

any such product manufactured on or after December 1, 2010 tested by a third party conformity assessment body accredited to do so and must issue a certificate of compliance with 16 CFR part 1215 based on that testing.

To ease the transition to the new standard and avoid a “bottlenecking” of products at conformity assessment bodies at or near the effective date of 16 CFR 1215, the Commission will accept certifications based on testing that occurred prior to the effective date of the new standard in certain prescribed circumstances. However, any such testing must comport with all CPSC requirements, including:

- At the time of product testing, the product was tested by a third party conformity assessment body that was ISO/IEC 17025 accredited by an ILAC-MRA member, and had been accepted by the Commission, at the time of the test.
- The accreditation scope in effect for the third party conformity assessment body at the time of testing expressly included testing to the test method(s) included in 16 CFR part 1215; and
- The test results show compliance with the test methods in the new regulation (16 CFR part 1215).

Dated: May 25, 2010.

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

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1215

[CPSC Docket No. CPSC-2009-0064]

Safety Standard for Infant Bath Seats: Final Rule

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”) requires the United States Consumer Product Safety Commission (“Commission,” “CPSC,” “we”) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. We are issuing a safety standard for infant bath seats in

response to the direction under section 104(b) of the CPSIA.

DATES: The rule will become effective on December 6, 2010 and apply to products manufactured or imported on or after that date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of December 6, 2010.

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SUPPLEMENTARY INFORMATION:

A. Background and Statutory Authority

Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (“CPSIA,” Public Law 110-314) requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. Section 104 includes infant bath seats among these products. *See* CPSIA, section 104(f). The standards developed under section 104 of the CPSIA are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. Section 104(b)(2) of the CPSIA directs the Commission to begin rulemaking for two standards by August 14, 2009. Under this provision, the Commission published a notice of proposed rulemaking (“NPR”) in the **Federal Register** of September 3, 2009 (74 FR 45719) proposing a safety standard for bath seats. The proposed standard was substantially the same as a voluntary standard developed by ASTM International (formerly known as the American Society for Testing and Materials), ASTM F 1967-08a, “Standard Consumer Safety Specification for Infant Bath Seats,” with some modifications to strengthen the standard in order to reduce the risk of injury associated with bath seats. The Commission is now issuing a final standard for infant bath seats that is almost the same as the proposed standard it published in September 2009.

B. The Product

Infant bath seats are used in a tub or sink to support a seated infant while he or she is being bathed. They are marketed for use with infants between the age of approximately 5 months (the time at which infants can sit up

unassisted) to the age of approximately 10 months (the time at which infants begin pulling themselves up to a standing position). Currently, there are two manufacturers and one importer of bath seats active in the United States (one fewer than at the time the Commission published its proposed rule). All are members of the Juvenile Products Manufacturers Association (“JPMA”), which is the major United States trade association representing juvenile product manufacturers and importers. All produce a variety of children’s products in addition to bath seats.

The exact number of bath seats currently sold or in use is not known. Data from a 2005 survey by the American Baby Group (*2006 Baby Products Tracking Study*), in conjunction with Centers for Disease Control (“CDC”) birth data, indicated annual sales of bath seats of about 1.5 million and about 1.8 million bath seats in use. In 2000, JPMA estimated annual sales of bath seats at about one million and estimated up to 2 million bath seats in use for infants under one year of age.

C. ASTM Voluntary Standard

ASTM F 1967, “Standard Consumer Safety Specification for Infant Bath Seats,” was first published in 1999. Between 2003 and 2007, the ASTM standard was subsequently revised several times to exclude tub-like products and to include requirements that the Commission had proposed in a notice of proposed rulemaking it issued in 2003, 68 FR 74878 (December 29, 2003).

In response to changes in the ASTM standard, the design of bath seats changed significantly. The new designs use an arm that clamps onto the side of the bath tub rather than relying on suction cups for stability. In its proposed rule, the Commission referenced ASTM F 1967-08a, which was published in December 2008, and contains the same labeling, stability and leg opening requirements as the 2007 version. In April 2010, ASTM published a new version of ASTM F 1967. The differences between the 2008 and 2010 standards are insubstantial (one word in section 8.1.1). The 2010 version adopted none of the changes the Commission proposed. Thus, the final standard continues to reference ASTM F 1967-08a.

JPMA provides certification programs for juvenile products, including bath seats. Manufacturers submit their products to an independent testing laboratory to test the product for conformance to the ASTM standard.

Currently only one bath seat model is certified to ASTM F 1967–08a.

The ASTM standard includes general requirements common to many ASTM standards for children's products; performance requirements specific to bath seats to address the hazards of the bath seat tipping over or the child becoming entrapped and/or submerged in the leg openings; and labeling requirements to address the child coming out of the bath seat.

General requirements in the ASTM standard, none of which the Commission is modifying, include:

- Requiring compliance with CPSC's standards concerning sharp points and edges, small parts, and lead paint (16 CFR parts 1303, 1500.48, 1500.49, 1500.50, 1500.51, and 1501);
- Requirements for latching and locking mechanisms;
- Requirements to prevent scissoring, shearing and pinching;
- Entrapment testing for accessible holes and openings;
- Torque/tension test for graspable components; and
- A requirement that warning labels be permanent.

The ASTM standard's requirements specifically related to hazards posed by bath seats (as discussed in part F of this preamble, the Commission's rule modifies aspects of some of these requirements) include:

- A test for stability performed on a test platform containing both a slip resistant surface and a smooth surface to test whether the bath seat may tip over during use;
- Requirements for restraint systems requiring passive crotch restraint to prevent a child from sliding through front or sides of the seat;
- Static load test to test whether the bath seat may break or become damaged during use;
- A requirement that suction cups (if used) adhere to the bath seat and the surface;
- A leg opening requirement to prevent children from sliding through these openings;
- A leg opening requirement restricting the expansiveness of the seating area to prevent the child from slumping and becoming entrapped in a reclined position; and
- Requirements for warning labels and instruction manual.

