

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 375

RIN 3064-AG07

Recordkeeping for Custodial Accounts; Extension of Comment Period

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: On October 2, 2024, the FDIC published in the **Federal Register** a proposed rule that would strengthen FDIC-insured depository institutions' (IDI) recordkeeping for custodial deposit accounts with transactional features and preserve beneficial owners' and depositors' entitlement to the protections afforded by Federal deposit insurance. The proposed rule provided for a 60-day comment period, which closes on December 2, 2024. The FDIC has determined that an extension of the comment period until January 16, 2025, is appropriate. This action will allow interested parties additional time to analyze the proposal and prepare comments.

DATES: The comment period for the proposed rule that published at 89 FR 80135 (October 2, 2024) is extended. Comments must be received on or before January 16, 2025.

ADDRESSES: You may submit comments on this document using any of the following methods:

- **Agency Website:** <https://www.fdic.gov/resources/regulations/federal-register-publications/>. Follow the instructions for submitting comments on the agency website.

- **Email:** comments@FDIC.gov. Include RIN 3064-AG07 in the subject line of the message.

- **Mail:** James P. Sheesley, Assistant Executive Secretary, Attention: Comments—RIN 3064-AG07, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

- **Hand Delivery:** Comments may be hand delivered to the guard station at the rear of the 550 17th Street NW Building (located on F Street) on business days between 7 a.m. and 5 p.m.

- **Public Inspection:** Comments received, including any personal information provided, may be posted without change to <https://www.fdic.gov/resources/regulations/federal-register-publications/>. Commenters should submit only information that the commenter wishes to make available publicly. The FDIC may review, redact, or refrain from posting all or any portion of any comment that it may deem to be inappropriate for publication, such as irrelevant or obscene material. The FDIC may post only a single representative example of identical or substantially identical comments, and in such cases will generally identify the number of identical or substantially identical comments represented by the posted example. All comments that have been redacted, as well as those that have not been posted, that contain comments on the merits of the notice will be retained in the public comment file and will be considered as required under all applicable laws. All comments may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Division of Resolutions and Receiverships: Shivali Nangia, Assistant Director, 972-761-2945, SNangia@FDIC.gov; Cathy K. Davis, Chief, Claims, 972-761-2336, CDavis@FDIC.gov. Division of Depositor and Consumer Protection: Luke H. Brown, Associate Director, Supervisory Policy, 202-898-3842, LuBrown@FDIC.gov; Meron Wondwosen, Assistant Director, Supervisory Policy, 202-898-7211, MeWondwosen@FDIC.gov; Edward J. Hof, Senior Policy Analyst, 202-898-7213, EdwHof@FDIC.gov. Legal Division: Vivek V. Khare, Senior Counsel, 202-898-6847, VKhare@FDIC.gov; James S. Watts, Counsel, 202-898-6678, JWatts@FDIC.gov.

SUPPLEMENTARY INFORMATION: On October 2, 2024, the FDIC published in the **Federal Register** (89 FR 80135) a document proposing requirements to strengthen IDI recordkeeping for custodial deposit accounts with transactional features. The proposed rule stated that the comment period would close on December 2, 2024. The FDIC has received requests to extend the

comment period. After reviewing the requests, the agency finds it appropriate to grant the requests and extend the comment period by an additional 45 days. An extension of the comment period will provide additional opportunity for the public to prepare comments to address the matters raised by the proposed rule. Therefore, the FDIC is extending the comment period for the recordkeeping-related proposed rule from December 2, 2024, to January 16, 2025.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on November 15, 2024.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2024-27097 Filed 11-19-24; 8:45 am]

BILLING CODE 6714-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1250

[CPSC Docket No. CPSC-2024-0039]

Mandatory Toy Safety Standards: Requirements for Neck Floats

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Improvement Act of 2008 (CPSIA) mandates that ASTM F963 shall be a mandatory toy safety standard. This toy safety standard sets forth only minimal labeling requirements for aquatic toys such as neck floats. The U.S. Consumer Product Safety Commission (CPSC or Commission) proposes to establish new performance and revised labeling requirements to address potentially deadly hazards associated with neck floats. The Commission also proposes to amend CPSC's list of notice of requirements (NORs) to include neck floats.

DATES: Submit comments by January 21, 2025. Submit comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature requirements by January 21, 2025.

ADDRESSES: Submit all comments, identified by Docket No. CPSC-2024-0039, 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. 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. CPSC typically does not accept comments submitted by email, except as described below.

Mail/Hand Delivery/Courier/Confidential Written Submissions: CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. You may, however, submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone: (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 email 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-2024-0039, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Zachary Goldstein, Project Manager, Division of Mechanical Engineering, Directorate for Laboratory Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone 301-987-2472; email: zgoldstein@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

Section 106(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) made ASTM

International’s (ASTM) voluntary standard for toys, ASTM F963–07, *Standard Consumer Safety Specification for Toy Safety* (except sections 4.2 and Annex 4), a mandatory safety standard for toys beginning 180 days after the enactment date of the CPSIA. 15 U.S.C. 2056b(a). The CPSIA states that ASTM F963 shall be considered a consumer product safety standard issued by the Commission under section 9 of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2058). Since 2009, CPSC has enforced ASTM F963 as a mandatory standard for toys.^{1,2} In 2017, the Commission codified the mandatory toy standard in 16 CFR part 1250, Safety Standard Mandating ASTM F963 for Toys, and incorporated by reference the newly revised ASTM standard at that time, ASTM F963–16. 82 FR 8989 (Feb. 2, 2017). Most recently, on January 18, 2024, the Commission updated part 1250 to incorporate by reference a 2023 revision, ASTM F963–23. 89 FR 3344.

ASTM F963–23 and 16 CFR part 1250 contain requirements for a category of toys known as “aquatic toys.” Section 3.1.4 of ASTM F963–23 defines an aquatic toy as an “an article, whether inflatable or not, intended to bear the mass of a child and used as an instrument of play in shallow water. This does not include bath toys, beach balls, and United States Coast Guard-approved life saving devices.” 16 CFR part 1250.

Section 5.4 of ASTM F963–23 (which is an element of the mandatory standard pursuant to CPSIA section 106 and 16 CFR part 1250) contains labeling requirements for “aquatic toys,” which include neck floats. The ASTM requirements are intended to communicate to the consumer that an aquatic toy is not a lifesaving device and to warn against leaving a child unattended while using the flotation device. However, as discussed in section IV of this preamble, ASTM F963–23 does not establish adequate requirements specific to neck floats because it does not include any performance requirements for these toys. Incident data, described in section III of this preamble, demonstrate that children have suffered drowning injuries and deaths associated with the use of neck floats. Accordingly, as described in section IV of this preamble,

¹ Since the CPSIA’s enactment in 2008, ASTM revised F963 five times: ASTM F963–08, ASTM F963–11, ASTM F963–16, ASTM F963–17, and ASTM F963–23 (approved August 1, 2023).

² Section 3.1.92 of ASTM F963–23 defines a toy as: “Any object designed, manufactured, or marketed as a plaything for children under 14 years of age.”

neck floats that comply with the labeling requirements in ASTM F963–23 still pose safety hazards.

This notice of proposed rulemaking (NPR) under section 106 of the CPSIA proposes additional requirements in part 1250 to establish a mandatory standard for neck floats which includes performance requirements and improved warning labels. CPSC proposes to define a “neck float” as “an article, whether inflatable or not, that encircles the neck, supports the weight of the child by being secured around the neck (such as by fastening, tightening, or other methods), and is used as an instrument of play in water environments including sinks, baths, paddling pools, and swimming pools, and is intended for use by children up to and including 4 years of age.” Further, this NPR proposes revising the title of part 1250 from “Safety Standard Mandating ASTM F963 for Toys” to “Safety Standards for Toys,” to reflect the inclusion of additional proposed requirements that are not included in the existing requirements in ASTM F963.^{3,4}

The Commission is authorized to issue this NPR pursuant to both sections 106(c) and (d) of the CPSIA, 15 U.S.C. 2056b(c) and (d). Section 106(c) requires the Commission to periodically review and revise its mandatory toy safety standards to ensure that such standards provide the highest level of safety for toys that is feasible. Section 106(d) further requires the Commission to examine and assess the effectiveness of its mandatory toy safety standards in protecting children from safety hazards, and then to promulgate consumer product safety standards that are more stringent than existing the existing standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with such toys. Consistent with the consultation requirement in section 106(d)(1) of the CPSIA, staff has worked with the ASTM F15.22 subcommittee task group since 2009 to update the toy standard. In addition, since August 2021, CPSC staff has been corresponding with the relevant ASTM Subcommittee and task group to discuss hazards associated with neck floats, including by sharing incident data

³ On October 23, 2024, the Commission voted (5–0) to publish this NPR.

⁴ On September 9, 2024, the Commission published an NPR to establish a mandatory standard for water beads, under Section 106(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA). *Safety Standard for Toys: Requirements for Water Beads*, 89 FR 73024. This NPR also proposed to revise the title of part 1250 from “Safety Standard Mandating ASTM F963 for Toys” to “Safety Standards for Toys.”

associated with neck floats as well as staff's recommendation to develop performance requirements to address the hazards identified in the incident data.

Building on staff's continued collaboration with ASTM and in consideration of the incident data, the Commission is issuing this NPR to address four identified hazard patterns associated with neck floats that are not adequately addressed by the current mandatory standard provision addressing aquatic toys. Specifically, the Commission proposes to address the following known hazards: (1) children slipping through the product due to deflation or underinflation; (2) children slipping through the product for reasons other than deflation or underinflation; (3) children slipping through the product due to a restraint system failure; and (4) children submerging in water without slipping through the product. Each of these hazard patterns presents a risk of drowning. The Commission proposes adding performance requirements to part 1250 to address these risks. The NPR also proposes revising labeling requirements for neck floats under part 1250, including mandating warnings on products and instructional literature. Lastly, the Commission is proposing a stockpiling prohibition under part 1250 for neck floats pursuant to section 9(g)(2) of the CPSA. 15 U.S.C. 2058(9)(g)(2).

This NPR provides an overview of staff's assessment and analysis, and it includes the Commission's basis for issuing the proposed rule. For the reasons explained here, the Commission preliminarily determines that the proposed neck float requirements comply with section 106 of the CPSIA because they are more stringent than the current requirements in ASTM F963–23, would further reduce the risk of injury associated with neck floats and would achieve the highest level of safety that is feasible for such products. The Commission seeks comments on these issues.

II. Description of Toys Within the Scope of the Rule

Neck floats are aquatic toys that are typically ring-shaped tubes with discontinuous ends that wrap around a child's neck. This placement is intended to allow the child's head to float above the water while supporting their body. As is the case with other aquatic toys,⁵ this design is intended to allow the

child to float and play in water when a child is incapable of floating on their own.

Neck floats are available as both inflatable and non-inflatable products. Inflatable variants rely on air to provide buoyancy and are generally packaged and distributed while deflated. Caregivers must inflate the neck float prior to their initial use and are generally advised to check and re-inflate the neck float prior to subsequent uses as well. Inflatable neck floats have not typically been sold with an air pump and are generally intended to be inflated by mouth. In contrast, an inherently buoyant neck float likely does not require any additional efforts from the caregiver to ensure that it floats.

Market research indicates that inflatable neck floats are primarily composed of plastic sheeting, typically polyvinyl chloride (PVC) plastic, held together through a process known as PVC welding. This manufacturing process fuses the plastic sheeting together by applying heat that melts the individual sheets (Foreman, 2024). The restraint systems of these neck floats also appear to be joined to the product using PVC welding. Non-inflatable or inherently buoyant neck floats are generally composed of two components, a buoyant internal ring made of open- or closed-cell foam that provides the neck float's shape and flotation, and a fabric cover that encases the foam, typically secured with a zipper, where the restraint systems are stitched into the fabric cover.

Neck floats are advertised for use by infants and toddlers based on minimum/maximum weight and suggested age ranges to identify appropriate product sizes. Most retailers advertise the products for children 0 to 6 months for small sizes, 6 to 18 months for medium sizes, and 2 to 5 years for large sizes. The products generally are marketed for use in bathtubs and pools with direct parental supervision. Retail prices for neck float products intended for children typically range from \$10 to \$60 depending on material type and art design, with inherently buoyant products being more expensive than inflatable products.

Section 3.1.92 of ASTM F963–23 defines a "toy" as "any object designed, manufactured, or marketed as a plaything for children under 14 years of age." Section 3.1.4 ASTM F963–23 defines an "aquatic toy" as "an article, whether inflatable or not, intended to bear the mass of a child and used as an instrument of play in shallow water. This does not include bath toys, beach balls, and United States Coast Guard-approved life saving devices." Neck

floats are subject to the mandatory toy standard as an aquatic toy because they are instruments of play that are designed to allow a child to play in water, including shallow water. In this NPR's proposed rule, the Commission defines a "neck float" as "an article, whether inflatable or not, that encircles the neck, supports the weight of the child by being secured around the neck (such as by fastening, tightening, or other methods), is used as an instrument of play in water environments including sinks, baths, paddling pools and swimming pools, and is intended for use by children up to and including 4 years of age."

Neck floats include: (1) inflatable neck floats; (2) inherently buoyant (non-inflatable) neck floats; and (3) neck floats that use a combination of inflatable and inherently buoyant components. All other products that are not neck floats, under the proposed definition of "neck float" in § 1250.5(b), are outside the scope of this rule. Life-saving flotation devices regulated by the Coast Guard, including those that attach to the neck of a user, are also outside the scope of this rule.

III. Incident Data and Hazard Patterns

The incidents and hazard patterns associated with neck floats are based on CPSC's Consumer Product Safety Risk Management System (CPSRMS). CPSRMS includes data primarily from three groups of sources: incident reports, death certificates, and in-depth follow-up investigation reports (IDIs). 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. The CPSRMS incidents identified for neck floats occurred from January 1, 2019, through January 25, 2024; however, the National Electronic Injury Surveillance System (NEISS) database contained no incident reports during that time period referencing neck floats.

From January 2019 through January 2024, staff identified 115 incidents in CPSRMS associated with the use of neck floats. Two of these incidents resulted in a fatality, two incidents led to hospitalization, five incidents led to

⁵ Section 3.1.4, in the definition of "Latex balloon," of ASTM F963–23 includes a list of toys that are used in aquatic activities such as rafts, water wings, swim rings, or other similar items.

emergency department (ED) treatment, and one incident led to care by a medical professional. The remaining 105 incidents identified in CPSRMS noted home care, possible but uncertain medical treatment, or the level of care was not reported. In many of the non-fatal incidents, drowning appears to have been averted only due to quick action by a caregiver to rescue the infant. Of the reported incidents that indicate a child's age, children's ages range from 17 days to 12 months old. Where specified, most incidents occurred in home bathtubs, though some reports indicated use in pools.

A. Overview of Neck Float Hazards

Based on staff's assessment of the incident data reported in CPSRMS and publicly available consumer-uploaded pictures and videos of the product in use, the Commission determines that neck floats pose a risk of drowning that can result in severe injury or death because of slipping through a neck float or being submerged in the water while using a neck float.

Drowning is a multiphase process of pathophysiological changes (e.g., asphyxia, electrolyte imbalance, blood volume changes, alterations in respiration) that results in death if not interrupted. In most drowning incidents, consciousness is lost after approximately two minutes, and irreversible brain damage occurs within four to six minutes. Survival without neurological impairment after five minutes is highly unlikely. Rapid initiation of CPR, which helps increase ventilation and oxygen delivery to the brain, will increase the chance for survival and/or optimal medical outcomes (Fields, 1992), such as in CPSC's IDI 230317CCC3554. Victims who survive anoxic episodes, such as in IDI 210114HCC1250, may need prolonged specialized care, including occupational and physical therapy, and can face lifelong disabilities (e.g., learning, language, and memory) that impact their life and those who care for them. Victims who cannot be resuscitated at the scene, are resuscitated with weak breathing and heart rhythm, or are transported in critical condition, will most likely suffer severe neurological impairment that may lead to organ failure and death as described in IDIs 200915HFE0001 and 190711CCC2487. Prolonged submersion in water for more than five to ten minutes usually leads to poorer prognosis or a fatal drowning.

During the drowning process, a victim experiences respiratory distress impairment because of submersion or immersion in liquid in the victim's

airway (Van Beeck et al., 2005). The drowning process begins either when the child's mouth and/or nose goes below the surface of the water (submersion) or when water splashes over the face (immersion). In most of the incidents, neck floats posed a risk of drowning because of a child's head slipping through the product with submersion of the mouth and nose. Seventy-seven incidents reported submersion of a child's airway (nose and/or mouth) in water either full (76 incidents) or partial (one incident), after slipping through the product. Additionally, 87 incidents reported a child's head slipping through the neck hole of the product. Three incidents report turning, rotating, or flipping in the product, leading to the submersion of the nose and mouth. Because infants generally cannot self-rescue, every slip through or submersion incident has the potential to be a drowning, resulting in injury or death, if caregivers do not intervene to quickly pull the infant from the water.

When water enters the airway of the drowning victim, the victim will attempt to spit out, cough up as a reflex response, or swallow the water, often inhaling more water involuntarily (Szpilman et al., 2012; Orłowski et al., 1989; Grmec et al., 2009). Incident reports describe choking, coughing, water ingestion, vomiting, and spitting up water. The risk of injury is dependent on the duration of submersion and amount of water that enters the lungs, as well as the immediacy of rescue and resuscitation efforts. Submersion durations were reported ranging from immediate rescue, where caregivers immediately pulled the child out of the water before the victim suffered any apparent injuries, to several minutes where the caregiver was not nearby or in the same room as the child. Water aspiration to the lungs and water ingestion can happen with very brief submersions. If the child is not rescued, the aspiration of water continues.

When large amounts of fluid are aspirated into the lungs, there is drastic mechanical impairment of gaseous exchange and lung function when the aspirated water destroys the pulmonary surfactant and disrupts the alveolar-capillary membranes. This injury to the lung leads to pulmonary edema, decreased lung compliance, and decreased exchange of oxygen and carbon dioxide. Incidents in which a victim is minimally symptomatic typically resolve without sustaining serious injuries or requiring continued medical treatment, but swallowing or aspirating significant amounts of water

can require medical attention or observation, especially for very young infants because of the risk of lung injury, hyponatremia,⁶ hypokalemia,⁷ or other types of electrolyte imbalance.

