

these devices already comply with the proposed special controls. Because reclassification will reduce regulatory costs with respect to ADCCs, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

## VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## VII. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

### List of Subjects in 21 CFR Part 864

Biologics, Blood, Laboratories, Medical devices, Packaging and containers.

### PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

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

2. Section 864.5220 is revised to read as follows:

#### **§ 864.5220 Automated differential cell counter.**

(a) *Identification.* An automated differential cell counter is a device used to identify one or more of the formed elements of the blood. The device may

also have the capability to flag, count, or classify immature or abnormal hematopoietic cells of the blood, bone marrow, or other body fluids. These devices may combine an electronic particle counting method, optical method, or a flow cytometric method utilizing monoclonal CD (cluster designation) markers. The device includes accessory CD markers.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA document entitled “Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA.”

Dated: January 3, 2002.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 02–792 Filed 1–11–02; 8:45 am]

**BILLING CODE 4160–01–5**

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 117

[CGD07–02–001]

#### **Drawbridge Operation Regulations; 63rd Street Bridge, Indian Creek, Mile 4.0, Miami Beach, Miami-Dade County, FL**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, Seventh Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the 63rd Street Bridge across Indian Creek, mile 4.0, Miami Beach, Miami-Dade County, Florida. This deviation allows the drawbridge owner or operator to not open the Bridge from January 15, 2002 to January 19, 2002. This temporary deviation is required to allow the bridge owner to safely complete repairs to the Bridge.

**DATES:** This deviation is effective from 12:01 a.m. on January 15, 2002 until 11:59 p.m. on January 19, 2002.

**ADDRESSES:** Material received from the public, as well as documents indicated in this preamble as being available in the docket and will be available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 S.E. 1st Avenue, Miami, FL 33131 between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Mr. Barry Dragon, Chief, Operations Section, Seventh Coast Guard District, Bridge Section at (305) 415–6743.

**SUPPLEMENTARY INFORMATION:** The 63rd Street Bridge across Indian Creek, Miami Beach, Miami-Dade County, Florida is a double leaf bridge with a vertical clearance of 11.0 feet above mean high water (MHW) measured at the fenders in the closed position with a horizontal clearance of 50 feet. On December 21, 2001, the Florida Department of Transportation, the drawbridge owner, requested a deviation from the current operating regulation in 33 CFR part 117 which requires the draw of the 63rd Street Bridge, mile 4.04 at Miami Beach, to open on signal. This temporary deviation was requested to allow necessary repairs to the drawbridge in a critical time sensitive manner.

The District Commander has granted a temporary deviation from the operating requirements listed in 33 CFR part 117 to complete repairs to the drawbridge. Under this deviation, the 63rd Street Bridge need not open either span from 12:01 a.m. on January 15, 2002 until 11:59 p.m. on January 19, 2002.

Dated: January 7, 2002.

**Greg E. Shapley,**

*Chief, Bridge Administration, Seventh Coast Guard District.*

[FR Doc. 02–859 Filed 1–11–02; 8:45 am]

**BILLING CODE 4910–15–P**

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 165

CGD01–01–211

RIN 2115–AA97

#### **Safety and Security Zone; Pilgrim Nuclear Power Plant, Plymouth, MA**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing temporary safety and security zones around the Pilgrim Nuclear Power Plant in Cape Cod Bay, Plymouth, MA from November 15, 2001 until June 15, 2002. The safety and security zones will temporarily close all waters within an approximate 1000-yard distance from the plant, and will also close shore areas adjacent to the plant. The safety and security zones prohibit entry into or movement within a portion of Cape Cod Bay and adjacent shore

areas and are needed to ensure public safety and prevent sabotage or terrorist acts.

**DATES:** This rule is effective from November 15, 2001 until June 15, 2002.

**ADDRESSES:** Documents as indicated in this preamble are available for inspection or copying at Marine Safety Office Boston, 455 Commercial Street, Boston, MA between the hours of 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant (junior grade) Dave Sherry, Marine Safety Office Boston, Maritime Security Operations Division, at (617) 223-3030.

**SUPPLEMENTARY INFORMATION:**

**Regulatory History**

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553, the Coast Guard finds that good cause exists for not publishing an NPRM. On September 11, 2001, two commercial aircraft were hijacked from Logan Airport in Boston, Massachusetts and flown into the World Trade Center in New York, New York inflicting catastrophic human casualties and property damage. National security and intelligence officials warn that future terrorist attacks against civilian targets may be anticipated.

