



ENVIRONMENTAL PROTECTION AGENCY

48 CFR Part 1503 and 1552

[EPA-HQ-OARM-2015-0657; FRL- 10012-65-OMS]

Environmental Protection Agency Acquisition Regulation (EPAAR); Scientific Integrity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is issuing a final rule to address scientific integrity requirements in the creation of a contract clause for inclusion in solicitations and contracts when the Contractor may be required to perform, communicate, or supervise scientific activities or use scientific information to perform advisory and assistance services. This clause will complement the EPA's Scientific Integrity Policy to ensure all scientific work developed and used by the Government is accomplished with scientific integrity.

DATES: This final rule is effective on **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. **EPA-HQ-OARM-2015-0657; FRL- 10012-65-OMS**. All documents in the docket are listed on the <http://www.regulations.gov> web site. Although listed in the index, some information is not publicly available, e.g., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Holly Hubbell, Policy, Training, and Oversight Division, Acquisition Policy and Training Branch (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. Background

The EPA's Scientific Integrity Policy is based on a Presidential Memorandum for the Heads of Executive Departments and Agencies, Subject Line: Scientific Integrity, Dated: March 9, 2009. The memorandum directs the Director of the Office of Science and Technology Policy (OSTP) to work with the Office of Management and Budget (OMB) and agencies to develop policies to ensure all scientific work developed and used by the Government is done so with scientific integrity. OSTP issued further guidance in the Scientific Integrity memorandum dated December 17, 2010.

This final rule requires EPA contractors to ensure that all personnel within their organization, subcontractors and consultants, that perform, communicate, or supervise scientific activities or use scientific information to perform advisory and assistance services under their specified contracts with EPA, have read and understand their compliance responsibilities regarding the EPA's Scientific Integrity Policy.

The proposed rule was published in the Federal Register (83 FR 48581-48584) on September 26, 2018, providing for a 60-day comment period. Interested parties were afforded the opportunity to participate in the making of this rule.

II. Public Comments on the Proposed Rule

The following is a summary of the public comments received on the proposed rule and the EPA's response to these comments.

1. *Comment:* Several commenters expressed concerns about the costs of making scientific information available online and also that requiring scientific information to be available online could compromise confidentiality of the scientific information.

Response: The proposed clause requirement at EPAAR § 1552.203-72(c)(1)(x) to make scientific information available online has been deleted.

2. *Comment:* One commenter suggested that the EPA inform contractors of their need to evaluate computer models in adherence to the EPA Models Guidance.

Response: This requirement is described in general terms because listing specific guidance may not be all-inclusive or the guidance may change in the future.

3. *Comment:* One commenter noted that preventing intimidation or coercion of scientists to alter their scientific findings is a crucial element of the EPA's Scientific Integrity Policy and proposed adding the terms "*attempted or actual* intimidation or coercion" to the clause to clarify that both attempted or actual intimidation or coercion would be a loss of scientific integrity.

Response: The EPA agrees and has added the terms "attempted or actual", defining intimidation or coercion to EPAAR 1552.203-72(c)(2)(i).

4. *Comment:* One commenter expressed concern that the proposed rule does not explicitly address whether an individual employee of a contractor has an obligation to report loss or potential loss of scientific integrity to the contracting officer, his or her supervisor, or both, or to whom and how to report.

Response: In this final rule, the EPA does clarify in paragraph (d) of the clause that an employee of the contractor must report any loss or potential loss of scientific integrity in writing to the contractor who must communicate it to the EPA.

5. *Comment:* Concern was expressed that there is no explicit mechanism for resolving a dispute if the contractor, or an individual contractor employee, feels that the contracting officer

has reached an incorrect conclusion or is applying an inappropriate remedy with regard to a loss of scientific integrity.

