test three times, rather than five. The maximum rest angle requirement was increased from 5 to 7 degrees, but the test procedure in the 2012 ASTM standard is much more severe; thus, staff believes the new requirement is equivalent to the 5 degree requirement proposed in the 2010 NPR. Staff believes that this adequately addresses the concerns identified in the 2010 NPR.

e) **Restraints:** The 2010 NPR included a requirement to eliminate the use of restraint straps in bassinets requiring action on the part of the caregiver. A stricter version of this requirement, which eliminates all restraints, was included as part of the 2012 version of the ASTM standard. Staff believes that this adequately addresses the concerns identified in the 2010 NPR.

The 2010 NPR included revisions to the **Scope and Terminology** section of ASTM F2194-07a$^{\varepsilon 1}$. Based on staff's review of public comments in response to the 2010 NPR, staff recommends the following modifications to F2194-12 compared to the 2010 NPR:

[18] 75 Fed. Reg. 22303, April 28, 2010.

f) **Scope and terminology**: The scope section in the 2010 NPR included reclined bassinets and hammocks. Staff has reevaluated that inclusion based on comments received in response to the 2010 NPR and no longer recommends including them in the bassinet standard. (See Tab C for more discussion on this matter.) The new recommendation, as presented in Appendix B to this memo (section 1.0), specifically excludes inclined and hammock-style bassinets but includes all flat (horizontal) and semi-inclined products (10 degrees or less incline from horizontal), as well as cradle swings.

The 2010 NPR included an additional requirement to address suffocation in segmented mattresses. The 2010 NPR included proposed performance requirements and associated test procedures. The improved requirements, recommended by staff to be proposed in the 2012 NPR, are described below:

g) **Mattress Flatness:** In the 2010 NPR, a mattress flatness performance test for all types of bassinets and cradles was included. The recommended mattress flatness performance requirement described in this memo only applies to segmented mattresses. CPSC staff's review of the data showed that only segmented mattresses used in play yards were involved in incidents. In addition, CPSC staff determined that an angle of 10 degrees or less would be as protective as the 5 degree angle specified in the 2010 NPR, and it would allow for testing variances and also address design and manufacturability concerns with segmented mattress pads. Staff's new recommendation has additional requirements for two-occupant bassinets. Changes to the testing methods were also made by using a rigid cylinder to simulate the infant, rather than using a soft/deformable CAMI dummy. This change provides more consistent test results. Tab C provides more discussion on the 10-degree test requirement.

VII COMMENTS TO APRIL 2010 NPR

Most of the technical comments to the 2010 NPR were submitted by the Juvenile Product Manufacturer Association (JPMA) in a letter dated September 10, 2010. The recommendations included in the letter were developed in cooperation with the ASTM F15.18 Subcommittee on Bassinets and Cradles in response to the 2010 NPR.

The following discussion is broken down by topic and includes a summary of the commenters' recommendations and CPSC's staff's responses.

Scope

Comment: Several comments were received regarding the inclusion of hammocks or other inclined sleeping products in the scope of the 2010 NPR. The comments were universally against such inclusion, citing that this would effectively ban a product that has some utility. The comments also opined that such a ban could increase hazards if parents use a substitute product. JPMA also recommended revising the scope to clarify that the standard covers products only intended for infants that have just started to push up on their hands and knees or younger children, and it includes products that are intended exclusively for sleeping.

CPSC staff response: CPSC staff agrees that the scope should clarify what products should be included and which should not and is recommending a modified scope to F2194-12. CPSC staff also agrees with the commenters and recommends that the scope of the standard be limited specifically to bassinets that are intended to provide a flat or nearly flat sleeping surface. This would exclude hammocks and inclined sleepers from the requirements in this proposed standard. ASTM is in the process of developing a new standard for inclined sleep products that should be published in 2013. CPSC staff is working with ASTM on this standard and intends to recommend a proposed rule on inclined sleeper products to be submitted for Commission consideration under the authority of CPSIA, shortly after publication of the ASTM standard. CPSC staff disagrees with the comment to limit the scope to products meant ***exclusively*** for sleeping. Instead, staff believes that the scope should cover products intended ***primarily*** for sleeping. This would ensure that a bassinet sold with a toy mobile, meant to entertain an infant who is lying in the bassinet, would still fall within the scope of this standard. A revised scope and associated definitions are recommended by staff to address these comments.

Bassinet Segmented Mattress Flatness Test

Comment: JPMA and other commenters provide recommendations or comments on the mattress flatness requirement. Generally, they recommend that the sum of the two angles formed by two panels of a segmented mattress should be less than or equal to 28 degrees rather than having a 5-degree requirement as outlined in the 2010 NPR.

CPSC staff response: After a thorough review of the comments, participation in ASTM task groups and subsequent testing, staff is now recommending a test requirement where any angle of a segmented mattress must be 10 degrees or less, when tested in accordance with the recommended test procedure developed by CPSC staff and ASTM. This requirement is based on anthropometric measurements of the user (see Tab C for rationale). ASTM has recently balloted the exact same test procedure recommended by staff, but has more complicated pass/fail criteria; requiring a total of three measurements to be taken and averaged, whenever the angle was measured to be between 10 and 14 degrees.

Rock/Swing Maximum and Rest Angle

Comment: JPMA and other commenters recommend a maximum rock/swing angle of 20 degrees and a maximum rest angle of 7 degrees for rocking cradles.

CPSC staff response: Since that comment was written, ASTM has included a rock/swing angle requirement that contains maximums of 20 degrees for the swing angle and 7 degrees for the rest angle in the 2012 version of the voluntary standard.

CPSC staff agrees with the comments regarding the rock/swing angle of 20 degrees. Staff also agrees with a 7-degree rest angle as published in the ASTM F2194-12 standard, rather than the 5-degree angle proposed in the 2010 NPR. The 5-degree angle was based on the Australian standard for rocking cradles. In the Australian standard, the angle is measured with the CAMI infant dummy placed in the center of the cradle. The intent is to ensure that the rocking cradle returns to a level position and provides a flat sleeping surface for the infant. In the 2012 NPR, and in ASTM F2194-12, the angle is measured with the CAMI infant dummy placed to one side

of the cradle. CPSC staff believes that the placement of the CAMI to one side results in a more stringent requirement than the Australian standard. For this reason a 7-degree rest angle is reasonable and is an achievable requirement for bassinets that will address suffocation hazards associated with an angled sleep surface. Therefore, staff is not making any recommendations with respect to this issue.

Fabric-Sided Enclosed Openings Test

Comment: JPMA recommended testing openings on fabric-sided products using a torso probe and a head probe, rather than just the torso probe, as presented in the 2010 NPR. JPMA opined that if an opening allowed the passage of both probes, then the opening would also allow the infant to pass through completely and not result in an entrapment.

CPSC staff response: CPSC staff does not believe an opening in a bassinet that is large enough to pass the head probe is acceptable due to the potential for the infant to fall through the opening onto the floor. CPSC staff recognizes that it will be necessary to redesign some bassinets by closing up existing openings in the frames or making the fabric non-removable in order to meet this requirement. CPSC staff believes this is necessary to prevent entrapment incidents without creating a fall hazard.

Since that comment was written, ASTM has revised the bassinet standard to include a fabric-sided enclosed openings test that does not use the head probe, as recommended by JPMA. The test included in the 2012 version of the standard is very close to what was included in the 2010 NPR, and thus, staff is not recommending any further changes relating to this hazard for this re-proposal.

Static Load and Stability

Comment: JPMA recommended adding a requirement to test play yard bassinet accessories at all four corners to ensure structural integrity of the product. JPMA also recommended testing bassinets for stability while the locks are engaged to prevent rocking/swinging.

CPSC staff response: CPSC staff agrees. The 2012 version of the ASTM standard has these static load and stability requirements included, and thus, staff does not need to recommend them for this re-proposal.

Marking &Labeling

Comment: JPMA recommends a font size of 0.2 inches or higher for the warnings, plus some wording changes to the suffocation warning.

CPSC staff response: CPSC staff believes that the size of the suffocation warning could be even bigger in an effort to draw attention to its importance. In ASTM F2194-12, the font size for the Suffocation Warning label was increased to 0.4 inches or higher. Therefore, staff is not making any further recommendations with respect to this issue.

Definition of a Double-Action Release Mechanism

Comment: JPMA recommends adding a definition for a *double action release mechanism.*

CPSC staff response: CPSC staff agrees. The 2012 version of the standard has this new definition included, and thus, staff is not recommending anything for this re-proposal.

Occupant Restraint

Comment: JPMA recommends adding a requirement to prohibit the use of any restraints in bassinets, and their recommendation was stricter than the requirement included in the 2010 NPR (which prohibited restraints that required caregiver action). Other commenters argue against prohibiting restraints.

CPSC staff response: CPSC staff agrees with the restraints requirement as recommended by JPMA. See Tab C for a discussion regarding the hazards associated with restraints. ASTM F2194-12 standard includes a new requirement that prohibits the use of any restraints, and thus, staff is not recommending any further change for this re-proposal.

Spacing of Rigid Components

Comment: Commenters point out that the 2010 NPR contained a modification to the spacing of rigid components requirement that was confusing because it relied on two different testing methods.

CPSC staff response: CPSC staff agrees. Since that comment was written, ASTM revised this section in their 2012 standard to address the comments adequately. Staff does not recommend any additional modifications to address this issue for this re-proposal.

VIII CONCLUSIONS

ESME staff recommends adopting the requirements specified in ASTM F2194-12 as the CPSC mandatory standard for bassinets and cradles, with the following modifications not currently found in the ASTM standard:

a) A modified scope and associated terminology to clarify what products are included in the scope of this standard;
b) A new performance requirement and associated test method for mattress flatness, to address fatal incidents associated with segmented mattress flatness issues;
c) A new performance requirement and associated test method for false latching/stability of removable bassinet beds, to address fatal and nonfatal incidents associated with the attachment mechanisms for removable bassinet beds to their stand/frame; and
d) A revision to the stability performance requirement to use the smaller CAMI newborn dummy, rather than the CAMI infant dummy.

Recommended language for these additional requirements and revisions is shown in Appendix B of this memo. CPSC staff believes this mandatory standard for bassinets and cradles will help reduce injuries and deaths associated with mattress flatness issues, false latching of removable bassinet beds and/or stability.