The Pilgrim Nuclear Power Plant is bordered on one side by water, exposing it to possible attack initiated from waters surrounding the power plant. Due to the potential catastrophic effect an exposure of radiation from the nuclear processes at the plant would have on the surrounding area, this rulemaking is urgently required to prevent potential future terrorist strikes against the Pilgrim Nuclear Power Plant. The delay inherent in the NPRM process is contrary to the public interest insofar as it may render people and facilities within and adjacent to the Pilgrim Nuclear Power Plant property vulnerable to subversive activity, sabotage or terrorist attack.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The measures implemented in this rule are intended to prevent possible terrorist attacks against the Pilgrim Nuclear Power Plant. They are needed to protect the facility, persons at the facility, the public and the surrounding community from potential sabotage or other subversive activity, and terrorist attacks, either from the water or by land through access to public trust lands between the low

water and high water tide lines adjacent to the facility. Immediate action is required to accomplish these objectives. Any delay in the effective date of this rule is impracticable and contrary to the public interest. These zones should have minimal impact on the users of Cape Cod Bay as vessels are able to pass safely outside the zones. Public notifications will be made to the maritime community via notice to mariners and marine information broadcasts informing them of boundaries of the zones.

**Background and Purpose**

In light of terrorist attacks on New York City and Washington, DC, on September 11, 2001, safety and security zones are being established to safeguard the Pilgrim Nuclear Power Plant, persons at the facility, the public and surrounding communities from sabotage or other subversive acts, accidents, or other events of a similar nature. The Pilgrim Nuclear Power Plant presents a possible target of terrorist attack, due to the potential catastrophic impact nuclear radiation would have on the surrounding area, its large destructive potential if struck, and its proximity to a population center. These safety and security zones prohibit entry into or movement within the specified areas.

This rulemaking establishes security and safety zones having identical boundaries in all waters of Cape Cod Bay and land adjacent to those waters enclosed by a line as follows: beginning at position 41°57'30" N, 070°34'36" W; then running southeast to position 41°56'36" N, 070°33'30" W; then running southwest to position 41°56'28" N, 070°34'38" W; then running northwest to position 41°56'50" N, 070°34'58" W; then running northeast back to position 41°57'30" N, 070°34'36" W. This rulemaking also removes safety and security zones established on September 24, 2001 under temporary rulemaking 33 CFR 165.T01-171(a)(4) (66 FR 49280, Sept. 27, 2001). That rulemaking established safety and security zones with identical boundaries in the following area: All waters of Plymouth Bay within a five hundred (500) yard radius of the cooling water discharge canal at the Pilgrim Nuclear Power Plant, Plymouth, MA. Those safety and security zones did not extend to the full boundaries of the facility. This rulemaking is necessary to provide complete protection of the waterfront areas of the Pilgrim Nuclear Power Plant. The increase of the boundaries of the zones seaward is necessary to ensure enforcement authorities enforcing the zone ample area to adequately prevent any incursions of the zone allowing

access to the plant. The safety and security zones established in this rulemaking extend the safety and security zones established in section 165.T01-171(a)(4) to an area roughly 1000-yards from the shoreline of the facility. That section, 165.T01-171(a)(4), was also temporarily removed by temporary rulemaking 33 CFR 165.T01-201 effective November 5 to November 15, 2001. The safety and security zones also close shore areas immediately adjacent to the facility to prevent access to the facility from the shore area.

No person or vessel may enter or remain in the prescribed safety and security zones at any time without the permission of the Captain of the Port. Each person or vessel in a safety and security zone shall obey any direction or order of the Captain of the Port or designated Coast Guard representative on-scene. The Captain of the Port may take possession and control of any vessel in a security zone and/or remove any person, vessel, article or thing from a security zone. No person may board, take or place any article or thing on board any vessel or waterfront facility in a security zone without permission of the Captain of the Port. These regulations are issued under authority contained in 50 U.S.C. 191, 33 U.S.C. 1223, 1225 and 1226.

**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).

The Coast Guard expects the economic impact of this rule to be so minimal that a full regulatory evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. The effect of this regulation will not be significant for several reasons: there is ample room for vessels to navigate around the zones in Cape Cod Bay, and advance notifications will be made to the local maritime community by marine information broadcasts.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), the Coast Guard considered 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 will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in a portion of Cape Cod Bay. For the reasons enumerated in the Regulatory Evaluation section above, these safety and security zones will not have a significant economic impact on a substantial number of small entities.

#### Assistance for Small Entities

Under subsection 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 [Pub. L. 104-121], the Coast Guard wants to assist small entities in understanding this final rule so that they can better evaluate its effects on them and participate in the rulemaking. If your small business or organization would be affected by this final rule and you have questions concerning its provisions or options for compliance, please call Lieutenant (junior grade) Dave Sherry, Marine Safety Office Boston, at (617) 223-3000. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

#### 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

The Coast Guard analyzed this rule under Executive Order 13132 and has determined that this rule does not have implications for federalism under that Order.

#### 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.

#### Taking of Private Property

This rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

#### Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

#### Protection of Children

The Coast Guard analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not pose 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. A rule with tribal implications has 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

The Coast Guard considered the environmental impact of this rule and concluded that, under figure 2-1, (34)(g), of Commandant Instruction M16475.ID, this rule is categorically excluded from further environmental documentation. A "Categorical Exclusion Determination" is available in the docket where indicated under **ADDRESSES**.

#### Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not

likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

#### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05-1(g), 6.04-1, 6.04-6, 160.5; 49 CFR 1.46.

2. Remove temporary § 165.T01-171(a)(4).

3. From November 15, 2001 until June 15, 2002, add temporary § 165.T01-211 to read as follows:

#### § 165.T01-211 Safety and Security Zones: Pilgrim Nuclear Power Plant, Plymouth, Massachusetts.

(a) *Location.* All waters and land enclosed by a line beginning at position 41°57'30" N, 070°34'36" W; then running southeast to position 41°56'36" N, 070°33'30" W; then running southwest to position 41°56'28" N, 070°34'38" W; then running northwest to position 41°56'50" N, 070°34'58" W; then running northeast back to position 41°57'30" N, 070°34'36" W.

(b) *Regulations.* (1) In accordance with the general regulations in §§ 165.23 and 165.33 of this part, entry into or movement within this zone is prohibited unless authorized by the Captain of the Port Boston.

(2) All vessel operators shall comply with the instructions of the COTP or the designated on-scene U.S. Coast Guard patrol personnel. On-scene Coast Guard patrol personnel include commissioned, warrant, and petty officers of the Coast Guard on board Coast Guard, Coast Guard Auxiliary, local, state, and Federal law enforcement vessels.

(3) No person may enter the waters or land area within the boundaries of the safety and security zones unless previously authorized by the Captain of the Port, Boston or his authorized patrol representative.

Dated: November 15, 2001.

**B.M. Salerno,**

*Captain, U.S. Coast Guard, Captain of the Port, Boston, Massachusetts.*

[FR Doc. 02-860 Filed 1-11-02; 8:45 am]

BILLING CODE 4910-15-P

## FEDERAL EMERGENCY MANAGEMENT AGENCY

### 44 CFR Part 65

#### Changes in Flood Elevation Determinations

**AGENCY:** Federal Emergency Management Agency, (FEMA).

**ACTION:** Final rule.

**SUMMARY:** Modified Base (1-percent-annual-chance) Flood Elevations (BFEs) are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

**EFFECTIVE DATES:** The effective dates for these modified BFEs are indicated on the table below and revise the Flood Insurance Rate Maps (FIRMs) in effect for the listed communities prior to this date.

**ADDRESSES:** The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Matthew B. Miller, P.E., Chief, Hazards Study Branch, Federal Insurance and Mitigation Administration, 500 C Street, SW., Washington, DC 20472, (202) 646-3461 or (E-mail) [matt.miller@fema.gov](mailto:matt.miller@fema.gov).

**SUPPLEMENTARY INFORMATION:** FEMA makes the final determinations listed below of the final determinations of modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The

Acting Administrator, Federal Insurance and Mitigation Administration, has resolved any appeals resulting from this notification.

The modified BFEs are not listed for each community in this notice. However, this rule includes the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection.

The modifications are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities.

These modified BFEs are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

The changes in BFEs are in accordance with 44 CFR 65.4. *National Environmental Policy Act.* This rule is

categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

**Regulatory Flexibility Act.** The Acting Administrator, Federal Insurance and Mitigation Administration, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

**Regulatory Classification.** This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

**Executive Order 12612, Federalism.** This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

**Executive Order 12778, Civil Justice Reform.** This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

#### List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 65 is amended to read as follows:

#### PART 65—[AMENDED]

1. The authority citation for part 65 continues to read as follows:

**Authority:** 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

#### § 65.4 [Amended]

2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location	Dates and names of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Indiana:					
Howard (FEMA Docket No. 7606.	Unincorporated Areas	July 20, 2001, July 27, 2001, <i>Kokomo Tribune</i> .	Mr. John Harbaugh, President, Howard County Board of Commissioners, 230 North Main, Kokomo, Indiana 46901.	June 27, 2001 .....	180414
Hendricks (FEMA Docket No. 7604).	Town of Plainfield .....	June 7, 2001, June 14, 2001, <i>Hendricks County Flyer</i> .	Mr. Richard A. Carlucci, Town Manager, Town of Plainfield, 206 West Main Street, Plainfield, Indiana 46268-0065.	Sept. 14, 2001 .....	180089