Response: The EPA agrees that a party who has been accused of a loss of scientific integrity should be able to respond to the Agency's decision regarding the loss of scientific integrity and the remedy. Section (e)(5) of the clause has been edited to state that if the party who has been accused of a loss of scientific integrity feels that the Agency has reached an incorrect conclusion or the Agency has applied an inappropriate remedy, that party may provide a written response to the Contracting Officer, Scientific Integrity Official, and/or Office of Inspector General (OIG).

6. *Comment:* One commenter noted that it was not clear if the proposed rule intended to cover a situation where a contractor, or employee of a contractor, became aware of a loss or suspected loss of scientific integrity by an EPA employee, but suggested the rule should cover this situation. Further, the commenter suggested such a loss or suspected loss of scientific integrity by an EPA employee be reported to someone other than the contracting officer or the contracting officer's representative.

Response: EPA agrees and has revised paragraph (d) of the clause to clarify that the final rule addresses the situation where a contractor, or employee of a contractor, becomes aware of an actual or suspected loss of scientific integrity by an EPA employee. Language has been added to state that, if the actual or potential loss of scientific integrity is by an EPA employee, the contractor may inform the EPA's Scientific Integrity Official in addition to the contracting officer or contracting officer's representative. An employee of the contractor must report any actual or potential loss of scientific integrity to the contractor who must communicate it to the EPA.

7. *Comment:* One commenter stated that the two clauses need to be further emphasized to

prevent bias during scientific inquiry.

Response: To clarify, there is only one clause, EPAAR § 1552.203-72. EPAAR § 1503.1071 is the prescription for the use of the clause. The EPA believes that there is sufficient emphasis in the clause requirements to prevent bias during scientific inquiries. Additionally, contractors are legally bound to adhere to all terms of the clause, if it is included in their contract(s).

8. *Comment:* One commenter noted that the proposed rule requires EPA contractors to adhere to the standards set forth in the EPA's Scientific Integrity Policy, but the commenter was concerned that contractors cannot comply with standards if they don't know about them. The commenter suggested additional language be added to the clause noting all the guidance upon which the EPA's Scientific Integrity Policy is built.

Response: The EPA believes such additional language is not necessary. Contractors are notified of the scientific integrity requirements, which includes a link to the EPA's Scientific Integrity Policy, when this clause is included in the solicitation and contract.

9. *Comment:* One commenter suggested that the rule should be designated as "significant" under Executive Order (EO) 12866, as other agencies may not require contractor compliance with the EPA's Scientific Integrity Policy, which could create serious inconsistencies when the EPA is working with the other agencies on matters of interest to both agencies. The commenter was also concerned that contractor adherence to the EPA's Scientific Integrity Policy could also raise legal or policy issues arising out of legal mandates, the President's priorities, or EO 12866.

Response: The Office of Management and Budget determines if a rule is a significant regulatory action. The EPA's Scientific Integrity Policy is based on OSTP guidance and developed in conjunction with OMB's approval.

10. *Comment:* One commenter expressed concern that the proposed rule provides that it is the

contracting officer who decides when the Scientific Integrity clause applies and when it should be inserted in a contract. The commenter was concerned that while some examples of activities that may trigger the rule's application are listed in the clause, the list of examples is not exhaustive, and the applicability may be misinterpreted by the contractor officer.

Response: The EPA agrees that the technical experts regarding applicability would be the EPA program office. Therefore, this final rule adds language so the contracting officer will consult with the program office regarding inclusion of the Scientific Integrity clause in a contract.

11. *Comment:* One commenter proposed adding language requiring contractors to use the most refined species location maps and best actual sampling and test data available.

Response: The EPA believes this language is redundant to what is already stated in the clause § 1552.203-72(c)(1)(i), which states the contractor agrees to produce scientific products of the highest quality, rigor and objectivity.

12. *Comment:* Several respondents that provided comments expressed their support of the scientific integrity requirement for contractors.

Response: EPA appreciates the support of the respondents.

