Approaches for Expressing and Resolving Differing Scientific Opinions

U.S. Environmental Protection Agency
Scientific Integrity Program
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Preamble: Scientific products and decisions are strengthened by considering all pertinent evidence and exploring various plausible explanations of that evidence. Vigorous internal discussion of different points of view helps to anticipate counter-arguments and alternative positions that could arise during public comment, peer review, and litigation. This process of challenging and improving ideas helps to guard against inadequate science and flawed analyses. It also creates a stimulating work environment where employees can develop professionally. Accordingly, EPA expects and encourages all employees to offer and welcome differing scientific opinions as a legitimate and necessary part of the scientific process. This document recommends a progression of approaches that employees and managers can use to encourage the expression and satisfactory resolution of differing scientific opinions.

1. Introduction

1.1 Purpose: This document aids the implementation of EPA's Scientific Integrity Policy[1] by encouraging the expression of differing scientific opinions and suggesting a progression of approaches for their resolution. The approaches begin with successive stages of internal deliberation and may involve the possible use of internal or external peer review. The objective is a timely, satisfactory resolution within the smallest possible organizational unit.

1.2 Policy: EPA's Scientific Integrity Policy "Mandates the Scientific Integrity Official, with input from the Deputy Scientific Integrity Officials, to develop a transparent mechanism for Agency employees to express differing scientific opinions [§IV.A.3]." The Scientific Integrity Policy is based on the Presidential memorandum on scientific integrity,[2] and the Office of Science and Technology Policy memorandum on scientific integrity.[3] In addition, under EPA's Principles of Scientific Integrity,[4] EPA employees must "Welcome differing views and opinions on scientific and technical matters as a legitimate and necessary part of the process to provide the best possible information to regulatory and policy decision-makers."

1.3 Applicability

The approaches suggested in this document apply to differing opinions regarding scientific data, interpretations, or conclusions. They do not apply to opinions regarding policy options or decisions. The distinction between science and policy is fundamental, and these approaches are focused on professional opinions regarding scientific information, methods, models, analyses, results, and conclusions. These approaches do not address personal opinions about scientific issues that are not accompanied by scientific arguments.

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[1] EPA Scientific Integrity Policy: https://www.epa.gov/scientific-integrity/epas-scientific-integrity-policy
[2] Presidential memorandum on scientific integrity (March 9, 2009): https://www.gpo.gov/fdsys/pkg/FR-2009-03-11/pdf/E9-5443.pdf
[3] OSTP memorandum on scientific integrity (December 17, 2010): https://obamawhitehouse.archives.gov/administration/eop/ostp/library/scientificintegrity
[4] EPA's Principles of Scientific Integrity (1999): https://19january2017snapshot.epa.gov/sites/production/files/2014-11/documents/epa-principles-of-scientific-integrity.pdf

These approaches apply to all EPA employees, including scientists, managers, and political appointees. These approaches do not apply to external parties, who have other means to express their opinions to EPA.

When there is overlap with other applicable rules and guidance, this document is not intended to preempt other authorities, but instead to work in conjunction with and supplement them. This document is intended to improve the internal management and operation of EPA. 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 [Scientific Integrity Policy, §III].

1.4 Other EPA procedures that take precedence

(a) Unaddressed Significant Risks to Public Health or the Environment (Elevation Policy): Multiple EPA Administrators have affirmed the importance of elevating risks to public health and the environment so EPA can respond in a timely and effective manner.[5] In the case of a perceived unaddressed significant risk within the scope of EPA authorities, employees should promptly notify their management or report it at https://work.epa.gov/epa/identify-unaddressed-significant-public-health-or-environmental-risk.

(b) Misconduct: In the case of data, interpretations, or conclusions that constitute misconduct (fabrication, falsification, or plagiarism)[6] beyond a difference of opinion, employees should promptly notify their management or the Office of Inspector General, or in the case of plagiarism, EPA's Scientific Integrity Official.[7]

1.5 Examples of similar procedures at other federal agencies

Several federal agencies have programs to encourage the expression of differing opinions promptly and without fear of reprisal. Some programs are broader in scope, for example, covering differing opinions on policies and decisions or differing opinions from contractors.

(a) The U.S. Nuclear Regulatory Commission supports a Differing Professional Opinion program "an employee or contractor can use when he or she has a conscientious expression of a judgment or position that differs from an established staff view, disagrees with a management decision or policy position, or takes issue with an established agency practice involving technical, legal, or policy issues (including administrative or corporate support issues)."[8]

[5] Elevation Policy: https://www.epa.gov/aboutepa/reaffirming-epas-elevation-policy-2024 and https://work.epa.gov/epa/notice-perceived-unaddressed-significant-public-health-or-environmental-risk

[6] Research misconduct is defined as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results" and does not include honest error or differences of opinion [65 FR 76262]. See the Federal Policy on Research Misconduct: https://www.gpo.gov/fdsys/pkg/FR-2000-12-06/pdf/00-30852.pdf

[7] Policy and Procedures for Addressing Research Misconduct (EPA Order 3120.5), section 9(A): https://www.epa.gov/sites/production/files/2014-04/documents/epapolicy.pdf

[8] https://www.nrc.gov/reading-rm/doc-collections/management-directives/volumes/vol-10.html (approved 11 Aug 2015)

(b) The U.S. Department of Energy has a Differing Professional Opinion process "for employees to raise technical concerns related to environment, safety, and health which cannot be resolved using routine processes."[9]

(c) The U.S. Food and Drug Administration's Center for Drug Evaluation and Research provides a procedure for staff members to express Differing Professional Opinions concerning "regulatory actions or policy decisions with significant public health impact in instances when the normal procedures for resolving internal disputes are not sufficient." The procedure provides short timeframes for review by qualified staff not directly involved in the decision so differing opinions can be resolved expeditiously.[10]

(d) The U.S. Food and Drug Administration's Center for Devices and Radiological Health provides a policy "for resolving internal differences of professional opinion and provides an approach for documenting scientific, clinical, and regulatory findings, perspectives, and opinions."[11]

1.6 Freedom from retaliation

EPA's Scientific Integrity Policy states that the policy "extends whistleblower protections to all EPA employees who uncover or report allegations of scientific and research misconduct, or who express a differing scientific opinion, from retaliation or other punitive actions [§IV.A.3]."[12] Differing scientific opinions should be welcomed and encouraged as a legitimate part of the scientific process. Retaliation, even the threat of retaliation, against employees who express differing scientific opinions shall not be tolerated and may result in disciplinary action.[13] An employee who experiences or fears retaliation based on expressing a differing scientific opinion may contact EPA's Scientific Integrity Official for advice and assistance.[14]

In addition, for employees who feel they cannot openly express a differing scientific opinion, a confidential option is available (section 6).

1.7 Definitions

Deliberative documents: documents prepared to assist in arriving at a decision and reflecting preliminary or candid internal views or advice. They are internal, pre-decisional, and have deliberative content. They may express personal ideas, staff opinions, recommendations or advice, options papers, issue papers, management briefing documents, edits or comments on draft documents, draft decision and supporting documents.[15]

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[9] https://www.directives.doe.gov/directives-documents/400-series/0442.2-BOrder-chg1-pgchg (updated 5 Oct 2016)

[10] https://www.fda.gov/media/82932/download#:~:text=A%20culture%20of%20scientific%20integrity%20is%20one%20that%20ensures%20that,integrity%20evaluation%20plan%20that%20articulates (effective 6 Dec 2023)

[11] https://www.fda.gov/about-fda/cdrh-ombudsman/center-devices-and-radiological-health-cdrh-standard-operating-procedure-sop-resolution-internal#Section1_Purpose (updated 4 Sept 2012)

[12] Information on whistleblower protection is available at: https://www.epa.gov/office-inspector-general/whistleblower-protection

[13] Information on protection from retaliation is available at: https://www.eeoc.gov/laws/types/retaliation.cfm

[14] Other resources include EPA's Whistleblower Protection Coordinator (https://www.epa.gov/office-inspector-general/whistleblower-protection#wbp_ombudsman), the Office of Inspector General Hotline (https://www.epa.gov/office-inspector-general/epa-oig-hotline#file_now), and the Office of Special Counsel (https://osc.gov/).

15 Administrative Records Guidance: https://www3.epa.gov/ogc/adminrecordsguidance09-00-11.pdf (Sept 2011)

Differing scientific opinion: a differing opinion of an EPA employee who is substantively engaged in the science that may inform an EPA decision. It generally contrasts with a prevailing staff opinion included in a scientific product under development. The differing opinion must concern scientific data, interpretations, or conclusions, not policy options or decisions. These approaches do not address personal opinions about scientific issues that are not accompanied by scientific arguments, are not part of a scientific product, and are not made in the context of an EPA decision.

Policy: A high-level statement of principles that defines a course of action for a specific purpose and establishes broad requirements that govern EPA's decision making[16].

Prevailing staff opinion: the opinion of the team developing a scientific product. As with differing scientific opinions, prevailing staff opinions are statements about scientific data, interpretations, or conclusions, not to include policy options or decisions.

Science, scientist: This document adopts the expansive view of science articulated in the Scientific Integrity Policy [§II] as including "the full spectrum of scientific endeavors, e.g., basic science, applied science, engineering, technology, economics, social sciences, and statistics." Similarly, a scientist is "anyone who collects, generates, uses, or evaluates scientific data, analyses, or products."

Scientific information: "factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page but does not include the provision of hyperlinks on a web page to information that others disseminate. This definition excludes opinions, where the agency's presentation makes clear that an individual's opinion, rather than a statement of fact or of the agency's findings and conclusions, is being offered."[17]

Scientific Integrity Official; Deputy Scientific Integrity Official: EPA's Scientific Integrity Official champions scientific integrity throughout EPA and chairs a committee of Deputy Scientific Integrity Officials representing each program office and region to provide oversight for the implementation of the Scientific Integrity Policy, to act as liaison for their respective offices, and to be available to address questions or concerns regarding scientific integrity at EPA [Scientific Integrity Policy §II].

Scientific product: products that contain scientific information. These include risk assessments, technical studies and guidance, analytic methods, scientific database designs, technical models, technical protocols, statistical surveys/studies, technical background materials, technical guidance, research plans, and research strategies. They can support a research agenda, regulatory program, policy position, or other EPA position or action.[18]

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[16] https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/termsandacronyms/search.do.

[17] Final Information Quality Bulletin for Peer Review: https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy2005/m05-03.html

[18] See EPA's Peer Review Handbook (https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf)

"Substantively engaged in the science": having contributed scientific expertise in an official capacity to the development or review of a scientific product, beyond presence at meetings or on mailing lists.

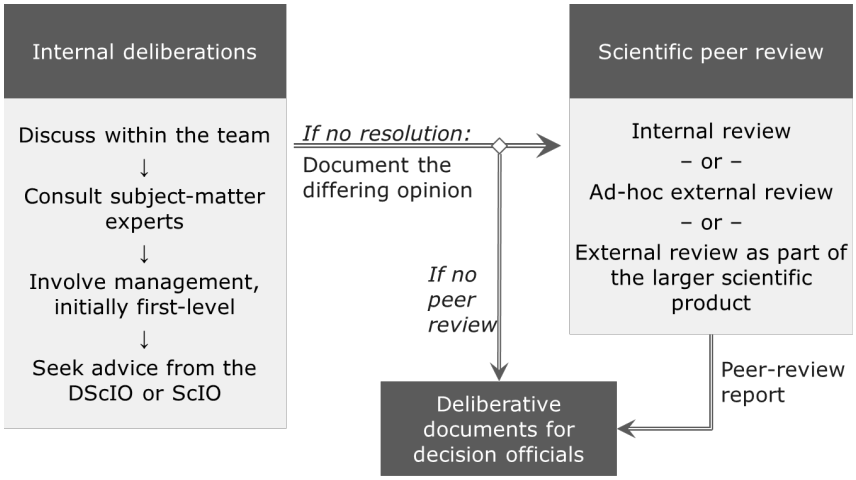
1.8 Effective date: This document is effective when released. After a pilot period of six months, the Scientific Integrity Program may revise the document based on experience and comments from EPA employees.

2. Overview

This document recommends a progression of approaches that employees and managers can use to encourage the expression and satisfactory resolution of differing scientific opinions. Recommended steps begin with discussions (Box 1) within the team developing a scientific product and can proceed to the engagement of additional subject-matter experts, managers, then to internal or external peer review of the scientific merit of the differing opinions, documenting the differing opinions for the policy makers (figure 1). This progression is in accord with EPA's Scientific Integrity Policy, which envisages the use of internal deliberations and scientific peer review (Box 2.).

BOX 1.
Hallmarks of a constructive, free and open discussion are:

- Being respectful of others and their views
- Listening to others without interrupting
- Including persons with different points of view, including potential dissenters
- Involving everyone in the discussion
- Linking to and building on what has already been said



The Deputy Scientific Integrity Officials (DScIO) and Scientific Integrity Official (ScIO) are available to advise and facilitate the process, not to decide the science.

Figure 1. Paths towards resolution of a differing scientific opinion

The ability to express differing scientific opinions exists in the context of a decision-making agency, where scientific information supports decision making in a broad policy context that includes many considerations other than science.

Any employee within the team developing a scientific product may initiate discussion of a differing scientific opinion. If the scientific product or a subsequent decision is time-sensitive or if other circumstances warrant, these approaches may be expedited or otherwise adapted, ideally in consultation with management. The employee initiating a differing scientific opinion may voluntarily terminate the process at any time.

A satisfactory resolution does not necessarily entail choosing one of the opinions, especially when there are multiple plausible methods, models, analyses, or conclusions. Many scientific products do not require that there be a single opinion, and differing scientific options are often supported by the uncertainty or variability in the underlying data. It may be appropriate to present the pros and cons of several alternatives in a scientific product or decision document. It also may be appropriate to recommend additional technical work to better inform or resolve the differing opinions, in which case management should be consulted to work through the implications for timing.

BOX 2.
"When an Agency employee substantively engaged in the science informing an Agency policy decision disagrees with the scientific data, scientific interpretations, or scientific conclusions that will be relied upon for said Agency decision, the employee is encouraged to express that opinion, complete with rationale, preferably in writing. It is expected that any differing scientific opinions will be resolved during internal deliberations and if not, will be addressed during scientific peer review. The report from the peer review panel will be made available for the policy makers' consideration. When no peer review occurs, differing scientific opinions will be reflected in the Agency's deliberative documents for the policy makers' consideration."
– Scientific Integrity Policy §IV.A.3

In the interests of fostering the expression of differing scientific opinions, policy makers are encouraged to communicate final decisions and their basis back to the team and anyone who has formally expressed a differing scientific opinion on that particular matter.

3. Resolving differing scientific opinions: internal deliberations among employees

EPA's Scientific Integrity Policy expresses the expectation that differing scientific opinions will be resolved during internal deliberations. To the extent possible, it is desirable to resolve differing scientific opinions through internal deliberations. These deliberations will likely begin among employees on a team developing a scientific product and can progress to include (1) additional scientists who are subject-matter experts, (2) managers responsible for the scientific product, (3) the organization's Deputy Scientific Integrity Official, and (4) EPA's Scientific Integrity Official (figure 1).

3.1 Discussions within a team developing a scientific product

All employees should welcome differing scientific opinions as a legitimate and necessary part of the scientific process. An employee (or group of employees) with a differing opinion should make reasonable attempts to engage in scientific discussions with their colleagues and managers. The ability to discuss differing opinions constructively and respectfully is a hallmark of a healthy scientific organization.

The objective of these discussions is to resolve the differing opinions, or if that cannot be achieved, to agree on how to present the alternative opinions in the scientific product so that the policy makers have the necessary information to make a well-informed policy decision. Possible forms of presentation may include:

— Presenting each alternative opinion with its underlying rationale for later resolution through peer review and possibly by senior EPA officials.
— Developing a new opinion that synthesizes elements from the original opinions.
— Agreeing that one opinion is preferable. In this case, alternative opinions with scientific merit also may be discussed as having been considered.

In each case, the discussions ensuing from the differing scientific opinion should lead to a stronger position than before or should result in stronger, more nuanced supporting arguments.

3.2 Discussions augmented by additional subject-matter experts

A team developing a scientific product may invite additional scientists who are subject-matter experts to enrich the discussion in the hope of resolving the differing opinions. Project teams are often small, and this can make it difficult to have in-depth scientific discussions when teams lack a breadth of perspectives and include only one or two people in an area of expertise.

The careful addition of subject-matter experts can promote confidence in the results of the augmented discussion. The ideal candidate would be a nationally recognized expert who is widely respected and trusted to be impartial. If the team cannot agree on impartial experts, another approach is for each group of proponents to invite one or two additional experts, then ask these experts to bring in others if they think it would be helpful.

An organization might consider creating standing discipline-specific groups of experts or communities-of-practice who can convene to discuss scientific issues in their area of expertise. Where such groups exist, a differing scientific opinion could be referred to a readily available group of subject-matter experts without the need to choose ad-hoc groups.

3.3 Involving office management responsible for the project

If the employees developing a scientific product are unable to resolve a differing scientific opinion through internal deliberations, the first-level manager responsible for the scientific product may intervene or be invited to help. If the first-level manager is already a proponent of one of the differing opinions, then it may be appropriate to ask another manager or the organization's Deputy Scientific Integrity Official to suggest additional approaches for resolution or additional subject-matter experts. The manager also might choose to become personally involved as a moderator between the employees with the differing opinions.

If another manager in the organization has substantive knowledge or experience pertinent to the issue or has the means of resolving this disagreement, the manager responsible for the scientific product may ask him or her to assume this role.

The responsible manager also might decide to seek advice from the next level of management.

If there is an impasse, the responsible manager would consult with the policy maker about whether to proceed to peer review (consistent with EPA's *Peer Review Handbook*) or to document the differing scientific opinion as described in section 4.1 and include it in the deliberative documents provided to policy makers. Although the Scientific Integrity Policy expresses the expectation that differing scientific opinions not resolved during internal deliberations will be addressed during scientific peer review, this document does not establish a right to peer review.

3.4 Seeking advice from the organization's Deputy Scientific Integrity Official

Each EPA program office and region has a Deputy Scientific Integrity Official who is available to assist in situations where there are differing scientific opinions. The Deputy may suggest that the employees resume their discussions, may suggest additional approaches for resolution or additional subject-matter experts, or may choose to become personally involved as a moderator between the employees with the differing opinions. Alternatively, the Deputy may consider engaging the services of a professional mediator.

> When acting in this capacity, Deputy Scientific Integrity Officials serve to uphold scientific integrity and not to advocate a scientific position. Their role is to advise and facilitate the process, not to decide the science.

If there is an impasse, the Deputy Scientific Integrity Official would consult with the manager responsible for the scientific product to determine, based on the nature of the issue and the timing of the decision, whether to proceed to peer review or to document the differing scientific opinion as described in section 4.1 and include it in the deliberative documents provided to policy makers.

3.5 Seeking advice from EPA's Scientific Integrity Official

Alternatively, EPA's Scientific Integrity Official is available to provide advice and assistance. Employees who feel that they cannot pursue a differing scientific opinion within their organization or with a Deputy Scientific Integrity Official may invite EPA's Scientific Integrity Official to assist in the activities described in section 3.4.

3.6 Discussions initiated from outside a team

Although differing scientific opinions ordinarily would arise within a team developing a scientific product, there may be other subject-matter experts at EPA whose advice would improve the scientific quality of the product. Discussions initiated from outside the team occur when an internal expert learns of a scientific product under development, believes an important issue is not being adequately addressed, and wants to give advice to the team.

The most collegial approach would be for the internal expert to call the leader of the team developing the scientific product to discuss the team's approach and the expert's perspectives. Together the expert and team leader would determine whether there is mutual interest in inviting the expert to team discussions.

A more formal approach would be for the internal expert to document his or her perspective as described in section 4.1, then to transmit it to the leader of the team developing the scientific product, bringing in scientific integrity officials and managers as needed. Consideration should be given to the potential for the expert's contribution to improve the scientific quality of the product, as well as schedule and resource constraints. In addition, the team leader or responsible manager may invite the expert to a team meeting. This discussion may expand as necessary to include additional subject-matter experts (section 3.2) or managers (section 3.3). The Deputy Scientific Integrity Official or EPA's Scientific Integrity Official may offer advice and assistance if necessary (sections 3.4–3.5).

In these ways, an internal expert not engaged in the development of a scientific product (though engaged in the science pertinent to the product) may initiate a differing scientific opinion. Such experts should have scientific publications, job experience, or specialized training pertinent to the specific issue, for example, publications on modeling the environmental fate of particulate matter or job experience assessing reproductive toxicity. This fulfills the mandate that EPA employees must welcome differing views and opinions and address them, with due consideration to management concerns about scheduling and resources.

4. Addressing differing scientific opinions through peer review

Although the Scientific Integrity Policy expresses the expectation that differing scientific opinions will be resolved during internal deliberations, it recognizes that this might not happen and that differing opinions may be addressed during scientific peer review[19].

This document does not establish a right to peer review. The managers responsible for the scientific product have key roles in decisions about peer review. If there is no peer review, the differing scientific opinions are documented and included in the deliberative documents provided to policy makers (section 5).

The peer review process, managed in accordance with the program's peer-review procedures, should engender trust so all parties can respect the outcome. The elements of peer review include:

- Selecting a process for peer review
- Documenting the differing scientific opinions so they can be reviewed
- Developing an unbiased charge to assist the peer reviewers in their task
- Selecting scientifically qualified peer reviewers, with due consideration of impartiality and conflicting interests, and protecting the panel from interference
- Writing the peer review report

The peer reviewers write joint or individual reports that evaluate the scientific merit of the differing opinion and respond to the charge. The manager responsible for the scientific product receives the report and transmits it to everyone involved in the internal deliberations and to the organization's Deputy Scientific Integrity Official. The manager also makes the report available for consideration by the policy makers.

4.1 Documenting a differing scientific opinion

If there will be a peer review of a differing scientific opinion, the employee(s) with the differing opinion should prepare a summary position, similar in coverage to the prevailing staff opinion. The summary should be factual, impartial, clear, concise, and not burdensome to develop or review. It may be read by peer reviewers or policy makers with various backgrounds. There is not a single format appropriate for all scientific disciplines and issues. One best practice might be to emulate scientific journal editors who have developed a common practice that works for expressing opinions across many fields. Readers of a published manuscript can express their opinions through a short letter-to-the-editor, commonly with a limit of up to 500 words, plus a table or figure if needed, and references

[19] See EPA's Peer Review Handbook (https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf)

One option would be for employees to adapt the practice of a prominent journal in their field and document their differing opinions in a similarly concise manner. Alternatively, they could agree to adopt an ad-hoc approach tailored to the specific issue.

4.2 Developing a charge for the peer review

All sides guided by the manager responsible for the scientific product or the organization's Deputy Scientific Integrity Official work together to formulate a charge to guide the peer review. The charge should not steer the peer reviewers towards a conclusion.

4.3 Peer review as part of a larger scientific product

If the differing scientific opinion is central to a larger scientific product that will undergo peer review, an option is to present the differing opinions to the peer reviewers of the scientific product. This option is possible if several peer reviewers have expertise pertinent to the issue. For example, in a toxicological review of adverse health effects associated with exposure to a chemical substance, a differing scientific opinion on whether a toxic effect has a threshold is central to the assessment and should be within the expertise of the peer reviewers. On the other hand, if the differing scientific opinion concerns a highly specialized modeling issue, there may not be adequate expertise on the peer review panel to address this issue. In the latter case, the panel could be augmented with the required expertise, or an ad-hoc peer review limited to the differing scientific opinion could be conducted prior to the peer review of the full scientific product (section 4.4).

There are several options for presenting a differing scientific opinion for peer review accompanying a larger scientific product. For example, the scientific product could be written to present the differing opinions consecutively as options under consideration. Alternatively, the scientific product could include a prevailing staff opinion, with the differing opinions presented in an appendix or separate document. Either way, the charge would ask peer reviewers to evaluate or compare the scientific merits of the differing opinions.

4.4 External peer review

An option for peer review limited to the differing scientific opinion is to use an ad-hoc panel of external subject-matter experts. This might be considered when few employees have the required expertise or when it would be useful to solicit the opinions of external experts.

Aside from the time and expense of a procurement process, external peer review includes the same elements as internal peer review: developing a charge, selecting scientifically qualified peer reviewers, and writing a peer review report.

4.5 Internal peer review

Another option for peer review limited to the differing scientific opinion is to use an ad-hoc panel of internal subject-matter experts. Internal peer review is an extension of the reviews employees regularly perform for each other in scientific organizations. This might be considered as a means of achieving a strong and defensible resolution of the differing opinions before public release.

Because differing scientific opinions by their nature involve scientific judgment about contentious or intractable issues, an impartial panel is essential. The ideal would be for the proponents of the differing opinions to mutually agree on the appropriate internal experts.

Alternatively, peer reviewers could be drawn from an established discipline-specific expertise group (section 3.2), if the organization has established one and if it is considered by each side to be impartial. An advantage of using a standing group of subject-matter experts is that it skips the step of identifying and selecting available subject-matter experts.

5. Presenting differing scientific opinions to policy makers

The Scientific Integrity Policy specifies that reports from peer reviews of differing scientific opinions will be made available for consideration by the policy makers, who are generally office directors or assistant administrators. It further specifies that if no peer review occurs, then differing scientific opinions will be included in the deliberative documents considered by the policy makers. These provisions ensure that policy makers are aware of all differing scientific opinions not resolved through internal scientist-to-scientist deliberations.

Some options for documenting differing scientific opinions appear in section 4.1.

5.1 Advance notice for policy makers

When it appears that internal deliberations will not resolve a differing scientific opinion, it is important to notify the policy makers. This is particularly true for issues that are important, contentious, precedent-setting, or highly visible. Such notification alerts the policy makers to a potential delay in completing the scientific product while the issue is addressed through peer review or other means.

5.2 Providing a peer review report to policy makers

The Scientific Integrity Policy specifies that reports from peer reviews of differing scientific opinions be made available for consideration by the policy makers. This is to ensure that policy makers are aware of the scientific merit of all differing opinions not resolved through internal scientist-to-scientist deliberations.

5.3 Presenting a differing scientific opinion to policy makers

If a differing scientific opinion is not resolved through internal deliberations or addressed through peer review, it should be reflected in the deliberative documents considered by the policy makers. This is to ensure that policy makers are aware of the differing opinions. If all issues were neither resolved nor peer reviewed, policy makers may need to consider seeking additional advice. Options include consulting their organization's science advisors or EPA's Science Advisor.

6. Option for confidential expression

In some cases, an employee may feel it necessary to seek confidentiality when expressing alternative scientific views. In these situations, the individual may contact EPA's Scientific Integrity Official for advice and assistance.

6.1 A proxy selected by the Scientific Integrity Official will meet with the employee to become familiar with the issue and, if necessary, may act in lieu of the employee in subsequent internal deliberations (section 3) or in preparing for peer review (section 4).

6.2 To the extent possible and as allowed by law, knowledge about the identity of the employee should be limited to those who need to know. Confidentiality cannot be guaranteed, however, especially in small teams. For concerns about confidentiality and freedom from retaliation, EPA's Scientific Integrity Official may be consulted for advice and assistance.

6.3 While confidential differing opinions will be accepted, anonymous differing opinions will not be accepted. An anonymous opinion could not be verified to meet the criteria for submitting a differing opinion under this document.

7. Appeal and Redress[20]

An employee who believes these approaches are not being applied fairly may contact EPA's Scientific Integrity Official for advice and assistance.

7.1 The findings of a properly conducted peer review generally cannot be appealed. This is in accordance with the Scientific Integrity Policy, where differing scientific opinions "will be resolved during internal deliberations and if not, will be addressed during scientific peer review [§IV.A.3]."

7.2 An employee who believes these approaches are not being followed may seek redress from EPA's Scientific Integrity Official.

8. Recordkeeping

8.1 Differing scientific opinions addressed through peer review require the peer reviewers to create a peer review report that should be made available for consideration by the policy makers. In addition, differing scientific opinions presented to policy makers without being addressed through peer review should be reflected in the deliberative documents considered by the policy makers [Scientific Integrity Policy §IV.A.3].

8.2 The organization's Deputy Scientific Integrity Official should transmit a summary of each DSO including date, office, subject area, and resolution to EPA's Scientific Integrity Official for use in evaluating the implementation of these approaches and in preparing the annual report on scientific integrity.

8.2 Free and open discussion should be frequent and routine in a healthy scientific organization. If the participants choose to document the outcome of the discussion for future reference, this need not be transmitted to EPA's Scientific Integrity Official.

[20] An *appeal* is a request for reconsideration when the proper procedures were followed. *Redress* is the term used when the proper procedures were not followed.

9. Examples

The following examples are illustrative but not exhaustive. Similar situations could be approached and resolved differently depending on the specifics of each case.

(a) *Situation:* A team of employees is completing a draft document for release for public comment and peer review. A team member believes that the data are inadequate and too uncertain for reaching a conclusion.

Possible approach: This is a legitimate topic for a differing scientific opinion, which need not be framed as *Conclusion A* versus *Conclusion B*. *Conclusion A* versus *No Conclusion* is equally valid. By raising the opinion that the data are inadequate for reaching any conclusion, the subsequent internal deliberations should force the team to reexamine their conclusion, and sharpen the supporting arguments. In this way, differing scientific opinions can improve the quality of the scientific product.

(b) *Situation:* An office has started to update a scientific product that will go to external peer review. One team member, the only modeler on the project, believes that there are flaws in a model that is central to the analysis but that were not discovered when the prior version was approved. The modeler would like to develop a better model, but the project manager rejected this proposed activity, believing the prior model to be adequate and new model development to be time-consuming. The modeler raises the modeling approach as a differing scientific opinion.

Possible approach: As there are no other modelers on the project, the first step could be to seek the views of other EPA modelers. If this does not resolve the issue, the next step could be an expedited peer review by an internal panel or by an external panel of qualified modelers. If the timeline becomes tight, the issue could be documented and presented to the peer review panel of the larger scientific product or to the policy maker.

(c) *Situation:* Five years ago, the Office of Research and Development developed an assessment of a chemical substance and, two years later, a headquarters program office used that assessment to set a national standard. A regional office is applying the national standard to evaluate chemical risks at a local site in the region. The regional employee responsible for the site assessment disagrees with the scientific conclusions of the ORD assessment and is considering initiating a differing scientific opinion.

Possible approach: The ORD assessment is not an appropriate topic for a differing scientific opinion, as the science in the ORD assessment is not what is under development or under review. The regional employee may, however, inform regional managers of the disagreement with the ORD assessment so that managers in the regional office, the headquarters program office, and ORD can jointly determine how to proceed.

(d) *Situation:* A team of employees has developed a new scientific product. Before it is released for external peer review, a senior manager who also is an expert in the subject matter changes a key scientific conclusion. The team members protest and ask that their previous scientific opinion be evaluated by the approaches in this document. The senior manager warns that this borders on insubordination.

Possible approach: A differing scientific opinion is never insubordination, and the team members in this case are expressing a scientific opinion and not refusing a lawful order. This is a situation where the manager responsible for the scientific product would quickly become involved. If the

team members believe the manager is not effective as a moderator, then they should invite the organization's Deputy Scientific Integrity Official to become involved. One outcome would be for the draft scientific product to include both conclusions as alternatives, with scientific rationales and a charge to ask the peer reviewers to evaluate the scientific merit of each conclusion.

(e) *Situation:* An external peer review panel reviewed a draft scientific product, and the staff believes a key peer review recommendation reflects a misunderstanding of the underlying data. They would like to reject the peer review recommendation and are considering pursuing this as a differing scientific opinion.

Possible approach: This should not be considered a differing scientific opinion, as EPA is not required to accept peer review recommendations with which it disagrees. The staff should carefully consider the recommendation and document the rationale for its decision. If the staff is split on whether to accept or reject the recommendation, the approaches to internal deliberations in section 3 might prove helpful.

(f) *Situation:* An external peer review panel reviewed a draft scientific product, and a key peer review recommendation is deliberately ignored when the final product is developed. A concerned employee protests and asks that the final product reflect the peer review recommendation.

Possible approach: Again, this should not be considered a differing scientific opinion, as EPA is not required to accept peer review recommendations (although all recommendations should be considered, not ignored). If the staff is split on whether to accept or reject the recommendation, the approaches to internal deliberations in section 3 might prove helpful. It would be up to the managers to decide who else needs to be involved.

(g) *Situation:* A team of employees has completed a peer reviewed assessment that showed the health hazards of a chemical are greater than previously believed. The program officials considered the new assessment and decided not to develop a stricter standard for allowable concentrations. The employees who developed the assessment believe a stricter standard is warranted and file a differing scientific opinion.

Possible approach: Differing scientific opinions apply only to scientific data, interpretations, or conclusions, not to policy options or decisions. Scientific integrity is concerned with the accurate representation of science to the policy makers, not with their policy decisions. A differing scientific opinion cannot be used to challenge subsequent policy decisions.

(h) *Situation:* A scientist and supervisor are coauthors of a manuscript being readied for submission to a scientific journal. They are having difficulty reaching agreement on the conclusions.

Possible approach: Only some of the approaches in this document apply to journal articles. For example, while products disseminated by EPA are subject to final approval by a policy maker, journal articles are written by a team of coauthors with peer review managed by the journal editor. Many journal editors require all coauthors of a manuscript to agree with the final version and be accountable for all its aspects. Thus, coauthors cannot be forced to adopt a conclusion that they cannot accept, including EPA's position, if there is one. (The manuscript should carry the disclaimer about not necessarily representing EPA's views and policies.) This highlights the importance of planning journal manuscripts and choosing coauthors. If the coauthors reach an impasse, they may draw on the approaches for internal deliberation in section 3 to seek advice from other subject-matter experts or from management, and such contributions should be recognized with an acknowledgment in the published manuscript.

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