



DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 10

[Docket No. USCG-2013-0009]

Medical Waivers for Merchant Mariner Credential Applicants
With a History of Seizure Disorders

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed policy change and request for
comments.

SUMMARY: The Coast Guard is seeking public comment regarding criteria for granting medical waivers to merchant mariners with a history of seizure disorders. Coast Guard regulations provide that convulsive disorders (also known as seizure disorders) are conditions that may lead to disqualification for a merchant mariner credential (MMC). Because a significant number of merchant mariner applicants have suffered from seizure disorders, it is important for the Coast Guard to develop and publish clear guidance regarding how such MMC applicants are evaluated. Prior to issuing a policy change on when waivers should be granted for seizure disorders, the Coast Guard will accept comments

from the public on whether the proposed criteria adequately address safety concerns.

DATES: Comments and related material must either be submitted to our online docket via

<http://www.regulations.gov> on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] or reach the Docket Management Facility by that date.

ADDRESSES: You may submit comments identified by docket number USCG-2013-0009 using any one of the following methods:

- (1) Federal eRulemaking Portal:

<http://www.regulations.gov>.

- (2) Fax: 202-493-2251.

- (3) Mail: Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

- (4) Hand delivery: Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation" portion of the SUPPLEMENTARY INFORMATION section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice, call or e-mail Lieutenant Ashley Holm, Mariner Credentialing Program Policy Division (CG-CVC-4), U.S. Coast Guard, telephone 202-372-1128, e-mail MMCPolicy@uscg.mil. If you have questions on viewing material in the docket, call Docket Operations at 202-366-9826.

SUPPLEMENTARY INFORMATION:

Public Participation

You may submit comments and related material regarding this proposed policy change. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided.

Submitting comments: If you submit a comment, please include the docket number for this notice (USCG-2013-0009) and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and use "USCG-2013-0009" as your

search term. Locate this notice in the results and click the corresponding "Comment Now" box to submit your comment. If you submit your comments 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 comments by mail and would like to know that 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.

Viewing the comments: To view comments, as well as documents mentioned in this notice as being available in the docket, go to <http://www.regulations.gov> and use "USCG-2013-0009" as your search term. Use the filters on the left side of the page to highlight "Public Submissions" or other document types. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act: Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act system of records notice regarding our public dockets in the January 17, 2008 issue of the Federal Register (73 FR 3316).

Background and Purpose

Coast Guard regulations in 46 CFR 10.215 contain the medical standards that merchant mariner applicants must meet prior to being issued an MMC. In cases where the MMC applicant does not meet the medical standards in 46 CFR 10.215, the Coast Guard may issue a waiver when extenuating circumstances exist that warrant special consideration (46 CFR 10.215(g)).

On September 15, 2008, the Coast Guard issued Navigation and Vessel Inspection Circular (NVIC) 04-08, "Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials."¹ NVIC 04-08 provides that MMC applicants with a history of seizure disorders should contact the National Maritime Center (NMC) for guidance.

¹ NVIC 04-08 is available for viewing on the Coast Guard's website at: <http://www.uscg.mil/hq/cg5/nvic/2000s.asp#2008>.

Since the issuance of NVIC 04-08, a number of MMC applicants have sought and received waivers for seizure disorders in accordance with 46 CFR 10.215(g). However, because NVIC 04-08 does not identify waiver criteria associated with seizure disorders, it has been difficult for Coast Guard personnel to consistently evaluate MMC applicants with a history of seizures and assess whether an individual applicant's medical condition warrants granting a medical waiver under 46 CFR 10.215(g). Accordingly, the Coast Guard is considering whether to change its policy regarding waivers for seizure disorders, and under what criteria an MMC applicant may be eligible for waiver consideration.

The Coast Guard intends to consider public input as well as the recommendations of the Merchant Mariner Medical Advisory Committee (MMMAC), established under the authority of 46 U.S.C. 7115, prior to establishing a final policy regarding which circumstances warrant granting waivers for seizure disorders. Due to the complexity of the medical and policy issues involved, the Coast Guard intends to thoroughly analyze the issues prior to issuing the final policy.

