

Improving Implementation of the Information Quality Act:

Frequently Asked Questions

The Office of Information and Regulatory Affairs (OIRA) is providing answers to frequently asked questions (FAQs) about the application of its Memorandum on Improving Implementation of the Information Quality Act, issued to agencies on April 24, 2019 (OMB M-19-15).¹

In 2000, Congress passed the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. No. 106-554); Section 515² of that legislation, commonly known as the Information Quality Act (IQA), required the Office of Management and Budget (OMB) to issue guidance to agencies “for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.” The IQA further required each agency to then issue their own information quality guidelines following OMB’s guidance and to “establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued.”

On September 28, 2001, OMB published guidelines in the Federal Register, alongside a detailed preamble explaining the underlying principles.³ At that time, OMB also took additional comments on an interim definition of the “capable of being substantially reproduced” standard.⁴ In early 2002, OMB made changes to the “capable of being substantially reproduced” standard, and summarized its response to comments in the 2002 preamble that supplements the original 2001 preamble.⁵ OMB’s guidelines (OMB Guidelines) required agencies to issue their own implementing guidelines by October 2002.

In April 2019, OMB issued OMB M-19-15 “to reinforce, clarify, and interpret agency responsibilities” under the IQA. OMB M-19-15 reaffirms the soundness of the principles and requirements described in the OMB Guidelines, and provides updates to “reflect recent innovations in information generation,

¹ Office of Management & Budget, *Improving Implementation of the Information Quality Act* (Apr. 24, 2019), <https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf> [hereinafter OMB M-19-15].

² 44 U.S.C. § 3516 note.

³ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 66 Fed. Reg. 49,718, 49,719 (Sept. 28, 2001) (detailing principles such as flexibility, workability, higher standards for more important information, and weighing the costs of information quality against the benefits).

⁴ See *id.* at 49,722 (providing an interim definition for the standard for public comment, as follows: “‘Capable of being substantially reproduced’ means that independent reanalysis of the original or supporting data using the same methods would generate similar analytical results, subject to an acceptable degree of imprecision.”).

⁵ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 Fed. Reg. 369 (Jan. 3, 2002) (original publication); Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 Fed. Reg. 5365 (Feb. 5, 2002) (correction); Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452 (Feb. 22, 2002) (republishing).

access, management, and use, and to help agencies address common problems with maintaining information quality.”⁶

The purpose of this FAQ document is to answer questions that federal agencies have often asked about how to apply OMB Guidelines and OMB M-19-15. Of additional relevance to this FAQ are the components of OMB M-19-15 that provide a bridge between those OMB Guidelines and subsequently promulgated OMB and Office of Science and Technology Policy (OSTP) policies designed to promote open data, open science, and evidence building. Because those policies have continued to evolve, this FAQ provides updated references to the most recent relevant OMB and OSTP policies (see, for example Question 3 below).

This FAQ draws from the long-standing core principles on information quality established in the OMB Guidelines and reaffirmed in OMB M-19-15. This FAQ does not alter existing requirements in any way. Nor does this FAQ fully summarize the entirety of OMB’s guidance or OMB M-19-15. For more complete guidance, please consult the IQA, the OMB Guidelines (including both the 2001 and 2002 preambles⁷), OMB’s Information Quality Bulletin for Peer Review,⁸ and OMB M-19-15.

General Application

1. How should agencies apply OMB M-19-15 together with the OMB Guidelines?

OMB M-19-15 builds on, and does not override or replace, the OMB Guidelines. It provided implementation updates in the context of innovations and subsequent policy in the information landscape as well as common questions that had arisen over the seventeen years since the OMB Guidelines were issued. OMB M-19-15 reaffirmed the “principles and core responsibilities” of the OMB Guidelines, which, pursuant to the IQA, had been developed with public and Federal agency involvement.⁹ The core principles of the OMB Guidelines apply even if certain provisions in OMB M-19-15 do not repeat them. For example, while OMB M-19-15’s Implementation Update 3.3 on communications around the use of non-government sources does not repeat protections for privacy and confidentiality, the overarching principles embodied in the OMB Guidelines on how to protect privacy and confidentiality still apply.¹⁰ Note also that OMB M-19-15 Implementation Update 3.4 speaks to such protections, stating that “All data disclosures must be consistent with statutory, regulatory, and policy

⁶ OMB M-19-15 at 1. *See also id.* at 2 (reaffirming agencies’ core responsibilities under the Guidelines).

