

seat and/or seat belt for each person is not required in all circumstances for part 91 operations.

In addition, the FAA notes that changing § 91.107(a)(3) may have far-reaching consequences that would best be addressed through a rulemaking. For example, in its comment, the NTSB acknowledged that some older airplanes currently have bench-style seating that can accommodate multiple passengers with one restraint system. The FAA notes that airplanes with these bench-style seats make up a significant portion of the part 91 community. In addition, aircraft with these types of seating have a significant diversity in their specific seating restraint arrangements—some aircraft with bench seats have a seat belt equipped for each individual passenger while other aircraft with bench seats have a single shared seat belt for use by everyone in the bench seat. Because a significant portion of the part 91 community currently uses some manner of a shared seat/seat belt, the FAA would need to consider, as part of a rulemaking, the effects that changing § 91.107(a)(3) would have on those members of the part 91 community.

Nevertheless, even though § 91.107(a)(3), as previously interpreted by the agency, may allow for shared use of a single restraint in certain situations, the FAA agrees with NTSB that having each passenger use a separate seat and a separate seat belt can be significantly safer than having passengers share a seat and/or seat belt. Accordingly, the FAA strongly encourages PICs in part 91 operations to ensure, whenever possible, that each passenger is seated in a separate seat and restrained by a separate restraint system. With regard to children, the FAA also strongly encourages children to be restrained in a separate seat by an appropriate child restraint system during takeoff, landing, and turbulence.

In its comments, the NTSB also expressed a concern that this clarification could be interpreted to permit multiple occupants to share a single shoulder harness. In response to NTSB's concern, the FAA emphasizes that the proposed clarification was drafted to address the shared use of seats and/or seat belts—not shoulder harnesses. Because the proposed clarification did not address shoulder harnesses, this clarification is limited solely to the shared use of seats and/or seat belts in part 91 operations.

In their comments, the NTSB and an individual commenter also asserted that the structural strength requirements for a seat and the approval and rating for a seat belt are not always available to a general aviation pilot because this

information is typically not included in the AFM. The individual commenter added that many older aircraft do not have an AFM, but instead have an owner's manual that contains even less information.

In response to these comments, the FAA notes that, even though the pertinent information is sometimes not contained in the AFM, information about seat usage limitations and seat belt approval and rating can, in many cases, be obtained from the equipment manufacturer. However, the FAA agrees with the commenters that this information cannot always be obtained from the equipment manufacturer. Accordingly, before multiple occupants are permitted to use the same seat and/or seat belt, if the pertinent information is available, the PIC should check whether: (1) The seat belt is approved and rated for such use; and (2) the structural strength requirements for the seat are not exceeded.

In addition, before seating multiple occupants in the same seat and/or seat belt, PICs should always check to ensure that the seat usage conforms to the limitations contained in the approved portion of the AFM or the owner's manual. Owner's manuals for older aircraft typically show the permissible seating arrangements that are to be used for the aircraft, and the number of people using a seat and/or seat belt should not exceed the number of people shown in the owner's manual seating arrangement.

Issued in Washington, DC, on May 18, 2012.

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[FR Doc. 2012-12554 Filed 5-23-12; 8:45 a.m.]

BILLING CODE 4910-13-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1450

Virginia Graeme Baker Pool and Spa Safety Act; Interpretation of Unblockable Drain

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule; revocation; extension of compliance date.

SUMMARY: On October 11, 2011, the Consumer Product Safety Commission (“Commission” or “CPSC”) announced that it was revoking its interpretation of the term “unblockable drain,” as used in the Virginia Graeme Baker Pool and Spa Safety Act, 15 U.S.C. 8001 et seq.

(“VGBA”). The Commission set a compliance date of May 28, 2012, for those who installed VGBA-compliant drain covers on or before October 11, 2011, in reliance on the Commission's initial interpretation. The Commission sought written comments regarding the ability of those who had installed VGBA-compliant unblockable drain covers on or before October 11, 2011, in reliance on the Commission's initial interpretation, to come into compliance with the revocation by May 28, 2012. The Commission is extending the compliance date to May 23, 2013, for those who have installed VGBA-compliant unblockable drain covers on or before October 11, 2011, in reliance on the Commission's original interpretive rule.¹

DATES: This document does not alter the current requirement that public pools and spas be in compliance with the VGBA, which became effective on December 19, 2008. The compliance date for those who installed VGBA-compliant unblockable drain covers on or before October 11, 2011, in reliance on the Commission's April 27, 2010 interpretation of unblockable drains is extended to May 23, 2013.

FOR FURTHER INFORMATION CONTACT: Perry Sharpless, Directorate for Laboratory Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone (301) 987-2288, or email: psharpless@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

In September 2011, the U.S. Consumer Product Safety Commission voted to publish in the **Federal Register** a final rule regarding the revocation of the prior definition of “unblockable drain.” (76 FR 62605). The **Federal Register** notice invited comments regarding the ability of those who had installed VGBA-compliant unblockable drain covers, as described at 16 CFR 1450.2(b), to come into compliance with the revocation by May 28, 2012.