D. Incident Data

Since publication of the NPR in the **Federal Register** of September 3, 2009, the CPSC staff identified five new fatalities and five new non-fatal incidents, all of which occurred in 2009. Three deaths and three additional non-

fatal incidents involved bath seat products (not combination infant bath tub-bath seat products) meeting the stability requirements of either F 1967–04 or F 1967–07. One death involved an earlier pre-2004 bath seat product and the remaining death involved a combination infant bath tub-bath seat product that was certified to the 2004 edition of the bath seat and bath ring standard (F 1967–04) but is no longer being produced. (Combination bath tub-bath seat products are no longer covered by F 1967 and will be covered by a new separate infant bath tub-specific standard.) This fatality is not included in the frequency statistics. The data update for the final rule also located additional information enabling CPSC staff to identify two 2005 fatality case reports, previously considered to be independent, as being a single case.

Taking into account these changes in the data, from 1983 through November 30, 2009, there have been 174 reported fatalities involving bath seats, although more fatalities may have occurred because fatality reporting is not considered to be complete for 2006, 2007, 2008, and 2009. All of these fatalities were submersions.

There were 300 non-fatal bath seat incidents reported to CPSC staff in this 1983 through November 30, 2009 time frame. A submersion hazard was identified in 154 of these non-fatal incidents of which 117 were actual submersion incidents. (Submersion is defined as the act of placing, or the condition of being, under water. A submersion hazard indicates that submersion is possible, as a direct result of the incident. An actual submersion is when the victim actually became submerged as a result of the incident.) The remaining 146 reports were non-submersion hazards such as lacerations and limb entrapments.

None of the identifiable products involved in the fatal bath seat incidents were certified to meet ASTM F 1967–08a or its predecessor, ASTM F 1967–07. Four of the non-fatal incidents involved products certified to ASTM F 1967–07, neither of which were submersion hazards, and thus were not life threatening.

Of the 174 fatal incidents, 23 involved products that were identified as being certified to the 2004 version of the ASTM standard. Three of these were due to the arm of the bath seat disengaging from the bath tub. Fifty-four of the non-fatal incidents involved bath seats certified to the 2004 version of the ASTM voluntary standard.

E. Response to Comments on the NPR of September 3, 2009

The Commission received seven comments on the NPR of September 3, 2009. Four comments from individual consumers supported a mandatory safety standard for infant bath seats. In addition, the Commission received three specific comments on various aspects of the NPR. These three comments were from IISG (an international testing laboratory); the Juvenile Products Manufacturers Association (JPMA); and one comment from various consumer groups (Consumers Union, Kids in Danger, and Consumer Federation of America). These comments and the Commission's responses to them are discussed below.

1. Leg Opening Requirement

a. *Comment:* One commenter asked that the rule be clarified to indicate that the torso probe shall be inserted in a straight direction and it is not allowed to be inserted partially and then rotated along some minor axis to make it pass through the hole.

Response: In the NPR, the Commission proposed a change to the voluntary standard that called for the torso probe to be inserted in all orientations of the leg openings to determine if any position can create a slip through and/or entrapment hazard. This change was proposed because the language in the ASTM standard, which stated that the probe should be inserted in the most adverse orientation, was open to interpretation by the person performing the test. The language the commenter suggests would actually make the requirement less restrictive than what is already in the voluntary standard. For this reason, the Commission disagrees with the recommendation.

b. *Comment:* One commenter argued that the proposed change to the leg opening torso probe would not have prevented the two incidents discussed in the NPR when children fit both their legs and hips through a single leg hole of the bath seat. The commenter asserted that reducing the leg opening might exacerbate entrapment and ingress and egress conditions. The commenter believes that the ASTM standard has optimized this probe size, is consistent with other standards that provide similar submarining protection, and should not be changed.

Response: Although in these two incidents children did become entrapped in the leg holes, of more concern is the fact the victims' pelvis and torso were able to penetrate the leg openings. Once the pelvis goes through

the leg hole, the victim is in serious danger of submersion because the waist and upper torso are more malleable and therefore more capable of squeezing through the leg holes. Therefore, contrary to the commenter's characterization of the incidents, the leg holes failed to prevent a potential submersion condition. The infants were not endangered by the entrapment as much as they were endangered by their position during their entrapment. These incidents show a failure in the design of the torso probe and the leg opening test which was developed to prevent the manufacture of leg holes that allow a pelvis to fit through them. As a photograph taken of the actual victim from one of the incidents clearly shows, in that incident the pelvis had fit through the leg opening. The current bath seat torso probe used to test the leg openings was based on probes from other juvenile products that do not normally entail use with wet, naked babies. The data associated with these two incidents suggest that the unique use of a bath seat in a watery, soapy environment requires a smaller probe. Reducing the size of leg openings by making the torso probe more rounded at the corners and slightly smaller will prevent future submersion incidents.

The issue of entrapment during ingress and egress is irrelevant to the leg hole opening test method. The Commission is aware that consumers have encountered difficulties with getting infants in and out of some models of bath seats currently sold in the United States. However, the size and shape of the leg hole opening is only one factor in the overall design of a bath seat's occupant retention space. Such features as the shape of the seat, the slope of the supports, and the thickness and the type of materials used to make the bath seat are not determined by the performance requirements of the standard. The leg hole opening test does not dictate any other dimensional or design requirements for bath seats, leaving the designer ample freedom to design a bath seat that allows easy entry and exit.

c. Comment: One commenter approved of the proposed change to the torso probe and conducting testing in all orientations, but stated that incident data indicate that leg openings on models currently meeting the ASTM standard may still pose this hazard.

Response: The Commission concurs. The Commission's changes to the torso probe are intended to address such incidents.

2. Stability Issues

a. Comment: One commenter states that the pass/fail criteria in the ASTM standard were specifically created to require that both the attachment disengage from the test platform and that the product fail to return to the manufacturer's intended use position after being tested. The commenter asserts that both conditions must be present in order to constitute a failure. The commenter argues that the proposal to consider a tilt angle of 12-degrees or more from the bath seat's initial starting position to be a failure is not indicative of an unsafe condition and "is a departure from the primary intent of the requirement which is to determine if the bath seat tips."