Appendix A - Review of Foreign Standards:

COMMON PERFORMANCE/TEST PARAMETERS

ESME compared European, Canadian, and Australian standards to the ASTM standard. The common performance/test parameters are given in the table

S. No.	Description	ASTM F2194 – 07ae1	EN 12790-2009 (reclined cradles) European	EN 1130 1&2:1996 (furniture, cribs and cradles) European	SOR/86-962 - 2010 Canadian	AS/NZS 4385:1996 Australian
1	Calibration and Standardization	4	6.1	N/A	N/A	8.1
2	Lead in Paints	5.1	4.1	N/A	23	4.2-4.6
3	Hazardous Sharp Edges or Points	5.2	5.4	4.2	20/13	6.8
4	Small Parts	5.3	5.5/6.4/6.2.3	4.2.8	17/SCHEDULE IV	N/A
5	Wood Parts	5.4	N/A	4.1	N/A	4.1
6	Scissoring, Shearing, Pinching	5.5	5.3	N/A	19	N/A
7	Unintentional Folding (latching or locking devices)	5.6/7.5.1 /7.5.2	5.8/6.6	5.10	6	6.4/6.5
8	Openings	5.7	5.2/6.3	4.2.2	11/SCHEDULE II	6.2/6.3/8.2/Appendix A
9	Labeling	5.8.1/7.2 .1-7.2.3	5.18/6.18	7	N/A	N/A
10	Fasteners	5.9	N/A	4.2.3	N/A	5.2/5.3
11	Corner Posts	5.10	5.4	N/A	12	N/A
12	Toys	5.11	N/A	N/A	N/A	7
13	Spacing of Rigid-Sided Bassinet/Cradle Components	6.1/7.1	N/A	4.4.1	11/SCHEDULE II	N/A
14	Openings for Mesh/Fabric-Sided Bassinet/Cradle	6.2/7.6	5.2/6.3	4.4.3	14	N/A
15	Static Load	6.3/7.3	5.13/6.12	4.3	16/SCHEDULE III	8.3/Appendix B
16	Stability	6.4/7.4	5.12/6.11/6.2.8/6.1/6.2.1/6.2.2	4.5	N/A	8.4/Appendix C
17	Sleeping Pad	6.5	N/A		15	N/A

18	Protective Components	6.6/7.7	N/A	5.4	21	6.7
19	Marking and Labeling	8	7.2	7	4	11
20	Instructional Literature	9/8.3/8.4	7.4/7.3/7.1	6	N/A	10.1/10.2
21	Flammability	N/A	4.2	N/A	24	N/A
22	Springs	N/A	5.7/6.5/6.2.2	N/A	22	N/A
23	Non-permeable packaging	N/A	8	5	N/A	9
24	Reclining system	N/A	5.9/5.10/6.7/6.8/6.2.1/6.2.2	N/A	N/A	6.5/ 8.6/Appendix E/ 8.7/Appendix F
25	Angle and height of seat unit	N/A	5.10/6.8/6.2.1/ 6.2.2	N/A	N/A	8.5/Appendix D
26	Rocks or Swing Angle.	6.8	N/A	N/A	7	6.4,6.5,8.5,8.6
27	Side height	6.5.4	N/A		8,9	6.1

ES believes the following performance requirements and tests address the more serious hazards. The following discussion compares the standards.

Unintentional Folding (latching or locking devices)

The European standard (EN 12790) is the most stringent standard on the basis of the specifications and the tests it requires for the performance of latching and locking mechanisms of cradles. It specifies a cyclic test of 300 cycles using a 33 lb force. The ASTM standard is rated the second most stringent as it has very specific requirements to evaluate the latching and locking mechanism for unintentional folding of the component with an application of a 10 to 20 lb force.

Openings

The ASTM, EN 1130 and Canadian standards address finger entrapments and head entrapment in openings. EN 12790 only addresses finger entrapments. The Australian standard has requirements to address finger, limb, and head entrapment. ASTM has unique requirements for fabric-sided bassinets and to test for entrapment when the fabric is not attached properly. ESME believes that the ASTM standard is the most stringent.

Static Load

The Canadian standard requires that the crib/bassinet withstand a cyclic test of 9,000 cycles using a 27 lb force. This requirement was designed to address hazards in rigid-sided products (cribs). The Australian standard is rated the second most stringent, as it has similar requirements. It prescribes a test load of 66 lbs, but there is no cyclic test. The ASTM standard prescribes a test load of 54 lbs or 3 times the manufacturer's recommended weight. The European standard (EN 1130) is the least stringent, with a test load of 44 lbs. Since these test parameters are not directly comparable, it is difficult to determine what is most stringent. With the exception of the Canadian cyclic tests, the other standards are similar in test methods.

Incident data reported to CPSC staff does not show that bassinets are collapsing, which indicates that the static load requirements are reasonable.

Stability

The ASTM standard is the most stringent on the basis of the test load and the type of tests conducted for the stability of the cradles. It requires the performance of a cradle under a test load of 23 lbs. The Australian standard is the least stringent, with a test load of 20 lbs, and with fewer requirements. The ranking is based on the test load/force, the number of tests conducted, and the number of requirements used to judge the stability of the cradle under the test conditions. The Canadian Regulation has no requirement for this parameter.

Sleeping Pad

The ASTM standard is more stringent as compared to the Canadian Regulations in the dimensional requirements of the Sleeping Pad/Mattress. The Australian and the European standards have no requirement for this parameter.

Rock/Swing angle

The European standards (EN 12790, EN 1130) do not have requirements for rock/swing angles. The Canadian standard specifies a maximum rock/swing angle of 20 degrees, but it does not specify a rest angle. The ASTM standard has a maximum rock/swing angle of 20 degrees and a maximum rest angle of 7 degrees with the CAMI positioned to the side of the rocking cradle. The Australian standard also has a maximum rock/swing angle of 20 degrees, but it requires that the cradle come to a rest angle of less than 5 degrees with the test dummy positioned along the centerline of the cradle. The position of the dummy in the center will help balance the cradle. Therefore, ASTM has the most stringent standard.

Side height

The Canadian, Australian, and ASTM standards specify a minimum side height. The Canadian and Australian standards specify the height from the mattress support. The ASTM specifies the side height from the mattress surface. Since mattress thickness can vary, staff believes that the ASTM requirement is the most effective.

Unique Requirements

ASTM is unique because the scope includes Bassinet/Cradle Attachment to Play Yard/Non-Full-Size Crib. The standard specifies that:

> *Bassinet/Cradle Accessory to Play Yard/Non-Full-Size Crib* –A bassinet accessory intended to be attached to, removable from, sold with, or separately from a play yard or non-full-size crib shall comply with the requirements of this specification and Consumer Safety Specification F406, when attached in the manufacturer's recommended use position.

Many play yards include a bassinet attachment. ASTM is the only standard that specifies these products. The Australian Standard, AS/NZS 4385:1996, has the unique requirement which specifies that all components of the rocking cradle shall be permanently fixed; or require the use of a tool to enable partial or total disassembly. This results in bassinet beds that cannot detach from the stand or base. This is a popular feature in the United States; however, there have been some incidents associated with detachable bassinet beds.

Appendix B
CPSC Staff-Recommended Revisions to ASTM F2194-12 Standard

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

A) Revised Scope and Associated Definitions

1.0 Scope
1.3 This consumer safety performance specification covers products primarily intended to provide sleeping accommodations ~~only~~ for an infant up to approximately 5 months in age, or when the child begins to push up on hands and knees, whichever comes first. Products used in conjunction with an inclined infant swing or stroller, or products that are intended to provide an inclined sleep surface (head-to-toe direction) of greater than 10° from horizontal, while in the rest (non-rocking) position, are not covered by this specification.

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 free standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which 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 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.

B) 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.

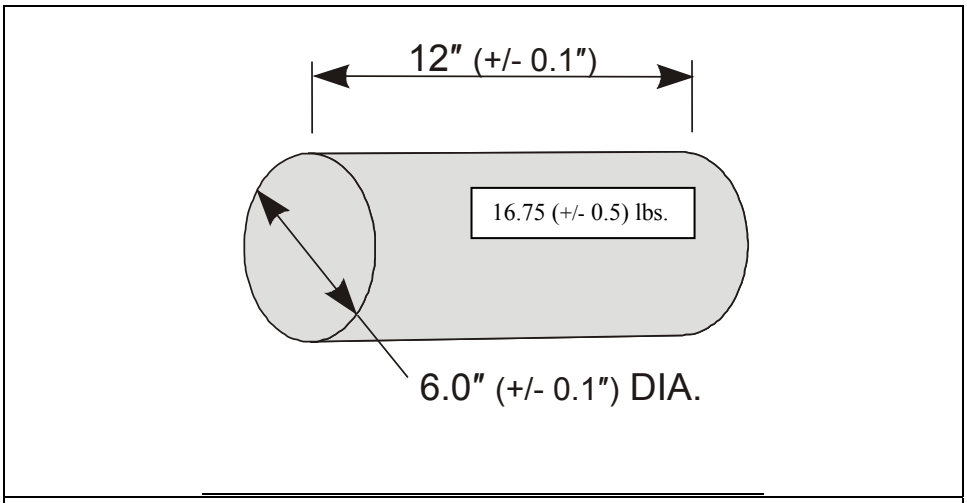


FIG. 13. Infant Test Cylinder

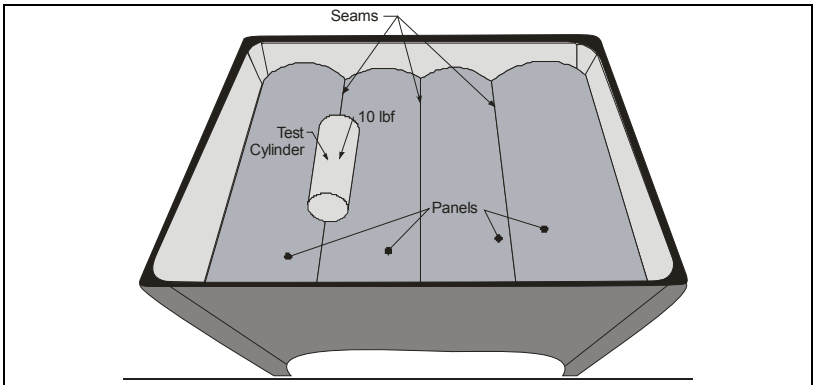


FIG. 14. Cylinder placement on mattress seam

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. 17. 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.

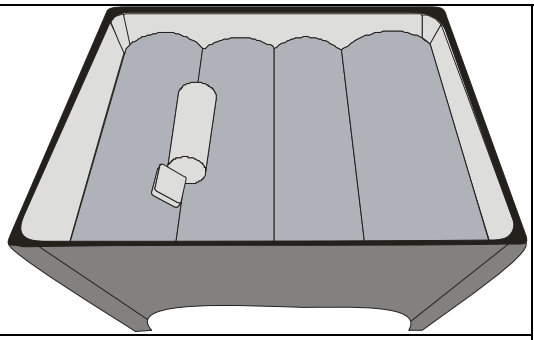


FIG. 15. Steel block in front of the cylinder for a single occupant bassinet

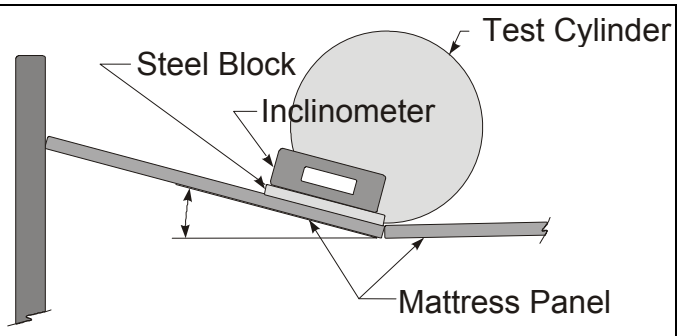


FIG.16. Inclinometer on steel block in front of the cylinder for a single occupant bassinet

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.

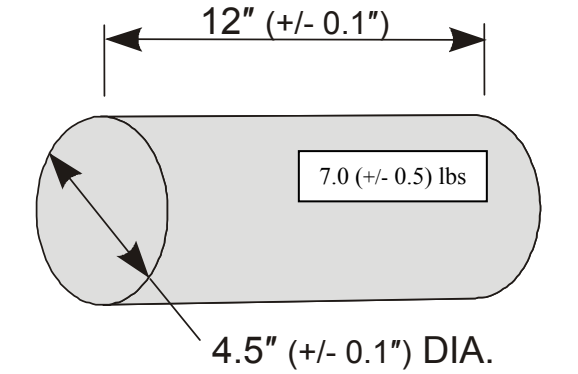


FIG. 17. Newborn Test Cylinder

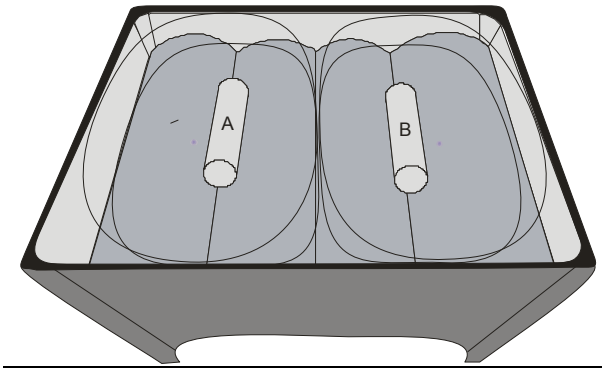


FIG. 18. Placement of cylinders for a 2 occupant bassinet

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.

