

include tissue culture media for human ex vivo tissue and cell culture processing applications as described in § 876.5885 of this chapter.

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PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 876.5885 is added to subpart F to read as follows:

§ 876.5885 Tissue culture media for human ex vivo tissue and cell culture processing applications.

(a) *Identification.* Tissue culture media for human ex vivo tissue and cell culture processing applications consist of cell and tissue culture media and components that are composed of chemically defined components (e.g., amino acids, vitamins, inorganic salts) that are essential for the ex vivo development, survival, and maintenance of tissues and cells of human origin. The solutions are indicated for use in human ex vivo tissue and cell culture processing applications.

(b) *Classification.* Class II (special controls); FDA guidance document, "Class II Special Controls Guidance Document: Tissue Culture Media for Human Ex Vivo Processing Applications; Final Guidance for Industry and FDA Reviewers."

Dated: May 7, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08-01-002]

RIN 2115-AE47

Drawbridge Operating Regulation; Inner Harbor Navigation Canal, New Orleans, LA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the regulation governing the operation of the SR 46 (St. Claude Avenue) bridge, mile 0.5 (GIWW mile 6.2 East of Harvey Lock), the SR 39 (Judge Seeber/

Claiborne Avenue) bridge, mile 0.9 (GIWW mile 6.7 East of Harvey Lock), and the Florida Avenue bridge, mile 1.7 (GIWW mile 7.5 East of Harvey Lock), across the Inner Harbor Navigation Canal in New Orleans, Orleans Parish, Louisiana. This rule allows for the uninterrupted flow of commuter traffic while still providing for the reasonable needs of navigation.

DATES: This rule is effective June 15, 2001.

ADDRESSES: Comments and materials received from the public, as well as documents indicated in this preamble as being available in the docket, will be available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, Room 1313, 501 Magazine Street, New Orleans, Louisiana 70130-3396 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. David Frank, Bridge Administration Branch, Commander (obc), Eighth Coast Guard District, 501 Magazine Street, New Orleans, Louisiana, 70130-3396, telephone number 504-589-2965.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On February 22, 2001, a notice of proposed rulemaking (NPRM) entitled Drawbridge Operating Regulation; Inner Harbor Navigation Canal, New Orleans, Louisiana, was published in the **Federal Register** (66 FR 11129). Sixteen letters of comment were received on the proposed rule. No public hearing was requested, and none was held.

Background and Purpose

To meet the needs of commuters who cross these three bridges in the morning and afternoon en route to and from work in the Lower Ninth Ward area of New Orleans and in St. Bernard Parish, the Coast Guard proposed to codify the historic accommodation with marine interests that allows the bridges to remain closed-to-navigation and open to vehicular traffic during the morning and afternoon rush hours.

During the past several years, although no regulation has ever been established, all parties have accepted the spirit of the "closure" during morning and afternoon rush hours and the bridges have not opened during these time periods. The Coast Guard proposes to codify the accepted historic practices of these three bridges. Another factor we considered is the relocation of the Industrial Canal Lock previously discussed in detail in the Notice of Proposed Rulemaking.

The rule would establish the same operation schedules for all three draws to facilitate the flow of vehicular traffic during rush hours while still meeting the reasonable needs of navigation.

Discussion of Comments and Changes

Sixteen letters were received containing signatures in support of or commenting on the NPRM published in the **Federal Register** and reprinted in a local Coast Guard Public Notice CGD08-05-01 mailed on March 8, 2001. Thirteen respondents, one being the Louisiana Department of Transportation and Development, wrote in support of the proposal with no changes requested. One response was received containing forty-nine signatures in support of the proposal. Two respondents wrote letters in support of the project but requested that a modification be made to the proposed hours of closure. These respondents were individual commuters who wanted the hours of the closure to begin earlier in the morning to accommodate their work hours. However, the Port of New Orleans and the Louisiana Department of Transportation and Development provided traffic counts with the proposal and the traffic counts indicated that the proposed hours of closure correspond to the peak traffic crossing the bridges for the majority of the commuters. Therefore, no changes to the proposal were made based upon these responses. No changes have been incorporated into the Final Rule.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979).

We expect the economic impact of this proposed temporary rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary.

This rule maintains the existing historically accepted curfews with a minor change allowing the bridge to remain closed-to-navigation an additional 30 minutes.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considers whether this rule would have a significant economic impact on a

substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

Under the 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we want to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Collection of Information

This rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520.).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule would not have implications for federalism under that Order. No comments were received with regards to federalism during NPRM comment period.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This rule would not impose an unfunded mandate. No comments were received with regards to unfunded mandates during NPRM comment period.

Taking of Private Property

This rule would not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights. No comments were received with regards to the taking of private property during NPRM comment period.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. No comments were

received with regards to the taking of private property during NPRM comment period.

Protection of Children

We have analyzed this rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Environment

We considered the environmental impact of this rule and concluded that, under figure 2-1, paragraph (32)(e), of Commandant Instruction M16475.IC, this rule is categorically excluded from further environmental documentation. Bridge Administration Program actions that can be categorically excluded include promulgation of operating regulations or procedures for drawbridges. A "Categorical Exclusion Determination" is available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 117

Bridges

Regulations

For the reasons set out in the preamble, the Coast Guard proposes to amend Part 117 of Title 33, Code of Federal Regulations, as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05-1(g); section 117.255 also issued under the authority of Pub. L. 102-587, 106 Stat. 5039.

2. In § 117.458, paragraphs (a) and (b) are redesignated paragraphs (b) and (c) and a new paragraph (a) is added to read as follows:

§ 117.458 Inner Harbor Navigation Canal, New Orleans.

(a) The draws of the SR 46 (St. Claude Avenue) bridge, mile 0.5 (GIWW mile

6.2 East of Harvey Lock), the SR 39 (Judge Seeber/Claiborne Avenue) bridge, mile 0.9 (GIWW mile 6.7 East of Harvey Lock), and the Florida Avenue bridge, mile 1.7 (GIWW mile 7.5 East of Harvey Lock), shall open on signal; except that, from 6:45 a.m. to 8:30 a.m. and from 4:45 p.m. to 6:45 p.m., Monday through Friday, except federal holidays, the draws need not open for the passage of vessels. The draws shall open at any time for a vessel in distress.

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Dated: May 2, 2001.

Paul J. Pluta,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District

[FR Doc. 01-12238 Filed 5-15-01; 8:45 am]

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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Parts 1220, 1228, 1232, 1234, and 1236

RIN 3095-AB02

Records Disposition; Technical Amendments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Final rule.

SUMMARY: NARA is correcting and updating internal references and form names covered in the records management regulations. This final rule will affect Federal agencies.

EFFECTIVE DATE: June 15, 2001.

FOR FURTHER INFORMATION CONTACT:

Nancy Allard or Lynn Dubose at telephone number 301-713-7360 or fax number 301-713-7270.

SUPPLEMENTARY INFORMATION: Several amendments were made to Part 1228 in 1999, however, some internal references to Part 1228 in other Parts in Subchapter B and forms were not updated at that time. This final rule contains technical amendments such as designations for NARA organizational components, addresses, form titles, and cross-references.

This final rule is not a significant regulatory action for the purposes of Executive Order 12866 and has not been reviewed by the Office of Management and Budget. As required by the Regulatory Flexibility Act, I certify that this final rule will not have a significant impact on a substantial number of small entities because it applies only to Federal agencies. This final rule has no federalism or tribalism implications.