Response: The two parts of the criteria were added to the ASTM standard at different times, and there is no language to suggest that both conditions must be met in order to constitute a failure. If that were the intent, then there would be no need to add the second pass/fail criteria because if the bath seat disengaged from the test platform (condition #1), then obviously it would not return to the manufacturer's intended use position (condition #2). This second condition was added in the 2007 standard to address those situations where a bath seat started tipping, to a degree that could be hazardous, but did not fully disengage from the tub. The Commission's modification to the ASTM standard clarifies the intent, as well as ensuring that a bath seat which significantly tips during the stability test, but returns to a fully upright condition, is not in compliance with the requirement.

b. Comment: The same commenter argues that the 12 degree tilt test "is unrelated to submersion risk and would not reduce the risk of injury and submersion incidences identified in the incident data. The risk of submersion presents itself when the position of the product indicates that the child's head area would be in a compromising position."

Response: CPSC agrees with the last statement presented above which is why the Commission is modifying the ASTM standard to provide a clearer definition of the pass/fail criteria. If the bath seat is tilted, children can slump over, lean over, and expose their faces to the water more easily than if the bath seat is not tilted.

c. Comment: The same commenter states that the 17-pound force used in the stability testing in the ASTM standard was based on the assumption that the older user of a bath seat would apply his/her total weight in the head

location when in a seated position. However, the commenter states, it is more likely that the child would exert only a percentage of his/her total body weight.

Response: According to the rationale in the ASTM standard (Appendix, part X1.17), the original basis for the 17-pound force is that it represents 60 percent of the 95th percentile (27.8 pound) body weight for oldest users (which was for 12 to 15 month old children at the time the requirement was developed), not the child's total body weight. A review of the incident data shows that fatal incidents that occurred in the newer style bath seats (which are designed for children who cannot yet pull themselves to a standing position) involved babies whose weights ranged from 15 to 30 pounds, with at least two of the victims (ages 8 and 9 months) being 30 pounds at the time of their deaths. Thus, it is foreseeable that a child of this size may use the product and, as the commenter recognizes, exert a percentage of his/her body weight. Thus, the 17-pound force is still valid.

d. Comment: The same commenter argues that the Commission's change to the failure definition (adding the 12 degree tilt angle test) would prohibit even "infinitesimal movements" of the bath seat with little affect on safety.

Response: The Commission disagrees that this additional requirement would prohibit infinitesimal movement. The ASTM standard could be interpreted very strictly to not allow any movement or tilt of the bath seat from the original position. By adding the 12 degree tilt limit, the stability test allows bath seats some controlled flexibility.

e. Comment: The same commenter asserts that the 12 degree tilt angle is random and lacks any rationale as to how exceeding this angle could result in a compromising unsafe condition.

Response: In developing this requirement, CPSC staff conducted an analysis looking at various water levels and possible head positions of occupants vs. angles of bath seats to determine what level of tilt was potentially hazardous. In addition, CPSC staff looked at other ASTM standards, such as those for infant bouncer seats and toys which use a 10 degree table or tilt when testing for stability. Lastly, staff acknowledged that the requirement must allow for the ductility of the aluminum rod test fixture combined with some expected ductility or flexing of the bath seat itself. Therefore, the staff conducted testing to determine the maximum level of tilt that might be expected solely due to the flexibility of the bath seat and the test rig. As a result of this work, staff

selected a tilt angle of 12 degrees as the pass/fail criteria to insure passing products will remain in the manufacturer's intended use position.

Thus, the 12 degree angle will allow for some inherent flexibility in the system (the product and the test rig) as a whole, but would fail a bath seat that: (1) Stayed firmly clamped to the bath tub but the bath seat itself experienced significant ductility (*i.e.*, its ability to be fashioned into a new form or drawn out without breaking) or flexibility (12 degrees or more) during the testing; or (2) had a clamping mechanism that lost firm contact with the bath tub and allowed the bath seat to tilt 12 degrees or more during the test.

f. Comment: The same commenter argues that, so long as the product remains attached, the angle at which it may tilt during testing does not affect the safety of the bath seat. The commenter asks, if the product were to reach a 15 degree angle, how would this angle result in an unsafe condition if the product remains attached?

Response: CPSC disagrees with the commenter's assertion that the condition of the product during the test has no bearing on safety. In the test, a 17-pound load is applied and then released. In real life, if a child leans over a bath seat railing, he/she may not be able to sit back upright. Young infants do not have a good sense of balance, and the more the bath seat allows them to tilt forward, the less likely they will be able to return to an upright position. If a child's body remains tilted forward, this could result in his/her face becoming submerged in the water. Once an infant's face is submerged, the infant may not pull his/her face out of the water. Infants may be physically capable of lifting their heads, but they may not do so because they do not recognize the need to do so or because they breathe in a lungful of water before trying to lift their head. Bath seats should never allow an infant's face to be submerged under water. In addition, another argument against allowing any significant tilt during the test is that the more the seat tilts forward, the higher the likelihood for a child to crawl out of the seat. When the seat is far enough forward, even if it has not tipped over, the child can stand (hunched over) on his/her feet with legs still through the leg holes, and this would also make a tilted seat hazardous.

g. Comment: One commenter agreed that the pass/fail criteria in the ASTM stability requirements need clarification, but recommended that the Commission consider any movement from the bath seat's originally fixed position to be a failure.

Response: There are three ways that a bath seat can fail the stability requirement as proposed in the NPR (and finalized in the rule): (1) If the bath seat tips over (and remains tipped over after the test); (2) if any attachment point disengages from (is no longer in contact with) the test platform (bath tub) and the bath seat fails to return to the manufacturer's recommended use position after the test; and (3) if the measured tilt angle during the test ever exceeds 12 degrees.