In four incidents, caregivers performed medical treatment at home (IDIs 220714CCC1021, 230629CAA1660, 210826CCC3606, 220714CCC3164). In two of those four incidents, caregivers intervened to resuscitate an infant that was not breathing after being pulled from the water (one report of CPR, IDI 220714CCC1021, and one report of back thumps, I2360082A). In nine incidents, caregivers sought medical attention by going to an emergency department (IDIs 230720CCC1766, 210826CCC1826, 210901CCC3625, and reports Y227C309G and Y2170991A), calling 911 (IDI 210910CCC1030), calling a nurse/medical helpline (IDIs 230317CCC3555 and 210901CCC1904), or by visiting an urgent care (IDI 210910CCC1029). The two incidents reporting injuries that required hospital admission (IDIs 230317CCC3554 and 210114HCC1250) and the two fatalities (IDIs 200915HFE0001 and 190711CCC2487) occurred in a home bathtub with the infant being submerged for an unknown length of time.

B. Incident Data Hazard Patterns

A neck float's ability to keep the child's mouth and/or nose above the water depends on the product's capability to remain buoyant and upright during use, and its ability to fit the child for the duration of use such that the child does not slip through the product's center opening to the extent that their mouth and nose become submerged in water.⁸ Staff examined the available incident data, incident and exemplar samples of inflatable and inherently buoyant child neck floats, and publicly available consumer-uploaded photos and videos demonstrating use of neck floats. Based on this information staff identified four hazard patterns associated with the risk of drowning: (1) slip-through not associated with inflation; (2) slip-through associated with inflation; (3) slip-through associated with restraint

⁶ Hyponatremia is a low concentration of sodium in the blood, which can cause neurological and metabolic problems.

⁷ Hypokalemia is a low concentration of potassium in the blood, which can cause neurological and metabolic problems.

⁸ The risk for partial slip-through poses the risk of aspiration of water through the mouth even if the nose is not submerged.

system failure; and (4) submersion without slip-through.⁹

1. Slip-Through Not Associated With Inflation

Fifty-two reported incidents involved an infant slipping through the product despite the neck float showing no signs of deflation, underinflation, or any other reported product issues. Forty-four of these incidents reported a child's mouth and/or nose submerging under the water, posing a risk of drowning or otherwise aspirating water. The other seven incidents involved a caregiver's immediate rescue which prevented submersion. Where reported, victims ranged in age from 17 days old to 8 months old. One fatal incident, IDI 200915HFE0001, involved the drowning of a 6-month-old female child using a neck float, who was unattended for an unknown amount of time in a bathtub. Upon returning, the mother found the neck float on the surface of the water, and the child was submerged in the tub, unresponsive. Subsequently, the child was hospitalized in critical condition and succumbed to her injuries six days later.

It is common for neck floats to rely solely on the size of the center opening being smaller than the size of a child's head to prevent the child's mouth and/or nose from submerging in water. Neck floats are typically marketed for a wide range of ages and weights. Anthropometric data provided by the World Health Organization (WHO),¹⁰ ¹¹ Centers for Disease Control and Prevention (CDC),¹² and other

⁸ The risk for partial slip-through poses the risk of aspiration of water through the mouth even if the nose is not submerged.

⁹ There is not enough information in reports for four incidents to associate them with one of the four hazard patterns.

¹⁰ See WHO growth charts for girls and boys ages 0 to 24 months: <https://www.cdc.gov/growthcharts/>

researchers (e.g., Schneider et al., 1986), demonstrate a large variability in weight, head, and neck dimensions for children, particularly head dimensions for children between the ages of 0 and 12 months. In addition, children's head weight data in the voluntary standard for childcare articles, CEN/TR 13387-1, *Child care articles—General safety guidelines—Part 1: Safety philosophy and safety assessment*, shows appreciable growth over the years, particularly between 0 and 12 months.¹³ This variability in sizes and weights increases the possibility of an ill-fitting neck float and increases the risk of a child slipping through the neck float.

Furthermore, a child's body weight and head mass will not necessarily correspond to their head, face, and neck dimensions. For instance, infants who have especially smaller dimensions, such as those who were born pre-term or those with developmental delays or other conditions that affect head size or shape, may have typical weights for their ages but their smaller cephalometry¹⁴ predisposes them to a higher risk of slip-through.¹⁵

[who/girls_length_weight.htm](https://www.cdc.gov/growthcharts/who/girls_length_weight.htm) and https://www.cdc.gov/growthcharts/who/boys_length_weight.htm.

¹¹ See "WHO child growth standards: head circumference-for-age, arm circumference-for-age, triceps skinfold-for-age and subscapular skinfold-for-age: methods and development"; <https://www.who.int/publications/i/item/9789241547185>.

¹² See "Anthropometric Reference Data for Children and Adults: United States, 2015-2018," U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/data/series/sr_03/sr03-046-508.pdf.

¹³ See CEN/TR 13387-1:2018, *Child care articles—General safety guidelines—Part 1: Safety philosophy and safety assessment*: <https://standards.iteh.ai/catalog/standards/cen/586a9a9d-14b2-4626-bae4-4e13a80ce111/cen-tr-13387-1-2018>.

¹⁴ The measurement and study of the proportions of the head and face, especially during development and growth.

Additionally, children's heads and faces are not uniformly spherical and are somewhat malleable. This can contribute to the risk of the child's head slipping through the neck float and will vary from child to child. In evaluating the incident data, staff observed that for incidents with known victim information and known product age and weight labeling, all victims had ages and weights consistent with the manufacturer-recommended guidance. Therefore, it is reasonably foreseeable that caregivers are likely to select and use neck floats marketed as appropriately sized for their child that may nonetheless be too large or too loose for their child.

Even if a neck float appears to fit a child securely, that is, around a child's neck with little to no extra space, the child's position and activity can cause them to slip through the product. Incident data and publicly available consumer-uploaded content of children in neck floats demonstrate that children will use neck floats on their back, on their chest, on their side, and while sitting or standing, and are likely to tilt their head forward and rearward, tuck their chin, bite the chin rest, twist their head in the product, wiggle their bodies, kick their legs, flail their arms, and even push up on the front underside of their product. These and other actions can separate the discontinuous ends, deform the center opening, or otherwise alter the fit of the neck float on the child, resulting in the child's mouth and nose sliding into the water. Figure 1 exemplifies children wearing neck floats and kicking off the tub floor, leaning back to the point that the tops of their heads are submerged, and pushing up on the front underside of the neck floats, as captured in a consumer's online video of twins wearing neck floats in a bathtub.



Figure 1: Children pushing up on the front underside of the neck float and leaning rearward into the discontinuous ends (partially blurred for privacy).

Neck float designs may include features intended to reduce the likelihood of slip-throughs. For example, some neck floats include a chin rest, which is intended to keep the child's mouth and nose from being submerged during use. However, many incidents involving submersions due-to slip-through involved neck floats designed with chin rests. Incident data and consumer videos of use show that children may lean and tilt their heads such that their chin bypasses the chin rest; they may twist their head in the product such that their chin is no longer supported by the chin rest; or their changes in direction or body position can cause the product to rotate during use. For example, IDI 210824HCC1797 indicates that the victim was using a neck float with a chin rest for approximately 10 minutes, when "the victim turned his head to the right and suddenly the victim's head slipped through the neck opening." In addition, incident data, such as fatal case IDI 200915HFE0001, demonstrate that caregivers may put neck floats on their children backwards, or otherwise without placing the child's chin on the chin rest, resulting in the child slipping through the center opening. Therefore, as shown in the incident data, a chin rest does not adequately prevent the submersion hazard.

Incident reports show it is common for children to wear neck floats in water shallow enough for them to sit or lay in a reclined position, yet still deep enough to allow their mouth and/or nose submerge and pose a drowning hazard. For example, IDI 220714CCC3164 reports that the victim was in a bathtub with only approximately 5 inches of water when the victim was suddenly and fully submerged in the water. If children can

push/kick off the floor or sides of the body of water, they are more likely to arch their heads back and separate the discontinuous ends of the neck float causing an expansion of the center opening, making it more likely for the child's mouth and/or nose to slip into the water. They may also have better leverage to lift the front underside of the product upward and over their face, as shown in Figure 1, resulting in the mouth and nose submerging in water. Where water depth was reported, most incidents (81 of 83) indicated the product was used in shallow water such as a bathtub or kiddie pool.

If there are obstacles such as tub walls, then it is easier for the product to be partially or fully held in place. If the product is immobilized and the child twists their head, then their chin may no longer be supported by a chin rest, making it more likely for their mouth and nose to slip into the water. If they twist enough that they face the discontinuous ends of the product, then the greater space and separation afforded by the discontinuous ends may make it easier for their mouth and nose to slip into the water. Additionally, if the product is immobilized and the child pushes off other surfaces into the discontinuous ends, they may generate force sufficient to expand the center opening and slip through the product. The University of Michigan Transportation Research Institute (UMTRI) conducted child strength research for CPSC, which demonstrated a wide range of two-foot seated push forces for children ages 6–47 months, such as children in the 6–8 month range at the 95th percentile generating up to 128.8 N (29 pound-force), and children in the 36–47 month range at the 95th percentile generating up to 547.3 N (123

pound-force).¹⁶ Another study found that fetal kick force reached 47 N (10.6 pound-force) at between 20 and 30 weeks of gestation, demonstrating that newborns can generate at least this amount of force or greater (Verbruggen et al., 2018).

The neck float can also be held in place by pressing up against other children in close proximity. Numerous incident reports and publicly available consumer-uploaded photos demonstrate that some children wear neck floats in confined spaces with siblings, even with siblings who are also wearing neck floats. For example, IDI 210901CCC1899, which involved slip-through, indicates that triplets wore infant neck floats in the same bathtub at the same time when the victim suddenly slipped through the product and went underwater for 2 to 10 seconds. Cases like this can result in a very confined space with the floats bumping into each other and even overlapping.

Caregivers are unlikely to understand how these environmental variables, such as shallow water and confined spaces, can contribute to the risk of slip-through by enabling the child to twist their head in the product and exert forces that expand the center opening. It is reasonably foreseeable that they will mistake such environments as providing an increased level of safety, security, and comfort by making the water

¹⁶ See "Corrected Age for Premies," American Academy of Pediatrics, <https://www.healthychildren.org/English/ages-stages/baby/preemie/Pages/Corrected-Age-For-Premies.aspx>; "NICU Family Information Packet, Appx. B, Growth," Agency for Healthcare Research and Quality, <https://www.ahrq.gov/patient-safety/settings/hospital/resource/nicu/packet/apb3.html>; Fenton Preterm Growth Charts <https://live-ucalgary.ucalgary.ca/resource/preterm-growth-chart/preterm-growth-chart>.

experience more controllable compared to a standard pool. As detailed further below, they may also underestimate the risk of drowning in shallow water, further affording them a false sense of security.

The slipperiness of the neck float's material, exposure of the neck float to lubricants, and motion can allow the product to slide more easily against the

child's skin, increasing the likelihood of the child twisting and slipping through the product during use. Many neck floats are marketed for use when bathing children. Several reports describe the use of soap and shampoo with the product. For example, IDI 210901CCC1906 reports that the caregiver applied soap to the victim's

head, and the soap made the victim's head and neck slippery, causing the victim's head to slip through the opening and submerge under the water. In reviewing products sold online and publicly available consumer-uploaded photos, staff observed that it is common for neck floats to be used in soapy environments (Figure 2).



Figure 2: Examples of publicly available consumer-uploaded photos of children wearing child neck floats in soapy environments. CPSC blurred and obscured portions of the photos for privacy.

2. Slip-Through Associated With Inflation

In 54 incidents, children slipped through or had the potential to slip through because the neck floats were more pliable or compressible at lower pressure levels or deflated during use. Thirty-three victims actually slipped through the product. The rest were at risk of slipping through the product because of issues pertaining to inflation (hole, tear, unknown deflation type, etc.). In one incident of a slip-through, it was intentionally underinflated.

Neck floats that are initially fully inflated also can deflate over time or during use, such as from air escaping through holes, tears, or open air valves.

Neck floats can be underinflated at the time the child begins to use the product due to numerous reasons, such as the caregiver's perception that the product is uncomfortably snug or the caregiver not realizing that air escaped from the product since the last time it was inflated.

Where reported, victims ranged in age from 28 days old to 10 months old. Two drowning injuries (IDIs 230317CCC3554 and 210114HCC1250) and one drowning death (IDI 190711CCC2487) were reported in this category and involved leaks or deflation during use.

There are unique risks of submersion for inflatable neck floats because they can be compressible and deform unevenly during use, vary in the

amount of inflation prior to use, and may lose air during use. Manufacturers typically recommend that neck floats are "fully" inflated when used; however, full inflation is difficult for consumers to estimate. Variability in inflation prior to and during use can impact product performance. The inflatable neck float's dependence on air to take shape means their dimensions vary by the amount of inflation and renders them compressible and unevenly deformable, especially if the product has discontinuous ends. Lower levels of inflation result in greater deformability and can allow the discontinuous ends to separate and expand the size of the center opening (Figure 3).

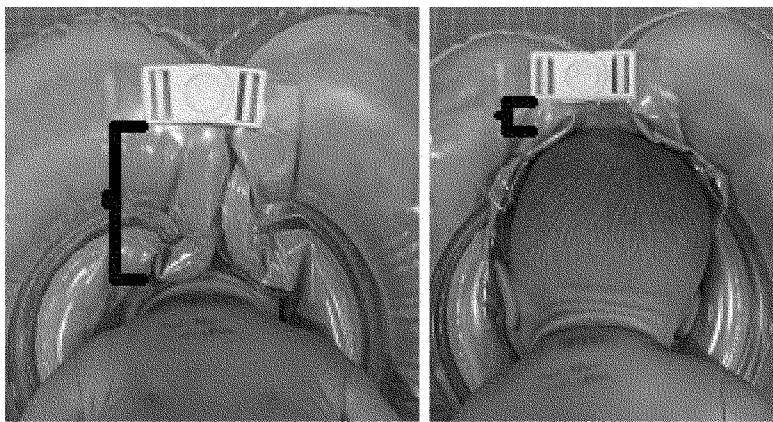


Figure 3: Images demonstrating how infant neck floats, particularly underinflated neck floats, can be compressed and unevenly deform during use. The image to the left shows the product is wrapped fully around the back of the doll’s head. As shown in the image to the right, pulling the doll’s head downward and rearward separates the discontinuous ends such that the head can pass through the center opening. Black brackets added to emphasize how the discontinuous ends are displaced, increasing the size of the center opening.

a. Deflation During Use

Fifty-two CPSRMS incidents involved holes, tears, or other leaks in neck floats at the time of the incident. For example, IDI 190711CCC2487 describes a fatal incident involving a 4-month-old male infant who was reportedly unattended for approximately 5 minutes in a bathtub wearing an inflatable neck float. He was found unresponsive floating face down without the neck float. The neck float was still secured in a closed position by both a Velcro strap and a buckle but appeared to be losing air. Another example, IDI 230317CCC3554, describes an injury to a 10-month-old male who was unattended for 5 minutes or less in a neck float in a bathtub. The child was found limp and cyanotic¹⁷ with his face underwater, and the neck float was found to be partially deflated due to a leak in the seam.

Some incidents involved tears, as in IDI 210901CCC1899, which describes a 3-month-old infant slipping through the neck float that had a tear near the safety clip and IDI 210826CCC3605, which describes a 2-month-old male who slipped through a product after it began to deflate due to a leak directly under the chin strap portion of the product. Several incidents, such as IDI 160512CBB2587, involved neck floats deflating during use due to problems with the air valve, such as the valve either opening or not being fully closed.

Manufacturers’ instructions often direct caregivers to check the product for tears, holes, valve issues, and other sources of leaks prior to each use of inflatable neck floats. However, instructions to perform these checks can be unclear and ineffective and, as a result, leaks may go undetected or develop after an inspection. It can be particularly difficult to find small leaks or tears, especially along seams. For example, IDI 220714CCC3155 indicates that after the product deflated during use, the caregiver performed the manufacturer-instructed inspection for leaks and did not observe any air coming out of the product. The caregiver continued to use the product with a 6-month-old child and the product deflated further, resulting in the child going “underwater [for] approximately 5 seconds.” In another example, IDI 220714CCC1014 indicates that the caregiver tested the neck float for leaks and could not find any, yet the product deflated resulting in the child slipping through.

Incident data also show that caregivers are unlikely to perform a leak check prior to every use of the product. For example, IDI 230720CCC1767 indicates the caregiver performed the manufacturer-instructed leak test prior to the first use of the product, but not thereafter—contrary to the manufacturer’s instructions—and the product deflated during use after being used “at least 10 times before the incident occurred.” Leak checks require time and effort, and studies have shown

that even small inconveniences can have a substantial negative effect on behavioral compliance with safety measures (Riley, 2006). Further, the neck floats that staff observed in incident data and on the market are simple and familiar in assembly and use, and they are marketed to keep children, even newborns, afloat in bathtubs and other bodies of water. These factors make it likely that consumers will overestimate the capabilities of the product, underestimate the importance of the checks, and underappreciate the nature and likelihood of the submersion hazard (Inaba et al., 2004; Woodson et al., 1992). This underappreciation of risk is especially likely after the caregiver has seen their child and/or other children (e.g., through online marketing and endorsements of neck floats) use the product safely without submersion (Godfrey & Allender, 1994; Vredenburg & Zackowitz, 2006; Ayres et al., 1989). As shown in the incident reports, it is common for caregivers to leave the product inflated between uses, and neither reinflate the product nor perform leak checks, prior to each use of the product. For example, IDI 210908CCC1983 indicates the product was inflated once and never re-inflated, despite being used several times.

Some incident reports, moreover, demonstrate that caregivers have continued to use neck floats despite being aware of leaks because they believed the leak was slow and perceived no hazard in continued use.

¹⁷ Cyanotic refers to a bluish discoloration of the skin resulting from poor circulation or inadequate oxygenation of the blood.

For example, IDI 210908CCC1982 indicated that the consumer was aware of a leak and “would simply re-inflate it and continue with the bath” until the day her child slipped through the product. Caregivers delay or even forego replacing neck floats with slow leaks for a myriad of reasons, such as underestimating the risk of slip-through and avoiding the practical burdens (*e.g.*, expense and time) of finding a replacement.

b. Underinflation

Even without an air leak, neck floats are likely to be used at lower levels of inflation that compromise the products’ fit and increase the likelihood of an infant slipping through. Neck float manufacturers often direct caregivers to “fully” inflate the products prior to use; however, as mentioned above, full inflation is likely to be interpreted differently from person-to-person. Consumers also vary in their capability to inflate neck floats and retain the air pressure as they switch from inflating it to closing the valve(s). Slip-through can occur at any level of inflation, but the risk is greater with lower inflation pressures. In examining neck float samples, staff observed that neck floats can take shape at as little as 0.1 pounds per square inch gauge (PSIG). Various factors (*e.g.*, motion) can cause the center opening to expand, and consumers are likely to underappreciate the risk posed by these factors. Staff observed in product samples and incident reports that neck floats can feel secure around a child’s neck and appear as though the child’s head cannot pass through the center opening, yet, during use, whether from deflation, the child’s activity, or both, the child’s head does slip through the product such that their mouth and nose become submerged. For example, IDI 210910CCC1030 indicates that the product felt “quite tight,” yet the victim still slipped through the product without observable deflation.

