

procedures of subpart 159.005 of this chapter, and shall apply for approval directly to a recognized independent laboratory. The following laboratories are recognized under § 159.010-7 of this part, to perform testing and approval functions under this subpart:

Underwriters Laboratories, 12 Laboratory Drive, P.O. Box 13995, Research Triangle Park, NC 27709-3995, (919) 549-1400.

(b) Production oversight must be performed by the same laboratory that performs the approval tests unless, as determined by the Commandant, the employees of the laboratory performing production oversight receive training and support equal to that of the laboratory that performed the approval testing.

§ 160.060-11 [Removed]

77. Section 160.060-11 is removed.

§ 160.060-12 [Removed]

78. Section 160.060-12 is removed.

Subpart 160.064—Marine Buoyant Devices

§ 160.064-5 [Removed]

79. Section 160.064-5 is removed.

§ 160.064-5a [Removed]

80. Section 160.064-5a is removed.

§ 160.064-5b [Removed]

81. Section 160.064-5b is removed.

82. Section 160.064-7 is revised to read as follows:

§ 160.064-7 Recognized Laboratory.

(a) A manufacturer seeking Coast Guard approval of a product under this subpart shall follow the approval procedures of subpart 159.005 of this chapter, and shall apply for approval directly to a recognized independent laboratory. The following laboratories are recognized under § 159.010-7 of this part, to perform testing and approval functions under this subpart:

Underwriters Laboratories, 12 Laboratory Drive, P.O. Box 13995, Research Triangle Park, NC 27709-3995, (919) 549-1400.

(b) Production oversight must be performed by the same laboratory that performs the approval tests unless, as determined by the Commandant, the employees of the laboratory performing production oversight receive training and support equal to that of the laboratory that performed the approval testing.

§ 160.064-8 [Removed]

83. Section 160.064-8 is removed.

§ 160.064-9 [Removed]

84. Section 160.064-9 is removed.

Subpart 160.066—Distress Signal for Boats, Red Aerial Pyrotechnic Flare

85. In § 160.066-11, paragraph (c) is revised to read as follows:

§ 160.066-11 Approval procedures.

* * * * *

(c) The approval tests must be performed by an independent laboratory accepted by the Commandant under Subpart 159.010 of this chapter.

§ 160.066-18 [Removed]

86. Section 160.066-18 is removed.

Subpart 160.077—Hybrid Inflatable Personal Flotation Devices

87. Section 160.077-9 is revised to read as follows:

§ 160.077-9 Recognized Laboratory.

(a) A manufacturer seeking Coast Guard approval of a product under this subpart shall follow the approval procedures of subpart 159.055 of this chapter, and shall apply for approval directly to a recognized independent laboratory. The following laboratories are recognized under § 159.010-7 of this part, to perform testing and approval functions under this subpart:

Underwriters Laboratories, 12 Laboratory Drive, P.O. Box 13995, Research Triangle Park, NC 27709-3995, (919) 549-1400.

(b) Production oversight must be performed by the same laboratory that performs the approval tests unless, as determined by the Commandant, the employees of the laboratory performing production oversight receive training and support equal to that of the laboratory that performed the approval testing.

Dated: March 20, 1996.

J.C. Card,

Rear Admiral, U.S. Coast Guard Chief, Office of Marine Safety, Security and Environmental Protection.

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46 CFR Part 160

[CGD 94-110]

RIN 2115-AE96

Recreational Inflatable Personal Flotation Device Standards

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is adopting a final rule that establishes structural and performance standards for inflatable personal flotation devices (PFDs) for

recreational boaters, as well as the procedures for Coast Guard approval of inflatable PFDs. These standards allow for approval of inflatable PFDs which are more amendable to continuous wear by recreational boaters than inherently buoyant PFDs, thereby encouraging use of PFDs by the boating public and saving lives.

DATES: This rule is effective on September 24, 1996.

ADDRESSES: Unless otherwise indicated, documents referred to in this preamble are available for inspection or copying at the office of the Executive Secretary, Marine Safety Council (G-LRA/3406), U.S. Coast Guard Headquarters, 2100 Second Street SW., room 3406, Washington, DC 20593-0001, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Mr. Robert L. Markle, U.S. Coast Guard, Marine Safety and Environmental Protection Directorate, telephone (202) 267-6446, facsimile (202) 267-1069, or electronic mail "mvi-3/G-M18@cgsmt.uscg.mil". A copy of this final rule may be obtained by calling the Coast Guard's toll-free Customer Infoline, 1-800-368-5647. In Washington, DC, call (202) 267-0780.

SUPPLEMENTARY INFORMATION:

Regulatory History

On November 9, 1993, the Coast Guard published an Advance Notice of Proposed Rulemaking (ANPRM) entitled "Inflatable Personal Flotation Devices" in the Federal Register (58 FR 59428). On June 23, 1995, the Coast Guard published an interim rule (IR) entitled "Inflatable Personal Flotation Device Standards" in the Federal Register (60 FR 32836). This IR became effective on July 24, 1995. Due to requests, a public meeting, announced in the August 2, 1995, Federal Register (60 FR 39268), was held at Coast Guard Headquarters on August 28, 1995. On October 10, 1995, the Coast guard published a notice in the Federal Register (60 FR 52631, October 10, 1995) extending the comment period on the IR from October 23, 1995, to November 6, 1995, to allow discussion of the rule at the National Boating Safety Advisory Council (NBSAC) meeting on October 30-31, 1995. Additionally, minor editorial changes reflecting Coast Guard organizational changes were made to the regulations established by the IR by a final rule published September 29, 1995, in the Federal Register (60 FR 50455).

In addition to this rulemaking project, a separate rulemaking project (CGD 93-055) resulted in the publication of a Notice of Proposed Rulemaking (NPRM) which proposed complementary rules governing the carriage, use, registration, and defect notification for inflatable PFDs for recreational boats (June 23, 1995, Federal Register (60 FR 32861)). Additional procedures for approval of inflatable PFDs, and other types of PFDs, were included in the NPRM. These provisions were proposed separately because they affect other types of PFDs besides inflatables. The Final Rule for this project (CGD 93-055) is being published elsewhere in today's Federal Register.

This rule, establishing minimum safety standards for inflatable PFDs, is being made effective 180 days after publication in the Federal Register pursuant to 46 U.S.C. 4302(b). Although the IR was effective 30 days after its publication, it provided a new category for approval of PFDs, and did not change any existing approval procedures. Since this Final Rule changes regulations now in effect, it could affect persons who relied upon regulations in the IR which are now being changed. For this reason, the 180 day delay in the effective date under 46 U.S.C. 4302(b) applies. This should not affect the progress of manufacturers' design and testing, and therefore should not result in delay in getting approved devices to market. Manufacturers can proceed with design and testing during this period.

Public Meeting

A number of initial comments to the IR expressed confusion about the basis and applicability of the "Life-Saving Index" (LSI) used in the IR as an alternative path for approval. The LSI is a probability based risk assessment tool designed to evaluate a PFD design's overall lifesaving potential. Based on comments, the Coast Guard held a public meeting and training seminar to aid interested persons in understanding and applying the LSI analysis process. The meeting was attended by six PFD manufacturers, two inflation system manufacturers, an official from a boat owners association, a member of the public from the National Boating Safety Advisory Council (NBSAC), and representatives from Underwriters Laboratories (UL), the only laboratory currently recognized to perform the approval tests for inflatable PFD devices. A summary and video tape of the meeting are available as part of the public docket for inspection and copying where indicated under **ADDRESSES**. During the meeting, Coast

Guard personnel discussed the history of this rulemaking, with emphasis on the development of the LSI and its role and usefulness in evaluating the overall lifesaving potential of various PFD designs. There was also a discussion of the PFD information pamphlet which accompanies the sale of inflatable PFDs and provides important information to the potential consumer before a PFD is purchased. Specific details of the meeting are discussed below in the appropriate sections.

Approval History

Under the IR, Coast Guard approval of inflatable PFDs and component materials has been possible since July 24, 1995. To this date, four manufacturers have started the approval process for at least 6 models of inflatable PFDs, but no device has yet received final approval. Additionally, no inflator or inflation chamber material has been completely tested to be accepted by the Coast Guard as meeting the requirements of the UL 1191 consensus standard for component materials incorporated by reference into the Coast Guard regulations. Although a number of manufacturers have completed preliminary testing of prototype designs of PFDs, sample PFDs for final testing have not been constructed. This is due to a lack of accepted component materials since a sample PFD undergoing final testing for Coast Guard approval must be constructed of the same or equivalent materials that will be used in commercially available manufactured products to ensure that the final products meet the approval standards.

Regulatory Information

The two main standards adopted by the IR and retained in this rulemaking are Underwriters Laboratories (UL) standards for inflatable PFDs and PFD components (UL 1180 and 1191, respectively). These standards were developed in accordance with the American National Standards Institute (ANSI) procedure for voluntary industry standards. In accordance with the ANSI procedures, interested parties were provided with an opportunity to participate in the development of the standards. The public was also given an opportunity to comment on the adoption of approval standards for inflatable PFDs in the ANPRM published on November 9, 1993 (58 FR 59428), and the IR published on June 23, 1995 (60 FR 32836). The ANPRM advised of the intention to use an industry consensus standard and encouraged interested, knowledgeable persons to participate in the ANSI

standards making process. On February 24, 1994, notice was published in the Federal Register (59 FR 9015) of the Coast Guard's participation in the first consensus standards meeting with UL. This notice again invited interested technical experts knowledgeable in the field to participate in the meeting and process. Comments received in response to the ANPRM and IR were generally in favor of development of structural and performance standards for inflatable personal flotation devices and procedures for Coast Guard approval of inflatable PFDs. The UL standard (UL 1180) is complete, with the exception of several reserved sections.

Background and Purpose

The regulations in this final rule are intended to allow approval of PFDs which may be more appealing to recreational boaters than currently approved PFDs, thereby increasing the percentage of PFDs actually used by the boating public and saving lives. However, the Coast Guard notes that the currently approved inherently buoyant PFDs have an excellent lifesaving record. The Coast Guard boating statistics show that while boating activity was increased several fold, the number of fatalities has dropped from about 1,800 to 800 per year over the past 25 years, and this decrease is in part due to use of these inherently buoyant PFDs. The Coast Guard also notes that inherently buoyant PFDs are more appropriate for non-swimmers than inflatable PFDs. Non-swimmers may panic when they enter the water, and may therefore not be able to manually or orally inflate an inflatable PFD. Moreover, there are a number of boating applications for which inflatable PFDs are not suitable, as listed in the PFD information pamphlet. Therefore, inherently buoyant PFDs will continue to play a vital role in boating safety programs for the public.

Advisory Committee and Other Consultations

In developing these regulations the Coast Guard consulted with the National Boating Safety Advisory Council (NBSAC) and the National Association of State Boating Law Administrators (NASBLA). In May 1994, NBSAC passed a resolution recommending approval for Type I, II, III, IV, and V inflatable PFDs. PFDs differ in Type based on the environment in which they are designed to perform and their intended use. The various Types of PFDs are described in more detail in the IR. In 1988, 1993 and 1994, NASBLA also passed resolutions urging that approvals for inflatable PFDs be

granted as soon as possible. Additionally, the National Transportation Safety Board has recommended that the Coast Guard approve inflatable PFDs.

