ENVIRONMENTAL PROTECTION AGENCY

48 CFR Parts 1535 and 1552

[EPA–HQ–OARM–2016–0046; FRL 9941–86–OARM]

Environmental Protection Agency Acquisition Regulation; Institutional Oversight of Life Sciences Dual Use Research of Concern

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is issuing a direct final rule to amend the EPA Acquisition Regulation (EPAAR) to include a new solicitation provision and contract clause to implement the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (iDURC Policy). This direct final rule requires certain domestic institutions that receive contract funding from EPA to conduct or sponsor life sciences research and institutions outside of the United States that receive contract funding from EPA to conduct or sponsor research with the agents or toxins listed in the iDURC Policy, to review and communicate their research responsibly in accordance with the iDURC Policy.

DATES: This rule is effective on June 27, 2016 without further notice, unless EPA receives adverse comment by May 26, 2016. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OARM–2016–0046; FRL 9941–86–OARM at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Holly Hubbell, Policy, Training, and Oversight Division (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 202–564–1091; email address: *Hubbell.holly@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Direct Final Rule

EPA is publishing this rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comment as this final rule amends the EPAAR to add a new solicitation provision and contract clause for iDURC Policy compliance. The iDURC policy was already published in the **Federal Register** for comment on September 25, 2014. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. Any parties interested in commenting must do so at this time.

II. Applicability

The EPA is promulgating a solicitation provision and contract clause to implement the iDURC Policy. The solicitation provision and contract clause notify institutions of the need to comply, and to ensure that institutions subject to the iDURC Policy represent that they shall comply with the iDURC Policy prior to or upon contract award. Institutions within the United States that receive funding from EPA to conduct or sponsor life sciences research are subject to the iDURC Policy if they conduct or sponsor research involving any of the agents or toxins listed in the iDURC Policy, regardless of the funding source. Institutions outside of the United States are subject to the iDURC Policy if they receive funding from EPA to conduct or sponsor research with any agents or toxins listed in the iDURC Policy. Institutions that are subject to the iDURC Policy have a number of responsibilities—at a minimum, they are advised to train laboratory personnel involved in such projects and maintain records of that training, establish an institutional review process to assess the research for its potential to meet the definition of *dual use research of concern,* and if it meets the definition, ensure the research is conducted and communicated responsibly.

III. Submitting Comments

A. Do not submit CBI to EPA through the Web site *http://www.regulations.gov* or by email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI, and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

B. Tips for Preparing Your Comments. When submitting comments, see the commenting tips at: *http://www2.epa.gov/dockets/commenting-epa-dockets* and remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) Part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

C. Make sure to submit your comments by the comment period deadline identified.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

The information collection activities in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2530.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The iDURC Policy instructs institutions subject to the Policy train individuals within their institution that are conducting research involving any of the agents or toxins identified in the Policy. Additionally, institutions are to maintain records of that training. EPA is submitting an information collection request for these recordkeeping requirements. EPA may collect the training records to ensure EPA is in compliance with the Policy, and that institutions receiving EPA funding are appropriately complying as well. EPA does not expect any issues of confidentiality to be relevant to this information collection.

Respondents/affected entities: Private Industry; Federal Government (in the form of government-owned/contractor-operated laboratories).

Respondent's obligation to respond: Mandatory (48 CFR Chapter 15, Part 52 and Part 35).

Estimated number of respondents: 12 to 24.

Frequency of response: Only once, or as necessary.

Total estimated burden: 36 to 64 hours per year.

Total estimated cost: $1,440 to $4,320.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

C. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et. seq.

This action is not subject to the RFA. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule pertains to contracts, which the APA expressly exempts from notice and comment rulemaking requirements under 5 U.S.C. 553(a)(2).

D. Unfunded Mandates Reform Act

This action does not contain any unfunded mandates as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. No substantial compliance costs are expected. There will be no impact on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28335 (May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act of 1995 (NTTAA)

This action does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment in the general public.

K. Congressional Review Act

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

48 CFR Part 1535

Environmental protection, Dual use research, Institutional oversight, Life sciences, Research and development.

48 CFR Part 1552

Environmental protection, Dual use research, Institutional oversight, Life sciences, Research and development.

Dated: April 19, 2016.

John R. Bashista,

Director, Office of Acquisition Management.

For the reasons stated in the preamble, 48 CFR parts 1535 and 1552 are amended as set forth below:

PART 1535—RESEARCH AND DEVELOMENT CONTRACTING

■ 1. The authority citation for part 1535 continues to read as follows:

Authority: Sec. 205(c), 63 Stat. 390, as amended, 40 U.S.C. 486(c).

■ 2. Amend section 1535.007 by adding paragraph (c) to read as follows:

1535.007 Solicitations.

* * * * *

(c) Contracting officers shall insert 48 CFR 1552.235–81—''Notice of Institutional Oversight of Life Sciences Dual Use Research of Concern-Representation'' when notified in the Advance Procurement Plan (APP) or by an EPA funding/requesting office, in accordance with the Institutional Oversight of Life Sciences Dual Use Research of Concern (iDURC) EPA Order 1000.19—''Policy and Procedures for Managing Dual Use Research of Concern,'' in solicitations that will result in a contract under which EPA funding will be used by the recipient to conduct or sponsor ''life sciences research''.

■ 3. Amend section 1535.007–70 by adding paragraph (h) to read as follows:

1535.007–70 Contract clauses.