Additionally, some caregivers intentionally inflate neck floats to air pressures that leave space around a child’s neck to address their perception of discomfort for their child, not appreciating that the likelihood of slip-through increases as the product’s inflation level decreases. Intentional underinflation has been reported even

for neck floats that have warnings against underinflation. For example, IDI 220714CCC3162 indicated that the caregiver intentionally underinflated the neck float because “she was worried about the product being too tight around the victim’s neck.” Inflatable neck floats typically do not have other means for adjustability of the fit around the child’s neck beyond the amount of inflation, so it is reasonably foreseeable that caregivers seeking to adjust the fit would intentionally underinflate the product.

3. Slip-Through Associated With Restraint System Failures

A restraint system is an interconnecting component, whether adjustable or not, that is integral to a neck float and is intended to hold the occupant in a fixed position relative to the neck float. Staff observed that latches, buckles, or Velcro straps are commonly used to bind the discontinuous ends of neck floats together during use, and keep the product wrapped securely and tightly around the child’s neck. Failure of the restraint system is likely to result in the child’s mouth and nose being submerged in water, whether from disconnecting entirely or simply loosening during use. According to report Y227Q815A, a 7-month-old infant slipped out of the product due to a latch/restraint failure: “the strap needs to be glued to the other side otherwise it opens.” The integrity of the fasteners, including their connection to each other and to the product, can be affected by user weights, sizes, and actions, such as children pushing up on the floats, kicking, and thrashing.

The locations of the latches may also be a significant factor, though repositioning the location of the latches alone is not enough to prevent slip-through. As shown in Figure 3, some neck floats with discontinuous ends have the latches located far from the child’s neck, affording greater separation of the part of the discontinuous ends closer to the child, where separation is most dangerous for center opening expansion.

4. Submersion Without Slip-Through

Children can be submerged in water while wearing neck floats without slip-

through or fastening and restraint system failures, putting them at risk of drowning. Where reported, victims ranged in age from 3 to 6 months old. In at least three incidents, children reportedly tilted, rotated, and/or flipped in the neck float such that their faces contacted the water. In IDI 220714CCC3166, the child tilted forward and ingested water; in IDI 220714CCC3156, the child was able to rotate his body such that his face was in contact with water; and in report Y217O989B, a child leaned back and flipped in the product. As discussed above, it is common for children wearing neck floats to exhibit a wide range of body positions and movements.

Additionally, at least one incident, IDI 220714CCC3158, involved an infant being pulled down into the water by an inflatable neck float that filled with water: “The neck float made a popping sound and began to accumulate water, pulling the infant down into the water.” This incident demonstrates another serious risk posed by inflatable neck floats, as numerous cases cite leaks in the products, and leaks can result in the product filling with water and weighing the child down. No injuries or deaths were reported in this category.

C. Availability of Incident Data

Upon publication of this NPR in the **Federal Register**, staff will make available for review and comment the CPRMS incident reports relied upon and discussed in the NPR, to the extent allowed by applicable law, along with the associated IDIs. The data can be obtained by submitting a request to: <https://forms.office.com/g/10Cqtd8JP6>. You will then receive a website link to access the data at the email address you provided. If you do not receive a link within two business days, please contact zgoldstein@cpsc.gov.

D. Recalls

In July 2015, the Commission’s Office of Compliance conducted one recall of a neck float product. Table 1 below summarizes the recall, notes the recall date, the firm involved, hazard, the approximate number of units affected, number of reported incidents/injuries, and the press release number.

Table 1 - Summary of Recalls Involving Neck Float Products

Recall Date	Firm	Hazard	Number of Recalled Units	Number of Incidents Reported (Injuries Reported)	Press Release Number
July 1, 2015	Otteroo	The seam on the flotation device can leak air and deflate, posing a risk of drowning.	About 3,000 units Baby Floats	No Injuries Reported	15-739 ¹⁸

IV. Review of Voluntary Standards

A. Standard Consumer Safety Specification for Toy Safety, ASTM F963-23

ASTM F963 includes performance requirements and test methods for toys, as well as requirements for warning labels and instructional literature, to reduce or prevent injury to children or death of children from mechanical, chemical, and other hazards associated with toy use. Toys must comply with this standard pursuant to 16 CFR part 1250. Similar to other ASTM standards, ASTM F963 contains the following sections: scope, terminology, referenced documents, safety requirements, labeling requirements, instructional literature, producer's markings, test methods, and additional sections appropriate for toys, such as age grading and flammability testing of certain types of toys. Since passage of the CPSIA in 2008, the voluntary standard has been revised five times: ASTM F963-08, ASTM F963-11, ASTM F963-16, ASTM F963-17, and ASTM F963-23. Pursuant to the update procedures in section 106 of the CPSIA, the Commission has accepted the sequential revisions as the mandatory standard. 15 U.S.C. 2056b(g); 16 CFR part 1250.

Neck floats are subject to the labeling requirements in section 5.4 of ASTM F963-23 for aquatic toys. This standard requires that aquatic toys and their packaging include a safety label that at minimum includes the following, or equivalent, text: “*This is not a lifesaving device. Do not leave child unattended while device is in use.*” It also requires “no advertising copy or graphics shall state or imply that the child will be safe

with such a toy if left unsupervised.” As detailed in section V.B. of this preamble, for the proposed requirements for marking, labeling, and instructional literature in this NPR, staff assesses that the warning requirements specified in section 5.4 of ASTM F963-23 are inadequate for neck floats because they do not address the hidden hazards specifically associated with these products, such as the risk of center opening expansion during use, the risk of drowning in very shallow water, and the risk of death associated with partial slip-through. Many of the reported incidents involved neck floats compliant with the labeling requirements specified in ASTM F963-23, thereby demonstrating that the existing labeling requirements are insufficient to address the hazards.

ASTM F963-23 does not establish any performance requirements for aquatic toys, including neck floats. In August 2022, the ASTM F15.22 subcommittee developed a dedicated aquatic toy revision task group to develop a draft ballot with performance requirements for aquatic toys. There have been no balloted draft requirements to date, however.

Incident data described in section III of this preamble demonstrate weaknesses in the current ASTM toy standard. Therefore, the Commission preliminarily determines that ASTM F963 fails to adequately address children slipping through neck floats or being submerged into water and fails to provide the highest level of safety feasible. Accordingly, the Commission proposes more stringent performance and labeling requirements that further reduce the risk of injury associated with neck floats and provide the highest level of safety for such products that is feasible.

B. Other Relevant Standards

The U.S. Coast Guard uses ANSI/CAN/UL 12402-5, *Personal Flotation Devices—Part 5: Buoyancy Aids (Level 50)—Safety Requirements*, and ANSI/CAN/UL 12402-9, *Personal Flotation Devices—Part 9: Test Methods* to evaluate level 50 Personal Flotation Devices (PFD's) such as life vests. Some PFDs utilize flotation devices located around the user's collar, similar to neck floats. PFDs are classified into levels based on intended use conditions, including calm versus stormy water and relative closeness to possible rescue such as at the beach versus offshore, with level 50 being the least stringent. These factors are not comparable or relevant to the use of neck floats in a pool or bathtub environment. ANSI/CAN/UL 12402-5:2022 does classify possible PFD users into four categories based on weight, with “Infant PFDs” being intended for users weighing less than 15 kg (33 lbs). However, certain performance requirement metrics for level 50 PFDs are listed as “not allowed” for the infant class. For these reasons, ANSI/CAN/UL 12402-5 and ANSI/CAN/UL 12402-9 are not appropriate to apply to regulate neck floats, without sufficient modification to adapt its otherwise universal test methods with acceptance criteria suited for the infant class.

BS EN ISO 13138, *Buoyant aids for swimming instruction*, is a multi-part standards collection for the European Union's (EU) three swimming aid classifications. Class A swimming aids such as swim seats, covered by BS EN ISO 13138-3, are intended to be used by children up to 36 months as a “passive” user to introduce them to the in-water environment. Class B swimming aids, covered by BS EN ISO 13138-1, are intended to introduce an “active” user

¹⁸ Otteroo Corp Recalls Inflatable Baby Floats | CPSC.gov.

to the range of swimming motions. Class C swimming aids, covered by BS EN 13138–2, are products held in the hands or by the body and are intended to aid “active” users with improving specific aspects of swimming strokes. Class C swimming aids are intended for use by advanced swimmers, or even adult beginners.

Class A devices as defined by BS EN ISO 13138 most closely align with the target users of neck float products within the scope of this NPR. However, BS EN ISO 13138 classifies flotation products that attach at the neck as Class B devices. Most of the general performance requirements in BS EN ISO 13138–1:2021 and 13138–3:2021 and the associated test methods across the two standards are largely identical, with some exceptions. Many of the unique tests for Class A devices in BS EN 13138–3:2021 do not apply to neck floats because Class A devices are swim seats. Tests for Class A products are not appropriate for neck floats because these flotation devices are placed and attached at the waistline versus at the neck for Class B flotation devices.

Additionally, test methods in BS EN ISO 13138–1 for Class B devices, including buoyancy testing, align with the test methods for their respective counterparts in ANSI/CAN/UL 12402 although the exact performance requirements differ. The risk management factors and tests of both ANSI/CAN/UL 12402 and BS EN ISO 13138–1 may address many of the hazards identified in section III of this preamble and are universal in application. However, to address the identified hazards associated with neck floats, the performance requirements and test methods will require modifications, discussed in more detail in section V of this preamble.

V. NPR Description of Proposed Provisions and Justifications

Based on incident data described in section III of this preamble and staff’s engineering, health sciences, and human factors assessments, the NPR proposes creating a new § 1250.5 to 16 CFR part 1250, Safety Standard Mandating ASTM F963 for Toys, with more stringent requirements by adding performance and labeling requirements for neck floats to further reduce the risk of injury associated with neck floats and to provide the highest level of safety for such products that is feasible. Further, this NPR proposes revising the title of part 1250 from Safety Standard Mandating ASTM F963 for Toys to “Safety Standard for Toys,” to reflect the inclusion of proposed requirements that do not incorporate by reference

existing requirements in the ASTM F963 voluntary standard.

To address the risk of injury described in section III of this preamble, this NPR proposes to add a definition for “neck float” discussed in section II of this preamble and to add new performance requirements and replace existing labeling requirements for neck float. The NPR proposes to add test requirements for conditioning, buoyancy, fastening systems, restraining systems, and neck opening and to update marking, labeling and literature requirements. The additional requirements are more stringent than the existing requirements in part 1250 to further reduce the risk of injury associated with neck floats and to provide the highest level of safety for such products that is feasible to address child drownings associated with neck floats. This section of the preamble describes the proposed additions in § 1250.5.

A. Performance Requirements To Address Drowning Hazards

Because ASTM F963–23 does not establish any performance requirements for aquatic toys, including neck floats, it fails to adequately address children slipping through neck floats or being submerged into water and does not provide the highest level of safety for such products that is feasible.

1. Conditioning Procedure

The NPR proposes conditioning requirements for neck floats prior to conducting any other tests under the proposed rule in § 1250.5(c)(1). The purpose of a conditioning procedure is to simulate the conditions in which the product may be stored or used. This helps to ensure that the product is tested under realistic circumstances. The proposed conditioning procedure involves subjecting the neck float to various stressors based on foreseeable use environments, which include exposure to cold, hot, and room temperature, exposure to chlorinated salt water, and exposure to ultraviolet (UV) light. All inflatable neck floats subject to the proposed rule should be deflated for the proposed testing requirements in the conditioning procedure.

a. Exposure to Varying Temperatures

Temperature changes can introduce both short- and long-term impacts on any material. For plastics and polymer chains, short-term effects can include expansion or contraction of objects’ shape, as well as softening of the material. Long-term exposure may result in deformation, or thermal degradation

leading to cracking or breaking.¹⁹ These material changes are typically associated with exposure to high temperature, as can be expected when the neck float is used for bathing purposes or is stored outside with other swim toys; however, transitioning between cold storage to hot use may also exacerbate the mechanical degradation.

Section 5.5.4.1 of ANSI/CAN/UL 12402–9:2022 includes a “Temperature cycling test” for inflatable PFDs. The temperature cycling test requires alternate exposure to hot temperature at $60 \pm 2 \text{ }^\circ\text{C}$ ($140 \pm 4 \text{ }^\circ\text{F}$) for 8 hours, then to cold temperature at $-30 \pm 2 \text{ }^\circ\text{C}$ ($-22 \pm 4 \text{ }^\circ\text{F}$) for 8 hours, repeated for two complete cycles.

The Commission proposes to incorporate this test method from section 5.5.4.1 of ANSI/CAN/UL 12402–9:2022, for both inflatable and inherently buoyant neck floats, with modifications, in the proposed rule under § 1250.5(c)(1). ANSI/CAN/UL 12401–9:2022 contains separate requirements for inherently buoyant PFDs that includes steps to fully open the devices to simulate donning and check for damage. However, as discussed in Section II of this preamble, the design of inherently buoyant neck floats does not typically include extraneous moving parts that require additional “opening” steps beyond being secured around the child’s neck. Therefore, CPSC proposes to apply the thermal conditioning procedure in section 5.5.4.1 of ANSI/CAN/UL 12402–9:2022 to both inflatable and inherently buoyant neck floats.

BS EN ISO 13138–1 also recommends temperature conditioning for swimming aids, with a hot temperature set point of $60 \pm 2 \text{ }^\circ\text{C}$ ($140 \pm 4 \text{ }^\circ\text{F}$) and cold temperature set point of $-10 \pm 2 \text{ }^\circ\text{C}$ ($14 \pm 4 \text{ }^\circ\text{F}$). Since it is not reasonable to expect that a neck float will be stored or operated in temperatures low enough to warrant conditioning to $-30 \pm 2 \text{ }^\circ\text{C}$ as recommended by section 5.5.4.1 of ANSI/CAN/UL 12409–9:2022, the NPR proposes to increase the temperature set point of the cold extreme from $-30 \pm 2 \text{ }^\circ\text{C}$ ($-22 \pm 4 \text{ }^\circ\text{F}$) up to $-10 \pm 2 \text{ }^\circ\text{C}$ ($14 \pm 4 \text{ }^\circ\text{F}$) based on the cold temperature recommended by BS EN ISO 13138–1 for comparable swimming devices.

Additionally, rather than repeat thermal conditioning for two, 8-hour alternating cycles, the NPR proposes to condition neck floats for a single 8-hour

¹⁹ Shawn, “Temperature Considerations in Plastic Thermoforming Material Selection.” *Productive Plastics Inc.*, 27 June, 2021, www.productiveplastics.com/temperature-considerations-plastic-thermoforming-material-selection.

period at both temperature extremes (60 ± 2 °C and -30 ± 2 °C), followed by a 24-hour period at room temperature (20 ± 2 °C (68 ± 4 °F)). The NPR proposes to reduce the number of thermal cycles required in section 5.5.4.1 of ANSI/CAN/UL 12402–9:2022 to more accurately reflect the use and storage conditions of neck floats in comparison to those of PFDs. Unlike PFDs, neck floats are not expected to be stored nor operated within the same extreme conditions expected of a life-saving device. The 24-hour requirement to hold the neck float at room temperature is sufficient to ensure that the hot and cold temperature exposures do not interfere with the remaining two conditioning requirements for neck floats (*i.e.*, chlorinated salt water and UV exposure).

b. Exposure to Chlorinated Salt Water

Exposure to chlorine environments, as may be expected of a pool, can result in an adverse chemical reaction with a plastic or polymer chain if the material has not been carefully selected for, or prepared with, suitable chemical resistance.²⁰ To address this, the proposed rule requires conditioning for exposure to chlorinated salt water to simulate the use of a neck float in a pool.

To condition for exposure to chlorinated salt water, section 6.1 of BS EN ISO 13138–1:2021 requires the swimming aids to be submerged in a chlorinated saltwater solution. Staff recommends adopting similar procedures to account for exposure to various use locations of neck floats, which may include chemically treated bodies of water such as pools. Accordingly, the NPR proposes to require that a neck float should be submerged in a chlorinated saltwater solution. The solution should be prepared by dissolving 32 g^{21} of sodium

²⁰ *Chemical Resistance Chart for Plastics—an In-Depth Look at Chemical and Acid Resistant Plastics* | a&C Plastics. www.acplasticsinc.com/informationcenter/r/a-chemical-resistance-guide-for-plastics.

²¹ Giovanisci, Matt. “How Much Salt to Add to Your Pool (Easy Pool Salt Calculation).” Swim

chloride (NaCl) in one liter of aqueous solution containing 2 ppm chlorine at pH 7.0–7.8.²² The neck float should be submerged in the necessary volume of the prepared chlorinated saltwater solution, in darkness and at room temperature (20 ± 2 °C (68 ± 4 °F)) for 8 hours.

c. Exposure to Ultraviolet Light

UV light can cause degradation of plastics and polymer chains through a photochemical effect.²³ Over continued exposure, plastics may weaken, begin to look discolored, take on a chalky appearance, or become brittle to the touch.²⁴

Section 4.2.1.1–4.2.1.4 of ANSI APSP ICC–16 (2017), *American National Standard for Suction Outlet Fitting Assemblies (SOFA) for Use in Pools, Spas and Hot Tubs*, includes the “Ultraviolet Light Exposure Tests” test method for exposure to ultraviolet light (UV). 16 CFR part 1450. Based on the test method requirements in section 4.2.1.1–4.2.1.4 of ANSI APSP ICC–16, a product is required to be exposed to UV light under one of the four UV exposure conditioning methods, selected per the discretion of the evaluator, incorporated here:

(a) 720 hours of twin enclosed carbon-arc (ASTM G153, Table X1.1 Cycle 1 except the Black Panel Temperature shall be 50 °C); or

(b) 720 hours of twin enclosed carbon-arc (ASTM G153, a programmed cycle of 20 minutes consisting of a 17-minute light exposure and a 3-minute exposure to water spray with light shall be used

University, 8 July 2024, www.swimuniversity.com/how-much-pool-salt.

²² Home Pool and Hot Tub Water Treatment and Testing.” Healthy Swimming, 10 May 2024, www.cdc.gov/healthy-swimming/about/home-pool-and-hot-tub-water-treatment-and-testing.html?CDC_AAref_Val=https://www.cdc.gov/healthywater/swimming/residential/disinfection-testing.html.

²³ What Does UV Radiation Actually Do to Degrade Plastics? | U.S. Plastic Corp. 11 Dec. 2009, www.usplastic.com/knowledgebase/article.aspx?contentkey=858.

