

Matters concerning participation in civil actions or proceedings or arbitration.

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CONTACT PERSON FOR MORE INFORMATION:
Judith Ingram, Press Officer. Telephone:
(202) 694-1220.

(Authority: Government in the Sunshine Act,
5 U.S.C. 552b)

Vicktorja J. Allen,

Deputy Secretary of the Commission.

[FR Doc. 2023-11243 Filed 5-23-23; 11:15 am]

BILLING CODE 6715-01-P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10 a.m., Tuesday, June
6, 2023.

PLACE: The Richard V. Backley Hearing
Room, Room 511, 1331 Pennsylvania
Avenue NW, Suite 504 North,
Washington, DC 20004 (enter from F
Street entrance).

*Phone Number for Listening to
Meeting:* 1-(866) 236-7472.

Passcode: 678-100.

STATUS: Open.

MATTERS TO BE CONSIDERED: The
Commission will consider and act upon
the following in open session: *Perry
County Resources, LLC*, Docket No.
KENT 2022-0024. (Issues include
whether the Judge abused his discretion
in denying the approval of the
settlement motion based on the
Secretary of Labor's refusal to provide a
section 104(b) order that was associated
with a citation that was a subject of the
motion to approve settlement.)

Any person attending this meeting
who requires special accessibility
features and/or auxiliary aids, such as
sign language interpreters, must inform
the Commission in advance of those
needs. Subject to 29 CFR 2706.150(a)(3)
and 2706.160(d).

CONTACT PERSON FOR MORE INFO:
Emogene Johnson (202) 434-9935/(202)
708-9300 for TDD Relay/1-800-877-
8339 for toll free.

(Authority: 5 U.S.C. 552b)

Dated: May 23, 2023.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2023-11289 Filed 5-23-23; 11:15 am]

BILLING CODE 6735-01-P

GENERAL SERVICES ADMINISTRATION

[Notice-MA-2023-02; Docket No. 2023-
0002; Sequence No. 3]

Fleet Management Information Systems

AGENCY: Office of Government-Wide
Policy (OGP), General Services
Administration (GSA).

ACTION: Notice of GSA FMR Bulletin B-
2023-55.

SUMMARY: Federal Management
Regulation (FMR) Bulletin B-2023-55
cancels and replaces Bulletin FMR B-15
to provide updated guidance for
Executive Agencies' fleet management
information systems (FMIS). This
bulletin also incorporates requirements
for asset level data and telematics. GSA
expects that, following this guidance,
the data accuracy contained in agencies'
FMIS will improve.

DATES: *Applicable:* May 25, 2023.

FOR FURTHER INFORMATION CONTACT:
James Vogelsinger, Director, Vehicle
Policy Division, at 202-501-1764 or
vehicle.policy@gsa.gov.

SUPPLEMENTARY INFORMATION:

Background

FMR Bulletin B-15 was published in
2007 to emphasize that executive
agencies are required to have FMIS.
While agencies are still required to
operate and maintain FMIS, Bulletin
FMR B-15 does not cover innovations
in fleet management technology such as
telematics and asset level data
requirements.

FMR Bulletin B-2023-55 is available
for download at [https://www.gsa.gov/
policy-regulations/regulations/federal-
management-regulation/federal-
management-regulation-fmr-related-
files#FMRBulletins](https://www.gsa.gov/policy-regulations/regulations/federal-management-regulation/federal-management-regulation-fmr-related-files#FMRBulletins).

Krystal J. Brumfield,

*Associate Administrator, Office of
Government-Wide Policy.*

[FR Doc. 2023-11154 Filed 5-24-23; 8:45 am]

BILLING CODE 6820-14-P

OFFICE OF GOVERNMENT ETHICS

Privacy Act of 1974; System Records

AGENCY: Office of Government Ethics.

ACTION: Notice of a new system of
records.

SUMMARY: Pursuant to the provisions of
the Privacy Act of 1974, the Office of
Government Ethics (OGE) proposes to
establish a new Governmentwide
system of records covering executive

branch legal expense fund trust
documents, reports, and other name-
retrieved legal expense fund records.

DATES: This system of records will be
effective on May 25, 2023, subject to a
30-day period in which to comment on
the routine uses, described below.
Please submit any comments by June 26,
2023.

ADDRESSES:

Email: Comments may be submitted
to OGE by email to *usoge@oge.gov*.
(Include reference to "OGE/GOVT-3
comment" in the subject line of the
message.)

Mail, Hand Delivery/Courier: Office of
Government Ethics, 1201 New York
Avenue NW, Suite 500, Attention:
Jennifer Matis, Associate Counsel,
Washington, DC 20005-3917.

Comments may be posted on OGE's
website, <https://www.oge.gov>. Sensitive
personal information, such as account
numbers or Social Security numbers,
should not be included. Comments
generally will not be edited to remove
any identifying or contact information.

FOR FURTHER INFORMATION CONTACT:
Jennifer Matis, Associate Counsel, at the
U.S. Office of Government Ethics;
telephone: 202-482-9216; TTY: 800-
877-8339; Email: *jmatis@oge.gov*.

SUPPLEMENTARY INFORMATION: OGE is
concurrently adding a new subpart J to
the Standards of Ethical Conduct for
Executive Branch Employees at 5 CFR
part 2635. See 87 FR 23769 (Apr. 21,
2022). The new subpart J contains the
standards for an employee's acceptance
of payments for legal expenses through
a legal expense fund for a matter arising
in connection with the employee's
official position, the employee's prior
position on a campaign, or the
employee's prior position on a
Presidential Transition Team.

In accordance with the Privacy Act of
1974, 5 U.S.C. 552a, this document
provides public notice that OGE is
creating a new Governmentwide system
of records to cover records collected,
generated, maintained, and disclosed
under OGE's legal expense fund (LEF)
regulation published at 5 CFR part 2635,
subpart J. A Governmentwide system of
records is a system of records where one
agency (in this case, OGE) has
regulatory authority over records in the
custody of multiple agencies and the
agency with regulatory authority
publishes a system of records notice that
applies to all of the records regardless
of their custodial location.

This system of records covers the
information required to be collected,
generated, maintained, and disclosed by
executive branch agencies pursuant to
the new subpart J, including

information from current Federal employees establishing, maintaining, and terminating legal expense funds, and information from legal expense fund trustees, donors, and payees. The system of records also permits agencies and OGE to share legal expense fund information with each other as necessary to administer the provisions of the regulation, and permits the posting of such information on OGE's website as required by the regulation.

The LEF regulation requires that employees who wish to establish a legal expense fund do so through a trust with a single, named employee beneficiary and a trustee. It also requires an employee beneficiary to file quarterly reports that include information regarding members of the public who contribute payments for legal expenses (donors) and members of the public who receive payments from a legal expense fund (payees), as well as termination reports upon the termination of the trust and/or executive branch employment. The trust documents, quarterly reports, and termination reports will be posted directly on OGE's website in accordance with 5 CFR 2635.1007(g). These trust documents and reports are generally first submitted to the Designated Agency Ethics Officials (DAEO) at the beneficiary's employing agency but transmitted to OGE for posting. However, the regulation permits anonymous whistleblowers to choose to submit their trust document and reports directly to OGE. DAEOs who create a LEF will also submit their trust document and reports directly to OGE.

This system of records also covers information collected or generated by executive branch agencies in the course of administering the LEF regulation, including information necessary to track and review LEF trust documents, quarterly reports, and termination reports, and information relevant to conflict-of-interest determinations.

SYSTEM NAME AND NUMBER:

OGE/GOVT-3, OGE Legal Expense Fund Trust Documents, Reports, and Other Name-Retrieved Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Office of Government Ethics, 1201 New York Avenue NW, Suite 500, Washington, DC 20005-3917, and designated agency ethics offices.

SYSTEM MANAGER(S):

(a) For records filed directly with the Office of Government Ethics by non-OGE employees: General Counsel,

Office of Government Ethics, Suite 500, 1201 New York Avenue NW, Washington, DC 20005-3917.

(b) For records filed with a Designated Agency Ethics Officials (DAEO) at the agency where the employee beneficiary is employed: The DAEO at the department or agency concerned.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title IV of the Ethics in Government Act of 1978, 5 U.S.C. 13101 *et seq.*; sections 201(a) and 403 of Executive Order 12674 (as modified by E.O. 12731); 5 U.S.C. 7301, 7351(c), and 7353(b)(1); 5 CFR part 2635, subpart J.

PURPOSE(S) OF THE SYSTEM:

The purpose of the system is to collect, generate, maintain, and disclose the information necessary to administer the provisions of the OGE legal expense fund (LEF) regulation at 5 CFR part 2635, subpart J. This includes, but is not limited to, obtaining information relevant to a conflict-of-interest determination and disclosing information on the OGE website pursuant to the regulation. It contains information from executive branch employees establishing legal expense funds as well as information regarding legal expense fund trustees, donors, and payees. It also contains related information collected or generated by OGE or other agencies in the process of collecting, reviewing, tracking, maintaining, and disclosing legal expense fund records. The system of records also permits agencies and OGE to share legal expense fund information with each other as necessary to administer the provisions of the regulation and permits the posting of such information on OGE's website as required by the regulation.

Although all beneficiaries must be current executive branch employees at the time the legal expense fund is created, information may be collected or remain in the system of records after the employee beneficiary has left employment with the executive branch.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system of records contains records about executive branch employees who seek to create a legal expense fund, pursuant to 5 CFR part 2635, subpart J, for the purpose of accepting donations and disbursing payments for legal expenses for a matter arising in connection with the employee's past or current official position, the employee's prior position on a campaign, or the employee's prior position on a Presidential Transition Team. Information may be collected or

remain in the system of records after the employee beneficiary has left employment with the executive branch. This system also contains records about members of the public who contribute payments for legal expenses (donors), members of the public who receive payments from a legal expense fund (payees), and members of the public who serve as a beneficiary's trustee or representative in establishing and maintaining a legal expense fund.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records contains all information or material, retrieved by name or other personal identifier, which is created or received by OGE or other agencies in the course of administering the legal expense fund provisions of the regulation at 5 CFR part 2635, subpart J. The system of records also contains records generated by agencies in the course of administering the legal expense fund provisions of 5 CFR part 2635, subpart J. The categories of records include, but are not limited to, the following:

- legal expense fund trust documents;
- quarterly reports;
- trust termination reports;
- employment termination reports;
- names and contact information of beneficiaries, beneficiary representatives, donors, and trustees; and
- tracking information and deliberative notes generated by the review of legal expense fund trust documents submitted for approval, quarterly reports, trust termination reports, and employment termination reports.

The data elements contained on these records include, but are not limited to, names, city and state of donor, employment information, information about contribution amounts, information about fund payments to service providers, and information about the purpose for which the legal expense fund was created. None of the records in the system of records shall contain Social Security numbers.

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by:

- a. The beneficiary of the legal expense fund and the legal expense fund's trustee or representative;
- b. Donors who contribute to the legal expense fund for the payment of legal expenses;
- c. Payees who receive payments distributed from a legal expense fund; and
- d. Executive branch employees, such as agency ethics officials and OGE

employees, who generate information and documents related to legal expense funds in the system in the course of their official duties.

As stated in the preamble to the proposed rule, OGE will create a form to collect information for the quarterly reports, trust termination reports, and employment termination reports. OGE will provide beneficiaries and trustees with a template for collecting information from donors and payees, as well as guidance on drafting trust documents. Together, this information collection is titled "OGE Legal Expense Fund Information Collection" and is subject to Paperwork Reduction Act approval by the Office of Management and Budget.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records and the information contained therein may be used:

a. To disclose information to authorized officials of OGE or the beneficiary's employing agency in accordance with the Ethics in Government Act of 1978, 5 U.S.C. 13101 *et seq.*, 5 CFR part 2635, subpart J, and other ethics-related laws, Executive orders, and regulations conferring pertinent authority on OGE.

b. To disclose information to the beneficiary's designated trustee or representative as necessary for the administration of the provisions of 5 CFR part 2635, subpart J.

c. To disclose on the OGE website legal expense fund trust documents, quarterly reports, and termination reports submitted to an agency pursuant to 5 CFR part 2635, subpart J.

d. To disclose pertinent information to the appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, where the disclosing agency becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

e. To disclose information to any source when necessary to obtain information relevant to a conflict-of-interest investigation or determination.

f. To disclose information to the National Archives and Records Administration in records management inspections conducted under authority of 44 U.S.C. 2904 and 2906.

g. To disclose information to the Office of Management and Budget at any stage in the legislative coordination and clearance process in connection with private relief legislation as set forth in OMB Circular No. A-19.

h. To disclose information when the disclosing agency determines that the

records are arguably relevant and necessary to a proceeding before a court, grand jury, or administrative or adjudicative body; or in a proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant and necessary to the proceeding.

i. To disclose information to a Member of Congress or a congressional office in response to an inquiry made on behalf of, and at the request of, an individual who is the subject of the record.

j. To disclose information to contractors, grantees, experts, consultants, detailees, and other non-Government employees performing or working on a contract, service, or other assignment for the Federal Government, when necessary to accomplish an agency function related to this system of records.

k. To disclose information to such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

l. To disclose information to appropriate agencies, entities, and persons when: (1) the agency maintaining the records suspects or has confirmed that there has been a breach of the system of records; (2) the agency maintaining the records has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the agency (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the agency's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

m. To disclose information to another Federal agency or Federal entity, when the agency maintaining the record determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

These records are maintained in electronic form, whenever possible. Records may be maintained in hardcopy form if necessary, as long as they are maintained in secured file cabinets to

which only authorized personnel have access.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The data will be retrieved by the names of all of the individuals identified in the "Categories of Individuals Covered by the System" section, as well as by other data points such as agency name, type of document, quarter and year, and/or report type. Beneficiaries, trustees, representatives, donors, and payees will all be provided with notices in accordance with 5 U.S.C. 552a(e)(3).

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

OGE records dispositions are pending. Related records will be maintained as permanent as required by the National Archives and Records Administration (NARA) until NARA has approved the retention and disposition schedule related to records for 5 CFR part 2635, subpart J.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records should be maintained and managed electronically whenever possible. Hardcopy records are maintained in secured file cabinets to which only authorized personnel have access. OGE maintains electronic records on the OGE network, including in OGE internal applications. They are protected from unauthorized access through password identification procedures, multifactor authentication, limited access, firewalls, and other system-based protection methods. Access to the systems is controlled based on user roles and responsibilities. Other executive branch agencies are responsible for properly safeguarding the records maintained in their systems using equivalent safeguards.

RECORD ACCESS PROCEDURES:

Individuals wishing to request access to their records should contact the appropriate office as shown in the Notification Procedure section. Individuals must furnish the following information for their records to be located and identified:

- a. Full name.
 - b. Department or agency and component with which employed, if applicable.
 - c. Date the legal expense fund was established, if applicable.
 - d. A reasonably specific description of the record content being sought.
- Individuals requesting access to records maintained at OGE must also follow OGE's Privacy Act regulations regarding verification of identity and

access to records (5 CFR part 2606). In addition, individuals seeking access to records filed with the DAEO at the agency where the employee beneficiary is employed must follow that agency's regulations regarding verification of identity and access to records.

CONTESTING RECORD PROCEDURES:

Because the information in these records is updated on a periodic basis, most record corrections can be handled through internal agency procedures for updating the records without the need for a formal request to amend pursuant to the Privacy Act. However, individuals can obtain information on the procedures for contesting the records under the provisions of the Privacy Act by contacting the appropriate office shown in the Notification Procedure section.

Individuals requesting records corrections of records maintained at OGE must also follow OGE's Privacy Act regulations regarding verification of identity and access to records (5 CFR part 2606). In addition, individuals requesting corrections to records filed with the DAEO at the agency where the employee beneficiary is employed must follow that agency's regulations regarding verification of identity and access to records.

NOTIFICATION PROCEDURES:

Individuals wishing to inquire whether this system of records contains information about them should contact, as appropriate:

a. For records filed directly with OGE, contact the General Counsel, Office of Government Ethics, Suite 500, 1201 New York Avenue NW, Washington, DC 20005-3917; and

b. For records filed with the DAEO where the employee beneficiary is employed, contact the DAEO at the department or agency concerned.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Approved: May 10, 2023.

Emory Rounds,

Director, U.S. Office of Government Ethics.
[FR Doc. 2023-10292 Filed 5-24-23; 8:45 am]

BILLING CODE 6345-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-1618]

Generally Accepted Scientific Knowledge in Applications for Drug and Biological Products: Nonclinical Information; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Generally Accepted Scientific Knowledge in Applications for Drug and Biological Products: Nonclinical Information." This draft guidance is intended to assist sponsors in determining whether it may be appropriate to rely on generally accepted scientific knowledge (GASK) to fulfill certain legal and regulatory requirements applicable to the new drug application (NDA) or biologics licensing application (BLA) in question. When final, this guidance will represent the Agency's current thinking on this topic.

DATES: Submit either electronic or written comments on the draft guidance by July 24, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2023-D-1618 for "Generally Accepted Scientific Knowledge in Applications for Drugs and Biological Products: Nonclinical Information." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- *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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.regulations.gov>