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

BP - Bassinets
Notice of Proposed Rulemaking (NPR)
The contents of this document will be discussed at the Open Commission Meeting on Wednesday, March 17, 2010

VOTE SHEET

DATE: March 10, 2010

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Maruta Budetti, Executive Director
Cheryl A. Falvey, General Counsel CAF
Philip L. Chao, Assistant General Counsel

FROM: Barbara E. Little, Attorney, GCRA BEL

SUBJECT: Notice of Proposed Rulemaking for Bassinets and Cradles under Section 104(b) of the Consumer Product Safety Improvement Act of 2008

Section 104(b) of the Consumer Product Safety Improvement Act ("CPSIA") directs the Commission to issue safety standards for durable infant or toddler products. Attached is a draft notice of proposed rulemaking ("NPR") proposing a rule under section 104(b) of the CPSIA for bassinets and cradles. The draft proposed rule incorporates by reference the applicable voluntary standard, ASTM F 2194 – 07a$^{\varepsilon 1}$, with certain additions and modifications to strengthen the standard.

Please indicate your vote on the following options.

I. Approve publication of the draft NPR proposing a standard for bassinets and cradles in the *Federal Register* without change.

_____ _____
(Signature) (Date)

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)
3/10/2010
THIS DOCUMENT HAS NOT BEEN
REVIEWED OR ACCEPTED BY THE
COMMISSION.

II. Do not approve publication of the draft NPR proposing a standard for bassinets and cradles in the *Federal Register.*

_____ _____

(Signature) (Date)

III. Publish the draft NPR proposing a standard for bassinets and cradles in the *Federal Register* with changes.

(Please specify.)

_____

_____

_____

_____ _____

(Signature) (Date)

IV. Other.

(Please specify.)

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_____ _____

(Signature) (Date)

Attachment: Draft *Federal Register* Notice

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

This document has been electronically approved and signed.

Date: March 10, 2010

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Maruta Z. Budetti, Executive Director

FROM : Robert J. Howell, Assistant Executive Director
Office of Hazard Identification and Reduction
Han Lim, Project Manager
Directorate for Engineering Sciences

SUBJECT : Staff Draft Proposed Rule for Bassinets and Cradles

I INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act (CPSIA), *Standards and Consumer Registration of Durable Nursery Products,* requires the U.S. Consumer Product Safety Commission (CPSC) to study and develop safety standards for certain infant and toddler products. The list of products in section 104 includes: full-size and non full-size cribs; toddler beds; high chairs, booster chairs, and hook-on chairs; bath seats; gates and other enclosures for confining a child; play yards; stationary activity centers; infant carriers; strollers; walkers; swings; and bassinets and cradles. The Commission is charged with promulgating consumer product safety standards that are substantially the same as the voluntary standards for toddler beds or more stringent than the voluntary standard if the Commission determines that more stringent standards would further reduce the risk of injury associated with bassinets/cradles. Section 104 of the CPSIA also requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers and independent child product engineers and experts to examine and assess the effectiveness of the voluntary standards. This consultation process commenced in October 2009 during the ASTM International (formerly known as the American Society for Testing and Materials) subcommittee meeting regarding the ASTM bassinet and cradle voluntary standard. Consultations with members of this subcommittee are ongoing.

This briefing package assesses the effectiveness of the current voluntary standard for bassinets and cradles (ASTM F 2194 – 07a $^{\varepsilon 1}$) and presents the staff's draft proposed rule for bassinets and cradles for Commission consideration.

rdh 3/10/2010
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UNDER CPSA 6(b)(1)

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION.

II BACKGROUND

Product Description

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.[1] Figures 1 to 3 show examples of various types of bassinets/cradles. These products are intended to provide sleeping accommodations for infants up to approximately 5 months in age.

Figure 1: Stationary Bassinet

Figure 2: Bassinet with Rocking Base

Figure 3: Swinging Cradle

Bassinet/cradle accessories for non-full size cribs or play yards fit the scope of this product category, as do bedside sleeper bassinets that can be converted to a four-sided bassinet that does not attach to an adult bed. See figures 4 and 5.

Figure 4: Play Yard Bassinet Combination (bassinet attachment suspended above the play yard)

Figure 5: Bedside Sleeper Convertible

[1] This is the definition found in the ASTM F 2194 – 07a$^{\varepsilon 1}$ voluntary standard.

Bassinets and cradles are typically manufactured and/or marketed by juvenile product manufacturers and distributors. CPSC staff believes that there are currently at least 48 known manufacturers and/or importers supplying bassinets and/or cradles to the U.S. marketplace[2].

Regulatory Activities

To date, the Commission does not have a history of any rulemakings or proposed rulemakings for bassinets and cradles. As part of the CPSIA, a bassinet/cradle is a product category that was selected for a mandatory rule. In the subsequent sections of this memo, including Tabs A through C, there are detailed discussions on ASTM F 2194-07a $^{\varepsilon 1}$ *Standard Consumer Safety Specification for Bassinets and Cradles*, which form the basis for the major portion of the staff's draft proposed rule for bassinets and cradles.

ASTM Voluntary Standard Overview

The voluntary standard for bassinets and cradles was first approved and published by ASTM in 2002 as ASTM F 2194 *Standard Consumer Safety Specification for Bassinets and Cradles.* It has been revised a number of times since then, and the current version, F 2194 – 07a $^{\varepsilon 1}$, was published in November 2007 and 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
- Bassinet/Cradle Attachment to Play Yard/Non-Full Sized Crib
- Spacing of Rigid Sided Bassinet/Cradle Components
- Openings for Mesh/Fabric Sided Bassinet/Cradle
- Static Load
- Stability
- Sleeping Pad Properties
- Protective Components

The Juvenile Products Manufacturers Association (JPMA) conducts a certification program for a variety of juvenile products, including bassinets and cradles. To obtain JPMA certification, manufacturers submit their products to an independent test laboratory for conformance testing to

[2] Memorandum from Jill Jenkins, Directorate for Economic Analysis to Han Lim, Project Manager for Bassinets and Cradles dated February 16, 2010, Subject: Initial Regulatory Flexibility Analysis of Proposed Standard for Bassinets and Cradles.

the most current voluntary standard. There are at least 48 firms supplying bassinets, cradles, or hammocks to the U.S. market. Currently, ten of those firms manufacture products that are JPMA certified[3] to ASTM F 2194 – 07a $^{\varepsilon 1}$. Included in this list is a manufacturer that makes infant hammocks, which fit the ASTM F 2194 – 07a $^{\varepsilon 1}$ definition of a bassinet/cradle. As discussed in Tab B, infant hammocks are included in the scope of the bassinet/cradle standard.

Infant Hammocks

While the current ASTM F 2194 – 07a $^{\varepsilon 1}$ standard does not explicitly state that infant hammocks are within the scope of the standard, JPMA has historically certified infant hammocks under the bassinet/cradle standard. A bassinet/cradle is defined as a small bed for infants supported by free-standing legs, a wheeled base, a rocking base, or which can swing relative to a stationary base. See Figure 6. At least thirteen firms supply infant hammocks that fit this definition because they swing relative to a stationary base. Two firms have hammocks certified by JPMA to the ASTM F 2194 – 07a $^{\varepsilon 1}$ standard. Because of their design characteristics, infant hammocks will be unable to meet the proposed performance criteria of a 5° rest angle, 5° flatness angle, and a 20° maximum rock/swing angle, which would effectively ban hammocks if published as proposed in the staff's draft proposed rule. Tab B contains detailed discussions on the performance requirements.

Figure 6: Infant Hammock

By nature of their design, most hammocks do not a have rigid sleep surface. Health Sciences staff believes that many of the current designs it has been studying result in uneven suspension of the product, which can cause the hammock to tip to one side, trapping the baby in a face

[3] JPMA website: http://jpma.org/index2.cfm?section=Programs&content=Certified#10
There are additional four firms that supply JPMA certified play yards with bassinet attachments.

down position and increasing the risk of positional asphyxia or suffocation Because of this hazard pattern, CPSC recently recalled an infant hammock. Since the sleeping environment of most hammocks differs from that of bassinets or cradles, CPSC staff believes a separate standard for hammocks may be necessary. Most hammocks have mattresses that are flexible and conform to the body contours of the infant, whereas bassinets and cradles have flat, mattresses with solid sides or fabric sides. In a November 17, 2009, CPSC/ASTM teleconference, ASTM agreed to form a subcommittee to develop requirements for a new hammock standard. Until a separate standard for hammocks is developed, CPSC staff believes it is prudent to include hammocks under staff's draft proposed rule for bassinets and cradles as an interim measure because the draft proposed rule addresses the hazard pattern which causes the infant to roll/press up against the side or corner of the product posing a risk of positional asphyxia or suffocation. The Commission may remove hammocks from the scope of a bassinets/cradles standard in the future, should ASTM develop an effective voluntary standard for hammocks.

III DISCUSSION

Incident Data (Tab A)

Bassinet and Cradle Incidents

CPSC staff has closely monitored incident reports involving bassinets and cradles since late 2007 as part of the Early Warning System (EWS) pilot project. The earliest bassinet-related incident in EWS occurred in April 2006. However, only a relatively small number of all bassinet-related reports with incident dates in 2006 were actually captured in EWS, since they preceded the start of the pilot project. To ensure completeness, CPSC staff analyzed all incidents contained in the CPSC epidemiological databases that were reported to have occurred since January 1, 2006. The number of emergency department-treated injuries associated with bassinets and cradles for this time period was insufficient to derive any reportable national estimates[4] and, therefore, no national estimates are included in this briefing package. However, the emergency department-treated injuries are included in the total count of reported injuries presented here.

CPSC Directorate for Epidemiology staff reports 209 incidents related to bassinets and cradles since 2006.[5] Of these incidents, 61 fatalities, 38 non-fatal injuries, and 110 non-injury incidents were related to bassinets and cradles. The 209 incidents were grouped into five categories: (a) product-related issues (sufficient information was available to describe the product failure modes or defects), (b) non-product-related issues, (c) unknown issues (incidents that lack specificity), (d) recalled product related issues, and (e) miscellaneous other issues.

Product Related Issues: Approximately 42 percent (87 out of 209) of the incidents involved defects or failures related to the product. The reported problems are listed below; beginning with the most frequently reported problems:

[4]According to the National Electronic Injury Surveillance System (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.

[5] Memorandum from Risana Chowdhury to Han Lim, "Bassinets, Cradles, and Infant Hammocks Related Deaths, Injuries, and Potential Injuries; 2006 - Present", February 3, 2010

- Inadequate ***structural integrity***, which included unstable bassinets or cradles, loose hardware, collapse of the product, loose wheels, etc.
- Issues with ***rocking/swinging*** bassinets and cradles – locking or tilting issues which caused the infant to roll/press up against the side/corner of the product – posing a suffocation hazard.
- Problems with ***mattress flatness***. Examples included mattresses that would not remain horizontal because of metal rods/other structures designed to be positioned underneath the mattress, lack of rigid mattress support, failure of straps/hooks designed to hold bassinets inside play yards, among others. Lack of mattress flatness can result in gaps between walls and the mattress, which could create possible entrapment and/or suffocation scenarios. One death was associated with a mattress flatness issue.
- Problems with battery powered bassinet ***mobiles***, which had components that overheated, smoked, or sparked.

Non-Product-Related Issues: Sixty (29 percent) of the 209 incident reports were of deaths and injuries that involved no product defect or failure. Fifty-seven of the 60 incidents were deaths where a determination of causation or associations is complicated by a confounding issue because of the inappropriate use of pillows, blankets, or mattresses that were not approved by the manufacturer.

Unknown Issues: Twenty-six incident reports (12 percent) had little or no information. Twenty-five of these reported a fall of the infant out of the bassinet or cradle.

Recalled Product-Related Issues: Nineteen reports (nine percent) involved recalled products. Some of the reports were received by CPSC staff prior to the recalls being announced. Among them were seven entrapments (three deaths, two non-fatal injuries, and two non-injury incidents) between the structural members of the bassinet. The remaining 12 reports were complaints or inquiries from consumers regarding a recalled product.

Miscellaneous Other Issues: The remaining 17 incident reports involved a host of miscellaneous problems ranging from a tear in the bassinet fabric to odors to product assembly/quality issues. Some of these were product-related issues as well.

All of the 61 fatalities reported to CPSC staff were asphyxiation deaths. The majority of the deaths (57 out of 61) were asphyxiations where the incident report noted the presence of soft or extra bedding in the bassinet, prone placement of the infant, or the infant getting wedged between the side of the bassinet and mattress or bedding. Soft or extra bedding and the prone placement of an infant are associated with infant mortality from asphyxiation, independent of any design hazard. A few were reported as asphyxiation deaths, with no further information available. Only four of these deaths were determined to have resulted from design flaws in the products. Three of the four deaths were due to entrapment of the infant between metal bars of a particular brand of bassinet. Of those three deaths, two of the three infants were six months old and should not have been using the bassinet or cradle because by definition they are only for use up to five months. The fourth death resulted from an infant suffocating in the corner of the bassinet when he rolled into that position due to the unlevel mattress pad.

Thirty-eight incidents reported an injury to an infant in a bassinet or a cradle. The vast majority of these (23 out of 38, or 61 percent) were identified as falls out of the bassinets. Since 22 of the 23 falls were reported through NEISS, the emergency department-treated injury surveillance system, little or no circumstantial information is available on how the falls occurred. However, the reports do indicate that 73 percent of the infants were six months or older in age and most of the falls resulted in head and facial injuries. Three of the infants required hospitalization.

Hammock Incidents

CPSC staff is aware of three fatalities, six non-fatal injuries, and five non-injury incidents related to infant hammocks that were reported to have occurred since 2006. All three fatalities reported to CPSC staff were asphyxiation deaths. One five-month old infant was found rolled into a corner in a prone position with the bed in an inclined position. A four-month old infant was found with her face flat against the foam mattress. In the third case, the medical examiner who reported the fatality expressed concern about the safety of the hammock as a sleeping environment. However, the death of the six-month old decedent, who was found in a prone position, was officially ruled to be asphyxiation due to respiratory infection.

All six non-fatal injuries were reported through NEISS. Five of the injuries were reported to have been falls out of hammocks, while the sixth injury was sustained when a broken component of the hammock struck the infant. Little or no circumstantial information is available on how the falls occurred, except that three of the six infants were eight months or older.

Two of the five non-injury reports involved infants (a seven-month old and a 12-month old) in near-strangulation incidents where the hammock flipped over with the infants dangling from restraints. The remaining three reports involved near-suffocation incidents where the infant rolled into a position from which it was unable to move or free itself. All three of these infants were under five months of age.

Assessment of ASTM F 2194 – 07a$^{\varepsilon 1}$ (Tab B)

To develop and support recommended changes to the ASTM bassinet/cradle standard, CPSC staff worked with ASTM to develop performance requirements, test methods, and markings/labeling to address hazards associated with bassinets and cradles such as the following: (a) suffocation due to placement of inappropriate bedding materials in the product, tilting of the product, lack of mattress "flatness", and (b) entrapments due to exposed rigid structural components and entrapment hazards from bounded areas of fabric and rigid sides.

CPSC staff conducted a variety of tests on JPMA certified and non-JPMA certified products to assess the following established procedures and new proposed test procedures:

- Tip stability test
- Static load test
- Maximum rock/swing angle and rest angle measurements
- Fabric sided testing

Warning Labels

To address the majority of the suffocation incidents which involved the presence of inappropriate bedding materials in the bassinets and cradles, CPSC staff recommends revised marking and labeling requirements. Since the pattern of behavior of parents or caregivers placing blankets and other bedding materials in bassinets/cradles is not a bassinet or cradle design-related issue, CPSC staff believes that improved warnings are necessary and proposes larger fonts, prominent presentation of the warnings, and more emphatic language that was drafted by the ASTM subcommittee for bassinets and cradles with input from CPSC Human Factors staff. Detailed discussions of the proposed updates are provided in Table 1 at the end of this memorandum and in Tab B.

Static Load and Tip Stability Performance Criteria

CPSC staff evaluated the current static load and tip stability test procedures in ASTM F 2194 – 07a $^{\varepsilon 1}$. CPSC staff performed the tip stability and static load tests on four products: a curved base rocking cradle, a cradle that swings via two pinned ends, a bassinet equipped play yard, and a battery powered motor driven swinging cradle. All products passed both tests per the standard. Additional tests where the placement of a CAMI Dummy, Mark II[6] (17.5 lb) was varied, the Newborn CAMI Dummy (7 lb) was used in lieu of the CAMI Dummy, Mark II, and the locking mechanisms (when applicable) were engaged produced passing results.

ASTM F 2194 – 07a $^{\varepsilon 1}$ includes a static load test using a 54 lb weight. The rationale provided by ASTM for the static load test is that the 54 lb weight is equivalent to three times the weight of the 95th percentile 3 to 5 month old infant. In cases where a manufacturer's recommended weight for their product is higher, then the higher weight is used for the static load test. For example, if the maximum weight recommended by a manufacturer is 20 lbs for a particular product, then a static load using a 60 lb weight will be necessary.

ASTM F 2194 – 07a $^{\varepsilon 1}$ includes a stability test. The rationale provided by ASTM for the stability test is that a 23 lb vertical load and horizontal 5 lb horizontal force applied simultaneously simulates an angled tipping force. The 23 lbs is based on the mean strength of a 2-year old male, perhaps a sibling or other child, pulling on the bassinet or cradle. CPSC Human Factors staff concurs that this test is appropriate and effective. No substantive revisions are recommended with regard to the static load and stability tests; however, CPSC staff recommends the inclusion of test scenarios where the bassinet or cradle is tested with the locking mechanism(s) engaged, if it is equipped with a locking mechanism to prevent swinging or rocking.

Rock/Swing Angle, Rest Angle, and Mattress Flatness

When a bassinet or cradle is not in a swinging or rocking mode, it needs to be level to facilitate a safe sleeping environment for infants. There was one death and several close calls associated with non-level bassinets/cradles. According to in-depth investigation (IDI) report 090706CWE8347, a two month old male died in a bassinet portion of a play yard. The infant

[6] Civil Aeromedical Institute (CAMI) Infant Dummy, Mark II, constructed in accordance with the Department of Transportation Specification dated April 29, 1975.

rolled, causing his face to be placed in the corner of the bassinet. One side was approximately five inches higher than the other. The metal poles that the bassinet is seated onto are too short to keep the sleep surface level. In one non-fatal incident, a mother found her two-week old male infant with his face against the mattress, covering his nose and mouth, after he slid down the side of the mattress. The product involved was a play yard – swinging bassinet combination. IDI 080814HCC3782 states that the locking mechanism to prevent the swinging motion disengaged when the mother placed her son in the product. There was no injury to the infant, and the mother returned the product to the store. In another non-fatal incident (IDI 081210CWE7920), a mother found her five-month old daughter in a bassinet – play yard combination asleep up against the back side of the bassinet portion. The infant was not injured when the strap holding the bassinet insert to the side of her play yard ripped causing it to tip sideways. The photographs from the IDI report showed the bassinet sleep surface at a substantial angle when the strap failure occurred. The infant could have been trapped between the bassinet and side of the play yard.

To address the mattress tilting issue, CPSC staff worked with ASTM to develop performance requirements and test procedures to reduce potential suffocations and entrapments. CPSC staff recommended three performance requirements and corresponding test procedures: a maximum allowable rock/swing angle of 20°, a maximum allowable rest angle (for rocking/swinging products) of 5°, and a maximum allowable 5° mattress angle for all rocking and non-rocking bassinets. The 5° recommendation for the mattress flatness angle and the rest angle is based on the Australian study, "The Danger of Freely Rocking Cradles" by S.M. Beal et al, *Journal of Pediatric Child Health* (1995) and AS/NZS 4385:1996, the Australian/New Zealand standard for infant's rocking cradles. The 20° recommendation is based on the Canadian regulation for cribs and cradles (SOR 86-962) and measurements/observations made by CPSC staff on recent model bassinets/cradles. These requirements will effectively ban infant hammocks currently on the market, which have swing angles greater than 20° and rest angles greater than 5°.

Entrapments Associated with Bassinet/Cradle Side Structural Members and Multi-Use Fabric Side Configurations

Seven incidents (among them three deaths) involved recalled products where infants were trapped between structural members on the side of a bassinet. CPSC staff believes a performance requirement and test procedure is necessary to reduce the risk of these entrapments. There are other related scenarios that can present similar entrapments such as hazards from bounded areas of fabric and rigid sides. On some multi-use products that can convert into a bedside sleeper configuration, CPSC staff believes use of various "loose" fabric configurations is foreseeable and probable. The chair of the ASTM subcommittee for bassinets and cradles proposed a test procedure to evaluate such scenarios. CPSC staff worked together with ASTM to refine this test procedure, which is described in Tab B. The proposed procedure is to test fabric-sided products to non-full size baby crib slat spacing requirements per 16 CFR 1509 (20 lb compression force test). Bassinets/cradles would be tested with the fabric on the product but without the snaps, zippers, etc fastened. CPSC staff believes that these additional requirements will reduce entrapment hazards with fabric-sided products.

Impact on Small Businesses (Tab C)

Bassinets and cradles are typically produced and/or marketed by juvenile product manufacturers and distributors. There are currently at least 48 known manufacturers or importers supplying bassinets, cradles, and/or hammocks to the U.S. market. Four are large domestic manufacturers and ten are foreign manufacturers or importers. Based on Small Business Administration definitions, there are 34 small firms—24 small domestic manufacturers, 9 small domestic importers, and one unknown small domestic firm—likely to be affected by the staff-recommended standard, as described in the Directorate for Economic Analysis memo (Tab C).

The proposed standard is likely to have a significant impact on a few small firms. The Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers, runs a voluntary certification program for several juvenile products. Of the small domestic businesses supplying bassinets, cradles, and/or infant hammocks to the U.S. market, 38 percent of manufacturers (nine of 24 firms) and 44 percent of importers (four of nine firms) have products that are ASTM compliant.[7]

Most firms are not JPMA-certified as compliant with ASTM's voluntary standard and are likely to have to make at least some product modifications to achieve compliance.[8] Even firms supplying JPMA-certified bassinets/cradles may have to make changes to meet the added CPSC staff-recommended requirements over and above those included in the current voluntary standard. The extent of the costs associated with these changes is unknown, but since product redevelopment would likely be necessary, it is possible that the costs could be large for some of the firms, particularly those with product lines that rely primarily or entirely on bassinets/cradles and related products, such as bedding. However, at least some of these costs are expected to be passed on to consumers without a reduction in firms' ability to compete due to the unique features associated with these products.

The small firms likely to be most significantly impacted by the staff-recommended rule, however, are those supplying infant hammocks intended for colicky babies. The majority of these firms have focused their entire product line on these goods. These suppliers, both manufacturers and importers, are unlikely to make even inexpensive modifications to meet the staff-recommended requirements. Any known fix would eliminate their niche market, thereby eliminating demand for their products, and may drive them out of business.

IV RECOMMENDATIONS

CPSC staff recommends adopting the requirements specified in ASTM F 2194 – 07a$^{\varepsilon 1}$ as a mandatory standard for bassinets and cradles with several modifications and edits that could further reduce suffocations and entrapments. The modifications and edits include updated

[7] This includes a small manufacturer that claims compliance with the ASTM standard but is not part of the JPMA Certification Program, as well as the firms with only some relevant product categories JPMA certified. It should also be noted that non-JPMA certified products will not necessarily fail to comply with the ASTM standard. Although there is currently no testing to support such an assumption for bassinets/cradles, testing of other products has revealed a pattern of non-correlation.