NBSAC formed a subcommittee to study the implementation of the various types of approvals that might be granted by the Coast Guard and developed an "inflatable PFD objectives statement" and "performance goals". Copies of these documents are included in the docket file for this rulemaking. The documents identified a number of goals that NBSAC determined to be appropriate in the effort to set standards for the manufacture and approval of inflatable PFDs. In November 1994, the full council passed a resolution supporting the objectives statement and goals.

After publication of the IR, NBSAC and NASBLA again considered the issue of inflatable PFD approval and passed resolutions recommending approval of inflatable PFDs. Both resolutions, though, objected to the modifications to the UL 1180 standard that the Coast Guard included in the IR. The details of the most recent deliberations and the resolutions are discussed with the appropriate comments below and the resolutions are included in the docket file for this rulemaking.

Inflatable PFD Studies

As discussed in the IR, the Coast Guard has sponsored two studies on the suitability of inflatable PFDs in the recreational boating environment: a 1981 Inflatable PFD Field Test, Report No. CG-M-84-1 and a 1993 study conducted by the BOAT/U.S. Foundation for Boating Safety. Each study involved the use of about 500 inflatable PFDs in a recreational boating environment. Copies of these studies are included in the docket file for this rulemaking. Initial review of these studies indicated that inflatable PFDs could not be approved without extensive servicing requirements or conditions on approval. However, as discussed below, developments in inflatable PFDs have allowed the Coast Guard to establish the approval standards for inflatable PFDs adopted in this final rule.

New Developments in Inflatable PFDs and UL Standards

New developments in the manufacture of inflatable PFDs, along with work done by UL in this area since the testing was conducted in the above studies, have improved the chances that inflatable PFDs will work when used and maintained by the average boater. The problems revealed by the two

studies discussed above have been addressed in the UL standard. Consequently, PFDs meeting the requirements of the new UL standard, along with certain additional requirements included in this final rule, should not have the problems that prevented the Coast Guard from approving recreational inflatable PFDs in the past.

The Coast Guard is issuing a final rule for approval of inflatable PFDs at this time based on the need for more wearable PFDs, boater demand for alternatives and the development of more "user serviceable" inflatable PFDs. With these user serviceable PFDs there is a good chance that the user of the PFD will (1) recognize when the PFD needs servicing and (2) be able to perform the servicing correctly. These improved PFDs are equipped with inflation mechanisms (inflators) that are more user-friendly than previous models. User-friendly features are often referred to as mechanisms that are designed with "good human factors". Good human factors relate to the ease with which boaters can determine when their inflatable PFD needs rearming and the ease with which they can correctly rearm the PFD. Good human factors design will decrease the incidence of unarmed inflatable PFDs that were evident in the studies discussed above.

The UL standard defines two different performance levels for inflators. For an inflator to meet the requirements of the UL standard, a high percentage of test subjects must be able to correctly identify whether an inflator is properly armed and to be able to rearm the device with no training other than use of the owner's manual provided by the manufacturer and toll-free calls to a manufacturer's help line, if one is available. The performance level assigned is based on the percentage of passing test results. At this time, an inflator capable of being accepted at the highest level is not available at a reasonable cost, but at least one such inflator is under development. The characteristics of the higher performing inflators (use code 1F) are described in item 1 of the discussion of specific comments below. If properly maintained, inflatable PFDs with the lower level performing inflation mechanisms provide high reliability, though the probability of proper maintenance (maintainability) remains a key component of ensuring their effectiveness. The information pamphlet and owner's manual required to accompany the sale of inflatable PFDs will emphasize the need for proper maintenance of these devices. Additionally, the inflatable PFD label

will include warnings to check that the unit is fully armed before donning and to perform a service test at least once each year.

Discussion of Comments and Changes

Seventy comments were received from fifty-seven individuals and organizations in response to the interim final rule (IR) published June 23, 1995. Thirty-eight of those commenting were boaters, nine were PFD and component manufacturers or PFD consultants, and seven were from organizations or associations representing manufacturers, boaters, cities or state boating law enforcement. The remaining three groups commenting were laboratories or dealers. A number of manufacturers and organizations commented more than once. The Coast Guard has reviewed all of the comments and revised the rule as appropriate. The comments have been grouped by general and specific issues, and are discussed below.

General Comments

None of the comments opposed Coast Guard approval of inflatable PFDs; 49 comments urged the Coast Guard to approve inflatable PFDs as soon as possible.

Boaters submitted the largest number of comments. Nearly all of their comments supported Coast Guard approval of inflatable PFDs as soon as possible, and many of them indicated that boaters would be inclined to wear an inflatable PFD more frequently than a currently approved PFD. Many of these comments either explicitly or implicitly cited the published views of a boating organization, which opposed many of the IR provisions. Two comments also specifically favored the use of inflatables for Coast Guard Auxiliary patrols because of their increased wearability. Additionally, one comment pointed out the potential increased safety benefit of greater flotation of inflatable PFDs when compared to presently approved inherently buoyant PFDs.

Wear Rates and Wearability: Ten comments noted that they favored the use of inflatable PFDs because of their comfort (i.e., easy to wear, not as hot, less bulky, and greater maneuverability when performing operations aboard a boat). Six commenters indicated that they currently owned yoke style inflatable PFDs that they were pleased with. Eight commenters, including all but one of the above owners, indicated they currently wear a PFD continuously. Eight more comments indicated that the writer would wear an inflatable if approved and available. In addition,

several comments from boaters indicated that they were not opposed to a requirement that inflatables be worn to be considered as approved devices. Approval of a PFD signifies that the PFD can be counted towards the "carriage requirements" (33 CFR 175, Subpart B) which requires boats to have on board specified quantities and Types of approved PFDs. This totals 21 comments whose writers either presently wear or would wear inflatable PFDs if they were approved. Three comments from boaters indicated that they opposed any condition that required PFDs to be worn to meet the carriage requirements.

Four comments indicated the belief that inflatable PFDs would save lives because people would be more apt to wear them. This view was bolstered by two comments which noted that 80 percent of drownings occur as a result of people not wearing PFDs, as opposed to wearing the wrong kind of PFD, and that these accidents were usually sudden events that precluded the donning of a PFD after recognizing the event was about to happen. Five other comments indicated that if an impact on boating accident drownings is expected, there needs to be an incentive to increase wear rate of PFDs, such as requiring that PFDs be worn to count as meeting the carriage requirements, particularly on small boats. The Coast Guard recognizes that increased wear of PFDs is essential to increase the number of lives saved.

Maintainability: Two comments noted that inflatable PFDs have been in military use since the beginning of World War II. One of these comments noted using Navy-issue inflatables in World War II and questioned why the Coast Guard would delay the approval of inflatables for the boating community, when a perfectly satisfactory inflatable PFD was available 50 years ago. The Coast Guard notes that inflatables used by the military both in the past and currently are not maintained by the individual user, but rather by trained professionals. As discussed in the ANPRM and IR, ensuring that inflatable PFDs are maintainable by the user has been one of the key concerns for introduction of inflatables to recreational boating. As previously mentioned, lack of proper maintenance adversely affects reliability due to the probability that some PFDs will not be rearmed or will be rearmed improperly. Due to the importance of this aspect of inflatable PFD use, the Coast Guard emphasizes that users should check their inflation mechanisms frequently.

Non-swimmers and Children: Six comments from boaters expressing support for approval of inflatable PFDs indicated that their support was based on concerns about the safety of family members who were either children or poor swimmers. These comments suggested that children and poor swimmers would be more likely to wear an inflatable PFD than other types of currently approved PFDs due to an inflatable PFD's increased comfort and more desirable appearance. These comments concern the Coast Guard because they suggest that the desire for a more comfortable device may lure people to use inflatable PFDs inappropriately. The Coast Guard notes that the consensus committee preparing the UL 1180 Standard, incorporated into this rule, specifically pointed out that PFDs approved under the standard are not suitable for non-swimmers or children. Additionally, this issue was specifically raised in the ANPRM and IR of this rulemaking. The Coast Guard emphasizes that under this rule, inflatable PFDs cannot be approved for children and that non-swimmers should be strongly discouraged from choosing this type of lifesaving device.

Approval of inflatable PFDs for children is not now considered appropriate by the Coast Guard and UL consensus standard committee due to concerns about a child's ability to take the necessary steps to initiate inflation in an emergency or perform backup inflation in case the primary system fails. The Coast Guard notes that the issue of inflatable devices for children may be revisited after more experience is gained with approval of inflatable PFDs for adults.

As for the use of inflatable PFDs by non-swimmers, as noted in the IR, the Coast Guard acknowledges that there is no practical way that law enforcement officials can conduct a field assessment of swimming abilities, and thus there are no regulations restricting the use of inflatable PFDs by non-swimmers. However, because of the unique risks associated with these devices, the labeling and information pamphlet for these PFDs are required to explicitly state that the devices are not recommended for use by non-swimmers.

Terminology: One comment suggested that the barrier between wearable inflatables and many potential consumers is that the use of the word "approved" by the Coast Guard to denote devices which have met the stated requirements, and that the term "approved" is not the most accurate or effective term. The comment suggested substituting "recognized as a required

device" or "meets Coast Guard minimum carriage requirements" for the term "approved". The Coast Guard has not adopted this suggestion. As previously discussed in the IR, the Coast Guard acknowledges that the term "approved" may cause some confusion and misperceptions to the public. However, both the terms suggested by the comment may cause even more confusion. The term "approved" is well recognized by the public and has been used by the Coast Guard for over 50 years to denote that a lifesaving device meets Coast Guard minimum safety standards. The term "recognized as a required device" may confuse the boating public as to the implications of a device being "recognized" versus "approved". As for the phrase "meets the Coast Guard minimum carriage requirements", in addition to possible confusion over the implications of a new term, the phrase is not being adopted because it may cause boaters to mistakenly believe that the carriage requirements are met by merely having that one device. In almost all cases, this is not true and to meet the carriage requirements, boaters may have to have several devices aboard their vessel.

Inflatable PFD Costs/Affordability: Thirteen comments from eleven boaters, one dealer, and a boat club addressed the issue of ensuring the approval of reasonably-priced inflatable PFDs. Comments on this issue were solicited in the initial ANPRM and were discussed in the IR. One comment acknowledged that Coast Guard approval of inflatable PFDs may bring costs down by increasing sales and competition. On the other hand, several of these comments indicated the belief that the Coast Guard's modifications to the UL 1180 standard would substantially increase the cost of approved inflatable PFDs without saving significantly more lives. Five of these comments specifically indicated the view that increased testing costs due to Coast Guard additions to the UL standard would keep manufacturers from seeking approval while another comment was concerned that Coast Guard approval would merely lead to the availability of limited products at high prices. Four comments thought that boaters would be less able to afford the PFDs made under the Coast Guard modifications than inflatable PFDs that only met the UL standard. Several others were simply concerned that the cost of inflatables would deter many boaters from buying an inflatable PFD. Two commenters specifically noted that they have been wearing the yoke style PFD with harness and found that

although many boaters inquired about the devices, the high cost seemed to be a deterrent to most boaters. One of these comments noted also that the rearming kits are fairly expensive.