²⁴ “UV And Its Effect on Plastics: An Overview.” Essentra Components U.S., 23 Jan. 2019, www.essentracomponents.com/en-us/news/manufacturing/injection-molding/uv-and-its-effect-on-plastics-an-overview.

with a black-panel temperature of 63 ± 3 °C); or

(c) 1000 hours of xenon-arc (ASTM G155, Table X3.1 Cycle 1 except the Black Panel Temperature should be 50 °C); or

(d) 750 hours of fluorescent (ASTM G154, Table X 2.1 Cycle 1 except the 8-hour UV shall be at a Black Panel Temperature of 50 °C and the 4-hour condensation Black Panel Temperature shall be 40 °C).²⁵

In § 1250.5(c)(1), the Commission proposes to incorporate sections 4.2.1.1–4.2.1.4 of ANSI APSP ICC–16 to simulate UV light exposure. This provision accounts for sun exposure during use of neck floats, which may include outdoor use and temporary or primary outdoor storage conditions.

2. Minimum Buoyancy Requirements

In § 1250.5(c)(2) the Commission proposes minimum buoyancy requirements to prevent unintentional submergence. Specifically, the Commission is proposing to require that all neck floats demonstrate a minimum upward buoyancy equal to or greater than 30 percent of the expected weight capacity of the neck float, which will ensure that a neck float is buoyant during use.²⁶ Additionally, the Commission proposes to require inherently buoyant neck floats to not lose more than 5 percent of their initial buoyancy after being submerged for a 24-hour period.

The expected weight capacity, as defined in § 1250.5(b), will be determined as the neck float’s maximum recommended user weight, or the weight provided in Table 2 based on the neck float’s maximum recommended user age, whichever is greater.

²⁵ American National Standards Institute (ANSI) and Association of Pool & Spa Professionals. *American National Standard for Suction Outlet Fitting Assemblies (SOFA) for Use in Pools, Spas, and Hot Tubs*. American National Standards Institute (ANSI), 18 Aug. 2017, APSP.org.

²⁶ Buoyancy is a property of the object’s density, and for inflatables is achieved by increasing the float’s volume by blowing it up, without substantially affecting the float’s mass.

Table 2 – Child weight in kg and lbs. for ages 0 to 4 years representing the 95th percentile male.²⁷

Age of Child	Weight in kg	Weight in lb
0-3 months	7.7	17.0
4-6 months	9.5	21.0
7-9 months	10.6	23.4
10-12 months	11.5	25.4
1 up to 2 years	17.6	38.8
2 up to 3 years	23.2	51.2
3 up to 4 years	23.7	52.3

Section 5.5.9.2 of ANSI/CAN/UL 12402–9:2022 requires the use of a weighted cage with a calibrated load cell²⁸ to submerge a swimming device in a tank of fresh water, with its upper surface at a depth of 100mm to 150mm below the water surface without touching any sides of the tank. In addition, the product must be secured within the cage such that both it and the cage always remain approximately horizontal and level. The test method requires the submerged weight of the cage be 1.1 times the expected buoyancy value of the swimming device to ensure there is sufficient load to fully submerge the weighted cage system when combined with the swimming device.

The procedure in section 5.5.9.3 of ANSI/CAN/UL 12402–9 directs that the cage should be suspended in the water tank at a temperature of (20 ± 5) °C. First, the weight of the immersed cage with the product should be recorded, as A. Next, the weighted cage and product should remain immersed for 24 hours, and the weight shall be re-recorded as B. Lastly, the product should be removed from the cage and the weight of the immersed cage alone, without the product, should be recorded as C. Section 5.5.9.4 of ANSI/CAN/UL 12402–9 explains that the initial buoyancy is determined by deducting A from C, and the final buoyancy is taken by deducting B from C. The buoyancy loss is taken by deducting the final buoyancy from the initial buoyancy.

The Commission proposes to incorporate this test method from sections 5.5.9.2–5.5.9.4 of ANSI/CAN/

UL 12402–9:2022, with modifications, in the proposed rule to determine the minimum buoyancy for all neck floats, under § 1250.5(c)(2). Section 5.5.9.3 of ANSI/CAN/UL 12402–9:2022 requires a swimming device to be inflated to the pressure provided by its primary means of inflation, or to 4.0 ± 0.1 kPa (0.58 ± 0.016 PSIG), whichever is less, if it contains inflatable components. This NPR, however, proposes that any neck float utilizing inflatable components must be inflated to the lower internal air pressure of 0.1 ± 0.01 PSIG for the duration of this test. It is foreseeable that a consumer could use the neck float while inflated to only 0.1 PSIG—even if that is below the proper operating pressure—because the float may appear to be in the proper shape and functional at this inflation level. An internal pressure of 0.1 PSIG is the lowest foreseeable operating pressure for neck floats, and therefore performance requirements that depend on inflation pressure (such as buoyancy) should be evaluated at that lowest limit. During experimental testing, staff found at least four sample inflatable neck floats (representing two distinct make/models) met the requirements of this NPR’s proposed buoyancy test when inflated to 0.1 PSIG internal pressure.

This NPR proposes to evaluate the minimum required buoyancy of the neck float as a function of its intended user weight. Requiring the upward buoyancy to be equal or greater than 30 percent of the expected weight capacity is based on applying a safety factor of three to 10 percent, which is the approximate body weight, on average, a human bears while submerged to their neck in water.²⁹ Using three as the

safety factor is based on performance requirements in ASTM F963 for toys intending to bear the weight of a child, such as the overload testing of ride-on toys and toy seats in section 8.28 of ASTM F963, which requires the test load to be three times the weight indicated by Table 7 in ASTM F963 or three times the manufacturer’s stated weight capacity, whichever is greater. In this instance, staff equates ASTM F963’s requirement for ride-on-toys to bear three times the dry-land weight of a child to the proposed buoyancy requirement that neck floats bear three times the in-water weight of a child.

In addition, the Commission proposes that inherently buoyant neck floats must demonstrate no more than a 5 percent loss of buoyancy after being submerged for 24 hours to ensure that inherently buoyant materials do not absorb enough water such that the product’s ability to float properly is adversely impacted. The 5 percent loss is based on the staff’s analysis of other relevant standards. Both ANSI/CAN/UL 12402–9 and BS EN 13138–1 evaluate the buoyancy of flotation devices after a 24-hour submergence period to determine how much buoyancy is lost. BS EN 13138–1 requires inherently buoyant swimming aids to lose no more than 10 percent of their initial buoyancy, while ANSI/CAN/UL 12402–9 requires PFDs to lose no more than 5 percent. The Commission preliminarily determines that the 5 percent loss metric is the more stringent of those two standards and is more appropriate to achieve the highest level of safety that is feasible.

3. Restraint Systems

To reduce the likelihood of a restraint system failure on a neck float, which can result in a child slipping through the product, the Commission proposes in § 1250.5(c)(3) requirements for the release mode of the fastening mechanism, and overall mechanical integrity of restraint systems. A

²⁷ See CDC “Data Table for Boys Length-for-age and Weight-for-age Charts”: https://www.cdc.gov/growthcharts/who/boys_length_weight.htm, for ages 0 to 12 months (weights by month). See CDC “Anthropometric Reference Data for Children and Adults: United States, 2015–2018”: https://www.cdc.gov/nchs/data/series/sr_03/sr03-046-508.pdf, for ages 2 to 4 years (weight by years).

²⁸ The calibrated load cell is used to record the cage weight measurements, with and without the product.

²⁹ Water cancels about 90 percent of a human’s body weight. DNP, Darcy Reber Aprn, C.N.P. “Aquatic Exercise: Gentle on Your Bones, Joints, Muscles.” *Mayo Clinic Health System*, 9 Apr. 2024. <https://www.mayoclinichealthsystem.org/hometown-health/speaking-of-health/aquatic-exercise-gentle-on-your-bones-joints-and-muscles>.

fastening mechanism, such as a buckle, on a neck float serve as a restraint system because it secures and holds the child in place during use. The requirements proposed are intended to reduce the likelihood of an unintentional release of a fastener mechanism during use, and to reduce the likelihood of component failures in a restraint system and detachment from the neck float as seen in Y227Q815A.

a. Fastening Mechanism

Section 5.4.2 of BS EN 13138–1:2021, *Fastening Systems*, requires parts of a swimming device used to attach the swimming device to the body or to connect any other functional components to have at least two simultaneous or sequential actions for release to prevent unintended opening. Alternatively, the standard allows for a single action release if it requires at least 50 N to open. The standard further directs that this testing must be performed in accordance with Annex C of BS EN 13138–1:2021, *Procedure for testing the security of the pressure release of buckles without double action (simultaneous/sequential) release*.

Annex C specifies that the buckle used to secure a swimming device should be positioned and loaded with 5 N on a plain, rigid surface. For single release, mechanisms, a force of 50 N is required to be applied at point 3, perpendicular to the release mechanisms of the buckle.

Section 4.13.1.2 of ASTM F963–23 also includes requirements for latching and locking mechanisms, which require either a double-action locking device with two distinct and separate actions to release, or a single-action locking device that requires a minimum force of 45 N to open. There are similar provisions in other ASTM standards for children's products that incorporate restraint straps, such as section 6.4.7 of ASTM F833–21, *Standard Consumer Safety Performance Specification for Carriages and Strollers*. 16 CFR part 1227. Based on these comparable restraint system requirements, the Commission proposes to require the release mechanism of neck float fasteners to have either a double-action release system with two distinct, but simultaneous actions to release, or a single-action release system that requires a minimum of 50 N to release. A minimum of 50 N to release is the greatest minimum force requirement for single-action release mechanisms in the applicable standards, and therefore ensures the highest level of safety.

Unlike in ASTM F963–23, which allows the double-action release mechanism to use two separate actions to release, the NPR proposes to require

two distinct, but simultaneous actions to release. Two simultaneous actions, such as depressing and twisting the cap of a medicine bottle open, are considered more difficult for a child in the age range considered by this NPR (0–4 years) to perform without assistance. Because there are no performance requirements for double-action release system, allowing the double-action release system to utilize sequential actions where each action can be performed one-at-a-time would be equivalent to allowing the neck float to rely on two unverified single-action release systems for fastening to the user.

b. Restraint System Mechanical Integrity

Section 6.4.4 of ASTM F833–21, requires that a restraint system and any closure mechanisms such as buckles must not part or slip more than 1 inch (25 mm) when tested in accordance with section 7.5 of ASTM F833–21. 16 CFR part 1227. Additionally, the standard requires that any anchorages must remain attached without separating from their attachment points during testing. The standard also requires that the restraint system may not move more than 2 inches (51 mm) when tested in accordance with section 7.5.2.8. Section 7.5.1, *Restraining System Integrity Test Method*, of ASTM F833–21 specifies the testing method for this requirement, which includes applying a force of 200 N (45 lbf) to a single attachment point on the restraining system. Specifically, the standard directs that force should be applied gradually within 5 seconds and maintained for an added 10 seconds, which should be repeated a total of 5 times with a 5 second maximum time interval between tests for each attachment point on the restraint system. The standard further requires that, after testing, the Civil Aeronautical Medical Institute (CAMI) dummy, required for this test, should not be fully released.

As noted in section III, the confined space of a bathtub environment provides the neck float occupant with possible surfaces to kick, pull, push, twist themselves off, or otherwise struggle against the surfaces of the bathtub. To account for this expected elevated force, the Commission proposes to incorporate section 6.4.4 and 7.5.1 of ASTM F833–21, with modifications to omit both the CAMI dummy evaluation following testing, and any evaluation to section 7.5.2 of ASTM F833–21, *Restraining System occupant Retention Test Method*. The CAMI dummy and section 7.5.2 testing have been omitted from the proposed restraint system requirements because

the seat-based retention tests are incompatible with the neck float retention method. Instead, the NPR will address occupant retention through the proposed neck opening requirements in section V.A.4.

The Commission has considered a potential requirement for neck floats to incorporate a secondary attachment system as a backup in the event the primary neck opening securement fails. CPSC staff, however, have identified a risk that a child could partially slip through the neck opening and be supported by the secondary system with their mouth below the waterline, creating a drowning hazard without a notable visual change to alert the caregiver to the danger. The addition of the secondary attachment system also may convey to the caregiver the incorrect impression that there can be no possibility for the child to slip through the product. The Commission requests comments on a secondary attachment system for neck floats to address hazards associated with use the of neck floats.

4. Neck Opening Test Requirements

To address the hazard of a child slipping-through a neck float, the Commission proposes requirements for the neck opening on a neck float under § 1250.5(c)(4). To meet the proposed requirement, the neck opening of the neck float must not admit the passage of a specified head probe when subjected to a specified dynamic movement, in accordance with the proposed test method. Currently, there are no existing standards or test methods developed to ensure that an aquatic toy such as a neck float will not pose a risk of drowning because of slip-throughs during its use. As a result, staff developed a test and test method to accommodate this need.

Under the proposed neck opening test, first the neck opening of the neck float is saturated with a soapy solution to simulate use in a bathtub or with a slippery substance such as sunscreen. Second, the specified head probe is be weighted to a specific mass (M1) and positioned in the neck float. Next, a hanging weight of another specific mass (M2) is suspended below the head probe at a specified distance (L) of the specified head probe (see Table 3 for details on M1, M2 and L for various user-age categories). Finally, the hanging weight is brought up to a 90-degree displacement angle and released such that it is swung front-to-back relative to the neck float's user as shown in Figure 4. The hanging weight must be allowed to move freely for 30 seconds in this manner. After 30 seconds have

passed, the hanging weight is brought up again to a 90-degree displacement angle and then released so that it swings side-to-side relative to the neck float's

user and allowed to move freely for 30 seconds in this manner. This alternating pattern is repeated for up to a total of

ten swinging cycles, five front-to-back and five side-to-side.

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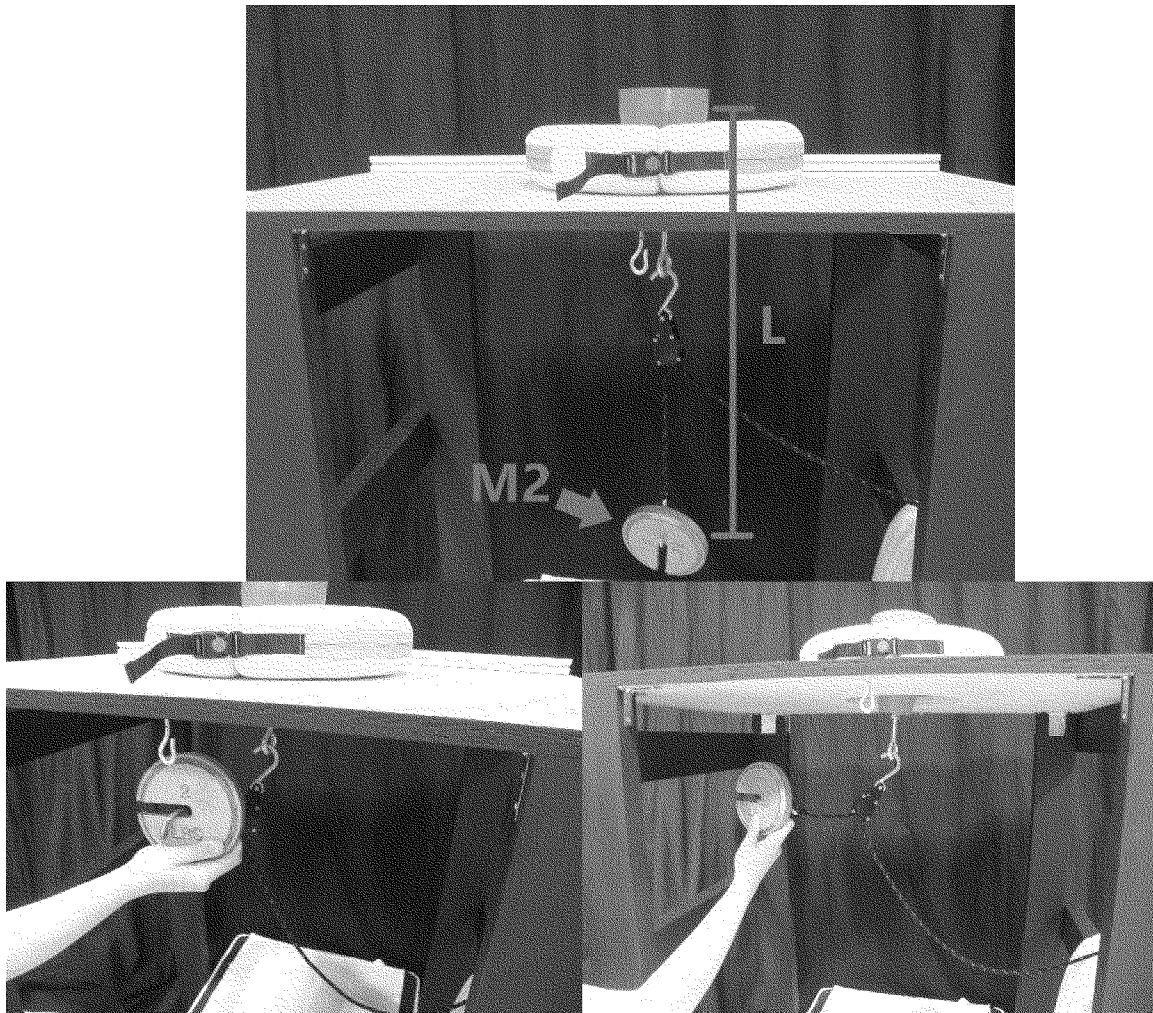


Figure 4: Illustrations of the proposed neck opening test. Top: the head probe is placed in the neck float, and the hanging mass M2 is positioned at distance L from the measuring point on the probe. Bottom, from left to right: the hanging mass is shown when raised to a 90-degree angle forward and to the side, in preparation for the release and swing.

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This dynamic test method was selected to account for the variety of movements children using this product have been reported to engage in, including kicking, back and belly floating, twisting, and pushing off of bathtub or pool walls and floors. The number of swing cycles, direction, and duration have been determined based on the CPRMS incidents which contained many reported the incident occurring within 10 minutes of use. Based on this, the minimum number of dynamic swing cycles in the proposed

test is set at ten swings and reflects the child shifting their body weight at least one time every minute. This approximation is considered a conservative estimate of a child's expected activity over the 10 minute duration. The proposal to alternate directions between front-to-back and side-to-side accounts for multi-direction movements. The 90 degree starting swing angle and 30 second swing cycle reflect the shift in body weight, from the child's transition from floating on their back or belly to one where their legs are positioned below them.

The proposed test for neck opening is required to be repeated for both the smallest and largest head probe in the neck float's recommended user range to ensure that the neck float adequately retains the occupant by preventing the occupant from slipping fully through the neck opening. Evaluating the neck float using the smallest specified head probe ensures the neck opening is not large enough, or cannot expand to become large enough during use, to allow the smallest foreseeable occupant to slip fully through it. Evaluating the neck float using the largest specified

head probe ensures the neck float can adequately support the forces generated by the largest foreseeable occupant such that they cannot fully slip through it, as well. If a neck float uses an adjustable fastening mechanism then the evaluation of both probes is performed at the largest, or loosest, possible size setting.