[8] To the extent that some of the products not certified by JPMA may still comply, the impact will be reduced.

warnings and new recommended performance requirements. The new performance requirements include limiting the rocking/swinging angle and rest angle of certain rocking/swinging cradles, reducing the probability of fabric sided products forming bounded areas which may suffocate infants, and requiring a flatness angle performance requirement. All of the recommended changes are summarized in Table 1, attached to this memo and detailed in Tab B of this briefing package.

CPSC staff recommends that the Commission proceed with a rulemaking process for bassinets and cradles by publishing a Notice of Proposed Rulemaking (NPR) as drafted by the Office of General Counsel and submitted separately from this briefing package. CPSC staff also recommends an effective date of six months after publication of the final rule.

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
Section 1.3	This consumer safety performance specification covers products intended to provide sleeping accommodations **only** for infants 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 infant swing are not covered by this specification.	CPSC staff is in agreement with ASTM regarding 5 months as the general appropriate age for these products. Additionally, the objective criteria of an infant capable of pushing up on hands and knees gives clarity to which products would be considered bassinets or cradles. These products should only be used in the early stages of an infant's development. Once an infant can push up by him/herself, a number of hazards are created, most notably falling hazards.
Section 2.3	CAMI Newborn Dummy (See Figure TBD)	Since the proposed standard requires testing with the 7 lb Newborn CAMI Dummy, this reference and photograph needs to be included.
Section 3.1.1	*bassinet/cradle, n*—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. **Products such as swings, full and non-full size cribs, hand carrying baskets, and travel beds are not included, unless the product is a bassinet/cradle attachment per the definition in Section 3.1.2.**	This updated definition clarifies that full-size and non-full size cribs are not covered. A bassinet or cradle is defined as a product that must be supported by a base per Section 3.1, thus hand carrying baskets, travel beds, and other similar products are not covered. The scope of the standard includes hammocks, as several hammocks in the marketplace fit the definition of 3.1.1. However, since current hammocks cannot meet the performance requirements for rest angle, mattress flatness angle, and rocking angle, hammocks will effectively be banned. CPSC staff observed that the use patterns of hammocks are somewhat different than that of bassinets/cradles. CPSC staff believes that study of the use patterns of hammocks and the associated hazards is necessary to develop appropriate performance requirements and test procedures to ensure that hammocks can facilitate a safe, level sleeping environment for infants. In the November 17, 2009 teleconference, ASTM agreed to form a subcommittee to start a hammock standard group.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
Section 3.1.2	*bassinet/cradle accessory, n* – accessory with a rigid frame that attaches to non-full size crib, play yard, or other base unit designed ~~for sleeping~~ **to convert the accessory into a bassinet/cradle.**	This updated definition of a bassinet/cradle accessory avoids confusion with accessories than can attach to products that are not intended exclusively for sleeping such as stroller attachments.
[New suggested] Section 3.1.12	***double action release mechanism*, n—mechanism requiring either two consecutive actions, the first of which must be maintained while the second is carried out or two separate and independent single action locking mechanisms that must be activated simultaneously to fully release.**	CPSC staff has observed various multi-use products that can convert from a rocking bassinet to a stationary one. During this conversion, there are dual-action locking mechanisms that require rotating pop-out casters and then engaging a "tab"-lock to prevent the casters from rolling. The above example is not a double action release mechanism although it may appear to be one. To avoid confusion in what constitutes a double action release mechanism, the definition from the ASTM high chair standard F 404-08 is reproduced here. While there are no reported injuries or deaths, CPSC staff believes that if a product is equipped with such a locking mechanism, it should work as intended and resist collapse and/or movement.
[New suggested] Section 3.1.13	***Removable cover, n* – A fabric cover, containing snaps or other fasteners such as zippers, Velcro, or buttons used to attach to a bassinet/cradle frame that requires consumer action as a step for removal or adjustment.**	CPSC staff recommends including a definition for removable cover. The term removable cover is referenced in the test procedure for evaluating possible scenarios of entrapment hazards from bounded areas of fabric and rigid sides. Detailed discussions are in Tab B.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 3.1.14	***Maximum deflection angle*, n—the maximum rock/swing angle measurement allowed by the product design in the manufacturer's use position in the manner normally associated with rocking/swinging and intended by the manufacturer when tested in accordance with 7.8.**	These angle measurement terms were added in reference to the performance test requirements as described in Sections E and F of this memorandum.
[New suggested] Section 3.1.15	***Rest angle*, n—the resulting angle measurement of bassinet/cradle sleeping surface or tilt angle of the bassinet/cradle bed after the maximum deflection angle is applied and released and the product has come to a complete rest when tested in accordance with 7.8.**	
[New suggested] Section 3.1.16	***Flatness angle*, n— the resulting angle measurement relative to the horizontal plane of the sleep support surface or tilt angle of the bassinet/cradle bed when a compression force is applied to the chest of the CAMI dummy in accordance with 7.9.**	
[New suggested] Section 4.6	**Angle measurements shall be obtained using a digital inclinometer capable of 0.1° minimum resolution.**	To minimize variability, CPSC staff recommends specifying the type of angle and force measurement instrumentation and the corresponding measurement resolution.
[New suggested] Section 4.7	**Equipment – Force gauge with a range of 0 to 25 lbf (111N) with a maximum tolerance of ± 0.25 lbf (1.11N) or a range of 0 to 50 lbf (222N) with a maximum tolerance of ± 0.25 lbf (1.11N). A calibration interval shall be maintained for the force gauges which will ensure that the accuracy does not drift beyond the stated tolerances.**	To minimize variability, CPSC staff recommends specifying the tolerance and calibration interval for the force gauge.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

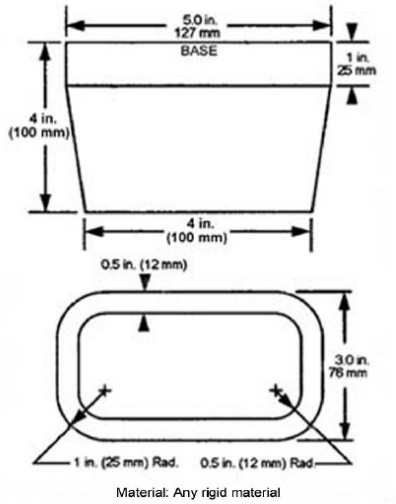
ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 5.13	***Restraints* – The bassinet shall not include any restraints system which requires action on the part of the caregiver to secure the restraint.**	Restraints are needed on products that require infants to be seated or propped up. Infants lying on a flat surface **do not** need restraints and their use could contribute to a possible strangulation hazard. CPSC staff is aware of at least two products that are equipped with crotch restraints.
Section 6.1	***Spacing of Rigid and Fabric Sided Bassinet/Cradle or Bassinet/Cradle attachment Components*** – Spacing must comply with 16 CFR Part 1509 Section 1509.4 when tested according to 7.1 **and 7.10**.	To address entrapment hazards from bounded areas of fabric and rigid sides, Section 6.1 will include an additional test procedure reference 7.10 for those products that have fabric sides.
Section 6.4	*Stability*—A product in all manufacturers' recommended use positions**, including positions where the locks are engaged for preventing rocking/swinging motion of the sleeping surface,** shall not tip over and shall retain the CAMI dummy[9] when subjected to the test described in 7.4.	The bold, underlined phrase was added for clarity and completeness to ensure that the testing laboratory would test the stability of the product in modes where the locks are engaged to prevent swinging/rocking. As noted before, hardware failures with locking mechanisms were identified in incident reports of potential entrapments and suffocations.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

[9] This Civil Aeromedical Institute (CAMI) Infant Dummy, Mark II, was constructed in accordance with the Department of Transportation Specification dated April 29, 1975.

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 6.7	***Rock/Swing Angle* – Bassinets or cradles that incorporate a rocking/swinging feature shall meet the following:**	
[New suggested] Section 6.7.1	**Maximum deflection angle measurement on any reading shall not exceed 20° when tested in accordance with 7.8.**	The 20° recommendation is based on the Canadian regulation for cribs and cradles (SOR 86-962) and measurements/observations made by CPSC staff on recent model bassinets/cradles. The 5° rest angle and bassinet/cradle surface orientation sleep surface angle are based on the Australian study "The Danger of Freely Rocking Cradles" by S.M. Beal et al, *Journal of Pediatric Child Health* (1995) and AS/NZS 4385:1996 the Australian/New Zealand standard for infant's rocking cradles.
[New suggested] Section 6.7.2	**The arithmetic mean of the rest angle measurements shall not exceeding 5° when tested in accordance with 7.8**	
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 6.8	***Bassinet/Cradle Flatness Angle –*** **The angle of the bassinet or cradle sleeping support surface or the tilt angle of the bassinet/cradle bed shall not be greater than 5° when tested in accordance to 7.9.**	For non-rocking/non-swinging bassinets or cradles, this performance requirement ensures that the sleep surface is flat and will not tilt when an infant is placed in a corner or edge. Incidents involving bassinet/play yard combos suggest that a sloped surface or a mattress with multiple seams (mattresses that double as a play yard cover) may have the potential for a positional asphyxia suffocation hazard.
[New suggested] Section 6.9	***Fabric Sided Enclosed Openings–*** **For bassinets or cradles with fabric sides, the fabric shall not release and form a completely bounded opening that allows the complete passage of the torso probe (Figure 1) when tested in accordance with Section 7.10.**  **Figure 1 – Torso Test Probe for Fabric Sided Testing**	On some multi-use products that can convert into a bedside sleeper configuration, CPSC staff believes use in the configuration described below is foreseeable and probable and therefore a probe test in this configuration should be performed. The chair of the ASTM subcommittee for bassinets and cradles submitted this proposed addition to the existing ASTM standard. ASTM commented that it is not foreseeable that a parent or caregiver will place a child in a "bare" bassinet while the fabric is completely removed for washing or cleaning. CPSC staff concurred with this observation. However, it is foreseeable that a parent or caregiver can loosely place the fabric back onto the bassinet or cradle after washing but may forget to fasten the snaps, zippers, or other fasteners. An example that is similar to the above scenario is the 2000 CPSC recall of Kids Line Inc. Le Cradle Bassinets[10]. Therefore in the scenario where the fabric is on the product without the snaps, zippers, etc. fastened, the product still needs to comply with the crib spacing requirements when subjected to the probe test as described in this section.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

[10] CPSC Recall Notice: "CPSC, Kids Line Inc. Announce Recall to Repair Le Cradle Bassinets," August 23, 2000. Website: http://www.cpsc.gov/cpscpub/prerel/prhtml00/00167.html

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 7.8	***Rock/Swing Angle Test***	This new suggested Section 7.8 was taken from the Task Group of the ASTM subcommittee for bassinets and cradles who were investigating rock angle measurements. CPSC staff is proposing changes to the draft ASTM procedure: additional testing with the Newborn Infant CAMI Dummy, specific angle measurement procedures, and additional testing in the head-to-toe direction, if applicable.
[New suggested] Section 7.8.1	**Side-to-Side Rock/Swing Test - for bassinets/cradles that have a side-to-side rocking/swinging feature.**	
[New suggested] Section 7.8.1.1	**Assemble bassinet/cradle in accordance with manufacturer's instructions and, if necessary, place the bassinet/cradle in rocking/swinging mode.**	
[New suggested] Section 7.8.1.2	**Place the bassinet/cradle and the inclinometer on a flat level horizontal plane (0° ± 0.5°) to establish a reference plane. Zero the inclinometer.**	
[New suggested] Section 7.8.1.3	**Disengage any locking mechanisms designed to prevent the unit from rocking/swinging, per the manufacturer's instructions.**	
[New suggested] Section 7.8.1.4	**Place the CAMI Infant Dummy, Mark II belly up, with both arms contacting the torso, and the right arm touching the left side wall in the bassinet/cradle. See Figure 2.**	Since it is reasonable to assume that a caregiver would place the infant belly up, the CAMI dummy should be positioned as such.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

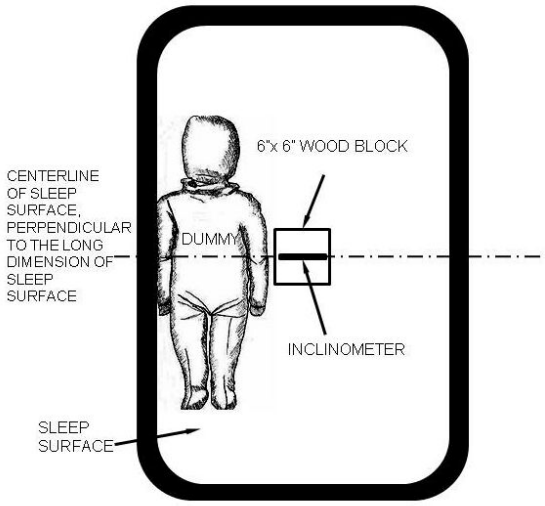
ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 7.8.1.5	**Manually deflect and hold the bassinet/cradle to the maximum side-to-side rock/swing angle allowed by the product design in the manufacturer's use position in the manner normally associated with rocking/swinging and intended by the manufacturer. Record the maximum deflection angle.**	
[New suggested] Section 7.8.1.6	**Release the bassinet/cradle and allow it to come to rest unassisted.**	
[New suggested] Section 7.8.1.7	**Place the 6 in. x 6 in. wood block (ref. Section 7.3.2) less than 1 in. from the dummy, where the horizontal center of the block is in line with the centerline of the mattress bed perpendicular to the head-to-toe axis of the dummy. See Figure 2. If a block cannot be placed in the prescribed location inside the mattress bed area due to mattress size constraints, dummy position, or if the mattress is substantially curved, then mount a 1 in. aluminum angle (ref. Section 7.4.2) on top of the rigid bassinet frame. See Figure 3.**  **Figure 2: Top View of CAMI Dummy and Inclinometer Placed in the Sleep Surface for the Side-to-Side Swing Test**	This section was added to account for wrinkles or any sagging of the mattress itself.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

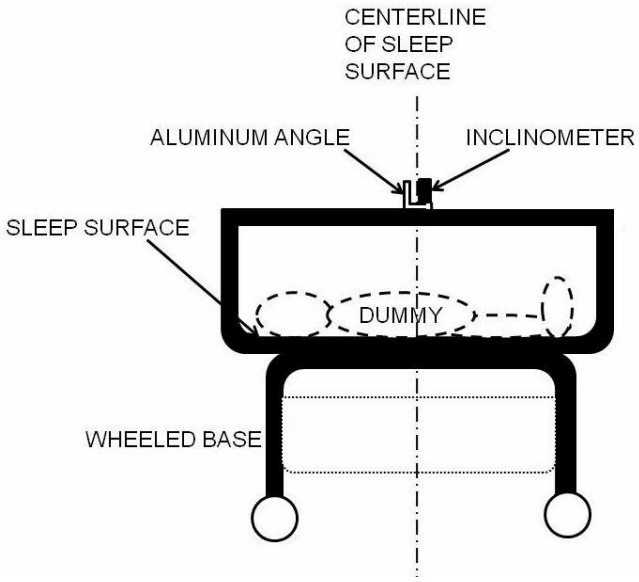
ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
	 **Figure 3: Side View of CAMI Dummy Placed in the Sleep Surface with the Inclinometer and Aluminum Angle Mounted on Top of the Product**	
[New suggested] Section 7.8.1.8	**Place the inclinometer on the top center of the 6 in. x 6 in. wood block or aluminum angle and record the resulting angle.**	
[New suggested] section 7.8.1.9	**Repeat steps 7.8.1.2 to 7.8.1.8 four additional times. Record each side-to-side maximum deflection angle and each resulting side-to-side rest angle measurement. Calculate the arithmetic mean of the five side-to-side rest angle measurements.**	
[New suggested] section 7.8.1.10	**Repeat steps 7.8.1.2 to 7.8.1.9 except place the CAMI infant dummy, Mark II belly up, with both arms contacting the torso, and the left arm touching the right side wall in the bassinet/cradle.**	Left and right directions need to be tested as many products in the market do not have symmetrical mattresses/sleeping areas.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] section 7.8.1.10	**Repeat steps 7.8.1.2 to 7.8.1.10 using a CAMI Newborn Dummy.**	Incident data have shown that the age and weight range of infants vary from newborn to greater than 5 months. CPSC staff recommends additional testing with the Newborn CAMI Dummy, as CPSC staff has observed that some products have better angle results with the Newborn CAMI Dummy and others get better results with the CAMI Dummy, Mark II. Since it is not clear to CPSC staff which dummy is the most severe for **all** products, CPSC staff recommends performing tests with both dummies.
[New suggested] section 7.8.2	***Front-to-Back Rock/Swing Test* – for bassinets/cradles that have a front-to-back (head-to-toe) rocking/swinging feature**	If some products can swing in the head-to-toe axis, then the product shall be tested in that direction as well.
[New suggested] section 7.8.2.1	**Assemble bassinet/cradle in accordance with manufacturer's instructions and, if necessary, place the bassinet/cradle in the front-to-back rocking/swinging mode.**	
[New suggested] section 7.8.2.2	**Place the bassinet/cradle and the inclinometer on a flat level horizontal plane (0° ± 0.5°) to establish a test plane. Zero the inclinometer.**	
[New suggested] section 7.8.2.3	**Disengage any locking mechanisms designed to prevent the unit from rocking/swinging, per the manufacturer's instructions.**	
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

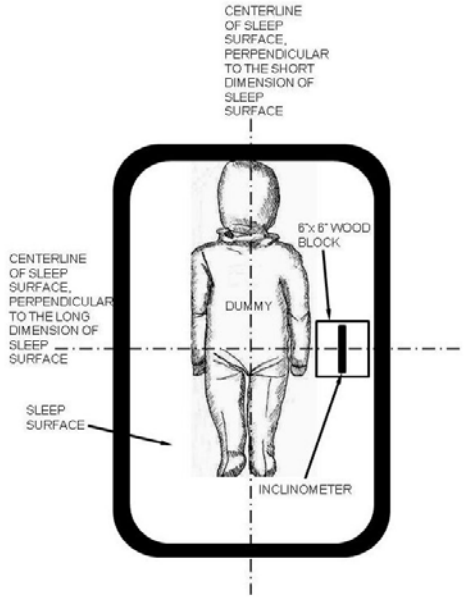
ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] section 7.8.2.4	**Place the CAMI infant dummy, Mark II belly up, with both arms contacting the torso, and the crown of the dummy's head touching the inside wall at one end of the sleep surface and the dummy's head-to-toe centerline is in line with the centerline perpendicular to the short dimension of the sleep surface. See Figure 4.**  **Figure 4: Top View of CAMI Dummy and Inclinometer Placed in the Sleep Surface for the Front-to-Back Swing Test**	
[New suggested] section 7.8.2.5	**Manually deflect and hold the bassinet/cradle to the maximum rock/swing angle in the front-to-back direction allowed by the product design in the manufacturer's use position in the manner normally associated with rocking and intended by the manufacturer. Record the maximum rock/swing angle.**	
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 7.8.2.6	**Release the bassinet/cradle and allow the bassinet/cradle to come to rest unassisted.**	
[New suggested] Section 7.8.2.7	**Place the 6 in. x 6 in. wood block (ref. Section 7.3.2) where the horizontal centerline of the wood block is in line with the horizontal centerline of the sleep surface. See Figure 4. If the wood block cannot be placed in the prescribed location on the mattress bed area due to mattress size constraints, dummy position, or if the mattress is substantially curved, then mount a 1 in. aluminum angle (ref. Section 7.4.2) spanning the top of the rigid bassinet frame in a direction parallel to the long dimension of the bassinet.**	
[New suggested] section 7.8.2.8	**Place the inclinometer on the top center of the 6 in. x 6 in wood block or aluminum angle. Record the resulting rest angle.**	
[New suggested] section 7.8.2.9	**Repeat steps 7.8.2.2 to 7.8.2.8 four additional times. Record each front-to-back maximum deflection angle and each resulting rest angle measurement. Calculate the arithmetic mean of the five rest angle measurements.**	
[New suggested] section 7.8.2.10	**Repeat 7.8.2.2 to 7.8.2.9 with the CAMI Dummy, Mark II feet touching the inside at one end of the sleep surface and the dummy's torso centerline in line with the centerline perpendicular to the short dimension of the sleep surface.**	
New suggested] section 7.8.2.11	**Repeat 7.8.2.2 to 7.8.2.10 with the Newborn CAMI Dummy.**	
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 7.9	***Bassinet/Cradle Flatness Angle Test***	This performance test ensures that the sleep surface is flat and will not tilt when either CAMI dummy is placed in a corner or edge. To mimic children flipping over in the mattress bed area (particularly a bassinet/play yard combo with multiple segmented seams), a dynamic test is needed. Several aspects of the existing standard are utilized such as the 6 in. x 6 in. wood block.
[New suggested] Section 7.9.1	**Disable the rocking/swinging feature if the product is equipped with such a feature. Place the CAMI Infant Dummy, Mark II belly up, on the sleep surface in the location most prone to creating a depression, slope, or tilt (e.g., near a seam in the mattress, in a corner, etc.).**	
[New suggested] Section 7.9.2	**Place the 6 in. x 6 in. wood block (ref. Section 7.3.2) on the chest of the dummy and apply a 10.0 ± 0.5 lb compression force within 2 seconds with a force gauge. Discontinue applying the force.**	
[New suggested] Section 7.9.3	**Place the 6 in. x 6 in. wood block (ref. Section 7.3.2) less than 1 in. from the dummy, where the horizontal centerline of the block is in line with the horizontal centerline of the dummy. If the wood block cannot be placed inside the sleep surface of a rocking/swinging product due to mattress size constraints, dummy position, or if the mattress is substantially curved, then mount the 1 in. aluminum angle (ref. Section 7.4.2) on top of the rigid bassinet frame.**	The 1 in. aluminum angle would be used to capture the tilt angle of the bassinet/cradle bed in cases where the sleep surface is relatively small and the mattress can become curved due to the mattress conforming to the shape of the dummy. Even if space was available to place the 6 in. x 6 in wood block to take an angle measurement, the resulting angle from a curved mattress would not be a useful quantity.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

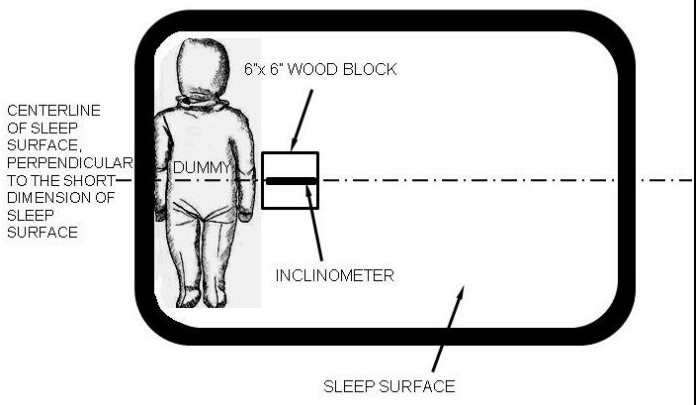
ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 7.9.4	**Record the resulting flatness angle along the dummy's head-to-toe axis and at 90° from the head-to-toe axis.**	
[New suggested] Section 7.9.5	**Repeat steps 7.9.1 to 7.9.4 four additional times. Record each angle measurement and calculate the arithmetic mean of the five angle measurements in the head-to-toe direction and 90° from the head-to-toe axis.**	
[New suggested] Section 7.9.6	**If the dummy's height is equivalent to or less than the width of the sleep surface then rotate the dummy 90° and repeat steps 7.9.1 to 7.9.5. See Figure 5.**  **Figure 5: Top View of CAMI Dummy and Inclinometer, Rotated 90°, Placed in the Sleep Surface for the Mattress Flatness Test**	
[New suggested] Section 7.9.7	**Repeat 7.9.1 to 7.9.6 with the Newborn CAMI Dummy.**	
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 7.10	***Fabric Release Test Methods for Enclosed Openings***	On some multi-use products that can convert into a bedside sleeper configuration, CPSC staff believes probe testing in all configurations is appropriate. The chair of the ASTM subcommittee for bassinets and cradles submitted this proposed addition to the existing ASTM standard.
[New suggested] Section 7.10.1	**Assemble and place the bassinet/cradle in the manufacturers in use position.**	
[New suggested] Section 7.10.2	**With the torso test probe attached to a force gauge, place the small end of the probe against the fabric inside wall of the product and between any structural elements in any locations deemed most likely to fail.**	This test procedure evaluates openings which might occur both in the test location and in another location exposed by the fabric release test.
[New suggested] Section 7.10.3	**Apply a 20 lb force to the probe over a period of 5 seconds and hold for an additional 5 seconds.**	The change from the originally proposed 35 lbs by ASTM to 20 lbs is to be consistent with the crib standard (16 CFR Part 1509). Also, 35 lbs appears to be unrealistic for infants in the age range of less than 5 months.
[New suggested] Section 7.10.4	**Upon completion of 7.10.3, if an opening occurs in a location, other than the location being tested, release the probe from the original test location and repeat 7.10.3 at this additional location without adjusting the fabric.**	
[New suggested] Section 7.10.5	**If the product has a removable cover, unfasten all fasteners and/or snaps and Repeat 7.10.2 to 7.10.4.**	
[New suggested] Section 7.10.6	**Repeat 7.10.1 to 7.10.5 in all manufacturers recommended use positions. For multiple use products, the test shall be performed in all possible use modes.**	
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

TABLE 1 – Staff Recommended Changes and Additions to ASTM F 2194 – 07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
Section 8.3.1	In the warning statements, the safety alert symbol ⚠ and the word **WARNING** shall precede the warning statements at each location where warnings are provided and shall not be less than 0.2 in. (5 mm) high. The remainder of the text shall be in letters not less than 0.1 in. (2.5 mm) high **except as specified in 8.4.2.**	The proposed change is based on input from the warnings ASTM task group for bassinets and cradles.
Section 8.4.2.1	Infants ~~can~~ **have** suffocate**d**: • In gaps between ~~an~~ extra pad**ding** and the side of the bassinet/cradle **and** • On soft bedding. ~~NEVER add a mattress, pillow, comforter, or padding.~~ **Use only the pad provided by the manufacturer. NEVER add a pillow, comforter, or another mattress for padding.**	The ASTM task group felt that the word "have" is more emphatic than "can".
[New suggested] Section 8.4.2.2	**8.4.2.2 The words "SUFFOCATION HAZARD" shall be bold face type not less than 0.2 in. (5 mm) high. The words "Infants have suffocated" shall be in characters whose upper case is not less than 0.16 in. (4 mm) high. The remainder of the warning statement shall be standard type style whose upper case shall be at least 0.1 in. (2.5 mm) high.**	The ASTM task group felt that "suffocation hazard" needs to be in a relatively large font to alert the caregiver. The current standard does not specify a font size.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

Tab A Incident Data

Date: Feb 3, 2010

TO : Han Lim
Division of Mechanical Engineering
Directorate for Engineering Sciences

THROUGH: Russell Roegner, Ph.D.
Associate Executive Director
Directorate for Epidemiology

Kathleen Stralka
Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM : Risana Chowdhury
Division of Hazard Analysis

SUBJECT : Bassinets, Cradles, and Infant Hammocks-Related Deaths, Injuries and Potential Injuries; 2006 – Present[11]

Introduction

This memorandum characterizes the number of deaths and injuries and the types of hazards related to bassinets and cradles (products coded as 1537) and infant hammocks (a subset of products coded as 1508, 1537, 1553, or 5037) over a period of about four years beginning in 2006.[12] These characterizations are based on reports received by CPSC staff. However, given the difference in the safety issues involved, the analysis of bassinet and cradle incidents is presented separately from that of infant hammocks.

The ASTM voluntary standard (F 2194-07a$^{\varepsilon 1}$) addresses safety issues related to infant bassinets and cradles. According to the ASTM definition, a bassinet or cradle is a small bed for infants supported by free standing legs, a wheeled base, a rocking base, or which can swing relative to a stationary base. As such, an infant hammock, which is a small bed that swings relative to a stationary base, is also covered under this definition. Additionally, a bassinet or cradle

[11] This analysis was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.
[12] Not all of these incidents are addressable by an action the CPSC could take; however, it was not the purpose of this memorandum to evaluate the addressability of the incidents, but rather to quantify the number of fatalities and injuries reported to CPSC staff and to update any estimates of emergency department treated injuries.

attachment, which is an accessory with a rigid frame that attaches to a non-full size crib or play yard designed for sleeping, is also considered in-scope under the voluntary standard. These products are intended to provide sleeping accommodations for an infant up to approximately five months in age.

I. Incident Data[13] on Bassinets and Cradles

CPSC staff has been closely monitoring incoming incident reports on 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 are drawn into EWS. It is important to note here that the date of entry into the databases is different from the date of the actual incident. A search revealed that the earliest bassinet-related incident in EWS occurred in April, 2006. However, only a handful of all bassinet-related reports with incident dates in 2006 were actually captured in EWS since they preceded the start of the pilot project. To ensure completeness, CPSC staff extracted and analyzed all incidents contained in the CPSC epidemiological databases that were reported to have occurred since January 1, 2006. The number of emergency department treated injuries associated with bassinets and cradles for this time period was insufficient to derive any reportable national estimates[14], and hence is not presented separately in this memo. However, the emergency department treated injuries are included in the total count of reported injuries presented here.

CPSC staff is aware of 61 fatalities, 38 non-fatal injuries, and 110 non-injury incidents related to bassinets and cradles that were reported to have occurred since 2006. Reporting is ongoing. The number of reported fatalities, non-fatal injuries, and non-injury incidents may change in the future.

Fatalities and Non-Fatal Injuries

A. Fatalities

All of the 61 fatalities reported to CPSC staff were asphyxiation deaths. The majority of the deaths (57 out of 61) were asphyxiations where the incident report noted the presence of soft or extra bedding in the bassinet, prone placement of the infant, or the infant getting wedged between the side of the bassinet and mattress or bedding. Soft or extra bedding and the prone placement of an infant are associated with infant mortality from asphyxiation, independent of

[13] 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). These 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 11/24/09. All data coded under product code 1537 was extracted. Upon careful joint review with ES 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. Any case where the official report cited a natural cause of death such as SIDS, pulmonary failure, etc. was excluded. Incidents where the involvement of the bassinet was incidental (such as an incident where the bassinet was knocked over, or an infant was dropped while being placed in or retrieved from a bassinet, or an infant, outside the bassinet, fell on it, for example) was considered out of scope as well. However, all incidents where hazardous environment in and around the bassinet resulted fatalities, injuries, or near-injuries were retained. See Appendix A for a complete listing of data records included in the analysis and Appendix B for a complete listing of data records excluded from the analysis.

[14] 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.

any design hazard. A few were reported as asphyxiation deaths, with no further information available. Only four of these deaths were determined to have resulted from design flaws in the products. Three of the four deaths were due to entrapment of the infant between metal bars of a particular brand of bassinet. Of those three deaths, two of the three infants were six months old and should not have been using the bassinet or cradle because by definition they are only for use up to five months. The fourth death resulted from an infant suffocating in the corner of the bassinet when he rolled into that position due to the unlevel mattress pad.

A comparison of the annual average fatalities in bassinets and cradles reported in this memo and the latest version of the annual report on nursery products[15] may indicate a rise in the number of fatalities in the recent years. However, such a comparison would be flawed. According to the nursery product report, there were 33 deaths (an average of 11 deaths per year) identified in bassinets and cradles for the period 2004-2006. However, the Methodology section in the Appendix of that report indicates that cases "where no direct or circumstantial information was available to determine how the death occurred", were excluded. As such, more cases were excluded from the nursery product report than in this memo. This is a plausible reason for the higher annual average of fatalities presented here.

B. Non-Fatal Injuries

A total of 38 incidents reported an injury to an infant in a bassinet or a cradle. The vast majority of these (23 out of 38, or 61 percent) were identified as falls out of the bassinets. Since 22 of the 23 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 73 percent of the infants were six months or older in age and most of the falls resulted in head and facial injuries. Three of the infants required hospitalization.

Among other serious injuries, there was a report of a skull fracture which resulted from an infant falling out of the bassinet due to non-level-mattress issues, a report of an arm fracture which resulted from a fall due to problems with a bassinet's rocking feature, and a report of a second-degree burn suffered by an infant from the bassinet's overheated mobile. The remaining injuries were mostly limited to contusions and abrasions.

Hazard Pattern Identification

CPSC staff considered all 209 incidents to identify hazard patterns associated with bassinet and cradle-related incidents. The incidents can be grouped into five broad categories:

- Product-related issues (these incidents provide sufficient information to indicate the defects or failure modes in the product)
- Non-product-related issues
- Unknown issues (these incidents lack sufficient information)
- Recalled product-related issues

[15] R.Chowdhury, "Nursery Product-Related Injuries and Deaths among Children under Five," CPSC, November 2009.

- Miscellaneous other issues.

A. *Product-related issues:* Eighty-seven of the 209 incidents (42 percent) reported some sort of failure or defect in the product itself. Listed below are the reported problems, beginning with the most frequently reported concerns:
   - Lack of ***structural integrity***, which includes instability, loose hardware, collapse of the product, and loose wheels, among others.
   - Problems with ***rocking*** bassinets and cradles, with locking or tilting issues which caused the infant to roll/press up against the side/corner of the product and posing a suffocation hazard.
   - Problems with ***mattress-flatness*** issues. Examples include mattresses that would not lay horizontal because of metal rods/other structures designed to be positioned underneath the mattress, lack of rigid mattress support, failure of straps/hooks designed to hold bassinets inside play yards, among others. One death was associated with a mattress flatness issue.
   - Problems with bassinet ***mobiles***, which have components that overheat, smoke, or spark.

B. *Non-product-related issues:* Sixty of the 209 incidents (29 percent) were reports of deaths and injuries that involved no product defect or failure. These included 57 deaths due to asphyxiation, usually attributed to soft/extra bedding or positioning.

C. *Unknown issues:* There were 26 reports (12 percent) where little or no information was available about the circumstances involved. Twenty-five of these reported a fall of the infant out of the bassinet or cradle.

D. *Recalled product-related issues:* There were 19 reports (nine percent) that involved recalled products. Some of the reports were received by CPSC prior to the recalls being published. Among them were seven entrapments (three fatal, two non-fatal injuries, and two non-injury incidents) between the metal rods of the bassinet. The remaining 12 reports were complaints or inquiries from consumers regarding a recalled product.

E. *Miscellaneous other issues:* The remaining 17 incidents reports involved a host of miscellaneous problems ranging from a tear in the bassinet fabric to odors to product assembly/quality issues. Some of these are product-related issues as well.

II. Incident Data on Infant Hammocks

Since there is no product code dedicated to identifying infant hammocks in the CPSC epidemiological databases, all infant hammock-related incidents were identified through a combination search of multiple product codes (1508: baby walkers or jumpers, 1537: bassinets or cradles, 1553: portable baby swings for home use, and 5037: hammocks), keyword ("hammock"), and age (limited to 12 months and under). Although the ASTM standard specifies the user age to be up to approximately five months, CPSC staff included a higher age limit to accommodate for the possibility of pre-mature or physically under-developed infants. To

maintain consistency with the bassinets and cradles-related incident data, staff extracted and analyzed all reports related to infant hammocks with incident dates since January 1, 2006[16]. The number of emergency department treated injuries associated with infant hammocks for this time period was insufficient to derive any reportable national estimates[17], and hence is not presented separately in this memo. However, the emergency department treated injuries are included in the total count of reported injuries presented here.

CPSC staff is aware of three fatalities, six non-fatal injuries, and five non-injury incidents related to infant hammocks that were reported to have occurred since 2006. As in the case of bassinet-related incident data in the previous section, it is important to note that the number of reported fatalities, non-fatal injuries, and non-injury incidents presented here may also change in the future since reporting is ongoing.

Fatalities, Non-Fatal Injuries, and Non-Injury Incidents

A. Fatalities

All three fatalities reported to CPSC staff were asphyxiation deaths. One five-month old infant was found rolled into a corner in prone position with the bed in an inclined position. A four-month old infant was found with her face flat against the foam mattress. In the third case, the medical examiner who reported the fatality expressed concern about the safety of the hammock as a sleeping environment. However, the death of the six-month old decedent, who was found in prone position, was officially ruled to be asphyxiation due to respiratory infection.

B. Non-Fatal Injuries

All six non-fatal injuries were reported through the emergency department treated injury surveillance system. Five were reported to have been falls out of the hammocks, while the sixth injury was sustained when a broken component of the hammock struck the infant. Little or no circumstantial information is available on how the falls occurred, except that three of the six infants were eight months or older.

C. Non-Injury Incidents

Two of the five reports involved infants (a seven-month old and a 12-month old) in near-strangulation incidents where the hammock flipped over with the infant dangling from restraints. The remaining three reports involved near-suffocation incidents where the infant rolled into a position from which it was unable to move or free itself. All three of these infants were under five months of age.

[16] Date of extraction for reported incident data on infant hammocks was 01/29/2010. See Appendix C for a complete listing of records included in and excluded from the analysis following the combination data search.
[17] 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.

Tab B Engineering Assessment of ASTM F 2194 – 07a $^{\varepsilon 1}$

Date: February 18, 2010

TO : Briefing Package

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

Linda Edwards
Acting Associate Executive Director
Directorate for Engineering Sciences

FROM : Han Lim
Mechanical Engineer, Division of Mechanical Engineering
Directorate for Engineering Sciences

SUBJECT : Engineering Assessment of ASTM F 2194-07a$^{\varepsilon 1}$, *Standard Consumer Safety Specification for Bassinets and Cradles*

I BACKGROUND / OVERVIEW

Section 104 of the Consumer Product Safety Improvement Act (CPSIA), *Standards and Consumer Registration of Durable Nursery Products*, requires the U.S. Consumer Product Safety Commission (CPSC) to assess the effectiveness of voluntary consumer product safety standards for durable infant and toddler products and to promulgate mandatory safety standards. Section 104 (b)(1)(B) states that "The Commission shall…promulgate consumer product safety standards that -- (i) are substantially the same as voluntary standards; or (ii) are more stringent than such voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products."

CPSC Division of Mechanical Engineering (ESME) staff conducted an assessment of the ASTM International[18] (ASTM) voluntary standard for bassinets and cradles, ASTM F 2194-07a$^{\varepsilon 1}$ *Standard Consumer Safety Specification for Bassinets and Cradles.* ESME staff recommends several changes to ASTM F 2194-07a$^{\varepsilon 1}$ to improve bassinet and cradle safety.

[18] Prior to 2001, ASTM International was known as American Society for Testing and Materials.

Incident Data Review

Bassinet/Cradle Incidents

CPSC Directorate for Epidemiology staff reports 209 incidents (related to bassinets and cradles) since 2006[19], of which there were 61 fatalities, 38 non-fatal injuries, and 110 non-injury incidents. The incidents were grouped into five categories: (a) product-related issues (sufficient information were available to describe the product failure modes or defects), (b) non-product related issues, (c) unknown issues (incidents that lack specificity), (d) recalled product-related issues, and (e) miscellaneous other issues.

Product-Related Issues: Approximately 42 percent (87 out of 209) of the incidents involved hardware failures or design issues related to the product. The reported problems are listed below, beginning with the most frequently reported incidents:

- Inadequate ***structural integrity***, which includes unstable bassinets or cradles, loose hardware, collapse of the product, loose wheels, etc.
- Issues with ***rocking/swinging*** bassinets and cradles, with locking or tilting issues which caused the infant to roll/press up against the side/corner of the product and posing a suffocation hazard.
- Problems with ***mattress flatness***. Examples include mattresses that would not remain horizontal because of metal rods/other structures designed to be positioned underneath the mattress, lack of rigid mattress support, failure of straps/hooks designed to hold bassinets inside play yards, among others. One death was associated with a mattress flatness issue.
- Problems with battery powered bassinet ***mobiles***, which had components that overheated, smoked, or sparked.

Non-Product-Related Issues: Sixty (29 percent) of the 209 incident reports were of deaths and injuries that involved no product defect or failure. Fifty-seven of the 60 incidents were deaths where a determination of causation or associations is complicated by a confounding issue because of the inappropriate use of pillows, blankets, or mattresses that were not approved by the manufacturer.

Unknown Issues: Twenty-six incident reports (12 percent) had little or no information. Twenty-five of these reported a fall of the infant out of the bassinet or cradle.

Recalled Product-Related Issues: There were 19 reports (nine percent) that involved recalled products. Some of the reports were received by CPSC prior to the recalls being published. Among them were seven entrapments (three deaths, two non-fatal injuries, and two non-injury incidents) between the structural members of the bassinet. The remaining 12 reports were complaints or inquiries from consumers regarding a recalled product.

[19] Memorandum from Risana Chowdhury to Han Lim, "Bassinets, Cradles, and Infant Hammocks Related Deaths, Injuries, and Potential Injuries; 2006 - Present", February 3, 2010

Miscellaneous Other Issues: The remaining 17 incident reports involved a host of miscellaneous problems ranging from a tear in the bassinet fabric to odors to product assembly/quality issues. Some of these are product-related issues as well.

Hammock Incidents

While the current ASTM F 2194 – 07a $^{\varepsilon 1}$ standard does not explicitly state that infant hammocks are within the scope of the standard, JPMA has historically certified infant hammocks under ASTM F 2194 – 07 a $^{\varepsilon 1}$. A bassinet/cradle is defined as a small bed for infants supported by free standing legs, a wheeled base, a rocking base, or which can swing relative to a stationary base. At least thirteen firms supply infant hammocks that fit this definition. Two firms have hammocks certified by JPMA to the ASTM F 2194 – 07a $^{\varepsilon 1}$ standard.

Due to a recent recall of an infant hammock, CPSC staff is aware of a known hazard with certain hammocks. Since the sleeping environment of most hammocks differs from that of bassinets or cradles, CPSC staff believes a separate standard for hammocks may be necessary. Most hammocks have mattresses that are flexible and conform to the body contours of the infant, whereas bassinets and cradles have flat, mattresses with solid sides or fabric sides. In a November 17, 2009 CPSC/ASTM teleconference, ASTM agreed to form a subcommittee to develop requirements for a new hammock standard. Until a separate standard for hammocks is developed, CPSC staff believes it is prudent to include hammocks under staff's draft proposed rule for bassinets and cradles as an interim measure. The Commission may remove hammocks from the scope of a bassinets/cradles standard in the future, should ASTM develop an effective voluntary standard for hammocks.

Since no product code dedicated to identifying infant hammocks exists in the CPSC epidemiological databases, all infant hammock-related incidents were identified through a combination search of multiple product codes (1508: baby walkers or jumpers, 1537: bassinets or cradles, 1553: portable baby swings for home use, and 5037: hammocks), keyword ("hammock"), and age (limited to 12 months and under). Although ASTM F 2194 – 07a $^{\varepsilon 1}$ specifies the user age to be up to approximately five months, CPSC staff included a higher age limit to accommodate for the possibility of pre-mature or physically under-developed infants that may have been using hammocks. To maintain consistency with the bassinets and cradles-related incident data, all reports related to infant hammocks with incident dates since January 1, 2006[20] were extracted and analyzed. The number of emergency department-treated injuries associated with infant hammocks for this time period was insufficient to derive any reportable national estimates[21]. However, the emergency department-treated injuries are included in the total count of reported injuries presented here. CPSC staff is aware of three fatalities, six non-fatal injuries, and five non-injury incidents related to infant hammocks that were reported to have occurred since 2006.

All three fatalities reported to CPSC staff were asphyxiation deaths. One five-month old infant was found rolled into a corner in prone position with the bed in an inclined position. A four-

[20] Date of extraction for reported incident data on infant hammocks was 01/29/2010.
[21] 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.

month old infant was found with her face flat against the foam mattress. In the third case, the medical examiner who reported the fatality expressed concern about the safety of the hammock as a sleeping environment. However, the death of the six-month old decedent, who was found in prone position, was officially ruled to be asphyxiation due to respiratory infection.

All six non-fatal injuries were reported through the emergency department treated injury surveillance system. Five were reported to have been falls out of the hammocks, while the sixth injury was sustained when a broken component of the hammock struck the infant. Little or no circumstantial information is available on how the falls occurred, except that three of the six infants were eight months or older.

Two of the five non-injury reports involved infants (a seven-month old and a 12-month old) in near-strangulation incidents where the hammock flipped over with the infant dangling from restraints. The remaining three reports involved near-suffocation incidents where the infant rolled into a position from which it was unable to move or free itself. All three of these infants were under five months of age.

A) Adequacy of the Current ASTM F 2194-07a$^{\varepsilon 1}$ Requirements

ASTM F 2194-07a$^{\varepsilon 1}$ contains several labeling and performance criteria. The standard addresses many of the same hazards associated with other durable nursery products and includes requirements for tip stability, unintentional folding of the product, lead in paints, sharp edges/sharp points, small parts, wood part splinters, scissoring/shearing/pinching, openings/entrapments, warning labels, and toys (which includes battery powered mobiles). ESME staff believes that updates and modifications in certain areas may also address the hazards described in the incident data, such as suffocation due to mattress tilting, placing of inappropriate bedding materials (e.g., pillows, additional blankets, etc.), and entrapment in the frame structure. While overheating of battery powered mobiles was identified in the incidents, those incidents were isolated to one company and it appeared that it was not an industry-wide problem.

B) Review of Foreign Standards

ESME staff reviewed foreign standards related to bassinets and/or cradles. These standards have areas of overlap with ASTM F 2194-07a$^{\varepsilon 1}$. Table 1 below shows the standards and the respective additional safety requirements ESME staff has used in the staff's draft proposed rule. Only the British standard did not have any additional requirements ESME staff deemed applicable.

TABLE 1: Review of Foreign Standards

Standard Number	Standard Name	Additional Requirement
AS/NZS 4385:1996	Australian/New Zealand Standard for Infant's Rocking Cradles – Safety Requirements	5° rest angle
SOR 86-962	Canadian Standard for Cribs and Cradles	20° maximum rock/swing angle
BS EN 12790:2002	British Standard for Child Care Articles – Reclined Cradles	--

A detailed discussion of the above criteria is provided in subsequent sections of this memorandum.

II STAFF'S PROPOSED SAFETY STANDARD FOR BASSINETS AND CRADLES

ESME staff recommends that ASTM F 2194-07a$^{\varepsilon 1}$ be adopted as the mandatory safety standard for bassinets and cradles with the following additions and modifications:

- Specify in the scope that the standard is a performance specification for bassinets and cradles and that the intended use is for infants that are not able to push up on hands and knees;
- Terminology that defines what constitutes a bassinet or cradle;
- Performance requirement and test procedure for maximum rocking angle and maximum rest angle of the mattress bed;
- Performance requirement and test procedure for fabric sided bassinets and cradles;
- Performance requirement and test procedure for locking mechanisms intended to prevent rocking/swinging cradles from rocking/swinging the mattress bed;
- Updated warnings to address proper use of bedding materials by providing more emphasis and prominence to the warnings; and
- Exclusion of strap restraints in bassinets and cradles.

