

required to mitigate these risks in Table 1.

TABLE 1—MEPROBAMATE TEST SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Clinical action based on incorrect test results (false positive results, false negative results) may lead to inappropriate clinical decision making.	Special controls (1) (21 CFR 862.3590(b)(1)), (2) (21 CFR 862.3590(b)(2)), and (3) (21 CFR 862.3590(b)(3)).
Incorrect understanding of the device and test system and results may lead to inappropriate clinical decision making.	Special controls (2) (21 CFR 862.3590(b)(2)) and (3) (21 CFR 862.3590(b)(3)).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, meprobamate test systems are for prescription use only.

### III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system

regulations, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

#### List of Subjects in 21 CFR Part 862

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

#### PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

- 1. The authority citation for part 862 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Add § 862.3590 to subpart D to read as follows:

##### § 862.3590 Meprobamate test system.

(a) *Identification.* A meprobamate test system is a device intended to measure meprobamate in human specimens. Measurements obtained by this device are used to detect the presence of meprobamate to diagnose the use or overdose of meprobamate or structurally-related drug compounds (e.g., prodrugs).

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include:

(i) Robust data demonstrating the accuracy of the device when used in the intended specimen matrix. The accuracy data must include a comparison between the meprobamate test system results and meprobamate results that are measured on an FDA-accepted measurement method that is specific and accurate (e.g., gas or liquid chromatography combined with tandem mass spectrometry).

(ii) Robust analytical data demonstrating the performance characteristics of the device, including,

but not limited to, specificity, cross-reactivity to relevant endogenous and exogenous substances, and the reproducibility of analyte detection around the cutoff(s).

(2) The intended use of the device must not include an indication for use in monitoring therapeutic drug concentrations or informing dosing adjustment decisions.

(3) Your 21 CFR 809.10 labeling must include the following:

(i) If indicated for use as a screening test to identify preliminary results for further confirmation, the intended use must state “This assay provides only a preliminary analytical result. A more specific alternative chemical confirmatory method (e.g., gas or liquid chromatography and mass spectrometry) must be used to obtain a confirmed analytical result. Clinical consideration and professional judgment must be exercised with any drug of abuse test, particularly when the preliminary test result is positive.”

(ii) A limiting statement that reads as follows: “This test should not be used to monitor therapeutic drug concentrations or to inform dosing adjustment decisions.”

Dated: October 29, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–23911 Filed 10–31–18; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### 23 CFR Part 625

[Docket No. FHWA–2017–0001]

RIN 2125–AF72

#### Design Standards for Highways

**AGENCY:** Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** This final rule updates the regulations governing design standards

and standard specifications that apply to new construction, reconstruction, resurfacing (except for maintenance resurfacing), restoration, and rehabilitation projects on the National Highway System (NHS). In issuing this final rule, FHWA incorporates by reference the latest versions of design standards and standard specifications previously adopted and incorporated by reference, and removes the corresponding outdated or superseded versions of these standards and specifications. Use of the updated standards is required for all NHS projects authorized to proceed with design activities on or after the effective date of the final rule.

**DATES:** This final rule is effective December 3, 2018. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of December 3, 2018. The incorporation by reference of certain other publications listed in the rule was approved by the Director of the Federal Register as of November 12, 2015.

**FOR FURTHER INFORMATION CONTACT:**

Elizabeth Hilton, Office of Program Administration (HIPA-20), (512) 536-5970, or via email at [Elizabeth.Hilton@dot.gov](mailto:Elizabeth.Hilton@dot.gov), or Jomar Maldonado, Office of the Chief Counsel (HCC-30), (202) 366-1373, or via email at [Jomar.Maldonado@dot.gov](mailto:Jomar.Maldonado@dot.gov). Office hours are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

**Electronic Access and Filing**

This document, the notice of proposed rulemaking (NPRM), and all comments received may be viewed online under the docket number noted above through the Federal eRulemaking portal at: <http://www.regulations.gov>. Electronic submission and retrieval help and guidelines are available on the website. Please follow the online instructions. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at: <http://www.archives.gov/federal-register> and the Government Publishing Office's website at: <http://www.gpo.gov/fdsys>.

