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Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters; Final Rule

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 151

46 CFR Part 162

[Docket No. USCG–2001–10486]

RIN 1625–AA32

Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending its regulations on ballast water management by establishing a standard for the allowable concentration of living organisms in ships' ballast water discharged in waters of the United States. The Coast Guard is also amending its regulations for engineering equipment by establishing an approval process for ballast water management systems. These new regulations will aid in controlling the introduction and spread of nonindigenous species from ships' ballast water in waters of the United States.

DATES: This final rule is effective June 21, 2012 except for 33 CFR 151.1513 and 151.2036 which contains information collection requirements that OMB has not approved. The Coast Guard will publish a document in the **Federal Register** announcing the effective date. Comments sent to the Office of Management and Budget (OMB) on collection of information must reach OMB on or before May 22, 2012. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register on June 21, 2012.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2001–10486 and are available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to *http://www.regulations.gov,* inserting USCG–2001–10486 in the ''Keyword'' box, and then clicking ''Search.''

Collection of Information Comments. If you have comments on the collection of information discussed in section VII.D of this final rule, you must send comments to the Office of Information and Regulatory Affairs (OIRA), OMB. To ensure that OIRA receives your comments on time, you should submit your comments through the preferred methods of email to *oira_submission@omb.eop.gov* (include the docket number and ''Attention: Desk Officer for Coast Guard, DHS'' in the subject line of the email) or fax at 202–395–6566. An alternate, though slower, method is by U.S. mail to the OIRA, OMB, 725 17th Street NW., Washington, DC 20503, Attn: Desk Officer, U.S. Coast Guard.

Viewing incorporation by reference material. You may inspect the material incorporated by reference at U.S. Coast Guard Headquarters, 2100 2nd St. SW., Washington, DC 20593 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–372–1433. Copies of the material are available as indicated in the ''Incorporation by Reference'' section of this preamble.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. John Morris, Project Manager, U.S. Coast Guard; telephone 202–372–1433, email *John.C.Morris@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Abbreviations

APA Administrative Procedure Act
APHIS U.S. Department of Agriculture's Animal and Plant Health Inspection Service
AMS alternate management system
BWDS ballast water discharge standard(s)
BWE ballast water exchange
BWM ballast water management
BWMS ballast water management system(s)
cfu colony forming unit(s)
COTP Captain of the Port
CSLC California State Lands Commission
DPEIS Draft Programmatic Environmental Impact Statement
DSA Danish Shipowners' Association
EEZ U.S. Exclusive Economic Zone
EIS Environmental Impact Statement
EPA U.S. Environmental Protection Agency
ESA Endangered Species Act
ETV Environmental Technology Verification
FIFRA Federal Insecticide, Fungicide, and Rodenticide Act
FPEIS Final Programmatic Environmental Impact Statement
FR final rule
GRT gross register tons
GSI Great Ships Initiative
GT gross tons
IEC International Electrotechnical Commission
IL Independent Laboratory
IMO International Maritime Organization
IRFA Initial Regulatory Flexibility Analysis
ISO International Organization for Standardization
ITC International Convention on Tonnage Measurement of Ships, 1969
MSC Marine Safety Center
NANPCA Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990
NARA National Archives and Records Administration
NBIC National Ballast Information Clearinghouse
NEPA National Environmental Policy Act
NFPA National Fire Protection Association
NIS nonindigenous species
NISA National Invasive Species Act of 1996
NPDES National Pollutant Discharge Elimination System
NPRM notice of proposed rulemaking
NRC National Research Council
OPA Oil Pollution Act of 1990, as amended
OMB Office of Management and Budget
PEIS Programmatic Environmental Impact Statement
PVA population viability analysis
PSU practical salinity unit
PWS RCAC Prince William Sound Regional Citizens' Advisory Council

RA Regulatory Analysis
ROS reduced operating status
SAB Science Advisory Board
SBA Small Business Administration
SNPRM supplemental notice of proposed rulemaking
STEP Shipboard Technology Evaluation Program
UV ultraviolet radiation
VGP Vessel General Permit
VHS Viral Hemorrhagic Septicemia

II. Regulatory History

On August 28, 2009, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled ''Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters'' in the **Federal Register** (74 FR 44632). In response, we received 662 letters to the docket for the rulemaking, which contained 2,214 individual comments on the NPRM. We summarize these comments in the preamble of this final rule (*see* V.B. Discussion of Comments).

We held six public meetings on the NPRM in the following locations: Seattle, WA; New Orleans, LA; Chicago, IL; Washington, DC; Oakland, CA; and New York, NY. Comments received at those meetings, both written and oral, are also summarized in this preamble (*see* V.B. Discussion of Comments).

III. Basis and Purpose

The Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (NANPCA), as amended by the National Invasive Species Act of 1996 (NISA), requires the Secretary of Homeland Security to ensure to the maximum extent practicable that aquatic nuisance species are not discharged into waters of the United States from vessels. 16 U.S.C. 4711(c)(2)(A). The statutes further stipulate that the Secretary may approve the use of certain alternative ballast water management (BWM) methods if she determines that those alternative methods are at least as effective as ballast water exchange (BWE) in preventing and controlling infestations of aquatic nuisance species. 16 U.S.C. 4711(c)(2)(D)(iii). The Secretary is further required to direct vessels to carry out management practices necessary to reduce the probability of unintentional discharges resulting from ship operations other than ballast water discharge. 16 U.S.C. 4711(c)(2)(E).

NISA also requires the Secretary to assess and, if dictated by that assessment, to revise the Department's BWM regulations not less than every 3 years based on the best scientific information available to her at the time of that review, and potentially to the exclusion of some of the BWM methods listed at 16 U.S.C. 4711(c)(2)(D). 16 U.S.C. 4711(e). The Commandant of the Coast Guard carries out these functions and authorities for the Secretary pursuant to a delegation of authority charging the Coast Guard with establishing and enforcing regulations to prevent the introduction and spread of aquatic nuisance species in the waters of the United States through the ballast water of vessels. Department of Homeland Security Delegation No. 0170.1(II.)(57).

Determining whether an alternative method of BWM is as effective as BWE is not an easy task. Results from several studies have shown the effectiveness of BWE varies considerably and is dependent on vessel type (design), exchange method, ballasting system configuration, exchange location, and method of study. These variables make comparing the effectiveness of an alternative BWM method to the effectiveness of BWE extremely difficult. Some studies suggest that the efficacy of BWE in reducing organism concentration is 80 to 99 percent per event (Hines and Ruiz 2000; Rigby and Hallegraeff 1993; Smith et al. 1996; Taylor and Bruce 2000; Zhang and Dickman 1999) although lower efficacies have been reported (e.g., Dickman and Zhang 1999). Other studies demonstrate that the volumetric efficiency of BWE ranges from 50 to 90 percent (Battelle 2003; USCG 2001; Zhang and Dickman 1999).[1] Thus, vessels with very large starting concentrations of organisms in their ballast tanks might still have large concentrations of organisms after BWE. In addition, a significant number of vessels are constrained by design or route from conducting BWE in compliance with existing regulations prior to their arrival into waters of the United States.

For these reasons, BWE is not well-suited as the basis for the protective BWM programmatic regimen envisioned by NISA, even though it has been a useful interim management practice and was a logical place to start. We have concluded that, as an alternative method to using BWE as the benchmark, establishing a standard for the concentration of living organisms that can be discharged in ballast water will advance the protective intent of NISA and simplify the process for Coast Guard approval of ballast water management systems (BWMS). We have found no other reasonable benchmarking approach.

We have further concluded, through analysis of BWMS on vessels enrolled or being reviewed for the Coast Guard Shipboard Technology Evaluation Program (STEP) and other information before the Coast Guard which is in the docket for this rulemaking, in accordance with the factors set forth in 151.1511(c) and 151.2030(c) of this final rule, that the specific ballast water discharge standard (BWDS) set forth in this rule is practicable.

Setting a BWDS promotes the development of innovative BWM technologies, facilitates enforcement of the BWM regulations, and assists in evaluating the effectiveness of the BWM program. Therefore, in this rule, we amend 33 CFR part 151 by establishing a BWDS. We also amend 46 CFR part 162 by adding an approval process for BWMS intended for use onboard vessels to meet the BWDS.

As part of that approval process, the Coast Guard will require the use of Independent Laboratories (ILs) to perform the testing to be used to support applications for approval. The Coast Guard has a long history of recognizing the qualifications of ILs working under our oversight. In 1979, the Coast Guard promulgated 46 CFR part 159, establishing procedures and standards for accepting ILs for witnessing or performing certain tests and conducting inspections for certain equipment and materials requiring Coast Guard approval. 44 FR 73038 (December 17, 1979). The Coast Guard promulgated 46 CFR part 159 under the authority in 46 U.S.C. 391a (1976) (Vessels carrying certain cargoes in bulk).[2] In 1983, Congress revised and recodified the maritime laws of the United States and moved the relevant authority for 46 CFR

[1] Copies of these studies are available in Docket No. USCG–2001–10486, and were available during the comment period following publication of the NPRM for this rulemaking. Please see **ADDRESSES** section of this rulemaking for accessibility information.

[2] 46 U.S.C. 391a stated ''(3) Rules and regulations[.] In order to secure effective provision (A) for vessel safety, and (B) for protection of the marine environment, the Secretary of the department in which the Coast Guard is operating * * * shall establish for the vessels to which this section applies such additional rules and regulations as may be necessary with respect to the design and construction, alteration, repair, and maintenance of such vessels, including, * * * equipment * * *.'' The Coast Guard determined that the use of ILs for witnessing or performing certain tests was ''necessary'' to carry out its responsibilities under this statutory section. In the NPRM proposing 46 CFR part 159, the Coast Guard explained that ''the Coast Guard's marine inspection responsibilities increased while the number of personnel available to perform these inspections has not increased at a comparable rate.'' (43 FR 49440, Oct. 23, 1978). The Coast Guard promulgated part 159 to ''free some of the Coast Guard's limited field personnel for other duties with no change in the quality of the approved equipment or material.'' *Id.; see* also 44 FR 73038 (December 17, 1979) (Final rule document promulgating part 159).

part 159 to new 46 U.S.C. 3306.[3] Public Law 98–89 Partial Revision of Title 45, U.S.C. ''Shipping''; House Report No. 98–338 (August 1, 1983), 1983 U.S.C.C.A.N. 924, 952–53.

The authority for current 46 CFR part 159 is 46 U.S.C. 3306, which ''contains broad authority to prescribe regulations for proper inspection and certification of vessels,'' (House Report No. 98–338 (August 1, 1983), 1983 U.S.C.C.A.N. 924, 954–53), including the specific requirement to prescribe regulations to carry out the statutory requirements ''in the most effective manner,'' (46 U.S.C. 3306(a)). The Coast Guard still finds the use of ILs in the Coast Guard's approval process to be ''the most effective manner'' of executing and carrying out its obligations under section 3306.

IV. Background

A full discussion of the legislative and regulatory history of the Coast Guard's actions to implement both NANPCA and NISA may be found in the NPRM for this rule, published on August 28, 2009. 74 FR 44632, 44633.

Vessels subject to today's final rule are also subject to the U.S. Environmental Protection Agency (EPA) Vessel General Permit (VGP) issued under section 402 of the Clean Water Act. The Coast Guard and EPA continue to work closely together in the development of ballast water discharge standards and to harmonize requirements, to the extent feasible and appropriate, under their respective statutory mandates. Under the CWA, EPA proposed the new draft VGP for public comment on November 30, 2011, with a proposed effective date of December 2013.

The draft EPA VGP contains discharge limits for a number of discharges incidental to the normal operation of vessels operating in a capacity as a means of transportation, including numeric limits for ballast water discharges. The Coast Guard notes that the draft VGP proposes to apply numeric treatment limits for ballast water discharges to a broader class of vessels than this final rule. Like the 2008 VGP, the draft 2013 VGP proposes some requirements that are broader in applicability, require additional management requirements, and require differing monitoring or other quality control requirements from today's rulemaking. The 2008 VGP applied requirements to tankers in the coastwise trade and required ballast water exchange for vessels engaged in Pacific nearshore voyages, among other ballast water requirements that differed from the Coast Guard regulation in effect in 2008. The Coast Guard notes that EPA must consider the information in its record, as well as the requirements of the Clean Water Act, as it finalizes the VGP. Therefore, it is possible that the final VGP will contain requirements that differ from those found in our rulemaking today.

For more information on EPA's current VGP or its next draft VGP, visit the EPA's Web site at: *http://www.epa.gov/npdes/vessels.* Nothing in this final rule is intended to limit, in any way, actions the EPA may take in the future with respect to regulation of ballast water discharge in the EPA VGP under its Clean Water Act authorities. *See, e.g.,* 16 U.S.C. 4711(b)(2)(C) and 4711(c)(2)(J).

V. Discussion of Comments and Changes

A. Summary of Changes From the NPRM

This final rule contains a number of changes from the rule proposed by the NPRM (74 FR 44632 (August 28, 2009)). While we list in this section all changes made to the rule since the NPRM, we are highlighting several of these changes not only because they are important, but also because a vast majority of the comments received in the docket addressed at least one of these topics. Most of the changes discussed below were made directly in response to those comments. A full discussion of comments and Coast Guard responses is found in section V.B. Discussion of Comments.

1. Deferral of Phase-Two Standard

Most notably, this final rule does not include the NPRM's proposed phase-two standard. This reflects a decision to move forward with the phase-one standard while the Coast Guard continues to assess the practicability of implementing a phase-two standard, gathers additional data on technology available to meet the phase-two standard for various vessel types, and develops a subsequent rule with an economic and environmental analysis to support a phase-two standard. The decision to remove this more stringent standard from this final rule should not be interpreted as a sign that the Coast Guard is not committed to its statutory responsibility to continually review the BWDS to increase the protectiveness of the BWDS.

Significantly, after this final rule was drafted, the EPA requested its Science Advisory Board (SAB) to review and provide advice regarding whether existing shipboard treatment technologies can reach specified concentrations of organisms in vessel ballast water, how these technologies might be improved in the future, and how to overcome limitations in existing data (EPA SAB 2011). Information was identified on 51 existing or developmental ballast water treatment technologies, although detailed data were available for only 15 specific BWMS. The SAB used this information as the source material for its assessment of ballast water treatment performance and, as requested by the EPA, used proposed ballast water discharge standards as the performance benchmarks. Based on its evaluation of the available data, the SAB concluded that the performance standards for discharge quality proposed by IMO and the Coast Guard are currently measurable, based on data from land-based and shipboard testing. However, current methods (and associated detection limits) prevent testing of BWMS to any standard more stringent than D–2/Phase 1 and make it impracticable for verifying a standard 100 or 1,000 times more stringent. New or improved methods will be required to increase detection limits sufficiently to statistically evaluate a standard 10 times more stringent than IMO D–2/Phase 1; such methods may be available in the near future. The SAB concluded that establishment of a ballast water discharge limit at the proposed Coast Guard Phase I/IMO discharge standard will result in a substantial reduction in the concentration of living organisms in the vast majority of ballast water discharges, compared to discharges of ballast water managed by mid-ocean exchange or discharges of unexchanged ballast water. The numeric limitations in today's final rule represent the most stringent standards that BWMS currently safely, effectively, credibly, and reliably meet (US EPA SAB, 2011.)

The cost, benefit, and environmental impact analyses included in the NPRM could not specifically assess all impacts related to the phase-two standard (although the analyses did include an evaluation of standards that are more stringent than the standard proposed herein as practicable). Many commenters addressed this issue, noting that the lack of analyses made it

[3] Section 3306 directs ''the Secretary shall prescribe necessary regulations to ensure proper execution of, and to carry out, this part [addressing inspection and regulation of vessels] in the most effective manner for (1) The design, construction, alteration, repair, and operation of those vessels [subject to inspection] * * *; (2) lifesaving equipment and its use; (3) firefighting equipment, its use, and precautionary measures to guard against fire; (4) inspections and tests related to paragraphs (1), (2), and (3) of this subsection; and (5) the use of vessel stores and other supplies of a dangerous nature * * *.''

impossible for them to comment on the phase-two standard in any meaningful manner.

To provide the public with as much information as possible on which to base comments, the Coast Guard will develop additional analyses regarding the potential costs, benefits, and environmental impacts of the proposed phase-two standard or any standard higher than phase-one. When these analyses are completed, the Coast Guard will make them available for public comment, either via a notice of availability or in conjunction with a subsequent rulemaking published in the **Federal Register**.

The Coast Guard still fully intends to issue a later rule that will establish a more stringent phase-two discharge standard once the additional research and analysis necessary to support this more stringent standard has been completed. To demonstrate our commitment, in the final rule text we are reserving the regulatory provisions where the phase-two standard will be found, to show that the Coast Guard does not view publication of this rule as completing the agency's work in controlling the introduction and spread of NIS from ships' ballast water.

2. Practicability Reviews

The NPRM proposed an initial practicability review to be published at least 3 years prior to the first compliance date under the BWDS implementation schedule, with a subsequent review no later than 2 years after the initial review. Because we have removed the phase-two standard from this final rule, we have also removed the recurring practicability reviews that were included in the NPRM. This final rule establishes clearer guidelines and criteria considered for the practicability review. Additionally, because the final rule defers establishing a phase-two standard, we wanted to prevent the scenario in which a finalized phase-two standard believed to be practicable when established should not be implemented according to the established timelines, either because it can be implemented sooner or because it cannot be implemented by the deadline established. To accomplish this, NISA requires regular reviews and strengthening of standards when determined practicable, so completing a review will be part of any future rulemaking. See 16 U.S.C. 4711(e).

This final rule does include one practicability review provision, which requires the Coast Guard to complete and publish the results of its practicability review no later than January 1, 2016. This review will draw a significant component of its information from the BWMS approval application packages that the Coast Guard expects to evaluate between the publication date of this final rule and the initial implementation date. The Coast Guard's practicability review will look at a variety of factors, including but not limited to economic factors and the efficacy and environmental safety of available BWMS technology. While we have listed a number of these factors in this final rule, we have also included a provision allowing us to consider additional factors. This is to ensure that the Coast Guard is not foreclosed from considering any unforeseen issues.

Some commenters argued against considering any factor other than best available technology. Whether the commenters meant ''best available technology'' as a term of art under the Clean Water Act or merely the best technology available in the marketplace, the Coast Guard acknowledges the importance of technology. However, the Coast Guard's authority does not limit the matters of concern to technology. Congress established a practicability standard in NISA; that standard requires that the Coast Guard consider more than just technology. A standard based solely on technology would be inconsistent with the statute.

3. Applicability

In the NPRM, we proposed requiring vessels discharging ballast water into waters of the United States to comply with the BWDS. This included vessels operating solely in coastwise trade and on the internal waters of the United States. Those vessels are not required to conduct a BWE under the existing Coast Guard regulations, and, as such, the proposal was seen as an expansion of those regulations. A large number of commenters questioned this expansion.

Commenters raised a number of issues regarding the applicability of the NPRM. These issues included uncertainty as to whether any of the currently available BWMS could be successfully installed on non-seagoing vessels, the cost of installation of BWMS on these industries, and the benefit of requiring these vessels to install a BWMS.

As a result of these comments, this final rule applies to two groups of vessels discharging ballast water into waters of the United States. The first group is comprised of those vessels currently required to conduct BWE. The second group, which previously was not required to conduct BWE, is comprised of seagoing vessels that do not operate beyond the U.S. Exclusive Economic Zone (EEZ), that take on and discharge ballast water in more than one Captain of the Port (COTP) Zone, and are greater than 1,600 gross register tons (GRT) (3,000 gross tons (GT) International Tonnage Convention (ITC)).

The Coast Guard fully intends to expand the applicability of the BWDS to all vessels not legislatively exempted that operate in U.S. navigable waters or territorial sea, as we proposed in the NPRM, but we have determined that additional analysis is necessary to support this expansion. We also intend to conduct additional research as necessary. We expect that this expansion will be part of the notice or other rulemaking document that addresses the phase-two standard, and that vessels covered by the expanded applicability will be required to install a BWMS that meets at least the phase-one standard.

In addition to the comments on applicability mentioned above, we also received comments questioning why we proposed using the presence of ballast tanks as the main applicability factor for BWMS installation, instead of the actual discharge of ballast water. We agree an important factor in deciding whether a vessel is required to have a BWMS onboard should be the threat that vessel presents to contributing to the threat of aquatic NIS. Vessels that pose a low level of risk, either because they do not discharge ballast water at all, discharge only to shoreside facilities, or discharge only water that presents little threat (public drinking water), should not be required to install a BWMS. For this reason, we revised 33 CFR 151.1510 and 151.2025 to (1) clarify that discharge of ballast water into waters of the U.S. is a threshold requirement for installation of a BWMS, and (2) include an additional BWM option for use of water from a U.S. public water supply meeting certain EPA drinking water standards. We have also slightly revised the applicability section in 33 CFR part 151 subpart C (Ballast Water Management for Control of Nonindigenous Species in the Great Lakes and Hudson River). We inserted a provision to clearly state that all vessels subject to subpart C are also subject to 33 CFR part 151 subpart D (Ballast Water Management for Control of Nonindigenous Species in Waters of the United States). This does not reflect an actual change to the regulations, as the general applicability provision in subpart D already applies to vessels subject to subpart C. Subpart D requires that these vessels comply with additional NIS reduction practices and the reporting and recordkeeping requirements. We are adding the clarifying statement to subpart C in order to ensure there is no confusion about the applicability of subparts C and

D. We made other slight modifications to align the applicability section of subpart C with that of subpart D, but these revisions do not change the substantive requirements of either subpart.

4. COTP Zone Exemption

Existing BWM regulations include a provision that exempts owners and operators of vessels operating in only one COTP Zone from reporting and recordkeeping requirements. 33 CFR 151.2010(b)(1). In the NPRM, we intended to remove this exemption from the reporting and recordkeeping requirements, but include an exemption from the BWDS for owners and operators of these vessels (those operating in only one COTP Zone). We explained this exemption by stating that ''it is unlikely that vessels operating in only one COTP Zone would introduce invasive species (from outside of that COTP Zone) into the waters of the COTP Zone.'' 74 FR 44634.

Unfortunately, the proposed regulatory text included erroneous cross references, did not actually exempt these vessels from the intended provisions, and did not remove the current reporting and recordkeeping exemption. This error confused many commenters. Other commenters based their comments on our intentions as stated in the preamble, and noted that COTP Zones are purely administrative in nature, not established based on any ecological or biological bases, and therefore are not appropriate boundaries to be used when addressing invasive species.

Because we have revised the applicability of this final rule, as discussed above, the BWDS will not apply to vessels operating within only one COTP Zone. However, we do intend to expand the applicability of the BWM requirement to include all vessels operating in waters of the United States that are not legislatively exempted, but have determined that additional analysis is necessary to support such an expansion. We also intend to conduct additional research as necessary. The issue of whether there are distinct zones or areas where it might be appropriate to include an exemption for vessels that do not leave that zone or area is still open to consideration as part of a subsequent notice or other rulemaking document.

Many commenters supported the concept of geographic exemptions; however, some objected to using COTP Zones as the basis for the exemption. For this reason, the Coast Guard will investigate other possible ways to create an exemption like this, using suggestions from commenters and our Federal agency partners.

We are also keeping intact the current exemption from recordkeeping and reporting requirements for these vessels which operate exclusively in one COTP Zone. We will, in the future, begin a separate rulemaking project addressing BWM recordkeeping and reporting requirements, and any changes to this exemption will be addressed in that project.

5. Removal of Ballast Water Reporting Form From CFR

We have removed the Ballast Water Reporting Form (Office of Management and Budget (OMB) Control No. 1625–0069) from the appendix to 33 CFR part 151 subpart D. This form is still the proper form to satisfy the reporting requirements in 33 CFR 151.2070. We have revised § 151.2070 to reference the National Ballast Information Clearinghouse (NBIC) Web site as the form's location. This change will not have any effect on the public, as the form will still be available and the requirement for filing the form is not being revised.

We have removed this form from the CFR in order to streamline future changes to the form. Any changes would need to comply with provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), which include providing notice to the public and opportunity for comment. Additionally, the form is part of an OMB-approved collection of information that must be renewed on a regular basis. These renewals also include an opportunity for public notice and comment on the form and the associated collection of information.

6. Adoption of Environmental Technology Verification (ETV) Protocol

In the NPRM, we noted that our proposed BWMS approval process was based, in part, on the draft Generic Protocol for the Verification of Ballast Water Treatment Technologies developed under EPA's ETV Program. 74 FR 44640 (Aug. 28, 2009). Since the publication of the NPRM, EPA has completed its development of this protocol, a process that included laboratory testing, stakeholder reviews, and public comment. The protocol may be found on the EPA Web site, under Research and Development, Risk Management Research Publications.[4] The Coast Guard and EPA have been formal partners in the process of developing this protocol. It has always been our intention to incorporate the final ETV Protocol into our BWMS approval process, which we are doing via this final rule.

While this incorporation was not part of the proposal included in the NPRM, we noted that the procedures in the NPRM were based on a preliminary version of the ETV Protocol (74 FR 44634, 44640). While the final ETV Protocol differs from earlier versions, the differences are due both to consensus revisions during finalization of the protocol, and to subsequent peer review and public comments. Some of the comments we received on the NPRM specifically suggested that we use the final ETV Protocol.

For all of these reasons, the Coast Guard has determined that incorporating the final ETV Protocol into this final rule is a logical outgrowth of what was proposed in the NPRM, and that further notice and comment on incorporating it by reference is not required.[5] We have revised the approval process regulations to incorporate the final ETV Protocol, and have removed those portions of the regulation that were made redundant by this incorporation.

7. Alternate Management System(s) (AMS) and Foreign Approvals

The NPRM included a provision to allow foreign type-approved BWMS to receive U.S. type approval subject to an equivalency determination. We have removed that provision in this final rule; however, we still allow manufacturers to use testing done to obtain type approval from a foreign administration, and the data from that testing, to satisfy the U.S. type-approval testing and application requirements if the Coast Guard determines the testing to be equivalent to what is required by our regulation. The language in 46 CFR 162.060–12 was revised; we have included more detail as to what a manufacturer with a foreign-approved BWMS must show in order to use their prior testing to satisfy our approval requirements, rather than vaguely calling for the manufacturer to show equivalency. Despite these revisions, the intent and effect of the changes are substantially similar to what appeared in the NPRM. As such, we view these changes as logical outgrowths of the

[4] EPA/600/R–10/146, version 5.1 (September 2010). Available at *http://www.epa.gov/nrmrl/pubs/600r10146/600r10146.pdf.*

[5] *See Int'l Union, United Mine Workers of Amer.* v. *Mine Safety and Health Admin.,* 626 F.3d 84, 95 (D.C. Cir. 2010) (''a final rule will be deemed to be the logical outgrowth of a proposed rule if a new round of notice and comment would not provide commenters with their first occasion to offer new and different criticisms which the agency might find convincing.'') (internal citations omitted).

NPRM, and thus further notice and comment is not required.

Despite the provision discussed in the previous paragraph, we are aware that many foreign-approved BWMS will require additional testing in addition to analysis under applicable U.S. environmental laws, such as the National Environmental Policy Act (NEPA) and the Endangered Species Act (ESA). This is due to differences between the international approval regime and the approval protocol adopted in the final rule. This will extend the amount of time required for foreign-approved systems to gain U.S. approval, although the process to secure U.S. approval should still be shorter than if the manufacturer were required to repeat all testing already completed for obtaining type approval from a foreign administration.

Implementing the U.S. approval process will likely take at least 3 years. We do not anticipate having U.S. approved systems that have satisfied the testing protocols required in 46 CFR subpart 162.060 prior to 2015.

To ensure there are BWMS available for vessel installation and use without having to delay the implementation schedule, and also to provide an incentive for the early installation and use of BWMS instead of relying exclusively on BWE, we have added a provision to 33 CFR 151.1510(a)(1), 151.2025(a)(3), and included a new provision (§ 151.2026) and definition (§ 151.1504) to allow for the temporary acceptance of foreign-approved BWMS, providing the Coast Guard determines that the BWMS is at least as effective as BWE. These alternate management systems (AMS) must be approved by foreign governments under the standards set forth in the International Convention for the Control and Management of Ships Ballast Water and Sediments (IMO BWM Convention), after it enters into force, or consistent with relevant guidelines developed by the IMO. This provision for AMS will also allow vessels with BWMS installed to meet requirements of other administrations and/or the standards set forth in the IMO BWM Convention to use such BWMS while operating in waters of the United States. We further note that pursuant to § 151.2025(e) of this final rule, any vessel using an AMS must comply with the terms and conditions of the VGP when operating in U.S. waters, including any applicable discharge limitations.

As with the process for U.S. approval of foreign-approved BWMS, these temporary acceptance determinations will be subjected to reviews under NEPA, ESA, and other environmental policy laws. However, we expect the AMS process will require less time than the more extensive type approval process, which will allow vessel owners to install BWMS prior to the implementation dates contained in the regulation. These earlier installations should result, at the earliest possible date, in a reduction of the risk of ballast water introducing or spreading NIS, as those vessels currently unable to conduct BWE due to safety concerns or voyage constraints will instead be subjecting their ballast water to some type of treatment before discharging it into the waters of the United States.

Use of an AMS will be allowed for up to 5 years after the vessel is required to comply with the BWDS. The 5-year period should provide the manufacturer or vendor with sufficient time to obtain U.S. approval, either using the data from the tests already completed, or by undergoing new tests designed specifically to comply with 46 CFR part 162.060.

8. Delay of Compliance Date for New Vessels

Even with the provision for acceptance of foreign type approvals, a process that is expected to be quicker than completing the full schedule of land-based and shipboard tests, we anticipate there will not be an adequate number of approved BWMS to allow vessel owners to meet the NPRM's proposed compliance date for new vessels. For this reason, we have pushed back the compliance date for new vessels to install Coast Guard-approved BWMS from January 1, 2012, to December 1, 2013. Additionally, the December 1st date will align the compliance date with the proposed effective date for the 2013 EPA VGP. We estimate this deferral could delay the compliance date for up to 600 newly constructed vessels.

We have also added a provision to both 33 CFR part 151 subparts C and D that will allow individual vessel owners to request that the Coast Guard extend their compliance date if, despite the owner's efforts, he or she cannot meet the published compliance dates. This change is in response to commenters who argued that the compliance timelines included in the NPRM were too aggressive.

9. Other Changes

The Coast Guard made additional changes in response to comments, and some of those changes warrant a summary here. The remaining changes are listed at the end of this section and discussed further in section V.B. Discussion of Comments.

First, we are adding a requirement to 33 CFR 151.2075 for sampling ports on each of the vessel's overboard ballast water discharge pipes. This change is a response to commenters who requested stronger enforcement and commenters who asked how enforcement would be achieved. Without the inclusion of sampling ports, Coast Guard inspectors would not be able to sample a vessel's ballast water without potentially delaying the vessel for significant periods of time. Sampling is necessary in order to determine if the BWMS is operating properly to produce ballast water that meets the BWDS. The inclusion of sampling ports is logical outgrowth of the NPRM because the Coast Guard must have means to ensure compliance, and the NPRM included a provision requiring vessel owners and operators to provide access to the Coast Guard for sampling. Also, commenters asked how enforcement would be achieved. Inclusion of this requirement improves Coast Guard enforcement and responds to both groups of these commenters.

Secondly, we received questions from commenters asking who should operate the BWMS during the shipboard testing. We have clarified in 46 CFR 162.060–28 that it should be the vessel crew operating the BWMS. This is most appropriate because the crewmembers are the ones who will need to operate the BWMS after it receives U.S. type approval. Additionally, having the crew operate the BWMS ensures that vendors and manufacturers, who have a stake in the success of the BWMS, are not able to influence the test results. This provision is a logical outgrowth of the NPRM because the NPRM listed the vessel crew as one of two groups that should operate the BWMS during testing. This change is a clarification to show which of those listed entities should operate the BWMS during land-based testing, and which should operate the BWMS during shipboard testing.

Finally, in response to comments, we reduced the time period required for shipboard testing from 12 months to 6 months, removed the requirement for testing to be in three distinct geographic regions, and reduced the number of required, valid test cycles. Several commenters requested these changes, noting that our proposed requirements were unnecessary and too burdensome. We agree that the suggested changes will still provide for adequate shipboard testing of BWMS, therefore, we have made these changes to reduce the burden associated with shipboard testing.

The remaining changes made in response to comments were replacing

the term ''build date'' with ''constructed'', in order to better align with the IMO BWM Convention and updating the civil penalty amounts to reflect their adjustment in a recent Coast Guard final rule.

The Coast Guard made several changes during the drafting of this final rule to eliminate redundancy and streamline the regulatory text. We revised the definitions section in 33 CFR part 151 subpart D by removing those definitions that are already defined in part 151 subpart C, as well as definitions for terms not used in part 151 subpart D. We added definitions for several terms that were used in 46 CFR subpart 162.060, and we updated the incorporation by reference section in that subpart to more clearly indicate those standards being incorporated into this regulation.

We deleted 33 CFR 151.2075(c), which referred to an assessment of vessel compliance with the now obsolete voluntary national program. That assessment has been completed for several years; therefore, it is no longer necessary to refer to it in the regulations.

We revised § 151.1510(a)(1) to clarify when BWE must be conducted. We also revised paragraphs (a)(3) and (d) of that section to improve readability and clarify requirements. Similar revisions were made in § 151.2025, also to improve readability and clarify requirements.

We corrected the BWDS in both subparts C and D to align with the IMO BWM Convention.

We removed proposed 33 CFR 151.2045 ''Safety exceptions,'' as we determined that those provisions were largely repetitive to what was proposed in 33 CFR 151.2040, entitled ''Discharge of ballast water in extraordinary circumstances.'' We moved the one non-repetitive provision to § 151.2040. As a result, § 151.2040 now includes the provision noting that nothing in the regulations relieves the master, owner, agent, or person in charge of the vessel from any responsibility, including the safety and stability of the vessel and the safety of the crew and passengers.

Throughout the regulatory text, we updated addresses for the Coast Guard Marine Safety Center, also adding in an email address option. We updated cross-references where necessary, and made changes to remove passive tense from the requirements. These changes improve the readability of the regulation, and clarify requirements.

We made a number of non-substantive changes to the approval procedures found in 46 CFR subpart 162.060. Like many of the changes we are making, these changes improve the readability of the regulation, and clarify requirements. We also revised the regulatory text that was proposed in 46 CFR 162.060–40. In the NPRM, that section included all requirements for ILs. In this final rule, we have split those requirements into two sections (46 CFR 162.060–40 and 162.060–42). The first section includes requirements for ILs applying for Coast Guard designation; the second section now contains the responsibilities imposed on ILs once they are designated by the Coast Guard.

These changes result in more easily understandable regulations, but do not make substantive changes. For this reason, the Coast Guard has determined that further notice and comment on the changes is unnecessary, pursuant to 5 U.S.C. 553(b).

B. Discussion of Comments

We received 662 comment letters on our NPRM, which contained 2,214 individual comments. We have divided our discussion of these comments into subject matter topics, and our responses are laid out in the following sections.

1. Applicability

One hundred and thirty four commenters addressed the applicability of the proposed regulations. Of these, 39 requested an exemption based on the segment of industry in which their vessel is engaged. These industry segments include: towing vessels and barges; offshore energy services support vessels; commercial fishing vessels; passenger vessels; offshore floating platforms; and vessels operating solely in the Great Lakes.

Many commenters generally criticized the application of the BWDS to their specific type of vessel. Forty eight commenters stated that various aspects of the design or operation of their vessels make it infeasible for them to practicably install a BWMS. The cited constraints include lack of space, lack of ballast piping, insufficient power available onboard, independent pumps and piping for each tank, insufficient BW holding times and pumping capacities in excess of current BWMS capabilities.

As we have discussed in this preamble, we have revised the applicability of this final rule so that the BWM requirements primarily apply to vessels with ballast tanks operating in waters of the United States after having operated outside of the EEZ (*see* V.B. Summary of Changes from the NPRM). Certain other vessels that operate exclusively in the EEZ and in more than one COTP Zone, and that meet certain size thresholds that make them similar to vessels operating on international routes are also required to comply. The Coast Guard, however, intends to expand this applicability in the near future after further study and will keep these commenters' requests in mind. We have also added, as discussed above, a provision for vessel owners who are required to comply with the BWDS but cannot do so for good reason (such as design and operating conditions or unavailability of systems) to request a delay in their compliance date.

Vessels Operating Solely in the Great Lakes

Twenty one commenters asked that vessels operating solely in the Great Lakes be treated differently from seagoing vessels due to the constraints cited above. Those commenters also requested that they be allowed to continue the best management practices currently in place instead of being required to install BWMS.

Conversely, 35 commenters urged the Coast Guard to regulate vessels operating solely in the Great Lakes. Five commenters asked the Coast Guard to hold vessels operating solely in the Great Lakes to the most stringent BWDS possible. One of these commenters submitted a petition with 8,905 individual signatures in support of stronger regulation of vessels that operate exclusively in the Great Lakes.

One commenter supported regulating vessels operating solely in the Great Lakes but felt the regulatory priority should be on preventing introductions of aquatic NIS by oceangoing vessels. Two commenters supported expanded regulation of vessels operating solely in the Great Lakes, but asked that the regulations take into account the unique design and operating characteristics of these vessels. Twenty seven additional commenters supported regulating this vessel population without providing a specific reason.

For the reasons we have discussed in this preamble, we are not requiring vessels that operate exclusively in the Great Lakes to comply with the BWDS in this final rule (*see* V.B. Summary of Changes from the NPRM). The Coast Guard intends to re-examine this decision in the near future, and will keep these commenters' requests in mind when developing subsequent rulemakings.

Municipal Water as Ballast

Twenty commenters urged the Coast Guard to exempt vessels from having to treat their ballast water if the water was obtained from a municipal water supply, as they believe this poses little risk of introducing or spreading NIS in

waters of the United States. The commenters stated that this is a common practice for inland towing vessels and/or barges, offshore energy services, and small business interests, and is authorized under existing Coast Guard policy.

Fifteen commenters proposed that vessels should be allowed to use municipal or potable water for ballast water. These commenters also proposed that vessels should be permitted to discharge that water into waters of the United States without having to use a Coast Guard-approved BWMS or to meet the BWDS.

The Coast Guard agrees that, in some situations, ballast water does not pose a significant threat of introducing or spreading NIS. We have some concerns about the variable quality of municipal water sources, but believe that water that satisfies the standards of the Safe Drinking Water Act (42 U.S.C. 300f–300j) should be acceptable for use as ballast water without posing a significant threat of introducing or spreading NIS. As a result, we have revised the regulation to allow for use of water from a U.S. public water system (PWS) meeting the requirements of the Safe Drinking Water Act as an alternative to installing a BWMS meeting the BWDS. We note, however, that with the exception of PWS water used under extraordinary circumstances in accordance with 33 CFR 151.1515, a vessel must exclusively use PWS water as ballast. Any mixture of water obtained from a source other than a facility meeting the requirements of the Safe Drinking Water Act will negate acceptability of water from a PWS as discharged ballast water. This change is found in 33 CFR 151.1510(a)(4) and 151.2025(a)(2).

COTP Zones

Seven commenters urged the Coast Guard to not grant regulatory exemptions for vessels operating exclusively in a single COTP Zone. They noted that these zones are not ecologically meaningful subdivisions and asked that any boundaries be based on scientific analysis of the risk of transferring invasive NIS.

Conversely, 17 commenters urged the Coast Guard to provide exemptions for vessels that operate exclusively in a single COTP Zone or conduct all ballast operations in a single COTP Zone. They argued that these practices would pose minimal environmental risk.

Four commenters requested a correction to the regulatory text to ensure that the proposed exemption for vessels operating exclusively in one COTP Zone (33 CFR 151.2015) extends to the BWM requirements (33 CFR 151.2025), consistent with the description of this provision in the preamble to the NPRM. One commenter called for the Coast Guard to continue to exclude vessels operating exclusively within one COTP Zone from the requirement to meet the BWDS.

For the reasons discussed earlier in this preamble, the BWM provisions of this final rule will not apply to vessels operating exclusively in a single COTP Zone (*see* V.A. Summary of Changes from the NPRM). The issue of whether there are distinct zones or areas other than COTP Zones where it might be appropriate to include an exemption for vessels that do not leave that zone or area remains open to consideration. The Coast Guard will investigate other possible ways to craft a geographic exemption, using suggestions from commenters and our Federal agency partners. The Coast Guard has determined that, for now, this is the best applicability delineation for the regulation based upon the available information and the Coast Guard's needs in effectively administering the ballast water program. The Coast Guard intends to re-examine this decision in the near future, and we will keep these commenters' requests in mind as we develop subsequent rules.

This rulemaking project has highlighted the need for additional research and analysis for ballast water regulatory efforts. A primary source of data for this research and analysis is the Ballast Water Reporting Form (available on the NBIC Web site at *http://invasions.si.edu/nbic/submit.html*), which vessels operating exclusively within a single COTP Zone are currently exempted from completing. In the future, the Coast Guard may initiate a separate rulemaking to expand the number of vessels submitting ballast water reports so that we can meet the statutory requirements for maintaining a clearinghouse on national ballast water data, and to collect additional data for use both in future regulations, and in future practicability reviews.

Great Lakes and Gulf of Mexico Ecosystems

Twenty two commenters urged the Coast Guard to designate the waters of the Ninth Coast Guard District as a single COTP Zone and exempt vessels operating exclusively in that zone from BWM requirements. In support of this position, the commenters noted that a ballast water bill passed by the U.S. House of Representatives in 2008 determined that the Great Lakes were an ''enclosed aquatic ecosystem'' and exempted vessels that confine their operations to those waters from installing BWMS.

Ten commenters suggested that vessels operating exclusively in the Gulf of Mexico be exempt from BWM requirements. In support of this position, the commenters noted a high level of connectedness between different areas of the Gulf of Mexico and the fact that the National Oceanic and Atmospheric Administration considers the Gulf of Mexico to be a single ''Large Marine Ecosystem'' based on ecological criteria.

The Coast Guard acknowledges the issues raised in these comments and will continue to work with the scientific community and regulatory agencies to investigate the bases for establishing more ecologically meaningful geographic zones for regulating ballast water operations.

Other Applicability

Two commenters urged the Coast Guard to consider the use of land-based or vessel/barge-based reception/treatment facilities. The Coast Guard agrees that use of shore-based or barge-based treatment might become a valid option for some vessels and has provided for this in the final rule. We have done so by revising the language in the regulations to make it clear that the BWDS only applies to those vessels falling within the rule's applicability thresholds (vessels that also discharge ballast water into waters of the United States). Those vessels discharging to land-based or vessel/barge-based reception/treatment facilities would not fall within this defined group, and therefore would not be required to install a BWMS that meets the BWDS. Any reception/treatment facilities used under this option would be subject to applicable state and local laws, as well as NPDES permitting if the treated water is discharged to waters of U.S.

Four commenters requested that the Coast Guard exempt any vessel that does not discharge ballast water in waters of the United States. Three additional commenters argued that vessels not discharging ballast water into the waters of the United States should not be subject to the requirement to install BWMS.

It was never the intention of the Coast Guard to require vessels to install a BWMS if they do not discharge ballast water into waters of the United States. We have clarified in this final rule that vessels not discharging ballast water into the waters of the United States are not required to install a BWMS. However, unless exempted, vessels are still required to report their BWM

practices on their Ballast Water Reporting Form.

One commenter suggested that applicability be based on a vessel's ballast water capacity. The Coast Guard notes that applicability of the rule is based, in part, on vessel ballast water capacity. While the discharge standard does not vary by vessel type, the dates at which vessels must meet the ballast water discharge standard if using a BWMS are based on vessel ballast water capacity.

As we move forward with expanding the applicability of this rule, however, we will continue to consider multiple factors, including ballast water capacity.

One commenter recommended exempting offshore floating platforms from the regulations, as these facilities rarely move. The Coast Guard does not believe that a categorical exemption is warranted. Under this final rule, an offshore floating platform would be exempted as long as it conducts ballast operations exclusively within a single COTP Zone. Additionally, we believe there are operational practices (e.g., offload to a reception vessel) that will allow an offshore floating platform to comply with the BWM regulations without having to install a BWMS.

One commenter suggested exempting reduced operating status (ROS) vessels that spend the majority of their time in layup or reduced crew status and are activated for short times (Maritime Administration Ready Reserve or Military Sealift Command vessels). The Coast Guard believes that if a vessel is not operating, it should not be discharging ballast water and there would be no requirements to meet when in ROS. In addition, in the event an ROS vessel meets the definition of a vessel of the Armed Forces under Section 312 of the Federal Water Pollution Control Act (33 U.S.C. 1322), it would be exempt from this final rule by section 151.2015(a)(191).

One commenter asked that exemptions and exceptions in the rule be consistent with the IMO BWM Convention. The Coast Guard believes that the commenter was referring to exemptions to the requirement to meet a BWDS that nation states could grant under the IMO BWM Convention once it enters into force. It is the Coast Guard's position that all vessels should take all practicable measures to ensure NIS are not discharged into the waters of the United States from vessels through ballast water; however, we note that we have included exemptions and exceptions in this final rule that are consistent with both our statutory mandate under NANPCA, as amended by NISA, and international law, including but not limited to the IMO BWM Convention (which has not yet entered into force). We will continue to develop our regulations and work with other countries to protect our environment.