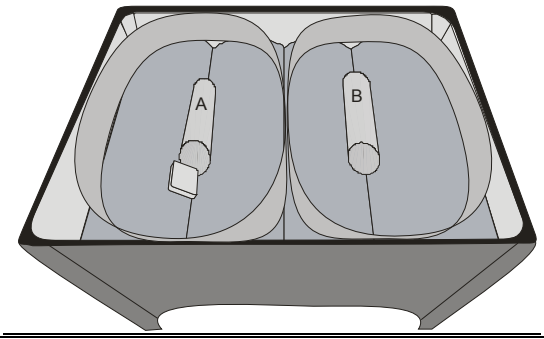


FIG. 19. Steel block in front of the cylinder for a 2-occupant bassinet

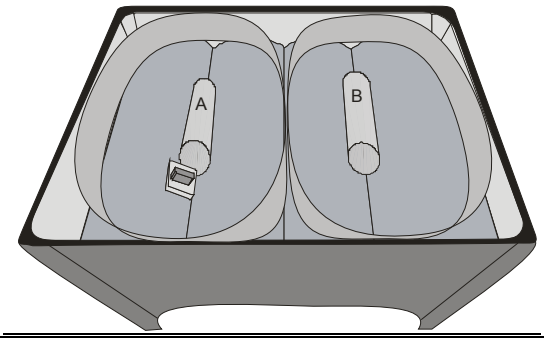


FIG. 20. Inclinometer on Steel block in front of the cylinder for a 2-occupant bassinet

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. 22.
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.

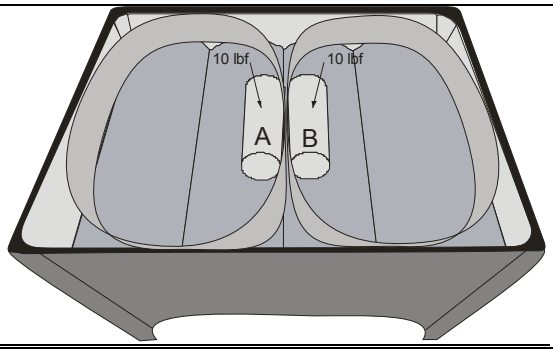


FIG. 21. Two cylinders (A and B) in contact with the inside wall

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.

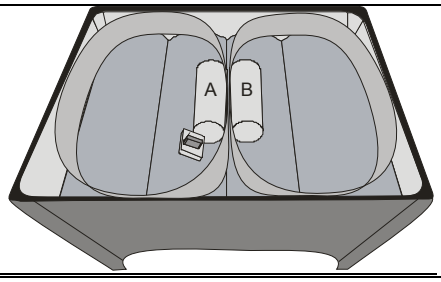


FIG.22 Angle measure in front of Cylinder A

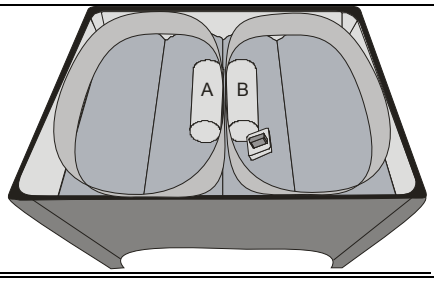


FIG. 23. Angle measure in front of Cylinder B

Rationale:

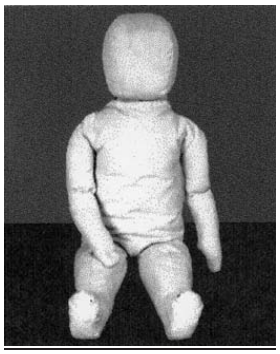
The cylinder used in 7.10.1 was copied from a European standard for baby walkers (EN 1273:2005) and appears to be based on the weight and torso dimensions of a child between 6 and 8 months old. This represents the heaviest intended occupant, which will result in a more conservative test.

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.

C) Revised Test Procedure for Bassinet Stability

3) Add reference for the CAMI Newborn dummy.

2.3 CAMI Newborn Dummy (See Fig 1a)[19]



[19] Drawing numbers 126-0000 through 126-0015 (sheets 1 through 3), 126-0017 through 126-0027, a parts list entitled "Parts List for CAMI Newborn Dummy", and a construction manual entitled "Construction of the Newborn Infant Dummy" (July 1992). Copies of the materials may be inspected at NHTSA's Docket Section, 400 Seventh Street, S.W., Room 5109, Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FIG. 1a CAMI Newborn Dummy

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

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 50th percentile 6-month-old infant.

D) 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 visually alert caregivers when a removable bassinet bed is not properly locked 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

6.10 *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 6.10.1, 6.10.2, 6.10.3, 6.10.4 or 6.10.5 when tested in accordance with 7.11.

6.10.1 The base/stand shall not support the bassinet bed (*i.e.*, the bassinet bed collapses from the stand and contacts the floor).
6.10.2 The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action).
6.10.3 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.
6.10.4 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.
6.10.5 The bassinet bed shall not tip over and shall retain the CAMI newborn dummy.

7.11 *Removable Bassinet Bed Attachment Tests*

7.11.1 Assemble the bassinet/cradle base/stand only, in accordance with manufacturer's instructions.
7.11.2 Place the base/stand in one of the manufacturer's recommended use positions.
7.11.3 Place the base/stand and the inclinometer on a flat level horizontal surface (0 +/- 0.5°) to establish a test plane. Zero the inclinometer.
7.11.4 Remove the mattress pad from the bassinet bed.

NOTE —For mattresses that are integral with the mattress support, do not remove the mattress and perform all angle measurements for 7.11 on a 6 by 6 by 3⁄8-in. nominal aluminum block placed on the center of the mattress.

7.11.5 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 (see Figure 24), the unit shall be evaluated in the lateral position most likely to fail the requirements outlined in 6.10.

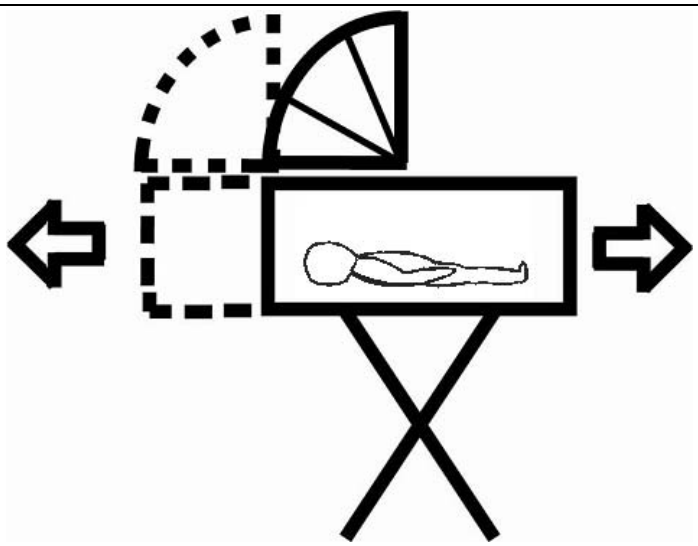


Figure 24: Bassinet Bed Resting on Stand,
Showing Possible Alternate Lateral Positions

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

7.11.5.2 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 6.10.4.

7.11.5.3 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 visual indicator, test the unit in accordance with sections 7.4.2-7.4.7.

7.11.6 Repeat 7.11.3 through 7.11.5.3 for all of the manufacturer's base/stand positions.

7.11.7 If the product design allows, repeat 7.11.2 through 7.11.6 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 properly locked/latched 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 properly engaged can create a false sense of security by appearing to be stable. Unsecured or misaligned lock/latch systems are a hidden hazard because they not easily seen by consumers due to being located beneath the bassinet or 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 properly secured.

6.10. allows bassinet bed designs that:
1) cannot be supported by the base/stand in an unlocked configuration,
2) automatically lock 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 properly locked onto the stand/base, or
5) have lock/latch mechanisms that are not necessary to provide needed stability.

TAB C:

Bassinets and Cradles Standard: Human Factors Issues

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

Memorandum

Date: July 30, 2012

TO : Patricia L. Edwards, Division of Mechanical Engineering, Directorate for Engineering Sciences

THROUGH: DeWane Ray, Assistant Executive Director, Office of Hazard Identification and Reduction

Robert B. Ochsman, Ph.D., Director, Division of Human Factors

FROM : Jonathan D. Midgett, Ph.D., Office of Hazard Identification and Reduction

SUBJECT : Bassinets and Cradles Standard: Human Factors Issues

I. Introduction

The Consumer Product Safety Improvement Act of 2008, Public Law 110–314 ('CPSIA') was enacted on August 14, 2008. The Danny Keysar Child Product Safety Notification Act requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission proposed a safety standard for bassinets and cradles in the *Federal Register* (75 Fed. Reg. 22303, April 28, 2010) based on the voluntary standard, ASTMF2194–07a$^{\varepsilon 1}$ "Standard Consumer Safety Specification for Bassinets and Cradles." This notice of proposed rulemaking (the 2010 NPR) requested comments from the public. On June 1, 2012, after several years of development and balloting, ASTM approved a substantial revision to the standard (F2194-12). This memorandum explains the major issues related to the human factors of bassinet and cradle use and injury prevention that have been discussed during ASTM subcommittee meetings and in comments submitted after the 2010 NPR.

II. Discussion

Scope of the Bassinet Standard

The scope of the 2010 NPR included infant hammocks. Most hammocks have mattresses that are inclined in a manner that elevates the head, and are flexible in order to conform to the body contours of the infant. They are also intended to allow swinging or bouncing motions. Sometimes these special features, especially elevating the head, are intended to possibly help

prevent reflux. Features that allow head elevation, swinging, and bouncing motions distinguish these products from common bassinets and cradles which generally have flat mattresses with solid or fabric-covered framed sides. Such specialized design features would prevent hammocks from meeting the performance criteria in the bassinet standard addressing rest angle, flatness angle, and maximum rock/swing angle. Including them in the scope would effectively ban hammocks.

Some commenters to the 2010 NPR feel that hammocks or other inclined sleeping products should not be included in the scope of the rule. The commenters express the belief that such products have some utility for consumers and noted that banning them might increase hazardous sleeping arrangements, by causing consumers to resort to a substitute product such as a car seat or makeshift soft bedding to prop up the infant. One commenter felt that Moses baskets (portable cradles, typically made from wicker or cloth, with no legs or a stand), which are currently outside the scope of the bassinet standard, should be included.

Staff agrees that alternative products or makeshift products would present additional hazards if consumers chose to use them instead of cribs, bassinets, or other common juvenile products intended for sleep. Due to significant progress in the development of a separate voluntary standard to address hammocks and inclined sleeping products, staff is now recommending that these products not be included in the scope of the proposed rule. Because Moses baskets have the added feature of portability, and therefore, match more closely the scope of the handheld infant carrier standard, staff favors excluding them from the proposed rule too, instead including them in the infant carrier standard.

The development of the bassinet standard affects other juvenile product standards, such as the inclined sleeper standard, the bedside sleeper standard, and the play yard standard, all of which either refer to the bassinet standard or have requirements meant to mirror those in the bassinet standard.

The current draft inclined sleeper standard defines an "inclined sleeper" as having more than a 10-degree incline sleep surface. This 10-degree minimum mirrors the ASTM definition(s) of a "bassinet/cradle" currently being considered for ballot. Writing the scope of each standard and their corresponding definitions in this manner ensures that all infant sleep products will be covered by at least one of the standards. This change in scope for the ASTM bassinet standard is in the balloting process, and thus, it is not part of F2194-12. For the bassinet NPR, staff recommends revising the scope and corresponding definitions in the bassinet standard to match what ASTM has balloted; staff also recommends excluding from the bassinet NPR products with sleeping surfaces greater than 10 degrees from the horizontal and clarifying exactly what products are included. The revised scope and the definitions can be found in Appendix B of Tab B, Engineering Sciences memorandum.

