

attending the meeting will have the opportunity to ask questions during the meeting.

IV. Comments

You may submit, on or before April 19, 2000, written comments to the Dockets Management Branch (address above). You may also send comments to the Dockets Management Branch via e-mail to FDADockets@oc.fda.gov or via the FDA Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>. You should annotate and organize your comments to identify the specific issues to which they refer. Please address your comment to the docket number given at the beginning of this notice. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document, except that you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.

V. Transcripts

You may request a transcript of the meeting in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting after April 14, 2000, at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Internet at <http://www.fda.gov>.

VI. Reference

We have placed the following reference on display in the Dockets Management Branch. You may see it at that office between 9 a.m. and 4 p.m., Monday through Friday.

1. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

REGISTRATION FORM

Public Meeting on Implementation of *Pearson* Court Decision and Expansion of Health Claims to Cover Claims of Effects on Existing Diseases

Instructions: To register, complete this form and mail or fax it to 301-827-3052 by March 28, 2000.

Name _____

Title _____

Company _____

Address _____

Telephone _____

Fax _____

E-mail _____

Please indicate the type or organization that you represent:

Industry _____

Government _____

Consumer Organization _____

Media _____

Healthcare Professional _____

Law Firm _____

Educational Organization _____

Other (specify) _____

Do you wish to make an oral presentation?

Yes _____

No _____

If yes, you also must submit the following:

1. A brief statement of the general nature of the views you wish to present,
2. The names and addresses of all persons who will participate in the presentation, and
3. An indication of the approximate time that you request to make your presentation.

Dated: March 10, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00-6509 Filed 3-13-00; 2:34 pm]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 95 and 177

[USCG-1998-4593]

RIN 2115-AF72

Revision to Federal Blood Alcohol Concentration (BAC) Standard for Recreational Vessel Operators

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to revise the Federal Blood Alcohol Concentration (BAC) standard under which a recreational vessel operator

would be considered operating while "intoxicated." For recreational vessel operators, the proposed rule would lower the current Federal BAC threshold from .10 BAC to .08 BAC. This change is appropriate because boating accident statistics show that alcohol use remains a significant cause of recreational boating deaths and because we support a trend in State recreational boating laws toward the .08 BAC standard. Further, the proposed Federal BAC standard will not supercede or preempt any enacted State BAC standard. Additionally, the proposed rule would replace the term "intoxicated" with the phrase "under the influence of alcohol or a dangerous drug." This change would bring the regulations into conformance with current statutory language. The proposed rule is expected to reduce the number of recreational boating deaths and injuries resulting from accidents caused by operators under the influence of alcohol or a dangerous drug.

DATES: Comments and related material must reach the Docket Management Facility on or before July 14, 2000.

ADDRESSES: To make sure your comments and related material are not entered more than once in the docket, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation, room PL-401, 400 Seventh Street SW., Washington, DC 20590-0001.

(2) By hand-delivery to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) Electronically through the Internet Site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL-401 on the Plaza level of the Nassif Building, at the address listed above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: For questions on this proposed rule, contact

Carlton Perry, Project Manager, Office of Boating Safety, U.S. Coast Guard, by telephone at 202-267-0979 or by e-mail at cperry@comdt.uscg.mil. For questions on viewing or submitting material to the docket, call Dorothy Walker, Chief, Dockets, Department of Transportation, telephone 202-366-9329.

You may obtain a copy of this notice by calling the U.S. Coast Guard Infoline at 1-800-368-5647 or by accessing either the Web Site for the Office of Boating Safety at <http://www.uscgboating.org>, or the Internet Site for the Docket Management Facility at <http://dms.dot.gov>.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (USCG-1998-4593), indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by mail, hand-delivery, fax, or electronically to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or hand-delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and want to know they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not plan to hold a public meeting. You may ask for one by submitting a request to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that a public meeting would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

(a) Regulatory History. On December 14, 1987, we published a final rule in the **Federal Register** (52 FR 47526), in which we set a Federal standard for intoxication applicable to recreational vessel operators using a .10 blood alcohol concentration (BAC). The rule adopted any enacted State BAC standard of intoxication as the Federal

BAC standard, and applied the State BAC standard to recreational vessel operators within that State. If a State did not have an enacted BAC standard for "intoxication," a provision allowed us to adopt a State BAC standard for "under the influence" or "while impaired," instead of "intoxicated." In that final rule, we noted that we would consider revising the Federal BAC standard if the States developed a trend toward adopting the .08 BAC standard for operating a vessel on the water.

(b) Reasons for this rulemaking. We drafted the changes proposed in this rulemaking in response to recommendations from the National Boating Safety Advisory Council (NBSAC), as a way to update the existing regulations, and to ensure that terminology in our regulations conforms with current statutory authorities.

Although the number of boating deaths dropped from 1100 in 1986 to 821 in 1997, the number of incidents where alcohol was positively identified as a factor remained stable at about 110. A review of statistics on recreational boating accidents during 1997 showed that there was evidence, or a reasonable likelihood, that alcohol was consumed by the vessel's occupants in 27 percent of all boating accidents involving a fatality.

The Oil Pollution Act of 1990 revised 46 U.S.C. 2302(c) by substituting the term "under the influence of alcohol, or a dangerous drug in violation of a law of the United States" for the term "intoxicated." The terms "intoxication" and "intoxicated" as used in 33 CFR parts 95 and 177, no longer conform to the current statutory authority and should be revised accordingly.

After studying recreational boating safety regulations in October 1997, NBSAC recommended that the Coast Guard track State BAC levels. They suggested that if we found a trend toward revising State standards to .08 BAC, then we should support that effort by revising the Federal standard, found in 33 CFR 95.020, to .08 BAC as well.

In 1987 only 21 States had enacted statutes using a BAC to define "intoxication" or "under the influence" for recreational vessel operation. Nineteen States used a .10 BAC and two States used a .08 BAC. Today 54 State jurisdictions, as defined in 46 U.S.C. 2101(36), have a BAC standard. Thirty-four use .10 BAC, nineteen use .08 BAC, and one uses .08 only when there has been an injury. Also, nine of the original twenty-one States revised their standard from .10 BAC to .08 BAC. We acknowledge that the trend among States is toward using a .08 BAC

standard and we are proposing to revise the Federal BAC standard accordingly.

In a memorandum dated March 3, 1998, the President directed the Secretary of Transportation to develop an Action Plan to promote adoption of the .08 BAC standard for operating a vehicle on "Federal property, including areas in national parks, and on Department of Defense installations, and ensuring strong enforcement and publicity of this standard." The Secretary's Action Plan includes the proposed revision of the Federal BAC standard for operator's of recreational vessels, providing support for the DOT effort on water as well as on land. The Federal BAC standard for operators of vessels that are inspected, or subject to inspection under Chapter 33 of Title 46, United States Code, will remain at .04 BAC.

Discussion of Proposed Rule

1. The headings for 33 CFR part 95 and § 95.020, as well as the text for §§ 95.001, 95.030, 95.040, and 177.07 would be revised by substituting the phrase "under the influence of alcohol or a dangerous drug" for "intoxication" or "intoxicated." This would bring the text into conformance with current statutory authority.

2. Section 95.010 would be revised by adding definitions required to bring this part in line with the new terminology and standards.

3. Section 95.020 would be revised to adopt the .08 BAC standard as the Federal standard.

4. Section 95.025 would be revised to address adoption of State BAC standards that are considered comparable to the Federal BAC standard of "under the influence" of alcohol.

The current regulations adopt State enacted BAC standards for "intoxication." If a State does not have a BAC standard for "intoxication," the regulations adopt State BAC standards for "under the influence," "impairment," or any comparable BAC standard.

The proposed rule would similarly adopt enacted State BAC standards for "under the influence." (typically .10 BAC or .08 BAC). However, if a State has not enacted a BAC standard for "under the influence," the proposed rule would adopt an enacted State BAC standard for "intoxication," "impairment," or a comparable BAC standard.

In States that have enacted multiple BAC standards for "under the influence," which are applicable to specific segments of the boating community—e.g. .02 BAC for operators under 21 years of age, the proposed rule

would adopt only the State BAC standard that applies to the general boating population.

Under the proposed rule, the revised Federal .08 BAC standard would only apply directly to recreational vessels operated in Iowa and New Mexico, which have not enacted a BAC standard; in South Carolina when its limited statute involving injury is not applicable; and, as defined in 33 CFR 2.05, on the navigable waters of the U.S. beyond State boundaries and on the high seas, for recreational vessels owned in the United States.