2. BWDS

General Concern

Eighteen commenters submitted general concerns on the BWDS. Seven commenters stated their general opposition to the NPRM and three commenters stated their general support. Two commenters believed there was insufficient scientific and technical support in the record for the proposed regulation.

Four commenters stated that the BWDS and implementation schedule must be protective of the Great Lakes and one commenter expressed this concern for all waters of the United States. One commenter requested that the final regulations reflect reasonable and balanced programs that harmonize the commercial importance and environmental value of the Great Lakes.

The Coast Guard acknowledges these general concerns. Many of these concerns are echoed in more specific comments that we received, and those are summarized and addressed previously in this preamble and in the text that follows.

Support Concept

Twelve commenters supported the concept of a numeric, concentration-based BWDS, and three commenters said that such a BWDS will create the necessary market conditions to encourage investment in and development of technologies capable of achieving the objective of this rule. The Coast Guard agrees with these comments, and believes that setting a numeric, concentration-based BWDS in this final rule is the best approach to reducing the threat of the introduction and spread of NIS into the waters of the United States.

Stringency of Standard

One commenter supported the idea of a U.S. BWDS that at least meets the IMO BWM Convention Regulation D–2 discharge standard (IMO discharge standard) and any subsequent standard improvements. Another commenter stated that although they support the development of a BWDS like the phase-two standard, they also believe that starting with the achievable, measurable, and protective phase-one standard poses a much lower risk to the environment than starting with a stricter standard that is unachievable and immeasurable.

Six commenters supported establishing a discharge standard that is more stringent than the proposed phase-one standard, two of which also said the implementation schedule would not be protective as quickly as needed. Six commenters supported the proposed phase-two standard that is equivalent to the most stringent State standards, currently 1,000 times more stringent than the IMO discharge standard. One commenter said that the standard should be alternative 5 of the Draft Programmatic Environmental Impact Statement (DPEIS), which is essentially sterilization of ballast water.

One commenter stated that they did not support the adoption of a standard more stringent than the IMO discharge standard due to the impracticability of performing the necessary measurements to approve BWMS and test compliance.

One commenter stated that no technology developers with whom they have discussed treatment efficacy have been willing to provide assurances that their BWMS could reliably meet the phase-two standard, which is 1,000 times more stringent than the IMO discharge standard. This commenter further disagreed with the California State Lands Commission's (CSLC) conclusion that several BWMS have demonstrated the potential to comply with California's performance standards for the discharge of ballast water, and called for the Federal Government to perform its own analysis when conducting the practicability review prior to full implementation of the phase-two standard.

One commenter noted that the Great Lakes are a drinking water source and an irreplaceable freshwater natural resource. This commenter stressed the importance of implementing strong environmental regulations to protect such waters from the introduction of new NIS as well as from the establishment of new populations of NIS that currently exist within these waters.

Two commenters noted what they termed a lack of sufficient scientific and technical support in the record for the proposed regulation.

As we have noted in this preamble, this final rule is implementing the phase-one standard, which is equivalent to the IMO discharge standard, and deferring action on the phase-two standard until we can complete more analyses and research into practicability (*see* V.A. Summary of Changes from the NPRM).

The EPA SAB study (EPA SAB 2010), issued after publication of the NPRM for this rulemaking, provides support for our conclusion that technology to

achieve the IMO discharge standard represents the limit of current practicability. The SAB found that ''* * * five of 34 categories of assessed BWMS achieved reductions in organism concentrations sufficient to comply with the first standard proposed by the USCG (i.e., the 'Phase 1' standard).'' Further, the SAB also concluded that '' * * * current test methods and detection limits preclude a complete statistical assessment of whether a BWMS meets any standard more stringent than Phase 1'' (U.S. EPA SAB, 2011). We agree with the commenter who stated that implementing a less stringent, attainable standard that provides at least as much protection as BWE as soon as possible provides more protection than establishing a stricter standard and continually postponing it or deferring enforcement until it is achievable. We note the findings and recommendations of the National Research Council's (NRC) Committee on Assessing Numeric Limits for Living Organisms, which concluded that ''The current state of science does not allow a quantitative evaluation of the relative merits of various discharge standards in terms of invasion probability.'' The Committee further recommended that ''(a)s a logical first step, a benchmark discharge standard should be established that clearly reduces concentrations of coastal organisms below current levels resulting from ballast water exchange (such as the IMO D–2 standard).''

While the Coast Guard agrees that it is necessary to have a protective standard in place as quickly as possible, we have delayed the initial implementation dates for newly constructed vessels to allow for the implementation of the U.S. type-approval process. The Coast Guard does not believe that it is possible to implement this process any faster, and that such a deferral is inevitable.

The Coast Guard disagrees with the commenters who stated there was an insufficient record for the NPRM as a whole. While we have already acknowledged that more analysis on the impacts of the phase-two standard should be completed, both the economic and environmental analyses that accompanied the NPRM contained information that, when combined with our discussion of the proposed rule in the NPRM preamble, provided reasonable justification for the NPRM.

Zero Discharge

Fifteen commenters advocated for the establishment of a zero-discharge standard, and said there should be no living organisms allowed in ships' ballast water. Four commenters said that NISA requires the Coast Guard to establish such a zero-discharge standard.

Conversely, three commenters opposed setting a zero-discharge standard, which they claimed would be operationally and practically unachievable. One commenter stated that the current knowledge of invasion biology seems to be insufficient to define no-risk discharge criteria.

Two commenters stated that the long-term goal should be zero discharge of live organisms.

The Coast Guard disagrees that NISA requires a zero-discharge standard. NISA requires the Coast Guard to develop regulations that prevent the introduction and spread of NIS to the maximum extent practicable, and we have no data that support setting a zero-discharge standard as being practicable. However, the Coast Guard is committed to implementing the most stringent BWDS that can practicably be achieved. As evidence of this, the Coast Guard has already indicated in this preamble that in a subsequent publication, after additional analysis and research, we intend to finalize the proposed phase-two standard or any standard higher than phase-one, as well as the recurring practicability reviews that were included in the NPRM, with the goal of determining and achieving the most protective BWDS practicable (*see* V.A. Summary of Changes From the NPRM).

Phase-One Standard

Fourteen commenters stated their support for the phase-one standard that is equivalent to the IMO discharge standard. One commenter requested that the phase-one standard become the permanent standard for the United States.

The Coast Guard agrees with the commenters who supported the phase-one standard, as we believe this standard is practicable, achievable, and provides a level of protection that is at least as effective as BWE. However, the Coast Guard also believes that future work, such as that suggested by the EPA SAB (EPA SAB 2011) and the NRC Committee (NAS 2011), may result in a better understanding of the need for more stringent standards and the development of improved technologies for treating ballast water on vessels, and will continue to work toward improving protective requirements in accordance with the directions and authorities in NANPCA 90.

Thirteen commenters opposed the phase-one standard on the grounds that it was not sufficiently protective. One commenter proposed that the phase-one standard be set at 10 times more stringent than the IMO discharge standard, 5 commenters proposed that the phase-one standard be set at 100 times more stringent than the IMO discharge standard, and 4 commenters proposed that the phase-one standard be set at 1,000 times more stringent than the IMO discharge standard, which would be the equivalent of the proposed phase-two standard.

One commenter suggested dropping the phase-one standard and immediately undertaking a practicability review of the phase-two standard, which the commenter believed would result in an indefinite deferral of the phase-two standard as non-practicable. One commenter opposed the phase-one standard proposed in the NPRM without giving specific reasons.

The Coast Guard has found, based on the best scientific information available to the Coast Guard (including the previously referenced EPA SAB study on technologies and systems to minimize the impacts of invasive species in vessel ballast water discharge (EPA SAB 2011)), that there are currently no BWMS that have demonstrated the capability to meet a standard more stringent than the phase-one standard. Additionally, there are no available, standardized testing protocols that can be used to demonstrate that a BWMS can meet a standard 100 or 1,000 times more stringent than the phase-one standard.

Implementing both the phase-one and a more stringent but unachievable standard in a single rulemaking would result in foregoing the near-term protection this rulemaking provides. The Coast Guard believes ensuring this near-term protection now is in line with our statutory mandate from NANPCA, as amended by NISA. As we explained in this preamble, we are not abandoning the phase-two standard (*see* V.A. Summary of Changes from the NPRM). We are committed to implementing a standard that provides the most protection that can practicably be achieved.

One commenter opposed the phase-one standard on the grounds that it would be difficult to assess and therefore enforce. The Coast Guard disagrees. The EPA has already issued its ETV Protocol, which is incorporated by reference into this final rule and will be used to assess a BWMS' success in meeting the BWDS. The Coast Guard's type-approval process provides a strong means of verifying whether a BWMS can likely achieve the BWDS when installed and operating. Finally, Coast Guard port-state control officers will provide the final enforcement check to

ensure that a BWMS is operating as it should to meet the BWDS.

One commenter requested a modification to the phase-one standard to account for organisms less than 10 micrometers in size. The Coast Guard disagrees that this is necessary for the phase-one standard, as the IMO discharge standard did not include this size category. We may consider additional size categories for the phase-two standard.

Two commenters requested that the phase-one standard be aligned with the IMO discharge standard and other provisions of the IMO BWM Convention. The Coast Guard believes that we have made the phase-one standard as consistent as possible with the IMO discharge standard. We have made a slight adjustment in our implementation schedule to allow for practical realities involved in implementing a U.S. type-approval program, but we have also included a provision to allow for BWMS that have been approved by foreign administrations under the IMO BWM Convention to be accepted on an interim basis (*see* discussion in V.A. Summary of Changes from the NPRM).

Phase-Two Standard

Thirteen commenters supported the phase-two standard as proposed in the NPRM. One commenter stated that vessels would benefit by having to install a BWMS only once at a potentially more protective standard. One commented that adopting the phase-two standard would encourage manufacturers to modify existing BWMS components and develop new technologies that could meet multiple stringency standards.

Conversely, 47 commenters opposed the phase-two standard as being counterproductive on the grounds that there are no accepted test protocols or BWMS that have been proven to meet any limits more stringent than phase-one. Two commenters opposed the phase-two standard because BWMS manufacturers have focused their research, development, and certification efforts on the IMO discharge standard, and may not have the resources to start over.

One commenter requested that a size category for organisms less than 10 micrometers be added to the phase-two standard. Two commenters requested removing the phase-two standard for viruses due to the impracticability of treating for viruses and the difficulty of testing virus viability. One commenter stated there are no technologies, scientific methods, or protocols to differentiate between active versus inactive virus-like particles, which would make it impossible to measure the efficacy of BWMS in achieving the proposed phase-two standard for viruses.

Two commenters said that the phase-two standard should only allow for use of less stringent standards under temporary special exemption cases (e.g., vessel types or discharge characteristics) as determined by a technology review. One commenter suggested an interim measure like Michigan's BWM regulation, which identified specific treatment processes. The commenter believed that such an approach could be implemented across the Great Lakes more quickly than the proposed standards.

Three commenters stated that the phase-two standard should be delayed until instrumentation and methods are available to measure the capability of BWMS to meet the standard. One commenter stated that the phase-two standard is unnecessarily stringent for vessels that operate in the Great Lakes. One commenter stated that the phase-two standard should not have a defined value before the results of the practicability review are known.

One commenter opposed the phase-two standard for vessels that operate solely on the Great Lakes, arguing that the large volumes of treated water being discharged would essentially distill the Great Lakes of essential organisms necessary for aquatic health.

One commenter stated that one BWMS could meet multiple stringency standards by adjustment of its operational parameters, although this may depend on the treatment methodology of a particular system.

One commenter recommended that phase-two technologies should be based on conversions of the existing phase-one platforms.

As we have discussed in this preamble, this final rule only contains implementation requirements for the phase-one standard (*see* V.A. Summary of Changes from the NPRM). We are taking all of the comments we received on the phase-two standard into consideration as we begin the process of completing economic and environmental analyses for the phase-two standard, and will continue to consider these comments as we draft a notice or other rulemaking document addressing the phase-two standard.

Grandfather Period

Seven commenters opposed any grandfather period. Two of these commenters argued that vessels that install a phase-one system should not be exempt from the phase-two standard. One of these commenters requested that best available technology be required at all times, which would eliminate the use of a grandfather period.

One commenter stated that the grandfather period should be decreased from 5 to 3 years, whereas two commenters argued that 5 years was an appropriate grandfather period.

Fifteen commenters stated that 5 years was not long enough for a grandfather period. Twelve commenters stated that an installed BWMS should be grandfathered for the useful life of the vessel, and 10 commenters stated that BWMS should be grandfathered for the effective life of the system. Fourteen commenters stated that an installed BWMS should be grandfathered for the life of either the vessel or BWMS, whichever ends first.

One commenter stated that the grandfather period should be increased from 5 years to 10 years or the lifetime of the vessel, one commenter stated that it should be increased to 15 years, two commenters stated that it should be increased to 15 years or the life of the vessel, and one commenter stated that vessels should be given a specific date by which to upgrade once a phase-two standard is established.

As discussed in this preamble in V.A. Summary of Changes from the NPRM, the Coast Guard is not including the phase-two standard in this final rule. Because the final rule only includes the phase-one standard, we have omitted the grandfather provision that we proposed in the NPRM. We expect to reconsider the grandfather provision when we address the proposed phase-two standard or any standard higher than phase-one in a notice or other rulemaking document. We will keep these comments in mind as we develop that proposal.

Practicability Review

Thirty nine commenters supported a practicability review that is sufficiently robust and comprehensive to determine whether a BWDS more stringent than the phase-one standard is achievable. One of these commenters said that the review should be limited to the testing and certification requirements of the IMO BWM convention and guidelines. Six commenters recommended that the practicability review ensure that any phase-two standard is effective, measurable, technologically feasible, commercially available, safe, and cost-effective for use with the characteristics of the vessel.

One commenter said the regulation should contain an express statement that the Coast Guard will not make upward revisions of the treatment

standard unless it is economically reasonable to do so, and that we should include criteria for that determination. Another commenter said that if and when a BWMS can achieve the phase-two standard of 1,000 times more stringent than the IMO discharge standard, no further practicability reviews should be conducted with regard to achieving even higher standards.

Ten commenters said that a practicability review should be conducted for the phase-one standard as well. Twenty three commenters said that the reviews must verify there are BWMS that are suited to the volumes, flow rates, and engine room specifications of Great Lakes vessels before imposing the phase-one standard on these vessels.

Six commenters agreed with the proposed 3-year cycle for practicability reviews, seven recommended that the reviews be conducted on a continuous basis, three recommended that the reviews be conducted every year, one suggested a 3- to 5-year cycle, and three recommended a 5-year cycle.

Six commenters wanted a firm deadline for practicability reviews. Six others stated that the timing and scope should be accelerated from 2010 to 2012 to inform both the phase-two standard and the 2013 renewal of the EPA VGP.

Conversely, 19 commenters opposed any practicability review that could indefinitely delay implementation of the final standard, calling it a ''loophole.'' Eight of these commenters requested an electronic docket and public comment period before any final determinations based on practicability reviews are made. One commenter stated that moving the practicability review would not allow time for vessels with a 2014 compliance date to implement technology that meets the phase-two standard. Two commenters said there is no evidence presented in the NPRM or DPEIS to justify claims that the phase-two standard is not currently achievable, and therefore the practicability review is not necessary.

Three commenters requested a definition for ''practicability'' and for the inclusion of specific content and format of the review. One commenter said the rule should place an upper limit on how long the implementation date can be extended at any given time. One commenter stated that there should be a practicability review for vessels based on the type of vessel and the geographic route(s) it serves, (i.e., ocean-going service, inland waters, Great Lakes, near coastal, etc.).

As discussed in this preamble in V.A. Summary of Changes from the NPRM, because we have removed the phase-two standard from this final rule, we have also removed the recurring practicability reviews that were included in the NPRM. We expect that regular assessments, per NISA's ''[p]eriodic review and revision'' provisions, codified at 16 U.S.C. 4711(e), will be part of any future rulemaking process. This will address the scenario in which a finalized phase-two standard either cannot be implemented according to the established timelines, or can be implemented more quickly than the established timeline.

There is one practicability review provision included in this final rule that requires the Coast Guard to complete and publically publish the results of a practicability review no later than January 1, 2016. This review will draw a significant component of its information from the type-approval application packages that the Coast Guard expects to evaluate between this final rule's publication date and the initial implementation date. Further, the findings and recommendations of the EPA SAB study (EPA SAB 2011) will usefully inform the development of the practicability review. The Coast Guard will look at a variety of factors, including but not limited to the efficacy and environmental safety of available technology, and economic factors. While we have listed a number of these factors in the rule, there is a provision allowing for consideration of additional factors. We included this provision because of the possibility that the Coast Guard may discover additional factors that would be relevant to a decision on whether or not it is practicable to increase the stringency of the BWDS.

These changes address some of the comments summarized previously. We will continue to keep comments related to the recurring practicability reviews in mind as we develop a notice or other rulemaking document implementing the phase-two standard. While we have not included a practicability review prior to the implementation of the phase-one standard, we have included a provision to allow vessel owners and operators to request an extension of their compliance date if they cannot practicably comply with the compliance date otherwise applicable to their vessel. Summary information concerning all extension decisions, including the name of the vessel and vessel owner, the term of the extension, and the basis for the extension will be promptly posted on the U.S. Coast Guard Maritime Information Exchange Web site (CGMIX), currently located at [*http://cgmix.uscg.mil/Default.aspx*].

Implementation Schedule

One commenter was opposed to extending the phase-two deadline unless a future public comment period establishes that such an extension is necessary to allow for practicable implementation of the phase-two standard. Four commenters agreed with the proposed schedule for implementation of both the phase-one and the phase-two standards.

Eighty one commenters requested that the implementation schedule be changed in some way. Eleven commenters stated that a BWDS should take effect immediately, and one commenter said it should be implemented in 1 year. One commenter said the phase-two standard should take effect immediately, while another said that 3 to 5 years is plenty of time. Three commenters stated that the phase-two standard should take effect by 2012 and one said it should take effect by 2016. Three commenters opposed reliance on drydocking schedules in favor of hard deadlines for compliance, unless justified by vessel-specific engineering constraints or lack of availability.

One commenter stated that existing vessels should be required to schedule their first drydocking by 2012, and to comply with the phase-one standard by 2014 unless the practicability review deems that deadline unattainable. One commenter suggested installation at the first dry dock after 2014. Two others suggested that a more appropriate timeline for all new and existing vessels would be 2012 or 2014, respectively.

Thirty three commenters said that the phase-one standard should be implemented by 2012 and the phase-two standard by 2016. Another commenter agreed with this schedule but with a more stringent phase-one standard. One commenter supported a phase-one standard 100 times more stringent than the Coast Guard's proposal by 2012 and a phase-two standard 1,000 times more stringent than phase one by 2016.

Two commenters considered the schedule for implementation of the proposed regulations to be too protracted, and called for implementation of the phase-two standard at an earlier date than proposed. These organizations did not support allowing shipowners so much time between the implementation date and their first scheduled drydock.

Conversely, 26 commenters requested that the implementation schedule be lengthened or allow more flexibility for vessel types or specific geographic areas. Thirteen commenters said that the dates should be delayed until

compatible BWMS are commercially available for their vessels and to accommodate standard drydocking cycles of twice in 5 years. One commenter said that vessels traveling to specific areas such as the Great Lakes could comply with the 2014 date, but did not think this was a realistic option to apply to vessels in all waters of the United States.

One commenter stated that the proposed schedule does not allow enough time for vendors to develop BWMS capable of meeting the phase-two standard, particularly since methods and facilities capable of testing to the phase-two standard will need to be available in order to develop such systems.

One commenter stated that vessels confined to the Great Lakes will not have sufficient shipyard availability to install equipment to meet the BWDS on the proposed schedule. Four commenters stated that some vessels operating in the Great Lakes have very short voyages (on the order of hours). If BWMS available for such vessels are limited to chemical systems with required minimum treatment times longer than the voyages, then significant delays will occur in the transportation chain. Two industry associations commented that the proposed schedule was not feasible due to a lack of available BWMS and a shortage of shipyard capacity for installation.

The Coast Guard considered these comments. First, to accommodate the implementation of the final rule in relation to delays encountered in the rulemaking process, the Coast Guard has revised the implementation schedule for the phase-one standard at 33 CFR 151.1512(b) and 151.2035(b) to provide new vessels the 2 years for implementation as presented in the 2009 proposed rule. Addressing concerns with the schedule more generally, while we agree with those commenters who would like to see a requirement that BWMS be installed on vessels as soon as possible, it is important to consider several factors that impact the timeline during which approved BWMS can be expected to be installed. These include the time required for the United States to implement a BWMS approval process, for manufacturers to establish production capacity, and for vessel owners to acquire and install BWMS within their vessels' normal operational and maintenance schedules. As a result, there will likely not be an adequate number of approved BWMS to allow for acceleration of the implementation schedule in the 2009 proposed rule. Phase-two and its implementation schedule are not addressed in this final rule. As discussed in the ''Summary of Changes from the NPRM'' section above, the Coast Guard will develop additional analyses regarding the potential costs, benefits, and environmental impacts of the proposed phase-two standard or any standard higher than phase-one and intends to address the issue in subsequent rulemaking document.

Language Clarification/Technical Change

One commenter requested that the proposed BWDS include language necessary for differentiation between living and nonliving organisms. Another said that the standard should allow for the presence of nonliving organisms since some treatment technologies act to kill living organisms without necessarily removing them from the ballast water.

The Coast Guard acknowledges that the proposed BWDS is slightly different in this respect from the IMO discharge standard, which uses the term ''viable'' instead of ''living.'' It is important to note that, while the text of the IMO BWM Convention refers to ''viable'' organisms, the G8 guidelines define ''viable'' as ''living.'' Therefore, the Coast Guard has decided that this issue is best addressed in the BWMS approval process, and will not alter the standard as suggested by these commenters. We note that the standard and approval process do allow for the presence of nonliving organisms. Additionally, we corrected a technical error present in the NPRM, which mistakenly omitted the term ''living'' from the proposed 33 CFR 151.1511(a). This final rule corrects that omission.

One commenter requested an addition to the BWM requirements in 33 CFR 151.2025(a)(1) that would read ''(i) Unless 151.2040(b) allows otherwise, the BWMS must be used prior to any discharge of ballast water to waters of the U.S. (ii) All treatment must be conducted in accordance with the BWMS manufacturer's instructions and standard of performance approved by the Coast Guard.''

The Coast Guard disagrees that this addition is necessary. Vessel owners/operators must comply with the BWDS for all ballast water discharged following treatment with a BWMS, and follow the manufacturer's Operation, Maintenance, and Safety Manual to maintain their systems in proper working order.

One commenter asked that a definition be provided for ''regular'' and ''regularly,'' as those terms are used in 33 CFR 151.2050, which requires vessels owners or operators to clean their ballast tanks regularly to remove sediments and to remove fouling organisms from hull, piping, and tanks on a regular basis. The Coast Guard disagrees, and believes that there should be some flexibility to schedule these activities according to a vessel's specific circumstances.

One commenter believes that portions of 33 CFR 151.2050 (additional requirements) are intended to be discretionary rather than mandatory, and should be separate categories. The Coast Guard disagrees. The Coast Guard included the term ''minimize or avoid'' in 33 CFR 151.2050(b) to ensure that vessel owners and operators always consider these additional requirements, while allowing some flexibility according to a vessel's specific circumstances.

One commenter suggested adding a definition for ''test report'' at 46 CFR 162.060–3, as the term is used in multiple places. The Coast Guard disagrees, as the Test Report is described in 46 CFR 162.060–34.

One commenter suggested revising the proposed definition for ''hazardous location'' found in 46 CFR 162.060–3. The Coast Guard agrees and revised the definition.

One commenter suggested requiring contact information, in addition to manufacturer's name, in 46 CFR 162.060–10(a)(1). This commenter also suggested that the phrase ''Name and type of BWMS'' in 46 CFR 162.060–10(a)(3) be revised to also require the mode of action or other information. The Coast Guard partially agrees; we have added a requirement for point of contact information for the manufacturer to 46 CFR 162.060–10. However, we have not made the requested change to 46 CFR 162.060–10(a)(3), as we believe this is already reflected in the existing text.

One commenter asked that the phrase ''novel processes'' in 46 CFR 162.060–10(e) be defined. The Coast Guard disagrees, because it does not wish to preclude any innovative approaches in BWMS.

One commenter asked whether the IL or manufacturer is required to submit the Test Report to the Coast Guard Marine Safety Center (MSC) as part of the approval process. The Coast Guard approval process places responsibility on the manufacturer to submit all necessary materials to the MSC, however, it is acceptable if the IL submits the report directly to the MSC.

One commenter was unsure what types of approvals are required under 46 CFR 162.060–14(a)(7), such as those from U.S. agencies, foreign administrations, classification societies,

and other organizations. The Coast Guard's response is that 46 CFR 162.060–14(a)(7) pertains to approval of BWMS using active substances, and that manufacturers are responsible for obtaining all required approvals external to the Coast Guard's approval process. We anticipate issuing guidance documents to aid manufacturers in complying with the approval process.

One commenter noted what appeared to be conflicting information as to exactly which vessels this rule would apply to and whether all vessels would be required to install BWMS. The Coast Guard responds that these are separate but related questions. First, 33 CFR 151.1502 in the existing regulations and 33 CFR 151.2010 (Applicability) of this final rule describe which vessels will be required to comply with 33 CFR part 151 subparts C and D, or subsections of them. This is a broad description, as many vessels not required to install a BWMS will need to comply with other requirements in 33 CFR part 151 subpart D, such as recordkeeping requirements. Several groups of vessels are exempted from BWM requirements under § 151.2015.

Secondly, 33 CFR 151.2025 (BWM requirements) of the final rule identifies which vessels must install a BWMS that complies with the BWDS, or manage their ballast water in another one of the methods listed in that section.

One commenter requested clarification of the requirement ''Records any bypass of the BWMS'' at 46 CFR 162.060–20(b)(5). The commenter noted that not all BWMS will be able to do this, as some bypasses may be achievable using systems or components that are outside of the BWMS. The Coast Guard agrees and has removed this provision.

Management Requirements

Two commenters suggested that the practicability of on-shore or vessel/barge-based ballast water treatment be explored. The Coast Guard encourages the development of alternative treatment methods that would allow some vessels to manage their ballast water without having to install a BWMS. The phase-one standard in this final rule will only apply to vessels that discharge ballast water into waters of the United States. Vessel owner/operators discharging ballast water to a facility onshore or to another vessel must ensure that all vessel piping and supporting infrastructure up to the last manifold or valve immediately before the dock manifold connection of the receiving facility or similar appurtenance on a reception vessel prevents untreated ballast water from being discharged into waters of the U.S.

Once Ballast water is pumped to an on shore treatment facility or a treatment vessel it would not be subject to 33 CFR part 151 subpart C or D. However, under the CWA any resulting discharges from these on-shore treatment facilities or treatment vessels are subject to the National Pollutant Discharge Elimination System (NPDES) program. Companies that intend to provide these services will be responsible for complying with these and other local, state, and Federal laws and regulations.

One commenter suggested requiring BWMS in addition to, rather than instead of, existing BWE requirements for ocean going vessels entering the Great Lakes-St. Lawrence Seaway system. The Coast Guard disagrees. Requiring both BWE and BWMS for oceangoing vessels entering the Great Lakes was not proposed in the NPRM and therefore beyond the scope of this rulemaking.

One commenter stated that the allowance of BWE under the phase-one standard is inconsistent with the goal of minimizing NIS introductions and should be eliminated as an option. The Coast Guard agrees that BWE should be eliminated as an option as soon as possible. The primary purpose of NANPCA, as amended by NISA, is to ''prevent the unintentional introduction and dispersal of nonindigenous species into waters of the United States through ballast water management and other requirements.'' 16 U.S.C. 4701(b). Permitting BWE to remain as a permissible management technique in light of other, more protective methods, would frustrate this clearly articulated statutory purpose and lead to an absurd result. *See Griffin* v. *Oceanic Contractors, Inc.,* 458 U.S. 564, 575, 102 S.Ct. 3245 (1982) (statutory interpretations ''which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available.'') The Coast Guard is thus phasing out BWE as a BWM method in favor of more protective methods to best prevent the introduction and spread of NIS into waters of the U.S. consistent with this statutory purpose.

We also believe that existing vessels should be given a reasonable period of time to come into compliance with the phase-one standard, and that BWE should continue as a viable BWM alternative for a vessel until the phase-one standard applies to that vessel. However, we note that once a vessel is required to comply with the phase-one standard, BWE will no longer be an acceptable routine management method.

One commenter noted the U.S. Administration's goal of expanding coastwise or short-sea shipping, and requested that BWE be added as a management option for these vessels. The Coast Guard notes that its existing regulations do not require coastwise vessels to conduct BWE unless their voyage takes them more than 200 nautical miles from any shore. For the final rule, we have revised 33 CFR 151.2015 to exempt certain vessels from the BWM requirements and 33 CFR 151.2025 to provide additional BWM options besides installing BWMS. These changes are discussed above under the heading ''Applicability.''

One commenter suggested retaining BWE for all vessels when practicable, requiring a combination of best available technology and BWE to improve BWMS performance, and requiring BWE as a minimal treatment in case the BWMS fails. Another suggested the addition of rules requiring BWE 50 nautical miles outside the continental baseline for vessels conducting coastal voyages, implementation of a BWE verification system, and allowance of BWE within 200 nautical miles when a safety exemption would otherwise allow un-exchanged water to be discharged at a State port. The Coast Guard disagrees, and believes that phasing out BWE in favor of the BWM requirements in this final rule will be at least as effective as BWE to prevent the introduction of NIS into the waters of the United States. The Coast Guard notes that under 33 CFR 151.2040(b), the COTP may allow the vessel to conduct BWE as a management option if the BWMS fails to operate or the vessel's BWM method is unexpectedly unavailable.

Preamble Text

One commenter disagreed with the statement in the NPRM that ''The effectiveness of BWE is highly variable, largely depending on the specific vessel and voyage'' (74 FR 44663). The commenter added that the Great Lakes Seaway Ballast Water Working Group's strict enforcement of BWE requirements in the St. Lawrence Seaway is the main reason that there have been no reports of the establishment of invasive species on the Great Lakes since 2006.

The Coast Guard acknowledges the bi-national success in achieving high rates of regulatory compliance with existing BWE requirements. However, we do not have evidence that this successful enforcement necessarily proves the effectiveness of BWE, as there are also other regulations and requirements

being enforced for vessels entering the St. Lawrence Seaway.

Enforcement

Seventeen submitters commented on how the Coast Guard intends to enforce the BWDS.

Three commenters said there should be significant financial penalties to provide incentives for industry to meet implementation deadlines. The Coast Guard notes that the existing civil and criminal penalties for 33 CFR part 151 subparts C and D are established by statute and were not changed in the NPRM. They may now be found at 33 CFR 151.2080 of the final rule. After publication of the NPRM, in a separate action, the Coast Guard made an adjustment to the civil penalty tables found at 33 CFR 27.3. (75 FR 36273, 36278 (June 25, 2010)).

Five commenters stated that the numeric discharge standard would impose significant problems for compliance enforcement, particularly when results need to be legally acceptable, because sufficient techniques or equipment are not currently available to test ballast water on the spot. The Coast Guard disagrees, and believes that setting a practicable, numeric BWDS such as this final rule's BWDS, combined with type approval of BWMS, will facilitate compliance enforcement.

Another commenter said that a phase-two standard 1,000 times more stringent than the phase-one standard will be virtually impossible to enforce, and will significantly increase enforcement costs, and possibly increase downtime for inspected vessels. The Coast Guard agrees that implementation of the phase-two standard at this time could be impracticable for several reasons, including enforcement, as suggested by the commenter.

Two commenters requested that a rigorous enforcement, inspection, and monitoring program be developed to determine compliance, similar to that currently being performed by the bi-national Great Lakes Seaway Ballast Water Working Group for all vessels entering the St. Lawrence Seaway. Three commenters requested routine or random testing of the contents of a vessel's ballast tanks and ballast water discharge. One commenter said this testing would be especially important for oceangoing vessels that would discharge treated ballast water into freshwater. Two commenters suggested testing for total residual oxidants in ballast water as a way to determine the completion of chemical treatment, and installing onboard sensors in vessels' ballast tanks to measure chemical levels.

Four commenters asked about port state control requirements. One commenter requested that a limit of once in any calendar year must be imposed on the number of times that a vessel can be tested to determine whether its BWMS is working properly, and that onboard sensor data or the captain's signed and sworn certification transmitted to the port state authority should be sufficient. Another commenter said that vessel-based BWMS would not enable the port state authority to monitor ballast water. Two commenters stated that proper and effective sampling and test protocols, as well as required facilities and proficiency, still need to be established. One commenter requested specific information indicating how the BWDS will be enforced after implementation.

The Coast Guard believes that the approval process for BWMS, found in 46 CFR part 162.060 of this final rule, will provide a strong basis from which enforcement actions can proceed based on review of the records required to be kept on the vessel. These reviews will occur during port and flag state control exams. We acknowledge that compliance exam procedures for BWMS will be an important component of enforcement, and such procedures are under development. As discussed in the Summary of Changes section above, we have added a provision requiring sampling ports in order to facilitate enforcement of the BWDS.

Reporting and Recordkeeping

One commenter requested that the Ballast Water Reporting Form and reporting and recordkeeping requirements be revised to accommodate all of the proposed BWM methods in advance of the phase-one standard taking effect. The Coast Guard agrees, and will propose revisions to the Ballast Water Reporting Form and instructions either through a separate rulemaking project or in conjunction with the next scheduled renewal of the collection by OMB.

One commenter said the NBIC should be given regular dates for reporting information that they obtain from submitted reports. The Coast Guard notes that the NBIC already provides database information to the public through its Web site. As more vessels use electronic reporting, the NBIC is reducing delays in updating that Web site.

3. BWMS

General

Two commenters addressed the safety exception in 33 CFR 151.2045. The first commenter recommended that ''vessel design limitations'' should not be considered an ''extraordinary condition'' under which a master or person in charge of a vessel would be exempt from the requirement to use a BWM practice, including BWE, under certain circumstances. The second commenter supported the inclusion of the exception and interpreted it as allowing the discharge of ballast water that fails to meet the BWDS under emergency circumstances.

The Coast Guard believes that they may have misunderstood this provision. Under NISA, masters or persons in charge of vessels are not required to conduct BWE if the practice would be unsafe due to weather or vessel design. 16 U.S.C. 4701(k)(1). We have included this provision in the regulation, and it is an allowable exception to BWE only as long as a vessel is allowed to use BWE. Additionally, we have removed proposed 33 CFR 151.2045 Safety exceptions, as we determined that it was largely repetitive to what was proposed in 33 CFR 151.2040 Discharge of ballast water in extraordinary circumstances. We moved the one non-repetitive provision to § 151.2040. As a result, § 151.2040 now includes the provision noting that nothing in the regulations relieves the master, owner, agent, or person in charge of the vessel from any responsibility, including the safety and stability of the vessel and the safety of the crew and passengers.

Once a vessel is required to meet the BWDS, the general safety provision in § 151.2040 no longer applies. If the master or person in charge of the vessel determines that operation of the BWMS would endanger the vessel for some reason, the master or person in charge must inform the COTP, prior to the vessel's arrival, that BWM has not been conducted due to safety reasons. The COTP will evaluate the situation and direct the vessel accordingly.

One commenter considered the BWMS design and construction requirements to be onerous and likely to result in systems being overly complicated and expensive. The commenter called for the Coast Guard to approve the use of very simple approaches, such as manually pouring additives into tanks. The Coast Guard disagrees, and believes that all BWMS must be carefully designed, constructed, and approved to protect the vessel, the crew and passengers, and the environment. With respect to the example, treatment of ballast water using chemicals designed to kill organisms has the potential to adversely affect the safety of the vessel, the crew and passengers, and the environment if

the chemicals and the manner of their use are not carefully evaluated in advance and controlled and managed during use of the system.

Seven commenters stated that there were serious constraints on the feasibility of installing BWMS that require electrical service on tank barges and tank ships. Several commenters cited Coast Guard regulations for electrical equipment as an impediment to such installation (46 CFR 111.105–31(1)). Likewise, six vessel owners asserted that safety and regulatory requirements prohibit the installation on tank barges of BWMS that use electricity.

The Coast Guard agrees that electrical requirements included in 46 CFR subpart 162.060 may make installation of BWMS more complicated on certain vessels. However, if these requirements make it impossible for a vessel owner to safely install a BWMS, they should qualify for an extension of the compliance date, per 33 CFR 151.1513 or 151.2036. An extension would provide additional time to determine how BWMS can be safely installed. An extension would postpone installation costs for affected vessels. Data is unavailable on the number of vessels that would require extensions. We have not estimated the quantitative impacts of extensions.

One commenter proposed that the Coast Guard should require best available technology and BWE as an interim measure if compliant BWMS are not available by the implementation dates. The Coast Guard disagrees that best available technology and BWE together should be considered the de facto acceptable method of compliance. The Coast Guard considers establishing a practicable and protective BWDS to be the best approach for preventing the introduction of NIS by the wide array of vessels that must discharge ballast water for safe operation.

The Coast Guard believes that BWMS meeting the phase-one BWDS will generally be available in time for vessel owners and operators to comply with the implementation schedule in this final rule. For those cases where this is not so, we have provided a provision in the regulation that allows a master, owner, operator, agent, or person in charge of a vessel to apply for an extension of the compliance date.

One commenter asserted that BWE is sufficiently protective in preventing introductions of invasive species. This commenter also suggested that BWE should be an acceptable method of BWM if a vessel can demonstrate through sampling and analysis that BWE can meet the BWDS. Two commenters asserted that BWE is sufficiently protective in preventing invasive species introductions to the Great Lakes. These commenters further suggested that BWE should be an acceptable method of BWM for vessels entering the Great Lakes.

The Coast Guard disagrees that BWE is sufficiently protective against introductions of invasive species. Vessels are not always able to conduct BWE. While BWE has undoubtedly reduced the risk of introductions compared to no BWM at all, the inherent variability in the efficacy of BWE among vessels and even within vessels argues for the consistent application of more effective BWM practices. Additionally, as vessels on coastwise voyages are not required to conduct BWE under Coast Guard regulations, a BWMS is also necessary to ensure the prevention of the spread, and not just the introduction, of NIS.

One commenter questioned whether BWMS will effectively remove all contaminants in ballast water and asserted that onboard treatment will not be a viable option until that is the case. The commenter suggested that, as an alternative, vessels could use multiple systems to address all contaminants. The Coast Guard appreciates the commenter's concerns, but disagrees that a BWMS required under this rule will have to remove all potential contaminants in ballast water. NANPCA, as amended by NISA, requires the Coast Guard to ensure, to the maximum extent practicable, introductions of NIS are not discharged into the waters of the United States from vessels, and does not pertain to vessel discharges outside of that threat. The statute also requires that certain methods of BWM used instead of BWE must be environmentally sound. By requiring such systems to meet applicable EPA requirements related to treatment chemicals and their disinfection by-products prior to discharge, the Coast Guard will help ensure that treatment of ballast water does not result in adverse environmental consequences. The issue of non-organism contaminants in ballast water is also addressed under the EPA VGP. By requiring BWMS to meet all applicable EPA requirements prior to type approval, the Coast Guard will help ensure that treatment of ballast water does not create adverse consequences.

One commenter questioned whether onboard treatment is the best approach, given that IMO approval of BWMS is proceeding slowly. The Coast Guard disagrees that the pace of BWMS type approval under the IMO BWM Convention is proceeding slowly. In fact, we note that foreign type-approved systems are available.

One commenter questioned whether onboard systems were the best approach for preventing the discharge of organisms and noted that, unless a vessel is fitted with a backup system, the failure of the onboard treatment system could result in the discharge of untreated ballast. The Coast Guard notes that the rule has been revised to clarify that vessel owners and operators have a range of options for BWM, including use of BWMS, retention onboard, discharge to a shoreside treatment facility, or use of a U.S. PWS meeting Safe Drinking Water Act standards. We also note that the regulation requires BWMS to signal an alert if there is a failure and for vessel owners to report failures of the BWMS to the COTP at their place of destination. In such a situation, the COTP may require the vessel to perform alternative BWM practices before allowing the discharge of the ballast water.

Active Substances or Chemicals

One commenter asserted that many currently available BWMS use chemicals, and that these BWMS may result in contamination of ballasted fish holds. The commenter further stated that the proposed regulation must include exemptions for this circumstance. The Coast Guard agrees that chemical contamination of ballasted fish holds may be a problem with the use of a chemically-based BWMS. However, the Coast Guard is aware of several systems that do not use chemicals, and believes that owners and operators of fishing vessels will have sufficient options for meeting the BWDS (e.g., ultraviolet/filtration). For those fishing vessels that cannot install a BWMS onboard, we have provided a provision in the regulation that allows a master, owner, operator, agent, or person in charge of a vessel to apply for an extension of the compliance date if they can document that, despite all efforts to meet the BWDS requirements, compliance by that deadline is not possible.

Three commenters called for clarification as to how the regulations proposed in the NPRM would prevent the discharge of harmful active substances resulting from the use of BWMS. The Coast Guard agrees that the use of chemicals such as biocides to treat ballast water creates the potential for unwanted discharges of such chemicals. All systems using chemicals must be registered by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as applicable, prior to consideration by the Coast

Guard for type approval. Discharges from vessels with systems using non-pesticide chemicals (or pesticides that are generated solely by the use of a device onboard the same vessel as the ballast water to be treated) will be covered under the EPA VGP, which contains requirements to meet discharge limits established by EPA for residuals and by-products of chemicals used in ballast water treatment. All chemicals used in BWMS requiring FIFRA registration will be registered with EPA prior to applying for Coast Guard type-approval of the BWMS. One commenter encouraged the Coast Guard to allow treatment of ballast water with biocides to address specific species on specific routes within the Great Lakes as an alternative method of compliance. The Coast Guard appreciates this commenter's input, but disagrees with the proposed approach. The identification, with appropriate specificity, of the location and identity of every infestation within the Great Lakes is not feasible, nor is the identification of the appropriate biocide for each specific species. The Coast Guard has determined that the most protective approach is to require the uniform treatment of ballast water to reduce concentrations of all organisms prior to discharge.

Alternatives to BWMS

Thirteen commenters disagreed with the requirement for all applicable vessels to install BWMS, and called for the Coast Guard to allow vessels the flexibility to use other approaches, such as discharging to receiving vessels or to shoreside facilities. The Coast Guard agrees. As discussed previously regarding the comments dealing with applicability, we have revised our regulation to clarify that only vessels discharging ballast water into waters of the United States are required to comply with the BWDS requirements at 33 CFR 151.1510 and 151.2025 of this final rule. However, the dependence of the vessel on the availability of appropriate reception facilities must be identified in the vessel's BWM plan, along with the alternative management practices that will be used if and when discharge to a reception facility is not possible. Further, the lack of availability of adequate reception facilities is not an acceptable reason for discharge of ballast water that does not meet the BWDS into the waters of the United States, and such a discharge will constitute a violation of this regulation.

One commenter stated that vessels should be required to discharge to a shore-side treatment facility prior to entering the Great Lakes. The Coast Guard disagrees that vessels should be required to discharge to a shore-side facility. The Coast Guard believes it is important that vessels have the flexibility to select the BWM practice that makes the most sense for their specific circumstances. If vessel owners and operators want to have the option of discharging to shore and sufficient market exists for such an option, then it is likely that such facilities will be created.

One commenter stated that it may not be technically or economically feasible for a vessel owner to retrofit existing vessels with an approved BWMS, and recommended that the Coast Guard allow other BWM options under such circumstances. As described in 33 CFR 151.2025 and 151.2026, ballast water management practices other than use of a Coast Guard-approved BWMS will be allowed.

Additionally, vessels will have the options of discharging to a shoreside treatment facility or receiving vessel, if available, or retaining ballast water onboard. The Coast Guard will evaluate claims that BWMS and other allowed BWM practices are not available for specific vessels and potentially extend the compliance date for those vessels.

Foreign Type Approvals

Eleven commenters discussed the Coast Guard's proposed provision for the acceptance of foreign type approvals of BWMS. Four of the commenters supported the Coast Guard's proposal that such acceptance should be granted only when the foreign procedures are equivalent to those of the Coast Guard. Conversely, six of the commenters stated that the Coast Guard should accept foreign type-approvals without verifying equivalency of testing protocols.

The Coast Guard's approval process is intended to provide a level of assurance that a BWMS is likely to work consistently, effectively (i.e., meet the BWDS), and safely under shipboard conditions. Testing conducted with insufficient rigor or under substantially less challenging conditions will not provide that assurance. The Coast Guard retains the prerogative to verify the equivalency of foreign type-approval procedures before accepting such approvals.

