

§ 5502.105 Agency procedures.

(a) The designated agency ethics official or, with the concurrence of the designated agency ethics official, each of the separate agency components of HHS listed in § 5501.102(a) of this chapter may prescribe procedures for the submission and review of each report filed under this part. These procedures may provide for filing extensions, for good cause shown, totaling not more than 90 days.

(b) For good cause, the designated agency ethics official may extend the reporting deadlines for reports required under this part during the initial implementation phase for any reporting requirement, without regard to the 90 day maximum specified in paragraph (a) of this section.

■ 3. Amend § 5502.106 by revising paragraph (c) to read as follows:

§ 5502.106 Supplemental disclosure of prohibited financial interests applicable to employees of the Food and Drug Administration and the National Institutes of Health.

* * * * *

(c) *Report of prohibited financial interests.*—(1) *New entrant employees.* A new FDA employee, other than a public filer or a confidential filer, shall report in writing within 30 days after entering on duty with the FDA any prohibited financial interest held upon commencement of employment with the agency. A new NIH employee, other than a public filer or a confidential filer, who enters on duty at the NIH after February 3, 2005, and before September 4, 2005, shall report in writing on or before October 3, 2005, any prohibited financial interest held upon commencement of employment with the agency. A new NIH employee, other than a public filer or a confidential filer, who enters on duty at the NIH on or after September 4, 2005, shall report in writing within 30 days after entering on duty with the NIH any prohibited financial interest held upon commencement of employment with the agency.

(2) *Reassigned employees.* An employee of a separate agency component other than the FDA or of the remainder of HHS who is reassigned to a position at the FDA shall report in writing within 30 days of entering on duty with the FDA any prohibited financial interest held on the effective date of the reassignment to the agency. An employee of a separate agency component other than the NIH or of the remainder of HHS who is reassigned to a position at the NIH after February 3, 2005, and before September 4, 2005, shall report in writing on or before

October 3, 2005, any prohibited financial interest held on the effective date of the reassignment to the agency. An employee of a separate agency component other than the NIH or of the remainder of HHS who is reassigned to a position at the NIH on or after September 4, 2005, shall report in writing within 30 days of entering on duty with the NIH any prohibited financial interest held on the effective date of the reassignment to the agency.

(3) *Incumbent employees.* An incumbent employee of the FDA who acquires any prohibited financial interest shall report such interest in writing within 30 days after acquiring the financial interest. An incumbent employee of the NIH who acquires any prohibited financial interest after February 3, 2005, and before September 4, 2005, shall report such interest in writing on or before October 3, 2005. An incumbent employee of the NIH who acquires any prohibited financial interest on or after September 4, 2005, shall report such interest in writing within 30 days after acquiring the financial interest. An incumbent employee on duty at the NIH on February 3, 2005, shall report in writing on or before October 3, 2005, any prohibited financial interest held on February 3, 2005.

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DEPARTMENT OF ENERGY

10 CFR Parts 600 and 733

48 CFR Parts 935, 952 and 970

RIN 1901-AA89

Policy on Research Misconduct

AGENCY: Department of Energy.

ACTION: Notice of interim final rulemaking and opportunity for comment.

SUMMARY: The Department of Energy (DOE) is publishing an interim final general statement of policy and interim final financial assistance and procurement requirements to implement the government-wide Federal Policy on Research Misconduct. These interim final rules are designed to protect the integrity of research and development funded by DOE.

DATES: The effective date is July 28, 2005. Written comments must be received on or before the close of business August 29, 2005.

ADDRESSES: Comments (5 copies) should be addressed to: Christine Chalk, SC-5,

U.S. Department of Energy, Office of Science, Room 3H-051, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Christine Chalk at 202-586-7203 (*Christine.Chalk@science.doe.gov*).

SUPPLEMENTARY INFORMATION:

I. Background.

II. Discussion of the General Statement of Policy and Standard Requirements.

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A. Review Under Executive Order 12866.

B. Review Under Executive Order 12988.

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D. Review Under the Paperwork Reduction Act.

E. Review Under the National Environmental Policy Act.

F. Review Under Executive Order 13132.

G. Review Under The Unfunded Mandates Reform Act of 1995.

H. Review Under the Treasury and General Government Appropriations Act, 1999.

I. Review Under the Treasury And General Government Appropriations Act, 2001.

J. Review Under the Small Business Regulatory Enforcement Fairness Act.

I. Background

In 1996, the White House Office of Science and Technology Policy (OSTP) began the process of formulating a uniform government-wide Federal policy on research misconduct. OSTP published a proposed policy on research misconduct in the **Federal Register** at 64 FR 55722, October 14, 1999, and published the final policy at 65 FR 76260, December 6, 2000 (Federal Policy). The Federal Policy is available on the Office of Science Web site at <http://www.sc.doe.gov/misconduct/finalpolicy.pdf>.

The objective of the Federal Policy is to create a uniform policy framework for Federal agencies for the handling of allegations of misconduct in federally funded or supported research. Within this framework, each Federal agency funding or supporting research is expected to fashion its own regulations to accommodate the various types of research transactions in which it is engaged. This rule implements the Federal Policy for DOE including the National Nuclear Security Administration. In keeping with these objectives, these DOE regulations incorporate key aspects of the Federal Policy. In particular, research misconduct is being defined as including fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, but not as including honest error or differences of opinion. In addition, a finding of research

misconduct requires a determination, based on a preponderance of the evidence, that research misconduct has occurred, including a conclusion that there has been a significant departure from accepted practices of the relevant research community and that it be knowingly, intentionally, or recklessly committed.

The core principle of the Federal Policy is that, while research organizations have the primary responsibility for the inquiry, investigation, and adjudication of allegations of research misconduct, Federal agencies have ultimate oversight authority for the research they fund or support. While there may be some overlap in the actions that may be pursued by Federal agencies and research organizations, DOE has designed this rule to assure that if an allegation of research misconduct is made against a contractor or recipient of financial assistance, either the contractor or recipient or, if appropriate, DOE, investigates that allegation. Federal law prescribes procedural frameworks for adverse contract actions, adverse assistance actions, suspensions, or debarments that are different from procedural frameworks for competing for Federal procurement or assistance awards, and for adverse personnel actions against Federal civil service employees. Further, the DOE Office of the Inspector General (OIG) may proceed under its previously existing administrative investigation process when misconduct is alleged against Federal civil service employees, contractors or recipients of financial assistance. In addition, if a contractor or financial assistance recipient cannot conduct its own research misconduct investigation the rule provides that DOE will be responsible for conducting the investigation.

In order to best implement the Federal Policy, DOE promulgates a new 10 CFR part 733 (Allegations of Research Misconduct), which sets forth a general statement of policy applicable to research conducted under a DOE contract or financial assistance agreement. Consistent with the general statement of policy, DOE today amends 10 CFR part 600 (Financial Assistance Rules), 48 CFR part 935 (Research and Development Contracting), 48 CFR part 952 (Solicitation Provisions and Contract Clauses), and 48 CFR part 970 (DOE Management and Operating Contracts). The Secretary of Energy has approved this notice for publication in the **Federal Register**. For all contracts, contracting officers must apply the DOE Acquisition Regulations (DEAR) changes (codified at 48 CFR) to

solicitations issued on or after the effective date of this rule and may, at their discretion, include these DEAR changes in solicitations issued before the effective date of this rule, provided award of the resulting contract(s) occurs on or after the effective date.

For management and operating contracts, contracting officers must apply these DEAR changes: to contracts extended in accordance with the Department's extend/compete policies and procedures (48 CFR 917.6, 48 CFR 970.1706, and internal guidance); and to options exercised under competitively awarded management and operating contracts (48 CFR 970.1706).

For management and operating contracts, contracting officers should modify existing contracts at the next fee negotiation/annual renewal after the effective date of this rule.

II. Discussion of the General Statement of Policy and Standard Requirements

Since research for DOE occurs pursuant to financial assistance agreements or contracts, the general statement of policy provides that DOE will implement the Federal Policy through the insertion in financial assistance agreements and contracts of standard requirements based on the Federal Policy. DOE expects that these standard requirements will result in most allegations of research misconduct being handled in accordance with the Federal Policy by the research institution where the research misconduct is alleged to have taken place.