Restraints

The 2010 NPR proposed prohibiting bassinets with restraints that require action on the part of the caregiver to secure the restraint. A commenter requested that bassinets be allowed to have restraints. Staff believes that a bassinet should be a safe area for sleeping and rolling around—whether in the center of the occupant retention space or at the edges. Staff believes that to be

safe, the sleeping surface should be free of barriers, loops, straps, buckles, and other obstacles commonly comprising restraint systems. The presence of a restraint on the sleeping surface might cause the consumer to place the baby next to the restraint when they do not want to use it, thinking that sleeping on the restraint would be uncomfortable. Also, caregivers might be inclined to add folded blankets or quilts on top of the restraints covering them to provide a more comfortable sleeping surface. This creates a suffocation hazard for infants.

Only the last of the commenter's reasons listed above would be addressed by the presence of a restraint. The primary reason staff believes that restraints should not be allowed in bassinets is that most bassinet uses do not require a restraint; so consumers have a strong motivation to avoid using restraints if they were to be provided. When unused, restraints have been known to entrap and strangle children in similar products, such as swings, handheld infant carriers, and bouncers. Based on the number of incidents associated with unused restraints and the limited utility of a restraint in a bassinet, the ASTM subcommittee chose to create a requirement that prohibits restraints in the recently approved voluntary standard, F2194-12. CPSC staff concurs with this new requirement. While none of the bassinet incidents noted by the commenter were associated with restraint harness strangulation, this is probably due to the fact that the presence of restraints on bassinets is rare, not because restraints would not present a hazard if they were present.

Alternative products intended for mobile use, in addition to sleep, should conform to other applicable standards. For instance, bassinets should not have the portability of a stroller, without meeting the requirements of the stroller standard.

Characterization of such multiuse products presents a perennial challenge to standards developers. Currently, products that provide a sleeping surface for infants include: carriages, strollers, swings, hammocks, bouncers, handheld carriers, bassinets, bedside sleepers, and inclined sleeping products. All of these product categories already have a standard or draft standard under development. It is possible to design multiuse products that could span two or more of these product categories. In general, industry members and consumer advocates recommend that a multiuse product should conform to all of the applicable standards.

A challenge is created for multiuse products by the restraint systems. Strollers are required to have a restraint, but bassinets are not allowed to have them. Staff recommends that the foreseeable uses of products dictate the categorization scheme. Products with sides that contain the infant should ***not*** have restraints because the sides of the product provide a strong incentive for consumers to avoid using the restraints, which would leave the occupant at risk of strangulation on the straps. Likewise, products that need restraints because they are meant to be moved or they rock and swing, should ***not*** have tall sides that appear to fully contain the child in such a manner that convinces consumers the restraints are extra. Consumers should have a strong incentive to use restraints if they are available. Providing two or more means of occupant containment can confuse users into relying on just one of the means of containment and avoiding the other. For this reason, flat sleeping surfaces should ***not*** have restraints, but they should have tall sides. Inclined sleeping surfaces *without sides* should have restraints. Inclined sleeping surfaces *with sides* do not need restraints unless the surface is very steep. If a sleeping surface provides containment of the occupant with contoured surfaces, those surface formations should be free of entrapping spaces, tilt angles, or any surface forms that could entrap occupants in a

hazardous position. In keeping with this reasoning, staff supports restricting the use of restraints in bassinets in the proposed rule.

Tilting Sleeping Surfaces

Bassinets that are commonly sold as accessories to play yards use the floor of the play yard (a segmented mattress pad) as the floor of the bassinet. Because this type of bassinet is suspended within the play yard, it is critical that the base of the bassinet be properly supported and attached to the top rail of the play yard. Staff has identified incidents associated with a sleeping surface that is not level, or flat, with respect to the horizontal. This hazard can present itself in two ways, either when lying in a valley, formed by a non-level segmented mattress or on a sleep surface that is tilted (*i.e.*, in a rocking bassinet). The play yard voluntary standard requires these accessories to meet the bassinet voluntary standard once assembled according to the manufacturer's instructions.

Despite the proven effectiveness of the recommendation to place infants to sleep on their backs to reduce the possibility of SIDS and suffocation, there remains a significant number of caregivers who continue to place infants to sleep in the prone (on the stomach) position. Infants under 6 months of age are at the highest risk for SIDS and suffocation. In addition to placing the infant in the prone position to sleep, the presence of large quilts, comforters and pillows placed under the infant can further add to the risk of suffocation.

Segmented Mattress Flatness:

Seams between segments of folding play yard bassinet accessory mattress pads have been known to create a valley shape, in a bassinet sleeping surface, in the crease between adjoining segments of the mattress. Safe sleep messages tell caregivers that infants should be placed to sleep on their backs on a firm sleep surface. This is because in the prone position young infants are not able to remove themselves from positions that compromise their breathing and puts them at risk for suffocation. However, an inclined sleeping surface (on a product not intended to provide a contour or other means to contain the child) can help an infant to roll, increasing the likelihood that they will be found face down and become trapped in a significant V-shaped crease which can obstruct the nose and mouth on both sides of the V. Furthermore, caregivers who are unaware of common safe sleep tenets may still opt to place their infants in the prone position. When lying prone in a valley (or V-shaped crease), infants may have more difficulty keeping their airways unobstructed than when on a flat surface because their faces are trapped in the juncture between adjacent surfaces. Their heads cannot rotate to the side as much as when the sleeping surface is flat. Immature head control and weak neck muscles may not allow them to free their airways.

Fatal incidents involving play yard attachment bassinets with insufficient mattress support (090213HCC1421, 090706CWE8347, 100421HCC1630, 110825CAA2853[20]) have introduced a new hazard for staff to consider, especially for infants placed to sleep in the prone position. Infant sleeping surfaces that are intended for common, everyday uses need to be as firm, flat and

[20] Note: This IDI is not included in the Epidemiology memo (Chowdhury, 2012, Tab A), because it was included in the data used for the Final Rule briefing package for play yards. It has been included here for discussion purposes because the manner of death is related to a non-level segmented mattress.

level as possible because soft, uneven and non-level surfaces may create a higher risk of suffocation than a level surface.

In the in-depth investigation, 090213HCC1421, the product was apparently assembled without two key structural support bars beneath the mattress pad of a bassinet accessory that was intended by the manufacturer to be mounted from the top rails of the play yard. The incident was categorized as a "level issue" by CPSC staff [see Chowdhury (2012)]. The incident summary states:

> *A 3 month and 26 day old male victim was found deceased inside a play yard. The medical examiner (ME) determined that the cause of the death was asphyxia. The victim was found face down in a crease produced by the mattress. He was pronounced deceased at the hospital.*

Staff notes that requirements to ensure that key structural supports are properly installed by consumers would have helped prevent this incident from occurring. The Bassinet Misassembly Provision NPR, expected to be published on August 29, 2012, is a Commission-directed NPR to amend the play yard mandatory standard to include a provision to address the hazards associated with play yard bassinet accessories that can be misassembled. However, there has never been a requirement for sleeping surfaces to be flat or even nearly flat, which is the critical feature of the product that constitutes a hazard. A play yard could be designed to position the occupant in a valley, such as the one seen above, and would still pass the play yard standard and the misassembly provision. Staff believes both requirements are necessary to address these hazards: (1) a missing component requirement to prevent installation/use of a bassinet accessory that has a key component missing; and (2) a flatness requirement to ensure segmented mattresses, like those found in bassinet accessories, are flat when assembled according to manufacturer's instructions.

In the in-depth investigation, 090706CWE8347, the victim was in a bassinet accessory to a play yard that was also misassembled (See Figure 1). The incident summary states:

> *A two month old male was found unresponsive in his . . . playard with no signs of trauma. The child had rolled in the bassinet section causing his face to be placed in the corner of the bassinet. He was lying on a blanket with another blanket on top of him. Investigators who initially measured the bassinet at the scene reported that one side was five inches higher than the other. I observed during my investigation that depending on weight and movement that there will be a variance in height within the unit.*

Other risk factors also may have contributed to the incident (*e.g.*, the placement of the infant to sleep in the prone position and the presence of a blanket under the infant), but staff mentions this case here because it illustrates the potential for non-level sleeping surfaces to contribute to bassinet occupants getting into fatal positions from which they may not be able to remove themselves.

Figure 1: Tilted mattress pad

In the in-depth investigation, 100421HCC1630, a victim with serious physical challenges who was placed face down to sleep (note – both of these are additional risk factors) was found in a sagging bassinet accessory to a play yard. The incident report states:

> *The mother was using the elevated playpen platform for her 5 month old male baby's sleeping area. He was born with multiple physical complications including the inability to swallow and would drool constantly. The parents placed the infant in the playpen at night face down and awoke to find he had expired in the middle of the night. The playpen elevated platform showed sagging in the center possibly due to incorrect assembly of the playpen.*

Figure 2 (below) shows the bottom of the mattress pad next to a straight table leg to show the curve of the mattress pad.

Figure 2: Sagging mattress pad

In the in-depth investigation, 110825CAA2853, a baby died in the corner of a tilted bassinet accessory on a play yard. A rod intended to be placed in a pocket at the end of the accessory was left out. When a clip on the corner of the bassinet came off for unknown reasons, the sleeping surface tilted downwards, allowing the infant's head to become entrapped.

> *An 89 day old female died while napping in a play yard with bassinet attachment. One of the corners of the bassinet attachment became detached from the frame of the play yard as a result of one of the plastic clasps somehow becoming dislodged from the frame of the play yard. This apparently caused the victim's head to become entrapped in a pocket in the corner of the bassinet attachment.*

In addition to the fatal incidents mentioned above, a nonfatal in-depth investigation, 100610HCC1837, was found to be associated with the same hazard. In this IDI, a child in a bassinet accessory of a play yard was noticed to roll into seams on the sleep surface, but she was not injured. The incident report states:

> *No injury occurred to a five-month-old female, who while asleep in the bassinet section of a portable and collapsible play yard rolled into a seam of the removable changing pad*

used with the bassinet. The mother of the five-month old noticed that the five month old had a tendency to roll into seams of the mattress pad when it was used with the bassinet.

Tilting in Rocking Bassinets and Cradles

Non-level (tilted) sleeping surfaces are also relevant to cradles and rocking bassinets, but the cause of tilting in cradles and rocking bassinets is different from the causes in bassinet accessories with segmented mattresses. The sleeping surfaces of rocking cradles and bassinet products are usually not segmented. When considering this issue in rocking bassinets, the hazard deals with products that remain at a tilted angle after the rocking action stops. In the in-depth investigation, 110304HCC1366, a rocking cradle was not locked to hold the sleeping surface in a level position, as intended. The resulting tilted sleep surface helped hold the child against the side of the cradle, where her airways were occluded. The incident summary states:

A one month old female was wrapped in a blanket and placed to sleep in a bassinet. The victim woke up for a feeding and her mother then placed the victim in the bassinet toward the top of the mattress pad on her back with a pacifier in her mouth. The victim was found deceased with her face pressed against the side of the rocking bassinet.

In the in-depth investigation, 081204HCC3172, the victim was rescued without injury after being pressed by gravity against the side of a tilted cradle. The incident report states:

The victim is a two-month-old male who was sleeping in a "rocking" bassinet, located in his parent's bedroom, which had been secured into a fixed position with a built in locking mechanism. The child's mother was awakened by sounds of respiratory distress from the infant. She found that the locking mechanism had released and the child had rolled to one side, causing the bassinet to lean sharply. The child's face was pressed into the bassinet's side. The mother picked him up and he recovered almost instantly, with no signs of injury. Medical attention was not sought.