Regulatory Evaluation

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

A draft Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT follows:

1. Cost of Proposed Rule

This rulemaking would impose no costs for the boating public. Costs to the government would be non-existent as well because the Coast Guard already trains its Boarding Officer personnel on use of the .08 BAC level to properly prepare them for working in those States with such a BAC level.

2. Benefit of Proposed Rule

This proposed rule is appropriate because boating accident statistics show that alcohol use remains a significant cause of recreational boating deaths and because we support a trend in State boating law toward the .08 BAC standard. The proposed rule is expected to reduce the number of recreational boating deaths and injuries resulting from accidents caused by operators under the influence of alcohol or a dangerous drug.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this proposed rule would have a significant economic effect 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.

This proposed revision of the Federal BAC standard applies to operators of recreational vessels on waters subject to the jurisdiction of the United States. These waters include navigable waters of the United States (as defined in 33 CFR 2.05), waters on lands owned by the United States (under 33 U.S.C. 733 by an authorized Federal Officer or over which the United States retains concurrent or exclusive jurisdiction), and waters within the territories and possessions of the United States and the Trust Territories of the Pacific Islands. This proposed revision of the Federal BAC standard will continue to apply to recreational vessels owned in the United States, while operating on the high seas (as defined in 33 CFR 2.05). Further, since this proposed rule would continue to adopt State enacted BAC standards, recreational vessel operators in States with enacted BAC standards would not be subject to a new BAC standard unless a State revises its own enacted BAC standard. Only those recreational vessel operators in States without enacted BAC standards and on navigable waters of the U.S. beyond State boundaries would be subject to a new BAC standard.

Because the provisions of the Regulatory Flexibility Act do not apply to individuals, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic effect on it, please submit a comment to the Docket Management Facility at the address under **ADDRESSES**. In your comment, explain why you think it qualifies and how and to what degree this rule would affect it.

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 this proposed rule so that they can better evaluate its effect 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 contact Carlton Perry, Project Manager, Office of Boating Safety, by telephone at 202–267–0979, or by e-mail at cperry@comdt.uscg.mil.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this proposed rule under E.O. 13132 and have determined that, because the Federal BAC standard will not supercede or preempt any enacted State BAC standard, this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local or tribal government, or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This proposed rule would not impose an unfunded mandate.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule 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.

Protection of Children

We have analyzed this proposed rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

We considered the environmental impact of this proposed rule and concluded that, under figure 2–1, paragraph (34)(a), of Commandant Instruction M16475.1C, this proposed rule is categorically excluded from further environmental documentation. The proposed rule makes a minor revision to the Federal BAC standard for the level at which an operator of a recreational vessel is deemed to be impaired. A "Categorical Exclusion Determination" is available in the

docket where indicated under
ADDRESSES.

List of Subjects

33 CFR Part 95

Alcohol and alcoholic beverages,
Drugs, Marine safety, Vessels.

33 CFR Part 177

Alcohol and alcoholic beverages,
Drugs, Marine safety, Recreational
vessels, Unsafe conditions.

For the reasons discussed in the
preamble, the Coast Guard amends 33
CFR parts 95 and 177 as follows:

SUBCHAPTER F—[AMENDED]

PART 95—OPERATING A VESSEL WHILE UNDER THE INFLUENCE OF ALCOHOL OR A DANGEROUS DRUG

1. The authority citation for part 95
continues to read as follows:

Authority: 33 U.S.C. 2071; 46 U.S.C. 2302;
49 CFR 1.46.

2. Revise the part heading to read as
shown above.

§ 95.001 [Amended]

3. In § 95.001(a), remove the words
“intoxication.” and “intoxicated” and
add, in their place, the words “under
the influence of alcohol or a dangerous
drug.”

4. Amend § 95.010 by adding the
following undesignated paragraphs in
alphabetical order with the rest of the
section as follows:

§ 95.010 Definition of terms as used in this part.

* * * * *

Blood Alcohol Concentration Level
means a certain percentage of alcohol in
the blood.

* * * * *

State means a State or Territory of the
United States of America including but
not limited to a State of the United
States, American Samoa, the
Commonwealth of the Northern
Marianas Islands, District of Columbia,
Guam, Puerto Rico, and the United
States Virgin Islands.