One commenter stated that since the phase-one BWDS is equivalent to the IMO discharge standard, the Coast Guard must consider the protocol in the G8 guidelines to be sufficiently strict. The Coast Guard disagrees, and will assess each foreign administration's type-approval procedures, including test protocols and quality assurance practices, to determine whether the performance assessment conducted by the foreign administration is equivalent to that of the Coast Guard and complies with applicable U.S. domestic laws. We will evaluate, in accordance with the standards in the revised 46 CFR 162.060, the data and supporting information in approval applications submitted by manufacturers whose BWMS have received foreign type approval. We will not grant U.S. type approval to BWMS approved by foreign administrations based on approval procedures that are substantively less rigorous than the U.S. approval testing without additional testing as necessary and appropriate for the specific circumstance.

The Coast Guard recognizes some time will elapse between the publication of this final rule and the availability of U.S. approved BWMS. The Coast Guard believes that ballast water discharged into waters of the United States should undergo some type of treatment designed to reduce the risk of ballast water spreading NIS at the earliest possible date, particularly for those vessels currently unable to conduct BWE, as we believe this will provide greater reduction in the risk of NIS being introduced or spread via ballast water. Therefore, we have added a provision to the final rule to allow for a temporary acceptance of a foreign administration's approval if it can be shown that the foreign-approved BWMS is at least as effective as BWE. This temporary acceptance will be granted for 5 years from the date when the vessel on which the BWMS is installed is required to comply with the BWDS.

Two commenters requested that the rule include more details about the procedures the Coast Guard will follow to make determinations regarding the acceptance of foreign type approvals. The Coast Guard agrees and has made changes to 46 CFR 162.060–12, which are discussed in the Summary of Changes section above. The Coast Guard expects to examine each foreign administration's type-approval report, which should include the testing protocols used and the testing results, and then make a determination as to whether the procedures and criteria used were essentially equivalent in rigor and challenge to those of the Coast Guard. Additionally, in order to grant U.S. type approval or the temporary acceptance (as an AMS), the Coast Guard must comply with NEPA and other applicable environmental laws.

One of the commenters suggested that the Coast Guard use an advisory panel of independent scientists and agency representatives to conduct the

equivalency determinations for foreign administration's type-approval programs. The Coast Guard will make use of appropriate expertise in reviewing proposals for acceptance of foreign type approvals, including, when necessary, consultation with other agencies and outside experts.

One commenter referenced the text in the NPRM preamble that states: ''Under today's proposal, foreign vessels equipped with and operating a BWMS that has been approved by a foreign administration would be allowed to use the BWMS for discharging ballast water into U.S. waters if the Coast Guard determines that the foreign administration's approval process is equivalent to the Coast Guard's approval process, the BWMS otherwise meets the requirements of this proposed rule, and the resulting discharge into waters of the U.S. meets the applicable (i.e., phase-one or phase-two) proposed discharge standard.'' The commenter suggested that this text be changed to replace ''foreign vessel'' with ''vessel,'' so that U.S.-flagged ships which currently have installed BWMS that have been type approved by a foreign administration under the specified conditions would be acceptable.

The Coast Guard has clarified the procedures in 46 CFR 162.060–12 which allow manufacturers of foreign type-approved BWMS to submit data developed during the foreign type-approval testing to support the submission of an application pursuant to 46 CFR 162.060–14. The Coast Guard will evaluate the application and determine if U.S. type approval will be granted. If U.S. type approval is granted, the BWMS can be installed and used on U.S. and foreign flagged vessels.

Availability of BWMS

One commenter stated that it is unlikely that any systems have documented test results to demonstrate compliance with a standard that is 100 or 1,000 times stricter than phase-one. The Coast Guard agrees that no sufficiently credible documentation exists of BWMS able to meet concentrations 100 or 1,000 times more stringent than the proposed phase-one standard. The Coast Guard notes that the EPA SAB came to the same conclusion in its recent report (EPA SAB 2011).

Two commenters stated that BWMS that can meet the Coast Guard's proposed BWDS are available now. The Coast Guard agrees that technologies capable of meeting the phase-one BWDS will be available for installation on applicable vessels on the required implementation schedule. We do not, however, agree that there is a currently available BWMS that has been shown to meet the phase-two BWDS.

In response to the Coast Guard's question, ''Are there technology systems that can be scalable or modified to meet multiple stringency standards after being installed?'' one commenter stated that technology is available, pending adjustments, for ''Lakers,'' vessels operating solely on the Great Lakes. The Coast Guard notes that our question specifically asked for quantitative information on technologies, necessary modifications, costs, and sources of such information. The comment did not include quantitative information. Therefore, we are unable to validate this claim.

One State government agency stated that the availability of technology that meets the phase-two standard is demonstrated by the findings of the CSLC report on BWM technologies. This report concluded that at least seven commercially available BWMS had demonstrated the capability to comply with California's performance standards.

The Coast Guard disagrees. In the CSLC 2010 report on the availability of technology to meet California requirements, the State Lands Commission acknowledged the limitations of testing data and clarified that the Commission's analysis determines whether or not systems have demonstrated the potential to comply with California's standards. (CSLC Sept 2010). The ''potential to comply'' determination was based on whether the reported efficacy data for the systems examined indicated that at least one test (averaged across replicates) met California's standards for every testable organism size class during either land-based or shipboard testing.

It is important to recognize that California's phase 2 discharge standard for organisms greater than 50 micrometers (one millionth of a meter, μm) is ''no detectable living organisms,'' and is not defined by a specific volumetric concentration (i.e., California's phase 2 discharge standard is not equivalent to a concentration 1,000 times smaller than the IMO standard, or to any other standard expressed as a concentration). In its report, the Commission concluded ''Thus, California's standard for this organism size class is not directly comparable to the IMO or standards proposed by other entities evaluated by these reports.''

Because of the difficulties of testing treatment technologies to meet standards more stringent than the IMO's, the Commission convened its Ballast Water Treatment Technology Technical Advisory Panel, which recommended that the best option for California was to maintain the ''no detectable organisms'' standard for larger organisms, and develop and adopt compliance verification protocols. At this point, it is not known what those protocols, or their detection limits, will be, but is instructive that the EPA SAB concluded that ''* * * current test methods and detection limits preclude a complete statistical assessment of whether a BWMS meets any standard more stringent than Phase 1.''

One commenter questioned whether a BWMS will be available to allow the industry to meet the BWM requirements on the schedule proposed in the NPRM. As discussed elsewhere in this preamble, the Coast Guard has made changes to the applicability in order to address this very question. We have also delayed the initial compliance date for new vessels by 2 years to provide time for the U.S. type-approval process to be implemented. It is our belief that there will be suitable BWMS on the market for those vessels required to comply with the BWDS in this final rule. The companies bringing BWMS to the market include many with international supply and service networks. Further, existing information indicates that not all BWMS will need to be installed in drydock or even while the vessel is out of service. However, to address the situation where, through no fault of their own, a vessel owner cannot install a BWMS on time, we have also included a provision allowing the Coast Guard to extend that particular vessel's compliance date.

One commenter stated that treatment technology is not available for barges with large ballast water capacity. The Coast Guard neither agrees nor disagrees with this comment. We recognize that some vessels will present challenges due to the specific nature of their design and operations. We have made adjustments to this final rule's applicability and implementation timeline to allow the Coast Guard to deal with these challenges either on a one-on-one basis (as with a request for an extension of compliance) or up front en masse (as with the removal of certain vessels from the BWDS applicability).

One commenter stated that the design of some vessels is not appropriate for current approaches to BWM and proposed that technical feasibility be taken into account. The commenter specifically referenced the lack of electrical power and personnel available to operate BWMS onboard unmanned, unpowered barges. The Coast Guard agrees that technical feasibility is an

important consideration, and has included it as one of many factors that must be considered during the Coast Guard's practicability review. Two commenters asserted that the installation of BWMS on their vessels would not be economically feasible, but did not provide any additional data. Given the issues raised by these and other commenters, the Coast Guard has revised the applicability of the BWDS rule. The Coast Guard is publishing this final rule to apply the phase-one BWDS only to the following vessels discharging ballast water into water of the United States: vessels entering waters of the United States from outside the EEZ, and those seagoing vessels that operate in more than one COTP Zone and are greater than 1,600 GRT (3,000 GT (ITC)). The Coast Guard has determined that additional analysis is needed before expanding the applicability in this final rule.

Additionally, the Coast Guard has decided the BWM requirements will not include vessels that operate solely in inland waters. The Coast Guard fully intends to expand the BWDS rule to all vessels, as noted in the final rule preamble section V.A. Summary of Changes from the NPRM, but has determined that additional analysis is necessary to support this expansion. We also intend to conduct additional research as necessary.

Eight commenters stated that they were unaware of any available BWMS designed for vessels operating exclusively in freshwater. The Coast Guard disagrees, as there are several BWMS currently on the market or advancing through approval procedures in other countries that are based on treatment processes that function independently of salinity, such as filtration and ultraviolet radiation (UV). Many BWMS using active substances, particularly electrolytic chlorination, can work effectively in freshwater if provided an appropriate source of ions such as seawater or brine held in a tank. While it still remains for these systems to be approved by the Coast Guard, the fact that they are being approved by other countries in accordance with the standards set forth in the IMO BWM Convention for use in meeting a standard equivalent to the phase-one standard indicates there are likely to be BWMS that will be effective when used on vessels that operate exclusively in freshwater.

One commenter stated that BWMS are available that are capable of treating small volumes and flow rates and would fit in vessels with low space availability. The Coast Guard notes this information.

Funding Issues

One commenter stated that it is incumbent on the Coast Guard and Canadian agencies to cooperatively assist companies to design and market BWMS that may need to be unique to the Great Lakes. The Coast Guard disagrees that the government of the United States, either alone or in cooperation with Canada, must assist companies to design and market BWMS beyond encouraging such actions through the establishment a BWDS.

Two commenters asserted that provision of adequate funding is necessary to facilitate the development of technology for treating ballast water and for implementation of the proposed regulation. The availability of funding for either development of technology or implementation of this final rule is outside the scope of this rule.

Four commenters stated that this regulation should include provisions for BWMS testing and application fees to support testing and review processes within Federal agencies and ILs. One submitter commented that there is a need for increased research and development funding for testing and development of BWM technologies. The Coast Guard disagrees that the rule should specify fees for testing and application review. Costs of testing will be determined by the ILs.

Specific BWMS Requirements

One commenter stated that the requirement for the BWMS to retain records of operation for 24 months is excessive and will result in significant additional costs. The commenter proposed instead that the period of record retention in the BWMS be reduced to 6 months, and that data older than that be acceptable if retained on disks. The Coast Guard agrees this would be more efficient and has clarified requirements for record retention to allow for electronic data collection in lieu of a hard copy by revising 46 CFR 162.060–20(b)(5) and (b)(6), and added 33 CFR 151.2070(d).

One commenter stated the Coast Guard should not automatically decertify a formerly approved BWMS when the manufacturer goes out of business or ceases to support a type-approved system. The Coast Guard agrees with the commenter that the issue of concern should be whether or not the BWMS is capable of being operated properly and effectively. The provision for de-certification is included to allow the Coast Guard to suspend approval of BWMS that cannot be properly maintained as a consequence of business decisions by the manufacturer.

One commenter stated the use of an operational, type-approved BWMS should be sufficient for compliance, and that vessel masters should not be held to discharge standards that they cannot themselves measure or understand without specialized scientific or engineering training. The Coast Guard disagrees with the commenter. The intent of NANPCA, as amended by NISA, is to prevent the introduction and spread of unwanted organisms in vessels' ballast water. For this reason, the Coast Guard has proposed a BWDS that we believe is practicable to implement. Type approval alone cannot ensure that vessel discharges meet the BWDS; it can only increase the probability that systems used to meet the BWDS will be effective. It is the vessel owner or operator's responsibility to meet the discharge requirement.

One commenter stated that failure to use an approved BWMS as required should be a violation, even when another allowable practice is used. The Coast Guard believes that the regulations as drafted in the final rule clarify as to whether a violation has in fact occurred would depend on the particular circumstances. Vessels with an inoperable BWMS will be required to inform the appropriate COTP prior to arrival. The COTP will evaluate the circumstances and inform the vessel of required alternatives, as well any finding of a violation that would result in an enforcement action.

Independent Laboratories (IL)

Three commenters questioned whether sufficient numbers of ILs will exist that can perform the required testing of BWMS for type approval. The Coast Guard acknowledges the key role that ILs will play in the type-approval process. The Coast Guard is aware of several organizations in the United States and abroad that have stated their intention to serve as ILs and that have taken steps to create the infrastructure and organizational capacities to perform the functions. The Coast Guard will not know definitively whether enough organizations capable of conducting the test procedures exist until such time as organizations apply for designation by the Coast Guard and are determined to meet the requirements for ILs testing BWMS. The Coast Guard will move quickly to announce its availability to accept applications for designation.

Five commenters discussed the importance of having a sufficient availability of qualified ILs for effective and timely implementation of the proposed rule. The Coast Guard agrees

that, as with other installed vessel equipment, ILs will play a critical role in ensuring that marketed technologies are highly likely to meet the regulatory requirements for which they are intended. It is our belief that the publication of this final rule, as well as our stated intent to follow up with a subsequent rule implementing a more stringent standard after additional analysis and research, will provide incentive for the creation of additional ILs.

Two commenters stated that the Coast Guard should audit ILs to ensure the integrity of the testing process. The Coast Guard agrees; audits are a standard component of the Coast Guard's oversight of ILs (46 CFR subpart 159.010).

Four commenters discussed ILs in reference to existing test facilities. Three advised that existing facilities that conduct tests of BWMS, particularly the Great Ships Initiative (GSI), should be utilized as ILs. One commenter advised the Coast Guard to work closely with established programs and other appropriate experts to develop testing procedures. The Coast Guard is aware of most, if not all, existing test facilities in the United States and internationally, including GSI, and would welcome IL applications from any qualified organization once the procedures for certification of ILs are implemented. The Coast Guard has worked with most of the existing test facilities in the United States in the development of standard test procedures for BWMS under the EPA ETV Protocol and will continue to do so.

One commenter stated that the timeframe for designation of ILs should be specified. The Coast Guard disagrees that specification of the time frame for designation of ILs should be part of the regulation. There are too many unknowns prior to receiving the applications to be able to set a deadline. Additionally, there should be no limit on a facility's opportunity to apply to become an IL after the initial round of applications and approvals are completed.

Three commenters requested, respectively, that academic institutions, classification societies, and agencies of foreign governments be eligible for consideration as ILs. The Coast Guard agrees with the commenters. We consider the existing specifications for ILs in 46 CFR 162.060–3 and 162.060–40 to be inclusive of the types of organizations identified by these commenters.

Three commenters called for the Coast Guard to approve a specific list of entities that could be accepted as ILs. The Coast Guard disagrees with the recommendation. Listing specific entities in the regulation could serve as a disincentive to other entities who could also meet all of the requirements to become an IL. The Coast Guard will make publicly available a list of accepted ILs on the Coast Guard Maritime Information Exchange (CGMIX) Web site, *http://cgmix.uscg.mil/.*

Three commenters recommended that the Coast Guard include provisions for adequate funding for its Federal activities and the activities of the ILs in this regulation. Two of the commenters specifically suggested setting fees for application review and testing. The Coast Guard clarifies that type-approval applicants must handle all IL testing costs through individual contracts for services with ILs. The Coast Guard currently does not have express authority to charge fees for implementing these BWM requirements.

Two commenters urged the Coast Guard to presumptively accept certified IL test results without conducting substantial additional reviews, in the interest of streamlining the type-approval process and avoiding unnecessary delays in making approved systems available. The Coast Guard agrees that delays should be minimized. The point of designation and regular oversight of ILs via audits is to avoid the need for time-consuming reviews of individual test reports. However, the Coast Guard must assess each individual test report for the BWMS being tested, and make an independent determination of the BWMS. This obligation cannot be delegated to the ILs. Additionally, the Coast Guard's type-approval determination is a Federal agency action that must be analyzed under NEPA and other applicable U.S. environmental laws.

Two commenters specifically supported the Coast Guard's proposed use of ILs to conduct testing associated with type-approval determinations.

One commenter recommended that a manufacturer or vendor should be allowed to use multiple ILs as necessary and efficient during the different phases of approval testing. The Coast Guard agrees that a BWMS vendor may use the services of more than one entity to most effectively conduct the required tests, and there are provisions in this final rule that allow for this. However, in the interest of organizational and administrative efficiency, the Coast Guard requires that one IL coordinates and oversees all testing and reporting for each type-approval application.

Changes to Specific Sections

Two commenters stated that all uses of ''should'' in 33 CFR 151.2050 need to be changed to ''must'' to reflect the fact that the previously voluntary provisions are now requirements. The Coast Guard agrees. We have revised 33 CFR 151.2050 accordingly.

One commenter requested that the definition of ''major conversion'' be consistent with the definition of the term in the IMO BWM Convention. The Coast Guard disagrees; we did not propose any changes to the ''major conversion'' definition in the NPRM, and do not believe any change is necessary at this time.

One commenter recommended changing the text in 33 CFR 151.2005(b) to revise the definition of ''empty/refill exchange'' to replace the word ''should'' with the word ''must.'' The Coast Guard agrees that the wording needs to reflect the mandatory nature of the requirement, thus we have revised the text accordingly.

One commenter called for the Coast Guard to revise the text of 33 CFR 151.2040(a) to read that a vessel retains ''all of its ballast water,'' instead of ''its ballast water,'' as currently written. The Coast Guard disagrees that the change is necessary, as the existing text is already inclusive.

Two commenters requested that the text in 33 CFR 151.2040 and 151.2045 clearly state that the responsibility to meet the legal requirements of the regulation still applies to vessels that claim extraordinary circumstances or invoke the safety exemption. The commenters presumed that while the infraction would exist, fines or penalties would be mitigated to reflect the circumstances. The Coast Guard agrees with the commenters' presumption. Vessels unable to meet the BWM requirements will be required to inform the COTP prior to arrival. The COTP will evaluate the circumstances and direct the vessel accordingly, which may include the imposition of fines or penalties.

One commenter recommended that the introductory paragraphs of the appendix to subpart D of 33 CFR part 151—Ballast Water Reporting Form and Instructions for Ballast Water Reporting Form introductory paragraph be revised to change the word ''should'' to the word ''must.'' The Coast Guard does not believe this change is necessary, as the legal requirement to submit amendments is clearly laid out in 33 CFR 151.2060(c). Additionally, as discussed earlier in this preamble, we are removing the Ballast Water Reporting Form from the CFR (*see* V.A.

Summary of Changes from the NPRM). We will keep the comment in mind, however, and reevaluate it when we update the OMB approved collection as part of our next regularly scheduled renewal package.

One commenter recommended revising 46 CFR 162.060–32 by changing ''appropriate dosages'' to ''appropriate dosages over all applicable temperatures'' to reflect the fact that chemical and biological processes are temperature dependent. The Coast Guard agrees and has included the clarifying language in the final rule text.

One commenter stated that because some types of treatment processes, such as UV, may act to make organisms unviable or unable to reproduce rather than killing them outright, the Coast Guard should include viability as a criterion for determination of BWMS efficacy. The Coast Guard disagrees. This issue has been the point of much discussion both in the United States and internationally in association with the IMO BWM Convention. The Coast Guard has decided to use live/dead rather than viable/unviable, because the latter designations would require culturing potentially large numbers of different kinds of organisms to determine whether they were capable of reproduction. This would be made even more problematic by the fact that scientists are not able to culture many of the organisms in question. Finally, it is more conservative, and thus more protective, to base efficacy decision on the basis of live/dead, rather than viable/unviable.

One commenter stated, in reference to 46 CFR 162.060–20(b)(5), that a BWMS should not have to record all by-passes of the BWMS. Rather, the commenter thought that such recording should be allowable either through electronic or hand entry in the logbook. The Coast Guard agrees and has revised the provision accordingly.

One commenter stated that a strong, environmentally protective, concentration-based, numerical, national BWDS is a critical and necessary component of the nation's invasive species program. The Coast Guard agrees.

One commenter requested a definition of the term ''Test Plan'' as it is used in the approval text in 46 CFR 162.060–10(d). The Test Plan is a document that describes the procedures for conducting a test or study according to protocol requirements for a specific BWMS at a particular test site. At a minimum, the Test Plan includes detailed instructions for test procedures, sample and data collection, sample handling and preservation, precision, accuracy, goals, quality assurance, and quality control procedures relevant to the particular site. We have not included a definition of Test Plan, but we have detailed the necessary requirements in 46 CFR 162.060–24. These details were included in the NPRM, as well.

One commenter asked the Coast Guard to clarify the definition of ''change in design'' in 46 CFR 162.060–16(a), and recommended following the same approach we used in defining ''major conversion'' as applied to a vessel. Another commenter stated the Coast Guard should better define what is meant by a ''design change'' in 46 CFR 162.060–16.

The Coast Guard disagrees that additional explanation is necessary. The language is the same as for other pollution prevention equipment subject to Coast Guard-approval. With the language as it is written, any change in the design of an approved BWMS must be submitted to the Coast Guard for review.

One commenter stated that the wording in 46 CFR 162.060–20(h) is too inflexible, and that the paragraph's goals could be achieved through assessments of individual systems. The Coast Guard disagrees. The requirements in 46 CFR 162.060–20(h) are important for the safe and effective operation of BWMS. If a developer considers that the requirements may be best met through other than ''equipped with a means to * * *'', then the developer may discuss alternatives with the Coast Guard.

Responses to Questions Posed in NPRM

One commenter stated, in response to the NPRM preamble question on costs, that it is not possible to estimate costs for BWMS capable of meeting higher stringency standards because such systems do not exist. The Coast Guard is currently undertaking additional studies to estimate the costs of BWMS capable of meeting more stringent standards.

One commenter stated, in response to another NPRM preamble question, that it is not feasible to assess whether BWMS are sufficiently scalable to be able to meet multiple stringency standards until methods and facilities capable of testing to the more stringent standards are available. The Coast Guard agrees that more exacting methods and improved facilities are needed to test to the more stringent standards.

One commenter responded to a specific question on industry readiness to implement the phase-two standard by stating that ILs and vendors are ready to implement the phase-two standard in 2014 (in place of phase-one). The Coast Guard disagrees with this comment. To date, there are no ILs (as defined in this rule), nor to the knowledge of the Coast Guard are there test facilities or vendors that have demonstrated their readiness to implement the phase-two standard in 2014. We again note the conclusion of the EPA SAB that test methods are not available to determine whether a BWMS meets any standard more stringent than the IMO's.

4. Approval Protocols

General

Two commenters said that they would accept a greater chance of type two statistical errors in determining whether BWMS were working effectively. The Coast Guard disagrees. A type two statistical error is when one accepts a null hypothesis (a hypothesis that is false) as true. In the case of approving BWMS, this would mean increasing the probability of approving a BWMS when it does not actually meet the BWDS.

Five submitters commented on the make-up of test organisms in challenge water, and on the use of cultured organisms. Two commenters recommended that specific concentrations of organisms be required in challenge conditions. One advocated requiring challenge water to have 100 times the threshold concentrations in the BWDS (for example, 1,000 organisms larger than 50 micrometers per m^3 for phase one and 1 organism larger than 50 micrometers per m^3 for the phase-two standard). The other commenter stated that the Coast Guard should establish minimum test conditions of 50,000 organisms larger than 50 micrometers per m^3 of water for all trials, with at least three trials having more than 100,000 organisms per m^3 of water; 1,000 organisms per m^3 of water for organisms between 10 and 50 micrometers in all replicate trials, with at least three trials having more than 2,000 organisms per m^3 of water; 10,000 colony forming units (cfu) of heterotrophic bacteria per mL of water; total suspended solids of 25 mg per L; dissolved organic carbon of 5 mg per L, and particulate organic carbon of 5 mg per L.

The Coast Guard disagrees and will not make these specific changes. The Coast Guard based the approval challenge conditions on those in the ETV Protocol, which is the product of a consensus process based on input from numerous experts from a wide range of scientific and engineering disciplines. As such, the ETV Protocol constitutes the best available validated procedure for evaluating BWMS. The issues raised by the commenters were

considered in the development of the ETV Protocol.

Two commenters called for publication of the testing protocols and procedures used by ILs prior to implementation of the phase-one standard in order to ensure transparency. The Coast Guard agrees with this comment. This final rule, as well as the NPRM before it, describes, in detail, the procedures and protocols for use by ILs in testing BWMS for purposes of type approval (*see* 46 CFR part 162.060).

One commenter stated the Coast Guard should review and revise the protocols for assessing biological and operational performance and environmental soundness of systems annually. The commenter further stated the reviews should be based on findings from type approvals, compliance tests, and independent research, and that these findings should be made publicly available in a database maintained by the Coast Guard and the EPA.

The Coast Guard agrees that the protocols should be reviewed regularly and that the performance data for BWMS should be publicly available, consistent with applicable privileges covering commercially sensitive information.

The Coast Guard disagrees that review and revision should occur annually and that performance data should necessarily be made available through a database. Under NISA, the Coast Guard must assess and as appropriate revise our ballast water regulations at least every 3 years. It remains to be seen what the most efficient and practicable method will be for making performance data available to the public. As the U.S. approval process evolves, we will evaluate the most efficient means for making information available to the public, as well as the appropriate time frame for conducting reviews.

Two commenters stated that the Coast Guard should base the approval testing and certification procedures on those laid out in the G8 guidelines and Procedure for Approval of Ballast Water Management Systems that make use of Active Substances (G9) (G9 procedure), which were developed to assist implementation of the IMO BWM Convention. The Coast Guard agrees with these commenters to a certain extent. The Coast Guard attempted to harmonize our type-approval procedures with these references to the extent practicable, and the proposed type-approval procedures do not conflict with those under the IMO BWM Convention. However, the G8 guidelines in particular are very unspecific on important details, subject to interpretation by individual administrations, and do not wholly reflect advances in ballast water science and technology that have occurred since the adoption of the G8 guidelines in 2005. The G9 procedure addresses the acceptability of chemicals used to treat ballast water. The closest parallel to the G9 procedure in the United States is the registration of biocides under FIFRA, which is administered by the EPA, not the Coast Guard.

Three submitters addressed the need for the Coast Guard's approval application review process to be completed in a timely fashion. Two of these three called for the Coast Guard to specify, in the regulations, the timeframes for review and approval of BWMS. The Coast Guard disagrees that the timeframe for review and decision should be specified in the regulation. A number of the components of the approval process, including environmental reviews and reviews to be completed by other Federal agencies, are inherently not amenable to pre-set timeframes. The Coast Guard appreciates the importance of minimizing the time required for review of applications, and will make efforts to do so.

EPA ETV Protocol

Six commenters urged the Coast Guard to release a final version of the EPA ETV Protocol for verification of BWMS. We agree that the final ETV Protocol is a key component to this rule and, as discussed previously, we have incorporated it by reference into our final rule at 46 CFR 162.060–5. We note that EPA released the ETV protocol in September 2010, and that it is available on the ETV web page (*http://www.epa.gov/nrmrl/std/etv/vp.html#wqpc*).

Two commenters urged the Coast Guard to use the EPA ETV Protocol as the basis for the approval tests to assess performance of BWMS in meeting the BWDS. Conversely, one commenter did not support the use of the revised ETV Protocol as the basis of the approval test procedures. The Coast Guard has adopted the ETV Protocol. The ETV Protocol is the product of a consensus process based on input from numerous experts from a wide range of scientific and engineering disciplines. As such, the ETV Protocol constitutes the best available validated procedure for evaluating BWMS.

The Coast Guard will work with EPA and other stakeholders to update the ETV Protocol as necessary and appropriate in the future. If future updates are made, we would update our rules and policies as necessary to reflect the ETV Protocol to be used in the U.S. approval process.

Two commenters called for the Coast Guard to define protocols and methods for approval testing that are clear and practicable. One commenter requested that Coast Guard do this prior to the implementation of the approval process. In this final rule, the Coast Guard has established procedures to be followed for shipboard testing as well as adopting the ETV Protocol. We believe these regulations are clear, but also anticipate issuing guidance to help manufacturers and vendors work their way through the U.S. approval process.

One commenter considered the proposed requirements for type approval to be thorough and well done. The Coast Guard notes their submission and endorsement of the protocols.

Land-Based Testing

One commenter stated that the land-based test protocols should include a requirement that the concentration of organisms in the discharge from control tanks be at least ten times the discharge limit set by the BWDS.

One commenter recommended the Coast Guard should consider requiring three short-term tests (18–24 hrs) and five 3–5 day tests at each of the required test facilities to enhance certainty that treatment systems will be effective over a range of voyage durations.

One commenter stated that required holding times for land-based tests should be 5 days, but that longer or shorter periods should be added as warranted by specific BWMS.

The Coast Guard disagrees and will not make these specific changes. The Coast Guard based the approval requirements for land-based testing on those in the ETV Protocol, which is the product of a consensus process based on input from numerous experts from a wide range of scientific and engineering disciplines. As such, the ETV Protocol constitutes the best available validated procedure for evaluating BWMS. The issues raised were considered in the development of the ETV Protocol.

One commenter stated that test tanks should be the unit of replication and that inline integrated samples of at least 5 m^3 for organisms larger than 50 micrometers, 5 L for both organisms 10–50 micrometers and bacteria, and indicator microbes should be collected for analysis. The Coast Guard disagrees that test tanks should be the unit of replication. Requiring multiple operations of the BWMS provides a useful test of the system's ability to work consistently. The Coast Guard also disagrees that the recommended minimum volumes for sample sizes

should be established in the regulation. The ETV Protocol addresses how to determine the necessary sample volumes for a test.

One commenter disagreed with the proposed requirements for testing in-tank (batch) treatments, and specifically proposed that a maximum of 10 m^3 of water would be sufficient. The Coast Guard disagrees. The requirement for a minimum of 200 m^3 of water reflects the importance of testing BWMS at a scale relevant to their intended use. Testing a BWMS intended for use on vessels using hundreds, if not tens of thousands, of cubic meters of ballast water by only using the BWMS to treat a few cubic meters would not adequately allow a determination of whether the system would work effectively to provide the necessary dose to the entire volume requiring treatment.

Three commenters discussed the difficulties of making determinations of live/dead status of organisms as part of approval testing, particularly for organisms in the 10–50 micrometers size range. The Coast Guard acknowledges the identified difficulties. The Coast Guard points out that the ETV Protocol, incorporated by reference in this final rule, on which the approval testing requirements are based, includes a multi-stain process because of these difficulties.

One commenter stated that methods for testing to the phase-two standard are not necessary, and that ''interim enforcement standards'' such as the use of a system approved as achieving some measurable concentration, would suffice.

As discussed in this preamble, this final rule only contains requirements for the phase-one standard (*see* V.A. Summary of Changes from the NPRM). We will consider all of the comments that we received on the phase-two standard as we draft a notice or other rulemaking document that addresses the phase-two standard.

Two commenters stated that simultaneous filling of treatment and control tanks during land-based testing should be required to assure comparability between the two, saying that sequential fills could result in different compositions and concentrations. The Coast Guard disagrees with the recommendation. Either simultaneous or sequential filling is allowed. The purpose of the control tanks is not to compare directly with treatment tanks, but to control for unexplained sources of mortality. One may accomplish this through comparisons of relative change rather than specific changes in abundance and composition.

One commenter stated that the Coast Guard should require five consecutive successful trials during land-based testing. The commenter specified that such successes must demonstrate below-threshold concentrations of living organisms, acceptable discharge toxicity, and absence of mechanical failures. The commenter added that more than two failures of any kind during testing should result in the Coast Guard requiring the BWMS to be removed from the test facility for refinement.

The Coast Guard notes that the NPRM did require five consecutive successful trials, a requirement that is retained in this final rule. The issue of when to cease testing on the basis of failures is a contractual issue between the manufacturer and the IL. It is important to note that the Coast Guard type-approval procedures require the results of all testing, including failures, be included in the Test Report.

One commenter stated that land-based test protocols should be updated regularly, and that approval results should be correlated with subsequent performance on vessels (as revealed by compliance assessments). The Coast Guard agrees with the commenter. Testing protocols used for type approval will be reviewed regularly, based on information developed by ILs, researchers, and the Coast Guard during enforcement actions. However, the Coast Guard has no plans to establish a specific review period or process within this rule.

Shipboard Testing

One commenter stated that BWMS should demonstrate that they are capable of meeting the discharge standard under a range of ballast flow rates, as a vessel would experience during cargo operations. The Coast Guard agrees. Shipboard testing is included as part of the approval requirements, and was included in the NPRM, to evaluate system efficacy under a range of operating conditions, including variable flow rates.

One commenter asked how long the ballast water must be held onboard vessels during shipboard testing. The Coast Guard has revised the shipboard testing protocol to clearly state that hold times are to be at least for the minimum time necessary to achieve full treatment and an acceptable discharge water quality, and for the time necessary for the vessel to conduct its normal BWM procedures from uptake to discharge. The Coast Guard has not required vessels conducting approval tests to hold treated water for specific periods of time.

One commenter stated that the Coast Guard should rely entirely on shipboard testing for BWMS type approval rather than requiring land-based testing. The Coast Guard disagrees. Land-based tests provide an important degree of control that is not possible under shipboard conditions. A comprehensive test regime that integrates land-based and shipboard testing provides the best evidence that a BWMS will likely perform satisfactorily once it is installed on a wide range of ships and operated under a wide range of challenging conditions.

Eleven commenters stated the proposed duration for shipboard testing (12 months, ten test cycles, or both) would be onerous and unnecessary. Three of the commenters specifically recommended the Coast Guard use the 6 month requirement of the G8 guidelines. The Coast Guard agrees with these comments and has revised the regulation accordingly.

Six commenters stated that the shipboard testing requirement of three geographic regions is too difficult to achieve on many vessels. Two commenters further recommended the Coast Guard follow the IMO or Shipboard Technology Evaluation Program (STEP) approaches for shipboard testing. The Coast Guard agrees and the shipboard testing protocols have been revised accordingly.

One commenter recommended that shipboard testing procedures incorporate sampling and analysis procedures similar to those used for land-based testing, to the degree possible and appropriate. The Coast Guard agrees with the general point. The shipboard testing procedures have been developed to make use of the same procedures as land-based to the degree appropriate.

One commenter recommended the Coast Guard allow systems to be tested on multiple vessels. The Coast Guard neither prohibits nor requires testing on multiple vessels.

Two commenters stated that shipboard testing should focus on operational performance parameters, rather than repeating the experimental testing performed on land. The Coast Guard notes that the shipboard testing requirements include assessing operational parameters as well as testing system efficacy in meeting the BWDS, but do not require the same level of experimental control as for the land-based testing.

Two submitters commented generally on the inclusion of a requirement for

shipboard testing. One considered the requirement to be unnecessary, given land-based testing is also required, while the other considered the requirement for shipboard testing to be completely appropriate. The Coast Guard agrees with the commenter who supported the inclusion of shipboard testing. Shipboard tests are intended to assess system performance under operational conditions, over a period of extended use. As such, shipboard tests are not repetitions of land-based tests and are necessary for effective approval evaluation.

One commenter recommended that safety and operational reliability aspects of approval testing should be dropped. The commenter believed that vessel owners and their consultants are capable of assessing these issues on their own. The Coast Guard disagrees; assessment of the suitability of equipment for shipboard circumstances is a fundamental aspect of the approval process.

Phase-Two Testing

Seven commenters involved in developing or testing BWM technologies stated that no methods appropriate for measuring BWMS' capability to meet the phase-two standard are currently available. The Coast Guard agrees that more developed methods and improved facilities are needed to more effectively test to the more stringent standards. This is one of the reasons we have deferred issuance of a more stringent phase-two standard.

One State commenter asserted that initial data from technology developers indicate that laboratories can test BWMS' ability to meet the phase-two standard. The Coast Guard disagrees with this interpretation of the available data. The Coast Guard has not seen quantitative validation that any laboratories can currently measure the ability of BWMS to meet the phase-two standard.

Salinity Classes

One commenter stated that BWMS should be tested for type approval in at least two of three salinity classes, but that the proposed 10 practical salinity unit (PSU) difference between salinity classes should not be required. Two commenters stated that the Coast Guard should require land-based testing of BWMS at three locations with different salinities.

The Coast Guard agrees that BWMS should be approved for the salinity regimes in which they will be used, and we have written the approval procedures to allow the manufacturer or vendor to determine in which salinity class(es) they will test their BWMS. The U.S. type approval will only apply to the salinity class for which the BWMS passed testing. This will allow some manufacturers to forego the cost of testing in freshwater, for example, if they do not expect to find a market in that salinity class.

Six submitters commented on the requirements for BWMS approved for freshwater use, and stated that such systems should be required to undergo testing in a land-based facility with natural freshwater challenge water. One of these commenters also stated that BWMS approved for use in the Great Lakes should be tested in the Great Lakes.

The Coast Guard agrees that systems type approved for use in freshwater should be tested in freshwater, and has clarified the requirements accordingly. The Coast Guard disagrees that we should require such freshwater BWMS testing in the Great Lakes. In many cases, BWMS treating ballast water that will be discharged in the Great Lakes will be doing so with water taken on outside the Great Lakes.

Sampling

One commenter stated that approaches for statistically-sound sampling to identify with confidence when a BWMS can meet phase-one limits in land-based and shipboard testing still require some refinement. The commenter identified number and volume of samples as two specific areas of concern. The Coast Guard agrees, and has incorporated additional requirements on sampling design in the testing protocol.

One commenter requested a different definition of ''representativeness'' in 46 CFR 162.060–3. The Coast Guard agrees that this definition needed refining, and we have replaced it with the term ''representative sample,'' which has a new definition. With respect to samples obtained in testing, a representative sample is a random sample in which every individual of interest in the larger population (organisms, molecules, etc.) has an unbiased chance of appearing in the sample.

Test Organisms

One commenter stated the Coast Guard should identify a list of microbes and appropriate microbial concentrations in challenge water for use in BWMS approval tests and then authorize vendors to add these organisms into the vessels' ballast water during shipboard tests. The Coast Guard disagrees. The use of added organisms in shipboard tests could, besides being extremely complicated and difficult, result in the risk of NIS introductions.

One commenter asked why the Coast Guard does not provide a list of specific test microbes for use in testing the efficacy of BWMS. The Coast Guard notes that, while standard test organisms are widely used in drinking and wastewater regulations, several constraints prevent them from being deemed appropriate for testing BWMS. First, there is no agreed list of organisms that would adequately represent all of the different kinds of organisms found in ballast water. Secondly, even for those organisms that have been identified as potential candidates for such use, there are concerns about difficulties associated with culturing the numbers needed for full-scale testing. Another concern is the potential for release of such organisms into the environment, given that the specific organisms would not be native in many places where testing would occur.

One commenter recommended that the Coast Guard develop a list of the conditions necessary for each BWMS to kill or inactivate the most resistant organisms representative of ballast water composition. The commenter cited work by NSF International, Old Dominion University, and University of Washington that identifies several candidate organisms for such use. The Coast Guard is aware of the cited work, which was conducted in support of the joint Coast Guard and EPA ETV Protocol efforts to identify appropriate standard test organisms for land-based BWMS tests. The Coast Guard disagrees that these organisms should be used as part of shipboard testing. We do not believe that using these organisms as part of shipboard testing would be practicable to develop a comprehensive understanding of the conditions necessary for each BWMS to kill or remove organisms.

Acceptance of Already-Tested BWMS

Two commenters proposed, as a way to avoid delays in the availability of approved BWMS, that the Coast Guard grant type approval to BWMS that have undergone prior testing by a variety of U.S. government-sponsored research programs or by independent researchers. The Coast Guard partly agrees. The Coast Guard shares the commenters' concerns about avoiding delays. We have included a provision under which U.S. type approval can be based on testing performed under protocols other than those specified in this final rule, provided that the testing determined to be equivalent to the U.S. type approval procedures. If BWMS developers have conducted substantive

testing prior to the availability of ILs, the developers can request a review and determination of equivalency by the Coast Guard. This review will be conducted in the same fashion as the assessment of foreign approval programs.

Two commenters stated that the Coast Guard should accept any testing protocol or procedure established or accepted by a number of different U.S. and foreign entities as equivalent to the proposed approval testing. The Coast Guard disagrees. The Coast Guard will evaluate the degree to which other testing protocols are equivalent to those implemented under this rule on a case-by-case basis, and will make decisions about equivalencies accordingly.

One commenter asserted that the Coast Guard should not require retesting of previously approved BWMS when new test methods are established. The Coast Guard agrees that retesting should not be automatically required of all BWMS approved under previous testing requirements. However, the Coast Guard will retain the right to require retesting of specific BWMS if subsequent information indicates the previously approved systems may not, in fact, effectively reduce the concentrations of organisms in vessels' ballast water.

One commenter stated that vessels enrolled in STEP should be grandfathered and not subjected to further equivalency evaluations under the approval process, since a BWMS accepted into STEP has been vigorously reviewed by the Coast Guard and will continue to be evaluated through the period of STEP participation. The commenter offered the opinion that requiring companies that have gone through the STEP process to meet additional requirements will constitute a punishment for acting proactively.

The Coast Guard agrees that vessels accepted into STEP should not be subjected to additional requirements associated with the use of type approved BWMS. However, the Coast Guard clarifies that STEP applies to vessels, not to BWMS. Thus, a vessel with a specific BWMS accepted into STEP is allowed to use that system as long as the vessel remains in good standing within STEP, regardless of whether the BWMS is granted type approval. Under this provision, it is use of the BWMS that constitutes meeting BWM requirements, not meeting the BWDS. The Coast Guard considers a vessel in STEP to be in Good Standing if the vessel has met reporting requirements, has or is engaged in testing the system in accordance with the accepted test plan, and is using the BWMS to treat all ballast water discharged to waters of the U.S.

One commenter proposed that information submitted for acceptance into STEP should be considered to meet the requirements for an approval application, saying that an applicant for type approval should be able to simply reference information previously submitted in a STEP application. The Coast Guard disagrees. Applicants for approval may submit copies of materials previously submitted for acceptance to STEP, providing that the approval application adequately references the pertinent sections of the STEP application materials. To do this, the applicant must include copies of any referenced STEP materials in the approval application. The applicant is responsible for submitting a complete approval application to the specified Coast Guard office.

One commenter proposed that a safety certification by any recognized ship classification society or flag state member of IMO should be considered conclusive proof that the so-certified BWMS is safe for use in vessels at sea. The Coast Guard disagrees. The Coast Guard has proposed a provision for acceptance of type approvals by foreign administrations, and will evaluate the procedures and criteria used in such approvals prior to accepting them as equivalent to Coast Guard requirements. Importantly, biocides may also require registration by the EPA under FIFRA and other statutes and must meet discharge limits established under EPA's Vessel General Permit.

Environmental Analyses of BWMS

Four commenters expressed concern that Coast Guard NEPA and ESA evaluations and EPA FIFRA evaluations will significantly delay the approval process, and hence the rate at which type-approved technologies can be brought to the market. The commenters made specific recommendations to minimize delays, including taking a programmatic approach to NEPA assessments for approval decisions, starting NEPA assessments at the time a developer first approaches the Coast Guard, maintaining a publicly available database of releasable NEPA assessment information that can be used in subsequent assessments, and integrating Coast Guard and EPA data and analysis requirements that stem from different programs.

The Coast Guard agrees that the analyses identified by the commenters could take a significant amount of time to complete. The Coast Guard already makes use of existing NEPA documentation to the degree appropriate when conducting the required assessments. We also conduct programmatic assessments, when appropriate, to avoid redundancies. The Coast Guard and EPA will seek to integrate or harmonize the analysis conducted under their separate statutory requirements to the maximum extent practicable. The Coast Guard and EPA are coordinating closely to identify opportunities to avoid or limit redundancies in our respective programs.

One commenter, a Federal agency, recommended that the Coast Guard explicitly state that national-level environmental analyses, including U.S. Fish and Wildlife and National Marine Fisheries Service review and response times, will most likely take months or years. The Coast Guard agrees that these reviews could take a significant amount of time, but we are working closely with our Federal agency partners to streamline these review and approval processes.

Miscellaneous Comments on the Approval Process

Two BWMS developers stated that the Coast Guard must clarify that type approval will apply to a specific BWMS, not to a specific manufacturer, and further stated that it should be the approval holder's responsibility to ensure that BWMS production units meet quality control specifications. The Coast Guard agrees that type approval applies to a specific BWMS rather than manufacturers, and reviewed the regulatory text to ensure it was clear on this point. We did not see a need to make any changes to the regulation in order to clarify this. The Coast Guard disagrees that type approval should not include examination of BWMS production unit manufacturers. The Coast Guard's approval procedures for other marine equipment include examinations of a manufacturers' ability to fabricate production units that conform to the design and specifications of the type-approved unit. This will be a fundamental component of the Coast Guard's BWMS approval process.

One commenter stated that classification societies, such as the American Bureau of Shipping or Bureau Veritas, should be able to review changes to approved BWMS and determine whether or not re-certification is necessary. The Coast Guard disagrees. Under the existing process for type approvals, all changes to the design or construction of type-approved equipment must be submitted to the Coast Guard for review.