Four comments urged the Coast Guard to make the regulations for inflatables stringent for safety purposes, but not to the point so as to drive the prices "out of sight". One of these comments expressed concern that the manufacturers would pass on the expense of additional approval requirements to the consumer, making the resultant PFDs unaffordable. The comment stated that safety of the boating public should be a high priority for the government and that the Coast Guard's requirements should result in an easy-to-wear, affordable, and comfortable inflatable lifejacket that meets the carriage requirements.

A number of PFD and component material manufacturers' comments also addressed cost. These comments objected to the IR's required use of use code 1F inflators, in place of the LSI evaluation. The objections centered on the fact that currently, the only use code 1F inflator which could be accepted would be disposable, and therefore prohibitively expensive to maintain. At the time the IR was published, the Coast Guard believed that use code 1F inflators would be available at a reasonable cost. Unfortunately, since that time, no affordable use code 1F inflator has been produced. However, while the IR did encourage use of 1F inflators, it did not require them for approval.

Additionally, several manufacturers objected to some of the costs of testing associated with the requirements added by the Coast Guard to the UL requirements. These objections are discussed further with the specific comments below.

The Coast Guard notes that the lowest priced PFDs permitted by the UL standard are eligible for approval under the IR and this final rule. Less expensive PFDs that differ from UL 1180 may also be approved under the equivalency provisions contained in the IR and which are being retained in the final rule. The additional testing costs imposed by the Coast Guard modifications to the UL standard requirements under the IR are minimal and will decrease under this final rule. In addition, the lifesaving benefits of the additional provisions retained in this final rule outweigh the associated costs as discussed under "Regulatory Evaluation."

Comments on specific requirements are discussed below under "Specific

Comments and Major Areas of Revision".

IR Consistency with UL Standards: Nine comments from manufacturers, manufacturing organizations, and boating organizations and various comments from boaters requested that the Coast Guard amend the requirements for approval of inflatable PFDs contained in the IR so as to make them more consistent or, in the case of a few comments, identical with the requirements of UL 1180 and UL 1191 standards.

A number of comments objected to the perceived delay in making Coast Guard-approved inflatable PFDs available to recreational boaters. These comments expressed the opinion that these delays were caused by the Coast Guard requirements contained in the two UL standards adopted, UL 1180 and 1191. The general consensus of these comments was that the increased safety benefits of having approved inflatables available and worn by boaters would outweigh any potential increase in safety benefits resulting from the manufacture of inflatable PFDs that met the IR's additional requirements. One comment suggested that the IR places too much emphasis on ensuring that the vests are 100 percent perfect, and other comments cited overregulation as the major obstacle to having the vests approved.

The Coast Guard notes that though a number of manufacturers have completed preliminary testing of designs, no inflatable PFD has yet been submitted for final testing and approval. This delay has been caused by the lack of accepted component materials (inflators of any use code and inflation chamber material) which are needed to produce any device submitted to the Coast Guard for final approval. The interim rule did not impose any additional requirements to the UL 1191 consensus standard, which sets the acceptance standards for component materials.

Several comments indicated that changes to the UL standard embodied in the IR were not consistent with the promises the Coast Guard made to the industry. The Coast Guard notes the statements in the ANPRM and meeting notice for the first consensus committee meeting which clearly define the Coast Guard's intentions and commitments in entering into the rulemaking process with the aim of using an industry consensus standard. These documents show that the Coast Guard anticipated the possible need for additions or modifications to the consensus standard to meet the minimum level of safety deemed necessary and clearly stated

that such modification or additions would be incorporated into the final approval standards if necessary.

Two of the comments discussed above requested that the final rule base Coast Guard approval on the requirements of UL 1180 with additional requirements limited to product marking and point-of-sale consumer information. UL commented that they expected the rule to contain a limited number of requirements supplemental to the UL 1180 and UL 1191 such as a USCG information pamphlet and PFD production quality control related requirements. UL also recommended that the Coast Guard make additional modifications and additions to the first edition of the 1180 standard, such as making trade-offs between requirements for donning and secureness of fit, revising the added visibility looking to the side test, and adding warning markings. The individual changes suggested are discussed below.

Two comments included resolutions requesting that the Coast Guard rescind those portions of the interim rule that impose additional requirements for Coast Guard approval beyond those imposed by UL 1180. As noted above, one of these resolutions was passed by the National Association of State Boating Law Administrators (NASBLA) which noted that its membership is deeply concerned that additional requirements beyond the UL 1180 standard may jeopardize the development and approval of fully inflatable PFDs. NASBLA recommended that the Coast Guard amend the IR to reflect only those standards currently in the incorporated UL standards.

The second resolution was submitted by the PFD Manufacturers Association (PFDMA), which represents manufacturers of PFDs and component materials. PFDMA and supporters commented that the Coast Guard should rescind almost all portions of the IR which impose additional requirements to the UL standards. However, the comments did note that the Coast Guard approval regulations do need to address labeling and information pamphlet requirements, areas which UL 1180 either does not address or does not do so adequately. The Coast Guard notes that two sections of the UL standard are "Reserved", those dealing with production quality control requirements and with the information pamphlet. As a result, the Coast Guard's requirements in these areas are the only requirements for those items.

NBSAC, an advisory committee charged with advising the Coast Guard on boating safety issues, approved a resolution, by a vote of 10 to 8, that

recommended that the Coast Guard requirements for approval of inflatable PFDs congruent with the consensus standard embodied in UL 1180 without exception or additional requirements. However, in a written survey of the NBSAC members, immediately following the meeting which adopted the resolution, many of the members indicated support for the Coast Guard's modifications to the UL standards. The Coast Guard therefore intends to raise some of these issues in the consensus committee when UL reopens UL 1180 and UL 1191 for revision.

Several comments from individuals favored the Coast Guard's modifications to the UL standards. One comment opposed the idea of merely adopting the UL standard by stating that it is not desirable to set a rigid pass/fail criteria for approval of any device in the form of an adopted consensus standard that fixes for a long period requirements based on currently available technology and designs. The comment continued by explaining that the Coast Guard's approval process should encourage and reward improvements in reliability and effectiveness above the level of what is feasible today at a reasonable cost. According to the comment, this approach would lead manufacturers into entering a desirable, continuing race to produce more comfortable and affordable PFDs, and that an industry consensus standard alone cannot provide such an incentive. Additionally, one comment from a PFD design consultant expressed the view that by having a clearly defined alternative to strict compliance with UL 1180, innovative and consumer responsive products would be more likely to make it to market. The Coast Guard notes that both the IR and this final rule allow for the possibility of approval of alternative designs that do not conform to the promulgated standards. As a result, manufacturers have had, and continue to have, the option of receiving approval for innovative inflatable PFD designs. The Coast Guard recognizes that trade-offs must be made between absolute safety and making inflatable PFDs both affordable and available to recreational boaters who would not typically wear currently approved devices and who are prepared to accept the increased care and servicing requirements needed to maintain reliability.

UL Standard Conflicts and Shortcomings: Comments from UL and manufacturers indicated that there were areas in the UL standard that need revisions or improvement as discussed below. Most of these changes are in areas addressed by the IR but some deal with conflicting requirements or

requirements that are believed by some manufacturers to be set unintentionally too high within the UL standard.

One comment stated that even without the most objectionable provisions of the IR, that is the LSI and "Approved Only When Worn" provisions, the standard as recommended by the consensus standard committee was problematic in many areas. The comment expressed the view that the UL standards were difficult and unrealistic in many areas, but might be "fixable". The commenter also expressed the belief that as large and complex as the UL documents were, they would likely have contradictions or deficiencies requiring correction consistent with the specification's stated goals. The commenter expected that, for example, the sections of the UL standard that conflicted with the use of disposable inflation mechanisms would be modified, and that the goal of having disposable inflators as an option would not be abandoned.

Missing Standards for Wearability and Approval Type: The Coast Guard notes that the UL standard calls for the USCG to set approval type for inflatable PFDs based on a PFD's performance, serviceability, and status indicators, but does not establish how these characteristics are to be used. As discussed at the first consensus standards meeting in March 1994, the Coast Guard indicated that its approval type would be determined after the characteristics of the PFDs were identified by the standards. As stated in the ANPRM "[t]he consensus standard may not address all the issues and characteristics essential to the Coast Guard," and alternatives "remaining unresolved will presented * * * for comment."

As initially drafted, the UL standard had a test for the projected wear rate that a PFD design would provide. This provision, which was referred to as "wearability", was deleted from the standard at the final standards committee meeting. The consensus committee was informed by the Coast Guard that the lack of a wearability standard would have to be justified or otherwise addressed. The committee failed to do so. Therefore, in the IR the Coast Guard provided conditional approval, requiring a device to be worn to meet carriage requirements, in addition to the UL standard as one way to address the lack of a wearability standard. One comment indicated that unconditional approval based on what is available today is undesirable and others supported the IR's conditional approval as discussed above. The lack of a wearability standard within the

consensus standard will require the Coast Guard to closely monitor accident statistics and revise the rules if necessary. Conditional approval is discussed further below.

Based on the above comments and on internal discussions within the Coast Guard detailed below, the Coast Guard is minimizing the additions and modifications to UL 1180 required for Coast Guard approval but retaining those which in the Coast Guard's judgment are essential to safety. The Coast Guard is retaining the two provisions of the IR for which the UL standard had reserved sections. These two areas, the PFD information pamphlet and production quality control, as mentioned above, were discussed by several commenters.

Nearly all the provisions being deleted from the IR may, in the future, further the lifesaving goals adopted by NBSAC and the Coast Guard as discussed in the IR. Therefore, those provisions will be proposed by the Coast Guard for inclusion in UL 1180. This will allow the Coast Guard to pursue the incorporation of these changes in concert with the industry and other interested parties, as many comments indicated the desire to proceed.

The Coast Guard notes that the PFDMA had expressed an interest in working with the Coast Guard, Underwriters Laboratories (UL), and others to revise the interim rule based on comments and resolutions which have been forwarded. As mentioned above, the Coast Guard does intend to continue to work with the consensus standards committee with the goal of incorporating as many of the provisions being deleted from the IR by this rulemaking as possible into UL 1180.

The comments on specific provisions of the regulation and the revisions made by this rulemaking are discussed below.

Timeline for approval: Two comments discussed the validity of the stated goal of the Coast Guard in the IR to have significant numbers of approved inflatable PFDs available to the public for the 1996 boating season. One comment noted that for approved inflatables to be available for the 1996 boating season, achievable and well defined requirements needed to be in place well in advance of the October 23, 1995, comment deadline for the IR. Another comment stated that it is highly unlikely that manufacturers will be able to make significant number of inflatable PFDs available to the public in 1996. The comment explained that because of the many unanticipated problems associated with meeting the requirements of the IR, manufacturers

would have to return to the design phase to re-engineer their products before submitting them for approval. According to the comment, when this process is completed, 1996 will probably be over. The comment projected that unless requirements are substantially changed, the regulation established by the IR would not result in inflatable PFDs becoming more than 3 percent of the total PFDs sold by the year 2007. The comment also stated that the Coast Guard and NBSAC goal of saving 210 lives by increasing the wear rate to 66 percent is desirable but not a rational projection resulting from the IR.

The Coast Guard shares the concerns regarding making approved inflatable PFDs available as soon as possible, however, it must balance that concern with the need to ensure that Coast Guard standards for approved inflatable PFDs will achieve a reasonable balance between safety and cost. The Coast Guard notes that nothing currently prevents the sale of non-approved inflatable PFDs to the public.

Specific Comments and Major Areas of Revision

The major areas of comment and revision to the IR standard are separated into categories and discussed below. For those areas in which the Coast Guard is deleting requirements from the IR, the Coast Guard intends to suggest that most of the deleted requirements be considered for inclusion in a revised version of the UL 1180 standard. Additionally, the Coast Guard intends to suggest the requirements from the IR which are being retained be considered for inclusion in a revised version of the UL 1180 standard. If the UL 1180 standard is revised to include the changes, the rules will be revised to delete these provisions from the subpart and update the incorporation by reference to cite the revised standard.

1. Lifesaving Index (LSI) and Use Code 1F Inflator [Sections 160.076-5, -7, -9, -13(c)(10), -21(e), -23(a)(1), -27, and -37(b)(4 & 5)]

As the IR's approval requirements concerning use code 1F inflators and the LSI are interdependent, they are being discussed as one category.

IR Requirement: Under the requirements for inflatable PFDs in the IR, the Coast Guard requires that, except for inflatable PFDs equipped with inflators with 1F use codes, an LSI analysis be performed to evaluate the overall lifesaving potential of an inflatable PFD submitted for approval. A use code 1F inflator, which has a cylinder seal indicator, provides a visible indication to the user of the

cylinder status. The same readily visible indication of inflation cylinder status is not available with use code 2F and 3F inflators. The LSI analysis, therefore, was provided as an alternative to allow other reliability and wearability factors to compensate for the lack of visible cylinder status indication. Under the IR, the Approval Type (I, II, III, or V) given to any particular PFD design, except for those with 1F inflators, would depend on the results of the LSI analysis. If, as a result of the LSI analysis, it was determined that a conditional approval would be appropriate for a particular PFD, the most likely condition for approval would be the requirement that a PFD would be required to be worn to count toward the PFD carriage requirement.

Comments on Use Code 1F Inflator Requirement: Thirteen commenters specifically discussed the requirements related to inflation system indicators with a 1F use code. Of these, four comments favored the IR's requirements regarding the use of a 1F inflator. One cylinder manufacturer described the IR as a great step towards saving lives and commended the Coast Guard and UL for properly addressing the gas cylinder issue by including indicators within the inflator mechanism. Another comment favoring use code 1F inflator requirements did so by reasoning that the Coast Guard's approval process should encourage and reward improvements in reliability and effectiveness beyond what is feasible today at reasonable cost and therefore should have a built in mechanism, such as the requirement for the LSI analysis and 1F inflators to encourage technological advances. Three comments, including one of the above, expressed hope that the Coast Guard's regulations would require approved PFDs to have an easy way to check the CO₂ cartridge to ensure it was charged, such as fire extinguisher gauges or push-and-release pop-out pins. Use code 1F inflators include indicators that satisfy this need.

The remaining nine commenters that discussed inflators disagreed with the IR's emphasis on cylinder indication to increase operational reliability of inflatable PFDs. Seven comments suggested that the Coast Guard withdraw the requirement to either have a use code 1F inflator or utilize the LSI analysis, for all but Type I inflatable PFDs. Four of these comments indicated that there is lack of current technology to provide full cylinder indication at a reasonable cost. These comments reasoned either that use code 1F inflators remain beyond state-of-the-art and therefore their use should not be

required or that the use code 1F requirement may possibly delay the production of Coast Guard approved inflatable PFDs. One comment added that the highest level of cylinder indicator was not necessary because the requirements for redundant inflation systems and for swimming ability, adequately compensates for the remote possibility of primary inflation system failure. The Coast Guard notes that a "recommendation" against use by non-swimmers is not equivalent to a "requirement" and that, as discussed above, any swimming requirement would be unenforceable.

One comment cautioned the Coast Guard with regard to drawing conclusions from the informal study at NASBLA's annual meeting discussed in the IR, where only 2 out of 18 participants were able to correctly identify the serviceability of 4 older style inflation mechanisms. The comment reminded the Coast Guard that the newer styles of inflators are designed so that it is easier to determine when an inflator has already been fired. The comment also cautioned the Coast Guard not to presume that all systems were represented in the field study, and that no mechanism is completely foolproof, including one with a cylinder seal indicator.

The Coast Guard remains concerned with the inflation systems used on inflatable PFDs. The design of the inflation mechanism is important because proper maintenance plays a crucial role in ensuring the reliability of an inflatable PFD. If the status of the inflator mechanism is easy to check, then it is more likely that a boater will check the status often and correctly. A recent Coast Guard study of the causes of marine casualties indicated that 80% or more of all marine casualties are caused by human error and that these were often induced by inadequate attention to human factors in the design and performance standards for equipment. The Coast Guard's findings on this subject are reported in the "Prevention Through People" quality action team report, the Notice of Availability of which was published in the February 16, 1996, Federal Register (61 FR 6283).

Comments on PFD Life-Saving Index Evaluation: Twelve commenters specifically noted reservations about the "Life-Saving Index" (LSI), while three comments expressed unqualified support of this alternative approval path, generally because of the flexibility and encouragement of improvements thought to be fostered by the LSI requirement. Additionally, the October 30, 1995, NBSAC resolution discussed

above favored continued development of the LSI for possible future use.

The three comments which supported the LSI concept thought that the LSI might be the most potentially beneficial portion of the IR, with one stating that it would "allow approval of unique and novel designs that offer lifesaving potential equal to or greater than that of approved devices * * * these designs may prove to be very comfortable, affordable and popular with the boating public." The comment continued that promoting innovation in design actually allows the end user to have a voice in what can be used to meet Coast Guard requirements.

Another comment which supported the LSI expressed pleasure with the results of the NBSAC member survey for retaining the LSI, in which 9 out of 14 respondents indicated that they favored retaining the LSI as a clearly defined alternative to strict compliance to UL 1180. The comment continued that through the LSI, innovative and consumer responsive products will be able to make it to market, and that without the LSI, inflatable PFDs will be static in design. Also the comment indicated that if the LSI were eliminated, the Coast Guard would be limiting the ability of manufacturers of innovative PFDs to fairly compete with current products. As mentioned above, the Coast Guard notes that both the IR and this final rule allow for the possibility of approval of alternative designs that do not conform to the promulgated standards. As a result, manufacturers have had, and continue to have, the option of receiving approval for innovative inflatable PFD designs.

One comment which supported the overall concept of the LSI objected to the LSI scheme if inflatable PFDs of low reliability or effectiveness receive the same Coast Guard approval status as other PFDs. If this were to occur, the comment continued, the boating public should be notified of the reduced reliability of the device at the point of sale.

On the other hand, most comments received by the Coast Guard expressed reservations about the LSI analysis as presented in the IR. Six of these comments expressing concerns noted that LSI concepts have merit in a broad application, but indicated apprehension about its application to individual items.

Five comments specifically requested that the Coast Guard delete the LSI from the IR. One of these comments also stated that, as opposed to the LSI, what the industry needs is a realistic standard of performance, keyed to individual product types. Another comment stated

that the LSI and conditional approval provisions added by the IR to the UL standard will hamper the Coast Guard's desire for a flow of innovative, new products.

Two comments and a number of participants in the public meeting stated that mandating the use of the LSI as an alternative to having the use code 1F inflation mechanism, is unacceptable. These comments criticized the LSI saying the validity of the LSI elements chosen and weights which have been applied, do not appear statistically valid, uniformly applied, or adequately defined. Another comment noted that adequate development of the LSI process would likely require an *ad hoc* committee effort.

A concern expressed at the public meeting on the LSI and in several comments, related to the IR's provisions for an annual review of the LSI. This concern focused on the fear that an annual review could potentially subject manufacturers to revocation of approval and the resulting possible liability. In addition, several other comments and meeting participants cautioned that the LSI factors will become moving targets that will unnecessarily invite litigation against manufacturers as factors and weights are changed.

Two comments noted that approval classification, i.e., the USCG Type designation for a PFD, should coincide directly with UL 1180 "performance type" without requiring an LSI evaluation for approval of any specific PFD model. These comments reasoned that because the performance required by UL 1180 is significantly higher than required for any other recreational use PFD, there is no need to ensure the lifesaving potential of a device through the LSI. The Coast Guard notes that while the UL standard requires in-water performance and other increases, it also permits a decrease in reliability compared to inherently buoyant PFDs. The Coast Guard believes that the increase in wearability expected by many commenters will be needed in addition to the UL performance increases for the lifesaving potential of most inflatable PFDs to equal that of inherently buoyant PFDs.

Final rule requirements: The requirement that a device either have a use code 1F inflator or be subjected to the LSI evaluation for approval was based on two studies, one conducted by BOAT/U.S. from 1990 to 1993 and one conducted by the Coast Guard with the USCG Auxiliary from 1979 to 1981. Both of these studies concluded that inflatable PFDs without visible indicators of the state of inflation cylinder charge would not be properly

maintained by a substantial percentage of typical users. The maintenance deficiencies reported in the studies were of such a nature that the devices would not operate as intended. The Coast Guard was concerned that if a substantial percentage of lower-performing inflatables were not properly maintained, as the studies suggest, the widespread use of these types of devices could actually lead to an increase in drowning fatalities. In addition, the Coast Guard was concerned that as the lower-performing devices would be the least expensive, and therefore most accessible to boaters, the risk of improper maintenance would be compounded. The use of the LSI as an approval evaluation tool was intended to ensure that the inherent lesser reliability of inflatable PFDs, coupled with the lower in-water effectiveness and the additional reduction in reliability for lower-performing devices due to human error as observed in the studies, would be offset by other features or approval conditions on the PFD.

Most of the comments received on the IR, as discussed above, opposed the use of the LSI as an approval evaluation tool. The comments cited the untested, and potentially subjective, nature of the LSI. As discussed above, these comments strongly urged the adoption of the UL 1180 consensus standard for approval of inflatable PFDs without any additions or modifications except to address those areas in which UL 1180 is incomplete or inadequate. This view was supported by resolutions of NBSAC, NASBLA, and PFDMA.

After careful review of all of the comments, the Coast Guard has reconsidered its previous interpretation of the study results the NBSAC recommendation, and of the improvements to PFD inflation hardware which occurred as a result of the development of UL 1180 and 1191. Upon reconsideration, the Coast Guard noted that the correlation of the study results to actual use patterns in the market may not be entirely conclusive. In particular, the different methodologies of the Coast Guard Auxiliary and BOAT/U.S. Foundation studies yielded somewhat different results, calling into question the relative validity of those methodologies in assessing the behaviors of the overall boating population. The Coast Guard notes that many comments received from boaters, as discussed below under "Approval Type", suggest that wear rates for approved inflatables would be higher than was observed in the studies. Additionally, the inflators on the PFDs used in the studies did not incorporate

the performance improvements mentioned above. Furthermore, the comments from PFD manufacturers indicated that the IR requirement for conducting an LSI analysis for devices with 2F and 3F inflators, which was based upon the Coast Guard's initial interpretation of the studies, would severely hamper the efforts of PFD manufacturers to bring inflatable PFDs to market thereby delaying the safety gains considered possible as a result of introducing approved inflatable PFDs.

In the absence of conclusive evidence that the use of the LSI to evaluate inflatable PFDs with use code 2F and 3F inflators is necessary to avoid undesirable outcomes as the result of approval of inflatable PFDs for recreational use, the Coast Guard has removed the LSI from this final rule as a required evaluation tool for approval of all PFDs not having a use code 1F inflator. As suggested in many comments, this final rule provides for approval of inflatable PFDs with use code 1F, 2F, or 3F inflators in accordance with the requirements of the UL 1180 consensus standard, supplemented only as needed to address the portions of UL 1180 which are acknowledged as being incomplete or having significant safety implications. The Coast Guard believes that the potential benefit of increased PFD wear as the result of approval of inflatable PFDs for recreational boaters, in conjunction with the inflatable PFD performance improvements established in UL 1180, outweigh the potential risk of PFD failures due to human error. Nevertheless, the Coast Guard is strongly encouraging PFD manufacturers to emphasize the need for proper maintenance in their marketing and instructional materials. As inflatable PFDs are introduced to the recreational boating market, the Coast Guard will carefully monitor casualty data to ensure that appropriate adjustments are made to the UL standards or requirements in the event of negative outcomes.

The Coast Guard notes that it has used the LSI to aid its evaluation and analysis of PFD rulemaking projects since 1985, but this is the first regulatory project in which it was to be used as an approval evaluation tool. The Coast Guard's intent in inserting this requirement was to provide more flexibility for design approval. Although it is no longer required as an approval evaluation tool, the Coast Guard anticipates that the LSI will be used in the future as an evaluation tool for novel designs not specifically covered by UL 1180 and to evaluate rule changes, establish policy, and make equivalency interpretations.

Additionally, the Coast Guard will continue development of the LSI as was suggested by a number of the comments discussed above, and the October 30, 1995, NBSAC resolution which favored continued development of the LSI for possible future use. Therefore the following sections are revised or deleted accordingly: §§ 160.076-5, -7(a)(1), -9(b), -13(c)(10), -21(e), -23(a)(1), -27, and -37(b)(4 & 5).

Future action: The uncertainty the LSI caused for manufacturers needs to be addressed in order for the probabilistic risk based assessment embodied in the LSI to be a truly viable alternate approval path. The Coast Guard will propose to develop the LSI as a consensus standard with participation of industry. If the LSI can be developed adequately to be a viable alternative path, it may be proposed as part of the approval process for PFDs in the future. As noted above, the Coast Guard will carefully monitor the effect of deleting the LSI and approving PFDs with either use code 1F, 2F or 3F inflators.

2. Approval Type [Sections 160.076-7, -9, and -39(c)]

IR Requirement: Under the approval requirements for inflatable PFDs in the IR, the Coast Guard provided the option of approving inflatable PFDs as Type V PFDs, which either would require that the PFD be worn to count towards the carriage requirement, or would have other conditions appropriate to their intended use. In the latter case, conditional approvals would be allowed for special PFDs designed for special circumstances, such as those for diving with recreational submersibles. Approval of this special category of devices is not addressed by the UL standard.

Comments on Conditional Approval and Approved Only When Worn:

Five comments indicated the need for an incentive, such as a condition that a PFD only be approved as meeting the carriage requirements if it is worn, to increase PFD wear rates. After noting that 80% of drownings occur because the victim is not wearing a PFD, one of these comments concluded that any regulation relating to PFDs should require that PFDs be worn, particularly on small boats, if the Coast Guard expects to have an impact on boating accident drownings. Several comments from boaters indicated that they were not opposed to a requirement for inflatables to be worn, and as discussed above, there were 21 comments that either favor required wear, presently wear, or would wear inflatable PFDs.

One of the comments requested that approval of all inflatable PFDs be

conditional on the PFD being worn and noted that approvals that are contingent on the device being worn may increase use, grant boaters access to approved devices, allow the industry to sell approved devices, and allow price and comfort to drive the market. Another comment from a manufacturer that also favored conditional approval for all inflatable PFDs, not just Type V, noted that the condition would benefit and promote: wear among those who purchase an inflatable PFD, better care and maintenance of the inflation among those who wear it, and redundancy in personal lifesaving equipment aboard vessels where space is not limited.

One comment suggested adding the condition "in presence of perceived danger" to the "approved only when worn" provision to make the conditional approval more acceptable and reasonable. It is the Coast Guard's view that for most accidents danger is often unperceived, and that such a requirement would, instead of encouraging increased wear, result in boaters wearing PFDs less often under the mistaken belief that the need for them was limited to situations when imminent danger is apparent. Additionally, as with a swimming ability requirement, it would not be feasible for law enforcement personnel to enforce such a condition.

Two comments that favored required wear, noted that to get more comfortable PFDs on the market and achieve wider use than currently approved PFDs, it may be necessary for the Coast Guard to relax the standards of reliability and effectiveness. One of these comments indicated that reduced "reliability or effectiveness" in combination with the condition that a PFD is "approved only when worn" should be an available approval option to permit manufacturers to reduce the cost of a device.

On the other hand, several comments from manufacturers and from boaters indicated that they were opposed to any requirement for inflatables to be worn. Three comments from boaters indicated that they opposed any condition that required PFDs to be worn to meet the carriage requirements. One stated that the introduction of the "Approved Only When Worn" concept is curious in light of the results of another Coast Guard interim rule which set approval standards for hybrid inflatable life jackets (50 FR 33923; August 22, 1985) which had adopted the same requirement. A hybrid PFD uses a mixture of inherently buoyant material and inflation to provide flotation. In the commenter's opinion the effect of the action was the "kiss of death" for hybrid

PFDs. In addition, the comment noted that if this requirement was truly justified for inflatables, then it is equally justified for inherently buoyant vests. The Coast Guard notes that there are two significant differences between the hybrid PFDs and inflatables: comfort and price. Hybrid PFDs do not provide as much improvement in comfort, and hence increased wearability, as inflatables because of their greater bulk and body coverage. Additionally, inflatables only have one means of buoyancy, and therefore will be less expensive than hybrids and represent a much smaller incremental increase above the cost of an inherently buoyant PFD. The Coast Guard also notes that the option of approving hybrid PFDs without the requirement that they be worn to be considered approved has been available since February 1995. Since that time only one manufacturer has sought approval without this condition. This fact appears to confirm that the approval condition is not the sole reason for the lack of retail success of hybrid PFDs.

Final rule requirements: The Coast Guard adopted the option of conditional approval in the IR for inflatable PFDs without use code 1F inflators but, as discussed above in the discussion of the use code 1F inflators and the LSI, the Coast Guard is deleting the use code 1F inflator provision as imposing conditional approval from the final rule for PFDs meeting UL 1180 because of the potential impediment that the conditions may have on the sales of devices to recreational boaters.

In this final rule, conditional approval is being used only for PFDs which do not comply with the UL standards and which are intended to be used in some special application or manner, such as diving with a "wet" submersible vessel, i.e., a vessel designed to propel a person using SCUBA, or partially wet submersible vessel. The Coast Guard believes that such designs can provide boaters with an effective lifesaving alternative only if the user understands the PFD's limitations and is used accordingly. Conditional approval serves these ends and may make more affordable alternatives available to users who wish to have an approved supplemental PFD on board for occasional use or who are willing to comply with the approval conditions to have the device count as a replacement PFD to meet the carriage requirements. The lack of a wearability standard within the consensus standard or conditional approval in the regulations will require the Coast Guard to closely monitor accident statistics and revise the rules if necessary. Therefore, the

following sections are revised or deleted accordingly: §§ 160.076-7, -9, and -39(c).

3. *Repack Evaluation (Section 160.076-25(c)(2))*

IR Requirement: UL 1180 does not address repacking. Under the IR, however, an inflatable PFD being tested for approval must pass an evaluation in which test subjects demonstrate that they can repack the PFD, or refold the yoke-style design so that it will function properly when donned and used again. After being repacked the PFD must be ready for donning and manual inflation in or out of the water, and for oral inflation in the water. There is no time limit associated with the test. The test is not required for devices the manufacturer requires to be professionally serviced.

Comments: One manufacturer commented that the requirement for a repack evaluation test is a good improvement, because most designs currently available are very difficult to repack. However, a second comment stated that the requirement that each test subject perform three repack evaluations is excessive and adds expense. The comment noted that a single repack evaluation would adequately address the necessary safety considerations. The Coast Guard notes that as the requirement is written in the IR, the PFD's suitability for use in the specific test conditions noted above must be assessed after the repacking. The Coast Guard believes that all of these conditions can be properly evaluated after the test subject performs only one repack. Therefore, only one repack evaluation is needed for approval, but a follow-up assessment must be conducted by the test laboratory to ensure that all of the cited UL 1180 conditions are evaluated.

Final rule requirements: The Coast Guard is retaining the repack evaluation requirement in § 160.076-25(c)(2), but is making editorial revisions to clarify that only one repack evaluation is required. Inflatable PFDs that pass this test will have a higher in-service operational reliability than designs not meeting the requirement because they will be less likely to be repacked or refolded such that inflation lanyards and the like are inaccessible for emergency use or unusable without disassembly.

4. *45-Sec. Average Donning Time, Donning Relaxation, and Reporting Subject Disqualification [Section 160.076-25(c)(1)]*

IR Requirements: A 45-second average donning time requirement was included in the IR in addition to the UL 1180

imposed 60-second maximum limit for each subject. Additionally, unusual problems with the reference vest used for the donning time test are required to be reported to the Coast Guard, as this is a new reference vest that has not been previously used for testing purposes. A longer donning time is permitted for designs requesting approval with conditions which are not yet addressed in UL 1180.

Comments: Except for the NBSAC survey discussed above, comments on the average donning time test were not favorable and advocated elimination of this requirement. One comment noted that in administering a donning time test, consideration should be given to the trade-off that exists between the simplicity of donning a PFD and the secureness of the device during water entry. The comment suggested that the Coast Guard eliminate the 45-second average donning time requirement and only require the 60-second maximum in UL 1180. Another comment indicated that the average time requirement has reduced the time limit from 60 to 45 seconds, and did not understand why an inflatable PFD should be donned faster than an inherently buoyant PFD. The Coast Guard notes that the 45-second average donning time requirement is actually a second requirement in addition to the UL 1180 60-second maximum donning time requirement. The requirement is not a significant reduction in donning time but a change in the method of evaluating the test results.

Final rule requirements: The average donning requirement was added in the IR as a supplement to the 60-second maximum time requirement contained in the UL 1180 standard, in order to effectively measure donning-time performance of PFDs. Historically, nearly all designs of inherently buoyant and hybrid PFDs that pass a 60-second maximum requirement, have been shown to pass a 45-second average requirement as well. The Coast Guard inserted the average requirement in the IR because, overall it is a better tool for assessing whether designs are improving or whether they are getting more difficult to don. No reasonable PFD design would be denied approval solely as a result of the average requirement. Unless PFDs are required to be worn, donning is a critical part of the survival process.

However, the average donning time test provides limited additional safety and may slow the availability of inflatable PFDs to boaters. Therefore, the Coast Guard is deleting the average donning time test requirements contained in the IR at § 160.076-25(c)(1)

but retaining the requirement that a PFD meet the 60-second maximum donning time requirement in UL 1180.

5. Average Freeboard for Type II and Freeboard Reporting (Section 160.076-25(c)(3)(i) and -25(c)(4)(i))

IR Requirement: UL 1180 contains both an average and minimum freeboard requirement for performance types I and III PFDs, but only contains a minimum freeboard requirement for performance type II PFDs. To make the requirements consistent for all types of PFDs, the IR contained an average freeboard requirement for approval Type II PFDs. As part of the IR, freeboard is required to be measured and reported in order that PFD performance trends can be effectively monitored by the Coast Guard.

Comments: One comment stated that the 4.25 inch average freeboard requirements for Type II PFDs contained in the IR is excessive based on the 3.25 inch per subject minimum freeboard requirement, contained in UL 1180. The commenter informed the Coast Guard that they had never seen an average freeboard requirement applied and were not aware of any body of data to support its use. As mentioned above, the Coast Guard notes that the UL 1180 standard has both minimum and average freeboard requirements already in place for performance type I and III PFDs and that the performance type II requirements are the exception.

Final rule requirements: Although UL 1180 contains both average and minimum freeboard requirements for type I and II PFDs, the UL standards committee could not come to an agreement on the average requirement for performance type II PFDs and therefore omitted the average requirement for type IIs only. As a result, UL 1180 only contains a minimum freeboard requirement for Type II PFDs and no average requirement. Although adequate for safety, a minimum requirement is not conducive to monitoring trends, comparing performance, or promoting continuous improvement.

The Coast Guard is deleting the average freeboard requirement for Type II PFDs as well as the freeboard reporting requirement, and will ask UL to voluntarily measure and calculate average freeboard and report the results to the Coast Guard. As a result, although the safety of any individual PFD will not be effected, until the UL standard can be updated, an inconsistency will remain between the freeboard evaluation method of performance type II PFDs versus types I and III.

6. Wearer's View from PFD (Section 160.076-25(c)(3)(ii) and -25(c)(4)(ii))

IR Requirement: The IR requirements ensure that the inflated PFD does not unduly interfere with the wearer's ability to see in front and to the sides ("side mark view") without having to tread water. The UL standard does not address these issues.

Comments: Three comments addressed these provisions. One comment suggested that the side mark view evaluation be performed at 20 feet, rather than the 3 m (10 ft) requirement in the IR, to make it consistent with other standards and regulations which use this type of PFD performance requirement. The Coast Guard notes that the approval requirements for hybrid and commercial inflatable PFDs require that this evaluation occur at 3 m rather than 20 feet (46 CFR Part 160.077 and 160.176). In addition, the comment indicated that the in-water performance evaluation relating to front and side views should only be conducted with the device positioned in its intended wear condition. The comment indicated that if the PFD shifts during water entry it should not be judged a failure for inadequacy of vision; it does not matter if unconscious people have their vision restricted. However, the comment agreed that the remaining in-water requirements (e.g., turns, freeboard, etc.) are applicable to both conscious and unconscious users. In addition, the comment requested that the front mark view requirement not apply to Type III PFDs.

The second comment also discussed the IR requirement that the water surface be visible to the subject when looking to the side. The comment suggested that this only apply to Type I devices and even then not rigidly. The comment added that a relaxed head position without constant visibility of the lowest point on the horizon is not an unsafe condition. Another comment stated that the IR requirement for static measurements of the side mark view, freeboard, and retroreflective material location creates an excessive amount of testing and continues to increase the cost of approval.

Final rule requirements: The Coast Guard is deleting both of the wearer view requirements contained in § 160.076-25(c)(3)(ii) and -25(c)(4)(ii) as these provisions add limited additional safety and may slow inflatable PFDs from being available to boaters.

7. Retroreflective Tape and Light Visibility (Section 160.076-25(c)(3)(iii))

IR Requirement: Any retroreflective tape or light provided on the PFD is

required to be visible while worn in the water. The Coast Guard instituted these requirements to ensure that the retroreflective material is effective for search and rescue purposes. The Coast Guard believes that it would be an unnecessary expense and misleading to the user to provide these materials at locations that do not aid search and rescue. The UL 1180 standard does not address these provisions.

Comments: One comment opposed the requirement in § 160.076-25(e)(3)(iii) that requires 75 percent of the reflective material to be above the water line. The comment noted that this type of requirement, and others like it, do not encourage improved performance. Instead, a minimum surface area of reflective material above the water line should be required. The comment added that manufacturers should be encouraged, not discouraged to provide more reflective material.

Final rule requirements: The Coast Guard is deleting the additional requirements relating to retroreflective material above those required in UL 1180. UL practice is to require manufacturers to ensure that the minimum area needed for effective search and rescue is covered with retroreflective material if the device is sold as one that will aid in search and rescue, or if sold for use on commercial vessels. Therefore, the Coast Guard expects that most PFDs with such material tested by UL will meet this requirement.

8. Chamber Material Physical Properties, Production Oversight, Production Tests, and Manufacturer's Records Sections 160.076(b) & (c), -25(d)(2), -29, -31, and -33]

IR Requirement: To set a baseline, the IR requires that tests be conducted on materials taken from prototypes of PFDs tested for approval. There are no pass/fail criteria associated with these tests during approval, but they provide baseline data essential for production quality control limits and for use at a later date if the manufacturer proposes changes in materials. The production oversight and tests established by the IR also cover all the usual elements of a quality control program including the division of production units into lots, running various tests on each lot, establishing and retaining certain records, and establishing criteria for product acceptance and resolution of problems.

Comments on inflation chamber properties: One comment indicated that § 160.076-25(d)(2), which requires testing of inflation chamber properties from the tested prototype PFD, should

be revised to permit PFD manufacturers to bypass the inflation chamber properties tests by using material from the same lot, or equivalent, as that evaluated for the compartment material manufacturer. The comment did not define equivalent, and the Coast Guard knows of no way to determine equivalence other than by testing these physical properties. However, other methods of demonstrating equivalence can be considered.

Another comment opposed this requirement because of the difficulty and questionable value of remaining within close limits of minimum design on all components and assembly parameters in an inflatable PFD used for approval testing. The comment went on to say that production lots of components occasionally dip below the assumed safe level, and that both wide deviations within relatively small lots as well as testing errors on a specific sample are possible. This comment points out the competing demands of economical production and assurance that a produced product is adequately represented by the samples which have been tested for safety during the approval process.

Comments on Lot numbering: One comment indicated that the § 160.076-29(d) requirement to change PFD lot numbers whenever an incoming component lot number changes, would create a hardship for manufacturers. Another comment indicated that changes in lot numbers for component lot changes should only be required for changing lots of fabric and inflation mechanisms. Additionally, one comment noted that the suggestion that PFDs be manufactured in batches and given sequential serial numbers is burdensome and unnecessary. The comment suggested that this method of numbering be an available option, but not a requirement. The Coast Guard notes that the lot numbering requirements in the IR are the same as for other kinds of PFDs and that in the IR providing sequential serial numbers is an option, not a requirement.

Comments on production tests: One comment questioned why § 160.76-29(e)(2) requires two sets of samples for every fifth lot, and indicated that the tests conducted by the inspectors should replace the tests conducted by manufacturers for these lots. The Coast Guard notes that these provisions are the same as for other PFDs and are based on the quality assurance concept of counter checking the primary quality control provider's results.

One comment indicated that § 160.076-29(e)(4) (vi) and (5)(iii) requires testing without regard to

production schedules. The Coast Guard notes that these paragraphs are notes to the manufacturer's and inspector's sampling plan tables and thus only apply to testing when there is production in process, as the comment indicated should be the case.

One comment indicated that the seam strength test in § 160.076-31(c)(2) is redundant with the over-pressure and air retention tests. The Coast Guard notes that in fact the latter tests provide no meaningful measure against which production control limits for the material or process can be set because they are simply pass/fail tests and thus cannot be used to monitor or predict developing problems. Seam strength offers a measure that can show trends and thereby indicate when to intervene to prevent problems.

Comments on supervision: One comment indicated that § 160.076-31(d)(3) which requires that the examiner not be supervised by someone who is responsible for meeting production schedules would sometimes initially cause problems in production start-up. The Coast Guard notes that such start-up conflicts are expected and are handled on a case by case basis, by waiving the requirement until the product line is established.

Comments on records retention: One comment questioned why § 160.076-33(a) requires the records for inflatable PFDs to be retained longer than for inherently buoyant PFDs. Another comment questioned why § 160.076-33(b)(4)(ii) requires dates of purchase and receipt of components to be recorded in addition to the component lot number. The comment indicated the lot number provides the necessary tracking information.

Final rule requirements: Performance of approval tests on production inflation chamber materials as required by the IR, avoids the necessity and cost for manufacturers to retest a PFD design in the event of a material change. The results of these types of material tests indicate the level of quality that the materials used in production must achieve to ensure production PFDs are capable of passing the UL 1180 approval tests. The production requirements section of UL 1180 is "Reserved". Production oversight is a fundamental component for all approval processes. The IR provisions require essentially the same production oversight as for other kinds of PFDs. Therefore, the Coast Guard is retaining the baseline material and production tests to establish the quality of the fundamental element of an inflatable PFD's ability to provide durable flotation. Under the IR and the final rule, manufacturers are provided

the option of qualifying several alternate inflation chamber materials, while still being prevented from unwittingly submitting a "lab queen" for initial approval. Inflation chamber material properties as well as production oversight and tests, as with all PFDs, are essential quality control provisions that ensure production units comply with specifications of the tested prototypes.

As to the lot numbering requirements, though the IR requirements are being retained in this final rule the Coast Guard will work with UL and the PFD industry to establish equivalent numbering systems, and if such a requirement is adopted into the UL standard the Coast Guard will delete the requirement for the Coast Guard regulations.

The Coast Guard is retaining the records and recordkeeping provisions in the final rule as published in the IR, because records are an essential element to its oversight responsibilities. The UL standard does not address these provisions. As the Coast Guard gains experience with regulated use and user servicing of inflatables, the Coast Guard believes that long-term records are necessary to allow for tracking of defects during the initial period of approval. Additionally, a more extensive record retention will benefit manufacturers by limiting the scope of any necessary defect notification solely to affected units. Inherently buoyant PFDs have a shorter records retention period than those for inflatables because of their "self inspecting" qualities of the PFDs as discussed in the ANPRM. The Coast Guard interprets the subpart lot recordkeeping requirement as being complied with if the component lot number provides the manufacturer with the other required information.

9. Waterproof Marking Durability [Section 160.076-31(c)(8)]

IR Requirement: The IR requires a waterproof marking test that is moderately more stringent than the test required for other kinds of PFDs.

Comments: One comment indicated that § 160.076-31(c)(8), waterproof marking test, should not require elevated temperature and mild detergent since the same is not required for other PFDs.

Final rule requirements: The Coast Guard agrees that all PFD marking should be tested in the same manner, but had established the test in the IR because the impermanence of markings is a common complaint on presently approved PFDs, and because the modified test is no challenge to current technology. However, to avoid excessive differences between this and other Coast

Guard regulations and UL requirements, the waterproof marking requirement in the IR is being revised in this final rule to make the test consistent with that applicable to other PFDs.

10. Inflator Marking [Sections 160.076-21(f) and -39(d)(1)(ii)]

IR Requirement: The IR requires that both inflators and PFDs be marked with the model number of the inflator used for approval testing.

Comments: PFDMA, the industry association, and one manufacturer acknowledged in comments the need for the Coast Guard to address PFD marking issues as the UL standard does not completely address these concerns.

Final rule requirements: The Coast Guard is retaining the marking requirements in the final rule to aid in enforcement of the serviceability requirements in Title 33 Part 175. Additionally, these provisions are to discourage boaters from switching to less reliable and less capable after-market inflators after purchasing a PFD, and to minimize the possibility of a boater being harmed as a result of an unauthorized modification to an approved PFD. The provision will also help to prevent inadvertent voiding of approval.

11. Adhesive Requirements [Section 160.076-21(d)]

IR Requirement: The IR requires that any adhesive used in the PFD must meet a simple performance standard. The UL standard is not specific in this area.

Final rule requirements: The Coast Guard has decided to drop this restriction from the final rule. Currently, adhesives are not extensively used in most inflatable PFDs produced. The Coast Guard included the requirement in the IR because adhesives have been used in the past and may possibly come into use again. Even without the Coast Guard requirement, if adhesives are used in a PFD submitted for approval, the adhesive will still need to be evaluated for suitability in the intended application according to section 1.4 of UL 1180, which provides general testing standards for components and materials different from the standard.

12. Inflation Discomfort [Section 160.076-23(a)(2)]

IR Requirement: PFDs must not be so uncomfortable during inflation or after inflation so as to cause distress or panic to the user.

Final rule requirements: The Coast Guard is removing this requirement from the final rule. The UL 1180 Standard partially covers this area in section 6.11.4, which requires the PFD

to have acceptable comfort up to 90% of the maximum inflation pressure. If after a design is approved, the Coast Guard determines that some boaters are experiencing distress upon inflation, the need for additional requirements in this area will be reevaluated.

13. Textile Cut Edges [Section 160.076-239b)]

IR Requirement: Textile cut edges must be finished to minimize premature unraveling failures. This is a durability and product value issue and not a safety issue.

Final rule requirements: The Coast Guard is removing this requirement from the final rule. As a result, some products will need to be removed from service sooner than if the requirement were in effect; however, a shortened life span should not be catastrophic or life threatening.

14. Pamphlet Requirements [Section 160.076-35]

IR Requirement: An information pamphlet must be provided which is similar in format to that required for inherently buoyant and hybrid PFDs, but which covers the features of inflatable PFDs.

Comments: In comments, PFDMA and three manufacturers acknowledged the need for this information pamphlet section. They provided no specific comments or suggested improvements to the requirements. The UL comments indicate that they expected the Coast Guard to fill in these requirements until the UL standard could be completed. The general consensus of the attendees at the public meeting, discussed above, was support of the approach to the pamphlet published in the IR.

Final rule requirements: All Coast Guard-approved PFDs are required by 33 CFR 181 to be provided with a PFD pamphlet. The UL standard has a section reserved for this item. Without requirements specific to inflatable PFDs in this section, the pamphlet for inherently buoyant PFDs specified in 33 CFR 181 would be required. This result would add no benefit to the public as that pamphlet fails to address inflatable PFDs. Therefore, the Coast Guard is retaining the requirement regarding the information pamphlet in the final rule as published in the IR. Proper selection guidance is critical for a potential inflatable PFD consumer to make an informed purchase decision.

15. Owner's manual [Section 160.076-37 (b)(1), (b)(2), (b)(3), (b)(4), and (b)(5)]

IR Requirement: In addition to the UL 1180 requirements for the type of information to be provided in an

owner's manual, the IR requires five additional issues to be addressed: (1) instructions to inform users to partially deflate a PFD to ease climbing out of the water; (2) service life disclosure; (3) warning against misuse that could be hazardous; (4) explanation of the meaning of any approval conditions; and (5) estimate of user's chances of survival if approval conditions are or are not met.

Comments: Several comments addressed this issue. One manufacturer acknowledged the need for the IR's owner's manual section. Two comments indicated that the requirement is § 160.076-37(b)(2), to state the expected service life in owner's manual, was not prudent due to enormous diversity of usage conditions. One of these comments went on to say that the components which will be used in the first inflatable PFDs are newly developed to meet the new standard and have no historical data to justify any claims of expected service life. Additionally, a comment from UL indicated that the example in § 160.076-37(b)(3), which requires a warning against wearing a PFD with automatic inflation under restrictive clothing, should be revised to indicate that such a warning be provided with all inflatable PFDs since any inflatable PFD worn under clothing is hazardous.

Final rule requirements: During the development of UL 1180, PFD manufacturers were divided on the service life disclosure issue, and the UL committee could not reach a consensus on the issue. Because the IR provisions requiring additional information to be included in owner's manual add limited additional safety benefits and may delay designs being available to boaters, those provisions are being deleted in the final rule. The UL standard still requires an owner's manual to be included and manufacturers who choose to, can include the material which would have been required by the IR.

16. PFD Markings [Section 160.076-39 (c), (d), and (f)]

IR Requirement: In addition to the UL 1180 marking requirements for PFDs and component materials, the IR requires several additional marking items including information about use on commercial vessels, the approved inflator model, and warnings of foreseeable hazards. Additionally, conditional approval markings are permitted for manufacturers seeking such approval.

Comments; General: The PFDMA acknowledged that, in general, the Coast Guard's marking provisions in the IR

were necessary. The Association provided no specific comments.

Comments; Marking size: There were two comments on the size of the marking required on the inflation handle of a manual inflator. Both comments indicated that smaller marking would be adequate.

Comments; Use on Commercial Vessels: There were two comments on the requirements in § 160.076–39(d)(1)(i) which require markings on an approved PFD to state that the PFDs are “NOT APPROVED FOR USE ON COMMERCIAL VESSELS.” Both comments believed that there was a high likelihood that the marking would be misinterpreted as prohibiting use of these recreational inflatable PFDs on commercial vessels. One comment noted that the marking would create the misperception in the minds of many crew members of commercial vessels, that they are not allowed to wear inflatable PFDs. The comment stated that as a result, the marking will be a disservice to thousands of men and women on board commercial vessels. Further, the comment noted, it will greatly diminish the stated objective of getting people to take the preventive measure of actually wearing a PFD and advocated that all inflatable PFDs be marked “Meets USCG Carriage Requirements Only When Worn.”

The other comment also favored use of the devices on uninspected vessels with certain conditions. This comment stated that for uninspected passenger vessels for hire, there appears to be no basis for allowing inflatable PFDs in lieu of inherently buoyant PFDs unless they are worn by the passengers during the voyage.

Comments; Reliability Disclosure: One of the comments discussed above also requested that inflatable PFDs be marked with their reliability (after five years of typical service), for the consumer’s information at the point of sale. The comment indicated that comparative figures for inherently buoyant PFDs should be allowed. The comment also suggested that the inflatable PFD should be marked with an indication of its reliability and effectiveness when worn.

Final rule requirements: Based on the comments the Coast Guard is revising the marking requirements in the final rule to require the PFDs to be marked “NOT APPROVED TO MEET CARRIAGE REQUIREMENTS ON COMMERCIAL VESSELS.” This will make it clear that Type I, II, or III inflatable PFDs may be used as additional equipment on uninspected commercial vessels, in the same fashion as most other recreational PFDs. This

would allow crew members to use these inflatables in addition to Type V PFDs permitted to be used on these vessels in accordance with their labels. In a future rulemaking the Coast Guard intends to consider revising 46 CFR part 25 to address use of these PFDs to meet certain commercial vessel carriage requirements and to address the associated maintenance responsibilities and perhaps wear requirements as suggested in the comments.

The Coast Guard has decided not to require markings concerning reliability of the PFD on the PFD label as requested because, among other things, it cannot be adequately explained in a brief statement. This information may be addressed in the information pamphlet or the owner’s manual. The pamphlet is intended for point of sale information. In this final rule, the Coast Guard is not requiring this information to be provided either on the label or in the owner’s manual because the rating would depend on how the PFD is used and cared for or would require the development of a standardized typical service life which is not available at this time.

As to the other comments on marking requirements in § 160.076–39, the Coast Guard is deleting paragraphs (d)(2) and (f) regarding foreseeable misuse and manual inflation handle marking, as these provisions add limited additional safety and may delay designs being available to boaters.

Editorial Corrections

In addition to the above changes, a number of editorial changes are being made in the final rule to conform the text of the rule to the new organization of the Coast Guard. Additionally, the production test and inspection sampling plan tables in § 160.076–29 are corrected in two areas. The lot size headings are relocated to not confuse them with the number of samples per lot. Also, in the notes to the tables the symbols “/@" are replaced with “\$”.

Incorporation by Reference

The following material is incorporated by reference in § 160.076–11: Fully Inflatable Recreational Personal Flotation Devices (UL 1180), first edition, May 15, 1995; Components for Personal Flotation Devices (UL 1191), May 16, 1995; Marine Buoyant Devices (UL 1123), February 17, 1995; American Society for Testing and Materials, ASTM D 751–79, Standard Methods of Testing Coated Fabrics, 1979; ASTM D 1434–75, Gas Transmission Rate of Plastic Film and Sheeting, 1975; and Federal Standards, Federal Test Method Standard No.

191A, July 20, 1978. Copies of the material are available for inspection where indicated under “ADDRESSES.” Copies of the material are available from the sources listed in § 160.076–11.

The Director of the Federal Register has approved the material in § 160.076–11 for incorporation by reference under 5 U.S.C. 552 and 1 CFR part 51. The material is available as indicated in that section.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979).

A Regulatory Evaluation under paragraph 10e of the DOT regulatory policies and procedures has been prepared and is available in the docket for inspection or copying where indicated under ADDRESSES. The Evaluation is summarized as follows.

The requirements of this final rule open up a new marketing opportunity for inflatable PFD manufacturers by allowing them to obtain Coast Guard approval of recreational inflatable PFDs, if they so choose. The final rule will also allow boaters to purchase and use inflatable PFDs on their boats, if they wish to do so. Manufacturers may still make and sell unapproved inflatable PFDs, and boaters may continue to use such PFDs as additional equipment. Manufacturers who wish to obtain approval will have to pay for the approval testing at the recognized laboratory, pay the cost of the required quality control and oversight, and provide the information pamphlet and manuals required by this rule.

The estimated total initial approval cost per inflatable PFD design is expected to be approximately \$18,500, excluding the cost of inflation system acceptance which could be amortized over several designs of PFDs. This cost is almost entirely due to tests required by the industry consensus standard, which are not included in the cost imposed by this rule. Costs to approve other types of PFDs are approximately \$6,000, excluding component acceptance costs. The additional cost to approve inflatable PFDs could easily be absorbed in the cost of the units produced. The cost increase per device would be small considering the number of devices which could be produced under authorization of each approval

certificate. The Coast Guard anticipates that it will approve 36 inflatable PFD designs within the first 10 years after issuing this rule.

Production inspection costs imposed by these regulations will be approximately \$1,000 for the largest size lot of inflatable PFDs permitted. This cost is similar to that incurred for other types of approved PFDs.

The retail cost, per device, is expected to be between \$50 and \$200 for inflatable PFDs. Currently approved PFDs range in price from \$7-\$200.

If 500,000 units per year are produced, costs for the requirements imposed over those imposed by the industry consensus standard is estimated to be \$618,000 annually to the industry.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider the economic impact on small entities of a rule for which a general notice of proposed rulemaking is required. "Small entities" may include (1) small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000.

As the requirements of this final rule open up a new marketing opportunity for inflatable PFD manufacturers by allowing them to obtain Coast Guard approval of recreational inflatable PFDs, a general notice of proposed rulemaking was not required. The Coast Guard has nevertheless reviewed this rule for its potential impact on small entities. The final rule will also allow boaters to purchase and use inflatable PFDs on their boats. As discussed above, the economic impact of the new requirements is expected to be minimal.

Therefore, the Coast Guard certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule contains collection-of-information requirements. The Coast Guard has submitted the requirements to the Office of Management and Budget (OMB) for review under section 3504(h) of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), and OMB has approved them. The section numbers are §§ 160.076-13, 160.076-21, 160.076-29, 160.076-31, 160.076-33, 160.076-35, and 160.076-39 and the OMB approval number is OMB Control Number 2115-0619.

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. This rulemaking establishes procedures for Coast Guard approval of inflatable PFDs. The authority to establish these requirements are committed to the Coast Guard by Federal statutes. Furthermore, since PFDs are manufactured and used in the national marketplace, safety standards for PFDs should be national in scope to avoid burdensome variances. Therefore, the Coast Guard intends this rule to preempt State action on the same subject matter.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that under paragraph 2.B.2 of Commandant Instruction M16475.1B, this rule is categorically excluded from further environmental documentation. This rule has no environmental impact other than reducing the volume of unicellular plastic foam being used in inherently buoyant PFDs. A "Categorical Exclusion Determination" is available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subjects in 46 CFR Part 160

Marine safety, Reporting and recordkeeping requirements, Incorporation by reference.

Accordingly, the interim rule amending 46 CFR part 160, which was published at 60 FR 32836 on June 23, 1995, is adopted as final with the following changes:

PART 160—LIFESAVING EQUIPMENT

1. The authority citation for part 160 is revised to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703 and 4302; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; 49 CFR 1.46.

2. Section 160.076-5 is amended by revising the definition of "Commandant", and removing the definition of "LSI" to read as follows:

§ 160.076-5 Definitions.

* * * * *
Commandant means the Chief of the Lifesaving and Fire Safety Standards Branch, U.S. Coast Guard Marine Safety and Environmental Protection Directorate. Address: Commandant (G-MMS-4), U.S. Coast Guard Headquarters, 2100 Second St. SW., Washington, DC 20593-0001; phone:

202-267-1444; facsimile: 202-267-1069; electronic mail: "mvi-3/G-M18@cgsmtmp.uscg.mil".

* * * * *

3. In § 160.076-7, paragraph (a) is revised to read as follows:

§ 160.076-7 PFD approval Type.

(a) An inflatable PFD may be approved without conditions as a Type I, II, or III PFD for persons over 36 kg (80 lb) if it meets the requirements of this subpart.

* * * * *

4. In § 160.076-9, paragraph (b) is revised to read as follows:

§ 160.076-9 Conditional approval.

* * * * *

(b) PFDs not meeting the performance specifications for type I, II, or III PFDs in UL 1180 may be classified as Type V, conditionally approved PFDs, when the Commandant determines that the performance or design characteristics of the PFD make such classification appropriate.

5. In § 160.076-11, paragraph (b) is revised to read as follows:

§ 160.076-11 Incorporation by reference.

* * * * *

(b) The materials approved for incorporation by reference in this subpart, and the sections affected are as follows:

American Society for Testing and Materials (ASTM)

100 Barr Harbor Drive, West Conshohocken, PA 19428-2959.
 ASTM D 751-79 Standard Methods of Testing Coated Fabrics, 1979, 160.076-25;
 ASTM D 1434-75 Gas Transmission Rate of Plastic Film and Sheeting, 1975, 160.076-25.

Federal Standards

Naval Publishing and Printing Center, Customer Service, 700 Robbins Avenue, Philadelphia, PA 19120.

In Federal Test Method Standard No. 191A (dated July 20, 1978) the following methods:

- (1) Method 5100, Strength and Elongation, Breaking of Woven Cloth; Grab Method, 160.076-25;
- (2) Method 5132, Strength of Cloth, Tearing; Falling-Pendulum Method, 160.076-25;
- (3) Method 5134, Strength of Cloth, Tearing; Tongue Method, 160.076-25.

Underwriters Laboratories (UL)

Underwriters Laboratories, Inc., P.O. Box 13995, Research Triangle Park, NC 27709-3995 (Phone (919) 549-1400; Facsimile: (919) 549-1842)

UL 1123, "Marine Buoyant Devices", February 17, 1995, 160.076-35;
 UL 1180, "Fully Inflatable Recreational Personal Flotation Devices", May 15, 1995, 160.076-7; 160.076-21; 160.076-23; 160.076-25; 160.076-29; 160.076-31; 160.076-37; 160.076-39.
 UL 1191, "Components for Personal Flotation Devices", May 16, 1995, 160.076-21; 160.076-25; 160.076-39.

§ 160.076-13 [Amended]

6. In § 160.076-13 paragraph (c)(10) is removed.

§ 160.076-21 [Amended]

7. In § 160.076-21 paragraphs (d) and (e) are removed and paragraph (f) is redesignated as paragraph (d).

8. In § 160.076-23, paragraphs (a)(2) and (b) are removed, paragraph (a)(3) is redesignated as (a)(2), and paragraph (a)(1) is revised to read as follows:

§ 160.076-23 Construction and performance requirements.

(a) * * *
 (1) Meet the requirements in UL 1180 applicable to the PFD performance type for which approval is sought; and

9. In § 160.076-25, paragraph (c) is revised to read as follows:

§ 160.076-25 Approval testing.

(c) Each test subject participating in the tests in UL 1180, section 6 shall in addition, demonstrate that the test

subject can repack the PFD such that it can be used in the donning tests and manual activation tests required by—

- (1) Section 6.2.3 of UL 1180; and
- (2) Sections 6.4.1, and 6.4.2 of UL 1180, if the test engineer cannot verify that the manual and oral inflators are properly stowed.

§ 160.076-27 [Removed and reserved]

10. § 160.076-27 is removed and reserved.

§ 160.076-29 [Amended]

11. In § 160.076-29, Tables 160.076-29A and 160.076-29B are revised to read as follows:

TABLE 160.076-29A—MANUFACTURER'S SAMPLING PLAN

	Number of Samples Per Lot (Lot size)					
	1-100	101-200	201-300	301-500	501-750	751-1000
Tests:						
Inflation Chamber Materials			See Note (a)			
Seam Strength	1	1	2	2	3	4
Over-pressure (b)(c)	1	2	3	4	6	8
Air Retention			EVERY DEVICE IN THE LOT			
Buoyancy and Inflation Medium Retention	1	2	3	4	6	8
Tensile Strength			See Note (d)			
Detailed Product Examination	2	2	3	4	6	8
Retest Sample Size (b)			13	13	20	20
Final Lot Inspection			EVERY DEVICE IN THE LOT			

Notes to Table:

- (a) See § 160.076-29(e)(4)(i).
- (b) See § 160.076-29(e)(4)(ii).
- (c) See § 160.076-29(e)(4)(iii).
- (d) See § 160.076-29(e)(4)(iv).

TABLE 160.076-29B—INSPECTOR'S SAMPLING PLAN

	Number of Samples Per Lot (Lot size)					
	1-100	101-200	201-300	301-500	501-750	751-1000
Tests:						
Over-pressure (a)	1	1	2	2	3	4
Air Retention	1	1	2	2	3	4
Buoyancy & Inflation Medium Retention	1	1	2	2	3	4
Tensile Strength			See Note (b)			
Waterproof marking			See Note (c)			
Detailed Project Examination	1	1	1	2	2	3
Retest Sample Size (a)	10	10	13	13	20	20
Final Lot Inspection	10	15	20	25	27	30

Notes to Table:

- (a) See § 160.076-29(e)(5)(i).
- (b) See § 160.076-29(e)(5)(ii).
- (c) See § 160.076-29(e)(5)(iii).

* * * * *
 12. In § 160.076-31, paragraph (c)(8) is revised to read as follows:

§ 160.076-31 Production tests and examinations.

* * * * *
 (c) * * *

(8) *Waterproof Marking Test.* Each sample must be completely submerged in fresh water for at least 30 minutes. The sample must then be removed, immediately placed on a hard surface, and the markings vigorously rubbed with the fingers for 15 seconds. If the

printing becomes illegible, the sample must be rejected.

* * * * *

13. In § 160.076-37, paragraph (b) is revised to read as follows:

§ 160.076-37 Owner's manual.

* * * * *

(b) *Manual contents.* Each owner's manual must contain the information specified in section 11 of UL 1180, and, if the PFD is conditionally approved, an explanation of the meaning of, and reasons for, the approval conditions.

14. In § 160.076-39, paragraph (d)(2) is removed and reserved, paragraphs (c) and (d)(1)(i) are revised and paragraph (f) is removed to read as follows:

§ 160.076-39 Marking.

* * * * *

(c) A Type V, conditionally approved, inflatable PFD must be marked with the approval conditions specified on the approval certificate.

(d) * * *

(1) * * *

(i) "NOT APPROVED TO MEET
CARRIAGE REQUIREMENTS ON
COMMERCIAL VESSELS."

* * * * *

Dated: March 20, 1996.

J.C. Card,

*Rear Admiral, U.S. Coast Guard, Chief, Office
of Marine Safety, Security and Environmental
Protection.*

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