



DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 10

[Docket No. USCG-2012-0734]

Medical Waivers for Merchant Mariner Credential Applicants with Anti-Tachycardia Devices or Implantable Cardioverter Defibrillators

AGENCY: Coast Guard, DHS.

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

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SUMMARY: The Coast Guard is seeking public comment regarding criteria for granting medical waivers to mariners who have anti-tachycardia devices or implantable cardioverter defibrillators (ICDs). Current Coast Guard guidance found in Navigation and Vessel Inspection Circular 04-08, Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials (NVIC 04-08), states that anti-tachycardia devices or ICDs are generally not waiverable. The Coast Guard is considering changing that policy. Prior to issuing a policy change on whether to grant waivers for anti-tachycardia devices or ICDs and the criteria for such waivers, the Coast Guard will accept

comments from the public on whether the proposed criteria would adequately address safety concerns regarding merchant mariners with ICDs.

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-2011-0734 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 Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Public Participation

You may submit comments and related material regarding whether this proposed policy change should be incorporated into a final policy on issuing medical waivers to mariners with ICDs. 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-2012-0734) 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 insert "USCG-2012-0734" in the "Search" box. Click "Search," find this notice in the list of Results, and then click on the corresponding "Comment Now" box. 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 insert "USCG-2012-0734" in the "Search" box. Click "Search" and 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 mariners must meet prior to being issued a merchant mariner credential (MMC). In cases where the mariner 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. See 46 CFR 10.215(g).

In NVIC 04-08, the Coast Guard states that anti-tachycardia devices and ICDs are generally not waiverable. Since the issuance of NVIC 04-08 on September 15, 2008, a number of mariners have sought and received waivers for

anti-tachycardia devices or ICDs in accordance with 46 CFR 10.215(g). However, because NVIC 04-08 does not identify waiver criteria associated with anti-tachycardia devices or ICDs, it has been difficult for Coast Guard personnel to consistently evaluate merchant mariners with anti-tachycardia devices or ICDs and assess whether an 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 anti-tachycardia devices or ICDs, and under what criteria a mariner 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, established under the authority of 46 U.S.C. §7115, prior to establishing a final policy on whether waivers should be granted for anti-tachycardia devices or ICDs, and if so, under what circumstances. Because of the complexity of the issues involved, the Coast Guard intends to thoroughly analyze the issues prior to issuing the final policy.

The Coast Guard specifically requests public comment on the likelihood of an ICD inappropriately firing and whether that shock could potentially incapacitate a merchant

mariner. Additionally, the Coast Guard seeks public comment on whether the criteria listed below are appropriate and sufficient to evaluate whether a mariner should be eligible for consideration for a medical waiver under 46 CFR 10.215(g).

Below is a series of 12 questions we are considering as the criteria for granting a medical waiver. A review of the mariner's record should lead the Coast Guard to answer "no" for each question in order for the mariner to be eligible for waiver consideration. We request public comment regarding whether the 12 questions below represent an appropriate and sufficient list of the criteria a mariner should be required to meet in order to be eligible for waiver consideration, or whether we should eliminate or modify any of the questions, or add other questions to the list.

- (1) Does the mariner have a diagnosis of a cardiac channelopathy affecting the electrical conduction of the heart (including Brugada syndrome, Long QT syndrome, etc.)?
- (2) Does the mariner have a prior history of ventricular fibrillation or episodes of sustained ventricular tachycardia and, if so, did the arrhythmia episode occur greater than three years

ago?

- (3) Was the ICD or anti-tachycardia device implanted more than three years ago?
- (4) Has the ICD fired or has the mariner required anti-tachycardia pacing within the last three years?
- (5) Does the mariner's condition present any confounding risk factors for inappropriate shock such as uncontrolled atrial fibrillation?
- (6) Is the mariner's ejection fraction greater than 40% with a steady or improving trend?
- (7) Does the mariner have a history of any symptomatic or clinically significant heart failure in the past two years?
- (8) Does the mariner's record contain any evidence of significant reversible ischemia on myocardial perfusion imaging exercise stress testing?
- (9) Has the mariner's exercise capacity been assessed to be greater than or equal to 10 metabolic equivalents (METs)?
- (10) Did the mariner provide a written opinion of the treating cardiologist or electrophysiologist that supports a determination that the mariner is at low risk for future arrhythmia, adverse cardiac

event or sudden incapacitation based upon  
objective testing and standard evaluation tools?

(11) Does the mariner have any other medical  
conditions which may alone, or in combination  
with an ICD or anti-tachycardia device, affect  
the mariner's fitness?

(12) Is the mariner applying for an original  
credential, raise-in-grade, or renewal of an  
existing credential?

Authority

We issue this request for public comments under the  
authority of 5 U.S.C. 552(a).

Dated: August 13, 2012

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

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