Policy for Evaluations and Other Evidence-Building Activities

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Policy for Evaluations and Other Evidence-Building Activities

Purpose

EPA's ability to pursue its mission to protect human health and the environment depends upon the availability and quality of data and evidence that support environmental policies, decisions, quidance, and regulations. This Policy provides a framework to comply with the Foundations for Evidence-Based Policymaking Act of 2018 and OMB guidance and to promote a culture of evaluation and continuous learning that ensures agency decisions are made on the best available evidence. EPA is committed to using evaluation, statistics, research, analysis, and other evidence to achieve our mission. This Policy establishes expectations for EPA's development and use of evaluations and other evidence-building activities.

Background

The Foundations for Evidence-Based Policy Making Act of 2018 (The Evidence Act) was signed into law with bipartisan support on January 14, 2019 [1]. The Evidence Act's goal is to ensure the availability and rigorous use of evidence and evaluation as a routine part of government operations to improve public policy and decision making. The Evidence Act promotes strategic evidence-building, addressing unintentional limits on data access, and strengthening agency capacity to develop the evidence needed to support regulatory and policy decisions.

EPA developed this Policy as part of the agency's effort to ensure that evaluations and evidence developed to support policy and decision making are relevant, rigorous, independent and objective, transparent, ethical, and consistent with scientific integrity. This Policy is issued pursuant to Office of Management and Budget (OMB) M-20-12 [2], M-19-23 [3], and M-21-27 [4], which require federal agencies to "establish, implement, and widely disseminate an agency evaluation policy" that "affirms the agency's commitment to conducting rigorous, relevant evaluations and to using evidence from evaluations to inform policy and practice," and to "ensure evaluation activities adhere to an evaluation



policy and that stakeholders are aware of its content and use." As described in OMB M-19-23 and reemphasized in OMB M-20-12 and M-21-27:

"These standards for evaluation are designed to operate in tandem with key Federal statutes, as well as implementing quidance for these statutes issued by OMB. Additionally, these standards and practices recognize the implementation of evaluation and evidence-building activities of the Evidence Act as a complement to principles of the Paperwork Reduction Act of 1995 [5], OMB's implementing quidance for the Information Quality Act [6], and the Performance Framework outlined in the Government Performance and Results Act Modernization Act of 2010 [7]. These standards and practices focus on evaluation, as is mandated by the Evidence Act [and other evidence-building activities] and are not addressed by other Federal policies and frameworks."

EPA's Policy for Evaluations and Other Evidence-Building Activities extends these principles to the suite of evidence-building activities developed by the agency to inform policy and decision-making. This Policy also builds upon and leverages existing EPA and government-wide policies, standards, and guidance to promote the quality, reliability, and accuracy of the information EPA develops and/or uses to inform policy and decision making. These include the 2002 OMB Information Quality Guidelines [6], the 2005 OMB Information Quality Bulletin for Peer Review [8], 1 EPA's Environmental Information Quality Policy [9], 2 EPA's Peer Review Policy [10] and Handbook for Internal and External Review of Scientific Products [11],³ EPA's Information Quality Guidelines [12]⁴ and Summary of General Assessment Factors for Evaluating the

⁴ In addition to data and analyses developed by EPA, the agency often uses existing data and information generated by third parties to inform its decisions. EPA's Information Quality Guidelines [6] also requires the quality and scientific soundness of this type of data to be reviewed and documented prior to use.



OMB's Bulletin for Peer Review [8] "establishes that important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal government." The Bulletin defines a "scientific assessment" as "an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information."

² EPA's Environmental Information Quality Policy [9] requires programs to: "Evaluate Information using the Information Quality Guidelines (Pre-Dissemination Review)[.] Plan for and assess all environmental information prior to use in supporting Agency actions or decisions to verify the information is of sufficient quality, objectivity, utility and integrity for their intended use and purpose[;] Ensure information disseminated by or for EPA conforms with the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency[; and] Retain documentation of predissemination review performed on disseminated information products."

