

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2010-N-0548 for "Good Laboratory Practice for Nonclinical Laboratory Studies." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential

with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vernon Toelle, Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., MPN4-142, Rockville, MD 20855, 240-402-5637; or Kristin Webster Maloney, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4373, Silver Spring, MD 20993, 240-402-4993.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 24, 2016, FDA published a proposed rule with a 90-day comment period to request comments on its proposal to amend the regulations for good laboratory practice for nonclinical studies. Comments on the proposed amendments will inform FDA's rulemaking to establish regulations for good laboratory practice for nonclinical laboratory studies.

The Agency has received requests for a 90-day extension of the comment period for the proposed rule. Each request conveyed concern that the

current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 60 days, until January 21, 2017. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: October 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-26244 Filed 10-28-16; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 250

[Docket ID: DOD-2015-OS-0126]

RIN 0790-A173

Withholding of Unclassified Technical Data and Technology From Public Disclosure

AGENCY: Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics, DoD.

ACTION: Proposed rule.

SUMMARY: This rulemaking establishes policy, assigns responsibilities, and prescribes procedures for the dissemination and withholding of certain unclassified technical data and technology subject to the International Traffic in Arms Regulations (ITAR) and Export Administration Regulations (EAR). It applies to DoD components, their contractors and grantees and is meant to control the transfer of technical data and technology contributing to the military potential of any country or countries, groups, or individuals that could prove detrimental to U.S. national security or critical interests.

DATES: Comments must be received by December 30, 2016.

ADDRESSES: You may submit comments, identified by docket number and/or RIN number and title, by any of the following methods:

- **Federal Rulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

- **Mail:** Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350-1700.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT:
Vakare Valaitis, 703-767-9159.

SUPPLEMENTARY INFORMATION:

Background

For the purposes of this regulation, public disclosure of technical data and technology is the same as providing uncontrolled foreign access. This rule instructs DoD employees, contractors, and grantees to ensure unclassified technical data and technology that discloses technology or information with a military or space application may not be exported without authorization and should be controlled and disseminated consistent with U.S. export control laws and regulations. These policies preserve the U.S. military's technological superiority, establish and maintain interoperability with allies and coalition partners, and manage direct and indirect impacts on defense industrial base. There are penalties for export control violations. For export control violations involving items controlled by the United States Department of State under the International Traffic in Arms Regulations (ITAR), including many munitions items, the statute authorizes a maximum criminal penalty of \$1 million per violation and, for an individual person, up to 10 years imprisonment. In addition, ITAR violations can result in the imposition of a maximum civil fine of \$500,000 per violation, as well as debarment from exporting defense articles or services. For export control violations involving dual-use and certain munitions items controlled by the United States Department of Commerce under the Export Administration Regulations, criminal and civil penalties are currently provided by the International Emergency Economic Powers Act (IEEPA), 50 U.S.C. 1705, which has continued the Export Administration Regulations (EAR) in effect while the Export Administration Act is in lapse through Executive Order 13222 of August 17, 2001 (3 CFR 2001 Comp. 783 (2002)), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129

(March 13, 2013) and as extended by successive Presidential Notices, the most recent being that of August 4, 2016 (81 FR 52587 (Aug. 8, 2016)). Under the EAR and IEEPA, as adjusted by 15 CFR 5.4(b), the penalty for persons who violate, attempt or conspire to violate, or cause a violation of the export control regulations includes civil penalties of not more than \$284,582 per transaction or twice the amount of the transaction, whichever is greater, and criminal penalties of not more than \$1,000,000, imprisonment of not more than 20 years, or both. Violations of the EAR may also result in the denial of export privileges and other administrative sanctions.

Authority To Issue This Regulation

In accordance with 10 U.S.C. 133 part (b)(2), the Under Secretary of Defense for Acquisition, Technology and Logistics (USD(AT&L)) may exercise powers relating to establishing policies for acquisition (including procurement of goods and services, research and development, developmental testing, and contract administration) for all elements of the Department of Defense. In addition, U.S. export control laws, including 22 U.S.C. 2778 (also known as the "Arms Export Control Act"); 50 U.S.C. chapter 35 (also known as the "International Emergency Economic Powers Act" (IEEPA)); 22 CFR parts 120 through 130 (also known as "International Traffic in Arms Regulations" (ITAR)); and 15 CFR parts 730 through 774 (also known as "Export Administration Regulations" (EAR)) govern this rule.

Summary of the Major Provisions of the Rulemaking

This proposed rule describes procedures for the release of technical information; discusses procedures for technical data and technology to be marked for distribution; and provides an example of the notice to accompany export-controlled technical data and technology.

Costs and Benefits

DoD is proposing this regulation to update the CFR and DoD Directive 5230.25 (available at <http://dtic.mil/whs/directives/corres/pdf/523025p.pdf>). The Department currently spends \$571,876 annually on export control certification activities. The costs to DoD contractors and grantee consist primarily of the time needed to organize, format, and submit information to the U.S./Canada Joint Certification Office to qualify for export controlled technical data and technology.

The program has no discernible increase in anticipated costs and benefits as the program is being updated to conform to national security guidance cited in the text in §§ 250.1 through 250.7.

