

certified by the NIH Director, a notice of certification will be sent by NIH OSP to the applicant and to the Institutional Biosafety Committee Chairs. A list of all currently certified host-vector systems is available from the Office of Science Policy, National Institutes of Health, preferably by submitting a request for this information to:

NIHGuidelines@od.nih.gov; additional contact information is also available here and on the OSP website (www.osp.od.nih.gov). The NIH Director may rescind the certification of a host-vector system (see Section IV-C-1-b-(2)-(g), *Minor Actions*). If certification is rescinded, NIH will instruct investigators to transfer cloned DNA into a different system or use the clones at a higher level of physical containment level, unless NIH determines that the already constructed clones incorporate adequate biological containment. Certification of a host-vector system does not extend to modifications of either the host or vector component of that system. Such modified systems shall be independently certified by the NIH Director. If modifications are minor, it may only be necessary for the investigator to submit data showing that the modifications have either improved or not impaired the major phenotypic traits on which the containment of the system depends. Substantial modifications to a certified host-vector system require submission of complete testing data.

Appendix I-II-B. Data To Be Submitted for Certification

Appendix I-II-B-1. Host-Vector 1 Systems Other Than *Escherichia coli* K-12

The following types of data shall be submitted, modified as appropriate for the particular system under consideration: (i) A description of the organism and vector; the strain's natural habitat and growth requirements; its physiological properties, particularly those related to its reproduction, survival, and the mechanisms by which it exchanges genetic information; the range of organisms with which this organism normally exchanges genetic information and the type of information exchanged; and any relevant information about its pathogenicity or toxicity; (ii) a description of the history of the particular strains and vectors to be used, including data on any mutations which render this organism less able to survive or transmit genetic information; and (iii) a general description of the range of experiments contemplated with emphasis on the need for developing such a Host-Vector 1 system.

Appendix I-II-B-2. Host-Vector 2 Systems

Investigators planning to request Host-Vector 2 systems certification may obtain instructions from NIH OSP concerning data to be submitted (see Appendices I-III-N and O, *Footnotes and References of Appendix I*). In general, the following types of data are required: (i) Description of construction steps with indication of source, properties, and manner of introduction of genetic traits; (ii) quantitative data on the stability of genetic

traits that contribute to the containment of the system; (iii) data on the survival of the host-vector system under non-permissive laboratory conditions designed to represent the relevant natural environment; (iv) data on transmissibility of the vector and/or a cloned DNA fragment under both permissive and non-permissive conditions; (v) data on all other properties of the system which affect containment and utility, including information on yields of phage or plasmid molecules, ease of DNA isolation, and ease of transfection or transformation; and (vi) in some cases, the investigator may be asked to submit data on survival and vector transmissibility from experiments in which the host-vector is fed to laboratory animals or one or more human subjects. Such *in vivo* data may be required to confirm the validity of predicting *in vivo* survival on the basis of *in vitro* experiments. Data shall be submitted to the Office of Science Policy, National Institutes of Health, preferably by email to: NIHGuidelines@od.nih.gov; additional contact information is also available here and on the OSP website (www.osp.od.nih.gov). Investigators are encouraged to publish their data on the construction, properties, and testing of proposed Host-Vector 2 systems prior to consideration of the system by NIH. Specific instructions concerning the submission of data for proposed *Escherichia coli* K-12 Host-Vector 2 system (EK2) involving either plasmids or bacteriophage in *Escherichia coli* K-12, are available from the Office of Science Policy, National Institutes of Health, preferably by submitting a request for this information to: NIHGuidelines@od.nih.gov; additional contact information is also available here and on the OSP website (www.osp.od.nih.gov).

None of the other sub-sections under Appendix I. Biological Containment will be amended.

Appendix L. Gene Therapy Policy Conferences (GTPCS) will be deleted in its entirety.

Appendix M. Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant or Synthetic Nucleic Acid Molecules into One or More Human Research Participants (Points to Consider) will be deleted in its entirety.

Dated: April 10, 2019.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

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BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2019-0139]

Certificate of Alternative Compliance for the Tug RANDY McCRAANEY

AGENCY: Coast Guard, DHS.

ACTION: Notification of issuance of a certificate of alternative compliance.

SUMMARY: The Coast Guard announces that the Fifth District, Chief of Prevention Division has issued a certificate of alternative compliance from the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), for the towing vessel RANDY McCRAANEY, Official Number (O.N.) 1292293, Master Boat Builders Hull Number 459. We are issuing this notice because its publication is required by statute. Due to its construction, purpose and service, the towing vessel RANDY McCRAANEY cannot fully comply with the light, shape, or sound signal provisions of the 72 COLREGS without interfering with the vessel's design and construction. This notification of issuance of a certificate of alternative compliance promotes the Coast Guard's marine safety mission.

DATES: The Certificate of Alternative Compliance was issued on March 15, 2019.

FOR FURTHER INFORMATION CONTACT: For information or questions about this notice call or email LCDR Ronaydee M. Marquez, District Five, Asst. Chief, Inspections and Investigations, U.S. Coast Guard; telephone: 757-398-6682, email: Ronaydee.M.Marquez@uscg.mil.

SUPPLEMENTARY INFORMATION: The United States is signatory to the International Maritime Organization's International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), as amended. The special construction or purpose of some vessels makes them unable to comply with the light, shape, or sound signal provisions of the 72 COLREGS. Under statutory law, however, specified 72 COLREGS provisions are not applicable to a vessel of special construction or purpose if the Coast Guard determines that the vessel cannot comply fully with those requirements without interfering with the special function of the vessel.¹

The owner, builder, operator, or agent of a special construction or purpose vessel may apply to the Coast Guard District Office in which the vessel is being built or operated for a determination that compliance with alternative requirements is justified,² and the Chief of the Prevention Division would then issue the applicant a certificate of alternative compliance (COAC) if he or she determines that the vessel cannot comply fully with 72 COLREGS light, shape, and sound signal

¹ 33 U.S.C. 1605.

² 33 CFR 81.5.

provisions without interference with the vessel's special function.³ If the Coast Guard issues a COAC, it must publish notice of this action in the **Federal Register**.⁴

The Fifth District, Chief of Prevention Division, U.S. Coast Guard, certifies that the RANDY McCRAANEY, O.N. 1292293 is a vessel of special construction or purpose, and that, with respect to the position of the sidelights, it is not possible to comply fully with the requirements of the provisions enumerated in the 72 COLREGS, without interfering with the normal operation, or design of the vessel. The vessel is a dual-mode Articulated Tug (ATB), which intends to operate as an ATB as well as multiple other modes such as towing alongside, harbor ship/barge assist tug and towing on a towline. Placing the sidelights at or near the side of the vessel would interfere with the vessel's purpose and operations, and would place the sidelights at risk of damage during the course of normal operations. The sidelights will be installed on the elevated pilothouse, 6'7" inboard from the sides of the vessel. The Fifth District, Chief of Prevention Division further finds and certifies that the sidelights are in the closest possible compliance with the applicable provisions of the 72 COLREGS.⁵

This notice is issued under authority of 33 U.S.C. 1605(c) and 33 CFR 81.18.

Dated: April 18, 2019.

J.R. Barnes,

CAPT, U.S. Coast Guard, Chief, Prevention Division, Fifth Coast Guard District.

[FR Doc. 2019-08406 Filed 4-25-19; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection [1651-0092]

Agency Information Collection Activities: Application for Withdrawal of Bonded Stores for Fishing Vessels and Certificate of Use

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the

following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and must be submitted (no later than May 28, 2019) to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to dhsdeskofficer@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229-1177, Telephone number (202) 325-0056 or via email CBP_PRA@cbp.dhs.gov. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877-227-5511, (TTY) 1-800-877-8339, or CBP website at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (83 FR 63522) on December 10, 2018, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3)

suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection:

Title: Application for Withdrawal of Bonded Stores for Fishing Vessels and Certificate of Use.

OMB Number: 1651-0092.

Form Number: CBP Form 5125.

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Abstract: CBP Form 5125, *Application for Withdrawal of Bonded Stores for Fishing Vessel and Certificate of Use*, is used to request the permission of the CBP port director for the withdrawal and lading of bonded merchandise (especially alcoholic beverages) for use on board fishing vessels involved in international trade. The applicant must certify on CBP Form 5125 that supplies on board were either consumed, or that all unused quantities remain on board and are adequately secured for use on the next voyage. CBP uses this form to collect information such as the name and identification number of the vessel, ports of departure and destination, and information about the crew members. The information collected on this form is authorized by 19 U.S.C. 1309 and 1317, and is provided for by 19 CFR 10.59(e) and 10.65. CBP Form 5125 is accessible at: <https://www.cbp.gov/newsroom/publications/forms?title=5125>.

Affected Public: Carriers.

Estimated Number of Respondents: 500.

Estimated Number of Total Annual Responses: 500.

Estimated Time per Response: 20 minutes.

Estimated Total Annual Burden Hours: 165.

³ 33 CFR 81.9.

⁴ 33 U.S.C. 1605(c) and 33 CFR 81.18.

⁵ 33 U.S.C. 1605(a); 33 CFR 81.9.