

§ 809.10 Labeling for in vitro diagnostic products.

(a) The label for an in vitro diagnostic product shall state the following information, except where such information is not applicable, or as otherwise specified in a standard for a particular product class, as provided in paragraph (e) of this section, or in the form of a symbol, *provided that* such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the in vitro diagnostic product. FDA may recognize a standardized symbol for all devices or only for certain types or categories of devices. Section 201(k) of the Federal Food, Drug, and Cosmetic Act provides that a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless a word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

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(b) Labeling accompanying each product, e.g., a package insert, shall state in one place the following information in the format and order specified in this paragraph, except where such information is not applicable, or as specified in a standard for a particular product class, or where such information is provided in the form of a symbol, *provided that* such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the in vitro diagnostic product. * * *

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(c) * * *
 (2) In the case of a shipment or delivery for an investigation that is not subject to part 812 (see § 812.2(c)), if the following conditions are met, including that, where information required by those conditions is provided in the form of a symbol, such symbol must either be accompanied by explanatory text adjacent to the symbol or contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act,

and explained in a symbols glossary that contemporaneously accompanies the in vitro diagnostic product:

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(d) The labeling of general purpose laboratory reagents (e.g., hydrochloric acid) and equipment (e.g., test tubes and pipettes) whose uses are generally known by persons trained in their use need not bear the directions for use required by § 809.10(a) and (b), if their labeling meets the requirements of this paragraph, except where such information is provided in the form of a symbol, *provided that* such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the reagent or equipment.

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(e)(1) The labeling for analyte specific reagents (e.g., monoclonal antibodies, deoxyribonucleic acid (DNA) probes, viral antigens, ligands) shall bear the following information, except where such information is provided in the form of a symbol, *provided that* such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the reagent:

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(f) The labeling for over-the-counter (OTC) test sample collection systems for drugs of abuse testing shall bear the following information in language appropriate for the intended users, except where such information is provided on labels in the form of a symbol, *provided that* such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the test sample collection system:

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Dated: April 15, 2013.
Leslie Kux,
Assistant Commissioner for Policy.
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BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2012-0202]

RIN 1625-AA11; 1625-AA87

Regulated Navigation Areas, Security Zones: Dignitary Arrival/Departure and United Nations Meetings, New York, NY

AGENCY: Coast Guard, DHS.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes amendments to its regulation establishing security zones that are enforceable in connection with the arrival or departure of international leaders for United Nations meetings in New York, NY. New regulated navigation areas would be established and some security zones would be modified, and the regulation would be rearranged. The proposed amendments would assist the Coast Guard in protecting public safety and visiting dignitaries during these events, and thus promote the Coast Guard's maritime safety and maritime security missions.

DATES: Comments and related material must be received by the Coast Guard on or before May 20, 2013.

Requests for public meetings must be received by the Coast Guard on or before April 26, 2013.

ADDRESSES: You may submit comments identified by docket number using any one of the following methods:

- (1) *Federal eRulemaking Portal:* <http://www.regulations.gov>.
- (2) *Fax:* 202-493-2251.
- (3) *Mail or Delivery:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is (202) 366-9329.

See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Jeff Yunker, Coast Guard Sector New York, Waterways Management Division; telephone (718)

354-4195, email Jeff.M.Yunker@uscg.mil or Lieutenant Isaac Slavitt, Coast Guard First District Waterways Management Branch, telephone (617) 223-8385, email Isaac.M.Slavitt@uscg.mil. If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms Port

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
SNPRM Supplemental Notice of Proposed Rulemaking
UNGA United Nations General Assembly
RNA Regulated Navigation Area
UN United Nations

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at <http://www.regulations.gov>, or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, type the docket number [USCG-2012-0202] in the "SEARCH" box and click "SEARCH." Click on "Submit a Comment" on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an

unbound format, no larger than 8½; by 11 inches, suitable for copying and electronic filing. If you submit comments 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 and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number (USCG-2012-0202) in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our 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 a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before April 26, 2013, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Regulatory History and Information

On September 11, 2012, we published a notice of proposed rulemaking (NPRM) entitled "Security Zones; Dignitary Arrival/Departure and United Nations Meetings, New York, NY" in the **Federal Register** (77 FR 55777). We received seven comments on the proposed rule.

One commenter said it would be good to know evacuation routes and protocols during incidents at the United Nations (UN) so the public could avoid the situation. UN evacuation protocols are

outside of the purview of this rulemaking.