A) Scope, Section 1 and References, Section 2 of ASTM F 2194 – 07a$^{\varepsilon 1}$

ESME staff believes that a clear definition of what constitutes a bassinet or cradle is needed to more precisely identify which products are covered in the staff's draft proposed rule. Table 2 below shows the suggested changes to the existing text in Section 1.3 and a new suggested Section 2.3 to include a reference for the Newborn CAMI Dummy.

TABLE 2: Suggested Changes to the Scope Section in ASTM F 2194-07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
Section 1.3	This consumer safety performance specification covers products intended to provide sleeping accommodations **only** for infants 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 infant swing are not covered by this specification.	CPSC staff is in agreement with ASTM regarding 5 months as the general appropriate age for these products. Additionally, the objective criteria of an infant capable of pushing up on hands and knees gives clarity to which products would be considered bassinets or cradles. These products should only be used in the early stages of an infant's development. Once an infant can push up by him/herself, a number of hazards are created, most notably falling hazards.
[New suggested] Section 2.3	Newborn CAMI Dummy (See Figure TBD)	Since the staff's draft proposed standard requires testing with the 7 lb Newborn CAMI Dummy, this reference and photograph needs to be included.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

B) Terminology, Section 3 of ASTM F 2194 – 07a$^{\varepsilon 1}$

ESME staff recommends improving the definition of bassinet/cradle by identifying the products that are excluded from this standard. Products such as swings, full and non-full size cribs and hand carrying baskets should not be considered a bassinet or cradle.

The ASTM subcommittee for bassinets and cradles and CPSC staff determined that definitions for double action release mechanisms, removable covers, and the various angle measurements are needed. Table 3 below shows the suggested changes to the existing text in the terminology Section 3 of ASTM F 2194-07a$^{\varepsilon 1}$.

TABLE 3: Suggested Changes to the Terminology in ASTM F 2194-07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
Section 3.1.1	*bassinet/cradle, n*—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. **Products such as swings, full and non-full size cribs, hand carrying baskets, and travel beds are not included, unless the product is a bassinet/cradle attachment per the definition in Section 3.1.2.**	This updated definition clarifies that full-size and non-full size cribs are not covered. A bassinet or cradle is defined as a product that must be supported by a base per Section 3.1, thus hand carrying baskets, travel beds, and other products are not covered. The scope of the standard includes hammocks, as several hammocks in the marketplace fit the definition of 3.1.1. ESME staff observed that the use patterns of hammocks are somewhat different than those of bassinets/cradles. ESME staff believes that study of the use patterns of hammocks and the associated hazards is necessary to develop appropriate performance requirements and test procedures to ensure that hammocks can facilitate a safe, level sleeping environment for infants.
Section 3.1.2	*bassinet/cradle accessory, n* – accessory with a rigid frame that attaches to non-full size crib, play yard, or other base unit designed ~~for sleeping~~ **to convert the accessory into a bassinet/cradle.**	This updated definition of a bassinet/cradle accessory avoids confusion with accessories than can attach to products that are not intended exclusively for sleeping such as strollers.

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 3.1.12	***double action release mechanism*, n—mechanism requiring either two consecutive actions, the first of which must be maintained while the second is carried out or two separate and independent single action locking mechanisms that must be activated simultaneously to fully release.**	ESME staff has observed various multi-use products that can convert from a rocking bassinet to a stationary one. During this conversion, there are dual-action locking mechanisms that require rotating pop-out casters and then engaging a "tab"-lock to prevent the casters from rolling. The above example is not a double action release mechanism although it may appear to be one. To avoid confusion in what constitutes a double action release mechanism, the definition from the ASTM high chair standard F 404-08 is reproduced here. While there are no reported injuries or deaths, ESME staff believes that if a product is equipped with such a locking mechanism, it should work as intended and resist collapse and/or movement.
[New suggested] Section 3.1.13	***Removable cover, n* – A fabric cover, containing snaps or other fasteners such as zippers, Velcro, or buttons used to attach to a bassinet/cradle frame that requires consumer action as a step for removal or adjustment.**	ESME staff recommends including a definition for removable cover. The term removable cover is referenced in the test procedure for evaluating possible scenarios of "pockets" that may create entrapment hazards from bounded areas of fabric and rigid sides. Detailed discussions are in Sections E and F of this memorandum.
[New suggested] Section 3.1.14	***Maximum deflection angle*, n—the maximum rock/swing angle measurement allowed by the product design in the manufacturer's use position in the manner normally associated with rocking/swinging and intended by the manufacturer when tested in accordance with 7.8.**	These angle measurement terms were added in reference to the performance test requirements as described in Sections E and F of this memorandum.
[New suggested] Section 3.1.15	***Rest angle*, n—the resulting angle measurement of bassinet/cradle sleeping surface after the maximum deflection angle is applied and released and the product has come to a complete rest when tested in accordance with 7.8.**	

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 3.1.16	***Flatness angle*, n— the resulting angle measurement of the sleep support surface or tilt angle of the bassinet/cradle bed when a compression force is applied to the chest of the CAMI dummy in accordance with 7.9.**	
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

C) Calibration and Standardization, Section 4 of ASTM F 2194 – 07a$^{\varepsilon 1}$

ESME staff recommends standardizing performance specifications for the measurement instrumentation used for measuring angles and forces for the various performance tests. Table 4 below shows the suggested changes to the existing text in the Calibration and Standardization Section 4 of ASTM F 2194-07a$^{\varepsilon 1}$.

TABLE 4: Suggested Additions to Calibration and Standardization in ASTM F 2194-07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 4.6	**Angle measurements shall be obtained using a digital inclinometer capable of 0.1° minimum resolution.**	To minimize variability, ESME staff recommends specifying the type of angle instrument and the measurement resolution.
[New suggested] Section 4.7	**Equipment – Force gauge with a range of 0 to 25 lbf (111N) with a maximum tolerance of ± 0.25 lbf (1.11N) or a range of 0 to 50 lbf (222N) with a maximum tolerance of ± 0.25 lbf (1.11N). A calibration interval shall be maintained for the force gauges which will ensure that the accuracy does not drift beyond the stated tolerances.**	To minimize variability, ESME staff recommends specifying the tolerance and calibration interval for the force gauge.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

D) General Requirements, Section 5 of ASTM F 2194 – 07a$^{\varepsilon 1}$

CPSC Directorate for Health Sciences staff recommends eliminating restraints on bassinets and cradles as they may introduce strangulation hazards. Infants under 5 months who cannot push up on hands and knees lying on a flat surface do not need restraints. ESME staff is aware of at least

two products that have triangular crotch restraints with adjustable straps. The suggested changes are shown in Table 5.

TABLE 5: Suggested Addition to the General Requirements in ASTM F 2194-07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 5.13	***Restraints* – The bassinet shall not include any restraint system which requires action on the part of the caregiver to secure the restraint.**	Restraints are needed on products that require infants to be seated or propped up. Infants lying on a flat surface **do not** need restraints and their use could contribute to a possible strangulation hazard. CPSC staff is aware of at least two products that are equipped with crotch restraints.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

E) Performance Requirements, Section 6 of ASTM F 2194 – 07a$^{\varepsilon 1}$

Entrapment and suffocation are two major hazards associated with bassinets and cradles. The following suggested changes may help reduce these hazards, as they address mattress bed tilting issues and any entrapment hazards from bounded areas of fabric and rigid sides.

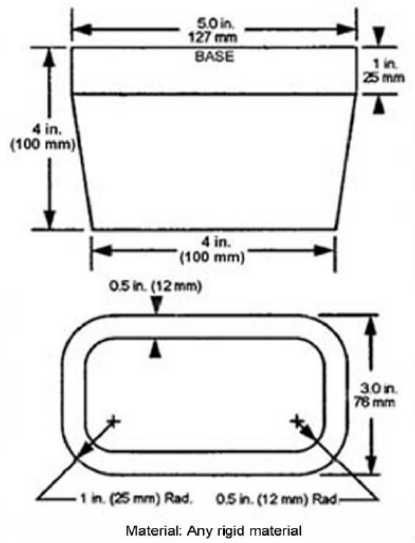
Additionally, examination of the current bassinet and cradle products in the marketplace has shown a number of features that provide conveniences for the parent or caregiver. These features include locking mechanisms to prevent a cradle from rocking/swinging and crotch restraints to keep infants from shifting inside a rocking/swinging cradle. Incident data show that locking mechanism failures have resulted in scenarios that can potentially be fatal (e.g., a locking mechanism fails to keep the cradle stationary which causes the infant roll over into a face-down suffocation scenario). ESME staff's suggested changes in Table 6 are provided to address these hazards, which may result in safer bassinets and cradles.

TABLE 6: Suggested Changes to the Performance Requirements in ASTM F 2194-07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
Section 6.1	***Spacing of Rigid and Fabric Sided Bassinet/Cradle Components*** – Spacing must comply with 16 CFR Part 1509 Section 1509.4 when tested according to 7.1 **and 7.10**.	To address entrapment hazards from bounded areas of fabric and rigid sides, Section 6.1 will include an additional test procedure reference 7.10 for those products that have fabric sides.

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
Section 6.4	*Stability*—A product in all manufacturers' recommended use positions**, including positions where the locks are engaged for preventing rocking/swinging motion of the sleeping surface,** shall not tip over and shall retain the CAMI dummy[22] when subjected to the test described in 7.4.	The bold, underlined phrase was added for clarity and completeness to ensure that the testing laboratory would test the stability of the product in modes where the locks are engaged to prevent swinging/rocking. As noted before, hardware failures with locking mechanisms were identified in incident reports of potential entrapments and suffocations.
[New suggested] Section 6.7	***Rock/Swing Angle* – Bassinets or cradles that incorporate a rocking/swinging feature shall meet the following:**	
[New suggested] Section 6.7.1	**Maximum deflection angle measurement on any reading shall not exceed 20° when tested in accordance with 7.8.**	The 20° recommendation is based on the Canadian regulation for cribs and cradles (SOR 86-962) and measurements/ observations made by CPSC staff on recent model bassinets/cradles. The 5° recommendation is based on the Australian study "The Danger of Freely Rocking Cradles" by S.M. Beal et al, *Journal of Pediatric Child Health* (1995) 31, 38-40 and AS/NZS 4385:1996 the Australian/New Zealand standard for infant's rocking cradles.
[New suggested] Section 6.7.2	**The arithmetic mean of the rest angle measurements shall not exceeding 5° when tested in accordance with 7.8**	
[New suggested] Section 6.8	***Bassinet/Cradle Surface Orientation* – The angle of the bassinet or cradle sleeping support surface or the tilt angle of the bassinet/cradle bed shall not be greater than 5° when tested in accordance to 7.9.**	For non-rocking and rocking bassinets or cradles, this performance requirement ensures that the sleep surface is flat and will not tilt when either CAMI Dummy is placed in a corner or edge. Incidents involving bassinet/play yard combos suggest that a sloped surface or a mattress with multiple seams (mattresses that double as a play yard cover) may have the potential for a positional asphyxia suffocation hazard.

[22] Civil Aeromedical Institute (CAMI) Infant Dummy, Mark II, constructed in accordance with the Department of Transportation Specification dated April 29, 1975.

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 6.9	***Fabric Sided Enclosed Openings*– For bassinets or cradles with fabric sides, the fabric shall not release and form a completely bounded opening that allows the complete passage of the torso probe (Figure 1) when tested in accordance with Section 7.10.**  **Figure 1 – Torso Test Probe for Fabric Sided Testing**	On some multi-use products that can convert into a bedside sleeper configuration, ESME staff believes use in this configuration is foreseeable and probable and therefore a probe test in the configuration described below should be performed. The chair of the ASTM subcommittee for bassinets and cradles submitted this proposed addition to the existing ASTM standard. ASTM commented that it is not foreseeable that a parent or caregiver will place a child in a "bare" bassinet while the fabric is completely removed for washing or cleaning. CPSC staff concurred with this observation. However, it is foreseeable that a parent or caregiver can loosely place the fabric back onto the bassinet or cradle after washing but may forget to fasten the snaps, zippers, or other fasteners. An example that is very similar to the above scenario is the 2000 CPSC recall of Kids Line Inc. Le Cradle Bassinets[23]. Therefore in the scenario where the fabric is on the product without the snaps, zippers, etc. fastened, the product still needs to comply with the crib spacing requirements when subjected to the probe test as described in this section.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

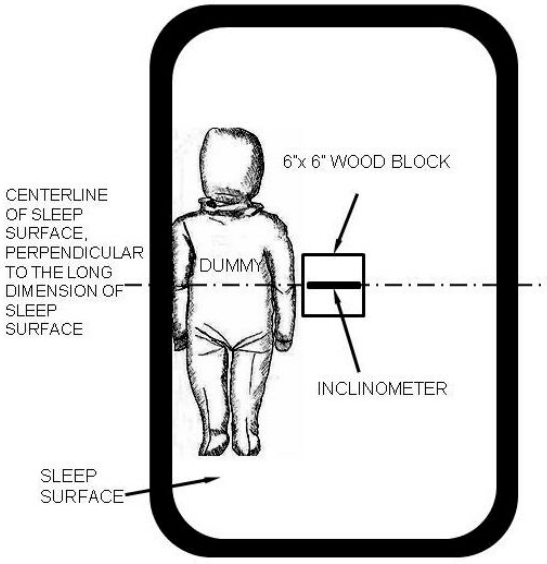
F) **Test Methods, Section 7 of ASTM F 2194 – 07a$^{\varepsilon 1}$**

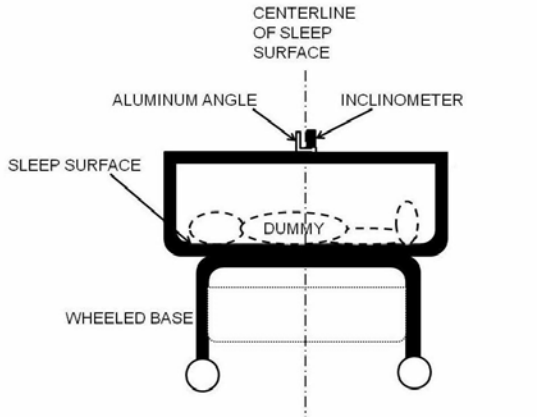
ESME staff proposes several performance tests to be conducted with the 7 lb Newborn Infant CAMI Dummy as well as the 17.5 lb, 50th percentile – 6 month CAMI Infant Dummy, Mark II. A new test method for evaluating tilt angle, as well as the maximum travel angle, is included to ensure that the infant does not suffocate as a result of being placed at an angle, where the infant can roll over and suffocate. The suggested changes are shown in Table 7.

[23] CPSC Recall Notice: "CPSC, Kids Line Inc. Announce Recall to Repair Le Cradle Bassinets," August 23, 2000. Website: http://www.cpsc.gov/cpscpub/prerel/prhtml00/00167.html

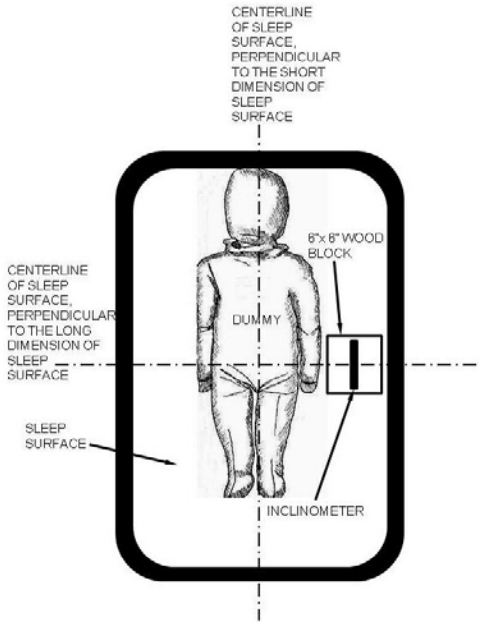
TABLE 7: Suggested Changes to the Test Methods in ASTM F 2194-07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 7.8	***Rock/Swing Angle Test***	This new suggested Section 7.8 was taken from the Task Group of the ASTM subcommittee for bassinets and cradles who were investigating rock angle measurements. ESME staff is proposing changes to the draft ASTM procedure: additional testing with the Newborn Infant CAMI Dummy, specific angle measurement procedures, and additional testing in the head-to-toe direction, if applicable.
[New suggested] Section 7.8.1	**Side-to-Side Rock/Swing Test - for bassinets/cradles that have a side-to-side rocking/swinging feature.**	
[New suggested] Section 7.8.1.1	**Assemble the bassinet/cradle in accordance with manufacturer's instructions and, if necessary, place the bassinet/cradle in rocking/swinging mode.**	
[New suggested] Section 7.8.1.2	**Place the bassinet/cradle and the inclinometer on a flat level horizontal plane (0° ± 0.5°) to establish a reference plane. Zero the inclinometer.**	
[New suggested] Section 7.8.1.3	**Disengage any locking mechanisms designed to prevent the unit from rocking/swinging, per the manufacturer's instructions.**	
[New suggested] Section 7.8.1.4	**Place the CAMI Infant Dummy, Mark II belly up, along the horizontal centerline of the bassinet/cradle with both arms contacting the torso, and the right arm touching the left side wall in the bassinet/cradle. See Figure 2.**	Since it is reasonable to assume that a caregiver would place the infant belly up, the CAMI dummy should be positioned as such.
[New suggested] Section 7.8.1.5	**Manually deflect and hold the bassinet/cradle to the maximum side-to-side rock/swing angle allowed by the product design in the manufacturer's use position in the manner normally associated with rocking/swinging and intended by the manufacturer. Record the maximum deflection angle.**	
[New suggested] Section 7.8.1.6	**Release the bassinet/cradle and allow it to come to rest unassisted.**	

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 7.8.1.7	**Place the 6 in. x 6 in. wood block (ref. Section 7.3.2) less than 1 in. from the dummy, where the horizontal center of the block is in line with the centerline of the mattress bed perpendicular to the head-to-toe axis of the dummy. See Figure 2. If a block cannot be placed in the prescribed location inside the mattress bed area due to mattress size constraints, dummy position, or if the mattress is substantially curved then mount a 1 in. aluminum angle (ref. Section 7.4.2) on top of the rigid bassinet frame. See Figure 3.**  **Figure 2: Top View of CAMI Dummy and Inclinometer Placed in the Sleep Surface for the Side-to-Side Swing Test**	This section was added to account for wrinkles or any sagging of the mattress itself.

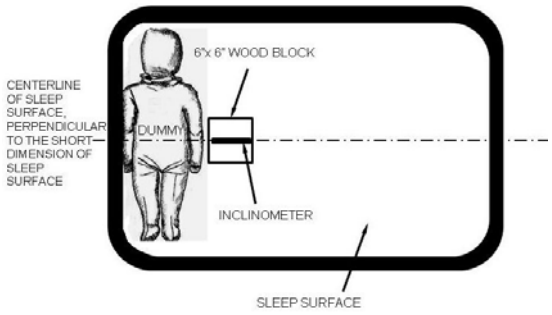
ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
	 **Figure 3: Side View of CAMI Dummy Placed in the Sleep Surface with the Inclinometer and Aluminum Angle Mounted on Top of the Product**	
[New suggested] Section 7.8.1.8	**Place the inclinometer on the top center of the 6 in. x 6 in. wood block or aluminum angle and record the resulting angle.**	
[New suggested] section 7.8.1.9	**Repeat steps 7.8.1.2 to 7.8.1.8 four additional times. Record each side-to-side maximum deflection angle and each resulting side-to-side rest angle measurement. Calculate the arithmetic mean of the five side-to-side rest angle measurements.**	
[New suggested] section 7.8.1.10	**Repeat steps 7.8.1.2 to 7.8.1.9 except place the CAMI infant dummy, Mark II belly up, with both arms contacting the torso, and the left arm touching the right side wall in the bassinet/cradle.**	Left and right directions need to be tested, as many products in the market do not have symmetrical mattresses/ sleeping areas.

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] section 7.8.1.11	**Repeat steps 7.8.1.2 to 7.8.1.10 using a CAMI Newborn Dummy.**	Incident data have shown that the age and weight range of infants vary from newborn to greater than 5 months. ESME staff recommends additional testing with the Newborn CAMI Dummy, as ESME staff has observed that some products have better angle results with the Newborn CAMI Dummy and others get better results with the CAMI Dummy, Mark II. Since it is not clear to ESME staff which dummy is the worst case scenario for **all** products, ESME staff recommends performing tests with both dummies.
[New suggested] section 7.8.2	***Front-to-Back Rock/Swing Test* – for bassinets/cradles that have a front-to-back (head-to-toe) rocking/swinging feature**	If a product can swing in the head-to-toe axis, then the product shall be tested in that direction.
[New suggested] section 7.8.2.1	**Assemble bassinet/cradle in accordance with manufacturer's instructions and, if necessary, place the bassinet/cradle in the front-to-back rocking/swinging mode.**	
[New suggested] section 7.8.2.2	**Place the bassinet/cradle and the inclinometer on a flat level horizontal plane (0° ± 0.5°) to establish a test plane. Zero the inclinometer.**	
[New suggested] section 7.8.2.3	**Disengage any locking mechanisms designed to prevent the unit from rocking/swinging, per the manufacturer's instructions.**	

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] section 7.8.2.4	**Place the CAMI infant dummy, Mark II belly up, with both arms contacting the torso, and the crown of the dummy's head touching the inside wall at one end of the sleep surface and the dummy's head-to-toe centerline is in line with the centerline perpendicular to the short dimension of the sleep surface. See Figure 4.**  **Figure 4: Top View of CAMI Dummy and Inclinometer Placed in the Sleep Surface for the Front-to-Back Swing Test**	
[New suggested] section 7.8.2.5	**Manually deflect and hold the bassinet/cradle to the maximum rock/swing angle in the front-to-back direction allowed by the product design in the manufacturer's use position in the manner normally associated with rocking and intended by the manufacturer. Record the maximum rock/swing angle.**	

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	
[New suggested] Section 7.8.2.6	**Release the bassinet/cradle and allow it to come to rest unassisted.**	
[New suggested] Section 7.8.2.7	**Place the 6 in. x 6 in. wood block (ref. Section 7.3.2) where the horizontal centerline of the wood block is in line with the horizontal centerline of the sleep surface. See Figure 4. If the wood block cannot be placed in the prescribed location on the mattress bed area due to mattress size constraints, dummy position, or if the mattress is substantially curved, then mount a 1 in. aluminum angle (ref. Section 7.4.2) spanning the top of the rigid bassinet frame in a direction parallel to the long dimension of the bassinet.**	
[New suggested] section 7.8.2.8	**Place the inclinometer on the top center of the 6 in. x 6 in wood block or aluminum angle. Record the resulting rest angle.**	
[New suggested] section 7.8.2.9	**Repeat steps 7.8.2.2 to 7.8.2.8 four additional times. Record each front-to-back maximum deflection angle and each resulting rest angle measurement. Calculate the arithmetic mean of the five rest angle measurements.**	
[New suggested] section 7.8.2.10	**Repeat 7.8.2.2 to 7.8.2.9 with the CAMI Dummy, Mark II feet touching the inside at one end of the sleep surface and the dummy's torso centerline in line with the centerline perpendicular to the short dimension of the sleep surface.**	
New suggested] section 7.8.2.11	**Repeat 7.8.2.2 to 7.8.2.10 with the Newborn CAMI Dummy.**	

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 7.9	***Bassinet/Cradle Flatness Angle Test***	This performance test ensures that the sleep surface is flat and will not tilt when either CAMI dummy is placed in a corner or edge. To mimic children flipping over in the mattress bed area (particularly a bassinet/play yard combo with multiple segmented seams), a dynamic test is needed. Several aspects of the existing standard are utilized such as the 6 in. x 6 in. wood block.
[New suggested] Section 7.9.1	**Disable the rocking/swinging feature if the product is equipped with such a feature. Place the CAMI Infant Dummy, Mark II belly up, on the sleep surface in the location most prone to creating a depression, slope, or tilt (e.g., near a seam in the mattress, in a corner, etc.).**	
[New suggested] Section 7.9.2	**Place the 6 in. x 6 in. wood block (ref. Section 7.3.2) on the chest of the dummy and apply a 10.0 ± 0.5 lb compression force within 2 seconds with a force gauge. Discontinue applying the force.**	
[New suggested] Section 7.9.3	**Place the 6 in. x 6 in. wood block (ref. Section 7.3.2) less than 1 in. from the dummy, where the horizontal centerline of the block is in line with the horizontal centerline of the dummy. If the wood block cannot be placed inside the sleep surface of a rocking/swinging product due to mattress size constraints, dummy position, or if the mattress is substantially curved, then mount the 1 in. aluminum angle (ref. Section 7.4.2) on top of the rigid bassinet frame.**	The 1 in. aluminum angle would be used to capture the tilt angle of the bassinet/cradle bed in cases where the sleep surface is relatively small and the mattress can become curved due to the mattress conforming to the shape of the dummy. Even if space was available to place the 6 in. x 6 in wood block to take an angle measurement, the resulting angle from a curved mattress would not be a useful quantity.

