petty officer who has been authorized by the Captain of the Port Baltimore to assist in enforcing the security zone described in paragraph (a) of this section.

(c) *Regulations.* (1) All persons are required to comply with the general regulations governing security zones found in 33 CFR 165.33.

(2) Entry into or remaining in this zone is prohibited unless authorized by the Coast Guard Captain of the Port Baltimore. Vessels already at berth, mooring, or anchor at the time the security zone is implemented do not have to depart the security zone. All vessels underway within this security zone at the time it is implemented are to depart the zone. The Captain of the Port Baltimore may, in his discretion, grant waivers or exemptions to this rule, either on a case-by-case basis or categorically to a particular class of vessel that otherwise is subject to adequate control measures.

(3) Persons desiring to transit the area of the security zone must first obtain authorization from the Captain of the Port Baltimore or his designated representative. To seek permission to transit the area, the Captain of the Port Baltimore and his designated representatives can be contacted at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Upon being hailed by a U.S. Coast Guard vessel, or other Federal, State, or local agency vessel, by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port Baltimore or his designated representative and proceed at the minimum speed necessary to maintain a safe course while within the zone.

(4) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State, and local agencies.

(d) *Enforcement period.* This section will be enforced from 4 a.m. on January 14, 2009, through 10 p.m. on January 25, 2009.

Dated: October 6, 2008.

Brian D. Kelley,

Captain, U.S. Coast Guard, Captain of the Port, Baltimore, Maryland.

[FR Doc. E8–25435 Filed 10–24–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 207, 235, and 252

RIN 0750–AF96

Defense Federal Acquisition Regulation Supplement; Protection of Human Subjects in Research Projects (DFARS Case 2007–D008)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to address requirements for the protection of human subjects involved in research projects. The proposed rule contains a clause for use in contracts that include or may include research involving human subjects.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before *December 26, 2008,* to be considered in the formation of the final rule.

ADDRESSES: You may submit comments, identified by DFARS Case 2007–D008, using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: dfars@osd.mil.* Include DFARS Case 2007–D008 in the subject line of the message.
- *Fax:* 703–602–7887.
- *Mail:* Defense Acquisition Regulations System, Attn: Mr. Mark Gomersall, OUSD (AT&L) DPAP (DARS), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062.
- *Hand Delivery/Courier:* Defense Acquisition Regulations System, Crystal Square 4, Suite 200A, 241 18th Street, Arlington, VA 22202–3402.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Gomersall, 703–602–0302.

SUPPLEMENTARY INFORMATION:

A. Background

This proposed rule addresses statutory and regulatory requirements for the ethical treatment of human subjects involved in research projects. The proposed rule contains a clause for use in contracts involving human subjects in research, to inform contractors of their responsibilities for compliance with 32 CFR Part 219; DoD Directive 3216.02; applicable DoD component policies; 10 U.S.C. 980; and, when applicable, Food and Drug Administration policies and regulations.

This proposed rule was subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

DoD does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the proposed rule is a reinforcement of existing requirements and obligations that apply with regard to the protection of human subjects involved in research projects. Therefore, DoD has not performed an initial regulatory flexibility analysis. DoD invites comments from small businesses and other interested parties. DoD also will consider comments from small entities concerning the affected DFARS subparts in accordance with 5 U.S.C. 610. Such comments should be submitted separately and should cite DFARS Case 2007–D008.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply, because the proposed rule does not contain any new information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 207, 235, and 252

Government procurement.

Michele P. Peterson,

Editor, Defense Acquisition Regulations System.

Therefore, 48 CFR Parts 207, 235, and 252 are proposed to be amended as follows:

1. The authority citation for 48 CFR Parts 207, 235, and 252 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 207—ACQUISITION PLANNING

2. Section 207.172 is added to read as follows:

207.172 Human research.

Any DoD component sponsoring research involving human subjects—

(a) Is responsible for oversight of compliance with 32 CFR Part 219, Protection of Human Subjects; and

(b) Must have a Human Research Protection Official, as defined in the clause at 252.235–70XX, Protection of Human Subjects, and identified in the DoD component's Human Research Protection Management Plan. This official is responsible for the oversight and execution of the requirements of the clause at 252.235–70XX and shall be identified in acquisition planning.

PART 235—RESEARCH AND DEVELOPMENT CONTRACTING

3. Section 235.072 is amended by adding paragraph (e) to read as follows:

235.072 Additional contract clauses.

* * * * *

(e) Use the clause at 252.235–70XX, Protection of Human Subjects, in solicitations and contracts that include or may include research involving human subjects in accordance with 32 CFR Part 219, DoD Directive 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.101(b).

The clause—

(1) Applies to solicitations and contracts awarded by any DoD component, regardless of mission or funding Program Element Code; and

(2) Does not apply to use of cadaver materials alone, which are not directly regulated by 32 CFR Part 219 or DoD Directive 3216.02, and which are governed by other DoD policies and applicable State and local laws.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

4. Section 252.235–70XX is added to read as follows:

252.235–70XX Protection of Human Subjects.

As prescribed in 235.072(e), use the following clause:

PROTECTION OF HUMAN SUBJECTS (XXX 2008)

(a) *Definitions.* As used in this clause—

(1) *Assurance of compliance* means a written assurance that an institution will comply with requirements of 32 CFR Part 219, as well as the terms of the assurance, which the Human Research Protection Official determines to be appropriate for the research supported by the Department of Defense (DoD) component (32 CFR 219.103).

(2) *Human Research Protection Official (HRPO)* means the individual designated by the head of the applicable DoD component and identified in the component's Human Research Protection Management Plan as the official who is responsible for the oversight and execution of the requirements of this clause, although some DoD components may use a different title for this position.

(3) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information (32 CFR 219.102(f)). For example, this could include the use of human organs, tissue, and body fluids from individually identifiable living human subjects as well as graphic, written, or recorded information derived from individually identifiable living human subjects.

(4) *Institution* means any public or private entity or agency (32 CFR 219.102(b)).

(5) *Institutional Review Board (IRB)* means a board established for the purposes expressed in 32 CFR Part 219 (32 CFR 219.102(g)).

(6) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements (32 CFR 219.102(h)).

(7) *Research* means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 32 CFR Part 219, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(d)).

(b) The Contractor shall oversee the execution of the research to ensure compliance with this clause. The Contractor shall comply fully with 32 CFR Part 219 and DoD Directive 3216.02, applicable DoD component policies, 10 U.S.C. 980 and, when applicable, Food and Drug Administration policies and regulations.

(c) The Contractor shall not commence performance of research involving human subjects that is covered under 32 CFR Part 219 or that meets exemption criteria under 32 CFR 219.101(b), or expend funding on such effort, until and unless the conditions of either the following paragraph (c)(1) or (c)(2) have been met:

(1) The Contractor furnishes to the HRPO, with a copy to the Contracting Officer, an assurance of compliance and IRB approval and receives notification from the Contracting Officer that the HRPO has approved the assurance as appropriate for the research under the Statement of Work and also that the HRPO has reviewed the protocol and accepted the IRB approval for compliance with the DoD component policies. The Contractor may furnish evidence of an existing assurance of compliance for acceptance by the HRPO, if an appropriate assurance has been approved in connection with previous research. The Contractor shall notify the Contracting Officer immediately of any suspensions or terminations of the assurance.

(2) The Contractor furnishes to the HRPO, with a copy to the Contracting Officer, a determination that the human research proposed meets exemption criteria in 32 CFR 219.101(b) and receives written notification from the Contracting Officer that the exemption is determined acceptable. The determination shall include citation of the exemption category under 32 CFR 219.101(b) and a rationale statement. In the event of a disagreement regarding the Contractor's furnished exemption determination, the HRPO retains final judgment on what research activities or classes of research are covered or are exempt under the contract.

(d) DoD staff, consultants, and advisory groups may independently review and inspect the Contractor's research and research procedures involving human subjects and, based on such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD procedures.

(e) Failure of the Contractor to comply with the requirements of this clause will result in the issuance of a stop-work order under Federal Acquisition Regulation clause 52.242–15 to immediately suspend, in whole or in part, work and further payment under this contract, or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the Contracting Officer.

(f) The Contractor shall include the substance of this clause, including this paragraph (f), in all subcontracts that may include research involving human subjects in accordance with 32 CFR Part 219, DoD Directive 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.101(b). This clause does not apply to subcontracts that involve only the use of cadaver materials.

(End of clause.)

[FR Doc. E8–25562 Filed 10–24–08; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 402

[FWS–R9–ES–2008–0093]

RIN 1018–AT50

DEPARTMENT OF COMMERE

National Marine Fisheries Service

50 CFR Part 402

[0808011023–81048–01]

RIN 0618–AX15

Interagency Cooperation Under the Endangered Species Act

AGENCIES: U.S. Fish and Wildlife Service, Interior; National Marine Fisheries Service, Commerce.

ACTION: Proposed rule; availability of Draft Environmental Assessment on proposed rule revising regulations implementing section 7 of the Endangered Species Act (ESA).