The potential benefits include greater public access and understanding of information about the qualifications needed for access to export controlled technical data and technology. Such information may help potential contractors and grantees to better understand their options for participating in DoD activities; to better enable funders and researchers to determine the need for information and technology; to provide more complete information of those who use information from DoD research and contracts to inform other decisions; and to better enable the scientific community to examine the overall state of information and technology in this area as a basis for engaging in quality improvement (e.g., with regard to research methods). The proposed rule is also expected to provide greater clarity about what is required for those who are authorized holders of export controlled technical data and technology.

This proposed rule is included in DoD's retrospective plan, completed in August 2011, and will be reported in future status updates of DoD's retrospective review in accordance with the requirements in Executive Order 13563. DoD's full plan can be accessed at: <http://www.regulations.gov/#!docketDetail;D=DOD-2011-OS-0036>.

Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review" and Executive Order 13563, "Improving Regulation and Regulatory Review"

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Although this rulemaking is not "economically significant" because it does not have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, it has been deemed "other significant" for raising novel legal or policy issues arising out of legal mandates, the President's priorities, or

the principles set forth in these Executive Orders. For that reason, it has been reviewed by the Office of Management and Budget (OMB).

Section 202, Public Law 104–4, “Unfunded Mandates Reform Act”

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) requires agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately \$141 million. This proposed rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

Public Law 96–354, “Regulatory Flexibility Act” (5 U.S.C. 601)

The Department of Defense certifies that this proposed rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Public Law 96–511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)

It has been certified that this proposed rule does impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995. These reporting requirements have been

approved by OMB under OMB Control Number 0704–0207 titled DD Form 2345, Militarily Critical Technical Data Agreement.

Cost to the Public

In exchange for Government-owned unclassified export controlled technical data and technology, a contractor provides basic company information, identifies a technical data and technology custodian, and describes need-to-know. The reporting burden is estimated to average 20 minutes per response. The DD Form 2345 and supporting documentation must be submitted to the U.S./Canada Joint Certification Office in hardcopy. Approximately 24,000 U.S. companies have active certifications.

24,000 responses	\$9.94 * per response	\$19.99 postage ** per response	\$638,400
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* U.S. Department of Labor. Bureau of Labor Statistics. 2014 median weekly earnings of full-time workers with at least a bachelor’s degree: \$1,193. <http://www.bls.gov/spotlight/2015/a-look-at-pay-at-the-top-the-bottom-and-in-between/home.htm>.

** Most applicants choose Priority Mail Express Flat Rate Envelope USPS Postage Price Calculator <http://postcalc.usps.com/>.

COST TO THE GOVERNMENT

4 FTE registrars	GS 9 step 5	\$59,036 *	\$236,144
1 FTE Team Lead	GS11 step 5	71,429 *	71,429
.5 FTE US Representative	GS13 step 5	101,807	50,904
.25 FTE Division Chief	GS14 step 5	120,303	30,075
.25 FTE Director	GS15 step 5	35,378 *	35,378
O&M for IT	SP4701–15–F–0031	2,958,915	147,946
Total	571,876

* 2014 General Schedule (Base) Office of Personnel Management Salaries and Wages <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2014/general-schedule/>.

Executive Order 13132, “Federalism”

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This proposed rule will not have a substantial effect on State and local governments.

List of Subjects in 32 CFR Part 250

Exports, Science and technology.
Accordingly, 32 CFR part 250 is proposed to be revised to read as follows:

PART 250—WITHHOLDING OF UNCLASSIFIED TECHNICAL DATA AND TECHNOLOGY FROM PUBLIC DISCLOSURE

- Sec.
- 250.1 Purpose.
- 250.2 Applicability.
- 250.3 Definitions.
- 250.4 Policy.

- 250.5 Responsibilities.
- 250.6 Procedures.
- 250.7 Directly arranged visits.

Authority: 10 U.S.C. 133.

§ 250.1 Purpose.

This part establishes policy, assigns responsibilities, and prescribes procedures for the dissemination and withholding of certain unclassified technical data and technology consistent with the requirements of 10 U.S.C. 130.

§ 250.2 Applicability.

This part:

(a) Applies to:

(1) The Office of the Secretary of Defense, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this part as the “DoD Components”).

(2) All unclassified technical data and technology that discloses technology or information with military or space application, in the possession or under the control of a DoD Component, that may not be exported lawfully without an approval, authorization, license, license exception, or exemption in accordance with U.S. export control laws and regulations: 22 U.S.C. 2778 (also known as the “Arms Export Control Act”); 50 U.S.C. chapter 35 (also known as the “International Emergency Economic Powers Act”); 22 CFR parts 120–130 (also known as “International Traffic in Arms Regulations” (ITAR)); and 15 CFR parts 730 through 774 (also known as “Export Administration Regulations” (EAR)).

(b) Does not modify or supplant the regulations governing the export of technical data and technology established by 22 U.S.C. 2778, 50 U.S.C. chapter 35, 22 CFR parts 120 through 130, 10 CFR 810, and 15 CFR parts 730 through 774.

(c) Does not apply to technical information under the control of the Department of Energy or the Nuclear

Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Nuclear Non-Proliferation Act of 1978, as amended.

(d) Does not introduce any additional controls on the dissemination of technical data and technology by private enterprises or individuals beyond those specified by export control laws and regulations or in contracts or other agreements, including certifications as specified in paragraph (a)(9) of § 250.5. Accordingly, the fact that DoD may possess such technical data and technology does not in itself provide a basis for control of such technical data and technology under this part.

(e) Does not introduce any controls on the dissemination of:

(1) Scientific, educational, or other items that are not subject to the EAR or exclusively controlled for export or reexport by another department or agency pursuant to 15 CFR 734.3, 734.7 through 734.8;

(2) Information in the public domain as described in 22 CFR 120.11 and technical data that has been approved for release in accordance with 22 CFR 125.4(b)(13)).

(f) Does not alter the responsibilities of the DoD Components to protect proprietary technical data and technology of a private party, including:

(1) In which the DoD has less than unlimited rights (e.g., pursuant to 48 CFR 227.7202, 252.227-7013, 252.227-7014, 252.227-7015, and 252.227.7018); and

(2) That is authorized to be withheld from public disclosure pursuant to 5 U.S.C. 552, also known and referred to in this part as the “Freedom of Information Act (FOIA).”

(g) Does not pertain to or affect the release of technical data and technology by DoD Components to foreign governments, international organizations or their respective representatives, or contractors pursuant to official agreements or formal arrangements with the U.S. Government (USG), or pursuant to USG-licensed transactions involving such entities or individuals. However, in the absence of such USG-sanctioned relationships this part does apply.

(h) Does not apply to classified technical data. However, after declassification, dissemination of the technical data and technology within the scope of paragraph (a)(2) of this section is governed by this part.

(i) Does not alter the responsibilities of the DoD Components to mark and protect information qualifying for designation as controlled unclassified information in accordance with Executive Order 13556, “Controlled

Unclassified Information,” as implemented by volume 4 of DoD Manual 5200.01, “DoD Information Security Program” (available at http://www.dtic.mil/whs/directives/corres/pdf/520001_vol4.pdf).

§ 250.3 Definitions.

Unless otherwise noted, these terms and their definitions are for the purpose of this part.

Certification. The United States-Canada Joint Certification Program certifies contractors of each country for access, on an equally favorable basis, to unclassified technical data and technology that discloses technology or information with military or space application controlled in the United States by this part and in Canada by Canada Minister of Justice, Technical Data Control Regulations SOR/86-345, May 27, 2014 current edition (available at <http://laws-lois.justice.gc.ca/PDF/SOR-86-345.pdf>).

Controlling DoD office. The DoD activity that sponsored the work that generated the technical data and technology or received the technical data and technology on behalf of the DoD and therefore is responsible for determining the distribution of a document containing the technical data and technology. In the case of joint sponsorship, the controlling office is determined by advance agreement and may be a party, a group, or a committee representing the interested activities or the DoD Components.

Critical technology. Technology or technologies essential to the design, development, production, operation, application, or maintenance of an defense or dual-use article or service, which makes or could make a significant contribution to the military potential of any country, including the United States (also referred to as militarily critical technology). This includes, but is not limited to, design and manufacturing know-how, technical data, keystone equipment including manufacturing, inspection, and test equipment that is required for the effective application of technical information and technical know-how.

(1) With respect to defense articles or defense services: Those technologies specified in 22 CFR 121.1.

(2) With respect to categories of systems, equipment, and components; test, inspection, and production equipment; materials; software; and technology subject to the EAR: Those technologies specified in 15 CFR part 774.

(3) With respect to nuclear equipment, materials, and technology:

Those technologies specified in 10 CFR part 810.

(4) With respect to select agents and toxins: Those technologies specified in 7 CFR part 331, 9 CFR part 121, and 42 CFR part 73; and any other technologies affecting the critical infrastructure.

(5) With respect to emerging critical defense technology: Research and engineering development, or engineering and technology integration that will produce a defense article or defense service, including its underlying technology and software, covered by 22 CFR parts 120 through 130, or a dual-use or munitions item, including its underlying technology and software, covered by 15 CFR parts 730 through 774.

Defense article. Defined at 22 CFR 120.6.

Defense services. Defined at 22 CFR 120.9.

Formal arrangement. An instrument that provides the formal authorization to establish a voluntary agreement between two or more parties for mutual sharing of resources and tasks to achieve a common set of objectives, such as The Technical Cooperation Program.

Legitimate business relationship. A relationship in which the DoD determines that a need exists to acquire, share, exchange, or disseminate DoD technical information to anyone other than a DoD employee for supporting the DoD mission. The relationship may be established by a memorandum of understanding, agreement, contract, or grant. The DoD has the sole responsibility for determining that a legitimate business relationship exists since the only purpose is to provide access to information created by or under the control of the DoD.

Relationships may be established with an individual or organization in another Federal department or agency; contractors, grantees, or potential DoD contractors; other branches of the Federal Government; State and local governments; and foreign countries.

Limited rights. The rights to use, modify, reproduce, release, perform, display, or disclose technical data and technology, in whole or in part, within the government.

Other legitimate business purposes. Include:

(1) Providing or seeking to provide equipment or technology to a foreign government with USG approval (for example, through foreign military sale).

(2) Bidding, or preparing to bid, on a sale of surplus property.

(3) Selling or producing products for the commercial domestic marketplace or for the commercial foreign marketplace,

providing that any required export license is obtained.

(4) Engaging in scientific research in a professional capacity.

(5) Acting as a subcontractor to a qualified contractor.

Potential DoD contractor. An individual or organization outside the DoD declared eligible for DoD information services by a sponsoring DoD activity.

Public disclosure. Making technical data available without restricting its dissemination or use.

Qualified contractor. A qualified U.S. contractor or a qualified Canadian contractor referred to in and governed by Canada Minister of Justice, Technical Data Control Regulations SOR/86-345, May 27, 2014 current edition and certified in the Joint Certification Program through acceptance of a valid DD Form 2345.

Qualified Canadian contractor. Canadian contractors are qualified for technical data and technology that do not require a license or other authorization for export to Canada under 22 CFR 126.5 by submitting a certification request to the United States-Canada Joint Certification Office established at the Defense Logistics Agency, Battle Creek, Michigan, in accordance with the "Memorandum of Understanding Between the Government of Canada and the Government of the United States Concerning Strategic Technical Exchange".

Qualified U.S. contractor. A private individual or enterprise that, in accordance with procedures established by the Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)) and as a condition of obtaining export-controlled technical data and technology subject to this part from the DoD:

(1) Certifies that the individual who will act as recipient of the export-controlled technical data and technology on behalf of the U.S. contractor is a U.S. citizen or a person admitted lawfully into the United States for permanent residence and is located in the United States.

(2) Certifies that such data and technology are needed to bid or perform on a contract with the DoD or other USG agency, or for other legitimate business purposes in which the U.S. contractor is engaged or plans to engage. The purpose for which the data and technology are needed must be described sufficiently in such certification to permit an evaluation of whether subsequent requests for data and technology are related properly to such business purpose.

(3) Acknowledges its responsibilities under U.S. export control laws and regulations (including the obligation, under certain circumstances, to obtain an export license prior to the release of technical data and technology within the United States) and agrees that it will not disseminate any export-controlled technical data and technology subject to this part in violation of applicable export control laws and regulations.

(4) Agrees that, unless dissemination is permitted by paragraph (i) of § 250.6, it will not provide access, including network access, to export-controlled technical data and technology subject to this part to persons other than its employees or persons acting on its behalf, and who meet the same citizenship or residency requirements without the permission of the DoD Component that provided the technical data and technology.

(5) To the best of its knowledge, knows of no person employed by it or acting on its behalf who will have access to such data and technology, who is debarred, suspended, or otherwise ineligible from performing on USG contracts; or has violated U.S. export control laws or a certification previously made to the DoD under the provisions of this part.

(6) Asserts that it is not debarred, suspended, or otherwise determined ineligible by any agency of the USG to perform on USG contracts, has not been convicted of export control law violations, and has not been disqualified under the provisions of this part.

(7) Requests the certification be accepted based on its description of extenuating circumstances when the certifications required by this definition cannot be made truthfully.

Restricted rights. The government's rights to use a computer program with one computer at one time. Applicable only to noncommercial computer software.

Technical data. Defined at 22 CFR 120.10.

(1) Classified data relating to defense articles and defense services on the U.S. Munitions List;

(2) Information covered by an invention secrecy order; or

(3) Software (see 22 CFR 120.45(f)) directly related to defense articles.

(4) The definition does not include information concerning general scientific, mathematical, or engineering principles commonly taught in schools, colleges, and universities, or information in the public domain as defined in 22 CFR 120.11 or telemetry data as defined in note 3 to Category XV(f) of in 22 CFR part 121. It also does not include basic marketing information

on function or purpose or general system descriptions of defense articles.

Technical information. Includes technical data and technology as defined in 15 CFR parts 730 through 774, as well as technical information that is not subject to 22 CFR parts 120 through 130 or 15 CFR parts 730 through 774. It also includes technical data or computer software of any kind that can be used or adapted for use in the design, production, manufacture, assembly, repair, overhaul, processing, engineering, development, operation, maintenance, adapting, testing, or reconstruction of goods or materiel; or any technology that advances the state of the art, or establishes a new art, in an area of significant military or space applicability in the United States. The data may be in tangible form, such as a blueprint, photograph, plan, instruction, or an operating manual, or may be intangible, such as a technical service or oral, auditory, or visual descriptions. Examples of technical data include research and engineering data, engineering drawings, and associated lists, specifications, standards, process sheets, manuals, technical reports, technical orders, catalog item identifications, data sets, studies and analyses and related information, and computer software.

Technology. Defined in 15 CFR 772.1.

United States. The 50 States, the District of Columbia, and the territories and possessions of the United States.

United States-Canada Joint Certification Office. The office established to certify contractors of each country for access, on an equally favorable basis, to unclassified technical data and technology disclosing technology controlled in the United States by this part and in Canada by Canada Minister of Justice, Technical Data Control Regulations SOR/86-345, May 27, 2014 current edition.

U.S. DoD contractor. Those qualified U.S. contractors currently holding grants or contracts with DoD or those contractors declared eligible for DoD information services by a sponsoring DoD activity on the basis of participation in a DoD Potential Contractor Program.

§ 250.4 Policy.

It is DoD policy that:

(a) Pursuant to 10 U.S.C. 130 and 133, the Secretary of Defense may withhold from public disclosure any technical data and technology with military or space application in the possession or under the control of the DoD, if such technical data and technology may not be exported lawfully without a license, exception, exemption, or other export

authorization, in accordance with U.S. export control laws and regulations (including 22 U.S.C. 2778, 50 U.S.C. chapter 35, 22 CFR parts 120 through 130, and 15 CFR parts 730 through 774). However, technical data and technology may not be withheld if regulations distributed in accordance with 22 U.S.C. 2778 authorize the export of such technical data and technology pursuant to a general unrestricted license or exemption.

(b) Because public disclosure of technical data and technology subject to this part is the same as providing uncontrolled foreign access, withholding such technical data and technology from public disclosure, unless approved, authorized, or licensed in accordance with export control laws, is necessary and in the national interest.

(c) Notwithstanding the authority in paragraph (c)(1) of this section, it is DoD policy to provide technical data and technology governed by this part to individuals and enterprises that are:

(1) Currently qualified U.S. contractors, when such technical data and technology relate to a legitimate business purpose for which the contractor is certified; or

(2) A certified Canadian contractor referred to in and governed by Canada Minister of Justice, Technical Data Control Regulations SOR/86-345, May 27, 2014 current edition (available at <http://laws-lois.justice.gc.ca/PDF/SOR-86-345.pdf>) and registered at the United States-Canada Joint Certification Office when a legitimate business relationship has been established between the government and the contractor.

(d) This part may not be used by the DoD Components as authority to deny access to technical data and technology to the Congress or to any Federal, State, or local government agency that requires the technical data and technology for regulatory or other official government purposes. Dissemination of the technical data and technology will include a statement that DoD controls it, in accordance with this part.

(e) The authority in this part may not be used to withhold from public disclosure unclassified information regarding DoD operations, policies, activities, or programs, including the costs and evaluations of performance and reliability of military and space equipment. When information does contain technical data and technology subject to this part, the technical data and technology must be excised from what is disclosed publicly.

(f) This part may not be used as a basis for the release of limited rights or restricted rights data as defined in 48 CFR or those that are authorized to be

withheld from public disclosure pursuant to the 5 U.S.C. 552.

(g) This part may not be used to provide protection for technical data that should be classified in accordance with Executive Order 13526, "Classified National Security Information," and volume 1 of DoD Manual 5200.01 (available at http://www.dtic.mil/whs/directives/corres/pdf/520001_vol1.pdf).

(h) This part provides immediate authority to cite section (b)(3) of 5 U.S.C. 552 (FOIA Exemption 3) described in 32 CFR part 286 as the basis for denials under 5 U.S.C. 552 of technical data and technology currently determined to be subject to the provisions of this part. The technical data will be withheld under the authority of 10 U.S.C.130. If the information originated or is under the control of a Government Agency outside the DoD, DoD Components will refer to that Government Agency for a release determination.

(i) Technical data and technology subject to this part must be marked in accordance with DoD Instruction 5230.24, "Distribution Statements on Technical Documents" (available at <http://www.dtic.mil/whs/directives/corres/pdf/523024p.pdf>) and volume 4 of DoD Manual 5200.01 and released in accordance with DoD Instruction 2040.02, "International Transfers of Technology, Articles, and Services" (available at http://www.dtic.mil/whs/directives/corres/pdf/204002_2014.pdf), DoD Directive 5230.09, "Clearance of DoD Information for Public Release" (available at <http://www.dtic.mil/whs/directives/corres/pdf/523009p.pdf>), DoD Instruction 5230.29, "Security and Policy Review of DoD Information for Public Release" (available at <http://www.dtic.mil/whs/directives/corres/pdf/523029p.pdf>), and 32 CFR part 285.

(j) Technical data and technology subject to this part, when disseminated electronically, must be marked in accordance with volume 4 of DoD Manual 5200.01 and are subject to all applicable security requirements specified in DoD Instruction 8500.01, "Cybersecurity" (available at http://www.dtic.mil/whs/directives/corres/pdf/850001_2014.pdf) and Chairman of the Joint Chiefs of Staff Instruction 6510.01F, "Information Assurance (IA) and Support to Computer Network Defense (CND)," February 9, 2011, as amended (available at http://www.dtic.mil/cjcs_directives/cdata/unlimit/6510_01.pdf).

(k) In accordance with DoD Instruction 5015.02, "DoD Records Management Program" (available at <http://www.dtic.mil/whs/directives/corres/pdf/501502p.pdf>), technical data

and technology subject to this part must be maintained and managed consistent with National Archives and Records Administration approved dispositions to ensure proper maintenance, use, accessibility, and preservation, regardless of format or medium.

§ 250.5 Responsibilities.

(a) The Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)) has overall responsibility for the implementation of this part and will designate an office to:

(1) Administer and monitor compliance with this part.

(2) Receive and disseminate notifications of temporary revocation of contractor qualification in accordance with paragraph (e) of § 250.6.

(3) Receive recommendations for contractor disqualification made in accordance with paragraph (f) of § 250.6, and act as disqualification authority.

(4) Provide technical assistance when necessary to the DoD Components to assess the significance of the military or space application of technical data and technology that may be withheld from public disclosure in accordance with this part.

(5) Maintain and update procedures and appropriate mechanisms for the certification of qualified contractors, in accordance with paragraph (c) of § 250.4 of this part.

(6) Ensure that the requirements of this part are incorporated into 48 CFR for application to contracts involving technical data and technology governed by this part.

(7) Develop, in conjunction with the Office of the General Counsel of the Department of Defense (GC DoD), guidelines for responding to appeals, as identified in paragraph (k) of § 250.6.

(8) Develop procedures to ensure that the DoD Components apply consistent criteria in authorizing exceptions in accordance with paragraph (j) of § 250.6.

(9) Prescribe procedures to develop, collect, and disseminate certification statements; to ensure their sufficiency, accuracy, and periodic renewal; and to make final determinations of qualification.

(10) Take such other actions that may be required to ensure consistent and appropriate implementation of this part within the DoD.

(b) The Under Secretary of Defense for Policy (USD(P)):

(1) Prepares and issues policy guidance regarding the foreign disclosure and security controls for information in international programs within the scope of this part.

(2) Provides consultation to DoD offices on export control and commodity jurisdiction determinations.

(c) The Deputy Chief Management Officer (DCMO) of the Department of Defense:

(1) Monitors the implementation of the provisions of this part that pertain to 5 U.S.C. 552 and 32 CFR part 285.

(2) Provides such other assistance as may be necessary to ensure compliance with this part.

(d) The GC DoD:

(1) Advises DoD Components with respect to the statutory and regulatory requirements governing the export of technical data and technology.

(2) Advises the USD(AT&L) regarding consistent and appropriate implementation of this part.

(e) The DoD Component heads:

(1) Disseminate and withhold from public disclosure technical data and technology subject to this part consistent with its policies and procedures.

(2) Designate a focal point to:

(i) Ensure implementation of this part.

(ii) Identify classes of technical data and technology whose release are governed by paragraph (d)(3) of § 250.6.

(iii) Act on appeals relating to case-by-case denials for release of technical data and technology.

(iv) Temporarily revoke a contractor's qualification in accordance with paragraph (e) of § 250.6.

(v) Receive and evaluate requests for reinstatement of a contractor's qualification in accordance with paragraph (e)(4) of § 250.6.

(vi) Recommend contractor's disqualification to the USD(AT&L) in accordance with paragraph (f) of § 250.6.

(3) Develop, distribute, and effect Component regulations to implement this part.

(4) Ensure that the controlling DoD office that created or sponsored the technical information exercises its inherently governmental responsibility to determine the appropriate marking in accordance with DoD Instruction 5230.24 and volumes 2 and 4 of DoD Manual 5200.01 (volume 2 available at http://www.dtic.mil/whs/directives/corres/pdf/520001_vol2.pdf) and that all technical documents, including research, development, engineering, test, sustainment, and logistics information, regardless of media or form, are marked correctly.

§ 250.6 Procedures.

(a) Procedures for release of technical information must be made under the following guidelines:

(1) DoD Components may make their technical information for other than military or space application available for public disclosure in accordance with DoD Directive 5230.09 and DoD

Instruction 5230.29. DoD has the authority to withhold technical data and technology as defined in § 250.3 from public disclosure.

(2) DoD Components will process FOIA requests from the public for technical information in accordance with 32 CFR part 286 and governing DoD Component issuances. All requested technical data and technology currently determined to be subject to the withholding authority in this part will be denied under Exemption 3 of 5 U.S.C. 552 and 10 U.S.C. 130. Any FOIA appeals for the denied information will be processed in accordance with 32 CFR part 286 and governing DoD Component issuances.

(3) DoD Components may give qualified contractors access to their technical data and technology as permitted by the provisions of this part.

(i) United States-Canada Joint Certification Office adjudicates certification of qualified contractors.

(ii) To qualify, U.S. and Canadian contractors must submit a completed DD Form 2345 "Militarily Critical Technical Data Agreement," to the United States-Canada Joint Certification Office.

(iii) To qualify, Canadian contractors will submit a completed DD Form 2345 when a Canadian contractor intends to request access to DoD-controlled technical data and technology.

(iv) A copy of the company's State/ Provincial Business License, Incorporation Certificate, Sales Tax Identification Form, ITAR Controlled Goods Registration letter or certificate, or other documentation that verifies the legitimacy of the company must accompany all DD Forms 2345.

(v) The contractor's business activity is a key element of the certification process since this information is used by the controlling office as a basis for approving or disapproving specific requests for technical data and technology. The business activity statement should be sufficiently detailed to support requests for any data that the contractor expects for legitimate business purposes.

(b) Upon receipt of a request for technical information in the possession of, or under the control of the DoD, the controlling DoD office for the requested information will determine whether the information is governed by this part.

(1) The determination will be based on whether

(i) The information is subject to 22 CFR part 121 or 15 CFR part 774.

(ii) The information would require a license, exception, exemption, or other export authorization in accordance with U.S. export control laws and regulations

in accordance with 22 U.S.C. 2778, 50 U.S.C. chapter 35, 22 CFR parts 120 through 130, and 15 CFR parts 730 through 774.

(iii) The information would not fall into the categories of information described in paragraphs (c) and (d) of § 250.2.

(2) In making such a determination, the controlling office may consult with the Defense Technology Security Administration for advice on whether U.S. export control laws or regulations apply. The controlling DoD office may request assistance in making this determination from the USD(AT&L), and if necessary, consult the Departments of State, Commerce, or Energy.

(c) The controlling DoD office will ensure technical data and technology governed by this part are marked for distribution in accordance with DoD Instruction 5230.24 and volume 4 of DoD Manual 5200.01.

(d) The controlling DoD office will authorize release of technical data and technology governed by this part to qualified contractors, as defined in § 250.3, unless either:

(1) The qualification of the contractor concerned has been temporarily revoked in accordance with paragraph (e) of this section;

(2) The controlling DoD office judges the requested technical data and technology to be unrelated to the purpose for which the qualified contractor is certified. When release of technical data and technology is denied in accordance with this paragraph, the controlling DoD office will request additional information to explain the intended use of the requested technical data and technology and, if appropriate, request a new certification (see § 250.3) describing the intended use of the requested technical data and technology; or

(3) The technical data and technology are being requested for a purpose other than to permit the requester to bid or perform on a contract with the DoD or other USG agency. In this case, the controlling DoD office will withhold the technical data and technology if the DoD Component focal point determines the release of the technical data and technology may jeopardize an important technological or operational military advantage of the United States.

(e) Upon receipt of substantial and credible information that a qualified U.S. contractor has violated U.S. export control law; violated its certification; made a certification in bad faith; or omitted or misstated material fact, the DoD Component will temporarily revoke the U.S. contractor's

qualification. Canadian contractors are disqualified in accordance with Canada Minister of Justice, Technical Data Control Regulations SOR/86-345, May 27, 2014 current edition.

(1) The DoD Component may delay such temporary revocations with the potential to compromise a USG investigation.

(2) Immediately upon a temporary revocation, the DoD Component will notify the contractor and the USD(AT&L).

(3) The contractor will be given an opportunity to respond in writing to the information upon which the temporary revocation is based before being disqualified.

(4) Any U.S. contractor whose qualification has been temporarily revoked may present information to the DoD Component showing that the basis for revocation was in error or has been remedied and be reinstated.

(f) When the basis for a contractor's temporary revocation cannot be removed within 20 working days, the DoD Component will recommend to the USD(AT&L) that the contractor be disqualified.

(g) After receipt of substantial and credible information that a qualified U.S. contractor has violated U.S. export control law, the DoD Component must notify the appropriate law enforcement agency.

(h) Charges for copying, certifying, and searching records rendered to requesters will be levied in accordance with chapter 4, appendix 2 of volume 11A of DoD 7000.14-R, "Department of Defense Financial Management Regulations (FMRs)" (available at http://comptroller.defense.gov/Portals/45/documents/fmr/Volume_11a.pdf). Normally, only one copy of the same record or document will be provided to each requester. Each release to qualified contractors of controlled technical data and technology governed by this part will be accompanied by a "Notice to Accompany the Dissemination of Export-Controlled Technical Data and Technology" (see Figure to § 250.6(h)).

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Figure to § 250.6(h)—Example of the Notice to Accompany Export-Controlled Technical Data and Technology

1. Export of information contained herein, including release to foreign nationals within the United States, without first obtaining approval or license from the Department of State for items controlled by the International Traffic in Arms Regulations (ITAR), or the Department of Commerce for items controlled by the Export Administration Regulations (EAR), may constitute a violation of law.
2. Under 22 U.S.C. §2778 the penalty for unlawful export of defense articles controlled under the ITAR is not more than 20 years imprisonment, a fine of \$1,000,000, or both.
3. Under 50 U.S.C. §1705 and 15 CFR §764.3, as adjusted for inflation by 15 CFR §6.4, the penalty for persons who violate, attempt or conspire to violate, or cause a violation of the EAR, while the EAR is continued in effect by Executive Order under the International Emergency Economic Powers Act, may include civil penalties of not more than \$284,582 per transaction (subject to further adjustment for inflation) or twice the amount of the transaction, whichever is greater and criminal penalties of not more than \$1,000,000, imprisonment of not more than 20 years, or both. Violations of the EAR may also result in the denial of export privileges.
5. In accordance with the certification that establishes you as a “qualified contractor,” unauthorized dissemination of this information is prohibited and may result in disqualification as a qualified contractor, and may be considered in determining your eligibility for future contracts with the Department of Defense.
6. The U.S. Government assumes no liability for direct patent infringement, contributory patent infringement, or misuse of technical data and technology.
7. The U.S. Government does not warrant the adequacy, accuracy, currency, or completeness of the technical data.
8. The U.S. Government assumes no liability for loss, damage, or injuries resulting from manufacture or use for any purpose of any product, article, system, or material involving reliance upon any or all technical data and technology furnished in response to the request for technical data and technology.
9. If the technical data and technology furnished by the government will be used for commercial manufacturing or other profit potential, a license for such use may be necessary. Any payments made in support of the request for data and technology do not include or involve any license rights.
10. A copy of this notice must be provided with any partial or complete reproduction of these technical data and technology that are provided to qualified contractors.

purposes consistent with their certification without the permission of the controlling DoD office or when dissemination is:

(1) To any foreign recipient for which the technical data and technology are approved, authorized, or licensed in accordance with 22 U.S.C. 2778 or 15 CFR parts 730 through 774.

(2) To another qualified U.S. contractor including existing or potential subcontractors, but only within the scope of the certified legitimate business purpose of the recipient.

(3) To the Departments of State and Commerce to apply for approvals, authorizations, or licenses for export pursuant to 22 U.S.C. 2778 or 15 CFR parts 730 through 774. The application will include a statement that the technical data and technology for which the approval, authorization, or license is sought is controlled by the DoD in accordance with this part.

(4) To the Congress or any Federal, State, or local governmental agency for regulatory purposes or otherwise as may be required by law or court order. Any such dissemination will include a statement that the technical data and technology are controlled by the DoD in accordance with this part.

(j) A qualified contractor desiring to disseminate technical data and technology subject to this part in a manner not permitted expressly by the terms of this part must be granted authority to do so by the controlling DoD office, consistent with U.S. export control laws and regulations specified in 22 U.S.C. 2778, 50 U.S.C. chapter 35, 22 CFR parts 120 through 130, and 15 CFR parts 730 through 774 and DoD policies.

(k) Any requester denied technical data and technology or any qualified U.S. contractor denied permission to disseminate such technical data and technology in accordance with this part will be promptly provided with a written statement of reasons for that action, and advised of the right to make a written appeal to a specifically identified appellate authority within the DoD Component. Other appeals will be processed as directed by the USD(AT&L).

(l) Denials will cite 10 U.S.C. 130 and 133 as implemented by this part. Implementing procedures will provide for resolution of any appeal within 20 working days.

§ 250.7 Directly arranged visits.

(a) USG officials and certified U.S. contractors and Canadian government officials and certified Canadian contractors may use the certification

process to facilitate directly arranged visits that involve access to unclassified technical data and technology. Activities under this process are limited to:

(1) Procurement activities such as unclassified pre-solicitation conferences, discussions related to unclassified solicitations, and collection of procurement unclassified documents.

(2) Performance of an unclassified contract.

(3) Scientific research, in support of unclassified U.S. or Canadian national defense initiatives.

(4) Attendance at restricted meetings, conferences, symposia, and program briefings where technical data and technology governed by this part or Canada Minister of Justice, Technical Data Control Regulations SOR/86-345, May 27, 2014 current edition will be presented, or the event is being held in an unclassified access controlled area.

(b) A directly arranged visit does not apply to uncertified U.S. or Canadian contractors; classified visits, where confirmation of the visitors' security clearances is required; or unsolicited marketing visits.

(c) A directly arranged visit related to the release of information controlled in the United States by this part or in Canada by Canada Minister of Justice, Technical Data Control Regulations SOR/86-345, May 27, 2014 current edition, is permitted when two conditions are satisfied.

(1) First condition:

(i) There is a valid license covering the export of the technical data and technology;

(ii) The export or release is permitted under the Canadian exemption on 22 CFR 126.5;

(iii) The export or release is covered by the general exemptions in 22 CFR 125.4; or

(iv) The export or release qualifies for a license exception under 15 CFR parts 730 through 774.

(2) Second condition:

(i) The distribution statement applied to the technical data and technology pursuant to DoD Instruction 5230.24 permits release; or

(ii) The originator or government controlling office authorizes release.

Dated: October 26, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R08-OAR-2016-0620; FRL-9954-67-Region 8]

Approval and Promulgation of Air Quality Implementation Plans; State of Utah; Revisions to Nonattainment Permitting Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to conditionally approve State Implementation Plan (SIP) revisions submitted by the state of Utah on August 20, 2013, with supporting administrative documentation submitted on September 12, 2013. These submittals revise the Utah Administrative Code (UAC) that pertain to the issuance of Utah air quality permits for major sources in nonattainment areas. The EPA proposes a conditional approval because while the submitted revisions to Utah's nonattainment permitting rules do not fully address the deficiencies in the state's program, Utah has committed to address additional remaining deficiencies in the state's nonattainment permitting program no later than a year from the EPA finalizing this conditional approval. If finalized, and upon the EPA finding a timely meeting of this commitment in full, the proposed conditional approval of the SIP revisions would convert to a final approval of Utah's plan. This action is being taken under section 110 of the Clean Air Act (CAA) (Act).

DATES: Written comments must be received on or before November 30, 2016.

ADDRESSES: Submit your comments, identified by EPA-R08-OAR-2016-0620 at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [regulations.gov](http://www.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