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 7.9.4	**Record the resulting flatness angle along the dummy's head-to-toe axis and at 90° from the head-to-toe axis.**	
[New suggested] Section 7.9.5	**Repeat steps 7.9.1 to 7.9.4 four additional times. Record each angle measurement and calculate the arithmetic mean of the five angle measurements in the head-to-toe direction and 90° from the head-to-toe axis.**	
[New suggested] Section 7.9.6	**If the dummy's height is equivalent to or less than the width of the mattress pad then rotate the dummy 90° and repeat steps 7.9.1 to 7.9.5. See Figure 5.**  **Figure 5: Top View of CAMI Dummy and Inclinometer, Rotated 90°, Placed in the Sleep Surface for the Mattress Flatness Test**	
[New suggested] Section 7.9.7	**Repeat 7.9.1 to 7.9.6 with the Newborn CAMI Dummy.**	
[New suggested] Section 7.10	***Fabric Release Test Methods for Enclosed Openings***	On some multi-use products that can convert into a bedside sleeper configuration, ESME staff believes probe testing in all configurations is appropriate. The chair of the ASTM subcommittee for bassinets and cradles submitted this proposed addition to the existing ASTM standard.

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
[New suggested] Section 7.10.1	**Assemble and place the bassinet/cradle in the manufacturers in use position.**	This test procedure evaluates openings which might occur both in the test location and in another location exposed by the fabric release test.
[New suggested] Section 7.10.2	**With the torso test probe attached to a force gauge, place the small end of the probe against the fabric inside wall of the product and between any structural elements in any locations deemed most likely to fail.**	The change from the originally proposed 35 lbs by ASTM to 20 lbs is to be consistent with the crib standard (16 CFR Part 1509). Also, 35 lbs appears to be unrealistic for infants in the age range of less than 5 months.
[New suggested] Section 7.10.3	**Apply a 20 lb force to the probe over a period of 5 seconds and hold for an additional 5 seconds.**	
[New suggested] Section 7.10.4	**Upon completion of 7.10.3, if an opening occurs in a location, other than the location being tested, release the probe from the original test location and repeat 7.10.3 at this additional location without adjusting the fabric.**	
[New suggested] Section 7.10.5	**If the product has a removable cover, unfasten all fasteners and/or snaps and Repeat 7.10.2 to 7.10.4.**	
[New suggested] Section 7.10.6	**Repeat 7.10.1 to 7.10.5 in all manufacturers recommended use positions. For multiple use products, the test shall be performed in all possible use modes.**	
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

G) Marking and Labeling, Section 8 of ASTM F 2194 – 07 a$^{\varepsilon 1}$

Since the majority of the deaths and non-fatal incidents involve suffocation due to caregivers and parents using bedding materials such as pillows and blankets that are not specified by the manufacturer, it is imperative to improve the warning labels. A task group was formed from the ASTM subcommittee for bassinets and cradles to craft language that would be more prominent than the existing warning label requirements as specified in the current ASTM F 2194 – 07a$^{\varepsilon 1}$. ESHF (Engineering Sciences Human Factors) Staff provided the suggested changes in Table 8.

TABLE 8: Suggested Changes to the Marking and Labeling Section in ASTM F 2194-07a$^{\varepsilon 1}$

ASTM F 2194 – 07a$^{\varepsilon 1}$ Section Number	Suggested Change	Explanation for the Proposed Change
Section 8.3.1	In the warning statements, the safety alert symbol ⚠ and the word **WARNING** shall precede the warning statements at each location where warnings are provided and shall not be less than 0.2 in. (5 mm) high. The remainder of the text shall be in letters not less than 0.1 in. (2.5 mm) high **except as specified in 8.4.2.**	The proposed change is based on input from the warnings ASTM task group for bassinets and cradles.
Section 8.4.2.1	Infants ~~can~~ **have** suffocate**d**: • In gaps between ~~an~~ extra pad**ding** and the side of the bassinet/cradle **and** • On soft bedding. ~~NEVER add a mattress, pillow, comforter, or padding.~~ **Use only the pad provided by manufacturer. NEVER add a pillow, comforter, or another mattress for padding.**	The ASTM task group felt that the word "have" is more emphatic than "can".
[New suggested] Section 8.4.2.2	**8.4.2.2 The words "SUFFOCATION HAZARD" shall be bold face type not less than 0.2 in. (5 mm) high. The words "Infants have suffocated" shall be in characters whose upper case is not less than 0.16 in. (4 mm) high. The remainder of the warning statement shall be standard type style whose upper case shall be at least 0.1 in. (2.5 mm) high.**	The ASTM task group felt that "suffocation hazard" needs to be in a relatively large font to alert the caregiver. The current standard does not specify a font size.
Proposed changes are in **bold underline**. Proposed deletions are ~~struck out~~.		

III CONCLUSIONS

ESME staff recommends adopting the requirements specified in ASTM F 2194 – 07a$^{\varepsilon 1}$ as the CPSC mandatory standard for bassinets and cradles with suggested editorial changes and additional requirements not currently found in the ASTM standard. CPSC staff believes this mandatory standard for bassinets and cradles will help reduce injuries and deaths associated with suffocation and entrapment hazards. The additions and edits to the existing ASTM F 2194 – 07a$^{\varepsilon 1}$ may improve bassinet and cradle safety. The proposed changes are to improve the warning labels, include performance standards for mattress bed tilting, and include a performance standard for fabric covered bassinets and cradles.

Tab C Initial Regulatory Flexibility Analysis of Proposed Standard for Bassinets and Cradles

Date: February 16, 2010

TO : Han Lim
Project Manager for Bassinets and Cradles

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 Proposed Standard for Bassinets and Cradles

Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, section 104 requires that Consumer Product Safety Commission (CPSC) staff evaluate the currently existing voluntary standards for durable infant or toddler products and promulgate a mandatory standard substantially the same as, or more stringent than, the applicable voluntary standard. Bassinets and cradles are among the durable products specifically named in section 104. Upon review, CPSC staff has decided to propose adopting the voluntary ASTM standard for bassinets and cradles (F 2194 – 07a$^{\varepsilon 1}$) with a few modifications.

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

1. a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
2. a description of the reasons why action by the agency is being considered;
3. a succinct statement of the objectives of, and legal basis for, the proposed rule;
4. a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the 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.

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

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. They are not intended to be used beyond the age of approximately 5 months.[24] Bassinet and cradle attachments for non-full-size cribs or play yards are considered a part of this product category, as are bedside sleeper bassinets that can be converted to a four-sided bassinet not attached to a bed. Additionally, infant hammocks fit this definition of a bassinet/cradle.[25]

On the other hand, full-size cribs and infant swings are *not* included under this product definition, nor are products used in conjunction with infant swings or strollers or Moses baskets. The exception would be Moses baskets and products used with infant swings or strollers that can be used as a bassinet or cradle by attaching it to a separate base unit. In this case, the product needs to comply when used with the base.[26]

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

1. Bassinets – this includes bedside sleeper bassinets *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 includes other products that can be attached to a base unit and used as a cradle;
3. Infant hammocks; and
4. Play yards – only those with bassinet/cradle attachments.

The Market for Bassinets/Cradles

Bassinets and cradles are typically produced and/or marketed by juvenile product manufacturers and distributors. CPSC staff believes that there are currently at least 48 known manufacturers or importers supplying bassinets and/or cradles to the U.S. market. Nine firms are domestic importers (19 percent), 28 firms are domestic manufacturers (58 percent), and 10 firms are foreign manufacturers (21 percent). There is an additional domestic firm whose status as a

[24] Under the proposed standard, the age limit would be extended to encompass a developmental limit as well; specifically that children should not use bassinets or cradles once they are able to push up on their hands or knees.
[25] Infant hammocks have been JPMA-certified under the ASTM bassinet/cradle standard in the past (two are currently certified).
[26] For example, several companies sell separate stationary (or, in some cases, rocking) bases for both Moses baskets and stroller bassinets.

manufacturer or importer could not be determined.[27] Thirteen of these firms, including the firm whose means of supply could not be determined, supply infant hammocks to the U.S. market.[28] The product lines for seven of these firms rely primarily or entirely on infant hammocks and related merchandise.

Under Small Business Administration (SBA) guidelines, a manufacturer of bassinets or cradles is small if it has 500 or fewer employees and an importer is considered small if it has 100 or fewer employees. Based on these guidelines, 22 of the domestic manufacturers and five of the domestic importers known to be supplying the U.S. market are small. The sizes of the four remaining domestic importers and two additional domestic manufacturers are unknown, but they are likely to be small as well, as is the firm whose supply source could not be determined. All of the firms supplying infant hammocks to the U.S. market are believed to be small. Two of these small firms are domestic manufacturers, four are domestic importers, six are foreign firms, and one is an unknown domestic firm. There are probably additional unknown small manufacturers and importers operating in the U.S. market.

Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers, runs a voluntary certification program for several juvenile products.[29] Approximately 33 percent of firms supply bassinets/cradles to the U.S. market that have been JPMA certified as compliant with the current ASTM voluntary standard (16 firms). Two of these firms supply more than one relevant product category, where one category of products is JPMA certified and another is not.[30] Additionally, one firm claims compliance although their products have not been certified by JPMA and one firm has recently had their product removed from JPMA's list of certified products. Of the small domestic businesses,[31] 38 percent of manufacturers (nine of 24 firms) and 44 percent of importers (four of nine firms) have products that are ASTM compliant. This includes the small manufacturer that claims compliance with the ASTM standard but is not part of the JPMA Certification Program, as well as the firms with only some product categories JPMA certified.[32]

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*),[33] 64 percent of new mothers[34] own bassinets, 18 percent own cradles, 18

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[27] Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites. Manufacturers include traditional manufacturers, as well as firms that send out their designs to be manufactured, and firms that import as well but are primarily manufacturers.

[28] There is an additional hammock on the U.S. market whose supplier could not be determined, as well as a small cottage industry in knitted and crocheted infant hammocks.

[29] JPMA has run this program since 1976, beginning with high chairs. Products voluntarily submitted by manufacturers are tested against the appropriate ASTM standard and only passing products are allowed to display JPMA's Certification Seal. See http://www.jpma.org/pdfs/certfacts08.pdf for more information.

[30] For example, one firm has JPMA certified bassinets, but not play yards.

[31] This includes firms suspected of being small as well as those known to be small.

[32] It should be noted that non-JPMA certified products will not necessarily fail to comply with the ASTM standard. Although there is currently no testing to support such an assumption for bassinets/cradles, testing of other products has revealed a pattern of non-correlation.

[33] 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, since the most recent survey information is from 2005, it may not reflect the current market.

percent own portable play yards with bassinet attachments, and 21 percent own full-size play yards with bassinet attachments. Approximately 50 percent of bassinets, 57 percent of cradles, 23 percent of portable play yards with bassinet attachments, and 17 percent of full-size play yards with bassinet attachments were handed down or purchased second-hand.[35] Thus about 50 percent of the bassinets, 43 percent of the cradles, 77 percent of the portable play yards with bassinet attachments, and 83 percent of the full-size play yards with bassinet attachments were acquired new. This suggests annual sales of about 1.4 million bassinets (.5 x .64 x 4.3 million births per year), 333,000 cradles (.43 x .18 x 4.3 million), 596,000 portable play yards with bassinet attachments (.77 x .18 x 4.3 million), and 749,000 full-size play yards with bassinet attachments (.83 x .21 x 4.3 million).[36] This yields a total of approximately 3.1 million units sold per year that might be affected by the proposed bassinet/cradle standard.

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

Section 104 of the CPSIA requires CPSC to promulgate a mandatory standard for bassinets/cradles that is substantially the same as, or more stringent than, the voluntary standard. CPSC staff is recommending several modifications to the current voluntary standard. Based on the severity and type of the known incidents,[37] CPSC staff believes that the more stringent proposed standard will further reduce the risk of injuries and deaths associated with bassinets, cradles, and infant hammocks.[38]

Compliance Requirements of the Proposed Rule

CPSC staff recommends adopting the voluntary ASTM standard for bassinets and cradles with several modifications. Key components of the current ASTM standard for bassinets and cradles (F 2194 – 07a$^{\varepsilon 1}$) include:[39]

- Spacing of rigid side components – intended to prevent child entrapment between both uniformly and non-uniformly spaced components, such as slats.

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[34] New mothers represent those who have recently given birth, as opposed to expectant mothers. Therefore, the application to annual births is appropriate.

[35] The data on second-hand products for new moms was not available. Instead, data for new moms and expectant moms was combined and broken into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers has been averaged to calculate the approximate percentage that was handed down or purchased second-hand.

[36] 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: Preliminary Data for 2007," *National Vital Statistics Reports* Volume 57, Number 12 (March 18, 2009): 6 (Table 1). Number of live births in 2007 is rounded from 4,317,119.

[37] Memorandum from Risana Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, dated February 3, 2010, Subject: Bassinets, Cradles, and Infant Hammocks-Related Deaths, Injuries and Potential Injuries; 2006 – Present.

[38] Memorandum from Han Lim, ESME, Directorate for Engineering Sciences, dated February 18, 2010, Subject: Engineering Assessment of ASTM F 2194-07 a$^{\varepsilon 1}$, Standard Consumer Safety Specification for Bassinets and Cradles..

[39] JPMA, *ASTM Standards listed in JPMA Directory*, http://www.jpma.org/pdfs/JPMA_Directory_Final2008.pdf.

- 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.
- Stability requirements – intended to ensure that the product does not tip over when pulled on by a two year old male.
- Sleeping pad thickness and dimensions – intended to minimize gaps and minimize the possibility of suffocation due to excessive padding.

The voluntary standard also includes: 1) torque and tension tests to assure 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) latching/locking mechanism requirements to prevent unintentional folding while in use; 4) requirements for the permanency and adhesion of labels; 5) requirements for instructional literature; and 6) corner post extension requirements intended to prevent pacifier cords, ribbons, necklaces, or clothing which a child may be wearing from catching on a projection.

CPSC staff recommends modifying the existing ASTM standard and adding several new requirements:[40]

1. Modifications:
    a. Tests of locking and latching mechanisms would be expanded to include double action release mechanisms.[41]
    b. Spacing requirements for rigid sided components would be extended to soft sided components. A 20 pound torso probe test would be performed. For products with removable covers, this test would be performed with and without the cover fastened.[42]
    c. Stability requirements would be expanded to include testing with the locking mechanism engaged.
    d. Suffocation warnings would be made larger and further emphasize the hazards of adding additional padding.
    e. Modify the scope to include developmental limits as well as age limits. Specifically, the proposed standard would state that the product should no longer be used when a child is able to push up on hands or knees (approximately five months).
    f. Clarify the definition of a bassinet/cradle and a bassinet/cradle attachment. This will effectively eliminate products when not used with a base, such as

[40] Memorandum from Han Lim, ESME, Directorate for Engineering Sciences, dated February 18, 2010, Subject: Engineering Assessment of ASTM F 2194-07 a$^{\varepsilon 1}$, Standard Consumer Safety Specification for Bassinets and Cradles..

[41] To assure consistency, the definition for a double action release mechanism was taken from the ASTM high chair standard (F 404-08).

[42] The staff-recommended rule defines "removable cover." This modification is intended to address "pockets" that may create entrapment hazards from bounded areas of fabric and rigid sides.

Moses (hand carrying) baskets, as well as hammocks. Specifically include infant hammocks within the scope of the staff-recommended rule.

2. New requirements
    a. Only passive restraints (those that do not require any action to engage them) would be allowed.
    b. Set maximum rocking (20°) and rest angles (5°) for products that incorporate a rocking/swinging feature based on standards from Canada and Australia/New Zealand respectively.[43] This includes rest angle testing with both a 17 pound CAMI Dummy, Mark II and a 7 pound Newborn Infant CAMI Dummy using side-to-side and front-to-back swing tests.[44]
    c. The maximum sleep surface angle for stationary products would be set at 5°. This would be tested using both a 17 pound CAMI Dummy Mark II and a 7 pound Newborn Infant CAMI Dummy in the location most prone to creating a depression, slope, or tilt.

Several of these staff recommended modifications and new requirements would be little to no burden on manufacturers or importers. The developmental limit modification (1e), as well as changes to suffocation warnings (1d), would only require changes to instructional literature and packaging. The product clarifications (1g) would effectively eliminate some products from the scope of the proposed standard. This would exclude some firms from compliance requirements entirely while reducing the number of products for others. As discussed below, however, the inclusion of infant hammocks will have a substantial effect on many of these suppliers. The possible need to eliminate product restraints (2a) would only affect a few firms and the impact would be minimal.[45]

Double action release mechanisms are typically used with multi-use products to convert a rocking bassinet to a stationary one. The expansion of locking and latching mechanism tests to cover double action release mechanisms (1a), as well as the addition of stability testing with these locks engaged (1c), are intended to resist collapsing or movement. There have been several cases where locking mechanisms have failed which caused the infant to roll/press up against the side/corner of the product, posing a suffocation hazard.[46] This modification is not expected to pose a substantial burden on firms. However, it is possible that a few firms might have to make product modifications to comply. This would most likely take the form of improved locking/latching mechanisms.

[43] The Canadian standard is SOR/86-962 and the Australian/New Zealand standard is AS/NZS 4385:1996. These requirements will automatically exclude baby hammocks.
[44] This requirement will automatically exclude baby hammocks since those currently available have swing angles greater than 20°. As mentioned earlier, ASTM has already begun work on a new standard to cover hammocks.
[45] It is possible that the lack of restraints could reduce product desirability from the consumer's perspective. However, this effect would be felt equally across all firms and is not expected to cause a significant reduction in demand for these products as a whole. CPSC staff believes that restraints are unnecessary for infants that are lying on a flat surface and could pose a strangulation hazard.
[46] Memorandum from Risana Chowdhury, EPI, Directorate for Epidemiology, dated February 3, 2010, Subject: Bassinets, Cradles, and Infant Hammocks-Related Deaths, Injuries and Potential Injuries; 2006 – Present. It should be noted that it is unclear how many of these lock failures were double action release mechanisms.

Expanding spacing requirements to openings in soft sided products (1b) could have a substantial effect on a small number of firms. Where products cannot pass the new requirements, substantial modifications and product redevelopment are likely. However, CPSC staff believes that the severity of the incidents involving these types of products and the recalls that resulted strongly support adding this requirement to the proposed standard.

There are currently no maximum requirements for rocking or rest angles on products intended to rock or swing. Tilting issues have resulted in suffocation hazards similar to those of locking mechanism failures.[47] It is believed that adding maximum angle requirements to the proposed standard (2b) could reduce future incidents, while affecting only a small number of firms. The fact that these requirements are already a part of non-U.S. safety standards indicates that compliance has not proven difficult. However, it is possible that a few firms might require product modifications to achieve compliance with these new requirements.

The maximum sleep surface angle requirement and test (2c) is primarily aimed at incidents involving bassinet/play yard combination products. These incidents suggest that products with sloped surfaces or mattresses with multiple seams could pose a suffocation hazard.[48] There are numerous such combination products on the market, but only a few known suppliers; therefore, this requirement could require product modifications (and possibly product redesign) by a few firms.

The last two requirements discussed—rock/rest angles (2b) and sleep surface angles (2c)—are likely to disproportionately affect most of the thirteen infant hammock suppliers. Infant hammocks typically hang from a standing base and rock naturally. Most have sleep surfaces that curve, molding to an infant's body.

However, two infant hammock suppliers have flat sleep surfaces. These two firms are not expected to require further modifications to comply with the recommended sleep surface angle requirement and it is likely that they will be able to meet the rock/rest angle requirements inexpensively, with known fixes running no more than $5 per unit.[49]

For the remaining eleven firms supplying infant hammocks, even though it would be possible to inexpensively modify their products to meet both the rock/rest angle and sleep surface angle requirements, such modifications would change their products too extensively to remain in the market. A niche market exists for hammocks that curve around babies' bodies and rock naturally among parents with colicky babies. Making the changes necessary to meet the staff-recommended requirements would effectively eliminate the market for their products which would no longer suit the purpose for which they are in demand.

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[47] Ibid.

[48] Memorandum from Han Lim, ESME, Directorate for Engineering Sciences, dated February 18, 2010, Subject: Engineering Assessment of ASTM F 2194-07 $a^{\varepsilon 1}$, Standard Consumer Safety Specification for Bassinets and Cradles and Memorandum from Risana Chowdhury, EPI, Directorate for Epidemiology, dated February 3, 2010, Subject: Bassinets, Cradles, and Infant Hammocks-Related Deaths, Injuries and Potential Injuries; 2006 – Present.

[49] For example, they could add a clipping mechanism that has been recently developed to limit the swing angle for hammocks involved in product recalls. Alternatively, they may be able to change the number and placement of the ties from which the hammock hangs.

Other Federal Rules

CPSC staff has not identified any federal or state rule that either overlaps or conflicts with the staff's draft proposed rule.

Impact on Small Businesses

There are approximately 48 firms currently known to be marketing bassinets, cradles, and/or infant hammocks in the United States. Four are large domestic manufacturers and ten are foreign manufacturers or importers. The impact on the remaining 34 small firms—24 small domestic manufacturers and 9 small domestic importers[50]—is the focus of the remainder of this analysis. Of these small firms, two domestic manufacturers and four domestic importers (as well as the unknown domestic firm) supply infant hammocks.