III. Final Rule

The final rule amends FAR Part 1503—Improper Business Practices and Personal Conflicts of Interests, Subpart 1503.10—Contractor Code of Business Ethics and Conduct, by adding EPAAR § 1503.1070 - *Scientific integrity* and 1503.1071 - *Contract clause*. FAR Part 1552-Solicitation Provisions and Contract Clauses is amended by adding EPAAR clause §1552.203-72 - *Scientific Integrity*.

1. EPAAR § 1503.1070 explains the basis for the subsection.
2. EPAAR § 1503.1071 establishes the prescription for use of EPAAR clause §1552.203-72 in

all solicitations and contracts when the contractor may be required to perform, communicate, or supervise scientific activities, or use scientific information to perform advisory and assistance services.

3. EPAAR § 1552.203-72 – *Scientific Integrity* clause states the applicability, term definitions as used in this clause, compliance requirements, reporting requirements, if an actual or suspected loss of scientific integrity is detected, and potential remedies.

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.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

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.*

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute; unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impact of this final rule on small entities, “small entity” is defined as:

(1) a small business that meets the definition of a small business found in the Small Business Act and codified at 13 CFR § 121.201; (2) a small governmental jurisdiction that is a government of

a city, county, town, school district or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. After considering the economic impacts of this rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, because the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives “which minimize any significant economic impact of the proposed rule on small entities” 5 U.S.C. §§ 503 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all the small entities subject to the rule. This action establishes a new EPAAR clause that will not have a significant economic impact on a substantial number of small entities. We continue to be interested in the potential impacts of the rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, Local, and Tribal governments and the private sector. This rule contains no Federal mandates (under the regulatory provisions of the Title II of the UMRA) for State, Local, and Tribal governments or the private sector. The rule imposes no enforceable duty on any State, Local or Tribal governments or the private sector. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure “meaningful and timely input by State and Local officials in the development of regulatory policies that have federalism implications. “Policies that have federalism implications” is defined in the Executive Order to include regulations that 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.” This rule 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

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” This rule does not have tribal implications as specified in Executive Order 13175.

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

Executive Order 13045, entitled “Protection of Children from Environmental Health and Safety Risks” (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be economically significant as defined under EO 12886, and (2) concerns an environmental health or safety risk that may have a proportionate effect on children. This rule is not subject to EO 13045 because it is not an economically significant rule as defined by Executive Order 12866,

and because it does not involve decisions on environmental health or safety risks.

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

This action is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use” (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)

Section 12(d) (15 U.S.C. § 272 note) of the National Technology Transfer and Advancement Act of 1995, Public Law No. 104-113, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-

income populations in the United States. EPA has determined that this proposed 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 in 48 CFR Parts 1503 and 1552: Environmental protection, Government procurement, Antitrust, Conflict of interest, Reporting and recordkeeping requirements.

Kimberly Patrick,
Director,
Office of Acquisition Solutions.

For the reasons stated in the preamble, EPA amends 49 CFR parts 1503 and 1552 as follows:

PART 1503—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTERESTS

1. The authority citation for part 1503 is revised to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 1707.

2. Add section 1503.1070 to read as follows:

1503.1070 Scientific integrity.

The EPA's Scientific Integrity Policy is based on a Presidential Memorandum for the Heads of Executive Departments and Agencies, Subject Line: Scientific Integrity, Dated: March 9, 2009. The memorandum directs the Director of the Office of Science and Technology Policy (OSTP) to work with the Office of Management and Budget (OMB) and agencies to develop policies to ensure all scientific work developed and used by the Government is done with scientific integrity. OSTP issued further guidance in the Scientific Integrity memorandum dated December 17, 2010. This section and clause complement the EPA's Scientific Integrity Policy.

3. Add section 1503.1071 to read as follows:

1503.1071 Contract clause.

Contracting Officers, with advisement from the program office, must insert the contract clause at 1552.203-72 - *Scientific Integrity*, in solicitations and contracts when the Contractor may be required to perform, communicate, or supervise scientific activities, or use scientific information to perform advisory and assistance services. Examples of such scientific activities include, but are not limited to, computer modeling, economic analysis, field sampling, laboratory experimentation, demonstrating new technology, statistical analysis, and writing a review article on a scientific issue.

