

(iv) Labeling must include a detailed description of any special capabilities (e.g., overdrive pacing or automatic mode switching); and

(v) Appropriate electromagnetic compatibility information must be included.

■ 3. In Subpart D, add § 870.3605 to read as follows:

**§ 870.3605 Pacing system analyzer.**

(a) *Identification.* A pacing system analyzer (PSA) is a prescription device that combines the functionality of a pacemaker electrode function tester (§ 870.3720) and an external pacemaker pulse generator (EPPG) (§ 870.3600). It is connected to a pacemaker lead and uses a power supply and electronic circuits to supply an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and intracardiac R-wave potential. A PSA may be a single, dual, or triple chamber system and can simultaneously deliver pacing therapy while testing one or more implanted pacing leads.

(b) *Classification.* Class II (special controls) for PSAs. The special controls for this device are:

(1) Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

(2) Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (i.e., battery power, AC mains connections, or both).

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;

(ii) Mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;

(iii) Simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (e.g. data storage, printing), and indicator(s) functionality under intended use conditions; and

(iv) Methods and instructions for cleaning the pulse generator and connection cables must be validated.

(4) Appropriate software verification, validation, and hazard analysis must be performed.

(5) Labeling must include the following:

(i) The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use;

(ii) Connector terminals should be clearly, unambiguously marked on the outside of the EPPG. The markings should identify positive (+) and negative (-) polarities. Dual chamber devices should clearly identify atrial and ventricular terminals. Triple chamber devices should clearly identify atrial, right ventricular, and left ventricular terminals;

(iii) The labeling must list all pacing modes available in the device;

(iv) Labeling must include a detailed description of any special capabilities (e.g., overdrive pacing or automatic mode switching);

(v) Labeling must limit the use of external pacing to the implant procedure; and

(vi) Appropriate electromagnetic compatibility information must be included.

Dated: September 9, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-21814 Filed 9-12-14; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF THE INTERIOR**

**Bureau of Indian Affairs**

**25 CFR Part 41**

**[145A2100DD.AADD001000.A0E501010.999900]**

**RIN 1076-AF08**

**Grants to Tribally Controlled Colleges and Universities, Diné College, and Tribally Controlled Postsecondary Career and Technical Institutions**

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice of tribal consultation sessions.

**SUMMARY:** The Bureau of Indian Education provides financial and technical assistance to tribally controlled colleges and universities and Diné College. In collaboration with the American Indian Higher Education Consortium, we have prepared a discussion draft that updates the policies and procedures for administration and oversight of these assistance programs and revises regulatory language to conform to statutory amendments. This notice announces tribal consultation sessions

and a comment period on the preliminary discussion draft.

**DATES:** Comments must be received by November 15, 2014. See the

**SUPPLEMENTARY INFORMATION** section of this notice for dates of the tribal consultation sessions.

**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section of this notice for locations of the tribal consultation sessions and the Web site where the preliminary discussion draft is available. You may submit comments by either of the following methods:

—Federal Rulemaking Portal: <http://www.regulations.gov>. This rule is listed under the agency name “Bureau of Indian Affairs” and Docket ID “BIA-2011-0002.”

—Mail or Hand-Delivery: Ms. Juanita Mendoza, Program Analyst, Bureau of Indian Education, U.S. Department of the Interior, 1951 Constitution Ave. NW., MS 312, Washington, DC 20240. Include “1076-AF08” on the cover of the submission.

**FOR FURTHER INFORMATION CONTACT:** Ms. Juanita Mendoza, Program Analyst, Bureau of Indian Education, U.S. Department of the Interior, 1951 Constitution Ave. NW., MS 312, Washington, DC 20240; or email to [juanita.mendoza@bie.edu](mailto:juanita.mendoza@bie.edu).

**SUPPLEMENTARY INFORMATION:** The BIE supports and encourages the establishment, operation, and improvement of tribally controlled colleges and universities (TCUs) to ensure continued and expanded educational opportunities for Indian students. The TCUs are both integral and essential to their communities, creating environments that foster American Indian culture, languages, and traditions. The TCUs serve a variety of people from young adults to senior citizens. The TCUs offer 358 total programs, including apprenticeships, diplomas, certificates, and degrees. These programs include 181 associate degree programs at 23 TCUs, 40 bachelor's degree programs at 11 TCUs, and 5 master's degree programs at 2 TCUs.

The BIE is revising the regulations at 25 CFR Part 41 and has prepared a preliminary discussion draft. Subpart B of the preliminary discussion draft concerns financial and technical assistance to tribal colleges and universities funded under the Tribally Controlled Colleges and Universities Assistance Act of 1978, as amended (25 U.S.C. 1801 et seq.). Subpart B does not concern financial assistance to Diné College or to tribally controlled postsecondary career and technical institutions. Subpart C of the

preliminary discussion draft applies to financial assistance to Diné College under the Navajo Nation Higher Education Act of 2008. Subpart A includes general provisions and applies to both subparts B and C.

This notice announces the availability of the preliminary discussion draft of potential revisions for public view at [www.bie.edu/consultation/index.htm](http://www.bie.edu/consultation/index.htm). Comments on the preliminary discussion draft are due by the date indicated in the **DATES** section of this

notice. BIE will host five meetings to obtain input on the preliminary discussion draft.

The meetings to obtain input will be held on the dates and at the locations shown below. All times are local.

Date	Time	Location	Venue
October 16, 2014	5:00 p.m.–8:00 p.m.	Anchorage, Alaska	NIEA Conference, Anchorage Convention Center, Room TBD, Anchorage, AK 99501.
October 20, 2014	12 p.m.–3 p.m.	Webinar	Register at web link: <a href="https://dcma100.webex.com/dcma100/k2/j.php?MTID=tf8923c96f8b2d86dc23136f450688e77">https://dcma100.webex.com/dcma100/k2/j.php?MTID=tf8923c96f8b2d86dc23136f450688e77</a> .
October 22, 2014	12 p.m.–3 p.m.	Gallup, NM	Navajo Regional Office, Bureau of Indian Affairs, Conference Room 162, 301 West Hill Street, Gallup, NM 87301.
October 27, 2014	9 a.m.–12 p.m.	Billings, MT	Department of Interior Building, 2021 4th Avenue North, 4th Floor, Plenty Coup Room, Billings, MT 59101.
October 29, 2014	9 a.m.–12 p.m.	Bloomington, MN	Bureau of Indian Education, Associate Deputy Director's Office, 2001 Killebrew Dr., Ste. 122, Bloomington, MN 55425.

Following the first round of consultation, we will review the comments received and then prepare a proposed rule for publication in the **Federal Register**. This will open a second round of consultation and a formal comment period to allow for further refining of the proposed rule before we publish a final rule.

Dated: September 10, 2014.

**Kevin K. Washburn,**

*Assistant Secretary—Indian Affairs.*

[FR Doc. 2014–21966 Filed 9–12–14; 8:45 am]

**BILLING CODE 4310–W7–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG–2013–0040]

RIN 1625–AA87

#### Revision of Safety/Security Zone Regulations; 2014 Tampa Bay; Captain of the Port St. Petersburg Zone, FL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to consolidate three security zone regulations into one regulation. In addition, the Coast Guard is proposing to disestablish two safety zone regulations, and convert those safety zones into security zones for all navigable waterways of Big Bend, Boca Grande, Crystal River, East Bay, Hillsborough Bay, MacDill Air Force Base, Manbirtee Key, Old Port Tampa, Port Manatee, Port Tampa, Port St.

Petersburg, Port Sutton, Rattlesnake, and Weedon Island, FL. The purpose of these revisions is to ensure the security of vessels, facilities, and the surrounding areas within these zones. Entry into the area encompassed by these revised security zones is prohibited without permission of the Captain of the Port St. Petersburg or a designated representative.

**DATES:** Comments and related material must be received by the Coast Guard on or before October 15, 2014.

**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 LTJG Brett Sillman, Sector St. Petersburg Waterways Management Division, U.S. Coast Guard; telephone (813) 228–2191, email [brett.s.sillman@uscg.mil](mailto:brett.s.sillman@uscg.mil). If you have questions on viewing or submitting material to the

docket, call Cheryl Collings, Program Manager, Docket Operations, telephone (202) 366–9826.

#### **SUPPLEMENTARY INFORMATION:**

##### **Table of Acronyms**

DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of Proposed Rulemaking

#### **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