Small Manufacturers (Other than Infant Hammock Manufacturers)

The impact of the proposed standard on small manufacturers will differ based on whether they are currently compliant with the voluntary ASTM standard. The proposed standard could have a substantial impact on some of the 15 firms that are not compliant with the current voluntary standard,[51] as their products would most likely have to be redesigned. Product development costs include product design, development and marketing staff time, product testing, and focus group expenses. These costs can be high, but they can be treated as new product expenses and amortized over time, as can other one-time costs such as the retooling of manufacturing equipment. There may also be increased costs of production, particularly if modifications to structural integrity are required, which could include additional raw materials. This could potentially increase shipping costs as well. The actual cost of such an effort is unknown, but could be substantial for some firms, particularly those with product lines that rely primarily or entirely on bassinets/cradles and related products, such as bedding.[52]

The impact on most of the 9 firms that are in compliance with the current voluntary standard is expected to be less substantial. The majority of the modifications recommended by CPSC staff are expected to have only minor effects on small manufacturers. There are, however, three recommended changes that could require product modifications (rocking/rest angles, sleep surface angle, and spacing requirements for soft sided products). While these requirements are expected to affect only a few firms, they may require product redevelopment, which has the potential to impose unknown but substantial costs.

Even though the proposed standard could potentially affect a few small firms significantly, the costs associated with compliance could be gradually recouped over the sales of numerous units. Bassinets and cradles are unique products designed to provide a sleeping environment for very young children that is smaller and more like the womb. Therefore, other sleeping products

[50] One unknown domestic firm is likely small as well.
[51] One of these firms produces only hammocks, while another produces both hammocks and bassinets.
[52] Other than firms that exclusively produce infant hammocks, there are approximately six firms with product lines that rely primarily or entirely on bassinets or cradles. None comply with the current voluntary standard.

are unlikely to be suitable substitutes for these products, allowing firms to pass at least some of their costs on to consumers and still compete effectively.[53]

The scenario described above assumes that only those firms that are JPMA-certified or claim ASTM compliance will pass the voluntary standard's requirements. This is not necessarily the case. CPSC staff has identified many cases where products not certified by JPMA are actually compliant with the relevant ASTM standard; however, there is insufficient evidence of this for bassinets/cradles to quantify this impact. Additionally, the effect of the new and modified requirements may be less substantial than outlined above to the extent that some products may already comply with non-U.S. standards with some more rigorous requirements. For example, a product that complies with the Australian standard would pass the proposed rock angle requirement. However, there is insufficient information to quantify this effect.

Small Importers (Other than Infant Hammock Importers)

Four of the nine small importers are compliant with the current voluntary standard.[54] Therefore, if their existing supplier does not come into compliance with the proposed standard, these firms will need to find an alternate source of bassinets and cradles. Manufacturers are likely to pass at least some of their costs onto importers, making the bassinets/cradles more expensive.[55] However, importers can follow suit, passing some of their costs on to consumers. Even if importers responded to the rule by discontinuing the import of their non-complying bassinets and cradles, either replacing them with a complying product or another juvenile product, deciding to import an alternative product would be a reasonable and realistic way to offset any lost revenue given that most import a variety of products. To the extent that some of these firms may actually comply with the current voluntary standard or one or more of the new/modified requirements in the proposed standard, the impact of the proposed rule would be lower.

Small Hammock Manufacturers and Importers

The impact of the staff recommended standard on small hammock manufacturers and importers depends primarily on two factors: one, whether their hammocks have a flat sleep surface; and two, whether their product line consists (primarily or entirely) of infant hammocks and related products. If a supplier's hammocks already have a flat sleep surface (as is the case with one known small domestic manufacturer), it is likely that they will modify their existing infant hammocks. CPSC staff believes that this modification can be made inexpensively based upon a recent product recall fix that minimized the rock/rest angle of these types of products.[56] However, the remaining small infant hammock suppliers, both manufacturers and importers, are unlikely to make even inexpensive modifications to meet the staff-recommended requirements.

[53] There is also the possibility, however, that some consumers may instead use unsuitable sleeping environments as substitutes, such as bouncers.
[54] Two of these compliant importers supply infant hammocks exclusively. Of the remaining five non-compliant importers, two supply infant hammocks exclusively.
[55] These products would also be expected to be higher quality given the additional safety requirements.
[56] The known fixes are unlikely to cost more than $5 per unit.

Doing so would eliminate their niche market for naturally-rocking, flexible-sleep-surface products intended to calm colicky babies. Among the six small domestic firms supplying this niche market, four small importers and one unknown firm rely entirely (or almost entirely) upon infant hammocks and related products. Therefore, the staff-recommended rule may be likely to put these firms out of business. The remaining small domestic manufacturer, however, does supply other products and the likely elimination of infant hammocks from their product line is not expected to drive them out of business, although it is likely to have a substantial effect on their sales revenue.

Alternatives

Under section 104 of the CPSIA, the primary alternative that would reduce the impact on small entities is to make the voluntary standard mandatory with no modifications. Adopting the current voluntary standard without any changes could potentially reduce the costs for nine of the 24 small manufacturers and four of the nine small importers who are already compliant with the voluntary standard. However, the actual reduction in impact for these firms (except for the two JPMA-certified infant hammock suppliers) is likely to be smaller, since many would likely not require substantial changes even under the proposed standard. For the six small domestic firms supplying infant hammocks to the U.S. market, making the current voluntary standard mandatory with no modifications would substantially reduce the impact. It would be likely to prevent five of these firms from going out of business, while the sixth might be spared a substantial decrease in sales revenue. It should also be noted that eliminating the market for potentially hazardous infant hammocks intended to lull colicky babies may have the unintended consequence of leading caregivers to use similar products intended for older children instead, a potentially new hazard.

Conclusion

The proposed standard is likely to have a significant impact on a few small firms. Most firms supplying bassinets and/or cradles to the U.S. market are not JPMA-certified as compliant with ASTM's voluntary standard and may therefore require at least some product modifications to achieve compliance.[57] For these firms, as well as a few of those who *are* JPMA-certified, additional changes to meet the more significant recommended requirements of the proposed standard may be required as well. The extent of these costs is unknown, but since product redevelopment would likely be necessary, it is possible that the costs could be large for some of the firms. However, at least some of these costs are expected to be passed on to consumers without a reduction in firms' ability to compete due to the unique features associated with these products.

The small firms likely to be most significantly impacted by the staff-recommended rule, however, are those supplying infant hammocks intended for colicky babies. The majority of these firms have focused their entire product line on these goods and the required modifications would eliminate demand for their products, and may drive them out of business.

[57] To the extent that some of the products not certified by JPMA may still comply, the impact will be reduced.

Draft Federal Register Notice
Safety Standard for Bassinets and Cradles
Notice of Proposed Rulemaking (NPR)

[Billing Code 6355-01-P]
CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1218

[CPSC Docket No. CPSC-]

Safety Standard for Bassinets and Cradles: Notice of Proposed Rulemaking

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: Section 104(b) of the Consumer Product Safety Improvement Act of 2008 ("CPSIA") requires the United States Consumer Product Safety Commission ("CPSC" or "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 is proposing a more stringent safety standard for bassinets and cradles that will further reduce the risk of injury associated with these products.

DATES: Written comments must be received by **[insert date 75 days after publication in *Federal Register*].**

ADDRESSES: Comments relating to the instructional literature and marking required by the proposed rule

relating to the Paperwork Reduction Act 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-____, may be submitted by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through www.regulations.gov.

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 502, 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 electronically. 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.

FOR FURTHER INFORMATION CONTACT: Han Lim, Project Manager, Directorate for Engineering Sciences, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7538; hlim@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008, Pub. Law 110-314 ("CPSIA") was enacted on August 14, 2008. Section 104(b) of the CPSIA requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. In this document the Commission proposes a safety

standard for bassinets and cradles. The proposed standard is more stringent in some respects than the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F 2194-07a$^{\varepsilon 1}$, "Standard Consumer Safety Specification for Bassinets and Cradles." The proposed modifications, if finalized, will further reduce the risk of injury associated with bassinets and cradles.

B. The Product

A bassinet or 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. A bassinet or cradle is not intended to be used with children who are beyond the age of approximately 5 months. Bassinet and cradle attachments for non-full-size cribs or play yards are considered a part of this product category, as are bedside sleeper bassinets that can be converted to a four-sided bassinet not attached to a bed.

Full-size cribs and infant swings are not included under the definition of bassinet or cradle. Products used in conjunction with infant swings or strollers or Moses baskets (hand-carrying baskets) are not included under the definition of bassinet or cradle. However, a Moses basket or a similar product used with infant swings or strollers

that can attach to a separate base which can convert it to a bassinet or cradle is considered a bassinet or cradle.

While the current ASTM F 2194 – 07a $^{\varepsilon 1}$ standard does not explicitly state that infant hammocks are within the scope of the standard, the Juvenile Products Manufacturers Association, (JPMA), historically has certified infant hammocks under the bassinet/cradle standard. Two firms have hammocks certified by JPMA to the ASTM F 2194 – 07a $^{\varepsilon 1}$ standard.

By nature of their design, most hammocks do not have a rigid sleep surface. The Commission believes that many of the current designs it has been studying result in uneven suspension of the product, which can cause the hammock to tip to one side, trapping the baby in a face down position and increasing the risk of positional asphyxia or suffocation. Because of this hazard pattern, CPSC recently recalled an infant hammock. Since the sleeping environment of most hammocks differs from that of bassinets and cradles, the Commission believes a separate standard for hammocks may be necessary. Most hammocks have mattresses that are flexible and conform to the body contours of the infant, whereas bassinets and cradles have flat mattresses with solid or fabric sides. In a November 17, 2009 CPSC/ASTM teleconference, ASTM agreed to form a

subcommittee to develop requirements for a new hammock standard. Until a separate standard for hammocks is developed, the Commission believes it is prudent to include hammocks under the proposed rule for bassinets and cradles as an interim measure because the proposed rule addresses the hazard pattern which causes the infant to roll/press up against the side or corner of the product posing a risk of positional asphyxia or suffocation. The Commission is aware that, by their nature, most infant hammocks will likely be unable to meet the proposed performance criteria of a 5° rest angle, 5° flatness angle, and a 20° maximum rock/swing angle in this proposed standard, and will thus be effectively banned. The Commission seeks comment on whether such action is necessary given the risk of positional asphyxia the rule attempts to address. The Commission may remove hammocks from the scope of a bassinets/cradles standard in the future, should ASTM develop an effective voluntary standard for hammocks. The Commission seeks information regarding proposals for an infant hammock standard.

Applying American Baby Group survey data from 2005 to the most recent U.S. birth data from the Centers for Disease Control and Prevention (CDC) yields annual estimates of about 1.4 million bassinets, 333,000 cradles,

596,000 portable play yards with bassinet attachments, and 749,000 full-size play yards with bassinet attachments. (The data collected for the ***Baby Products Tracking Study*** does not represent an unbiased statistical sample.) This yields a total of approximately 3.1 million units sold per year.

C. ASTM Voluntary Standard

ASTM first approved and published the voluntary standard for bassinets and cradles in 2002 as ASTM F 2194, "***Standard Consumer Safety Specification for Bassinets and Cradles.***" ASTM has revised the standard a number of times since 2002, with the current version, ASTM F 2194-07a$^{\varepsilon 1}$, published in November 2007. ASTM F 2194-07 $^{\varepsilon 1}$ contains requirements to address the following:

- lead in paint;
- hazardous sharp edges or points;
- small parts;
- wood parts;
- scissoring, shearing, pinching;
- unintentional folding;
- openings;
- labeling;
- fasteners;

- corner posts;
- toy accessories;
- bassinet/cradle attachments to play yards/non-full sized cribs;
- spacing of rigid sided bassinet/cradle components;
- openings for mesh/fabric-sided bassinet/cradle;
- static load;
- stability;
- sleeping pad properties; and
- protective components.

JPMA operates a certification program to certify bassinets and cradles to the voluntary standard. To obtain JPMA certification, manufacturers submit their products to an independent test laboratory for conformance testing to the most current voluntary standard. Currently, bassinets or cradles supplied by eight small manufacturers and four small importers are JPMA certified to ASTM F 2194-07a$^{\varepsilon 1}$.

D. Incident Data

1. *Categories of Incidents*

The CPSC Directorate for Epidemiology reports that there have been 209 incidents related to bassinets and cradles since 2006, of which there were 61 fatalities, 38 non-fatal injuries, and 110 non-injury incidents. The

incidents were grouped into five categories: (a) product-related issues, in which sufficient information was available to describe the product failure modes or defects; (b) non-product-related issues; (c) unknown issues (incidents that lacked specificity), (d) recalled product-related issues; and (e) miscellaneous other issues.

a. ***Product-Related Issues.*** Eighty-seven of the 209 incidents, or approximately 42%, involved hardware failures or design issues related to the product. The reported problems are listed below, beginning with the most frequently reported problems:

- Inadequate structural integrity, which included unstable bassinets or cradles, loose hardware, collapse of the product, loose wheels, etc.;
- Locking or tilting issues with the bassinets or cradles, which cause the infant to roll or press up against the side or corner of the product, posing a suffocation hazard;
- Problems with mattress-flatness, such as mattresses that would not remain horizontal because of metal rods or other structures designed to be positioned underneath the mattress, lack of rigid mattress support, and failure of straps or hooks designed to

hold bassinets inside play yards. One death was associated with a mattress flatness issue; and

- Problems with battery-powered bassinet mobiles which had components that overheated, smoked, or sparked.

b. ***Non-Product-Related Issues.*** Sixty of the 209 incident reports, or 29%, were of deaths or injuries that could not be attributed to a product defect or failure. Fifty-seven of the 60 incidents were deaths where a determination of causation or association was complicated by the inappropriate use of pillows, blankets, or mattresses.

c. ***Unknown Issues.*** Twenty-six of the incidents, or 12%, had little or no information. Twenty-five of these reported a fall of the infant out of the bassinet or cradle.

d. ***Recalled Product-Related Issues.*** There were 19 reports (9%) that involved recalled products. Among them were seven entrapments (three deaths, two non-fatal injuries, and two non-injury incidents) between the metal rods of the bassinet. The remaining 12 reports were complaints or inquiries from consumers regarding a recalled product.

e. ***Miscellaneous Other Issues.*** The remaining 17

incident reports involved a host of miscellaneous problems, including a tear in the bassinet fabric, odors, and product assembly or quality issues.

2. *Deaths and Injuries.*

All 61 fatalities reported to CPSC staff were asphyxiation deaths. The majority of deaths (57 out of 61) were asphyxiations where the incident report noted the presence of soft or extra bedding in the bassinet, prone placement of the infant, or the infant getting wedged between the side of the bassinet and mattress or bedding. Soft or extra bedding and the prone placement of an infant are associated with infant mortality from asphyxiation, independent of any design hazard. A few were reported as asphyxiation deaths, with no further information available. Only four of these deaths were determined to have resulted from design flaws of the product. Three of the four deaths were due to entrapment of the infant between the metal bars of a particular brand of bassinet. Of those three deaths, two of the three infants were six months old and should not have been using the bassinet or cradle because by definition they are only for use up to five months. The fourth death resulted from an infant suffocating in the corner of the bassinet when he rolled into that position due to the unlevel mattress pad.

Thirty-eight incidents reported an injury to an infant. Twenty-three out of the 38 incidents, or 61%, were identified as falls out of the bassinets. Serious injuries included a skull fracture resulting from an infant falling out of the bassinet due to non-level mattress issues, an arm fracture resulting from a fall due to problems with a bassinet's rocking feature, and a second-degree burn resulting from the bassinet's overheated mobile. The remaining injuries were mostly limited to contusions and abrasions.

3. *Hammock Incidents.*

The Commission is aware of three fatalities, six non-fatal injuries, and five non-injury incidents related to infant hammocks that were reported to have occurred since 2006. All three fatalities reported to CPSC were asphyxiation deaths. One five-month old infant was found rolled into a corner in a prone position with the bed in an inclined position. A four-month old infant was found with her face flat against the foam mattress. In the third case, the medical examiner reporting the fatality expressed concern about the safety of the hammock as a sleeping environment. However, the death of the six-month old infant, who was found in a prone position, was officially ruled to be asphyxiation due to respiratory infection.

All six non-fatal injuries were reported through the National Electronic Injury Surveillance System ("NEISS"). Five of the injuries were reported to have been falls out of hammocks, while the sixth injury was sustained when a broken component of the hammock struck the infant. Little or no circumstantial information is available on how the falls occurred, except that three of the six infants were eight months or older.

Two of the five non-injury reports involved infants (a seven-month old and a 12-month old) in near-strangulation incidents where the hammock flipped over with the infants dangling from restraints. The remaining three reports involved near-suffocation incidents where the infant rolled into a position from which it was unable to move or free itself. All three infants were under five months of age.

E. Assessment of Voluntary Standard ASTM F 2194-07a$^{\varepsilon 1}$ and Description of Proposed Changes and the Proposed Rule

1. Assessment of Voluntary Standard ASTM F 2194-07a$^{\varepsilon 1}$

Section 104(b) of the CPSIA requires the Commission to assess the effectiveness of the voluntary standard in consultation with representatives of consumer groups, juvenile product manufacturers, and other experts. This consultation process began in October 2009 during the ASTM International subcommittee meeting regarding the ASTM

bassinet and cradle voluntary standard. Consultations with members of this subcommittee are still ongoing.

ASTM F 2194-07a$^{\varepsilon 1}$ contains several labeling and performance criteria. The standard addresses many of the same hazards associated with other durable nursery products and includes requirements for tip stability, unintentional folding of the product, lead in paints, sharp edges/sharp points, small parts, wood part splinters, scissoring/shearing/pinching, openings/entrapments, warning labels, and toys (which includes battery-powered mobiles). The Commission believes that updates and modifications in certain areas also may address the hazards described in the incident data, such as suffocation due to mattress tilting, placing of inappropriate bedding materials (e.g., pillows, additional blankets, etc.), and entrapment in the frame structure. While overheating of battery-powered mobiles was identified in the incidents, those incidents were isolated to one company.

2. Proposed Changes to the ASTM Standard's Requirements

Consistent with section 104(b) of the CPSIA, the Commission, through this proposed rule, would establish a new 16 CFR part 1218, "Safety Standard for Bassinets and Cradles." The new part would incorporate by reference the

requirements for bassinets and cradles in ASTM F 2194-07a$^{\varepsilon 1}$ with certain changes to specific provisions and additions to the standard, as discussed below. The proposed modifications and additions to the standard will further reduce the risk of injury associated with bassinets and cradles. Therefore, the proposed rule would adopt ASTM F 2194-07a$^{\varepsilon 1}$ as the mandatory safety standard for bassinets and cradles with the following additions and modifications:

- Specify in the scope that the standard is a performance specification for bassinets and cradles and that the intended use is for infants who are not able to push up on their hands and knees;
- Add terminology that defines what constitutes a bassinet or cradle;
- Add a performance requirement and test procedure for maximum allowable rocking angle, maximum allowable rest angle of the sleep surface, and maximum allowable flatness angle;
- Add a performance requirement and test procedure for fabric-sided bassinets and cradles;
- Add a performance requirement and test procedure for locking mechanisms intended to prevent rocking or

swinging cradles from rocking or swinging the mattress bed;

- Add updated warnings to address proper use of bedding materials by providing more emphasis and prominence to the warnings; and
- Exclude strap restraints in bassinets and cradles.

Following is a more detailed discussion of these additions and modifications. To best understand the proposed standard, it is helpful to view the current ASTM F 2194-07a$^{\varepsilon 1}$ standard for bassinets and cradles and the Commission's proposed modifications along with the explanations provided in section E.2 of the preamble. The ASTM standard is available for viewing for this purpose during the comment period through this link: http://www.astm.org/cpsc.htm.

a. Scope (Proposed § 1218.2(b)(1))

Bassinets and cradles should only be used in the early stages of an infant's development. Once an infant can push up by him/herself, a number of hazards are created, most notably falling hazards. Thus, the proposed rule would add objective criteria of an infant capable of pushing up on hands and knees to the scope of the standard to clarify which products would be considered bassinets or cradles. The proposed rule also would clarify that the

bassinet or cradle should be used *only* for infants up to approximately five months of age.

b. Newborn Infant CAMI Dummy (Proposed § 1218.2(b)(2))

Because the proposed standard would require testing with a 7 pound Newborn CAMI Dummy in the Rock/Swing Angle test and the Bassinet/Cradle Flatness Angle test, proposed § 1218.2(b)(2) would provide this reference and a photograph.

c. Definition of Bassinet/Cradle (Proposed §1218.2(b)(3))

Proposed § 1218.2(b)(3) would improve the definition of bassinet/cradle by identifying the products that are excluded from the standard. The updated definition would clarify that full-size and non-full size cribs are not covered. Also, because a bassinet or cradle is defined as a product that must be supported by a base, hand-carrying baskets would not be covered.

d. Bassinet/Cradle Accessory (Proposed § 1218.2(b)(4))

The proposal would update the definition of a bassinet/cradle accessory to avoid confusion with accessories that can attach to products that are not intended exclusively for sleep, such as strollers.

e. Double Action Release Mechanism (Proposed § 1218.2(b)(5))

Section 5.6.3 of ASTM F 2194 – 07a $^{\varepsilon 1}$ requires that products with a "double action release mechanism" latching or locking device require two distinct and separate actions for release of the mechanism. The voluntary standard does not define "double action release mechanism." The Commission has observed various multi-use products that can convert from a rocking bassinet to a stationary one. During this conversion, there are dual-action locking mechanisms that require rotating pop-out casters and then engaging a "tab"-lock to prevent the casters from rolling. Despite appearances, such dual-action locking mechanisms are not double action release mechanisms. To avoid confusion in what constitutes a double action release mechanism and to ensure that the locking mechanism works as intended in resisting collapse and/or movement, the Commission is proposing to adopt the same definition as used in the voluntary ASTM high chair standard F 404-08. Specifically, the proposed rule would define a double action release mechanism as a "mechanism requiring either two consecutive actions, the first of which must be maintained while the second is carried out or two separate and independent single action locking mechanisms that must be activated simultaneously to fully release."

f. Removable Cover (Proposed § 1218.2(b)(6))

Because the term removable cover is referenced in the test procedure for evaluating possible scenarios of entrapment hazards from bounded areas of fabric and rigid sides of a bassinet or cradle in proposed § 1218.2(b)(17), the proposed rule would add a definition of "removable cover" to the standard.

g. Maximum Deflection Angle and Rest Angle. (Proposed § 1218.2(b)(7), 1218.2(b)(12), and 1218.2(b)(15))

When a bassinet or cradle is not in a swinging or rocking mode, it needs to be level to facilitate a safe sleeping environment for infants. There was one death and several close calls associated with non-level bassinets/cradles. According to an in-depth investigation (IDI) report, a two month old male died in a bassinet portion of a play yard. The infant rolled, causing his face to be placed in the corner of the bassinet. One side was approximately five inches higher than the other. The metal poles upon which the bassinet was seated were too short to keep the sleep surface level. In one non-fatal incident, a mother found her two-week old male infant with his face against the mattress, covering his nose and mouth after he had slid down the side of the mattress. The product involved was a play yard-swinging bassinet combination. The IDI report states that the locking

mechanism to prevent the swinging motion disengaged when the mother placed her son in the product. The infant was not injured, and the mother returned the product to the store. In another non-fatal incident, a mother found her five-month-old daughter in a bassinet-play yard combination asleep up against the back side of the bassinet portion. The infant was not injured when the strap holding the bassinet insert to the side of her play yard ripped, causing the bassinet to tip sideways. The photographs from the IDI report showed the bassinet sleep surface at a substantial angle when the strap failure occurred. The infant could have been trapped between the bassinet and side of the play yard.