As discussed in section III, some reports indicated that caregivers loosened or intentionally deflated a neck float because they believed it was too tight around their child's neck (IDIs 220714CCC3162 and 180403CCC1583). To ensure that a neck float achieves the highest-possible level of safety, the proposed test therefore includes testing the smallest recommended child using a product at the loosest available setting. If the neck float utilizes inflatable

components, those components must be inflated to an internal pressure of 0.1 ± 0.01 PSIG for the duration of this test. The internal air pressure specified by this test method has been discussed at length in the section V.A.2 of this preamble.

As part of this test, the Commission proposes including the soapy water solution as described in "Baby Wash Test Solution" from section 7.4.1.5 of ASTM F1967–19 *Standard Consumer Safety Specification for Infant Bath Seats* in the proposed rule for neck floats under § 1250.5. 16 CFR part 1215. ASTM F1967 requires the use of an established baby wash solution mix to evaluate the stability of infant bath seats under the same onerous soapy conditions. Incidents discussed in section III of this preamble support that

neck floats may be used in soapy water solutions. Therefore, to achieve the highest-level of safety that is feasible, a test sample must be saturated with soap to simulate the most slippery foreseeable use condition to evaluate the neck float's ability to prevent the user from slipping through the neck float.

The choice of specified head probe, mass M1, mass M2, and length L is based on the manufacturer's recommended user age range, in conjunction with Table 3. If the recommended user age falls between two ranges, then the lower range shall be used to determine the smallest probe and associated testing conditions, and the higher range shall be used to determine the largest probe and associated testing conditions.

Table 3 – The values in this table are used to direct the testing parameters of the neck opening test based on one recommended user age. If the recommended user age falls between two ranges, then the lower range shall be used to determine the smallest probe and associated testing conditions, and the higher range shall be used to determine the largest probe and associated testing conditions.

Head Probe Designation	Age Range (months)	Head Probe Mass M1 (kg.) ³⁰	Hanging Weight M2 (lbs.) ³¹	Distance L (in.) ³²
A	0-3	1.5	3.4	12.45
B	4-6	2	4.2	13.8
C	7-9	2.2	4.68	14.65
	10-12	2.4	5.08	15.6
	13-18	2.6	7.76	16.55
D	19-24	2.8	7.76	17.55
	25-30	3	10.24	18.75
	31-36	3	10.24	19.4
	37-42	3.2	10.46	20.45
	43-48	3.2	10.46	21.3

Dimensions of the four specified head probes, depicted in Figure 5, are based on available anthropometric data (Schneider et al., 1986). The narrowest end of the probe is an ellipse whose semi-major axis corresponds to the neck depth, and whose semi-minor axis

corresponds to the neck breadth. The widest end of the probe is an ellipse whose semi-major axis corresponds to the head length, and whose semi-minor axis corresponds to the head breadth on the plane passing through the point of greatest protrusion on the forehead and

the point of greatest protrusion on the back of the head. The distance between the narrowest and widest circumferences on the probe is equal to the height of the head.

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³⁰ See BSI Standards Publication. "Child Care Articles—General Safety Guidelines—Part 1: Safety Philosophy and Safety Assessment." 2018. *BSI Standards Publication*, report, 2018.

³¹ Values here are 20 percent of respective 95th percentile weights provided by CDC "Data Table for

Boys Length-for-age and Weight-for-age Charts": https://www.cdc.gov/growthcharts/who/boys_length_weight.htm, for ages 0 to 12 months. See CDC "Anthropometric Reference Data for Children and Adults: United States, 2015–2018": <https://>

www.cdc.gov/nchs/data/series/sr_03/sr03-046-508.pdf, for ages 2 to 4 years.

³² See Schneider et al., 1986).

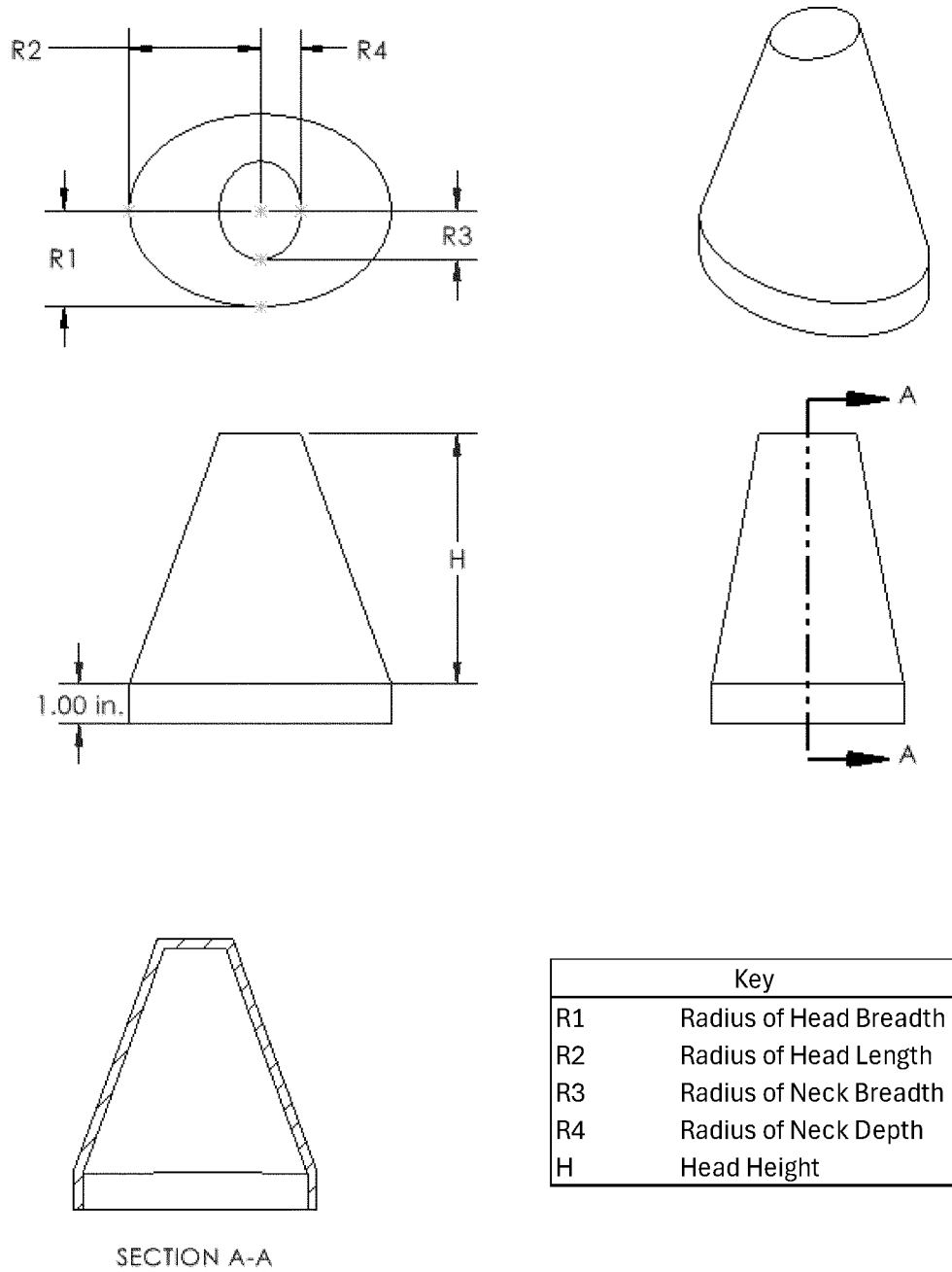


Figure 5: Drawing of the head probe design. Dimensions of the head probe shall comply with the values given in Table 4. Section A-A demonstrates that the head probe may be hollow for the purposes of adding mass M1, however it is not a requirement of the probe.

Table 4 – The dimensions used to construct the head probes based on anthropometric data (Schneider et al., 1986), given in inches.

Probe Designation	R1 (head breadth/2)	R2 (head length/2)	R3 (neck breadth/2)	R4 (neck depth/2)	H (head height)
A	1.85	2.5	0.9	0.85	4.6
B	2.05	2.8	0.95	0.8	4.9
C	2.2	2.95	1.1	1	5.2
D	2.35	3.2	1.2	1	6.1

BILLING CODE 6355-01-C

The four head probes represent children of various ages. Probe A is used to test products intended for children from 0 up to 3 months old, Probe B covers products for children up to 6 months old, Probe C covers products for children up to 18 months old, and Probe D covers products for children up to 48 months old. CPSC staff established these subsets based on the change in overall rate of growth of the head from 0–48 months, which generally develops and grows more rapidly until around 7–9 months. All dimensions used for the head probes represent the 5th percentile measurement of the specified age range for that probe. Where a probe is designated for use to evaluate multiple age ranges, the smallest 5th percentile measurement for that span has been selected.

Staff note that the maximum neck circumference of a 43–48-month-old (10.2 in.) is smaller than the minimum head circumference of a 0–3-month-old (14.6 in.). Based on these measurements, a neck float intended to accommodate the neck of a 48-month-old should still be expected to prevent the head of a 3-month-old from slipping through it. If the head probe can slip through the neck opening then that means the neck opening is either large enough, or can expand during use to be large enough, to allow that child's head to fully slip through the neck opening and submerge underwater. Staff assess this slip through metric to be a conservative representation of the slip through event.

To simulate foreseeable use stresses on neck floats during use, each head probe is weighted to mass M1 and using a hanging weight of mass M2 positioned at distance L during the evaluation. Mass M1 represents the 95th percentile weight of a child's head, alone, for the

specified age range. Mass M2 has been selected as 20 percent of the 95th percentile weight of the user in the specified age range. As noted in section V.A.2, the average human bears 10 percent of their dry-land weight when submerged up to their necks. The hanging weight used in this assessment is double the expected amount, or 20 percent of the dry-land weight for that user, to incorporate an appropriate factor of safety. Distance L has been determined as half of the 95th percentile stature of the user in the specified age range. This choice is made to approximate the position of the hanging mass at roughly the user's center of mass. Distance L includes the length between the narrowest and widest circumferences of probe to account for that distance as being the length of the user's head, as described in the paragraphs above.

The four hazard patterns addressed in this NPR may not be exhaustive of the hazards associated with this product category. For example, the United States Food and Drug Administration (FDA) has warned about the risk of death due to suffocation, strain, and injury to a baby's neck.³³ Accordingly, the Commission is seeking comment on whether it should strengthen these performance requirements to address other hazards, or whether it should promulgate alternative performance requirements.

³³ See U.S. Food & Drug Admin., *Do Not Use Baby Neck Floats Due to the Risk of Death or Injury: FDA Safety Communication* (June 28, 2022), available at <https://www.fda.gov/medical-devices/safety-communications/do-not-use-baby-neck-floats-due-risk-death-or-injury-fda-safety-communication>.

B. Marking, Labeling, and Instructional Literature Requirements

Section 5.4 of the ASTM F963–23 requires aquatic toys, such as neck floats, and their packaging to have a warning that states: “*This is not a lifesaving device. Do not leave child unattended while device is in use.*” The incidents discussed in section III of this preamble reflect that the existing safety messaging by way of marking, labeling, and instructional literature has had limited effectiveness for preventing the submersion hazard associated with neck floats. Indeed, it is reasonably foreseeable that caregivers will disregard warnings and instructions for neck floats and fail to adhere to them for each use. Many of the reported incidents involved products that not only met but exceeded the existing ASTM F963–23 requirements. Safety messaging has inherent weaknesses compared to designing the hazard out of a product or guarding consumers from the hazard (Laughery & Wogalter, 2011), and it cannot, alone, adequately address the specific identified hazards from neck floats. Drowning statistics and water safety campaigns have shown that caregiver supervision can be imperfect and insufficient to avoid drowning hazards, and many children drown every year.³⁴ ³⁵ Further, warnings and instructional literature depend on persuading the consumer to change their behavior to avoid a hazard, and various factors can impede the effectiveness of these mediums. Conversely, the requirements for safety

³⁴ See AAP on drowning: <https://www.aap.org/en/patient-care/early-childhood/early-childhood-health-and-development/safe-environments/drowning/>; accessed on March 20, 2024.

³⁵ See CDC on drowning facts: Drowning Facts | Drowning Prevention | CDC; accessed on March 20, 2024.

messaging can be improved to increase the likelihood of consumers seeing, reading, remembering, and heeding the warnings and instructions, and better support the Commission's proposed performance requirements. Accordingly, the Commission proposes in § 1250.5(d) to require the following marking, labeling, and instructional literature requirements for all products within the scope of the NPR and seeks comment on the format, location, and content requirements of the proposed warnings.

1. Product and Package Marking and Labeling

The primary U.S. voluntary consensus standard for product safety signs and labels, ANSI/NEMA Z535.4, *American National Standard for Product Safety Signs and Labels*,³⁶ recommends that on-product warnings include content that addresses the following three elements:

- a description of the hazard;
- information about the consequences of exposure to the hazard; and
- instructions regarding appropriate hazard-avoidance behaviors.

Providing more explicit or detailed information in a warning has been

found to increase warning effectiveness (Laughery & Smith, 2006) by increasing the perception of injury severity and perceived hazard (DeJoy, 1999). Vividness of message content has been found to increase message salience by triggering motivation to act in consideration of the warning (Murray-Johnson & Witte, 2003). Accordingly, the Commission proposes, in § 1250.5(d)(1), that the products within scope of the rule, and their retail packaging, contain the warning message shown in Figure 6, including the use of bolding and the formatting of the text, the safety alert symbol, and the signal word, in the order presented.

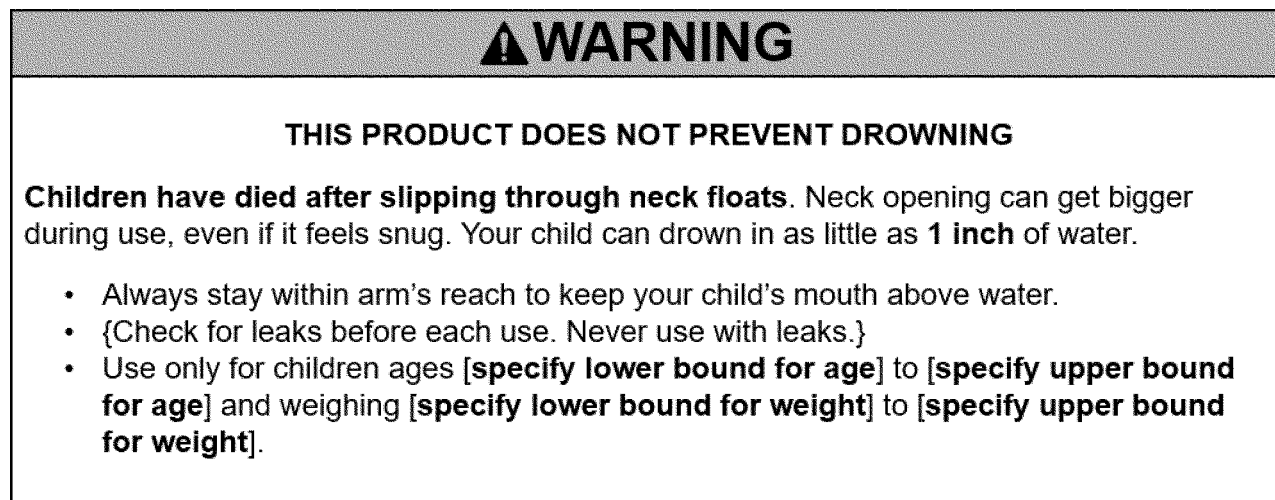


Figure 6: Warning for Child Neck Floats. Image not to scale.

The portion, “[specify lower bound for age],” is to be filled with the lowest age intended for use of the product and in bold font. The portion, “[specify upper bound for age],” is to be filled with the highest age intended for use of the product and in bold font. The portion, “[specify lower bound for weight],” is to be filled with the minimum intended weight in pounds for use of the product and in bold font. The portion, “[specify upper bound for weight],” is to be filled with the maximum intended weight in pounds for use of the product and in bold font. The portion, “{Check for leaks before each use. Never use with leaks.},” is only required and appropriate for child neck floats with inflatable components. The brackets are to be omitted from the label in each case above.

a. Content

In developing the proposed message panel, among other sources, staff considered the available incident data, reasonably foreseeable use, warnings required for “Aquatic Toys” per ASTM F963, warnings recommended and required by other standards and bodies, and recommendations and requirements specified in ANSI/NEMA Z535.4. Additionally, the Commission considers that consumers are less likely to read, heed, and remember safety messaging if they feel overwhelmed by the volume and/or depth of the information. The Commission encourages manufacturers to include additional product-specific warnings where necessary; however, such warnings shall neither contradict nor confuse the intended meaning of the required warnings.

The statement, “THIS PRODUCT DOES NOT PREVENT DROWNING,”

begins the message panel by articulating clearly that children can still drown even though they use the product. Each letter in this statement shall be bold and capitalized to strengthen the statement and attract the consumer's attention to the warning label. If the consumer reads nothing else, this statement may challenge some consumers' perception that the product will necessarily keep the child's mouth and nose above the water. This perception of safety is dangerous because it may lead consumers to provide inadequate supervision of the child using the product in water. This language is required by the Australian Competition & Consumer Commission (ACCC) for floatation aids as specified in the Australian standard, AS/NZS 1900:2014, *Flotation aids for water*

³⁶ ANSI Z535.4, *American National Standard for Product Safety Signs and Labels* is the primary U.S.

voluntary consensus standard for the design, application, use, and placement of on-product

warning labels when developing or assessing the adequacy of warning labels.

familiarization and swimming tuition.³⁷ Similar language is required for Aquatic Toys per section 5.4 of ASTM F963–23 (i.e., “This is not a lifesaving device.”) and for infant bath seats per ASTM F1967 (i.e., “NOT A SAFETY DEVICE.”).³⁸ 16 CFR part 1215. However, the Commission preliminarily determines that the statement, “This is not a lifesaving device,” is not appropriate for the product because the proposed warnings better satisfy the intent to communicate that the product does not prevent drowning, and to include it in addition to the other warnings could dilute the warnings and increase the risk of warning exhaustion. Therefore, instead of complying with the warning text “This is not a lifesaving device.” in section 5.4 of ASTM F963–23, the Commission proposes to require the language in Figure 6.