**Background**

This rulemaking updates existing regulations governing new construction, reconstruction, resurfacing (except for maintenance resurfacing), restoration, and rehabilitation projects on the NHS (including the Interstate System), by incorporating by reference the current versions of design standards and standard specifications previously

adopted and incorporated by reference under 23 CFR 625.4, and removing the outdated or superseded versions of these standards and specifications. Several of these design standards and standard specifications were established by the American Association of State Highway and Transportation Officials (AASHTO) and the American Welding Society (AWS) and were previously adopted by FHWA through rulemaking. The new standards or specifications replace previous versions of these documents and represent the most recent refinements that professional organizations have formally accepted. The FHWA formally adopts them for NHS projects.

The revisions include referencing the 2016 edition of the *AASHTO A Policy on Design Standards—Interstate System*; the 2017 edition of *Transportation Materials, parts 1–3*; the 2017 edition of the *AASHTO Load and Resistance Factor Design (LRFD) Bridge Construction Specifications*; the 2015 edition of the *AASHTO/AWS D1.5M/D1.5:2015 Bridge Welding Code* (as reprinted in 2016), with 2018 Interim Revisions; and the 2017 edition of the *AASHTO LRFD Bridge Design Specifications*. The revisions will also adopt two alternative specifications: the 2013 edition of AASHTO's *Standard Specifications for Structural Supports of Highway Signs, Luminaires, and Traffic Signals* (including Errata September 2013), with 2015 Interim Revisions, as well as the 2015 edition of AASHTO's *LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals*, with 2017 and 2018 Interim Revisions.

The AASHTO is an organization that represents 52 State highway and transportation agencies (including the District of Columbia and Puerto Rico). Its members consist of the duly constituted heads and other chief officials of those agencies. The Secretary of Transportation is an ex-officio member, and DOT staff participates in various AASHTO activities as nonvoting representatives. Among other functions, AASHTO develops and issues standards, specifications, policies, guides, and related materials for use by the States for highway projects. Many of the standards, policies, and standard specifications that were approved by FHWA and incorporated into 23 CFR part 625 were developed and issued by AASHTO.

While these adopted standards and specifications apply to all projects on the NHS (including the Interstate System), FHWA encourages the use of flexibility and a context-sensitive approach to consider a full range of

project and user needs and the impacts to the community and natural and human environment. The FHWA also encourages State departments of transportation (State DOT) and local agencies to consider using design exceptions to achieve a design that balances project and user needs, performance, cost, environmental implications, and community values. These adopted design standards provide a range of acceptable values for highway features, and this flexibility should allow for a design that best suits the desires of the community while satisfying the purpose for the project and needs of its users.

At a minimum, State DOTs and local agencies should select design values based on an evaluation of the context of the facility, needs of all the various project users, safety, mobility (i.e., traffic performance), human and natural environmental impacts, and project costs. For most situations, there is sufficient flexibility within the range of acceptable values to achieve a balanced design. However, when this is not possible, a design exception may be appropriate. State and local agencies may consider designs that deviate from the design standards when warranted based on the conditions, context, and consequences of the proposed projects. Additional information on FHWA's adopted design standards and design exceptions is available at: <http://www.fhwa.dot.gov/design/standards> and in FHWA's publication titled *Mitigation Strategies for Design Exceptions*, available at: [http://safety.fhwa.dot.gov/geometric/pubs/mitigationstrategies/fhwa\\_sa\\_07011.pdf](http://safety.fhwa.dot.gov/geometric/pubs/mitigationstrategies/fhwa_sa_07011.pdf).

**Discussion Under 1 CFR Part 51**

The documents that FHWA is incorporating by reference are reasonably available to interested parties, primarily State DOTs and local agencies carrying out Federal-aid highway projects. These documents represent the most recent refinements that professional organizations have formally accepted and are currently in use by the transportation industry. The documents are also available for review at DOT's National Transportation Library or may be obtained from AASHTO or AWS. The specific standards are discussed in greater detail elsewhere in this preamble.