To ensure a level sleeping environment for infants, the proposal would establish a performance requirement and test method for the maximum allowable rock/swing angle and maximum allowable rest angle of the bassinet/cradle. CPSC staff worked with ASTM to develop these performance requirements and test procedures to reduce potential suffocations and entrapments. The 20° maximum rock/swing angle recommendation is based on the Canadian regulation for cribs and cradles (SOR 86-962, available in its entirety at http://www.canlii.org/en/ca/laws/regu/sor-86-962/latest/sor-86-962.html), as well as on observations and

measurements made by the Commission on recent model bassinets and cradles. The Canadian crib and cradle regulation is a widely accepted standard. The Commission believes the 20° limit included in the Canadian regulation allows sufficient rocking/swinging motion while maintaining safety. The 5° recommendation for the mattress rest angle is based on conclusions from the Australian study, "The Danger of Freely Rocking Cradles," by S.M. Beal et al, *Journal of Pediatric Child Health* (1995) and the performance requirements from AS/NZS 4385:1996 the Australian/New Zealand standard for infant's rocking cradles. The conclusions from the Australian study suggest that a maximum 5° 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 Commission seeks comment on the Australian study and any other literature that may be relevant to the recommendation on the mattress rest angle.

The test method for the maximum allowable rock/swing angle and rest angle performance requirements, the "Rock/Swing Angle test," is found in proposed § 1218.2(b)(15). The test method is based on the procedure developed by the Task Group of the ASTM subcommittee for bassinets and cradles, with specific changes proposed by

the Commission. CPSC test data have shown that some products have better angle measurement results (i.e., a less steep angle) with the Newborn CAMI Dummy, and others get better results with the CAMI Dummy, Mark II. Thus, the proposal would require that the testing be done with the Newborn Infant CAMI Dummy, in addition to the CAMI Dummy, Mark II. Test data also showed that the placement of the dummy in the sleep surface can affect the results. For example, placing the dummy next to the wall in a rocking cradle may produce an angle that is more severe compared to placing the dummy in the center. Therefore, the proposed procedures would describe how the dummy should be placed in the sleep surface. The proposed rule would also provide specific angle measurement procedures. Finally, because some products can swing along the head-to-toe axis, the proposed rule would require such products to be tested in that direction as well.

h. Flatness Angle (Proposed § 1218.2(b)(7), 1218.2(b)(13), and 1218.2(b)(16)

Incidents involving bassinet/play yard combinations suggest that a sloped surface or a mattress with multiple seams (mattresses that double as a play yard cover) may have the potential for an asphyxia suffocation hazard, as an infant's head may become entrapped between the sloped

mattress and bassinet wall surface. Proposed § 1218.2(b)(13) would require that the angle of the bassinet or cradle sleeping support surface not be greater than 5° when tested in accordance with the test procedures in proposed § 1218.2(b)(16). This is to ensure that the mattress does not deform and create a depression, sloped surface, or an appreciable gap between a bassinet wall surface and the mattress.

Proposed § 1218.2(b)(16) includes testing with the CAMI Infant Dummy, Mark II and the Newborn CAMI Dummy. The test is intended to ensure that the sleep surface of the bassinet or cradle is flat and will not tilt when either CAMI dummy is placed in a corner or edge of the sleeping surface. A dynamic test, which is a force applied over a relatively short period of time, is needed because it will simulate children turning themselves over in the mattress bed area, particularly in a bassinet/play yard combination product with multiple segmented seams.

i. Testing equipment (Proposed § 1218.2(b)(8))

In the standardization and calibration section, proposed § 1218.2(b)(8) would specify the type of angle instrument and its measurement resolution to minimize angle measurement variability. Also, proposed § 1218.2(b)(8) would specify the tolerance and calibration interval for

the force gauge required on several performance tests to minimize force measurement variability.

j. Restraints (Proposed § 1218.2(b)(9))

Infants lying on a flat surface do not need restraints and the use of restraints could contribute to a possible strangulation hazard. Therefore, proposed § 1218.2(b)(9) would add language to the standard to clarify that bassinets should not include any restraint system that requires action on the part of the caregiver to secure the restraint.

k. Spacing of Rigid and Fabric-Sided Bassinet/Cradle Components (Proposed § 1218.2(b)(10), 1218.2(b)(14) and 1218.2(b)(17))

Seven incidents (among them three deaths) involved recalled products where infants were trapped between structural members of the bassinet. Bassinets and cradles with fabric sides can present similar entrapment hazards from bounded areas of fabric and rigid sides of a bassinet or cradle. ASTM F 2194 – 07a$^{\varepsilon 1}$ contains performance requirements and test methods for the spacing of rigid sided bassinet and cradle components, intended to minimize torso and/or head entrapments. Because similar hazards are presented by fabric-sided bassinets and cradles, the proposed rule would include performance requirements and

test methods for fabric-sided bassinets and cradles as well. For some types of bassinets or cradles with fabric removable covers, it is foreseeable that a parent or caregiver will place fabric back loosely onto a bassinet or cradle after washing and forget to fasten the snaps, zippers, or other fasteners. If the fabric should slip and separate from the structural members of the bassinet/cradle wall, an infant's torso may become entrapped between two structural members of a bassinet/cradle. Also, it is possible that an infant can suffocate if he or she is trapped in a bounded area between structural members and fabric. Thus, the proposed rule would require testing in this configuration, i.e., where the fabric cover is placed loosely on the bassinet or cradle but is unfastened, as well.

The test method for this performance requirement is found in proposed § 1218.2(b)(17). Proposed § 1218.2(b)(17) would require that fabric-sided bassinets or cradles comply with the crib spacing requirements in 16 CFR Part 1509.4 when subjected to the 20 pound (lb) probe test. The fabric must not fully release and form a completely bounded opening which would allow complete passage of the torso test probe. The bassinets and cradles must comply both when the fabric cover is fastened and when it is

unfastened. The Commission believes it is reasonable to use the crib spacing requirements in 16 CFR Part 1509.4, given that infants of similar ages are utilizing bassinets or cradles and cribs. While the ASTM committee initially proposed a 35 lb force for the probe test, the Commission believes that 20 lbs appears to be consistent with the crib standard (16 CFR Part 1509.6) and is more realistic for infants in the age range of less than five months. ASTM subcommittee for bassinets and cradles, with CPSC staff's input, developed the proposed test procedures.

k. Stability (Proposed § 1218.2(b)(11))

Because at least three of the 87 product-related incidents involved a locking mechanism failure or malfunction, proposed rule § 1218.2(b)(11) would include test scenarios where the bassinet or cradle is tested with the locking mechanism(s) engaged if it is equipped with a locking mechanism to prevent swinging or rocking. This requirement would ensure the stability of the product in modes where the locks are engaged to prevent swinging or rocking.

l. Marking and Labeling section (Proposed §§ 1218.2(b)(18)through (b)(20))

Because many deaths and non-fatal incidents involve suffocation due to caregivers and parents using bedding

materials (such as pillows and blankets) that are not specified by the manufacturer, and because these incidents cannot be addressed by the design of the bassinet or cradle, it is imperative to improve the warning labels regarding padding and soft bedding in the standard. Consequently, proposed §§ 1218.2(b)(18) through (20) would require certain warning statements or labeling information regarding a suffocation hazard.

F. Request for Comments

This proposed rule begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for 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.

G. Effective Date

The Administrative Procedure Act ("APA") generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). To allow time for bassinets and cradles to come into compliance, the Commission intends that the standard would become effective six months after publication of a final rule. The Commission seeks comment on how long it would

take manufacturers of bassinets and cradles to come into compliance with the rule.

H. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA") generally requires that agencies review proposed rules for their potential economic impact on small entities, including small businesses. 5 U.S.C. 603.

1. The Market

Bassinets and cradles are typically produced and/or marketed by juvenile product manufacturers and distributors. There are currently at least 48 known manufacturers or importers supplying bassinets and/or cradles to the United States market. (These counts also include firms solely producing hammocks for infants as well. However, under the standard proposed by the Commission, most hammock products will no longer be able to conform. ASTM has started working on a new standard to cover these products.) Nine firms (19 percent) are domestic importers, 28 firms (58 percent) are domestic manufacturers, and 10 firms (21 percent) are foreign manufacturers. There is an additional domestic firm whose status as a manufacturer or importer could not be determined. Thirteen firms, including the firm whose means of supply could not be determined, supply infant hammocks

to the United States market. (There is an additional hammock on the United States market whose supplier could not be determined, as well as a small cottage industry in knitted and crocheted infant hammocks.) The product lines for seven of these firms rely primarily or entirely on infant hammocks and related merchandise. (These determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites. Manufacturers include traditional manufacturers, as well as firms that send out their designs to be manufactured, and firms that import as well but are primarily manufacturers.)

Under Small Business Administration (SBA) guidelines, a manufacturer of bassinets or cradles is small if it has 500 or fewer employees, and an importer is considered small if it has 100 or fewer employees. Based on these guidelines, 22 of the domestic manufacturers and five of the domestic importers known to be supplying the United States market are small. The sizes of the four remaining domestic importers and two additional domestic manufacturers are unknown, but they are likely to be small as well, as is the firm whose supply source could not be determined. All of the firms supplying infant hammocks to the United States market are believed to be small. Two of these small firms are domestic manufacturers, four are

domestic importers, six are foreign firms, and one is an unknown domestic firm. There are probably additional unknown small manufacturers and importers operating in the United States market.

JPMA, the major United States trade association that represents juvenile product manufacturers and importers, operates a voluntary certification program for several juvenile products. Products voluntarily submitted by manufacturers are tested against the appropriate ASTM standard and only passing products are allowed to display JPMA's Certification Seal. (See http://www.jpma.org/pdfs/certfacts08.pdf for more information.) Approximately 33 percent of firms supply bassinets/cradles to the United States market that have been JPMA certified as compliant with the current ASTM voluntary standard (16 firms). Two of these firms supply more than one relevant product category, where one category of products is JPMA certified and another is not. (For example, one firm has JPMA certified bassinets, but its play yards are not JPMA certified.) Additionally, one firm claims compliance although its products have not been certified by JPMA, and one firm has recently had its product removed from JPMA's list of certified products. Of the small domestic businesses (this includes firms

suspected of being small as well those known to be small), 38 percent of manufacturers (nine of 24 firms) and 44 percent of importers (four of nine firms) have products that are ASTM compliant. This includes the small manufacturer that claims compliance with the ASTM standard, but is not part of the JPMA Certification Program, as well as the firms with only some product categories JPMA certified. (It should be noted that non-JPMA certified products will not necessarily fail to comply with the ASTM standard. Although there is currently no testing to support such an assumption for bassinets and cradles, testing of other products has revealed a pattern of non-correlation.)

2. *Compliance Requirements of the Proposed Rule.*

Several of the recommended modifications and new requirements to the standard would be little to no burden on manufacturers or importers. The developmental limit modification (limiting the product use to when a child is able to push up on hands or knees), as well as the changes to suffocation warnings, would only require changes to instructional literature and packaging. The clarifications to what is included and excluded from the definition of the product would effectively eliminate some products from the scope of the proposed standard. This would exclude some

firms from compliance requirements entirely, while reducing the number of products for others. As discussed herein, however, the inclusion of infant hammocks will have a substantial effect on many of these suppliers. The possible need to eliminate product restraints would only affect a few firms and the impact would be minimal. (It is possible that the lack of restraints could reduce product desirability from the consumer's perspective. However, this effect would be felt equally across all firms and is not expected to cause a significant reduction in demand for these products as a whole. The Commission believes that restraints are unnecessary for infants who are lying on a flat surface and could pose a strangulation hazard.)

Double action release mechanisms are typically used with multi-use products to convert a rocking bassinet to a stationary one. The expansion of locking and latching mechanism tests to cover double action release mechanisms, as well as the addition of stability testing with these locks engaged, are intended to resist collapsing or movement. There have been several cases where locking mechanisms have failed which caused the infant to roll and press up against the side or corner of the product, posing a suffocation hazard. (See Memorandum from Risana Chowdhury, EPI, Directorate for Epidemiology, dated

February 3, 2010, Subject: Bassinets, Cradles, and Infant Hammocks-Related Deaths, Injuries and Potential Injuries; 2006-Present. It should be noted that it is unclear how many of these lock failures were double action release mechanisms.) This modification is not expected to pose a substantial burden on firms. However, it is possible that a few firms might have to make product modifications to comply. This would most likely take the form of improved locking/latching mechanisms.

Expanding spacing requirements to openings in soft-sided products could have a substantial effect on a small number of firms. Where products cannot pass the new requirements, substantial modifications and product redevelopment are likely. However, the Commission believes that the severity of the incidents involving these types of products and the recalls that resulted strongly support adding this requirement to the proposed standard.

There are currently no maximum requirements for rocking or rest angles on products intended to rock or swing. Tilting issues have resulted in suffocation hazards similar to those of locking mechanism failures. It is believed that adding maximum angle requirements to the proposed standard could reduce future incidents, while affecting only a small number of firms. The fact that

these requirements are already a part of non-United States safety standards indicates that compliance has not proven difficult. However, it is possible that a few firms might require product modifications to achieve compliance with these new requirements.

The maximum sleep surface angle requirement and test is primarily aimed at incidents involving bassinet/play yard combination products. These incidents suggest that products with sloped surfaces or mattresses with multiple seams could pose a suffocation hazard. (See Memorandum from Han Lim, ESME, Directorate for Engineering Sciences, dated February 16, 2010, Subject: Engineering Assessment of ASTM F 2194-07 $a^{\varepsilon 1}$, Standard Consumer Safety Specification for Bassinets and Cradles; see also Memorandum from Risana Chowdhury, EPI, Directorate for Epidemiology, dated February 3, 2010, Subject: Bassinets, Cradles and Infant Hammocks-Related Deaths, Injuries and Potential Injuries; 2006 – Present.) There are numerous such combination products on the market, but only a few known suppliers; therefore, this requirement could require product modifications (and possibly product redesign) by a few firms.

The rock/rest angles and sleep surface angles are likely to disproportionately affect most of the thirteen

infant hammock suppliers. Infant hammocks typically hang from a standing base and rock naturally. Most have sleep surfaces that curve, molding to an infant's body.

However, two infant hammock suppliers have flat sleep surfaces. These two firms are not expected to require further modifications to comply with the recommended sleep surface angle requirement, and it is likely that they will be able to meet the rock/rest angle requirements inexpensively, with known fixes running no more than $5 per unit. For example, they could add a clipping mechanism that has been recently developed to limit the swing angle for hammocks involved in product recalls. Alternatively, they may be able to change the number and placement of the ties from which the hammock hangs.

For the remaining eleven firms supplying infant hammocks, even though it would be possible to inexpensively modify their products to meet both the rock/rest angle and sleep surface angle requirements, such modifications would change their products too extensively to remain in the market. A niche market exists among parents with colicky babies for hammocks that curve around babies' bodies and rock naturally. The suppliers, both manufacturers and importers, are unlikely to make even inexpensive modifications to meet the requirements as proposed. Any

known fix would eliminate their niche market, thereby eliminating demand for their products, and may drive them out of business.

3. *Impact of the Proposal on Small Business.*

There are approximately 48 firms currently known to be marketing bassinets, cradles, and/or infant hammocks in the United States. Four are large domestic manufacturers and ten are foreign manufacturers or importers. The impact on the remaining 34 small firms—24 small domestic manufacturers and 9 small domestic importers (one of these firms produces only hammocks, while another produces both hammocks and bassinets)—is the focus of the remainder of this analysis. Of these small firms, two domestic manufacturers and four domestic importers (as well as the unknown domestic firm) supply infant hammocks.

Small Manufacturers (Other than Infant Hammock Manufacturers). The impact of the proposed standard (if finalized) on small manufacturers will differ based on whether they are currently compliant with the voluntary ASTM standard. For the 15 firms that are not complaint with the current voluntary standard, the proposed standard could have substantial impact because their products would most likely have to be redesigned. Product development costs include product design, development and marketing

staff time, product testing, and focus group expenses. These costs can be high, but they can be treated as new product expenses and amortized over time, as can other one-time costs such as the retooling of manufacturing equipment. There also may be increased costs of production, particularly if modifications to structural integrity are required, which could include additional raw materials. This could potentially increase shipping costs as well. The actual cost of such an effort is unknown, but could be substantial for some firms, particularly those that rely primarily or entirely on bassinets/cradles and related products, such as bedding.

The impact on most of the nine firms that comply with the current voluntary standard is expected to be less substantial. The majority of modifications recommended by the Commission are expected to have only minor effects on small manufacturers. There are, however, three recommended changes (rocking/rest angles, sleep surface angle, and spacing requirements for soft-sided products) that could require product modifications. While these requirements may affect only a few firms, they may require product redevelopment, which has the potential to impose unknown but substantial, costs. The Commission seeks comment on the cost associated with these product modifications.

Even though the proposed standard could potentially affect a few small firms significantly, the costs associated with compliance could be gradually recouped over the sales of numerous units. Bassinets and cradles are unique products designed to provide a sleeping environment for very young children that is smaller and more like the womb. Therefore, other sleeping products are unlikely to be suitable substitutes for these products, allowing firms to pass at least some costs on to consumers and to still compete effectively. (There is also the possibility, however, that some consumers may instead use unsuitable sleeping environments, such as bouncers, as substitutes.)

The scenario just described assumes that only those firms that are JPMA-certified or claim ASTM compliance will meet the voluntary standard's requirements. This is not necessarily the case. CPSC has identified many cases where products not certified by JPMA do comply with the relevant ASTM standard; however, there is insufficient evidence of this for bassinets/cradles to quantify this impact. Additionally, the effect of the new and modified requirements may be less substantial than just outlined to the extent that some products may already comply with non-United States standards with some more rigorous requirements. For example, a product that complies with

the Australian standard would pass the proposed rock angle requirement. However, there is insufficient information to quantify this effect.

Small Importers (Other than Infant Hammock Importers). Four of the nine small importers are compliant with the current voluntary standard. Two of these compliant importers supply infant hammocks exclusively. Of the remaining five non-compliant importers, two supply infant hammocks exclusively. Therefore, if their existing supplier does not come into compliance with the proposed standard, these firms will need to find an alternate source of bassinets and cradles. Manufacturers are likely to pass at least some costs onto importers, making the bassinets/cradles more expensive. (These products would also be expected to be higher quality given the additional safety requirements.) However, importers can follow suit, passing some costs on to consumers. Even if importers responded to the rule by discontinuing the import of their non-complying bassinets and cradles, either replacing them with a complying product or another juvenile product, deciding to import an alternative product would be a reasonable and realistic way to offset any lost revenue given that most import a variety of products. To the extent that some firms may comply with the current

voluntary standard or one or more of the new/modified requirements in the proposed standard, the impact of the proposed rule would be lower.

Small Hammock Manufacturers and Importers. The impact of the proposed standard on small hammock manufacturers and importers depends primarily on two factors: (1) whether their hammocks have a flat sleep surface; and (2) whether their product line consists (primarily or entirely) of infant hammocks and related products. If a supplier's hammocks already have a flat sleep surface (as is the case with one known small domestic manufacturer), it is likely that it will modify its existing infant hammocks. This modification can be made inexpensively based upon a recent product recall fix that minimized the rock/rest angle of these types of products. (The known fixes are unlikely to cost more than $5 per unit.) However, the remaining small infant hammock suppliers, both manufacturers and importers, are unlikely to make even inexpensive modifications to meet the proposed requirements. Doing so would eliminate their niche market for naturally-rocking, flexible-sleep-surface products intended to calm colicky babies. Among the six small domestic firms supplying this niche market, four small importers and one unknown firm rely entirely (or almost entirely) upon infant hammocks and related products.

Therefore, the proposed rule, if finalized, may be likely to put these firms out of business. The remaining small domestic manufacturer, however, does supply other products, and the likely elimination of infant hammocks from its product line is not expected to drive it out of business, although it is likely to have a substantial effect on its sales revenue. The Commission seeks comment on the effect of the proposed modifications to the standard on small hammock manufacturers and importers.

3. Alternatives. Under section 104 of the CPSIA, the primary alternative that would reduce the impact on small entities is to make the voluntary standard mandatory with no additions or modifications. Adopting the current voluntary standard without any changes could potentially reduce the costs for nine of the 24 small manufacturers and four of the nine small importers who already comply with the voluntary standard. However, the actual reduction in impact for these firms is likely to be smaller, since many would likely not require substantial changes even under the proposed standard. For the six small domestic firms supplying infant hammocks to the United States market, making the current voluntary standard mandatory with no modifications would substantially reduce the impact. It would be likely to prevent five firms from going out of

business, while the sixth might be spared a substantial decrease in sales revenue. It also should be noted that eliminating the market for potentially hazardous infant hammocks intended to lull colicky babies may have the unintended consequence of leading caregivers to use similar products intended for older children instead, thereby creating a potentially new hazard.

4. Conclusion of initial regulatory flexibility analysis

It is possible that the proposed standard, if finalized, could have a significant impact on a few small firms. Most firms supplying bassinets and/or cradles to the United States market are not JPMA-certified as compliant with ASTM's voluntary standard and may therefore require at least some product modifications to achieve compliance. (To the extent that some of the products not certified by JPMA may still comply, the impact will be reduced.) For these firms, as well as a few of those who are JPMA-certified, additional changes to meet the more significant recommended requirements of the proposed standard may be required as well. The extent of these costs is unknown, but since product redevelopment would likely be necessary, it is possible that the costs could be large for some of the firms. However, at least some of these costs are expected to be passed on to consumers

without a reduction in the firms' ability to compete due to the unique features associated with these products. The Commission seeks comment on what these costs may be, whether they may be passed on to the consumer, and how these costs will impact small businesses.

The small firms likely to be most significantly impacted by the staff-recommended rule, however, are those supplying infant hammocks intended for colicky babies. The majority of these firms have focused their entire product line on these goods and the required modifications would eliminate demand for their products, and may drive them out of business.

I. Environmental Considerations

The Commission's regulations provide a categorical exemption for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement as they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This proposed rule falls within the categorical exemption.

J. Paperwork Reduction Act

Sections 8 and 9 of the voluntary standard, ASTM F 2194-07a$^{\varepsilon 1}$, which is being proposed by the Commission as a mandatory standard, contain requirements for marking, labeling, and instructional literature that are

"information collection requirements" under the Paperwork Reduction Act ("PRA"), 44 U.S.C. 3501-3520. This part of the preamble to the proposed rule describes the collection on information requirements, with an estimate of the annual burden thereby imposed.

Section 8.1.1 of the voluntary standard requires that the name and "either the place of business (city, state, and mailing address, including zip code) or telephone number, or both" of the manufacturer, distributor, or seller be clearly and legibly marketed on "each product and its retail package." Section 8.1.2 of the voluntary standard requires that "a code mark or other means that identifies the date (month and year as a minimum) of manufacture" be clearly and legibly marked on "each product and its retail package." Section 9.1 of the voluntary standard requires instructions to be supplied with the product.

Sections 8.1.1 and 8.1.2 require information to be placed on both the product and the retail package. The information is intended to identify the manufacturer/importer and production date. This is information that would customarily be collected by manufacturers/importers to assist with production and distribution. In fact, much of the information is already

placed on both retail containers and the product itself, because of its information value both to the manufacturer/importer and the end retailer.

There are 48 known firms supplying bassinets and/or to the United States market. Eighteen of the 48 firms are known to already produce labels that comply with sections 8.1.1 and 8.1.2 of the standard, so there would be no additional burden on these firms. The remaining 30 firms are assumed to already use labels on both their products and their packaging, but would need to make some modifications to their existing labels. The estimated time required to make these modification is about 30 minutes per model. Each of these firms supplies an average of 7 different models of bassinets/cradles, therefore, the estimated burden hours associated with labels is 30 minutes x 30 firms x 7 models per firm = 6,300 minutes or 105 annual hours.