The statement, “Children have died after slipping through neck floats,” may reduce the likelihood of consumers otherwise inferring that the life-threatening hazard is just an unlikely potential risk rather than a hazard that has occurred and may happen to their child. As detailed above in section III, at least 87 incidents involved a child’s head slipping through, two of which resulted in the child dying as a result of drowning. In most cases, the caregiver immediately intervened such that the child either did not fully submerge or was only submerged briefly. Had the caregiver not been present, these incidents could have resulted in the child drowning. Similar language is used in numerous other standards, such as for infant bath seats per ASTM F1967, infant bathtubs per ASTM F2670, *Standard Consumer Safety Specification for Infant Bathtubs*, and Beach Umbrellas per ASTM F3681, *Standard Consumer Safety Specification for Beach Umbrellas and Anchor Devices*.^{39 40}

³⁷ See ACCC web page on “Swimming & flotation aids”: [³⁸ See ASTM F1967, *Standard Consumer Safety Specification for Infant Bath Seats*: \[³⁹ See ASTM F2670, *Standard Consumer Safety Specification for Infant Bath Tubs*: \\[The statement, “Neck opening can get bigger during use, even if it feels snug,” addresses the critical and hidden hazard of center opening expansion, because consumers are likely to expect that the center opening will not permit the child’s mouth to go underwater if the product is tightly fitted, even though this is possible and has occurred in reported incidents \\\(e.g., IDI 210910CCC1030 detailed above\\\). Without dispelling this false assumption of safety, the consumer is more likely to discredit the warning messages and use the product without taking all necessary precautions, particularly if they have previously used the product without incident or seen others use the product without incident. Of the 21 incident reports that mentioned whether the neck float felt snug when placed on the victim at the time of the incident, 19 of the incident reports indicated the neck float did have a tight fit.\\]\\(https://www.astm.org/f2670-22.html;accessed on March 27, 2024. ASTM F2670 on infant bath tubs and F1967 on infant bath seats specify that the warning label shall address that babies have drowned while using the respective products.</p>
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The statement, “Your child can drown in as little as 1 inch of water,” communicates an important point that may help maintain the consumer’s attention and educate them, as they are unlikely to be familiar with this fact,⁴¹ and they are likely to be caught off guard by it. It serves an important role by emphasizing that even very shallow water can be lethal, which may contradict the consumer’s expectation of safety associated with using the product in shallow water, such as in bathtubs. The statement is also personalized to the reader by using the words: “Your child,” as opposed to “a child,” or similar language, which can more easily be disregarded by the consumer as not applying directly to the child for whom they are responsible.⁴² Other standards, such as ASTM F3681 on beach umbrellas, also take the approach of personalized language regarding the risk of death.⁴³

The message panel includes bulleted statements for important information about how to avoid the drowning hazard. The statement, “Always stay within arm’s reach to keep your child’s mouth above water,” emphasizes the

⁴⁰ See ASTM F3681, *Standard Consumer Safety Specification for Beach Umbrellas and Anchor Devices*: [⁴¹ For example, see “Water Safety for Parents” from John Hopkins Medicine: \[⁴² ASTM F1967 on infant bath seats specifies the following warning regarding supervision using the word “your”: “Stay in arm’s reach of your baby.”\]\(https://www.hopkinsmedicine.org/health/wellness-and-prevention/water-safety-for-parents;accessed on June 13, 2024.</p>
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<div data-bbox=\)](https://www.astm.org/f3681-24.html;accessed on June 12, 2024. ASTM F3681 on beach umbrellas specifies that the warning shall state that beach umbrellas have killed people.</p>
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⁴³ ASTM F3681 on beach umbrellas specifies the following warning regarding the risk of death, using the word “you”: “You can be killed too!”

importance of a caregiver’s attentiveness to a child while using a neck float to be able to rescue the child immediately if their mouth and/or nose submerges. Unattended children using neck floats in bathtubs sustained injuries and two reportedly died (e.g., IDIs 190711CCC2487 and 200915HFE0001). Again, caregivers may develop a false sense of security when using the neck float, relaxing their supervision of the child for numerous reasons, such as past incident-free experiences, the perception that the neck float is too tight for the child to slip through, and the presumption of safety associated with the neck float being a consumer product marketed to such young ages for the purpose of keeping their mouth and nose above the water (Woodson et al., 1992).

The American Academy of Pediatrics (AAP) has encouraged caregivers to use “touch supervision” that is, remaining within arm’s reach of infants and toddlers swimming in pools.⁴⁴ Section 5.4 of ASTM F963–23 requires a warning statement that addresses the following: “Do not leave child unattended while device is in use.” Similar juvenile product standards, such as ASTM F1967 and ASTM F2670, also support the use of statements pertaining to supervision and proximity.⁴⁵ The proposed language is stronger for neck floats because it highlights the risk of partial slip-through, which is a small movement that requires a more attentive caregiver than simply monitoring for a large motion, such as the child fully submerging. Further, the personalization via “your child” may help encourage the consumer to see the warning as applying to the child for whom they are responsible and increase its impact.

The statements specific to inflatable products, “Check for leaks before each use. Never use with leaks,” are intended to motivate consumers using inflatable neck floats to check for leaks before each use and to never use neck floats with leaks. Detailed in section III of this preamble, numerous incidents involved products that had leaks. In many cases, the consumers did not report testing the product for leaks prior to every use, and some cases mentioned that the consumers were aware of slow leaks and continued to use the product anyway

⁴⁴ See AAP on drowning and touch supervision. “A Parent’s Guide to Water Safety.” Pediatric Patient Education, 1 Jan. 2021, https://doi.org/10.1542/peo_document110.

⁴⁵ ASTM F1967 on infant bath seats and F2670 on infant bath tubs specify the following warning regarding supervision: “Stay in arm’s reach of your baby.”

due, in part, to past incident-free experiences and the costs associated with having to replace the product. The proposed instructional literature requirements, detailed below, complement this warning with specific instructions to help the consumer avoid the risks of underinflation. The Commission cautions that, while the proposed statements may help some consumers prevent submersion associated with leaks, most reported incidents involved products with warnings and instructions pertaining to leaks.

Lastly, the statements in brackets pertaining to the child's age and weight are intended to help and encourage the consumer to select and use the appropriate product for their child; though, as explained above, children can vary considerably in the key face, head, and neck measurements relevant to slip-through, regardless of their age and weight. Discussed below, the Commission proposes instructional literature requirements to further aid the consumer in accurately taking the necessary measurements. Providing the intended age and weight also serves to guide testing of the products to increase the safety of the products for the intended and foreseeable end users.

b. Format

CPSC commonly uses ANSI/NEMA Z535.4 as a reference for warning formatting requirements. Human factors experts and warnings literature regularly cite ANSI/NEMA Z535.4 when discussing the design and evaluation of on-product warning labels and generally consider the ANSI Z535 series of requirements as the benchmark and state of the art standards against which warning labels should be evaluated for adequacy (Vredenburg & Zackowitz, 2005; Wogalter & Laughery, 2005). Furthermore, the scope of ANSI/NEMA Z535.4 is broad enough to encompass nearly all consumer products, including children's products and toys (Kalsher & Wogalter, 2008).

Signal words, colors, graphics, and placement all increase conspicuity. The salience of a visual warning can be enhanced using large and bold print, high contrast, color, borders, pictorial symbols, and special effects like flashing lights. Therefore, the NPR proposes that the warning label design requirements for children's neck floats adopt the current recommendations from ASTM's Ad Hoc Language Task Group (Ad Hoc Task Group).⁴⁶ Staff has

⁴⁶ ASTM Ad Hoc Wording Task Group (Ad Hoc TG) consists of members of various durable nursery product voluntary standards committees, including

worked closely with the Ad Hoc Task Group to develop warning recommendations that are based largely on the ANSI/NEMA Z535.4 requirements. The recommendations provide permanent, conspicuous, and consistently formatted warning labels across juvenile products. Warnings that meet the recommendations address numerous format issues related to capturing consumer attention, improving readability, and increasing hazard perception and avoidance behavior. Such recommendations include requiring that the proposed warnings conform to ANSI/NEMA Z535.4 sections 6.1–6.4, 7.2–7.6.3, and 8.1, with the following changes to the ANSI standard:

- For enforceability, in sections 6.2.2, 7.3, 7.5, and 8.1.2, replace the word “should” with “shall;”
- Also, for enforceability, in section 7.6.3, replace the phrase “should (when feasible)” with the word “shall;” and
- To allow greater production flexibility without affecting the efficacy of the warnings, strike the word “safety” when used immediately before a color (e.g., replace “safety white” with “white”).

Further, certain text in the message panel must be in bold and in capital letters as shown in the example warning label in Figure 6, above, to provide emphasis and capture the reader's attention. The signal word “WARNING” must appear in sans serif letters in upper case only and be at least 1/8 inch (3.2 mm) in height and be center or left aligned. The height of the exclamation point inside the safety alert symbol, an exclamation mark in a triangle, as shown in the example warnings must be at least half the height of the triangle and be centered vertically inside the triangle. The message panel text capital letters cannot be less than 1/16” (1.6 mm) and the message panel text shall be center or left aligned and appear in sans serif letters. The text in each column should be arranged in list or outline format, with precautionary (hazard avoidance) statements preceded by bullet points. Precautionary statements must be separated by bullet points if paragraph formatting is used.

c. Placement

Warning research indicates that warning labels with prominent

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 nursery product voluntary standards. The latest version of the Ad Hoc-approved recommended language is published in the “Committee Documents” section of the Committee F15 ASTM website.

placement increase the likelihood of being noticed (Rogers et al., 2000). Further, warnings that are placed directly on a product and/or the packaging have a higher noticeability rate (Wogalter et al., 1987; Frantz & Rhoades, 1993) because consumers are more likely to see such warnings when first examining the product prior to purchase. ANSI/NEMA Z535.4 provides general guidance on the placement of warnings, stating that warnings must be placed so they are “readily visible to the intended viewer” and will “alert the viewer to the hazard in time to take appropriate action.”⁴⁷ Similarly, both the Ad Hoc Task Group and section 5.3.6 of ASTM F963–23 require warnings to be conspicuous.

Accordingly, the Commission proposes that the warning label identified in Figure 6 is positioned conspicuously on the product, such that it is visible clearly and, in its entirety, when the product is placed on the child.

For the product's packaging, to ensure that the label is in an area of the packaging that stands out and is visible, the Commission proposes that the warning label in Figure 6 must be placed in the principal display panel, which is defined in ASTM F963 as “the display panel for a retail package or container, bin, or vending machine that is most likely to be displayed, shown, presented, or examined under normal or customary conditions of display for retail sale.”

2. Instructional Literature

The Commission proposes to require that instructions are provided with all neck float products and that they must be easy to read and understand, and shall be in the English language, at a minimum, consistent with the Ad Hoc recommended language under § 1250.5(d)(2). These instructions must be printed on the product and provided separately, such as a user manual, and include information on assembly, installation, maintenance, cleaning, and use, where applicable. The instructions must explain how to check for adequate fit of the product to prevent the child from slipping through the center opening. Instructional literature provided with the product, but not printed on the product, must include all warnings specified above in section 1 on content. Any instructions provided in addition to those required in this section must neither contradict nor confuse the meaning of the required

⁴⁷ American National Standards Institute. (2011). *ANSI Z535.4. American national standard: Product safety signs and labels*. Rosslyn, VA: National Electrical Manufacturers Association, Section 9.1.

information, nor be otherwise misleading to the consumer.

For products with inflatable components, the Commission proposes that the instructional literature includes clear directions for testing the product for leaks. These directions are important for reducing the likelihood of the product losing air during use, as air loss may increase the amount of deformation and center opening expansion. Absent these directions, caregivers are less likely to identify leaks in their products prior to the children being submerged in water.

The Commission assesses that these instructional literature requirements support the proposed performance requirements and may help some consumers to select, use, and maintain the products safely. Instructional literature, however, is likely to have limited effectiveness to address this hazard, as consumers using inflatable neck floats would need to remember and choose to follow the instructions every time they use the product, and it is reasonably foreseeable they will forego doing so for the reasons detailed above. Most neck floats involved in incidents provided instructional literature in the forms of user manuals and on-product labels, and many of the products were used contrary to the instructions, resulting in the children being submerged in water.

VI. Prohibited Stockpiling

The Commission is proposing in § 1250.5(e) an anti-stockpiling provision to prevent firms from manufacturing or importing large quantities of noncompliant neck floats before the rule takes effect and seeks comment on this provision. Under this proposal, firms could not manufacture or import noncompliant products in a given month more than a rate of 105 percent of the base period. The base period is the average monthly manufacturing or import volume within the last 13 months of production that immediately precedes the month of promulgation of the final rule.

Neck float products have characteristics that make them ideal for firms seeking to stockpile, such as low inventory costs due to their small size (particularly for inflatable products before sale), durability, and low costs of production. Additionally, the new requirements may cause some firms to exit the market. Exiting firms would have an incentive to sell stockpiled neck floats to support the costs of switching to manufacturing another product. These firms would be relatively unconstrained by reputational concerns surrounding their sale of stockpiled

non-compliant neck floats after the effective date of a final rule. Further, because many neck floats are sold primarily or exclusively on manufacturers' or importers' own websites, the responsible business practices of retailers that refuse to take noncompliant toys into their inventory, even before the effective date of a new safety regulation, would have little constraining effect on stockpiling by manufacturers and importers themselves. These firms could expect to sell their stockpiled noncompliant products even as other sellers limit their sales to compliant products.

VII. Feasibility of Proposed Requirements

Pursuant to section 106(c) of the CPSIA, Congress directed the Commission to "periodically review and revise the rules set forth under this section to ensure that such rules provide the highest level of safety for such products that is feasible." 15 U.S.C. 2056b(c). Based on the staff's analysis provided in this NPR, the Commission preliminarily determines that the NPR is technically and economically feasible, and requests comment on this determination.

A. Technological Feasibility

A proposed rule is technically feasible if it is capable of being done. For example, compliant products might already be on the market; or the technology to comply with the requirements might be commercially available; or existing products could be made compliant; or alternative practices, best practices, or operational changes would allow manufacturers to comply. See, e.g., 15 U.S.C. 1278a(d) (discussing lead limits). The Commission preliminarily concludes that the NPR's proposals meet technical feasibility criteria. No new or even emerging technology is needed to manufacture a compliant product.

In addition, though testing laboratories may need to procure additional equipment to accommodate the conditioning, buoyancy, and neck opening requirements, the tools required for those test methods are not proprietary or exclusive items and may be reasonably sourced from commercial providers. Of the testing tools proposed by the NPR, only the specified head probes are unique; however, staff were able to fabricate those probes using commercially available resources. Additionally, many of the test methods proposed by the NPR are already either included in CPSC mandatory standards or come from other previously published external safety standards.

B. Economic Feasibility

The proposed rule is economically feasible because the cost of compliance would not threaten the viability of the industry. CPSC expects a significant economic effect on firms supplying inflatable neck floats and a de minimis impact on firms supplying inherently buoyant neck floats, which are more easily made compliant with the rule. The availability of inherently buoyant products that, CPSC staff assesses, are compliant or readily could be compliant with the proposed rule, demonstrates that the proposed rule is economically feasible.

VIII. Incorporation by Reference

Proposed section 1250.5 would incorporate by reference portions of ANSI/CAN/UL 12402-9, ANSI APSP ICC-16, ANSI/NEMA Z535.4-2023, ASTM F833-21 and ASTM F1967-19. The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. Under those regulations, agencies must discuss, in the preamble to a final rule, ways in which the material the agency incorporates by reference is reasonably available to interested parties and how interested parties can obtain the material. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b)(3).

In accordance with the OFR regulations, section V of this preamble summarizes the provisions of ANSI/CAN/UL 12402-9, ANSI APSP ICC-16, ASTM F833-21, ASTM F1967-19 and ANSI/NEMA Z535.4-2023 that the Commission proposes to incorporate by reference into proposed § 1250.5. The standards are reasonably available to interested parties by permission of the relevant standards developing organization (SDO) to be viewed as a read-only document during the comment period on this NPR, at:

- <https://www.surveymonkey.com/r/DQVJYMKforANSI/CAN/UL12402-9>,
- <https://codes.iccsafe.org/content/ANSIAPSPICC162017/title-page-for-ANSI-APSP-ICC-16>,
- <https://www.surveymonkey.com/r/DQVJYMKforANSI/NEMA-Z535.4-2023>,
- <https://www.astm.org/products-services/reading-room.html> for ASTM F833-21, and
- <https://www.astm.org/products-services/reading-room.html> for ASTM F1967-19.

Interested parties can also schedule an appointment to inspect a copy of the standards at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West

Highway, Bethesda, MD 20814, telephone: (301) 504-7479; email: *cpssc-os@cpssc.gov*. Alternatively, interested parties can purchase copies from the following sources:

(1) Pool and Hot Tub Alliance (PHTA), 1650 King Street, Suite 602, Alexandria, VA 22314; phone: (703) 838-0083; website: *www.phta.org*
(i) ANSI APSP ICC-16, *American National Standard for Suction Outlet Fitting Assemblies (SOFA) for Use in Pools, Spas, and Hot Tubs*, (approved August 18, 2017).

(2) Underwriters Laboratories (UL), 1250 Connecticut Avenue NW, Suite 520, Washington, DC 20036; phone: (202) 296-7840; website: *www.ul.com*.

(i) ANSI/CAN/UL 12402-9, *Standard for Personal Flotation Devices—Part 9: Test Methods*, (published February 11, 2021).

(3) National Electrical Manufacturers Association (NEMA), 1300 17th St. N, Arlington, VA 22209; phone: (703) 841-3200; website: *www.nema.org*.

(i) ANSI/NEMA Z535.4-23, *American National Standard for Product Safety Signs and Labels* (approved December 14, 2023).

(4) ASTM International (ASTM), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959; phone: (610) 832-9585; website: *www.astm.org*.

(i) ASTM F833-21, *Standard Consumer Safety Performance Specification for Carriages and Strollers*, (approved June 15, 2021).

(ii) ASTM F1967-19, *Standard Consumer Safety Specification for Infant Bath Seats*, (approved May 1, 2019)

IX. 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 neck floats manufactured after the effective date. 15 U.S.C. 2058(g)(1).

Some neck floats may already comply with the proposed requirements; however, most neck floats would need to be redesigned, manufacturing equipment may need to be retooled, and all neck floats would require third-party testing to the new requirements. 15 U.S.C. 2063(a)(3).⁴⁸ Accordingly, to provide time to comply with the rule, to ensure adequate lab capacity to test and certify toys, and to spread the cost of compliance over a period of months, the

Commission proposes to make this rule effective 180 days after publication of the final rule in the **Federal Register**.

The effective date of 180 days should be sufficient for firms to come into compliance, because the proposed tests are consistent with testing required in 16 CFR parts 1215, 1227, and 1450. For other proposed tests that are based on ANSI/CAN/UL 12402-9:2022, no unique tools will be required. For the neck opening testing, staff were able to fabricate head probes within a reasonable time using commercially available resources. Accordingly, CPSC expects that these laboratories are competent to conduct the required testing and obtain 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 testing and the amount of time needed to come into compliance with a final rule.