Because there is no medical literature that specifically addresses the safety implications that seizure

disorders in mariners might have on both mariners and the public, the Coast Guard reviewed the guidelines and recommendations of the Federal Motor Carrier Safety Administration (FMCSA) Medical Review Board (January 28, 2008) and FMCSA's Medical Expert Panel (MEP) (October 15, 2007) with regard to commercial motor vehicle drivers with seizure disorders. Although the FMCSA provides guidelines and medical regulations specific to drivers of commercial motor vehicles, the FMCSA's mission of promoting public safety by evaluating the medical fitness of drivers is similar to the Coast Guard's mission of promoting public and maritime safety by evaluating the medical fitness of merchant mariners. While the FMCSA standards are not binding on the Coast Guard, they provide a sound basis for the Coast Guard to use in formulating policy with respect to evaluating merchant mariner applicants with seizure disorders and assessing whether an MMC applicant's condition warrants granting a medical waiver. We used the FMCSA standards as a starting point in formulating our proposed policy detailed below.

In October 2007, the MEP conducted a review of the medical literature and revised its recommendations for medical certification of commercial motor vehicle drivers with seizure disorders. The MEP presented the following

recommendations and findings to the FMCSA Medical Review Board on January 28, 2008:²

(1) On the basis of the medical literature review, the MEP concluded that the longer an individual remains seizure-free, the less likely the individual is to have a recurrent seizure. Specifically, the MEP found that individuals who have been seizure-free for at least 8 years have less than a 2 percent risk of seizure recurrence per year, while those who have been seizure-free for 10 years have less than a 1 percent chance of seizure recurrence per year.

(2) The MEP asserted that a seizure recurrence risk of less than two percent was sufficiently low so as to permit an individual to be certified to drive a commercial motor vehicle. The MEP recommended that an individual with a history of epilepsy (a type of seizure disorder) may be granted conditional certification to drive, provided that the individual meets certain criteria. Although the MEP recommended an 8-year seizure-free period, the FMCSA Medical Review Board opted to retain stricter guidelines, recommending a minimum 10-year seizure-free period, to

² Seizure Disorders and CMV Driver Safety: Recommendations of the MEP, October 15, 2007; available for viewing at <http://www.fmcsa.dot.gov/rules-regulations/TOPICS/mep/report/Seizure-Disorders-MEP-Recommendations-v2-prot.pdf>.

reduce the risk of seizure recurrence to less than 1 percent.

Proposed Policy

The Coast Guard is considering granting waivers to MMC applicants with seizure disorders under the conditions delineated below. The Coast Guard has been using an interim policy of an eight-year seizure-free period for determining whether or not a waiver is warranted. The Coast Guard recognizes that in some situations, a shorter period may be justified. The Coast Guard requests public comment on whether the criteria listed below are appropriate and sufficient for determining whether an MMC applicant should be eligible for consideration for a medical waiver under 46 CFR § 10.215(g).

Unprovoked Seizures

Unprovoked seizures are those seizures not precipitated by an identifiable trigger. Mariners with a history of unprovoked seizure(s) may be considered for a waiver.

(1) Mariners with a history of epilepsy or seizure disorder may be considered for a waiver if the mariner has been seizure-free for a minimum of eight years (on or off anti-epileptic drugs (AEDs)); and

(a) If AEDs have been stopped, the mariner must

have been seizure-free for a minimum of eight years since cessation of medication; or

(b) If still using AEDs, the mariner must have been on a stable medication regimen³ for a minimum of two years.

(2) Mariners with a single unprovoked seizure may be considered for a waiver if the mariner has been seizure-free for a minimum of four years (on or off AEDs); and

(a) If all AEDs have been stopped, the mariner must have been seizure-free for a minimum of four years since cessation of medication; or

(b) If still using AEDs, the mariner must have been on a stable medication regimen for a minimum of two years.

Provoked Seizures

Provoked seizures are those seizures precipitated by an identifiable trigger. Mariners with a history of provoked seizure(s) may be considered for a waiver.

