

2011 for the Wage Rule (the Effective Date Rule).

In anticipation of the revised effective date of the Wage Rule, the Department issued supplemental prevailing wage determinations to those employers granted labor certification for an H-2B application where work would be performed on or after September 30, 2011. Those supplemental determinations were provided to employers to enable them to meet their amended wage obligations.

Both the Wage Rule and the Effective Date Rule were challenged in two separate lawsuits<sup>2</sup> seeking to bar their implementation. In consideration of the two pending challenges to the Wage Rule and its new effective date, and the possibility that the litigation could be transferred to another court,<sup>3</sup> the Department issued a final rule, 76 FR 59896, Sep. 28, 2011, postponing the effective date of the rule from September 30, 2011, until November 30, 2011, in accordance with the Administrative Procedure Act, 5 U.S.C. 705.

Following the postponement of the effective date to November 30, 2011, and in anticipation of the new effective date, the Office of Foreign Labor Certification (OFLC) issued participating employers two simultaneous (or dual) wage determinations for work to be potentially performed before and after the new effective date of the Wage Rule. The first determination was based on the former regulations that applied until November 30, and the second determination was based on the new prevailing wage methodology set forth in the Wage Rule, that was to be effective for work performed on and after November 30, 2011.

On November 18, 2011, the President signed into law the Consolidated and Further Continuing Appropriations Act, 2012, Pub. L. 112-55, Div. B, Title V, § 546 (Nov. 18, 2011) (the November Appropriations Act). The November Appropriations Act contains language preventing the expenditure of funds to implement, administer, or enforce the Wage Rule prior to January 1, 2012. Accordingly, the Department issued a

final rule in the **Federal Register**, 76 FR 73508 (Nov. 29, 2011), again postponing the effective date of the rule, this time from November 30, 2011, until January 1, 2012. As a result, the Department issued in the first half of December 2011 prevailing wage determinations, with the advisory that additional determinations would be forthcoming.

On December 23, 2011, the President signed into law the Consolidated Appropriations Act, 2012, which provides that “[n]one of the amounts made available under this Act may be used to implement the [Wage Rule].” Because of the distinct possibility that we would be unable to operate the H-2B program for the remainder of FY 2012 if the effective date of the Wage Rule were not postponed, the Department determined that this situation constituted an emergency warranting the publication of a final rule under the good cause exception of the Administrative Procedure Act to delay the effective date of the Wage Rule to October 1, 2012. Consequently, the Department is publishing a final rule to extend the effective date of the Wage Final Rule to October 1, 2012. See the final rule delaying the effective date of the H-2B Wage Rule, published elsewhere in this issue of the **Federal Register**.

In light of the postponement of the effective date of the Wage Rule until October 1, 2012, the Department is hereby providing public notice that the wage determinations previously issued in anticipation of the effective date of, and in accordance with, the Wage Rule will not be effective until October 1, 2012, and will then apply only to work performed on or after that date, if applicable. In addition, we are hereby providing notice that those prevailing wage determinations issued under the Labor Certification Process and Enforcement for Temporary Employment in Occupations Other Than Agriculture or Registered Nursing in the United States (H-2B Workers), and Other Technical Changes; Final Rule, 73 FR 78020, Dec. 19, 2008 (the 2008 H-2B Rule), which were listed as valid until either November 30, 2011 or December 31, 2011, are now valid for a period of 90 days beyond December 31, 2011, i.e. until March 30, 2012, and only apply to work performed on or before September 30, 2012.

Any employer who received an H-2B prevailing wage determination issued in anticipation of the September 30, 2011, November 30, 2011, or January 1, 2012 effective dates of the Wage Rule is not required to pay, and the Department’s Wage and Hour Division will not enforce, the wage provided in those

prevailing wage determinations issued in anticipation of the effective date of the Wage Rule for any work performed by H-2B workers or U.S. workers recruited in connection with the H-2B application process until October 1, 2012. Employers are expected to continue to pay at least the prevailing wage as provided in a prevailing wage determination issued under the 2008 H-2B Rule for any work performed before October 1, 2012. Further, employers who received a supplemental H-2B prevailing wage determination, or a prevailing wage determination issued in anticipation of the effective date of the Wage Rule, who are still employing H-2B workers employed under labor certifications issued in connection with those prevailing wage determinations, must pay at least the wage issued under the Wage Rule to any H-2B worker and any U.S. worker recruited in connection with the labor certification for work performed on or after October 1, 2012.

The Department is providing notice that, as a result of the December Appropriations Act, it is precluded from addressing issues raised in Center Director Review requests submitted by employers in connection with prevailing wage determinations issued in anticipation of the effective date of, and in accordance with, the Wage Rule.

Last, the Department in anticipation of questions from the filing community and as a measure of customer service has established the following email box for questions: [H2Bwagerule@dol.gov](mailto:H2Bwagerule@dol.gov).

Signed at Washington, DC, this 23rd day of December 2011.

**Jane Oates,**

*Assistant Secretary for Employment and Training.*

**Nancy Leppink,**

*Deputy Administrator, Wage and Hour Division.*

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## DEPARTMENT OF LABOR

### Office of Workers’ Compensation Programs

#### 20 CFR Part 701

**RIN 1240-AA02**

### Regulations Implementing the Longshore and Harbor Workers’ Compensation Act: Recreational Vessels

**AGENCY:** Office of Workers’ Compensation Programs, Labor.

**ACTION:** Final rule.

<sup>2</sup> See *Louisiana Forestry Association, Inc., et al. (LFA) v. Solis, et al.*, Civil Docket No. 11-1623 (WD LA, Alexandria Division); and *Bayou Lawn & Landscape Services, et al. (Bayou) v. Solis, et al.*, Civil Docket No. 11-445 (ND FL, Pensacola Division).

<sup>3</sup> On December 12, 2011, the LFA court granted a motion to transfer venue over the litigation to the Eastern District of Pennsylvania, the court in which the CATA case remains pending. However, the Bayou court denied the defendant’s motion to transfer the Bayou litigation to the Eastern District of Pennsylvania the same day.

**SUMMARY:** This final rule contains regulations implementing amendments to the Longshore and Harbor Workers' Compensation Act (LHWCA) by the American Recovery and Reinvestment Act of 2009 (ARRA), relating to the exclusion of certain recreational-vessel workers from the LHWCA's definition of "employee." These regulations clarify both the definition of "recreational vessel" and those circumstances under which workers are excluded from LHWCA coverage when working on those vessels. The final rule also withdraws a proposed rule that would have codified current case law and the Department's longstanding view that employees are covered under the LHWCA so long as some of their work constitutes "maritime employment" within the meaning of the statute.

**DATES:** This rule is effective January 30, 2012.

**FOR FURTHER INFORMATION CONTACT:** Gary A. Steinberg, Acting Director, Division of Longshore and Harbor Workers' Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, Room S-3524, 200 Constitution Avenue NW., Washington, DC 20210. Telephone: (202) 693-0031 (this is not a toll-free number). TTY/TDD callers may dial toll free 1-(800) 889-5627 for further information.

**SUPPLEMENTARY INFORMATION:**

**I. Background of This Rulemaking**

On August 17, 2010, the Department issued a Notice of Proposed Rulemaking (NPRM) under the LHWCA, 33 U.S.C. 901 *et seq.*, proposing rules implementing amendments to LHWCA section 2(3)(F) governing recreational vessels. 75 FR 50718-30 (Aug. 17, 2010). The Department reissued the proposal on October 15, 2010, to implement a technical amendment to the title of 20 CFR chapter VI and to allow an additional 30 days for public comment. 75 FR 63425-27 (Oct. 15, 2010). The comment period closed on November 17, 2010.

As explained in the NPRM, 75 FR 50718-19, LHWCA section 2(3) defines "employee" to mean "any person engaged in maritime employment, including any longshoreman or other person engaged in longshoring operations, and any harbor-worker including a ship repairman, shipbuilder, and ship-breaker \* \* \*." 33 U.S.C. 902(3). The section then lists eight categories of workers who are excluded from the definition of "employee" and therefore excluded from LHWCA coverage. 33 U.S.C. 902(3)(A)-(H). Section 2(3)(F) in particular excluded from coverage "individuals employed to

build, repair, or dismantle any recreational vessel under sixty-five feet in length," provided that such individuals were "subject to coverage under a State workers' compensation law." 33 U.S.C. 902(3)(F).

Section 803 of Title IX of the American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 115, 127 (2009), amended the section 2(3)(F) exclusion. That provision now excludes "individuals employed to build any recreational vessel under sixty-five feet in length, *or individuals employed to repair any recreational vessel, or to dismantle any part of a recreational vessel in connection with the repair of such vessel,*" and retains the state-workers'-compensation-coverage proviso. 33 U.S.C. 902(3)(F), as amended by Pub. L. 111-5 section 803, 123 Stat. 115, 187 (2009) (emphasis added).

The Department's proposed rules were intended to implement amended section 2(3)(F) and clarify its application in several respects. The proposed rules set standards for when the amendment applied, refined the definition of "recreational vessel," clarified what types of recreational-vessel work may result in an individual being excluded from the definition "employee," and revised the current regulatory definition of how recreational-vessel length is measured. The proposal also codified the Department's longstanding view that employees are covered under the LHWCA so long as some of their work constitutes "maritime employment" within the meaning of the statute. Finally, the Department included a summary of its initial regulatory flexibility analysis.

The Department received many written comments in response to the NPRM from a variety of sources connected to the recreational-vessel community. The commenters included Longshore claimant and employee groups, recreational vessel manufacturers, marina owners and operators, repair shop owners, insurance-industry members, members of Congress, and the Small Business Administration's Office of Advocacy. The Department has found these comments very helpful and, in several important respects, has revised the final rule in response.

**II. General Response to Significant Comments and Explanation of Major Changes**

**A. The LHWCA "Situs" Test**

As an initial matter, the Department notes that several comments responding

to the NPRM appear to be based on the fundamental misunderstanding that these rules eliminate the LHWCA's "situs" requirement. For example, one commenter uses a hypothetical landlocked vessel manufacturing facility to illustrate how in its view the proposed rules would be unworkable. Similarly, several landlocked vessel manufacturers commented that the proposed rules would add to their costs of doing business, potentially resulting in a loss of jobs.

Neither the proposed nor the final rules eliminate the LHWCA's situs requirement for recreational-vessel workers. As explained in the NPRM, 75 FR 50723-24 (Aug. 17, 2010), the LHWCA imposes both a "situs" and a "status" requirement. *Northeast Marine Terminal Co. v. Caputo*, 432 U.S. 249, 256-265 (1977) (describing history of "situs" and "status" tests). The situs test considers whether the injury occurred on "the navigable waters of the United States (including any adjoining pier, wharf, dry dock, terminal, building way, marine railway, or other adjoining area customarily used by an employer in loading, unloading, repairing, dismantling, or building a vessel." 33 U.S.C. 903(a); *Caputo*, 432 U.S. at 279. The status test considers whether the worker was "engaged in maritime employment" and therefore a covered "employee" when injured. 33 U.S.C. 902(3); *Caputo*, 432 U.S. at 265.

Because the ARRA amendment revised the definition of "employee," the proposed rules chiefly pertain to the status test. But the regulations in no way eliminate the situs requirement. Thus, workers at completely landlocked recreational vessel manufacturing facilities, repair shops, boat dealers and the like (*i.e.*, facilities that do not meet the situs test) are not covered by the LHWCA, regardless of the section 2(3)(F) exclusion for recreational-vessel workers.

**B. Exclusion for Marina Workers**

A significant number of marinas and a marina trade association submitted comments in response to the NPRM. Most of these commenters expressed concern that the proposed rules would require marinas to purchase LHWCA insurance in addition to state workers' compensation insurance. The Department notes, however, that the LHWCA excludes from the term "employee" those "individuals employed by a marina and who are not engaged in construction, replacement, or expansion of such marina (except for routine maintenance)," provided the worker is subject to a state compensation law. 33 U.S.C. 902(3)(C).

This exclusion has rarely been tested in litigation, and the LHWCA does not define the term “marina.” Whether any particular facility is a marina and whether its workers are excluded under the terms of section 2(3)(C) is a highly fact-bound question. *See generally Keating v. City of Titusville*, 31 BRBS 187 (1997). But at least some of these marinas’ workers would likely be excluded from LHWCA coverage under section 2(3)(C).

#### C. Definition of “Recreational Vessel”

The Department received many comments addressing the proposed “recreational vessel” definition and has made several important changes to the final rule. The proposed definition incorporated the Coast Guard’s standards for categorizing vessels as recreational and non-recreational. While the Department has retained those standards, the final rule contains two additional provisions designed to make the definition easier to apply. First, the final rule provides that manufacturers and builders may determine whether a vessel is recreational by the nature of the vessel’s design rather than the end use of the vessel. And second, the rule includes within the definition of recreational vessels non-military vessels that are recreational by design and owned or chartered by federal, state or municipal governments. Both of these changes are explained in detail below. The Department believes that these changes answer many of the concerns raised by the commenters.

#### D. Walking In and Out of Qualifying Maritime Employment

The Department has decided to withdraw proposed § 701.303. This rule codified both the Director’s longstanding position and controlling case law that the LHWCA covers a maritime employee if he or she regularly performs at least some duties that come within the ambit of the statute as part of his or her overall employment (*i.e.*, “qualifying” employment). 75 FR 50722 (Aug. 17, 2010). The rule also clarified that LHWCA coverage does not depend on whether the employee is performing qualifying maritime work or non-qualifying work at the time of injury. In discussing the proposal, the Department conducted an exhaustive review of the governing Supreme Court case law and noted the Court’s “bedrock principle that ‘maritime employment’ for LHWCA purposes is a unitary concept: Coverage is established whether or not the employee was performing a particular covered activity when injured so long as his overall employment includes ‘some’ qualifying maritime employment.” 75

FR 50723, *quoting Caputo*, 432 U.S. at 265, 273. The Department viewed the rule as important to advising the regulated public of the LHWCA’s coverage. 75 FR 50722.

The Department received many comments on the proposed regulation. A great number of these commenters saw proposed § 701.303 as an unwarranted expansion of the LHWCA’s coverage and expressed great concern over the additional costs employers would incur if required to carry LHWCA insurance. Most of these comments focused on the nature of the facility (*e.g.*, repair shop, manufacturing plant) where recreational vessel work is performed or the identity of the employer, rather than on the nature of an employee’s work at those facilities. The commenters stated that it would be difficult to ascertain when a particular facility or employer conducted sufficient LHWCA-covered operations to trigger LHWCA coverage for the entire facility. Stating that the “some” standard was too vague and would lead to litigation, the commenters urged the Department to adopt a bright-line rule that would be easy to administer and set a high threshold for coverage to comport with the purpose of the recreational-vessel exclusion. Most commenters proposed an 80%–20% split: So long as less than 20% of a facility’s or employer’s work was on commercial vessels and the remainder on recreational vessels, all work at the facility would be excluded from LHWCA coverage.

The comments misconstrue both the section 2(3)(F) exclusion and the import of proposed § 701.303. Some of the exclusions from the definition of “employee” in LHWCA section 2(3) focus on the nature of the employer. For instance, section 2(3)(B) excludes “individuals employed by a club, camp, recreational operation, restaurant, museum, or retail outlet.” 33 U.S.C. 902(3)(B) (emphasis added). *See Boomtown Belle Casino v. Bazor*, 313 F.3d 300, 303–04 (5th Cir. 2002) (holding that plain language of section 2(3)(B) exclusion turns “on the nature of the employing entity, and not on the nature of the duties an employee performs”). But section 2(3)(F) excludes individuals based solely on the type of work they do: It excludes “individuals employed to build \* \* \* repair \* \* \* or to dismantle \* \* \* in connection with the repair” of a recreational vessel. 33 U.S.C. 902(3)(F) (emphasis added). *Cf. Boomtown Belle Casino*, 313 F.3d at 303–04 (contrasting section 2(3)(B)’s recreational exclusion with section 2(3)(C)’s exclusion for certain marina employees based on their job duties).

Thus, for recreational vessel workers, the statute focuses exclusively on the kind of work the employee performs and not on the identity of the employer or the type of facility where the work is performed. Those comments urging the Department to adopt an 80%–20% rule based on the nature of the work performed by a particular employer or at a particular facility as a whole are inconsistent with the statute’s plain language.

Moreover, as noted, proposed § 701.303 was not intended to expand LHWCA coverage. Rather, the rule codified the Supreme Court’s interpretation of the LHWCA. The Department stands by its analysis of the governing case law. Thus, even in the absence of a regulation, a worker who regularly performs at least some duties that come within the ambit of the LHWCA as part of his or her overall employment is covered under the LHWCA, even if the injury occurs while the worker was not performing qualifying maritime duties. *Caputo*, 432 U.S. at 273. So too is a worker who is injured while performing qualifying maritime duties, regardless of his or her other job duties, so long as that employment is not excluded under section 2(3). *See, e.g., Chesapeake and Ohio Ry. Co. v. Schwalb*, 493 U.S. 40, 47 (1989) (“It is irrelevant that an employee’s contribution to the loading process is not continuous or that repair or maintenance is not always needed. Employees are surely covered when they are injured while performing a task integral to loading a ship.”).

Nevertheless, the Department has elected to withdraw the proposed rule. The Department appreciates the difficulties recreational-vessel employers and facilities face in determining whether their workers are performing LHWCA-covered activities in order to purchase the appropriate insurance. Further investigation into the industry’s needs is warranted. Moreover, even though this rule would have an impact on the entire longshoring industry, the Department received only a few comments from individuals or groups with interests extending beyond the recreational-vessel segment of that industry. This result is not surprising because the NPRM chiefly involved implementation of the section 2(3)(F) exclusion for recreational-vessel workers. Given the rule’s broad application, however, the Department is reluctant to promulgate the rule without input from the greater longshoring community.

### E. Date of Injury Rules

In response to a number of persuasive comments, the final rule makes several changes and one addition to proposed § 701.504. This rule sets out standards for determining the date of injury, which governs whether the section 2(3)(F) amendment applies. The final rule makes the date of harmful or causative workplace exposure—rather than the date of death or manifestation—the date of injury for determining whether the amendment applies in cases of occupational disease, hearing loss, and death. The rule also adds a new section addressing date of injury for cumulative trauma, which fixes the date of injury as any date on which a workplace trauma worsened the individual's condition.

### III. Section-by-Section Explanation

#### 701.301

The Department proposed only technical revisions to this section to accommodate other substantive additions. In particular, the Department moved this section's lengthy definition of "employee" into a new § 701.302. No comments were received, and the rule is promulgated as proposed.

