

that the Menlo Report precludes the Common Rule is conjecture that appeared in one of the comments, and it is important to mention that this is not substantiated by evidence from the Menlo Report. This criticism does not reflect what is presently allowed by the Common Rule in terms of waivers (see 45 CFR 46.116, specifically subsections (c) and (d)). The Menlo Report currently is framed in such a way as to be congruous with the predominant REB model in the United States, IRB. The Menlo Report will be revised to include text that clarifies that the Menlo Report does not take any stance on addressing the situation when laws are viewed by the public to be unethical. It was also apparent from the comments that the Menlo Report needs to clarify that researchers are not authorized to waive consent. The Menlo Report will also be updated in the Respect for Law and Public Interest section to address conflicts with principles of compliance, transparency, and accountability and with the privacy interests of individuals.

G. Privacy of Individuals vs. Corporations

Multiple comments highlighted a problem regarding the discussion on the privacy of an organization in relation with enhancing cyber security.

Response: This discussion will be removed from the next version of the Menlo Report. The comments correctly identified a potential inconsistency.

H. Ethical Considerations for Future Contemplation and Study

Finally, there were comments suggesting a general call for further study and engagement with various communities and agencies in order to create workable guidance.

Response: Much additional work will be done as a follow on to the Menlo Report to spur additional discussion of the approach to ethics in ICTR presented in the Menlo Report. Some of this research has already been undertaken and is included in a companion report to the Menlo Report.

I. Standalone Comments

There were several comments that did not fall into the preceding categories but did spur further changes to the Menlo Report. The following will be reflected as updates to the Menlo Report:

1. A clarification will be added explaining that while the Menlo Report adopts Belmont Report principles and the Common Rule regime in framing the principles and applications for evaluating and applying ethics in ICTR, it also highlights areas within the

Common Rule that are more frequently exercised by ICTR or that may cause problems in applying it to ICTR.

2. Language to more clearly discuss how to make inclusion/exclusion decisions in conformance with Justice and Equity considerations will be added.

3. In general, the revised Menlo Report will take a well-rounded perspective to include the end-user perspective, in addition to a researcher-centric perspective.

4. The discussion of the existence and management of pre-existing data will be expanded.

5. The discussion regarding the creation of the Internet and its growth to include the hosting databases with personally identifiable information will be clarified.

6. The description or context of the use of the term "reasonable researcher" will be updated.

7. Explanatory language to address the issue of record retention will be included in the Mitigation of Realized Harms section.

8. The term "evidence-based consideration" will be clarified.

Dated: November 30, 2012.

Tara O'Toole,

Under Secretary for Science and Technology.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Deferral of Duty on Large Yachts Imported for Sale

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

ACTION: 30-Day notice and request for comments; extension of an existing collection of information: 1651-0080.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security 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: Deferral of Duty on Large Yachts Imported for Sale. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the

public and affected agencies. This proposed information collection was previously published in the **Federal Register** (77 FR 60133) on October 2, 2012, 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 1320.10.

DATES: Written comments should be received on or before January 10, 2013.

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 oir_submission@omb.eop.gov or faxed to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street NW., 5th Floor, Washington, DC 20229-1177, at 202-325-0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Deferral of Duty on Large Yachts Imported for Sale.

OMB Number: 1651-0080.

Form Number: None.

Abstract: This collection of information is required to ensure compliance with 19 U.S.C. 1484b which provides that an otherwise dutiable yacht that exceeds 79 feet in length, is used primarily for recreation or pleasure, and had been previously sold by a manufacturer or dealer to a retail customer, may be imported without the payment of duty if the yacht is imported with the intention to offer for sale at a boat show in the United States. The statute provides for the deferral of payment of duty until the yacht is sold but specifies that the duty deferral period may not exceed 6 months. This collection of information is provided for by 19 CFR 4.94 which requires the submission of information to CBP such as the name and address of the owner of the yacht, the dates of cruising in the waters of the United States, information about the yacht, and the ports of arrival and departure.

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).

Affected Public: Businesses and Individuals.

Estimated Number of Respondents: 50.

Estimated Number of Total Annual Responses: 50.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 50.

Dated: December 6, 2012.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Declaration for Free Entry of Returned American Products

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

ACTION: 30-Day notice and request for comments; extension of an existing collection of information: 1651-0011.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security 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: Declaration for Free Entry of Returned American Products (CBP Form 3311). This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (77 FR 58564) on September 21, 2012, 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 1320.10.

DATES: Written comments should be received on or before January 10, 2013.

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 oir_submission@omb.eop.gov or faxed to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street NW., 5th Floor, Washington, DC 20229-1177, at 202-325-0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs).

The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Declaration of Free entry of Returned American Products.

OMB Number: 1651-0011.

Form Number: CBP Form 3311.

Abstract

CBP Form 3311, *Declaration for Free Entry of Returned American Products*, is used by importers and their agents when duty-free entry is claimed for a shipment of returned American products under the Harmonized Tariff Schedules of the United States. This form serves as a declaration that the goods are American made and that (a) they have not been advanced in value or improved in condition while abroad, (b) were not previously entered under a Temporary Importation Under Bond provision, and (c) drawback was never claimed and/or paid. CBP Form 3311 is authorized by 19 CFR 10.1, 10.5, 10.6, 10.66, 10.67, 12.41, 123.4, 142.11, 143.21, 143.23, 143.25 and is accessible at http://forms.cbp.gov/pdf/CBP_Form_3311.pdf.

Action

CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to CBP Form 3311.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 12,000.

Estimated Number of Responses per Respondent: 35.

Estimated Number of Total Annual Responses: 420,000.

Estimated Time per Response: 6 minutes.

Estimated Total Annual Burden Hours: 42,000.

Dated: December 6, 2012.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

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