Lifesaving Index (LSI) must demonstrate, to the satisfaction of the Commandant, a minimum overall lifesaving potential, and a minimum effectiveness and reliability of the PFD design in accordance with this section.

(b) The manufacturer shall submit to the Commandant an analysis, accepted by a recognized laboratory, demonstrating the LSI of the design that includes—

(1) The LSI calculations using the formula provided in paragraph (d) of this section, and the value assigned to each term of the calculation;

(2) Statements justifying the value assigned to each term of the formula provided in paragraph (d) of this section; and

(3) Explanation of any assumptions used in performing the required calculation.

(c) *Minimum LSI*. Each PFD design approved under this section must be demonstrated to have an LSI that is not less than that of a Type III inherently buoyant PFD. The Commandant will determine the LSI of a Type III inherently buoyant PFD using the equation in paragraph (d) of this section and will publish the LSI value annually.

(d) *Equation and terms.* (1) The LSI must be determined by the following equation:

$$LSI = \sum_{i=1}^{8} P_i + P_k$$

Where:

$$\begin{split} P_i &= \text{Probability associated with the ith} \\ & \text{ou0tcome, where each outcome is a} \\ & \text{sequence of events where the PFD} \\ & \text{will aid in the user's survival. Each} \\ & \text{sequence of events must be} \\ & \text{mutually exclusive.} \end{split}$$

And P_i is defined by the following equations:

- $P_1 = (S1)(W_{S1})(I1_{S1})(E)(R)$
- $P_2 = (S1)(W_{S1})(I2_{S1})(SA1_{S1})(SDS1)(E)(R)$
- $P_3 = (S1)(W_{S1})(I3_{S1})(SA1_{S1})(E)(R)$
- $P_4 = (S1)(W_{S1})(I3_{S1})(SA2_{S1})(E_{S1,I3})(R)$
- $P_5 = (S2)(W_{S2})(I1_{S2})(E)(R)$
- $P_6 = (S2)(W_{S2})(I2_{S2})(SA1_{S2})(SD_{S2})(E)(R)$
- $P_7 = (S2)(W_{S2})(I3_{S2})(SA1_{S2})(E)(R)$
- $P_8 = (S2)(W_{S2})(I3_{S2})(SA2_{S2})(E_{S2,I3})(R)$
- P_k = The probability of other sequences of events that significantly enhance the lifesaving potential of the PFD under consideration.

The terms used in the P_i equations are defined as follows:

- S1 = Probability PFD user can swim.
- S2 = Probability PFD user cannot swim.
- W = Probability PFD is worn prior to an accident. (W_{S1} for swimmer; W_{S2} for non-swimmer)
- I1 = Probability PFD is used in a fully inflated condition prior to accident.

- I2 = Probability PFD is used in an uninflated condition prior to accident.
- I3 = Probability PFD is used in a partially inflated condition prior to accident.
- SA1 = Probability of PFD inflating, including the probabilities of correct inflator rearming; inflator status check; and inflator its activated automatically, manually, or orally, as applicable.
- SA2 = Probability of PFD not inflating.
- SD = Probability of completing the donning process after inflation, if required, when the PFD is worn. (SD = 1 when no additional donning required.)
- E = Probability PFD is effective in the water when inflated. ($E_{S1,I3}$, $E_{S2,I3}$ for partially inflated PFD and swimmer, non-swimmer, respectively)
- R = Probability PFD is reliable.

(2) Application of equation. To determine the LSI for a PFD using the equation in paragraph (d)(1) of this section, the calculations must be performed in accordance with the following:

(i) For inherently buoyant PFDs, use only equations P_1 and P_5 , with I1 equal to 1.

(ii) For non-belt-style inflatable PFDs, all P_i equations apply.

(iii) For belt-pack style PFDs, use only equations P_1 , P_2 , P_5 , and P_6 , with I1 meaning that the PFD is fully donned and inflated.

(e) *Minimum effectiveness and reliability.* In addition to meeting the requirements of paragraph (c) of this section, each PFD design approved under this section must be demonstrated to possess the following characteristics:

(1) Inflated in-water effectiveness (E), that is not less than that of—

(i) A performance type I PFD in accordance with UL 1180 for Type I approval or equivalent;

(ii) A performance type II PFD in accordance with UL 1180 for Type II approval or equivalent; or

(iii) A performance type III PFD in accordance with UL 1180 for Type III approval or equivalent; and

(2) Reliability (R) that is not less than that of—

(i) A performance type I PFD in accordance with UL 1180 for Type I approval or equivalent; or

(ii) A performance type II PFD in accordance with UL 1180 for Type II and III approval or equivalent.

(f) *Ranking.* The recognized laboratory shall compile a ranking, according to the calculated LSI, of PFDs for which

approval is sought under this section and submit to the Commandant the characteristics affecting wearability, effectiveness, and reliability of the PFDs ranked immediately above and immediately below the PFD for which approval is sought.

(g) *Review*. The Commandant may annually review each analysis and design approved under this section to determine whether the design continues to provide the minimum LSI and level of effectiveness and reliability required by paragraphs (c) and (e) of this section. The Commandant will compare the values assigned to the characteristics of the device to the values assigned to other approved devices in determining whether the values were appropriately assigned and whether the LSI should be recalculated. Where recalculated LSIs of approved designs fall below the minimum required LSI established by the Commandant in accordance with paragraph (c) of this section, the approval will be terminated or suspended in accordance with §159.005–15 of this chapter.

§160.076-29 Production oversight.

(a) Production tests and inspections must be conducted in accordance with this section and subpart 159.007 of this chapter unless the Commandant authorizes alternative tests and inspections. The Commandant may prescribe additional production tests and inspections necessary to maintain quality control and to monitor compliance with the requirements of this subpart.

(b) Production oversight must be performed by the same laboratory that performs the approval tests unless the Commandant determines that the employees of an alternative laboratory have received training and have access to the same information as the inspectors of the laboratory that conducted the approval testing.

(c) In addition to responsibilities set out in part 159 of this chapter and the accepted Laboratory Follow-up Procedures, each manufacturer of an inflatable PFD and each recognized laboratory inspector shall comply with the following, as applicable:

(1) *Manufacturer*. Each manufacturer must—

(i) Except as provided in paragraph (e)(2) of this section, perform all required tests and examinations on each PFD lot before any required inspector's tests and inspection of the lot;

(ii) Follow established procedures for maintaining quality control of the materials used, manufacturing operations, and the finished product;