#### 701.302

Proposed paragraph (c)(6) updated the paragraph in the definition of "employee" pertaining to the recreational vessel exclusion, which currently appears at § 701.301(a)(12)(i)(F), to incorporate the amended section 2(3)(F) language and cross-reference new §§ 701.501–701.505. No comments were received, and the rule is promulgated as proposed.

#### 701.303

As discussed above, the Department has decided to withdraw this proposed regulation.

#### 701.501

(a) The Department proposed an updated and refined definition of "recreational vessel." The Department explained that the current regulations, promulgated in 1984, adopted the definition of recreational vessel from a statute administered by the Coast Guard. 75 FR 50721 (Aug. 17, 2010). That statute, and the Department's current regulations, define "recreational vessel" as a vessel "manufactured or operated primarily for pleasure, or rented, leased or chartered by another for the latter's pleasure." 20 CFR 701.301(a)(12)(iii)(F) (2009). See 46 U.S.C. 2101(25); 51 FR 4273 (Feb. 3, 1986). Prior to the ARRA amendment, this definition was limited

by length: Section 2(3)(F) excluded only those individuals who worked on recreational vessels under sixty-five feet in length. Because the ARRA amendment removed the vessel-length limitation for workers who either repair recreational vessels or dismantle them for repair, the Department noted that both employers and employees could more frequently encounter difficulties determining which vessels were recreational. 75 FR 50721. The Department also wanted to ensure that individuals who perform repair work on vessels that have a significant commercial purpose were not improperly excluded under amended section 2(3)(F). 75 FR 50721.

To accomplish these goals, the Department proposed using Coast Guard vessel categories to define a "recreational vessel." Essentially, the Coast Guard deems the following to be recreational: Any unchartered passenger vessel used for pleasure and carrying no passengers-for-hire (*i.e.*, paying passengers); and any chartered passenger vessel used for pleasure with no crew provided and with fewer than twelve passengers, none of whom is for hire. All other passenger-carrying vessels fall into one of the following three non-recreational categories: Uninspected passenger vessel; small passenger vessel; and passenger vessel. 46 CFR 2.01–7; Navigation and Vessel Inspection Circular No. 7–94 (Sept. 30, 1994).

The Department noted that these categories were used in boating safety and environmental contexts, and thus would be generally known to the recreational boating community. *Id.* The categories also provided a clear, objective basis by which employers and employees could readily ascertain whether a vessel being repaired was a "recreational vessel" for LHWCA coverage purposes. The Department received many comments regarding this proposed rule and has made several significant changes to the final rule in response.

(b) Many comments state that the proposed "recreational vessel" definition is ambiguous. Some of the more specific criticisms state that the proposed definition would be difficult to apply in cases where a boat has multiple uses or is in-between uses, and where, over the course of its operations, the boat falls within different Coast Guard inspection categories. Some believe that the Coast Guard definitions are unfamiliar to boat builders and repairers.

The Department has revised the rule to clarify that the time for evaluating the vessel's use is when the vessel is being

built, repaired or dismantled. But the final rule continues to use the Coast Guard classifications to identify recreational vessels. In general, the comments did not offer any constructive alternatives to using the Coast Guard classifications except to leave the "recreational vessel" definition unchanged. As set forth in the NPRM, the Department believes that the definition needs greater clarity so that employers and employees may properly evaluate both their obligations and their rights under the LHWCA.

The Coast Guard categories set a bright-line rule for determining whether any particular vessel is recreational. Presumably, a vessel's owner or operator is familiar with its use and whether the vessel is inspected or uninspected under the Coast Guard standards. An employer's simple inquiry may be all that is necessary to resolve the question. Further, as noted in the NPRM, some outward indicia point to a vessel's non-recreational status. For instance, passenger vessels and small passenger vessels must display certificates of inspection, and uninspected passenger vessels are subject to certain safety requirements and must have a licensed operator. These indicia of non-recreational status will make it easier for employers and employees to recognize vessels that should not be considered "recreational vessels" for purposes of the section 2(3)(F) exclusion.

(c) One commenter suggests simplifying the rule by describing the vessel categories excluded from the definition of "recreational vessel" rather than cross-referencing the Coast Guard statutes. The Department has not adopted this suggestion. Outside of the manufacturing and building context, a vessel's use at the time the repair or dismantling led to the compensable injury determines its recreational status. Using the general Coast Guard categories will allow the definition of "recreational vessel" to remain current and consistent with the term as used in the recreational boating industry. The Department has made a technical revision to the language in proposed § 701.501(c) to simplify it. No change in meaning is intended by this revision.

(d) Many comments state the proposed definition would unduly burden employers by requiring them to investigate their customers' vessel usage in order to determine whether the boat is recreational. Another comment urges a rule that uses the intent of the owner in buying a vessel instead of its actual use. Others question the feasibility and fairness of holding employers to account

for usage of a boat when off their premises.

The Department does not believe a change in this requirement is necessary. Since 1984, the regulatory “recreational vessel” definition has required employers to determine whether a vessel is “manufactured or operated primarily for pleasure.” 20 CFR 701.301(a)(12)(iii)(F) (2009). To the Department’s knowledge, making this inquiry has not proved to be problematic. In fact, two commenters stated that for insurance purposes, they track how much work they do on commercial vessels and how much on recreational vessels. That would only be possible by evaluating whether the vessels they service are used for pleasure. Moreover, using a standard other than usage could lead to the improper exclusion of workers from LHWCA coverage. As one commenter pointed out, vessels manufactured to recreational-vessel standards may in fact be used entirely for commercial purposes. *See, e.g., Munguia v. Chevron U.S.A. Inc.*, 999 F.2d 808, 809–10 (5th Cir. 1993) (noting that employer maintained a fleet of small vessels, including Lafitte skiffs, Boston whalers, and Jo-boats, solely to allow its employees to service an oil-production field located on water). Retaining the “primarily for pleasure” touchstone and looking to the vessel’s use avoids the problem of improperly excluding a worker from LHWCA coverage.

(e) Several comments from recreational-vessel manufacturers object to defining a recreational vessel by the vessel’s end use because a manufacturer typically does not know it. Instead, manufacturers usually build to recreational-vessel standards established by the Coast Guard and market their products through retail sales channels. These commenters ask the Department to adopt a specific rule defining recreational vessels for manufacturers building new vessels or doing warranty work along the following lines: “recreational vessel \* \* \* means a vessel which by design and construction is intended by the manufacturer to be operated primarily for pleasure \* \* \* (rather than for commercial or military purposes).” In a related vein, one comment urges the Department to hold the manufacturer responsible for producing evidence regarding the relevant percentage of end-user purposes to establish that its purported intent is legitimate.

The Department has revised the final rule to accommodate the manufacturers’ concerns. A recreational-vessel manufacturer or builder is usually in a different position than entities that

service, repair and dismantle vessels while in use because the manufacturer may not know either the purchaser’s identity or the vessel’s actual use. Thus, the final rule provides that a vessel being manufactured or built (including warranty service) is a recreational vessel when intended, based on design and construction, to be for ultimate recreational use. The final rule also places the burden on the manufacturer or builder to prove that the vessel or vessels under construction are built in accordance with applicable recreational-vessel standards. Because recreational-vessel manufacturing facilities are typically landlocked, the Department does not expect this change in the final rule to have a significant impact on the number of employees covered by the LHWCA.

(f) Some commenters urge the Department to base the recreational-vessel definition on a vessel’s design or construction for repairers as well as for manufacturers, because repair work on vessels that are recreational by design is less hazardous than other maritime work covered by the LHWCA. The statutory language does not support this result. In setting forth section 2(3)(F), Congress described the vessels subject to its exclusion simply as “recreational,” a term which naturally denotes a form of usage. Manufacturers receive the benefit of a different definition solely because of the impracticality of a usage-based definition. Indeed, the statute from which the current regulatory definition is derived, 46 U.S.C. 2101(25), offers a bifurcated approach under which some vessels may be recreational if they are “manufactured” for pleasure, and others if they are “operated” for pleasure, thus suggesting that the definition might vary depending on the setting. In a repair setting, where a vessel’s operations are ascertainable, usage is the more appropriate approach.

(g) One comment states that paragraphs (a) and (b) of the proposed definition are in tension because a vessel used “primarily for pleasure” may still have incidental use as a passenger vessel or other commercial purpose that renders the vessel non-recreational under the Coast Guard categories set forth in paragraph (b). This commenter suggests that the regulation be rewritten so that incidental non-recreational use does not make the boat non-recreational for purposes of the section 2(3)(F) exclusion. While agreeing that a bright line may be necessary to determine recreational status, the commenter suggests looking to Coast Guard registration or state registration, whether

a vessel is routinely engaged in various forms of commercial activity, and whether it falls within the Coast Guard definition of a non-recreational vessel less than 20% of the time. Other commenters echo this incidental use concern.

The Department agrees that occasional non-recreational use does not alter the vessel’s core recreational purpose and should not take a vessel outside of the “recreational vessel” definition. To clarify this point and to resolve the tension the commenter notes between paragraphs (a) and (b), the final rule provides that a vessel remains recreational unless it falls within the designated Coast Guard vessel categories on a more than infrequent basis during the time the vessel is in operation.