⁷ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452 (Feb. 22, 2002) (“In developing agency-specific guidelines, agencies should refer both to the Supplementary Information to the final guidelines published in the Federal Register on September 28, 2001 . . . and also to the Supplementary Information published today.”) (citations omitted).

⁸ Office of Management & Budget, *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664 (Jan. 14, 2005). *See also* Office of Management & Budget, *Issuance of OMB’s “Final Information Quality Bulletin for Peer Review”* (Dec. 16, 2004), https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2005/m05-03.pdf.

⁹ 44 U.S.C. § 3516 note (a).

¹⁰ Implementation Update 3.5 (OMB M-19-15 at 9), discussed further below in the section on “Addressing Both Reproducibility and Privacy,” speaks to promising ways agencies are providing wider access to some types of protected data without compromising privacy and confidentiality.

requirements for protections of privacy and confidentiality, proprietary data, and confidential business information.”

2. What discretion do agencies have in implementing the OMB Guidelines and OMB M-19-15?

The OMB Guidelines and OMB M-19-15 embody best practices from a good government and good science perspective, but how agencies implement those best practices includes an appropriate degree of flexibility and discretion. OMB has never expected that its Guidelines would be “implemented in the same way by each agency,” and OMB instead has stressed that each agency should seek “common sense and workable” applications that do not lead to duplicative processes and are consistent with the type of information that the agency produces pursuant to its mission and duties.¹¹

On the issue of requests for correction, for example, the OMB Guidelines provide that agencies should “determine the appropriate level of correction for a complaint received,” considering the “nature and timeliness of the information involved.”¹² (See the section below on “Requests for Correction” for more details on agency discretion in responding to such requests.)

3. Are there one-size-fits-all requirements for how agencies must communicate influential information to meet standards for transparency and reproducibility?

No. OMB designed its Guidelines “to apply to a wide variety of government information dissemination activities that may range in importance and scope” and “to avoid the problems that would be inherent in developed detailed, prescriptive, ‘one-size-fits-all’ government-wide guidelines that would artificially require different types of dissemination activities to be treated in the same manner.”¹³

For example, while OMB M-19-15’s Implementation Update 3.1 recommends that agencies consult OSTP’s 2010 scientific integrity memorandum with respect to communicating underlying assumptions, uncertainties, and probability descriptions as a best practice for conveying scientific and technological information to the public, probabilities associated with both optimistic and pessimistic projections (including best-case and worst-case scenarios) may not always be technically feasible or appropriate for all communications. While full descriptions of probabilities may be feasible and useful to the public’s understanding of fitness of purpose for some kinds of analyses, it may not be feasible in other cases, and for some disseminations such distributions might not be a useful communication tool. We note that in OMB M-19-15, we inadvertently left out the clause “where appropriate” that appeared in OSTP’s 2010

¹¹ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8453 (Feb. 22, 2002) (further articulating that “agencies must apply these standards flexibly”).

¹² Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 66 Fed. Reg. 49,718, 49,721 (Sept. 28, 2001); see also OMB M-19-15 at 2 (explaining that during pre-dissemination review, agencies “should consider the appropriate level of quality for each of the products that it disseminates based on the likely use of that information”).

¹³ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452 (Feb. 22, 2002).

memorandum;¹⁴ agencies should not interpret that omission as a change in policy or application of the 2010 memorandum. The more overarching touchstone embodied in OMB M-19-15 is that the public should be able to understand the information's fitness for both their own use and the way it is used by the agency to support a policy decision.¹⁵ More recent 2022 guidance from OSTP on scientific integrity also acknowledges that there are not "one-size-fits-all" approaches while explaining that it broadly improves transparency to clearly communicate what is known about the provenance, validity, and accuracy of the data and methods, especially when the resulting information is derived from emerging technology and new modes of science, such as big data analytics.¹⁶

Agencies may rely on professional judgment and consider evolving scientific and statistical approaches for using certain kinds of disclosure tools and practices, such as probability distributions, when disseminating particular kinds of information.

