

General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jodi N. Anderson, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3680.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 9, 2006 (71 FR 6778), FDA announced the availability of the draft guidance document entitled "Class II Special Controls Guidance Document: Class II Special Controls Guidance Document: Intervertebral Body Fusion Device." Interested persons were invited to comment on the draft guidance document by May 10, 2006.

In the same **Federal Register** (71 FR 6710), FDA published a proposed rule to reclassify the intervertebral body fusion devices that contain bone grafting material, from class III (premarket approval) into class II (special controls), and retain those that contain any therapeutic biologic (e.g., bone morphogenetic protein) in class III. FDA received twelve comments on the proposed rule and draft guidance. Ten comments were on the proposed rule and are addressed in the final rule published elsewhere in this issue of the **Federal Register**. The two comments on the draft guidance suggested that FDA clarify its discussion of device sterilization and mechanical testing. FDA has updated the guidance to clarify its recommendations about these two topics.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on intervertebral body fusion devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Class II Special Controls Guidance Document: Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1540 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 31, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7-11235 Filed 6-11-07; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2007-27657]

Cooperative Research and Development Agreement: Command Center Decision Support Tools and Concept of Operations

AGENCY: Coast Guard, DHS.

ACTION: Notice of intent; request for public comments.

SUMMARY: The Coast Guard announces its intent to enter into a Cooperative Research and Development Agreement (CRADA) with Raytheon Corporation's Mission Innovation Group, to identify and investigate, via currently available modeling and simulation techniques, the potential of conceptual Next Generation, Command Center Decision Support Tools and Concept of Operations (CONOPS) for enhancing maritime security. The Coast Guard invites public comment on the proposed CRADA and also invites other non-Federal participants, who have the interest and capability to bring similar in-kind contributions to this type of research, to be considered for entry into similar CRADAs.

DATES: Comments and related material on the proposed CRADA, and preliminary inquiries about participation in CRADAs, must reach the Docket Management Facility on or before July 12, 2007. Proposals from other potential, non-Federal CRADA participants must reach the Docket Management Facility on or before December 10, 2007.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2007–27657 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Web Site:* <http://dms.dot.gov>.

(2) *Mail:* Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

(3) *Fax:* 202–493–2251.

(4) *Delivery:* Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

Potential, non-Federal CRADA participants may submit inquiries and CRADA proposals to James W. Gynther, U.S. Coast Guard Research and Development Center, 1082 Shennecossett Road, Groton, CT 06340–6048 (e-mail: James.W.Gynther@uscg.mil).

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, contact James W. Gynther, U.S. Coast Guard Research and Development Center, 1082 Shennecossett Road, Groton, CT 06340–6048, telephone 860–441–2858, e-mail:

James.W.Gynther@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–493–0402.

SUPPLEMENTARY INFORMATION:

Request for Comments

All comments received will be posted, without change, to <http://dms.dot.gov> and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's "Privacy Act" paragraph below.

Submitting comments: If you submit a comment, please include your name and address, identify the docket number for this notice (USCG–2007–27657) and give the reason for each comment. You may submit your comments by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8 by 11 inches, suitable for copying and electronic

filing. If you submit them by mail and would like to know that they reached the Docket Management Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments received during the comment period.

Viewing comments and documents: To view comments, go to <http://dms.dot.gov> at any time, click on "Simple Search," enter the last five digits of the docket number for this notice, and click on "Search." You may also visit the Docket Management Facility, West Building Ground Floor W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, 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 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 the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://dms.dot.gov>.

Cooperative Research and Development Agreements

Cooperative Research and Development Agreements, or CRADAs, are authorized by the Federal Technology Transfer Act of 1986 (Pub. L. 99–502, codified at 15 U.S.C. 3710a). A CRADA promotes the transfer of technology to the private sector for commercial use as well as specified research or development efforts that are consistent with the mission of the Federal parties to the CRADA. The Federal party or parties agree with one or more non-Federal parties to share research resources (but the Federal party does not contribute funding). The Department of Homeland Security (DHS), as an executive agency under 5 U.S.C. 105, is a Federal agency for purposes of 15 U.S.C. 3710a and may enter into a CRADA. DHS delegated its authority to the Commandant of the Coast Guard (see DHS Delegation No. 0160.1, para. 2.B(34)) and the Commandant has delegated his authority to the Coast Guard Research and Development Center.

CRADAs are not procurement contracts. Care is taken to ensure that CRADAs are not used to circumvent the contracting process. This typically includes advertisement in the **Federal Register** to give all potential CRADA partners opportunity to participate, remove any appearance of favoritism, and limit the risk of future litigation by

non-CRADA partners. CRADAs have a specific purpose and should not be confused with other types of agreements such as procurement contracts, grants, and cooperative agreements.

