

Vote Sheet

TO: The Commission

Alberta E. Mills, Secretary DATE: February 28, 2024

THROUGH: Jessica L. Rich, General Counsel

Austin C. Schlick, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel, Regulatory Affairs

Charlotte G. Alton, Attorney, Regulatory Affairs Mary A. House, Attorney, Regulatory Affairs

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

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: March 20, 2024

The Office of the General Counsel is forwarding for the Commission's consideration a draft notice of proposed rulemaking (NPR) for *Federal Register* publication to amend the Safety Standard for Bassinets and Cradles, 16 C.F.R. part 1218, originally promulgated in 2013. Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), 15 U.S.C. § 2056a(b)(2), requires the Commission to periodically review and revise existing rules for durable infant or toddler products to ensure that they provide the highest level of safety for such products that is feasible. Accordingly, the draft NPR proposes to revise the existing rule for bassinets/cradles to ensure that they address the identified hazards and provide the highest level of safety feasible.

CPSC staff recommends that the Commission publish the draft NPR, which would update the incorporation by reference from the 2013 version of the voluntary standard to the more recent, ASTM F2194 – 22^{ϵ_1} , Standard Consumer Safety Specification for Bassinets and Cradles (ASTM F2194 – 22^{ϵ_1}), with modifications to provide the highest level of safety for bassinets/cradles that is feasible.

Please indicate your vote on the following options:

I.	Approve publication of the attached notice in	tne <i>Federal Register</i> , as draπed.	
	(Signature)	(Date)	

U.S. Consumer Product Safety Commission 4330 East-West Highway Bethesda, MD 20814 National Product Testing and Evaluation Center 5 Research Place Rockville, MD 20850

II. Approve publication of the atta	Approve publication of the attached notice in the <i>Federal Register</i> , with the specified change				
(Signature)	(Date)				
II. Do not approve publication of t	Do not approve publication of the attached notice in the Federal Register.				
(Signature)	(Date)				
V. Take other action specified be	low.				
(Signature)	(Date)				

Attachment: Draft Notice of Proposed Rulemaking: Safety Standard for Bassinets and Cradles

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Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1218

[CPSC Docket No. CPSC-2010-0028]

Safety Standard for Bassinets and Cradles

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: In 2013, the United States Consumer Product Safety Commission (Commission or CPSC) published a safety standard for bassinets and cradles (bassinets/cradles). By statute, after promulgating a mandatory rule, the Commission must periodically review and revise rules for durable infant or toddler products to ensure that they provide the highest level of safety for such products that is feasible. Accordingly, this proposed rule (NPR) would revise the existing rule for bassinets/cradles to ensure that it addresses identified hazards and that these sleep products for young infants provide the highest level of safety feasible.

DATES: Submit comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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

Submit all other comments, identified by Docket No. CPSC-2010-0028, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: https://www.regulations.gov. Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by e-mail, except through www.regulations.gov. CPSC

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encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/Hand Delivery/Courier/Confidential Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504-7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may e-mail them to: cpsc-os@cpsc.gov.

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to https://www.regulations.gov. Do not submit through this website: Confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier/confidential written submissions.

Docket: For access to the docket to read background documents or comments received, go to: https://www.regulations.gov, and insert the docket number, CPSC-2010-0028, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Celestine T. Kish, Project Manager, Division of Human Factors, Directorate for Engineering Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; 301-987-2547; ckish@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), 15 U.S.C. 2056a(b), requires the Commission to promulgate standards for durable infant or toddler

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products that are "substantially the same as" any applicable voluntary standards, or more stringent than the voluntary standards, if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. 15 U.S.C. 2056a(b)(1)(B). Pursuant to section 104(b)(1) of the CPSIA, the Commission promulgated the current mandatory standard for bassinets and cradles (bassinets/cradles) in October 2013, *Safety Standard for Bassinets and Cradles*, codified at 16 CFR part 1218 (part 1218). 78 FR 63019 (Oct. 23, 2013).

The current bassinet/cradle rule found in part 1218 incorporates by reference the 2013 version of the bassinets/cradles voluntary standard, ASTM F2194 – 13, *Standard Consumer Safety Specification for Bassinets and Cradles* (ASTM F2194 – 13), with modifications to make the standard more stringent, to further reduce the risk of injury associated with bassinets/cradles.¹ Part 1218 modifies ASTM F2194 – 13 by: clarifying the scope of rule, exempting from the flatness requirement bassinets with seams less than 15 inches long, requiring a more stringent stability test, and requiring a smaller CAMI dummy² for testing. After issuing the mandatory standard in 2013, ASTM International (ASTM) published several revisions to ASTM F2194, including ASTM F2194 – 2013a, -2016, and -2016^{c1}. ASTM did not notify CPSC of these revisions, so the mandatory rule has not been updated since 2013. However, ASTM F2194 – 2016^{c1} is substantially the same as the existing mandatory rule for bassinets/cradles codified in part 1218. 86 FR 33022, 33034-35 (June 3, 2021).

In June 2021, also pursuant to section 104 of the CPSIA, the Commission promulgated a *Safety Standard for Infant Sleep Products* (ISP Rule), codified at 16 CFR part 1236. 86 FR 33022

¹ Bassinets/cradles are durable infant or toddler products that, since 2013, require product registration cards and certificates based on testing by a CPSC-accepted third party laboratory. Section 104(f)(2)(L) of the CPSIA specifically identifies bassinets/cradles as durable infant or toddler products. The NPR proposes to add testing and labeling requirements that will not change the existing requirements for product registration cards and third party testing and certification. Additionally, although ASTM F2194 − 22^{ε1} is copyrighted, by permission of ASTM the voluntary standard can be viewed as a read-only document during the comment period at: http://www.astm.org/cpsc.htm.
² Designated ASTM testing device. CAMI (Civil Aeromedical Institute) dummies are based on child anthropometric data and come in multiple sizes. The CPSC mandatory safety standard for bassinets and cradles specifies the newborn size CAMI.

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(June 23, 2021). The ISP Rule applies to products that are marketed or intended to provide a sleeping accommodation for infants up to five months of age that do not already meet the requirements of one of the following CPSC sleep standards: full-size cribs, non-full-size cribs, play yards, bedside sleepers, or bassinets/cradles. The ISP Rule requires that such infant sleep products, at a minimum, have a head-to-toe sleep surface angle of 10 degrees or less from horizontal, and meet the mandatory rule for bassinets/cradles, including the definition of a bassinet/cradle, which means that products must have a stand. Because of the ISP Rule, the bassinets/cradles rule provides a safe sleep baseline for infant sleep products.³ The intent of the ISP Rule was to ensure that infants are placed to sleep on a firm, flat sleep surface and that caregivers are discouraged from placing infant sleep products, including those bassinets that were lightweight and low to the ground, on unsafe surfaces, such as beds, couches, tables, and countertops.

In 2022, ASTM approved and published another revised voluntary standard for bassinets/cradles – ASTM F2194 – 22^{ε1} – and notified CPSC of the revision on July 18, 2022. Revised ASTM F2194 – 22^{ε1} added a new product category – compact bassinets/cradles – and new requirements for these products, including stability requirements and marking and labeling requirements. Among its other provisions, ASTM F2194 – 22^{ε1} eliminated stands for compact bassinets/cradles, but also included new requirements for battery compartments, warnings, and instructional literature. CPSC issued a notice of availability (NOA) requesting comment on the revised ASTM standard. 87 FR 45303 (July 28, 2022).

Pursuant to the procedure outlined for revised voluntary standards in section 104(b)(4) of the CPSIA, 15 U.S.C. 2056a(b)(4), CPSC had 90 days from receiving notice of ASTM's 2022 revision to either allow the revised ASTM F2194 to become the new mandatory standard for bassinets/cradles, or to notify ASTM that the Commission determined that the revised ASTM

³ After challenge, the United States Court of Appeals for the District of Columbia Circuit held that CPSC did not exceed its authority in promulgating the ISP Rule. *Finnbin, LLC v. CPSC*, 45 F.4th 127 (D.C. Cir. Aug. 2, 2022).

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standard did not improve the safety of bassinets/cradles and that CPSC was retaining the existing mandatory standard. On September 14, 2022, CPSC staff provided to the Commission a Staff Briefing Package: ASTM's Notice of a Revised Voluntary Standard for Bassinets and Cradles (2022 Bassinet Rejection Staff Briefing Package) which reviewed the comments from the NOA and assessed ASTM F2194 – 22^{ɛ1}. Staff recommended that the Commission reject ASTM F2194 – 22^{ɛ1}.

In the 2022 Bassinet Rejection Staff Briefing Package, staff advised that the requirements for compact bassinets/cradles in ASTM F2194 – $22^{\epsilon 1}$ were less stringent than the requirements for traditional bassinets/cradles in the existing bassinets/cradles rule (part 1218), in part because ASTM F2194 – 22^{ɛ1} did not require that compact bassinets/cradles have a stand. Moreover, because the ISP Rule, part 1236, makes the bassinet rule, part 1218, the baseline for safe sleep requirements, amending part 1218 to allow compact bassinets that are low to the ground, as specified in ASTM $F2194 - 22^{\epsilon l}$, would also allow infant sleep products that were less stable and could be placed on unsafe surfaces, such as elevated and soft surfaces. Staff explained in the 2022 Bassinet Rejection Staff Briefing Package that consumers are likely to place smaller, lighter, and more portable compact bassinets in unsafe locations, such as elevated and soft surfaces (tables, counters, couches, and beds), and that CPSC's data demonstrate that infants have suffered serious head injuries and death when using these products in unsafe locations.⁵ Additionally, staff advised that ASTM F2194 $-22^{\epsilon l}$ added a new stability test that applies only to compact bassinets/cradles, and that this new stability test is less stringent than the stability test for regular-sized bassinets/cradles. Staff advised that infant sleep products without a stand present a risk of injury from falls that may lead to suffocation, head injuries, and/or death.

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⁴ Available at: https://www.cpsc.gov/s3fs-public/ASTMs-Notice-of-a-Revised-Voluntary-Standard-for-Bassinets-and-Cradles.pdf? VersionId=x73F5OmeW4AJujWJEq8.kBZ28aTFLb2x.

⁵ Tab A of the 2022 Bassinet Rejection Staff Briefing Package discusses consumer behavior with portable, compact products.

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On September 23, 2022, the Commission voted 5-0 to determine that ASTM F2194 – 22^{ε1} did not improve the safety of bassinets and cradles or infant sleep products.⁶ Staff notified ASTM of the Commission's rejection of ASTM F2194 – 22^{ε1} by letter on October 6, 2022.⁷ Subsequent to the Commission's rejection of ASTM F2194 – 22^{ε1}, staff continued to work with the ASTM F15.18 Bassinets and Cradles Subcommittee and the ASTM F15.18 Bassinet Elevated Surface and Data Task Group to revise the performance requirements for bassinets/cradles to set acceptable baseline safe sleep requirements for bassinets/cradles and for infant sleep products.

The Commission is now proposing to revise the existing rule for bassinets/cradles to address the hazards identified in this NPR and ensure that the mandatory bassinet/cradle regulation in part 1218 provides the highest level of safety feasible. The Commission is authorized to issue this NPR pursuant section 104(b)(2) of the CPSIA, 15 U.S.C. 2056a(b)(2), which requires that after the Commission issues mandatory safety standards for durable infant or toddler products, the Commission shall periodically review and revise the standards to ensure that such standards provide the highest level of safety for such products that is feasible. Building on staff's continued work with ASTM on safe sleep requirements, the Commission is issuing this NPR to adopt ASTM F2194 – 22⁸¹ with modifications. The proposed modifications remove the compact bassinet category and address five hazard patterns associated with young infants placed in or on:

- Non-level bassinets/cradles (suffocation hazard);
- Bassinets/cradles on elevated and soft surfaces such as beds, couches, tables, and countertops (falls, suffocation, skull fractures, and asphyxia hazards);
- Mattresses that are non-flat, too thick, too soft, ill-fitting, or unattached to the bassinet/cradle (suffocation hazard);
- Bassinets/cradles with design issues, such as low to the ground or unstable, or with loose sidewalls and/or non-mesh sidewalls (containment, tipping, gap entrapment, and suffocation hazards); and

⁶ See Record of Commission Action at: https://www.cpsc.gov/s3fs-public/RCA-ASTMs-Notice-of-a-Revised-Voluntary-Standards-for-Bassinets-and-Cradles.pdf?VersionId=cfj.qZe5KlTS2AY3G69UwltalltP4LRk.

⁷ October 6, 2022 letter to K. Morgan, available at: https://www.cpsc.gov/s3fs-public/Bassinet_Rule_Update_letter_to_ASTM_2022-10-06%2010-7-2022.pdf? VersionId=PpvmrIEhQT.z3P57h8lhtc1UTvQITpSR.

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• Products with electrical problems such as smoke, shock, and battery leakage (shock and burn).

The Commission is also proposing to align the rule's warnings with ASTM F2194 $-22^{\epsilon 1}$ but not to include warnings related solely to compact bassinets. The NPR proposes to require warnings on all bassinets within the scope of the rule.

Staff provided a February 28, 2024, Memorandum, Staff's Draft Proposed Rule to Revise the Safety Standard for Bassinets and Cradles in support of the NPR, which is available at: [insert link]. This NPR contains an overview of staff's assessment and analysis, and the Commission's basis for issuing this NPR, which is also based on the 2022 Bassinet Rejection Staff Briefing Package. Based on the information and analysis in this NPR and the above staff packages, the Commission preliminarily determines that the proposed requirements are more stringent than the requirements in ASTM F2194 – 22^{ɛ1}, would further reduce the risk of injury associated with products within the scope of the NPR, and would provide the highest level of safety that is feasible for such products. The Commission specifically seeks comment on the feasibility of each proposed requirement, including technical feasibility.

II. The Product

A. Definition of Bassinet/Cradle

The existing mandatory standard defines a "bassinet/cradle" based on the incorporated section 3.1.1 of ASTM F2194 – 13, as a "small bed designed primarily to provide sleeping accommodations for infants, supported by free standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which can swing relative to a stationary base." The definition also requires that while a bassinet/cradle is in a resting, non-rocking, or swinging position, "a bassinet/cradle is intended to have a sleep surface less than or equal to 10° from horizontal."

ASTM F2194 – $22^{\epsilon 1}$ introduced a new "compact bassinet" product category, defined as "a bassinet/cradle having a distance of less than 6.0 inches (152.4 mm) between the lowest point of the

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underside of the sleep surface support and the product support surface (floor)." In the 2022

Bassinet Rejection Staff Briefing Package, staff assessed the compact bassinet category and advised the Commission that including compact bassinets/cradles within the scope of the voluntary standard, which contain product characteristics that the Commission specifically stated in the ISP Rule were not safe for infant sleep, and allowing a less-stringent stability test for these products, contradicts the Commission's safe sleep goals in part 1218 and in the ISP Rule.

The Commission now proposes to amend part 1218 to incorporate ASTM F2194 – $22^{\epsilon 1}$ by reference, but with modifications that exclude from the mandatory rule "compact bassinets" and associated requirements. As described in section V of this preamble, the modifications in the NPR further clarify the products within the scope of the rule and seek to enhance the safety requirements in part 1218, and thus also the minimum safe sleep requirements in the ISP Rule.

B. Scope of Products Within the NPR

The NPR would apply to: (1) bassinets and cradles; (2) combination products in bassinet or cradle mode, including play yards, bedside sleepers, strollers, and cradle swings that have a bassinet or cradle mode; (3) play yard and stroller bassinet accessories, when used separately from the play yard or stroller; (4) small bassinets, sometimes marketed as "travel bassinets" or "floor bassinets," including both items with rigid frames and with soft sides; (5) Moses baskets, sold with or without a stand; (6) travel bassinets, outdoor bassinets, and "play pens" that do not meet the side height requirements of the mandatory play yard standard and are marketed for sleep; and (7) after-market bassinet mattresses.⁸

Commonly, bassinets have multiple-use modes and therefore fall within the scope of multiple CPSC regulations, particularly the standard for hand-held infant carriers in 16 CFR part

⁸ Several related products are out of scope of this NPR. A few products marketed as "bassinets" have relatively high side rails, rigid sides, and a distance between the top rail and the sleep surface of at least 22 inches. Some of these products are marketed as compliant with the mandatory safety standard for non-full-size cribs and play yards. These

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1225, and/or the standard for infant sleep products in 16 CFR part 1236. Combination products must meet the bassinet standard when in the bassinet mode. All multi-mode products, as sold, including stroller bassinets, play yard bassinets, and Moses baskets, would need to meet the requirements of a revised rule, regardless of whether the product is sold with or without a stand. This means that stroller and play yard bassinets marketed for use without the stand, or that can be foreseeably used without the stand, would need to meet the requirements of a final rule.

Part 1218 requires bassinets to be sold with a mattress and includes requirements for these mattresses and original equipment manufacturer (OEM) replacements that are equivalent in dimensions and specifications to the mattress provided with the original product. This NPR proposes also to include after-market bassinet mattresses within the scope of the rule. After-market bassinet mattresses are sold separately from the bassinet and are typically small oval or rectangular mattresses marketed to fit a bassinet, including products marketed to fit a bassinet accessory product to a play yard or stroller. OEM replacement mattresses are, and have always been, included in part 1218 and are not considered after-market mattresses. The NPR also includes products marketed as "mattress toppers" as a type of after-market bassinet mattress.

C. Market Description

As discussed in section VIII of this preamble, staff estimates the annual sales of new bassinets/cradles, including items with a bassinet mode or attachment, to be approximately 3.1 million units per year in the United States. Staff estimates the annual U.S. sales of used

products may be within the scope of the mandatory standard for non-full-size cribs and play yards specified in 16 CFR part 1220, rather than this rule, but the performance requirements of the two standards are very similar. Moreover, hospital bassinets are medical devices regulated by the Food and Drug Administration (FDA) and are not within the scope of this rule. See 21 CFR 880.5145 "Medical bassinet." Finally, thin mattress protectors and covers, such as waterproof mattress covers, that cannot be used as a standalone mattress, are not within the scope of this proposed rule.

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bassinets/cradles to be 500,000 units per year, and the annual sales of new after-market bassinet mattresses to be 680,000 units per year.

Prices for traditional bassinets range from under \$50 to more than \$1,500, with most products in the \$50 to \$125 range. Prices for cradles range from \$100 to more than \$1,000, with most products in the \$100 to \$200 range. Solid hardwood cradles are available for more than \$1,000. Combination bedside sleeper/bassinets typically sell for \$75 to more than \$600, with most products in the \$125 to \$200 range. Bassinet attachments to play yards are usually not priced or sold separately. Some stroller bassinet attachments are sold separately, with most such products in the \$100 to \$200 range. Play yard and stroller bassinet attachments are designed to attach to a specific model or set of models from one manufacturer, and/or to a stand sold separately by that manufacturer. The stands typically sell for \$125 to \$175. Prices for after-market bassinet mattresses range from \$20 to \$180, with most products in the \$30 to \$40 range.

Bassinets do not have a single, best-selling size, price range, or set of features. The wide range of prices and features reflect that parents and other caregivers buy bassinets for different purposes, including but not limited to as primary sleep space or for occasional use, and as a permanent piece of nursery furniture or an easily portable sleep space. With approximately 3.1 million new bassinets sold per year, including items such as bedside sleepers, play yards, and strollers with a bassinet mode, at an average price of approximately \$100 per unit, the total U.S. bassinet market is approximately \$310 million dollars in sales per year. This total does not include the market for used items. At an estimated used price of \$40, based on observed prices of used bassinets on Ebay and Mercari as a percentage of original retail prices, the used market represents approximately \$20 million dollars in sales per year. Staff estimates annual unit sales of new aftermarket bassinet mattresses to be 680,000 units, with a market of \$23.8 million per year.

Many manufacturers and importers, as well as foreign direct shippers, supply bassinets and cradles to the U.S. market. In March 2023, CPSC staff identified more than 120 suppliers,

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including suppliers that sell play yards or strollers with bassinet attachments. The Juvenile Product Manufacturers Association (JPMA) currently has 22 member companies that are certified for bassinets/cradles. Bassinets and cradles are available from online general retail sites, online baby product sites, and brick and mortar general retail stores, including "big box" stores. Additionally, hundreds of suppliers, including importers and U.S. based hand crafters, supply after-market bassinet mattresses, which are sold almost exclusively online.

III. Incident Data and Hazard Patterns

Staff searched two CPSC-maintained databases to identify incidents and hazard patterns addressed in this NPR that are associated with bassinets and cradles: the Consumer Product Safety Risk Management System (CPSRMS)^{9, 10} and the National Electronic Injury Surveillance System (NEISS).¹¹ From these sources, for this NPR staff identified seven fatalities and 13 injuries related to bassinets/cradles from January 1, 2017 through December 31, 2022. CPSC staff is also aware of 182 non-injury incidents from January 1, 2021 through December 31, 2022. Staff identified the following hazard patterns from this data.

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⁹ CPSRMS includes data primarily from three groups of sources: incident reports, death certificates, and in-depth follow-up investigation reports. A large portion of CPSRMS consists of incident reports from consumer complaints, media reports, medical examiner or coroner reports, retailer or manufacturer reports (incident reports received from a retailer or manufacturer involving a product they sell or make), safety advocacy groups, law firms, and federal, state, or local authorities, among others. It also contains death certificates that CPSC purchases from all 50 states, based on selected external cause of death codes (ICD-10). The third major component of CPSRMS is the collection of in-depth follow-up investigation reports. Based on the incident reports, death certificates, or National Electronic Injury Surveillance System (NEISS) injury reports, CPSC Field staff conduct in-depth investigations (on-site, telephone, or online) of incidents, deaths, and injuries, which are then stored in CPSRMS.

¹⁰ Staff searched all data coded under product code 1537 (Bassinets or Cradles). In addition, staff extracted data coded under 1513 (Playpens and Play Yards), 1529 (Portable Cribs), 1542 (Baby Mattresses or Pads), 1505/1522 (Baby Carriages/Strollers), 1519/1548 (Car Seats/Baby Carriers), 1502 (Baby Changing Tables), 1558 (Baby Bouncer Seats), and 1553 (Portable Baby Swings). Staff further screened data searched from this wide range of products using keywords to identify the potentially in-scope bassinet accessories or multi-mode products that may have been used as a bassinet at the time of the incident. Staff extracted data on January 13, 2023, and restricted age to 12 months and younger. Upon careful joint review with CPSC's Directorates for Engineering Sciences, Health Sciences, and Economics, staff considered many cases out-of-scope for the purposes of this NPR. For example, staff excluded from this analysis cases with Sudden Unexpected Infant Death (SUID) or other pre-existing medical conditions as official cause of death and no additional circumstantial information available.

¹¹ NEISS is the source of the injury estimates; it is a statistically valid injury surveillance system. NEISS injury data are gathered from EDs of about 100 hospitals, with 24-hour EDs and at least six beds, selected as a probability sample of all U.S. hospitals. The surveillance data gathered from the sample hospitals enable staff to make timely national estimates of the number of injuries associated with specific consumer products.

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A. Products Not Sitting Level

Two deaths, three non-emergency department (ED)-treated injury, and 95 of the 182 non-injury product-related incident reports describe a bassinet or cradle not sitting level. The narratives describe the products as non-level, leaning forward or to one side, and having legs or sides with uneven heights. A bassinet not sitting level creates a hazardous situation where an infant is more likely to roll into a compromising position as described below, whether the infant is developmentally capable of rolling or not, thereby posing a risk of asphyxia/suffocation. The fatal incidents involve infants rolling to the side, often into the mesh/siding of the bassinet:

- In CPSC In-Depth Investigation (IDI)¹² 200211HCC3248, a 2-month-old male was found unresponsive in his bassinet after moving into a compromising position where his nose was positioned adjacent to a crease on the right side of the bassinet. The bassinet was not level, and the edge of an adult bed was protruding into the mesh right sidewall of the bassinet.
- In IDI 190610CCC3431, a 1-month-old male was found unresponsive in his bassinet after a non-level sleep surface allowed the victim to roll into a compromising position in the presence of excess bedding.

According to the American Academy of Pediatrics (AAP), infants should be placed to sleep in a supine position (on their back) on a firm, flat, level surface without soft bedding in the sleep setting.^{13,14} Positional asphyxia is a type of asphyxia associated with abnormal body position, where the position of the subject compromises adequate breathing.^{15,16,17} Infants under 12 months

¹² IDIs are CPSC-generated investigation summaries of events surrounding product-related injuries or incidents. Based on victim/witness interviews, the reports provide details about incident sequence, human behavior, and product involvement.

Moon RY, Carlin RF, Hand I. The Task Force on Sudden Infant Death Syndrome and the Committee on Fetus and Newborn; Evidence Base for 2022 Updated Recommendations for a Safe Infant Sleeping Environment to Reduce the Risk of Sleep-Related Infant Deaths. Pediatrics July 2022; 150 (1): e2022057991. 10.1542/peds.2022-057991.
 Task Force on Infant Positioning and SIDS. Positioning and infant death syndrome (SIDS): update Arch Pediatr Adolesc Med. 1996;150:834-837.

¹⁵ Chmieliauskas S, Mundinas E, Fomin D, Andriuskeviciute G, Laima S, Jurolaic E, Stasiuniene J, Jasulaitis A. Sudden deaths from positional asphyxia: A case report. Medicine (Baltimore). 2018 Jun;97(24):e11041. doi: 10.1097/MD.000000000011041. PMID: 29901602; PMCID: PMC6023692.

¹⁶ Gordon I, Shapiro HA. Deaths usually initiated by hypoxia or anoxic anoxia. In: Gordon I, Shapiro HA, editors. Forensic medicine: 2nd ed. Edinburgh, UK: Churchill Livingstone, 1982; 95–129.

¹⁷ Gordon I. The medicolegal aspects of rapid deaths initiated by hypoxia and anoxia. Leg Med Annu. 1975:29-47. PMID: 768671.

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of age are considered at risk of positional asphyxia, but infants 2 to 6 months of age, premature infants, and infants who are born as a set of multiples are particularly vulnerable and at highest risk because they may be developmentally capable of moving around in the sleep environment and moving into a vulnerable situation but do not yet have the physical capability to extricate themselves from a hazardous situation. ^{18,19,20,21,22,23}

An infant can suffocate/asphyxiate against anything that partially or fully obstructs the nose and mouth and prevents breathing.²⁴ Once an infant's airflow is compromised, decreased levels of oxygen in the blood can further impair the infant's ability to respond to the situation. If an infant cannot respond, a feedback loop of decreased heart and respiration rate develops that can eventually lead to cessation of breathing and may become fatal if uninterrupted.^{25,26,27,28,29} The prognosis for hypoxic (experiencing a state of low levels of oxygen in body tissues) victims due to smothering depends primarily on the extent of oxygen deprivation, the duration of unconsciousness, and the speed at which cardiopulmonary resuscitation (CPR) is attempted relative to the timing of cardiac

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¹⁸ Dwyer T, Ponsonby A-L, Blizzard L, Newman NM, Cochane JA. The contribution of changes in prevalence of prone sleeping position to the decline in sudden infant death syndrome in Tasmania. JAMA. 1995;273:783-789.

¹⁹ Byard RW, Beal S and Bourne AJ. Potentially dangerous sleeping environment and accidental asphyxia in infancy and early childhood. Arch Dis Child 1994; 71: 497-500.

²⁰ Fleming PJ, Blair PS, Bacon C, et al. Environment of infants during sleep and risk of the sudden infant death syndrome: results of 1993-5 case-control study for confidential inquiry into stillbirths and deaths in infancy. BMJ. 1996;313:191-195.

²¹ Hauck FR, Herman SM, Donovan M, et al. "Sleep Environment and the Risk of Sudden Infant Death Syndrome in an Urban Population: The Chicago Infant Mortality Study." Pediatrics 2003; (111): 1207-1214.

²² Ponsonby AL, Dwyer T, Gibbons LE, Cochrane JA, Wang Y-G. Factors potentiating the risk of sudden infant death syndrome associated with prone position. N Engl J Med. 1993;329:377-382.

²³ Smialek, JE, Smialek, PZ and Spitz, WU. Accidental bed deaths in infants due to unsafe sleeping situations. Clinical Pediatrics 1977; 15 (11):1031-1035.

²⁴ Wanna-Nakamura S. White Paper – Unsafe Sleep Settings: Hazards associated with the infant sleep environment and unsafe practices used by caregivers: a CPSC staff perspective. Bethesda, MD: Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 2010.

²⁵ Rosen CL et al., Two siblings and recurrent cardiorespiratory arrest; Munchausen syndrome by proxy or child abuse Paediatrics 1983; 71:715-720.

²⁶ Medalia AA, Merriam AE, Ehrenreich JH. The neuropsychological sequelae of attempted hanging. J Neurol Neurosurg Psychiatry. 1991; 54:546–8.

²⁷ Jongewaard WR, Cogbill TH, Landercasper J. Neurologic consequences of traumatic asphyxia. J Trauma. 1992 Jan;32(1):28-31. doi: 10.1097/00005373-199201000-00006. PMID: 1732570.

²⁸ Polson CJ. Hanging In: Polson CJ and Gee DJ (eds.) Essentials of forensic medicine Oxford England, 1973 371-404.

²⁹ Spitz WU. Asphyxia. In: Spitz WU, Spitz DJ, editors. Spitz and Fisher's medico-legal investigation of death: guidelines for the application of pathology to crime investigation, 4th edn.

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arrest. Rapid reversal of the hypoxic state is essential to prevent or limit the development of pulmonary and cerebral edema that can lead to serious injury or death. Thus, victims who are oxygen deprived for short durations or quickly receive cardiopulmonary resuscitation to reestablish air flow have the most favorable clinical outcomes.

Because the brain is the organ in the body most sensitive to oxygen deprivation, a period of oxygen deprivation of as short as three minutes can lead to a wide range of serious injuries. The severity of oxygen deprivation ultimately governs the infant's chance for survival and the degree of neurological damage. The extent of injury is directly related to the duration and magnitude of hypoxia. Inadequate supply of oxygen to the brain can lead to loss of consciousness, cardiac arrest, and death. Victims who are rescued from oxygen deprivation of less than four minutes can still suffer a wide range of serious injuries and lasting neurological issues, including delays to reach milestones, paralysis, sensory disturbances, seizures, cognitive and memory deficits, and neuropsychological problems. Patients who survive cardiac arrest can remain in a coma for various periods and some may remain in a persistent vegetative state. Patients who survive prolonged anoxic episodes require a multidisciplinary rehabilitation that may include speech therapy, physical therapy, and/or prolonged specialized care inside or outside of the home, with the level of care dependent on the severity of the injury.

B. Bassinet Mattresses and Mattress Supports

Mattresses that are not flat (e.g., bent, warped, sagging, with bumps, bulges, or dips) or not well-fitting, or mattress boards that are bent, warped, pop out of place, or provide little or no

³⁰ Dzikienė R, Lukoševičius S, Laurynaitienė J, Marmienė V, Nedzelskienė I, Tamelienė R, Rimdeikienė I, Kudrevičienė A. Long-Term Outcomes of Perinatal Hypoxia and Asphyxia at an Early School Age. Medicina (Kaunas). 2021 Sep 18;57(9):988. doi: 10.3390/medicina57090988. PMID: 34577911; PMCID: PMC8466311.

³¹ Jongewaard WR, Cogbill TH, Landercasper J. Neurologic consequences of traumatic asphyxia. J Trauma. 1992 Jan;32(1):28-31. doi: 10.1097/00005373-199201000-00006. PMID: 1732570.

³² van Handel, M., Swaab, H., de Vries, L.S. *et al.* Long-term cognitive and behavioral consequences of neonatal encephalopathy following perinatal asphyxia: a review. *Eur J Pediatr* 166, 645–654 (2007). https://doi.org/10.1007/s00431-007-0437-8.

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support, or that have bars (that support the mattress boards) that are broken or not staying in place, can lead to an uneven sleep surface, putting the infant at risk of asphyxia/suffocation. Staff illustratively identified two deaths, one ED visit, one non-ED injury, and 75 of the 182 non-injury product-related incidents that demonstrate this hazard. These non-injury incidents could have resulted in asphyxiation/suffocation if someone had not intervened to rescue the occupant. One death associated with a bassinet mattress involved a depression in the middle of the mattress, while the other death involved poor fit of the mattress, which allowed enough space for the infant to get wedged between the mattress and the sidewall of the bassinet.

- In IDI 220804HCC1109, a 3-month-old male was found unresponsive in a concave depression in the center of a bassinet.
- In IDI 210824HCC1792, a 3-month-old female was found prone wedged in a gap between the bassinet mattress and bassinet frame under a pillow.

Any object that obstructs an infant's airway, including an overly soft mattress, can lead to serious injury or death. This category includes a bassinet that was subject to a CPSC safety recall because the mattress support was disengaging, posing fall and entrapment hazards.³³

C. Structural Integrity/Quality

Products with insufficient structural robustness (including components of the bassinet/cradle that reportedly break or crack; hardware coming loose; and stitching coming undone) can also increase the potential for infants to get into a compromising position, increasing the risk of asphyxiation/suffocation. Staff identified one reported hospitalization (laceration injury), one reported ED visit (broken metal piece injured infant), and seven of the 182 non-injury product-related incidents that demonstrate this hazard pattern.

³³ DaVinci Recalls Bassinets Due to Fall and Entrapment Hazards (Recall Alert) | CPSC.gov.

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D. Product Design

Product design can lead to safety concerns, including products being unstable (increasing risk of rolling into a compromising position and suffocating), products sitting too low to the ground (allowing easier access by older siblings and creating suffocation hazards), and products having non-mesh sidewalls that create a suffocation hazard. Staff identified two deaths, one non-ED injury, and three of the 182 non-injury product-related incident reports that demonstrate this hazard. One product reportedly was unstable, while another reported that the non-mesh sidewall was a suffocation hazard. The two deaths involved play yard accessories that were reportedly very low to the ground, allowing access by older siblings.

- In IDI 210929HCC1229, a 1-month-old female was found unresponsive in a bassinet placed on the floor with her 2-year-old sibling partially resting on top of her.
- In IDI 200713HCC2638, a 5-month-old female was found unresponsive in a bassinet placed on the floor with her 15-month-old sibling asleep on top of the victim.

E. Electrical Problems

Some bassinets contain battery-operated or plug-in powered features including sounds, lights, vibrations, and motorized rocking movements. Electrical problems with bassinets can result in smoke, shock, or battery leakage. Staff identified one hospitalization, one non-ED-treated injury, and two of the 182 non-injury product-related incident reports demonstrating this hazard pattern.

F. Falls From Elevated Heights

In the 2022 Bassinet Rejection Staff Briefing Package, staff of CPSC's Division of Human Factors, Directorate for Engineering Sciences (HF staff), examined the revisions made to ASTM F2194 – 22^{£1} and expressed concern regarding the inclusion of "compact bassinets/cradles" and products with a "compact bassinet/cradle mode" within the scope of the voluntary standard. Specifically, HF staff concluded that products covered by the definition of a "compact bassinets/cradle" are significantly more likely to be placed onto a soft and/or elevated surface, such

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as a table, sofa, countertop, or bed, and that the less stringent stability requirements for compact products make them more prone to tipping over.

In the same briefing package, staff identified one fatality and three injuries related to infants falling out of compact bassinets, where the product was placed on an elevated or soft surface, such as an adult bed, countertop, and couch. Of these three incidents, one incident (IDI 200940506) involved placement on a countertop, one (IDI 201234191) involved placement on a couch, and one (IDI 210246657) involved placement on a chair. The incidents involving placement on a countertop and couch resulted in head injuries. Staff is also aware of several additional incidents in which bassinets were placed on soft/elevated surfaces resulting in one fatal incident (IDI 2101050001), when a bassinet was placed on top of an adult bed, leaning against a nearby wall. Staff is also aware of an incident (IDI 211207687) in which an infant climbed out of a bassinet placed on an adult bed and fell off the bed. Further, customer reviews of various compact bassinets indicate use in/on mattresses, sofas, tables, and countertops.

G. National Estimates from NEISS

Based on NEISS data, staff estimates 3,500 injuries (sample size=160, coefficient of variation=0.23) related to bassinets and cradles were treated in U.S. hospital emergency departments over a five-year period from 2017 through 2021. Of the 160 sample cases, four incidents were fatal. About 59 percent of the injuries involved infants 5 months of age or younger and about 89 percent involved infants 8 months or younger. Forty-one percent of the injuried infants were male, while 59 percent were female. The most commonly occurring ED-treated injuries related to bassinets and cradles were falls and interaction with other children.

- Falls (52 percent): the majority of reports did not specify the manner or cause of the fall. An additional 5 percent indicated that the infant had been dropped, and another 2 percent indicated that the infant had climbed out of the bassinet/cradle and fallen.
- Interaction with other children (24 percent): many of the reports involved siblings or other young children pulling/tipping the bassinet over, tripping on the bassinet and tipping it over, attempting to pull/lift an infant out of the bassinet, or climbing into the

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bassinet to be with the infant. These incidents are usually associated with infants falling out of the product. A few scenarios described infants sustaining contusions/lacerations from older children striking/biting them.

Sixty-nine percent of reported injuries were to the infant's head, while 9 percent were to the infant's face. Seven percent of reported injuries did not state the injury location. Injury types include internal organs (58 percent) and fractures (10 percent), among others. Regarding patient disposition, 82 percent were treated and released, 14 percent were admitted to the hospital or transferred to another hospital, and 2 percent died from their injuries.

H. Availability of Incident Data

Upon publication of this NPR in the *Federal Register*, CPSC will make available for review and comment the CPSRMS and NEISS incident reports relied upon and discussed in this NPR, to the extent allowed by applicable law, along with the associated IDIs. Upon publication of this NPR, these data will be made available on the rulemaking docket on Regulations.gov.

I. Bassinet/Cradle Recalls

From June 2012 through March 2023, the Office of Compliance and Field Operations conducted 10 recalls of bassinets, cradles, and related products as described in Table 1, including recalls of bassinets, cradles, and multi-modal products where the recall involved the bassinet mode. This summary includes recalls of Infant Sleep Products with flat sleep surfaces that must, pursuant to the ISP Rule, comply with 16 CFR part 1218, Safety Standard for Bassinets and Cradles, because such products are not subject to another mandatory safety standard for a sleep product. Not included in this recall summary are recalls of inclined infant sleep products and multi-modal products where the recall did not involve the bassinet mode, or after-market bassinet mattresses. The recalls involved products with risks of suffocation, entrapment, fall, and choking hazards and involved one reported death, two reported injuries, and 132 reported other incidents. Recalls affected approximately 396,500 units.

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Table 1 – Summary of Bassinet and Cradle Recalls

Press Release Date	Firm	Hazard	Approximate Number of Recalled Units / Product Type ³⁴	Number of Incidents (Injuries & Deaths) Reported ³⁴	Press Release Number
October 23, 2012	Dorel Juvenile Group	Suffocation	97,000 Bassinet	17 incidents (2 injuries, 0 deaths)	13-017 ³⁵
November 16, 2012	KidCo, Inc.	Suffocation and Entrapment	220,000 Baby tent	6 incidents (0 injuries, 1 death)	13-043 ³⁶
January 15, 2013	Bugaboo Americas	Fall and choking	46,300 Carriage/stroller with removable carrycot bassinet	58 incidents (0 injuries, 0 deaths)	13-092 ³⁷
March 27, 2013	Bugaboo Americas	Fall	9,200 Carriage/stroller with removable carrycot bassinet	16 incidents (0 injuries, 0 deaths)	13-153 ³⁸
November 13, 2013	Dream on Me Inc.	Fall	700 Cradle	2 incidents (0 injuries, 0 deaths)	14-019 ³⁹
March 3, 2015	Dream on Me Inc.	Fall	13,000 Bassinet	1 incident (0 injuries, 0 deaths)	15-088 ⁴⁰
September 2, 2015	Sleeping Partners International Inc.	Fall	5,500 baskets and 800 stands Hand-held infant carrier and Bassinet	0 incidents (0 injuries, 0 deaths)	15-23041
January 18, 2018	Multipro Limited	Fall and Entrapment	1,000 Cradle	0 incidents (0 injuries, 0 deaths)	18-716 ⁴²
December 5, 2019	Bexco Enterprises, D/B/A DaVinci	Fall	3,000 Bassinet	19 incidents (0 injuries, 0 deaths)	20-711 ⁴³
July 9, 2020	Bexco Enterprises, D/B/A DaVinci	Fall and Entrapment	3,000 Bassinet	13 incidents (0 injuries, 0 deaths)	20-762 ⁴⁴
Total			396,500 ⁴⁵	132 incidents (2 injuries, 1 death)	10

IV. Voluntary Standard Development

A. Description and Assessment of ASTM $F2194 - 22^{\epsilon l}$

ASTM F2194 $-22^{\epsilon 1}$ is the voluntary standard for bassinets/cradles, which includes the general requirements present in most durable infant or toddler product standards, such as restrictions related to

³⁴ When the recall press release delineates the approximate number of recalled units, number of incidents, or number of injuries by country, this summary only includes the reported United States values.

³⁵ https://www.cpsc.gov/Recalls/2013/Dorel-Juvenile-Group-Recalls-Eddie-Bauer-Rocking-Wood-Bassinets-Due-to-Infant-Suffocation-Hazard.

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lead in paint, small parts, hazardous sharp edges and points, wood parts, scissoring, shearing, or pinching, as well as performance and labeling requirements specific to bassinets/cradles, such as performance tests for static load and segmented mattresses. Compared to previous versions of the F2194 standard, ASTM F2194 – $22^{\epsilon l}$ contains revisions to the scope, terminology, performance requirements, test methods, marking and labeling requirements, and instructional literature requirements for bassinets/cradles. Many of these changes relate to the introduction of compact bassinets/cradles. Tabs A and C of the 2022 Bassinet Rejection Staff Briefing Package provide staff's full description of ASTM F2194 – $22^{\epsilon l}$ and detailed human factors and engineering assessments of the revised voluntary standard.

Based on staff's recommendation in the 2022 Bassinet Rejection Staff Briefing Package that elements of the revised standard decreased safety, the Commission voted to reject ASTM F2194 – $22^{\epsilon 1}$ and retain the existing mandatory standard in part 1218. The primary reason the Commission stated for rejecting ASTM F2194 – $22^{\epsilon 1}$ involved the addition of compact bassinets/cradles with legs shorter than six inches,⁴⁶ because caregivers are likely to place smaller and more portable compact bassinets in unsafe locations, such as elevated and soft surfaces (tables, counters, couches, and beds). CPSC's data demonstrate that infants have suffered serious head injuries and death when using small, portable products in unsafe locations. Moreover, ASTM F2194 – $22^{\epsilon 1}$ added a new stability test that applied only to compact bassinets/cradles that is less stringent than the

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³⁶ https://www.cpsc.gov/Recalls/2013/Suffocation-Entrapment-Risks-Prompt-Recall-of-PeaPod-Travel-Tents-by-KidCo.

³⁷ https://www.cpsc.gov/Recalls/2013/bugaboo-recalls-strollers-due-to-fall-and-choking-hazards.

³⁸ https://www.cpsc.gov/Recalls/2013/Bugaboo-Recalls-Cameleon3-Strollers.

³⁹ https://www.cpsc.gov/Recalls/2014/Dream-On-Me-Recalls-Cradle-Gliders.

⁴⁰ https://www.cpsc.gov/Recalls/2015/Dream-on-Me-Recalls-2-in-1-Bassinet-to-Cradle.

⁴¹ https://www.cpsc.gov/Recalls/2015/Tadpoles-Baby-and-Kids-Recalls-Moses-Basket-and-Stand.

⁴² https://www.cpsc.gov/Recalls/2018/Bassinets-Recalled-Due-to-Violation-of-Bassinet-Cradle-Standard-Made-By-Multipro-Recall-Alert.

⁴³ https://www.cpsc.gov/Recalls/2020/DaVinci-Recalls-Bassinets-Due-to-Fall-Hazard-Recall-Alert.

⁴⁴ https://www.cpsc.gov/Recalls/2020/DaVinci-Recalls-Bassinets-Due-to-Fall-and-Entrapment-Hazards-Recall-Alert.

⁴⁵ The Bexco Enterprises D/B/A DaVinci December 5, 2019 and July 9, 2020 recalls involve different hazards with the same products, and so the approximate number of recalled units are not counted twice in the total.

⁴⁶ <u>RCA-ASTMs-Notice-of-a-Revised-Voluntary-Standards-for-Bassinets-and-Cradles.pdf (cpsc.gov).</u>

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stability test for regular bassinets/cradles. The Commission determined that, taken together, these additions decrease the safety of bassinets/cradles, as well as other infant sleep products subject to the bassinet standard.

B. Voluntary Standards Development Since September 2022

The ASTM subcommittee formed the F15.18 Bassinets Elevated Surface and Data Task Group (Task Group) to work with CPSC staff to develop performance requirements to address the hazards of consumers placing bassinets/cradles on elevated and/or soft surfaces. The Task Group met three times between November 2022 and February 2023^{47, 48, 49} to develop a proposal that all bassinets/cradles must meet either one of the following requirements:

- 1. The bassinet/cradle only fully supports infants and functions when the top rail is 16 inches or greater above the external floor with a minimum internal side height of 7.5 inches.

 Examples of ways to meet this requirement include:
 - (a) Bassinet collapses/fails when removed from the stand, so that it cannot be used when removed from the stand.
 - (b) Bassinet does not have a removable stand.
 - 2. The smallest lateral dimension shall be equal to or greater than 24 inches, with a minimum internal side height of 7.5 inches.

CPSC staff assessed these proposed requirements developed by the ASTM task group, as follows:

Minimum 16-inch external side height requirement: CPSC staff assesses that a 16-inch external product side height is likely to be too low to the ground and to require the caregiver to

⁴⁷ Meeting Log for November 16, 2022 task group: https://www.cpsc.gov/s3fs-public/ASTM-F15-18-Data-and-Compact-Bassinet-TG.pdf? VersionId=iMqK1Fy3s2xLSxuhFAbBVY5FJxIQNAgo.

⁴⁸ Meeting Log for December 14, 2022 task group: https://www.cpsc.gov/s3fs-public/F15-18-Bassinets-Elevated-Surface-and-Data-Task-Group-Meeting.pdf? VersionId=4sDOc.36I7O1.pSw8OLJM7bYmGzTOoTZ.

⁴⁹ Meeting Log for February 28, 2023 task group: https://www.cpsc.gov/s3fs-public/ASTM-F15-18-Bassinet-Elevated-Hazard-Task-Group-Meeting-Log.pdf?VersionId=xi2Cs5BZSnJWSbBEnBr7jF2gaqoflYbT.

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squat or bend significantly to attend to the infant (Figure 1, first two images on the top left). For a variety of reasons, including to improve their posture while interacting with the baby, caregivers may choose to move the bassinet onto an elevated surface as shown in Figure 1, such as a countertop, dining table, coffee table, sofa, chair, or adult bed, despite this putting the infant at risk.

Figure 1 demonstrates a 16-inch-tall bassinet positioned on elevated surfaces. Even a 50th percentile female (height 64 inches⁵⁰) would have to bend over considerably to access the child on the ground and thus staff assesses that caregivers are likely to use the bassinet in combination with a raised surface. Because of this likelihood, staff assesses that the minimum height of 16 inches may not be sufficient to discourage caregivers from using the bassinet on elevated surfaces.

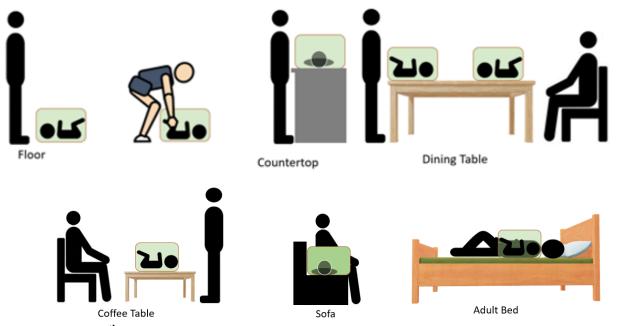


Figure 1: A 50th percentile female in relation to a 16-inch-tall bassinet on various surfaces.

Minimum 24-inch lateral dimension requirement: CPSC staff and the ASTM Bassinets Subcommittee also discussed a 24-inch lateral dimension as a means of deterring use of bassinets on soft and/or elevated surfaces. This dimension represents the upper end of typical sofa seat depth range (i.e., distance from a typical couch seat bight to edge).⁵¹ Based on its discussion with the

⁵⁰ PeopleSize Pro v 2.02, US Female 18-64.

⁵¹ The typical sofa seat depth is 21 inches to 24 inches. https://blog.roomstogo.com/what-do-i-need-to-know-about-couch-depth/#:~:text=Outside%20depth%20ranges%20from%2031,sit%20with%20an%20upright%20posture.

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ASTM Bassinets Subcommittee, CPSC staff assesses that "wide footprint" bassinets/cradles are likely to somewhat visually discourage caregivers from placing bassinets/cradles on soft/elevated surfaces. Specifically, the "wide footprint" requirement (*i.e.*, all lateral dimensions greater than 24 inches) could reduce consumers' ability and likelihood to place products onto soft and/or elevated surfaces to a limited degree, as those products will be less portable and will either no longer fit onto soft/elevated surfaces or will take up enough space that caregivers may not wish to place the product onto said surfaces.

Figure 2 shows three bassinets of varying lateral dimensions on a sofa with a seat depth of approximately 20.25 inches. Staff assesses that the two bassinets with a lateral dimension greater than or equal to 24 inches (bottom two photos) are less likely to be placed on a narrow sofa because they hang partially off of the edge of the sofa, whereas the bassinet with a smaller lateral dimension (top photo) is more likely to be placed on a sofa, as it fits entirely on the sofa. However, sofas with a larger seat depth, such as "deep-seated" sofa depths which can extend to 36 inches, can accommodate placement of a wide bassinet.⁵²

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⁵² https://www.thesofareview.com/guides/the-best-deep-seated-sofas https://blog.roomstogo.com/what-do-i-need-to-know-about-couch-depth/#:~:text=Outside%20depth%20ranges%20from%2031,sit%20with%20an%20upright%20posture.

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Figure 2: Comparison of overhang for three bassinets with different lateral dimensions on a sofa with a seat depth of approximately 20.25 inches

Note that sofa depths can range to 26 inches.

Staff also analyzed the ability to place a wide footprint bassinet on traditional mattress sizes. Staff assesses that a full size mattress, a queen size mattress, and a king size mattress can accommodate a single adult caregiver and a 24-inch-wide bassinet. For two-caregiver households, a 24-inch footprint would take up too much space to allow for two adult occupants in a full size bed. For queen size beds, the bassinet would take up a significant amount of space but would still allow for two adult occupants. For king size beds, two parents can comfortably fit a 24-inch bassinet on the bed. Overall, staff assesses that a bassinet with a 24-inch-wide footprint is still likely to be used on full, queen, and king size adult beds with one or two caregivers (Figure 3). For this reason, staff

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assesses that the 24-inch footprint does not adequately address the hazard of bassinets being used on adult beds. Additionally, based on typical countertop, dining table, and coffee table dimensions, staff assesses that the 24-inch footprint alone does not deter consumers from placing bassinets on these elevated surfaces, because a bassinet with a 24-inch-wide footprint will likely fit onto many of these surfaces, and consumers would easily be able to reach into the product to place/retrieve the infant.⁵³

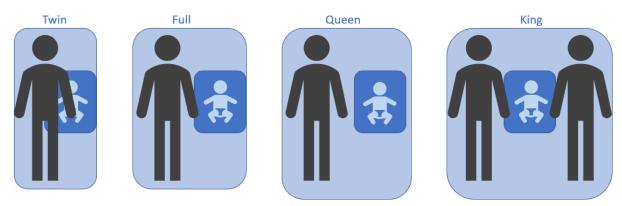


Figure 3: Scaled illustrations of a 24-inch-wide bassinet and a 50th percentile adult male (stature & shoulder breadth) on a twin (38"x75"), full (53"x75"), queen (60"x80"), and king (76"x80") size mattress.⁵⁴

V. NPR Description and Explanation

A. ASTM Approaches Not Requiring Modification

The Commission preliminarily determines that three particular aspects of the current part 1218 rule, which are not proposed for revision in ASTM F2194 – $22^{\,\epsilon l}$, remain adequate to address associated hazards and do not require modification: locking/latching mechanism (section 5.6 of ASTM F2194 – $22^{\,\epsilon l}$), product finish-related requirements (sections 5.2 and 5.4 of ASTM F2194 –

⁵³ Standard countertop depth is 25.5 inches. Dining tables are generally 36" wide at minimum. Coffee tables often exceed 24" in length and width.

⁵⁴ The 50th percentile adult male (18-64) height is 69.64 inches and shoulder breadth is 19 inches (PeopleSize, Pro v 2.02)

 $22^{\epsilon 1}$), and the static load requirement to address mattress support issues (section 7.3 of ASTM F2194 – $22^{\epsilon 1}$).

ASTM developed locking/latching requirements for bassinets/cradles to address incidents associated with collapse of the product. After reviewing the reported incidents potentially implicating these requirements, none of which included evidence of injury, staff advises that the existing requirements address the hazard of the product collapsing or folding. Therefore, the Commission preliminarily concludes that the existing performance requirements address the hazard and do not require modification.

Currently, no provisions in part 1218 address rough product surfaces. Incidents regarding product finish, such as rough mesh surfaces and labels with sharp edges (addressed in Sections 5.2 and 5.4 of ASTM F2194 – $22^{\,\epsilon l}$) were not widespread in the incident data; all but one infant in this type of reported incident received only non-medical treatment. The Commission will continue to monitor these incidents and, in particular, invites comment on how to address the rough mesh surface hazard.

Finally, the static load requirement in the existing part 1218, requiring the product to support up to three times the heaviest intended infant, adequately verifies that the bassinet/cradle sleep area is designed to hold and not break or create a hazardous condition when subject to the weight of a child. The NPR does not modify this test and proposes to apply it to all bassinets within the scope of the standard.

B. Mechanical and Electrical Hazards Addressed in the NPR

Based on incident data (described in section III of this preamble) and staff's engineering and human factors assessments, the NPR proposes revisions and additions to some of the performance and labeling requirements in ASTM F2194 – 22 ^{ɛ1} that would better address known hazards and provide the highest level of safety feasible for bassinets/cradles.

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1. Requirements to Discourage Product Use on Unsafe Surfaces

To reduce the likelihood of consumers placing bassinets/cradles onto elevated and/or soft surfaces, the NPR proposes both of the following performance requirements and test methods.

- a. The bassinet/cradle only fully supports infants and functions when the lowest portion of the top side/rail is 27 inches or greater above the product support surface (*i.e.*, floor) with a minimum internal side height of 7.5 inches. Examples that would meet this requirement include:
 - (1) Products with a removeable stand that collapses or fails when removed.
 - (2) Products that do not have a removeable stand.
- b. The occupant support surface (*i.e.*, mattress) shall be at least 15 inches from the product support surface (*i.e.*, floor).

As shown in Figure 4, with these modifications caregivers can comfortably reach and attend to the infant in a 27-inch-tall bassinet located on the floor and will not need to elevate the bassinet. In fact, elevating a 27-inch-tall bassinet into a hazardous position makes it more difficult and inconvenient to reach the baby. Figure 4 demonstrates a 50th percentile female in relation to a bassinet with the proposed requirements on various elevated surfaces. These elevated surfaces are unlikely to be utilized due to caregivers' difficulty to reach the baby compared to their reach when the bassinet is located on the floor (Figure 4, first two images on the top left).

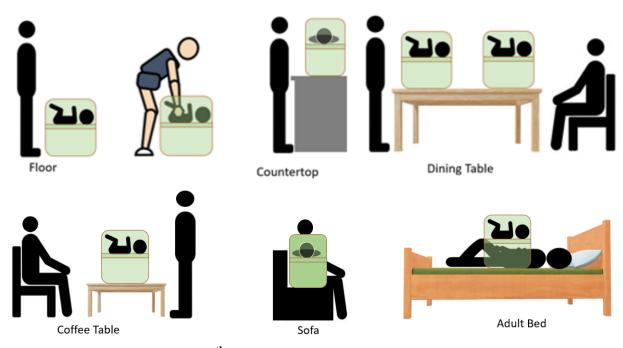


Figure 4: A 50th percentile female in relation to a bassinet with the proposed requirements on various surfaces.

While caregivers can easily reach into a 27-inch-tall bassinet when it is on the floor, they may have difficulty reaching their infant if the mattress is positioned too low to the ground (Figure 5); therefore, the combination of the two proposed dimensions would improve the safety of the bassinet by discouraging its use on elevated surfaces while making it more comfortable and convenient to use on the floor.

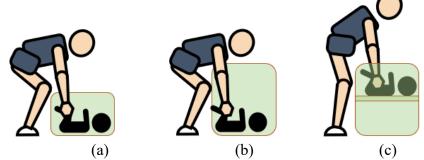


Figure 5: A 50th percentile female's reach to an infant positioned (a) 16-inch bassinet on the floor, (b) 27-inch bassinet on the floor, (c) 27-inch bassinet on the floor with a sleep surface 15-inch off the floor.

In the 2022 Bassinet Rejection Staff Briefing Package, staff expressed concern about ASTM's removal from the voluntary standard of the requirement for a bassinet to have a stand or

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base and the Commission rejected the revised standard that included "compact bassinets." The requirements proposed in this NPR address CPSC's concerns regarding bedsharing and unsafe placement by requiring specific occupant sleep surface and side rail height requirements, while still subjecting products to the same stability requirements as bassinets with a traditional stand.

CPSC staff reviewed a variety of products (see Figure 6 for two examples) and determined that some products available to consumers already meet the 27-inch top rail height and 15-inch mattress height requirement. Therefore, implementation of this NPR requirement is feasible.

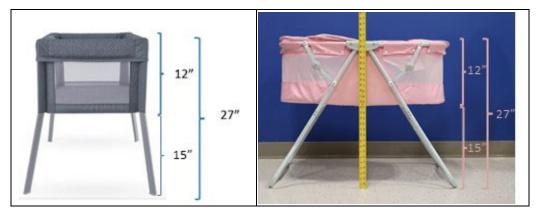


Figure 6. Example of bassinets that meet the proposed requirements

Regarding hazards associated with other children attempting to climb into the bassinet, staff advises that given children's propensity for climbing (*see* Staff Briefing Package for Clothing Storage Units⁵⁵), a 27-inch side height is unlikely to dissuade children from attempting to climb into the product. However, setting a minimum side height taller than 27 inches would likely result in products being significantly less stable in the event of a child climbing them, and would not prevent

 $[\]frac{\text{55 https://www.cpsc.gov/s3fs-public/Final-Rule-Safety-Standrd-for-Clothing-Storage-}{\text{Units.pdf?VersionId} = X2prG3G0cqqqgUwZh3rk01mkmFB40Gjf}$

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children from climbing. 56,57,58,59,60 Incidents demonstrate toddlers' ability to climb on raised surfaces including cribs, showing that increasing the bassinet exterior side height to more than 27 inches would not effectively address sibling's access to the product.

Caregivers depend on infant sleep products to be safe places in which to leave an infant for sleep; accordingly, these products must be safe for infant sleep as sold. While these modifications, as written, would not necessarily require bassinets/cradles to have a stand, they would ensure that bassinets and cradles, including small portable products, areu raised off the ground to discourage caregivers from placing them on elevated and soft surfaces such as beds and couches. The proposed requirements would thus work toward achieving the highest level of safety feasible for sleeping infants left to sleep unattended while in the product.

2. Requirements for Sidewall Rigidity

The current mandatory rule in part 1218 does not have a sidewall rigidity requirement. Many bassinets/cradles on the market have sidewalls constructed of fabric, foam, fiberfill, mesh, or cardboard, which can deflect downward, inward, and/or outward when subjected to a load. CPSC is concerned that bassinets with non-rigid sidewalls may permanently deform or collapse and not

⁵⁶ The incident data reported in section III of this preamble contains two climbing-associated deaths: an older sibling (15 months and two years old) climbed into the bassinet and laid on top of the infant inside, suffocating them. Older 1-year-olds are known to be capable of climbing on and off furniture without assistance.⁵⁷ Gross motor play and the use of climbers are dominant, starting at about 1-½ years of age.⁵⁸ Two-year-old children especially enjoy climbing, and can climb steps, short ladders, and jungle gyms.^{59,60} Moreover, incident data reported to CPSC include numerous cases involving children climbing on furniture as well as cribs. For example, in an incident reported through NEISS (IDI 210108288), a two-year-old male climbed up on a nightstand and was climbing into baby crib. In another NEISS incident (IDI 200740286), a 22-month-old female climbed into her brother's crib. In another NEISS incident (IDI 200130999), the two-year-old girl climbed into a portable play yard or crib and bit her 15-month-old sister. In a fatal incident (IDI X19C0292A), a one-year-old male was put down for a nap in a room with his toddler brother. The toddler climbed into the crib with him with a pillow and a blanket.

⁵⁷ Therrell, J.A., Brown, P., Sutterby, J.A., Thornton, C.D., (2002). Age Determination Guidelines: Relating Children's Ages to Toy Characteristics and Play Behavior. T. P. Smith (Ed.), Bethesda, MD: U.S. Consumer Product Safety Commission.

⁵⁸ Frost, J.L., Wortham, S., & Reifel, S. (2001). Play and Child Development. Upper Saddle River, NJ: Prentice-Hall.

⁵⁹ Therrell, Brown, Sutterby, & Thornton, 2002.

⁶⁰ Hughes, F.P. (1991). *Children, Play, and Development*. Boston: Allyn & Bacon.

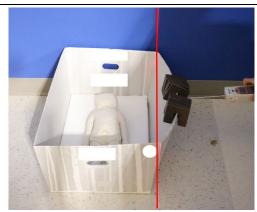
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contain the infant if an external force is applied to the sidewall, such as when a sibling pulls on the sidewall of an occupied bassinet.

CPSC engineering staff considered whether the existing bassinet stability test, which simulates a 2-year-old pulling on the bassinet sidewall, could also be used to test adequate sidewall rigidity to contain an infant. To test this concept, staff conducted the stability test in ASTM F2194 – 13 on three non-rigid sided bassinets as shown in Figures 7-9.⁶¹ Staff applied a 23-pound downward force and a five-pound outward force on the bassinets as specified in the stability test. The cardboard box bassinets bowed outward 3-5 inches (Figure 7b, 8b) during stability testing. The soft sided compact bassinet was not able to support the 23-pound load and collapsed more than 8 inches outward (Figure 9b). These tests demonstrate that bassinets with non-rigid sidewalls may permanently deform or collapse and not contain the infant if an external force is applied to the sidewall of an occupied bassinet, for instance by a sibling pulling on it.



Figure 7a. Cardboard compact bassinet unloaded



Deflection ~ 5 inches

Figure 7b. Cardboard compact bassinet with 23 lb. downward load and 5 lb. horizontal force

⁶¹ The laser line used to determine deflection is enhanced for visibility.



Figure 8a. Cardboard compact bassinet unloaded



Deflection ~ 3 inches

Figure 8b. Cardboard compact bassinet with 23 lb. downward load and 5 lb. horizontal force

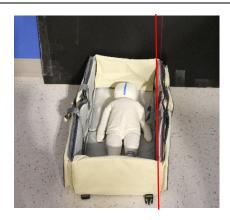
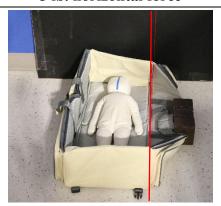


Figure 9a. Soft sided compact bassinet unloaded



Deflection > 8 inches

Figure 9b. Soft sided compact bassinet with 23 lb. on the sidewall.

Staff next conducted this same stability test on rigid-sided bassinets, which did not deflect or deform during testing. Staff advises that 0.5 inch of deflection in any direction during the stability test allows for reasonable movement of rigid sidewalls to account for minor movements in fasteners in the construction of the product. Based on this testing, the NPR proposes two requirements. First, unlike ASTM F2194 – 22 ^{ɛ1}, the NPR proposes to subject all bassinets/cradles to the stability requirement. Second, the NPR proposes that during this stability test, sidewall deflection can also be measured, requiring that the sidewall shall not deflect in any direction more

 $^{^{62}}$ As explained in section I of this preamble, the ASTM F2194 - 22 $^{\epsilon 1}$ that the Commission has rejected created a new category of "compact bassinets" and subjected this category to a new, less stringent, stability test.

than 0.5 inches. These proposed modifications ensure bassinet/cradle stability and containment of the infant.

3. Requirements for Mattresses and Mattress Supports

a. Requirements for Sleep Surface Deflection/Firmness

The NPR proposes mattress firmness requirements consistent with the mandatory crib mattress requirements in 16 CFR part 1241 to address incidents of infant's face/head conforming to the sleep surface. The mandatory crib mattress rule requires a firmness test intended to prevent the hazard of positional asphyxia involving infants suffocating when face down in a soft mattress that can conform to an infant's face. The firmness test involves placing a test fixture, as shown below in Figure 10, level on the sleep surface of the mattress. The mattress must be sufficiently firm and flat to support the weight of the test fixture (approximately 11.5 lb.) so that the feeler arm does not make any contact with the surface of the mattress.

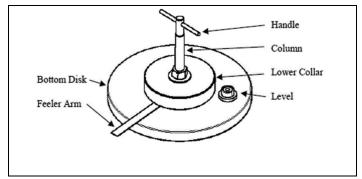


Figure 10. Mattress Firmness Test Fixture.

Disc diameter = 203+/-1mm, thickness = 15+/-0.2 mm.

Total weight of test fixture = 5200+/-20 g.

Staff tested two samples using the mattress firmness test fixture. Figure 11 shows the mattress firmness test fixture feeler arm touching the surface of the mattress, indicating that the mattress is too soft and fails the draft firmness requirement. Test results showed that some products failed the firmness test (feeler arm contacting the surface of the mattress) because the mattress was too soft (Figure 11).

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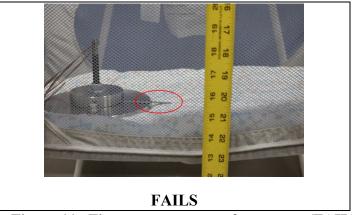


Figure 11. Firmness test on a soft mattress (FAIL)

Accordingly, to verify that the bassinet sleep surface (mattress and/or support) is not too soft and does not form a concavity that can pose a positional asphyxia hazard to infants, the NPR proposes to include in part 1218 the same mattress firmness test as is found in the crib mattress rule.

b. Requirements for Structural Integrity of Bassinet Mattresses and Mattress Supports

Part 1218 currently specifies a static load requirement for the sleep enclosure of the product. Section 6.3 of ASTM F2194 – 13, Static Load, specifies that the product shall support the static load without causing any hazardous conditions as identified within Section 5 (General Requirements). The static load test (Section 7.3) consists of placing a 54-pound load or three times the manufacturer's recommended weight (whichever is greater) within 5 seconds on an aluminum block and maintain for 60 seconds. For play yard bassinets, the test is conducted in all four corners of the product.

The static load test verifies that the bassinet/cradle sleep area is designed to hold and not break or create a hazardous condition upon the weight of a child by requiring the product to support up to three times the heaviest intended occupant (95th percentile 5-month-old male (19.8 lb.)). Although staff advises that the static load requirement is adequate to address some of the mattress and/or support issues, the mattress firmness test (discussed in section V.B of this preamble) is an

added verification of the flatness of the sleep surface (mattress and/or support), to further address these mattress/supports issues.

c. Requirements for After-Market Mattresses for Bassinets/Cradles

The crib mattress rule (part 1241) includes performance requirements for after-market mattresses but does not specifically identify bassinet/cradle mattresses as being included in the regulation. Instead, part 1218 establishes requirements for mattresses sold with bassinets/cradles (generally known as OEM mattresses.) CPSC is aware, however, of incidents that have arisen from consumer use of ill-fitting after-market mattresses. Based on the prominent availability and use of after-market bassinet/cradle mattresses, and the use of bassinets/cradles for infant sleep, the NPR proposes performance requirements for after-market bassinet mattresses to ensure the same level of safety as OEM bassinet/cradles mattresses and after-market mattresses for other infant sleep products.

Crib mattresses and bassinet/cradle mattresses, including after-market bassinet/cradle mattresses, share common hazard patterns associated with poorly fitting and overly soft mattresses. The mandatory crib mattress rule in part 1241 addresses similar hazards found in after-market play yard mattresses and non-full-size crib mattresses. Part 1241 requires such mattresses to meet the same performance requirements as the OEM mattress sold with the product, when tested with the product for which the after-market mattress is intended. In particular, these mattresses must have a minimum level of firmness (section V.B.3 of this preamble). Part 1241 already requires after-market mattresses intended for use in the bassinet attachment of a play yard to meet the provisions in the existing bassinet rule, part 1218, when tested with each bassinet/cradle brand and model in which the mattress is intended to be used. 16 CFR 1241.2(b)(5)(iv). Additionally, the crib mattress rule requires that after-market mattresses must be at least the same size as the OEM mattress or larger and must lay flat, must include a floor support structure that is at least as thick as the OEM

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mattress, and must include equivalent storage accommodations (such as a pouch for the product instruction manual). 16 CFR 1241.2(b)(4).

To reduce the risk of injury caused by poorly fitting and overly soft mattresses associated with after-market mattresses for bassinets/cradles, the NPR proposes to adopt the after-market requirements from the crib mattress rule into the bassinet/cradle mandatory standard.

4. Requirements for Bassinet Sleep Surface Angles

Minimum safe sleep requirements for young infants, particularly those 5 months old and younger, require that infants be placed to sleep on their backs on a firm, flat, sleep surface. As described in section III of the preamble, this avoids the hazard created by bassinets that are non-level—for example leaning forward or to one side, or with legs or sides with uneven heights—which could cause the infants to roll to the side, often into the mesh/siding of the bassinet/cradle before the infant is developmentally capable of rolling.

a. Requirement for Head-To-Toe Incline Angle

The definition of bassinet in part 1218 (based on ASTM F2194 – 13) states that "[w]hile in a rest (non-rocking or swinging) position, a bassinet/cradle is intended to have a sleep surface less than or equal to 10° from horizontal." 16 CFR 1218.2(b)(1)(i) citing section 1.3 of ASTM F2194-13. The angle limitation in the definition is intended to ensure that the bassinet provides a safe, flat sleep surface. However, neither ASTM F2194 – 13 nor the revised ASTM F2194 – 22 ^{ε1} contain a test to measure the sleep surface incline to ensure that the sleep surface does not exceed 10 degrees from horizontal. The Commission's ISP Rule in part 1236 contains a test to measure the head-to-toe sleep surface angle. This test consists of placing a Hinged Weight Gauge–Infant (17.5 lb.) on the product and measuring the lengthwise incline angle along the upper torso/head area. This 10-degree head-to-toe safe sleep angle is supported in a report by Erin M. Mannen, Ph.D., the

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Biomechanical Analysis of Inclined Sleep Products – Final Report September 18, 2019.⁶³ Dr. Mannen's testing showed that angles greater than 20 degrees present a hazard that infants may move into a compromising position in the product from which they cannot self-rescue. Based on the results of Dr. Mannen's biomechanical study, "fewer differences in muscle activity or lying posture were revealed at a 10-degree mattress incline compared to the zero-incline surface. Ten degrees is likely a safe incline for sleep on a crib mattress type of surface." The NPR proposes to remove the head-to-toe sleep surface angle statement from the definition of a bassinet, and instead to add a performance and test requirement for the 10-degree head-to-toe sleep surface angle limit, using the same incline test from the ISP Rule. This is an improvement to safety because it will ensure consistent and repeatable testing across test labs for all bassinets/cradles.

b. Side-to-Side Tilt Angle

Part 1218 specifies a side-to-side tilt angle of no more than 7 degrees for rocking bassinets/cradles when they are at rest (section 6.9.2 of ASTM F2194-13), but does not specify side-to-side tilt requirements for bassinets/cradles without a rocking function. On December 7, 2021, CPSC staff sent a letter⁶⁴ to the ASTM subcommittee chair for bassinets/cradles regarding four fatal incidents (occurring from 2019 through 2021) involving bassinets with a cantilever design in which infants reportedly rolled into the side of the bassinet, or into a prone position. The cantilever design supports the bassinet by a leg/frame on one side of the product so that the suspended side without a support can be positioned over an adult bed. In the December 7, 2021 letter, CPSC staff stated concern with the then-current ASTM F2194 – 16^{£1} allowance of a side-to-

⁶³ The 10 degree incline angle requirement in the Infant Sleep Product Final Rule, available at: https://www.cpsc.gov/s3fs-public/Final-Rule-Safety-Standard-for-Infant-Sleep-Products.pdf, is based on findings in the 2019, Biomechanical Analysis of Inclined Sleep Products – Final Report 09.18.2019 by Erin M Mannen Ph.D., available at: https://www.cpsc.gov/s3fs-public/Dr-Mannen-Study-FINAL-Report-09-18-2019 Redacted.corrected 0.pdf?g.Jao0IN zU.TjiX4FeSUM3SPc3Zt 25.

⁶⁴ Staff letter to Mr. Lewis, chair of ASTM F15.18 on Bassinets and Cradles, dated December 7, 2021. https://www.cpsc.gov/s3fs-public/BassinetwcantileverltrAttachedSpreadsheet-120821.pdf?VersionId=fyFz2 Ac9HFDyp0yWa83WphujK.KJHEVS.

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side 7-degree maximum tilt angle, because minimum safe sleep guidance requires infants be placed to sleep on a firm, flat surface.⁶⁵

However, on February 14, 2023, ASTM proposed side-to-side tilt requirements in the voluntary standard for non-rocking bassinets/cradles stating that the bassinet sleep surface shall not exceed a side-to-side tilt angle of 7 degrees. This angle limit is based on the existing rocking bassinet/cradle rest angle requirement in section 6.9.2 of ASTM F2194 – 13. The test consists of two parts: simulating a five-month-old infant located against each side of the sleep surface, and then simulating a low weight newborn infant located against each side and the center of the sleep surface. The current side-to-side tilt angle for at rest rocking bassinets/cradles cannot exceed 7 degrees in either test. Based on this, ASTM's proposed modified test requirements for non-rocking bassinets/cradles provides the following:

- (i) <u>Five-month-old infant</u>. The Hinged Weight Gauge-Infant (17.4 lb.) is placed parallel to and contacting one of the lateral sidewalls of the bassinet/cradle, equidistant between both head and toe ends of the sleep surface. The side-to-side angle is measured on top of the Hinged Weight Gauge-Infant. The angle measurement is taken three times and then averaged. The test then is repeated on the other side of the sleep surface.
- (ii) Newborn infant. A 6 by 4 by 0.5-inch nominal thickness steel block weighing 3.3 lb. is placed parallel to and contacting one of the lateral sidewalls of the bassinet/cradle, equidistant between both head and toe ends of the sleep surface. The side-to-side angle is measured on top of the steel block. The angle measurement is taken three times and then averaged. The test then is repeated on the other side and in the geometrical center of the sleep surface.

⁶⁵ After staff's further review of bassinet-related data, the tilt hazard pattern is evidenced in the 2 deaths, 3 injuries, and 95 non-injury incidents summarized in section III of this preamble.

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CPSC staff has assessed ASTM's proposal. Based on incident data, cantilevered designed bassinets that have 7 degree or less side-to-side tilt angle⁶⁶ can still facilitate infants rolling before they are developmentally capable of rolling and present the potential for a suffocation hazard. CPSC staff conducted testing on 10 products with cantilevered designs (see Table 2 below), using the NPR proposed test. Four products, A, B, D, H, were associated with incidents that involved the infant rolling over into a compromising position. Fortunately, the caregiver was able to intervene in these cases before suffocation ensued. However, in one case, Product B, involved a fatality incident (IDI 200211HCC3248). Product H had the largest tilt angle (7.1 degrees) and product D had the smallest tilt angle (1.2 degrees) of models associated with incidents.

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⁶⁶ CPSC proposes that bassinets/cradles have two different tilt angle requirements for head-to-toe and side-to-side, based on how the suffocation hazard manifests. The hazard associated with a head-to-toe tilt greater than 10 degrees occurs when an infant unexpectedly rolls (either side-to-side or into a chin-to-chest position) and the infant cannot self-rescue when on an incline and can suffocate. However, when a bassinet/cradle has a side-to-side tilt, even if the tilt is less than 7 degrees, incident data and sample analysis suggest that this tilt can facilitate rolling before an infant is developmentally capable of rolling and cannot self-rescue. A suffocation hazard presents when the infant's nose and mouth become occluded in the side or mattress.

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Table 2 Bassinet Tilt Testing Results

Product ID	Height Setting (Note 1)	Max Side-to-Side Tilt Angle [degrees]		
	Lowest (mattress upper position)	5.6		
A	Highest (mattress upper position)	6.3		
(Note 2)	Lowest (mattress lower position)	6.1		
	Highest (mattress lower position)	5.7		
В	Lowest	3.3		
В	Highest	1.8		
C	Lowest	3.9		
	Highest	4.4		
D	Lowest	1.8		
D	Highest	1.2		
Г	Lowest	2.2		
E	Highest	2.5		
Г	Lowest	3.9		
F	Highest	3.5		
G	Lowest	2.7		
G	Highest	2.7		
	Lowest	6.0		
Н	Highest	7.1		
т	Lowest	1.4		
I	Highest	1.0		
	Lowest	2.5		
J	Highest	3.0		

Notes:

- (1) All products had several height settings. Staff tested each sample on the highest and lowest height setting.
- (2) Product A has several height settings as well as two mattress positioning settings. Staff tested on the highest and lowest height setting for each of the two mattress positioning settings.

Based on review of incidents and testing, staff determined that the current ASTM side-to-side tilt restriction of 7 degrees does not adequately address the rolling and suffocation hazard. Staff testing showed that cantilevered bassinets with tilt angles of 1.2 - 7.1 degrees were associated with rollover incidents. Accordingly, to address the potential for infants to roll into unsafe sleep positions and to provide the highest level of safety that is feasible, the NPR proposes to add the

side-to-side tilt angle test requirements from ASTM's February 14, 2023, proposal, with two modifications: (1) decrease the allowed tilt angle to 0 +/-1 degree, which means a maximum angle not to exceed one degree from horizontal, and (2) apply this requirement to both rocking bassinets at rest and non-rocking bassinets. The NPR also proposes that for bassinets with adjustable heights, the side-to-side tilt test be performed on both the highest and lowest height settings. The Commission requests comment on a side-to-side tilt angle limit (including the proposed 0-degree angle) and an appropriate manufacturing tolerance (including the proposed 1-degree maximum variation) that is as consistently close to flat as is feasible.

5. Requirements for Electrical Systems

Section III of the preamble describes hazards associated with electrical systems, including smoke, shock, and battery leakage. While part 1218 does not address electrical hazards, other Commission rules for durable infant or toddler products, such as the infant swings rule, 16 CFR part 1223, incorporating ASTM F2088-22, *Standard Consumer Safety Specification for Infant and Cradle Swings*, include adequate requirements to address electrical hazards, such as the conditions that can lead to battery leakage. To address bassinet/cradle incidents associated with defective electrical systems, the NPR proposes to include the battery compartment requirements from part 1223 in part 1218.

6. Requirements for Multi-Use Products

Regarding multi-use products, section 5.14 of ASTM F2194 – 22^{£1} states that if "converted into another product for which a consumer safety specification exits, the product shall comply with the applicable requirements of that standard when in that use mode." Because the Commission's mandatory standard and ASTM's "consumer safety specifications" can diverge and are not always the same, the NPR proposes that multi-use products comply with the applicable mandatory CPSC consumer product safety standard when in each use mode, rather than the applicable voluntary standard. This modification clarifies CPSC's expectation and creates certainty for test labs.

C. Revised Requirements for Marking, Warning, Labeling, and Instructional Literature

Tab A of Staff's 2022 Bassinet Rejection Staff Briefing Package provides a detailed description of the marking and warning requirements in ASTM F2194 – 22^{£1} and an analysis of whether the revised labeling requirements improve the safety of bassinets and cradles. Modifications in ASTM F2194 – 22^{£1} include additional language or changes addressing battery-related hazards, product warnings, compact bassinets and compact bassinets made of cardboard, and the warning language currently incorporated by reference in part 1218.

After considering literature, incident data, and consumer feedback, the Commission preliminarily finds that the marking, warning, labeling, and instructional literature requirements specified in ASTM F2194 – $22^{\,\epsilon l}$ are largely adequate but require several modifications to provide the highest level of safety feasible.

Battery Compartment Warnings – ASTM revised section 8 of ASTM F2194 – $22^{\epsilon l}$ to include specific marking requirements for battery-operated products (Section 8.4 – Battery-Operated Product Marking). The ASTM standard now requires that, for battery-operated products, the product's battery compartment, battery compartment door/cover, or area immediately adjacent to the battery compartment must be marked or labeled permanently and legibly to show the correct battery polarity, size, and voltage. ASTM F2194 – $22^{\epsilon l}$ exempts products using one or more non-replaceable batteries, except when they are accessible with the use of a coin, screwdriver, or other common household tool, in which case they must be marked or labeled permanently and legibly with a statement that the batteries are not replaceable. If marking or labeling the product is not practicable, then this statement shall be included in the instructions. The bassinet subcommittee

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adopted these marking/labeling requirements from ASTM's Ad Hoc Language Task Group⁶⁷ and the requirements are consistent with other juvenile product standards.

Staff advises that these requirements are adequate and necessary to address hazards associated with battery-operated products that are not currently addressed in part 1218. Accordingly, the NPR proposes to incorporate Section 8.4 of ASTM F2194 – $22^{\epsilon 1}$ without modification.

Alignment with Ad Hoc Warnings – Section 8 of ASTM F2194 – $22^{\epsilon 1}$ also contains multiple revisions intended to align with current recommendations from ASTM's Ad Hoc Language Task Group. ASTM F2194 – $22^{\epsilon 1}$ now specifies that warnings shall be in English at minimum, states that any additional markings or labels shall not contradict or confuse the required information or mislead the consumer, and sets formatting requirements for warnings (*e.g.*, font size, text alignment, safety alert symbol, bullet points for cautionary statements).

Per Ad Hoc Recommendations, the standard uses ANSI Z535.4-2011, *Product Safety Signs and Labels*, as a reference for its warning formatting requirements. ANSI Z535.4 is the primary United States voluntary consensus standard for product safety signs and labels. For example, CPSC staff consistently uses this standard when developing or assessing the adequacy of warning labels. Literature on the design and evaluation of on-product warnings frequently cites ANSI Z535.4 as the minimum set of requirements governing products sold in the United States containing such labels, and human factors experts generally consider the ANSI Z535 series of requirements the benchmark and state of the art standards against which warning labels should be evaluated for adequacy. The NPR proposes to adopt all warnings that align with ANSI Z535.4 formatting requirements.

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⁶⁷ ASTM Ad Hoc Language Task Group (Ad Hoc TG) consists of members of various durable nursery product voluntary standards committees, including CPSC staff. The Ad Hoc TG's purpose is to harmonize the wording of common sections (e.g., introduction, scope, protective components) and warning label requirements across durable infant and toddler product voluntary standards.

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Suffocation Hazard Warnings – Section 8 of ASTM F2194 – $22^{\epsilon 1}$ also contains multiple revisions to the warning statements incorporated in part 1218, specifically to the language for suffocation hazards. ASTM F2194 – $22^{\epsilon 1}$ specifies that the statement "Failure to follow these warnings and the instructions could result in death or serious injury" shall be the first warning to appear in a message panel, followed immediately by a suffocation hazard warning addressing the following:

SUFFOCATION HAZARD

Babies have suffocated:

- on pillows, comforters, and extra padding
- in gaps between a wrong-size mattress, or extra padding and product sides
- **NEVER** add soft bedding or padding.
- Use **ONLY** mattress provided by manufacturer.

ASTM F2194 – $22^{\epsilon 1}$ also requires that warnings address the following statement:

Always place baby on back to sleep to reduce the risk of SIDS and suffocation.

ASTM F2194 – $22^{\epsilon 1}$ requires compact bassinets to address the following:

Product can roll over on soft surfaces and suffocate child. NEVER place product on beds, sofas or other soft surfaces.

The Commission rejected the inclusion of compact bassinets into the mandatory standard for bassinets and cradles in 2022. However, staff advises that this warning language addresses hazards associated with all bassinets/cradles and recommends that this language be required for all products within the scope of the standard. Accordingly, the NPR proposes to require this warning for all bassinets/cradles within the scope of the rule.

Fall Hazard Warnings – ASTM F2194 – 22^{ɛ1} does not change the existing warning language related to fall hazards. However, in the voluntary standard, fall hazard statements are now required to appear after the suffocation hazard warning statements. Additionally, the warning language, "FALL HAZARD," required for products where the bassinet bed is removeable from the base/stand without the use of tools and contains a lock/latch mechanism that secures the bassinet bed to the base/stand, is no longer required, as the message is instead required to be located in the

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fall hazard section of the warning, making the inclusion of a second "FALL HAZARD" statement redundant. However, ASTM F2194 – $22^{\epsilon l}$ requires that compact products address the following statements in the "FALL HAZARD" section:

- (1) Always use product on the floor. Never use on an unintended elevated surface.
- (2) Do not carry baby in the [manufacturer to insert type of product]. [Exception: A product that is intended to carry a baby is exempt from this requirement].
- (3) Compact bassinet/cradles constructed of cardboard shall also address: Do not reuse [manufacturer to insert type of product] for second child.

Like the suffocation warnings for compact bassinets, staff advises that these fall hazard warnings will address fall hazards that are associated with all bassinets/cradles, not just compact bassinets. Accordingly, the NPR proposes that these fall hazard warnings be required for all products within the scope of the standard with two modifications. Specifically, the NPR proposes that the phrase "an unintended elevated surface" in warnings statement (1) be changed to "any elevated surface," as any elevated surface presents a potential fall hazard. Additionally, for warning statement (3), the NPR proposes that the reference to "compact" bassinets be removed consistent with the Commission's rejection of this product category.

The fall hazard warning language in ASTM F2194 – $22^{\epsilon 1}$ also contains requirements for products where the bassinet bed uses a lock/latch mechanism to secure the bassinet bed to the base/stand, so that the bassinet bed is removable without the use of tools. ASTM F2194 – $22^{\epsilon 1}$ requires the following warning language for these products:

Always check that the bassinet is securely locked on the base/stand by pulling upwards on the bassinet bed.

Lastly, ASTM added three example warnings to the standard: one for bassinet/cradle products, one for compact bassinet/cradles, and one for compact bassinet/cradles made of cardboard. Shown below is an example warning that complies with part 1218 (Figure 12), as well as the example warnings shown in ASTM F2194 – 22^{ε1} (Figures 13-14). While the warnings shown in Figure 14 are intended for compact products, and the NPR proposes to remove references to

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"compact" bassinets from the mandatory standard, the text included in the warnings meets proposed NPR requirements and does not make a specific reference to "compact" bassinets, other than the title of the figures. The warnings in Figure 14 contain a statement warning against use on "unintended" elevated surfaces. Fall hazards, however, can occur with non-compact products and on *any* elevated surface. Additionally, the warning in Figure 13, which is intended for "standard' bassinets/cradles, does not contain language warning consumers against using the product on soft or hard elevated surfaces or carrying infants in the product. Therefore, this NPR proposes that the warning shown in Figure 13 (Fig. 29 in ASTM F2194 – 22^{E1}) be removed, and that the warnings shown in Figure 14 (Fig. 30-31 in ASTM F2194 – 22^{E1}) be renumbered and renamed to remove the reference to "compact" products and revised so that the statement warning against use on "an unintended elevated surface" instead warns against use on "any elevated surface."

A WARNING:

WARNING: Do not use this bassinet if you cannot exactly follow the accompanying instructions. Failure to follow these warnings and the instructions could result in serious injury or death.

FALL HAZARD: To help prevent falls, DO NOT use this product when the infant begins to push up on hands and knees or has reached manufacturer's recommended maximum weight of 15lbs. (6.8kg), whichever comes first.

SUFFOCATION HAZARD INFANTS HAVE SUFFOCATED:

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

Use only the pad provided by

manufacturer that is no thicker than 1 1/2" (3.5 cm) and is of such a size that, when pushed against any side of the product, it does not leave a gap of more than 1 1/4" (3 cm) between then mattress and sides.

NEVER add a pillow, comforter, or another matress for padding.

If a sheet is used with the pad, use only the one provided by the bassinet or cradle manufacturer or one specifically designed to fit the dimension of the bassinet mattress.

To reduce the risk of SIDS, pediatricians recommend healthy infants be placed on their backs to sleep, unless otherwise advised by your physician.

Do not leave child unattended in the bassinet when it is in the "rocking" mode. Always make sure the wheels or stands are in the locked "down" position.

Always attach all provided fasteners tightly according to the instructions. Check frequently. Do not use if there are any loose or missing parts or signs of damage. Do not substitute parts, Contact the manufacturer for replacement parts.

Toys are not to be "mouthed" by the baby and should be positioned clearly out of reach of the baby's face and mouth.

Do not place cords, straps or similar items that could become wound around the child's neck in or near this product and do not place product near a window or patio door.

When used as a changing table:

FALL HAZARD: To prevent death or serious injury, always keep child within arm's reach.

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Figure 12: Example of a warning label compliant with part 1218

WARNING

Failure to follow these warnings and the instructions could result in death

SUFFOCATION HAZARD **Babies have suffocated:**

- On pillows, comforters and extra padding.
- In gaps between a wrong size mattress, or extra padding and product sides.
- **NEVER** add soft bedding or padding.
- Use **ONLY** mattress provided by manufacturer.
- Always place baby on back to sleep to reduce the risk of SIDS and
- If a sheet is used with the pad, use only the one provided by the product manufacturer or one specifically designed to fit the dimension of the product mattress.

FALL HAZARD: To help prevent falls,

• Do not use this product when the infant begins to push up on hands and knees or has reached [Insert manufacturer's recommended weight], whichever

Figure 13: ASTM F2194 – $22^{\epsilon 1}$ warning label for Bassinets/Cradles*68

WARNING

Failure to follow these warnings and the instructions could result in death

SUFFOCATION HAZARD Babies have suffocated:

- On pillows, comforters and extra padding.
- In gaps between a wrong size mattress, or extra padding and product sides.
- NEVER add soft bedding or padding.
- Use **ONLY** mattress provided by manufacturer.
- Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- If a sheet is used with the pad, use only the one provided by the product manufacturer or one specifically designed to fit the dimension of the product mattress.
- Product can roll over on soft surfaces and suffocate child. NEVER place product on beds, sofas or other soft surfaces.

- FALL HAZARD: To help prevent falls,

 Do not use this product when the infant begins to push up on hands and knees or has reached [Insert manufacturer's recommended weight], whichever
- Always use product on the floor. Never use on an unintended elevated surface. Do not carry baby in the [Manufacturer to insert type of product].

WARNING

Failure to follow these warnings and the instructions could result in death or serious injury

FFOCATION HAZARD Babies have suffocated:

- On pillows, comforters and extra padding.
- In gaps between a wrong size mattress, or extra padding and product sides.
- NEVER add soft bedding or padding.
- Use ONLY mattress provided by manufacturer.
- Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- If a sheet is used with the pad, use only the one provided by the product manufacturer or one specifically designed to fit the dimension of the product mattress.
- Product can roll over on soft surfaces and suffocate child. NEVER place product on beds, sofas or other soft surfaces.

- FALL HAZARD: To help prevent falls,

 Do not use this product when the infant begins to push up on hands and knees or has reached [Insert manufacturer's recommended weight], whichever
- Always use product on the floor. Never use on an unintended elevated surface.
- Do not carry baby in the [Manufacturer to insert type of product].
- Do not reuse [Manufacturer to insert type of product] for second child.

Figure 14: ASTM F2194 – 22^{£1} warning label for Compact Bassinets/Cradles* (left) and ASTM F2194 – 22^{E1} warning label for Cardboard Compact Bassinets/Cradles* (right)

⁶⁸ All figures with "*" denotation are reprinted, with permission, from ASTM F2194 – 22e1 Standard Consumer Safety Specification for Bassinets and Cradles, copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428. A copy of the complete standard may be obtained from ASTM International, www.astm.org.

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After-Market Bassinet/Cradle Mattresses Warnings – Included in this final rule are warning requirements for after-market mattresses. As discussed above in section V.B.3.c of this preamble, the safety standard for crib mattresses (part 1241) includes performance requirements for after-market mattresses but does not specifically identify bassinet/cradle mattresses as being included in the regulation. However, given the existence of after-market bassinet/cradle mattresses, as well as the similar manners of sleep use between bassinets/cradles, cribs, and play yards, staff advises that similar warning requirements for after-market bassinet/cradle mattresses are appropriate and necessary. Accordingly, the NPR proposes that the warning shown in Figure 15, which is identical to the warning used in part 1241 for after-market mattresses, be required for after-market bassinet/cradle mattresses.

Additionally, the NPR proposes that the statement "Use ONLY mattress provided by manufacturer," appearing in the warnings for bassinets/cradles in part 1218 and in ASTM F2194 – 22^{ɛ1}, be replaced with the statement "USE ONLY one mattress at a time." This revision communicates to consumers to only use a single mattress in the bassinet/cradle; when combined with other warning statements, the revision signals that the use of after-market bassinet/cradle mattresses is acceptable when the mattress has the appropriate fit for the bassinet/cradle; and will ensure that the warnings on bassinets/cradles are consistent with the warnings on after-market mattresses. This also addresses the potential hazard presented by after-market mattresses marketed as "mattress toppers."

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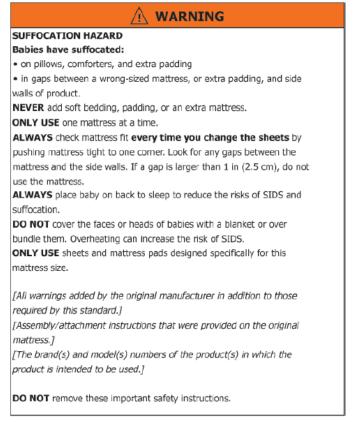


Figure 15: Warning label for After-Market Bassinet/Cradle Mattresses

Instructional Literature Warnings – The instructional literature requirements in ASTM F2194 – $22^{\epsilon l}$ contain multiple revisions. Many revisions are intended to ensure consistency with on-product markings and warnings and current recommendations from ASTM's Ad Hoc Language Task Group. ASTM F2194 – $22^{\epsilon l}$ now specifies that instructions shall be in English at minimum, state that any additional instructions shall not contradict or confuse the required information or mislead the consumer, and sets formatting requirements for warnings (*e.g.*, font size, text alignment, safety alert symbol, bullet points for cautionary statements). Per the Ad Hoc Language Task Group's recommendations, the ASTM F2194 – $22^{\epsilon l}$ standard uses ANSI Z535.4-2011 as reference for its warning formatting requirements.

Additionally, ASTM F2194 – $22^{\epsilon 1}$ requires that instructions for battery-operated products address the following:

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↑ CAUTION

To prevent battery leaks, which can burn skin and eyes:

- Remove batteries when storing product for a long time.
- Dispose of used batteries immediately.

ASTM F2194 – $22^{\epsilon l}$ provides that instructions for products that use more than one battery in any one circuit shall also address the following under the same CAUTION header:

- Always replace the entire set of batteries at one time.
- Never mix old and new batteries, or batteries of different brands or types.

Additionally, ASTM F2194 - 22 $^{\epsilon 1}$ states that instructions are now required to address the following statements:

Do not use if any part of the (manufacturer to insert type of product) is broken, torn, or missing.

Additionally, ASTM F2194 – $22^{\epsilon 1}$ requires that the instructions for products constructed of cardboard must now address the following statements:

Use only on a flat, dry floor.

Do not place the (manufacturer to insert type of product) near a space heater, open fire or other source of strong heat.

Lastly, ASTM F2194 $-22^{\epsilon 1}$ contains two example instructional literature warnings, one for bassinet/cradle products, and one for battery-powered bassinets. Figure 16 provides these two example warnings:

A WARNING

Failure to follow these warnings and the instructions could result in death or serious injury.

SUFFOCATION HAZARD Babies have suffocated:

- On pillows, comforters and extra padding.
- In gaps between a wrong size mattress, or extra padding and product sides.
- NEVER add soft bedding or padding.
- Use **ONLY** mattress provided by manufacturer.
- \bullet Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- If a sheet is used with the pad, use only the one provided by the product manufacturer or one specifically designed to fit the dimension of the product mattress.

FALL HAZARD: To help prevent falls,

 Do not use this product when the infant begins to push up on hands and knees or has reached [Insert manufacturer's recommended weight], whichever comes first.

A WARNING

Failure to follow these warnings and the instructions could result in death or serious injury.

SUFFOCATION HAZARD Babies have suffocated:

- On pillows, comforters and extra padding.
- In gaps between a wrong size mattress, or extra padding and product sides.
- NEVER add soft bedding or padding.
- Use **ONLY** mattress provided by manufacturer.
- Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- If a sheet is used with the pad, use only the one provided by the product manufacturer or one specifically designed to fit the dimension of the cradle mattress.

FALL HAZARD: To help prevent falls,

 Do not use this product when the infant begins to push up on hands and knees or has reached [Insert manufacturer's recommended weight], whichever comes first.

A CAUTION

- Remove batteries when storing product for a long time.
- Dispose of used batteries immediately.
- Always replace the entire set of batteries at one time.
- Never mix old and new batteries, or batteries of different brands or types.

Figure 16: Example Instruction Warnings;

ASTM F2194 – $22^{\epsilon 1}$ warning label for Bassinets/Cradles* (left) and ASTM F2194 – $22^{\epsilon 1}$ warning label for Bassinets/Cradles with Batteries* (right)

The Commission preliminarily determines that the instructional literature requirements in ASTM $F2194 - 22^{\epsilon l}$ are adequate and proposes to adopt these warnings provisions into the mandatory standard.

VI. Incorporation by Reference

The Commission proposes incorporating ASTM F2194 – 22^{ε1} by reference into the mandatory standard for bassinets/cradles codified in part 1218, with modifications to reduce the risk of injury associated with these products and to ensure the standard provides the highest level of safety that is feasible. The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. For a proposed rule, agencies must discuss in the preamble of the NPR ways that the materials that the agency proposes to incorporate by reference are reasonably available to interested persons, and how interested parties can obtain the materials. Additionally, the preamble to the rule must summarize the material. 1 CFR 51.5(b).

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In accordance with the OFR's requirements, section IV.A of this preamble summarizes the provisions of ASTM F2194 – 22^{£1} that the Commission proposes to incorporate by reference.

ASTM F2194 – 22^{£1} is copyrighted. By permission of ASTM, the standard can be viewed as a read-only document during the comment period on this NPR, at http://www.astm.org/cpsc.htm. To download or print the standard, interested persons may purchase a copy of ASTM F2194 – 22 ^{£1} from ASTM through its website (http://www.astm.org), or by mail from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428. Alternatively, interested parties may inspect a copy of the standard at CPSC's Office of the Secretary by contacting Alberta E.

Mills, Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301-504-7479; e-mail: cpsc-os@cpsc.gov.

VII. 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). The Commission proposes a 180-day effective date for this rule. The rule would apply to all bassinets/cradles and after-market bassinet mattresses manufactured after the effective date. 15 U.S.C. 2058(g)(1). This amount of time is typical for durable infant or toddler rules promulgated under section 104 of the CPSIA.⁶⁹ Six months is also the period that the JPMA typically allows for products in their certification program to shift to a new standard once a new standard is published. Therefore, juvenile product manufacturers are accustomed to adjusting to new standards within this timeframe.

Moreover, although the NPR proposes to add requirements, the test methods and test equipment are not unique, in that other CPSC rules also use the same methods and equipment. For example, 41 third party laboratories are CPSC-accepted to test to part 1218. Eleven of 12 laboratories accepted to test to the crib mattress rule are also accredited for testing to the bassinet

⁶⁹ See, e.g., Safety Standard for Infant Swings, 77 FR 66713 (Nov. 7, 2012); Safety Standard for Crib Mattresses, 87 FR 8640 (Feb. 15, 2022).

standard. Accordingly, the CPSC expects that these laboratories are competent to conduct the required testing and can have their International Organization for Standardization (ISO) accreditation and CPSC-acceptance updated in the normal course. The Commission invites comments, particularly from small businesses, regarding the proposed additional testing and the amount of time needed to come into compliance with a final rule.

VIII. Regulatory Flexibility Act (RFA)

The RFA requires that agencies review a proposed rule for the rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency publishes an NPR. 5 U.S.C. 603. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objectives and minimize any significant economic impact of the proposed rule on small entities.

This proposed rule would have a significant economic impact on a substantial number of small U.S. entities, primarily from redesign costs in the first year that the final rule would be effective. A significant impact would occur for small companies whose products do not meet the proposed revised requirements, particularly suppliers of small bassinets and bassinet accessory products for strollers and play yards, as well as suppliers of cantilever style bassinets and aftermarket bassinet mattresses. Third party testing costs should not be a new significant cost for most small firms, given that bassinet suppliers should already be testing to the current mandatory standard in part 1218. However, for after-market bassinet mattress suppliers, the third party testing costs to comply with the final rule would be new, although these firms already incur costs for testing to establish compliance with other relevant CPSC regulations, including those for lead and phthalate content.

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A. Reason for Agency Action, NPR Objectives, Product Description, and Market Description

Section I of this preamble explains why CPSC proposes to update the mandatory rule for bassinets/cradles and provides a statement of the objectives of, and legal basis for, the proposed rule. Section II of this preamble describes the types of products within the scope of the NPR, the market for bassinets/cradles, and the use of bassinets/cradles in the U.S. The requirements in the NPR are more stringent than the ASTM voluntary standard for bassinets/cradles, as described in sections IV and V of this preamble. The NPR addresses known hazards, discussed in section III of this preamble, that the current rule does not adequately address, as well as products on the market that were not common when the current rule was promulgated, such as products that resemble short play yards with canopies marketed for outdoor infant sleep.

The scope of this proposed rule also includes after-market bassinet mattresses, which are not in scope of the current regulation in part 1218 or the crib mattress regulation in 16 CFR part 1241. Accordingly, the registration card already required for bassinets/cradles under section 14 of the CPSA (15 U.S.C. 2056a(d)) will now be required for after-market mattresses as well. Registration cards are exempt from PRA or RFA analysis, per section 104(d)(1) of the CPSIA. 15 U.S.C. 2056a(d)(1).

B. Small Entities to Which the NPR Would Apply

Section II of this preamble describes the products within the scope of the rule and an overview of the markets for bassinets/cradles and for after-market bassinet mattresses. This section XIII.B of the preamble provides additional detail on the market for products within the scope of the rule.

Annual Units Sold: CPSC estimates the annual U.S. sales of new bassinets, including items with a bassinet mode or attachment, to be – rounded for the purposes of further analysis – 3.1 million units per year. CPSC made this estimate using Centers for Disease Control (CDC) data on

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the number of newborns,⁷⁰ State Department data on adoptions from foreign countries,⁷¹ and a survey by Statista⁷² in 2017 on the estimated ownership of bassinets, play yards, and strollers, also taking into account the market for used items.

Specifically, CPSC estimates the total sales of new bassinets in the U.S. as the total of the sales of traditional bassinets and cradles, plus play yard bassinets, plus stroller bassinets, plus bedside sleepers with a bassinet mode, which is 3,080,942, rounded for the purposes of analysis to 3.1 million (see Table 3). While this may seem high (corresponding to roughly 80 percent of the number of newborns in the U.S. each year), it is consistent with the prevalence of multi-mode products with a bassinet mode or attachment.

CPSC estimates the annual sales of used bassinets and products with bassinet mode to be 500,000 units per year, rounded for the purpose of analysis. Table 3 below displays the calculations, providing the sources in footnotes, for CPSC's estimation of sales for new and used bassinets and cradles.

⁷⁰ https://www.cdc.gov/nchs/nvss/births.htm.

⁷¹ https://travel.state.gov/content/travel/en/Intercountry-Adoption/adopt_ref/AnnualReports.html.

https://www.statista.com/forecasts/987681/ownership-of-baby-furniture-in-the-us. This data from 2017 is consistent with the Durable Nursery Products Exposure Survey that a contractor conducted for CPSC in 2013, which found that about 30% of families with children under age 6 owned a bassinet, cradle, or infant hammock.

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Table 3 – Estimated Sales for New and Used Bassinets/Cradles

Product ⁷³	Number of	Families/	and bought it	Percentage of	Estimated annual	Estimated annual unit
	newborns	caregivers	new or	these items	unit new sales in	used sales in scope of
		who own this	received it new	that include a	scope of this rule	this rule
		item ⁷⁴	as a gift ^{75 76}	bassinet		
					(e) =	
					$(a) \times (b) \times (c) \times (d)$	(f) =
	(a)	(b)	(c)	(d)		$(a) \times (b) \times (1 - c) \times (d)$
Bassinet/cradle		38 percent		100 percent	1,198,074	195,035
Play yard		66 percent		35 percent ⁷⁷	728,303	118,561
Stroller	3,666,077	96 percent	86 percent	17 percent ⁷⁸	514,541	83,763
Bedside		29 percent		70 percent ⁷⁹	640,024	104,190
crib/bassinet		_				
Total					3,080,942	501,549

Some families might have more than one newborn, some parents with a newborn might have separate residences, and non-parent caregivers also buy these items, so sales could be higher.

However, because the expected product life and warranty for these items is typically several years, while the recommended use per infant is only five months, parents may use the same bassinet for subsequent children or obtain a used one through gift or purchase.

CPSC estimates the size of the used market for all bassinet products, including products with bassinet attachments, at 501,549 units, rounded to 500,000 for the purposes of the cost analysis.

CPSC assumes that at least a majority of consumers in the secondary market would choose to dispose of the used mattress and purchase a new after-market mattress. For this analysis, CPSC conservatively assumes that 75 percent of parents purchasing a used bassinet will buy a new after-market mattress. CPSC also assumes that roughly 10 percent of parents who buy a bassinet or

⁷³ The number of newborns is from CDC data on births and State Department data on adoptions from other countries; the data on product ownership is from the Statista survey.

⁷⁴ https://www.statista.com/study/49911/baby-products-in-the-us/?locale=en. A survey by Statista in 2017 of parents with children under the age of 4.

⁷⁵ https://www.statista.com/forecasts/987072/ownership-of-a-rocking-crib-amongst-parents-in-the-us

⁷⁶ A Statista report from the same survey group in 2017 found that 14 percent of parents bought a "rocking crib" second hand. CPSC assumes that the secondary market is similar for bassinets. If 14 percent of bassinet or cradle owners are used, then 86 percent are bought new.

⁷⁷ Based on internet search in January 2023, seven of the top 20 best-selling play came with a bassinet attachment. Thus, approximately 35 percent.

⁷⁸ The Statista survey also found that 17 percent of parents reported that their stroller had a "removable carrycot" feature ("bassinet" feature was not a survey item).

⁷⁹ Based on a popular online general retail site in March 2023, fourteen of the top 20 best-selling beside sleepers came with a bassinet mode. Thus, approximately 70 percent.

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product with bassinet attachment new will also purchase a new after-market mattress for use by a subsequent sibling, or for the same infant due to heavy soiling. Therefore, CPSC estimates the total annual market for after-market mattresses at 75 percent of the used sales $(75\% \times 501,549 = 376,162)$ plus 10 percent of new sales $(10\% \times 3,080,942 = 308,094)$, for a total of 684,256 units, rounded to 680,00 for the purpose of the cost analysis.

The availability of hundreds of after-market bassinet mattresses online confirms that there is substantial demand for after-market mattresses, as well as a substantial volume of sales. The top seller by volume on Amazon currently sells more than 1,800 after-market bassinet mattresses per month. The Commission requests comments from the public on the estimated annual sales volume, including any information that would validate a different estimate on the rate of after-market mattress sales (number of units sold per year).

While other possible outlets for bassinet and after-market bassinet mattress sales exist that are not included in this estimate (specifically, sales to hotels, daycares, and hospitals), they are likely to be minimal. Hotels generally provide a sleep space that can accommodate larger children, typically cribs or play yards without a bassinet. Similarly, daycare centers typically purchase cribs and play yards rather than traditional bassinets; and major daycare and hospitality child furniture suppliers do not sell bassinets or cradles, although daycares may use consumer grade play yards with bassinet attachments. Hospital ownership of bassinets is small, reported as only 55,085 units in 2019,80 and hospital bassinets are medical devices regulated by the Food and Drug Administration (FDA), and thus out of scope of this NPR.

Prices and Features: Prices for traditional bassinets range from under \$50 to more than \$1,500, with most products in the \$50 to \$125 range. The least expensive products tend to be under 30 inches high and come with legs rather than a stand or base. The more expensive products tend to

⁸⁰ https://www.statista.com/statistics/824751/total-hospital-bassinet-numbers-in-the-us/.

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be larger and come with features that include canopies, motorized sounds or vibrations, attached toy bars, and pouches or shelves for storing diapers and bottles. Prices for cradles range from \$100 to more than \$1,000, with most products in the \$100 to \$200 range. Solid hardwood cradles are available for more than \$1,000. Some products advertised as "rocking bassinets" are physically identical to cradles, with a curved rocker base. Combination bedside sleeper/bassinets typically sell from \$75 to more than \$600, with most products in the \$125 to \$200 range. Attachments to play yards are usually not priced or sold separately. Some stroller bassinet attachments are sold separately, with most such products in the \$100 to \$200 range. Play yard and stroller bassinet attachments are designed to attach to a specific model or set of models from one manufacturer, and/or to a stand sold separately by that manufacturer. The stands typically sell for \$125 to \$175.

The wide range of prices and features reflect that parents and other caregivers buy bassinets for different purposes. Some people buy a large bassinet with a non-folding stand as a primary sleep space for the nursery, while others buy small portable items for travel, napping, or occasional care by a non-parent. No one best-selling size, price range, or set of features exists for bassinets. For example, the ten best-selling bassinets on Amazon in February 2023 ranged in price from \$42 to \$200 and included two small traditional bassinets that fold for transport, five bassinet/bedside sleeper combination products, two large cantilever bassinets, and an "infant lounger" with a rigid frame. Prices and features on Walmart.com had a similar variety, with prices of the ten best-selling bassinets ranging from \$50 to \$150. The best-selling products there included small portable bassinets, traditional bassinets on a stand that do not fold for transport, a combination bassinet/play yard, and several combination bassinet/bedside sleepers.

With approximately 3.1 million new bassinets sold per year, including items with a bassinet mode, at an average price of approximately \$100 per unit, CPSC estimates the total U.S. bassinet market is approximately \$310 million in sales per year. This total does not include the market for used items. Based on this IRFA's estimate of approximately 500,000 used units per year (see

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previous section), and an estimated used price of \$40 based on observed prices of used bassinets on Ebay and Mercari as a percentage of original retail prices, the used market would represent approximately \$20 million dollars in sales per year.

Prices for after-market bassinet mattresses range from \$20 to \$180, with most products in the \$30 to \$40 range, which is also the price range for replacement mattresses from the original bassinet supplier. The high end of the price range for after-market mattresses are hand-crafted items with a specialty fill and/or cover, such as natural rubber or organic fiber. Most after-market mattresses are sold online by small importers and foreign direct shippers. Several hundred U.S.-based crafters sell after-market mattresses that appear to have been hand-cut from upholstery foam. With a typical price of \$35 and annual sales of 680,000 units per year, the after-market bassinet mattress market is approximately \$23.8 million per year.

Bassinet and Bassinet Mattress Suppliers: Many manufacturers and importers, as well as foreign direct shippers, supply bassinets and cradles. CPSC identified more than 120 suppliers in March of 2023, including suppliers that sell play yards or strollers with bassinet attachments. Most companies that supply bassinets also supply a variety of other infant and children's products; bassinets are typically not their only or main product line. JPMA currently has 22 member companies that are certified for bassinet/cradles, ⁸¹ including companies that manufacture or import stroller bassinets and play yard bassinet attachments, although one of the 22 does not appear to currently have any products on the U.S. market.

Bassinets and cradles are available from online general retail sites, online baby product sites, and brick and mortar general retail stores, including "big box" stores. Two brick and mortar specialty chain stores for infants and children sell bassinets. Multiple online furniture stores associated with religious communities sell traditional solid hardwood cradles made in the U.S. A

⁸¹ JPMA runs a certification program for members, which includes third party testing to current ASTM and CPSC standards. See https://www.jpma.org/page/certification.

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few woodworkers from foreign countries sell carved wooden cradles on a prominent online site for hand-crafted items.

Hundreds of suppliers, including importers and U.S.-based hand crafters, supply aftermarket bassinet mattresses. These products are sold almost exclusively online, although a few are available to pick up in local big box stores after ordering online. While replacement mattresses from the original supplier are also sold primarily online, a few are similarly available for pick up in a big box or children's specialty store after ordering online.

Small Entities to Which the Proposed Rule Would Apply: Currently, over 120 firms supply more than 250 models of bassinets to the U.S. market. Large U.S. business and foreign businesses of all sizes constitute the majority of the suppliers of the available models. Most of the U.S.-based manufacturers and importers are small companies based on Small Business Administration (SBA) size standards. Of the identified 50 U.S-based suppliers to the U.S. market, 43 are small importers or small manufacturers, five are large U.S. manufacturers, and two are large U.S. importers. The rest of the market is foreign direct shippers⁸² and foreign manufacturers. Eight foreign manufacturers have U.S. distribution/warehouse operations that would meet the SBA size standard for a small importer if considered separately.⁸³

The total number of suppliers estimated here is approximate because online third party sellers (primarily small importers and foreign direct shippers) sell a wide variety of products, and can enter and exit the market quickly. In addition, as noted, multiple online furniture stores associated with religious communities sell wooden bassinets and cradles manufactured in the U.S.;

⁸² CPSC uses this term to refer to sellers who ship directly to the consumer from an address in a foreign country.

⁸³ The SBA regulations in 13 CFR 121.105 specify that a U.S. small business for the purposes of SBA program eligibility is "a business entity organized for profit, with a place of business located in the United States, and which operates primarily within the United States or which makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor." Consistent with this definition, CPSC considered a company to be a U.S. manufacturer if they have a headquarters and design products in the U.S., and market products with their own brand name, although production may take place overseas. Similarly, we considered a U.S. company affiliated with a foreign company, such as a licensed distributor, to be a U.S. importer if they ship from a U.S. address, because shipping from a U.S. address would require "use of American products, materials or labor."

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CPSC was unable to estimate how many individual small manufacturers each of these furniture distributors might represent. The SBA size standards for small entities are based on the number of employees or the annual revenue of the firm, and there is a specific size standard for each 6-digit North American Industry Classification Series (NAICS) category.⁸⁴ The U.S. Census Bureau conducts an annual survey of small businesses in the U.S. and counts how many large and small businesses are in each NAICS category.⁸⁵

A NAICS category specifically for bassinet manufacturing or importing does not exist. Companies that manufacture bassinets may be categorized as furniture, textile product, toy and game, or apparel manufacturers. Importers are generally considered a type of merchant wholesaler, as are furniture wholesale distributors. Other NAICS categories may apply to companies that manufacture or import bassinets, but for whom bassinets are not their main product line. As seen in the table below of applicable NAICS categories, the SBA small entity threshold for manufacturers is generally 500 to 1000 employees, while it is generally 100 to 150 employees for importers and wholesalers.

Companies that manufacture or import bassinets would fit into the NAICS categories shown in Table 4. As shown in Table 4, the majority of the U.S. businesses in the applicable categories for manufacturing and importing bassinets are small businesses, and there are thousands of such small businesses.

⁸⁴ The North American Industry Classification System (NAICS) is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. For more information, see https://www.census.gov/naics/. Some programs use 6-digit NAICS codes, which provide more specific information than programs that use more general 3- or 4-digit NAICS codes.

⁸⁵ https://www.census.gov/programs-surveys/susb/data/tables.html.

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Table 4 – NAICS Categories for Manufacturers and Importers of Bassinets/Cradles

NAICS series number	NAICS Series Description	SBA Size Standard for Small Business	Number of Businesses in Series	Number of Small Businesses in Series	Percentage of Businesses that are Small
314999	All Other Miscellaneous Textile Product Mills	500 employees	2,415	2,396	99%
315240	Women's, Girls', and Infants' Cut and Sew Apparel Manufacturing	750 employees	888	888	100%
337122	Non-upholstered Wood Household Furniture Manufacturing	750 employees	1992	1982	99%
337124	Metal Household Furniture Manufacturing	750 employees	258	252	98%
337125	Household Furniture (except Wood and Metal) Manufacturing	750 employees	151	151	100%
337910	Mattress Manufacturing	1000 employees	324	315	97%
339930	Doll, Toy, and Game Manufacturing	500 employees	507	503	99%
423220	Home Furnishing Merchant Wholesalers	100 employees	5,784	5,511	95%
423920	Toy and Hobby Goods and Supplies Merchant Wholesalers	150 employees	1904	1859	98%
424330	Women's, Children's, and Infants' Clothing and Accessories Merchant Wholesalers	100 employees	6,669	6,458	97%
TOTAL			20,892	20,315	97%

The applicable NAICS category for after-market mattress manufacturers is 337910 "Mattress manufacturing," for which the SBA size standard for a small business is 1,000 employees. For after-market mattress importers, the applicable NAICS category is 423210 "Furniture Merchant Wholesalers," for which the SBA size standard for a small business is 100 employees. In the 2019 Census data, 324 businesses manufactured mattresses and 4,824 businesses were furniture merchant wholesalers. More than 95 percent of these suppliers were small businesses using the SBA size standards.

The proposed rule would not impose any requirements or direct impacts on retailers of any size, unless they themselves manufacture or import bassinets or after-market mattresses, because the rule would not prevent the sale of products manufactured or imported before the effective date.

Indirect impacts could occur if the rule were to reduce consumer demand for bassinets or after-

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market mattresses, but it is unlikely that impact would be significant (more than one percent of annual revenue) for any retailer.

C. Compliance, Reporting, Paperwork, and Recordkeeping Requirements of the Proposed Rule

The proposed rule would require suppliers (manufacturers and importers) of bassinets to meet performance, warning label, and user instruction requirements, and to conduct third party testing to demonstrate compliance. This section discusses the reporting and paperwork requirements; compliance costs are analyzed in detail in section VIII.E of this preamble.

Suppliers must demonstrate that they have met the performance requirements of the rule by providing a children's product certificate. As specified in 16 CFR part 1109, suppliers who are not the original manufacturer, such as importers, may rely on the testing or certification suppliers provide, as long as the requirements in part 1109 are met. Manufacturers and importers are required to furnish certificates to retailers and distributors (section 14(g)(3) of the CPSA); retailers are not required to third party test the children's products that they sell unless they are also the manufacturer or importer. Suppliers must also provide product registration cards. The recordkeeping and compliance documentation does not require specialized expertise, nor does it include new requirements. CPSC's public website provides instructions and examples for how to develop the children's product certificates and product registration cards.⁸⁶

The proposed reporting and recordkeeping requirements are the same as those in the current mandatory bassinet standard. The proposed rule does not require additional packaging or instructions beyond what the current standard requires. While the proposed rule revises the warning label to match the current ASTM standard, with modifications, the cost to implement the requirement should be the same as under the existing part 1218 requirement. All children's

⁸⁶ See, for example: https://www.cpsc.gov/Testing-Certification/Childrens-Product-Certificate-CPC and https://www.cpsc.gov/Business--Manufacturing/Business-Education/Durable-Infant-or-Toddler-Products/FAQs-Durable-Infant-or-Toddler-Product-Consumer-Registration.

products under OMB Control Number 3041-0159 require Certificates of Conformance. However, CPSC is seeking a new OMB control number for bassinets/cradles and after-market bassinet mattresses. When the Children's Product Testing and Certification OMB Control Number 3041-0159 is next updated, the Information Collection burden estimates for the products within the scope of this rule will be updated to reflect current estimates of the number of suppliers and to add the requirement for warning labels on after-market bassinet mattresses. Registration cards are exempt from PRA burden analysis under section 104(d)(1) of the CPSIA.

D. Federal and State Rules that May Overlap with this NPR

CPSC has not identified any other Federal rules that duplicate, overlap, or conflict with the proposed rule. Some products marketed as "bassinets" may be within the scope of CPSC's mandatory standards for infant sleep products, hand-held infant carriers, or non-full-size cribs. The FDA regulates medical bassinets, so those products are not within scope of this rule and thus there is no overlap with FDA regulations. Combination products, such as bedside sleepers with a bassinet mode, must meet the requirements of both standards. Also, the rules for after-market bassinet mattresses and crib mattresses do not overlap, as after-market bassinet mattresses are not within scope of the Safety Standard for Crib Mattresses, codified at 16 CFR part 1241.

If finalized, the proposed rule will impact infant sleep product suppliers that are compliant with the current ISP Rule but do not meet the requirements of this NPR because the ISP Rule references part 1218. Therefore, all infant sleep products within the scope of the ISP Rule must comply with the updated bassinet performance requirements.

E. Potential Impact on Small Entities

Some products currently on the market would likely meet the proposed requirements without physical modifications, particularly larger traditional bassinets and cradles, many combination bedside sleeper/bassinets, and mesh attachments to play yards that meet the current standard. However, small bassinets, floor bassinets, in-bed sleepers, Moses baskets, and stroller and

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play yard bassinets that are shorter than 27 inches at the top side/rail, or do not have a sleep surface 15 inches above the floor, would need to be modified to meet the standard or taken off the market. Bassinets and cradles that are not flat may not meet the new, more stringent requirement for resting angle. Products with soft mattresses or other types of non-rigid floors may not meet the new mattress firmness requirement. Products with soft sides may not meet the new side rigidity requirement. Some multi-mode products with adjustable heights have settings lower than 15 inches, which will require modification to achieve compliance. After-market mattresses that are thicker than the required maximum thickness, do not meet the firmness requirements, or have a larger than allowable gap between the mattress and the side of the intended product would require modification. All after-market mattresses will require warning labels and registration cards.

Based on staff's review of products currently on the market, the majority of the bassinet products that appear to be too short to meet the proposed height requirements are sold by foreign companies, including foreign direct shippers. However, at least 19 small U.S. manufacturers and nine small U.S. importers may be significantly impacted by this proposed rule because they would have to modify or discontinue some or all of their products. This represents slightly more than half of the 43 small U.S. firms identified as bassinet manufacturers or importers. CPSC considers a cost impact of greater than or equal to one percent of annual revenue to be a "significant" economic impact, consistent with other federal government agencies.

1. <u>Products that Would Require Modification, Cost of Modifying Product</u>

Products on the market that would need to be redesigned to meet the new standard,
particularly the side/rail height requirement, include:

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- Small rigid-framed conventional bassinets, sometimes marketed as portable, travel, or compact bassinets, with a top side/rail height of less than 27 inches, and short feet or legs.⁸⁷
- Small soft-sided bassinets, sometimes marketed as in-bed sleepers or compact bassinets, with a top rail height of less than 27 inches, and short feet or legs.
- Bassinets of any size or type that do not meet the requirements for sidewall structural integrity or mattress firmness.
- Rocking bassinets or cradles, cantilever products, and any other bassinet that does not meet the new, more stringent requirement for resting angle.
- Moses baskets sold without a stand.
- Travel and outdoor bassinets, sometimes marketed as "play pens," that are shorter than 27 inches high at the top side/rail and have very short or no legs.
- Combination bedside sleeper/bassinets with adjustable heights where at least some of the height settings have the sleep surface less than 15 inches from the floor.
- Play yard and stroller attachments that are sold separately, and are below 27 inches in height at the top side/rail and have short or no legs.
- Play yard and stroller attachments sold with the play yard or stroller that are below 27 inches in height, have short or no legs, and can be used as a bassinet separately from the play yard or stroller.
- After-market mattresses that are marketed for use with unspecified brands/models of bassinet, cradle, or bassinet accessory, because it would not be possible to verify that such mattress meets the gap requirement.
- After-market mattresses that do not meet the thickness, firmness, or gap requirements in the rule.

Bassinets and Cradles: Some manufacturers would need to redesign their bassinet products, at a cost of approximately \$80,000 per model (calculation explained in the next paragraph) or remove the products from the market. The cost of modifying the product to meet the standard could be significant for small entities whose products do not meet the performance requirements in the NPR.

⁸⁷ Small bassinets under 27 inches high with short feet or legs may be compliant with the current bassinet standard, and the ISP standard, in part because they have feet or legs. But they will not meet the requirements of this NPR if they are under 27 inches high at the side/rail or have less than 15 inches of "ground clearance" between the sleep surface and the floor.

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Based on level of effort, CPSC estimates a one-time redesign at 400 hours of professional staff time per model, including in-house testing of the prototypes. ⁸⁸ Using Bureau of Labor Statistics (BLS) Employer Costs of Employee Compensation, ⁸⁹ the estimated cost per supplier for labor, at a current cost for professional labor of \$62.65 per hour, is \$25,060 (which can be rounded to \$25,000 for the purpose of this cost estimate). Given that many bassinets have metal or molded plastic parts, new molds or metal templates may be required. These materials costs for prototyping are estimated to be up to \$10,000, with up to \$100,000 for new molds or templates for the eventual final design if those are required. Therefore, CPSC estimates the total cost of redesign is approximately \$35,000 to \$125,000 per model, with a midpoint estimate of \$80,000.

In many cases, the redesign cost would not be significant. For example, redesigning mesh sides or making a mattress firmer would not require significant expenses or new templates or molds. Also, changing a resting side angle tilt from 7 degrees to 1 degree may be a minor redesign for models without motorized movements. Making a short rigid bassinet that otherwise meets all the stability and structural requirements a few inches taller may also not require a significant redesign. Modifying a bedside sleeper/bassinet combination product to remove the lowest height settings below 15 inches would not require a significant redesign. Some companies may offer a wide selection of fabric coverings and attachments such as canopies and toy bars on structurally similar models where the cost of redesign per model could be less for structurally similar models from the same supplier. In some cases, the redesign of a stroller bassinet or Moses basket to achieve compliance could involve requiring it to be sold only with the stroller or stand, which might require redesigning the packaging. Many bassinet designs are physically similar, so it is possible that

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⁸⁸ This reflects an estimate of 10 weeks of professional engineering, design, and testing staff time per model. While a redesign of one product could take less effort, this estimate reflects that an iterative process with multiple attempts to meet the NPR requirements may be required. This estimate also reflects time to design the molds or templates to scale up for commercial production.

⁸⁹ https://www.bls.gov/news.release/archives/ecec_03172023.pdf. These costs reflect the employers' cost for salaries, wages, and benefits for civilian workers in December 2022.

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smaller manufacturers will be able to learn from innovative redesign solutions by other manufacturers. Redesigning a mattress to be a compliant thickness and shape to fit a specific bassinet product should not require iterative prototyping or changes in production inputs. If a thick mattress is redesigned in a way that uses less material, the cost of production might be less in the long term. In most cases, redesigning an after-market mattress will also require redesigning the marketing and packaging to specify which bassinet product it fits with the required maximum "gap."

Many manufacturers have outsourced production to Asia, but design their products in North America, thus reflecting U.S. labor and materials costs for prototype designs. Manufacturers with a range of physically similar products may be able to reduce the design cost per model. However, smaller manufacturers would be less likely to be able to benefit from such economies of scale. For example, a large manufacturer may have several dozen play yard models with bassinet inserts or attachments, while a smaller manufacturer may have only one or two such models. While importers would not directly pay for the cost of redesign, the cost of redesign by others would almost certainly be reflected in the wholesale price. Small importers are less likely than large importers to have the market power to negotiate wholesale prices.

CPSC considers one percent of revenue to be a "significant" economic impact, consistent with other federal government agencies. Eighty thousand dollars would be one percent of revenue for a firm with \$8 million in revenue, which would represent sales of about 80,000 units at a retail price of \$100. Given that there are more than 250 models in this market, with annual sales for the whole industry estimated at 3.1 million units per year, the average number of sales per model is estimated at less than 12,500 units. Thus, the cost could be significant for small U.S. firms with limited sales volume whose products are not compliant with the new requirements. However, no small firms appear to have bassinets as their only product, so the cost of bassinet redesign could be less significant when the revenues from other products are considered. CPSC estimates that 19

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small U.S. manufacturers and nine U.S. importers supplying about 70 different models may need to redesign some or all of their products or remove them from the market. CPSC also estimates that the cost could be significant for some of those small firms, depending on their revenue from other products and on how much redesign is required.

With an estimated 70 bassinet models from 28 small U.S. businesses that need to be redesigned, at \$80,000 per model, the total cost for all small U.S. entities is estimated at about \$5.6 million for redesign only in the first year after that the proposed rule would be published. While cosmetic redesigns each year are typical in this industry, the structural redesigns required by this proposed rule would not have occurred in the status quo. Therefore, they should properly be considered a cost of the rule, and not routine costs. The ongoing cost of compliance after the first year that the final rule is in effect is expected to be minimal for materials and labor, as the redesigned products would likely use the same types of materials and production methods as current products. There may be additional, indirect costs as a result of this proposed rule, such as redesigning packaging to accommodate different physical designs, or increased shipping costs for larger products. As noted earlier, there may be additional costs for suppliers of infant sleep products that are compliant with the current ISP rule but will require modification to comply with the final rule that will follow this NPR. As also noted earlier, CPSC analysis indicates that there will likely not be a substantial number of impacted small ISP suppliers, as many short, small products in scope of the ISP regulation (that are not bassinets) have been recalled or voluntarily removed from the market since the ISP rule was published.

In addition to these estimates of the cost to small businesses, the estimated total cost to the bassinet industry for compliance with the proposed rule in the first year is approximately \$10.25 million. This estimate is based on \$80,000 in redesign costs per model, times 125 models (about half the existing models), which is \$10 million, plus another \$1000 per model for testing, times 250 models, which is \$250,000. This amount is the *incremental* cost for bassinets/cradles to comply

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with the proposed rule, above the cost of complying with the current rule. Therefore, this estimate does not include packaging, shipping, labeling, or marketing costs, because those would be costs suppliers would already be incurring to comply with the existing part 1218.

After-Market Bassinet Mattresses: The majority of after-market bassinet mattress on the market appear to be not compliant with this rule because the mattress is thicker than specified in this NPR, and/or the mattress is not marketed to be used with a specific product for which the fit has been verified. No after-market mattresses currently on the market have the required warning label. There are hundreds of suppliers, many of which appear to be small U.S.-based importers and handcrafters. The cost of modifying an after-market mattress design is expected to take 200 hours of time at an estimated hourly rate of \$62.65 according to BLS Employer Costs of Compensation for professional labor, which equates to approximately \$12,500 per model. For crafters, the redesign may be as simple as purchasing different filling and cutting to the appropriate size, and adding a warning label, in which case the cost of redesign could be less than \$12,500. If a thick mattress is redesigned in a way that uses less material, the cost of production might decrease in the long term.

For after-market mattresses suppliers, \$12,500 would be one percent of revenue for a firm with \$1.25 million in revenue, which would represent sales of about 41,667 units. Given that there are hundreds of models in this market, with annual sales for the whole industry estimated at 680,000 units per year, the average number of sales per model is far less than 41,667 units. Thus, the cost for a one-time redesign could be significant for small U.S. manufacturing firms, particularly hand crafters, with limited sales of after-market mattresses. However, if crafters can make their product compliant by simply using thinner foam, their cost of redesign might be less than \$12,500. Small mattress manufacturers would likely not have bassinet mattresses as their only product, so the cost of redesign could be less than one percent of their total revenue from all products combined. For importers, foreign manufacturers will likely spread the redesign cost across a large number of units

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so that the impact on importers is not significant. In addition, most importers do not have bassinet mattresses as their only product.

For after-market mattress suppliers, the cost to U.S.-based importers could be minimal, if their foreign suppliers spread the cost of redesign across many units. For example, if a foreign manufacturer redesigns a model at a cost of \$12,500, and sells 10,000 units to U.S. importers, the cost per model of the redesign is \$1.25. It would not be a significant cost for the importer if their supplier raises the price by just over one dollar on an item that retails for \$35. It is also likely that importer would be able to raise the retail price by \$1.25 without reducing demand for the product. Similarly, if crafters can source a thinner foam material easily, their cost of redesign may be minimal. As noted earlier, the cost of a warning label is expected to be less than \$1 per unit.

Assuming that 50 small manufacturers have to redesign their product at a cost of \$12,500, the total cost to U.S. small manufacturers for redesign would be about \$625,000 in the first year that the rule is effective. This cost may not be significant for some small manufacturers, particularly if they manufacture and/or import other products, which is common, and therefore they can cover at least some of the cost of redesign with revenue from other products.

In addition to these estimates of the cost to small businesses, the estimated total cost to the after-market bassinet mattress industry for compliance with the proposed rule in the first year is approximately \$4.05 million, comprised of \$12,500 per model in redesign costs, times 300 models (nearly all the existing models), which is \$3.75 million, plus another \$1000 per model for testing, times 300 models, which is \$300,000. This amount is the *total* cost for after-market to comply with the proposed rule, above the cost of complying with any other applicable CPSC regulations such as those for lead and phthalate content.

2. Products that May be Removed from the Market, Cost of Discontinuing Products

The cost estimate in the previous sections assumes that all non-compliant products supplied

by small U.S. entities would be redesigned. A similarly significant impact could occur for small

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firms if products are instead removed from the market, causing small companies to lose sales revenue from those products. For in-bed sleepers, the performance requirements are intended to discourage use on an elevated or soft surface, and it is likely that all in-bed sleepers would be removed from the market rather than redesigned. Two small U.S. manufacturers and two U.S. importers (included in the count above of 28 impacted U.S. small businesses) currently sell such products that are less than 27 inches tall, as well as more than a dozen foreign direct shippers.

Stroller bassinets could be redesigned to meet the requirements of the standard, because some soft-sided stroller bassinets already collapse/fold so they cannot be used off the stroller as a bassinet. Some are already sold only with the stroller, so that the stroller itself provides the compliant side/rail height, or so they could be re-packaged to be sold only with the stroller. However, some non-compliant rigid stroller bassinets may be removed from the market rather than redesigned to be 27 inches tall, sold only with the stroller, or designed to collapse/fold when not on the stroller. Three small U.S. manufacturers and five small importers currently sell such products, as well as more than a dozen foreign direct shippers and foreign companies with U.S. distributors.

Outdoor bassinets or "play pens" that are too short to meet the play yard mandatory standard and have short legs or no legs could be redesigned to meet the requirements of either this standard or the play yard standard. However, they may be removed from the market instead, as redesigning them to meet either standard would involve making them 10 to 16 inches taller. Two small U.S. manufacturers currently sell such product, as well as multiple large and foreign companies.

Compliant after-market mattresses will serve the same consumer need as non-compliant mattresses. Therefore, it is unlikely that they will be removed from the market rather than redesigned, except for a few handcrafter firms for which the redesign cost could be significant.

Even a very small manufacturer with limited sales may be able to raise the retail price to partially cover the one-time cost of redesign. However, after-market mattresses suppliers will no longer be able to market their products for use with a generic bassinet because of the gap requirement (which

requires a close fit between the bassinet and mattress). The demand for mattresses of a specific bassinet product may be lower than the demand for mattresses for generic/universal fit, therefore the rule could contribute to an overall decrease in demand for after-market mattresses and result in some firms exiting the market.

3. Third Party Testing Costs

This NPR would require manufacturers and importers of bassinets to comply with its performance requirements and demonstrate that compliance through third party testing. As specified in 16 CFR part 1109, entities that are not manufacturers of children's products, such as importers, may rely on the certificate of compliance provided by others. Manufacturers and importers of after-market bassinet mattresses would also be required to demonstrate compliance through third party testing.

While this proposed rule would require all manufacturers and importers of bassinets to arrange and pay for third party testing, this should not be a new cost for any supplier because they are already required to conduct third party testing on their products to comply with the current version of the CPSC mandatory safety standard as specified in part 1218. In addition, 22 of the suppliers are members of the JPMA certification testing program, which provides discounted third party testing to CPSC and ASTM standards. JPMA currently has 22 member companies that are certified specifically for bassinet/cradles, including companies that manufacture or import stroller bassinets and play yard bassinet attachments. JPMA's program requires annual testing, as well as more frequent testing when the product design has been updated or the underlying standard has been revised.

Third party testing will be a new requirement for suppliers of after-market mattresses.

Based on testing costs for other consumer products, testing could be \$500 to \$1000 per model, for the relatively simple tests to confirm thickness and fit. Given that mattresses may already require

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testing for compliance with other CPSC requirements for lead and phthalates content, the incremental cost of testing to this rule may be less as part of a bundled testing price.

The NPR would require new tests for sidewall integrity, mattress firmness, side-to-side tilt, and sleep surface incline for bassinets, and would require the use of new equipment during testing, including a metal plate to measure side tilt and a tool to test mattress firmness. The NPR proposes an effective date 180 days after publication of the final rule, giving suppliers limited time to test to the new standard. Annual testing costs for bassinets may rise by \$100 to \$200 per model, to pay for one to two hours of additional laboratory personnel time to test and document the testing results per model. Given the 180-day proposed effective date of the rule, it is possible that companies would be able to replace their annual testing for the current standard with the testing required for this standard without having to conduct an extra testing cycle.

F. Efforts to Minimize Impact, Alternatives Considered

The RFA specifies that the IRFA should describe alternatives to the proposed rule which accomplish the rule's objective but minimize the economic impact to small entities. Exempting small entities from this rule or parts of this rule would not be consistent with the applicable statutes, because this is a safety rule for durable infant or toddler products. 15 U.S.C. 2063(d)(4)(C). The statute allows CPSC to provide "small batch" exemptions to testing requirements or alternative requirements for small providers of certain products, but not durable infant or toddler products. The proposed rule does not have design requirements, so CPSC has already provided performance requirements rather than a design standard. CPSC considered several alternatives to this rule to minimize the impact on small entities, including:

- Not revising the mandatory standard;
- Incorporating the ASTM 2022^{E1} standard by reference without modifications; and
- A later effective date.

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Not revising the mandatory standard: Part 1218 currently incorporates the 2013 version of the ASTM standard by reference, with some additional requirements. Section 104(b)(2) of the CPSIA requires CPSC to "periodically review and revise the standards set forth under this subsection to ensure that such standards provide the highest level of safety for such products that is feasible." Given CPSC's statutory mandate, and continuing incidents associated with bassinets/cradles as described in section III of this preamble, the Commission has decided to prioritize the safety of infant sleep products ensuring that infant sleep products provide a firm, flat, sleep surface and that caregivers are discouraged from using bassinets/cradles on unsafe elevated and soft surfaces.

The current bassinet standard only specifies that a product must have legs, a base, or a stand, without specifying any specific height for the bassinet, which has led to a proliferation of "compact" or "floor" bassinets that can foreseeably be misused on elevated and soft surfaces. In addition, this means some in-bed sleepers and "travel beds" with very short legs and soft sides may be compliant with the current bassinet standard and the ISP rule. If CPSC does not revise the mandatory bassinet standard, suppliers could offer in-bed sleepers with one inch tall "feet" and meet the standard with a product shorter than 10 inches at the top rail. In addition, the current regulation does not include after-market bassinet mattresses in scope, nor are those products included in the scope of the crib mattress regulation. Therefore, if CPSC did not revise the mandatory standard, suppliers could continue to offer thick, soft after-market mattresses marketed to fit an unspecified (generic) bassinet or cradle, with an unknown gap between the mattress and the sidewall.

While not revising the mandatory standard would have no impact on U.S. small businesses, it would not address the known hazards. Most of the small bassinets and in-bed sleepers currently on the market are not supplied by small U.S. businesses, but rather by foreign businesses and particularly foreign direct shippers, so the impact of this rule on small U.S. businesses is limited.

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Incorporating the ASTM 2022^{c1} standard by reference without modifications, or waiting for ASTM to make additional modifications: The Commission considered incorporating the ASTM 2022^{c1} standard by reference, and unanimously voted against doing so. The Commission reached this decision after considering staff's analysis that the requirements for "compact bassinets" in the 2022 version of the standard are less stringent and less safe than the current standard. Since the Commission's decision, ASTM has continued to meet to consider additional revisions to the standard to address the Commission's concerns. However, to date, ASTM has not issued a ballot to revise the voluntary standard. CPSC is unsure whether such a ballot would include revisions consistent with this NPR. Based on this uncertainty, the Commission is choosing to move forward with rulemaking. While waiting for ASTM would delay the impact on small businesses, it would not necessarily reduce the impact, depending on the stringency of ASTM's revisions.

A later effective date: The recommended effective date for the final rule is 180 days after publication in the Federal Register. This is consistent with other CPSIA section 104 rules, and with JPMA's certification program, which generally allows manufacturers 180 days to comply with a newly published standard. A longer effective date period of one year after publication would reduce the burden on entities of all sizes by allowing more time to redesign and test products. Several hundred products from more than 100 companies would need to test to this standard, and there are currently 41 test labs accredited to the current bassinet standard. In addition, test labs will need to become accredited to the new standard before any product can be tested to this standard. Smaller companies are less likely to have the resources to quickly redesign products than larger ones, and some of the small U.S. companies that have products in scope of this proposed rule have multiple products that do not appear to meet the new performance requirements. However, given that many products already meet the proposed requirements, many labs are already accepted to test the existing bassinet standard and after-market mattresses, and providing a longer effective date

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would allow the hazards of current bassinets/cradles to continue for a longer period of time, the Commission proposes a 180-day effective date for the final rule.

G. Impact on Testing Labs

In accordance with section 14 of the CPSA, all children's products that are subject to a children's product safety rule must be tested for compliance by a third-party conformity assessment body that has been accredited by CPSC. Testing laboratories that conduct this testing must meet the Notice of Requirements (NOR) for third party conformity testing. CPSC has codified NORs in 16 CFR part 1112.

If finalized, the rule should not have an adverse impact on testing laboratories. CPSC is not proposing to amend part 1112 because bassinets/cradles are already part of that rule. Also, third party labs will not require new testing equipment for the modifications described in the NPR, other than a mattress firmness testing device and a metal plate to measure resting side tilt. The instrument for measuring mattress firmness is the same one specified in the regulation for crib mattresses. No laboratory is required to provide testing services. The only laboratories that would be expected to provide such services are laboratories that anticipate receiving sufficient revenue from the mandated testing to justify procuring the testing equipment and obtaining accreditation. However, CPSC expects that most of the existing 41 labs accredited to test bassinets would request updated accreditation because they are already accredited and have met the NOR for the current standard. Also, most laboratories are not small U.S. businesses; more than 30 of those labs are in Asia or Europe.

IX. Environmental Consideration

The Commission's regulations address whether the agency is required to prepare an environmental assessment or an environmental impact statement. Under these regulations, certain categories of CPSC actions normally have "little or no potential for affecting the human environment," and therefore do not require an environmental assessment or an environmental

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impact statement. Safety standards providing performance and labeling requirements for consumer products come under this categorical exclusion. 16 CFR 1021.5(c)(1). The NPR falls within the categorical exclusion.

X. Paperwork Reduction Act

This proposed rule for bassinets and cradles contains information collection requirements that are subject to public comment and review by the Office of Management and Budget ("OMB") under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth a:

- Title for the collection of information;
- Summary of the collection of information;
- Brief description of the need for the information and the proposed use of the information;
- Description of the likely respondents and proposed frequency of response to the collection of information;
- Estimate of the burden that shall result from the collection of information; and
- Notice that comments may be submitted to the OMB.