PART 1552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

4. The authority citation for part 1552 is revised to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 1707.

5. Add section 1552.203-72 to read as follows:

1552.203-72 Scientific integrity.

As prescribed in § 1503.1071 , insert the following clause:

SCIENTIFIC INTEGRITY (MONTH YEAR)

(a) *Applicability.* This contract will require the Contractor to perform, communicate, or supervise scientific activities or use scientific information to perform advisory and assistance services. When performing, communicating, supervising, or utilizing scientific activities or scientific information, the Contractor must adhere to the EPA's Scientific Integrity Policy.

(b) *Definitions.* The following definitions apply:

Advisory and assistance services (see 48 CFR 2.101).

Scientific activities means those activities leading to the systematic knowledge of the physical or material world, largely consisting of observation and experimentation. It also includes the supervision, utilization, and communication of these activities.

Scientific information means factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes any communication or representation of knowledge, such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page but does not include the provision of hyperlinks on a web page to information that others disseminate. This definition excludes opinions, where the agency's presentation makes clear that

an individual's opinion, rather than a statement of fact or of the agency's findings and conclusions, is being offered.

Scientific Integrity means the adherence to professional values and practices, that is, the codes of ethics and behaviors in the scientists' fields of study, when conducting, supervising, communicating, and utilizing the results of science and scholarship. It ensures objectivity, clarity, reproducibility, and utility. It also provides insulation from bias, fabrication, falsification, plagiarism, improper outside interference, and censorship.

(c) *Compliance with policy.* Prior to beginning performance under this contract, the Contractor must ensure that all personnel within their organization, including subcontractors and consultants, that perform, communicate, or supervise scientific activities, or use scientific information to perform advisory and assistance services under this contract, have read and understand their compliance responsibilities with the EPA's Scientific Integrity Policy. This requirement applies to any personnel that will supervise, conduct, utilize, or communicate scientific activities or scientific information. Examples of such scientific activities include, but are not limited to, computer modeling, economic analysis, field sampling, laboratory experimentation, demonstrating new technology, statistical analysis, and writing a review article on a scientific issue.

(1) Consistent with the objective of promoting a culture of scientific integrity and transparency, as discussed in the EPA's Scientific Integrity Policy, the Contractor agrees to:

(i) Produce scientific products of the highest quality, rigor, and objectivity, by adhering to applicable EPA information quality policy, quality assurance policy, and peer review policy;

(ii) Prohibit suppressing, altering, or otherwise impeding the timely release of scientific findings or conclusions;

(iii) Adhere to the *Peer Review Handbook*, current edition, for the peer review of scientific and technical work products generated through this contract;

(iv) Act honestly and refrain from acts of research misconduct, including publication or reporting, as described in EPA Order 3120.5 Policy and Procedures for Addressing Research Misconduct. Research misconduct does not include honest error or differences of opinion;

(v) Require that reviews of the content of a scientific product be based only on scientific quality considerations, e.g., the methods used are clear and appropriate, the presentation of results and conclusions is impartial;

(vi) Ensure scientific findings are generated and disseminated in a timely and transparent manner, including scientific research performed by subcontractors and consultants who assist with developing or applying the results of scientific activities;

(vii) Include an explication of underlying assumptions, accurate contextualization of uncertainties, and a description of the probabilities associated with both optimistic and pessimistic projections when communicating scientific findings, if applicable;

(viii) Document the use of independent validation of scientific methods; and

(ix) Document any independent review of the Contractor's scientific facilities and testing activities, as occurs with accreditation by a nationally or internationally recognized sanctioning body.