In the in-depth investigation, 091201CWE8548, the victim was rescued with CPR after rolling over in a cradle that could tilt to one side. The incident report states:

A new bassinet tilted to one side while it was locked causing a 21-day-old female, who had been lying face up in it, to turn face down. The incident happened in her parents' bedroom after she was left alone in the bassinet for less than 30 minutes. When the mother found the baby face down, she thought the baby was not breathing and quickly did CPR on her. The infant suffered no injury.

The incidents involving rocking cradles underscore the need for sleeping surfaces to remain level during the night. Unlike a hammock or inclined sleepers that have sleep surfaces designed to conform around the occupant, bassinets need a level sleeping surface because tilted or non-level sleeping surfaces can allow the infant's body to roll or slide down toward the tilted end of the sleep area and become trapped in positions where their airways may be obstructed. Depending upon the degree of the tilted sleep surface, the infant may not be able to roll or move out of the

hazardous position. Tilted or non-level sleeping surfaces can also help an infant to roll sooner than their caregivers would expect.

The 2010 NPR had two requirements to ensure that sleeping surfaces remained level, one to address the concerns with rocking bassinets, and the other to address the hazards with segmented mattress pads. The first requirement proposed to prevent rocking bassinets from coming to a final resting position that was more than 5 degrees from the horizontal. This 5-degree requirement was based on research findings reported by Beal, et al. (1995) and the requirements in the Australian/New Zealand standard for infant's rocking cradles (AS/NZS 4385:1996). The conclusions from the Australian study suggest that a maximum 5-degree rest angle from rocking cradles could minimize the risk of an infant rolling and getting trapped in a corner or other entrapment/asphyxiation scenario.

The recently revised ASTM standard contains a new requirement that sets a maximum rest angle of rocking bassinets to 7 degrees. Staff is supportive of the new requirement, even though it is greater than the 5 degrees allowed in the 2010 NPR. The 5-degree limit was based on a test method that manually rocked a CAMI doll that had been placed in the center of the bassinet. After the manual rocking, the bassinet is allowed to come to rest, and then the angle measurement is taken on the sleep surface. The ASTM test method requires the CAMI doll to be pushed into one side of the bassinet, then manually rocked, and allowed to come to rest. This is a severe condition intended more for screening purposes than to reflect actual use. Because of the severity in the test condition, staff believes these two requirements, within their respective test contexts, are basically equivalent.

The second surface flatness requirement in the 2010 NPR specified a 5-degree maximum tilt angle for segmented sleeping surfaces, like those found in play yard bassinet accessories. The ASTM subcommittee for bassinets believed that the 5-degree maximum angle was not achievable within the tolerances necessary to manufacture play yard bassinet accessories; accordingly, they considered alternative test methods and requirements for sleeping surface flatness in products containing panels that are designed to fold the sleeping surface when the unit is stored.

In lieu of the 5 degrees proposed in the 2010 NPR for segmented mattresses, the ASTM subcommittee sent out to ballot a requirement that allowed up to 14 degrees on either side of a valley formed at a seam, with higher inclines possible if the sum of the two angles on either side of the valley did not exceed 28 degrees in total. This ASTM ballot item received many negative votes and was not approved for the standard.

The 14-degree angle was based on an extrapolation of angles formed by dimensions of *average* infant faces. By combining an infant's mandible width with dimensions of nasal protrusion, an isosceles triangle can be created that represents a cross-section of the volume of space beneath the nose. From this cross-section, one can extrapolate both the angle of the valley and the angle of the incline of the surface that would contact a prone infant's face. The angle resulting from the combination of the *average* facial dimensions is 15 degrees, from which the ASTM subcommittee subtracted a single degree for a factor of safety.

Note that this rationale treats the combination of these facial dimensions as if they represented rigid structures. In reality, faces are malleable and compressible. Furthermore, the malleability and compressibility of the sleep surface will have an effect on how much a valley conforms to an infant's face, too. Given these uncertainties, and the variability of the systems involved, Human Factors staff is uncomfortable using the *average* infant facial dimension as the basis for this requirement. A product that has a 14-degree angle in the valley formed at the seam of the mattress would leave about half of the potential occupant population unprotected from suffocation. Human Factors staff would normally recommend using the smallest users' anthropometrics for justifying requirements of this nature. If the facial measurements of the smallest infants are used [5th percentile, 0–5 month old, combined gender, mandible width—65.67 mm; 5th percentile, same age/gender, nasal protrusion—6.4 mm (Farkas, 1994)] to form the isosceles triangle, the resulting valley is 158 degrees, which yields an 11-degree angle of sleep surface incline from the horizontal (see Figure 3). If a single degree is subtracted from this incline angle for a minor factor of safety, the requirement becomes a 10-degree maximum incline from the horizontal. Assuming the angles derived from this anthropometric extrapolation are protective, the test should use the weight of the largest expected infants and a failure threshold equal to the smallest expected infants. This requirement would be designed to protect a majority of bassinet occupants, from the smallest to the largest.

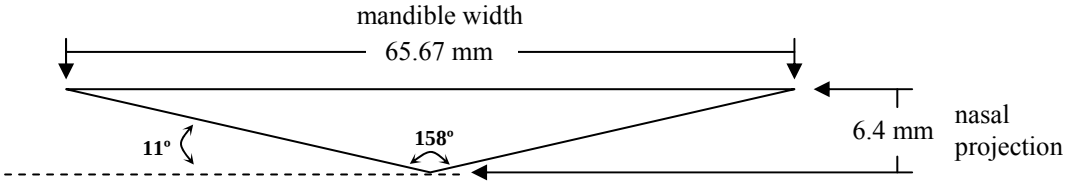


Figure 3: Mandible width and nasal projection

The main objective of the flatness test is to avoid valley-shaped indentations in a sleeping surface that require occupants to have to push against gravity to keep their airways unobstructed. In the staff's recommended test, each seam of a folding bassinet sleeping surface is tested with a pass/fail criterion of 10 degrees maximum for either side of the valley formed by a weighted cylinder.

In August 2012, ASTM reballoted the mattress flatness test. Several modifications were made to the test procedure, and CPSC staff was involved throughout the development of this requirement. The actual test procedure that was reballotted by ASTM is identical to staff's recommendation. However, the test requirement (the pass/fail criteria) is different. As mentioned above, staff is recommending a 10-degree maximum for any measurement taken. This is based on taking a single measurement on each side of each seam (for a total of 6 or 8 measurements per bassinet). ASTM is balloting a pass for 10 degrees or less for all measurements, a fail for one or more measurements that are greater than 14 degrees, and a two-step process for any angle measurement between 10 and 14 degrees, where the test lab would take two additional measurements at that location and average them, and then use 10 degrees as the final pass/fail criterion.

With regard to the test method itself, the 2010 NPR's method for testing flatness used a CAMI dummy to weight the surface prior to measuring the side angles of the valley formed in the sleeping surface. However, CPSC staff and the ASTM subcommittee prefer a rigid cylinder to help increase the reliability of the test across test laboratories. This is because CAMI dummies tend to vary slightly with age because of the nature of their construction. Staff tested a variety of cylinder diameters and lengths and found that small differences in the footprint of the test cylinder were not critical to differentiating hazardous from nonhazardous products. The most critical factor was the design of the mattress support structure. An exact replica of the human form is not necessary for this type of screening, and the benefits of using standardized, readily available test methods are appreciated by industry. As previously mentioned, the test procedure staff is recommending is identical to what ASTM recently balloted. The exact language for staff's recommendation for this test requirement and procedure are outlined in Appendix B of the Engineering Sciences memorandum, Tab B, of this briefing package.

Removable Bassinet Bed Stability

Staff is aware of several incidents involving bassinets that were designed to be removed from their stand, four of which have in-depth investigations (101101HCC3107, 101115HCC1107, 110512HCC2531, 110804CCC2788). During the incidents, the bed portion of the unit was not completely locked or attached to its stand. The bed portion of the unit appeared to be stable, giving the caregivers a false sense of security. For various reasons, the bed portion fell or tilted off of its stand. In one case (110512HCC2531), a 3-month-old infant was killed. CPSC staff was also informed by Health Canada, of a second death. In that e-mail correspondence from Health Canada staff, the following was reported:

> *It strongly appears the bassinet was not attached to the base when the infant was put down for a nap. When the infant was found, the bassinet was perpendicular to the base and had fallen into the base opening at an angle suspending the infant. The straps and hooks attaching the bassinet to the base were not snapped in.*

Staff has been actively involved in an ASTM task group that is currently developing requirements to address the hazards associated with bassinets with removable bed portions. To date, the task group language that has been drafted has not yet been balloted. Staff recommends adding a new requirement for the NPR, based on what the ASTM task group has developed to date. The recommended requirement allows multiple options to pass. These options will either ensure that the bed portion of the unit is inherently stable when it is placed on the stand unlatched, or it will give obvious feedback that the unit is not latched. One option allows the unit to give an extreme appearance of instability by being tilted 20 degrees or more. The 20-degree minimum is twice the allowable deviation from horizontal that staff recommends for sleeping surface flatness. This angle was extrapolated from an in-depth investigation report (101101HCC3107) of a caregiver who noticed that a bassinet was tilted. From photographs of the incident product, the ASTM task group assigned to examine the problem estimated that the unit produced about a 17-degree angle, which they felt would be reasonable to round up to 20 degrees for the standard. A sleeping surface at 20 degrees from the horizontal seems severe enough that consumers would notice that it was not level. This requirement is slightly less than the angle proposed to address similar hazards in the play yard standard (*i.e.,* 30 degrees from the horizontal), but the ASTM subcommittee reasoned that bassinets are different in structural

design and materials and will appear to be misassembled more easily than the suspended and segmented mattress supports used in play yards.

In addition to the options listed above, a bassinet that has a removable bed can also pass the requirement if it has a visual indicator to alert a caregiver that the bassinet bed is not properly locked onto the stand. Or, the bassinet can also pass the requirement if it can pass the standard's stability test, while in an unlocked position.

The reason that such designs need inherent stability (or obvious instability) is consumers will sometimes avoid activating lock or latch mechanisms if it appears that the bassinet bed is stable when placed on its stand/base. Consumers may do this because the locks or latches seem redundant or because they are worried about making noise when activating locks or latches around a sleeping infant. Locks and latches also accidentally may give feedback that they are locked when they are not. This constitutes a "false latching" situation. Because of these foreseeable use patterns, this requirement will make bassinets with a removable bed portion inherently stable or have visible indicators to show when it is not properly attached.

Stability Test Dummy

During evaluations of the test methods for removable bassinet beds, the ASTM task group and staff made comparisons of the stability of products weighted with either the newborn CAMI dummy (7.45 lbs) or the infant CAMI dummy (17.4 lbs). ASTM F2194-12 contains a stability requirement that uses the heavier infant CAMI dummy. Because bassinets are intended for use with newborns, staff believes that bassinet stability should be tested with the newborn dummy. The newborn CAMI is readily available to test labs and represents the 50th percentile newborn that is about 10 pounds lighter. Therefore, staff is including this change in our recommendations.

The Prominence of Warnings about Soft Bedding

The revised ASTM standard for bassinets, F2194-12, includes an enhancement of the soft bedding warnings by increasing the font size of the required labels and adding emphasis by stating that "Infants have suffocated, etc." rather than stating that "Infants can suffocate, etc." Staff supports the strengthening of warning label factors as included in the latest revision of the ASTM voluntary standard.

Some commenters advocate the use of pictorial elements in warning labels. Staff acknowledges that such elements could be developed with some empirical study; however, staff does not have the resources allocated for such a project at this time and could not validate a warning graphic without research. Staff is not making any more recommendations with regard to warnings at this time.

Warning about Replacement Mattresses

Although not specifically addressed by the 2010 NPR, several commenters present arguments against the statement currently used in the warnings in the ASTM bassinet standard: "*Use only the pad provided by the manufacturer*." The commenters believe that consumers should be able to purchase aftermarket replacement mattresses (called a "pad" in the warning) from firms other than the original manufacturer because aftermarket products can have additional benefits (organic materials or chemical-free) and be just as well suited to a product as one purchased from

the original manufacturer, and makeshift bedding would be more hazardous than an aftermarket replacement mattress.

The argument to change the warning label was also recently presented to ASTM for consideration in the voluntary standard. Many manufacturers felt uncomfortable allowing consumers to believe that using an aftermarket mattress (one not supplied by the manufacturer) was safe. Because of the objections, the ASTM subcommittee declined to ballot this proposal. CSPC staff is not making any recommendations with regard to this issue because it is not aware of any incidents associated with the use of replacement aftermarket mattresses or incidents associated with consumers encountering difficulties acquiring mattresses from manufacturers.

Baby Size Limits

Although not specifically addressed by the proposed standard, a commenter noted that, because "bassinets provide an important tool for parents to monitor premature babies," a target age range for infant occupants may be necessary to enhance the understanding of the developmental milestones used in the warning. They also suggest that if there is "a size at which a bassinet becomes unsafe for a baby" then that factor should be listed in the product's instructions and warnings. The 2012 version of the ASTM standard now includes a reference to the maximum recommended weight in the FALL HAZARD warning label. Staff supports this addition to the standard and does not feel anything else is warranted at this time to address this comment.

Sleeping Surface Thickness and Firmness

Although not specifically mentioned in the 2010 NPR, some commenters suggest that the 1-inch thickness limit on bassinet mattress pads could be encouraging consumers to add extra padding to infant sleep settings because they perceive the 1-inch pads to be uncomfortable. Some speculated that providing a thicker mattress with the same pliability would mitigate this perception and discourage, or at least not promote, the use of extra padding.

The reason that 1-inch pads were specified by the ASTM standard was because mesh or fabric-sided products can pose an entrapment hazard between the edge of a thick mattress and a fabric side. The fabric side can push outwards, allowing the infant to get wedged in the gap at the side of the mattress. If a product was designed not to allow a gap to form between the mattress and the sides of the unit, then the thickness of the mattress pad would be irrelevant, presuming it was also sufficiently firm. Mattress firmness is a concern because overly soft mattresses can pose a risk of asphyxiation to infants.

While soft bedding injuries are well known, how to quantify the firmness of a sleeping surface has been a challenge. Staff has considered a few mattress firmness test strategies, but due to the complexity of the testing and evaluation, we cannot validate them in time to meet the current schedule of rulemaking. Staff is continuing to pursue reliable methods of quantifying mattress firmness in the ASTM task group for crib mattresses.

The recently revised ASTM standard now allows rigid sided bassinets to have thicker mattresses. The standard's restrictions on gaps at the edges of mattresses are still sufficient to prevent hazardous areas from forming in rigid sided bassinets. With this revision, the mattress requirements for rigid sided bassinets are in alignment with those found for non-full-size cribs in

ASTM F406. Both of these products provide similar uses and construction, so staff concurs with the revision to the bassinet standard.

Side Heights

Side heights were not addressed in the 2010 NPR. However, several commenters from the bassinet industry, consumer advocacy groups, and Health Canada request that bassinets have a standard side-height requirement. The ASTM subcommittee for bassinets repeatedly debated a side-height requirement, and finally reached a consensus on the proper rationale for justifying one dimension over another, by aligning with Health Canada's requirement of 230 mm (9 inches) measured from the upper surface of the mattress support to the top of the side rail. This yields an effective side height of about 7.5 inches, after subtracting the allowable mattress thickness. The 2012 revision of the ASTM bassinet standard now contains a side-height requirement of 7.5 inches, as measured above the top of the mattress. Staff supports this revision and believes it may help reduce fall hazards.

III. Conclusion

Human Factors recommends the following modifications to the ASTM standard F2194-12 for the proposed rule:

1) the addition of a test requirement and test procedure to address the hazards associated with segmented mattress flatness;
2) the revision of the scope and corresponding definitions to add clarity with regard to when other products are under the scope of the standard;
3) the addition of a new test requirement, test procedure and associated definitions, to address the hazards associated with removable bassinet beds; and
4) the revision of the stability test procedure to use the newborn CAMI dummy instead of the infant CAMI dummy.

The exact wording for each of these recommendations can be found in Appendix B of Tab B, memorandum from Mark Kumagai, Engineering Sciences.

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TAB D:

Durable Nursery Products: Summary of Bassinets Recalls and Associated Injuries from October 2007 to June 2012

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

Memorandum

Date: August 17, 2012

TO Patricia Edwards, Bassinets Project Manager, Division of Mechanical Engineering, Directorate for Engineering Sciences

THROUGH Marc J. Schoem, Acting Director, Office of Compliance and Field Operations

Mary F. Toro, Director, Division of Regulatory Enforcement

Troy Whitfield, Mechanical Team Leader, Division of Regulatory Enforcement

FROM Edward Williams, Jr., Compliance Officer, Mechanical Team

SUBJECT Durable Nursery Products: Summary of Bassinets Recalls and Associated Injuries from October 2007 to June 2012

Purpose

This memorandum responds to a request from the Project Manager for the Bassinet/Cradle rulemaking team for compliance information relevant to the drafting of a safety standard for bassinets. Section 104 of the Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, 122 Stat. 3016 (August 14, 2008) (CPSIA), requires the Commission to study and develop safety standards for infant and toddler products, which includes bassinets. CPSC staff is drafting a rule for a bassinet standard for Commission consideration. The proposed standard addresses the hazards associated with bassinets through performance requirements that address bassinet stability, structural integrity, mattress flatness, swing and rest angles, entrapment potential, and recommended warning labels. This memo discusses recalls conducted by the Office of Compliance and Field Operations ("Compliance") and the reported injuries related to those recalls.

Compliance Investigation Information

Compliance staff reviewed the recalls and cases opened on bassinets from October 2007 to June 2012. During that time period, there have been a total of five consumer-level recalls involving bassinets.

On May 9, 2012, a recall conducted by Kolcraft Enterprises Inc. involved about 46,000 Tender Vibes & Light Vibes bassinets, manufactured from July 2008 through May 2010. The recall involved the latching system between the bassinet bed and the base. The latches that attach the bassinet base onto the metal frame can appear to be locked in place but still remain

unlocked. An unlocked bassinet can become detached from the metal frame, causing the bassinet to fall, potentially injuring the infant. There were seven incidents reported to CPSC and Kolcraft. One infant received a bruised cheek when the bassinet detached from the metal frame and landed sideways on the floor with the infant inside. Consumers were sent a repair kit, which consisted of straps to better secure the bassinet to the base.

A recall conducted by Burlington Basket Company on February 16, 2011, involved all bassinets manufactured before June 2010 that have folding legs attached to the basket with white plastic pins. If the cross-bracing rails were not fully locked into position, the bassinet could collapse, potentially causing infants to fall to the floor or fall within the bassinet and suffer injuries. Burlington received 10 reports of incidents in which two infants received minor injuries as a result of the collapses, including bruises to the head and shoulder. Consumers were supplied with better instructions and guidance on how to properly install the cross-braces.

A recall conducted by Dorel Juvenile Group Inc. in December 2009 involved five bassinet models. The recall was associated with the metal bars used to support the floorboard of the bassinet attachment. The bars can come out of the fabric sleeves and create an uneven sleeping surface, posing a risk of suffocation or positional asphyxiation. Dorel received no reports of injuries. Consumers were supplied with a repair kit, including replacement bassinet fabric, bassinet bars, and installation instructions.

Another recall conducted by Dorel Juvenile Group Inc. in May 2009, was associated with Eddie Bauer Soothe & Sway portable play yards. The two convertible play yard models involved included a bassinet and changing station feature. All 05046 models and 05044 models manufactured before December 1, 2008 were included in the recall. The play yard's rocking bassinet attachment was tilting, even when secured by straps in the non-rocking mode, or stayed tilted without returning to a level sleeping surface while in the rocking mode. These conditions could cause an infant to roll to the corner or side of the bassinet and become wedged in the corner or pressed against the side or bottom of the bassinet, posing a risk of suffocation or positional asphyxiation. Dorel and CPSC received 10 reports of infants rolling to one side, including six that had their faces pressed against the side or the bottom of the bassinet. One child reportedly was turning purple and was out of breath when discovered. No other injuries were reported. Consumers were asked to immediately stop using the bassinet attachment of the play yard. No repair kit was provided.

Simplicity conducted a recall in September 2008, involving bassinets with the Graco logo sold between 2001 and 2004, and a Winnie-the-Pooh motif, sold between 2002 and 2008. 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.® The fabric is folded down when the bassinet is converted into a bedside sleeper position. If the Velcro® is not properly re-secured when the flap is adjusted, an infant can slip through the opening and become entrapped in the metal bars and suffocate. CPSC learned that on August 21, 2008, a 6½-month-old girl from Shawnee, Kansas, died when she became entrapped and strangled between the bassinet's metal bars. This was the second strangulation death that the CPSC had learned of involving the co-sleeper bassinets. On September 29, 2007, a 4-month-old girl became entrapped in the metal bars of the bassinet and

died. Consumers were asked to immediately stop using the close-sleeper/bedside sleeper bassinets manufactured by Simplicity Inc. A number of retailers voluntarily agreed to recall the product and provide a refund or store credit to consumers.

TAB E:
Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Bassinets and Cradles

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

Memorandum

Date: July 16, 2012

TO : Patricia L. Edwards
Project Manager, Bassinets
Division of Mechanical Engineering
Directorate for Engineering Sciences

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

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

FROM : Jill L. Jenkins, Ph.D.
Economist
Directorate for Economic Analysis

SUBJECT : Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Bassinets and Cradles

Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires that the U.S. Consumer Product Safety Commission ("CPSC" or "Commission") evaluate the existing voluntary standards for durable infant or toddler products and promulgate a mandatory standard that is substantially the same as, or more stringent than, the applicable voluntary standard. Bassinets and cradles are among the durable products specifically named in the Danny Keysar Child Product Safety Notification Act.

On April 28, 2010, the CPSC published a notice of proposed rulemaking (NPR) in the *Federal Register* (FR) (75 Fed. Reg. 22303). The proposed rule incorporated by reference the voluntary ASTM International (formerly known as the American Society for Testing and Materials) standard for bassinets and cradles (F2194-07a$^{\varepsilon 1}$), with several modifications, including mattress flatness and rock/swing angle requirements.

As a result of new issues raised during the 2010 NPR comment period, and due to some changes in staff recommendations, the staff recommends that the Commission publish a

supplemental NPR for bassinets and cradles. Consequently, for this NPR, staff recommends adopting as a mandatory standard, the current voluntary ASTM standard for bassinets and cradles (F2194-12), with two new requirements and two modifications to existing provisions.

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 NPR 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 type of professional skills necessary for the preparation of reports or records; and
5. an identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

The Product

A bassinet/cradle is a small bed for infants supported by free-standing legs, a wheeled base, a rocking base, or that can swing relative to a stationary base. Neither a bassinet nor a cradle is intended to be used beyond the age of approximately 5 months or when a child is able to push up on their hands and knees. Bassinet and cradle attachments for non-full-size cribs or play yards are considered a part of this product category, as are bedside sleepers that can be converted to a four-sided bassinet not attached to a bed.

Cribs, Moses baskets[21], and products used in conjunction with an inclined infant swing or stroller, and products that are intended to provide an inclined sleep surface of greater than 10 degrees from horizontal, are *not* included under this product definition. However, Moses baskets and carriage accessories that can be converted into a bassinet or a cradle by attaching the Moses basket to a separate base unit would need to comply with the staff-recommended proposed standard for bassinets and cradles when the Moses basket is used with the base.[22]

Therefore, for purposes of the proposed standard, there are three relevant categories of products:

[21] A Moses basket is a portable cradle, typically made from wicker or cloth, with no legs or a stand.
[22] For example, several companies sell separate stationary (or, in some cases, rocking) bases for both Moses baskets and stroller carriage accessories.