One commenter recommended that documentation submitted for type

approval in accordance with the IMO BWM Convention should be accepted as meeting the requirements for Test Reports in 46 CFR 162.060–34(b)–(f). The Coast Guard agrees that documents prepared in accordance with approval requirements under the IMO BWM Convention may be used in an application for type approval under the Coast Guard's regulation. However, these documents must demonstrate that the tested BWMS meets the BWDS and that the test protocols used are equivalent to the U.S. approval process. Such documents must be included in the approval application package and all references to data or other information in the documents submitted for IMO approval must refer to specific sections and pages.

One commenter asserted that the proposed approval procedures will guarantee a government-created, shortage of available technology. The Coast Guard disagrees with this perspective. By type approving treatment technologies in accordance with rigorous and credible test procedures and requirements, the Coast Guard will create a class of treatment options in which vessel owners and operators can have a high degree of confidence. Without sufficient testing requirements, vessel owners and operators would have no means beyond vendors' claims of assessing whether a BWMS on the market is likely to be effective or not.

One commenter requested that the Coast Guard clarify whether BWMS undergoing type approval will need to demonstrate efficacy in meeting both the phase-one and phase-two standards. The Coast Guard clarifies that type approval under the final rule will focus on assessing the efficacy of the BWMS in meeting the phase one standard. The data generated from these tests may or may not provide information on the ability of the BWMS to meet more stringent standards.

One commenter recommended that the Coast Guard require that BWMS approval testing involve full-production units with full installation, operation, and maintenance manuals, and be operated by test facility staff or the vessel crew during tests to ensure that generally installed systems have a high probability of working effectively. The Coast Guard agrees. The approval requirements have been revised to clarify that tests must be conducted on production units installed in the manner intended for normal shipboard operation and that systems must be operated by ILs during land-based testing and vessel crews during shipboard testing.

One commenter stated that the approval procedures should incorporate BWMS type approval for a rated capacity range, similar to that contained in the G8 guidelines. The Coast Guard agrees with the recommendation, and has revised the approval procedure accordingly.

One commenter disagreed with the Coast Guard's proposal in 46 CFR 162.060–18 that type approval could be suspended or withdrawn if the BWMS is no longer manufactured or supported by the manufacturer. The commenter stated their belief that this would be unreasonably punitive to shipowners, and that properly maintained and operating systems should be acceptable regardless of the manufacturer's status.

The Coast Guard takes this opportunity to clarify that a type-approved system no longer manufactured or supported by the manufacturer would not automatically lose its type approval. However, use of parts or materials not specified for the originally type-approved system may trigger a design change review under 46 CFR 162.060–16.

One commenter stated that the proposed requirements for testing and approving BWMS were excessively complex, expensive, unnecessary for the purpose of proving effectiveness or vessel safety, and likely to delay installation of certified equipment. The Coast Guard disagrees. The general process of land-based and shipboard testing for approval of BWMS has been widely discussed and accepted internationally. The Coast Guard has reconsidered alternatives to specific sections of the approval process and the determinations and resolutions of these considerations are described in this preamble in section V.B. Discussion of Comments.

One commenter called for IL Test Reports submitted in association with a request for approval of a BWMS to be made electronically available to the public immediately after they are submitted to the Coast Guard. The Coast Guard disagrees that test data should be made publicly available immediately upon application, as such data may include confidential business information and other privileged information, which is not subject to public release under the Freedom of Information Act (5 U.S.C. 522). Test Reports, or appropriate portions thereof, will be made public as part of the approval procedure when the Coast Guard announces a proposed decision on an application.

5. Legal

Preemption of State Action

Twelve commenters directly requested that the Coast Guard preempt all State ballast water treatment standards and requirements in favor of a uniform, national, water quality-based treatment standard. One commenter argued that numerous States are already unconstitutionally burdening interstate commerce with conflicting State BWM regulations. The commenter noted that interstate shipping will quickly become impossible if the Coast Guard fails to preempt all State treatment regulations and likened the patchwork of State regulations to a ''destructive economic balkanization.'' Another commenter agreed with this sentiment, stating that without preemption, BWM regulations on a State-by-State basis create the potential to restrict trade and severely impact the economies of ''nearly every State which relies on waterborne commerce.''

Another of the commenters requesting Federal preemption of BWM regulation noted that different rules for different States or regions within the United States will create confusion and delays in the primary objective of eliminating aquatic NIS invasions. Two of the commenters quoted a resolution passed by the Great Lakes Commission in May of 2007 which urged a Federal ballast water treatment regime that would preempt States. One commenter called the idea of preemption by the Coast Guard ''a very positive step.''

One of the commenters requesting Federal preemption noted that Federal standardization of the methodology and technological requirements of BWM is integral to the future success of any ballast water treatment regime. Another commenter argued that the varying State standards have already created a patchwork of requirements that are economically inefficient, highly cumbersome to implement, and unproven in regards to prevention of aquatic NIS invasions.

Three commenters approved of and agreed with our determination to not preempt State BWM standards. One of these commenters noted that the Federal regulations should set a minimum compliance standard applicable to all waters of the United States but allow the States to enact stronger water quality standards applicable to their own waters. Another noted that States only began implementing their own standards after what they called ''decades of delay and inaction at the Federal level.''

One commenter agreed that lack of Federal action in regard to

implementing a BWDS caused States to step in and begin regulating. This commenter, however, also urged for Federal preemption of even those already implemented State standards.

One commenter urged the Coast Guard to seek passage of a single Federal law which would preempt all State and any other Federal laws. Another commenter urged the Coast Guard to advocate to Congress the need to preempt States' BWM laws and to coordinate U.S. standards with international standards.

As we noted in the NPRM and again in section VII.E. Federalism of this preamble, NANPCA, as amended by NISA, contains a ''savings provision'' that saves to the States their authority to ''adopt or enforce control measures for aquatic nuisance species, [and nothing in the Act would] diminish or affect the jurisdiction of any States over species of fish and wildlife.'' 16 U.S.C. 4725. In light of this provision, the Coast Guard cannot legally preempt State action to regulate discharges of ballast water within State waters.

One commenter noted the statutory restriction, but urged the Coast Guard to work with States to harmonize BWDS, noting that regulatory consistency between State, Federal, and international requirements is a critical component to moving forward in the field of BWM. Two other commenters also urged the Coast Guard to work with individual States, but argued for Federal preemption as well.

The Coast Guard agrees that we must work with the States, as our statutory authority clearly envisions a Federal/State partnership. We have been in frequent contact with representatives from all of the States which have already implemented their own BWDS. We will continue to work with these contacts in an attempt to harmonize BWDS as much as we can.

Unified Federal Action

Two commenters urged the Administration to assert that these regulations supersede any action by the EPA or by States under any provision of the Clean Water Act. Another questioned whether these regulations would be consistent with the existing EPA VGP, and sought clarification. This commenter noted that the Coast Guard and EPA must be in accord in regards to the proper standard to apply to the treatment of ballast water. One commenter requested that the preamble to the NPRM be revised to include a discussion of the EPA VGP, and also urged the Coast Guard to ''outline and cross-reference'' the regulations with the EPA VGP.

The Coast Guard agrees that, to the extent possible and appropriate, there should be consistency between Coast Guard and EPA ballast water requirements. We maintain a very close working relationship with EPA. We consulted with them on matters relating to the EPA VGP and we also sought their comments on both the NPRM and this final rule. NANPCA, as amended by NISA, and the Clean Water Act provide both the Coast Guard and EPA, respectively, with the authority to regulate discharge of ballast water from vessels. However, these statutes contain different language and we will continue to work with the EPA to ensure that, to the greatest extent possible, given our separate statutory authorities, each agency's actions are consistent and do not work at cross-purposes to the other agency's actions.

We note that the NPRM preamble did briefly discuss the EPA's 2008 VGP (74 FR 44634), including the address for an EPA Web site where the reader could find more information. As we move forward and implement today's final rule, we will work closely with EPA to try and provide a type of ''crosswalk'' guidance between Coast Guard regulations on ballast water discharge and EPA's VGP.

Thirty-one commenters supported establishing a uniform, protective, national standard for ballast water discharge from vessels calling at U.S. ports. Six commenters also said that it is vital that international shipping regulations, including those for ballast water, are standardized globally. However, both NANPCA, as amended by NISA, and the Clean Water Act allow for concurrent State regulatory action with regard to ballast water discharge.

Compliance With NISA

One commenter argued that the proposed phase-one BWDS would violate NISA, as it would not be at least as effective as BWE at preventing or reducing the introduction of NIS into waters of the United States. The commenter cited 16 U.S.C. 4711(c)(D)(iii). The Coast Guard disagrees. As we noted in both the NPRM and the DPEIS, the effectiveness of BWE varies widely, not only from vessel to vessel but also on individual vessels from voyage to voyage. Given the wide range of effectiveness of BWE moving from a scheme where you might get a poor BWE or none at all, if the vessel faced safety hazards, to one where all technologies would be tested and certified as meeting the BWDS, provides a level of protectiveness that is not only at least as effective as BWE, but in many cases much better than BWE.

Two commenters argued that legal precedent interpreting the phrase ''maximum extent practicable'' limits the proposed practicability review to considering one factor: Technological feasibility. These commenters cited several Federal court cases to bolster their argument. (*Biodiversity Legal Foundation* v. *Babbit,* 146 F.3d 1249 (10th Cir. 1998); *Fund for Animals* v. *Babbitt,* 903 F. Supp. 96, D.D.C. 1995); *Wyoming* v. *United States,* 279 F.3d 1214 (10th Cir. 2002)).

The Coast Guard disagrees with the commenters' interpretation of the cited cases. In each of these cases, the deciding court noted that the phrase ''to the maximum extent practicable'' certainly limits agency discretion. However, the United States Court of Appeals for the Tenth Circuit noted in the Biodiversity decision that the phrase itself is ''facially ambiguous.'' (*Biodiversity,* 146 F.3d 1249 at 1254.) In such a scenario, where the statutory mandate is ambiguous, courts must defer to an agency's interpretation so long as that interpretation is permissible. *See Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.,* 467 U.S. 837, 842–43 (1984).

Interpreting ''maximum extent practicable'' to include factors other than technological feasibility is permissible. If Congress had wanted to limit the Coast Guard's review to technological feasibility alone, it certainly could have done so but did not.

''Practicable'' is defined as ''that which is performable, feasible, [or] possible.'' *Biodiversity* at 1254, citing Black's Law Dictionary 1172 (6th ed. 1991). In order to determine whether a proposed phase-two standard or any standard higher than phase-one is performable, feasible, and/or possible, it will be necessary to look at more than just technological feasibility. Whether a standard is practicable could also require, among other factors, a determination as to whether the technology is effective, can be implemented by vessels required to meet the BWDS, which necessarily includes a review of whether that technology can be produced in large enough quantities to be installed on those vessels, the probable duration of that installation period, whether vessel owners can afford to install the technologies, and, if they cannot, what the potential ramification on the national transportation system might be if vessel owners opt to go out of business instead.

Two commenters argued that the language from NANPCA directing regulation of vessels entering the Great

Lakes from outside of the EEZ (16 U.S.C. 4711(b)) does not allow for the proposed practicability review because this paragraph of NANPCA does not contain the same ''maximum extent practicable'' language later added by NISA for vessels entering waters of the United States in general. The Coast Guard disagrees. NISA was enacted to build upon the requirements of NANPCA; therefore it is proper to apply the practicability review to the Great Lakes as well.

One commenter requested that we revise the preamble to the NPRM to explicitly state that NISA establishes the objective of a zero-discharge standard. We agree that the objective of NISA is to prevent the introduction and spread of NIS in waters of the United States, with caveats for doing so to the maximum extent practicable. We believe this response is consistent with the Coast Guard's legal requirements and should satisfy the commenter's concern.

APA Concerns

One commenter argued that the NPRM violated the APA because while the IMO Treaty (presumably the commenter intended to reference the IMO BWM Convention) allows ratifying countries to impose more stringent treatment standards if they find it a necessity for public health or the environment, the NPRM made no such finding. The Coast Guard disagrees with this comment. First, the Coast Guard is implementing NISA and not the IMO BWM Convention. While the Coast Guard supports international efforts for the prevention and control of NIS from ships' ballast water, the Coast Guard is not under an obligation at this time to implement the IMO BWM Convention as the United States is not a Party to the IMO BWM Convention and there is no enacted domestic legislation implementing the IMO BWM Convention. Thus, the Coast Guard must comply with its mandate under NISA and applicable U.S. laws on issuing regulations, which we have done. Moreover, the BWM Convention has not entered into force at this time for any countries, even those that have ratified it. The Coast Guard also disagrees with the commenter's characterization of the IMO BWM Convention's provisions regarding Parties' implementation of more stringent measures than those contained in the IMO BWM Convention. The IMO BWM Convention clearly states that: ''Nothing in this Convention shall be interpreted as preventing a Party from taking * * * more stringent measures with respect to the prevention, reduction or elimination of the transfer of Harmful Aquatic Organisms and Pathogens through the control and management of ships' Ballast Water and Sediments, consistent with international law''.

Three commenters argued that the regulation, particularly the practicability reviews, should include more detail in order to prevent legal challenges. The Coast Guard agrees that the regulations must not be overly vague in order to avoid a finding that they are arbitrary and capricious under the APA. We drafted the NPRM and have drafted this rule in a manner that is intended to eliminate vagueness. In regards to the practicability review, we have included more specific details of what the Coast Guard will consider; however, the regulation does allow for the consideration of additional criteria not listed. This is to ensure that the Coast Guard is not foreclosed from considering an issue that cannot be foreseen today.

Eight commenters argued that the NPRM violated the APA by not explaining the rationale for including vessels that are not currently required to conduct BWE in the requirement to comply with the BWDS in the NPRM. They argued that the NPRM is based on ''inaccurate assumptions'' and ''incomplete research'' and also that the DPEIS and NPRM RA lacked sufficient rationale to justify applying the NPRM's proposed requirements to vessels operating only on the Great Lakes or to barges and towing vessels operating in the U.S. domestic trade.

As we have noted in this preamble, we have revised the applicability of this rule such that most vessels operating in the waters of the United States without having entered waters of the United States from outside the EEZ will not be required to comply with the BWDS in this rule (*see* V.A. Summary of Changes from the NPRM). In the future, and after further analysis, we do intend to extend this applicability to vessels operating in waters of the United States, whether or not they ever operate outside of the EEZ. We also intend to conduct additional research on this issue as necessary. We will reconsider the commenters' arguments at that time and ensure that the public is allowed to comment on our information, rationale, and data before that extension is implemented.

Seven commenters argued that the inclusion of a phase-two standard violated the APA, as it was arbitrary and capricious ''on its face''. They cited the lack of any factual or scientific rationale for its inclusion, as well as the lack of any discussion relevant to the phase-two standard in either the NPRM RA or the DPEIS.

Four commenters stated that the phase-two standard was not properly promulgated for appropriate scrutiny within the regulatory process and also requested the necessary economic and environmental analyses for other alternatives as part of a separate rulemaking that would give stakeholders an opportunity to provide meaningful comments.

As noted in preamble section V.A. Summary of Changes from the NPRM, we are only moving forward with the phase-one BWDS at this time. We fully intend to issue regulations in the future that will include a more stringent standard, after completing additional research and analysis. Those future regulations will be supported by all legally required environmental and economic analyses, which will be made available to the public for comment as required by applicable laws related to Federal rulemaking. We will keep the commenters' concerns in mind as we draft those regulations and analyses.

Authority To Issue Regulations

Twenty-one commenters argued that the Coast Guard does not have the authority to require vessels to comply with a BWDS if those vessels do not enter the waters of the United States from outside the EEZ. These commenters all cited the provision in 16 U.S.C. 4711(c)(2)(D) which specifically allows the Coast Guard to direct a vessel to conduct a BWE or alternative BWM method if that vessel operated beyond the EEZ. They argued that this specific authority must be read to limit the broader grants of authority in 16 U.S.C. (c)(1), (c)(2)(A), (e), and (f).

The Coast Guard disagrees that we do not have the statutory authority under NISA to regulate ballast water on vessels that do not operate outside of the EEZ. NISA requires that the Coast Guard ''ensure to the maximum extent practicable that aquatic nuisance species are not discharged into waters of the United States from vessels * * *.'' 16 U.S.C. 4711(c)(2)(A). This mandate includes promulgating standards for vessels that do not operate outside of the EEZ, as 16 U.S.C. 4711(c)(2)(B) makes NISA applicable to ''all vessels equipped with ballast water tanks that operate in waters of the United States'' without regard to whether those vessels ever operate outside of the EEZ. This is supported by other language in NISA, which is clear that ''discharge,'' in this context, is not limited to the introduction of NIS into waters of the United States from waters outside of the EEZ but also covers the internal spread of NIS.

The Coast Guard disagrees with the commenters' reading of NISA, including their arguments that the statutory authority found in subparagraphs (c)(2)(A) and (c)(2)(B) of 16 U.S.C. 4711 are ''broad'' grants limited by ''specific'' grants of other subparagraphs of 16 U.S.C. 4711(c). The mandate included in 16 U.S.C. 4711(c)(2)(A) is also a ''specific'' requirement and cannot be deemed a nullity by the existence of 16 U.S.C. 4711(c)(2)(D). Subparagraph (D) of 16 U.S.C. 4711(c)(2) merely sets forth the initial ballast water requirements for a certain subset of vessels. Ultimately, the Coast Guard must read the statute as a whole and follow all of the paragraphs and subparagraphs of 16 U.S.C. 4711 when we promulgate our BWDS under NISA.

Two additional commenters noted that NISA requires the Coast Guard to take into account a variety of factors, including vessel types and differing operating conditions, when issuing regulations. The commenters cited 16 U.S.C. 4711(c)(2)(H). They argued that by proposing a ''one size fits all'' BWDS, the Coast Guard violated the authority to regulate provided within NISA.

The Coast Guard disagrees with the allegation that its BWDS violates NISA, but agrees that it must comply with 16 U.S.C. 4711(c)(2)(H), just as it must comply with the other subparagraphs in 16 U.S.C. 4711. A ''one size fits all'' BWDS would not take into proper consideration all of the elements of 16 U.S.C. 4711(c)(2)(H), including the possibility that BWMS may not currently be available for all vessel types in all operating conditions. As such, the NPRM included exceptions and alternatives to using a BWMS for extraordinary circumstances, such as heavy weather or BWMS failure, and those exceptions and alternatives are retained in the final rule. We have also revised 33 CFR 151.1510 and 151.2025 to include alternatives to using a BWMS.

Tribal Impacts

We received one comment that cited tribal concerns, however, the commenter did not raise any issues that would require consultation under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. Rather, the commenter noted that invasions of aquatic NIS into the waters of certain Great Lakes could cause substantial hardships to tribal commercial and subsistence fisheries, which might in turn require a reconsideration of a Federal court-ordered Consent Decree between several tribes, the Federal Government, and the State of Michigan.

We do not disagree with this assessment. We are issuing this rule in order to prevent NIS invasions, and the very hardships that the commenter relays.

Technical Issues

Two commenters questioned our use of the term ''U.S. waters'' in several sections, instead of the term ''waters of the United States,'' which we explicitly defined in the NPRM. We agree that the proper term should be ''waters of the United States'' and have revised 33 CFR 151.1512, 151.2005, 151.2025, and 151.2035 to use this term.

One commenter suggested that the definition for the term ''ballast water'' be revised to state explicitly that it does not include water sealed in ballast tanks, water permanently ballasted and changed only in connection with drydocking, and water taken into ballast tanks from commercial or municipal freshwater sources.

The Coast Guard agrees with the commenter and believes the final rule addresses the concern. The regulation, as written, already accomplishes the requested relief for the first two categories by allowing vessels subject to the requirements of 33 CFR subpart C to ''retain the ballast water onboard the vessel'' (33 CFR 151.1510(a)(2)). For vessels subject to the requirements of 33 CFR subpart D, we have clarified 33 CFR 151.2025(a) to require only those vessels discharging ballast water into the waters of the United States to employ one of the required ballast water management methods. The suggestions pertaining to ballast water purchased from commercial or municipal sources have also been incorporated into 33 CFR 151.1510(a)(4) and 151.2025(a)(2), by allowing for the use of water meeting Safe Drinking Water Act requirements as an alternative to requiring installation of a BWMS.

One commenter questioned whether revisions made to the proposed phase-two standard, after the practicability review from proposed 33 CFR 151.1511(c), would include an opportunity for public comment. While neither those revisions nor the phase-two standard are included in this final rule, we had always anticipated that any changes to an effective rulemaking would be subject to the notice and comment provisions of the APA unless the change fell within one of the narrow exemptions included within the APA. *See* 5 U.S.C. 553(b). Likewise, any changes made to this rule, including reinsertion of a phase-two standard, will need to comply with the APA.

One commenter argued that proposed 33 CFR 151.2045(b)(1) contained a cross reference to a section (33 CFR 151.1514) that does not exist. We believe the commenter was confused; 33 CFR 151.1514 does exist in the CFR, but we did not propose any amendments to that section, therefore it did not appear in the NPRM. We have not made any revisions in response to this comment.

One commenter argued that penalty provisions were too low. The penalty provisions included in proposed 33 CFR 151.2080 have been adjusted for inflation per the civil penalty adjustment table in 33 CFR 27.3. *See* 75 FR 36278 (June 25, 2010). Our statutory authority sets the maximum penalty that we may levy, with the allowance that penalties may be readjusted for inflation.

Two commenters urged that the Coast Guard assign accountability for BWDS compliance to the vessel owner of record, instead of to ''the owner, operator, agent, or person in charge,'' as we proposed. We disagree with this suggestion. Persons at every level of authority, whether owner, lessee, or operator, may be held responsible for the failure of a vessel to follow the BWM practices required by this regulation, including use of an approved BWMS.

One commenter agreed with our proposal to keep ballast water regulations for the Great Lakes separate from ballast water regulations for waters of the United States in general, citing the distinction also found in NISA. This final rule carries that distinction forward.

One commenter noted that we define the term ''build date'' in proposed 33 CFR 151.2005, but never use the term. Instead, proposed 33 CFR 151.2035 used the term ''vessel's construction date.'' The commenter recommended that we use the latter, and add a definition for it to replace the one for ''build date.'' Other commenters recommended that we use the same definition for ''build date'' as the IMO used for ''constructed'' in the IMO BWM Convention.

We agree that the term used in the regulation should be the same as that defined. We have revised 33 CFR 151.2005 to define the term ''constructed,'' and have revised the tables in 33 CFR 151.1512 and 151.2035 to use this term. We chose the term ''constructed,'' as suggested by the second commenter, because this is the term used in the IMO BWM Convention. Thus, we have also revised the actual definition for ''constructed'' to mirror the definition from the IMO BWM Convention. This change in terminology does not reflect a substantive change from the NPRM.

One commenter requested that we remove the word ''foreign'' from proposed 33 CFR 151.2020, which provides an exemption for vessels in ''innocent passage.'' They argued that it is possible, if rare, for a U.S. vessel to operate in waters of the United States on a route where it does not call on a U.S. port. The Coast Guard disagrees that the ''innocent passage'' exclusion should apply to U.S. vessels, as this concept concerns foreign-flagged vessels operating in a coastal state's territorial sea, and therefore has retained the ''foreign'' vessel distinction in 33 CFR 151.2020.

One commenter asked for an explanation of proposed 33 CFR 151.1505 and 151.2013 (Severability). These provisions are included in order to protect as much of the regulations as possible, in the event that their promulgation is subjected to a legal challenge. In short, they direct a reviewing court, upon a determination that portions of the regulations are invalid, to invalidate only those portions and leave the remaining provisions intact.

One commenter requested we add a reference to 33 CFR 151.2015 (Exemptions) in 33 CFR 151.2010 (Applicability). The Coast Guard agrees with this suggestion and has made the requested edit.

One commenter requested that we add a reference in 33 CFR 151.2015(b) (Exemptions) to the statutory exemption for crude oil tankers found at 16 U.S.C. 4711(c)(3)(L). The Coast Guard has not made this change; the authority citation for 33 CFR part 151 subpart D already lists 16 U.S.C. 4711, therefore, adding a specific citation into the regulatory section would be redundant.

One commenter requested that we amend the NPRM preamble to add a discussion of additional provisions of NANPCA and NISA exempting crude oil tankers in the coastwise trade from complying with BWM, specifically citing provisions regarding the statutorily required ''Crude oil Tanker Ballast Facility Study'' (16 U.S.C. 4711(k)(3)). The commenter also requested that a discussion of the referenced study be added to the preamble of the NPRM.

The Coast Guard has added the referenced report to the docket for this rule, as the commenter noted their inability to locate it. However, the Coast Guard disagrees with including a discussion of the study in the preamble to this final rule, as the report is not pertinent to the BWDS. To address the commenter's recommendation to remove the exemption for crude oil tankers in the coastwise trade from the regulation, the Coast Guard notes that NISA's statutory exemption precludes such action at this time (16 U.S.C. 4711(c)(3)(L)). The Coast Guard notes, however, that the statutory exemption for crude oil tankers engaged in Coastwise trade found in NISA is not found in the CWA; therefore, these vessels must comply with all CWA requirements.

One commenter requested that we include the specific zone demarcations in our definition of COTP. The Coast Guard has not made the requested change; the definition points to 33 CFR part 3, which already contains the specific delineations requested by the commenter.

One commenter questioned the exemption for warships, naval auxiliaries, or other government vessels found in proposed 33 CFR 151.2015(a) and requested more information as to why that exemption was added.

Our regulation is designed to be consistent with international law and practice, and international agreements relating to the protection and preservation of the marine environment routinely state expressly that they do not apply to any warship, naval auxiliary, or other vessels owned or operated by a nation and used, for the time being, only on government non-commercial service. However, this does not exonerate such vessels from implementing environmentally sound practices. Under such agreements, nations generally must ensure that such vessels act in a manner consistent, so far as reasonable and practicable, with the provisions of the agreements.

One commenter requested that we specifically note that the Snell and Eisenhower Locks fall within the definition of ''ports or places in the United States.'' Another commenter requested the addition of a definition of the phrase ''port or place of the United States.'' The Coast Guard has not made these changes; the current definitions for ''port or place of destination,'' ''United States,'' and ''waters of the United States,'' when read together, provide a definition for the phrase ''port or place of the United States,'' which would include the specified Locks. Adding a specific reference to only these two Locks into the regulation would inevitably lead to questions as to whether other Locks, waterways, or other places were also meant to be included in the regulation, adding unnecessary ambiguity.

One commenter pointed out that the headers in the tables in 33 CFR 151.1512 were improperly aligned with the information presented in the table. The Coast Guard has corrected this problem in this final rule.

One commenter requested we either add definitions for the following terms or change the terms used to clarify their meaning. The terms (and locations in the proposed regulation) were: ''discharge port'' (as used in 33 CFR 151.1516), ''crew'' (as used in 33 CFR 151.2050), and ''jurisdiction of the United States'' (as used in 33 CFR 151.2070).

The Coast Guard agrees, in part. These terms are used but not defined in the referenced sections; however, they are terms that have existed in regulation for many years. The Coast Guard has not received any indication that the use of these terms is confusing to the regulated industry or public in general. In light of this fact, we are not adding the requested definitions.

Other Legal Issues

One commenter requested consultation with the Prince William Sound Regional Citizens' Advisory Council (PWS RCAC), citing the Oil Pollution Act of 1990 (OPA) requirement to do so. However, the applicable portion of OPA reads ''[E]ach Federal department, agency, or other instrumentality shall, with respect to all permits, site-specific regulations, and other matters governing the activities of and actions of the terminal facilities which affect or may affect the vicinity of the terminal facilities, consult with the [PWS RCAC] prior to taking substantive action.'' OPA sec. 5002(g). This final rule is not site-specific, nor is it governing activities of a terminal facility. It is regulating vessel activity. As such, the OPA consultation requirement does not apply to this rule.

One commenter noted that the Great Lakes States have repeatedly urged Congress to pass comprehensive legislation to prevent the introduction and spread of NIS from all sources. This is beyond the scope of this rule, as it concerns a request for legislative relief and is not a comment on the NPRM.

One commenter requested that the NPRM be revised to remove what the commenter called a ''presumption'' in the proposed practicability review which the commenter felt favored delay of the phase-two compliance date. As we have noted in this preamble, we have removed the phase-two standard, as well as its compliance dates, from this final rule (*see* V.A. Summary of Changes from the NPRM). We will keep the commenter's concern in mind as we work to issue a subsequent rule that addresses a phase-two standard, as that rulemaking would most likely include a

recurring practicability review provision.

One commenter stated that the applicability of the rule is confusing and needs to be specifically defined and consistent. As noted in preamble section V.A. Summary of Changes from the NPRM, the applicability of the final rule has changed from what was included in the NPRM. We have carefully constructed the applicability section in order to make it less confusing.

One commenter urged that the implementation of the proposed rule be delayed in order to allow time for further research, which could then be used to encourage the development of one uniform, nationwide BWDS. The Coast Guard fully supports all research efforts into the subject of BWM and treatment; however, it would not be prudent to delay implementation of the phase-one standard at this time. As noted earlier in this section, the legislative authority for this rule does not allow the Coast Guard to preempt State actions to implement a more stringent BWDS.

Additional BWM Requirements

Nine commenters asked that the regulations be more specific in how other vessel-related vectors for invasive NIS movements (anchors, anchor chains, hulls) would be managed and enforced.

The Coast Guard agrees that protecting the environment from invasive NIS requires addressing these other vessel-related vectors and will continue to explore how to accomplish this. Aside from clarifying where cleaning of ballast tanks should take place, the final rule continues the applicable requirements from 33 CFR 151.2035 and moves them to 33 CFR 151.2050. The Coast Guard is acting under the legislative mandate in NANPCA, as amended by NISA to direct vessels to carry out management practices necessary to reduce the probability of unintentional discharges resulting from ship operations other than ballast water discharge. 16 U.S.C. 4711(c)(2)(E).

One commenter urged the Coast Guard to expand the language in 33 CFR 151.2050 to specifically address ballasting activities that could affect units of the National Park Service.

The Coast Guard believes the existing regulatory language appropriately captures the units of the National Park Service.

6. Regulatory Assessment (RA) and Initial Regulatory Flexibility Act (IRFA)

Affected Population

Two commenters noted that the NPRM RA addressed only the impact on U.S.-flagged vessels. One of these commenters stated that it is illogical and incorrect to ignore the costs that this rule would impose on foreign-flagged vessels calling at U.S. ports.

The Coast Guard estimated cost impacts for foreign-flagged vessels in the NPRM RA (see Appendix C) and the final rule RA (see Appendix D). As previously discussed, we have also made the phase-one standard as consistent as possible with the IMO BWM Convention's discharge standard. We assume foreign governments that become a party to the IMO BWM Convention and the foreign-flagged vessels they administer to be responsible for the implementation and compliance with the IMO BWM Convention once it comes into force. We assume these foreign government administrations and the foreign-flagged vessels they administer to be responsible for the costs associated with the implementation and compliance of the IMO BWM Convention.

Therefore, in the analyses of the NPRM and this final rule, our primary cost estimate of the phase-one standard rule includes costs to U.S. flagged-vessels only. Historically, Coast Guard's assessment of impacts from regulations related to international conventions have taken into account the costs incurred by U.S. vessels and owners and operators only (e.g., regulations related to The Standards of Training, Certification & Watchkeeping Convention (STCW) and regulations related to the International Convention for the Prevention of Pollution From Ships (MARPOL)).

The Coast Guard received a total of 98 comments related to inland, Great Lakes, and coastwise industries. The breakdown of the comments was 35 comments related to the Great Lakes and 63 related to inland and coastwise vessels. The inland and coastwise industry comments mentioned the following vessel types: towing vessels, barges, and offshore supply vessels. The commenters raised many different issues related to the ballast water operations from these industries, such as the use of municipal/potable water, technology cost and its potential impact on the industry, size limitations, and benefits. The majority of the comments were related to the underestimation of the affected population in the NPRM RA, which did not account for inland vessels, and issues pertaining to the Great Lakes vessels and operations.

Given the issues raised by these and other commenters, the Coast Guard has revised the applicability of the BWDS rule. The Coast Guard is publishing this final rule to apply the phase-one BWDS only to the following vessels intending to discharge ballast water into waters of the United States: vessels entering waters of the United States from outside the EEZ, and those seagoing vessels that operate in waters of the United States in more than one COTP Zone and are greater than 1,600 GRT (3,000 GT (ITC)). The Coast Guard is conducting additional feasibility analysis needed before expanding the applicability in this final rule.

Additionally as noted above, the Coast Guard has decided at this time to exempt vessels that operate solely in inland waters from the phase-one BWDS. The Coast Guard fully intends to expand the BWDS rule to such vessels, as noted in the final rule preamble section V.A. Summary of Changes from the NPRM, but has determined that additional analysis is necessary to support this expansion. We also intend to conduct additional research as necessary.

Regarding the comments about underestimation of affected population, the Coast Guard acknowledges that some inland vessels, towing vessels, and crew boats were not included in the NPRM RA due to their lack of ballasting operations or non-traditional ballast water operations. Detailed justification for not including these vessels is presented on chapter 2, page 37 of the NPRM RA (available in the docket).

Phase-Two Standard

Four commenters expressed concern that the cost estimates for the proposed phase-two standard were not included in any of the supporting documentation or analysis.

One commenter argued that skipping phase-one in favor of adopting phase-two is unrealistic for many reasons, including: (a) An onerous cost of research and development would result to the technology industry, which has already borne the expense of development to the international standards with no appreciable return on investment due to the slow pace of implementation; and (b) the maritime industry would be asked to invest, at a higher cost, in technology that does not have a validated environmental benefit over that resulting from use of systems compliant with other standards.

The Coast Guard acknowledges the comments which stated that the analyses included in the NPRM did not

address the phase-two standard specifically. The Coast Guard has determined that additional analysis is needed, and has already begun development of these analyses. The Coast Guard has decided to move forward with the phase-one standard with the publication of this final rule that does not include the phase-two standard. The Coast Guard will work on developing the economic and environmental analyses to support the evaluation of the phase-two standard.

Phase-One Cost

Five commenters provided statements on the costs of BWMS. One commenter provided cost information for purchasing BWMS ranging between $400,000 and $580,000. Based on this information, this commenter argued that the installation BWMS costs presented in the NPRM are very optimistic. Another commenter provided costs comparisons with the 2009 CSLC Report, ''Assessment of Efficacy, Availability and Environmental Impacts of Ballast Water Treatment Systems for Use in California Waters,'' and a study from the Danish Shipowners' Association (DSA) from June 2009. The commenter noted that the reports present the following acquisition costs ranges: from $150,000 to $2,300,000 and $640,000 to $1,670,000 per system, from the CSLC and the DSA reports, respectively. This commenter also argued that cost to industry could be higher for the phase-two standard, depending on the practicability review. One commenter also cited the 2009 CSLC report presenting estimates of BWMS of 1 to 2 percent of the total cost of a vessel.

Another commenter provided acquisition and installation costs for systems currently being tested from $250,000 to over $2,000,000, depending on the methods used to treat the ballast water. This commenter argued that, although a number of vendors have provided cost estimates to potential customers, these estimates are not based on actual shipboard installations and consequently do not reflect real world issues. This commenter also argued that costs associated with systems which could meet the more stringent standards are expected to be significantly higher.

Another commenter argued that there are insufficient data available related to the actual operation/maintenance costs for use of any system due to the fact that many systems are yet only at the stage of testing to determine efficacy. This commenter also stated that anticipated acquisition and installation costs for systems designed to meet the more stringent phase-two standard are expected to be considerably higher than for the currently available systems.

The Coast Guard acknowledges these comments and has incorporated additional data provided by the commenters in the cost analysis of the final rule RA. The Coast Guard notes that these additional data are within the range of estimates presented in the NPRM RA available on the docket. In the NPRM RA, chapter 3 (table 3.4) presents costs for installation of the BWMS ranging from $250,000 to approximately $2,500,000, depending on the type of the system and the ballast water pumping capacity. Commenters provided estimates ranging from $250,000 to $2,300,000. Thus, the Coast Guard disagrees with the comment that the costs in the NPRM are very optimistic, as the cost ranges provided by the commenters are within the range of the Coast Guard estimates.

Because this type of specialized equipment cannot be independently priced, the cost estimated in the NPRM relied largely on manufacturer-provided data. Manufacturers supplied data for acquisition, installation, operation, and maintenance costs of BWMS. The Coast Guard's cost estimates are based on the best data available at the time of the analysis. The Coast Guard's estimates are consistent with other notable cost estimates such as those made by Lloyds' Register ($145,000 to $2,000,000) and the Congressional Budget Office ($300,000 to $1,000,000).

The Coast Guard is continuously monitoring BWMS technologies for new developments and changes in costs. Contrary to the assertion made by a commenter, the Coast Guard has not estimated the BWMS costs based on vessel values. The Coast Guard acknowledges the comment that achieving higher standards might represent higher BWMS cost. The Coast Guard is working with the industry to identify the potential costs of more stringent standards.

One commenter argued that the installation costs for phase-one approved systems were underestimated in the NPRM RA by three to four times due to the fact that the cost estimates for BWMS uses the smallest system size (system flow) as an average system size. The commenter also provided data based on Shipbuilding Market Forecast. According to the commenter, the data show that the average system size processes between 1,200 m^3 and 1,500 m^3 of water per hour, depending on assumptions regarding relation between dead weight tonnage, total ballast water capacity, and flow. The commenter argued that the cost for such a system could easily be $600,000–$700,000, to which an installation cost of another 25 to 75 percent has to be added depending on whether the vessel is a new build or retrofitted.

The Coast Guard disagrees with the argument that the cost estimates for BWMS in the NPRM RA were based on the smallest BWMS cost. The Coast Guard developed low and high installation cost estimates for BWMS to various vessel types and ballast water capacities. The Coast Guard estimated the BWMS installation costs based on the average costs for each available BWMS. The low costs are related to the least expensive treatment available for different types of vessel with different ballast water pump capacities. The Coast Guard recognizes that not all systems are appropriate for all vessel types. Chapters 3 and 4 of the NPRM RA, available on the docket, present a detailed description on costs estimates.

Benefits

One commenter proposed that the Coast Guard should represent the invasive species' environmental harm in addition to economic harm estimates presented in table 8 of the NPRM.

Table 8 of the NPRM presents estimates of the number of NIS that may cause severe economic damages. The derivation of these estimates is more fully detailed in chapter 5, section 5.5 of the NPRM RA available on the docket. The purpose of chapter 5 of the NPRM RA is to estimate the value of the economic harm caused by NIS in order to estimate monetary benefits from the proposed rule to compare against cost estimates. Chapter 5 presents the total number of NIS invasions due to ballast water in table 5.6, which includes all invasions that cause environmental harm, economic harm or cause no harm. The Coast Guard then limits the further analysis of benefits to those invasions that cause economic damage that can be expressed in monetary terms. The Coast Guard believes that this approach was appropriate for use in the NPRM RA.

The Coast Guard recognizes that some NIS invasions may cause environmental harm that cannot be easily monetized. The Final Programmatic EIS (FPEIS), available in the docket for this rule, further describes the potential environmental harm of invasive NIS.

One commenter suggested that the costs associated with introduced invasive NIS considered during practicability reviews should not be limited to a 10-year time frame but should, instead, be considered permanent costs, since NIS introductions are difficult to fully eradicate and long-term control or containment is often necessary. The

commenter argued that projected costs would likely outweigh the costs of technology development, installation, and maintenance over the long run.

The Coast Guard recognizes that the rule will continue to accrue benefits beyond the time-frame of the NPRM RA. The Coast Guard has added analysis of additional timeframes to the final rule RA representing potential benefits of the rule beyond the 10-year period.

One commenter asked what the additional avoided environmental and social damages and economic benefits of a BWDS would be at more stringent standards.

The Coast Guard included the evaluation of potential benefits from standards that are more stringent than the phase-one standard in the NPRM RA, section 5.7 (available on the docket). The benefits evaluation was based on the mathematical model developed for the DPEIS, which estimated the reduction in the mean rate of successful introductions of various alternatives standards. The mid-range of benefits for more stringent standards varies from $286 million to $447 million.

One commenter argued that ''while the initial costs to implement the proposed standard would likely be several million dollars annually for the first five years, subsequent costs would be significantly lower, likely by an order of magnitude. Vessel owners can generally choose whether/how to spread out such costs over time, since installation costs are usually capital costs that can be amortized over several years. The actual cost for an individual vessel to install and maintain appropriate technology would vary depending on vessel type and size. Therefore, a cost benefit comparison reveals the potential for a significant economic benefit resulting from the relatively small investment by vessel owners.''

The Coast Guard agrees that there are potential significant economic and environmental benefits from this final rule.

Regulatory Flexibility Analysis

One commenter noted that the Coast Guard did not take into account the cumulative impact of other Coast Guard regulations on small businesses. The commenter argued that the BWDS rule will impose more costs on top of the other regulations for affected passenger vessel operations.

For the proposed rule, the Coast Guard completed an Initial Regulatory Flexibility Analysis (IRFA). The specific statutory requirements of an IRFA can be found at 5 U.S.C. 603(b). Under these statutory requirements, we did not consider the cumulative impact of other Coast Guard regulations on small businesses or affected passenger vessel operations. The Coast Guard acknowledges that other Coast Guard regulations have imposed additional costs on vessel owners and operators subject to this rule, which contains revised applicability that excludes most vessels operating solely in coastwise trade as previously discussed.

Many of these published regulations implement international agreements such as the International Convention for the Prevention of Pollution from Ships (MARPOL) and the International Convention for the Safety of Life at Sea (SOLAS). The United States is obligated to implement and comply with these international agreements to which the United States is a party, and to do so, under U.S. law the Coast Guard usually must promulgate regulations that are consistent with these agreements. If U.S. vessels on foreign voyages are not in compliance with applicable international law, it could reduce their ability to engage in commerce and trade. This rule generally aligns with the standards adopted in the International Convention for the Control and Management of Ships Ballast Water and Sediments, 2004 (IMO BWM Convention), which has not entered into force at this time and which seeks to establish global minimum ballast water discharge standards.

Additionally, for this rule, the Coast Guard is acting under the legislative mandates in NANPCA, as amended by NISA, to authorize the use of any alternative methods of BWM that are used in lieu of mid-ocean BWE. As previously discussed, these mandates require the Secretary of Homeland Security to ensure to the maximum extent practicable that aquatic nuisance species are not discharged into waters of the United States from vessels. 16 U.S.C. 4711(c)(2)(A). In addition, NISA requires the Secretary to assess and revise the Department's BWM regulations not less than every 3 years based on the best scientific information available to her at the time of that review, and potentially to the exclusion of some of the BWM methods listed at 16 U.S.C. 4711(c)(2)(D). 16 U.S.C. 4711(e). The Coast Guard is publishing this final rule based on these mandates.

Two commenters argued that, as a part of the financial burden, it is important for vessel companies to note the amount of employees/mariners they have.

The Coast Guard agrees with the commenters and would like to note that the number of employees is taken into consideration in the IRFA. The IRFA is in chapter 7 of the NPRM RA available on the docket. The IRFA's goal is to assess the proposed rule's impact on small entities. Company revenue and number of employees (as well as number of vessels) are variables used in the estimation of potential economic impacts to small businesses.

Small Business Administration (SBA)—Office of Advocacy

The Coast Guard received comments from the SBA Office of Advocacy regarding the impact that the proposed rule would have on small entities. The comments provided by the SBA focused on small businesses within the tugboat, towing vessel, and supply barge industries. According to the SBA letter, these small businesses are concerned that the Coast Guard's economic analysis does not account for a significant number of vessels operated by small businesses. These businesses also contend that installing the required BWMS will not be economically feasible for the large number of vessels that discharge relatively small amounts of ballast water. The SBA also expressed concern about the cumulative effect of the proposed regulations should the phase-two standard be implemented without a longer grandfather period than the 5-year period proposed.

The SBA made the following suggestions to improve the Coast Guard small entities analysis:

(a) Expand the scope of regulatory flexibility analysis to include more vessels (vessels less than 100 feet in length, tugboats, towing and supply vessels).

(b) Consider additional regulatory alternatives to increase flexibility for small business (such as exemption for vessels with relatively low-volume ballast tanks).

(c) Include a grandfather provision in the phase-two standard.

The Coast Guard acknowledges the SBA concerns related to the vessels mentioned previously and is studying the BWM options for small vessels and vessels less than 1,600 GT that operate solely in coastwise trade and inland waters of the United States. The Coast Guard has received numerous comments from these industries and has revised the applicability of the rule. As noted earlier in this preamble, the BWDS in this final rule applies only to vessels entering waters of the United States from outside the EEZ, to coastwise vessels that are more than 1,600 GT, and to certain other seagoing vessels meeting specific size thresholds (*see* V.A. Summary of Changes from the NPRM). The Coast Guard fully intends

to expand the BWDS rule to all vessels, as proposed in the NPRM, but has determined that additional analysis is necessary to support this expansion and to consider issues related to grandfathering for the phase-two standard. We also intend to conduct additional research as necessary.