(2) To assure protection of Contractor staff supported by this contract, consistent with the objectives described in the EPA's Scientific Integrity Policy, the Contractor agrees to:

(i) Prohibit attempted or actual intimidation or coercion of scientists to alter scientific data, findings, or professional opinions or non-scientific influence of scientific advisory boards.

In addition, the Contractor agrees to inform its employees, subcontractors, and consultants,

including scientists and managers, of their responsibility not to knowingly misrepresent, exaggerate, or downplay areas of scientific uncertainty; and

(ii) Prohibit retaliation or other punitive actions toward employees who uncover or report allegations of scientific and research misconduct, or who express a differing scientific opinion. The Contractor must afford employees who have allegedly engaged in scientific or research misconduct the due process protections provided by law, regulation, and applicable collective bargaining agreements, prior to any action. The Contractor must ensure that all employees, subcontractors, and consultants are familiar with these protections and avoid the appearance of retaliatory actions.

(d) *Loss of Scientific Integrity*. If during performance of this contract the Contractor becomes aware of an actual or suspected loss of scientific integrity, the Contractor must immediately inform the Contracting Officer and the Contracting Officer's Representative with a description of the actual or suspected issue in writing. If the actual or suspected loss of scientific integrity is by an EPA employee, the Contractor may inform the Agency's Scientific Integrity Official, in addition to the Contracting Officer and Contracting Officer's Representative. The Contractor must ensure that its employees are aware of their responsibility to immediately report any actual or suspected loss of scientific integrity to the Contractor, who must communicate it to the EPA in writing. The Contracting Officer and the Contracting Officer's Representative must consult with the Agency's Scientific Integrity Official on all issues related to an actual or suspected loss of scientific integrity under this contract and with the EPA Office of Inspector General (OIG), in accordance with *EPA Order 3120.5 Policy and Procedures for Addressing Research Misconduct*, on all issues related to research misconduct. The Agency's Scientific Integrity Official and/or OIG must advise the Contracting Officer and Contracting Officer's Representative on the appropriate remedy for any actual or suspected loss of scientific integrity.

The Contractor bears the primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred under the contract in association with its own institution. However, the EPA retains the ultimate oversight authority for the EPA-supported research. The Contractor must take the actions required as described in EPA Order 3120.5 *Policy and Procedures for Addressing Research Misconduct* when research misconduct is suspected or found under its contract.

(e) *Remedies*. The Contracting Officer in consultation with the Scientific Integrity Official and OIG, if applicable, will make the final determination on any remedy to an actual or suspected loss of scientific integrity. Potential remedies include:

(1) Acceptance of the Contractor's proposed mitigation plan to the scientific integrity issue;

(2) Acceptance of an alternate mitigation plan negotiated by the parties listed in the first paragraph of this section;

(3) Termination for convenience, in whole or in part, if no mitigation plan will adequately resolve the actual or suspected loss of scientific integrity; or

(4) Termination for default or cause, in whole or in part, if the Contractor was aware of an actual or suspected loss of scientific integrity under this contract and did not disclose it or misrepresented relevant information to the EPA. Additionally, the Government may debar or suspend the Contractor from Government contracting or pursue other remedies as may be permitted by law or this contract.

(5) *Opportunity to Respond* - If the party who has been accused of a loss of scientific integrity feels that the Agency has reached an incorrect conclusion or the Contracting Officer has

applied an inappropriate remedy, the party may provide a written response to the Contracting Officer, Scientific Integrity Official, and/or OIG.

(f) *Subcontractors and Consultants.* The Contractor agrees to insert language in any subcontract or consultant agreement placed hereunder which must conform substantially to the language of this clause, including this paragraph (f), unless otherwise authorized in advance in writing by the Contracting Officer.

(g) *Additional Resources.* For more information about the EPA's Scientific Integrity Policy, an introductory video can be accessed at: <https://youtu.be/FQJCy8BXXq8>. A training video is available at: <https://youtu.be/Zc0T7fooot8>.

(End of clause)