* * * * *

Under the Influence means impaired
or intoxicated by a drug or alcohol as a
matter of law.

* * * * *

5. Amend § 95.020 by revising the
section heading, the introductory text,
and paragraph (a) to read as follows:

§ 95.020 Standard for under the influence of alcohol or a dangerous drug.

An individual is under the influence
of alcohol or a dangerous drug when:

(a) The individual is operating a
recreational vessel and has a blood

alcohol concentration (BAC) level of .08
percent or more, by weight, in their
blood;

* * * * *

6. Amend § 95.025 by revising the
section heading, and paragraphs (a) and
(b) to read as follows:

§ 95.025 Adoption of State blood alcohol concentration levels.

(a) This section applies to operators of
recreational vessels on waters within
the geographical boundaries of any State
that has established by statute a blood
alcohol concentration level for purposes
of determining whether a person is
operating a vessel under the influence of
alcohol.

(b) If the applicable State statute
establishes a blood alcohol
concentration level at which a person is
considered or presumed to be under the
influence of alcohol, then that level
applies within the geographical
boundaries of that State instead of the
level provided in § 95.020(a) of this part.

* * * * *

§ 95.030 [Amended]

7. Amend § 95.030 by revising the
section heading and the introductory
text to read as follows:

§ 95.030 Evidence of under the influence of alcohol or a dangerous drug.

Acceptable evidence of when a vessel
operator is under the influence of
alcohol or a dangerous drug includes,
but is not limited to:

* * * * *

§ 95.040 [Amended]

8. In § 95.040, paragraph (a), remove
the word “intoxicated” and add, in its
place, the words “under the influence of
alcohol or a dangerous drug.”

PART 177—CORRECTION OF ESPECIALLY HAZARDOUS CONDITIONS

9. The authority citation for part 177
continues to read as follows:

Authority: 46 U.S.C. 4302, 4311; 49 CFR
1.45, and 1.46.

§ 177.07 [Amended]

10. In § 177.07(b), remove the word
“intoxicated” and add, in its place, the
words “under the influence of alcohol
or a dangerous drug.”

* * * * *

Dated: March 8, 2000.

Ernest R. Riutta,

*Rear Admiral, U.S. Coast Guard, Assistant
Commandant for Operations.*

[FR Doc. 00-6224 Filed 3-15-00; 8:45 am]

BILLING CODE 4910-15-U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 140, 141, 142, 143, 144, 145, 146, and 147

[USCG-1998-3868]

RIN 2115-AF39

Outer Continental Shelf Activities

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking;
extension of comment period.

SUMMARY: The Coast Guard is extending
the periods for public comment on its
notice of proposed rulemaking on Outer
Continental Shelf Activities. We
received several requests to extend the
comment period for an additional 90
days because of the length and
complexity of the proposed rulemaking.
We are changing the deadline for receipt
of comments from April 5, 2000, to July
5, 2000. Also, due to requests submitted
both to the Docket Management Facility
and to the Office of Management and
Budget (OMB), we are changing the
deadline for receipt of comments by
OMB on the proposed collection-of-
information requirements from February
7, 2000, to July 5, 2000.

DATES: Comments and related material
must reach the Docket Management
Facility on or before July 5, 2000.
Comments sent to OMB on collection of
information must reach OMB on or
before July 5, 2000.

ADDRESSES: To make sure your
comments and related material are not
entered more than once in the docket,
please submit them by only one of the
following methods:

(1) By mail to the Docket Management
Facility, (USCG-1998-3868), U.S.
Department of Transportation, room PL-
401, 400 Seventh Street SW.,
Washington, DC 20590-0001.

(2) By hand to room PL-401 on the
Plaza level of the Nassif Building, 400
Seventh Street SW., Washington, DC,
between 9 a.m. and 5 p.m., Monday
through Friday, except Federal holidays.
The telephone number is 202-366-
9329.

(3) By fax to the Docket Management
Facility at 202-493-2251.

(4) Electronically through the Web
Site for the Docket Management System
at <http://dms.dot.gov>.

You may also mail comments on
collection of information to the Office of
Information and Regulatory Affairs,
Office of Management and Budget, 725
17th Street NW., Washington, DC 20503,
ATTN: Desk Officer, U.S. Coast Guard.