Other

One commenter stated that our use of certain terms such as ''uncertain'' and ''potential'' does not ''inspire confidence in your justification for the broad scope of the proposed rule.''

The Coast Guard notes that within the regulatory assessment process, the presence of uncertainty is common as information and data are sometimes only partially available or not available at all due to a variety of factors, such as the stages of technologies in research and development. The language used in the NPRM RA correctly reflects the uncertainty inherent in the state of available information and technology. The Coast Guard is monitoring the development of technology and analyzing papers on aquatic NIS for additional data.

Economic Comments Raised in the Context of the DPEIS

The Coast Guard received several comments on the BWDS DPEIS that concerned issues related to economics.

One commenter stated that the range of quantified benefits and annual costs needs to be presented for alternatives 3 to 5 to allow comparison among the alternatives. Another commenter asked if the benefits of ballast water treatment were only evaluated for alternative 2 and further adds that there are few details provided on these cost-benefit numbers and methods. One commenter stated that further discussion and analysis of costs vs. benefits, addressing all of the alternatives considered, would be useful.

In the NPRM RA (available on the docket), chapter 5 (table 5.12), the Coast Guard presents the total potential benefit from different proposed alternatives. The values presented in this table enable the comparison of the benefits of alternatives 2, 3, and 4. Data to support the analysis of alternative 5 is not yet available. In addition, the Coast Guard is further investigating costs and benefits of more stringent standards.

One commenter inquired as to what are the additional avoided environmental and social damages and economic benefits of BWDSs at more stringent standards and asked that the Coast Guard provide quantitative data and sources for all information. The commenter suggested that a study be done on the environmental benefits of marine transportation, especially in terms of higher energy efficiency. The requested study on the benefits of marine transportation is beyond the scope of this rule.

7. DPEIS

Adequacy of Document

One commenter stated that the DPEIS does not provide scientific data to show that alternatives 2 through 4 will ensure that the residual NIS population will not survive, persist, spread, or proliferate in the receiving waters. The Coast Guard agrees with this assessment, but notes that our scientifically-based analytical approach is not intended to show that any of these alternatives will specifically ensure that the residual NIS population will not survive, persist, spread, or proliferate, but rather to evaluate the probabilities of decreased introductions and spreading of NIS among the different alternatives. The NRC report ''Assessing the Relationship Between Propagule Pressure and Invasion Risk in Ballast Water'' states that ''The available methods for determining a numeric discharge standard for ballast water are limited by a profound lack of data and information to develop and validate models of risk-release relationship. Therefore, it was not possible with any certainty to determine the risk of nonindigenous species establishment under existing discharge limits [* * *]'' Chapter 4 of the NRC report discusses in detail the risk-release relationship and a wide range of models related to invasion risk as a function of the probability of a species establishment. The NRC recommendations included: ''In short-term, mechanistic single-species models are recommended to examine risk-release relationships for best case (for invasion)-scenario species.''

One commenter stated that the DPEIS alternatives rely on indicator microorganisms to prevent bacterial invasion, yet the selection of *Vibrio cholera, E. coli,* and Enterococci for this purpose is not well supported and the presence or abundance of these bacteria does not verify the composition or abundance of other potential invasive microbes in the ballast water.

The Coast Guard disagrees with this comment. We developed the DPEIS alternatives through a rigorous process including three separate expert panel workshops, public scoping meetings, and cooperating agency participation. The presence or abundance of the selected indicator organisms is not intended to verify the composition or abundance of other potential invasive microbes in the ballast water but, rather, their purpose is to indicate their presence.

One commenter stated that the DPEIS requires further refinement at all levels because some information is out-of-date, that many of the existing data are not properly cited, and that there are issues with grammar, punctuation, and clarity. The Coast Guard disagrees with this comment. The DPEIS was reviewed by scientific experts and cooperating agencies, and is sufficiently current to describe the affected environment and evaluate the impacts of the discharge standard alternatives. In order to ensure future environmental analysis documents are of the highest quality, the Coast Guard made typographical changes in the Final PEIS (FPEIS), as appropriate.

One commenter requested that the phase-one and phase-two standards listed in the proposed rule should clearly refer back to the alternatives analyzed in the DPEIS. The Coast Guard identified alternative 2 of the DPEIS as its preferred alternative, and this is now the phase-one standard. The phase-two standard was removed from the final rule and will be part of a supplemental environmental analysis, which will be issued either with a notice or other rulemaking document.

One commenter suggested changing DPEIS page breaks so table and figures are not broken up, and not confusing the labeling between tables and figures. The Coast Guard agrees that this can make comprehension of a document difficult, and made changes in the FPEIS, as appropriate.

One commenter suggested defining the term ''microorganism,'' updating the IMO BWM Convention status and data on States' expenditures for bioinvasion mitigation and NIS management, adding a cited reference to Literature Cited, correcting other cites, and providing additional references. The Coast Guard reviewed the indicated DPEIS sections and made changes in the FPEIS, as appropriate.

One commenter stated that a sentence in a discussion of the crab *Hemigrapsus sanguineus* in the DPEIS was incorrectly attributed to the United States Geological Survey and gave an alternate citation. The Coast Guard verified the citation in the DPEIS is correct and the Coast Guard was not able to readily locate the relevant information in the alternate citation provided by the commenter.

One commenter stated that the DPEIS fails to make the case for applying requirements that may be appropriate

for oceangoing vessels to Great Lakes vessels. As we have discussed in this preamble, the Coast Guard has the authority to regulate Great Lakes vessels in this way, and is charged with minimizing introduction and spread of NIS in waters of the United States to the maximum extent practicable (*see* V.B.5 Discussion of Comments: Legal). We note, however, that this final rule does not require Great Lakes vessels to comply with the BWDS at this time, and we must take into consideration the factors identified in 16 U.S.C. 4711(c)(2)(H). We will keep this comment in mind in our evaluation of the practicability of expanding the BWDS applicability to all vessels discharging ballast water in waters of the U.S.

One commenter stated concern that current Coast Guard staffing levels will not be adequate to enforce the criteria during land-based and shipboard reviews of independent certification facilities, or ILs, and that needs to be discussed in the FPEIS. Staffing decisions and needs of Federal agencies are beyond the scope of this rule. However, we note that the Coast Guard has been conducting oversight of ILs for several decades.

The PWS RCAC requested that a copy of the Crude Oil Tanker Ballast Facility Study be included in the FPEIS for this rule and that the 1997 analysis for technology available for current onshore water treatment be updated to 2009 data. PWS RCAC further stated that the proposed rule and DPEIS should be revised and reissued for a second public comment review to ensure that comments and concerns were accurately reflected and included to improve both products.

The Coast Guard acknowledges this comment. The Crude Oil Tanker Ballast Facility Study is now available to the public in the docket for this rule. Finally, while we are not subjecting the NPRM and DPEIS to a second round of comments, we anticipate that we will open another comment period when addressing the phase-two standard and an expanded applicability.

Adequacy of Standard

One commenter stated that the FPEIS must provide a sound scientific basis to support alternative 2 thresholds as means for eliminating or substantially mitigating NIS invasion, not just simply selecting NIS reduction thresholds that are two or three orders of magnitude lower than what arrives in ballast water today. The commenter further stated that the DPEIS does not provide a sound scientific basis for its size distinction and that, empirically, the threat posed by NIS is not a function of organism size.

The Coast Guard disagrees with this comment. The goal of a BWDS, as stated in the DPEIS, is reduction or prevention of NIS introductions and associated impacts. We developed the DPEIS alternatives through a rigorous process including three separate expert panel workshops, public scoping meetings, and cooperating agency participation. The Coast Guard based the resulting standards on an allowable concentration of organisms larger than a specified size criterion, providing a balance between protection and practicability and taking into account the expected capabilities of technology. The BWDS alternatives do not represent the minimum viable populations for all taxonomic groups.

One commenter stated that the proposed *E. coli* and intestinal enterococci standards are not strong enough in that they are less stringent than the EPA's criteria for recreational water contact. The Coast Guard acknowledges that the standards in the BWDS may appear to be less stringent than EPA standards for water quality. However, the water quality standards are for ambient conditions, not discharge standards.

One commenter pointed out that the concept of indicator organisms as surrogates for pathogens has served the drinking water supply industry well since its establishment of presence/absence testing that is now routinely used. The Coast Guard agrees with this comment, and notes that the DPEIS included indicator organisms in some of the alternatives.

One commenter stated that, based on scientific reports from both the United States and Canada, the current BWM measures in place in the St. Lawrence Seaway and the Great Lakes (BWE and salt-water flushing for no ballast onboard vessels) protect the waters of the Great Lakes, making the proposed BWDS unnecessary. The commenter further stated that the proposed phase-one BWDS, according to available science, will ensure that aquatic NIS are not discharged into waters of the United States from vessels. The commenter added that the approach discussed in the NPRM that would bypass phase one and go directly to the phase-two standard is not practicable and it is doubtful that it would provide greater protection of the aquatic environment.

The Coast Guard acknowledges that there have been no new reports of introductions of invasive NIS into the Great Lakes since implementation of the BWM measures mentioned by the commenter. While the lack of reports of new introductions into the Great Lakes is promising and there is a reason to be optimistic that current BWM methods are having an effect, there are continuing reasons to be concerned and not to accept these findings as definitive. For instance, the lack of comprehensive sampling may mean that some events have not been detected. Other possibilities are that there have been introductions, but that there have been lags in species establishment. Also, we note that the practicability review process referenced by the commenter was designed to ensure that any bypass of phase one to phase two would only occur if it could be practicably achieved.

Consideration of Treatment Method Impacts

Two commenters pointed out that the DPEIS does not address the impacts of specific BWMS.

Another commenter said that the statement in the DPEIS that alternatives 2 through 5 would not have additional adverse impacts on environmental and socioeconomic resources might not be an acceptable assumption for some treatment options (such as chemical disinfectants).

Two commenters recommended that the Coast Guard explicitly consider the environmental impacts of approaches to meet BWDS. The first commenter focused on methods that could involve active substances at high concentrations that could be persistent, toxic, or both. The second commenter recommended that the Coast Guard assess treatment technologies in coordination with the EPA by conducting a FPEIS in conjunction with the practicability review and include the impacts of both biocide residuals and treatment byproducts, cumulative impacts (multiple discharging ships and multiple types of active substances), and to ensure that discharges are consistent with Clean Water Act requirements.

One commenter stated that the DPEIS does not analyze the effects of potential technologies and methods for achieving BWDS, including chemical residuals, reaction by-products, thermal pollution, energy use, and dockside impacts, and that until those are evaluated, impacts on ESA listed species cannot be assessed. The commenter stated that the agency understands that the ''action'' is establishing standards, and continues to support the process for establishing the standards.

The Coast Guard acknowledges these comments and clarifies that ballast water treatment systems were not included in the DPEIS. However Appendix F of the FPEIS does include an analysis of ballast water treatment

technologies in use by vessels enrolled or being reviewed by STEP as a means to show the practicability of the BWDS set forth in this rule. This information is not meant to be detailed or all-inclusive. Methods to achieve the standard will be evaluated in separate environmental analyses as part of the approval process. All appropriate actions, resources, and impacts will be taken into account.

One commenter inquired about a statement in the DPEIS under the description of chlorine as a biocide that impact to ships' ballast tanks from the corrosion is a concern, asking whether it is a Coast Guard or a maritime industry concern, and why. The Coast Guard is concerned with any potential corrosion issues that could affect the safety or life of a vessel. Any BWMS that is going to require additional maintenance or shorten the life of the vessel has the potential to cause ripple effects through the maritime transportation system.

One commenter stated that it is very difficult, given the current stage of scientific evidence and BWMS, to discuss the merits of more stringent standards than those imposed by IMO, especially as extreme an alternative as sterilization. The commenter further stated that sterilization of ballast water would task the maritime industry with an unwarranted standard and would probably be impossible to achieve. The Coast Guard agrees that the total sterilization of ballast water, specifically in regards to microbiological organisms, is challenging, if not impossible to achieve. The preferred alternative was developed taking into consideration environmental protection and practicability, including the economic and technical aspects of implementing BWDSs.

One commenter stated that destruction of spore-like phases of marine life may be impracticable without actually distilling ballast water and, even so, any residue may well have to be treated as toxic waste. Another commenter stated that BWM will prevent organisms from reproducing and releasing larvae into the environment.

The Coast Guard does not agree or disagree with these comments, as they relate to specific types of BWMS. As noted earlier, specific BWMS were not included in the DPEIS. These specific BWMS will be evaluated in separate environmental analysis as part of the approval process. All appropriate actions, resources, and impacts will be taken into account in that process.

Two commenters stated that the foundation for setting any BWDS under NEPA is the ability to conduct a cost/benefit assessment, but that it cannot be done because there is no way to predict or quantify the environmental benefit (measurement of invasions which did not occur) of the treatment alternatives. The commenter explained that a reasonable cost/efficacy ratio and measurable reduction of introduced organisms are needed, and without a reasonable, scientifically-based metric to show continual improvement, the perceived benefit may not meet measured benefit, leading to more stringent regulation and additional implementation costs.

The Coast Guard disagrees with these comments. As we have discussed, specific BWMS were not included in the DPEIS, but the FPEIS does include an analysis of STEP vessels with ballast water treatment technologies as a means to show the practicability of the BWDS set forth in this rule. Methods to achieve the BWDS will be evaluated in separate environmental analyses during the approval process for each BWMS. Additionally, the Coast Guard did conduct a scientifically based analysis to predict the relative probability of NIS establishment for the discharge standard alternatives in the DPEIS. For purposes of complying with NEPA, the Council on Environmental Quality regulations state that weighing of the merits and drawbacks of the various alternatives need not be displayed in a monetary cost-benefit analysis and should not be when there are important qualitative considerations.

DPEIS Modeling Comments

One commenter stated that treating a lack of current science as meeting the ''best available science'' requirement of NISA may be a practical necessity in order to adopt an environmentally protective and economically rational standard in the near future. The commenter did not think it is reasonable to assess in advance the biological effectiveness of this ''first established standard,'' as there would be no other numeric standard to compare to. The commenter also stated that the relationship between the frequency and magnitude of introductions and the probability of successful NIS establishment should be a priority for future research to establish a baseline for future adjustments to discharge standards.

The Coast Guard disagrees with this comment. First, the statutory requirement from NANPCA, as amended by NISA, is that we use ''best scientific information available,'' not ''best available science.'' Second, although the amount of scientific information available on aquatic NIS is not ideal, the Coast Guard conducted a scientifically-based analysis to predict the relative probability of NIS establishment for the BWDS alternatives in the DPEIS. New information on the probability of aquatic NIS establishment will be considered for future evaluation of discharge standards.

Two commenters stated that the Coast Guard argues convincingly that population viability analysis (PVA) is the most suitable analytical methodology to use for the NEPA analysis, and that we should consider revisiting the approach if new information becomes available in intervening years. The Coast Guard agrees with the comment. New information on the probability of aquatic NIS establishment will be considered for future evaluation of discharge standards.

One commenter asked whether there is precedent for using PVA for the type of NIS application that the DPEIS addresses. Another commenter expressed concern that the Coast Guard has not provided sufficient documentation to support the use of PVA ''in a marine or aquatic situation with invertebrates and/or microorganisms.''

As the Coast Guard noted in the DPEIS, the application of PVA to marine and aquatic invertebrates and microorganisms is novel. However, this does not affect the underlying scientific logic of this approach (e.g., Andersen 2005). PVA has been applied to terrestrial invertebrates (e.g., Schultz and Hammond 2003). The diffusion model on which the PVA in the report is based has been applied to microbial populations (e.g., Ponciano et al 2005).

One commenter stated that an evaluation of extinction probability needs to consider cumulative ballast discharges from multiple ships rather than just individual discharges from single ships, and examine the assumption that an initial population released from an individual ship is completely separate and isolated from other organisms released in the same area, since several discharges in the same area may build a population to viability before extinction can occur.

The Coast Guard acknowledges this comment and will take this opportunity to clarify. Based on available data, the analysis focused explicitly on a single discharge. In order to address the broader question of the effect of the proposed BWM measures on the rate of species introductions from multiple discharges, the Coast Guard would require information about the number, magnitude, and timing of the multiple

discharges and about the species present in each discharge. As identified in the NRC report, there are data gaps (''a profound lack of data and information'') and therefore, there is no presently available information on multiple discharges. As recommended by NRC, models need to be developed to assess these risks and to link to new information as they become available. The Coast Guard will consider models that may be available during their practicability review under NISA. This may provide additional information to address the risk associated with multiple ballast discharges.

One commenter claimed that the analysis assumes that ''a percentage reduction in abundance is directly and linearly related to reduction in successful invasion probability.'' The Coast Guard disagrees with this comment. The relationship between a percentage reduction in abundance and the probability of successful invasion is not assumed, it is based on the underlying diffusion model for population growth. Furthermore, the relationship is not specifically linear for this model; reducing initial abundance by a factor f increases the probability of extinction (i.e., unsuccessful invasion) by a factor f^{-c} where the parameter c depends on the parameters of the population model.

A commenter stated that it would be helpful for the DPEIS to give at least some consideration to organisms 10 micrometers and smaller, given the potential for pathogenic microorganisms to be transported in ballast water, using the framework adopted in Appendix A for larger organisms. Another commenter was concerned that the technical approach in the DPEIS does not adequately consider pathogens in the analysis. The Coast Guard disagrees with these comments. Microorganisms and pathogens were considered throughout development of the BWDS alternatives and are included in the BWDS in the form of indicator species. The PVA analysis in Appendix A was not applied to microorganisms because, for smaller organisms, the lower bound of the mean density range is already below the limits of alternatives 2 through 4 and that the Coast Guard was not aware of any basis for a scientific, defensible, and enforceable discharge standard for microorganisms.

One commenter stated that the technical approach to justify the proposed standards needs to include the transportation of bacterial and viral NIS pathogens, including the fish-killing Viral Hemorrhagic Septicemia (VHS) virus, by larger NIS that are infected. The commenter said that ballast water discharge containing infected organisms could transmit the pathogens, whether the host is alive or dead.

The Coast Guard agrees with this comment. Microorganisms and pathogens were considered throughout development of the BWDS alternatives and are included in the standards themselves in the form of indicator species. The analysis' technical approach addressed the two larger size classes of organisms in alternatives 2 through 4, not microorganisms, given that for smaller organisms, the lower bound of the mean density range is already below the limits of alternatives 2 through 4. The Coast Guard was not aware of any basis for a scientific, defensible, and enforceable discharge standard for microorganisms.

One commenter stated that the DPEIS assumption for the PVA model, that N(t) follows geometric Brownian Motion, should be better clarified and defined, and is probably inappropriate for larger organisms than the smaller than 50 micrometer class, since larger organisms move based on several variables such as habitat and water temperature (which could also affect motion of organisms smaller than 50 micrometers).

The Coast Guard disagrees with the comment. The diffusion model does not assume that individuals do not move in response to environmental factors. It is possible that the commenter confused the population model—which is called Brownian motion—with a model of the same name of the movement of individuals.

One commenter stated that the complexity of predicting the introduction and establishment of NIS and the lack of the necessary detailed information do not justify the Coast Guard's use of a ''generic data-poor approach'' to analysis. The commenter also questioned whether PVA is appropriate or useful for an unknown, large number of different species with differing characteristics and dynamics that may be present within a ballast tank, since the Coast Guard states ''PVA is typically used to assess the status of a particular population and therefore typically involves the development of a model of each population of interest separately,'' and is ''a routine tool for assessing the dynamics and extinction properties of a single population.''

The Coast Guard notes that the commenter's acknowledgment of the lack of detailed information implies that any approach will be ''data-poor.'' The diffusion model PVA approach used in the DPEIS is the best available to science that is appropriate for this purpose. The application of PVA to ''an unknown (but large) number of different species'' was necessitated by the problem at hand: namely, to evaluate alternative national standards for BWM. The diffusion model used here is quite general and applicable to different populations. The values of the parameters of this model are likely to vary from species to species and environment to environment. To account for this, the analysis considered a reasonable range of parameter values. As discussed in the NRC report, the PVA model is acknowledged as one of a group of models that can assess the relationship between invasion risk and propagule pressure. The NRC report goes on to conclude that ''models of any kind are only as informative as their input data. In the case of ballast water, both invasion risk and organisms density discharged from ballast water are characterized by considerable and largely unquantified, uncertainty.''

One commenter stated that there are gaps in the knowledge of invasion biology required to assess the impacts of a treatment standard and the relative degree of added benefit as compared to BWE. The Coast Guard acknowledges this comment. Although the abundance of scientific information on aquatic NIS is not ideal, the Coast Guard conducted a scientifically based analysis to predict the relative probability of NIS establishment for the discharge standard alternatives in the DPEIS.

One commenter suggested that the statement from DPEIS Appendix A that ''considerable uncertainty attaches to the estimate of the extinction probability factor and the mean rate of successful introductions relative to the baseline'' needs to be included as a disclaimer in the main body of the PEIS. The Coast Guard agrees and made that addition in the FPEIS.

One commenter stated that separate risk analysis and assumptions are needed for the freshwater environment on the Great Lakes and offered general information and references on salinity toxicity effects, expected number of future invasions, and BWE effectiveness. The Coast Guard disagrees with this comment. Given that the PEIS is programmatic to apply to the wide variety of ecosystems in the affected environment and the generic nature of the PVA diffusion model, the analysis is applicable over the range of the impacted area.

Two commenters questioned the assumed range of 0.001 to 0.1 of for the values of c, the biological population parameter. The first commenter stated that the instantaneous growth rates for many planktonic organisms are well-known and others can easily be determined experimentally. The second

commenter stated that there is no justification for the selection of this range, and no discussion of whether populations might typically tend towards either end. The first commenter further stated that the values for the statistical representation of the estimated total initial number of organisms released in a single ballast water discharge is extremely variable and questioned how the values can give a good representation of the number of organisms discharged from a typical ballast tank.

The Coast Guard neither agrees nor disagrees with these comments. As we explained in Appendix A of the DPEIS, we chose this range to reflect the best available estimates of the extinction probability for species introduced through ballast water discharge. The paper by Calbet and Landry (2004) provides daily growth rates for planktonic organisms in their native habitats. A central issue regarding NIS is the fate of organisms introduced into habitats that are not their native ones. Furthermore, the critical parameter c depends not only on the growth rate of a population, but also on its variability. The values characterizing the initial number of organisms are based on the work of Minton et al. (2005) and provide the best available representation of variability in the number of organisms released in a single ballast water discharge.

One commenter stated that the assumptions that the ballast water of a single vessel contains 12 ''new'' species, that the most abundant is 50 percent of the total abundance, and that the ordered relative abundances follow the geometric model is an ''extremely huge'' set of assumptions to make and there is lack of reasoning behind them. Furthermore, the commenter was concerned that a large number of species may have been missed, since the 12 value comes from a study evaluating organisms of a different size class than the alternatives, and was concerned that there is no presentation of variation around the mean for 12 new species.

The Coast Guard disagrees with this comment. We provided the rationale for each assumption in Appendix A of the DPEIS, which states that the assumed values were based on the paper by Smith, et al. (1999). Despite its limitations, this study reflects the best available information on the species composition of ballast water. The application of the PVA diffusion model was conducted by experts in the biological and statistical fields and reviewed by others, including cooperating agencies. The PVA diffusion model provided a generic, non-species-specific model that, in conjunction with other information, was used to provide insight into the potential relative impacts of the alternatives, based on probability of NIS establishment.

One commenter stated that there should be more consistent use of lower and upper case letters for variables/parameters in the DPEIS, and that the clarity of the extinction probability equation would be improved by indicating the baseline extinction probability with a different term/subscript, providing more information on its derivation, and correcting the relationship to read $f_e = f^{-c} f_e = f^{-c}$. The commenter also suggested that q(m) (the probability that at least one species is successfully introduced) should be defined in the DPEIS body text and that Ne (the percent increase in q(m) over the baseline scenarios) should be defined.

The Coast Guard disagrees with the comment regarding the extinction probability equation. The equation follows from simple algebraic substitution and no further details should be needed. On the notation for baseline extinction probability, Appendix A already distinguishes between baseline extinction probability and extinction probability when initial abundance is reduced by a factor f. The Coast Guard agrees the correct relationship is $f_e = f^{-c} f_e = f^{-c}$ and changed the FPEIS from ''extinction probability factor $f_e = f^{-c} f_e = f^{-c}$'' to ''extinction probability factor $f_e = f^{-c} f_e = f^{-c}$'', as in Equation (7). The Coast Guard acknowledges the comment regarding the terms q(m) and Ne and made changes in the FPEIS, as appropriate.

One commenter stated that there is no sensitivity analysis or quantification of model error with which to evaluate the PVA model used in the DPEIS. The Coast Guard disagrees with this comment. Throughout the DPEIS, results are given for alternative values of key parameters.

One commenter stated that discussion in the DPEIS on the importance of default values for multiple species is incomplete, and that examples of predictions for probability of at least one introduction in multiple species scenarios could convey a false sense of security. The commenter also stated that using a default value of only twice the median number of organisms released results in a nonzero, albeit small, probability of at least one species being introduced in the alternative 4 scenario and that this sensitivity issue should be discussed in the DPEIS.

The Coast Guard disagrees with the comment. We provided the rationale for these default values in Appendix A of the DPEIS. The commenter's own calculation of the effect of doubling the default of the total number of organisms in a discharge event shows that these results are not highly sensitive to changes in the default values.

One commenter stated that the modeling results for multiple species support the conclusion that more stringent treatment alternatives will substantially reduce the likelihood of new NIS introductions via ballast water. The Coast Guard acknowledges this comment, but notes that the correctness of this statement depends on the definition of ''substantially.''

One commenter responded to a question in the NPRM asking for any studies on the effects of propagule pressure on successful establishment of a NIS in aquatic ecosystems by referring to the research being performed by the Canadian Aquatic Invasive Species Network in relation to shipping mode and route, and factors affecting establishment success. The Coast Guard may use this information in a future evaluation of discharge standards. The Coast Guard will continue to follow the relevant literature in this area.

One commenter stated that it seems, from the relative effectiveness results of the analysis of BWDS alternatives, that the approach assumes that discharges in compliance with the different alternatives contain the stated number of organisms in the respective groups, and that the proposed phase-one standard is equivalent to the IMO discharge standard. The Coast Guard agrees with the comment.

One commenter cited an error in Appendix A, table 5–8. For the scenario with Ne = 100, c = 0.00008 and alternative 3, q(m) should be 0.00025, not 0.0025. The Coast Guard agrees with this comment and made this correction in the FPEIS. Ne is the percent increase in q(m) over the baseline scenarios, q(m) is the probability that at least one species is successfully introduced, and c is the biological population parameter.

One commenter stated there is no evidence to suggest that the standards outlined in alternatives 1 through 4 are biological thresholds that represent minimum viable populations for all taxonomic groups. The Coast Guard agrees with this comment, however, this is not relevant to the analysis. The BWDS alternatives do not represent the minimum viable populations for all taxonomic groups. We developed these alternatives through a rigorous process including three separate expert panel workshops, public scoping meetings,

and cooperating agency participation, and the Coast Guard based the BWDS alternatives on an allowable concentration of organisms larger than a specified size criterion, providing a balance between protection and practicability and taking into account the expected capabilities of technology.

DPEIS Affected Environment Comments

One commenter suggested that the Coast Guard expand the scope of the DPEIS to encompass the ''big picture'' by including other adjacent, interconnected water bodies, such as the Canadian waters of the Great Lakes, and including other interacting programs such as U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). The commenter also suggested including information in the DPEIS from an authority on VHS and Federal agency publications on treatment methods.

The Coast Guard disagrees with this comment. The DPEIS is a programmatic document, and areas were addressed at the national and ecosystem level, including a freshwater ecosystems section. APHIS participated in the preparation of the DPEIS as a cooperating agency in accordance with 40 CFR 1501.6. BWMS were not included in the DPEIS and methods to achieve the standard will be evaluated in separate environmental analysis as part of the approval process. Vessels with BWMS enrolled in STEP are included in the FPEIS as a means evidence the practicability of the BWDS proposed in this rule.

Another commenter suggested including a major western freshwater system under the DPEIS section on freshwater ecosystems and cited the Columbia River and its watershed as very significant. The Coast Guard agrees with this comment, and added the Columbia River as an additional example in the FPEIS.

One commenter suggested separating public health and shipping safety, and expanding the latter in the Affected Environment chapter of the DPEIS. The Coast Guard agrees and made these changes in the FPEIS.

One commenter stated that the proposed rule and DPEIS are both over-inclusive (too many vessels and areas) and under-inclusive (some remedies not considered, such as using other water or other ballasting methods). The Coast Guard made changes to the final rule, including revised applicability to include additional exemptions and clarification of other water and ballasting methods, which address the examples given as evidence that the NPRM and DPEIS were both over- and under-inclusive. These changes are summarized in this preamble in V.A. Summary of Changes from the NPRM.

One commenter explained that the physical environment of the Great Lakes is more susceptible to ecosystem damage due to isolation and slow flushing rates as compared with estuarine and ocean coastal areas. The Coast Guard notes this comment, but did not include Great Lakes flushing rates in the FPEIS because it analyzed the BWDS alternatives from a nationwide scope, not by specific geographic area.

One commenter stated that since the Great Lakes are one of the primary freshwater resources affected by BWDS, the DPEIS could include additional Great Lakes-specific information and references. The commenter further suggested that it may be useful to highlight Lake Superior as a less stressed system than the other Great Lakes and discuss the Great Lakes Fishery Commission's fishery management objectives pertaining to habitat in the Great Lakes. The Coast Guard disagrees with this comment. The Great Lakes were addressed as a whole in the DPEIS, not individually.

Two commenters stated that the Coast Guard recognizes the environmental damage caused by NIS, and they explained that the rapid spread of freshwater invaders from the Great Lakes illustrates that protecting the Great Lakes from ballast-mediated invasions protects freshwater ecosystems across North America. The Coast Guard acknowledges these comments.

One commenter suggested adding Asian clams to the DPEIS discussion of the round goby and updating the analysis to include costs of the second underwater electric barrier. The same commenter suggested modifying the statement about the abundance of Diporeia in Lakes Michigan and Huron from non-existent to vastly declined, and highlighting additional examples of food web changes related to NIS. The Coast Guard disagrees with the first comment. The round goby was cited as an example and does not need elaboration. The remaining changes were made, as appropriate.

One commenter suggested that waters within many National Park units may represent the best available examples of healthy marine ecosystems, and should be recognized explicitly in the DPEIS and NPRM via a clear prohibition of ballast water discharge within their boundaries. The Coast Guard disagrees with the recommendation for a blanket prohibition of ballast water discharge within National Park waters. We note, however, that 33 CFR 151.2050 requires vessel owners to avoid ballast water discharge in marine sanctuaries, marine preserves, marine parks, or coral reefs.

One commenter stated that habitat destruction and loss should be included as a stressor impacting marine, estuarine, and freshwater environments, being that it has been implicated as the greatest threat to imperiled species and gave a reference. The commenter also stated that the other stressors and examples in the DPEIS need to have citations for the references used. The Coast Guard disagrees with the comment. Habitat destruction and loss already are mentioned and cited in several places in the DPEIS.

One commenter stated that the DPEIS doesn't quantify some of the worst NIS, such as zebra mussels. The commenter also takes issue with the apparent focus on populated aquatic environments that are already compromised by NIS at the expense of protecting all aquatic environments, from the pristine to the heavily used. The commenter said that when all the economic benefits of protecting environments from NIS are evaluated, a preventative mode is more cost effective than mitigating undesired effects.

The Coast Guard disagrees with this comment. The effects of zebra mussels and other NIS are mentioned in several places in the DPEIS. A BWDS under NANPCA/NISA is intended as a practicable standard that significantly reduces the risk of invasions in all aquatic environments.

One commenter suggested that the Coast Guard define ''dead zones,'' or use the terms ''anoxia'' or ''hypoxia'' to better describe the situation. The Coast Guard agrees with this comment, and made the changes in the FPEIS to clarify that there will be fewer introductions and spreading of NIS in comparison to a scenario without a BWDS.

One commenter pointed out an apparent inconsistency where the DPEIS states two different numbers of NIS reportedly established in San Francisco Bay. The Coast Guard made the changes in the FPEIS.

One commenter suggested that the Coast Guard explain what is meant by ''increased competition'' in the DPEIS description of impacts on bird health. The Coast Guard made the changes in the FPEIS.

One commenter suggested that the Coast Guard update all of the economic information in the DPEIS Economic Status section to reflect the recent downturn in the economy. The commenter specified that they believed the statement that tourism and recreation have provided all of the job

growth to the U.S. ocean economy within the last decade was outdated and not accurately cited. The Coast Guard disagrees with this comment, as the socioeconomic information in the DPEIS is intended to represent a longer term, e.g., a decade or more. We verified the citation and the statement is accurately cited.

One commenter pointed out that billions of dollars are spent and anticipated for dealing with NIS. The commenter also felt that the value of Michigan's extensive water resources and their uses must be taken into account, and that the cost of not pursuing a more rigorous standard for the Great Lakes is billions of dollars annually and will result in incalculable natural resource losses. The Coast Guard neither agrees nor disagrees with this comment, however, the PEIS is a programmatic document, and areas, including socioeconomic impacts such as water resources, were addressed at the national and ecosystem level not the State level.

PEIS Alternatives Comments

One commenter expressed general support of the DPEIS, stating their appreciation of the use of the best available science and models to justify the numeric discharge standard. The Coast Guard notes that the standard from NANPCA, as amended by NISA, is for the Coast Guard to use ''best scientific information available,'' not ''best available science.''

One commenter stated that the sizes range for the alternative standards should extend to below 0.01 micrometers, to incorporate most pathogenic viruses, including the VHS fish virus. The commenter also said that the possibility of man-made pathogens or fragments of viruses which could be used to contaminate freshwater city water supplies on the Great Lakes and deserve special treatment due to their risk of adversely affecting most native fisheries in the Great Lakes and adjacent waters.

The Coast Guard disagrees with this comment. Three separate expert panel workshops, public scoping meetings, and cooperating agency participation contributed to progressive development of the BWDS alternatives. As a result, the Coast Guard decided that pathogenic microorganisms, which include viruses, would be represented in terms of indicator bacteria. The BWDS alternatives do not apply by specific area.

One commenter recommended that the PEIS define organism size classes for BWDS alternatives in more detail by specifying where on the organism the measurement is done and to use organism taxa in the categorization. The commenter also recommended clarification on whether chain forming algae should be classified by size of individual cells or size of colonies. The commenter stressed that the Coast Guard must keep in mind the ultimate goals of reducing or eliminating the risk of invasive species when classifying organisms by size. The Coast Guard reviewed the information provided but did not make changes in the FPEIS, as we believe there is sufficient information in the FPEIS as it stands.

One commenter stated that he or she does not support a no-action alternative. The Coast Guard appreciates the commenter's input, however, the no-action alternative is used as a baseline in the environmental analysis, not as an action alternative. Council on Environmental Quality regulations require the Coast Guard to evaluate the no-action alternative. 40 CFR 1502.14(d).

One commenter stated that the discussion of the no-action alternative should include that a vessel-by-vessel approach is not practical, and that using BWE as the benchmark for system effectiveness is not sufficiently protective of the waters of the United States. The Coast Guard disagrees with this comment. Council on Environmental Quality regulations require the Coast Guard to evaluate the no-action alternative; it is used as a baseline in the environmental analysis, not as an action alternative. *Id.*

One commenter stated that ballast water retention, part of the no-action alternative, would eliminate the introduction of species via ballast water discharge, thus it is not appropriate for the DPEIS to state that the no-action alternative will not eliminate the introduction and spread of NIS. The commenter further stated that the DPEIS should make it clear that, while a BWDS is more protective than BWE, ballast water retention is more protective than a BWDS, and that many vessels do not have to take any BWM actions under current regulations and can release untreated coastal ballast water.

The Coast Guard disagrees with the comment. The no-action alternative is intended to reflect a set of options, any of which a vessel may use or not use, due to preferences or capabilities. Thus the no-action alternative as a whole will not eliminate the introduction and spread of NIS. The Coast Guard acknowledges in the DPEIS that some vessels may not be able to conduct BWE depending on vessel design, age, load, sea conditions, and safety concerns.

One commenter stated that it is confusing to include ballast water treatment under the no-action alternative, and wondered if the Coast Guard intended to state that treatment that is equal to or better than BWE, without the development of a BWDS, is part of the no-action alternative. The Coast Guard disagrees with this comment. The no-action alternative reflects the baseline of current BWM requirements, which includes the option of using an approved treatment that is equal to or better than BWE. The no-action alternative is intended to reflect a set of options, any of which a vessel may use or not use, due to preferences or capabilities.

A commenter stated that the DPEIS overstates the difficulty of achieving alternative 5 because a number of sterilization options listed in Appendix F, including gaseous chlorine, which is widely used at municipal water treatment facilities, essentially sterilize drinking water. This commenter also said that the DPEIS further overstates alternative 5's difficulty by asserting that alternative 5 is the same as elimination of ballast water discharge. The Coast Guard disagrees with this comment. Specific BWMS were not included in the DPEIS and the BWMS analyzed in Appendix F of the FPEIS is limited to providing a rational basis of the practicability of a proposed alternative. Methods to achieve the standard will be evaluated in separate environmental analysis. The DPEIS did not state that alternative 5 is the same as elimination of ballast water discharge but, rather, that the most feasible approach for achieving it is through the elimination of ballast water discharge.

Two commenters stated that, in 1997, Congress required the Coast Guard to examine the feasibility of modifying the Valdez Marine Terminal to prevent the introduction of NIS, and suggested that such a study be included in the docket and examined in the PEIS. They further suggested that the PEIS should include an alternative that examines whether a NIS treatment option can be accelerated at the Valdez Marine Terminal ahead of the proposed phase-one and phase-two schedules. The commenters also stated there are onshore treatment solutions for vessels, including crude oil carriers.

The Coast Guard disagrees with this comment. Vessels discharging ballast water to shore or vessel/barge-based treatment facilities essentially achieve alternative 5 (near sterilization) by not discharging to the waters of the United States. It would not be practicable to develop a PEIS alternative involving shoreside facilities, as there are not currently any available that are designed

to remove living organisms from ballast water. They can be viewed as one of the potential options available to vessels.

One commenter stated that ballast water treatment must ensure that ballast does not contain NIS of sufficient quantity to allow survival and inoculation, and that DPEIS alternatives 2 through 4 do not assure this standard can be met, but that alterative 5 does. This commenter and one other stated that the alternative 2 standard is not appropriate for the entire United States, because site-specific treatment options may be able to achieve treatment that exceeds the alternative 2 standard. The first commenter stated that alternative 5 should be the goal, with reduced standards allowed only when it is proven technically infeasible to meet this goal.

The Coast Guard disagrees with these comments. The DPEIS evaluated the BWDS alternatives, not the means of meeting them. Any methods to achieve the standard, including ballast water treatment, will be evaluated in a separate environmental analysis as part of the approval process. However, as stated previously, the FPEIS does analyze STEP vessels with BWMS to determine the practicability of the BWDS set forth in this rule. The goal of a BWDS, as stated in the DPEIS, is the reduction of NIS introductions and spread and associated impacts.

One commenter stated that the Coast Guard should attempt to implement the most protective alternative available in the absence of detailed environmental data to determine the population level at which an introduced species will survive. The commenter also noted the difficulty in comparing the effectiveness of alternatives 1 through 4, and acknowledged that alternative 5 will not remove the risk of all NIS introductions. The commenter further recommended that alternative treatment systems, such as onshore facilities, be considered in more detail during the practicability review.

The Coast Guard disagrees with this comment. NEPA does not require a Federal agency to select the most environmentally protective alternative. Currently, there are no U.S. type-approved BWMS intended for use onboard vessels that can practicably and safely achieve complete sterilization of ballast water. Although difficult, the Coast Guard made a scientifically-founded evaluation of the alternatives. The preferred alternative was developed taking into consideration environmental protection and practicability, including economic and technical aspects.

The Coast Guard also disagrees with the commenter's suggestion to take onshore facilities into account during practicability reviews. The purpose of the practicability review is not to establish that there are alternatives to shipboard BWMS capable of meeting the applicable BWDS, but to determine specifically whether such shipboard BWMS are practicably available. The presence of onshore facilities will not factor into that analysis.

One commenter requested that the DPEIS be revised to provide a complete quantitative analysis of alternative 5, as required by NEPA. The Coast Guard disagrees with this comment. NEPA does not require a quantitative analysis of each alternative, but rather ''to document and define changes in the natural environment, including the plant and animal systems, and to accumulate necessary data and other information for a continuing analysis of these changes or trends and an interpretation of their underlying causes.'' Since alternative 5 is the only alternative that assures that no living organisms larger than 0.1 micrometer are released via ballast water the impacts on environmental resources are expected to be minimal.

One commenter stated that the Coast Guard's preferred alternative does not achieve a sufficient reduction in the predicted mean rate of successful NIS introductions. The Coast Guard disagrees with this comment. Under NISA, Congress authorized the use of environmentally sound alternative BWM methods that are at least as effective as BWE in preventing and controlling infestations of aquatic NIS. The preferred alternative achieves that requirement.

One commenter provided the information that over 80 percent of vessels arriving in California retain all ballast onboard, to refute the DPEIS statement that few vessels have the ability to retain ballast onboard. The commenter further stated that vessels may conduct internal ballast transfers or alter cargo handling operations to reduce the need to de-ballast.

The Coast Guard disagrees with the comment. The Coast Guard does not believe that such retention percentages are applicable to many vessels calling at U.S. ports. Ballasting operations depend on whether vessels are offloading or loading cargo, on vessels' ability to carry near-maximum cargo loads on all legs of a voyage, and on the design and configuration of the vessel (e.g., bulk carriers cannot retain ballast water, whereas container vessels may have the physical capacity to do so).

One commenter stated that the PEIS should note that the existing BWM strategy (mid-ocean BWE) is not enforceable to any degree of accuracy. This comment is beyond the scope of the DPEIS. We note, however, that the Coast Guard enforces the BWE requirement during both port state control boardings and annual inspections of vessels, and that there have been a variety of civil penalty actions which directly contradict the commenter's assertion.

One commenter stated that since alternative 2 is not the most environmentally protective one, the Coast Guard must further discuss why this alternative is preferred. The Coast Guard's environmental and socioeconomic rationale for selecting alternative 2 as the preferred alternative is stated in the FPEIS.

One commenter pointed out that the DPEIS states that a 2001 workshop in Oakland, CA recommended, as a long-term proposal, the complete removal or inactivity in ballast water for the first two functional groups (coastal holoplankton-meroplankton-demersals and phytoplankton-cysts-algal propagules). The commenter wanted to know why this is not considered as a long term goal, even if it were to be a protracted implementation.

The Coast Guard used information from the 2001 workshop and from other expert panel workshops, public scoping meetings, cooperating agency participation, and other sources in developing the proposed BWDS. The goal of a BWDS is prevention of NIS introductions and spread and associated impacts. The phase-two standard proposed in the NPRM was based on the most stringent quantitative standards currently in place in a state. However, under NANPCA/NISA, any proposal of a standard must consider practicability, which accounts for the non-inclusion of a no living organism standard.

PEIS Environmental Consequences

One commenter stated that the phase-one standard is less effective than BWE. The Coast Guard disagrees with this comment. Chapter 4 and appendix A of the PEIS show that alternatives 2 and 3 are more effective than the no-action alternative.

One commenter stated that nektonic organisms were not included in chapter 4 of the DPEIS. The Coast Guard disagrees with this comment. Nektonic organisms (e.g. fish), though not directly addressed as a group, are indirectly addressed throughout the FPEIS.

One commenter suggested that ballast water discharge is one of the key vectors for viral transmission, especially VHS. The commenter said that, with no special regulation for Great Lakes vessels, viruses (such as VHS) could

spread through Lake Superior and possibly move into other waterways.

The Coast Guard has not identified any studies that directly identify ballast water as a documented VHS vector in the Great Lakes. There is a need for further information on possible vectors, including ballast water, vessel fouling, and live and dead fish. The Coast Guard notes that the BWDS alternatives do not generally apply by specific geographic area, but rather are nationwide in scope. However, we will keep this comment in mind as we conduct more research into the effects of implementing a BWDS in the Great Lakes, as well as nationwide.

One commenter stated that impacts of a BWDS need to be clarified as far as it would affect ecology, the economy, industry, and society, among other aspects. The Coast Guard believes that the DPEIS addressed those issues at the programmatic level.

One commenter suggested that the sentence ''Economic sectors dependent on the health of aquatic and coastal resources would benefit from overall healthier ecosystems with fewer invasive species'' in chapter 4 was misleading because a BWDS will not result in fewer existing invasive NIS, but fewer introductions in the future. The Coast Guard agrees with this comment and changed the sentence in the FPEIS to clarify that there will be fewer introductions and spreading of NIS in comparison to a scenario without a BWDS.