The first two pass/fail criteria above were already required under the voluntary standard, and the third one was proposed by CPSC as a new additional requirement in the NPR, and is also in the final rule. With regard to the third criteria, there are two different ways in which a bath seat can tilt during stability testing. The first is the tilt that might occur when the bath seat attachment slips or moves from its original fixed position. The second is the tilt that can occur due to the flexibility between all the parts of the bath seat and the bath seat test fixture (the aluminum rod and clamping devices). Depending on the product, it is possible to have both factors contribute to the tilt, or just have the second factor contribute to the tilt.

There is no way to eliminate the flexibility of the system (the bath seat and the test fixture) entirely. The flexibility of the aluminum rod itself can result in a two degree tilt. When the clamping fixtures and then the expected flexibility of the plastic used in the product are added, there is inherent flexibility in the system that cannot be totally eliminated. A tilt test must allow for this flexibility among all the components of the system. Twelve degrees allows for some practical amount of flexibility that is inherent in a bath seat and the test rig, but is still not a significant tilt angle that might compromise the safety of the occupant.

3. Changes to Test Platform Preparation

Comment: One commenter stated that, while it agrees with the application of the soap solution inside and outside of the tub, it believes that the soap solution should be applied once the product has been installed, if manufacturers present this as a prerequisite to use in instructional literature because clamping mechanisms rely on a clean tub side surface for effectiveness.

Response: Regardless of instructional literature or warnings, it is foreseeable that caregivers will install the bath seat on a wet and soapy tub; therefore, bath seats should be tested under such conditions.

4. Weighing the Seat Down

Comment: One commenter recommended adding a statement requiring removal of the weight once the seat is flooded to eliminate the potential for a counterweight to be included during the test.

Response: The Commission agrees with this comment and has included such a statement in the final rule.

5. Maximum Water Level

Comment: One commenter recommended that all bath seats be labeled to indicate a maximum water level to be used. The comment stated that, because 96% of all deaths, injuries, and other incidents involve bath seats used in water depths greater than one or two inches, the fill line demarcation should be specified at depths of no greater than two inches.

Response: The Commission is concerned that a water line could imply a safe water level. However, children can drown in very little water. In addition, because of various bath seat designs, some of which may elevate the bath seat, two inches of water in the tub can correspond to a water level insufficient to cover the occupant's legs. Thus, the maximum water level recommended would change based on the design of the bath seat, and would not necessarily reflect a "safe level". The Commission believes that the ASTM wording required in the user instruction, "Babies can drown in as little as 1 inch of water. ALWAYS bathe your infant using as little water as necessary," describes the risk associated with any level of water in a more accurate manner. If there was a water line indicator that could visually express the increasing risk with increasing water depth without implying that a shallow level was "safe," then CPSC staff may agree with the suggestion. At this time, CPSC staff does not believe a maximum water level requirement should be added to the standard, but does believe it is something that manufacturers could consider for their products. CPSC staff will continue to monitor this issue and the Commission could add such a requirement in the future if it is feasible.

6. Incident Data

Comment: One comment notes that the numbers of fatalities stated in the NPR do not reflect the increased fatality rate of recent years. Although the 171 reported fatalities involving bath seats from 1983 through 2008 represents an average of 6.6 reported deaths per year over the 26 year period, an analysis of the most recent years for which there is

complete data (1998 through 2007) shows an average of 9.7 reported deaths per year—nearly 50 percent more than stated. The commenter notes that, in comparison, baby bath tubs (a popular alternative) showed an average fatality rate of only 1.7 deaths per year during this same time period.

Response: Some fatalities in recent years involved older products. Caution should be used in any analysis since this product, its standards, and markets have changed significantly over the years. Comparisons between bath seats and infant bath tubs are not straightforward due to differences in the product and target population. Also, incidents are voluntarily reported and represent a minimum count. An updated memorandum of incident data was provided as part of the briefing package for the final rule.

7. Risks Related to Bath Seats and Risks Related to Bath Tubs

Comment: The same commenter noted that comparing the risks related to bath seats and those related to bath tubs indicates that the ASTM F 1967 standard has not been effective in reducing infant deaths in bath seats and that bath seats are inherently more dangerous than infant bath tubs.

Response: Risk analysis is very difficult to perform with these products due to changes in the market, standards, and product. Without accurate usage data, it was not possible for CPSC staff to perform this analysis. Comparisons between bath seats and infant bath tubs are not straightforward due to differences in the product and target population. Based on the ownership data that is available for infant bath seats and infant bath tubs, it is clear that infant bath tubs are far more prevalent than infant bath seats. It is also clear that many of those surveyed own both products, possibly using them at different stages in their child's development. It is also apparent that ownership rates for bath seats increased substantially between 1993 and 2002, but have since dropped off. In 2004, the ASTM standard was significantly modified (with additional changes made in 2007 and 2008), which means that determining the effectiveness of the voluntary standard requires examining the incidents with pre-2004 infant bath seats and comparing them to incidents involving post-2004 bath seats—in particular those that comply with the voluntary standard. Therefore, looking at only the number of annual incidents is insufficient to evaluate the voluntary standard's effectiveness or to evaluate its likely effectiveness, were it mandatory.

8. Unattended Bath Seats

Comment: One commenter stated that the bath seat standard must address the primary hazard pattern with these products—leaving an infant unattended—and encouraged the CPSC to “explore technology to ensure that it would be difficult to use a bath seat unless a caregiver is in close proximity to the product.”

Response: The Commission is open to suggestions to overcome the tendency of caregivers to feel confident leaving children unsupervised in bath seats. To date, no practical solutions to this serious problem have been developed, except for warning labels, which were last strengthened in the ASTM voluntary standard in 2007.

9. CPSIA Process

a. *Comment:* One commenter stated that the Commission “should not modify existing effective standards unless it can clearly substantiate on the record before it that such changes will provide a demonstrable reduction of injury.” The commenter noted that the ASTM standard was originally published in 1999 and has undergone several revisions since then through the ASTM subcommittee and task group process and that CPSC has participated in this process. The commenter states that it sees “little value in revising the current requirements in this standard by using the NPR regulatory process” and is “concerned that the imposition of additional requirements without demonstrable evidence that they will both enhance bath safety and not create unintended entrapment related hazards, will restrict the availability of potentially lifesaving products.”