Mariners in this group can be divided into those with low risk of recurrence and those with a higher risk of

³ As used in this document, a stable medication regimen is considered to be a dosage within the therapeutic range that is consistent given changes in the mariner's weight or other factors such as drug interactions. Significant dosage reductions or tapering of the medication dosage would not be considered stable. Additionally, changes in the type or classification of anti-epileptic medication utilized would not be considered stable.

recurrence (e.g., with a structural brain lesion).

(1) If a mariner is determined to be low-risk for seizure recurrence, does not require AEDs, and the precipitating factor is unlikely to recur, a waiver may be considered when the mariner has been seizure-free and off AEDs for a minimum of one year.

(2) Generally, mariners with one of the following precipitating factors will be considered low-risk for recurrence:

- (a) Lidocaine-induced seizure during a dental appointment;
- (b) Concussive seizure, loss of consciousness ≤ 30 minutes with no penetrating injury;
- (c) Seizure due to syncope not likely to recur;
- (d) Seizure from an acute metabolic derangement not likely to recur;
- (e) Severe dehydration;
- (f) Hyperthermia; or
- (g) Drug reaction or withdrawal.

(2) If a mariner is determined to be at higher risk for seizure recurrence, a waiver may be considered if the mariner has been seizure-free for a minimum of eight years (on or off AEDs); and

- (a) If all AEDs have been stopped, the mariner must

have been seizure-free for a minimum of eight years since cessation of medication; or

(b) If still using AEDs, the mariner must have been on a stable medication regimen for a minimum of two years.

(3) Generally, mariners with a history of provoked seizures caused by a structural brain lesion (e.g., tumor, trauma, or infection) characterized by one of the following precipitating factors will be considered at higher risk for recurrence:

(a) Head injury with loss of consciousness or amnesia ≥ 30 minutes or penetrating head injury;

(b) Intracerebral hemorrhage of any etiology, including stroke and trauma;

(c) Brain infection, such as encephalitis, meningitis, abscess, or cysticercosis;

(d) Stroke;

(e) Intracranial hemorrhage;

(f) Post-operative brain surgery with significant brain hemorrhage; or

(g) Brain tumor.

(4) Under exceptional circumstances in which a mariner has had provoked seizures with structural brain lesions, individuals may be considered for a waiver once

they have been seizure-free for a minimum of four years, provided that objective evidence supports extremely low risk of seizure recurrence.

Additional Specific Questions

The Coast Guard also specifically requests public comment on the following questions:

- (1) Is there evidence that the chronic use of AEDs for the treatment of epilepsy impairs judgment or reaction time?
- (2) Is there evidence that individuals who have been seizure-free and off AEDs for a period of time have a lower likelihood of seizure recurrence than individuals who have been apparently seizure-free and on stable AED dosing?
- (3) What is the risk of seizure recurrence as a function of time since last seizure among individuals on AEDs who are apparently seizure-free?
- (4) What is the likelihood of seizure recurrence as a function of time in individuals who are seizure-free following removal of a benign brain tumor?
- (5) Are there instances in which the Coast Guard should issue credentials to mariners with seizure disorders, provided that the credentials contain operational limitations that would allow such mariners a limited role in industry without causing an undue safety risk?
- (6) Should mariners who are granted a waiver be restricted

from solo-watchkeeping in ports, harbors, and other waters subject to congested vessel traffic or other hazardous circumstances?

(7) Are there individuals with seizure disorders due to a structural brain lesion that are at low-risk for seizure recurrence?

In addition to submitting public comments in response to this notice, the public may also wish to participate in the MMMAC public meetings. MMMAC meetings are advertised separately in the Federal Register and on the NMC's website at <http://www.uscg.mil/nmc>.

Authority

This notice is issued under the authority of 5 U.S.C. 552(a), 46 U.S.C 7101 et seq., 46 CFR 10.215, and Department of Homeland Security Delegation No. 0710.1.

Dated: March 14, 2013

P. F. THOMAS
Captain, U.S. Coast Guard
Director of Inspections and Compliance

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