(h) A few comments note that some repairers work on a small number of government-operated boats which resemble recreational vessels in design aspects. Examples given of government-owned vessels serviced include fish and wildlife enforcement boats, public-safety boats, and recreational vessels used by police in undercover operations. The commenters observe that they would have to discontinue this work (which they often perform at a discounted rate as a service to their communities) if repairing this small number of vessels would bring them under LHWCA coverage.

The Department agrees that servicing publicly owned or bareboat-chartered vessels that would otherwise be considered recreational generally should not be considered commercial work subject to LHWCA coverage. The final rule changes the definition of “recreational vessel” to accommodate this approach.

The final rule reflects a framework used in maritime and environmental statutes to define public vessels. *See* 33 U.S.C. 1321(4) (definition of public vessel for environmental protection statute); 46 U.S.C. 2101(24) (definition of public vessel for Coast Guard statute); *Blanco v. U.S.*, 775 F.2d 53, 57–60 (2d Cir. 1985) (discussing “public vessels” as defined in various maritime statutes). This definition requires that the governmental entity own or charter the vessel and use it for a non-commercial and non-military purpose. It encompasses the various kinds of government vessels that the commenters seek to have excluded from LHWCA coverage: Firefighting vessels, police vessels, some Coast Guard vessels, sheriff’s office vessels, and state natural-resource-department vessels. But to ensure the definition is not over-expansive, vessels owned or chartered

by a governmental entity that are not of conventional recreational vessel construction or design, or that perform a traditionally commercial service (such as ferrying passengers), or that are military in nature are not considered public vessels.

To identify the governmental entity that must own or operate a vessel in order for it to be eligible for “public vessel” status, the final rule uses the phrase “the United States, or by a State or political subdivision thereof.” The Department intends this phrase to be construed broadly, and to include entities such as a State’s municipalities that meet the well-established factor-based inquiry for determining whether a public entity is a subdivision. *See Wheaton v. Golden Gate Bridge, Highway & Transportation District*, 559 F.3d 979, 981–82 (9th Cir. 2009).

#### 701.502

(a) The Department proposed this rule to clarify what types of recreational-vessel work were covered both before and after the ARRA amendment. 75 FR 50721–22. The rule also made clear that the amendment did not have retroactive effect and that its application was based on the worker’s date of injury. The section further defined the terms “length,” “repair” and “dismantle.” Finally, the rule cross-referenced § 701.303 and provided that workers who engaged in both excluded recreational vessel work and qualifying maritime work were covered by the LHWCA.

(b) Proposed paragraph (a) established that with respect to injuries before the amendment’s effective date, February 17, 2009, a worker employed to repair, build, or dismantle any recreational vessel less than sixty-five feet in length is not an “employee” under the LHWCA, provided he or she is covered under a state workers’ compensation law for such work. 75 FR 50729. On or after the amendment’s effective date, a worker employed to build any recreational vessel under sixty-five feet in length, or repair or dismantle for repair any recreational vessel of any length is not an “employee” under the LHWCA, again provided he or she is covered under a state workers’ compensation law. *Id.* This paragraph also establishes that the amendment only operates prospectively from its effective date. In the accompanying preamble, the Department noted that building recreational vessels sixty-five feet in length or greater and dismantling recreational vessels of any length (except in connection with a repair) was LHWCA-covered employment post-amendment. 75 FR 50722. The

Department believed that this paragraph’s provisions were consistent with congressional intent and the rules of statutory construction.

No comments found fault with this section, and several offered approval of some aspects of it, including the non-retroactivity of the amendment, the state workers’ compensation proviso, and the treatment of dismantling of vessels. Accordingly, paragraph (a) is promulgated as proposed.

(c) Proposed paragraph (b)(1) defined vessel “length,” notably excluding bow sprits, bumpkins, rudders, outboard motor brackets, handles and other similar fittings, attachments and extensions from the vessel-length measurement. It also defined “repair” and “dismantle”. 75 FR 50729. In establishing these definitions, the Department relied on common-sense and industry-familiar definitions to make these concepts clearer and more objective, with the goal of avoiding future litigation. 75 FR 50722.

Several comments supported the changes to the definition of length. There were no comments critical of these definitions. Thus, the final rule is promulgated as proposed.

(d) The Department has made a technical change to the final definition of “dismantle” in paragraph (b)(3). As explained in the NPRM, 75 FR 50721–22, section 2(3)(F) originally excluded workers employed to “dismantle” recreational vessels less than sixty-five feet in length. This unqualified term would have excluded workers who dismantled a vessel at the end of the vessel’s life. The amended statute, however, excludes only those workers who dismantle recreational vessels “in connection with the repair of such vessel.” Given this express limitation, the Department concluded that workers governed by the amended statute would not be excluded from LHWCA coverage when employed to dismantle obsolete recreational vessels. Although § 701.502(a)(1) and (2) make this distinction clear, proposed paragraph (b)(3)’s definition of “dismantle” does not. Accordingly, the Department has added the language “if the date of injury is on or after February 17, 2009” to paragraph (b)(3)’s last phrase.

(e) Proposed paragraph (c) essentially reiterated the walking-in-and-out rule that was set forth more fully in proposed § 701.303, *i.e.*, it stated that a worker engaged part of the time in excepted recreational vessel work and part of the time in qualifying work is covered by the LHWCA. 75 FR 50729. Because the Department has withdrawn § 701.303, paragraph (c) has been deleted from the final rule.

#### 701.503

This proposed rule reiterated the basic thrust of the amendment—to amend the recreational vessel exclusion—and set forth the amendment’s effective date based on congressional intent and governing principles of statutory construction. No negative comments were received on the proposed rule, and it remains unchanged in the final regulation.

#### 701.504

(a) In the NPRM, the Department defined what date constitutes the “date of injury” for different kinds of claims. 75 FR 50720, 50729–30 (Aug. 17, 2010). The date of injury is the date at which a legally recognized harm occurs to a worker, giving rise to a compensation claim. It is the relevant point in time for determining whether the section 2(3)(F) amendment applies to a given claim: If the date of injury is on or after the amendment’s effective date, February 17, 2009, then the amendment’s provisions apply to a claim; otherwise, the pre-amendment statute governs. The NPRM set forth different rules for traumatic injury, occupational disease, hearing loss and death claims.

(b) *Traumatic injury.* For traumatic injury, proposed paragraph (a)(1) defined the date of injury as the date the worker is harmed. One comment generally supported this provision; no negative comments were received. Accordingly, this paragraph is promulgated as proposed.

(c) *Occupational disease.* For occupational disease, proposed paragraph (a)(2) adopted the manifestation date—*i.e.*, the date that the individual actually became aware of a disabling, work-related condition—to define the date of injury. The Department reasoned that this approach was consistent with judicial precedent and other statutory language making the manifestation date relevant for various purposes. 75 FR 50720.

While a few comments offered general support for the proposed rule with respect to occupational disease, other comments strongly questioned the proposed rule’s approach. Several comments pointed out that linking the date of injury to disease manifestation inappropriately borrows from statute-of-limitations contexts and is otherwise unfair and contrary to the position taken by the Department in the past. Instead, one comment urged using a rule that makes the date of exposure to harmful stimuli the relevant date for determining the ARRA amendment’s applicability.

The Department agrees with these comments and the final rule makes the

date of injurious exposure the date of injury for occupational diseases. Such an approach is both fairer and more consistent with the position taken by the Department in the past.

Using an exposure date is far less arbitrary than using a manifestation date for occupational diseases. The causative physiological harm occurs when an employee is exposed to the noxious substance, even though the deleterious effects might not be felt until years later; in addition, the date the disease's symptoms manifest may vary greatly among individuals. Indeed, under a rule that makes manifestation the date of injury, similarly-situated employees may be treated differently: An employee who was both exposed and developed symptoms before the amendment would be accorded pre-amendment coverage, while one who was exposed pre-amendment but happened to develop symptoms after the amendment's effective date would not.

And, as the comments allude to, using the exposure date as the date of injury affords workers, insurers, and employers the benefit of their legal expectations. Employees going to work on vessels that were covered pre-amendment did so with the expectation that they would benefit from LHWCA coverage for harmful on-the-job exposures, regardless of when those exposures manifested themselves in the form of a debilitating disease. Concomitantly, employers paid for insurance coverage in the event of harm to an employee caused by on-the-job exposure—whether harm from the exposure was realized immediately or in the long-run.

As the comments also note, the Department has previously recognized the fundamental fairness of a rule that makes the date of exposure determinative for gauging the effective date of an amendment. Analyzing whether the District of Columbia Workmen's Compensation Act of 1928, D.C. Code 36–501 *et seq.*, which extended LHWCA coverage to private workers in the District from 1928 to 1982, should continue to apply to claims based on employment events prior to that Act's repeal, the Department concluded that, “for the purpose of determining whether a workers’ compensation statute applies to such an injury (‘coverage’), the relevant legal provisions are those in effect at the time of the employment exposure to the conditions that cause the disease.” 51 FR 4270, 4272 (Feb. 3, 1986). The Department reasoned that “[w]orkers’ compensation laws operate upon the employment relationship. The occurrence of an event or events in the

course of that relationship is the foundation of any compensation-law liabilities that arise thereafter. The insurance requirement that is a socially and practically critical aspect of compensation legislation attaches to the conduct of covered employment.” Because insurers are responsible for diseases resulting from exposure during the terms of their policies, a manifestation rule would unfairly “relieve[] [insurance carriers] of liabilities they contracted to bear.” *Id.* at 4272–73.