One commenter stated that vessels may be able to meet the preferred alternative for organisms larger than 50 micrometers without BWE or treatment. The Coast Guard neither agrees nor disagrees with this statement, but notes that the BWDS is to be used for measuring the effectiveness of BWMS during the approval process in addition to measuring compliance from vessels at the point of discharge. It is not intended that vessels be allowed to assert their non-BWMS method of dealing with ballast water meets the BWDS.

One commenter stated that heterotrophic bacteria may also bloom within a ballast tank as a result of the increased substrate. The Coast Guard agrees with this comment, but saw no need to make changes to the FPEIS.

One commenter suggested that hull fouling is a larger factor than ballast water for NIS introductions from vessels. The Coast Guard acknowledges that biofouling is mentioned in the DPEIS, however, this comment is beyond the scope of this rule. We note that 33 CFR 151.2050 does include some provisions for preventing hull fouling.

One commenter stated that a cited author never intended to create a link between the economics of development of a BWDS and an increase in hull fouling. The Coast Guard has reviewed the use of this author's work and removed that text from the FPEIS.

One commenter noted that the threat of species introductions comes not only from foreign vessels, but also from vessels operating in the coastal waters of the United States. The Coast Guard agrees with this statement, and notes that the NPRM proposed requiring all vessels to comply with the BWDS. For reasons discussed elsewhere in this document, some of those requirements are being reevaluated. The PEIS does not intend to imply that NIS introductions come only from foreign vessels.

One commenter pointed out that the impacts of seawater should be considered regarding ballast water discharge. This comment is beyond the scope of this rule, which evaluates the impacts of NIS, but not the seawater in the discharge.

One commenter observed that the analyses of BWDS efficacy relative to BWE fails to account for the differences in potential risk associated with species that are sourced from different biogeographical habitats. The Coast Guard disagrees with this comment. The impacts of NIS invasions necessarily evaluate species that are transferred from one biogeographical area to a different one, and the effects, including risk, are described in the DPEIS.

One commenter stated that the Coast Guard should fully consider the economic input required for the alternatives. The Coast Guard agrees with this comment, and notes that the preferred alternative was developed taking into consideration environmental protection and practicability, including but not limited to economic and technical considerations.

One commenter stated that the evaluation of extinction probability applies only to individual ballast discharges from single ships without considering cumulative discharges from multiple ships, which could substantially increase the initial population of released organisms. The Coast Guard acknowledges that the PVA diffusion model provided a generic, non species-specific model that we used, in conjunction with other information, to provide insight into the potential relative impacts of the alternatives, i.e., the focus was on relative comparison of alternatives in terms of probability of NIS establishment. Cumulative impacts at the macro level are addressed in the FPEIS.

One commenter suggested that the Coast Guard insert the phrase ''with the implementation of a federal BWDS'' into page 4–23, line 34, of the DPEIS, where it states, ''Thus, if the volume of shipping remains at the same level, ballast-mediated invasions are likely to be reduced.'' The Coast Guard disagrees with this comment. The sentence in the Cumulative Impacts section that the commenter referred to, as well as the following sentence, set the context for the last sentence in that paragraph, ''Thus, a BWDS would be expected to decrease NIS introductions from distinct [ballast water] discharge events, but the total number of introductions could still increase due to increases in global trade.'' The commenter's suggested change would alter the intended meaning.

One commenter noted that if alternatives 2 through 4 can provide minor to major reductions, then alternative 5 should provide at least moderate to major reductions. The Coast Guard agrees with this comment. The DPEIS states that the impacts of NIS on the environment under alternative 5 would likely be greatly reduced compared to the other alternatives.

One commenter stated that there was vague language in specific sentences in the section on impacts of alternatives on listed species and habitat and in the cumulative impacts section of the Environmental Consequences, chapter 4 of the DPEIS. The Coast Guard reviewed and corrected the cited sentences and made changes in the FPEIS, as appropriate.

One commenter observed that the 8 percent reduction of NIS between 10 and 50 micrometers noted in the preferred alternative was not worthwhile given the effort. The Coast Guard disagrees with this comment. The preferred alternative was developed taking into consideration environmental protection and practicability, including economic and technical aspects.

One commenter stated that the Coast Guard must send a consistency determination to the State of New York. The Coast Guard agrees with this comment. We submitted Initial Coastal Zone Management Consistency determinations to the 34 coastal states and territories, including New York, in March 2010.

One commenter noted that the DPEIS failed to account for the differences in potential risk associated with species that are sourced from, and discharged into, low salinity habitats. The commenter also stated that Washington and Oregon will require a higher BWDS.

The Coast Guard prepared a PEIS because a BWDS would impact a large geographic area and a wide variety of U.S. ecosystems. The PEIS does not

evaluate specific areas or ecosystems. Additionally, we note that the final rule does not preempt the States from setting more stringent standards.

Two commenters stated that the Coast Guard's own modeling in the NPRM and associated DPEIS shows that only the degree of NIS infestation of the Great Lakes from ballast water discharge changes with the various scenarios of implementation dates for the phased BWDS. The Coast Guard acknowledges this comment, but does not feel that any action is necessary.

One commenter stated that the Coast Guard should perform additional scientific research to assess the effectiveness of current BWM efforts for coastal waters. The Coast Guard disagrees. The DPEIS sufficiently analyzed this issue for purposes of the rule.

One commenter stated that the Coast Guard did not discuss details of enforcement or compare the enforceability of different alternatives in the DPEIS. The Coast Guard does not believe that the PEIS is the appropriate place to discuss enforcement details.

One commenter stated that the Coast Guard should conduct a phase-one practicability review of the technical and economic barriers related to implementation of a BWDS for vessels operating primarily in the Great Lakes and St. Lawrence Seaway system. Another commenter stated that the precise risk of NIS introductions by domestic commercial vessels, particularly the domestic Great Lakes trade, requires further research. The commenter said that, therefore, application of the proposed rule to the ships in the domestic Great Lakes trade is inappropriate.

The Coast Guard agrees with the intent of these comments. We note that, in general, a phase-one practicability review is effectively taking place through the type approval of systems to meet the IMO discharge standard, which is indicative of BWMS being available. However, as discussed in this preamble in V.A. Summary of Changes from the NPRM, we have revised the applicability in this final rule such that non-seagoing vessels; vessels that take on and discharge ballast exclusively in one COTP Zone; and seagoing vessels that operate in more than one COTP Zone and do not operate outside of the Exclusive Economic Zone (EEZ), and are less than or equal to 1,600 gross register tons or less than or equal to 3,000 gross tons (International Convention on Tonnage Measurement of Ships, 1969) will not need to comply with the BWDS at this time. We are continuing to analyze the practicability of implementing any BWDS to these vessels. We also intend to conduct additional research, as necessary. The results of which will be included in a notice or other rulemaking document.

Miscellaneous Comments on the DPEIS

Six commenters pointed out that the DPEIS contains no evidence to suggest that ballast water discharged by towing vessels and barges operating only on the U.S. inland waterways has resulted in or contributed to the introduction or spread of NIS. Five of these commenters further stated that the same comment also applies to towing vessels and barges operating within the same coastal ecosystem, and that they are not aware of a Coast Guard effort to analyze NBIC data to determine the role of vessels, particularly domestic towing vessels, in the introduction and spread of invasive NIS.

An additional commenter pointed out that there is no evidence of NIS introduction or spread by towing vessels and barges operating primarily in U.S. coastal zones. Two commenters stated that it is unfair to regulate domestic towing vessels and barges with much smaller ballast water capacity than crude oil tankers in the U.S. coastwise trade which NISA exempts from BWM requirements.

One commenter stated that requiring the installation of very expensive BWMS on thousands of towing vessels and barges with very limited ballast water capacity is cost-prohibitive or not cost-effective. The commenter argued that costs must be considered both in absolute terms and against lack of evidence that towing vessels or barges operating primarily in U.S. coastal zones have contributed to the introduction or spread of invasive species, their smaller volumes of ballast water, and technological and operational impediments to the installation of BWMS.

These comments are not directly relevant to the DPEIS; they are instead comments on the NPRM itself. The Coast Guard has addressed the issue of applicability to towing vessels in our responses in this preamble in V.B.1 Discussion of Comments: Applicability.

One commenter recommended a study of species-by-species NIS risk analysis on the Great Lakes to focus the need for regulatory efforts on specific routes, where reducing the risk of species transfer would have the greatest benefit. The Coast Guard disagrees with this recommendation. It would not be practicable to develop risk profiles of specific routes, because risk profiles change as functions of the environmental characteristics of the locations, the traffic between them, and the introduction of new species by vessels and multiple non-ship vectors.

One commenter stated that onshore ballast water treatment facility options must be examined by the Coast Guard in the PEIS since there are proven, technically-feasible onshore treatment solutions for vessels with dedicated trade routes. They suggested that the Valdez Marine Terminal could be retrofitted with NIS control to treat crude oil vessels engaged in foreign trade regulated under the proposed rule and crude oil vessels engaged in coastwise trade regulated under the Clean Water Act.

The Coast Guard disagrees with this comment. The scope of the PEIS encompasses the standard for discharges from vessels, not an analysis of the means to achieve the standard. While discharge to shore is an option for vessels under the NPRM, provided there are facilities available, it is beyond the Coast Guard's authority to require shoreside facilities in all ports. NANPCA, as amended by NISA, grants Coast Guard the authority to regulate vessel BWM practices, and this authority does not extend to onshore ballast water treatment facilities. 16 U.S.C 4711. Ballast water discharged to a shore-side facility is not subject to the Coast Guard's proposed BWDS as it would not be a discharge into waters of the United States from a vessel. Discharges to waters of the United States from such shoreside treatment facilities would be subject to regulation under the CWA NPDES permit program.

One commenter stated that the proposed phase-one standard is biologically inadequate and inconsistent with the United States' initial position in discussions during the development of the IMO discharge standard. This initial U.S. position was for a more stringent standard (less than 0.01 per m^3 of water as the concentration standard for Zooplankton and less than 0.01 per mL for smaller organisms).

The Coast Guard disagrees that the phase-one standard is ''biologically inadequate''. As described in the DPEIS, the standard will be more effective than BWE. The initial U.S. negotiating position on the IMO ballast water discharge standard in 2004 is beyond the scope of this rulemaking; however, as stated in section V.A.1 of the preamble, it is our intention to work toward a more stringent standard.

One commenter stated that information about the resulting damages avoided by implementing alternatives 3 through 5 needs to be presented in the DPEIS on page H–10, paragraph 3, so that all alternatives can be compared on

equal footing. The NPRM RA (available on the docket for this rule) presents the total potential benefit from different proposed BWDS alternatives in chapter 5 (table 5.12). The values presented in this table enable the comparison of the benefits of alternatives 2, 3, and 4.

One commenter stated that the production and retrofitting of any heavy equipment onboard the world fleet would add not only cost, but also additional energy requirements and emissions. One commenter stated that in addition to the economic burden imposed by the additional power and gear requirements to operate BWMS, there will also be an associated increase in air pollutants and greenhouse gas emissions from additional fuel combustion.

We expect that our environmental analysis of individual BWMS, as part of the approval process, would indicate whether that specific BWMS might increase vessel energy requirements and emissions, which would be taken into consideration before U.S. type approval is granted.

One commenter stated that the DPEIS fails to provide a set of criteria or rubric for how the Coast Guard compared each of the alternatives in order to arrive at alternative 2 as the preferred alternative. The commenter also stated that there is a lack of references for key facts and insufficient cost data to support the argument that alternatives 3 and 4 are prohibitively expensive.

The Coast Guard acknowledges the comment that the analyses included in the DPEIS (and NPRM) did not present a detailed cost analysis of more stringent BWDS. There are very limited cost data available for technologies that would meet more stringent standards. The Coast Guard used the best information available at the time of the analysis to evaluate alternatives 3 and 4. Therefore, we have determined that additional analysis is needed, and have already begun its development. As noted in this preamble in V.A. Summary of Changes from the NPRM, as we complete this work, the Coast Guard has decided to move forward with the proposed phase-one standard (or alternative 2) with this final rule, which does not include a more stringent BWDS.

One commenter asked whether the costs that appear in Appendix H of the DPEIS are based on installation of treatment systems on U.S.-flagged vessels only or if it includes all vessels that will be discharging in the waters of the United States. The costs of installation that the Coast Guard presented in Appendix H—table H–3, ''Costs to the U.S. vessels to comply with IMO BWM Convention (Alternative 2) BWD Standard ($Mil)''—are for U.S. vessels only. Appendix C of the NPRM RA (available in the docket), presents cost estimates for the foreign-flagged vessels.

One commenter stated that the argument that capital and operation costs will double and quadruple for alternative 3 and alternative 4, respectively, is not accurate based on data presented in Lloyd's Register (2008) and Dobroski et al. (2009). A second commenter requested that the Coast Guard provide some basis for why it believes that the costs for alternative 3 would double those of alternative 2 and that the costs for alternative 4 would quadruple those for alternative 2. This commenter echoed the belief that cost data presented in recent reports by Lloyd's Register (2008) and the CSLC (Dobroski et al. 2009) do not agree with Coast Guard estimates. The commenter added that up-to-date facts and figures are needed to clearly demonstrate that such an increase in costs will be observed in the event that these alternatives are implemented.

As the Coast Guard noted previously in our discussion of the comments received on the NPRM RA, cost estimates presented in Lloyd's Report and in the CLSC ''Assessment of Efficacy, Availability and Environmental Impacts of Ballast Water Treatment Systems for Use in California Waters'' (Dobroski, Scianni, Gehringer and Falkner, 2009) are related to systems that meet the current IMO discharge standard only and are consistent with the Coast Guard's cost estimates ($258,000 to $2,525,000) and the Congressional Budget Office ($300,000 to $1,000,000).

Nevertheless, the Coast Guard acknowledges that the NPRM, DPEIS, and the NPRM RA did not present a detailed cost analysis of more stringent standards. There are very limited cost data available for technologies that would meet more stringent standards. Therefore, the Coast Guard has determined that additional analysis is needed, and has already begun its development. Noted in preamble section V.A. Summary of Changes from the NPRM, as we complete this work, the Coast Guard has decided to move forward with the proposed phase-one standard (or alternative 2) with this final rule, which does not include a more stringent standard.

One commenter requested that sources and dates be provided for the cost estimate data for installation and operation of the BWMS. One commenter requested the Coast Guard provide a source for the estimate that BWMS cost two to four times the cost of using mid-ocean BWE.

In Chapter 3 of the NPRM RA (available on the docket), the Coast Guard presented the data sources and timeframe used for the cost data. In Chapter 1 of the NPRM RA, the Coast Guard also mentioned the timeframe used for the estimates. The Coast Guard's cost estimates in the NPRM and DPEIS relied on manufacturer-provided data. Manufacturers supplied costs for equipment and installation. Data collection started in 2005/2006 and costs were updated in 2007/2008.

The Coast Guard's estimates are consistent with other notable cost estimates such as those made by Lloyds' Register (2008) ($145,000 to $2,000,000) and the Congressional Budget Office ($300,000 to $1,000,000). The Coast Guard is continuously monitoring BWMS technologies for new developments and changes in costs.

Section 6.3 and Appendix B of the NPRM RA provided a comparison of BWDS and BWE. The BWE cost was based on the framework used in the 2004 BWM RA adjusted for recently collected NBIC data. We did not find the BWMS cost to be two to four times the cost of using mid-ocean BWE. We estimated the annualized costs for BWE to be less than .01 percent of the annualized costs of the phase-one standard.

One commenter asked whether the conclusions presented in page H–7, paragraph 1 of the DPEIS still hold, given the recent economic downturn, and if there is any evidence to show that costs won't be passed on to consumers.

The Coast Guard did not analyze the impact of the recent economic downturn and the potential impact on the consumers. We did include a discussion on the uncertainties related to the cost estimates (NPRM RA, section 3.6) and compared the costs of implementing Alternative 2 for BWDS (the alternative proposed in the NPRM) to shipping revenues and consumer retail prices for goods typically transported by vessels. We compared amortized installation costs to long-term charter rates (NPRM RA, section 4.5). The NPRM costs typically represent less than one percent of charter rates suggesting reduced impact on consumers. Costs to the consumer are further reduced because maritime transportation costs generally represent only one to two percent of the retail cost of goods.

One commenter stated that the calculations to determine the number of invasions and amount of economic damage that would be reduced seem excessively convoluted and

inappropriate. The commenter also stated that the shipping-based invasion rates of invertebrates are projected into the future and are used to estimate the number of plant and fish invasions based on historical relationships between the three groups (even though there is no mention whether the relationships used take into account that the shipping-based invertebrate invasions are only a portion of the overall invertebrate invasions). The commenter added that these values are then adjusted back to account for only those invasions that are attributable to ballast water (even though this type of data involve a great deal of uncertainty, *see* Fofonoff et al., 2003) and that these values are then adjusted again to account for those invasions that cause economic harm.

The Coast Guard acknowledges that the calculations to determine the number of invasions and economic damage that could be reduced by the proposed BWMS are complicated and subject to uncertainty. However, the Coast Guard believes that each of the steps is appropriate and necessary in order to narrow the number of invasions considered to only those that could be reduced specifically by BWMS. In addition, as these calculations were used to develop monetized estimates of benefits, we also needed to limit the analysis to those invasions that cause economic harm.

One commenter asked what damages are likely to result from the implementation of alternatives 3 through 5. In the NPRM RA (available on the docket), chapter 5 (table 5.12), the Coast Guard presents the total potential benefit from different proposed BWDS alternatives. The values presented in this table enable the comparison of the benefits of alternatives 2, 3, and 4. As stated in the DPEIS, it is assumed that the implementation of alternatives 2 through 5 would not have additional adverse impacts on environmental and socioeconomic resources. Based on this assumption, the alternatives considered in the DPEIS differ only in their potential to reduce the probability of NIS threatening the ecological stability of infested waters or other resources dependent on such waters. The impact of implementing the BWDS defined under each alternative is determined by the respective reduction in the number of living organisms that are introduced.

One commenter stated their concern about the completeness and accuracy of the information used in the DPEIS. The commenter added that the economic and environmental benefits of effective controls on ballast water discharge are grossly underestimated in chapters 3 and 4 of the DPEIS. The commenter recommended that, if it is determined that additional work on the cost/benefit analysis is warranted, the Coast Guard should work closely with the States to gather the latest economic information on the actual and potential impacts NIS have on our water resources.

The Coast Guard used the best data available at the time of the research; we reviewed peer-reviewed papers on invasion-related costs and benefits. These papers included some local (regional) data as well as national. The Coast Guard will continue to monitor peer-reviewed literature to incorporate new studies and estimates as they become available.

One commenter stated that it was unclear in the DPEIS whether the cost associated with failure to achieve the objectives (e.g., habitat loss or modification, lost productivity of commercially viable native species, lost value of existing mitigation/restoration actions) was addressed for each of the alternatives. The commenter further states that the true cost of implementing an alternative should include the cost to the environment associated with NIS introductions under that alternative.

The Coast Guard acknowledges that some environmental costs of invasions cannot be easily monetized. The Coast Guard used the best data available at the time of the research; we reviewed peer reviewed papers on invasion-related costs and benefits. In addition to the DPEIS, chapter 5 of the NPRM RA presents an estimate of the value of the economic harm caused by invasive NIS. We calculated these values in order to estimate the range of monetary benefits from the proposed rule to compare against cost estimates.

One commenter stated that the benefits presented for alternative 2 should also be presented for alternatives 3 through 5. In the NPRM RA (available on the docket), chapter 5 (table 5.12), the Coast Guard presents the total potential benefits from different proposed alternatives. The values presented in this table enable the comparison of the benefits of alternatives 2, 3, and 4. In addition, the Coast Guard is now further investigating costs and benefits of more stringent standards.

One commenter requested that the 3 and 7 percent discount rates be explained in the DPEIS, as they are not commonly understood by individuals outside of finance. The Coast Guard followed the guidelines from OMB Circular A–4, which provides guidance to Federal agencies on the development of regulatory analysis as required under paragraph 6(a)(3)(c) of Executive Order 12866, ''Regulatory Planning and Review,'' also the Regulatory Right-to-Know Act, and a variety of related authorities. According to OMB Circular A–4 (page 34), the RA should provide costs and benefits estimates using both 3 and 7 percent discount rates. For more detailed explanation on the use of discount rates for regulatory analysis see OMB Circular A–4, pages 31 to 34.

One commenter stated that the proposed rule and the DPEIS are deficient in providing accurate costs, and thus justification on a cost/benefit basis for implementation of the rule as proposed. The commenter also states that NPRM provides much information relative to the compliance costs for U.S.-flagged vessels but little more than a passing comment on compliance costs for foreign-flagged vessels (74 FR 22643).

The Coast Guard estimated cost impacts for foreign-flagged vessels in the NPRM RA (see Appendix C) and the final rule RA (see Appendix D). As previously discussed, we have also made the phase-one standard as consistent as possible with the IMO BWM Convention's discharge standard. We assume foreign government administrations that adopt the IMO BWM Convention and the foreign-flagged vessels they administer to be responsible for the implementation and compliance with the IMO BWM Convention once it comes into force. We assume these foreign government administrations and the foreign-flagged vessels they administer to be responsible for the costs associated with the implementation and compliance of the IMO BWM Convention. Therefore, in the analyses of the NPRM and this final rule, our primary cost estimate of the phase-one standard rule includes costs to U.S. flagged-vessels only. This is similar to Coast Guard's assessment of impacts from regulations related to other international conventions, which take into account the costs incurred by U.S. vessels and owners and operators only (e.g., regulations related to The Standards of Training, Certification & Watchkeeping Convention (STCW) and regulations related to the International Convention for the Prevention of Pollution From Ships (MARPOL)).

Nonetheless, the Coast Guard estimated the foreign vessel costs of this rule in order to illustrate the potential economic impact to foreign-flagged vessel owners operating in the waters of the United States. The detailed description of the economic impact on foreign vessels is presented in the NPRM RA (Appendix C), available on the docket.

One commenter suggested adding a column to the DPEIS' ''Estimated Number of Ballast Water Invasions that Cause Harm'' table for diseases, viruses, etc., and an ''Other'' column for fish, plants, and invertebrates. The commenter cited VHS in particular, stating that while it is uncertain that ballast water was the mechanism for introduction of VHS, it is the likely cause, and that State and Federal agency costs to address VHS infection will continue to rise as the disease spreads throughout the Great Lakes and inland waters. The Coast Guard disagrees with this comment and believes there is sufficient information in the FPEIS as it stands.

One commenter stated that while the proposed rule uses the words ''introduction'' and ''spread'' in relation to ballast water, the solution makes no distinction between these vastly different issues. The commenter said that the DPEIS fails to calculate the costs and benefits of BWMS regarding the introduction to or spread within an ecosystem separately which the commenter believes is counter to the conclusions of the Great Lakes Regional Collaboration that the most appropriate response to NIS was to require BWMS on ocean-going vessels and Best Management Practices on Great Lakes vessels. The Coast Guard disagrees with this comment, as we believe the BWDS must be used to combat both the introduction and spread of NIS in waters of the United States.

Modal Shift Comments on the DPEIS

Two commenters stated that it is important to consider the potentially devastating environmental impacts of a large-scale modal shift in their region, which already has a high volume of truck traffic to facilitate border trade and the North American Free Trade Agreement corridor. Another commenter raised the possibility that the cost of retrofitting vessels for BWMS could result in a modal shift of cargoes to surface transportation, resulting in the ''unintended consequences'' of less carbon-efficient transportation, increased air emissions, more severely crowded roadways and increased infrastructure costs.

As previously discussed in the NPRM RA, we compared the costs of implementing the BWDS to shipping revenues and consumer retail prices for good typically transported by vessels. We have also compared amortized installation costs to long-term charter rates. These costs typically represent less than one percent of long-term charter rates. Although the overall cost of implementing this rule is significant, the cost will have minimal impact on the costs of goods and services. In addition, there are only a few substitutes for the maritime transportation of goods from overseas and producers. The Coast Guard did not find information or data indicating that there will be large modal shifts.

Phase-Two Comments

Twenty commenters addressed the phase-two standard in one way or another. Additionally, nine commenters stated that the NPRM and DPEIS do not evaluate the phase-two standard and that they are incomplete without an assessment of the environmental impacts of this standard. One of these commenters also stated that the DPEIS should clarify that alternative 5 (elimination of all living organisms larger than 0.1 micrometer) does not correspond to the proposed phase-two standard.

As we discussed in this preamble in V.A. Summary of Changes from the NPRM, the Coast Guard has removed the proposed phase-two standard from this final rule. However, after additional analysis and research we intend to issue a rule addressing the proposed phase-two standard or any standard higher than phase-one, and will keep these comments in mind as we develop that rule.

One commenter recommended that the standard 1,000 times more stringent than phase one be included in the PEIS, as well as a zero-discharge alternative that also restricts ocean vessel access to the Great Lakes. The Coast Guard partly agrees with this comment. We acknowledge that the PEIS must include the proposed phase-two standard. We have already begun this process, and expect to issue a revised PEIS when we address the proposed phase-two standard or any standard higher than phase-one. However, the PEIS evaluates a BWDS that applies to the entire United States, and not by individual geographic areas.

8. Beyond the Scope

We received many comments that were beyond the scope of this rule. Below, we summarize these comments, and respond to those that though beyond the scope, do have some relevance to this rule.

Two commenters encouraged the United States to ratify the IMO BWM Convention. One commenter recommended conducting a multinational risk assessment of vessel-mediated invasions of Arctic areas. One commenter suggested methods of funding the eradication of existing aquatic nuisance species. Another commenter expressed concerns about the Coast Guard directing sufficient funding to the implementation of the regulations. One commenter recommended that the Coast Guard revise 33 CFR 151.2050(c) to more accurately reflect when local, State, or Federal regulations apply to sediment disposal, such as under controlled arrangements at port or drydock. These comments are beyond the scope of this rule.

One commenter suggested the Coast Guard enter into a Memorandum of Understanding with the Department of the Interior to address invasive species concerns.

The Coast Guard strives to work closely and collaboratively with all Federal agencies on matters of mutual interest. More formal arrangements will be pursued when necessary.

One commenter recommended that STEP permit the enrollment of vessel fleets as an incentive for participation. Another commenter recommended providing incentives to companies that could lead to the development of freshwater BWDS.

The STEP processes and development of ballast water treatment technologies are beyond the scope of this rule. The comments will be forwarded to the STEP managers and appropriate Coast Guard office for consideration.

One commenter questioned whether treated ballast water would be subject to the EPA VGP or be considered an industrial discharge and therefore require a separate NPDES permit.

We consulted EPA and confirmed that ballast water treated and discharged in waters of the United States, as that term is defined in the Clean Water Act, by a vessel under this regulation would be subject to the EPA VGP.

One commenter stated that a rapid response program to mitigate infestations of invasive NIS should be a guiding principle of the regulations.

Rapid response to invasions is beyond the scope of the rule, which focuses on preventing the introduction of new invasions. However, as a member of the Aquatic Nuisance Species Task Force, the Coast Guard works with other Federal and State agencies to improve the nation's invasive species response capabilities.

Fifty-four commenters urged the Coast Guard to work closely with the EPA, the States, Canada and the IMO in developing a coordinated Federal ballast water program. One commenter urged the administration to consider NISA as the sole standard for ballast water discharge by ocean-going vessels. Conversely, one commenter asked that

ballast water regulation of vessels in the offshore energy services be left to States.

These comments are beyond the scope of this rule, however, we note that we have worked and will continue to work closely with Federal, international, and State partners to develop a consistent, coordinated ballast water program.

Four commenters provided suggestions on implementation and enforcement of the BWM program and information sharing among governmental agencies and the public.

While they did not address any proposals from the NPRM, these comments had merit and will be kept in mind as the Coast Guard continues to refine its BWM program.

Seven commenters urged the removal of the exemption for crude oil tankers engaged in coastwise trade under NISA.

While we appreciate the commenters' intent, the Coast Guard lacks the authority for the requested action, therefore this request is outside of the scope of this rule. 16 U.S.C. 4711(c)(2)(L). However, crude oil tankers engaged in coastwise trade will be subject to all other applicable U.S. laws, such as the CWA, which does not contain an exemption.

VI. Incorporation by Reference

The Director of the Federal Register has approved the material in 46 CFR 162.060–5 for incorporation by reference under 5 U.S.C. 552 and 1 CFR part 51. You may inspect this material at U.S. Coast Guard Headquarters where indicated under **ADDRESSES.** Copies of the material are available from the sources listed in 46 CFR 162.060–5.

VII. Regulatory Analyses

We developed this final rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 14 of these statutes or executive orders.

A. Regulatory Planning and Review

This final rule is an economically significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review. OMB has reviewed it under those Orders. It requires an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866. We have revised the estimates from the NPRM Preliminary Regulatory Analysis (''NPRM RA'') to reflect the changes described in this preamble under V. Discussion of Comments and Changes. A final rule Regulatory Analysis (''Final Rule RA'') with revised impact estimates of the phase-one BWDS is available in the docket as indicated under **ADDRESSES**. A summary of the findings follows.

The final rule RA provides an evaluation of the economic impacts associated with this final rule, which is the implementation of the phase-one BWDS.

Table 1 provides a comparison of regulatory impacts resulting from changes between the NPRM and the final rule.

TABLE 1—COMPARISON OF REGULATORY IMPACTS RESULTING FROM CHANGES BETWEEN THE NPRM AND FINAL RULE

Category	NPRM	Final rule
Applicability	All vessels discharging ballast water into U.S. waters.	Oceangoing vessels and some coastwise vessels (>1,600 GT) discharging ballast water in U.S. waters.
Compliance Start Date	Beginning 2012	Revised, beginning 2013.
Number of BWMS Installations on Vessels (10-year period of analysis).	4,758	3,046.
Costs ($ millions,7 percent discount rate)	$167 (annualized) $1,176 (10-year).	$92 (annualized). $649 (10-year).
Benefits ($ millions,7 percent discount rate)	$165–$282 (annualized) $1,161–$1,977 (10-year).	$141–$240 (annualized) $989–$1,684 (10-year).

Note: The Regulatory Analysis in the docket for this rulemaking presents additional discussion of calculations and ranges for costs and benefits.

Based on data from the Marine Information for Safety and Law Enforcement system and the NBIC, we estimate that approximately 3,046 existing and new U.S. vessels will potentially be required to install and operate approved BWMS over a 10-year period of analysis.[6] As originally discussed in the NPRM, we consider the phase-one BWDS regulatory costs of this rule to involve U.S. vessels, as foreign-flagged vessels are expected to comply pursuant to the IMO BWM Convention, which is the phase-one BWDS.[7]

Costs

The primary cost drivers of this rule are installation related costs. We estimate operation and maintenance costs to be substantially less. Costs vary by year based on the implementation schedule of this rule. Over a 10-year period of analysis, the total discounted present value cost for U.S. vessels is approximately $649 million at a 7 percent discount rate (rounded primary estimate).[8] We estimate the annualized cost over the same period of analysis to be about $92 million at a 7 percent discount rate. Our cost assessment includes existing and new vessels.

Benefits

NIS introductions contribute to the loss of marine biodiversity and have significant social, economic, and environmental impacts. Avoided costs associated with future initial NIS invasions and secondary spread of invasions (which may result from the initial invasion) represent the primary benefits of BWM. Economic costs (damages) from invasions of NIS range in the billions of dollars annually. The most extensive review to date on the economic costs of introduced species in the United States includes estimates for many types of NIS and is summarized in Table 2.

[6] This 10-year period of analysis was used to estimate costs and benefits in the NPRM. *See* the NPRM RA and the final rule RA for additional discussion and detail on costs and benefits over various periods of time.

[7] Foreign government administrations signing on to the IMO Convention and the foreign-flagged vessels they administer will be responsible for compliance with the IMO Convention once it comes into force. The final rule RA presents supplemental cost estimates for foreign-flagged vessels projected to call in waters of the United States.

[8] Cost and benefit estimates discussed in this final rule are based on a 7 percent discount rate. *See* the final rule RA in the docket for additional discussion and estimates using other discount rates.

TABLE 2—ESTIMATED ANNUAL COSTS ASSOCIATED WITH AQUATIC NIS INTRODUCTION IN THE UNITED STATES

[$ in 2007]

Species	Costs
Fish	$5.7 billion.
Zebra and Quagga Mussels	$1.06 billion.
Asiatic Clam	$1.06 billion.
Aquatic Weeds	$117 million.
Green Crab	$47 million.

Source: Pimentel, D. *et al.,* 2005. ''Update on the environmental and economic costs associated with alien-invasive species in the United States,'' *Ecological Economics.* 52:273–288.

Though a particular invasion may have small direct economic impacts, the accumulation of these events may cost in the billions of dollars every year. Only a few invasions to date have led to quantified cost estimates in the billions of dollars per year.

The benefits of BWDS are difficult to quantify because of the complexity of ecosystems and a lack of information to estimate the probabilities of invasions based on prescribed levels of organisms in ballast water. However, evaluation of costs associated with previous invasions (described previously) allows a comparison of the costs of BWDS versus the costs of avoided damages.

The primary benefit of this rule comes from a reduction in the concentration of all organisms, leading to lower numbers of these organisms being introduced per discharge. This further reduces the number of new invasions because the likelihood of establishment decreases with reduced numbers of organisms introduced per discharge.

The quantified benefits have decreased between the NPRM and the final rule due to the longer phase-in period (see Table 1 this section). We use the same benefits model for the final rule as we did for the NPRM. This model quantifies benefits resulting from the reduction in ''initial invasions'' from vessels engaged in ocean-going trade. We have not found complete data or identified appropriate models to quantify the possible benefits associated with reducing the secondary spread of invasions. Therefore, we do not expect the exemption of inland vessels to reduce the estimate of quantified benefits given data and modeling limitations. See the Benefits chapter of the final rule RA for more discussion on the data and modeling framework used for this rulemaking.

We calculate potential benefits of the phase-one BWDS by estimating the number of initial invasions reduced and the range of economic damage avoided. The FPEIS estimates the reduction in the mean rate of successful introductions for the phase-one standard. In comparison with the existing practice of BWE, the proposed phase-one BWDS is between 37 percent and 63 percent more effective in preventing invasions when fully implemented (*see* the FPEIS for further details on effectiveness). We use these estimates of the reduction in the rate of invasions to estimate the economic costs avoided (or benefits) as a result of a BWDS.

Over a 10-year period of analysis, we estimate the total discounted present value benefits of the phase-one BWDS to be $0.989 billion to $1.684 billion (rounded primary estimate).[9] We estimate the annualized benefits over the same period of analysis to be $141 million to $240 million per year.

As previously discussed, the annualized cost for domestic vessels over the period of analysis for the phase-one BWDS is estimated at about $92 million. Thus, quantified average benefits exceed quantified average costs for the phase-one BWDS. We also expect quantified benefits to increase as technology is developed to achieve more stringent discharge standards than the phase-one BWDS.

B. Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this final rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

A Final Regulatory Flexibility Analysis discussing the impact of this final rule on small entities is available in the docket where indicated under **ADDRESSES**.

Based on available data, we estimate that about 29 percent of entities affected by the final rule requirements are small under the Regulatory Flexibility Act and the SBA size standards (compared to the 57 percent of entities affected by the NPRM provisions). This is due to the changes in the applicability (detailed explanation of applicability changes on section V.B.3 of this final rule). Based on our assessment of the impacts from the phase-one BWDS, we determined that small entities would incur a significant economic impact (more than 1 percent impact on revenue) during installation. After installation, however, we found most small businesses would not incur a significant economic impact from annual recurring operating costs. We have determined that this final rule will have a significant economic impact on a substantial number of small entities.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email Mr. John Morris, Project Manager, U.S. Coast Guard, telephone 202–372–1433, email *John.C.Morris@uscg.mil.* The Coast Guard will not retaliate against small entities that question or complain about this final rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

D. Collection of Information

This final rule calls for new collection of information under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520). As defined in 5 CFR 1320.3(c), ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling, and other, similar actions. The title and description of the information collections, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection. This new collection of information is due to the final rule provision that allows vessel owners and operators to request a compliance extension.

[9] Estimates discussed in this final rule are based on a 7 percent discount rate. *See* the final rule RA in the docket for additional discussion and estimates using other discount rates.

In the NPRM, we found that there was no new collection of information for BWMS approval. This finding was based on the fact that our research indicated that there are 25–30 manufacturers developing BWMS for installation onboard vessels.[10] We expect to receive less than 10 BWMS approval requests per year. This figure is less than the threshold of 10 per 12-month period for collection of information reporting purposes under the PRA of 1995.

The final rule's new collection of information is a result of public comments received in the NPRM. In this final rule, we have included a paperwork provision to allow vessel owners and operators to request an extension of their compliance date if they cannot practicably comply with the compliance date otherwise applicable to their vessel. This extension provision will give flexibility to vessel owners and operators to comply with this rule. Summary information concerning all extension decisions, including the name of the vessel and vessel owner, the term of the extension, and the basis for the extension will be promptly posted on the U.S. Coast Guard Maritime Information Exchange Web site (CGMIX), currently located at [*http://cgmix.uscg.mil/Default.aspx*].

The Coast Guard is amending the existing collection of information (OMB Control Number: 1625–0069) to add the above mentioned requests for extension.

Title: Ballast Water Management for Vessels with Ballast Tanks Entering U.S. Waters.

Summary of the Collection of Information: The information is needed to carry out the requirements of 16 U.S.C. 4711 regarding the management of ballast water, to prevent the introduction and spread of aquatic nuisance species into U.S. waters. Respondents are owners and operators of certain vessels. The Coast Guard is amending the existing collection of information to include application for extensions as established in this final rule (33 CFR 151.1513 or 151.2036).

Need for Information: The Coast Guard may grant an extension to the implementation schedule only in those cases where the master, owner, operator, agent, or person in charge of a vessel subject to this subpart can document that, despite all efforts, compliance with the requirements of this final rule is not possible, giving flexibility to vessel owners and operators to comply with this final rule.

Extension evaluations will be on a per-vessel basis. Summary information concerning all extension decisions, including the name of the vessel and vessel owner, the term of the extension, and the basis for the extension will be promptly posted on the Internet. Extensions will be for no longer than the minimum time needed, as determined by the Coast Guard, for the vessel to comply with the requirements of § 151.2030.

Any extension request must be made no later than 12 months before the scheduled implementation date listed in § 151.1512(b) of this subpart and submitted in writing to the Commandant (CG–522), U.S. Coast Guard Office of Operating and Environmental Standards, 2100 2nd St. SW., Stop 7126, Washington, DC 20593–7126.

Proposed Use of Information: The Coast Guard will use the information provided in the extension request to evaluate whether to grant extension and for what period of time, and to keep records of vessels not meeting the established compliance date. The compliance extension provides additional time to determine how BWMS can be safely installed. An extension postpones installation costs for affected vessels.

Description of the Respondents: Vessel owners and operators subject to the requirements of this final rule (see section V.A.3. Applicability).

Number of Respondents: We do not have information on the potential number of vessel owners and operators that will take advantage of the compliance extension at this time. We estimate that between 10 and 30 percent of owners and operators of U.S. vessels affected by this final rule might request the extension based on preliminary information from industry, BWMS vendors and Coast Guard experts. We anticipate that extension requests will be based on issues related to safety and regulatory requirements of electrical equipment, vessel capacity to accommodate BWMS, vessel age, shipyard availability, and other reasons. At this time, we do not have the data to determine the potential number of requests for extension. We expect to obtain this information as we process the requests. We will revise this collection of information as we post the requests on the Web site or as needed.

We estimate that owners and operators of approximately 146 to 438 vessels (estimated total U.S. vessel affected by this rule is 1,459) might request compliance extensions for the reasons listed above. We estimate the total average number of vessels that will submit a request for extension to be 292.

Frequency of the Response: Vessel owners and operators will submit a compliance extension request once.

Burden of Response: We estimate that there could be an average of 292 existing vessels that could request an extension for installing a BWMS. The 292 is the total number of vessels estimated to request the extension. We estimate that the average time burden to prepare and submit a request is approximately 8 hours (6 hours management and 2 hours clerical) [11] but burden may vary depending on type of vessel and reason for the extension request. The total average burden hours of vessels requesting an extension is approximately 2,336 hours (292 vessels × 8 hours for completing and submitting the extension documentation). The total burden cost is $141,328, calculated by (a) + (b):

(a) Assuming someone at a management level (equivalent to GS–12 (out-of-government rate)) prepares the submission to the Coast Guard, the applicable wage rate is $69/hour.[12] Therefore, the total management cost for preparing the extension request is $69 × 6 hrs × 292 vessels = $120,888.

(b) Assuming someone at the clerical level (equivalent to GS–5 (out-of-government rate)) files the copies, then the applicable wage rate is $35/hour.[13] Therefore, the total management cost for preparing the extension request is $35 × 2hrs × 292 vessels = $20,440.

The estimated cost per vessel is $484 ($141,328/292 vessels). The final cost of the final rule does not change given the amount of this paperwork requirement.

Estimate of Total Annual Burden: At this time, we do not have information on how many vessel owners and operators will be requesting compliance extension per year. We expect to obtain this information as we process the requests. If we assume that 10 percent of the estimated owners of 292 vessels (see ''*Burden of Response,*'' above) will be applying to an extension every year, then the annual burden will be equal to approximately 234 hours (29.2 vessels × 8 hrs or 10 percent of 2,336 hours). The

[10] **Sources:** Lloyds Register Report, Ballast Water Treatment Technology-Current Status, September 2008; and California State Lands Commission Report, Assessment of the Efficacy, Availability, and Environmental Impacts of Ballast Water Treatment Systems in California Waters, January 2009.

[11] This estimate is based on an existing collection of information (OMB Control Number 1625–0095) for requests of exemption and alternatives for Oil and Hazardous Materials Pollution and Safety Records Equivalent.

[12] Wage rate obtained from Enclosure (2) to COMDTINST 7310.1M and validated based on the Bureau of Labor Statistics (BLS) subcategory Managers (Occupation Code 11–9199).

[13] Wage rate obtained from Enclosure (2) to COMDTINST 7310.1M and validated based on the Bureau of Labor Statistics (BLS) subcategory First-line Supervisor of office and Administrative Support Worker (Occupation Code 43–1011).

annual cost will be approximately $14,132 (10 percent of $141,328).

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we will submit a copy of this rule to the Office of Management and Budget (OMB) for its review of the collection of information.

We ask for public comment on the proposed collection of information to help us determine how useful the information is; whether it can help us perform our functions better; whether it is readily available elsewhere; how accurate our estimate of the burden of collection is; how valid our methods for determining burden are; how we can improve the quality, usefulness, and clarity of the information; and how we can minimize the burden of collection.

If you submit comments on the collection of information, submit them both to OMB and to the Docket Management Facility where indicated under **ADDRESSES**, by the date under **DATES**.

You need not respond to a collection of information unless it displays a currently valid control number from OMB. Before the Coast Guard could enforce the collection of information requirements in this rule, OMB would need to approve the Coast Guard's request to collect this information.

E. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them.

We have analyzed this rule under that Order and have determined that it does not have implications for federalism. NANPCA, as amended by NISA, contains a ''savings provision'' that saves to the States their authority to ''adopt or enforce control measures for aquatic nuisance species, [and nothing in the Act would] diminish or affect the jurisdiction of any State over species of fish and wildlife.'' 16 U.S.C. 4725. It also requires that ''[a]ll actions taken by Federal agencies in implementing the provisions of [the Act] be consistent with all applicable Federal, State and local environmental laws.'' Thus, the congressional mandate is clearly for a Federal-State cooperative regime in combating the introduction and spread of NIS into the waters of the United States from ships' ballast water. This makes it unlikely that preemption, which would necessitate consultation with the States under Executive Order 13132, would occur.

We received a number of comments, from organizations, individuals, and States, on the issue of preemption. These comments are summarized and addressed in this preamble in V.B.6. Legal.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate or by the private sector, of $100,000,000 (adjusted for inflation with a base year of 1995) or more in any 1 year (2 U.S.C. 1532). The Coast Guard currently uses an inflation-adjusted value of about $140.8 million in lieu of $100 million.[14] The private sector will incur costs exceeding the $140.8 million threshold during the third and fourth years of the rule implementation period (see Regulatory Analysis in the docket for additional details).

In accordance with 2 U.S.C. 1532(a)(1), this rule generally would be promulgated under the authority of 46 U.S.C. Chapter 45 and also under the authority of the statutes, Executive Orders, and delegations cited in the ''Authority'' lines of the specific Code of Federal Regulations parts we propose to amend. We include the assessments and estimates that would be required by 2 U.S.C. 1532(a)(2) through (a)(4) in the Regulatory Analysis report available in the docket as indicated under the **ADDRESSES** section of this preamble.

G. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

H. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

[14] The value equivalent to $100,000,000 in calendar year 1995 adjusted for inflation to calendar year 2009 is about $140,800,000 (rounded to the nearest 100,000) using the Consumer Price Index for All Urban Consumers (CPI–U) as published by the Bureau of Labor Statistics, series CUUR0000SA0, *http://www.bls.gov/data/top20.htm* (accessed 4/26/2010). Calendar year 2009 is the latest complete year for the annual CPI–U data series. This adjustment is based on recent Department of Transportation guidance on adjustments to the annual threshold (see *http://regs.dot.gov/*).

I. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. Though this rule is economically significant, it does not create an environmental risk to health or risk to safety that may disproportionately affect children.

J. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

K. Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order. Though it is a ''significant regulatory action'' under Executive Order 12866, it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

L. Technical Standards

The National Technology Transfer and Advancement Act (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule uses a number of technical standards, all of which are voluntary consensus standards. These may be found in the technology approval program amendments to 46 CFR part 162 and are listed below.

The voluntary consensus standards used by this rule are:

(1) International Electrotechnical Commission (IEC), 529, Degrees of Protection Provided by Enclosures, 1989;

(2) International Organization for Standardization (ISO) and the IEC, ISO/IEC 17025, General Requirements for the Competence of Calibration and Testing Laboratories, 2005; and

(4) Environmental Protection Agency's Environmental Technology Verification (ETV) Program Generic Protocol for the Verification of Ballast Water Treatment Technologies.

M. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with NEPA (42 U.S.C. 4321–4370f), and have concluded that this action may have a significant effect on the human environment. A Final Programmatic Environmental Impact Statement and Record of Decision are available in the docket where indicated under **ADDRESSES**, and include a summary of our actions to comply with NEPA.

List of Subjects

33 CFR Part 151

Administrative practice and procedure, Ballast water management, Oil pollution, Penalties, Reporting and recordkeeping requirements, Water pollution control.

46 CFR Part 162

Ballast water management, Fire prevention, Incorporation by reference, Marine safety, Oil pollution, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 151 and 46 CFR part 162 as follows:

Title 33—Navigation and Navigable Waters

CHAPTER I—COAST GUARD

Subchapter O—Pollution

PART 151—VESSELS CARRYING OIL, NOXIOUS LIQUID SUBSTANCES, GARBAGE, MUNICIPAL OR COMMERCIAL WASTE, AND BALLAST WATER

Subpart C—Ballast Water Management for Control of Nonindigenous Species in the Great Lakes and Hudson River

■ 1. The authority citation for subpart C continues to read as follows:

Authority: 16 U.S.C. 4711; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 151.1502 to read as follows:

§ 151.1502 Applicability.

This subpart applies to all non-recreational vessels, U.S. and foreign, that are equipped with ballast tanks that, after operating on the waters beyond the Exclusive Economic Zone during any part of its voyage, enter the Snell Lock at Massena, New York, or navigates north of the George Washington Bridge on the Hudson River, regardless of other port calls in the United States or Canada during that voyage, except as expressly provided in 33 CFR 151.2015(a). All vessels subject to this subpart are also required to comply with the applicable requirements of 33 CFR 151.2050, 151.2060, and 151.2070.

■ 3. In § 151.1504, add, in alphabetical order, definitions for the terms ''Alternate management system (AMS)'', ''Ballast water management system (BWMS)'', ''Constructed'', and ''Waters of the United States'' to read as follows:

§ 151.1504 Definitions.

* * * * *

Alternate management system (AMS) means a ballast water management system approved by a foreign administration pursuant to the standards set forth in the International Maritime Organization's International BWM Convention, and meeting all applicable requirements of U.S. law, and which is used in lieu of ballast water exchange.

* * * * *

Ballast water management system (BWMS) means any system which processes ballast water to kill, render harmless, or remove organisms. The BWMS includes all ballast water treatment equipment and all associated control and monitoring equipment.

* * * * *

Constructed in respect to a vessel means a stage of construction when—

(1) The keel of a vessel is laid;

(2) Construction identifiable with the specific vessel begins;

(3) Assembly of the vessel has commenced and comprises at least 50 tons or 1 percent of the estimated mass of all structural material, whichever is less; or

(4) The vessel undergoes a major conversion.

* * * * *

Waters of the United States means waters subject to the jurisdiction of the United States as defined in 33 CFR 2.38, including the navigable waters of the United States. For 33 CFR part 151, subparts C and D, the navigable waters include the territorial sea as extended to 12 nautical miles from the baseline, pursuant to Presidential Proclamation No. 5928 of December 27, 1988.

* * * * *

■ 4. Add new § 151.1505 to read as follows:

§ 151.1505 Severability.

If a court finds any portion of this subpart to have been promulgated without proper authority, the remainder of this subpart will remain in full effect.

■ 5. In § 151.1510—

■ a. Revise the section heading; b. Revise paragraphs (a)(1) and (a)(3) and add new paragraph (a)(4); c. Add new paragraph (d).

The revisions and additions read as follows:

§ 151.1510 Ballast water management requirements.

(a) * * *

(1) Carry out an exchange of ballast water on the waters beyond the U.S. Exclusive Economic Zone (EEZ), from an area more than 200 nautical miles from any shore, and in waters more than 2,000 meters (6,560 feet, 1,093 fathoms) deep, such that, at the conclusion of the exchange, any tank from which ballast water will be discharged contains water with a minimum salinity level of 30 parts per thousand, unless the vessel is required to employ an approved ballast water management system (BWMS) per the schedule in § 151.1512(b) of this subpart. This exchange must occur prior to entry into the Snell Lock at Massena, NY, or navigating on the Hudson River, north of the George Washington Bridge. An alternative management system (AMS) that meets the requirements of 33 CFR 151.2026 may also be used, so long as it was installed on the vessel prior to the date that the vessel is required to comply with the ballast water discharge standard in accordance with § 151.1512(b) of this subpart. If using an AMS, the master, owner, operator, agent, or person in charge of the vessel subject to this subpart may employ the AMS for no longer than 5 years from the date they would otherwise be required to comply with the ballast water discharge standard in accordance with § 151.1512(b) of this subpart.

* * * * *

(3) Install and operate a BWMS that has been approved by the Coast Guard under 46 CFR part 162, in accordance with § 151.1512(b) of this subpart. Following installation of a BWMS, the master, owner, operator, agent, or person in charge of the vessel must maintain the BWMS in accordance with all manufacturer specifications.

(i) Requirements for approval of BWMS are found in 46 CFR part 162.060.

(ii) Requests for approval of BWMS must be submitted to the Commanding Officer (Marine Safety Center), U.S. Coast Guard Marine Safety Center, 2100 2nd St. SW., Stop 7102, Washington, DC 20593–7102, or by email to *msc@uscg.mil*.

(4) Use only water from a U.S. public water system (PWS), as defined in 40 CFR 141.2 and that meets the requirements of 40 CFR parts 141 and 143, as ballast water. Vessels using water from a PWS as ballast must maintain a record of which PWS they received the water and a receipt, invoice, or other documentation from the PWS indicating that water came from that system. Furthermore, they must certify that they have met the conditions in paragraphs (a)(4)(i) or (ii) of this section, as applicable. Vessels using water from a PWS must use such water exclusively for all ballast water unless the usage is in accordance with § 151.1515 of this subpart. Vessels using PWS water as ballast must have either—

(i) Previously cleaned the ballast tanks (including removing all residual sediments) and not subsequently introduced ambient water; or

(ii) Never introduced ambient water to those tanks and supply lines.

* * * * *

(d) Unless otherwise expressly provided for in this subpart, the master, owner, operator, agent, or person in charge of vessels employing a Coast Guard-approved BWMS must meet the applicable ballast water discharge standard, found in § 151.1511 of this subpart, at all times of ballast water discharge into the waters of the United States.

■ 6. Add new § 151.1511 to read as follows:

§ 151.1511 Ballast water discharge standard (BWDS).

(a) Vessels employing a Coast Guard-approved ballast water management system (BWMS) must meet the following BWDS by the date in § 151.1512(b) of this subpart:

(1) For organisms greater than or equal to 50 micrometers in minimum dimension: discharge must include fewer than 10 living organisms per cubic meter of ballast water.

(2) For organisms less than 50 micrometers and greater than or equal to 10 micrometers: discharge must include fewer than 10 living organisms per milliliter (mL) of ballast water.

(3) Indicator microorganisms must not exceed:

(i) For Toxicogenic *Vibrio cholerae* (serotypes O1 and O139): a concentration of less than 1 colony forming unit (cfu) per 100 mL.

(ii) For *Escherichia coli:* a concentration of fewer than 250 cfu per 100 mL.

(iii) For intestinal enterococci: a concentration of fewer than 100 cfu per 100 mL.

(b) [Reserved]

(c) The Coast Guard will conduct a practicability review as follows:

(1) No later than January 1, 2016, the Coast Guard will publish the results of a practicability review to determine—

(i) Whether technology to comply with a performance standard more stringent than that required by paragraph (a) of this section can be practicably implemented, in whole or in part, and, if so, the Coast Guard will schedule a rulemaking to implement the more stringent standard; *and*

(ii) Whether testing protocols that can accurately measure efficacy of treatment against a performance standard more stringent than that required by paragraph (a) of this section can be practicably implemented.

(2) If the Coast Guard determines on the basis of a practicability review conducted under paragraph (c)(1) of this section that technology to achieve a significant improvement in ballast water treatment efficacy could be practicably implemented, the Coast Guard will report this finding and will, no later than January 1, 2017, initiate a rulemaking that would establish performance standards and other requirements or conditions to ensure to the maximum extent practicable that aquatic nuisance species are not discharged into waters of the United States from vessels. If the Coast Guard subsequently finds that it is not able to meet this schedule, the Coast Guard will publish a notice in the **Federal Register** so informing the public, along with an explanation of the reason for the delay, and a revised schedule for rule making that shall be as expeditious as practicable.

(3) When conducting the practicability review as required by paragraph (c)(1) of this section, the Coast Guard will consider—

(i) The capability of any identified technology to achieve a more stringent ballast water discharge standard, in whole or in part;

(ii) The effectiveness of any identified technology in the shipboard environment;

(iii) The compatibility of any identified technology with vessel design and operation;

(iv) The safety of any identified technology;

(v) Whether the use of any identified technology may have an adverse impact on the environment;

(vi) The cost of any identified technology;

(vii) The economic impact of any identified technology, including the impact on shipping, small businesses, and other uses of the aquatic environment;

(viii) The availability, accuracy, precision, and cost of methods and technologies for measuring the concentrations of organisms, treatment chemicals, or other pertinent parameters in treated ballast water as would be required under any alternative discharge standards;

(ix) Any requirements for the management of ballast water included in the most current version of the U.S. Environmental Protection Agency's Vessel General Permit and any documentation available from the EPA regarding the basis for these requirements; and

(x) Any other factor that the Coast Guard considers appropriate that is related to the determination of whether identified technology is performable, practicable, and/or may possibly prevent the introduction and spread of non-indigenous aquatic invasive species.

§ 151.1512 and 151.1514 [Redesignated as §§ 151.1514 and 151.1515]

■ 7. Redesignate §§ 151.1512 and 151.1514 as §§ 151.1514 and 151.1515, respectively.

■ 8. Add a new § 151.1512 to read as follows:

§ 151.1512 Implementation schedule for approved ballast water management methods.

(a) In order to discharge ballast water into the waters of the United States, the master, owner, operator, agent, or person in charge of a vessel subject to § 151.1510 of this subpart must either ensure that the ballast water meets the ballast water discharge standard as defined in § 151.1511(a), use an AMS as provided for under § 151.1510(a)(1) or ballast exclusively with water from a U.S. public water system, as described in § 151.1510(a)(4), according to the schedule in paragraph (b) of this section.

(b) *Implementation Schedule for the Ballast Water Management Discharge Standard for vessels using a Coast Guard approved BWMS to manage ballast water discharged to U.S. waters.* After the dates listed in Table 151.1512(b), vessels may use a USCG-

approved BWMS and comply with the discharge standard, or employ an approved alternative ballast water management method per § 151.1510(a)(1) and (4).

TABLE 151.1512(b)—IMPLEMENTATION SCHEDULE FOR BALLAST WATER MANAGEMENT DISCHARGE STANDARDS FOR VESSELS USING COAST GUARD APPROVED BALLAST WATER MANAGEMENT SYSTEMS

	Vessel's ballast water capacity	Date constructed	Vessel's compliance date
New vessels	All	On or after December 1, 2013.	On delivery.
Existing vessels	Less than 1500 m^3	Before December 1, 2013	First scheduled drydocking after January 1, 2016.
	1500–5000 m^3	Before December 1, 2013	First scheduled drydocking after January 1, 2014.
	Greater than 5000 m^3	Before December 1, 2013	First scheduled drydocking after January 1, 2016.

■ 9. Add new § 151.1513 to read as follows:

§ 151.1513 Extension of Compliance Date.

The Coast Guard may grant an extension to the implementation schedule in § 151.1512(b) of this subpart only in those cases where the master, owner, operator, agent, or person in charge of a vessel subject to this subpart can document that, despite all efforts, compliance with the requirement under § 151.1510 is not possible. Any extension request must be made no later than 12 months before the scheduled implementation date listed in § 151.1512(b) of this subpart and submitted in writing to the Commandant (CG–522), U.S. Coast Guard Office of Operating and Environmental Standards, 2100 2nd St. SW., Stop 7126, Washington, DC 20593–7126. Summary information concerning all extension decisions, including the name of the vessel and vessel owner, the term of the extension, and the basis for the extension will be promptly posted on the Internet. Extensions will be for no longer than the minimum time needed, as determined by the Coast Guard, for the vessel to comply with the requirements of § 151.1510.

■ 10. Revise newly redesignated § 151.1515 as follows:

§ 151.1515 Ballast water management alternatives under extraordinary conditions.

(a) As long as ballast water exchange (BWE) remains an option under the schedule in § 151.1512(b) of this subpart, the master of any vessel subject to this subpart who uses BWE to meet the requirements of this subpart and, due to weather, equipment failure, or other extraordinary conditions, is unable to effect a BWE before entering the U.S. Exclusive Economic Zone, and intends to discharge ballast water into the waters of the United States, must request permission from the Captain of the Port (COTP) to exchange the vessel's ballast water within an area agreed to by the COTP at the time of the request and then discharge the vessel's ballast water within that designated area.

(b) Once BWE is no longer an option under the schedule in § 151.1512(b) of this subpart, if the ballast water management system required by this subpart stops operating properly during a voyage or the vessel's BWM method is unexpectedly unavailable, the master, owner, operator, agent, or person in charge of the vessel must ensure that the problem is reported to the COTP as soon as practicable. The vessel may continue to the next port of call, subject to the directions of the COTP or the Ninth District Commander, as provided by 33 CFR part 160.

■ 11. Revise § 151.1516(a) to read as follows:

§ 151.1516 Compliance Monitoring.

(a) The master of each vessel equipped with ballast tanks must provide, as detailed in § 151.2070 of this part, the following information, in written form, to the Captain of the Port (COTP):

* * * * *

■ 12. Revise subpart D of part 151 to read as follows:

Subpart D—Ballast Water Management for Control of Nonindigenous Species in Waters of the United States

Sec.

Authority: 16 U.S.C. 4711; Department of Homeland Security Delegation No. 0170.1.

Subpart D—Ballast Water Management for Control of Nonindigenous Species in Waters of the United States

§ 151.2000 Purpose and scope.

This subpart implements the provisions of the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (16 U.S.C. 4701–4751), as amended by the National Invasive Species Act of 1996.

§ 151.2005 Definitions.

(a) Unless otherwise stated in this section, the definitions in 33 CFR 151.1504, 33 CFR 160.204, and the United Nations Convention on the Law of the Sea apply to this subpart.

(b) As used in this subpart:

Captain of the Port (COTP) means the Coast Guard officer designated by the Commandant to command a COTP Zone as described in part 3 of this chapter.

Constructed in respect of a vessel means a stage of construction when—

(1) The keel of a vessel is laid;

(2) Construction identifiable with the specific vessel begins;

(3) Assembly of the vessel has commenced and comprises at least 50 tons or 1 percent of the estimated mass of all structural material, whichever is less; or

(4) The vessel undergoes a major conversion.

Exchange means to replace the water in a ballast tank using one of the following methods:

(1) *Flow-through exchange* means to flush out ballast water by pumping in mid-ocean water at the bottom of the

tank and continuously overflowing the tank from the top until three full volumes of water has been changed to minimize the number of original organisms remaining in the tank.

(2) *Empty/refill exchange* means to pump out the ballast water taken on in ports, estuarine, or territorial waters until the pump(s) lose suction, then refilling it with mid-ocean water.

International Maritime Organization (IMO) ballast water management guidelines mean the Guidelines for the Control and Management of Ships' Ballast Water to Minimize the Transfer of Harmful Aquatic Organisms and Pathogens (IMO Resolution A.868 (20), adopted November 1997).

National Ballast Information Clearinghouse (NBIC) means the National Ballast Information Clearinghouse operated by the Coast Guard and the Smithsonian Environmental Research Center as mandated under the National Invasive Species Act of 1996.

Port or place of departure means any port or place in which a vessel is anchored or moored.

Port or place of destination means any port or place to which a vessel is bound to anchor or moor.

Seagoing vessel means a vessel in commercial service that operates beyond the boundary line established by 46 CFR part 7. It does not include a vessel that navigates exclusively on inland waters.

Shipboard Technology Evaluation Program (STEP) means a Coast Guard research program intended to facilitate research, development, and shipboard testing of effective BWMS. STEP requirements are located at: *http://www.uscg.mil/environmental_standards/.*

United States means the States, the District of Columbia, Guam, American Samoa, the Virgin Islands, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, and any other territory or possession over which the United States exercises sovereignty.

Voyage means any transit by a vessel destined for any United States port or place.

§ 151.2010 Applicability.

This subpart applies to all non-recreational vessels, U.S. and foreign, that are equipped with ballast tanks and operate in the waters of the United States, except as expressly provided in §§ 151.2015 or 151.2020 of this subpart.

§ 151.2013 Severability.

If a court finds any portion of this subpart to have been promulgated without proper authority, the remainder of this subpart will remain in full effect.

§ 151.2015 Exemptions.

(a) The following vessels are exempt from all of the requirements of this subpart:

(1) Any Department of Defense or Coast Guard vessel subject to the requirements of section 1103 of the Nonindigenous Aquatic Nuisance Prevention and Control Act, as amended by the National Invasive Species Act; or any vessel of the Armed Forces, as defined in the Federal Water Pollution Control Act (33 U.S.C. 1322(a)), that is subject to the ''Uniform National Discharge Standards for Vessels of the Armed Forces'' (33 U.S.C. 1322(n)).

(2) Any warship, naval auxiliary, or other vessel owned or operated by a foreign state and used, for the time being, only on government non-commercial service. However, such vessels should act in a manner consistent, so far as is reasonable and practicable, with this subpart.

(b) The following vessels are exempt from the requirements of §§ 151.2025 (ballast water management (BWM) requirements), 151.2060 (reporting), and 151.2070 (recordkeeping) of this subpart:

(1) Crude oil tankers engaged in coastwise trade.

(2) Vessels that operate exclusively within one Captain of the Port (COTP) Zone.

(c) The following vessels are exempt only from the requirements of § 151.2025 (BWM requirements) of this subpart:

(1) Seagoing vessels that operate in more than one COTP Zone, do not operate outside of the Exclusive Economic Zone (EEZ), and are less than or equal to 1,600 gross register tons or less than or equal to 3,000 gross tons (International Convention on Tonnage Measurement of Ships, 1969).

(2) Non-seagoing vessels.

(3) Vessels that take on and discharge ballast water exclusively in one COTP Zone.

§ 151.2020 Vessels in innocent passage.

A foreign vessel that is merely traversing the territorial sea of the United States (unless bound for, entering or departing a U.S. port or navigating the internal waters of the U.S.) does not fall within the applicability of this subpart.

§ 151.2025 Ballast water management requirements.

(a) The master, owner, operator, agent, or person in charge of a vessel equipped with ballast tanks that operates in the waters of the United States must employ one of the following ballast water management methods:

(1) Install and operate a ballast water management system (BWMS) that has been approved by the Coast Guard under 46 CFR part 162. The BWMS must be installed in accordance with § 151.2035(b) of this subpart. Following installation, the master, owner, operator, agent, or person in charge of the vessel subject to this subpart must properly maintain the BWMS in accordance with all manufacturer specifications. Unless otherwise expressly provided for in this subpart, the master, owner, operator, agent, or person in charge of vessels employing a Coast Guard-approved BWMS must meet the applicable ballast water discharge standard (BWDS), found in § 151.2030 of this subpart, at all times of discharge into the waters of the United States.

(2) Use only water from a U.S. public water system (PWS), as defined in 40 CFR 141.2, that meets the requirements of 40 CFR parts 141 and 143 as ballast water. Vessels using water from a PWS as ballast must maintain a record of which PWS they received the water from as well as a receipt, invoice, or other documentation from the PWS indicating that water came from that system. Furthermore, they must certify that they have met the conditions in paragraphs (a)(2)(i) or (ii) of this section, as applicable, and describe in the BWM plan the procedures to be used to ensure compliance with those conditions, and thereafter document such compliance in the BW record book. Vessels using water from a PWS must use such water exclusively unless the usage is in accordance with § 151.2040 of this subpart. Vessels using PWS water as ballast must have either—

(i) Previously cleaned the ballast tanks (including removing all residual sediments) and not subsequently introduced ambient water; or

(ii) Never introduced ambient water to those tanks and supply lines.

(3) Perform complete ballast water exchange in an area 200 nautical miles from any shore prior to discharging ballast water, unless the vessel is required to employ an approved BWMS per the schedule found in § 151.2035(b) of this subpart. An alternate management system (AMS) that meets the requirements of § 151.2026 of this subpart may also be used, so long as it was installed on the vessel prior to the date that the vessel is required to comply with the BWDS in accordance with § 151.2035(b) of this subpart. If using an AMS, the master, owner, operator, agent, or person in charge of the vessel subject to this subpart may

employ the AMS for no longer than 5 years from the date they would otherwise be required to comply with the BWDS in accordance with § 151.2035(b) of this subpart;

(4) Do not discharge ballast water into waters of the United States.

(5) Discharge to a facility onshore or to another vessel for purposes of treatment. Any vessel owner/operator discharging ballast water to a facility onshore or to another vessel must ensure that all vessel piping and supporting infrastructure up to the last manifold or valve immediately before the dock manifold connection of the receiving facility or similar appurtenance on a reception vessel prevents untreated ballast water from being discharged into waters of the United States.

(b) Requests for approval of BWMS must be submitted to the Commanding Officer (Marine Safety Center), U.S. Coast Guard Marine Safety Center, 2100 2nd St. SW., Stop 7102, Washington, DC 20593–7102, or by email to *msc@uscg.mil,* in accordance with 46 CFR part 162.

(c) A vessel engaged in the foreign export of Alaskan North Slope Crude Oil must comply with §§ 151.2060 and 151.2070 of this subpart, as well as with the provisions of 15 CFR 754.2(j)(1)(iii). Section 15 CFR 754.2(j)(1)(iii) requires a mandatory program of deep water ballast exchange unless doing so would endanger the safety of the vessel or crew.

(d) This subpart does not authorize the discharge of oil or noxious liquid substances (NLS) in a manner prohibited by United States or international laws or regulations. Ballast water carried in any tank containing a residue of oil, NLS, or any other pollutant must be discharged in accordance with applicable laws and regulations.

(e) This subpart does not affect or supersede any requirement or prohibition pertaining to the discharge of ballast water into the waters of the United States under the Federal Water Pollution Control Act (33 U.S.C. 1251 to 1376).

(f) This subpart does not affect or supersede any requirement or prohibition pertaining to the discharge of ballast water into the waters of the United States under the National Marine Sanctuaries Act (16 U.S.C. 1431 et seq.).

(g) Vessels with installed BWMS for testing and evaluation by an Independent Laboratory in accordance with the requirements of 46 CFR 162.060–10 and 46 CFR 162.060–28 will be deemed to be in compliance with paragraph (a)(1) of this section.

§ 151.2026 Alternate management systems.

(a) A manufacturer whose ballast water management system (BWMS) has been approved by a foreign administration pursuant to the standards set forth in the International Convention for the Control and Management of Ships' Ballast Water and Sediments, 2004, may request in writing, for the Coast Guard to make a determination that their BWMS is an alternate management system (AMS). Requests for determinations under this section must include:

(1) The type-approval certificate for the BWMS.

(2) Name, point of contact, address, and phone number of the authority overseeing the program;

(3) Final test results and findings, including the full analytical procedures and methods, results, interpretations of the results, and full description and documentation of the Quality Assurance procedures (i.e., sample chain of custody forms, calibration records, etc.);

(4) A description of any modifications made to the system after completion of the testing for which a determination is requested; and

(5) A type approval application as described under 46 CFR 162.060–12.

(i) Once ballast water management systems are type approved by the Coast Guard and available for a given class, type of vessels, or specific vessel, those vessels will no longer be able to install AMS in lieu of type approved systems.

(ii) [Reserved]

(b) Requests for determinations must be submitted in writing to the Commanding Officer, U.S. Coast Guard Marine Safety Center, 2100 2nd St. SW., Stop 7102, Washington, DC 20593–7102.

(c) If using an AMS that was installed on the vessel prior to the date that the vessel is required to comply with the ballast water discharge standard in accordance with § 151.2035(b), the master, owner, operator, agent, or person in charge of the vessel subject to this subpart may employ such AMS for no longer than 5 years from the date they would otherwise be required to comply with the ballast water discharge standard in accordance with the implementation schedule in § 151.2035 (b) of this subpart. To ensure the safe and effective management and operation of the AMS equipment, the master, owner, operator, agent or person in charge of the vessel must ensure the AMS is maintained and operated in conformity with the system specifications.

(d) An AMS determination issued under this section may be suspended, withdrawn, or terminated in accordance with the procedures contained in 46 CFR 162.060–18.

§ 151.2030 Ballast water discharge standard (BWDS).

(a) Vessels employing a Coast Guard-approved ballast water management system (BWMS) must meet the following BWDS by the date listed in § 151.2035(b) of this subpart:

(1) For organisms greater than or equal to 50 micrometers in minimum dimension: Discharge must include fewer than 10 organisms per cubic meter of ballast water.

(2) For organisms less than 50 micrometers and greater than or equal to 10 micrometers: Discharge must include fewer than 10 organisms per milliliter (mL) of ballast water.

(3) Indicator microorganisms must not exceed:

(i) For toxicogenic *Vibrio cholerae* (serotypes O1 and O139): A concentration of less than 1 colony forming unit (cfu) per 100 mL.

(ii) For *Escherichia coli:* a concentration of fewer than 250 cfu per 100 mL.

(iii) For intestinal enterococci: A concentration of fewer than 100 cfu per 100 mL.

(b) [Reserved]

(c) The Coast Guard will conduct a practicability review as follows:

(1) No later than January 1, 2016, the Coast Guard will publish the results of a practicability review to determine—

(i) Whether technology to comply with a performance standard more stringent than that required by paragraph (a) of this section can be practicably implemented, in whole or in part, and, if so, the Coast Guard will schedule a rulemaking to implement the more stringent standard; and

(ii) Whether testing protocols that can assure accurate measurement of compliance with a performance standard more stringent than that required by paragraph (a) of this section can be practicably implemented.

(2) If the Coast Guard determines on the basis of a practicability review conducted under paragraph (c)(1) of this section that technology to achieve a significant improvement in ballast water treatment efficacy could be practicably implemented, the Coast Guard will report this finding and will, no later than January 1, 2017, initiate a rulemaking that would establish performance standards and other requirements or conditions to ensure to the maximum extent practicable that aquatic nuisance species are not discharged into waters of the United States from vessels. If the Coast Guard

subsequently finds that it is not able to meet this schedule, the Coast Guard will publish a notice in the **Federal Register** so informing the public, along with an explanation of the reason for the delay, and a revised schedule for rule making that shall be as expeditious as practicable.

(3) When conducting the practicability review as described in paragraph (c)(1) of this section, the Coast Guard will consider—

(i) The capability of any identified technology to achieve a more stringent BWDS, in whole or in part;

(ii) The effectiveness of any identified technology in the shipboard environment;

(iii) The compatibility of any identified technology with vessel design and operation;

(iv) The safety of any identified technology;

(v) Whether the use of any identified technology may have an adverse impact on the environment;

(vi) The cost of any identified technology;

(vii) The economic impact of any identified technology, including the impact on shipping, small businesses, and other uses of the aquatic environment;

(viii) The availability, accuracy, precision, and cost of methods and technologies for measuring the concentrations of organisms, treatment chemicals, or other pertinent parameters in treated ballast water as would be required under any alternative discharge standards;

(ix) Any requirements for the management of ballast water included in the most current version of the Environmental Protection Agency's Vessel General Permit and any documentation available from the EPA regarding the basis for these requirements; and

(x) Any other factor that the Coast Guard considers appropriate that is related to the determination of whether identified technology is performable, practicable, and/or may possibly prevent the introduction and spread of non-indigenous aquatic invasive species.

§ 151.2035 Implementation schedule for approved ballast water management methods.

(a) To discharge ballast water into waters of the United States, the master, owner, operator, agent, or person in charge of a vessel subject to § 151.2025 of this subpart must either ensure that the ballast water meets the ballast water discharge standard as defined in § 151.2030(a), use an AMS as described in § 151.2025(a)(3) or ballast with water from a U.S. public water system, as described in § 151.2025(a)(2), according to the schedule in paragraph (b) of this section.

(b) *Implementation Schedule for the Ballast Water Management Discharge Standard for vessels using a Coast Guard approved BWMS to manage ballast water discharged to waters of the U.S.* After the dates listed in Table 151.2035(b), vessels may use a USCG-approved BWMS and comply with the discharge standard, use PWS per § 151.2025(a)(2), or use a previously installed AMS per § 151.2025(a)(3).

TABLE 151.2035(b)—IMPLEMENTATION SCHEDULE FOR APPROVED BALLAST WATER MANAGEMENT METHODS

	Vessel's ballast water capacity	Date constructed	Vessel's compliance date
New vessels	All	On or after December 1, 2013	On delivery.
Existing vessels	Less than 1500 m^3	Before December 1, 2013	First scheduled drydocking after January 1, 2016.
	1500–5000 m^3	Before December 1, 2013	First scheduled drydocking after January 1, 2014.
	Greater than 5000 m^3	Before December 1, 2013	First scheduled drydocking after January 1, 2016.

§ 151.2036 Extension of compliance date.

The Coast Guard may grant an extension to the implementation schedule listed in § 151.2035(b) of this subpart only in those cases where the master, owner, operator, agent, or person in charge of a vessel subject to this subpart can document that despite all efforts to meet the ballast water discharge standard requirements in § 151.2030 of this subpart, compliance is not possible. Any extension request must be made no later than 12 months before the scheduled implementation date listed in § 151.2035(b) of this subpart and submitted in writing to the Commandant (CG–522), U.S. Coast Guard Office of Operating and Environmental Standards, 2100 2nd St. SW., Stop 7126, Washington, DC 20593–7126. Summary information concerning all extension decisions, including the name of the vessel and vessel owner, the term of the extension, and the basis for the extension will be promptly posted on the Internet. Extensions will be for no longer than the minimum time needed, as determined by the Coast Guard, for the vessel to comply with the requirements of § 151.2030.

§ 151.2040 Discharge of ballast water in extraordinary circumstances.

(a) The Coast Guard will allow the master, owner, operator, agent, or person in charge of a vessel that cannot practicably meet the requirements of § 151.2025(a) of this subpart, either because its voyage does not take it into waters 200 nautical miles or greater from any shore for a sufficient length of time and the vessel retains ballast water onboard or because the master of the vessel has identified safety or stability concerns, to discharge ballast water in areas other than the Great Lakes and the Hudson River north of the George Washington Bridge.

(1) The Coast Guard will not allow such a discharge if the vessel is required to have a Coast Guard-approved ballast water management system (BWMS) per the implementation schedule found in § 151.2035(b) of this subpart.

(2) If the Coast Guard allows the discharge of ballast water as described in paragraph (a) of this section, the master, owner, operator, agent, or person in charge of the vessel must discharge only that amount of ballast water operationally necessary to ensure the safety of the vessel for cargo operations.

(3) Ballast water records must be made available to the local Captain of the Port (COTP) upon request.

(4) Vessels on a voyage to the Great Lakes or the Hudson River north of the George Washington Bridge must comply with the requirements of 33 CFR 151.1515.

(b) If the installed BWMS required by this subpart stops operating properly during a voyage, or the vessel's BWM method is unexpectedly unavailable, the person directing the movement of the vessel must ensure that the problem is

reported to the nearest COTP or District Commander as soon as practicable. The vessel may continue to the next port of call, subject to the directions of the COTP or District Commander, as provided by part 160 of this chapter.

(1) The Coast Guard will normally allow a vessel that cannot practicably meet the requirements of § 151.2025(a)(1) of this subpart because its installed BWMS is inoperable, or the vessel's BWM method is unexpectedly unavailable, to employ one of the other ballast water management (BWM) methods listed in § 151.2025(a) of this subpart.

(2) If the master of the vessel determines that the vessel cannot employ other BWM methods due to the voyage or safety concerns listed in paragraph (a) of this section, the Coast Guard will normally allow the vessel to discharge ballast water in areas other than the Great Lakes and the Hudson River north of the George Washington Bridge.

(3) If the Coast Guard approves such an allowance, the vessel must discharge only that amount of ballast water operationally necessary to ensure the safety and stability of the vessel for cargo operations. Ballast water records must be made available to the local COTP upon request.

(c) Nothing in this subpart relieves the master, owner, operator, agent, or person in charge of a vessel of any responsibility, including ensuring the safety and stability of the vessel and the safety of the crew and passengers.

§ 151.2050 Additional requirements—nonindigenous species reduction practices.

The master, owner, operator, agent, or person in charge of any vessel equipped with ballast water tanks that operates in the waters of the United States must follow these practices:

(a) Avoid the discharge or uptake of ballast water in areas within, or that may directly affect, marine sanctuaries, marine preserves, marine parks, or coral reefs.

(b) Minimize or avoid uptake of ballast water in the following areas and situations:

(1) Areas known to have infestations or populations of harmful organisms and pathogens (e.g., toxic algal blooms).

(2) Areas near sewage outfalls.

(3) Areas near dredging operations.

(4) Areas where tidal flushing is known to be poor or times when a tidal stream is known to be turbid.

(5) In darkness, when bottom-dwelling organisms may rise up in the water column.

(6) Where propellers may stir up the sediment.

(7) Areas with pods of whales, convergence zones, and boundaries of major currents.

(c) Clean the ballast tanks regularly to remove sediments. Sediments must be disposed of in accordance with local, State, and Federal regulations.

(d) Discharge only the minimal amount of ballast water essential for vessel operations while in the waters of the United States.

(e) Rinse anchors and anchor chains when the anchor is retrieved to remove organisms and sediments at their places of origin.

(f) Remove fouling organisms from the vessel's hull, piping, and tanks on a regular basis and dispose of any removed substances in accordance with local, State and Federal regulations.

(g) Maintain a ballast water management (BWM) plan that has been developed specifically for the vessel and that will allow those responsible for the plan's implementation to understand and follow the vessel's BWM strategy and comply with the requirements of this subpart. The plan must include—

(1) Detailed safety procedures;

(2) Actions for implementing the mandatory BWM requirements and practices;

(3) Detailed fouling maintenance and sediment removal procedures;

(4) Procedures for coordinating the shipboard BWM strategy with Coast Guard authorities;

(5) Identification of the designated officer(s) in charge of ensuring that the plan is properly implemented;

(6) Detailed reporting requirements and procedures for ports and places in the United States where the vessel may visit; and

(7) A translation of the plan into English, French, or Spanish if the vessel's working language is another language.

(h) Train the master, operator, person in charge, and crew on the application of ballast water and sediment management and treatment procedures.

(i) When discharging ballast water to a reception facility in the United States, discharge only to reception facilities that have an NPDES permit to discharge ballast water.

§ 151.2055 Deviation from planned voyage.

As long as ballast water exchange (BWE) is an allowable ballast water management option under §§ 151.2025 and 151.2035 of this subpart, the Coast Guard will not require a vessel to deviate from its voyage or delay the voyage in order to conduct BWE. A vessel may be required to deviate from its voyage or delay the voyage if BWE is directed by a Captain of the Port pursuant to § 151.2040(b) of this subpart.

§ 151.2060 Reporting requirements.

(a) Ballast water reporting requirements exist for each vessel subject to this subpart bound for ports or places of the United States regardless of whether a vessel operated outside of the Exclusive Economic Zone (EEZ), unless exempted in § 151.2015 of this subpart.

(b) The master, owner, operator, agent, or person in charge of a vessel subject to this subpart and this section must provide the information required by § 151.2070 of this subpart in electronic or written form to the Commandant, U.S. Coast Guard or the appropriate Captain of the Port (COTP). The Ballast Water Reporting Form (Office of Management and Budget form Control No. 1625–0069) and the instructions for completing it are available on the National Ballast Information Clearinghouse's Web site at *http://invasions.si.edu/nbic/submit.html*. Information must be submitted as follows:

(1) *For any vessel bound for the Great Lakes from outside the EEZ:*

(i) Fax the required information at least 24 hours before the vessel arrives in Montreal, Quebec to the U.S. Coast Guard (USCG) COTP, Buffalo, Massena Detachment (315–769–5032).

(ii) Non-U.S. and non-Canadian flag vessels may complete the ballast water information section of the form required by the St. Lawrence Seaway, ''Pre-entry Information from Foreign Flagged Vessels Form,'' and submit it in accordance with the applicable Seaway notice as an alternative to this requirement.

(2) *For any vessel bound for the Hudson River north of the George Washington Bridge entering from outside the EEZ:* Fax the required information to the USCG COTP, New York (718–354–4249) at least 24 hours before the vessel enters New York, NY.

(3) *For any vessel that is equipped with ballast water tanks and bound for ports or places in the United States and not addressed in paragraphs (b)(1) and (b)(2) of this section:* If a vessel's voyage is less than 24 hours, report the required information before departing the port or place of departure. If a voyage exceeds 24 hours, report the required information at least 24 hours before arrival at the port or place of destination. The information must be sent to the National Ballast Information Clearinghouse using only one of the following means:

(i) Via the Internet at *http://invasions.si.edu/nbic/submit.html*.

(ii) Email to *NBIC@BallastReport.org*.
(iii) Fax to 301–261–4319.
(iv) Mail to U.S. Coast Guard, c/o Smithsonian Environmental Research Center, P.O. Box 28, Edgewater, MD 21037–0028.

(c) If the information submitted in accordance with this section changes, the master, owner, operator, agent, or person in charge of the vessel must submit an amended report before the vessel departs the waters of the United States.

§ 151.2065 Equivalent reporting methods for vessels other than those entering the Great Lakes or Hudson River after operating outside the U.S. Exclusive Economic Zone or Canadian equivalent.

For vessels required to report under § 151.2060(b)(3) of this subpart, the Chief, Environmental Standards Division (CG–5224), acting for the Assistant Commandant for Marine Safety, Security, and Stewardship (CG–5), may, upon receipt of a written request, consider and approve alternative methods of reporting if—

(a) Such methods are at least as effective as those required by § 151.2060 of this subpart; and

(b) Compliance with § 151.2060 of this subpart is economically or physically impractical. The Chief, Environmental Standards Division (CG–5224), will approve or disapprove a request submitted in accordance with this section within 30 days of receipt of the request.

§ 151.2070 Recordkeeping requirements.

(a) The master, owner, operator, agent, or person in charge of a vessel bound for a port or place in the United States, unless specifically exempted by § 151.2015 of this subpart, must ensure the maintenance of written records that include the following information:

(1) *Vessel information.* This includes the name, International Maritime Organization (IMO) number (official number if IMO number is not issued), vessel type, owner or operator, gross tonnage, call sign, and State of registry (flag).

(2) *Voyage information.* This includes the date and port of arrival, vessel agent, last port and country of call, and next port and country of call.

(3) *Total ballast water information.* This includes the total ballast water capacity, total volume of ballast water onboard, total number of ballast water tanks, and total number of ballast water tanks in ballast. Use units of measurements such as metric tons (MT), cubic meters (m^3), long tons (LT), and short tons (ST).

(4) *Ballast water management (BWM).* This includes the total number of ballast tanks/holds that are to be discharged into the waters of the United States or to a reception facility.

(i) If the vessel uses an alternative BWM method, note the number of tanks that are managed using an alternative method, as well as the type of method used.

(ii) Indicate whether the vessel has a BWM plan and IMO ballast water management guidelines onboard, and whether the BWM plan is used.

(5) *Information on ballast water tanks that are to be discharged into the waters of the United States or to a reception facility.* Include the following:

(i) The origin of ballast water. This includes date(s), location(s), volume(s) and temperature(s). If a tank has undergone ballast water exchange (BWE), list the loading port of the ballast water that was discharged during the exchange.

(ii) The date(s), location(s), volume(s), method, thoroughness (percentage exchanged, if BWE conducted), and sea height at time of exchange of any ballast water exchanged or otherwise managed.

(iii) The expected date, location, volume, and salinity of any ballast water to be discharged into the waters of the United States or to a reception facility.

(6) *Discharge of sediment.* Include the name and location of the facility where sediment disposal will take place, if sediment is to be discharged within the jurisdiction of the United States.

(7) *Certification of accurate information.* Include the master, owner, operator, agent, person in charge, or responsible officer's printed name, title, and signature attesting to the accuracy of the information provided and certifying compliance with the requirements of this subpart.

(b) The master, owner, operator, agent, or person in charge of a vessel subject to this section must retain a signed copy of this information onboard the vessel for 2 years.

(c) Two alternative ways to meet the requirements of this section are—

(1) Completing and retaining the Ballast Water Reporting Form contained in the IMO ballast water management guidelines; or

(2) Completing the ballast water information section of the form required by the St. Lawrence Seaway Pre-entry Information from Foreign Flagged Vessels.

(d) The master, owner, operator, agent, or person in charge of a vessel subject to this section must retain the monitoring records required in 46 CFR 162.060–20(b) for 2 years. These records may be stored on digital media but must be viewable for Coast Guard inspection.

(e) The information required by this subpart may be used to satisfy the ballast water recordkeeping requirements for vessels subject to § 151.2025(c) of this subpart and 33 CFR part 151 subpart C.

§ 151.2075 Enforcement and compliance.

(a) The master, owner, operator, agent, or person in charge of a vessel must provide the Captain of the Port (COTP) with access to the vessel in order to take samples of ballast water and sediment, examine documents, and make other appropriate inquiries to assess the compliance of any vessel subject to this subpart.

(b) The master, owner, operator, agent, or person in charge of a vessel subject to this section must provide the records to the COTP upon request, as required by § 151.2070 of this subpart.

(c) Vessels with installed ballast water management systems are subject to Coast Guard inspection. Every vessel must have a sampling port(s) designed and installed in accordance with 46 CFR 162.060–28(f) and (f)(2) at each overboard discharge point.

(d) In this subpart, wherever multiple entities are responsible for compliance with any requirement of the rule, each entity is jointly liable for a violation of such requirement.

§ 151.2080 Penalties.

(a) A person who violates this subpart is liable for a civil penalty not to exceed $35,000. Each day of a continuing violation constitutes a separate violation. A vessel operated in violation of the regulations is liable in rem for any civil penalty assessed under this subpart for that violation.

(b) A person who knowingly violates the regulations of this subpart is guilty of a class C felony.

Appendix to Subpart D of Part 151 [Removed]

Appendix to Subpart D [Removed]

■ 13. Remove the Appendix to subpart D of part 151.

Title 46—Shipping

CHAPTER I—COAST GUARD

Subchapter Q—Equipment, Construction, and Materials: Specifications and Approval

PART 162—ENGINEERING EQUIPMENT

■ 14. Add subpart 162.060 to part 162 to read as follows:

Subpart 162.060—Ballast Water Management Systems

Sec.
162.060–1 Purpose and scope.

Authority: 16 U.S.C. 4711; Department of Homeland Security Delegation No. 0170.1.

Subpart 162.060—Ballast Water Management Systems

§ 162.060–1 Purpose and scope.

This subpart contains procedures and requirements for approval of complete ballast water management systems to be installed onboard vessels for the purpose of complying with the ballast water discharge standard of 33 CFR part 151, subparts C and D.

§ 162.060–3 Definitions.

As used in this subpart—

Active substance means a chemical or an organism, including a virus or a fungus, that has a general or specific action on or against nonindigenous species.

Administration means the government of the nation/State under whose authority a vessel is operating.

Ballast water means any water and suspended matter taken onboard a vessel to control or maintain trim, draught, stability, or stresses of the vessel, regardless of how it is carried.

Ballast water management system (BWMS) means any system which processes ballast water to kill, render harmless, or remove organisms. The BWMS includes all ballast water treatment equipment and all associated control and monitoring equipment.

Ballast water system means the tanks, piping, valves, pumps, sea chests, and any other associated equipment that the vessel uses for the purposes of ballasting.

Ballast water treatment equipment means that part of the BWMS that mechanically, physically, chemically, or biologically processes ballast water, either singularly or in combination, to kill, render harmless, or remove organisms within ballast water and sediments.

Challenge water means water just prior to treatment. In land-based tests, source water may be augmented to achieve required challenge water conditions.

Control and monitoring equipment means that part of the BWMS required to operate, control, and assess the effective operation of the ballast water treatment equipment.