B. Comments

The majority of comments the Commission received were unrelated to the ability of the respondents to comply with the May 28, 2012 effective date. The comments that did address the May 28, 2012 compliance date fell into four basic categories. These comments were addressed in the staff's briefing memorandum, “Summary of public

¹ Commissioners Adler, Nord, and Northup voted to extend the compliance date to May 23, 2013. Chairman Tenenbaum voted against extending the compliance date to May 23, 2013.

comments received regarding revocation of the definition of unblockable drain covers," dated March 30, 2012.

Commission staff's summary and response to these comments follow:

1. Cost of compliance (142 comments) and dire financial circumstances (131 comments).

Comment: Members of the American Hotel & Lodging Association, the Illinois Department of Health, and others assert that the cost of retrofitting pools again would put an undue burden on them and cite to the impact of the poor economy on their operating revenues and the loss of revenue that will be incurred while the pools are closed for the modifications that will be required to bring them into compliance. Commenters in this category also mention the respondents' "dire financial circumstances" as a reason against the revocation of the Commission's April 27, 2010 definition of "unblockable drain."

Response: Commission staff agrees that there may be financial hardship, but only to those who relied upon the Commission's interpretive rule and installed an unblockable drain cover in lieu of installing a secondary system. Thus, Commission staff believes it seems reasonable to provide firms that relied on the Commission's prior interpretation the time to budget and plan for the expenditure needed to install a secondary system.

2. Apply prospectively (4 comments).

Comment: Commenters in this category cited the lack of injuries as a reason to apply the revocation only to facilities that are newly constructed or renovated in the future.

Response: Commission staff does not agree with prospective application to new construction or renovation. The law has required pools to be compliant with the VGBA for almost four years. Only firms that relied on the unblockable drain interpretive rule of April 27, 2010, and installed VGBA-compliant unblockable drain covers on or before October 11, 2011, are affected by the revocation decision. Thus, prospective application is overly broad, and applying it to firms that did not install VGBA-compliant unblockable drain covers on or before October 11, 2011, would not follow the statutorily mandated effective date, would create confusion, and would unduly complicate enforcement.

3. Comments Requesting Delay of Enforcement (2 comments).

Comment: Two commenters requested that the Commission delay the implementation of enforcement. One requested that the CPSC delay implementation of the enforcement of

the change for one year because they had relied upon the original interpretation and installed unblockable drain covers and now would have to go back and "re-do" their work, which they said would penalize them unfairly for their compliance with the prior interpretation. The commenter also noted that the unblockable drain covers were far more expensive than typical smaller fittings, and asserted that they represented a major investment on the basis that, once the covers were installed, additional equipment would not be required. The other commenter requested that the Commission delay the implementation date to January 1, 2013, or prior to 2013 operation dates for seasonal pools and spas. The commenter also stated that regulated pools and spas that had already invested to comply with the requirements of the VGBA would be required to add secondary anti-entrapment systems or make other modifications at considerable expense, in addition to expenditures necessary to comply with state law and U.S. Department of Justice pool and spa accessibility requirements.

Response: Commission staff agrees that those who relied upon the Commission's interpretive rule and installed an unblockable drain cover in lieu of installing a secondary system will now face additional expenditures to bring their pools into compliance with the VGBA. Thus, Commission staff believes that it seems reasonable to provide those who installed VGBA-compliant unblockable drain covers on or before October 11, 2011, time to budget and plan for the expenditure needed to install a secondary system.

4. Compliance Date Is Acceptable (1 comment).

Comment: One comment was received in support of the May 28, 2012, compliance date. The commenter, the National Multi Housing Council/National Apartment Association (NMHC/NAA), expressed the belief that if the Commission offered additional guidance to the regulated community to assist with compliance, the majority of their members could comply by the deadline; but NMHC/NAA urged the CPSC to reevaluate the progress being made by pool owners and adjust the deadline, if necessary.

Response: CPSC staff has a concern about the number of requests that may be received for assistance with compliance and whether the pool operator is seeking a plan review and not just limited advice about how to handle the revocation decision. The only circumstance in which staff believes there could be any need for compliance assistance due to the

revocation of the unblockable drain interpretive rule is with respect to pool operators who relied on the Commission's April 27, 2010 decision and installed VGBA-compliant unblockable drain covers on or before October 11, 2011. The guidance to those firms is that your unblockable drain cover is VGBA-compliant and does not need to be removed; but pool operators need to install a secondary anti-entrapment system to come into compliance, unless the pool uses a gravity drain system or the underlying drain is unblockable. Accordingly, if a pool operator installed an unblockable drain cover over a drain that is blockable, staff believes it is reasonable to allow them time to budget and plan for the expenditure required to install a secondary anti-entrapment system.

C. Commission Determination

Upon being presented with the staff briefing package, the Commission voted to extend the compliance date to May 23, 2013. Only firms that relied on the unblockable drain interpretive rule of April 27, 2010, and installed VGBA-compliant unblockable drain covers on or before October 11, 2011, will have until May 23, 2013, to install a secondary system, as necessary. Firms that did not rely on the unblockable drain interpretive rule of April 27, 2010, and did not install VGBA-compliant unblockable drain covers on or before October 11, 2011, should be compliant with the VGBA, and will not have additional time to come into compliance if they are not.

Dated: May 17, 2012.

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

[FR Doc. 2012-12335 Filed 5-23-12; 8:45 a.m.]

BILLING CODE 6355-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 610, and 680

[Docket No. FDA-2011-N-0080]

RIN 0910-AG16

Amendments to Sterility Test Requirements for Biological Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a