1. Bassinets—this includes bedside sleepers, *if* they can be used as a four-sided bassinet, and other products that can be attached to a base unit and used as a bassinet;
2. Cradles—this is a rocking bassinet and includes other products that can be attached to a base unit and used as a cradle; and
3. Play yards—only those with bassinet/cradle attachments.

Although included in the 2010 NPR, staff is now recommending that infant hammocks and other inclined sleep products be excluded from the staff-recommended proposed standard and instead be covered by a separate standard that is still under development by ASTM and CPSC staff.

The Market for Bassinets/Cradles

Bassinets and cradles are typically produced and/or marketed by juvenile product manufacturers and distributors, or by furniture manufacturers and distributors, some of which have separate divisions for juvenile products. CPSC staff believes that there are currently at least 55 suppliers of bassinets and/or cradles to the U.S. market; 24 are domestic manufacturers, and 11 are domestic importers. An additional 14 domestic firms have unknown bassinet/cradle supply sources; three of those firms are retailers, and nine specialize in bedding, some of which is sold with bassinets or cradles. There are also six foreign firms supplying the U.S. market: five manufacturers and one importer that imports from foreign companies and distributes from outside of the United States.[23]

Bassinets and cradles from 12 of the 55 firms have been certified as compliant by the JPMA, the major U.S. trade association that represents juvenile product manufacturers and importers. Firms supplying bassinets or cradles would be certified to the ASTM voluntary standard F2194-10, while firms supplying play yards with bassinet/cradle attachments would also have to meet F406-11b.[24] Nine additional firms claim compliance with the relevant ASTM standard for at least some of their bassinets and cradles.

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*),[25] 64 percent of new mothers own bassinets, 18 percent own cradles, and 39 percent own play yards with bassinet attachments. Approximately 50 percent of bassinets, 56 percent of cradles, and 18 percent of play yards were handed down or purchased secondhand.[26]

[23] Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.
[24] JPMA typically allows 6 months for products in their certification program to shift to a new standard once it is published. F2194-12, the voluntary standard upon which the staff-recommended proposed standard is based, will become effective for JPMA certification purposes in January 2013.
[25] The data collected for the *Baby Products Tracking Study* does not represent an unbiased statistical sample. The sample of 3,600 new and expectant mothers is drawn from American Baby magazine's mailing lists. Also, because the most recent survey information is from 2005, it may not reflect the current market. In particular, it is possible that the mandatory crib standard that went into effect for manufacturers, importers, and retailers on June 28, 2011, could have changed the demand for bassinets/cradles and play yards with bassinet/cradle attachments.
[26] The data on secondhand products for new mothers was not available. Instead, data for new mothers and expectant mothers was combined and broken into first-time mothers and experienced mothers. Data for first-time mothers and

Thus, about 50 percent of bassinets, 44 percent of cradles, and 82 percent of play yards were acquired new. This suggests annual sales of about 1.3 million bassinets (.5 x .64 x 4.1 million births per year), 325,000 cradles (.44 x .18 x 4.1 million), and 1.3 million play yards with bassinet attachments (.82 x .39 x 4.1 million).[27] This yields a total of approximately 3 million units sold per year that could be affected by the proposed bassinet/cradle standard.

Annual injury estimates could not be made because there were an insufficient number of National Electronic Injury Surveillance System (NEISS) cases to meet Epidemiology publication criteria. Therefore, risk of injury estimates could not be made for bassinets/cradles.

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 a mandatory standard for bassinets/cradles that is substantially the same as, or more stringent than, the voluntary standard. CPSC staff worked closely with ASTM to develop the new requirements and test procedures that have been added to the voluntary standard since 2010. These new requirements address several known hazard patterns that will help to reduce injuries and deaths in bassinets and cradles, and they have resulted in the current voluntary standard, F2194-12, upon which the staff-recommended proposed rule is based.[28]

However, CPSC staff recommends adding two new requirements to F2194-12, as well as modifying the scope and the test CAMI used in the existing stability test. The first new requirement would address suffocation and positional asphyxia hazards that have occurred as a result of problems with segmented mattress flatness in play yard bassinet accessories. The second would address the stability of bassinets with removable bassinet beds, particularly the attachment mechanisms. Staff also recommends modifying the scope (and some of the terminology) to ensure that inclined sleepers (including infant hammocks) will no longer be covered under the bassinet/cradle standard, unless they recline to 10 degrees or less. The expanded scope would also include Moses baskets and stroller carriage accessories when used in conjunction with a stationary stand. These modifications will also ensure that there are no gaps in product coverage (*i.e.,* products that may be used for sleep will be included under at least one durable nursery product standard).[29] Finally, staff recommends that the CAMI newborn dummy be used for stability testing because it resembles more closely the characteristics of bassinet users than the CAMI infant dummy in F2194-12.

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experienced mothers have been averaged to calculate the approximate percentage that was handed down or purchased secondhand.

[27] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, "Births: Final Data for 2009," *National Vital Statistics Reports* Volume 60, Number 1 (November 2011): Table I. Number of births in 2009 is rounded from 4,130,665.

[28] Memorandum from Risana T. Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, dated April 10, 2012, Subject: Bassinet and Cradle-Related Deaths, Injuries, and Potential Injuries Reported Between November 2007 - December 2011; memorandum from Mark E. Kumagai, Division Director, Division of Mechanical Engineering, dated July 30, 2012, Subject: ESME Recommendations for the Bassinet & Cradles Standard; and memorandum from Jonathan D. Midgett, Office of Hazard Identification and Reduction, dated July 30, 2012, Subject: Bassinets and Cradles Standard: Human Factors Issues.

[29] Kumagai, 2012; and Midgett, 2012.

Requirements of the Draft Proposed Rule

CPSC staff recommends adopting the voluntary ASTM standard for bassinets and cradles (F2194-12) with a new mattress flatness requirement, a new stability requirement for bassinets with removable beds, a revised scope, and a modified CAMI dummy for the existing stability requirement. Some of the more significant requirements of the current voluntary standard for bassinets and cradles (ASTM F2194-12) are listed below. The requirements that were added to the ASTM voluntary standard or that have been modified since the 2010 NPR are italicized.

- Spacing of rigid side components—intended to prevent child entrapment between both uniformly and non-uniformly spaced components, such as slats. *This has been modified for clarity to remove duplicative test references.*
- Openings for mesh/fabric—intended to prevent the entrapment of children's fingers and toes, as well as button ensnarement.
- Static load test—intended to ensure structural integrity even when a child three times the recommended (or 95th percentile) weight uses it. *This has been modified to also test play yard bassinets in all four corners.*
- Stability requirements—intended to ensure that the product does not tip over when pulled on by a two year old male. *ASTM adopted the revised test requirements included in the 2010 NPR (includes testing with locks/latches engaged).*
- Sleeping pad thickness and dimensions—intended to minimize gaps and the possibility of suffocation due to excessive padding. *F2194-12 allows thicker mattresses for rigid-sided products because a thicker mattress does not pose the same suffocation hazard when used in rigid-sided, rather than soft-sided, products.*
- Tests of locking and latching mechanisms—these are intended to prevent unintentional folding while in use.
- Suffocation warning label—intended to help prevent soft bedding incidents. *F2194-12 requires the warning to use a larger font than the 2010 NPR.*
- *Fabric-sided openings test—intended to prevent entrapments. This test was included in the 2010 NPR and has been adopted in F2194-12 with a few editorial changes.*
- *Rock/swing angle requirement—intended to address suffocation hazards that can occur when latch/lock problems and excessive rocking or swinging angles press children into the side of the bassinet/cradle. The 2010 NPR recommended a maximum rocking angle of 20 degrees and a maximum rest angle of 5 degrees. ASTM F2194-12 adopts the maximum deflection angle of 20 degrees, but includes a maximum rest angle of 7 degrees with a more severe test condition where the CAMI doll is positioned at the side, rather than the center, of the bassinet/cradle.*
- *Occupant restraints—intended to prevent incidents where unused restraints have entrapped and strangled children. The 2010 NPR proposed that only passive restraints be allowed. ASTM F2194-12 is even stricter, allowing no restraints to be used in a bassinet/cradle configuration.*
- *Side height requirement—intended to prevent falls. This requirement, which is new to F2194-12, arose from the comments to the 2010 NPR. A bassinet/cradle side height of 7½ inches from the top of the uncompressed mattress is now required.*

The voluntary standard also includes: (1) torque and tension tests to ensure that components cannot be removed; (2) requirements for several bassinet/cradle features to prevent entrapment and cuts (minimum and maximum opening size, small parts, hazardous sharp edges or points, and edges that can scissor, shear, or pinch); (3) requirements for the permanency and adhesion of labels; (4) requirements for instructional literature; and (5) corner post extension requirements intended to prevent pacifier cords, ribbons, necklaces, or clothing that a child may be wearing from catching on a projection.[30]

CPSC staff recommends modifying the scope (see section A below), using the more appropriate infant CAMI dummy for stability testing (section B), and adding new mattress flatness (section C) and attachment of removable bassinet bed (section D) requirements to ASTM F2194-12. As part of these changes, there would also be several new or revised definitions, including bassinet/cradle, bassinet/cradle accessory, and bassinet bed.

A. Scope

There are three major changes staff recommends making to the scope of the bassinet/cradle standard:

1. Specify that it is to cover products primarily used to provide sleeping accommodations. This expands the scope beyond products only used to provide sleeping accommodations.
2. Exclude products with a greater than 10 degree incline, while encompassing products with a lower degree of incline. ASTM and CPSC staffs have developed this demarcation across product standards to ensure complete coverage of sleep products. This would include cradle swings which, by definition, recline less than 10 degrees from horizontal.
3. Include products that can be supported by a stationary frame/stand. This would bring in carriage attachments to strollers and Moses baskets *only* when used with a stationary or rocking stand.

These scope changes may affect suppliers in several ways. First, it would provide additional clarity to suppliers regarding which products would be covered under what standards. Reduced confusion means less time reviewing, testing, and making necessary modifications.[31] Second, "cradle swings," defined by the infant swings standard, F2088-11a, as an infant swing intended for use by a child lying flat (*i.e.,* horizontal), would be covered under both the bassinet standard and the infant swings standard. Staff believes that cradle swings currently on the market should be able to meet the staff-recommended proposed standard for bassinets without additional

[30] ASTM F2194-12 also contains modified calibration and standardization requirements included as part of the 2010 NPR, an updated referenced documents section, and several revised and new definitions.

[31] Because infant hammocks would no longer be covered under the staff-recommended standard, they would not be technically affected by the proposed rule. However, it should be noted that they were covered under the 2010 NPR, which would have been impossible for most infant hammocks to pass without eliminating many of the design features sought by consumers. Therefore, there is a substantial positive impact on infant hammock suppliers as compared to the 2010 NPR. Infant hammocks and other inclined sleep products will be covered (and eventually regulated) under the inclined sleeper standard currently under development.

modifications. Third, Moses baskets and carriage attachments to strollers would now be subject to the bassinet/cradle standard when used in conjunction with a separate stand. However, this would apply only to Moses baskets and carriages that are produced and sold by the same company that makes the stand, and therefore, are intended to be used together. Firms that supply bassinet/cradle stands, as well as either Moses baskets or carriage attachments for strollers, would need to ensure that their Moses baskets and/or carriage attachments meet the staff-recommended bassinet/cradle standard when attached to the stand(s). This would likely require some redesign, most notably to meet the side height and stability requirements, and it would affect 10 known firms. Alternatively, they could stop supplying the stands.