The general statement of policy also sets forth guidance to DOE offices with regard to the processing of allegations of research misconduct made directly to DOE. The guidance provides for initial handling of such allegations by the DOE office programmatically responsible for an assistance agreement or contract. That office in turn will consult with the DOE Office of the Inspector General (IG) to determine whether that office will choose to investigate the allegation. If the IG declines to investigate, the DOE program office will refer the allegation to the appropriate contracting officer responsible for the administration of the assistance agreement or contract for processing by the assistance recipient or contractor consistent with requirements of the applicable research misconduct requirements. If the Department elects to act in lieu of the contractor or financial assistance recipient, the research misconduct investigation shall be conducted by the DOE office programmatically responsible for the assistance agreement or contract with

support from other departmental elements, as appropriate.

DOE is amending the DEAR at 48 CFR part 935 to prescribe the inclusion of requirements on research misconduct in all DOE contracts that involve research. DOE also is amending part 952 of the DEAR and 10 CFR part 600, respectively, to add requirements that by accepting the funds under a contract, including a management and operating contractor a financial assistance award, the recipient of DOE funds is making assurances that it has established an administrative process for reviewing, investigating, and reporting allegations of research misconduct and that it will comply with its own administrative process and the requirements of 10 CFR part 733 for review, investigation, and reporting of research misconduct. DOE also is amending part 970 of the DEAR to provide that records generated by a management and operating contractor during the course of responding to allegations of research misconduct will be considered owned by the contractor.

As suggested in the Federal Policy, DOE expects debarment and suspension would be available as possible recommended remedies for a finding of research misconduct. These remedies would exclude a person or organization from participating in research activities funded by the Federal Government. DOE's non-procurement suspension and debarment rule is promulgated at 10 CFR part 606, while the Federal procurement suspension and debarment rule is promulgated at 48 CFR part 909. Both regulations require a fact-finding process if there are any facts in dispute prior to a suspension or debarment determination. The fact-finding process used to make a determination of research misconduct under this rule would satisfy the requirements for a fact-finding hearing as adopted in the DOE's non-procurement debarment and suspension regulations, as well as the requirements for a fact-finding hearing as described in the FAR.

III. Public Comment Procedures

Interested persons are invited to participate by submitting data, views or arguments with respect to the new regulation in this rulemaking. Five copies of written comments should be submitted to the address indicated in the **ADDRESSES** section of this notice of rulemaking. All comments received will be available for public inspection as part of the administrative record on file for this rulemaking in the Department of Energy Freedom of Information Reading Room, Room 1E-090, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-

3142, between the hours of 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. All written comments received by the date indicated in the **DATES** section of this notice of rulemaking and all other relevant information in the record will be carefully assessed and fully considered prior to the publication of the final rule. Any information or data considered to be exempt from public disclosure by law must be so identified and submitted in writing, one copy, as well as one complete copy from which the information believed to be exempt from disclosure is deleted. DOE will determine if the information or data is exempt from disclosure.

IV. Procedural Review Requirements

A. Review Under Executive Order 12866

This regulatory action has been determined to be a "significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," (58 FR 51735, October 4, 1993). Accordingly, this action was subject to review under that Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB). OMB has completed its review.

B. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. The review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section

3(b) to determine whether they are met or it is unreasonable to meet one or more of them. The Department has completed the required review and determined that, to the extent permitted by law, the regulations meet the relevant standards of Executive Order 12988.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, requires that a Federal agency prepare a regulatory flexibility analysis for any rule for which the agency is required to publish a general notice of rulemaking. Today's rule consists of a general statement of policy, amendments to financial assistance regulations, and amendments to procurement regulations. Each part of today's rule is exempt from the requirement to publish a general notice of proposed rulemaking under the Administrative Procedure Act (5 U.S.C. 553) or any other law. Therefore, the Regulatory Flexibility Act does not apply to this rulemaking.

D. Review Under the Paperwork Reduction Act

No new information collection requirements subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, are imposed by today's regulatory action.

E. Review Under the National Environmental Policy Act

The Department has concluded that promulgation of this rule falls into a class of actions which would not individually or cumulatively have significant impact on the human environment, as determined by Department of Energy regulations (10 CFR part 1021, subpart D) implementing the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*). Specifically, this rule is categorically excluded from NEPA review because the rule and amendments to the Department of Energy Acquisition Regulation (DEAR) would be strictly procedural (categorical exclusion A6). Therefore, this rule does not require an environmental impact statement or environmental assessment pursuant to NEPA.