**Section-by-Section Discussion of Changes to 23 CFR Part 625**

The FHWA is removing the introductory text of § 625.4. It is duplicative of information contained in paragraph (d) and does not meet Office of the Federal Register formatting

requirements for incorporation by reference.

The FHWA is revising § 625.4(a)(2) to replace the reference to the January 2005 edition of *A Policy on Design Standards—Interstate System* with the May 2016 edition. This Policy is a comprehensive manual to assist State DOTs and local agencies in administrative, planning, and educational efforts pertaining to design formulation for projects on the Dwight D. Eisenhower National System of Interstate and Defense Highways (Interstate). The AASHTO May 2016 edition incorporates the latest research and current industry practices, and is applicable to new construction and reconstruction projects on the Interstate except in Alaska and Puerto Rico (23 U.S.C. 103(c)(1)(B)(ii)). Resurfacing, restoration, and rehabilitation projects must meet the Interstate standards that were in place at the time of original construction or inclusion into the Interstate System. The updated guide clarifies ambiguities in the prior edition and provides additional flexibility regarding the design traffic volumes to be accommodated. It increases the median width in rural areas to reduce cross-median crashes and adds recommendations about extended access control and multimodal considerations at interchanges. Basic criteria for other geometric design standards remain essentially the same. The Agency considers the changes made in the 2016 version minor in nature.

With respect to the design standards and standards specifications for bridges and structures under § 625.4(b), FHWA is adopting the current versions of the standards and specifications it has previously adopted from AASHTO and AWS. The updated documents contain changes that represent discoveries or improvements in the state-of-the-knowledge and practices of State DOTs and local agencies that have occurred since the previous standards and specifications were incorporated by reference into 23 CFR part 625.

The FHWA is revising § 625.4(b)(2) to incorporate by reference the current version of the revised AASHTO bridge construction specifications entitled *LRFD Bridge Construction Specifications*, 4th Edition. These specifications, which are intended for use in the construction of bridges, employ the LRFD methodology and are designed to be used in conjunction with the below referenced *AASHTO LRFD Bridge Design Specifications*. Changes in the 4th Edition reflect the latest research and developments, and specifications promulgated by AASHTO.

The FHWA is revising § 625.4(b)(3) to incorporate by reference the current version of the revised AASHTO bridge design specifications entitled *AASHTO LRFD Bridge Design Specifications*, 8th Edition. The *AASHTO LRFD Bridge Design Specifications* are intended for use in the design, evaluation, and rehabilitation of bridges, and are mandated by the FHWA for use on all bridges using Federal funding. These Specifications employ the LRFD methodology using factors developing from current statistical knowledge of loads and structural performance. Changes in the 8th Edition reflect the latest research, developments, and specifications promulgated by AASHTO.

The FHWA is making a minor editorial correction to the reference to the *LRFD Movable Highway Bridge Design Specifications* referenced in paragraph § 625.4(b)(4) to change “including” to “with” when citing the Interim Revisions, but is not changing the material that is already incorporated.

The FHWA is revising § 625.4(b)(5) to incorporate by reference the current version of the revised AASHTO bridge welding code entitled *AASHTO/AWS D1.5M/D1.5:2015–AMD1 Bridge Welding Code*; AASHTO, as corrected and reprinted in 2016, and including 2018 Interim Revisions (The 2015 publication was the 7th edition). This document covers AASHTO welding requirements for welded highway bridges made from carbon and low-alloy construction steels. Chapters cover design of welded connections, workmanship, technique, procedure and performance qualification, inspection, and stud welding. Changes in the 7th Edition, including the 2018 Interim Revisions, reflect the latest research, developments, and specifications promulgated by AASHTO and AWS.