Hazardous location means areas where fire or explosion hazards may exist due to the presence of flammable gases/vapors, flammable liquids, combustible dust, or ignitable fibers, as determined in accordance with the standards of construction applicable to the vessel on which the BWMS is to be installed.

Hazardous materials means hazardous materials as defined in 49 CFR 171.8; hazardous substances designated under 40 CFR part 116.4; reportable quantities as defined under 40 CFR 117.1; materials that meet the criteria for hazard classes and divisions in 49 CFR part 173; materials under 46 CFR 153.40 determined by the Coast Guard to be hazardous when transported in bulk; flammable liquids defined in 46 CFR 30.10–22; combustible liquids as defined in 46 CFR 30.10–15; materials listed in Table 46 CFR 151.05, Table 1 of 46 CFR 153, or Table 4 of 46 CFR part 154; or any liquid, liquefied gas, or compressed gas listed in 49 CFR 172.101.

Independent laboratory means an organization that meets the requirements in 46 CFR 159.010–3. In addition to commercial testing laboratories, which may include not-for-profit organizations, the Commandant may also accept classification societies and agencies of governments (including State and Federal agencies of the United States) that are involved in the evaluation, inspection, and testing of BWMS.

In-line treatment means a treatment system or technology used to treat ballast water during normal flow of ballast uptake, discharge, or both.

In-tank treatment means a treatment system or technology used to treat ballast water during the time that it resides in the ballast tanks.

Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest as defined under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et.seq.) and 40 CFR 152.3.

Preparation means any commercial formulation containing one or more active substances, including any additives. This definition also includes any active substances generated onboard a vessel for the purpose of ballast water management to comply with the ballast water discharge standard codified in 33 CFR part 151 subpart C or D.

Quality Assurance Project Plan (QAPP) means a project-specific technical document reflecting the implementation of Quality Assurance and Quality Control activities, including specifics of the BWMS to be tested, the independent laboratory, and other conditions affecting the actual design and implementation of the required tests and evaluations.

Relevant chemical means any transformation or reaction product that is produced during the treatment process or in the receiving environment and which may be of concern to the aquatic environment and human health when discharged.

Representative sample means a random sample, in which every item of interest (organisms, molecules, etc.) in the larger population has an unbiased chance of appearing.

Sampling port means the equipment installed in the ballast water piping through which representative samples of the ballast water being discharged are extracted. This is equivalent to the term ''sampling facility'' under the International Maritime Organization (IMO) Guidelines for Ballast Water Sampling (G2), published as IMO Resolution MEPC.173(58) on October 10, 2008.

Source water means the body of water from which water is drawn for either land-based or shipboard testing.

Test facility means the location where the independent laboratory conducts land-based, component, active substance, and relevant chemical testing and evaluations, as required by this subpart.

§ 162.060–5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Coast Guard must publish notice of change in the **Federal Register** and the material must be available to the public.

All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Also, it is available for inspection from the Commandant (CG–52), Commercial Regulations and Standards Directorate, U.S. Coast Guard, 2100 2nd St. SW., Stop 7126, Washington, DC 20593–7126, and is available from the sources listed below.

(b) International Electrotechnical Commission (IEC), 3 rue Varembe, P.O. Box 131, 1211 Geneva 20, Switzerland.

(1) IEC 60529, Classification of Degrees of Protection by Enclosures (IP Code), Edition 2.1 consolidated with amendment 1:1999 (dated February, 2001), IBR approved for § 162.060–30.

(2) [Reserved]

(c) International Organization for Standardization (ISO), ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case postale 56 CH–1211 Geneva 20, Switzerland.

(1) ISO/IEC 17025:2005(E), General Requirements for the Competence of Calibration and Testing Laboratories, Second Edition (dated May 15, 2005), IBR approved for § 162.060–36.

(2) ISO/IEC 17025:2005/Cor.1:2006(E), General Requirements for the Competence of Testing and Calibration Laboratories, Technical Corrigendum 1, (dated August 15, 2006), IBR approved for § 162.060–36.

(d) U.S. Environmental Protection Agency (EPA), Environmental Technology Verification Program, National Risk Management Research Laboratory Office of Research and Development, U.S. Environmental Protection Agency, 2890 Woodbridge Avenue (MS–104), Edison, New Jersey 08837.

(1) EPA/600/R–10/146, Generic Protocol for the Verification of Ballast Water Treatment Technologies, version 5.1, (dated September 2010), IBR approved for §§ 162.060–26 and 162.060–28 (ETV Protocol).

(2) [Reserved]

§ 162.060–10 Approval procedures.

(a) Not less than 30 days before initiating any testing of a ballast water management system (BWMS), the results of which are intended for use in an application for type approval, the manufacturer must submit a Letter of Intent (LOI) providing as much of the following information as possible to the Commanding Officer, U.S. Coast Guard Marine Safety Center (MSC), 2100 2nd St. SW., Stop 7102, Washington, DC 20593–7102, or by email to *msc@uscg.mil:*

(1) Manufacturer's name, address, and point of contact, with telephone number or email address.

(2) Name and location of independent laboratory and associated test facilities and subcontractors, plus expected dates and locations for actual testing.

(3) Model name, model number, and type of BWMS.

(4) Expected date of submission of full application package to the Coast Guard.

(5) Name, type of vessel, and expected geographic locations for shipboard testing.

(b) The manufacturer must ensure evaluation, inspection, and testing of the BWMS is conducted by an independent laboratory, accepted by the Coast Guard, in accordance with §§ 162.060–20 through 162.060–40 of this subpart. Testing may begin 30 days after submission of the LOI unless otherwise directed by the Coast Guard.

(1) If an evaluation, inspection, or test required by this section is not practicable or applicable, a manufacturer may submit a written request to the Commanding Officer, U.S. Coast Guard MSC, 2100 2nd St. SW., Stop 7102, Washington, DC 20593–7102, or by email to *msc@uscg.mil,* for approval of alternatives as equivalent to the requirements in this section. The request must include the manufacturer's justification for any proposed changes and contain full descriptions of any proposed alternative tests.

(2) The Coast Guard will notify the manufacturer of its determination under paragraph (b)(1) of this section. Any limitations imposed by the BWMS on testing procedures and all approved deviations from any evaluation, inspection, or testing required by this subpart must be duly noted in the Experimental Design section of the Test Plan.

(c) The manufacturer must submit an application for approval in accordance with § 162.060–14 of this subpart.

(d) Upon receipt of an application completed in compliance with § 162.060–14 of this subpart, the MSC will evaluate the application and either approve, disapprove, or return it to the manufacturer for further revision.

(e) In addition to tests and evaluations required by this subpart, the Coast Guard will independently conduct environmental analyses of each system in accordance with the National Environmental Policy Act, the Endangered Species Act, and/or other environmental statutes. The Coast Guard advises applicants that applications containing novel processes or active substances may encounter significantly longer reviews during these environmental evaluations.

(f) A BWMS is eligible for approval if—

(1) It meets the design and construction requirements in § 162.060–20 of this subpart;

(2) It is evaluated, inspected, and tested under land-based and shipboard conditions in accordance with §§ 162.060–26 and 162.060–28 of this subpart, respectively, and thereby demonstrates that it consistently meets the ballast water discharge standard in 33 CFR part 151, subparts C and D;

(3) All applicable components of the BWMS meet the component testing requirements of § 162.060–30 of this subpart;

(4) The BWMS meets the requirements of § 162.060–32 of this subpart if the BWMS uses an active substance or preparation; and

(5) The ballast water discharge, preparation, active substance, or relevant chemical are not found to be persistent, bioaccumulative, or toxic when discharged.

(g) After evaluation of an application, the Coast Guard will advise the applicant in accordance with 46 CFR 159.005–13 whether the BWMS is approved. If the BWMS is approved, a certification number will be issued and an approval certificate sent to the applicant in accordance with 46 CFR 2.75–5. The approval certificate will list conditions of approval applicable to the BWMS.

§ 162.060–12 Use and acceptance of existing test data.

(a) A manufacturer whose ballast water management system (BWMS) has completed approval testing for a foreign administration in accordance with the International Maritime Organization's Guidelines for Approval of Ballast Water Management Systems (G8) may use the data and information developed during such approval testing to support the submission of an application pursuant to § 162.060–14 of this subpart. The applicant must submit the data and other information developed during approval testing and evaluation for another administration, and include a concise but thorough explanation of how the submission meets or exceeds the requirements of this subpart in respect to design, material and manufacture, and ability to meet the BWDS requirements.

(b) Applications under paragraph (a) of this section will not need to comply with the requirements for advance notice under § 162.060–10(a) of this subpart for testing that has already occurred; or with the requirements that

all evaluation, inspection, and testing of the BWMS is conducted by an independent laboratory, previously accepted by the Coast Guard, under § 162.060–10(b) of this subpart. However—

(1) If the applicant determines, prior to submission of an application, that one or more aspects of the Coast Guard's requirements for approval of a BWMS are not satisfied by the data and information developed for approval by another administration, and that additional testing and evaluation is required, the applicant will notify the Coast Guard of the intent to conduct the new testing in accordance with the requirements of § 162.060–10(a) and (b)(1) of this subpart.

(2) While laboratories and test facilities that conducted the test and evaluation for approval by another administration are not required to have been designated as independent laboratories under the requirements of this subpart at the time of such work, as would otherwise be required under § 162.060–10(b) of this subpart, all laboratories and test facilities must have met the requirements under 46 CFR 159.010–3 and 159.010–5(a) at the time of such work. It is the responsibility of the applicant to ensure that the satisfaction of this requirement is adequately documented in the application.

§ 162.060–14 Information requirements for the ballast water management system (BWMS) application.

(a) A complete BWMS application must contain all of the following information:

(1) The name and location of the independent laboratory conducting approval tests and evaluations.

(2) Two sets of plans describing the BWMS, as specified in 46 CFR 159.005–12.

(3) An Operation, Maintenance, and Safety Manual for the BWMS that meets the requirements in § 162.060–38 of this subpart.

(4) A bill of materials showing all components and specifications of the BWMS.

(5) A list of any systems or components of the BWMS that may require certification as marine portable tanks.

(6) A list of any pressure vessels used as a part of the BWMS, along with a description of the pressure vessel building standard, or code, or why the pressure vessel should be considered exempt from any requirements. Manufacturers must also submit detailed pressure vessel plans if they intend to fabricate pressure vessels, heat exchangers, evaporators, and similar appurtenances.

(7) Documentation of all necessary approvals, registrations, and other documents or certifications required for any active substances, preparations, or relevant chemicals used by the BWMS. The documentation must include the following:

(i) A list of any active substances, preparations, or relevant chemicals that are used, produced, generated as a byproduct, and/or discharged in association with the operation of the BWMS.

(ii) A list of all limitations or restrictions that must be complied with during the approval testing and evaluations, including any water quality limits established by the Environmental Protection Agency, States, or tribes, under the Clean Water Act.

(8) A detailed description of Quality Control procedures, in-process and final inspections, tests followed in manufacturing the item, and construction and sales record keeping systems.

(9) The completed Test Report required by § 162.060–34 of this subpart prepared and submitted by the IL.

(b) The completed application must be sent by the manufacturer to the Commanding Officer, U.S. Coast Guard Marine Safety Center, 2100 2nd St. SW., Stop 7102, Washington, DC 20593–7102.

(c) If examination of the application reveals that it is incomplete, the Coast Guard will return it to the applicant with an explanation.

(d) Additional information, including electronic submission criteria, is available at *http://homeport.uscg.mil/msc*.

§ 162.060–16 Changes to an approved ballast water management system (BWMS).

(a) The manufacturer of a BWMS that is approved by the Coast Guard must notify the Commanding Officer, U.S. Coast Guard Marine Safety Center (MSC), in writing of any change in design or intended operational conditions of the BWMS.

(b) The notification required by paragraph (a) of this section must include—

(1) A description of the change and its advantages; and

(2) An indication of whether or not the original BWMS will be discontinued.

(c) After receipt of the notice and information, the Coast Guard will notify the manufacturer, in writing, of any tests or evaluations that must be conducted, and then determine if BWMS recertification and/or modification is required. The manufacturer may appeal this determination to the Commandant (CG–52), Commercial Regulations and Standards Directorate, U.S. Coast Guard, 2100 2nd St. SW., Stop 7126, Washington, DC 20593–7126.

§ 162.060–18 Suspension, withdrawal, or termination of approval.

The Coast Guard may suspend an approval issued under this subpart or alternate management system (AMS) determination issued under 33 CFR 151.2026(d) of a ballast water management system (BWMS) in accordance with 46 CFR 2.75–40, withdraw an approval or AMS determination in accordance with 46 CFR 2.75–50(a), or terminate an approval or AMS determination in accordance with 46 CFR 2.75–50(b) if the BWMS or AMS, as manufactured—

(a) Is found non-compliant with the conditions of approval;

(b) Is unsuitable for the purpose intended by the manufacturer;

(c) Does not meet the requirements of applicable laws, rules, and regulations, and other Federal requirements when installed and operated as intended by the manufacturer; or

(d) Cannot be maintained to operate as designed, due to lack of parts or necessary support services.

§ 162.060–20 Design and construction requirements.

(a) Unless otherwise authorized by the Commandant, each ballast water management system (BWMS) must be designed and constructed in a manner that—

(1) Ensures simple and effective means for its operation;

(2) Allows operation to be initiated, controlled, and monitored by a single individual, with minimal interaction or attention once normal operation is initiated;

(3) Is robust and suitable for working in the shipboard environment and adequate for its intended service;

(4) Meets recognized national or international standards for all related marine engineering and electrical engineering applications; and

(5) Operates when the vessel is upright, inclined under static conditions at any angle of list up to and including 15°, and when the vessel is inclined under dynamic, rolling conditions at any angle of list up to and including 22.5° and, simultaneously, at any angle of trim (pitching) up to and including 7.5° by bow or stern. The Coast Guard may permit deviations from these angles of inclination by considering the type, size, and service of intended vessels and

considering how the BWMS is to be operated. These deviations must be included on the certificate issued in accordance with § 162.060–10(g) of this subpart.

(b) Each BWMS must have control and monitoring equipment that—

(1) Automatically monitors and adjusts necessary treatment dosages, intensities, or other aspects required for proper operation;

(2) Incorporates a continuous self-monitoring function during the period in which the BWMS is in operation;

(3) Records proper functioning and failures of the BWMS;

(4) Records all events in which an alarm is activated for the purposes of cleaning, calibration, or repair;

(5) Is able to store data for at least 6 months and to display or print a record for official inspections as required; and

(6) In the event that the control and monitoring equipment is replaced, actions must be taken to ensure the data recorded prior to replacement remain available onboard for a minimum of 24 months.

(c) Each BWMS must be designed and constructed with the following operating and emergency controls:

(1) Visual means of indicating (both on the BWMS and in a normally manned space) when the BWMS is operating, including a visual alarm activated whenever the BWMS is in operation for the purpose of cleaning, calibration, or repair.

(2) Audio and visual alarm signals in all stations from which ballast water operations are controlled in case of any failure(s) compromising the proper operation of the BWMS.

(3) Means to activate stop valves, as applicable, if the BWMS fails.

(4) Suitable manual by-passes or overrides to protect the safety of the vessel and personnel in the event of an emergency.

(5) Means that compensate for a momentary loss of power during operation of the BWMS so that unintentional discharges do not occur.

(6) Means of automatic operation for BWMS installed in unoccupied machinery spaces, from the time placed on-line until the time secured.

(7) Adequate alarms for the unintentional release of active substances, preparations, relevant chemicals, or hazardous materials used in or produced by the BWMS.

(d) A BWMS must comply with the relevant requirements for use in a hazardous location, as defined in 46 CFR subpart 111.105, or its foreign equivalent, if it is intended to be fitted in a hazardous location. Any electrical equipment that is a component of the BWMS must be installed in a non-hazardous location unless certified as safe for use in a hazardous location. Any moving parts which are fitted in hazardous locations must be arranged in a manner that avoids the formation of static electricity. Certificates issued under § 162.060–10(g) for systems approved for installation in hazardous locations must be so noted.

(e) To ensure continued operational performance of the BWMS without interference, the following conditions must be incorporated into the design:

(1) Each part of the BWMS that the manufacturer's instructions require to be serviced routinely or that is liable to wear or damage must be readily accessible in the installed position(s) recommended by the manufacturer.

(2) To avoid interference with the BWMS, every access of the BWMS beyond the essential requirements, as determined by the manufacturer, must require the breaking of a seal, and, where possible for the purpose of maintenance, activate an alarm.

(3) Simple means must be provided aboard the vessel to identify drift and repeatability fluctuations and re-zero measuring devices that are part of the control and monitoring equipment.

(f) Each BWMS must be designed so that it does not rely in whole or in part on dilution of ballast water as a means of achieving the ballast water discharge standard as required in 33 CFR part 151, subparts C or D.

(g) Adequate arrangements for storage, application, mitigation, monitoring (including alarms), and safe handling must be made for all BWMS that incorporate the use of, produce, generate, or discharge a hazardous material, active substance, preparation and/or pesticide in accordance with Coast Guard regulations on handling/storage of hazardous materials (33 CFR part 126) and any other applicable Federal, State, and local requirements.

(h) For any BWMS that incorporates the use of or generates active substances, preparations, or chemicals, the BWMS must be equipped with each of the following, as applicable:

(1) A means of indicating the amount and concentration of any chemical in the BWMS that is necessary for its effective operation.

(2) A means of indicating when chemicals must be added for the proper continued operation of the BWMS.

(3) Sensors and alarms in all spaces that may be impacted by a malfunction of the BWMS.

(4) A means of monitoring all active substances and preparations and relevant chemicals in the treated discharge.

(5) A means to ensure that any maximum dosage or maximum allowable discharge concentration of active substances and preparations is not exceeded at any time.

(6) Proper storage of each chemical defined as a hazardous material in 49 CFR 171.8 that is specified or provided by the manufacturer for use in the operation of a BWMS. Each such chemical that is stowed onboard must be labeled and stowed in accordance with the procedures in 46 CFR part 147.

§ 162.060–22 Marking requirements.

(a) Each ballast water management system (BWMS) manufactured for Coast Guard approval must have a nameplate which is securely fastened to the BWMS and plainly marked by the manufacturer with the information listed in paragraph (b) of this section.

(b) Each nameplate must include the following information:

(1) Coast Guard approval number assigned to the BWMS in the certificate of approval.

(2) Name of the manufacturer.

(3) Name and model number of the BWMS.

(4) The manufacturer's serial number for the BWMS.

(5) The month and year of manufacture completion.

(6) The maximum allowable working pressure for the BWMS.

(c) The information required by paragraph (b) of this section must appear on a nameplate attached to, or in lettering on, the BWMS. The nameplate or lettering must be capable of withstanding the combined effects of normal wear and tear and exposure to water, salt spray, direct sunlight, heat, cold, and any substance used in the normal operation and maintenance of the BWMS without loss of readability. The nameplate must not be obscured by paint, corrosion, or other materials that would hinder readability.

§ 162.060–24 Test Plan requirements.

(a) The Coast Guard requires Test Plans for land-based, shipboard, and component testing conducted to meet the requirements of §§ 162.060–26, 162.060–28 and 162.060–30 of this subpart, respectively. Test Plans must include an examination of all the manufacturer's stated requirements and procedures for installation, calibration, maintenance, and operations that will be used by the ballast water management system (BWMS) during each test, as appropriate for the specific test.

(b) Test Plans must also include potential environmental, health, and safety issues; unusual operating

requirements; and any issues related to the disposal of treated ballast water, by-products, or waste streams.

(c) For land-based testing, a Test Plan prepared under the ETV Protocol may be submitted (ETV Protocol incorporated by reference, *see* § 162.060–5). Otherwise, each Test Plan must be in the following format:

(1) Title page, including all project participants.

(2) Table of contents.

(3) Project description and treatment performance objectives.

(4) Project organization and personnel responsibilities.

(5) Description of the independent laboratory and all test facilities and subcontractors.

(6) BWMS description.

(7) Experimental design (including installation/start-up plan for tested equipment).

(8) Challenge conditions and preparation (including the test facility's standard operating procedures for achieving such conditions).

(9) Sampling, data acquisition, and analysis plan, including all necessary procedures.

(10) Data management, analysis, and reporting.

(11) Quality Assurance Project Plan, in accordance with the requirements of § 162.060–36 of this subpart.

(12) Environmental, health, and safety plans.

(13) Applicable references.

§ 162.060–26 Land-based testing requirements.

(a) Each ballast water management system (BWMS) must undergo land-based tests and evaluations that meet the requirements of the ETV Protocol (incorporated by reference, *see* § 162.060–5). The land-based testing will determine if the biological efficacy of the BWMS under consideration for approval is sufficient to meet the applicable ballast water discharge standard (BWDS) and validate those aspects of the operating and maintenance parameters presented by the manufacturer that are appropriate for assessment under the relatively short-term, but well-controlled, circumstances of a land-based test.

(b) The test set up must operate as described in the ETV Protocol Test Plan requirements during at least five consecutive, valid, and successful replicate test cycles. No adjustments to the BWMS are permitted unless specifically detailed in the Operation, Maintenance and Safety Manual. The BWMS must be operated by independent laboratory or independent laboratory subcontractor personnel.

(c) Each valid test cycle must include—

(1) Uptake of source water by pumping at a minimum of 200 m^3/hr;

(2) Treatment of a minimum of 200 m^3 of challenge water with the BWMS;

(3) Pumping of a minimum of 200 m^3 of control water through the test facility in a manner that is in all ways identical to paragraph (c)(2) of this section, except that the BWMS is not used to treat the water;

(4) Retention of the treated and control water in separate tanks for a minimum of 24 hours; and

(5) Discharge of the treated and control water by pumping.

(d) The BWMS must be tested in water conditions for which it will be approved. For each set of test cycles, a salinity range must be chosen. With respect to the salinity of water bodies where the BWMS is intended to be used, the challenge water used in the test set-up must have dissolved and particulate content as described in the ETV Protocol.

(e) The approval certificate issued in accordance with § 162.060–10(g) will list the salinity ranges for which the BWMS is approved.

(f) The BWMS must be tested at its rated capacity or as specified in paragraph (f)(1) of this section for each test cycle and must function to the manufacturer's specifications during the test.

(1) Treatment equipment may be downsized for land-based testing, but only when the following criteria are met:

(i) Treatment equipment with a treatment rated capacity (TRC) equal to or less than 200 m^3/h must not be downscaled.

(ii) Treatment equipment with a TRC greater than 200 m^3/h but less than 1,000 m^3/h may be downscaled to a maximum of 1:5 scale, but must not be less than 200 m^3/h.

(iii) Treatment equipment with a TRC equal to or greater than 1,000 m^3/h may be downscaled to a maximum of 1:100 scale, but must not be less than 200 m^3/h.

(iv) The manufacturer of the BWMS must demonstrate by using mathematical modeling, computational fluid dynamics modeling, and/or by calculations, that any downscaling will not affect the ultimate functioning and effectiveness onboard a vessel of the type and size for which the BWMS will be approved.

(2) Greater scaling may be applied and lower flow rates used other than those described in paragraph (f)(1) of this section if the manufacturer can provide evidence from full-scale shipboard testing, in accordance with paragraph (f)(1)(iv) of this section, that greater scaling and lower flow rates will not adversely affect the testing's ability to predict full-scale compliance with the BWDS. The procedures of § 162.060–10(b)(1) of this subpart must be followed before scaling of flow rates other than those provided in paragraph (f)(1) of this section may be used.

(g) The test set-up, TRC, and scaling of all tests (including mathematical and computational fluid dynamics modeling) must be clearly identified in the Experimental Design section of the Test Plan.

§ 162.060–28 Shipboard testing requirements.

(a) The ballast water management system (BWMS) manufacturer is responsible for making all arrangements for a vessel on which to conduct shipboard tests, including the provision and installation of a BWMS.

(b) Shipboard tests must be conducted throughout a period of operation of at least 6 months. During the period of testing, all ballast water discharged to waters of the United States must be treated by the BWMS.

(c) BWMS approved under this subpart must undergo shipboard tests and evaluations that meet the requirements of this section. The shipboard testing will verify—

(1) That the BWMS under consideration for approval, when installed and operated in the vessel in a location and configuration consistent with its final intended use on operating vessels (e.g., in the engine room or pump room), consistently results in the routine discharge of ballast water that meets the ballast water discharge standard (BWDS) requirements of 33 CFR part 151, subparts C and D; and

(2) That the operating and maintenance parameters identified by the manufacturer in the Operation, Maintenance, and Safety Manual (OMSM) are consistently achieved.

(d) The BWMS to be tested must be installed and operated in the vessel in a location and configuration consistent with its final intended use on operating vessels. Vessel crew must operate the BWMS during testing.

(e) The vessel used as a platform for shipboard testing under this section must be selected to meet the following criteria:

(1) The volumes and rates of ballast water used and treated are representative of the upper end of the treatment rated capacity for which the BWMS is intended to be used. Vessel tank size and flow rates must be equal

to or exceed those used during land-based tests.

(2) The circumstances of the vessel's operation during the period of shipboard testing provide an acceptable range of geographic and seasonal variability conditions.

(i) The source water used for testing is representative of harbor or coastal waters. Testing must include temperate, semi-tropical, or tropical locations with ambient organism concentrations that will provide a significant challenge to the efficacy of the BWMS.

(ii) Concentrations of organisms greater than or equal to 50 micrometers, and organisms less than 50 micrometers and greater than or equal to 10 micrometers in the source water must exceed 10 times the maximum permitted values in the BWDS.

(3) The ports that the vessel visits provide adequate availability of transportation and scientific support needed to accomplish the necessary sampling and analytical procedures during the shipboard tests.

(f) The vessel's ballast water system must be provided with sampling ports arranged in order to collect representative samples of the vessel's ballast water. In addition to the sampling ports designed and installed in accordance with the specifications in the ETV Protocol (incorporated by reference, *see* § 162.060–5), sampling ports must be located—

(1) As close as practicable to the BWMS prior to treatment to determine concentrations of living organisms upon uptake;

(2) As close as practicable to the BWMS overboard outlet prior to the discharge point to determine concentrations of living organisms prior to discharge; and

(3) Elsewhere as necessary to ascertain the proper functioning of the BWMS.

(g) All test results must be reported in accordance with paragraph (i) of this section. The efficacy of the BWMS must be confirmed during at least five consecutive valid test cycles.

(1) A test cycle entails—

(i) The uptake of ballast water by the vessel;

(ii) The storage of ballast water on the vessel;

(iii) Treatment of the ballast water by the BWMS, except in control tanks, if used, with no fine-tuning or adjustment of the system except as specifically detailed in the OMSM; and

(iv) The discharge of ballast water from the vessel.

(2) All test cycles must include quantification of the water quality parameters on uptake.

(3) All test cycles must include discharge tests and quantification of the concentration of living organisms in the treated ballast water on discharge. Sampling and analysis for living organisms will be in accordance with the ETV Protocol.

(4) A test cycle must meet the following criteria in order to be considered valid:

(i) The uptake of the source water must be conducted in accordance with paragraph (e)(2)(i) of this section.

(ii) Source waters must be analyzed for organisms greater than or equal to 50 micrometers and organisms less than 50 micrometers and greater than or equal to 10 micrometers. To simplify the testing program, these source water samples need only be collected and properly preserved and transported for counting by trained microscopists in land-based laboratories. The reported data by taxa (to the lowest reasonably identifiable taxonomic grouping) will be used to characterize the source water biological test conditions.

(iii) The BWMS must operate successfully as designed, maintaining control of all set points and treatment processes, including any pre-discharge conditioning to remove or neutralize residual treatment chemicals or by-products.

(iv) All design or required water quality parameters must be met for the discharged water.

(v) Whole effluent toxicity testing must be conducted in accordance with the December 2008 Environmental Protection Agency (EPA) Vessel General Permit (VGP) requirements (VGP Section 5.8; available at *http://www.epa.gov/npdes/pubs/vessel_vgp_permit.pdf).*

(5) The source water for all test cycles must be characterized by measurement of water quality parameters as follows:

(i) For all BWMS tests, salinity, temperature, and turbidity must be measured either continuously during or at the beginning, middle, and end of the period of ballast water uptake, as appropriate and practicable for the parameters to be measured.

(ii) Water quality parameters (e.g., dissolved and particulate organic material, pH, etc.) that may affect the efficacy of BWMS that make use of active substances or other processes, or water quality parameters identified by the manufacturer and/or the independent laboratory as being critical, must be measured either continuously during or at the beginning, middle, and end of the period of ballast water uptake, as appropriate and practicable for the parameters to be measured.

(h) Samples of ballast water must be collected from in-line sampling ports in accordance with the sampling specifications in the ETV Protocol.

(i) The following information must be documented during the entire period of BWMS testing operations conducted on the vessel:

(1) All ballast water operations, including volumes and locations of uptake and discharge.

(2) All test cycles, even those in which the BWMS failed to meet the BWDS, must be documented. The possible reasons for an unsuccessful test cycle must be investigated and included in the Test Report.

(3) All weather conditions and resultant effects on vessel orientation and vibration.

(4) Scheduled maintenance performed on the BWMS.

(5) Unscheduled maintenance and repair performed on the BWMS.

(6) Data for all engineering parameters monitored as appropriate to the specific BWMS.

(7) Consumption of all solutions, preparations, or other consumables necessary for the effective operation of the BWMS.

(8) All parameters necessary for tracking the functioning of the control and monitoring equipment.

(9) All instrument calibration methods and frequency of calibration.

(j) All measurements for numbers and viability of organisms, water quality parameters, engineering performance parameters, and environmental conditions must be conducted in accordance with the ETV Protocol. Where alternative methods are necessary, given constraints of the BWMS and/or the vessel, standard methods from recognized bodies such as EPA (in 40 CFR part 136), the International Standards Organization, or others accepted by the scientific community must be used, and must be accepted in advance by the Coast Guard.

(k) Test vessels discharging treated ballast water into the waters of the United States must be enrolled in the U.S. Coast Guard's Shipboard Technology Evaluation Program. Test vessels discharging treated ballast water into waters of other countries must secure all necessary approvals and permits required for discharges of treated ballast water.

§ 162.060–30 Testing requirements for ballast water management system (BWMS) components.

(a) The electrical and electronic components, including each alarm and control and monitoring device of the BWMS, must be subjected to the

following environmental tests when in the standard production configuration:

(1) A resonance search vertically up and down, horizontally from side to side, and horizontally from end to end, at a rate sufficiently low as to permit resonance detection made over the following ranges of oscillation frequency and amplitude:

(i) At 2 to 13.3 Hz with a vibration amplitude of +/−1 mm.

(ii) At 13.2 to 80 Hz with an acceleration amplitude of +/− 0.7 g.

(2) The components must be vibrated in the planes specified in paragraph (a)(1) of this section at each major resonant frequency for a period of 4 hours.

(3) In the absence of any resonant frequency, the components must be vibrated in each of the planes specified in paragraph (a)(1) of this section at 30 Hz with an acceleration of +/− 0.7 g for a period of 4 hours.

(4) Components that may be installed in exposed areas on the open deck or in enclosed spaces not environmentally controlled must be subjected to a low temperature test of −25° C and a high temperature test of 55° C for a period of 2 hours at each temperature. At the end of each test, the components are to be switched on and must function normally under the test conditions.

(5) Components that may be installed in enclosed spaces that are environmentally controlled, including an engine room, must be subjected to a low temperature test at 0° C and a high temperature test at 55° C, for a period of 2 hours at each temperature. At the end of each test, the components are to be switched on and must function normally under the test conditions.

(6) Components must be switched off for a period of 2 hours at a temperature of 55° C in an atmosphere with a relative humidity of 90 percent. At the end of this period, the components must be switched on and must operate satisfactorily for 1 hour under the test conditions.

(7) Components that may be installed in exposed areas on the open deck must be subjected to tests for protection against heavy seas in accordance with IP 56 of publication IEC 60529 (incorporated by reference, *see* § 162.060–5) or its equivalent.

(8) Components must operate satisfactorily with a voltage variation of +/− 10 percent together with a simultaneous frequency variation of +/− 5 percent, and a transient voltage of +/− 20 percent together with a simultaneous transient frequency of +/− 10 percent and transient recovery time of 3 seconds.

(9) The components of a BWMS must be designed to operate when the vessel is upright and inclined at any angle of list up to and including 15° either way under static conditions and 22.5° under dynamic, rolling conditions either way and simultaneously inclined dynamically (pitching) 7.5° by bow or stern. Deviation from these angles may be permitted only upon approval of a written waiver submitted to the Coast Guard in accordance with § 162.060–10(b)(1) of this subpart, taking into consideration the type, size, and service conditions and locations of the vessels and operational functioning of the equipment for where the system will be used. Any deviation permitted must be documented in the type-approval certificate.

(10) The same component(s) must be used for each test required by this section and testing must be conducted in the order in which the tests are described, unless otherwise authorized by the Coast Guard.

(b) There must be no cracking, softening, deterioration, displacement, breakage, leakage, or damage of components or materials that affect the operation or safety of the BWMS after each test. The components must remain operable after all tests.

§ 162.060–32 Testing and evaluation requirements for active substances, preparations, and relevant chemicals.

(a) A ballast water management system (BWMS) may not use an active substance or preparation that is a pesticide unless the sale and distribution of such pesticide is authorized under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use in ballast water treatment prior to submission to the Coast Guard for approval of the BWMS. This requirement does not apply to the use of active substances or preparations generated solely by the use of a device (as defined under FIFRA) onboard the same vessel as the ballast water to be treated.

(b) The manufacturer of a BWMS that uses an active substance or preparation that is not a pesticide, or that uses a pesticide that is generated solely by the use of a device (as defined under FIFRA) onboard the same vessel as the ballast water to be treated, must prepare an assessment demonstrating the effectiveness of the BWMS for its intended use, appropriate dosages over all applicable temperatures, hazards of the BWMS, and means for protection of the environment, and public health. This assessment must accompany the application package submitted to the Coast Guard.

§ 162.060–34 Test Report requirements.

The Test Report prepared and submitted by an independent laboratory must be formatted as set out below. The Test Report must include, in addition to the information required by 46 CFR 159.005–11, information as follows:

(a) Summary statement with the following information:

(1) Name of the independent laboratory (IL) and all test facilities, subcontractors, and test organizations involved in testing the ballast water management system (BWMS).

(2) Name of manufacturer.

(3) BWMS model name.

(4) The IL's assessment that the BWMS—

(i) Has demonstrated, under the procedures and conditions specified in this subpart for both land-based and shipboard testing, that it meets the ballast water discharge standard requirements of 33 CFR part 151, subparts C and D;

(ii) Is designed and constructed according to the requirements of § 162.060–20 of this subpart;

(iii) Is in compliance with all applicable U.S. Environmental Protection Agency (EPA) requirements;

(iv) Operates at the rated capacity, performance, and reliability as specified by the manufacturer;

(v) Contains control and monitoring equipment that operates correctly;

(vi) Was installed in accordance with the technical installation specification of the manufacturer for all tests; and

(vii) Was used to treat volumes and flow rates of ballast water during the shipboard tests consistent with the normal ballast operations of the vessel.

(b) Executive summary.

(c) Introduction and background.

(d) Description of the BWMS.

(e) For each test conducted, summary descriptions of—

(1) Test conditions;

(2) Experimental design;

(3) Methods and procedures; and

(4) Results and discussion.

(f) Appendices, including—

(1) Complete Test Plans for land-based, shipboard, and component tests, for which an EPA Environmental Technology Verification (ETV) Verification Report produced in accordance with the ETV Protocol can substitute for the land-based test plan;

(2) Manufacturer supplied Operation, Maintenance, and Safety Manual that meets the requirements of § 162.060–38 of this subpart;

(3) Data generated during testing and evaluations;

(4) Quality Assurance and Quality Control records;

(5) Maintenance logs;

(6) Relevant records and tests results maintained or created during testing;

(7) Information on hazardous materials, active substances, relevant chemicals, and pesticides as detailed in paragraph (g) of this section; and

(8) Permits, registrations, restrictions, and regulatory limitations on use.

(g) The Test Report for a BWMS that may incorporate, use, produce, generate as a by-product and/or discharge hazardous materials, active substances, relevant chemicals and/or pesticides during its operation must include the following information in the appendix of the Test Report:

(1) A list of each active substance or preparation used in the BWMS. For each active substance or preparation that is a pesticide and is not generated solely by the use of a device onboard the same vessel as the ballast water to be treated, the appendix must also include documentation that the sale or distribution of the pesticide is authorized under the Federal Insecticide, Fungicide, and Rodenticide Act for use for ballast water treatment. For all other active substances or preparations, the appendix must include documentation of the assessment specified in § 162.060–32(b) of this subpart.

(2) A list of all hazardous materials, including the applicable hazard classes, proper shipping names, reportable quantities as designated by 40 CFR 117.1, and chemical names of all components.

§ 162.060–36 Quality Assurance Project Plan (QAPP) requirements.

The approval testing and evaluation process must contain a rigorous Quality Assurance and Quality Control program consisting of a QAPP developed in accordance with ISO/IEC 17025:2005(E), as amended ISO/IEC 17025:2005/Cor.1:2006(E) (incorporated by reference, *see* § 162.060–5). The independent laboratory performing approval tests and evaluations is responsible for ensuring the appropriate Quality Assurance and Quality Control procedures are implemented.

§ 162.060–38 Operation, Maintenance, and Safety Manual (OMSM).

(a) Each OMSM must include the following sections:

(1) Table of contents.

(2) Manufacturer's information.

(3) Principles of ballast water management system (BWMS) operation, including—

(i) A complete description of the BWMS, methods and type(s) of technologies used in each treatment stage of the BWMS;

(ii) The theory of the BWMS' operation;

(iii) Any process or technology limitations of the BWMS;

(iv) Performance ranges and expectations of the system; and

(v) A description of the locations and conditions for which the BWMS is intended.

(4) Major system components and shipboard application, including—

(i) A general description of the materials used for construction and installation of the BWMS;

(ii) A list of each major component that may be fitted differently in different vessels with a general description of the different arrangements schemes;

(iii) Any vessel type(s), services, or locations where the BWMS is not intended to be used;

(iv) Maximum and minimum flow and volume capacities of the BWMS;

(v) The dimensions and weight of the complete BWMS and required connection and flange sizes for all major components;

(vi) A description of all actual or potential effects of the BWMS on the vessel's ballast water, ballast water tanks, and ballast water piping and pumping systems;

(vii) A list of all active substances, relevant chemicals, and pesticides generated or stored onboard the vessel to be used by the BWMS; and

(viii) Information on whether the BWMS is designed to be used in hazardous locations.

(5) System and major system component drawings as applicable, including—

(i) Process flow diagram(s) of the BWMS showing the main treatment processes, chemicals, and monitoring and control devices for the BWMS;

(ii) Footprint(s), drawings, and system schematics showing all major components and arrangements;

(iii) Drawings, containing a bill of materials, for the pumping and piping arrangements, and all related equipment provided with the BWMS;

(iv) All treatment application points, waste or recycling streams, and all sampling points integral to the BWMS;

(v) All locations and the sizes of all piping and utility connections for power, water, compressed air or other utilities as required by the BWMS;

(vi) Electrical wiring diagrams that include the location and electrical rating of power supply panels and BWMS control and monitoring equipment;

(vii) Unit(s), construction materials, standards, and labels on all drawings of equipment, piping, instruments, and appurtenances; and

(viii) An index of all drawings and diagrams.

(6) A description of the BWMS's control and monitoring equipment and how it will be integrated with the existing shipboard ballast system, including—

(i) Power demand;

(ii) Main and local control panels;

(iii) Power distribution system;

(iv) Power quality equipment;

(v) Instrumentation and control system architecture;

(vi) Process control description;

(vii) Operational set points, control loops, control algorithms, and alarm settings for routine maintenance, and emergency operations; and

(viii) All devices required for measuring appropriate parameters, such as pressure, temperature, flow rate, water quality, power, and chemical residuals.

(7) A description of all relevant standard operating procedures including, but not limited to—

(i) BWMS start-up and shutdown procedures and times;

(ii) Emergency shutdown and system by-pass procedures;

(iii) Requirements to achieve treatment objectives (e. g., time following initial treatment, critical dosages, residual concentrations, etc);

(iv) Operating, safety, and emergency procedures;

(v) BWMS limitations, precautions, and set points;

(vi) Detailed instructions on operation, calibration and zeroing of each monitoring device used with the BWMS; and

(vii) Personnel requirements for the BWMS, including number and types of personnel needed, labor burden, and operator training or specialty certification requirements.

(8) A description of the preventive and corrective maintenance requirements of the BWMS, including—

(i) Inspection and adjustment procedures;

(ii) Troubleshooting procedures;

(iii) An illustrated list of parts and spare parts;

(iv) A list of recommended spare parts to have during installation and operation of the BWMS;

(v) Use of tools and test equipment in accordance with the maintenance procedures; and

(vi) Point(s) of contact for technical assistance.

(9) A description of the health and safety risks to the personnel associated with the installation, operation, and maintenance of the BWMS including, but not limited to—

(i) The storage, handling, and disposal of any hazardous wastes;

(ii) Any health and safety certification/training requirements for personnel operating the BWMS; and

(iii) All material safety data sheets for hazardous or relevant chemicals used, stored, or generated by or for the system.

(b) If any information in the OMSM changes as a result of approval testing and evaluations, a new OMSM must be submitted.

§ 162.060–40 Requirements for Independent Laboratories (ILs).

(a) For designation by the Coast Guard as an independent laboratory for the evaluation, inspection, and testing of BWMS, an independent laboratory must demonstrate compliance with 46 CFR 159.010–3, 46 CFR 159.010–5, and 46 CFR 159.010–11 through 159.010–19.

(b) Each request for designation as an independent laboratory authorized under paragraph (a) of this section must be delivered to the Commandant (CG–521), Office of Design and Engineering Standards, U.S. Coast Guard, 2nd St. SW., Stop 7126, Washington, DC 20593–7126, in a written or electronic format.

(c) A list of independent laboratories designated by the Coast Guard under paragraph (b) of this section may be found at *http://cgmix.uscg.mil/,* or may be obtained by contacting the Commandant (CG–521), Office of Design and Engineering Standards, U.S. Coast Guard, 2100 2nd St. SW., Stop 7126, Washington, DC 20593–7126.

§ 162.060–42 Responsibilities for Independent Laboratories (ILs).

(a) Upon receipt of a request from a manufacturer for approval testing of a ballast water management system (BWMS), the independent laboratory will conduct a readiness evaluation and determine the acceptability of the BWMS for testing.

(1) The readiness evaluation will examine the design and construction of the BWMS to determine whether there are any fundamental problems that might constrain the ability of the BWMS to manage ballast water as proposed by the manufacturer or to operate it safely onboard vessels. This evaluation must determine that the BWMS—

(i) Is designed and constructed according to the requirements of § 162.060–20 of this subpart;

(ii) Meets all existing safety and environmental regulatory requirements for all locations and conditions where the system will be operated during the testing and evaluation period; and

(iii) Meets the definition of a complete BWMS, as defined in this subpart, to include both ballast water treatment equipment and control and monitoring equipment. Only complete systems in the configurations in which they are intended for sale and use will be accepted for type-approval testing.

(2) The independent laboratory has the right to reject a proposed BWMS for type-approval testing if it does not satisfy the requirements in paragraph (b) of this section, is not deemed ready for approval testing or if, for technical or logistical reasons, that independent laboratory does not have the capability to accommodate the BWMS for testing or evaluation.

(3) Upon determination that the BWMS is ready for testing, the independent laboratory will notify the Commandant (CG–52), Commercial Regulations and Standards Directorate, 2100 2nd St. SW., Stop 7126, Washington, DC 20593–7126, and provide the estimated date for commencement of type-approval testing.

(b) The independent laboratory must prepare a written Test Plan for each approval test to be completed, in accordance with § 162.060–24 of this subpart.

(c) Prior to land-based testing, the independent laboratory must ensure that the BWMS supplied by the manufacturer is set up in accordance with the BWMS' Operation, Maintenance, and Safety Manual (OMSM).

(d) Prior to shipboard testing, the independent laboratory must ensure that the BWMS supplied by the manufacturer is installed in a vessel in accordance with the OMSM and the vessel's administration's requirements and can be tested in accordance with § 162.060–28 of this subpart.

(e) Prior to commencing land-based or shipboard testing required under this subpart, the independent laboratory must require the BWMS manufacturer to sign a written statement to attest that the system was properly assembled and installed at the test facility or onboard the test vessel.

(f) The independent laboratory or its subcontractor(s) must conduct all approval testing and evaluations in accordance with testing requirements of this subpart and within the range or rated capacity of the BWMS.

(g) Upon completion of all approval tests and evaluations, the independent laboratory must follow the requirements of § 162.060–34 of this subpart and forward a complete Test Report to the Commanding Officer, U.S. Coast Guard Marine Safety Center, 2100 2nd St. SW., Stop 7102, Washington, DC 20593–7102, or by email to *msc@uscg.mil.*

Dated: March 9, 2012.

Robert J. Papp Jr.,

Admiral, U.S. Coast Guard, Commandant.

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