* * * * *

(h) Contracting officers shall insert 48 CFR 1552.235–82—''Institutional

Oversight of Life Sciences Dual Use Research of Concern'' into all solicitations containing 48 CFR 1552.235–81 and in existing contracts that are bilaterally modified at the request of an EPA funding/requesting office in accordance with EPA Order 1000.19.

PART 1552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. The authority citation for part 1552 continues to read as follows:

Authority: 5 U.S.C. 301 as amended, 40 U.S.C. 486(c); and 41 U.S.C. 418b.

■ 5. Add section 1552.235–81 to read as follows:

1552.235–81 Institutional oversight of life Sciences dual use research of concern—representation.

As prescribed in 1535.007(c), insert the following solicitation provision:

Institutional Oversight of Life Sciences Dual Use Research of Concern—Representation (JUNE 2016)

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

Institution means any government agency (Federal, State, tribal, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity conducting research.

Life Sciences research means a systematic investigation designed to develop or contribute to generalizable knowledge involving living organisms (*e.g.,* microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, microbiology, synthetic biology, virology, molecular biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches to understanding life at the level of ecosystems, populations, organisms, organs, tissues, cells, and molecules. Life sciences research does not include routine product testing, quality control, mapping, collection of general-purpose statistics, routine monitoring and evaluation of an operational program, observational studies, and the training of scientific and technical personnel.

(b) *Representation.* By submission of its offer or quotation, the Offeror represents that if it is:

(1) An institution within the United States that conducts or sponsors life sciences research that involves one or more of the agents or toxins listed in section 6.2.1 of the ''United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern'' (*iDURC Policy*), even if the research is not supported by United States Government funds; or

(2) An institution outside of the United States that receives funds to conduct or sponsor research that involves one or more of the agents or toxins listed in section 6.2.1 of the *iDURC Policy*; then the Offeror will comply with the *iDURC Policy.*

(c) *Resources.* Information about dual use research in the life sciences, as well as specific details on the *iDURC Policy* can be found on the U.S. Department of Health and Human Services *Dual Use Research of Concern* page: *http://www.phe.gov/s3/dualuse/Pages/default.aspx.*

(End of Provision)

■ 6. Add 1552.235–82 to read as follows:

1552.235–82 Institutional oversight of life sciences dual use research of concern.

As prescribed in 1535.007–70(h), insert the following contract clause:

Institutional Oversight Of Life Sciences Dual Use Research Of Concern (JUNE 2016)

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

Institution means any government agency (Federal, State, tribal, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity conducting research.

Life Sciences research means a systematic investigation designed to develop or contribute to generalizable knowledge involving living organisms (*e.g.,* microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, microbiology, synthetic biology, virology, molecular biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches to understanding life at the level of ecosystems, populations, organisms, organs, tissues, cells, and molecules. Life sciences research does not include routine product testing, quality control, mapping, collection of general-purpose statistics, routine monitoring and evaluation of an operational program, observational studies, and the training of scientific and technical personnel.

(b) *Compliance.* The Contractor agrees that it shall comply with the ''United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern'' (*iDURC Policy*) during the period of performance of this contract, including all option periods or other extensions, if the Contractor:

(1) Is an institution within the United States that conducts or sponsors, or begins to conduct or sponsor life sciences research that involves one or more of the agents or toxins listed in Section 6.2.1 of the *iDURC Policy,* even if the research is not supported by United States Government funds; or

(2) Is an institution outside the United States that receives funds through this contract to conduct or sponsor research that involves one or more of the agents or toxins listed in Section 6.2.1 of the *iDURC Policy.*

(c) *Resources.* Information about dual use research in the life sciences as well as specific details on the *iDURC Policy* can be found on the U.S. Department of Health and Human Services *Dual Use Research of Concern* page: *http://www.phe.gov/s3/dualuse/Pages/default.aspx.*

(End of clause)

[FR Doc. 2016–09601 Filed 4–25–16; 8:45 am]

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NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1815, 1842, and 1852

NASA Federal Acquisition Regulation Supplement

AGENCY: National Aeronautics and Space Administration.

ACTION: Technical amendments.

SUMMARY: NASA is making technical amendments to the NASA FAR Supplement (NFS) to provide needed editorial changes.

DATES: *Effective:* April 26, 2016.

FOR FURTHER INFORMATION CONTACT: Manuel Quinones, NASA, Office of Procurement, Contract and Grant Policy Division, via email at *manuel.quinones@nasa.gov,* or telephone (202) 358–2143.

SUPPLEMENTARY INFORMATION:

I. Background

As part NASA's retrospective review of existing regulations, NASA is conducting periodic reviews of NASA FAR Supplement (NFS) to ensure the accuracy of information and guidance disseminated to the acquisition community This rule corrects typographical errors as well as inadvertent omissions from past rulemaking actions. A summary of changes follows:

- Section 1815.408–70(c) is revised to correct a typographical error.
- Subpart 1842.70 is revised to reinsert sections 1842.7002 and 1842.7003 inadvertently removed by amendatory instruction 2 of final rule 80 FR 52644 issued on September 1, 2015.
- Sections 1852.215–79, 1852.217–72, 1852.223–73 (ALTERNATE I), 1852.223–75, 1852.227–88, 1852.228–71, 1852.239–70, 1852.245–73, 1852.245–82, 1852.245–83, 1852.246–73 are revised to correct their prescription references.