Title: Safety Standard for Bassinets and Cradles

Description: As described in section V.C of this preamble, the proposed rule would update the existing labeling and instruction requirements for bassinets and cradles, which has an OMB control number (3041-0159). This NPR would also add after-market bassinet mattresses to the scope of the rule and require new labeling. CPSC will seek a new OMB control number for this update and then move the revised estimate into control number 3041-0159 in the next PRA update for Children's Products. The NPR proposes that bassinets and cradles meet the requirements of ASTM F2194 – 22^{e1}, Standard Consumer Safety Specification for Bassinets and Cradles, with the proposed additional requirements and modifications summarized in section V of this preamble. Sections 8 and 9 of ASTM F2194 – 22^{e1} contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of "collection of information," as defined in 44 U.S.C. 3502(3).

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Description of Respondents: Persons who manufacture or import bassinets, cradles, and after-market mattresses for bassinets/cradles. Over 120 firms supply more than 250 models of bassinets to the U.S. market. Based on an evaluation of suppliers, most of the U.S.-based manufacturers and importers are small companies, using SBA size standards. In addition, hundreds of firms supply after-market bassinet mattresses to the U.S. market, including many small importers and hand-crafters in the U.S., as well as foreign direct shippers.

Estimated Burden: The estimated burden of this collection of information is as follows:

Table 5 – Estimated Annual Reporting Burden

Estimated limital Reporting Burden					
Burden Type	Number of	Frequency	Total	Hours per	Total
	Respondents	of	Annual	Response	Burden
	_	Responses	Responses	_	Hours
Labeling and	220	2	440	2	880
instructions					

This estimate is based on the following: CPSC estimates there are 220 suppliers that would respond to this collection annually, and that the majority of these entities would be considered small businesses. CPSC assumes that on average each firm that reports annually would respond twice, as product models for bassinets and cradles are brought to market and new labeling and instruction materials are created, for a total of 440 responses annually (220 respondents × 2 responses per year). CPSC assumes that on average it will take one hour for each respondent to create the required label and one hour for them to create the required instructions, for an average response burden of two hours per response. Therefore, the total burden hours for the collection is estimated to be 880 hours annually (440 responses × 2 hours per response = 880 total burden hours).

CPSC uses \$37.87⁹⁰ from BLS as the hourly compensation for the time required to create and update labeling and instructions. Therefore, the estimated annual cost of the burden

⁹⁰ U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," September 2023, Table 4, total compensation for all sales and office workers in goods-producing private industries: https://www.bls.gov/news.release/archives/ecec 12152023.pdf.

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requirements is \$33,326 (\$37.87 per hour x 880 hours = \$33,325.60). No operating, maintenance, or capital costs are associated with the collection. Based on this analysis, the proposed revisions to the standard would impose a burden to industry of 880 hours at a cost of \$33,326 annually.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], to the Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this notice).

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

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

XI. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), states that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 104(b) of the CPSIA refers to the rules to be issued as "consumer product safety

rules." Therefore, the preemption provision of section 26(a) of the CPSA would apply to a revised rule for bassinets and cradles.

XII. Certification and Notice of Requirements

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children's products subject to a children's product safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish an NOR for the accreditation of third-party conformity assessment bodies (or laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The Commission already issued an NOR for bassinets/cradles in 2013 when the existing rule was promulgated.

Test laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the revised standard for bassinets/cradles would be required to meet the third-party conformity assessment body accreditation requirements in part 1112. Testing laboratories should not be adversely impacted as a result of this rule. Approximately 41 third party testing laboratories are CPSC-accepted to test compliance with part 1218. Staff expects that these labs will become accredited and CPSC-accepted to test to a revised bassinet standard in the normal course of business. No new testing equipment is required for the modifications described in the NPR, other than a mattress firmness testing device, and a metal plate to measure resting side tilt. The instrument for measuring mattress firmness is the same as specified in the regulation for crib mattresses; 11 of 12 laboratories that are CPSC-accepted to conduct crib mattress testing are also accredited to test requirements for bassinets/cradles. CPSC expects that these laboratories will be able to test to a new rule in a short time period. Furthermore, no laboratory is required to provide

testing services. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from the mandated testing to justify procuring the testing equipment and obtaining accreditation.

XIII. Request for Comments

This proposed rule is part of a rulemaking proceeding under section 104(b)(2) of the CPSIA to revise the consumer product safety standard for bassinets and cradles to ensure that this standard provides the highest level of safety that is feasible. The Commission requests comments on the proposal to incorporate by reference ASTM F2194 – 22^{E1} , with the modifications discussed in sections IV and V of this preamble. The Commission also requests comments on the proposed effective date, and any aspect of this proposal. During the comment period, ASTM F2194 – 22^{E1} is available as a read-only document at: http://www.astm.org/cpsc.htm. Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this document.

Specifically, CPSC requests comment on the following topics:

- A. Proposed Side Height Requirements
- 1. Is the proposed requirement for a minimum 27-inch external side/rail height feasible? Please provide any rationale, data, tests, and/or scientific studies to support your comment.
- 2. Will the 27-inch proposed external side/rail height requirement address the hazard of using the bassinet on an elevated surface such as a bed or sofa? Is there a different height that can better address the same hazard?
- 3. Does the 27-inch proposed external side/rail height requirement cause a reduced utility, such as reduced portability, and would this impact safety in a negative manner?
- 4. Will the 27-inch proposed external side/rail height requirement impact bedside sleepers that are designed to fit lower to the ground adult beds?

- 5. Should an exemption to the 27-inch proposed external side/rail height requirement be included for bedside sleepers because they are designed to be used next to the adult bed and not on top of the adult bed?
- 6. Are there studies, surveys or anecdotal consumer feedback that show the 16-inch external side/rail height set by ASTM F2194 22 $^{\epsilon 1}$ will discourage use on elevated surfaces including an adult bed?
- 7. Are there other potential requirements, such as leg designs, to address the hazard of using the bassinet on an elevated surface?
 - 8. Should a defined "stand" be required to discourage use on an elevated surface?
 - B. Proposed Requirements For A Minimum 15-Inch Occupant Sleep Surface Height
- 1. Will the proposed minimum 15-inch occupant sleep surface height requirement address the hazard of using the bassinet on an elevated surface such as a bed or sofa? If not, is there a more adequate occupant sleep surface height and why?
- 2. Are there any other performance requirements needed for bassinets that have a 27-inch external side/rail height and 15-inch occupant sleep surface height?
 - C. Proposed Side Wall Rigidity Requirements
- 1. Are the proposed side wall rigidity requirements adequate to address the risks of suffocation and falls from products?
- 2. Are there any other performance requirements CPSC should consider to address the risks of suffocation and falls?
 - D. Proposed Mattress Firmness Requirements
- 1. Are the proposed mattress firmness requirements adequate to address the risk of suffocation?
- 2. Are there any other performance requirements CPSC should consider to address the risk of suffocation?

- E. Firmness Requirements for Soft Sided Bassinets
- 1. Should CPSC propose side firmness requirements to address infants rolling their face into the side of a bassinet?
- 2. If side firmness testing is necessary, what test method would adequately evaluate side firmness?
 - *F. Proposed Tilt and Incline Limitation Requirements*
- 1. Is a 0-degree limitation on the side-to-side tilt of a bassinet, with a maximum tilt angle limit not to exceed one degree (a tolerance limit) for each direction independently ($0 \pm 1^{\circ}$) feasible? If not, what angle/tolerance is feasible, please provide data.
- 2. Is the maximum 10-degree head to toe angle limitation adequate to address chin to chest incidents?
 - G. Inclusion of After-Market Bassinet/Cradle Mattresses Within the Scope of the NPR
 - 1. Is the proposed warning label for after-market bassinet mattresses appropriate?
- 2. Is the estimated annual sales volume in the IRFA (section VIII of this preamble) accurate? If not, please provide any information that would validate a different estimate on the rate of after-market mattress sales (number of units sold per year).
 - H. Proposed Warning Label Requirements for Bassinets/Cradles
- 1. Are the proposed warnings adequate to address the hazards associated with bassinets/cradles and after-market bassinet mattresses? Should CPSC consider additional warnings?
- 2. Section 8.6.2.6 of ASTM F2194 22^{E1} requires a specific statement warning consumers not to carry infants in bassinets/cradles constructed of cardboard; should all bassinets have this statement except those that meet 16 CFR part 1225, Safety Standard for Hand-Held Infant Carriers?

- I. Initial Regulatory Flexibility Analysis and other Topics
- 1. Significant impact. Is CPSC's estimated cost of redesign to achieve compliance accurate? If not, please provide additional information and support for your proposed correction.

 Also, do the estimated costs represent more than one percent of annual revenue for individual small U.S. manufacturers and importers?
- 2. *Testing costs*. Will third party testing costs for bassinets increase as a result of the requirements in this NPR, and if so, by how much?
- 3. *Testing costs*. Is CPSC's estimated third party testing costs for after-market mattresses accurate? If not, please provide supporting data, and the extent to which this cost will impact small businesses.
- 4. Effective date of 6 months. How much time is required to come into compliance with a final rule (including product compliance and third party testing)? Please provide supporting data with your comment, particularly from small businesses.
- 5. Alternatives to reduce the impact on small businesses. Are there any alternatives to the rule that could reduce the impact on small businesses without reducing safety? Please provide supporting data with your comment, particularly addressing small businesses.
 - J. Feasibility
- 1. Are the proposed requirements in this NPR feasible, both technically and economically?
- 2. What would be the total cost to industry of implementing this rule? Please be specific about labor and/or materials costs to redesign products, and costs of third party testing.
- 3. Will complying with this rule increase the costs of production or the retail price of bassinets? Why? By how much?
- 4. Will complying with this rule permanently increase the costs of production or the retail price of after-market bassinet mattresses? Why? By how much?

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List of Subjects

16 CFR Part 1218

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

Enforcement, and Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the

Code of Federal Regulations as follows:

PART 1218-SAFETY STANDARD FOR BASSINETS AND CRADLES

1. Revise the authority citation for part 1218 to read as follows:

Authority: 15 U.S.C. 2056a.

2. Revise § 1218.2 to read as follows:

§ 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 F2194 – 22^{E1} , Standard Consumer Safety Specification for

Bassinets and Cradles (approved on July 15, 2022). 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. This

material is available for inspection at the U.S. Consumer Product Safety Commission and at the

National Archives and Records Administration (NARA). Contact the U.S. Consumer Product

Safety Commission at: the Office of the Secretary, U.S. Consumer Product Safety Commission,

4330 East West Highway, Bethesda, MD 20814, telephone (301) 504-7479, email: cpsc-

os@cpsc.gov. For information on the availability of this material at NARA, email

fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html. A free,

read-only copy of the standard is available for viewing on the ASTM website at

https://www.astm.org/READINGLIBRARY/. You may also obtain a copy from ASTM

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International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959; phone: (610) 832-9585; www.astm.org.

- (b) Comply with the ASTM F2194 -22^{E1} standard with the following additions or exclusions:
- (1) Instead of complying with section 1.3.1 through 1.3.1.5 of ASTM F2194 22^{E1} , comply with the following:
 - (i) 1.3.1 Examples of Products under the Scope:
 - (ii) 1.3.1.1 Bassinets, cradles, and after-market mattresses for bassinets and cradles.
 - (iii) 1.3.1.2 Cradle swings with an incline less than or equal to 10° from horizontal while in the rest (non-rocking) position.
 - (iv) 1.3.1.3 Multi-use products when they are in the bassinet/cradle use mode as defined in 3.1.1.
 - (v) 1.3.1.4 Bassinet/cradle accessories to products when removed from the product and used in the bassinet/cradle mode. See 3.1.2 for an example.
 - (vi) 1.3.1.5 Bassinet/cradle features for carriage/stroller when removed from the carriage/stroller and used in the bassinet/cradle mode.
 - (2) Do not comply with sections 1.3.2 through 1.3.2.3 of ASTM F2194 $22^{\epsilon l}$.
- (3) Renumber sections 3.1.1, 3.1.1.1, 3.1.1.2, 3.1.1.3, and 3.1.1.4 of ASTM F2194 $-22^{\epsilon 1}$ to sections 3.1.2, 3.1.2.1, 3.1.2.2, 3.1.2.3, and 3.1.2.4.
 - (4) Insert a new section 3.1.1 and 3.1.1.1 of ASTM F2194 $22^{\epsilon 1}$:
 - (i) 3.1.1 After-market mattress, n—a mattress sold or distributed for a bassinet or cradle.
 - (ii) 3.1.1.1 Discussion—This does not include a replacement mattress provided or sold by an original equipment manufacturer (OEM) if, and only if, it is equivalent with respect to dimensions, and specifications to the mattress that was provided with the original product.
- (5) Instead of complying with the newly designated section 3.1.2 of ASTM F2194 $22^{\epsilon 1}$, comply with the following:

- (i) 3.1.2 bassinet/cradle, n—small bed that provides sleeping accommodations for infants, supported by free standing legs, a stationary base/stand/frame, a wheeled base, a rocking base, or a base which can swing relative to a stationary base.
 - (ii) [Reserved]
- (6) Instead of complying with section 3.1.3 and 3.1.3.1 of ASTM F2194 $22^{\epsilon 1}$, comply with the following:
 - (i) 3.1.3 bassinet/cradle accessory, n—a supported sleep surface that attaches to a crib or play yard designed to convert the product into a bassinet/cradle.
 - (ii) Note to paragraph (b)(5)(i) Rationale the definition was modified to clarify that bassinets can have a variety of bases. The 10-degree sleep surface was moved into the performance requirement section.
 - (7) Instead of complying with section 5.14 of ASTM F2194 $22^{\epsilon 1}$, comply with the following:
 - (i) 5.14 If the bassinet/cradle product can be converted into another product for which a mandatory consumer product safety standard exists, the product shall comply with the applicable requirements of the consumer product safety standard when in that use mode.
 - (ii) [Reserved]
 - (8) Instead of complying with section 6.4.1 of ASTM F2194 $22^{\epsilon 1}$, comply with the following:
 - (i) 6.4.1 Stability Bassinet/cradle—A product in all manufacturer's 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 when tested in accordance with 7.4.1.
 - (ii) [Reserved]
 - (9) Remove section 6.4.2 of ASTM F2194 $22^{\epsilon 1}$.
- (10) Instead of complying with section 6.10.2 of ASTM F2194 $22^{\epsilon 1}$, comply with the following:

- (i) 6.10.2 The arithmetic mean of the rest angle measurements shall not exceed 1 degree when calculated for each rock/swing direction independently, when tested in accordance with 7.10.
 - (ii) [Reserved]
- (11) Add section 6.12 to ASTM F2194 $22^{\epsilon 1}$:
 - (i) 6.12 Product and Bassinet/Mattress Support Height.
 - (ii) 6.12.1 The lowest top side/rail shall be at minimum 27 inches from the floor.
- (iii) 6.12.2 The mattress support height shall be at least 15 inches from the floor to the bottom of the mattress support surface.
- (iv) 6.12.3 *Removable Bassinet Beds* can only fully support infant and function when top rail is 27 inches or greater above the external floor with a minimum internal side height of 7.5 inches. (Example: Bassinet collapses/fails or is otherwise unusable when removed from the stand.)
- (12) Add section 6.13 to ASTM F2194 $22^{\epsilon 1}$:
 - (i) 6.13 Sidewall Rigidity.
- (ii) 6.13.1 Sidewall being tested during the stability test (section 7.4) shall not deflect in any direction more than 0.5 in.
- (13) Add section 6.14 to ASTM F2194 $22^{\epsilon 1}$:
 - (i) 6.14 Sleep Surface Deflection/Firmness.
- (ii) 6.14.1 All products within the scope of this standard, when tested in accordance with 7.13, shall not allow the feeler arm of the test fixture to contact the sleep surface of the product.

 (14) Add section 6.15 to ASTM F2194 22^{ε1}:
 - (i) 6.15 Maximum Sleep Surface Head-to-Toe Angle.
- (ii) 6.15.1 The angle of the sleep surface along the occupant's head-to-toe axis relative to the horizontal shall not exceed 10 degrees when tested in accordance with 7.14.

- (15) Add section 6.16 to ASTM F2194 $22^{\epsilon 1}$:
 - (i) 6.16 Maximum Side-to-Side Tilt Angle for Non-Rocking Bassinets.
 - (ii) 6.16.1 The unit shall meet 6.16.1.1 and 6.16.1.2.
- (iii) 6.16.1.1 The lateral angles of the weighted occupant sleep surface shall not be greater than 1 degree for each direction independently when tested in accordance with 7.15.1.
- (iv) 6.16.1.2 The lateral angles low-weight occupant sleep surface shall not be greater than 1 degree for each direction independently when tested in accordance with 7.15.2.
- (16) Add section 6.17 to ASTM F2194 $22^{\epsilon 1}$:
- (i) 6.17 Electrically Powered Bassinets/Cradles (remote control devices are exempt from the requirements in 6.17):
- (ii) 6.17.1 Each battery compartment shall provide a means to contain the electrolytic material in the event of a battery leakage. This containment means shall not be accessible to the occupant.
- (iii) 6.17.2 Positive protection from the possibility of charging any primary (non-rechargeable) battery shall be achieved either through physical design of the battery compartment or through the use of appropriate electrical circuit design. This applies to situations in which a battery may be installed incorrectly (reversed), and in which a battery charger may be applied to a product containing primary batteries. This section does not apply to a circuit having one or two batteries as the only source of power.
- (iv) 6.17.3 The surfaces of any accessible electrical component, including batteries, shall not achieve temperatures exceeding 160 °F (71 °C) when tested in accordance with 7.16. At the conclusion of the test, there shall be no battery leakage, explosion, or fire, to any electrical component. This test shall be performed prior to conducting any other testing within the performance requirements section.

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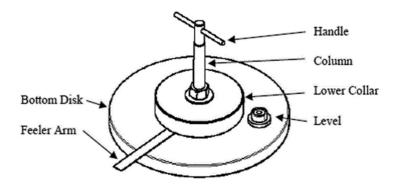
- (v) 6.17.4 AC adapters supplied with the product must denote compliance with the appropriate current national safety standard for AC adapters from a Nationally Recognized Testing Laboratory (NRTL). AC adapters must have a nominal output voltage less than 30 VDC (42.4 VAC (peak)) and must not be capable of delivering more than 8 amps into a variable resistive load for one minute.
- (17) Add section 6.18 to ASTM F2194 $22^{\epsilon 1}$:
 - (i) 6.18 After-market Mattress
- (ii) 6.18.1 After-market mattresses shall meet the requirements of 6.5.2, 6.5.3, 6.6, 6.8, and 6.14 when tested with each brand and model for which it is intended to be used.
- (iii) 6.18.2 The after-market mattress must be at least the same size as the original equipment mattress or larger and lay flat on the floor of the product, in contact with the mattress support structure or floor.
- (iv) 6.18.3 If the original equipment mattress includes a floor support structure, the aftermarket mattress must include a floor support structure that is at least as thick as the original equipment mattress floor support structure.
- (v) 6.18.4 If the original equipment mattress includes storage accommodations for the product instruction manual, the after-market mattress shall provide equivalent storage accommodations for the product instruction manual.
- (18) In section 7.4 of ASTM F2194 $22^{\epsilon l}$, replace the word "Stability" with the words "Stability and Sidewall Rigidity."
- (19) Renumber sections 7.4.1.3, 7.4.1.4, and 7.4.1.5 of ASTM F2194 $-22^{\epsilon 1}$ to sections 7.4.1.4, 7.4.1.5, and 7.4.1.6.
- (20) In the newly designated section 7.4.1.4, replace "7.4.1.4" in the last sentence with "7.4.1.5."
 - (21) Add a new section 7.4.1.3 to ASTM F2194 $22^{\epsilon 1}$ as follows:

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- (i) 7.4.1.3 Establish a reference line along the length of the upper side rail/wall being tested.
 (22) Add new sections 7.4.1.7, 7.4.1.8, and 7.4.1.9 to ASTM F2194 22^{ε1} as follows:
- (i) 7.4.1.7 Measure the displacement of the upper side rail/wall being tested from the reference line to the new position.
- (ii) 7.4.1.8 If necessary, hold the unit to prevent it from tipping over while taking the displacement measurement. Release the product to continue with the stability test.
 - (iii) 7.4.1.9 Test the unit in all manufacturer's recommended use positions.
- (23) Do not comply with sections 7.4.2 through 7.4.2.6 of ASTM F2194 $22^{\epsilon 1}$.
- (24) Add section 7.13 to ASTM F2194 $22^{\epsilon 1}$:
 - (i) 7.13 Sleep Surface Deflection/Firmness Test
 - (ii) 7.13.1 Test Fixture:
- (iii) 7.13.1.1 The fixture, as shown in Figure 1 to paragraph (b)(24)(iii), shall be a rigid, robust object with a round footprint of diameter 7.99 in. \pm 0.039 in. (203 mm \pm 1 mm), and an overall mass of 11.46 lb. \pm 0.045 lb. (5200 g \pm 20 g). The lower edge of the fixture shall have a radius not larger than 0.039 in. (1 mm.) Overhanging the footprint by 1.57 in. \pm 0.079 (40 mm \pm 2 mm) shall be a flexible, flat bar of width 0.47 in. \pm 0.008 (12 mm \pm 0.2 mm) with square-cut ends. This bar may be fashioned from a shortened hacksaw blade. The bar shall rest parallel to the bottom surface of the fixture and shall be positioned at a height of 0.59 in. \pm 0.008 in. (15 mm \pm 0.2 mm) above the bottom surface of the fixture. The bar shall lay directly over a radial axis of the footprint (i.e., such that a longitudinal centerline of the bar would pass over the center of the footprint).

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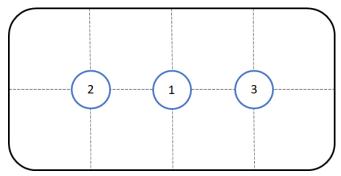
Figure 1 to paragraph (b)(24)(iii) – Mattress Firmness Test Fixture



- (iv) 7.13.1.2 Included on the fixture, but not overhanging the footprint, shall be a linear level that is positioned on a plane parallel to the bar, and in a direction parallel to the bar.
- (v) 7.13.1.3 Other parts of the fixture, including any handle arrangement and any clamping arrangement for the bar, shall not comprise more that 30 percent of the total mass of the fixture, and shall be mounted as concentric and as low as possible.
 - (vi) 7.13.2 Test Method:
 - (vii) 7.13.2.1 Assemble bassinet/cradle in accordance with manufacturer's instructions.
- (viii) 7.13.2.2 Shake and/or agitate the mattress in order to fully aerate and distribute all internal components evenly.
- (ix) 7.13.2.3 Place the mattress inside the product in the manufacturer's recommended used position and let the mattress rest for at least 5 minutes.
- (x) 7.13.2.3.1 Where a user of a mattress could possibly position either side face up, even if not an intended use, then both sides of the mattress shall be tested.
 - (xi) 7.13.2.4 Place the bassinet/cradle on the floor.
- (xii) 7.13.2.5 Test the unit in all manufacturer's recommended use positions that could affect the sleeping surface's deflection/firmness.
- (xiii) 7.13.2.6 Mark a longitudinal centerline on the mattress surface and divide this line in half. This point will be the first test location. Then further divide the two lines on either side of

the first test location into halves as shown in Figure 2 to paragraph (b)(24)(xiii). These will be the second and third test locations.

Figure 2 to paragraph (b)(24)(xiii) – Mattress Firmness Test Points



(xiv) 7.13.2.7 Position the test fixture on each of the test locations, with the footprint of the fixture centered on the location, with the bar extending over the centerline and always pointing at the same end of the mattress sleep surface.

(xv) 7.13.2.7.1 At each test location in turn, rotate the bar to point in the required direction, and gently set the fixture down on the mattress sleep surface, ensuring that the footprint of the fixture does not extend beyond the edge of the mattress. The fixture shall be placed as horizontal as possible, using the level to verify. If the bar makes contact with the top of the mattress sleep surface, even slightly, the mattress is considered to have failed the test.

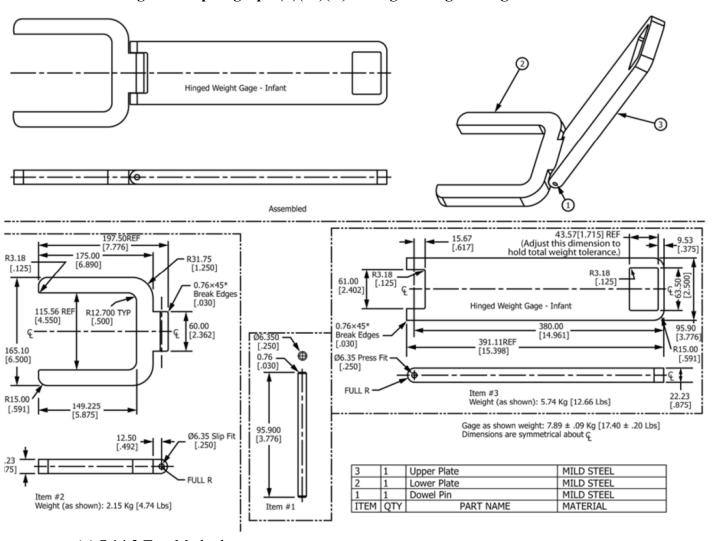
(xvi) 7.13.2.7.2 Repeat Step 7.13.2.7.1 at the remaining locations identified in 7.13.2.6.

(xvii) 7.13.2.7.3 Repeat Step 7.13.2.7.1 at a location away from the centerline most likely to fail (*e.g.*, a very soft spot on the sleep surface or at a raised portion of the sleep surface). In the case of testing a raised portion of a sleep surface, position center of the fixture such that the bar is over the raised portion, to simulate the position of an infant's nose.

(xviii) 7.13.2.7.4 In the event that the fixture is not resting in a nearly horizontal orientation, repeat the test procedure at that location by beginning again from paragraph 7.13.2.7.1. However, if the test produces a failure even with the device tilted back away from the bar so as to raise it, then a failure can be recorded.

- (25) Add section 7.14 to ASTM F2194 $22^{\epsilon 1}$:
 - (i) 7.14 Maximum Sleep Surface Head-to-Toe Angle Test.
 - (ii) 7.14.1 Equipment:
 - (iii) 7.14.1.1 Digital Protractor.
 - (iv) 7.14.1.2 Hinged Weight Gauge–Infant (Figure 3 of paragraph (b)(25)(iv)).

Figure 3 to paragraph (b)(25)(iv) – Hinged Weight Gauge–Infant⁹¹



(v) 7.14.2 Test Method

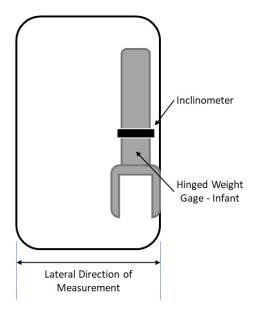
(vi) 7.14.2.1 Assemble bassinet/cradle in accordance with manufacturer's instructions.

⁹¹ Reprinted, with permission, from ASTM F3118-17a Standard Consumer Safety Specification for Infant Inclined Sleep Products (withdrawn 2022), copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428. A copy of the complete standard may be obtained from ASTM International, www.astm.org.

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- (vii) 7.14.2.2 Place the unit and the inclinometer on a flat level horizontal plane ($0 \pm 0.5^{\circ}$) to establish a test plane. Zero the inclinometer.
- (viii) 7.14.2.3 Place the Hinged Weight Gauge–Infant (Figure 3 of paragraph (b)(25)(iv)) in the product equidistant between both head and toe ends and in the geometrical lateral center of the sleep surface. If the unit is circular, square or has no obvious lateral sides, test four perpendicular sides.
 - (ix) 7.14.2.4 Place a digital protractor on the upper torso/head area lengthwise.
- (26) Add section 7.15 to ASTM F2194 $22^{\epsilon 1}$:
 - (i) 7.15 Maximum Side-to-Side Tilt Angle.
 - (ii) 7.15.1 Determination of the weighted, lateral angle
- (iii) 7.15.1.1 Assemble the unit in accordance with manufacturer's instructions. If applicable, the unit shall be in the lowest height setting with the mattress pad in place.
- (iv) 7.15.1.2 Place the unit and the inclinometer on a flat level horizontal plane ($0 \pm 0.5^{\circ}$) to establish a test plane. Zero the inclinometer.
- (v) 7.15.1.3 Place the Hinged Weight Gauge Infant (Figure 3 to paragraph (b)(25)(iv)) on the occupant sleep surface with the left side of the gauge parallel to and contacting one lateral, sidewall of the unit and equidistant between both ends of the sleep surface.
- (vi) 7.15.1.4 Place the inclinometer on the center of the Upper Plate of the Infant Hinged Weight Gauge and record the lateral angle (Figure 4 to paragraph (b)(26)(vi)).

Figure 4 to paragraph (b)(26)(vi) – Weighted, lateral angle measurement

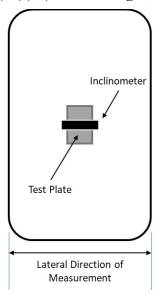


- (vii) 7.15.1.5 Remove the Hinged Weight Gauge Infant (Figure 3 to paragraph (b)(25)(iv)). Remove, agitate and replace the mattress (if applicable) to normalize the occupant sleep surface.
- (viii) 7.15.1.6 Repeat 7.15.1.3 7.15.1.5 twice for a total of three measurements. Average the measurements to establish a weighted, lateral angle.
- (ix) 7.15.1.7 Repeat the steps in 7.15.1.3 7.15.1.6 except place the Hinged Weight Gauge Infant (Figure 3 to paragraph (b)(25)(iv)) so that its right side is touching the opposite sidewall in the bassinet/cradle. If the unit is circular, square or has no obvious lateral sides, test four perpendicular sides.
 - (x) 7.15.1.8 Repeat the steps 7.15.1.1 7.15.1.7 at the highest height setting, if applicable.
 - (xi) 7.15.2 Determination of the low-weight, lateral angle
- (xii) 7.15.2.1 Assemble the unit in accordance with manufacturer's instructions. If applicable, the unit shall be in the lowest height setting with the mattress pad in place.
- (xiii) 7.15.2.2 Place the unit and the inclinometer on a flat level horizontal plane (0 ± 0.5 degrees) to establish a test plane. Zero the inclinometer.

(xiv) 7.15.2.3 Place a test plate [6 by 4 by 0.5 in. (152 by 101.6 by 12.7 mm) nominal thickness steel block weighing 3.3 ± 0.2 lb.] on the center of the unit's occupant sleep surface with the long sides parallel to the long sides of the unit. If the unit is circular, square or has no obvious lateral sides, determine the most onerous orientation of the test plate.

(xv) 7.15.2.4 Place the inclinometer on the center of the test plate and record the lateral angle (see Figure 5 to paragraph (b)(26)(xv)).

Figure 5 to paragraph (b)(26)(xv) – Low-weight, lateral angle measurement



(xvi) 7.15.2.5 Remove the test plate. Remove, agitate and replace the mattress (if applicable) to normalize the occupant sleep surface.

(xvii) 7.15.2.6 Repeat 7.15.2.3 - 7.15.2.5 twice for a total of three measurements. Average the measurements to establish the center, lateral angle.

(xviii) 7.15.2.7 Repeat the steps in 7.15.2.3 - 7.15.2.6 with the test plate on the occupant sleep surface with the left side of the plate parallel to and contacting one lateral, sidewall of the unit and equidistant between both ends of the sleep surface.

(xix) 7.15.2.8 Repeat the steps in 7.15.2.3 - 7.15.2.6 with the test plate on the occupant sleep surface with the right side of the plate parallel to and contacting one lateral, sidewall of the unit and equidistant between both ends of the sleep surface.

- (xx) 7.15.2.9 Repeat the steps 7.15.2.1 7.15.2.7 at the highest height setting, if applicable. (27) Add section 7.16 to ASTM F2194 $-22^{\epsilon 1}$:
- (i) 7.16 The bassinet/cradle shall be tested using fresh alkaline batteries or an AC power source. If the bassinet/cradle can be operated using both, then both batteries and AC power must be tested separately. If another battery chemistry is specifically recommended for use in the bassinet/cradle by the manufacturer, repeat the test using the batteries specified by the manufacturer. If the bassinet/cradle will not operate using alkaline batteries, then test with the type of battery recommended by the manufacturer at the specified voltage. The test is to be carried out in a draft-free location, at an ambient temperature of 68 °F \pm 9 °F (20 °C \pm 5 °C).
- (ii) 7.16.1 Secure the bassinet/cradle so that the sleep surface cannot move during the test.

 Operate the bassinet/cradle at the maximum speed. Do not disable any mechanical or electrical protective device, such as clutches or fuses. Operate the bassinet/cradle continuously, and record peak temperature. The test shall be discontinued 60 min after the peak temperature is recorded. If the bassinet/cradle shuts off automatically or must be kept "on" by hand or foot, monitor temperatures for 30 seconds, resetting the bassinet/cradle as many times as necessary to complete the 30 seconds of operation. If the bassinet/cradle shuts off automatically after an operating time of greater than 30 seconds, continue the test until the bassinet/cradle shuts off.
- (28) Instead of complying with section 8.6.2.3, 8.6.2.6, 8.6.5, and 8.6.6 of ASTM F2194 $22^{\epsilon 1}$, comply with the following:
 - (i) 8.6.2.3 Product can roll over on soft surfaces and suffocate child. NEVER place product on beds, sofas or other soft surfaces.
 - (ii) 8.6.2.6 Products shall also address the following:
 - (A) Always use product on the floor. Never use on any elevated surface.
 - (B) Do not carry baby in the [manufacturer to insert type of product]. [Exception: A product that is intended to carry a baby is exempt from this requirement].

- (C) Bassinets/cradles constructed of cardboard shall also address:
- (1) Do not reuse [manufacturer to insert type of product] for second child.
- (iii) 8.6.4 See Figure 6 of paragraph (b)(28)(iii) for example warnings for bassinets/cradles.

Figure 6 to paragraph (b)(28)(iii) – Example Product Warning for Bassinet/Cradle Products

AWARNING

Failure to follow these warnings and the instructions could result in death or serious injury.

SUFFOCATION HAZARD Babies have suffocated:

- · on pillows, comforters, and extra padding
- in gaps between a wrong-size mattress, or extra padding and product sides
- NEVER add soft bedding or padding.
- · Use ONLY one mattress at a time.
- Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- Product can roll over on soft surfaces and suffocate child. NEVER place product on beds, sofas or other soft surfaces.

FALL HAZARD - To help prevent falls:

- Do not use this product when the infant begins to push up on hands and knees or has reached [insert manufacturer's recommended maximum weight], whichever comes first.
- Always use product on the floor. Never use on any elevated surface.
- Do not carry baby in the [manufacturer to insert type of product].
- (iv) 8.6.5 See Figure 7 of paragraph (b)(28)(iv) for example warnings for bassinets/cradles made of cardboard.

Figure 7 to paragraph (b)(28)(iv) – Example Product Warning for Bassinet/Cradle Products Made of Cardboard

A WARNING

Failure to follow these warnings and the instructions could result in death or serious injury.

SUFFOCATION HAZARD Babies have suffocated:

- · on pillows, comforters, and extra padding
- in gaps between a wrong-size mattress, or extra padding and product sides
- NEVER add soft bedding or padding.
- Use ONLY one mattress at a time.
- Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- Product can roll over on soft surfaces and suffocate child. NEVER place product on beds, sofas or other soft surfaces.

FALL HAZARD - To help prevent falls:

- Do not use this product when the infant begins to push up on hands and knees or has reached [insert manufacturer's recommended maximum weight], whichever comes first.
- Always use product on the floor. Never use on any elevated surface.
- Do not carry baby in the [manufacturer to insert type of product].
- Do not reuse [manufacturer to insert type of product] for second child.

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(v) 9.7 See Figure 8 of paragraph (b)(28)(v) for example of instruction warnings for bassinet/cradle products.

Figure 8 to paragraph (b)(28)(v) – Example Product Instruction Warnings for Bassinet/Cradle Products

▲WARNING

Failure to follow these warnings and the instructions could result in death or serious injury.

SUFFOCATION HAZARD Babies have suffocated:

- · on pillows, comforters, and extra padding
- in gaps between a wrong-size mattress, or extra padding and product sides
- NEVER add soft bedding or padding.
- · Use ONLY one mattress at a time.
- Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- Product can roll over on soft surfaces and suffocate child. NEVER place product on beds, sofas or other soft surfaces.

FALL HAZARD - To help prevent falls:

- Do not use this product when the infant begins to push up on hands and knees or has reached [insert manufacturer's recommended maximum weight], whichever comes first.
- Always use product on the floor. Never use on any elevated surface.
- Do not carry baby in the [manufacturer to insert type of product].
- Strings can cause strangulation! Do not place items with a string around a child's neck, such as hood strings or pacifier cords. Do not suspend strings over a product or attach strings to toys.
- •Do not use if any part of the (manufacturer to insert type of product) is broken, torn, or missing.
- (vi) 9.8 See Figure 9 of paragraph (b)(28)(vi) for example of instruction warnings for

bassinet/cradle products with batteries.

Figure 9 to paragraph (b)(28)(vi) – Example Product Instruction Warnings for Bassinet/Cradle Products with Batteries

AWARNING

Failure to follow these warnings and the instructions could result in death or serious injury.

SUFFOCATION HAZARD Babies have suffocated:

- · on pillows, comforters, and extra padding
- in gaps between a wrong-size mattress, or extra padding and product sides
- · NEVER add soft bedding or padding.
- · Use ONLY one mattress at a time.
- Always place baby on back to sleep to reduce the risk of SIDS and suffocation.
- Product can roll over on soft surfaces and suffocate child. NEVER place product on beds, sofas or other soft surfaces.

FALL HAZARD - To help prevent falls:

- Do not use this product when the infant begins to push up on hands and knees or has reached [insert manufacturer's recommended maximum weight], whichever comes first.
- · Always use product on the floor. Never use on any elevated surface.
- Do not carry baby in the [manufacturer to insert type of product].
- Strings can cause strangulation! Do not place items with a string around a child's neck, such as hood strings or pacifier cords. Do not suspend strings over a product or attach strings to toys.
- •Do not use if any part of the (manufacturer to insert type of product) is broken, torn, or missing.

A CAUTION

To prevent battery leaks, which can burn skin and eyes:

- Remove batteries when storing product for a long time.
- · Dispose of used batteries immediately.
- · Always replace the entire set of batteries at one time.
- Never mix old and new batteries, or batteries of different brands or types.
- (29) Do not comply with section X1.3 from the Appendix X1 RATIONALE of ASTM F2194 $22^{\varepsilon 1}$.
- (30) Add sections X1.5, X1.6, and X1.7 to the Appendix X1 RATIONALE of ASTM F2194 22^{ε1}.
 - (i) X1.5 *Rationale for 6.12.1* A 27-inch height will likely discourage bed sharing because the baby is not accessible to the caregiver sleeping next to the bassinet. Use on table is unlikely because the bassinet in front of the sitting caregiver is cumbersome.
 - (ii) X1.6 Rationale for 6.12.2 A 15-inch mattress support height places the baby at a comfortable height for a 50-percentile female to lean over and pick up the baby. The height should promote use of the bassinet on the floor rather than placing it on an elevated surface.

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(iii) X1.7 Rationale for 6.12.3 A removable bassinet bed must not function as a bassinet absent of the stand. This requirement is intended to prevent use of the bassinet bed on an unsafe elevated surface or soft surface such as an adult bed.

Alberta E. Mills Secretary, Consumer Product Safety Commission



Memorandum

TO: The Commission DATE: February 28, 2024

Alberta E. Mills, Secretary

THROUGH: Jessica L. Rich, General Counsel

Austin C. Schlick, Executive Director

DeWane Ray, Deputy Executive Director of Operations

FROM: Duane E. Boniface, Assistant Executive Director,

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Celestine T. Kish, Bassinet and Cradle Project Manager, Division of Human

Factors, Directorate for Engineering Sciences

Alisa Hwang, Mathematical Statistician, Division of Hazard Analysis, Directorate

for Epidemiology

Ashley Johnson, Ph.D., Physiologist, Division of Pharmacology and Physiology

Assessment, Directorate for Health Sciences

Zachary Foster, Industrial Engineer, Division of Human Factors, Directorate for

Engineering Sciences

Carlos Torres, Mechanical Engineer, Division of Mechanical and Combustion

Engineering, Directorate for Engineering Sciences

Samantha Michael, Mechanical Engineer, Division of Mechanical Engineering,

Directorate for Laboratory Sciences

Susannah Proper, Economist, Directorate for Economic Analysis

Maureen Danskin, Compliance Officer, Division of Regulatory Enforcement, Office

of Compliance and Field Operations

SUBJECT: Staff's Draft Proposed Rule to Revise the Safety Standard for Bassinets and Cradles

On October 23, 2013, the Commission (CPSC or Commission) published a final rule establishing the Safety Standard for Bassinets and Cradles pursuant to section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), 15 U.S.C. § 2056a, codified at 16 C.F.R. part 1218 (part 1218). 78 Fed. Reg. 63,019. Part 1218 incorporates by reference ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles*, with modifications to make the standard more stringent. By incorporating section 3.1.1 of ASTM F2194-13, the bassinet rule defines a "bassinet/cradle" as "a small bed designed primarily to provide sleeping accommodations for infants, supported by free standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which can swing relative to a stationary base. While in a rest (non-rocking or swinging) position, a bassinet/cradle is intended to have a sleep surface less than or equal to 10° from horizontal." See Figure 1 below for examples of different bassinet types.



Figure 1. Examples of Bassinets and Cradles

The draft proposed rule (NPR) reflects the views and recommendations of the above-listed staff. The NPR is intended to reduce the risk of asphyxia, suffocation, falls, skull fractures, and burns associated with five identified hazard patterns:

- Non-level bassinets, which can increase the likelihood of the infant rolling over into a compromised position and suffocating;
- Placement of bassinets on elevated and soft surfaces, which can lead to hazardous tipover incidents, potentially resulting in suffocation in soft materials (e.g., if bassinet is placed on the bed) and/or head or other injuries from falls from an elevated location onto a hard surface;
- Mattresses that are non-flat, too thick, too soft, ill-fitting, or unattached to the bassinet/cradle, creating the potential for uneven sleep surfaces and increased risk of suffocation; and
- Bassinets with design issues (such as being low to the ground or unstable), which can cause overlay by siblings or tipover incidents similar to hazardous placements, or with electrical issues that can lead to electrocutions and chemical burns.

As discussed in section III of the draft NPR regarding Incident Data and Hazard Patterns, staff identified 7 deaths associated with a problem or malfunction of a bassinet/cradle feature. Two deaths occurred in products that were not level; the non-level sleep surface allowed the infants to roll into an unsafe position that led to their deaths. Two deaths are associated with bassinet mattress

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features including a depression in the middle of the mattress and poor fit of the mattress which allowed enough space for the infant to get wedged between the mattress and the sidewall of the bassinet. Two deaths are associated with an older sibling who climbed into play yard accessory bassinets located on the floor, and lay on top of the infant inside, suffocating them. The low height of the bassinet facilitated access by the older sibling. One death was associated with an infant falling out of a compact bassinet that had been placed on an adult bed.

Staff identified 2 hospitalizations, 1 resulting from a fall injury and 1 from a battery chemical burn. Two emergency department treated injuries were attributed to a mattress support board moving, and an unspecified part of the bassinet breaking and hitting the infant while asleep. Staff is also aware of 6 other, less-severe, product-related injuries. In addition to the injuries listed above, 3 injuries were associated with infants falling out of compact bassinets, where the product was placed on elevated or soft surfaces, such as adult beds, countertops, and couches. Staff is also aware of 182 non-injury incidents that further demonstrate these hazard patterns.

The For Official Use Only (due to 6b and privacy information being included) versions of the incident data that staff relied upon (which are summarized in the draft Federal Register Notice) are being provided separately. These data are in the process of being redacted by staff and that version will be placed in the record, to the extent allowed by applicable law, upon publication of the NPR for public comment.

Although the Commission rejected ASTM's F2194-22^{£1} update based on staff's recommendation, this NPR includes portions of that revision that staff assesses improve safety. Specifically, as explained in section V of the draft NPR regarding the Description and Explanation of the NPR, while the staff recommendation of rejection was largely based on modifications for compact bassinets/cradles (including removal of stand requirements with the consequence of increasing the likelihood of placement on soft surfaces like beds and couches, as well as less stringent stability tests), other revisions in that updated standard (such as locking/latching mechanism, product finish-related, static load and warning requirements) were viewed by staff as an improvement to safety and are recommended in the draft NPR.

Specifically, staff from the Directorate for Engineering Sciences, Division of Mechanical and Combustion and Division of Human Factors, and Directorate for Laboratory Sciences, Division of Mechanical Engineering, through testing and evaluation, recommend the following modifications and additions to ASTM F2194-22^{£1}:

- Remove all references to "compact" bassinets, eliminating a primary concern about less safe designs that led to CPSC's 2022 rejection;
- Clarify the "bassinet" definition by moving the 10-degree sleep surface angle statement into an actual performance requirement with specific testing requirements;
- Refer to CPSC's regulation instead of a voluntary standard for multi-use products to ensure that bassinets comply with the current regulatory requirements;
- Include performance requirements and associated test methods for:
 - Discouraging product use on unsafe surfaces to address the associated tipover and fall hazards;
 - External side/rail height provides easier access to the infant when the bassinet is on the floor, thus reducing the likelihood of the product being placed on an elevated surface;

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- Height of occupant sleep surface from the floor provides easier access to the infant when the bassinet is on the floor, thus reducing the likelihood of the product being placed on an elevated surface;
- Sidewall rigidity to prevent deformation/collapse if an external force is applied such as sibling pulling on the side;
- Mattresses and mattress supports
 - Sleep surface deflection/firmness requirements to reduce the likelihood of the mattress conforming to the face and causing suffocation;
 - Structural integrity requirements to reduce the likelihood of the infant getting into a compromised position and suffocating;
 - After-market mattress requirements to ensure after-market mattresses provide the same level of safety as those provided by the original equipment manufacturer
- Sleep surface angles
 - Head-to-toe incline angle to require a flat, sleep surface;
 - Side-to-side tilt restrictions to reduce the likelihood of the infant rolling over into a compromised situation and suffocating;
- Electrical system requirements;
- Warning and instructional literature to adopt elements of ASTM F2194-22^{ε1} that staff found improved safety.

Section 603 of the Regulatory Flexibility Act (RFA, 5 U.S.C. §603) generally requires the Commission to prepare an Initial Regulatory Flexibility Analysis (IRFA) for a proposed rule, describing the impact of the proposed rule on small entities and identifying efforts by the Commission to reduce those impacts. Staff's IRFA, set out in section VIII of the draft NPR, assesses that this proposed rule would have a significant economic impact on a substantial number of small U.S. entities, primarily from redesign costs in the first year that the final rule would be effective. Alternatives that could reduce the impact on small entities include adopting the current ASTM standard without modification or instituting a longer effective date. However, adopting the current ASTM standard without modifications would not address the identified hazards, and applying a longer effective date would delay addressing these hazards. Because this draft proposed rule would be issued under section 104 of the CPSIA, a cost/benefit analysis is not required.

For the reasons stated in section VII of the draft NPR regarding the Effective Date, staff recommends an effective date of 6 months after publication of the final rule to allow time for bassinet/cradle and after-market bassinet mattress manufacturers to bring their products into compliance and to test to the revised standard. Staff generally considers 6 months to be sufficient time for suppliers (manufacturers and importers, including foreign direct shippers) to come into compliance with a new standard, and this amount of time is typical for other CPSIA section 104 rules. Six months is also the period that the Juvenile Product Manufacturers Association (JPMA) typically allows for products in their certification program to comply with a new standard once that new standard is published. Staff also recommends posing a number of questions for comment to further inform a final rule.