F. Review Under Executive Order 13132

Executive Order 13132 (64 FR 43255, August 10, 1999) requires agencies 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." As defined in the Executive Order, policies that have Federalism implications

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. The Department has examined this rule and has determined that it would not have a substantial direct effect 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. No further action is required by Executive Order 13132.

G. Review Under the Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) generally requires a Federal agency to perform a detailed assessment of costs and benefits of any rule imposing a Federal Mandate with costs to State, local or tribal governments, or to the private sector, of \$100 million or more. This rulemaking affects private sector entities, and the impact is less than \$100 million.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105-277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule or policy that may affect family well-being. Today's rule does not impact on the autonomy or integrity of the family institution. Accordingly, the Department has concluded that it is not necessary to prepare a Family Policymaking Statement.

I. Review Under the Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to the general guideline issued by OMB. OMB's guidelines were published at 67 FR 8452 (February 22, 2002) and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed today's rulemaking under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

J. Review Under the Small Business Regulatory Enforcement Fairness Act

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of today's interim final rule prior to its effective date. The report will state that the rule is not a major rule under 5 U.S.C. 804(2).

List of Subjects

10 CFR Part 600

Administrative practice and procedure.

10 CFR Part 733

Investigations, Reporting and recordkeeping requirements, Research, Science and technology, Scientists.

48 CFR Parts 935, 952, and 970

Government procurement.

Issued in Washington, DC on June 20, 2005.

Raymond L. Orbach,

Director of Science.

■ For the reasons set out in the preamble, Chapters II and III of title 10 and Chapter 9 of title 48 of the Code of Federal Regulations respectively, are to be amended as set forth below:

PART 600—FINANCIAL ASSISTANCE RULES

■ 1. The authority citation for 10 CFR part 600 continues to read as follows:

Authority: 42 U.S.C. 7101 *et seq.*; 31 U.S.C. 6301–6308; 50 U.S.C. 2401 *et seq.*, unless otherwise noted.

■ 2. Add § 600.31 to subpart A to read as follows:

§ 600.31 Research misconduct.

(a) A recipient is responsible for maintaining the integrity of research of any kind under an award from DOE including the prevention, detection, and remediation of research misconduct, and the conduct of inquiries, investigations, and adjudication of allegations of research misconduct in accordance with the requirements of this section.

(b) For purposes of this section, the following definitions are applicable:

Adjudication means a formal review of a record of investigation of alleged research misconduct to determine whether and what corrective actions and sanctions should be taken.

Fabrication means making up data or results and recording or reporting them.

Falsification means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Finding of Research Misconduct means a determination, based on a preponderance of the evidence, that research misconduct has occurred. Such a finding requires a conclusion that there has been a significant departure from accepted practices of the relevant research community and that it be knowingly, intentionally, or recklessly committed.

Inquiry means information gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

Investigation means the formal examination and evaluation of the relevant facts.

Plagiarism means the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research means all basic, applied, and demonstration research in all fields of science, medicine, engineering, and mathematics, including, but not limited to, research in economics, education, linguistics, medicine, psychology, social sciences statistics, and research involving human subjects or animals.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, but does not include honest error or differences of opinion.

Research record means the record of all data or results that embody the facts resulting from scientists' inquiries, including, but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

(c) Unless otherwise instructed by the contracting officer, the recipient must conduct an initial inquiry into any allegation of research misconduct. If the recipient determines that there is sufficient evidence to proceed to an investigation, it must notify the contracting officer and, unless otherwise instructed, the recipient must:

(1) Conduct an investigation to develop a complete factual record and an examination of such record leading to either a finding of research misconduct and an identification of appropriate remedies or a determination that no further action is warranted;

(2) Inform the contracting officer if an initial inquiry supports an investigation and, if requested by the contracting officer thereafter, keep the contracting officer informed of the results of the investigation and any subsequent adjudication. When an investigation is complete, the recipient will forward to

the contracting officer a copy of the evidentiary record, the investigative report, any recommendations made to the recipient's adjudicating official, and the adjudicating official's decision and notification of any corrective action taken or planned, and the subject's written response to the recommendations (if any).

