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DEPARTMENT OF DEFENSE

Defense Acquisitions Regulations System

48 CFR Parts 235, 237, and 252

RIN 0750-AI22

Defense Federal Acquisition Regulation Supplement; Animal Welfare (DFARS Case 2013-D038)

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

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to comply with the Department of Defense Instruction that addresses the use of animals in DoD programs.

DATES: Comment date: Comments on the proposed rule should be submitted in writing to the address shown below on or before **[Insert date 60 days after date of publication in the FEDERAL REGISTER]**, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2013-D038 using any of the following methods:

o Regulations.gov: <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by entering "DFARS Case 2012-D038" under the heading "Enter keyword or ID" and selecting "Search." Select the link "Submit a Comment" that

corresponds with "DFARS Case 2013-D038." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "DFARS Case 2012-D038" on your attached document.

- o E-mail: osd.dfars@mail.mil. Include DFARS Case 2013-D038 in the subject line of the message.
- o Fax: 571-372-6094.
- o Mail: Defense Acquisition Regulations System, Attn: Ms. Janetta Brewer, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301-3060.

Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Janetta Brewer, Defense Acquisition Regulations System, OUSD(AT&L)DPAP/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301-3060, Telephone 571-372-6104.

SUPPLEMENTARY INFORMATION:

I. Background

This rule proposes to revise DFARS 235.072, 237.1, and the clause at 252.235-7002, Animal Welfare, to be consistent with

the Department of Defense Instruction (DoDI) 3216.01 entitled "Use of Animals in DoD Programs," which governs DoD-supported research, development, test, and evaluation or training that uses vertebrate animals, and the acquisition of animals.

II. Discussion and Analysis

The rule proposes to prescribe inclusion of the clause at DFARS 252.235-7002 in solicitations and contracts involving research, development, test, and evaluation or training that uses live vertebrate animals. Contractors shall acquire and care for animals in accordance with the pertinent laws of the United States, the regulations of the Department of Agriculture, DoDI 3216.01, and agency implementing regulations. The rule also proposes to make contractor facilities available for inspection by the appropriate officials. It also adds DFARS 237.17X to address training that uses live vertebrate animals and to provide a cross-reference to DFARS 235.072.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563

emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. 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. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

The data obtained from the Office of Assistant Secretary of Defense for Research Development Animal Research Development Test & Evaluation Protection Programs shows an estimate of 50 new DoD Research, Development, Test, and Evaluation contracts awarded in Fiscal Year 2012 that involved animal testing. Forty eight of these contracts were awarded to small businesses entities, which could be impacted by this rule. However, any cost burden caused by this rule will be outweighed by the effect of the rule preventing cruelty to animals.

The rule does not add any new information collection requirements. The rule does not duplicate, overlap, or conflict with any other Federal rules. No alternatives were identified that will accomplish the objectives of the rule.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2013-D038), in correspondence.

V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 235, 237, and 252

Government procurement.

Amy G. Williams,

Deputy, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 235, 237, and 252 are proposed to be amended as follows:

1. The authority citation for parts 235, 237, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 235—RESEARCH AND DEVELOPMENT CONTRACTING

2. Amend section 235.072 by revising paragraph (a) to read as follows:

235.072 Additional contract clauses.

(a) Use the clause at 252.235-7002, Animal Welfare, or one substantially the same, in solicitations and contracts awarded involving research, development, test, and evaluation or training that uses live vertebrate animals.

* * * * *

PART 237—SERVICE CONTRACTING

3. Add section 237.17X to subpart 237.1 to read as follows:

237.17X Training that uses live vertebrate animals.

When contracting for training that will use live vertebrate animals, see 235.072.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

4. Revise section 252.235-7002 to read as follows:

252.235-7002 Animal Welfare.

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

ANIMAL WELFARE (DATE)

(a)(1) The Contractor shall register its research, development, test, and evaluation or training facility with the

Secretary of Agriculture in accordance with 7 U.S.C. 2136 and 9 CFR subpart C, and section 2.30, unless otherwise exempt from this requirement by meeting the conditions in 7 U.S.C. 2136 and 9 CFR parts 1 through 4 for the duration of the activity. The Contractor shall have its proposed animal use approved in accordance with Department of Defense Instruction (DoDI) 3216.01 by a DoD Component Headquarters Oversight Office. The Contractor shall furnish evidence of such registration and approval to the Contracting Officer before beginning work under this contract.

(2) The Contractor shall make its animals, and all premises, facilities, vehicles, equipment, and records that support animal care available during business hours and at other times mutually agreeable to the Contractor and United States Department of Agriculture office of Animal and Plant Health Inspection Service (USDA/APHIS) representative, personnel representing the DoD component oversight offices, as well as the Contracting Officer, to ascertain that the Contractor is compliant with 7 U.S.C. 2131-2159 and 9 CFR parts 1 through 4.

(b) The Contractor shall acquire animals in accordance with Department of Defense Instruction (DoDI) 3216.01, Use of Animals in DoD Programs (<http://www.dtic.mil/whs/directives/corres/pdf/321601p.pdf>).

(c) The Contractor agrees that the care and use of animals will conform with the pertinent laws of the United States,

regulations of the Department of Agriculture, and policies and procedures of the Department of Defense (see 7 U.S.C. 2131 et seq., 9 CFR subchapter A, parts 1 through 4, DoDI 3216.01, Army Regulation 40-33/SECNAVINST 3900.38C/AFMAN 40-401(I)/DARPAINST 18/USUHSINST 3203). The Contractor shall also comply with DoDI 1322.24 if this contract includes acquisition of training.

(d) The Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract for failure to comply with the requirements of paragraphs (a) through (c) of this clause.

(1) The suspension will stay in effect until the Contractor complies with the requirements.

(2) Failure to complete corrective action within the time specified by the Contracting Officer may result in termination of this contract and if applicable, removal of the Contractor's name from the approved vendor list for live animals used in medical training.

(e) The Contractor may request registration of its facility by contacting USDA/APHIS/AC, 4700 River Road, Unit 84, Riverdale, MD 20737-1234 or via the APHIS-Animal Care website at:

<http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare>.

(f) The Contractor shall include this clause, including this paragraph (f), in all subcontracts involving research, development, test, and evaluation or training that uses live vertebrate animals.

(End of clause)

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