One commenter said we should consider limiting access to security zone enforcement notifications, to prevent subversives or terrorists from gaining an advantage via these notifications. By law, we must make such notifications public. We disagree that they provide information that would otherwise be unavailable to potential bad actors, because UN meetings and dignitary visits are well publicized in the commercial media and other open sources. This commenter also said we should clarify how a vessel may obtain permission to enter an in-force security zone and whether this permission is temporary or permanent, and that vessels should be able to obtain pre-established clearance to travel through in-force security zones. Our proposed amendments clearly describe how to obtain entry permission, which is for the duration of the enforcement period. Pre-establishing clearance is not advisable since the specific terms on which entry may be authorized will vary depending on the exact nature of each dignitary's visit. Lastly, this commenter said we should develop a contingency plan for emergency scenarios that addresses acute high volume boat traffic and evacuation. This is outside the purview of this rulemaking.

One commenter said our Randalls and Wards Islands coordinates are incorrect. We verified the published coordinates and confirmed they are correct, with no changes necessary.

One commenter said that permanently prohibiting freedom of movement takes a vote of elected officials in place of a regulation. The Coast Guard's legal authority to establish RNAs and security zones is outlined in the Basis and Purpose section.

One commenter said the UN should relocate to Dubai and that the UN building should be converted to apartments or condominiums. This is outside the purview of this rulemaking.

The New York City Water Trail Association Steering Committee stated that last minute changes to security zone activation times of even a few minutes can make adjusting plans difficult or impossible for small, human-powered boats, borne by the tide. Dignitary schedule changes are outside of the Coast Guard's authority. We will provide as much advance information, and publish it as widely, as it is possible for us to do under the circumstances and when practicable. The commenter also raised concerns about the inclusion of the Bronx Kill in the proposed Randalls and Wards Island security

zone and stated we did not include a thorough explanation of the security rationale for closing the Bronx Kill. Inclusion of the Bronx Kill area is necessary to prevent vessels or persons from bypassing the security measures established on shore for the events and engaging in waterborne terrorist actions during the highly-publicized events. The commenter additionally stated that a legal launch site on the northwest corner of Randalls Island on the Bronx Kill would be rendered off limits during activation of this security zone. The New York City Water Trail Map displayed on the NYC Parks Web site did not display a launch site on Randalls Island when checked on November 27, 2012 and on February 4, 2013 at <http://www.nycgovparks.org/facilities/kayak>. The Coast Guard does not control vessel launch activities on the Bronx Kill at the northwest corner of Randalls or Wards Islands. This reported launch site is outside of the boundaries of this security zone. The commenter also stated it can be difficult for paddlers and rowers to communicate requests for on-site permission to transit the security zone. Paddlers and rowers can reach the Coast Guard on VHF-FM radio using handheld radios to communicate requests to transit a security zone. In addition, those mariners solely carrying mobile phones may contact the COTP at (718) 354-4356 to request to transit through the security zone. Furthermore, the commenter states that there should be a provision for passage along the pierhead line on the opposite side of the river and that the Coast Guard should outline specific procedures and standards for obtaining permission to transit the security zone. The commenter also states that small, un-motorized boats pose no threat to targets one half mile away. We reiterate that security measures would be limited to the minimum necessary to mitigate identified risks to safety or security. Lastly, the commenter said we should meet with all harbor stakeholders before creating more security zones. While there may be a number of security zones and regulated navigation areas in place throughout the Captain of the Port New York zone, their purposes and the events for which they are enforced are different and rarely overlapping in time or location. We do not expect more than one of the zones or areas affected by this rulemaking to be enforced at the same time, given the length of the meetings being attended.

C. Basis and Purpose

The legal basis for the proposed rule is 33 U.S.C 1226, 1231; 46 U.S.C

Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, 160.5; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to establish RNAs and security zones. The purpose of this rulemaking is to regulate navigation in waters near the United Nations (UN) during UN visits by international leaders. The purpose of this supplemental NPRM is to notify the public that we have determined an RNA to be a legally more appropriate tool than a security zone for certain areas described in the NPRM.

D. Discussion of Proposed Rule

The Coast Guard proposes amending the existing security zone regulation relating to the arrival and departure of dignitaries for UN meetings in New York City, 33 CFR 165.164. Our proposals are substantively similar to the proposals contained in our 2012 NPRM, but we are proposing some rearrangement and non-substantive revision of § 165.164, and we are proposing redesignating some existing or proposed security zones as regulated navigation areas. Please see the NPRM for a further discussion of how we have enforced § 165.164 security zones in the past. We have now determined that an RNA is the more appropriate means to regulate the movement of vessels or individuals instead of the security zones originally proposed or already codified at 33 CFR 165.164. We would designate the Wall Street Heliport, Randalls and Wards Islands, and United Nations Full River Closure security zones as RNAs. The Marine Air Terminal, United Nations, and United Nations West Channel Closure security zones would remain designated as security zones as they do not completely restrict vessel traffic on that portion of the Bowery Bay and East River during enforcement of the security zones.

We would reorganize § 165.164 and add descriptive designations to name each of the several locations covered by that regulation.

We propose revising § 165.164(a)(1) relating to the Wall Street Heliport. We would remove a reference to Pier 13, which no longer exists, but otherwise the boundaries of the designated area would not change. The existing security zone would become a regulated navigation area.

We would add new § 165.164(a)(2) and establish an RNA on the waters of the East River and Bronx Kill in the vicinity of Randalls and Wards Islands. The RNA would be approximately 2,150 yards long and 860 yards wide, and would encompass approximately 0.21 square nautical miles. It would be

enforced from 30 minutes before a dignitary's arrival until 15 minutes after the dignitary's departure from the area.

We propose no changes to § 165.164(a)(3), other than to designate it as the Marine Air Terminal, La Guardia Airport Security Zone.

We propose designating the security zone created by § 165.164(a)(4) as the United Nations Security Zone, and we propose rewording the description of this zone's boundaries for clarity, without changing its geographical coordinates. In new paragraph (d), we propose stating that this zone is in force at all times.

We propose transferring the security zone described in existing § 165.164(a)(5) to paragraph (a)(6), and designating it the United Nations Full River Closure RNA. The content of existing paragraph (a)(6) would be addressed in new paragraph (d). When enforced, the UN Full River Closure RNA would fully close the East River to vessel traffic within its boundaries. We would create a new security zone in paragraph (a)(5), to be designated the United Nations West Channel Closure Security Zone. When in force, it would close only a portion of the western channel of the river. Vessels capable of transiting the shallower waters of the eastern channel could do so.

The content of existing paragraph (a)(7) would be addressed in new paragraph (d).

We propose adding a new § 165.164(b) to define terms used in the regulation. The content of existing paragraph (b) would be moved to paragraph (c).

We propose adding a new § 165.164(d) to describe how and when each regulated navigation area or security zone would be enforced, and how the public will be notified that enforcement is in effect.

Finally, we propose adding a new § 165.164(e) to describe how vessel operators may obtain permission to enter or operate within a regulated navigation area or security zone.

E. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes or executive orders.

1. Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and

does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

This determination is based on the limited time that vessels would be restricted from the Randalls and Wards Islands RNA. The RNA would be activated for approximately 60 minutes approximately six times per year or when necessary. The Coast Guard expects minimal adverse impact to mariners from the RNA's activation based on the limited duration of the enforcement period, the limited geographic area affected and because affected mariners may request authorization from the COTP or the designated on-scene representative to transit the RNA.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities.

This proposed rule would affect the following entities, some of which may be small entities: The owners and operators of vessels intending to transit or anchor in a portion of the East River or Bronx Kill, in the vicinity of Randalls or Wards Islands, NY during the enforcement periods.

These RNA's will not have a significant economic impact on a substantial number of small entities for the following reasons: The RNA is of limited size and duration. Persons or vessels may request permission to transit the RNA from the COTP or the designated on-scene representative.

Additionally, before and during the enforcement period, the Coast Guard would issue maritime advisories widely available to users of the waterway, including marine information broadcasts, and distribute a written notice online at <http://homeport.uscg.mil/newyork>.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

This proposed rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect 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. We have analyzed this proposed rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This proposed rule would not cause a taking of private property or otherwise have taking implications under

Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This proposed 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.

10. Protection of Children From Environmental Health Risks

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

11. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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.

12. Energy Effects

This proposed rule is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule may be categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An

environmental analysis checklist will be available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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 proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREA

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

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

- 2. Revise § 165.164 to read as follows:

§ 165.164 Regulated Navigation Areas, Security Zones: Dignitary Arrival/Departure and United Nations Meetings, New York, NY.

(a) *Location*. The following areas are regulated navigation areas (RNA) or security zones:

(1) *Wall Street Heliport RNA*. All waters of the East River within the following boundaries: East of a line drawn between approximate position 40°42'01" N, 074°00'39" W (east of The Battery) to 40°41'36" N, 074°00'52" W (point north of Governors Island) and north of a line drawn from the point north of Governors Island to the southwest corner of Pier 7 North, Brooklyn; and south of a line drawn between 40°42'14.8" N, 074°00'20.3" W (Wall Street, Manhattan), and the northwest corner of Pier 2 North, Brooklyn (NAD 1983).