³ EPA's Peer Review Policy [10] encourages and expects peer review "of all scientific and technical information that is intended to inform or support Agency decisions." The Peer Review Handbook [11] "should be used as guidance by EPA staff and managers to ensure that the Agency's Peer Review Policy is implemented effectively and that the integrity of our peer review activities can be demonstrated transparently to the American public." The Handbook describes peer review as "a documented process for enhancing a scientific or technical work product so that the decision or position taken by the Agency, based on that product, has a sound, credible basis.... [Peer review] is conducted by qualified individuals (or organizations) who are independent of those who performed the work and who are collectively equivalent in technical expertise to those who performed the original work (i.e., peers). Peer review is conducted to ensure that activities are technically defensible, competently performed, properly documented and consistent with established quality criteria. Peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria and conclusions pertaining to the scientific or technical work product, and of the documentation that supports them. Peer review also may provide an evaluation of a topic where quantitative methods of analysis or measures of success are unavailable or undefined."

Quality of Scientific and Technical Information [13],⁵ EPA's Enterprise Data Management Policy [14],⁶ EPA's Policy and Procedures on Protection of Human Subjects in EPA Conducted or Supported Research [15],⁷ EPA's Plan to Increase Access to Results of EPA-Funded Scientific Research [16],⁸ and EPA's Scientific Integrity Policy [19].⁹

Policy Applicability

As of the effective date, all agency employees, including staff, managers, and political appointees, are required to follow this Policy when engaging in, supervising, managing, influencing, or communicating evaluations or other evidence-building activities. In addition, all contractors, grantees, and student volunteers of the agency who engage in evaluations and other evidence-building activities are expected to uphold the standards established by this Policy and may be required to do so as part of their respective agreements with EPA. Where practicable, EPA should consider how different implementation methods, tools, or technologies could assist in the application of this policy.

This Policy guides agency activities in an area that is already subject to several laws, rules, and policies for various purposes. When there is overlap with other applicable rules and guidance, this Policy is not intended to preempt other authorities, but instead to work in conjunction with and supplement them. This

⁹ EPA's Scientific Integrity Policy [19] "provides a framework intended to ensure scientific integrity throughout the EPA and promote scientific and ethical standards, including quality standards; communications with the public; the use of peer review and advisory committees; and professional development." The Scientific Integrity Policy applies to all agency employees "engaging in, supervising, managing, or influencing scientific activities; communicating information in an official capacity about Agency scientific activities; and utilizing scientific information in making Agency policy or management decisions." The Scientific Integrity Policy also applies to contractors and grantees. For the purpose of the Scientific Integrity Policy, ""science" and "scientific" are expansive terms that refer to the full spectrum of scientific endeavors, e.g., basic science, applied science, engineering, technology, economics, social sciences, and statistics. The term "scientist" refers to anyone who collects, generates, uses, or evaluates scientific data, analyses, or products."



⁵ EPA's General Assessment Factors for Evaluating the Quality of Scientific and Technical Information were developed as a "resource for Agency staff as they evaluate the quality and relevance of information, regardless of source," to "enhance the transparency about EPA's quality expectations for information that is voluntarily submitted to or gathered or generated by the Agency for various purposes," and to "inform

information-generating scientists about quality issues that should appropriately be taken into consideration at the time information is generated." The assessment factors include soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review.

⁶ EPA's Enterprise Data Management Policy (EDMP) "updates EPA's standard approach to developing, managing, and using data and information to support the development of evidence and evidence-based decision-making. It strengthens EPA's data and information management principles, practices, and standards to ensure data are discoverable, understandable, accessible, useable, and re-useable by internal and external users seeking to conduct analyses and develop evidence." The EDMP "incorporates the data and information planning, governance, and OPEN (Open, Public, Electronic, and Necessary) data management requirements of the Foundations for Evidence-Based Policymaking Act of 2018; codifies the Chief Data Officer's (CDO) role for leading and coordinating EPA's data management functions as defined by the Act; and provides a framework for promoting an EPA culture of open, active, collaborative, and evidence-based data management."

⁷ EPA's Policy and Procedures on Protection of Human Subjects in EPA Conducted or Supported Research requires that all "human subjects research conducted or supported by EPA must either be approved or be acknowledged as exempt research by the EPA Human Subjects Research Review Official (HSRRO) before any work involving human subjects research can begin." The policy defines research to mean, "a systematic investigation, including research, development, testing, and evaluation designed to develop or contribute to generalizable knowledge."

⁸ EPA's Plan to Increase Access to Results of EPA-Funded Scientific Research [16] "describes how the Agency intends to increase access to peer-reviewed scholarly publications and digital data resulting from EPA-funded scientific research... The policies and approaches outlined in [the] Plan are consistent with the OSTP [Office of Science and Technology Policy] Memo [17] and with the Office of Management and Budget (OMB) Open Data Policy (M-13-13) issued May 9, 2013 [18]."

Policy reinforces EPA's Scientific Integrity Policy and other policies related to ethical conduct, information and scientific quality, and public dissemination. In implementing this Policy, the Evaluation Officer will consult and coordinate with other relevant EPA officials (e.g., Chief Data Officer, Chief Information Officer, Human Subjects Research Review Official, Science Advisor, Scientific Integrity Official, and Statistical Official).

This Policy is intended to improve the internal management and operation of the agency. It does not create any obligation, right, or benefit for any member of the public, substantive or procedural, enforceable by law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees or agents, or any other person.

Actions taken in accordance with this Policy are subject to the availability of appropriated funds and must be authorized under and consistent with existing authorities, including applicable law and regulations, Executive Orders, and Federal and EPA ethics, information, and personnel rules and policies.

Policy Scope

This Policy applies to evidence-building activities, including but not limited to evaluations, policy analysis, foundational fact finding (e.g., aggregate indicators, exploratory studies, descriptive statistics, and other research), performance measurement, data collection, data acquisition, and data management (see Section VI. Definitions).

EPA strives to use quality data and evidence to inform policy and decision making. This Policy builds on existing agency policies and aims to ensure the scientific integrity, quality, and accountability of EPA's evaluation and other evidence-building activities and provide EPA staff, managers, political appointees, and agency stakeholders "with a clear understanding of the expectations related to key principles, such as evaluation relevance and utility, rigor, independence and objectivity, transparency, and ethics" [20].

Policy for Evaluations and Other Evidence-Building Activities

It is EPA's policy that the following standards will be applied to all evaluations and other evidencebuilding activities planned, funded, conducted, or used to support agency regulations, policies, directives, guidance, reports, and plans. These standards are based on, and are consistent with, OMB's "Federal Program Evaluation Standards" in OMB M-20-12 [2] and M-21-27 [4]. Applying each standard "requires the integration of all of the other standards; however, at times adherence to one or more of these standards must be judiciously balanced with adherence to others" [2]. The agency recognizes that the best policies and decisions are informed by data and evidence that adhere to the following principles:



- Relevance and Utility: EPA will carry out evaluations and other evidence-building activities that reflect policy and programmatic priorities of the agency and have the potential to impact those priorities. EPA's evaluations and other evidence-building activities will address high priority questions and serve information needs of EPA and EPA's stakeholders, including the general public. EPA will work to ensure that findings from evaluations and other evidence-building activities are actionable and timely, and that information is presented clearly so that it can inform agency decision making in areas such as policy development, strategic program planning, budgeting, rulemaking, program design and improvement, management, and accountability.
- Rigor: EPA will produce findings that are credible and that internal and external stakeholders can rely upon. The Agency will use approaches for data collection, evaluation, and other evidence-building activities that are of appropriate quality for their intended use. EPA will include clear explanations of limitations as part of its findings. The agency will ensure that evaluations and other evidence-building activities are staffed and managed by qualified personnel with the appropriate education, skills, and experience for the methods undertaken. EPA will ensure that evaluations and other evidence-building activities use the most appropriate design and methods to answer identified questions, while balancing goals, scale, timeline, feasibility, and availability of staff and resources.
- **Independence and Objectivity:** It is important that evaluations and other evidence-building activities are objective to ensure that agency decisions are based on facts and unbiased research and information. It is also important that evaluations and other evidence-building activities are viewed as objective so that agency decisionmakers, stakeholders, internal and external experts, and the public accept the findings. EPA will ensure the independence and objectivity of personnel conducting and managing evaluations and other evidence-building activities. Stakeholders may have an important role in helping the agency identify evaluation and other evidence-building priorities, but EPA will insulate the implementation of evaluations and other evidence-building activities, including how evidence-building project staff and managers are selected and how they operate, from political and other undue influences that may affect their objectivity, impartiality, and professional judgment. Agency evaluation and other evidence-building staff and managers will strive for objectivity in the planning and conduct of evaluations and evidence-building activities, and in the interpretation and dissemination of findings. Objectivity in evaluations and other evidence-building activities supports agency decision-making informed by facts, and unbiased research and information. Agency evaluation and evidence-building staff and managers will avoid conflicts of interest, balance bias, and other partiality.
- Transparency: EPA is committed to ensuring that internal and external researchers, agency collaborators, policymakers, and the public can learn from its work; EPA evaluations and other evidence-building activities and their underlying data should be open by default and to the extent possible under applicable law. ¹⁰ To the extent possible, before conducting an evaluation or other evidence-building activity, EPA will clearly document and broadly share the purpose and objectives (including internal versus public use) of evaluations and other evidence-building activities, the range of stakeholders who will have access to details of the work and findings, the

¹⁰ EPA's Enterprise Data Management Policy states that, "It is EPA policy to develop and manage its data as an open data asset and to use it as critical input in developing evidence to support agency decision-making."



design and methods, and the timeline and strategy for releasing findings. To the extent possible under all applicable laws, including but not limited to the Freedom of Information Act and the Privacy Act, once evaluations and other evidence-building activities are complete, EPA will publicly release the findings in a timely manner and will provide enough detail so that others can review, interpret, or reanalyze the work.

EPA will make information about evaluations and other evidence-building activities and their findings broadly available and accessible, typically on the Internet. This includes providing the names of key personnel who contribute to individual evidence building activities, 11 releasing study plans, and describing the methods. EPA will publicly release results in a timely manner of all evaluations and other evidence-building activities that are not specifically focused on internal management, legal, or enforcement procedures, or that are not otherwise privileged or prohibited from disclosure.

Ethics: EPA will conduct evaluations and other evidence-building activities in an ethical manner and safeguard the dignity, rights, safety, and privacy of participants. Evidence-building staff and managers will comply with all applicable ethical and legal requirements. Evaluations and other evidence-building activities will be fair and just, and will consider multiple contextual factors that could influence the findings or their use.



¹¹ EPA's Scientific Integrity program published Best Practices for Designating Authorship to (1) affirm "the Agency's commitment to transparency in its interactions with the public...[recognizing that the] designation of authorship plays a critical role in transparency by identifying who is responsible for the information and conclusions in EPA work products and how they were developed; and (2) fulfill "the need for a common understanding of the best practices for recognizing the contributions of individuals through authorship of EPA work products."

Definitions¹³

Data: As defined in the Foundations for Evidence-Based Policymaking Act of 2018 (§202(a)), "the term 'data' means recorded information, regardless of form or the media on which the data is recorded" [1].

Evaluation and Program Evaluation: OMB defines evaluations and program evaluations in 5 U.S.C. § 311(3) to mean "an assessment using systematic data collection and analysis of one or more programs, policies, and organizations intended to assess their effectiveness and efficiency" [2, 20]. OMB further defines the following five types of evaluations [2]:

- Impact Evaluation: This type of evaluation assesses the causal impact of a program, policy, or organization, or aspect of them on outcomes, relative to a counterfactual. In other words, this type of evaluation estimates and compares outcomes with and without the program, policy, or organization, or aspect thereof. Impact evaluations include both experimental (i.e., randomized controlled trials) and quasi-experimental designs. An impact evaluation can help answer the question, "does it work?" or "did the intervention lead to the observed outcomes?"
- Outcome Evaluation: This type of evaluation measures the extent to which a program, policy, or organization has achieved its intended outcome(s) and focuses on outputs and outcomes to assess effectiveness. Unlike impact evaluation above, it cannot discern causal attribution but is complementary to performance measurement. An outcome evaluation can help answer the question, "were the intended outcomes of the program, policy, or organization achieved?"
- Process or Implementation Evaluation: This type of evaluation assesses how the program or service is delivered relative to its intended theory of change, and often includes information on content, quantity, quality, and structure of services provided. These evaluations can help answer the question, "was the program, policy, or organization implemented as intended?" or "how is the program, policy, or organization operating in practice?"
- Formative Evaluation: This type of evaluation is typically conducted to assess whether a program, policy, or organizational approach – or some aspect of these – is feasible, appropriate, and acceptable before it is fully implemented. It may include process and/or outcome measures. However, unlike outcome and impact evaluations, which seek to answer whether the program, policy, or organization met its intended goals or had the intended impacts, a formative evaluation focuses on learning and improvement and does not answer questions of overall effectiveness.
- Descriptive Studies: These studies can be quantitative or qualitative in nature, and seek to describe a program, policy, organization, or population without inferring causality or measuring effectiveness. While not all descriptive studies are evaluations, some may be used for various evaluation purposes, such as to understand relationships between program activities and participant outcomes, measure relationships between policies and outcomes, describe program participants or components, and identify trends or patterns in data.

¹³ Additional definitions related to this Policy are found in OMB M-20-12 [2] and M-21-27 [4].



Evidence: OMB broadly defines evidence as "the available body of facts or information indicating whether a belief or proposition is true or valid. As such, evidence can be quantitative or qualitative and may come from a variety of data and information sources, including foundational fact finding (e.g., aggregate indicators, exploratory studies, descriptive statistics, and other research), performance measurement, policy analysis, and program evaluation. Evidence has varying degrees of credibility, and the strongest evidence generally comes from a portfolio of high quality, credible sources rather than a single source" [2]. In addition, the Evidence Act defines "evidence" per 44 U.S.C. § 3561(6) to mean "information produced as a result of statistical activities conducted for a statistical purpose" [1]:

- 44 U.S.C. § 3561(10) defines the term " statistical activities" as "the collection, compilation, processing, or analysis of data for the purpose of describing or making estimates concerning the whole, or relevant groups or components within, the economy, society, or the natural environment and includes the development of methods or resources that support those activities, such as measurement methods, models, statistical classifications, or sampling frames."
- 44 U.S.C. § 3561(12) defines the term "statistical purpose" as "the description, estimation, or analysis of the characteristics of groups, without identifying the individuals or organizations that comprise such groups and ... includes the development, implementation, or maintenance of methods, technical or administrative procedures, or information resources that support [those] purposes."

Evidence-building activities: Consistent with OMB guidance [3], evidence building activities include, but are not limited to:

- Program evaluation (see definition above).
- Policy analysis (including analysis of data, such as general-purpose survey or program-specific data, to generate and inform policy, e.g., estimating regulatory impacts and other relevant effects).
- Foundational fact finding (including foundational research and analysis such as aggregate indicators, exploratory studies, descriptive statistics, and basic research).
- Performance measurement (including ongoing, systematic tracking of information relevant to policies, strategies, programs, projects, goals/objectives, and/or activities).
- Data collection, acquisition, and management.
- Research plans, research roadmaps, enterprise learning agendas, or evaluation strategic plans.
- Planning and managing or conducting specific evaluations and other evidence-building activities, summarizing findings for particular programs or policies, when supporting other offices within EPA or other agencies to interpret findings, and bringing evidence to bear in decision-making.



Roles and Responsibilities

The Evaluation Officer is the primary agency official responsible for implementing this Policy. The Evaluation Officer is responsible for:

- Promoting agency compliance with this Policy, including safeguarding against, and instituting mechanisms to ensure accountability for, any alteration or manipulation of evaluations or other evidence-building activities by agency managers and leaders.
- Issuing additional guidance, standards, procedures, and reporting necessary to implement and assess the effectiveness of this Policy.
- Consulting and coordinating with other relevant agency officials to ensure implementation of this Policy is consistent with and supports implementation of related laws and policies.
- Providing training, seminars, and other opportunities to make agency staff and management aware of the Policy and its role in guiding the agency's evaluation and other evidence-building activities.