Response: Section 104(b) of the CPSIA requires the Commission to use the notice and comment rulemaking process under the Administrative Procedure Act to promulgate consumer product safety standards for durable infant or toddler products. The CPSIA directs the Commission to issue a rule that is “substantially the same as” the applicable voluntary standard or “more stringent than” the voluntary standard if the more stringent standard “would further reduce the risk of injury associated with the product.” See section 104(b)(1)(B) of the CPSIA. The statute does not require that the Commission, in the commenter's words, “clearly substantiate on the record before it that such change will provide a demonstrable reduction in injury.” Section 104 of the CPSIA takes durable infant or toddler products out of the Commission's usual rulemaking procedure and all of the findings that

would be required under sections 7 and 9 of the Consumer Product Safety Act (“CPSA”). For these products, Congress wanted “the highest level of safety for such products that is feasible.” See section 104(b)(2) of the CPSIA. The Commission recognizes that the ASTM standard has been in place for numerous years and has been refined through ASTM's standard-setting process. Nevertheless, incidents continue to occur. Under the mandate of section 104 of the CPSIA, the Commission is promulgating more stringent requirements where necessary to address certain design features that CPSC staff believes contribute to some of these continuing deaths and torso entrapments. The staff has conducted testing and performed analyses to support the requirements that are different from the ASTM requirements and that it believes will reduce the risk of injury from infant bath seats.

b. *Comment:* The same commenter states that it believes “the most streamlined approach to following the primary congressional mandate that standards required to be developed are to be ‘substantially the same as’ applicable voluntary standards, would be to adopt a regulation that wholly adopts the existing ASTM standard, with the ability to subject it to the ASTM update and review process. CPSC can assure itself veto authority as part of an implementing regulation, which provides it with the ability to restrict diminution of effective ASTM standard provisions, similar to the authority applicable under CPSIA Section 106, as a check to changes that reduce stringent protections.” The commenter suggests that CPSC adopt ASTM F 1967–08a as a consumer product safety standard issued by the Commission under section 9 of the CPSA and that any additional changes to the pending ASTM standard be submitted to the ASTM standard setting process. The commenter states, “this process could also incorporate a provision by rule that a reservation of right to the CPSC to object to any subsequent revisions to the ASTM Standard, similar to that afforded under CPSIA Section 106(g).”

Response: The standard the Commission proposed for infant bath seats incorporates by reference most of ASTM F 1967–08a with a few modifications to strengthen the standard. Section 104(b) of the CPSIA sets forth the procedure for these standards for durable infant or toddler products, and it is different from what Congress provided in section 106 of the CPSIA. It is doubtful that the Commission, by rule, could change the procedure Congress provided for rules

under section 104 of the CPSIA to the one Congress provided for rules under section 106 of the CPSIA.

F. Assessment of Voluntary Standard ASTM F 1967–08a and Description of the Final Rule

1. Section 104(b) of the CPSIA: Consultation and CPSC Staff Review

Section 104(b) of the CPSIA requires the Commission to assess the effectiveness of the voluntary standard in consultation with representatives of consumer groups, juvenile product manufacturers and other experts. This consultation process began in October 2008 during the ASTM subcommittee meeting regarding the ASTM infant bath seat voluntary standard. The Commission has reviewed the incident data and the ASTM F 1967–08a standard and conducted testing on bath seats to assess the ASTM standard.

Consistent with section 104(b) of the CPSIA, this rule establishes a new 16 CFR part 1215, “Safety Standard for Bath Seats.” The new part incorporates by reference the requirements for bath seats in ASTM F 1967–08a with certain changes to specific provisions to strengthen the ASTM standard as discussed below. These modifications are almost identical to the changes the Commission proposed in the NPR of September 3, 2009. Differences from the NPR are noted in the discussion below.

2. Description of the Final Rule, Including Changes to the ASTM Standard’s Requirements

While most requirements of the ASTM standard are sufficient to reduce the risk of injury posed by bath seats, the Commission has determined to modify several provisions in the standard to make them more stringent and further reduce the risk of injury and to clarify the test procedures. The following discussion describes the final rule, including changes to the ASTM requirements, and notes any changes from the NPR. In addition, some editing and formatting changes have been made which make the final text different from the NPR. These changes were made at the request of the Office of the **Federal Register** and do not alter the substance of the rule.

a. Scope (§ 1215.1)

The final rule states that part 1215 establishes a consumer product safety standard for infant bath seats manufactured or imported on or after a date which would be six months after the date of publication of a final rule in the **Federal Register**.

The Commission received no comments on this provision in the NPR and is finalizing it without change.

b. Incorporation by Reference (§ 1215.2(a))

Section 1215.2(a) explains that, except as provided in § 1215.2(b), each infant bath seat must comply with all applicable provisions of ASTM F 1967–08a, “Standard Consumer Safety Specification for Infant Bath Seats,” which is incorporated by reference. Section 1215.2(a) also provides information on how to obtain a copy of the ASTM standard or to inspect a copy of the standard at the CPSC.

The Commission received no comments on this provision in the NPR and is finalizing it without change.

c. Definition of Bath Seat (§ 1215.2(b)(1)(i))

In the NPR, the Commission proposed changing the definition of bath seat to the definition in a previous NPR the Commission had issued in 2003—“an article that is used in a bath tub, sink, or similar bathing enclosure and that provides support, at a minimum, to the front and back of a seated infant during bathing by a caregiver * * *.”

The Commission received no comments on this provision and is finalizing it without change.

d. Stability Requirement

Limiting the tilt of the bath seat (§ 1215.2(b)(2)(i), (b)(4)(i), and (b)(5)(i)). As discussed in the preamble to the proposed rule (74 FR at 45720 through 45721), when testing bath seats, CPSC staff found that the clamping mechanism on the JPMA-certified bath seat lifted from the side of the tub and continued to tip when force was applied. The clamp did not disengage from the tub, but the arm rest contact points were no longer in contact with the tub surface. This situation allows for possible misinterpretation of the ASTM standard’s pass/fail criteria because the bath seat tilted from its original position while the clamp remained attached to the side of the tub. Moreover, this scenario could present a hazard to an infant using a bath seat. As explained in greater detail in the response to comments in section E of this preamble above, with the bath seat in this position an infant could submerge his/her face in the water, and the tilt of the seat could increase the likelihood the infant will crawl out of the seat. Thus, the NPR proposed a requirement to limit the allowable tilt angle of the bath seat during the stability test. This modification is added in several places of the ASTM standard: To section 6.1,

between sections 7.4.2.2 and 7.4.2.3, and between sections 7.4.2.3 and 7.4.2.4. The Commission proposed that a bath seat capable of tilting 12 degrees or more during testing be considered a failure. This limit was determined after measuring, and allowing for the flexibility of, current products. CPSC staff also considered other ASTM standards such as those for infant bouncer seats and toys. These standards use a 10 degree table or tilt when testing stability, and so the Commission proposed a tilt angle just above that level.

The final rule retains the 12 degree tilt limit. (We discussed comments relating to stability at part E of this preamble.)

The final rule also clarifies the language in section 6.1 of the ASTM standard to make it consistent with the definition of bath seat. This is a change from the NPR. Thus, the final rule removes the beginning phrase in section 6.1: “for bath seats which provide support for an occupant’s back and support for the sides or front of the occupant or both.” Given the definition of bath seat in the final rule, this phrase is redundant, and the final rule, therefore, eliminates it.

Clarifying the order of steps in the stability test (§ 1215.2(b)(3)). The final rule retains other proposed changes clarifying the order of steps to be performed when conducting the stability test. The Commission proposed re-ordering the steps specified in the ASTM standard for preparing the test surface and installing the bath seat to clarify that the test platform should be flooded before installing the bath seat.

Test solution application (§ 1215.2(b)(3)(i)(B)). The Commission proposed that a test solution be applied to all areas where the product may make contact while in use. As explained in the NPR’s preamble (74 FR at 45721), the ASTM standard requires that a soapy test solution “thoroughly saturate the coverage area” which is defined in the ASTM standard as any internal surface of the tub well or tub bottom that makes contact with the product. In its testing of bath seats, CPSC staff found that spraying the soap solution on the top and outer surface contact points as well as the interior surfaces affected the final position of the bath seat and therefore could affect the results of the test. The Commission recognizes that the outside of a tub may become wet, and this may affect the ability of a bath seat’s attachment arm to remain stable. The final rule retains this requirement. (We discussed comments relating to test platform preparation at part E of this preamble.)

Measuring water levels (§ 1215.2(b)(3)(i)(D)). When testing the stability of bath seats, CPSC staff noted that it can be difficult to obtain accurate water level measurements because the unoccupied bath seat may float when the test platform is flooded. To address this, the Commission proposed to add a clarifying statement: “For the purpose of measuring the water level, the product’s seating surface can be temporarily weighed down to prevent the seat from floating.”

In response to a comment to the NPR (see part E of this preamble), the final rule retains this change, but also adds the following clarifying language: “The weight shall be removed following the measurement of the water level and prior to conducting the test.”

e. Leg Opening Requirement (§ 1215.2(b)(6)(i) Through (8))

According to recent incident reports, children have fit both legs and their hips through a single leg hole of a bath seat that complies with the ASTM standard. The torso probe specified in the ASTM standard used to test the size of the leg openings is not sufficiently analogous to the human infant in this wet environment. This has resulted in a child’s torso fitting through a leg hole when the ASTM torso probe does not. The Commission proposed decreasing the length of the vertical and horizontal axes of the wood torso probe specified in the ASTM standard by approximately five percent and rounding the corners of the probe resulting in a 1.45” radius rather than the current 1” radius size of the probe. To accomplish this, the Commission proposed modifications to Figure 4 in the ASTM standard that shows the torso probe. As explained in the preamble to the NPR (see 74 FR at 45721) and in the response to comments in section E above, the Commission believes that changes in the test probe would not restrict the utility of the product, but would still allow many possible designs for bath seats, even ones which would accommodate large children.

The NPR also proposed changing (at § 1215.2(b)(6)(i) and (7)(i)) the ASTM standard’s instruction in section 7.7.1 and 7.7.2 of the ASTM standard to insert the test probe “* * * in the most adverse orientation into each opening.” The Commission proposed changing this language because the terms “the most” appearing with respect to adverse orientation is open to interpretation. The final rule retains the proposed wording that the probe needs to be inserted “in *all* orientations to determine if any position can create a slip through and/or entrapment hazard.”

f. Size of Warning Label Requirement (§ 1215.2(b)(9) and (10))

According to the incident data, one hazard associated with almost all of the deaths that are reported involving bath seats is caregivers leaving children unattended in the bath seat. For example, of the 23 deaths reported from 2004–2009, where the bath seat product was certified to meet the stability requirements of ASTM F 1967–04, 21, or more than 91%, occurred when caregivers reported leaving the child for as little as 1 minute. (This data, collected by CPSC staff only reflects full reporting of deaths through 2006.)

While ASTM 1967–07 updated the language of the warning label (see 1967–07 section 8.1), the size of the warning label has not changed in any of the prior four updates to this standard. (The previous standards required letters not less than 0.2 in. (5 mm) in height for the safety alert symbol, the signal word, and all other words that are all capital letters, with all remaining text not less than 0.1 in. (2.5 mm) in height.) The warning label explains, among other things, caregivers should “ALWAYS keep baby within adult’s reach.” The final rule doubles the size of this warning in order to raise the visibility of this vital information to caregivers.

G. Effective Date

In the NPR, the Commission proposed that the standard would become effective six months after publication of a final rule. The Commission received no comments on the proposed effective date. The final rule provides that the rule will become effective six months after publication and thus will require that bath seats manufactured or imported on or after that date must meet this standard.

H. Regulatory Flexibility Act

The Regulatory Flexibility Act (“RFA”) generally requires that agencies review final rules for their potential economic impact on small entities, including small businesses. 5 U.S.C. 604.

Three firms currently market infant bath seats in the United States: One large domestic manufacturer, one small foreign manufacturer and one small domestic importer. All of these companies’ bath seats are expected to require modifications to meet the bath seat standard. This final regulatory flexibility analysis focuses on the small domestic importer.

As noted in the NPR preamble (see 74 FR at 45722), the effect of the regulation on importers of bath seats would be felt indirectly, requiring a shift in suppliers

rather than the design and production of a different product. The impact on the small domestic importer is expected to be small. The small domestic importer would most likely respond by discontinuing the import of its non-complying bath seat, either replacing the bath seat with a complying product or another juvenile product (the firm currently imports approximately 165 juvenile products, of which three are substitutes for its imported bath seat).

Hence, even if the cost of developing a compliant product did prove to be a barrier for individual small firms, the loss of bath seats as a product category is expected to be minor and would likely be mitigated by increased sales of competing products, such as multi-stage infant bathtubs, or entirely different juvenile products.

I. Environmental Considerations

The Commission’s regulations provide a categorical exclusion for the Commission’s safety standards from any requirement to prepare an environmental assessment or an environmental impact statement as they “have little or no potential for affecting the human environment.” 16 CFR 1021.5(c)(1). This rule falls within the categorical exclusion.

J. Paperwork Reduction Act

Sections 8 and 9 of ASTM F 1967–08 contain requirements for marking, labeling and instructional literature that are considered “information collection requirements” under the Paperwork Reduction Act, 44 U.S.C. 3501–3520. In a separate notice in this issue of the **Federal Register**, the Commission is publishing a notice requesting comments on this collection of information.

K. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a “consumer product safety standard under [the CPSA]” is in effect and applies to a product, no State or political subdivision of a State may either establish or continue in effect a requirement dealing with the same risk of injury unless the State requirement is identical to the Federal standard. (Section 26(c) of the CPSA also provides that States or political subdivisions of States may apply to the Commission for an exemption from this preemption under certain circumstances.) Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules,” thus implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section

104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

L. Certification

Section 14(a) of the 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). Such certification must be based on a test of each product or on a reasonable testing program or, for children's products, on tests on a sufficient number of samples by a third party conformity assessment body recognized by the Commission to test according to the applicable requirements. As discussed above in section K, section 104(b)(1)(B) of the CPSIA refers to standards issued under that section, such as the rule for infant bath seats established in this notice, as "consumer product safety standards." By the same reasoning, such standards would also be subject to section 14 of the CPSA. Therefore, any such standard would be considered to be a consumer product safety rule to which products subject to the rule must be certified.

Because infant bath seats are children's products, they must be tested by a third party conformity assessment body accredited by the Commission. The Commission is issuing a separate notice of requirements to explain how laboratories can become accredited as a third party conformity assessment bodies to test to this new infant bath seat safety standard. (Infant bath seats also must comply with all other applicable CPSC requirements, such as the lead content requirements of section 101 of the CPSIA and potentially the phthalate content requirements in section 108 of the CPSIA should the bath seat incorporate a toy component, the tracking label requirement in section 14(a)(5) of the CPSA, and the consumer registration form requirements in section 104 of the CPSIA.)

List of Subjects in 16 CFR 1215

Consumer protection, Incorporation by reference, Imports, Infants and children, Labeling, Law enforcement, and Toys.

■ Therefore, the Commission amends Title 16 of the Code of Federal Regulations by adding part 1215 to read as follows:

PART 1215—SAFETY STANDARD FOR INFANT BATH SEATS

Sec.

1215.1 Scope.

1215.2 Requirements for infant bath seats.

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

§ 1215.1 Scope.

This part 1215 establishes a consumer product safety standard for infant bath seats manufactured or imported on or after December 6, 2010.

§ 1215.2 Requirements for infant bath seats.

(a) Except as provided in paragraph (b) of this section, each infant bath seat shall comply with all applicable provisions of ASTM F 1967–08a, Standard Consumer Safety Specification for Infant Bath Seats, approved November 1, 2008. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; telephone 610–832–9585; www.astm.org. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) Comply with the ASTM F 1967–08a standard with the following additions or exclusions:

(1) Instead of complying with section 3.1.1 of ASTM F 1967–08a, comply with the following:

(i) 3.1.1 *Bath seat, n*—an article that is used in a bath tub, sink, or similar bathing enclosure and that provides support, at a minimum, to the front and back of a seated infant during bathing by a caregiver. This does not include products that are designed or intended to retain water for bathing.

(ii) [Reserved]

(2) In addition to section 6.1 of ASTM F 1967–08a, comply with the following:

(i) 6.1 *Stability*—* * * If any time during the application of force, the seat is no longer in the initial 'intended use position' and is tilted at an angle of 12 degrees or more from its initial starting position, it shall be considered a failure.

(ii) [Reserved]

(3) Instead of complying with section 7.4.1. of ASTM F 1967–08a, comply with the following:

(i) 7.4.1 *Surface Preparation and Product Installation:*

(A) 7.4.1.1 Prepare the test surface as follows:

(B) 7.4.1.2 For all surfaces on the test platform where the product makes contact, clean the coverage area (as defined in 7.4.3.3) with a commercial cleaner intended for bath tubs, then wipe the coverage area with alcohol and allow to dry.

(C) 7.4.1.3 Using a spray bottle containing a 1:25 mixture of test solution (see table 1) to distilled water, immediately before each test run, thoroughly saturate all test platform surfaces above the water line where the product makes contact and where contact might be expected.

(D) 7.4.1.4 Flood the test platform with clear water that is at an initial temperature of 100 to 105° F (37.8 to 10.6° C) and a depth of 2 in. (51 mm) above the highest point of the occupant seating surface. Install the product according to the manufacturer's instructions onto the test platform specified in 7.4.3. For the purpose of measuring the water level, the product's seating surface can be temporarily weighed down to prevent the seat from floating. The weight shall be removed following the measurement of the water level and prior to conducting the test.

(ii) [Reserved]

(4) After section 7.4.2.2 and before section 7.4.2.3 of ASTM F 1967–08a, comply with the following:

(i) Rigidly install an inclinometer to the test bar above the location where force is to be applied. The weight of the inclinometer and the fastening method shall be less than or equal to 2.2 pounds. The inclinometer shall have a measurement tolerance of less than or equal to 0.5 degrees. Measure and record the pre-test angle of the test bar.

(ii) [Reserved]

(5) Between section 7.4.2.3 (including Note 2) and section 7.4.2.4 of ASTM F 1967–08a, comply with the following:

(i) Measure and record the maximum angle of the test bar during the application of the 17.0 lbf load. Calculate the absolute value of the Change in Angle in degrees. Change in Angle = (Angle measured during test)—(Angle measured pre-test).

(ii) [Reserved]

(6) Instead of complying with the first sentence in section 7.7.1 of ASTM F 1967–08a, comply with the following:

(i) 7.7.1 With the bath seat in each of the manufacturer's recommended use position(s), insert the tapered end of the Bath Seat Torso Probe (see Fig. 4) in all orientations into each opening. * * *

(ii) [Reserved]

(7) Instead of complying with the first sentence in section 7.7.2 of ASTM F 1967–08a, comply with the following:

(i) 7.7.2 With the bath seat in each of the manufacturer's recommended use position(s), insert the tapered end of the

Bath Seat Shoulder Probe (*see* Fig. 6) in all orientations into each opening.
* * *

(ii) [Reserved]
(8) Instead of Figure 4 of ASTM F 1967–08a, use the following:

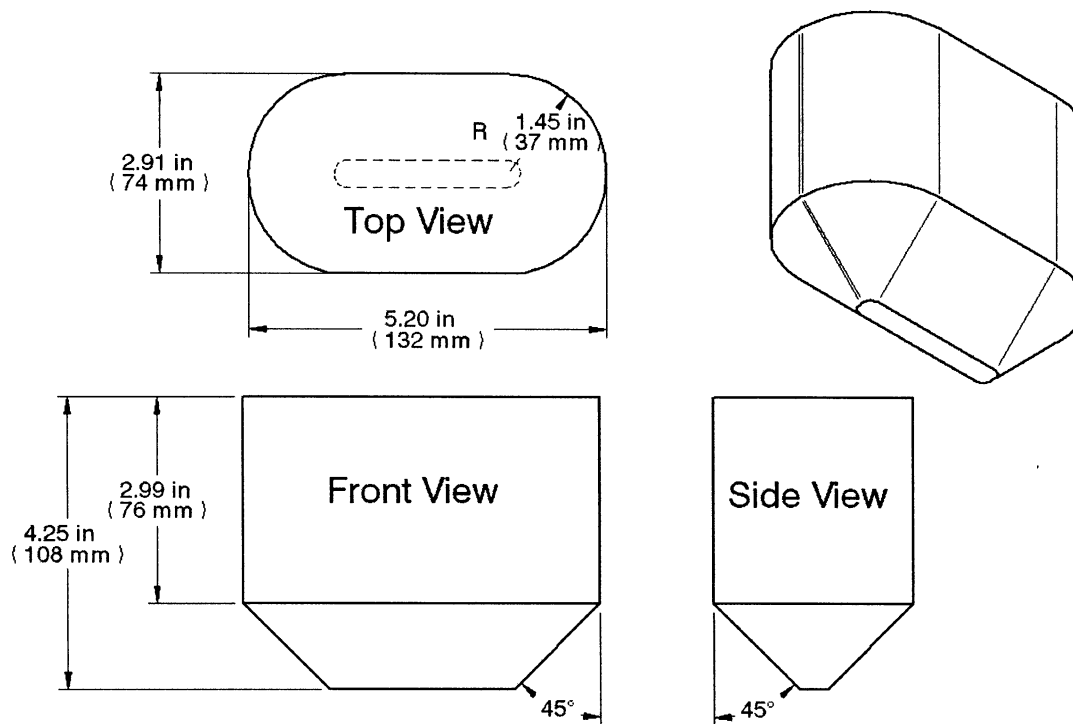


Figure 4: Modified Bath Seat Torso Probe

(9) Instead of complying with section 8.1.1 of ASTM F 1967–08a, comply with the following:

(i) 8.1.1 The safety alert symbol, the signal word, and all other words that are all capital letters shall be in sans serif type face with letters not less than 0.4 in. (10 mm) in height, with all remainder of the text not less than 0.2 in. (5 mm) in height. Specified warning(s) on both the product and the package shall be distinctively separated from any other wording or designs and shall appear in the English language at a minimum. They shall also be highly visible and in a contrasting color to the background on which they are located.

(ii) [Reserved]

(10) In addition to complying with section 8.2 of ASTM F 1967–08a, comply with the following:

(i) 8.2 * * * The specified warnings may not be placed in a location that allows the warning(s) to be obscured or rendered inconspicuous when in the manufacturer's recommended use position.

(ii) [Reserved]

Dated: May 25, 2010.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

25 CFR Part 900

DEPARTMENT OF THE INTERIOR

25 CFR Part 1000

Bureau of Indian Affairs

25 CFR Part 900

Indian Health Service

25 CFR Part 900

RIN 1076–AE86

Indian Self-Determination Act Contracts and Annual Funding Agreements—Appeal Procedures

AGENCIES: Bureau of Indian Affairs, Interior; Indian Health Service, Health and Human Services.

ACTION: Final rule.

SUMMARY: The Bureau of Indian Affairs (BIA) in the Department of the Interior (DOI) and the Indian Health Service (IHS) in the Department of Health and