(3) If the investigation leads to a finding of research misconduct, conduct an adjudication by a responsible official who was not involved in the inquiry or investigation and is separated organizationally from the element which conducted the investigation. The adjudication must include a review of the investigative record and, as warranted, a determination of appropriate corrective actions and sanctions.

(d) The Department may elect to act in lieu of the recipient in conducting an inquiry or investigation into an allegation of research misconduct if the contracting officer finds that:

(1) The research organization is not prepared to handle the allegation in a manner consistent with this section;

(2) The allegation involves an entity of sufficiently small size that it cannot reasonably conduct the inquiry;

(3) DOE involvement is necessary to ensure the public health, safety, and security, or to prevent harm to the public interest; or,

(4) The allegation involves possible criminal misconduct.

(e) DOE reserves the right to pursue such remedies and other actions as it deems appropriate, consistent with the terms and conditions of the award instrument and applicable laws and regulations. However, the recipient's good faith administration of this section and the effectiveness of its remedial actions and sanctions shall be positive considerations and shall be taken into account as mitigating factors in assessing the need for such actions. If DOE pursues any such action, it will inform the subject of the action of the outcome and any applicable appeal procedures.

(f) In conducting the activities in paragraph (c) of this section, the recipient and the Department, if it elects to conduct the inquiry or investigation, shall adhere to the following guidelines:

(1) *Safeguards for information and subjects of allegations.* The recipient shall provide safeguards to ensure that individuals may bring allegations of research misconduct made in good faith to the attention of the recipient without suffering retribution. Safeguards include: protection against retaliation; fair and objective procedures for examining and resolving allegations;

and diligence in protecting positions and reputations. The recipient shall also provide the subjects of allegations confidence that their rights are protected and that the mere filing of an allegation of research misconduct will not result in an adverse action. Safeguards include timely written notice regarding substantive allegations against them, a description of the allegation and reasonable access to any evidence submitted to support the allegation or developed in response to an allegation and notice of any findings of research misconduct.

(2) *Objectivity and expertise.* The recipient shall select individual(s) to inquire, investigate, and adjudicate allegations of research misconduct who have appropriate expertise and have no unresolved conflict of interest. The individual(s) who conducts an adjudication must not be the same individual(s) who conducted the inquiry or investigation, and must be separate organizationally from the element that conducted the inquiry or investigation.

(3) *Timeliness.* The recipient shall coordinate, inquire, investigate and adjudicate allegations of research misconduct promptly, but thoroughly. Generally, an investigation should be completed within 120 days of initiation, and adjudication should be complete within 60 days of receipt of the record of investigation.

(4) *Confidentiality.* To the extent possible, consistent with fair and thorough processing of allegations of research misconduct and applicable law and regulation, knowledge about the identity of the subjects of allegations and informants should be limited to those with a need to know.

(5) *Remediation and sanction.* If the recipient finds that research misconduct has occurred, it shall assess the seriousness of the misconduct and its impact on the research completed or in process. The recipient must take all necessary corrective actions. Such action may include but are not limited to, correcting the research record and as appropriate imposing restrictions, controls, or other parameters on research in process or to be conducted in the future. The recipient must coordinate remedial actions with the contracting officer. The recipient must also consider whether personnel sanctions are appropriate. Any such sanction must be consistent with any applicable personnel laws, policies, and procedures, and must take into account the seriousness of the misconduct and its impact, whether it was done knowingly or intentionally, and whether

it was an isolated event or pattern of conduct.

(g) By executing this agreement, the recipient provides its assurance that it has established an administrative process for performing an inquiry, mediating if possible, investigating, and reporting allegations of research misconduct; and that it will comply with its own administrative process and the requirements and definitions of 10 CFR part 733 for performing an inquiry, possible mediation, investigation and reporting of allegations of research misconduct.

(h) The recipient must insert or have inserted the substance of this section, including paragraph (g), in subawards at all tiers that involve research.

PART 733—ALLEGATIONS OF RESEARCH MISCONDUCT

■ 3. Part 733 is added to Chapter III of title 10 of the Code of Federal Regulations to read as follows:

PART 733—[ADDED]

Sec.

733.1 Purpose.

733.2 Scope.

733.3 Definitions.

733.4 Research misconduct requirements.

733.5 Allegations received by DOE.

733.6 Consultation with the DOE Office of the Inspector General.

733.7 Referral to the contracting officer.

733.8 Contracting officer procedures.

Authority: 42 U.S.C. 2201; 7254; 7256; 7101 *et seq.*; 50 U.S.C. 2401 *et seq.*

§ 733.1 Purpose.

The purpose of this part is to set forth a general statement of policy on the treatment of allegations of research misconduct consistent with Federal Policy on Research Misconduct established by the White House Office of Science and Technology Policy on December 6, 2000 (65 FR 76260–76264).

§ 733.2 Scope.

This part applies to allegations of research misconduct with regard to scientific research conducted under a Department of Energy contract or an agreement.

§ 733.3 Definitions.

The following terms used in this part are defined as follows:

Contract means an agreement primarily for the acquisition of goods or services that is subject to the Federal Acquisition Regulations (48 CFR Chapter 1) and the DOE Acquisition Regulations (48 CFR Chapter 9).

DOE means the U.S. Department of Energy (including the National Nuclear Security Administration).

DOE Element means a major division of DOE, usually headed by a Presidential appointee, which has a delegation of authority to carry out activities by entering into contracts or financial assistance agreements.

Fabrication means making up data or results and recording or reporting them.

Falsification means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Financial assistance agreement means an agreement the primary purpose of which is to provide appropriated funds to stimulate an activity, including but not limited to, grants and cooperative agreements pursuant to 10 CFR Part 600.

Finding of research misconduct means a determination, based on a preponderance of the evidence, that research misconduct has occurred. Such a finding requires a conclusion that there has been a significant departure from accepted practices of the relevant research community and that it be knowingly, intentionally, or recklessly committed.

Plagiarism means the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research means all basic, applied, and demonstration research in all fields of science, engineering, and mathematics, such as research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, but does not include honest error or differences of opinion.

Research record means the record of all data or results that embody the facts resulting from scientists' inquiries, including, but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles

§ 733.4 Research misconduct requirements.

DOE intends to apply the research misconduct policy set forth in 65 FR 76260–76264 by including appropriate research misconduct requirements in contracts and financial assistance awards that make contractors and financial recipients primarily responsible for implementing the policy in dealing with allegations of research

misconduct in connection with the proposal, performance or review of research for DOE .

§ 733.5 Allegations received by DOE.

If DOE receives directly a written allegation of research misconduct with regard to research under a DOE contract or financial assistance agreement, DOE will refer the allegation for processing to the DOE Element responsible for the contract or financial assistance agreement.

§ 733.6 Consultation with the DOE Office of the Inspector General.

Upon receipt of an allegation of research misconduct, the DOE Element shall consult with the DOE Office of the Inspector General which will determine whether that office will elect to investigate the allegation.

§ 733.7 Referral to the contracting officer.

If the DOE Office of the Inspector General declines to investigate an allegation of research misconduct, the DOE Element should forward the allegation to the contracting officer responsible for administration of the contract or financial assistance agreement to which the allegation pertains.

§ 733.8 Contracting officer procedures.

Upon receipt of an allegation of research misconduct by referral under § 733.7, the contracting officer should, by notification of the contractor or financial assistance recipient:

(a) Require the contractor or the financial assistance recipient to act on the allegation consistent with the Research Misconduct requirements in the contract or financial assistance award to which the allegation pertains; or

(b) In the event the contractor or the financial assistance recipient is unable to act:

(1) Designate an appropriate DOE program to conduct an investigation to develop a complete factual record and an examination of such record leading to either a finding of research misconduct and an identification of appropriate remedies or a determination that no further action is warranted; and

(2) Make the appropriate findings consistent with the Research Misconduct requirements contained in the contract or financial assistance award, in order to act in lieu of the contractor or financial assistance recipient.

Title 48

PART 935—RESEARCH AND DEVELOPMENT CONTRACTING

■ 4. The authority citation for 48 CFR part 935 continues to read as follows:

Authority: 42 U.S.C. 7101 *et seq.*; 41 U.S.C. 418b; 50 U.S.C. 2401 *et seq.*

■ 5. Sections 935.070 and 935.071 are added to read as follows:

935.070 Research misconduct.

(a) *Applicability.* The DOE research misconduct policy set forth at 10 CFR part 733 addresses research misconduct by individuals who propose, perform or review research of any kind for the Department of Energy pursuant to a contract. The regulation applies regardless of where the research or other activity is conducted or by whom.