Requests for Correction

4. How should agencies respond to requests for correction that largely or entirely repeat requests, arguments, or comments previously submitted to the agency by the petitioner?

After determining that a request is duplicative with prior requests (such as, for example, requests made during prior rounds of public participation), agencies may respond to such requests for correction in a brief letter that acknowledges receipt of the request, refers to the prior interaction, and presents the process through which those prior comments from the petitioner or a person or entity affiliated with that petitioner were or are being addressed. If the issues raised by the requestor were already addressed, for example, in a prior peer review, then the agency may refer to the prior peer review record and is not obligated to provide an additional point-by-point response on those issues.

¹⁴ Office of Science and Technology Policy, *Scientific Integrity 2* (Dec. 17, 2010), <https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf> ("... including best-case and worst-case scenarios *where appropriate*") (emphasis added).

¹⁵ See Implementation Update 2.2 (OMB M-19-15 at 5).

¹⁶ National Science and Technology Council, *Protecting the Integrity of Government Science* xii, 27-28 (Jan. 2022), <https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting-the-Integrity-of-Government-Science.pdf> (discussing emerging technology and modes of science, including big data analytics, AI, and machine learning, as well as citizen science and community-engaged research). Implementation Updates 3.1-3.2 and n. 26 (OMB M-19-15 at 7-8) also addressed the importance of data quality in the context of machine learning and AI. See also National Science & Technology Council, *A Framework for Federal Scientific Integrity Policy and Practice* n. 14 (Jan. 2023), <https://www.whitehouse.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf> (on guarding against misrepresenting the underlying assumptions, uncertainties, or probabilities of scientific products). Note that other approaches to verifying quality, providing transparency, and facilitating reproducibility may apply to other kinds of evidence that can be considered as elements of best available science, such as indigenous knowledge. See Office of Science and Technology Policy and Council on Environmental Quality, *Guidance for Federal Departments and Agencies on Indigenous Knowledge* (Nov. 30, 2022), <https://www.whitehouse.gov/wp-content/uploads/2022/12/OSTP-CEQ-Indigenous-Knowledge-Guidance.pdf> (discussing that use of indigenous knowledge in Federal policy, research, or decision making does not require validation against other forms of knowledge, but rather offers factors agencies might use to explore fitness for purpose, consistent with the IQA).

The OMB Guidelines empowered agencies “to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved.”¹⁷ The request for correction process is intended to provide a mechanism to correct errors or address whether the disseminated product does not meet OMB’s or the agency’s information quality guidelines. The process is not intended to duplicate or interfere with other agency processes that, through public participation, already allow individuals to raise questions about whether any information is incorrect or otherwise does not comply with OMB’s or the agency’s Guidelines.¹⁸

Members of the public planning to submit a request for correction under the IQA should first consider whether their requests—or something substantially equivalent in substance—have already been submitted to and addressed by the agency during a prior round of comments. Note that, to avoid sharing pre-decisional information, in many cases agencies may not respond to requests for correction until they have adjudicated all comments received during the prior public engagement process.

5. How should agencies respond to requests for correction concerning agencies’ interpretations of data or applications of data to inform policy choices?

In general, the OMB Guidelines provide that agencies should “determine the appropriate level of correction for a complaint received,” considering the “nature and timeliness of the information involved.”¹⁹

OMB M-19-15 makes clear that the request for correction process is *not* an opportunity for the agency or requestor “to debate the policy itself” but is only an opportunity to request corrections to the technical facts or scientific determinations that are the basis for the information underlying such policies. Whereas OMB M-19-15 advises agencies to provide “a point-by-point response to any data quality arguments contained in the RFC [request for correction],” OMB M-19-15 made clear that “agencies should not opine” in their response to an RFC on “the requestor’s or the agency’s policy position.”