The Commission estimates that hourly compensation for the time required to create and update labels is $27.78 (Bureau of Labor Statistics, September 2009, all workers, goods-producing industries, Sales and office, Table 9). Therefore, the estimated annual cost associated with the Commission recommended labeling requirements is

approximately $2,917 ($27.78 per hour x 105 hours = $2916.90, which we have rounded up to $2917).

Section 9.1 requires that instructions, including warning information which the Commission recommends modifying, be included with the product. This is also a practice that is customary with bassinets and cradles. These are products that generally require some installation and maintenance and products sold without such information would not be able to successfully compete with products supplying this information. Therefore, any burden associated with the mandatory requirements of 9.1 would consist of (at most) revising the warning labels and reprinting. It is estimated that these modifications would take at most 30 minutes per model for each of the 48 known firms supplying the United States market with bassinets/cradles. Assuming each firm supplies an average of 7 models, the annual burden associated with the product instructions would be 168 hours (48 firms x 7 models x 30 minutes = 10,080 minutes or 168 hours).

The Commission estimates that hourly compensation for the time required to modify instruction manuals is $27.78 (Bureau of Labor Statistics, September 2009, all workers, goods-producing industries, Sales and office, Table 9). Therefore, the estimated annual cost associated with the

staff-recommended instruction manual is $4,667 ($27.78 per hour s 168 hours = $4,667.04, which we have rounded down to $4,667).

Based on this analysis, the requirements of the Commission-recommended bassinet and cradle rule would impose a burden to industry of 284 hours at a cost of $7,584 annually.

K. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a "consumer product safety standard under [the CPSA]" is in effect and applies to a product, no State or political subdivision of a State may either establish or continue in effect a requirement dealing with the same risk of injury unless the State requirement is identical to the Federal standard. (Section 26(c) of the CPSA also provides that States or political subdivisions of States may apply to the Commission for an exemption from this preemption under certain circumstances.) Section 104(b) of the CPSIA refers to the rules to be issued under that section as "consumer product safety rules," thus implying that the preemptive effect of section 26(a) of the CPSA would apply. Furthermore, in ***Natural Resources Defense Council v. CPSC,*** 597 F. Supp. 2d 370 (S.D. NY 2009), the court held that "[d]esignating the phthalate prohibitions [in section 108

of the CPSIA] as consumer product safety standards brings them within a well established statutory preemption scheme [of section 26(a) of the CPSA]." Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

L. Certification

Section 14(a) of the Consumer Product Safety Act ("CPSA") imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product or on a reasonable testing program or, for children's products, on tests on a sufficient number of samples by a third-party conformity assessment body accredited by the Commission to test according to the applicable requirements. As discussed in Section K, section 104(b)(1)(B) of the CPSIA refers to standards issued under that section, such as the rule for bassinets and cradles being proposed in this notice, as "consumer product safety standards." Furthermore, the designation as consumer product safety standards subjects such standards

to certain sections of the CPSA, such as section 26(a), regarding preemption. By the same reasoning, such standards would also be subject to section 14 of the CPSA. Therefore, any such standard would be considered to be a consumer product safety rule to which products subject to the rule must be certified.

In addition, the CPSIA is another act enforced by the Commission, and the standards issued under section 104(b)(1)(B) of the CPSIA are similar to consumer product safety rules. For this reason also, bassinets and cradles will need to be tested and certified as complying with the safety standard when it becomes effective. Because bassinets and cradles are children's products, they must be tested by a third-party conformity assessment body accredited by the Commission. In the future, the Commission will issue a notice of requirements to explain how laboratories can become accredited as a third-party conformity assessment body to test to the new safety standard. (Bassinets and cradles also must comply with all other applicable CPSC requirements, such as the lead content and phthalate content requirements in sections 101 and 108 of the CPSIA, and the tracking label requirement in section 14(a)(5) of the CPSA, and the consumer registration form requirements in section 104 of the CPSIA.)

List of Subjects in 16 CFR 1218

Consumer protection, Imports, Infants and Children, Labeling, Law enforcement, and Toys.

Therefore, the Commission proposes to amend Title 16 of the Code of Federal Regulations by adding a new part 1218 to read as follows:

PART 1218 – SAFETY STANDARD FOR BASSINETS AND CRADLES

Sec.

1218.1 Scope, application and effective date.

1218.2 Requirements for bassinets and cradles.

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

§ 1218.1 Scope, application and effective date.

This part establishes a consumer product safety standard for bassinets and cradles manufactured or imported on or after (insert date 6 months after date of publication of a final rule in the FEDERAL REGISTER).

§ 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 2194-07a$^{\varepsilon 1}$, Standard

Consumer Safety Specification for Bassinets and Cradles, approved October 1, 2007. 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; www.astm.org. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 502, 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) The following provisions replace, or are added to, the indicated sections of the ASTM F 2194-07a$^{\varepsilon 1}$ standard.

(1) Instead of section 1.3:

"1.3 This consumer safety performance specification covers products intended to provide sleeping accommodations only for infants up to approximately 5 months of age or when the child begins to push up on hands and knees, whichever comes first. Products used in conjunction with an infant swing are not covered by this specification."

(2) Add under section 2.3:

"CAMI Newborn Dummy (see Fig. 1A)"

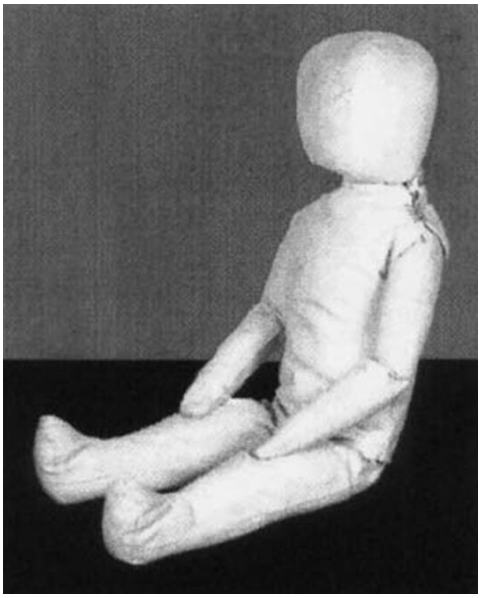

FIGURE 1A – Newborn CAMI Dummy

(3) Instead of section 3.1.1:

"3.1.1 ***bassinet/cradle, n***—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. Products such as swings, full and non-full size cribs, hand carrying baskets, and travel beds are not included, unless the product is a bassinet/cradle attachment per the definition in Section 3.1.2.

(4) Instead of section 3.1.2:

"3.1.2 ***bassinet/cradle accessory, n***—accessory with a rigid frame that attaches to non-full size crib, play yard,

or other base unit designed to convert the accessory into a bassinet/cradle.

(5) Add new section 3.1.12:

"3.1.12 ***double action release mechanism, n***—mechanism requiring either two consecutive actions, the first of which must be maintained while the second is carried out or two separate and independent single action locking mechanisms that must be activated simultaneously to fully release.

(6) Add new section 3.1.13:

"3.1.13 ***removable cover, n***—a fabric cover, containing snaps or other fasteners such as zippers, Velcro, or buttons used to attach to a bassinet/cradle frame that requires consumer action as a step for removal or adjustment."

(7) Add new sections 3.1.14 through 3.1.16:

"3.1.14 ***Maximum deflection angle, n***—the maximum rock/swing angle measurement allowed by the product design in the manufacturer's use position in the manner normally associated with rocking/swinging and intended by the manufacturer when tested in accordance with 7.8.

"3.1.15 ***Rest angle, n***—the resulting angle measurement of bassinet/cradle sleeping surface or tilt angle of the bassinet/cradle bed after the maximum deflection angle is

applied and released and the product has come to a complete rest when tested in accordance with 7.8

"3.1.16 ***Flatness angle, n***—the resulting angle measurement of the sleep support surface or tilt angle of the bassinet/cradle bed when a compression force is applied to the chest of the CAMI dummy in accordance with 7.9"

(8) Add new sections 4.6 through 4.7:

"4.6 Angle measurements shall be obtained using a digital inclinometer capable of 0.1° minimum resolution.

"4.7 Equipment – Force gauge with a range of 0 to 25 lbf (110N), with a maximum tolerance of ± 0.25 lbf (1.11N) or a range of 0 to 50 lbf (222N) with a maximum tolerance of ± 0.25 lbf (1.11N). A calibration interval shall be maintained for the force gauges which will ensure that the accuracy does not drift beyond the stated tolerances.

(9) Add new section 5.13:

"5.13 ***Restraints***— The bassinet shall not include any restraints system which requires action on the part of the caregiver to secure the restraint."

(10) Instead of section 6.1:

"6.1 ***Spacing of Rigid and Fabric-Sided Bassinet/Cradle Components or Bassinet/Cradle attachment Components***—Spacing must comply with 16 CFR Part 1509 Section 1509.4 when tested according to 7.1 and 7.10."

(11) Instead of section 6.4:

"6.4 ***Stability***—A product in all manufacturers' recommended use positions, including positions where the locks are engaged for preventing rocking/swinging motion of the sleeping surface, shall not tip over and shall retain the CAMI Infant Dummy, Mark II, when subjected to the test described in 7.4."

(12) Add new sections 6.7 through 6.7.2:

"6.7 ***Rock/Swing Angle***—Bassinets or cradles that incorporate a rocking/swinging feature shall meet the following:

6.7.1 Maximum deflection angle measurement on any reading shall not exceed 20° when tested in accordance with 7.8.

6.7.2 The arithmetic mean of the rest angle measurements shall not exceed 5° when tested in accordance with 7.8.

(13) Add new section 6.8:

"6.8: ***Bassinet/Cradle Surface***—The angle of the bassinet or cradle sleeping support surface or the tilt angle of the bassinet/cradle bed shall not be greater than 5° when tested in accordance with 7.9.

(14) Add new section 6.9:

"6.9: ***Fabric-Sided Enclosed Openings***—For bassinets

or cradles with fabric sides, the fabric shall not release and form a completely bounded opening that allows the complete passage of the torso probe (Figure 3A) when tested in accordance with Section 7.10.

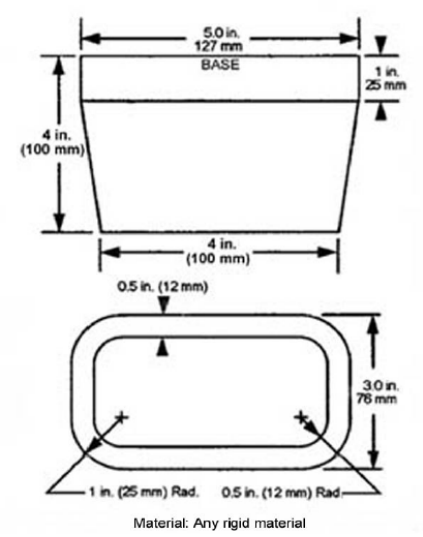

Figure 3A – Test Probe for Fabric Sided Testing"

(15) Add new sections 7.8 through 7.8.2.11:

"7.8 ***Rock/Swing Angle Test:***

"7.8.1 ***Side to Side Rock/Swing Test***—for bassinets/cradles that have a side-to-side rocking/swinging feature.

"7.8.1.1 Assemble bassinet/cradle in accordance with manufacturer's instructions and, if necessary, place the bassinet/cradle in rocking/swinging mode.

"7.8.1.2 Place the bassinet/cradle and the inclinometer on a flat level horizontal plane (0° ± 0.5°) to establish a reference plane. Zero the inclinometer.

"7.8.1.3 Disengage any locking mechanisms designed to prevent the unit from rocking/swinging, per the manufacturer's instructions.

"7.8.1.4 Place the CAMI Infant Dummy, MARK II belly up, with both arms contacting the torso, and the right arm touching the left side wall in the bassinet cradle. See Figure 4A.

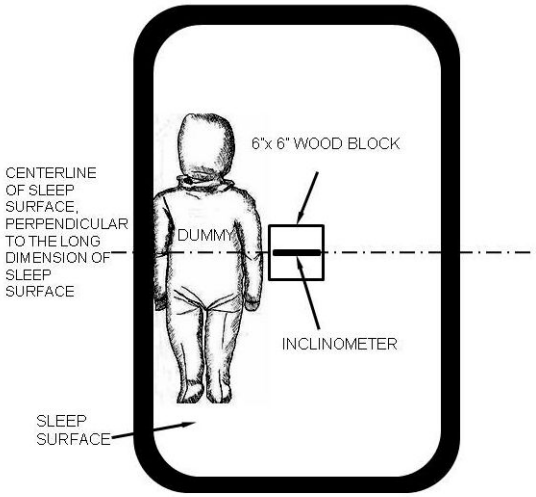

Figure 4A: Top View of CAMI Dummy and Inclinometer Placed in the Sleep Surface for the Side-to-Side Swing Test

"7.8.1.5 Manually deflect and hold the bassinet/cradle to the maximum side-to-side rock/swing angle allowed by the product design in the manufacturer's use position in the manner normally associated with rocking/swinging and intended by the manufacturer. Record the maximum deflection angle.

"7.8.1.6 Release the bassinet/cradle and allow it to

come to rest unassisted.

"7.8.1.7 Place the 6 in. x 6 in. wood block (ref. Section 7.3.2) less than 1 in. from the dummy, where the horizontal center of the block is in line with the centerline of the mattress bed perpendicular to the head-to-toe axis of the dummy. See Figure 4A. If a block cannot be placed in the prescribed location inside the mattress bed area due to mattress size constraints, dummy position, or if the mattress is substantially curved, then mount a 1 in. aluminum angle (ref. Section 7.4.2) on top of the rigid bassinet frame. See Figure 4B.

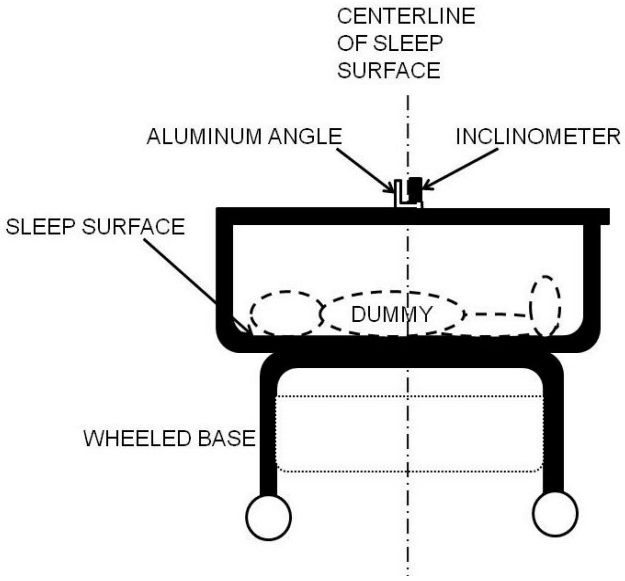

Figure 4B: Side View of CAMI Dummy Placed in the Sleep Surface with the Inclinometer and Aluminum Angle Mounted on Top of the Product

"7.8.1.8 Place the inclinometer on the top center of

the 6 in. x 6 in. wood block or aluminum angle and record the resulting angle.

"7.8.1.9 Repeat steps 7.8.1.2 to 7.8.1.8 four additional times. Record each side-to-side maximum deflection angle and each resulting side-to-side rest angle measurement. Calculate the arithmetic mean of the five side-to-side rest angle measurements.

"7.8.1.10 Repeat steps 7.8.1.2 to 7.8.1.9 except place the CAMI infant Dummy, Mark II belly up, with both arms contacting the torso, and the left arm touching the right side wall in the bassinet/cradle.

"7.8.1.11 Repeat steps 7.8.1.2 to 7.8.1.10 using a CAMI Newborn Dummy.

"7.8.2 ***Front-to-Back Rock/Swing Test***—for bassinets/cradles that have a front-to-back (head-to-toe) rocking/swinging feature

"7.8.2.1 Assemble bassinet/cradle in accordance with manufacturer's instructions and, if necessary, place the bassinet/cradle in the front-to-back rocking/swinging mode.

"7.8.2.2 Place the bassinet/cradle and the inclinometer on a flat level horizontal plane (0° ± 0.5°) to establish a test plane. Zero the inclinometer.

"7.8.2.3 Disengage any locking mechanisms designed to prevent the unit from rocking/swinging, per the

manufacturer's instructions.

"7.8.2.4 Place the CAMI Infant Dummy, Mark II belly up, with both arms contacting the torso, and the crown of the dummy's head touching the inside wall at one end of the sleep surface and the dummy's head-to-toe centerline is in line with the centerline perpendicular to the short dimension of the sleep surface. See Figure 4C.

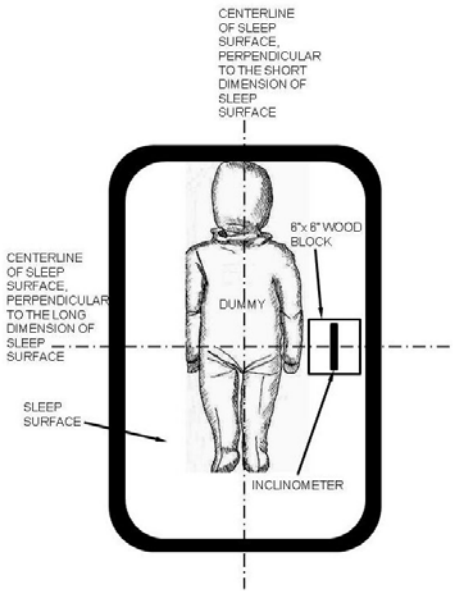

Figure 4C: Top View of CAMI Dummy and Inclinometer Placed in the Sleep Surface for the Front-to-Back Swing Test

"7.8.2.5 Manually deflect and hold the bassinet/cradle to the maximum rock/swing angle in the front-to-back direction allowed by the product design in the manufacturer's use position in the manner normally associated with rocking and intended by the manufacturer. Record the maximum rock/swing angle.

"7.8.2.6 Release the bassinet/cradle and allow it to come to rest unassisted.

"7.8.2.7 Place the 6 in. x 6 in. wood block (ref. Section 7.3.2) where the horizontal centerline of the wood block is in line with the horizontal centerline of the sleep surface. See Figure 4. If the wood block cannot be placed in the prescribed location on the mattress bed area due to mattress size constraints, dummy position, or if the mattress is substantially curved, then mount a 1 in. aluminum angle (ref. Section 7.4.2) spanning the top of the rigid bassinet frame in a direction parallel to the long dimension of the bassinet.

"7.8.2.8 Place the inclinometer on the top center of the 6 in. x 6 in. wood block or aluminum angle. Record the resulting rest angle.

"7.8.2.9 Repeat steps 7.8.2.2 to 7.8.2.8 four additional times. Record each front-to-back maximum deflection angle and each resulting rest angle measurement. Calculate the arithmetic mean of the five rest angle measurements.

"7.8.2.10 Repeat 7.8.2.2 to 7.8.2.9 with the CAMI Dummy, Mark II feet touching the inside at one end of the sleep surface and the dummy's torso centerline in line with the centerline perpendicular to the short dimension of the

sleep surface.

"7.8.2.11 Repeat 7.8.2.2 to 7.8.2.10 with the Newborn CAMI Dummy.

(16) Add new sections 7.9 through 7.9.7:

"7.9 ***Bassinet/Cradle Flatness Angle Test***

"7.9.1 Disable the rocking/swinging feature if the product is equipped with such a feature. Place the CAMI Infant Dummy, Mark II belly up, on the sleep surface in the location most prone to creating a depression, slope, or tilt (e.g., near a seam in the mattress, in a corner, etc.)

"7.9.2 Place the 6 in. x 6 in. wood block (ref. Section 7.3.2) on the chest of the dummy and apply a 10.0 ± 0.5 lb compression force within 2 seconds with a force gauge. Discontinue applying the force.

"7.9.3 Place the 6 in. x 6 in. wood block (ref. Section 7.3.2) less than 1 in. from the dummy, where the horizontal center of the block is in line with the horizontal centerline of the dummy. If the wood block cannot be placed inside the sleep surface of a rocking/swinging product due to mattress size constraints, dummy position, or if the mattress is substantially curved, then mount the 1 in. aluminum angle (ref. Section 7.4.2) on top of the rigid bassinet frame.

"7.9.4 Record the resulting flatness angle along the

dummy's head-to-toe axis and at 90° from the head-to-toe axis.

"7.9.5 Repeat steps 7.9.1 to 7.9.4 four additional times. Record each angle measurement and calculate the arithmetic mean of the five angle measurements in the head-to-toe direction and 90° from the head-to-toe axis.

"7.9.6 If the dummy's height is equivalent to or less than the width of the sleep surface then rotate the dummy 90° and repeat steps 7.9.1 to 7.9.5. See Figure 4D.

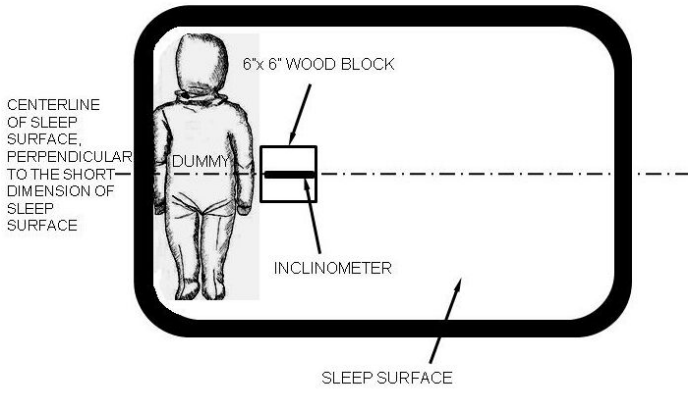

Figure 4D: Top View of CAMI Dummy and Inclinometer, Rotated 90º, Placed in the Sleep Surface for the Mattress Flatness Test

"7.9.7 Repeat 7.9.1 to 7.9.6 with the Newborn CAMI Dummy."

(17) Add new sections 7.10 through 7.10.6:

"7.10 *Fabric Release Test Methods for Enclosed Openings*

"7.10.1 Assemble and place the bassinet/cradle in the

manufacturers use position.

"7.10.2 With the torso test probe attached to a force gauge, place the small end of the probe against the fabric inside wall of the product and any structural elements in any locations deemed most likely to fail.

"7.10.3 Apply a 20 lb force to the probe over a period of 5 seconds and hold for an additional 5 seconds.

"7.10.4 Upon completion of 7.10.3, if an opening occurs in a location, other than the location being tested, release the probe from the original test location and repeat 7.10.3 at this additional location without adjusting the fabric.

"7.10.5 If the product has a removable cover, unfasten all fasteners and/or snaps and repeat 7.10.2 to 7.10.4

"7.10.6 Repeat 7.10.1 to 7.10.5 in all manufacturers recommended use positions. For multiple use products, the test shall be performed in all possible use modes.

(18) Instead of section 8.3.1:

"8.3.1 In the warning statements, the safety alert symbol ⚠ and the word WARNING shall precede the warning statements at each location where warnings are provided and shall not be less than 0.2 in. (5 mm) high. The remainder of the text shall be in letters not less than 0.1 in. (2.5

mm) high except as specified in 8.4.2.

(19) Instead of section 8.4.2.1:

"Infants have suffocated:

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

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

(20) Add section 8.4.2.2:

"8.4.2.2 The words "SUFFOCATION HAZARD" shall be bold face type not less than 0.2 in. (5 mm) high. The words "Infants have suffocated" shall be in characters whose upper case is not less than 0.16 in. (4 mm) high. The remainder of the warning statement shall be standard type style whose upper case shall be at least 0.1 in. (2.5 mm) high.

Dated: _____

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