B. Stability Testing with Newborn CAMI Dummy

Because bassinets and cradles are intended to be used by very young children, it is appropriate that the smaller newborn CAMI dummy be used for stability testing. The heavier (17.5 pound) infant CAMI currently used for stability testing in F2194-12 could make these products more stable when tested than they would actually be in a real-world situation. Based on preliminary staff testing, it appears that most bassinet/cradles will be able to pass this modified test procedure without modification. However, when tested by ESME staff, one product failed the stability test with the newborn CAMI, while it passed with the infant CAMI. It is possible that a few products may require modifications to meet the revised stability test procedure. It is likely to affect only a few manufacturers, but it is unlikely to require product redesign. Affected firms would most likely increase the stability of their product by widening the structure, making the bassinet bed deeper, or making the base heavier. If meeting the modified requirement necessitates a change to the hard tools used to manufacture the bassinet, the cost could be more significant.[32]

C. Mattress Flatness

CPSC staff recommends adding a mattress flatness requirement and test method to the proposed standard, as well. The 2010 NPR also included requirements intended to address the suffocation and positional asphyxia hazard that can result from excessive mattress angles. However, concerns about test validity and repeatability have resulted in significant modifications since the 2010 NPR.[33] In particular, staff now recommends that a 17 pound test cylinder (rather than two different CAMI dummies) be tested in every seam (rather than just those deemed to be the most problematic). Also, a bassinet attachment with a segmented mattress would fail the staff-recommended requirement if any tested seam created an angle greater than 10 degrees (5 degrees was proposed in the 2010 NPR).

The mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented mattresses. These incidents suggest that

[32] During the production process, a hard tool, which is a mold of the desired bassinet component shape, is injected with plastic or another material using a molding machine.
[33] See Midgett, 2012 for a detailed discussion of the development of the current staff-recommended requirement and test procedure.

products with mattresses that have multiple seams could pose a suffocation hazard.[34] Based on staff testing, it appears that the play yard bassinet attachments of many suppliers (both compliant and noncompliant with F2194-10) would pass this staff-recommended requirement without any modifications. Those that do require modifications would need to increase the mattress support in their bassinets. This could be accomplished, for example, by retrofitting their play yard bassinets to use longer rods or a better-fitting mattress shell. The cost of such a retrofit is unknown and would likely vary from product to product; however, it should be less expensive than a product redesign. Based on this information, it appears that at least a few play yard bassinets may require modifications, which could include product redesign. However, it is believed that most firms would opt for the less expensive option of retrofitting their existing designs.

D. Removable Bassinet Beds

Finally, staff recommends adding a new requirement and test method to address the attachment of removable bassinet beds. There are several manufacturers with bassinet designs that allow for the bassinet bed to be removed from the stand easily (*i.e.,* without the use of tools) and used separately. In many cases, the bassinet bed sits securely on the stand without any attachment mechanism. In other cases, clips or locks may be used to ensure that the stand retains the bassinet bed during use. Incidents have arisen where the attachments have either failed or have not been used, rendering the bassinet bed unstable. Therefore, CPSC staff, in conjunction with ASTM, has developed a requirement and test methods to address the potential instability of some removable bassinet beds when used with a stand.

There are several firms supplying bassinets with removable bassinet beds to the U.S. market. The majority will not need modifications to meet the staff-recommended requirement. However, at least four firms will need to make changes to one or more of their bassinets. Essentially, the products will need to be modified so that they are either inherently stable (automatically lock or stable even without the locks) or obviously unstable (unsupportable or obviously tilted without locks or visual indicator that locks not in use). There are numerous ways that firms could meet this new requirement if their product(s) required modification, including redesigning the product entirely. However, it seems likely that many firms would opt for less expensive alternatives, such as more sensitive locks that activate with little pressure (*i.e.,* with just the weight of the bassinet).

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

[34] Ibid; Chowdhury 2012; and Kumagai, 2012.

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 bassinets/cradles 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.

Impact on Small Businesses

There are approximately 55 firms currently known to be marketing bassinets and/or cradles in the United States. Under Small Business Administration (SBA) guidelines, a manufacturer of bassinets or cradles is small if it has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, 38 are small firms—19 domestic manufacturers, 8 domestic importers, and 11 firms with unknown supply sources (including 9 specializing in bedding). The remaining firms are five large domestic manufacturers, three large domestic importers, three large retailers with unknown supply sources, and six foreign firms. There may be additional unknown small bassinet/cradle suppliers operating in the U.S. market.

Small Manufacturers

The expected impact of the staff-recommended proposed standard on small manufacturers will differ based on whether their bassinets/cradles are already compliant with F2194-10.[35] Firms whose bassinets and cradles meet the requirements of F2194-10 are likely to continue to comply with the voluntary standard as new versions are published. In addition, they are likely to meet any new standard within 6 months because this is the amount of time JPMA allows for products in their certification program to shift to a new standard. Many of these firms are active in the ASTM standard development process and compliance with the voluntary standard is part of an established business practice. Therefore, it is likely that firms supplying bassinets and cradles that comply with ASTM F2194-10 (which went into effect for JPMA certification purposes in November 2010) would also likely comply with F2194-12 by January 2013, even in the absence of a mandatory standard.

It is possible that the direct impact for manufacturers whose products are likely to meet the requirements of ASTM F2194-12 (10 of 19 firms) could be significant for one or more firms if they must redesign their bassinets to meet the staff-recommended proposed rule. While none of these manufacturers would be newly covered due to the staff-recommended change in scope (A), seven would be affected by the mattress flatness requirement (*i.e.,* they produce play yards with bassinet attachments) (C), and at least two (and possibly four) may be affected by the removable bassinet bed stability requirement (D). For the most part, the bassinets/cradles and bassinet

[35] Play yards with bassinet attachments must comply with the effective play yard standard (F 406), which includes a requirement that the attachment meet the bassinet/cradle standard.

cradle attachments supplied by these firms will be able to meet the staff-recommended changes to ASTM F2194-12, without modification. In cases where modifications are necessary, they would most likely opt to retrofit their products, rather than undertake an expensive redesign. However, it is possible that some products may require redesign, particularly to meet the new removable bassinet bed stability requirement (D); therefore, costs could be significant in some cases.

Meeting ASTM F2194-12's requirements could necessitate product redesign for at least some bassinets/cradles not believed to be compliant with F2194-10 (9 of 19 firms). Two of these firms produce either Moses baskets or carriage stroller attachments along with separate stands, and, therefore, they are included only because of the staff-recommended change in scope.[36] The remaining seven firms could require redesign, regardless of the staff-recommended modifications. A redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric, but it could be more significant if changes to the frame are required, including changes to side height. One manufacturer estimated that a complete play yard redesign, including engineering time, prototype development, tooling, and other incidental costs, would cost approximately $500,000. Staff believes that a bassinet redesign would tend to be comparable. Consequently, the staff-recommended proposed rule could potentially have a significant direct impact on small manufacturers whose products do not conform to F2194-10. However, any direct impact might be mitigated if costs are treated as new product expenses that can be amortized.

It is possible that some firms supply bassinets/cradles that are compliant with F2194-10, even though they are not certified or marketed as compliant. CPSC staff has identified many such cases with other products. To the extent that some of these firms may supply compliant bassinets/cradles and have developed a pattern of compliance with the voluntary standard, the direct impact of the staff-recommended proposed standard will be less significant than described above. There are also two small firms with unknown supply sources, none of which appear to comply with F2194-10 (one is covered by the staff-recommended proposed rule due to the expanded scope). If these firms are manufacturers, they may also require redesign to meet the staff-recommended proposed standard.

In addition to the direct impact of the staff-recommended proposed standard described above, there are indirect impacts. These impacts are considered indirect because they do not arise directly as a consequence of the bassinet/cradle rule's requirements. Nonetheless, they could be significant. Once the rule becomes final and the notice of requirements is in effect, all manufacturers will be subject to the additional costs associated with the third-party testing and certification requirements. This will include any physical and mechanical test requirements specified in the final rule; lead and phthalates testing is already required, and hence, not included here.[37]

[36] Since no Moses baskets or carriage attachments for strollers are currently tested to the ASTM bassinets/cradles standard, it is assumed that none would meet ASTM F2194-10 without modifications.
[37] Bassinet and cradle suppliers already must third party test their products to the lead and phthalate requirements. Therefore, these costs are left out of the analysis above.

One manufacturer estimated that testing to the ASTM voluntary standard runs around $1,000 per model sample, although they noted that the costs could be lower for some models where the primary difference is fabric rather than structure. Testing overseas could potentially reduce some testing costs, but this may not always be practical.

On average, each small domestic manufacturer supplies eight different models of bassinets/cradles and/or play yards with bassinet/cradle accessories to the U.S. market annually. Therefore, if third party testing were conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about $8,000 annually. Based on a review of firm revenues, the impact of third party testing to ASTM F2194-12 is unlikely to be significant if only one bassinet/cradle sample per model is required. However, if more than one sample would be needed to meet the testing requirements, third party testing costs could have a significant impact on a few of the small manufacturers.

Small Importers

As with manufacturers of compliant bassinets/cradles, the four small importers of bassinets/cradles currently in compliance with F2194-10 could experience significant direct impacts as a result of the staff-recommended proposed rule, if product redesign is necessary. In the absence of regulation, these firms would likely continue to comply with the voluntary standard as it evolves and likely the final mandatory standard as well. Any increase in production costs experienced by their suppliers may be passed on to them.

Importers of bassinets/cradles would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the staff-recommended proposed rule, which may be the case with the four importers of bassinets/cradles not believed to be in compliance with F2194-10 (two of which are covered by the staff-recommended proposed rule due to the expanded scope). Some could respond to the rule by discontinuing the import of their noncompliant bassinets/cradles, possibly discontinuing the product line altogether. However, the impact of such a decision could be mitigated by replacing the noncompliant bassinets/cradles with compliant bassinets/cradles. Deciding to import an alternative product would be a reasonable and realistic way to offset any lost revenue.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, they will experience costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers that must perform the testing themselves if more than one sample per model were required.

Bassinets with Specialized Bedding Suppliers

There are nine known small firms specializing in the supply of bedding, including bedding for bassinets and cradles. Each firm sells basic bassinet or cradle shells, covered with their bassinet and cradle bedding. While it is clear that these firms do not manufacture the structural

parts of the bassinets or cradles themselves, it is unclear whether they purchase them domestically or from overseas. Regardless, these firms will be affected by the staff-recommended proposed rule in a manner similar to importers.

Since none of these firms is believed to supply bassinets or cradles in compliance with F2194-10, they would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the staff-recommended proposed rule. Unlike most importers, however, they would not have the option of replacing a noncompliant bassinet/cradle with another product. While they could opt to sell the bedding without the associated bassinet/cradle, this is the standard method of sale and might make it more difficult to compete in the bassinet/cradle market.

As with manufacturers and importers, these firms will also be subject to third party testing and certification requirements, and they will experience costs similar to those for manufacturers if their supplying firm(s) does not perform third party testing. The resulting costs could have a significant impact on some of these small bassinet/cradle suppliers that must perform the testing themselves.

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. Doing so would eliminate the impact on the six small firms that would be newly covered under the bassinet/cradle standard due to the staff-recommended change in scope. These firms all supply Moses baskets or carriages, along with stationary stands; staff believes that these products require additional safety features when used for sleeping purposes. Adopting the voluntary standard without modifications could also reduce the impact on other small manufacturers and importers whose ASTM-compliant bassinets/cradles would require modifications due to the staff-recommended changes. However, because of the severity of the incidents associated with instability and mattress tilt,[38] staff does not recommend this alternative.

A second alternative would be to set an effective date later than the staff-recommended 6 months that is generally considered sufficient time for suppliers to come into compliance with a proposed rule. Setting a later effective date would allow suppliers additional time to modify and/or develop compliant bassinets/cradles and spread the associated costs over a longer period of time.

[38] Chowdhury, 2012.