The IQA can be used to petition for corrections to statements of fact or errors in their attribution, errors in the data, misapplication of statistical or laboratory techniques, or representations of knowledge that are inconsistent with the principles in the OMB Guidelines. In many cases such corrections can be accomplished with an errata sheet that explains the errors and the implication of the fix to the conclusions of the report. However, if a new analysis must be conducted, and that analysis has significant implications for results that are influential to policy, additional steps may be necessary (see below questions 7 and 11).

¹⁷ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 66 Fed. Reg. 49,718, 49,721 (Sept. 28, 2001).

¹⁸ See *ibid.* (“[T]he correction process should serve to address the genuine and valid needs of the agency and its constituents without disrupting agency processes.”).

¹⁹ *Ibid.*

OMB's definition of "information" includes "representation of knowledge," which may include assessments of data.²⁰ There could be a range of defensible scientific views about how to interpret data or to bridge information gaps. Under the OMB Guidelines, the standard for assessing such questions is embodied in the definition of "objectivity." The focus is on "whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased."²¹ This involves a careful look at the underlying theoretical and empirical literature in the context of the intended or likely uses of that information—the fitness for the intended purpose.

In considering requests to correct such assessments of data, requesters should avoid duplicating information quality issues raised during prior rounds of comment. If an agency has already considered and responded to a viewpoint on the way the agency assessed the data or conducted the analyses, such as during prior public comments, duplicative requests can be handled by referring petitioners back to such earlier responses.

Furthermore, agencies may rely on the presumption of objectivity associated with data or analysis "that has been subjected to formal, independent, external peer review"²²—in particular, a response to a request for correction could refer to the responses of experts provided during a peer review of that information.²³ In addition, OMB declined to set a "'confirmation' of results" standard for influential scientific and statistical information, finding such a standard to be "too stringent."²⁴ When responding to a request to correct its assessment of data, an agency need not "confirm" its assessment. Rather, if appropriate, the agency can articulate how its original assessment met the standards for objectivity. Agencies have a variety of mechanisms to demonstrate the objectivity of their assessments: for example, information or assessments that have gone through peer review are presumptively objective.

6. How should an agency respond to a request for correction submitted on the basis of data or literature that only became available after the agency's original dissemination?

Agencies have reasonable discretion regarding if, when, and how they might revise an information product for which new data and/or analyses are submitted as part of a request for correction. Agencies can draw on their extensive experience considering how many resources to dedicate to addressing new information that becomes available to the agency. When assessing such tradeoffs, agencies typically

²⁰ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8460 (Feb. 22, 2002).

²¹ *Id.* at 8453.

²² *Id.* at 8454 (identifying the peer review criteria associated with this presumption). See also Office of Management & Budget, *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664, 2675 (Jan. 14, 2005) (providing further guidance on this issue, including the importance of independence of reviewers from the agency and the use of "charge" instructions to identify the key questions relevant to how the agency intends to use the information that is being peer reviewed); Office of Management & Budget, *Issuance of OMB's "Final Information Quality Bulletin for Peer Review"* (Dec. 16, 2004), https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2005/m05-03.pdf.

²³ See Implementation Update 4.3 (OMB M-19-15 at 10), which encourages referring to a peer review that directly considered the issued being raised, if available.

²⁴ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8457 (Feb. 22, 2002).

consider the likely potential impact on the public (e.g., health and safety) of new information; the extent and cost required to generate a revision; competing judicial or statutory deadlines; and public commitments.

For instance, when the information product in question is a synthesis of the available scientific literature, the submission of a single new study might not trigger an urgent need to update the synthesis. When agency resources are focused on more time-sensitive or higher-impact mission-related activities, the agency may choose to respond to the requestor that the new data or analyses will be considered during the next scheduled revision cycle for that product. This option would be consistent with the OMB Guidelines and its intention not to create duplicate processes or interfere with the orderly conduct of agency missions.

The preamble to the OMB Guidelines includes another example. In responding to whether an agency would be required to correct weather forecasts “after the fact” based on new data, OMB clarified that the “correction process should serve to address the genuine and valid needs of the agency and its constituents without disrupting agency processes. Agencies, in making their determinations of whether or not to correct information, . . . are required to undertake only the degree of correction that they conclude is appropriate for the nature *and timeliness* of the information involved.”²⁵

Ultimately, whether an agency might choose to incorporate new information, thereby superseding an existing information product, is a programmatic decision that depends on relevance, need, resources, and other factors, and such revisions are not automatically required by a request for correction.