Goal of Proposed CRADA

Under the proposed agreement, the Coast Guard's Research and Development Center (USCG R&DC) would collaborate with non-Federal participants. Together, the R&DC and its CRADA participants would identify and investigate, via currently available modeling and simulation techniques, the potential of conceptual Next Generation, Command Center Decision Support Tools and CONOPS to enhance maritime security. This joint research would also provide additional understanding of the processes and support tools within USCG and other command centers, which have the responsibility to detect, assess, and interdict maritime threats within the coastal waters of a sovereign state.

The R&DC, with its CRADA participants, will create and employ a structured and collaborative test environment to evaluate concepts and technologies for Next Generation Command Center Decision Support Tools.

Party Contributions

We anticipate that the Coast Guard's contributions under the proposed CRADA will include the following:

(1) Provide candidate Command Center Decision Support Tool Concepts;
(2) Provide Command Center personnel to serve as (a) Subject Matter Experts during simulation environment and conceptual support tool development and (b) Test Subjects during the concept evaluation exercises; and

(3) Review of the CRADA partner's Draft Results Report after each concept evaluation exercise.

We anticipate that the non-Federal participants' contributions under the proposed CRADA will include the following:

(1) The provision of appropriate modeling and simulation environment(s) for evaluating conceptual Next Generation, Command Center Decision Support Tools;

(2) Development and execution of a modeling and simulation test plan(s);

(3) Analysis of modeling and simulation results;

(4) Development of a Draft CRADA Results Report after each concept evaluation exercise; and

(5) The provision to the U.S. Coast Guard Research and Development Center of all Final CRADA Results

Reports in electronic format suitable for distribution to other interested, qualified parties upon request.

Selection Criteria

The Coast Guard reserves the right to select for CRADA participants all, some, or none of the proposals in response to this notice. The Coast Guard will provide no funding for reimbursement of proposal development costs. Proposals (or any other material) submitted in response to this notice will not be returned. Proposals submitted are expected to be unclassified and have no more than four single-sided pages (excluding cover page and resumes). The Coast Guard will select proposals at its sole discretion on the basis of:

(1) How well they communicate an understanding of, and ability to meet, the proposed CRADA's goal; and

(2) How well they address the following criteria:

(a) Technical capability to support the non-Federal party contributions described; and

(b) Resources available for supporting the non-Federal party contributions described.

This is a technology transfer/development effort. Presently, the Coast Guard has no plan to procure the Next Generation, Command Center Decision Support technology being investigated under this CRADA. Since the goal of this CRADA is "to identify and investigate the potential of conceptual Next Generation, Command Center Decision Support Tools," and not to set future CG acquisition requirements for same, non-Federal CRADA partners will not be excluded from any future CG procurements based solely on their participation within this CRADA.

Special consideration will be given to small business firms/consortia, and preference will be given to business units located in the U.S.

Dated: May 29, 2007.

T.W. Jones,

CAPT, USCG, Commanding Officer, R&D Center.

[FR Doc. E7-11257 Filed 6-11-07; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Generic Clearance of Customer Service Surveys; OMB Control No. 1615-0077.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on March 27, 2007, at 72 FR 14288. The notice allowed for a 60-day public comment period. No comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until July 12, 2007. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, 3rd floor, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202-272-8352 or via e-mail at rfs.regs@dhs.gov, and to the OMB USCIS Desk Officer via facsimile at 202-395-6974 or via e-mail at kastrich@omb.eop.gov.

When submitting comments by e-mail please make sure to add OMB Control Number 1615-0077 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of existing information collection.

(2) *Title of the Form/Collection:* Generic Clearance of Customer Service Surveys.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* No Agency Form Number; File OMB-9. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. Individuals complete the customer service survey so that USCIS can determine the kind and quality of services customers want and expect, their level of satisfaction with existing services, and the type of services which they project may be required within a 3 to 5 year time frame.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 34,200 responses at 30 minutes (.50 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 17,100 annual burden hours.

If you have additional comments, suggestions, or need a copy of the information collection instrument, please contact Richard A. Sloan, Chief, Regulatory Management Division, U.S. Citizenship and Immigration Services, 111 Massachusetts Avenue, NW., 3rd Floor, Suite 3008, Washington, DC 20529; 202-272-8377.

Dated: June 6, 2007.

Richard Sloan,

Chief, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. E7-11269 Filed 6-11-07; 8:45 am]

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