X. 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, unless the rule would not have a significant economic impact on substantial number of small entities. 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. The IRFA must also contain:

(1) a description of why action by the agency is being considered;

(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;

(3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

(4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule; and

(5) an identification to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

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 requirements.

A. Reason for Agency Action, NPR Objectives and Legal Basis

Section I of this preamble explains why the Commission proposes to establish a mandatory rule for neck float and provides a statement of the objectives of, and legal basis for, the proposed rule. The proposed requirements in the NPR are more stringent than ASTM F963-23, which the Commission incorporated into the mandatory rule in 16 CFR part 1250, *Safety Standard Mandating ASTM F963 for Toys*, as described in sections IV and V of this preamble. The NPR addresses the known hazards presented by neck floats, discussed in section III of this preamble, that the current mandatory toy safety standard does not adequately address.

B. Small Entities to Which the Rule Will Apply

Section II of this preamble describes the products within the scope of the proposed rule, provides an overview of the market for neck floats and the use of these products in the U.S. This section provides additional details on the market for products within the scope of the rule.

The North American Industry Classification System (NAICS) defines product codes for U.S. firms. Firms that manufacture neck floats may be categorized under various NAICS product codes. Most of these firms likely fall under NAICS code such as 339930 Doll, Toy, and Game Manufacturing, 326190 Other Plastics Product Manufacturing, and 326199 All Other Plastic Product Manufacturing. Importers of these products could also vary among different NAICS codes, with a majority of the firms categorized under NAICS codes as wholesalers: 423920 Toy and Hobby Goods and Supplies Merchant Wholesalers, and 424610 Plastics Materials and Basic Forms and Shapes Merchant Wholesalers.

Currently, unlike inherently buoyant neck floats, the inflatable versions of these products are not available for purchase through larger retailers and retailers with physical store locations. Retailers of neck floats fall under NAICS codes 459120 Hobby, Toy, and Game Stores, 452210 Department Stores, 452310 General Merchandise Stores Including Warehouse Clubs and Supercenters, and 454390 Other Direct Selling establishments. Floatation products can be sold among varying

⁴⁸ Section 14(a)(3) specifies laboratories must have at least 90 days to implement new third-party testing requirements.

retail channels focused on swimming or toddler products. Therefore, the NAICS codes listed in this IRFA for retailers, importers, and manufacturers are unlikely to be exhaustive.

Under the U.S. Small Business Administration (SBA) guidelines, a manufacturer, importer, and retailer of neck float products is categorized as “small” based on the SBA’s size

thresholds associated with the NAICS code. SBA uses the number of employees to determine whether a manufacturer or importer is a small business while SBA uses annual revenues to consider retailers. Based on 2021 Statistics of U.S. Businesses (SUSB) data,⁴⁹ and a review of publicly available data on annual revenues,

CPSC estimated the number of firms classified as small for the most relevant NAICS codes. Table 6 and Table 7 provide the estimated number of small firms by each NAICS code.⁵⁰ CPSC estimates that a total of 19 small U.S. manufacturers and importers, and 27,260 small U.S. retailers, deal in neck floats.

Table 6 – Estimate of Number of Small Manufacturers and Importers

NAICS Code	Description	SBA Size Standard for Firms (# of Employees)	Number of Firms that meet size standard (Based on SUSB data)
339930	Doll, Toy, and Game Manufacturing	700	3
326190	Other Plastics Product Manufacturing	750	1
326199	All Other Plastic Product Manufacturing	750	6
423920	Toy and Hobby Goods and Supplies Merchant Wholesalers	175	3
424610	Plastics Materials and Basic Forms and Shapes Merchant Wholesalers	150	6

Table 7 – Estimate of Number of Small Retailers

NAICS Code	Description	SBA Size Standard for Firms (Annual Revenue) Millions \$	Number of Firms that meet size standard (Based on SUSB data)
452210	Department Stores	\$40.0	15
451120	Hobby, Toy, and Game Stores	\$35.0	4,660
452310	General Merchandise Stores, Including Warehouse Clubs and Supercenters	\$47.0	8,006
454390	Other Direct Selling establishments	\$11.5	14,579

The data indicated that all the manufacturers/importers of these products are considered to be small businesses. CPSC assesses that the total size of this market likely does not exceed \$5 million in aggregate.

C. Compliance Reporting and Recordkeeping Requirements of the Proposed Rule

The NPR would require manufacturers and importers of neck floats to meet performance, warning label, and instructional material requirements, and to conduct third-party testing to demonstrate compliance. Section V of this preamble

describes the performance, warning label and instructional material requirements.

Manufacturers 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

⁴⁹ Census Bureau, 2023. Statistics of US Businesses (SUSB) 2021. Suitland, MD. Census Bureau.

⁵⁰ Some discrepancies exist between the published SBA size standard NAICS code and the SUSB code. Staff used the code description to match the size standard to the correct value.

Retailer size determination is made using 2017 SUSB data by applying the ratio of firms that meet the standard to the 2021 data values.

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. Under section 14 of the CPSA, manufacturers, importers, and private labelers of neck float products would be required to certify, based on a test of each product by an ISO-accredited, CPSC-accepted third party conformity assessment body, that their products comply with the requirements of the proposed rule. Each children's product certificate of compliance must identify the third-party conformity assessment body that conducted the testing upon which the certificate depends.

D. Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule

CPSC has not identified any other Federal rules that duplicate, overlap, or conflict with the proposed rule.

E. Potential Impact on Small Entities

The Commission expects small firms of inflatable products to incur a significant cost from redesign/retooling, and material changes as a result of the proposed rule. If the rule is finalized, small manufacturers would incur one-time costs related to redesign, retooling, testing, labeling/literature updates and ongoing certification costs to comply with the rule for product lines that currently do not meet the proposed requirements. Generally, CPSC considers an impact to be potentially significant if it exceeds 1 percent of a firm's revenue. Based on the aforementioned costs, CPSC expects approximately 19 small firms to incur a cost that exceeds 1 percent of the annual revenue of the firm. The Commission seeks comments from small firms stating their annual revenue and estimated compliance costs.

Staff assesses that a large majority of inflatable neck float products cannot, as currently constructed, meet the proposed requirements of the rule. These products will require redesign, retooling and additional components to comply with the proposed rule. Major design changes are needed to meet the performance requirements related to durability, buoyancy, and the neck opening. The Commission anticipates that design and/or material changes, which may include modifying the shape of the neck float or modifying the structure by transitioning between or combining inherently buoyant and

inflatable flotation components, would be required to the entirety of the product. The potential product costs are therefore the incremental cost for the material change and the one-time labor cost to perform the redesign and retooling. Inherently buoyant neck floats are expected to incur significantly lower costs.

CPSC estimates that the incremental costs of the material change to be \$6 per product based on a comparison of retail prices of inflatable neck floats with non-inflatable neck floats. This assumes that most inherently buoyant neck floats are likely to meet the proposed performance standards without costly modification, while inflatable neck floats are likely not to comply with the performance requirements. CPSC assumes the observed premium of 20 percent of retail price⁵¹ for non-inflatables represents the incremental cost of material between the types. CPSC estimates a range of 3 to 4 months of labor by a material engineer would be required for neck float redesign. Data from the Bureau of Labor Statistics (BLS) indicates that the average full hourly compensation rate of a material engineer, which includes wages⁵² and benefits,⁵³ is \$79.64 per hour.⁵⁴ Because neck float designs are very similar across product models and firms, CPSC assesses that firms would be able to incorporate design changes across all products lines that the manufacturer offers without additional effort required for each product line. CPSC staff estimates a range of possible redesign costs of \$38,227 to \$50,970 per firm.⁵⁵

Some additional costs might be incurred related to updating and/or adding labels/literature. Generally, the costs associated with modifying or adding warning labels or instructional literature are low on a per unit basis because manufacturers of these products are already required to provide labels with their product. Nearly every manufacturer also provides some literature with their product. A one-time update is expected to be less than \$0.01 in cost per product sold. Therefore,

⁵¹ Non-inflatable neck floats were on average 20 percent more than the most popular inflatable neck float.

⁵² The mean hourly wage of a material engineer is \$53.09 per hour as of May 2023 according to BLS. <https://www.bls.gov/oes/current/oes172131.htm>.

⁵³ The ratio of full compensation to wages for someone in *Professional and related occupations* in the Manufacturing industry is 1.50 (\$68.47 compensation per hour + \$45.60 wage per hour) as of December 2023. Table 4. Private industry workers by occupational and industry group—2023 Q04 Results ([bls.gov](https://www.bls.gov)).

⁵⁴ \$79.64 per hour = \$53.09 wage per hour × 1.50 compensation factor.

⁵⁵ \$79.64 per hour × 480 hours (3 months) = \$38,227, \$79.64 × 640 hours (4 months) = \$50,970.

CPSC expects the incremental cost related to the labeling and instructional literature provisions to be *de minimis*.

F. Third-Party Testing Costs

The NPR would require manufacturers and importers of neck floats to comply with performance requirements and demonstrate compliance by required 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.

Neck float manufacturers could incur some additional costs for certifying compliance with the proposed rule. The certification of must be completed by a third party conformity assessment body. Based on quotes from testing laboratories for ASTM F963 testing services, the cost of certification testing would range from \$130 to \$250 per product sample. For neck floats, the average number of models per firm is two, based on manufacturer websites, which would equate to a testing and certification cost range of \$260 to \$500 per firm.

H. Efforts To Minimize Impact, Alternatives Considered

The Commission considered four alternatives to the proposed rule that could reduce the impact on small entities: (1) not establishing a mandatory standard for neck floats, (2) establishing an information and education campaign for neck floats, (3) incorporating existing international standards without modification, and (4) setting a later effective date.

1. Not Establishing a Mandatory Standard

Section 106 of the CPSIA requires CPSC to promulgate toy safety standards that are "more stringent than" the applicable voluntary standard if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product, as well as to periodically review and revise the rules set forth under section 106 to ensure that such rules provide the highest level of safety for such products that is feasible. 15 U.S.C. 2056b(c), (d). Given CPSC's statutory mandate, and continuing incidents associated with neck float as described in section III of this preamble, the Commission has determined that it must address the safety of children using neck float to ensure that the risk of drowning is mitigated. While failing to promulgate a mandatory standard for neck floats would have no direct impact on U.S. small businesses, it would allow

unsafe products to remain on the market and ignore a known drowning hazard to children, with reported fatalities. After preliminarily determining that the existing requirements in ASTM F-963 are inadequate, in section IV, the Commission is moving forward with this rulemaking to comply with its statutory mandate and prioritize the safety of children by mitigating potential child slip-throughs and submergence in water associated with the use of neck floats.

2. Information and Education Campaign

CPSC could create an information and education campaign to better alert parents and caregivers regarding the drowning hazard associated with neck floats. This would require consumer outreach efforts like advertising and marketing related to the hazards. This alternative could be implemented independent of regulatory action. Although information campaigns may be helpful, there have been deaths associated with these products while CPSC was conducting extensive drowning prevention educational campaigns. This demonstrates that information and education alone are inadequate to address the drowning hazard associated with neck floats. Therefore, the Commission preliminary finds that while information campaigns might be helpful, performance standards would be more effective in preventing deaths associated with the use of neck floats.

3. Incorporate BS EN 13138-1:2021 Without Modifications

The Commission could adopt BS EN 13138-1:2021 without modifications, discussed above in section V, because it has similar requirements as the proposed rule. Some neck float products currently available in the U.S. are advertised as meeting these requirements and as a result these products would be unaffected by

proposed requirements. Adopting this alternative would lower the number of firms affected by the proposed rule. However, the international standards do not include specifications for slip-through hazards associated with neck floats. Therefore, this alternative is unlikely to prevent drowning related injuries to children who may slip through neck floats.

4. Later Effective Date

To reduce burden on small businesses, the Commission could adopt an effective date later than 180 days after **Federal Register** publication, to spread the cost of compliance over a longer period. Although some neck floats already comply with most of the proposed requirements, most neck floats (primarily inflatable neck floats) would need to be redesigned, and all neck floats would require third-party testing to the new requirements. In this case, as described above, 180 days is reasonable for firms to comply with the rule, and many labs are already CPSC-accepted to conduct the same or similar testing and products expected to already be compliant are currently available for purchase.

XI. Environmental Considerations

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 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.

XII. Paperwork Reduction Act

This proposed rule for neck floats 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:

- 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 Toys: Requirements for Neck Floats.

Description: As described in section V of this preamble, the proposed rule would require new labeling and instructions for neck floats toys. The NPR proposes that neck float meet the proposed requirements of § 1250.5, which are summarized in section V of this preamble.

Section 5 of ASTM F963-23 contains requirements for marking, labeling, and instructional literature of children’s toys in general. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3). CPSC will request an OMB control number for the proposed collection.

Description of Respondents: Persons who manufacture or import neck floats.

Estimated Burden: We estimate the burden of this collection of information as follows:

Table 8 – Estimated Annual Reporting Burden

Burden Type	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
Labeling and instructions	20	1	20	2	40

This estimate is based on the following: CPSC estimates there are 20 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

respondent that reports annually would respond once, as product models for neck floats are brought to market and new labeling and instruction materials are created, for a total of 20 responses annually (20 respondents × 1 responses per year). CPSC assumes that on average

it will take 1 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 2 hours per response. Therefore, the total burden hours for the collection are estimated to be 40 hours

annually (20 responses × 2 hours per response = 40 total burden hours).

CPSC estimates the hourly compensation for the time required to create and update labeling and instructions is \$41.76.⁵⁶ Therefore, the estimated annual cost of the burden requirements is \$1,670 (\$41.76 per hour × 40 hours = \$1,670.40). No operating, maintenance, or capital costs are associated with the collection. Based on this analysis, the proposed information collection would impose a burden to industry of 40 hours at a cost of \$1,670 annually.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we will submit the information collection requirements of this proposed rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by January 21, 2025, (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.

XIII. 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 106(f) of the CPSIA deems rules issued

under that provision "consumer product safety standards." Therefore, once a rule issued under section 106 of the CPSIA takes effect, it will preempt in accordance with section 26(a) of the CPSA.

XIV. 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 proposed rule would create a new 16 CFR 1250.5 as part of 16 CFR part 1250. If issued as a final rule, the proposed rule would be a children's product safety rule that requires the issuance of a NOR.

16 CFR part 1112 establishes requirements for accreditation of third-party conformity assessment bodies to test for conformity with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. Part 1112 also codifies all of the NORs issued previously by the Commission. To meet the requirement that the Commission issue an NOR for the proposed standard, the Commission proposes to add neck floats to the list of children's product safety rules for which CPSC has issued an NOR.

Testing laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the standard for neck floats would be required to meet the third-party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to CPSC to have 16 CFR 1250.5, Safety Standard or Toys: Requirements for Neck Floats, included within the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: <https://www.cpsc.gov/cgi-bin/labsearch/>.

Testing laboratories should not be adversely impacted as a result of this rule. CPSC expects that laboratories will be able to test to this proposed 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.

XV. Request for Comments

The Commission requests comments on the proposed rule to promulgate a mandatory standard for neck floats under section 106 of the CPSIA. During the comment period, ASTM F963–23 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.

CPSC requests comments on all aspects of this rulemaking and specifically comment on the following topics:

A. Neck Float Definition

1. The proposed rule defines a "neck float" as "an article, whether inflatable or not, that encircles the neck, supports the weight of the child by securing around the neck (such as by fastening, tightening, or other methods), and is used as an instrument of play in water environments including sinks, baths, paddling pools and swimming pools, and is intended for use by children up to and including 4 years of age." Should the proposed rule use a different definition of neck floats?

B. NPR Scope

1. Are there any other products that should be included within the scope of this NPR as neck floats?

2. Based on FDA's warning about the risk of death due to suffocation, strain, and injury to a baby's neck, should the Commission strengthen the proposed performance requirements to address other hazards, or should the Commission promulgate alternative performance requirements?

C. Proposed Requirements To Address Slip-Through Due to Deflation

1. Are there any other performance requirements CPSC should consider to address the hazards associated with slipping through the product as a result of deflation?

⁵⁶ U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," March 2024, Table 4, total compensation for all sales and office workers in goods-producing private industries: https://www.bls.gov/news.release/archives/ecec_06182024.htm.

D. Proposed Requirements To Address Slip-Through Without Deflation

1. Are there any other performance requirements CPSC should consider to address the hazards associated with slipping through the product without deflation?

E. Proposed Requirements To Address Restraint System Failure

1. Are there any other performance requirements CPSC should consider to address the hazards associated with restraint system failures?

2. Should CPSC consider performance requirements to include secondary attachment systems? Please, provide details of any secondary attachment system that should be considered.

F. Proposed Requirements To Address Submergence Without Slip-Through

1. Are there any other performance requirements CPSC should consider to address the hazards associated with submergence during the use of the product without slipping through?

G. Proposed Test Methods

1. Does the proposed internal air pressure of 0.1 PSIG adequately simulate use conditions to address the hazard associated with deflation?

2. Are the proposed neck opening performance requirements adequate to address the hazards associated with slip-through?

H. Proposed Warning Label and Instructional Material Requirements for Neck Floats

1. Are the proposed warnings adequate to address the hazards associated with neck floats? Should CPSC consider additional warnings? Should other warning formats be considered?

2. Are the proposed instructional material requirements adequate to address the hazards associated with neck floats? Should CPSC consider requiring additional information to be provided?

I. Initial Regulatory Flexibility Analysis

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 neck floats increase as a result of this requirements in this NPR, and if so, by how much? Are test labs currently accredited to test for

ASTM F963–23 equipped to test neck floats in accordance with this proposal?

3. *Effective date of 180 days.* 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.

4. *Anti-Stockpiling Provision.* Should CPSC finalize with the anti-stockpiling provision as proposed, or is it not unnecessary for neck floats? If an anti-stockpiling provision is included, are there any changes that should be included? 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 neck floats? Why? By how much?

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List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third-party conformity assessment body.

16 CFR Part 1250

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

For the reasons discussed in the preamble, the Commission proposes to amend 16 CFR parts 1112 and 1250 as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

■ 1. The authority citation for part 1112 is revised to read as follows:

Authority: 15 U.S.C. 2063.

■ 2. Amend § 1112.15 by adding paragraph (b)(32)(ii)(LL) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule and/or test method?

* * * * *

(b) * * *

(32) * * *

(ii) * * *

(LL) 16 CFR part 1250.5,

Requirements for Neck Floats.

* * * * *

■ 3. The title of part 1250 is revised to read as follows:

PART 1250—SAFETY STANDARD FOR TOYS

■ 4. Revise the heading to part 1250 to read as set forth above.

