

(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]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 402

[FWS–R9–ES–2008–0093]

RIN 1018–AT50

DEPARTMENT OF COMMERCE

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).

SUMMARY: The United States Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (collectively, “Services” or “we”) previously proposed to amend regulations governing interagency cooperation under the Endangered Species Act of 1973 (Act) (73 FR 47868–47875; August 15, 2008).

The Services proposed these regulatory changes to improve the effectiveness and efficiency of the section 7(a)(2) consultation process. This **Federal Register** notice advises the public that we (FWS and NOAA) have prepared a Draft Environmental Assessment (Draft EA) under the National Environmental Policy Act (NEPA) that assesses the potential environmental effects of the proposed regulatory changes currently under consideration. The Draft EA is available for public review at the following Web site: <http://www.doi.gov/issues/esa.html>.

DATES: To ensure consideration, we must receive written comments by November 6, 2008.

ADDRESSES: Comments may be submitted in two ways: (1) Through the Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the instructions on the Web site for submitting comments; or (2) by U.S. mail or hand-delivery to Public Comment Processing, Attention: 1018-AT50, Division of Policy and Directives Management, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Suite 222, Arlington, VA 22203. We will not accept e-mail or faxes.

Our practice is to make comments, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home address from public disclosure, which we will honor to the extent allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public disclosure in their entirety.

FOR FURTHER INFORMATION CONTACT:

Office of the Assistant Secretary for Fish and Wildlife and Parks, 1849 C Street, NW., Washington, DC 20240, telephone: 202–208–4416; or James H. Lecky, Director, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910; telephone: 301–713–2332.

SUPPLEMENTARY INFORMATION: The Endangered Species Act of 1973, as amended (“Act”; 16 U.S.C. 1531 *et seq.*) provides that the Secretaries of the Interior and Commerce (the “Secretaries”) share responsibilities for implementing most of the provisions of the Act. Generally, marine species are under the jurisdiction of the Secretary of Commerce and all other species are under the jurisdiction of the Secretary of the Interior. With respect to agency consultation pursuant to Section 7 of the Act, authority to administer the Act has been delegated by the Secretary of the Interior to the Director of the FWS and by the Secretary of Commerce through the Administrator of the National Oceanic and Atmospheric Administration to the Assistant Administrator for NMFS.

On May 15, 2008, Secretary Kempthorne announced that he would propose common sense modifications to the existing regulations that implement this section of the ESA in order to provide greater clarity and certainty to the inter-agency consultation process. In the **Federal Register** notice proposing the regulatory modifications analyzed in this EA, the Services noted the importance of refining the ESA section 7(a)(2) consultation process to better set forth certain regulatory definitions and the applicability of this important interagency process.

While neither NEPA nor its implementing regulations require that EAs be made available for public comment, the Services’ have concluded that it is appropriate in this instance to provide an opportunity for public review and comment on the draft EA, as set forth above.

Dated: October 23, 2008.

David M. Verhey,

Acting Assistant Secretary, Fish and Wildlife and Parks, Department of the Interior.

Samuel D. Rauch,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service, National Oceanic and Atmospheric Administration.

[FR Doc. E8–25678 Filed 10–23–08; 4:15 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 080723890–81314–01]

RIN 0648–AX03

Atlantic Highly Migratory Species; Atlantic Commercial Shark Management Measures

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: This proposed rule would adjust quotas for the 2009 fishing season for sandbar sharks, non-sandbar large coastal sharks (LCS), small coastal sharks (SCS), and pelagic sharks managed under Amendment 2 to the 2006 Consolidated Atlantic Highly Migratory Species (HMS) Fishery Management Plan (FMP) based on any over- and/or underharvests experienced during the 2008 Atlantic commercial shark fishing season. The purpose of this proposed action is to provide advance notice of quotas for the Atlantic commercial shark fishery and address any over- and/or underharvests that may have occurred in the Atlantic shark fishery during the 2008 fishing season.

DATES: Written comments will be accepted until November 26, 2008.

ADDRESSES: You may submit comments, identified by 0648–AX03, by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal <http://www.regulations.gov>
- Fax: 301–713–1917, Attn: Karyl Brewster-Geisz
- Mail: 1315 East–West Highway, Silver Spring, MD 20910. Please mark the outside of the envelope “Comments on Proposed Rule for 2009 Atlantic Commercial Shark Fishing Season.”

Instructions: All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain