

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
803.17	220	1	220	3.3	726
803.18(c) and (d)	30,000	1	30,000	1.5	45,000
Total					45,726

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Part 803 requires user facilities to report to the device manufacturer, and to FDA in the case of a death, incidents where a medical device caused or contributed to a death or serious injury. Manufacturers of medical devices are required to report to FDA when they become aware of information indicating that one of their devices may have caused or contributed to death or serious injury or has malfunctioned in such a way that should the malfunction recur it would be likely to cause or contribute to a death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown, then the reports are sent to FDA.

The number of respondents for each CFR section in table 1 of this document is based upon the number of respondents entered into FDA's internal databases. FDA estimates, based on its experience and interaction with the medical device community, that all reporting CFR sections are expected to take 1 hour to complete, with the exception of § 803.19. Section 803.19 is expected to take approximately 3 hours to complete, but is only required for reporting the summarized data quarterly to FDA. By summarizing events, the total time used to report for this section is reduced because the respondents do not submit a full report for each event they report in a quarterly summary report.

The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the medical device reporting (MDR) requirements as part of their internal quality control system. There are an estimated 30,000 medical device distributors. Although they do not submit MDR reports, they must maintain records of complaints, under § 803.18(d).

The agency has estimated that on average, 220 user facilities, importers, and manufacturers would annually be required to establish new procedures, or

revise existing procedures, in order to comply with this provision.

Therefore, FDA estimates the one-time burden to respondents for establishing or revising procedures to be 2,200 hours (220 respondents x 10 hours). For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers, not required to revise their written procedures to comply with this provision, are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered "usual and customary" under 5 CFR 1320.3(b)(2).

The annual burden for recordkeeping to respondents follows. Under § 803.17, FDA estimates 220 respondents will spend approximately 3.3 hours to complete the requirements for this section. The number of respondents was estimated by consolidating the total of all new reporting entities together. The 3.3 hours was estimated by FDA, as this section deals with a respondent creating new MDR procedures and is a one-time function. The "total hours" for this section equals approximately 726 hours.

Under § 803.18, 30,000 respondents represent distributors, importers, and other respondents to this information collection. FDA estimates that it should take them approximately 1½ hours to complete the recordkeeping requirement for this section. Total hours for this section equal 45,000 hours.

Dated: December 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2005-23285]

Collection of Information Under Review by Office of Management and Budget: OMB Control Number 1625-0048

AGENCY: Coast Guard, DHS.

ACTION: Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to seek the approval of OMB for the renewal of an Information Collection Request (ICR). The ICR is 1625-0048, Vessel Reporting Requirements. Before submitting the ICRs to OMB, the Coast Guard is inviting comments on them as described below.

DATES: Comments must reach the Coast Guard on or before February 21, 2006.

ADDRESSES: To make sure that your comments and related material do not enter the docket [USCG-2005-23285] more than once, please submit them by only one of the following means:

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

(2) By 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 Web Site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice 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, 400 Seventh Street SW., Washington, DC, 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>.

Copies of the complete ICR are available through this docket on the Internet at <http://dms.dot.gov>, and also from Commandant (CG-611), U.S. Coast Guard Headquarters, room 6106 (Attn: Mr. Arthur Requina), 2100 Second Street SW., Washington, DC 20593-0001. The telephone number is 202-475-3523.

FOR FURTHER INFORMATION CONTACT: Mr. Arthur Requina, Office of Information Management, telephone 202-475-3523, or fax 202-475-3929, for questions on these documents; or telephone Ms. Renee V. Wright, Program Manager, Docket Operations, 202-493-0402, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to respond to this request for comments by submitting comments and related materials. We will post all comments received, without change, to <http://dms.dot.gov>; they will include any personal information you have provided. We have an agreement with DOT to use the Docket Management Facility. Please see the paragraph on DOT's "Privacy Act Policy" below.

Submitting comments: If you submit a comment, please include your name and address, identify the docket number [USCG-2005-23285], indicate the specific section of the document to which each comment applies, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit them by only one means. If you submit them by mail or 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 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. We may change the documents supporting this collection of information or even the underlying requirements in view of them.

Viewing comments and documents: To view comments, as well as documents mentioned in this notice as being available in the docket, go to

<http://dms.dot.gov> at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in 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.

Privacy Act: Anyone can search the electronic form of all comments received in 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 the Privacy Act Statement of DOT in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://dms.dot.gov>.

Information Collection Request

1. **Title:** Vessel Reporting Requirements.

OMB Control Number: 1625-0048.

Summary: The information obtained from these reports will be used by the Coast Guard to determine if the vessel reported on is in distress and if so, to take action to provide needed assistance. These reports (a) increase the likelihood of timely assistance to vessels in distress, especially those that cannot communicate their distress to the vessel's owner or others in a position to help, and (b) to place a burden of responsibility upon the owner, charterer, managing operator or agent for the safety of the vessels. This is of the utmost importance since these persons are often the only ones with knowledge of the vessels' intended movements.

Need: Paragraph (a) of 46 U.S.C. 2306 requires the owner, charterer, managing operator or agent of a vessel of the United States to immediately notify the Coast Guard if there is reason to believe that the vessel may have been lost or imperiled. Further, the owner, charterer, managing operator or agent of a vessel required to report to the United States Flag Merchant Vessel Location Filing System (USMER) must immediately notify the Coast Guard if more than 48 hours have passed since last receiving communication from the vessel. These reports must be followed by written communication submitted to the Coast Guard within 24 hours. Paragraph (c) of 46 U.S.C. 2306 gives the Secretary of Transportation authority to prescribe regulations to carry out 46 U.S.C. 2306. The Secretary has delegated this 46 U.S.C. 2306 responsibility to the Coast Guard in Department of Homeland Security Delegation No. 0170-2(92)(a). The Coast Guard has implemented these reporting requirements for all vessels

regulated under Title 46 CFR. The implementing regulations are 46 CFR Part 4.

Respondents: Owners, charterers, managing operators or agents of a vessel of the United States.

Frequency: On occasion.

Burden Estimate: The estimated burden remains 137 hours a year.

Dated: December 19, 2005.

R.T. Hewitt,

Rear Admiral, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD08-05-016]

RIN 1625-AA01

Anchorage Regulations; Mississippi River Below Baton Rouge, LA, Including South and Southwest Passes

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The United States Coast Guard will meet to discuss the comments received relating to the Notice of Proposed Rulemaking (NPRM) for Kenner Bend Anchorage as published in the **Federal Register**, Vol. 70, No. 80 on Wednesday, April 27, 2005.

DATES: The meeting will be held on Wednesday, January 4, 2006, from 9 a.m. to 12 p.m. This meeting may adjourn early if all business is finished.

ADDRESSES: The meeting will be held in the Basement Conference Room at the Hale Boggs Federal Building, 500 Poydras Street, New Orleans, Louisiana. This notice is available on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade (LTJG) Melissa Owens, Waterways Management Division, telephone (504) 846-5923, fax (504) 589-8919.

Background

Runway 1-19 at the Louis Armstrong New Orleans International Airport is positioned in a north-south line running parallel to the Airport Access Road. Aircraft approaching the runway from the south or departing the runway from the north pass over the Lower Kenner Bend Anchorage. Due to the close proximity of Runway 1-19 to Kenner Bend, aircraft occasionally descend and