(b) *Definition.* Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion. A finding of research misconduct means a determination, based on a preponderance of the evidence, that research misconduct has occurred, including a conclusion that there has been a significant departure from accepted practices of the relevant research community and that it be knowingly, intentionally, or recklessly committed.

935.071 Contract clause.

The contracting officer must insert the clause at 952.235–71, Research Misconduct, in contracts, including management and operating contracts, that involve research.

PART 952—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 6. The authority citation for part 952 continues to read as follows:

Authority: 42 U.S.C. 2201, 2282a, 2282b, 2282c, 7101 *et seq.*; 41 U.S.C. 418b; 50 U.S.C. 2401 *et seq.*

■ 7. Section 952.235–71 is added to read as follows:

952.235–71 Research Misconduct.

As prescribed in 48 CFR Part 935.071, insert the following clause:

Research Misconduct (JUL 2005)

(a) The contractor is responsible for maintaining the integrity of research performed pursuant to this contract award including the prevention, detection, and remediation of research misconduct as defined by this clause, and the conduct of

inquiries, investigations, and adjudication of allegations of research misconduct in accordance with the requirements of this clause.

(b) Unless otherwise instructed by the contracting officer, the contractor must conduct an initial inquiry into any allegation of research misconduct. If the contractor determines that there is sufficient evidence to proceed to an investigation, it must notify the contracting officer and, unless otherwise instructed, the contractor must:

(1) Conduct an investigation to develop a complete factual record and an examination of such record leading to either a finding of research misconduct and an identification of appropriate remedies or a determination that no further action is warranted;

(2) If the investigation leads to a finding of research misconduct, conduct an adjudication by a responsible official who was not involved in the inquiry or investigation and is separated organizationally from the element which conducted the investigation. The adjudication must include a review of the investigative record and, as warranted, a determination of appropriate corrective actions and sanctions.

(3) Inform the contracting officer if an initial inquiry supports a formal investigation and, if requested by the contracting officer thereafter, keep the contracting officer informed of the results of the investigation and any subsequent adjudication. When an investigation is complete, the contractor will forward to the contracting officer a copy of the evidentiary record, the investigative report, any recommendations made to the contractor's adjudicating official, the adjudicating official's decision and notification of any corrective action taken or planned, and the subject's written response (if any).

(c) The Department may elect to act in lieu of the contractor in conducting an inquiry or investigation into an allegation of research misconduct if the contracting officer finds that:

(1) The research organization is not prepared to handle the allegation in a manner consistent with this clause;

(2) The allegation involves an entity of sufficiently small size that it cannot reasonably conduct the inquiry;

(3) DOE involvement is necessary to ensure the public health, safety, and security, or to prevent harm to the public interest; or,

(4) The allegation involves possible criminal misconduct.

(d) In conducting the activities under paragraphs (b) and (c) of this clause, the contractor and the Department, if it elects to conduct the inquiry or investigation, shall adhere to the following guidelines:

(1) *Safeguards for information and subjects of allegations.* The contractor shall provide safeguards to ensure that individuals may bring allegations of research misconduct made in good faith to the attention of the contractor without suffering retribution. Safeguards include: protection against retaliation; fair and objective procedures for examining and resolving allegations; and diligence in protecting positions and reputations. The contractor shall also provide

the subjects of allegations confidence that their rights are protected and that the mere filing of an allegation of research misconduct will not result in an adverse action. Safeguards include timely written notice regarding substantive allegations against them, a description of the allegation and reasonable access to any evidence submitted to support the allegation or developed in response to an allegation and notice of any findings of research misconduct.

(2) *Objectivity and Expertise.* The contractor shall select individual(s) to inquire, investigate, and adjudicate allegations of research misconduct who have appropriate expertise and have no unresolved conflict of interest. The individual(s) who conducts an adjudication must not be the same individual(s) who conducted the inquiry or investigation, and must be separate organizationally from the element that conducted the inquiry or investigation.

