oxides, Ozone, Particulate matter, Regional haze, Reporting and recordkeeping requirements, Sulfur dioxide.

Dated: December 2, 2016.

Sarah Dunham,

Director, Office of Atmospheric Programs.

[FR Doc. 2016–29442 Filed 12–7–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 5b

[Docket Number NIH–2016–0001]

RIN 0925–AA63

Privacy Act; Implementation

AGENCY: Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or Department), through the National Institutes of Health (NIH), proposes to exempt, from certain requirements of the Privacy Act, a subset of records in a new system of records, System No. 09–25–0225, NIH Electronic Research Administration (eRA) Records (NIH eRA Records), which covers records used in managing NIH research and development applications and awards throughout the award lifecycle. Elsewhere in today's **Federal Register**, HHS has published a proposed System of Records Notice (SORN) for System No. 09–25–0225 for public notice and comment.

The subset of records proposed to be exempted is material that would inappropriately reveal the identities of referees who provide letters of recommendation and peer reviewers who provide written evaluative input and recommendations to NIH about particular funding applications under an express promise by the government that their identities in association with the written work products they authored and provided to the government will be kept confidential. Only material that would inappropriately reveal a particular referee or peer reviewer as the author of a specific work product (*e.g.,* reference or recommendation letters, reviewer critiques, preliminary or final individual overall impact/priority scores, and/or assignment of peer reviewers to an application and other evaluative materials and data compiled by NIH/OER) is proposed to be exempted. The exemptions would protect not only an author's name in association with their written work product but any content that could enable the author to be identified from context.

The Privacy Act provisions from which the material is proposed to be exempted are those that require the agency to provide an accounting of disclosures, access and amendment, and notification, which are contained in subsections (c)(3) and (d) of the Privacy Act.

DATES: Submit either electronic or written comments regarding this notice by February 6, 2017.

ADDRESSES: You may submit comments, identified by Docket Number NIH–2016–0001 via any of the following methods:

Electronic Submission

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions provided for submitting comments.

Written Submission

Submit written submissions in the following ways:

- *Fax:* 301–402–0169.
- *Mail:* Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852–7669. To ensure timely processing of comments, the HHS/NIH is no longer accepting NPRM comments submitted to the agency by email. The HHS/NIH encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions.*

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and follow the instructions provided for conducting a search, using the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852–7669, telephone 301–496–4607, fax 301–402–0169, email *jm40z@nih.gov.*

SUPPLEMENTARY INFORMATION:

NIH research and development award programs provide funds through contracts, cooperative agreements, and grants to support biomedical and behavioral research and development projects and centers, training, career development, small business, and loan repayment and other research programs. The NIH is responsible to Congress and the U.S. taxpayers for carrying out its research and development award programs in a manner that facilitates research cost-effectively and in compliance with applicable statutes, rules and regulations, including 42 U.S.C. 217a, 281, 282, 41 U.S.C. 423 and 45 CFR part 75. The NIH uses an award process that relies on checks and balances, separation of responsibilities, and a two-level peer review system to ensure that funding applications submitted to NIH are evaluated in a manner that is fair, equitable, timely, and free of bias. The two-level peer review system is authorized by 42 U.S.C. 216; 42 U.S.C. 282(b)(6); 42 U.S.C. 284(c)(3); and 42 U.S.C. 289a and governed by regulations at 42 CFR part 52h, ''Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects.'' The two-level system separates the scientific assessment of proposed projects from policy decisions about scientific areas to be supported and the level of resources to be allocated, which permits a more objective and complete evaluation than would result from a single level of review. The two-level review system is designed to provide NIH officials with the best available advice about scientific and technical merit as well as program priorities and policy considerations. The initial or first level review involves panels of experts established according to scientific disciplines, generally referred to as Scientific Review Groups (SRGs), whose primary function is to evaluate the scientific merit of grant applications. The second level of review of grant applications is performed by National Advisory Boards or Councils composed of both scientific and lay representatives. The recommendations made by these Boards or Councils are based not only on considerations of scientific merit as judged by the SRG but also on the relevance of a proposed project to the programs and priorities of NIH. Referees are those individuals who supply reference or other letters of recommendations for a grant or cooperative agreement applicant. Confidential referee and peer reviewer identifying material is contained in records such as reference or

recommendation letters, reviewer critiques, preliminary or final individual overall impact/priority score records, and/or assignment of peer reviewers to an application and other evaluative materials and data, which referees and peer reviewers provide to the NIH Office of Extramural Research (OER) under express promises that they will not be identified as the sources of the information, and which NIH/OER compiles solely for the purpose of determining applicants' suitability, eligibility, or qualifications for federal contracts, grants, or cooperative agreements. To the extent that records in System No. 09–25–0225 are retrieved by personal identifiers for individuals other than the referees and reviewers (for example, individual applicants), the exemptions proposed for the new system will enable the agency to prevent, when appropriate, those individual record subjects from having access to, and other rights under the Privacy Act with respect to, confidential source-identifying material in the records.

Under the Privacy Act (5 U.S.C. 552a), individuals have a right of access to records about them in federal agency systems of records, and other rights with respect to those records (such as notification, amendment, and an accounting of disclosures), but the Act permits certain types of systems of records (identified in § 552a (j) and (k)) to be exempted from certain requirements of the Act. Subsection (k)(5) permits the head of an agency to promulgate rules to exempt from the requirements in subsections (c)(3) and (d) of the Act investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal contracts, to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence.

Confidential referee and peer reviewer-identifying material in NIH award program records covered by System No. 09–25–0225 qualifies for exemption under subsection (k)(5) because it is investigatory material that NIH/OER compiles solely for the purpose of determining applicants' suitability, eligibility, or qualifications for federal research and development contracts, grants, and cooperative agreements.

The exemptions are necessary to maintain the integrity of the NIH extramural peer review and award processes, which depend on receiving accurate, objective, and unbiased recommendations and evaluations from referees and peer reviewers about funding applications. Protecting their identities as the sources of the information they provide protects them from harassment, intimidation, and other attempts to improperly influence award outcomes, and ensures that they are not reluctant to provide sensitive information or frank assessments. Case law has held that exemptions promulgated under subsection (k)(5) may protect source-identifying material even where the identity of the source is known.

The specific rationales that support the exemptions, as to each affected Privacy Act provision, are as follows:

- *Subsection (c)(3).* An exemption from the requirement to provide an accounting of disclosures to record subjects is needed to protect the identity of any referee or peer reviewer source who is expressly promised confidentiality. Release of an accounting of disclosures to an individual who is related to the application under assessment or evaluation could identify particular referees and peer reviewers as sources of recommendations or evaluative input received, or to be received, on the application. Inappropriately revealing their identities in association with the nature and scope of their assessments or evaluations and could lead them to alter or destroy their assessments or evaluations or subject them to harassment, intimidation, or other improper influences, which would impede or compromise the fairness and objectivity of the grant or contract review process.
- *Subsection (d)(1).* An exemption from the access requirement is needed both during and after a grant or contract review proceeding, to avoid inappropriately revealing the identity of any referee or peer reviewer source who was expressly promised confidentiality. Protecting confidential referee and peer reviewer identifying material from inappropriate access by record subjects is necessary for the integrity of the peer review process to ensure such sources provide candid assessments or evaluations to the government without fear that their identities as linked to a specific work product will be inappropriately revealed. Allowing an individual applicant or other individual who is the subject of an assessment or evaluation to access material that would inappropriately reveal a confidential referee or peer reviewer source could interfere with or compromise the objectivity and fairness of grant and contract review proceedings, constitute an unwarranted invasion of the personal privacy of the source and violate the express promise of confidentiality made to the source.
- *Subsections (d)(2) through (d)(4).* An exemption from the amendment provisions is necessary while one or more related grant and/or contract review proceedings are pending to avoid inappropriately revealing the identity of any referee or peer reviewer source who was expressly promised confidentiality. Allowing an individual applicant or other individual who is the subject of an evaluation or assessment an opportunity to amend extramural assistance program records in a pending proceeding could interfere with that proceeding, could constitute an unwarranted invasion of the personal privacy of a source, and would violate the express promise of confidentiality made to the source, if the information sought to be amended was provided by the source under an express promise of confidentiality and if acknowledging the existence of the record and discussing its contents as required to process the amendment request would inappropriately reveal the source's identity.

Accordingly, pursuant to 5 U.S.C. 552a(k)(5), the agency proposes to exempt the following source-identifying material in system of records-–25–0225 NIH eRA Records from the accounting, access, amendment and notification provisions of the Privacy Act (paragraphs (c)(3), and (d)), based on the specific rationales indicated above: Material that would inappropriately reveal the identities of referees who provide letters of recommendation and peer reviewers who provide written evaluative input and recommendations to NIH about particular funding applications under an express promise by the government that their identities in association with the written work products they authored and provided to the government will be kept confidential; this includes only material that would reveal a particular referee or peer reviewer as the author of a specific work product (*e.g.,* reference or recommendation letters, reviewer critiques, preliminary or final individual overall impact/priority scores, and/or assignment of peer reviewers to an application and other evaluative materials and data compiled by NIH/OER); it includes not only an author's name but any content that could enable the author to be identified from context.

Notwithstanding the exemptions, consideration will be given to any requests for notification, access, and amendment that are addressed to the System Manager, as provided in the

SORN for system of records 09–25–0225.

Analysis of Impacts

The HHS/NIH has examined the impacts of this rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is not a significant regulatory action under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the rule imposes no duties or obligations on small entities, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. The NIH does not expect that a final rule consistent with this NPRM would result in any 1-year expenditure that would meet or exceed this amount.

List of Subjects in 45 CFR Part 5b

Privacy.

For the reasons set out in the preamble, the Department proposes to amend its part 5b of title 45 of the Code of Federal Regulations, as follows:

PART 5b—PRIVACY ACT REGULATIONS

■ 1. The authority citation for Part 5b continues to read as follows:

Authority: 5 U.S.C. 301, 5 U.S.C. 552a.

■ 2. Amend § 5b.11 by adding paragraph (b)(2)(vii)(E) as follows:

§ 5b.11 Exempt systems.

* * * * *

(b) * * *

(2) * * *

(vii) * * *

(E) NIH Electronic Research Administration (eRA) Records, HHS/NIH/OD/OER, 09–25–0225 (*e.g.,* reference or recommendation letters, reviewer critiques, preliminary or final individual overall impact/priority scores, and/or assignment of peer reviewers to an application and other evaluative materials and data compiled by the NIH Office of Extramural Research).

Dated: October 14, 2016.

Francis S. Collins,

Director, National Institutes of Health.

Approved: October 18, 2016.

Sylvia Matthews Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–29058 Filed 12–7–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 224

[Docket No. 141216999–6999–02]

RIN 0648–XD669

Endangered and Threatened Wildlife and Plants: Notice of 12-Month Finding on a Petition To List the Gulf of Mexico Bryde's Whale as Endangered Under the Endangered Species Act (ESA)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule, request for comments.

SUMMARY: We, NMFS, announce a 12-month finding and listing determination on a petition to list the Gulf of Mexico Bryde's whale (*Balaenoptera edeni*) as threatened or endangered under the Endangered Species Act (ESA). We have completed a Status Review report of the Gulf of Mexico Bryde's whale in response to a petition submitted by the Natural Resources Defense Council. After reviewing the best scientific and commercial data available, including the Status Review report, and consulting with the Society for Marine Mammology's Committee on Taxonomy, we have determined that the Gulf of Mexico Bryde's whale is taxonomically a subspecies of the Bryde's whale thus meeting the ESA's definition of a species. Based on the Gulf of Mexico Bryde's whale's small population (likely fewer than 100 individuals), its life history characteristics, its extremely limited distribution, and its vulnerability to existing threats, we believe that the species faces a high risk of extinction. Based on these considerations, described in more detail within this action, we conclude that the Gulf of Mexico Bryde's whale is in danger of extinction throughout all of its range and meets the definition of an endangered species. We are soliciting information that may be relevant to inform both our final listing determination and designation of critical habitat.

DATES: Information and comments on the subject action must be received by January 30, 2017. For the specific date of the public hearing, see Public Hearing section.

ADDRESSES: You may submit comments, information, or data on this document, identified by the code NOAA–NMFS–2014–0101 by any of the following methods:

- *Electronic submissions:* Submit all electronic comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2014-0101,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments;
- *Mail:* NMFS, Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701;
- *Hand delivery:* You may hand deliver written information to our office during normal business hours at the street address given above.

The Status Review of Bryde's Whales in the Gulf of Mexico (Rosel *et al.,* 2016) and reference list are available by submitting a request to the Species Conservation Branch Chief, Protected Resources Division, NMFS Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701–5505, Attn: Bryde's Whale 12-month Finding. The Status Review report and references are also available electronically at: *http://sero.nmfs.noaa.gov/protected_resources/listing_petitions/index.html.*

FOR FURTHER INFORMATION CONTACT: Laura Engleby or Calusa Horn, NMFS, Southeast Regional Office (727) 824–5312 or Marta Nammack, NMFS, Office of Protected Resources (301) 427–8469.

SUPPLEMENTARY INFORMATION:

Background

On September 18, 2014, we received a petition from the Natural Resources Defense Council to list the Gulf of