The FHWA is revising § 625.4(b)(7) to incorporate by reference two alternative Specifications applicable to the structural design of supports for highway signs, luminaires, and traffic signals. State DOTs must choose one of these alternative Specifications to guide the design, fabrication, and erection of these types of supports. The first alternative is the most current version of the revised AASHTO structural support specification entitled *Standard Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals*, 6th Edition, AASHTO, 2013, with 2015 Interim Revisions. Changes in the 2015 Interim Revisions reflect more recent research, developments, and specifications promulgated by AASHTO than the prior

adopted version. The second alternative Specification is AASHTO’s *LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals*, 1st Edition, AASHTO, 2015, with 2017 and 2018 Interim Revisions. While the LRFD specification is a more comprehensive, improved specification that reflects the latest research and knowledge, the agency has determined that design pursuant to either Specification provides for safe and reliable structural supports for highways signs, luminaires, and traffic signals.

The FHWA is revising § 625.4(c)(2) to incorporate by reference the current version of the revised AASHTO sampling and testing specification entitled 2017 Edition of *Transportation Materials* AASHTO, 2017. It contains specifications, test methods, and provisional standards commonly used in the construction of highway facilities. This edition of the standard specifications will replace those adopted by AASHTO in 1995. Changes in the 2016 standard specifications reflect current materials and testing technologies and practices.

The FHWA is revising § 625.4(c)(3) to update the title and cross-reference of the referenced regulation to “Quality Assurance Procedures for Construction.”

Use of the updated standards will be required for all NHS projects authorized to proceed with design activities on or after the effective date of the final rule, subject to the exceptions in 23 CFR 625.3(f).

#### Summary Discussion of Comments Received in Response to the NPRM

On May 11, 2018, FHWA published an NPRM in the **Federal Register** at 83 FR 21972 soliciting public comments on its proposal to update the existing regulations. The following presents an overview of the comments received to the NPRM. The docket contained 4 total comments. The FHWA appreciates the feedback the commenters provided, carefully reviewed and analyzed all the comments that were submitted, and made revisions to the NPRM to incorporate suggestions where necessary.

An individual commented that the *Standard Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals*, 6th Edition, AASHTO, 2013 with 2015 Interim Revisions had been superseded by the *LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals*, 1st Edition, AASHTO, 2015, with 2017 and 2018 Interim Revisions.

The *LRFD Specification* does not supersede the *Standard Specification*. At this time, many State DOTs are using the *Standard Specification* and are not ready to fully implement the *LRFD Specification*. Because the *LRFD Specification* is a more comprehensive, improved specification that reflects the latest research and knowledge, FHWA plans to work with AASHTO to develop a timeline to phase out use of the *Standard Specification* in the future. However, the agency has determined that design pursuant to either *Specification* provides for safe and reliable structural supports for highways signs, luminaires, and traffic signals.<sup>1</sup> Therefore, in the interim, FHWA is adopting the updated *Standard Specification* and the *LRFD Specification* as alternative Specifications applicable to the structural design of supports for highway signs, luminaires, and traffic signals. States DOTs must choose one of these alternative Specifications to guide the design, fabrication, and erection of these types of supports. Accordingly, FHWA has revised § 625.4(b)(7) to accommodate State DOTs that are ready to begin transitioning to the *LRFD Specification*.

That individual also commented that 2018 Interim Revisions had been released for the *2015 Bridge Welding Code*, 7th Edition.

These Interim Revisions were not available when the NPRM was developed, however, FHWA has decided to incorporate the 2018 Interim Revisions by reference in this final rule because they reflect the latest research, developments, and specifications promulgated by AASHTO and AWS.

An individual commenter suggested that rather than adopt specific editions of standards, FHWA should adopt “the most current version at the time of contract advertisement,” to eliminate the need to continuously revise 23 CFR part 625.

Procedures and requirements for incorporation by reference are covered in 1 CFR part 51, which requires that the language incorporating a publication by reference be precise and complete and must clearly state the title, date, edition, author, publisher and identification number of the

publication. Therefore, no change was made to the final rule.

An individual commented that the updated standards would not allow certain products and therefore provided for a lower margin of safety.