(3) *Timeliness.* The contractor shall coordinate, inquire, investigate and adjudicate allegations of research misconduct promptly, but thoroughly. Generally, an investigation should be completed within 120 days of initiation, and adjudication should be complete within 60 days of receipt of the record of investigation.

(4) *Confidentiality.* To the extent possible, consistent with fair and thorough processing of allegations of research misconduct and applicable law and regulation, knowledge about the identity of the subjects of allegations and informants should be limited to those with a need to know.

(5) *Remediation and Sanction.* If the contractor finds that research misconduct has occurred, it shall assess the seriousness of the misconduct and its impact on the research completed or in process. The contractor must take all necessary corrective actions. Such action may include but are not limited to, correcting the research record and as appropriate imposing restrictions, controls, or other parameters on research in process or to be conducted in the future. The contractor must coordinate remedial actions with the contracting officer. The contractor must also consider whether personnel sanctions are appropriate. Any such sanction must be considered and effected consistent with any applicable personnel laws, policies, and procedures, and shall take into account the seriousness of the misconduct and its impact, whether it was done knowingly or intentionally, and whether it was an isolated event or pattern of conduct.

(e) DOE reserves the right to pursue such remedies and other actions as it deems appropriate, consistent with the terms and conditions of the award instrument and applicable laws and regulations. However, the contractor's good faith administration of this clause and the effectiveness of its remedial actions and sanctions shall be positive considerations and shall be taken into account as mitigating factors in assessing the need for such actions. If DOE pursues any such action, it will inform the subject of the action of the outcome and any applicable appeal procedures.

(f) *Definitions.*

Adjudication means a formal review of a record of investigation of alleged research

misconduct to determine whether and what corrective actions and sanctions should be taken.

Fabrication means making up data or results and recording or reporting them.

Falsification means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Finding of Research Misconduct means a determination, based on a preponderance of the evidence, that research misconduct has occurred. Such a finding requires a conclusion that there has been a significant departure from accepted practices of the relevant research community and that it be knowingly, intentionally, or recklessly committed.

Inquiry means information gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

Investigation means the formal examination and evaluation of the relevant facts.

Plagiarism means the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research means all basic, applied, and demonstration research in all fields of science, medicine, engineering, and mathematics, including, but not limited to, research in economics, education, linguistics, medicine, psychology, social sciences statistics, and research involving human subjects or animals.

Research Misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, but does not include honest error or differences of opinion.

Research record means the record of all data or results that embody the facts resulting from scientists' inquiries, including, but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

(g) By executing this contract, the contractor provides its assurance that it has established an administrative process for performing an inquiry, mediating if possible, or investigating, and reporting allegations of research misconduct; and that it will comply with its own administrative process and the requirements of 10 CFR part 733 for performing an inquiry, possible mediation, investigation and reporting of research misconduct.

(h) The contractor must insert or have inserted the substance of this clause, including paragraph (g), in subcontracts at all tiers that involve research.

(End of Clause)

PART 970—MANAGEMENT AND OPERATING CONTRACTS

■ 7. The authority citation for part 970 continues to read as follows:

Authority: 42 U.S.C. 2201, 2282a, 2282b, 2282c; 42 U.S.C. 7101 *et seq.*; 41 U.S.C. 418b; 50 U.S.C. 2401 *et seq.*

■ 8. Section 970.5204–3 is amended by revising paragraph (b)(1) to read as follows:

970.5204–3 Access to and ownership of records.

* * * * *

(b) * * *

(1) Employment-related records (such as worker's compensation files; employee relations records, records on salary and employee benefits; drug testing records, labor negotiation records; records on ethics, employee concerns; records generated during the course of responding to allegations of research misconduct; records generated during other employee related investigations conducted under an expectation of confidentiality; employee assistance program records; and personnel and medical/health-related records and similar files), and non-employee patient medical/health-related records, except for those records described by the contract as being maintained in Privacy Act systems of records.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. CE227; Special Condition No. 23–169–SC]

Special Conditions: Diamond Aircraft Industries, DA–42; Diesel Cycle Engine Using Turbine (Jet) Fuel

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Diamond Aircraft Industries (DAI) DA–42 airplane. This airplane will have a novel or unusual design feature(s) associated with the installation of a diesel cycle engine utilizing turbine (jet) fuel. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for installation of this new technology engine. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is June 22, 2005.