7. What process governs the dissemination of information that has been corrected in response to a request for correction?

When OMB was developing its Guidelines, multiple commenters “expressed strong concerns about the possibility of a Federal agency that would ‘correct’ scientific information without carrying out the scientific analysis to support the correction.”²⁶ OMB explained that corrections should adhere to the same policies, practices, and processes that the agency would use to determine whether to disseminate any new information.²⁷ The correction process should be consistent with the goals of the OMB Guidelines to ensure the quality, objectivity, utility, and integrity of information—including any corrected information. Before disseminating any revised information, agencies should “substantiate the quality of the [revised] information . . . through documentation or other means appropriate to the [type of] information.”²⁸

²⁵ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 66 Fed. Reg. 49,718, 49,721 (Sept. 28, 2001) (emphasis added).

²⁶ *Ibid.*

²⁷ Similarly, OMB suggests that requests for correction made “without justification” should be rejected, thus further implying that corrections require justification. *Ibid.*

²⁸ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8458-59 (Feb. 22, 2002).

8. Who may conduct the review of an appeal of a request for correction?

Agencies may want the relevant technical experts who produced the original dissemination to conduct the response to any request for information as well as any appeal of such response. However, the appeal process is designed as an independent evaluation of whether the initial response by the technical experts addressed the issues raised, giving due consideration to the agency's discretion (discussed in FAQs 4-6 above). To that end, the OMB Guidelines explain, "An objective [appeals] process will ensure that the office that originally disseminates the information does not have responsibility for *both* the initial response and resolution of a disagreement."²⁹ OMB M-19-15's Implementation Update 4.5 echoes this point by advising agencies not to select the same individuals who were involved in the initial response to the request for correction to also review a subsequent appeal. For those individuals reviewing an appeal, exhaustive first-hand knowledge of the underlying information is relatively less essential than the ability to objectively review prior responses in the context of the larger agency mission.

Objectivity and integrity are, ultimately, the goals to pursue during appeals. Within those general guideposts, agencies retain discretion. Agencies could, for example, establish a standing committee to examine appeals, which would have the added value of ensuring consistency in the reasons various appeals are granted or dismissed. The technical experts responsible for originally disseminating the information or for preparing the initial response to a request for correction may also present their views on the scientific merits of the appeal to the agency personnel charged with considering the appeal. Another option is for the management in an organizational unit that sits above the unit responsible for generating the document being challenged to take responsibility for deciding who should conduct the appeal. The objectivity and integrity of the review process also depend, as OMB M-19-15 advises, on ensuring that any staff reviewing any appeal are sufficiently "versed in the process of interpreting the type of evidence in question (e.g., financial, scientific, or statistical information)" so that the sufficient technical proficiency in science policy can be brought to bear.

Addressing Both Reproducibility and Disclosure Limitations, like Privacy

9. Does the goal of reproducibility conflict with responsibilities for protecting privacy and other limitations on access to original and non-governmental data?

No. Most importantly, OMB M-19-15 does not alter agencies' responsibility to implement existing OMB guidance for protecting privacy, confidentiality, national and homeland security, or confidential business information. Implementation Update 3.4 instead states that "[a]ll data disclosures must be consistent with statutory, regulatory, and policy requirements for protections of privacy and confidentiality, proprietary data, and confidential business information." Such policy requirements include the protections and limitations outlined in the OMB Guidelines. OMB M-19-15 also encourages agencies to explore new tools that may facilitate data access consistent with these important protections. For example, the new information landscape includes "[n]ew approaches to secure data access using cutting-edge technologies [that] reduce the risk of re-identification," such as "tiered access," as noted in Implementation Update 3.5.

²⁹ *Id.* at 8458 (emphasis added).