The final rule adopts current versions of industry publications and does not pertain to specific merchandise or products. Use of these current publications will improve safety because the newer versions incorporate updated research within each specific area of concern. Therefore, no change was made to the final rule.

An individual commented that existing practice of allowing for design exceptions undermined existing regulations.

Design exceptions, which have been allowed by the regulations for decades, are essential to developing projects that are congruent with the natural surroundings, community context, and the purpose and need of the project. Therefore, no change was made to the final rule.

#### Rulemaking Analyses and Notices

*Executive Order 12866 (Regulatory Planning and Review)*, *Executive Order 13563 (Improving Regulation and Regulatory Review)*, *Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)*, and *USDOT Regulatory Policies and Procedures*

The FHWA has determined that this action does not constitute a significant regulatory action within the meaning of Executive Order (E.O.) 12866 or within the meaning of DOT regulatory policies and procedures. The amendments update several industry design standards and standard specifications adopted and incorporated by reference under 23 CFR part 625 and removes the corresponding outdated or superseded versions of these standards and specifications. In addition, this action complies with the principles of E.O. 13563. After evaluating the costs and benefits of these amendments, FHWA anticipates that the economic impact of this rulemaking is minimal. These incremental changes are not anticipated to adversely affect, in any material way, any sector of the economy. In addition, these changes will not create a serious inconsistency with any other agency's action or materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. These updated standards and specifications represent the most recent refinements that professional organizations have formally accepted. The FHWA anticipates that the economic impact of this rulemaking

will be minimal; therefore, a full regulatory evaluation is not necessary. Finally, this rule is not an E.O. 13771 regulatory action because it is not significant under E.O. 12866.

#### Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354; 5 U.S.C. 601–612), FHWA has evaluated the effects of this final rule on small entities, such as local governments and businesses. Based on the evaluation, FHWA anticipates that this action does not have a significant economic impact on a substantial number of small entities. The amendments update several industry design standards and standard specifications adopted and incorporated by reference under 23 CFR part 625. The FHWA believes the projected impact upon small entities that utilize Federal-aid highway program funding for the development of highway improvement projects on the NHS is negligible. Therefore, I certify that the action will not have a significant economic impact on a substantial number of small entities.

#### Unfunded Mandates Reform Act of 1995

The FHWA has determined that this rule does not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). The actions in this final rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$155 million or more in any 1 year (when adjusted for inflation) in 2014 dollars for either State, local, and Tribal governments in the aggregate, or by the private sector. In addition, the definition of “Federal Mandate” in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or Tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility.

#### Executive Order 13132 (Federalism Assessment)

The FHWA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132. The FHWA has determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment. The FHWA has also determined that this action does not preempt any State law or State regulation or affect the

<sup>1</sup> This determination is supported by National Cooperative Highway Research Program Report 796: *Development and Calibration of AASHTO LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals*, which found that “[t]he [LRFD Specifications] were calibrated using the AASHTO [Standard Specifications] allowable stress design method as a baseline,” which means that both the *Standard Specifications* and the *LRFD Specifications* ensure a consistent level of safety.

States' ability to discharge traditional State governmental functions.

*Executive Order 12372*  
(Intergovernmental Review)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program. This E.O. applies because State and local governments are directly affected by this regulation, which is a condition on Federal highway funding. Local entities should refer to the Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction, for further information.

*Paperwork Reduction Act*

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget for each collection of information they conduct, sponsor, or require through regulations. The FHWA has determined that this final rule does not contain collection of information requirements for the purposes of the PRA.

*National Environmental Policy Act*

The FHWA has analyzed this final rule for the purposes of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321, *et seq.*) and has determined that this action does not have any effect on the quality of the human and natural environment because it only makes technical changes and incorporate by reference the latest versions of design standards and standard specifications previously adopted and incorporated by reference under 23 CFR part 625 and removes the corresponding outdated or superseded versions of these standards and specifications. The final rule qualifies as a categorical exclusion to NEPA under 23 CFR 771.117(c)(20).