■ 5. The authority citation for part 1250 is revised to read as follows:

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

■ 6. Revise § 1250.1 to read as follows:

§ 1250.1 Scope

This part establishes a consumer product safety standard for toys.

■ 7. Add § 1250.5 to read as follows:

§ 1250.5 Requirements for neck floats.

(a) *Scope and purpose.* This section establishes performance and labeling requirements for neck floats to reduce the risk of children drowning while using a neck float. The provisions of this part are intended to address the risk of injury and death to children from neck float hazards. This section adds requirements for neck float in addition to the requirements of § 1250.1 and § 1250.2.

(b) *Definitions.* In addition to the definitions incorporated by reference in § 1250.2(a), the following definitions apply for the purposes of this section:

Expected weight capacity means the maximum weight capacity the neck float is rated for, per the manufacturer's recommended use instructions.

Neck float means an article, whether inflatable or not, that encircles the neck, supports the weight of the child by being secured around the neck (such as by fastening, tightening, or other methods), is used as an instrument of play in water environments including sinks, baths, paddling pools and swimming pools, and is intended for use by children up to and including 4 years of age in water environments including sinks, baths, paddling pools and swimming pools.

Restraint system means interconnecting components, whether adjustable or not, that are integral to a neck float and are intended to hold the occupant in position relative to the neck float. A restraint system uses fastening mechanisms, such as buckles or Velcro straps, to secure together.

(c) *Performance requirements.* In addition to any general requirements from § 1250.1 or § 1250.2, all neck floats within the scope of the rule must meet the performance requirements in this section to reduce the risk of children drowning while using a neck float.

(1) *Conditioning procedure.* Neck floats shall undergo thermal conditioning in accordance with section 5.5.4.1 of ANSI/CAN/UL 12402–9:2022, with modifications provided in this section. Following thermal conditioning, a neck float shall undergo exposure conditioning in a chlorinated saltwater bath. The chlorinated saltwater bath shall be prepared by dissolving 32 grams of sodium chloride (NaCl) in 1 liter of aqueous solution containing 2 ppm chlorine at pH 7.0–7.8. The necessary volume of solution at those concentrations shall be prepared to fully submerge the neck float, in darkness and at room temperature (20 ± 2 °C (68 ± 4 °F)) for 8 hours. Lastly, the neck float shall undergo ultraviolet light exposure conditioning in accordance with sections 4.2.1.1–4.2.1.4 of ANSI APSP ICC–16 (2017), with the modifications provided in this section, prior to any testing in accordance with paragraphs (2)–(4) of this section. Any inflatable component(s), if applicable, of the neck float shall be deflated during the conditioning procedure.

(i) The words “Inflatable PFDs” shall be removed and replaced with “Neck floats” in section 5.5.4.1 of ANSI/CAN/UL 12402–9:2022.

(ii) The cold temperature “– 30 ± 2 °C” shall be removed and replace with “– 10 ± 2 °C” in section 5.5.4.1 of ANSI/CAN/UL 12402–9:2022.

(iii) The words “for two complete cycles,” and the paragraph after item b) “Inflatable PFDs, shall be . . . inflated for (5,0±0.1) min.” shall be removed from section 5.5.4.1 of ANSI/CAN/UL 12402–9:2022.

(iv) The words “1. Twelve new cover/grates” shall be removed and replaced with “Neck floats” in section 4.2.1 of ANSI APSP ICC–16.

(v) The words “and 4.2.15 through 4.2.17” shall be removed in section 4.2.1 of ANSI APSP ICC–16.

(2) *Minimum buoyancy requirements.* Neck floats shall demonstrate a minimum upward buoyancy equal to or greater than 30 percent the expected weight capacity of the neck float, and neck floats utilizing inherently buoyant components shall lose no more than 5 percent of their initial buoyancy, when tested in accordance with sections 5.5.9.2–5.5.9.4 of ANSI/CAN/UL 12402–9:2022 with the following additions and exclusions:

(j) The words “PFD” shall be removed and replaced with “neck float.”
 (ii) The weight of the cage shall be equal to 1.1 times the expected weight capacity of the neck float, which shall

be determined based on either the maximum weight capacity according to the manufacturer’s recommended user weight, or the weight given by Table 1 to paragraph (c)(2) according to the

manufacturer’s recommended user age, whichever is greater. If the manufacturer’s recommended user age falls between two age range options, the older range shall be used.

TABLE 1 TO PARAGRAPH (c)(2)(i)—EXPECTED WEIGHT CAPACITY

Age of child	Weight in kg	Weight in lb
0–3 months	7.7	17.0
4–6 months	9.5	21.0
7–9 months	10.6	23.4
10–12 months	11.5	25.4
1 up to 2 years	17.6	38.8
2 up to 3 years	23.2	51.2
3 up to 4 years	23.7	52.3

(iii) The sentence “If the PFD contains inflatable . . . whichever is less” shall be removed from the first paragraph of section 5.5.9.3 of ANSI/CAN/UL 12402–9:2022. In its place, the following sentence shall be added to the beginning of that section: “Any inflatable component(s), if applicable, of the neck float shall be inflated to an internal air pressure of 0.1 ± 0.01 PSIG.”

(iv) Add “If the neck float contains inherently buoyant components” to the beginning of the third paragraph (“The assembly shall remain . . . recorded as B”) of section 5.5.9.3 of ANSICAN/UL 12402–9.

(v) Remove the last two paragraphs “The water temperature . . . immersion period” from section 5.5.9.3 of ANSI/CAN/UL 12402–9.

(vi) Remove the last paragraph “The water temperature . . . and pressure conditions” from section 5.5.9.4 of ANSI/CAN/UL 12402–9.

(3) *Restraint system requirements.* All restraint systems used to attach the neck float to the body or to connect

components of the neck float together shall require the release of the fastening mechanism to have either a double-action release system that requires two distinct, but simultaneous actions to release, or a single-action release system that requires a minimum of 50 N to release. The restraint system shall also comply with the requirements of section 6.4.4 when tested in accordance with section 7.5.1 of ASTM F833–21, with the following additions and exclusions:

(i) The sentence “At the . . . 2 in. (51 mm).” of section 6.4.4 of ASTM F833–21 shall be removed.

(4) *Neck opening test requirement.* The neck opening of the neck float shall not admit the passage of a specified head probe when tested in accordance with the following test procedure:

(i) *Test method.* The neck float shall be placed on an elevated platform and positioned directly above and centered about a circular opening in that platform large enough to allow the head probes to fall fully through it. The surfaces of the neck float shall be saturated with

baby wash solution, prepared in accordance with section 7.4.1.5 of ASTM F1967–19.

(ii) If the neck float includes adjustable restraint straps, then all applicable head probes shall be evaluated at the loosest (largest) setting.

(iii) Any inflatable components of the neck float shall be inflated to an internal air pressure of 0.1 ± 0.01 PSIG.

(iv) A specified head probe shall then be weighted to mass M1 and positioned in the neck opening. A hanging weight of mass M2 shall then be suspended below the head probe at distance L, where L includes the length between the narrowest and widest circumference of the specified head probe. The choice of specified head probe, mass M1, mass M2, and distance L shall be determined using Table 2 to paragraph (c)(4) based on the manufacturer’s recommended youngest and oldest user age. If the manufacturer’s recommended user age falls between two age range options, the younger or older range shall be considered, as is appropriate.

TABLE 2 TO PARAGRAPH (c)(4)(ii)—NECK OPENING TEST

Head probe designation	Age range (months)	Head probe mass M1 (kg)	Hanging weight M2 (lbs)	Distance L (in)
A	0–3	1.5	3.4	12.45
B	4–6	2	4.2	13.8
C	7–9	2.2	4.68	14.65
D	10–12	2.4	5.08	15.6
	13–18	2.6	7.76	16.55
	19–24	2.8	7.76	17.55
	25–30	3	10.24	18.75
	31–36	3	10.24	19.4
	37–42	3.2	10.46	20.45
	43–48	3.2	10.46	21.3

(v) If the neck float’s recommended age range could apply to two or more head probes this procedure will be conducted first using the smallest

applicable head probe, then repeated using the largest applicable head probe.

(vi) The hanging weight shall be swung for a total of ten 30-second cycles by raising the hanging weight to a 90-

degree angle and releasing it. Alternate between a front-to-back swinging direction interval and side-to side interval, relative to the intended position of the neck float user. The 10

alternating swing cycles shall occur consecutively.

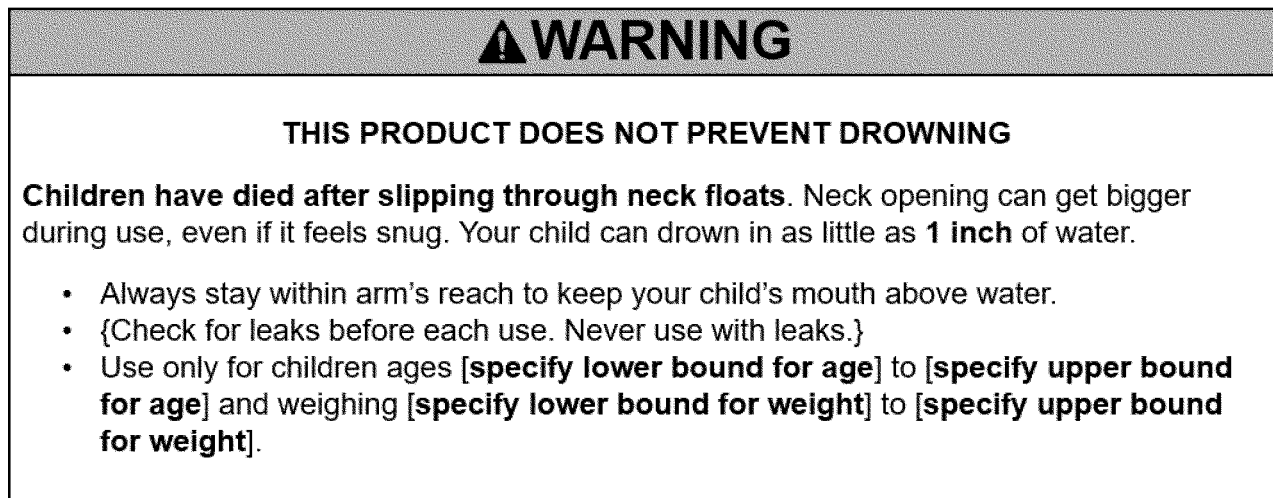
(d) *Labeling requirements.* All neck floats and the packaging of neck floats must meet the marking, labeling, and instructional literature requirements in this section to reduce the risk of

children drowning while using a neck float.

(1) *Requirements for Marking and Labeling.* (i) Instead of complying with the warning text of section 5.4 of ASTM F963–23, neck floats and the packaging of neck floats must include the safety

alert symbol, signal word, and word message as shown in Figure 1 to paragraph (d)(1)(i).

**Figure 1 to Paragraph (d)(1)(i)—
Warning for Neck Floats and Packaging**



(ii) The warnings shall be in the English language at a minimum.

(iii) The warnings shall be conspicuous and permanent on the principal display panel as defined in section 3.1.62 of the version of ASTM F963 incorporated by reference in § 1250.2(a) and in a distinct color contrasting to the background on which it appears.

(iv) The warnings shall conform to ANSI/NEMA Z535.4–2023, sections 6.1–6.4, 7.2–7.6.3, and 8.1, with the following changes:

(A) In sections 6.2.2, 7.3, 7.5, and 8.1.2, of ANSI/NEMA Z535.4–2023 replace the word “should” with the word “shall.”

(B) In section 7.6.3 of ANSI/NEMA Z535.4–2023, replace the phrase “should (when feasible)” with the word “shall.”

(C) In section X of ANSI/NEMA Z535.4–2023, strike the word “safety” when used immediately before a color (for example, replace safety white” with “white”).

(v) Certain text in the message panel must be in bold and in capital letters as shown in the example warning labels in figures 3 and 4 to paragraph (d)(1)(ii). Text must use black lettering on a white background or white lettering on a black background.

(vi) The message panel text shall appear in sans serif letters and be center or left aligned. Text with precautionary (hazard avoidance) statements shall be preceded by bullet points.

(vii) Multiple precautionary statements shall be separated by bullet points if paragraph formatting is used.

(viii) The safety alert symbol ▲ and the signal word “WARNING” shall appear in sans serif letters and be at least 1/8” (3.2mm) high and be center or left aligned. The remainder of the text shall be in characters whose upper case shall be at least 1/16” (1.6mm) high.

(ix) The safety alert symbol, an exclamation mark in a triangle, when used with the signal word, must precede the signal word. The base of the safety alert symbol must be on the same horizontal line as the base of the letters of the signal word. The height of the safety alert symbol must equal or exceed the signal word letter height. The exclamation mark must be at least half the size of the triangle centered vertically.

(x) The warning contained within { } “Check for leaks before use. Never use with leaks.” is only required for neck floats utilizing inflatable components.

(2) *Requirements for Instructional Literature.* Instructions shall have the same warning labels that must appear on the product and provided separately, as a user manual, with similar formatting requirements, but without the need to be in color. However, the signal word and safety alert symbol shall contrast with the background of the signal word panel, and the warnings shall contrast with the background of the instructional literature. The instructions shall include information

on assembly, installation, maintenance, cleaning and use, where applicable. The instructions shall explain how to check for adequate fit of the neck float around the child’s neck to prevent slipping through the center opening. For inflatable neck floats, the instructions shall include clear directions for testing the neck float for leaks. Any additional instructions provided, that are not required, shall neither contradict nor confuse the meaning of the requirements.

(e) *Prohibited stockpiling.*

(1) Prohibited acts. Manufacturers and importers of neck floats shall not manufacture or import neck floats that do not comply with the requirements of this part between [DATE OF PUBLICATION OF FINAL RULE] and [EFFECTIVE DATE OF FINAL RULE] at a rate that is greater than 105 percent of the rate at which they manufactured or imported neck floats during the base period for the manufacturer or importer.

(2) Base period. The base period for neck floats is the average monthly manufacturing or import volume within the last 13 months of production immediately preceding [DATE OF PUBLICATION OF THE FINAL RULE].

(f) *Incorporation by reference.* Certain material is incorporated by reference into this section with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference material is available for inspection at the Consumer Product

Safety Commission and at the National Archives and Records Administration (NARA). Contact the U.S. Consumer Product Safety Commission at: Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone (301) 504-7479, email cpssc-0s@cpssc.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from the following sources:

(1) Pool and Hot Tub Alliance (PHTA), 1650 King Street, Suite 602, Alexandria, VA 22314; phone: (703) 838-0083; website: www.phta.org.

(i) ANSI APSP ICC-16, *American National Standard for Suction Outlet Fitting Assemblies (SOFA) for Use in Pools, Spas, and Hot Tubs*, (approved August 18, 2017).

(ii) [Reserved]

(2) Underwriters Laboratories (UL), 1250 Connecticut Avenue NW, Suite 520, Washington, DC 20036; phone: (202) 296-7840; website: www.ul.com.

(i) ANSI/CAN/UL 12402-9, *Standard for Personal Flotation Devices—Part 9: Test Methods*, (published February 11, 2021).

(ii) [Reserved]

(3) National Electrical Manufacturers Association (NEMA), 1300 17th St. N, Arlington, VA 22209; phone: (703) 841-3200; website: www.nema.org.

(i) ANSI/NEMA Z535.4-23, *American National Standard for Product Safety Signs and Labels* (approved December 14, 2023).

(ii) [Reserved]

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

(i) ASTM F833-21, *Standard Consumer Safety Performance Specification for Carriages and Strollers*, (approved June 15, 2021).

(ii) ASTM F1967-19, *Standard Consumer Safety Specification for Infant Bath Seats*, (approved May 1, 2019).

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2024-25446 Filed 11-19-24; 8:45 am]

BILLING CODE 6355-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-116017-24]

RIN 1545-BR36

Administrative Requirements for an Election To Exclude Applicable Unincorporated Organizations From the Application of Subchapter K

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; notice of public hearing.

SUMMARY: This document contains proposed regulations that would provide certain administrative requirements for unincorporated organizations taking advantage of modifications to the rules governing elections to be excluded from the application of partnership tax rules. These proposed regulations would affect unincorporated organizations and their members, including tax-exempt organizations, the District of Columbia, State and local governments, Indian Tribal governments, Alaska Native Corporations, the Tennessee Valley Authority, rural electric cooperatives, and certain agencies and instrumentalities. The proposed regulations would also update the procedure for obtaining permission to revoke a section 761(a) election.

DATES: Written or electronic comments must be received by January 21, 2025. A public hearing on these proposed regulations has been scheduled for February 7, 2025, at 10 a.m. Eastern Standard Time (EST). Requests to speak and outlines of topics to be discussed at the public hearing must be received by January 21, 2025. If no outlines are received by January 21, 2025, the public hearing will be cancelled. Requests to attend the public hearing must be received by 5 p.m. on February 5, 2025.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically via the Federal eRulemaking Portal at <https://www.regulations.gov> (indicate IRS and REG-116017-24) by following the online instructions for submitting comments. Requests for a public hearing must be submitted as prescribed in the “Comments and Public Hearing” section. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish

for public availability any comments submitted to the IRS’s public docket.

Send paper submissions to:
CC:PA:01:PR (REG-116017-24), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulations, contact Cameron Williamson at (202) 317-6684; and concerning submissions of comments and requests for a public hearing, contact the Publications and Regulations Section at (202) 317-6901 (not toll-free numbers) or by email to publichearings@irs.gov (preferred).

SUPPLEMENTARY INFORMATION:

Authority

This document contains proposed amendments to the Income Tax Regulations (26 CFR part 1) under section 761(a) of the Internal Revenue Code (Code) issued by the Secretary of the Treasury or her delegate (Secretary) under the express authority granted under sections 761(a), 6031(a), 6417(d) and (h), and 7805(a) of the Code (proposed regulations).

Section 761(a) provides, in part, an express grant of regulatory authority for section 761(a) stating, “[u]nder regulations the Secretary may, at the election of all the members of an unincorporated organization, exclude such organization from the application of all or a part of this subchapter.”

Section 6031(a) provides an express grant of a regulatory authority for the Secretary to prescribe in forms or regulations partnership reporting information required “for the purpose of carrying out the provisions of subtitle A.”

Section 6417(d) provides several express delegations of authority to the Secretary to enforce requirements for elective payments of applicable credits under section 6417 and recapture excessive payments. Section 6417(h) requires the Secretary to issue regulations or other guidance as may be necessary to carry out the purposes of section 6417, including guidance to ensure that the amount of the payment or deemed payment made under this section is commensurate with the amount of the credit that would be otherwise allowable (determined without regard to section 38(c)).

Finally, section 7805(a) authorizes the Secretary to “prescribe all needful rules and regulations for the enforcement of [the Code], including all rules and regulations as may be necessary by reason of any alteration of law in relation to internal revenue.”