The OMB Guidelines recognized that the need to “protect the confidentiality of research subjects and encourage public participation in research” is “particularly salient in medical and public health research.”³⁰ Further, the OMB Guidelines are clear that “the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.”³¹ The OMB Guidelines also recognize “that information quality comes at a cost.”³² Assessments of costs and benefits of increased reproducibility should include the costs of making data available, including for “maintenance of needed privacy, and assurances of suitable confidentiality.”³³

As background, in 2001 OMB first considered exempting original data from reproducibility standards,³⁴ but OMB decided instead to “provide flexibility to the agencies” to determine “which categories of original and supporting data should be subject to the reproducibility standard and which should not.”³⁵ In 2002, OMB offered several factors to inform this judgment, encouraging agencies to:

- “consult directly with relevant scientific and technical communities on the feasibility of having the selected categories of original and supporting data subject to the reproducibility standard”;³⁶
- “address ethical, feasibility, and confidentiality issues with care”;³⁷
- consider whether it would be “feasible” to grant access to a qualified third party “under the same confidentiality protections as the original analysts”;³⁸ and
- consider intellectual property interests and “other compelling interests.”³⁹

Since then, statutory and OMB policies associated with open data, open science, and evidence-building were stimulated by innovations in the information landscape. In response, OMB M-19-15’s Implementation Update 3.4 encouraged agencies to prioritize the resources they have available for increasing public access to those data and analytical frameworks (e.g., models) used to generate influential information. As that update makes clear, as agencies pursue their own priorities for increasing data access, they must apply all required protections for privacy and confidentiality.

³⁰ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 66 Fed. Reg. 49,718, 49,722 (Sept. 28, 2001).

³¹ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8460 (Feb. 22, 2002).

³² *Id.* at 8452-53.

³³ *Id.* at 8453.

³⁴ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 66 Fed. Reg. 49,718, 49,722 (Sept. 28, 2001).

³⁵ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8455 (Feb. 22, 2002). See also *id.* at 8460 (“With regard to original and supporting data related [to influential scientific, financial, or statistical information], agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement.”).

³⁶ *Id.* at 8455.

³⁷ *Id.* at 8455-56 (further stating “OMB urges caution in the treatment of original and supporting data because it may often be impractical or even impermissible or unethical to apply the reproducibility standard to such data.”).

³⁸ *Id.* at 8456.

³⁹ *Id.* at 8460.

10. What can agencies do if underlying data or information cannot be made publicly available for reanalysis without raising significant ethical, feasibility, or confidentiality issues?

If published peer-reviewed research is suitable for the agency's intended use but contains or relies on underlying data or information that cannot be made publicly available for reanalysis without raising significant ethical, feasibility, and confidentiality issues, the agency may use that information but is encouraged to advance the goal of reproducibility and transparency in other ways to the extent appropriate and feasible, consistent with the government's open science and scientific integrity policies.⁴⁰ Even when the data cannot be made publicly available in full, it may sometimes be made available in a limited access format (e.g., redacted variables) and/or venue (e.g., agreements that restrict who may use the data and how they may use it).⁴¹ When agencies cannot access the data underlying published analyses, they are still responsible for assessing the fitness of the data for its intended purpose.

Reproducibility is one factor in assessing the objectivity of information, and "the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections."⁴² OMB also incorporated into its 2002 definition of "objectivity" the recommendation that, for analysis of risks to human health, safety, and the environment, agencies should "adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996."⁴³ In that statute Congress directed use of "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods."⁴⁴

Agencies should generally try to hold analytical results to a higher standard of reproducibility than original data.⁴⁵ As the 2002 OMB Guidelines explain, when "public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytical results and document what checks were undertaken . . . [and] disclos[e] the specific data

⁴⁰ See National Science and Technology Council, *Protecting the Integrity of Government Science* (Jan. 2022), [https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting the Integrity of Government Science.pdf](https://www.whitehouse.gov/wp-content/uploads/2022/01/01-22-Protecting-the-Integrity-of-Government-Science.pdf); OMB M-19-15.

⁴¹ See Implementation Update 3.5 (OMB M-19-15 at 9).

⁴² Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8460 (Feb. 22, 2002).

⁴³ *Ibid.*

⁴⁴ *Id.* at 8457 (citing 42 U.S.C. § 300g-1(b)(3)(A)).