*Executive Order 13175 (Tribal Consultation)*

The FHWA has analyzed this final rule under EO13175, and believes that it will not have substantial direct effects on one or more Indian Tribes, does not impose substantial direct compliance costs on Indian Tribal governments, and does not preempt Tribal law. This rule does not impose any direct compliance requirements on Indian Tribal governments nor does it have any economic or other impacts on the viability of Indian Tribes. Therefore, a Tribal summary impact statement is not required.

*Executive Order 13211 (Energy Effects)*

The FHWA has analyzed this final rule under E.O. 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. The FHWA has determined that this action is not a significant energy action under the E.O. and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required.

*Executive Order 12630 (Taking of Private Property)*

The FHWA has analyzed this rule under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights. The FHWA does not anticipate that this action will effect a taking of private property or otherwise have taking implications under E.O. 12630.

*Executive Order 12988 (Civil Justice Reform)*

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

*Executive Order 13045 (Protection of Children)*

The FHWA has analyzed this action under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. The FHWA certifies that this action will not cause an environmental risk to health or safety that may disproportionately affect children.

*Regulation Identifier Number*

A Regulation Identifier Number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

**List of Subjects in 23 CFR Part 625**

Design standards, Grant programs—transportation, Highways and roads, Incorporation by reference.

Issued on: October 24, 2018.

**Brandye L. Hendrickson,**  
*Deputy Administrator, Federal Highway Administration.*

In consideration of the foregoing, FHWA amends 23 CFR part 625 as follows:

**PART 625—DESIGN STANDARDS FOR HIGHWAYS**

■ 1. The authority citation for part 625 continues to read as follows:

**Authority:** 23 U.S.C. 109, 315, and 402; Sec. 1073 of Pub. L. 102–240, 105 Stat. 1914, 2012; 49 CFR 1.48(b) and (n).

■ 2. Amend § 625.4 by:

- a. Removing the introductory text;
- b. Revising paragraphs (a)(2), (b)(2) through (5), (7), (c)(2) and (3), the introductory text of paragraph (d), and paragraphs (d)(1)(ii), (iv), (v), (vii), and (viii);
- c. Adding paragraphs (d)(1)(ix) and (x); and
- d. Revising the introductory text of paragraph (d)(2).

The revisions and additions read as follows:

**§ 625.4 Standards, policies, and standard specifications.**

(a) \* \* \*

(2) A Policy on Design Standards—Interstate System, AASHTO (paragraph (d) of this section).

\* \* \* \* \*

(b) \* \* \*

(2) AASHTO LRFD Bridge Construction Specifications (paragraph (d) of this section).

(3) AASHTO LRFD Bridge Design Specifications (paragraph (d) of this section).

(4) AASHTO LRFD Movable Highway Bridge Design Specifications (paragraph (d) of this section).

(5) AASHTO/AWS D1.5M/D1.5 Bridge Welding Code (paragraph (d) of this section).

\* \* \* \* \*

(7) Standard Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals, (paragraph (d) of this section); or LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals (paragraph (d) of this section).

\* \* \* \* \*

(c) \* \* \*

(2) Transportation Materials, AASHTO (paragraph (d) of this section).

(3) Quality Assurance Procedures for Construction, refer to 23 CFR part 637, subpart B.

(d) *Documents incorporated by reference.* The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at U.S. Department of Transportation's National Transportation Library at 1200 New

Jersey Avenue SE, Washington, DC 20590; (800) 853-1351 and is available from the sources indicated below. It is also 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 [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html).

(1) \* \* \*

(ii) A Policy on Design Standards—Interstate System, May 2016.

\* \* \* \* \*

(iv) AASHTO-LRFD Bridge Construction Specifications, 4th Edition, copyright 2017.

(v) AASHTO LRFD-8, LRFD Bridge Design Specifications, 8th Edition, 2017.