(2) *Randalls and Wards Islands RNA*: All waters of the East River between the Hell Gate Rail Road Bridge (mile 8.2), and a line drawn from a point at approximate position 40°47'27.12" N, 073°54'35.14" W (Lawrence Point, Queens) to a point at approximate position 40°47'52.55" N, 073°54'35.25" W (Port Morris Stacks), and all waters of the Bronx Kill southeast of the Bronx Kill Rail Road Bridge (mile 0.6) (NAD 1983).

(3) *Marine Air Terminal, La Guardia Airport Security Zone*: All waters of Bowery Bay, Queens, New York, south of a line drawn from the western end of La Guardia Airport at approximate position 40°46'47" N, 073°53'05" W to

the Rikers Island Bridge at approximate position 40°46'51" N, 073°53'21" W and east of a line drawn between the point at the Rikers Island Bridge to a point on the shore in Queens, New York, at approximate position 40°46'36" N, 073°53'31" W (NAD 1983).

(4) *United Nations Security Zone*. All waters of the East River bound by the following points: 40°44'37" N, 073°58'16.5" W (the base of East 35th Street, Manhattan), then east to 40°44'34.5" N, 073°58'10.5" W (about 175 yards offshore of Manhattan), then northeasterly to 40°45'29" N, 073°57'26.5" W (about 125 yards offshore of Manhattan at the Queensboro Bridge), then northwesterly to 40°45'31" N, 073°57'30.5" W (Manhattan shoreline at the Queensboro Bridge), then southerly along the shoreline to the starting point at 40°44'37" N, 073°58'16.5" W (NAD 1983).

(5) *United Nations West Channel Closure Security Zone*. All waters of the East River north of a line drawn from approximate position 40°44'37" N, 073°58'16.5" W (the base of East 35th Street, Manhattan), to approximate position 40°44'31.04" N, 073°58'03.10" W (approximately 400 yards east of the Manhattan shoreline), all waters west of a line drawn from approximate position 40°44'31.04" N, 073°58'03.10" W (approximately 400 yards east of the Manhattan shoreline), to the southern tip of Roosevelt Island at approximate position 40°44'57.96" N, 073°57'41.57" W, then along the western shoreline of Roosevelt Island to the Queensboro Bridge, and all waters south of the Queensboro Bridge (NAD 1983).

(6) *United Nations Full River Closure RNA*. All waters of the East River north of a line drawn from approximate position 40°44'37" N, 073°58'16.5" W (the base of East 35th Street, Manhattan), to approximate position 40°44'23" N, 073°57'44.5" W (Hunters Point, Long Island City), and south of the Queensboro Bridge (NAD 1983).

(b) *Definitions*. As used in this section—

Designated representative means any Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP to act on the COTP's behalf. The designated representative may be on a Coast Guard vessel, or onboard a federal, state, or local agency vessel that is authorized to act in support of the Coast Guard.

Dignitary means the President or Vice President of the United States, or visiting heads of foreign states or governments.

(c) *Regulations*. In accordance with the general regulations in 33 CFR part

165, no person or vessel may enter or move within a RNA or security zone created by this section during enforcement periods unless granted permission to do so by the COTP New York or the designated representative. Vessel operators and persons given permission to enter or operate in the RNA or security zone must comply with all directions given to them by the COTP or the designated representative. Upon being hailed by a U.S. Coast Guard or New York City police vessel by siren, radio, flashing lights, or other means, the operator of a vessel must proceed as directed, and follow any instructions to anchor or moor up to a waterfront facility.

(d) *Enforcement*. The security zone described in paragraph (a)(4) of this section is effective and will be enforced at all times. Coast Guard Sector New York will provide actual notice to mariners for the purpose of enforcement for the regulated navigation areas and security zones described in paragraphs (a)(1), (a)(2), (a)(3), (a)(5), and (a)(6). The Captain of the Port will also provide notice to the maritime public regarding the activation of these RNAs and security zones by appropriate means, which may include but are not limited to a Local Notice to Mariners or marine information broadcasts, and at <http://homeport.uscg.mil/newyork>.

(e) *Contact Information*. Vessel operators desiring to enter or operate within a RNA or security zone shall telephone the COTP at (718) 354-4356 or the designated representative via VHF channel 16 to obtain permission to do so.

Dated: April 9, 2013.

D.B. Abel,

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

[FR Doc. 2013–09278 Filed 4–18–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2013–0174]

RIN 1625–AA00

Safety Zone; Atlantic Intracoastal Waterway; Wrightsville Beach, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Coast Guard proposes to extend the temporary safety zone established on the waters of the Atlantic