⁴⁵ Office of Management & Budget, *Information Quality Guidelines 2* (Oct. 1, 2002), https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/assets/OMB/inforeg/iqg_oct2002.pdf. See also Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8460 (Feb. 22, 2002) (distinguishing the standards for data from the standards for analytical results).

sources that have been used and the specific quantitative methods and assumptions that have been employed.”⁴⁶

Peer Review

11. When should agencies conduct a second peer review following a significant change in influential information that was previously peer reviewed?

OMB M-19-15's Implementation Update 1.4 advises agencies to conduct a second peer review when influential information that was previously peer reviewed changes “significantly,” such as in response to peer reviewer comments or additional analysis. The “significance” of a change in influential information that would prompt another peer review is left to agency discretion. Implementing suggested changes made by peer reviewers, for example, would not necessarily require a second round of peer review. In considering whether a change is sufficiently significant to warrant additional peer review, agencies may consider two original principles underlying the flexibility that is built into OMB Guidelines: one, that “[t]he more important the information, the higher the quality standards to which it should be held,” and two, that because “information quality comes at a cost . . . agencies should weigh the costs . . . and the benefits of higher information quality.”⁴⁷ In OMB M-19-15 this is captured in the term “fitness for purpose.”⁴⁸ Agencies should first and foremost consider how influential the information being changed is to the policy implications of the relevant agency decision and how sensitive the overall findings are to the assumptions the agency needed to make to bridge any uncertainties. Armed with that information, it may be easier to weigh the costs of additional review, including the costs of delay, against the increase in presumed objectivity provided by a second peer review.

12. Can one agency rely on another agency's peer review of information to create a presumption of objectivity for use by the first agency of the same information?

Yes. OMB's Information Quality Bulletin for Peer Review⁴⁹ states:

For information subject to this section of the Bulletin, agencies need not have further peer review conducted on information that has already been subjected to adequate peer review. In determining whether prior peer review is adequate, agencies shall give due consideration to the novelty and complexity of the science to be reviewed, the importance of the information to

⁴⁶ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication*, 67 Fed. Reg. 8452, 8460 (Feb. 22, 2002) (further specifying that “Each agency is authorized to define the type of robustness checks, and the level of detail for documentation thereof, in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.”).

⁴⁷ Office of Management & Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 66 Fed. Reg. 49,718, 49,719 (Sept. 28, 2001).

⁴⁸ See OMB M-19-15 at 2-4 (describing fitness for purpose). See also *id.* at 4 (“Implementation Update 1.3: When conducting peer review, agencies should ensure reviewers are asked to evaluate the objectivity of the underlying data and the sensitivity of the agency's conclusions to analytic assumptions.”).

⁴⁹ Office of Management & Budget, *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664, 2675 (Jan. 14, 2005). See also Office of Management & Budget, *Issuance of OMB's “Final Information Quality Bulletin for Peer Review”* (Dec. 16, 2004), https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2005/m05-03.pdf.

decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review. Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed.

For example, if a methodology was reviewed by Agency X for use in regulatory impact analyses, Agency Y may choose to use that methodology in support of their regulatory impact analyses without additional peer review if they determine that Agency X's peer review addressed the issues that are important for use in the context in which Agency Y plans to use the methodology. The determination and its justification should be memorialized in the document disseminated by Agency Y (e.g., in the preface).

13. If one agency requests that another agency conduct research or develop a scientific analysis about a particular topic, which of the agencies is responsible for conducting the peer review?

Agencies retain significant flexibility in this area, and may coordinate and arrange for either agency to be the lead or conduct any needed peer reviews. For example, an agency that has statutory responsibility for regulating on a topic may not house all the Federal experts on the science underlying the phenomenon they are regulating or may not have the resources to conduct a new inquiry or review. In such cases the agency may ask another agency to conduct a synthesis, impact assessment, or other data analysis instead of hiring outside contractors. Either agency may initiate the appropriate peer review of the scientific analysis. In some cases, the agency generating the scientific analysis prefers to conduct the peer review because it allows them to retain responsibility for the assessment until it is complete (i.e., they choose how to respond to the peer reviewer comments.) In other cases, the requesting agency prefers to contract for the peer review (e.g., to ensure that the charge questions reflect how they will use the information).