Based on this analysis, the Department has reconsidered the reasoning it gave in the NPRM to support adopting a manifestation rule in occupational disease claims. Although cases the Department cited have applied the manifestation rule to determine the applicability of the 1972 amendments to the LHWCA, which expanded the categories of workers covered by the LHWCA, those cases relied on congressional intent specific to those amendments. In *SAIF Corp./Oregon Ship v. Johnson*, 908 F.2d 1434, 1439 (9th Cir. 1990), the court worried that an exposure rule would be contrary to Congress’ intent to maximally expand LHWCA coverage. In order to conform to congressional intent, the court held that the manifestation date determined the amendments’ coverage, because such a rule swept in the greatest number of workers. *Id.*; see also *Insurance Company of North America v. Dep’t of Labor*, 969 F.2d 1400, 1404 (2d Cir. 1992) (describing *SAIF* as holding that “the manifestation rule best comports with the LHWCA’s ‘paramount goal’ of compensating workers for lost earning capacity stemming from occupational diseases”).

The ARRA amendments present a different scenario. Under the ARRA amendment, a manifestation rule could result in fewer LHWCA-covered employees. But there is no evidence that Congress intended to exclude the largest number of workers possible from LHWCA coverage. Rather, by expanding the recreational-vessel exclusion via the ARRA amendment, Congress primarily sought to relieve businesses from paying for duplicative state workers’ compensation and LHWCA insurance coverage for recreational-vessel workers. See H. Rpt. 111–4, at 49 (Jan. 26, 2009). A manifestation rule does not serve that purpose. When the harmful exposure occurred while working on a covered vessel pre-amendment, the insurance in place at the time would cover that injury. Any expense to businesses for pre-amendment exposures has already been incurred, and an exposure rule does not impose any new prospective

LHWCA financial obligations. Thus, there is no basis to believe that Congress wished to deny workers the legal remedy in place when they were exposed to an injurious stimulus.

In the NPRM, the Department cited other provisions of the LHWCA making manifestation the date of injury in a statute of limitations context. 75 FR 50720. See 33 U.S.C. 912, 913. But as the comments point out, this analogy was inapt. The definition of date of injury in a statute of limitations context is designed to preserve the ability to file a claim for individuals who might not have notice of their right to compensation until manifestation. The date of injury in the context of a statutory amendment serves a far different goal: Satisfying congressional intent and ensuring that the legitimate expectations of the parties with respect to coverage are met.

One comment questioned how the last-employer rule would operate under the proposed manifestation-date rule. See generally *Travelers Ins. Co. v. Cardillo*, 225 F.2d 137 (2d Cir. 1955). The commenter noted concern about how the liable employer and insurance carrier would be identified in claims involving exposure at both covered and non-covered employment, and in cases with multiple employers. Because the final rule adopts date of exposure as the date of injury, current precedent provides clear guidance on the questions the commenter raised. The Department adheres to the well-established rule that the employee is eligible for LHWCA benefits if some of the exposure leading to the occupational disease occurred while covered under the Act. See *Newport News Shipbuilding and Dry Dock Co. v. Stille*, 243 F.3d 179, 183–84 (4th Cir. 2001). In cases where the harmful exposure spans both an employee’s covered pre-amendment work and his or her exempt post-amendment work, or spans covered commercial vessel work and exempt recreational vessel work, the employee will be eligible for benefits based on the covered work. The last employer for whom the employee performed covered work and that exposed him or her to a harmful stimulus is responsible for LHWCA benefits payable when injury results. See generally *Avondale Industries, Inc. v. Director, Office of Workers’ Compensation Programs*, 977 F.2d 186 (5th Cir. 1992) (setting forth last covered employer rule).

(d) *Hearing loss.* For hearing loss cases, proposed paragraph (a)(3) adopted the audiogram date—i.e., the date that the individual received a diagnosis quantifying hearing loss via



an audiogram—to define the date of injury. The Department offered similar reasons to those offered in support of a manifestation rule in occupational disease cases, and additionally pointed out the difficulty of pinpointing a date of exposure in hearing loss cases.

Although some comments offer general support for the proposed rule, other comments raise compelling questions similar to those raised concerning the date of injury for occupational disease cases. One commenter questions the fairness of an audiogram-date rule for hearing loss claims. For the same reasons the Department has now adopted an exposure rule in occupational disease cases, the Department also adopts an exposure rule for hearing loss cases as well. Such a rule is less arbitrary, recognizes that the genesis of the injury is when the exposure occurs, and is fair to all parties by giving them the benefit of an insurance contract that covers injuries based on when the exposure occurred.

The comments suggest, and the Department agrees, that the reasoning set forth in the NPRM for using an audiogram rule is unpersuasive. There, the Department posited that an audiogram date was a better measure than an exposure rule for determining the ARRA amendment's applicability because of the difficulty in determining a precise date of harmful exposure. However, although exposure in hearing-loss claims typically occurs over an extended period of time, determining a single precise date is not necessary to administration of an exposure rule, and current law provides ample tools for handling claims involving exposure over periods of time. If some or all exposures occurred prior to February 17, 2009, the amendment would simply not apply with respect to a disability resulting from those exposures. And a worker would be eligible for full benefits if any of the exposure occurring during LHWCA-covered employment resulted in a hearing loss. See *Port of Portland v. Director, Office of Workers Compensation Programs*, 932 F.2d 836, 839–40 (9th Cir. 1991). Moreover, pursuant to the last-covered-employer rule, the most recent employer, if any, for whom the claimant performed LHWCA-covered work at which he or she suffered harmful exposure would be responsible for benefits. See *id.*

(c) *Death claims.* For death claims, proposed paragraph (a)(4) adopted the date of death as the date of injury for determining the amendment's application. The Department based this proposal on court precedent applying

the law in place at the time of death in death benefit cases.

Although some comments expressed general support for the proposed rule, others urged the Department to use the date of the harmful workplace exposure or event that ultimately led to death as the date of injury, arguing that such a rule was more equitable. For essentially the same reasons stated above in the discussion of occupational disease cases, the Department agrees. Notably, as one comment suggests, in death cases, businesses have already paid and insurers have received the appropriate premiums to cover the death based on a causative workplace event that occurred while a worker was in covered employment.

In the proposal, the Department relied on *Insurance Company of North America v. Dep't of Labor*, 969 F.2d 1400, 1406 (2d Cir. 1992), and similar cases for the proposition that death should be the date of injury. However, although the court held that the time of one's death was the date of injury for determining the applicability of the 1972 amendments, it observed that the goal of the 1972 amendments was “an expansion \* \* \* of the class of persons entitled to benefits under the Act.” *Id.* Here, the core purpose of the ARRA amendment is sparing businesses from the expense of duplicative state workers' compensation and LHWCA insurance coverage. One simply cannot infer that Congress sought to deny LHWCA benefits where workers were injured while covered by the LHWCA, but died post-amendment, given that employers would have already paid for LHWCA insurance coverage for a death resulting from an injury while a worker was performing LHWCA-covered employment.

(d) *Cumulative trauma.* In the NPRM, the Department did not specifically address the date of injury in claims involving cumulative trauma. One comment urged that the final rule address this issue. To avoid any confusion on this subject, the Department agrees, and the final rule adds a new paragraph for cumulative trauma injuries. The rule states that the date of injury is any date on which a work-related trauma occurs that contributes to the cumulative condition. See *Metro. Stevedore Co. v. Crescent Wharf and Warehouse Co.*, 339 F.3d 1102, 1105–06 (9th Cir. 2003) (a trauma that worsens a cumulative condition is generally compensable). If, however, the injury is the result of a natural progression of an earlier trauma, then the date of the earlier trauma is the date of injury.

(e) Proposed paragraph (b) and (c) set out the consequences of applying the date-of-injury to the ARRA amendment's effective date. If that date occurs before February 17, 2009, ARRA's effective date, then the pre-amendment section 2(3)(F) exclusion applies; if that date occurs on or after February 17, 2009, the post-amendment exclusion applies. The Department received no specific comments on these rules and they are promulgated without substantive change. To make these two paragraphs consistent, however, the Department has made a technical change to paragraph (c). The Department has replaced the phrase “employee's eligibility,” which appeared in the proposed rule, with the phrase “individual's entitlement” in the final rule.

#### 701.505

The proposed rule provided that an employer may not stop paying compensation for an injury awarded prior to February 17, 2009, the ARRA amendment's effective date, even if that employee's work is excluded from coverage by the amendment. The Department proposed this paragraph in accordance with basic principles of finality and the presumption against retroactivity. The Department has received no specific comments on this section but has received some generally positive remarks on its interpretation of the non-retroactive character of the ARRA amendment. Thus, the proposed rule remains unchanged in the final regulation.

#### IV. Statutory Authority

Section 39(a) of the LHWCA (33 U.S.C. 939(a)) authorizes the Secretary of Labor to prescribe rules and regulations necessary for the administration and enforcement of the LHWCA and its extensions.

#### V. Information Collection Requirements (Subject to the Paperwork Reduction Act) Imposed Under the Proposed Rule

The final rule imposes no new collections of information.

#### VI. Executive Order 12866 (Regulatory Planning and Review)

This rule has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), entitled “The Principles of Regulation.” The Department has determined that the rule is not a “significant regulatory action” under Executive Order 12866, section 3(f). Accordingly, it does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. Moreover, because it is not a



significant rule within the meaning of the Executive Order, the Office of Management and Budget has not reviewed it.

#### **VII. Small Business Regulatory Enforcement Fairness Act of 1996**

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996, enacted as Title II of Public Law 104–121 §§ 201–253, 110 Stat. 847, 857 (1996), the Department will report promulgation of this final rule to both Houses of the Congress and to the Comptroller General prior to its effective date. The report will state that the Department has concluded that the rule is not a “major rule” as defined under 5 U.S.C. 804(2).

#### **VIII. Unfunded Mandates Reform Act of 1995**

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector, “other than to the extent that such regulations incorporate requirements specifically set forth in law.” For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased expenditures by State, local, and tribal governments, or increased expenditures by the private sector of more than \$100,000,000.

#### **IX. Regulatory Flexibility Act and Executive Order 13272 (Proper Consideration of Small Entities in Agency Rulemaking)**

The Regulatory Flexibility Act of 1980, as amended (5 U.S.C. 601 *et seq.*), requires an agency to prepare a regulatory flexibility analysis when it proposes regulations that will have “a significant economic impact on a substantial number of small entities,” or to certify that the proposed regulations will have no such impact, and to make the analysis or certification available for public comment.

The Department believes that the LHWCA itself accounts for most, if not all, of the costs imposed on the industry, and that this final rule does not directly add to those costs. The primary cost of the LHWCA lies in purchasing commercial insurance or qualifying as a self-insurer to insure covered workers. This requirement is imposed by statute. 33 U.S.C. 904, 932. By expanding the number of recreational vessel workers who will be excluded from coverage, the section 2(3)(F) amendment will generally reduce the recreational vessel industry’s costs for purchasing workers’

compensation insurance or, in the case of a self-insurer, providing compensation. This final rule simply seeks to make the potentially ambiguous language of the ARRA amendment clearer and more easily applied, and it does not deliberately seek to expand or contract businesses’ eligibility for the recreational vessel exclusion. Moreover, to the extent comments have raised concerns that the proposed rule might be improved by making its provisions more easily workable for businesses without compromising the rule’s underlying objective, the final rule, as discussed below, has accommodated such comments.

Nonetheless, because the recreational vessel building and repair industries include many small firms, and because the comments raise issues concerning how the Department might maximize benefits to small businesses via rulemaking, the Department has evaluated how the ARRA amendment, as implemented in this final rule, might affect small businesses. The Department prepared an initial regulatory flexibility analysis (IRFA) before proposing this rule and included a summary of that analysis in the NPRM. 75 FR 50725–28 (Aug. 17, 2010). The Department incorporates those documents by reference into this final regulatory flexibility analysis.

#### *Need for, and Objectives of, This Rule*

The primary goal of this rule is to provide a clear, workable definition of “recreational vessel.” Because the ARRA amendment to section 2(3)(F) removed the sixty-five-foot limitation on what constitutes a recreational vessel for all purposes but construction, the amended exclusion presents more opportunities for confusion among vessel-repair enterprises and their workers about whether the boats they work on are “recreational vessels” within the meaning of the LHWCA. The Department determined that the current regulatory definition of “recreational vessel” does not provide adequate guidance to the industry and its employees, and therefore adopts this rule to more clearly define the term.

This definition, in turn, serves several purposes. It gives entities that build or repair vessels guidance regarding the classification of vessels their employees are working on so that they may insure themselves under the appropriate workers’ compensation scheme (*i.e.*, the LHWCA or a state law). Similarly, the definition provides guidance to workers who might otherwise be unsure of their rights under the LHWCA. Finally, a clear definition reduces the possibility

of litigation over the applicability of the section 2(3)(F) exclusion.<sup>1</sup>

The Director, Office of Workers’ Compensation Programs, has the legal authority to issue this final rule. The LHWCA empowers the Secretary of Labor “to make such rules and regulations \* \* \* as may be necessary” to administer the statute. 33 U.S.C. 939(a). The Secretary has delegated her authority to the Director, Office of Workers’ Compensation Programs. Secretary’s Order 10–2009 (Nov. 6, 2009). In addition, the Department, like any other administrative agency, possesses the inherent authority to promulgate regulations in order to fill gaps in the legislation that it is responsible for administering. *Chevron v. Natural Resources Defense Council*, 467 U.S. 837, 843–44 (1984).

#### *Response to Significant Issues Raised by Public Comments and the Small Business Administration’s Office of Advocacy*

(a) Comments from the Small Business Administration’s Office of Advocacy (SBA) and the National Marine Manufacturers Association (NMMA) raise questions as to whether the IRFA utilized correct data to estimate the number of small businesses affected by this rule. The Department has fully addressed these comments in the following section regarding the estimate of the number of small entities to which the final rule will apply.

(b) Some commenters, including the SBA, assert that using the Coast Guard standards for classifying recreational vessels will expand the number of small businesses covered by the LHWCA, thereby increasing their costs. Because the term “recreational vessel” has been only generally defined in the past, it is impossible to ascertain the extent to which the revised definition will alter the exclusion’s scope and thereby affect small entities. Moreover, the final rule retools the definition so that it involves significantly less verification effort, and to make the definition’s scope clear so that businesses can avoid purchasing LHWCA insurance on a precautionary basis.

<sup>1</sup> As expressed in the NPRM, 75 FR 50725, the Department also anticipated that in the absence of a size limitation, more questions would be raised regarding coverage for workers who perform a combination of qualifying work (*e.g.*, building a seventy-foot recreational vessel) and non-qualifying work (*e.g.*, repairing a seventy-foot recreational vessel). The proposed rule sought to clarify how the LHWCA applies to workers engaged in qualifying maritime employment whose job duties also include tasks that do not come within the ambit of the LHWCA. As set forth above, however, the Department has withdrawn this proposed rule.

(c) Addressing proposed § 701.501, the NMMA comments that the definition of recreational vessel and its use of the Coast Guard standards is ambiguous and will impose additional costs on small businesses that may not be able to determine whether a vessel meets the definition and, as a result, may turn away important work rather than incur the costs associated with LHWCA insurance. The NMMA also posits that insurance firms will be less apt to write LHWCA policies on these businesses, again increasing costs. The NMMA further encourages the Department to adopt a different recreational-vessel definition for boat manufacturers that focuses on the manufacturer's intent in building the vessel rather than on its end use. The SBA similarly states that the Department should consider this regulatory alternative. In addition, a few small repair businesses note that under the proposed definition, they would have to turn away public-vessel work if performing such work made purchasing LHWCA insurance necessary.

The Department has set forth its full response to these and other comments pertaining to the recreational-vessel definition in the section-by-section analysis for § 701.501 above. The Department has made two important changes to the final recreational-vessel definition in response to these comments. These changes will help small businesses identify recreational vessels within the meaning of the section 2(3)(F) exclusion and make informed decisions regarding their need to obtain LHWCA insurance. First, the Department has promulgated an alternative definition for manufacturers and builders, which allows them to assess a vessel's recreational nature based on design and construction data reasonably available to them. Second, the final rule carves out an exception for public-purpose vessels so that businesses that repair these vessels in addition to other recreational vessels will not have to purchase LHWCA insurance.

(d) Addressing proposed § 701.303, many comments expressed the view that the Department should have considered alternative measures for determining coverage for workers who perform both qualifying maritime duties and non-qualifying work (walking-in-and-out of qualifying coverage). The commenters believed the rule would force businesses to secure expensive LHWCA insurance for their workers, instead of less expensive state workers' compensation insurance. In this regard, several commenters rejected the Department's suggestion that businesses could

minimize the cost implications of the proposed rule by segmenting their workplaces into recreational and non-recreational vessel operations. 75 FR 50728. These commenters (mostly small businesses) noted that their staffs were too small to segregate in this fashion. Most commenters proposed an 80%–20% split as an alternative: So long as less than 20% of a facility's or employer's work was on commercial vessels and the remainder on recreational vessels, all work at the facility would be excluded from LHWCA coverage. The SBA also suggested that the Department adopt this alternative.

The Department has set forth its full response to these comments in subsection D of the General Response to Significant Comments and Explanation of Major Changes section above. For the reasons explained there, the Department is withdrawing proposed § 701.303 and has not promulgated it in this final rule.

#### *Small Entities to Which the Final Rule Will Apply*

(a) In the IRFA, the Department looked to available data to estimate the number of small entities that might be affected by the proposed rule. 75 FR 50725–27. The IRFA estimated that, in 2007, there were 1,102 recreational vessel building establishments, employing 53,466 workers, generating \$11.1 billion in shipments, and with a payroll of \$1.9 billion; and 1,837 recreational boat repair establishments, employing 12,203 workers, generating \$1.6 billion in revenue, and with \$436 million in annual payroll. These entities were predominantly estimated to be small businesses.

In reaching its conclusions, the IRFA recognized difficulties in finding well-tailored NAICS categories to capture the affected small businesses. The Department relied chiefly on two NAICS industry categories: (1) NAICS industry 336612 (Boat Building); and (2) NAICS industry 811490 (Other Personal and Household Goods Repair and Maintenance). The NAICS system is described in detail in the IRFA. 75 FR 50726.