\* \* \* \* \*

(vii) AASHTO/AWS D1.5M/D1.5: 2015-AMD1, Bridge Welding Code, Amendment: Second Printing December 12, 2016; with

(A) AASHTO BWC-7-I1-OL, 2018 Interim Revisions to AASHTO/AWS D1.5M/D1.5: 2015 Bridge Welding Code, 7th Edition, copyright 2017.

(B) [Reserved]

(viii) AASHTO LTS-6, Standard Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals, 6th Edition, copyright 2013, with:

(A) AASHTO LTS-6-I1, 2015 Interim Revisions to Standard Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals, copyright 2014.

(B) [Reserved]

(ix) AASHTO LRFDLTS-1, LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals, 1st Edition, copyright 2015, with:

(A) AASHTO LRFDLTS-1-I1-OL, 2017 Interim Revisions to LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals, copyright 2016, and

(B) AASHTO LRFDLTS-1-I2-OL, 2018 Interim Revisions to LRFD Specifications for Structural Supports for Highway Signs, Luminaires, and Traffic Signals, copyright 2017.

(x) 2017 Edition of Transportation Materials, Parts 1-3, copyright 2017.

(2) American Welding Society (AWS), 8669 NW 36 Street, #130 Miami, FL 33166-6672; [www.aws.org](http://www.aws.org); or (800) 443-9353 or (305) 443-9353.

\* \* \* \* \*

[FR Doc. 2018-23821 Filed 10-31-18; 8:45 am]

BILLING CODE 4910-22-P

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 4

RIN 2900-AO19

### Schedule for Rating Disabilities: The Hematologic and Lymphatic Systems

#### Correction

In rule 2018-23517 beginning on page 54250 in the issue of Monday, October 29, 2018, make the following correction:

#### § 4.117 [Corrected]

■ In § 4.117, On page 54255, in the table, entry 7703 should read as follows:

7703 Leukemia (except for chronic myelogenous leukemia):	
When there is active disease or during a treatment phase .....	100
Otherwise rate residuals under the appropriate diagnostic code(s).	
Chronic lymphocytic leukemia or monoclonal B-cell lymphocytosis (MBL), asymptomatic, Rai Stage 0 .....	0
<b>Note (1):</b> A 100 percent evaluation shall continue beyond the cessation of any surgical therapy, radiation therapy, antineoplastic chemotherapy, or other therapeutic procedures. Six months after discontinuance of such treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter. If there has been no recurrence, rate on residuals.	
<b>Note (2):</b> Evaluate symptomatic chronic lymphocytic leukemia that is at Rai Stage I, II, III, or IV the same as any other leukemia evaluated under this diagnostic code.	
<b>Note (3):</b> Evaluate residuals of leukemia or leukemia therapy under the appropriate diagnostic code(s). Myeloproliferative Disorders: (Diagnostic Codes 7704, 7718, 7719).	

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 170817779-8161-02]

RIN 0648-XG477

### Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Greater Than or Equal to 60 Feet Length Overall Using Pot Gear in the Bering Sea and Aleutian Islands Management Area

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS is prohibiting directed fishing for Pacific cod by catcher vessels greater than or equal to 60 feet (18.3 meters (m)) length overall (LOA) using pot gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2018 Pacific cod total allowable catch allocated to catcher vessels greater than or equal to 60 feet (18.3m) LOA using pot gear in the BSAI.

**DATES:** Effective 1200 hours, Alaska local time (A.l.t.), October 30, 2018, through 1200 hours, A.l.t., December 31, 2018.

**FOR FURTHER INFORMATION CONTACT:** Josh Keaton, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under

authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2018 Pacific cod total allowable catch (TAC) allocated to catcher vessels greater than or equal to 60 feet (18.3m) LOA using pot gear in the BSAI is 15,235 metric tons (mt) as established by the final 2018 and 2019 harvest specifications for groundfish in the BSAI (89 FR 8365, February 27, 2018).

In accordance with § 679.20(d)(1)(iii), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2018 Pacific cod TAC allocated as a directed fishing allowance to catcher vessels greater than or equal to 60 feet (18.3m) LOA using pot gear in the BSAI will soon be reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher vessels greater than or