The Evaluation Officer collaborates with the Statistical Official and Chief Data Officer, Scientific Integrity Official, as well as program staff; other evaluation, statistics, analysis, data, enterprise risk management, and performance units and personnel in the agency; policy staff; regulatory staff; privacy and information law and policy personnel; and agency leadership [20]. Specifically:

The **Statistical Official** is the Agency's senior advisor for statistical policy, techniques, and procedures to support the conduct of credible, accurate, and objective statistical activities used for evaluation and evidence-building. The Statistical Official is responsible for promoting the use of techniques that provide necessary levels of data quality, confidentiality, and rigor, along with procedures that implement those techniques systematically and efficiently in the implementation of this Policy.

The Chief Data Officer is responsible for Agency data management throughout the information lifecycle from data collection and creation through records management. The Chief Data Officer further ensures that, to the extent possible, agency data and data management conforms with data management best practices. The Chief Data Officer strives to ensure that the agency maximizes the use of data across the agency, particularly with respect to production of evidence. The Chief Data Officer will support this Policy by identifying procedures and providing data governance that maximizes the use of EPA data in agency evaluation and other evidence-building activities.

The Chief Information Officer is the EPA senior management official for quality management and leads Agency-wide implementation of EPA's Environmental Information Quality Policy and Quality Program. The Chief Information Officer will collaborate with the Chief Data Officer, Statistical Official, and Evaluation Officer to promote adherence of evaluations and other evidence-building activities with agency data and information policies and procedures.



The agency's **Evidence Act Workgroup** ¹⁴ will advise the Evaluation Officer to ensure consistent implementation of this Policy, including providing advice on the applicability of the Policy to specific evidence-building activities and assisting in the development and dissemination of, and compliance with, implementation guidances, standards, procedures, and reporting pursuant to this Policy.

References

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- 2. Office of Management and Budget, Memorandum M-20-12: Phase 4 Implementation of the Foundations for Evidence-Based Policymaking Act of 2018: Program Evaluation Standards and Practices. March 10, 2020.
- 3. Office of Management and Budget, Memorandum M-19-15: Improving Implementation of the Information Quality Act. April 24, 2019.
- 4. Office of Management and Budget, Memorandum M-21-27: Evidence-Based Policymaking: Learning Agendas and Annual Evaluation Plans. June 30, 2021.
- 5. Information Quality Act, Section 515 of the Consolidated Appropriations Act, 2001.
- 6. Office of Management and Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies. Feb. 22, 2002.
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- 8. Office of Management and Budget, Final Information Quality Bulletin for Peer Review. Jan. 14, 2005.
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- 10. U.S. Environmental Protection Agency, Peer Review and Peer Involvement at the U.S. Environmental Protection Agency. Jan. 31, 2006.
- 11. U.S. Environmental Protection Agency, Science and Technology Policy Council, Peer Review Handbook, 4th Edition. Oct. 2015.
- 12. U.S. Environmental Protection Agency, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency (EPA/260R-02-008). 2002.

¹⁴ The Evidence Act Workgroup is co-chaired by the three Evidence Act designated officials. Workgroup membership is outlined in its Charter and includes: Learning Priority Leads (Headquarter offices and assigned Lead Regions), Headquarter representatives, and Lead Region for each of the following offices Office of the Chief Financial Officer, Office of Mission Support, and Office of Policy. Note that EPA's Lead Region system assigns regional offices to work with EPA National Program Managers to identify and synthesize the concerns of all ten regions into a "regional view" that can be effectively factored into Agency decision-making.



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- 18. Office of Management and Budget, Memorandum M-13-13: Open Data Policy—Managing Information as an Asset. May 9, 2013.
- 19. U.S. Environmental Protection Agency, Scientific Integrity Policy (601B17001). Jan.15, 2010.
- 20. Office of Management and Budget, Circular No. A-11: Preparation, Submission and Execution of the Budget. Dec. 2019.