(b) Several commenters, notably the NMMA and the SBA, state that the universe of affected small entities is larger than estimated in the IRFA. These commenters note that the IRFA did not look to several relevant NAICS categories in developing its profile of the small entities affected: NAICS industry 713930 (Marinas), NAICS industry 441222 (Boat Dealers), and NAICS industry 441221 (Personal Watercraft Dealers). These commenters also suggest that NAICS industry

811490 (Other Personal and Household Goods Repair and Maintenance) may be too broad to be useful in assessing the number of small recreational vessel repairers. The commenters assert that businesses falling into these categories are mostly small under the Small Business Association's size standards.

While there is data suggesting that the additional categories pointed to by the commenters consist mostly of small businesses, it is analytically impossible to determine a precise number that actually perform work on recreational vessels. Some dealers may simply sell boats without performing repairs, while some marinas may simply offer docking space, but not repair services. This difficulty is compounded by the fact that, as noted in the IRFA, 75 FR 50726 n.1, some marinas' workers are excluded from LHWCA coverage by section 2(3)(C) of the statute. Nonetheless, although these categories pose analytical difficulties, the Department notes that they likely include affected small businesses.

Based on industry surveys, the NMMA and the SBA state that in 2008, there were approximately 33,000 retail/repair businesses employing 217,788 individuals; and 5,284 marine manufacturers employing 135,900 individuals. The vast majority of these are claimed to be small businesses. However, this data does not distinguish businesses that solely conduct retail sales versus those that repair recreational vessels. The data also does not consider whether some portion of the manufacturers are landlocked—the comments made clear that some portion of this industry is not located on navigable waterways and thus does not meet the LHWCA's situs requirement.

(c) The Department fully acknowledges the data put forward by comments, including the industry surveys and the additional NAICS categories. However, it is impossible to state, in this informational vacuum, the accuracy of this data relative to the Department's conclusions in the IRFA. In any event, assuming the larger number of affected small businesses suggested by the commenters is correct, this final rule maximizes, to the extent consistent with sound administration of the LHWCA, the benefit of the recreational vessel exemption for small businesses by adopting several alternative proposals raised by, or on behalf of, small businesses. Because the final rule addresses these substantive concerns and ensures that small business can take maximum advantage of the section 2(3)(F) recreational vessel exclusion, while nevertheless protecting those employees whose duties are

covered by the LHWCA, the Department believes that reaching a precise conclusion concerning the number of affected small businesses is not critical.

*Projected Reporting, Recordkeeping and Other Compliance Requirements for Small Entities*

The final rule does not directly impose any reporting or recordkeeping requirements on any entities, regardless of size. Nor do the rules impose other significant costs beyond those imposed by the LHWCA itself. The statute requires employers whose employees are covered by the LHWCA to secure the payment of compensation either by purchasing commercial insurance or qualifying as a Department-approved self-insurer. 33 U.S.C. 904, 932. The ARRA amendment to section 2(3)(F) significantly expanded the exclusion for recreational vessel workers, thereby reducing the number of workers considered employees for LHWCA coverage purposes. Thus, both small and large businesses that repair recreational vessels sixty-five feet or greater in length who had previously been required to purchase LHWCA insurance may be relieved of that obligation. Instead, these employers generally will only be required to purchase lower-cost state insurance for their workers who repair recreational vessels.

In preparing the IRFA, the Department surveyed the cost of purchasing LHWCA insurance and compared it to the cost of various states' workers' compensation insurance. On average, LHWCA insurance is 50–100 percent more expensive than state workers' compensation insurance. This range is based on data collected by the National Council on Compensation Insurance (NCCI), which discloses the premium or load that states impose on businesses that carry LHWCA insurance. Because the premium for both LHWCA and state workers' compensation coverage is calculated as a percentage of the employer's payroll, regardless of payroll size, the cost for both small establishments and larger employers is the same in relative terms.

One insurance broker who commented agreed with the Department's cost estimate. But the SBA's comment suggests that the increase in insurance costs will be higher than the Department's estimate, and individual comments suggest a wide range of potential cost increases. In positing that costs in the Maryland-Delaware-Virginia region will increase 200 to 300 percent, the SBA states that an increase from \$20,000 to \$53,000 would be a 265 percent change. By the

Department's calculations, such a change would only be a 165 percent increase. Further, the state of Virginia imposes a 1.77 factor on each sector of the marine industry subject to the Longshore Act, while the state of Maryland imposes a 1.55 factor. Thus, the cost of LHWCA insurance in these regions is 55 to 77 percent greater than the cost of state workers' compensation insurance.

The comments, including SBA's, present anecdotal and geographically specific assertions on cost differences for LHWCA coverage. The Department acknowledges the possibility of such differences, including higher cost premiums, in different locations. However, the higher cost of LHWCA coverage, whatever it may be, is made less of a factor by the final rule's revisions to the proposal; as noted above, these revisions clarify the need for some businesses to carry LHWCA coverage and maximize the effect of the recreational vessel exemption to the extent feasible and permissible under the statute.

Several comments raise the prospect of a compliance-related burden, in that businesses will have to determine and document the nature of vessels they work on. But it is the statute itself that implicitly imposes this burden if employers wish to claim their workers are excluded from LHWCA coverage under section 2(3)(F). Moreover, the burden is a modest and unavoidable one. The stronger point made by some comments is that the proposed rule would make it more cumbersome to investigate and determine a vessel's status as recreational. The revisions made to the final recreational vessel definition should make this determination less burdensome to businesses.

*Steps Taken To Minimize the Significant Economic Impact on Small Entities*

The exemption for recreational-vessel workers is a creature of statute. All businesses, small or otherwise, must make determinations regarding their need to procure LHWCA or state workers' compensation insurance. The Department has fully explained the factual, policy and legal reasons for adopting the final rule—as well as its reasons for rejecting other significant alternatives—in the sections above titled General Response to Significant Comments and Explanation of Major Changes and Section-by-Section Analysis. As already explained, the Department adopted several alternatives suggested by the commenters that will

serve to minimize the economic impact on small entities.

**List of Subjects in 20 CFR Part 701**

Longshore and harbor workers, Organization and functions (government agencies), Workers' compensation.

For the reasons set forth in the preamble, the Department of Labor amends 20 CFR part 701 as follows:

**PART 701—GENERAL; ADMINISTERING AGENCY; DEFINITIONS AND USE OF TERMS**

■ 1. The authority citation for Part 701 is revised to read as follows:

**Authority:** 5 U.S.C. 301 and 8171 *et seq.*; 33 U.S.C. 939; 36 DC Code 501 *et seq.*; 42 U.S.C. 1651 *et seq.*; 43 U.S.C. 1331; Reorganization Plan No. 6 of 1950, 15 FR 3174, 3 CFR, 1949–1953 Comp., p. 1004, 64 Stat. 1263; Secretary's Order 10–2009; Pub. L. 111–5 § 803, 123 Stat. 115, 187 (2009).

■ 2. In § 701.301, revise the preceding undesignated center heading and the section heading, remove paragraph (a)(12), and redesignate paragraphs (a)(13) through (16) as paragraphs (a)(12) through (15).

The revisions read as follows:

**Definitions and Use of Terms**

**§ 701.301 What do certain terms in this subchapter mean?**

\* \* \* \* \*

■ 3. Add § 701.302 to read as follows:

**§ 701.302 Who is an employee?**

(a) *Employee* means any person engaged in maritime employment, including:

(1) Any longshore worker or other person engaged in longshoring operations;

(2) Any harbor worker, including a ship repairer, shipbuilder and shipbreaker; and

(3) Any other individual to whom an injury may be the basis for a compensation claim under the LHWCA as amended, or any of its extensions;

(b) The term does not include:

(1) A master or member of a crew of any vessel; or

(2) Any person engaged by a master to load or unload or repair any small vessel under eighteen tons net.

(c) Nor does this term include the following individuals (whether or not the injury occurs over the navigable waters of the United States) where it is first determined that they are covered by a state workers' compensation act:

(1) Individuals employed exclusively to perform office clerical, secretarial, security, or data processing work (but not longshore cargo checkers and cargo clerks);

(2) Individuals employed by a club (meaning a social or fraternal organization whether profit or nonprofit), camp, recreational operation (meaning any recreational activity, including but not limited to scuba diving, commercial rafting, canoeing or boating activities operated for pleasure of owners, members of a club or organization, or renting, leasing or chartering equipment to another for the latter's pleasure), restaurant, museum or retail outlet;

(3) Individuals employed by a marina, provided they are not engaged in its construction, replacement or expansion, except for routine maintenance such as cleaning, painting, trash removal, housekeeping and small repairs;

(4) Employees of suppliers, vendors and transporters temporarily doing business on the premises of a covered employer, provided they are not performing work normally performed by employees of the covered employer;

(5) Aquaculture workers, meaning those employed by commercial enterprises involved in the controlled cultivation and harvest of aquatic plants and animals, including the cleaning, processing or canning of fish and fish products, the cultivation and harvesting of shellfish, and the controlled growing and harvesting of other aquatic species; or

(6) Individuals employed to build any recreational vessel under sixty-five feet in length, or individuals employed to repair any recreational vessel, or to dismantle any part of a recreational vessel in connection with the repair of such vessel. For purposes of this paragraph, the special rules set forth at §§ 701.501 through 701.505 apply.

■ 4. Add a new undesignated center heading following § 701.401 and add § 701.501 to read as follows:

**Special Rules for the Recreational Vessel Exclusion From the Definition of "Employee"**

**§ 701.501 What is a recreational vessel?**

(a) *Recreational vessel* means a vessel—

(1) Being manufactured or operated primarily for pleasure; or

(2) Leased, rented, or chartered to another for the latter's pleasure.

(b) In applying the definition in paragraph (a) of this section, the following rules apply:

(1) A vessel being *manufactured or built*, or being repaired under warranty by its manufacturer or builder, is a *recreational vessel* if the vessel appears intended, based on its design and construction, to be for ultimate recreational uses. The manufacturer or

builder bears the burden of establishing that a vessel is recreational under this standard.

(2) A vessel being *repaired, dismantled for repair, or dismantled at the end of its life* is not a *recreational vessel* if the vessel had been operating, around the time of its repair or dismantling, in one or more of the following categories on more than an infrequent basis—

(A) "Passenger vessel" as defined by 46 U.S.C. 2101(22);

(B) "Small passenger vessel" as defined by 46 U.S.C. 2101(35);

(C) "Uninspected passenger vessel" as defined by 46 U.S.C. 2101(42);

(D) Vessel routinely engaged in "commercial service" as defined by 46 U.S.C. 2101(5); or

(E) Vessel that routinely carries "passengers for hire" as defined by 46 U.S.C. 2101(21a).

(3) Notwithstanding paragraph (b)(2) of this section, a vessel will be deemed recreational if it is a *public vessel*, i.e., a vessel owned or bareboat-chartered and operated by the United States, or by a State or political subdivision thereof, at the time of repair, dismantling for repair, or dismantling, provided that such vessel shares elements of design and construction with traditional recreational vessels and is not normally engaged in a military, commercial or traditionally commercial undertaking.

(c) All subsequent amendments to the statutes referenced in paragraph (b)(2) of this section and the regulations implementing those provisions in Title 46 of the Code of Federal Regulations will apply when determining whether a vessel is recreational.

■ 5. Add § 701.502 to read as follows:

**§ 701.502 What types of work may exclude a recreational-vessel worker from the definition of "employee"?**

(a) An individual who works on recreational vessels may be excluded from the definition of "employee" when:

(1) The individual's date of injury is before February 17, 2009, the injury is covered under a State workers' compensation law, and the individual is employed to:

(i) Build any recreational vessel under sixty-five feet in length; or

(ii) Repair any recreational vessel under sixty-five feet in length; or

(iii) Dismantle any recreational vessel under sixty-five feet in length.

(2) The individual's date of injury is on or after February 17, 2009, the injury is covered under a State workers' compensation law, and the individual is employed to:

(i) Build any recreational vessel under sixty-five feet in length; or

(ii) Repair any recreational vessel; or

(iii) Dismantle any recreational vessel to repair it.

(b) In applying paragraph (a) of this section, the following principles apply:

(1) "Length" means a straight line measurement of the overall length from the foremost part of the vessel to the aftmost part of the vessel, measured parallel to the center line. The measurement must be from end to end over the deck, excluding sheer. Bow sprits, bumpkins, rudders, outboard motor brackets, handles, and other similar fittings, attachments, and extensions are not included in the measurement.

(2) "Repair" means any repair of a vessel including installations, painting and maintenance work. Repair does not include alterations or conversions that render the vessel a non-recreational vessel under § 701.501. For example, a worker who installs equipment on a private yacht to convert it to a passenger-carrying whale-watching vessel is not employed to "repair" a recreational vessel. Repair also does not include alterations or conversions that render a non-recreational vessel recreational under § 701.501.

(3) "Dismantle" means dismantling any part of a vessel to complete a repair but does not include dismantling any part of a vessel to complete alterations or conversions that render the vessel a non-recreational vessel under § 701.501, or render the vessel recreational under § 701.501, or, if the date of injury is on or after February 17, 2009, to scrap or dispose of the vessel at the end of the vessel's life.

■ 6. Add § 701.503 to read as follows:

**§ 701.503 Did the American Recovery and Reinvestment Act of 2009 amend the recreational vessel exclusion?**

Yes. The amended exclusion was effective February 17, 2009, the effective date of the American Recovery and Reinvestment Act of 2009.

■ 7. Add § 701.504 to read as follows:

**§ 701.504 When does the recreational vessel exclusion in the American Recovery and Reinvestment Act of 2009 apply?**

(a) *Date of injury*. Whether the amended version applies depends on the date of the injury for which compensation is claimed. The following rules apply to determining the date of injury:

(1) *Traumatic injury*. If the individual claims compensation for a traumatic injury, the date of injury is the date the employee suffered harm. For example, if the individual injures an arm or leg in the course of his or her employment, the

date of injury is the date on which the individual was hurt.

(2) *Occupational disease or infection.* Occupational illnesses and infections generally involve delayed onset of symptoms following exposure to a harmful workplace substance or condition. If the individual claims compensation for an occupational illness or infection, the date of injury is the date the individual was exposed to the substance or condition.

(3) *Hearing loss.* If the individual claims compensation for hearing loss, the date of injury is the date the individual was exposed to harmful workplace noise or other stimulus that is capable of causing hearing loss.

(4) *Death-benefit claims.* If the individual claims compensation for an employee's death, the date of injury is the date of the workplace event or incident that caused, hastened, or contributed to the death.

(5) *Cumulative trauma.* If the individual claims compensation for cumulative trauma, in which multiple traumas contribute to an overall medical condition, such as a neck condition resulting from repetitive motion, the date of injury is any date on which a workplace trauma worsened the individual's condition. A workplace event will not be deemed a contributing trauma if a corresponding worsening of the condition is due solely to its natural progression, rather than the workplace event.

(b) If the date of injury is before February 17, 2009, the individual's entitlement is governed by section 2(3)(F) as it existed prior to the 2009 amendment.

(c) If the date of injury is on or after February 17, 2009, the individual's entitlement is governed by the 2009 amendment to section 2(3)(F).

■ 8. Add § 701.505 to read as follows:

**§ 701.505 May an employer stop paying benefits awarded before February 17, 2009 if the employee would now fall within the exclusion?**

No. If an individual was awarded compensation for an injury occurring before February 17, 2009, the employer must still pay all benefits awarded, including disability compensation and medical benefits, even if the employee would be excluded from coverage under the amended exclusion.

Signed at Washington, DC, this 19th day of December 2011.

**Gary A. Steinberg,**

*Acting Director, Office of Workers' Compensation Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 866

[Docket No. FDA-2011-D-0028]

#### Medical Devices; Ovarian Adnexal Mass Assessment Score Test System; Labeling; Black Box Restrictions

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulation classifying ovarian adnexal mass assessment score test systems to restrict these devices so that a prescribed warning statement that addresses a risk identified in the special controls guidance document must be in a black box and must appear in all labeling, advertising, and promotional material. The black box warning mitigates the risk to health associated with off-label use as a screening test, stand-alone diagnostic test, or as a test to determine whether or not to proceed with surgery.

**DATES:** *Effective Date:* January 30, 2012.

**FOR FURTHER INFORMATION CONTACT:** Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5543, Silver Spring, MD 20993-0002, (301) 796-6217.

#### SUPPLEMENTARY INFORMATION:

##### I. What is the background of this final rule?

###### A. Ovarian Adnexal Mass Assessment Score Test System

An ovarian adnexal mass assessment score test system is a device that measures one or more proteins in serum or plasma. It yields a single result for the likelihood that an adnexal pelvic mass in a woman for whom surgery is planned, is malignant. The test is for adjunctive use, in the context of a negative primary clinical and radiological evaluation, to augment the identification of patients whose gynecologic surgery requires oncology expertise and resources.

###### B. Identified Risk to Health

The ovarian adnexal mass assessment score test system is not indicated for use as a screening or diagnostic test for ovarian cancer. Off-label use of the test (e.g., in patients who are not already identified as needing surgery for pelvic mass or without reference to an

independent clinical/radiological evaluation of the patient), may lead to a high frequency of unnecessary further testing and surgery due to false positive results, or to delay in tumor diagnosis due to false negative results.

##### II. Why is FDA requiring black box warnings on ovarian adnexal mass assessment score test system labeling, advertising, and promotional material?

FDA has determined that in order to provide reasonable assurance of safety and effectiveness, it is necessary to restrict the ovarian adnexal mass assessment score test system to sale, distribution, and use with labeling, advertising, and promotional material that bears a warning statement in a black box that alerts users to the risk associated with off-label use as a screening test, stand-alone diagnostic test, or as a test to determine whether or not to proceed with surgery. In the **Federal Register** of March 23, 2011 (76 FR 16292 at 12694), FDA published a final rule that classified this device into class II and established as a special control the guidance entitled "Class II Special Controls Guidance Document: Ovarian Adnexal Mass Assessment Score Test System" that recommends a black box warning to address the risk of off-label use. In the **Federal Register** of March 23, 2011 (76 FR 16425), FDA published a notice of availability of this special controls guidance document. However, FDA believes it is necessary to require this warning in labeling and advertising by restricting the device under section 520(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(e)). In the **Federal Register** of March 23, 2011 (76 FR 16350 at 16352), FDA published a proposed rule to require the black box warning.

For devices that have significant risks that would make the devices unsafe if used inappropriately, FDA may require that the risks be explained in warning statements placed in a black box that is displayed prominently in the labeling, advertising, and promotional material to ensure awareness by the end user. Awareness of these important risks by the end user enables these devices to be used safely. In this case, a prominent black box warning, which alerts the user to the limitations of this device, is necessary in all labeling, advertising, and promotional materials to allow ovarian adnexal mass assessment score test system devices to be used safely. The prominent black box warning must read as follows: