Best Practices for Clearance of Scientific Products at EPA

Scientific Integrity Program
U.S. Environmental Protection Agency

Executive Summary

The U.S. Environmental Protection Agency has a longstanding commitment to the timely release of scientific information to the public. Before release, scientific products go through clearance, which is a process of obtaining management's approval for public release. Clearance is required for scientific products developed as part of an EPA employee's official duties.

EPA's Scientific Integrity Policy directs the Scientific Integrity Committee to "develop a framework for Agency clearance procedures for scientific products" and to evaluate program, office, and regional clearance procedures and make recommendations as appropriate. *Best Practices for Clearance of Scientific Products at EPA* were developed for programs, offices, and regions to refer to when developing, evaluating, or revising their clearance procedures to promote transparency, clarity, timeliness, predictability, and consistency.

These *Best Practices* are focused on the clearance of scientific products developed by an EPA author, or a group of authors including at least one EPA author, as part of his/her official duties, that do not routinely undergo an existing or an alternate clearance procedure.

This document does not focus on clearance processes for Agency-disseminated non-scientific products, purely policy documents, or media products. Also, specific clearance processes already exist for some Agency-disseminated documents (e.g., documents developed as part of an Action Development Process and Integrated Science Assessments). These Best Practices do not duplicate, amend, replace, or create new requirements for the clearance processes for these types of documents. However, the *Best Practices* may provide useful suggestions for developing, evaluating, or revising a clearance process for such products.

Best Practices for Clearance of Scientific Products at EPA compiles practices that are taken from EPA policies and from the current procedures used across EPA's programs, offices, and regions. This document recognizes the range of requirements and processes that currently exist for scientific products (e.g., peer review, data quality) and is not intended to duplicate these processes. It provides an overview of the clearance process and includes information about scientific review that is relevant to the clearance process. Scientific review and clearance are related processes. Scientific review involves quality review, internal technical review, and/or external peer review. Clearance occurs after quality review and internal technical review if needed, but before release or, for example, before review by a scientific journal.

The best practices are summarized and outlined in the last section to illustrate how they apply to the clearance process from initiation to final approval for release. These best practices include verifying that the appropriate scientific reviews have occurred before initiating clearance, establishing essential elements of clearance procedures, planning for clearance, processing scientific products through clearance, making clearance decisions, tracking clearance, and training employees on clearance procedures. The document is a resource for EPA programs, offices, and regions as they consider how these best practices can enhance their clearance processes.

This document provides best practices for clearance of scientific products at EPA and is not policy or guidance.

Contributors and Acknowledgments

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Contents

Introduction and Background

Members of the public should have access to the scientific research and analyses that are the foundations for EPA's policy decisions (Box 1). Before a scientific product is released, it goes through clearance, which is an internal review and approval process performed by managers.

The Scientific Integrity Policy[1] (hereafter "the Policy") charges the EPA Scientific Integrity Committee to "develop a framework for Agency clearance procedures for scientific products as a guidance for Program Offices and Regional Offices" and "evaluate Program Offices' and Regional Offices' clearance procedures for scientific products and make recommendations as appropriate to promote standardization across the Agency."

The best practices in this document cover the clearance of scientific products that are developed by an EPA author, or a group of authors including at least one EPA author, as part of his/her official duties, that do not routinely undergo an existing or alternate clearance procedure. Although these *Best Practices* do not focus on clearance for Agency-disseminated non-scientific products, they may provide useful suggestions for developing, evaluating, or revising a clearance process for such products. This best practices document is not a policy or guidance.

Box 1: Release of Scientific Information to the Public

Scientific research and analysis comprise the foundation of all major EPA policy decisions. Therefore, the Agency should maintain vigilance toward ensuring that scientific research and results are presented openly and with integrity, accuracy, timeliness, and the full public scrutiny demanded when developing sound, high quality environmental science. This policy is intended to outline the Agency s expectations for developing and communicating scientific information to the public, to the scientific community, to Congress, and to the news media by further providing for and protecting the EPA's longstanding commitment to the timely and unfiltered dissemination of its scientific information uncompromised by political or other interference. This policy recognizes the importance of, and the need to foster a culture of, openness regarding the results of research, scientific activities, and technical findings. To that end, the EPA strongly encourages and supports transparency and active, open communications through various forms including, but not limited to, publication in peer reviewed or refereed journals, conference papers and presentations, media interviews, responses to Congressional inquiries, web postings, and news releases.

EPA s Scientific Integrity Policy, Section IV.B

Because clearance and scientific review are related processes at EPA, general aspects of scientific review are also discussed. There are multiple EPA documents relevant to scientific review, including the Peer Review Handbook[2], Best Practices for Designating Authorship[3], Quality Policy[4], and EPA's Public Access Plan[5]. Authors should consult these documents as needed.

[1] EPA. 2012. *Scientific Integrity Policy*. https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf
[2] EPA. 2015. *Peer Review Handbook*, 4th Edition. https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015
[3] EPA. 2016. *Scientific Integrity: Best Practices for Designating Authorship.* https://www.epa.gov/osa/authorship-best-practices
[4] EPA. 2000. *Policy and Program Requirements for the Mandatory Agency-wide Quality System.* EPA Order CIO 2105.0. https://www.epa.gov/sites/production/files/2015-09/documents/epa_order_cio_21050.pdf
[5] EPA. 2016. *Plan to Increase Access to Results of EPA-Funded Scientific Research*. https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

About Best Practices for Clearance of Scientific Products at EPA

The Scientific Integrity Program asked EPA programs, offices, and regions to submit information about their current clearance processes. Some procedures are contained in unique documents, some are embedded in other operating procedures, and some are unwritten. Scientific Integrity Program staff collected and organized this information to produce this best practices document. In addition, this document provides both best practices based on EPA policy and best practices based on practices used in Agency programs, offices, and regions. Both are displayed inside boxes and are organized in the manner described below.

- Policy-derived best practice: These are practices that are derived from EPA policy and guidance.
  - The name of the policy from which a practice has been derived.

- Program-derived best practice: These are practices already in use by EPA programs, offices, and regions.
  - Appendices relevant to the practice.

Applicability

These practices are intended to apply to the clearance of scientific products and other types of scientific communications. It may not be necessary to incorporate every best practice described in this document, but each program, office, and region should give consideration as to how these best practices could enhance their clearance process.

These practices focus on the clearance of scientific products that are developed or based upon work conducted as a part of an EPA employee's official duties. These include journal articles, meeting presentations, and other scientific products that have an EPA employee listed as an author and routinely do not undergo an existing or alternate clearance mechanism (for a list of examples see Appendix A). It should be determined as early as possible whether the scientific product is based on work conducted as part of an EPA employee's official duties. A scientific product prepared as part of an employee's official duties makes use of Agency resources, time, and equipment in preparation and is cleared before public release. Whether a product falls within an employee's official duties should be determined in advance with his or her supervisor. In general, approval of official duty activities for the development of scientific products should be documented.

- Program-derived best practice: Encourage authors and supervisors to discuss in advance whether a scientific product will be considered a part of official duties. Approval of official duty activities should generally be documented.

Some Agency-disseminated scientific products (e.g., science assessments, risk assessments) typically undergo their own existing specific clearance process. These *Best Practices* may provide useful suggestions for developing, evaluating, or revising a clearance process for such products, if necessary.

Not every clearance practice is necessary for every scientific product. For example, a manager's approval may be all that is needed before submitting an abstract to a conference.

These clearance practices do not apply to scientific products developed through assistance agreements or by grantees, fellows, interns, or volunteers who are not employed by EPA. Scientific products developed under EPA-funded grants generally do not need EPA clearance, unless an EPA employee is listed as a co-author. EPA clearance requirements for scientific products produced under an EPA-funded cooperative agreement or contract should be based upon the specified funding agreement. These best practices for clearance also do not apply to products covered by the Action Development Process[6] or to media products that go through EPA's Office of Public Affairs (OPA) Product Review Tracking System (PROTRAC).[7]

Goal

The goal of this document is to assist programs, offices, and regions in developing, evaluating, or revising clearance procedures to promote transparency, clarity, timeliness, predictability and consistency. For this reason, consistency within programs, offices, and regions, and not uniformity across the Agency, is the goal.

Clearance procedures for scientific products should articulate the entire process from start to finish and be consistent with the elements outlined in the Scientific Integrity Policy (e.g., "procedures will include guidance for review elements, time frames for review and approval, and a process for redress if clearance procedures are not met."). Each program, office, and region is expected to have clearance procedures that prioritize transparency, clarity, timeliness, predictability, and consistency (Box 2).

Box 2: Goals of the Clearance Process

Transparency makes the steps of the process visible

Clarity articulates the roles and responsibilities of those who clear scientific products.

Timeliness ensures that scientific products move through the clearance process in a reasonable amount of time.

Predictability allows EPA employees to know what to expect in procedures as well as the appropriate time required for each step.

Consistency requires that written procedures are followed and do not randomly change, regardless of the content of the product.

[6] For more information about the Action Development Process, see the library at http://intranet.epa.gov/adplibrary/.
[7] Access to the Product Review Tracking System (PROTRAC) in SharePoint is available at https://usepa.sharepoint.com/sites/OA_Applications/ProTrac.

Scientific Integrity Policy

EPA's Scientific Integrity Policy notes the importance of the proper conduct, use, and communication of science so that EPA can carry out its mission (Box 3). All EPA employees, regardless of grade level, position, or duties -- including scientists, managers and political appointees -- are required to follow EPA's Scientific Integrity Policy when engaging in, supervising, managing, or influencing scientific activities; communicating information in an official capacity about EPA scientific activities; and utilizing scientific information in making Agency policy or management decisions. This section highlights important statements (see Boxes) in the Scientific Integrity Policy that relate to clearance.

Box 3: Science is the Backbone of EPA s Decision Making

The Agency s ability to pursue its mission to protect human health and the environment depends upon the integrity of the science on which it relies. The environmental policies, decisions, guidance, and regulations that impact the lives of all Americans every day must be grounded, at the most fundamental level, in robust, high quality science. When working with science, it is the responsibility of every EPA employee, contractor, grantee, collaborator, and student volunteer to conduct, utilize, and communicate science with honesty, integrity, and transparency, both within and outside the Agency.

EPA s Scientific Integrity Policy, Section II

Scientific Quality Review

The Scientific Integrity Policy limits reviews by Agency managers and other leadership of a scientific product to its scientific quality considerations only (Box 4). This provision aims to ensure that scientific information and scientific methods are free of political or other types of interference.

Box 4: Scientific Quality Review

To enhance transparency within Agency scientific processes, this policy requires reviews by Agency managers and other Agency leadership regarding the content of a scientific product to be based only on scientific quality considerations, e.g., the methods used are clear and appropriate, the presentation of results and conclusions is impartial.

EPA s Scientific Integrity Policy, Section IV.A.2

- Policy-derived best practice: Ensure that reviews of scientific information by Agency managers and other leadership are based only on scientific quality considerations.
  - Scientific Integrity Policy, Section IV.A.2

Timely Release and Redress Procedures

Releasing scientific information is vital to EPA's operations. The public and federal agency personnel should have timely access to the scientific products resulting from EPA scientific activity. To aid in the timely release of scientific information, clearance procedures should include time frames for review and approval and a process for redress if clearance procedures are not met (Box 5).

Box 5: Timely Response and Redress Procedures

The EPA Scientific Integrity Committee will develop Agency wide best practices for the approval of scientific products and communications. Each Program Office and Regional Office will use these to develop and document consistent, transparent, and predictable procedures for clearance, consistent with the Scientific Integrity Committee s best practices. The procedures will include guidance for clearance elements, time frames for clearance, and a process for redress if clearance procedures are not met.

EPA s Scientific Integrity Policy, Section IV.B.1

- Policy-derived best practice: Develop clearance procedures for scientific products.
  - Scientific Integrity Policy, Section V.A
- Policy-derived best practice: Develop time-frames that articulate how many days should be designated for each clearance step.
  - Scientific Integrity Policy, Section V.A
- Policy-derived best practice: Develop a process for redress if clearance procedures are not met.
  - Scientific Integrity Policy, Section IV.B.1

Release of Scientific Information to the Public

The Scientific Integrity Policy promotes openness and communication of scientific information to the public. Clearance procedures should allow for the free flow of information. Internal communication throughout the development of a scientific product is a way to make the clearance process run smoothly so that EPA's scientific products are released to the public in a timely manner. Authors, project teams, and managers should communicate regularly to identify any potential issues throughout the clearance process.

Box 6: Openness and Communication

This policy is intended to outline the Agency s expectations for developing and communicating scientific information to the public, to the scientific community, to Congress, and to the news media by further providing for and protecting the EPA s longstanding commitment to the timely and unfiltered dissemination of its scientific information uncompromised by political or other interference. This policy recognizes the importance of, and the need to foster a culture of, openness regarding the results of research, scientific activities, and technical findings.

EPA s Scientific Integrity Policy, Section IV B

- Policy-derived best practice: Foster a culture of openness by ensuring that clearance procedures allow for the timely release of unfiltered scientific information to the public.
  - Scientific Integrity Policy, Section IV.A.1
- Program-derived best practice: Encourage communication among project teams and managers to identify any potential issues throughout the clearance process and address them appropriately.

1. Before Clearance: Consideration of EPA Policies and Scientific Review

Planning for clearance should happen early in the scientific research project planning process. Before beginning the clearance process for EPA scientific products, it is important that staff and supervisors properly identify which scientific products are subject to the office's clearance procedures. Future problems may be avoided if the expected responsibilities of those involved are clearly outlined at the onset of a new project.

This section describes policies or requirements that may apply to scientific products and types of scientific review. Authors should consider these elements early in the development of a scientific product. As part of the clearance process, managers will confirm that the scientific product was adequately reviewed and that it meets requirements of applicable EPA policies and procedures. If authors do not address these before initiating the clearance process, it could significantly delay the release of the product.

A. Policies and Planning That May Apply to Scientific Products

Advance Notice

Advance notice is a process for ensuring that senior leadership are made aware of and adequately prepared for the release of scientific products that are highly visible, sensitive, or influential. (See Appendix B for a glossary of key terms used in this document.) This includes scientific products that can reasonably be anticipated to draw the attention of Congress, the scientific community, the media, industry groups, other agencies or governments, a specific community, or that may significantly impact specific demographic groups or communities more than others.[8] Scientific products that relate to a Presidential initiative or either pending or established policy decisions may also warrant advance notice.[9]

Some scientific products may warrant advance notice to be sent to other EPA programs, offices, and regions, e.g., if the content of the product has implications for their work or for a community located in their region. In these cases, the clearance process should not be the first time the other program, office, or region is informed about the product. Authors and management should discuss scientific products that potentially have implications for the work of other EPA programs, offices, or regions with the appropriate managers in those offices and regions as early as possible in the project or product development phase.

[8] EPA, ORD. 2016. *ORD Policies and Procedures Manual*, Section 14.03, "ORD Clearance Policy and Procedures." https://intranet.ord.epa.gov/about-ord/ord-policies-and-procedures-manual

[9]EPA, Office of Chemical Safety and Pollution Prevention (OCSPP), Environmental Fate and Effects Division. 2004. *Clearance and Review Process for Technical Information Products*.

Programs, offices, and regions should establish considerations for determining which scientific products require advance notice. Advance notice procedures should identify the management chain to be notified. The need for advance notice should not result in a denial of clearance.

- Program-derived best practice: Establish criteria for when scientific products may warrant advance notice.
- Program-derived best practice: Establish advance notice procedures for routing products through the appropriate management chain in other programs, offices, or regions.
- Program-derived best practice: If advance notice is anticipated, authors and management should begin conversations about the product as early as possible with the programs, offices, and regions to be notified.

Allowing Adequate Time for Clearance; External Collaborators

Authors working on scientific products that have intra-Agency or external collaborators should plan for the appropriate amount of time needed for the product to route through their office's clearance procedure before the designated release or publication date. Authors and managers should identify any clearance issues early and address them appropriately. Authors should consult their first-line supervisors to make sure that a scientific product is ready for clearance initiation.

Communications Check-in

Various individuals within EPA may need to be notified upon the initiation of clearance for a scientific product. If this is the case, authors should prepare a communications strategy for the scientific product early in the planning stages of a project. Additional information can be found in Section 2 on the Clearance Process.

Highly visible scientific products should have communications materials developed prior to release. The communication materials, such as fact sheets or communications strategies, serve to give senior leadership an overview of the scientific product's findings and to help prepare the leadership for questions from external stakeholders and media once the product is released. Clearing authors should submit communication materials along with the scientific product for clearance.

- Program-derived best practice: Specify that highly visible scientific products are submitted along with appropriate communications materials for clearance.
- Program-derived best practice: Remind authors and managers about having and implementing a communications strategy by listing a communications check-in on the clearance routing form.

Public Access to Scientific Results

EPA has a Plan to make its peer-reviewed, scientific research publications and underlying research data available to the public.[10] Publications subject to the Plan are required to be deposited into the National Institutes of Health (NIH) PubMed Central and the underlying data for a publication to be submitted to the EPA Environmental Data Gateway.

All projects that collect or utilize scientific data must have a Scientific Data Management Plan (SDMP) that addresses public access to publications and the underlying research data. Clearing managers should verify that the scientific product has a SDMP that describes public access to publications and underlying research data. Upon publication, clearance contacts should be able to track and verify that publications and underlying data have been made accessible according to the SDMP.

Quality Assurance

Quality Assurance (QA) ensures that products generated or funded by EPA are scientifically valid and reliable for informing Agency decisions. QA is "an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer."[11] The Quality Systems Policy for Environmental Data provides quality system requirements for all EPA organizations, including the development of a Quality Management Plan (QMP) and the required use of Quality Assurance Project Plans (QAPPs) for any project involving environmental data.

The clearance process should ensure and verify that all QA requirements and procedures were followed throughout the duration of the project and the development of the scientific product. This includes adherence to the QAPP, if applicable, as well as any documentation of QA that should be included in the final scientific product. Oversight and review of QA activities is typically the responsibility of the organizational Quality Assurance Manager (QAM) or related official.

- Policy-derived best practice: Verify that quality system requirements have been reviewed and performed and that any comments have been adequately addressed.
  - Quality Systems Policy for Environmental Data, Section 3.4.3
- Program-derived best practice: Authors submit QA documentation along with the scientific product for clearance.

[10] EPA. 2016. *Plan to Increase Access to Results of EPA-Funded Scientific Research*. https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

[11] EPA, Office of Environmental Information (OEI). 2002. *Overview of the EPA Quality System for Environmental Data and Technology*, EPA/240/R-02/003. https://www.epa.gov/sites/production/files/2015-08/documents/overview-final.pdf

Human Subjects Research

The Program in Human Research Ethics and Oversight is responsible for ensuring ethical conduct and regulatory compliance of human subjects research (HSR) conducted or funded by EPA.[12] All EPA-funded projects, whether intramural or extramural, that involve human subjects must be reviewed and approved by the Human Subjects Research Review Official (HSRRO) prior to initiating such research. If a scientific product is based on human subjects research, clearing managers should confirm that the project received HSRRO approval and that the product is in compliance with HSR regulations.

Dual-Use Research of Concern

EPA has a Dual-Use Research of Concern (DURC) Policy for managing life sciences research that is beneficial, but, in the wrong hands, could be misused to harm national security and/or public health.[13] According to this policy, "EPA organizations and principal investigators that fund or conduct 'life sciences' research, primarily in ORD, will be required to screen for potential DURC projects."[14] These projects typically include experimentation with agents and toxins that pose a significant threat to human health or other living organisms. Authors, project teams, and managers should flag scientific products that qualify as dual-use research of concern. If a scientific product is of dual-use research concern, clearing managers should confirm that the project was in compliance with the DURC policy. See the DURC Policy for categories of research that are subject to the policy.

Legal Concerns

Legal issues sometimes arise in the course of clearance. Possible issues include intellectual property, conflict of interest, and government ethics concerns. Publication agreements often contain provisions and requirements that pose legal concern for EPA and other federal employees (e.g., forms for transfer of copyright). In this case, it is important to have a mechanism for contacting and collaborating with the relevant EPA legal teams. In the event that a scientific product raises legal concerns, the author, project team, or manager should forward the legal concerns attachment to the clearance routing form along with a copy of the scientific product to EPA's Office of General Counsel (OGC) or Office of Regional Counsel (ORC) for resolution. Consult the relevant ORC website or the OGC's intranet webpage to learn more about the types of legal assistance available.[15]

[12] EPA, Office of the Science Advisor (OSA), Human Subjects Research Program. http://intranet.ord.epa.gov/p2/HSR/home

[13] EPA. 2016. *Policy and Procedures for Managing Dual Use Research of Concern*. EPA Order 1000.19. http://intranet.epa.gov/ohr/rmpolicy/ads/orders/1000_19.pdf

[14]EPA, Office of Research and Development (ORD). "Dual-Use Research of Concern Policies." https://intranet.ord.epa.gov/homeland-security/dual-use-research-concern-durc-policies

[15] U.S. EPA, Office of General Counsel (OGC), The Ethics Program. http://intranet.epa.gov/ogc/ethics.htm

Authorship

The designation of authorship plays an important role in transparency by identifying who contributed to a scientific product and how that product was developed. Everyone who made a significant contribution to a scientific product should be recognized appropriately. EPA has developed *Best Practices for Designating Authorship*, which can be consulted for more information.[16]

Original Author Review

To ensure that scientific information used in policymaking is accurate, the Scientific Integrity Policy expects EPA scientists and managers to review, correct, and approve the scientific content of any proposed Agency document intended for public dissemination that significantly relies on their research, identifies them as an author, or represents their scientific opinion (Box 7). This applies regardless of the clearance procedure that is used. It does not give EPA scientists and managers authority to revise EPA policy based on their science.

Box 7: Original Author Review

The Agency s scientists and managers are expected to review, correct, and approve the scientific content of any proposed Agency document intended for public dissemination that significantly relies on their research, identifies them as an author, or represents their scientific opinion

EPA s Scientific Integrity Policy IV B 1

- Policy-derived best practice: Ensure that EPA scientists and managers are able to review the scientific content of a proposed Agency document that is based on their scientific activities before its public release.
  - Scientific Integrity Policy, IV B 1

Disclaimers on Scientific Products

Disclaimers are used on scientific products to clarify the intended use and interpretation of the product. For scientific products that are produced in an EPA author's personal capacity, an ethics disclaimer is required. Appendix C of this document provides OGC/Ethics guidance for when to use an ethics disclaimer.

Scientific products that are produced as part of an EPA author's official duties do not need an ethics disclaimer, but may still require a different type of disclaimer. For example, an EPA employee could be approved as part of official duties to write an article that the Agency would not officially disseminate as an EPA document. EPA would still review and clear the article for release, even though it is not an official dissemination. In this situation, a disclaimer stating that the article does not represent EPA's official position is still needed – as per EPA's Information Quality Guidelines, the OMB Guidelines, and Peer Review Handbook.

[16] U.S. EPA, 2016. *Scientific Integrity: Best Practices for Designating Authorship*. https://www.epa.gov/osa/authorship-best-practices

A publication written as part of official duties that the Agency uses to disseminate an EPA official position also needs a disclaimer that the publication has been approved as an EPA document. Appendix D includes examples of appropriate disclaimers for EPA scientific products.

Disclaimers should be tailored to the particular document and may be edited based on advice from the Office of General Counsel (OGC) or, if a regional product, from the Office of Regional Counsel (ORC). EPA programs, offices, and regions may have more stringent procedures than those in the OMB Guidelines regarding when to include other disclaimers. Including guidance on disclaimers in clearance procedures promotes consistency.

- Program-derived best practice: Verify that scientific products are in compliance with all applicable EPA standards for human subjects research, dual-use research of concern, and legal concerns.

- Program-derived best practice: Provide guidance on the use of ethics and other disclaimers on scientific products and verify that scientific products use the appropriate disclaimers during clearance.
  - See Appendix C: When to Use an Ethics Disclaimer
  - See Appendix D: Additional Disclaimers

B. Scientific Review

Scientific review and clearance are related processes. Verifying that a scientific product has been subjected to all appropriate levels of scientific review is an important part of the clearance process. Scientific review includes review by the authors or project team, their EPA supervisors or managers, and any needed internal technical review or external peer review. According to EPA's Peer Review Handbook, peer review includes 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."[17] All comments received during the various review processes should be carefully considered.

The type of review needed for a scientific product is determined by the product type, significance, and intended use. Both internal technical and external peer review decisions and activities should be documented in a peer review record.[18] This includes the type of review performed, information about reviewers, comments from reviewers, and authors' responses to those comments.

Major changes based on external review comments may necessitate going through the clearance process again, with a response-to-comments document. Journal-convened peer review generally does not require a second round of clearance unless there are significant changes in the study results or conclusions.

[17] EPA. 2015. Peer Review Handbook, 4th Edition. https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf

[18] See Section 6.5. of the *Peer Review Handbook*, 4th Edition, "The Peer Review Record."

Identification and Categorization of Scientific Products

Authors should identify scientific products that may likely be produced in the life of a project. Clearing authors and managers should categorize these scientific products by considering the product type, significance, policy implications, complexity, and intended audiences. Authors should plan for appropriate review and clearance based upon the categorization of the product.[19]

List of Scientific Products

Programs, offices, and regions should prepare a list of scientific products that are routinely developed by their staff. This list can be referenced by employees and managers deciding whether a product must be cleared. Early identification of scientific products that may be subject to the clearance process enables employees to plan appropriately.

- Program-derived best practice: Create a list of scientific products that are routinely developed by staff and provide guidance on which scientific products need clearance.
  - See Appendix A: Examples of EPA Scientific Products

Internal Technical Review

Review by EPA experts, often referred to as internal technical review, ensures that the product is technically sound and meets the project's objectives. While project managers are the key coordinators of a product's development and review, reviewers are key to the accuracy and quality of the product.

As defined in the Peer Review Handbook, internal technical review is "technical or scientific review by individuals from within the Agency who have the appropriate expertise and are independent from the development of the work product. Internal peer or technical reviewers should come from a different organizational unit than the one in which the work originates. An internal peer review is an assessment of the scientific and technical quality of a work product by independent Agency experts prior to the publication or release of the work product outside the Agency."[20] The use of diverse and rotating reviewers decreases the likelihood of bias. An internal technical review is a valuable opportunity to ensure scientific integrity when qualified reviewers are given a clear charge that elucidates the key issues. The extent of the internal technical review may vary based on the type of product. Thorough and critical reviews from different perspectives are crucial. Obtaining agreement from the immediate supervisor for an internal technical review often facilitates the clearance process.

Journal-Convened External Peer Review

Scientific products submitted to a peer-reviewed journal undergo external peer review by scientific experts convened by the Editor of the scientific journal.

[19] EPA. 2015. *Peer Review Handbook*, 4th Edition. https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf

[20] EPA. 2015. *Peer Review Handbook*, 4th Edition. https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015

Other External Peer Review

Some scientific products, e.g., those not submitted to a peer-reviewed journal, may need peer review by experts outside of EPA, depending upon the nature, complexity, and significance of the work. Types of external peer review include letter or panel review or review by a federal advisory committee. Scientific products should be internally reviewed and cleared before being released for external peer review. The Peer Review Handbook provides more information about the sequence and timing of external peer review procedures.

- Policy-derived best practice: Verify that all applicable scientific review procedures have been followed as appropriate. This includes both internal technical reviews and external peer reviews.
  - Peer Review Policy

- Program-derived best practice: Authors submit the scientific review record along with the scientific product for clearance.

2. Clearance Process

After a scientific product has been appropriately internally reviewed, it should be submitted for clearance before it is released outside of the Agency. Clearance is not the same as internal technical review or external peer review. For most scientific products submitted to a peer-reviewed scientific journal, the journal's review is the external peer review, and clearance precedes submission to the journal.

A. Roles and Responsibilities

Clearance guidelines should describe the roles and responsibilities of authors, managers, and other individuals involved in the clearance process. It is important that author and manager roles are clearly defined, so that development of the scientific product and its routing through both the review and clearance chains are as predictable and seamless as possible.

- Program-derived best practice: Define the roles and responsibilities of a scientific product's authors, clearing managers, and other individuals that contribute to the clearance process.
  - See Appendix B: Glossary

- Program-derived best practice: Identify an alternate when a clearing manager is unavailable to approve a scientific product for clearance.

Clearing Author

The individual responsible for initiating clearance and serving as the point of contact for a scientific product as it routes through the clearance process is the "clearing author." The clearing

author is typically the first-listed author from the program, office, or region. The clearing author is responsible for ensuring that all co-authors review the scientific product, initiating clearance, responding to comments received throughout the clearance process, and fulfilling all procedures until and after clearance is granted.

Clearing Manager

Any manager involved in approving the scientific product for release during the clearance process is considered a "clearing manager." Clearing authors of scientific products need to plan for clearance and keep their management informed throughout the duration of the development of a scientific project. Planning and communication should happen early and often to help avoid misunderstanding and to improve the timely release of scientific products.

In situations where a clearing manager is unavailable to review and approve a scientific product for clearance, procedures should provide guidance on identifying an alternate to serve as a replacement.

An author should not serve as a clearing manager on his/her own scientific product, and a manager should not clear a scientific product on which he/she is an author. Additionally, clearance is not a substitute for internal technical review or external peer review, if needed.

- Program-derived best practice: An author should not serve as a technical reviewer or clearance manager on his/her own scientific product.

Clearance Contact

Programs, offices, and regions may choose to designate a clearance contact at the office level, who would be familiar with the clearance process. The clearance contact should be able to monitor a product's progress through the clearance process and answer questions to ensure that clearance procedures are followed.

- Program-derived best practice: Establish a clearance contact to monitor the clearance process and provide guidance to authors and managers.

Communications Lead

A member of the communications staff who helps coordinate the release of scientific products requiring advance notification. When applicable, clearing authors are to give the communications lead ample notification so that enough time is allotted for planning and processing a scientific product's release.

Deputy Ethics Official

The employee who is responsible for overseeing the ethics program in his/her program, office, or region. Responsibilities related to product clearance may include approving requests for outside

activity, providing ethics advice, or consulting with the Office of General Counsel (OGC) when necessary.

Deputy Scientific Integrity Official
The member of the Scientific Integrity Committee for the program, office, or region who assists with resolving disputes associated with the clearance or dissemination of a scientific product, if the dispute cannot be resolved first by the authors and their supervisors.[21]

First-Line Supervisor
The immediate supervisor of the clearing author, who evaluates and approves the scientific product upon clearance initiation, ensures that the product meets all Agency standards before it is routed through clearing managers, and verifies whether clearance should include another office. The first-line supervisor also verifies that designation of authorship for the product follows Best Practices for Designating Authorship.[22]

Human Subjects Coordinator
The point of contact in the program, office, or region who ensures appropriate approvals of human subjects research have been obtained.[23]

Peer Review Coordinator
An employee in the program, office, or region who helps a project manager navigate the Agency's peer review process for scientific products.

Quality Assurance Manager
The point person for quality assurance procedures in a program, office, or region who is responsible for providing written comments to the clearing author documenting any quality assurance (QA) issues noted during QA review, and verifying that all QA procedures were implemented prior to clearance.

B. Clearance Initiation

The clearing author is responsible for initiating clearance by either completing and submitting a form or using a designated electronic system. See Appendix E: Sample Clearance Routing Form for Scientific Products. The clearing author designates the type and category of the product and whether advance notice is necessary (see Section 1A on Advance Notice). When applicable, the clearing author submits the following accompanying documents with the scientific product for clearance:

- Scientific review record documenting scientific review activities (internal technical review and external peer review) and responses to reviewers' comments

[21] EPA, Office of the Science Advisor (OSA). Scientific Integrity Program. https://intranet.ord.epa.gov/p2/scientific-integrity/home
[22] EPA. 2016. *Scientific Integrity: Best Practices for Designating Authorship.* https://www.epa.gov/osa/authorship-best-practices
[23] EPA, Office of the Science Advisor, Human Subjects Research Program. http://intranet.ord.epa.gov/p2/HSR/home

- Communications strategy that explains how the product will be released once cleared.
- Documentation that it meets QA requirements

The clearing author informs management if the scientific product:

- Needs advance notice
- Contains research that qualifies as Human Subjects Research or Dual-Use Research of Concern
- Could raise legal concerns
- Has any authorship issues
- Includes a disclaimer

C. Clearance Workflows for Different Scientific Products

Scientific products may need to be routed through different levels of approval determined by the product type, significance, policy implications or intended audiences. For example, highly visible documents may need to be cleared by higher level officials, while others may not. Programs, offices, and regions should establish workflows that clearly describe which managers are responsible for approval and discuss when exceptions might be appropriate. These workflows should be documented (see Appendix F) and consistently followed to make the clearance process predictable and transparent, regardless of the product's level of visibility or potential controversy.

Authors, project teams, and managers should determine early in the project what types of scientific review are appropriate. Programs, offices, and regions may establish a table of clearance guidelines providing procedures based upon scientific product type, complexity, length, and anticipated impact.

- Program-derived best practice: Establish clearance workflows for scientific products that need different levels of approval, and provide criteria for determining which workflow is appropriate.

- Program-derived best practice: Encourage project teams and authors to plan for clearance early in the project.
  - See Appendix F: Sample Routing Flowcharts for Scientific Products, as one example of how such processes can be described.

Clearance through the Appropriate Management Chain

Typically, the clearing author, usually the first-listed author in the program, office, or region, clears the product through his/her management. The clearing author's supervisor is responsible for verifying whether clearance should include another office.

Intra-Agency Clearance

Any EPA programs, offices, and regions that have employees working on a scientific product may need to clear that product. Clearance procedures should therefore include guidance for intra-Agency clearance with other EPA programs, offices, and regions. The clearance contact for each program, office, or region should coordinate, track, monitor, and document, as needed, intra-Agency clearance. Time limits for intra-Agency clearance should be encouraged and monitored. Authors and managers should plan for intra-Agency clearance early in a project to ensure that scientific products are cleared and released in a timely manner.

- Program-derived best practice: Include intra-Agency clearance procedures for scientific products that need to be cleared by other EPA programs, offices, or regions.

Clearance for Scientific Products with External Collaborators

Scientific products developed with external collaborators, including those developed through cooperative agreements, grants, contracts, or interagency agreements, need to be cleared by EPA if an Agency employee is listed as an author. This provision, as well as the procedures of other agencies, can be written into an interagency agreement prior to the initiation of a scientific project. EPA employees should work with external collaborators to plan for the appropriate amount of time that it takes for the product to be cleared by EPA (and the other involved institutions if required) before release and subsequent publication.

- Program-derived best practice: Include clearance procedures for scientific products that have external collaborators.

- Program-derived best practice: Encourage employees and external collaborators to plan for the appropriate amount of time that it takes to clear a product before its proposed release and publication date.

Previously Cleared Scientific Products

Once a scientific product has been cleared, revisions that do not change the results or conclusions may not need rerouting through the clearance process. Generally, additional clearance is not needed when responding to journal-convened external peer review comments or when using the same product, such as a scientific presentation, more than once. Changes in results or conclusions of scientific products, particularly for scientific products that need advance notice, should be resubmitted for clearance. A scientific product submitted to an external peer review may need to be submitted to a second round of clearance together with responses to major comments.

D. Routing

Scientific products should be routed through the various levels of management based upon the product type and category (see Appendix G). It is crucial that the product route through the clearance process in a timely manner to support the release of scientific information to the public.

The routing process for clearance can be captured in an electronic routing system or paper- (and/or electronic-) based routing form. An example of a clearance routing form is provided in Appendix E. Where a relatively large number of products need clearance, program, office, and region should consider the advantages of an electronic routing system.

Tracking

Scientific products should be tracked as they route through the clearance process to allow clearing authors and managers to determine the status of the product, who in the management chain has seen the product, what comments or edits have been suggested and not accepted, and what decisions have been made.

Programs, offices, and regions should consider a standard method of tracking that can provide real-time status updates and notifications, version control, and record keeping. Many have found electronic or online tracking systems preferable, because they can help to automate and streamline the clearance process. Electronic systems are already used by some EPA offices for tracking scientific products during the clearance process. An example is ORD's Scientific and Technical Information Clearance System (STICS). Electronic systems can be used to track a scientific product through a clearance chain, sending alerts of an approaching deadline to authors and reviewers at each stage of the process.

- Program-derived best practice: Select a standard method of tracking scientific products through the clearance process that provides real-time tracking, notification, version control, and record keeping. For best results, use an electronic or online tracking system.

Timely Response

Scientific products should follow a predictable, pre-established timeline for clearance to ensure timely reviewer response. Expectations for timeframes should be discussed in program, office, and regional clearance procedures and consider product type, level of clearance, intra-Agency clearance if appropriate, complexity, length, and potential impact. For example, a short abstract could be cleared in a relatively short time, but a significantly longer or more complex scientific publication could require more time. Clearing authors and clearing managers should share the same expectations for the timeliness of the clearance process. Sample timeframes for scientific products are listed in Appendix G.

- Policy-derived best practice: Develop time frames that articulate how many days are designated for each clearance step.
  - Scientific Integrity Policy, Section IV.B.1; Appendix G

- Policy-derived best practice: Define what reasonably constitutes "timely" sign-off for each type of scientific product at each clearance stage. This will vary depending on the product type, complexity, length, and potential impact.
  - Peer Review Policy

- Program-derived best practice: Relay the importance of timely response to EPA personnel at all levels.

- Program-derived best practice: Develop procedures for situations when no response or communication is received from a clearing manager, such as automatically routing the scientific project to an alternate or the next in-line manager or next step in the clearance process.

E. Verifications by the Clearing Managers

Clearance procedures should include a checklist for clearing managers to verify that the scientific product meets requirements of applicable EPA policies and procedures. See the section, "Before Clearance: Consideration of EPA Policies and Scientific Review" for more information on each item in the checklist.

The checklist should include:

- Advance notification
- Public access to scientific results
- Quality assurance
- Human subjects research
- Dual-use research of concern
- Legal concerns
- Authorship
- Disclaimers
- Scientific Quality Review
- Original Author Review
- Technical review (where applicable)
- Peer review (where applicable)

F. Communications Strategy

Various individuals within EPA may need to be notified upon the initiation of clearance for a scientific product. If this is the case, authors should prepare a communications strategy for the scientific product early in the planning stages of a project. For some highly visible scientific products, accompanying communication materials should be submitted along with the product for clearance.

A communications strategy might include plans for using social media, notifying stakeholders, or working with the Office of Public Affairs. Various individuals within the Agency may need to be notified upon clearance of a scientific product. Timely communication ensures a unified response to potential inquiries regarding the product. The clearance process can serve as a reminder to authors and managers to refer to the communications strategy. Additional information can be found in the section on Advance Notice.

- Program-derived best practice: Remind authors and managers about having and implementing a communications strategy by listing a communications check-in on the clearance routing form.
  - See Appendix E: Sample Clearance Routing Form for Scientific Products

G. Clearance Decisions and Documentation

Clearing managers are responsible for approving scientific products for release or explaining what steps need to be taken to clear the scientific product for release. To enhance transparency consistent with the EPA Scientific Integrity Policy, clearing managers of scientific products should make decisions about release based on the product's scientific and technical information. Clearing managers also have the responsibility of reviewing and commenting on aspects of the scientific product that have policy implications and thus may draw the attention of policymakers, media, members of the public, and other stakeholders so that EPA can plan accordingly.

Decisions about the clearance and release of a scientific product should not be based on the potential policy implications of the science, controversial content, or a differing scientific opinion. Concerns about these issues should be discussed between authors and managers prior to clearance initiation.

- Policy-derived best practice: Specify that clearing managers of scientific products should make decisions about release that are based only on scientific quality considerations.
  - Scientific Integrity Policy, Section IV.A.2

Clearance Granted

Clearance for release is granted when all clearing managers have approved a scientific product and no changes are needed (see Figure 1). It is the clearing author's responsibility to inform co-authors and perform the next steps.

- Program-derived best practice: Develop clearance procedures that explain the next steps that an author can take after clearance is granted.

Conditional Clearance

Conditional clearance may occur when a scientific product is approved only under the condition that all outstanding issues are addressed prior to release. For example, a clearing manager may find that the scientific product proposes conclusions that necessitate a desk statement or press release or that minor editing of the product is necessary before release. In these cases, managers should explain to clearing authors why the scientific product has been conditionally cleared and whether or not it must be reviewed again before release (see Figure 1).

- Program-derived best practice: Develop clearance documentation that calls a clearing author's attention to any issues that need to be addressed when conditional clearance is given.
  - Appendix E: Sample Clearance Routing Form for Scientific Products

Clearance Denied

There are some situations in which it is appropriate for a manager to deny clearance. Examples include, but are not limited to, substandard scientific quality or noncompliance with Agency quality assurance policies, information quality guidelines, peer review policies, or public access requirements. To avoid these situations, clearing authors should consult with their first-line supervisors to ensure that a product is ready before initiating clearance.

The manager who denies clearance of a scientific product is responsible for preparing documentation that includes the reasons for denial (see Figure 1). An author of a scientific product that has been denied clearance has the right to know why, speak with the individuals who raised the concerns, and be given an opportunity to revise the scientific product.

- Program-derived best practice: Encourage clearing authors to consult with their first-line supervisors to make sure that the scientific product is ready for clearance initiation.

When an author resubmits a scientific product for clearance, the revised document should be reviewed in the context of the comments provided during the clearance process. Clearing managers should ensure that they provide thorough feedback for authors to make the necessary revisions required to avoid another denial of clearance. It is possible for new comments to arise when the scientific product is resubmitted for clearance, but these should primarily be based on the revisions made and new content.

- Program-derived best practice: Specify that a clearing manager who denies clearance should document his/her reasoning using the electronic system or sign and date his/her reasoning on the clearance routing form.
  - Appendix E: Sample Clearance Routing Form for Scientific Products

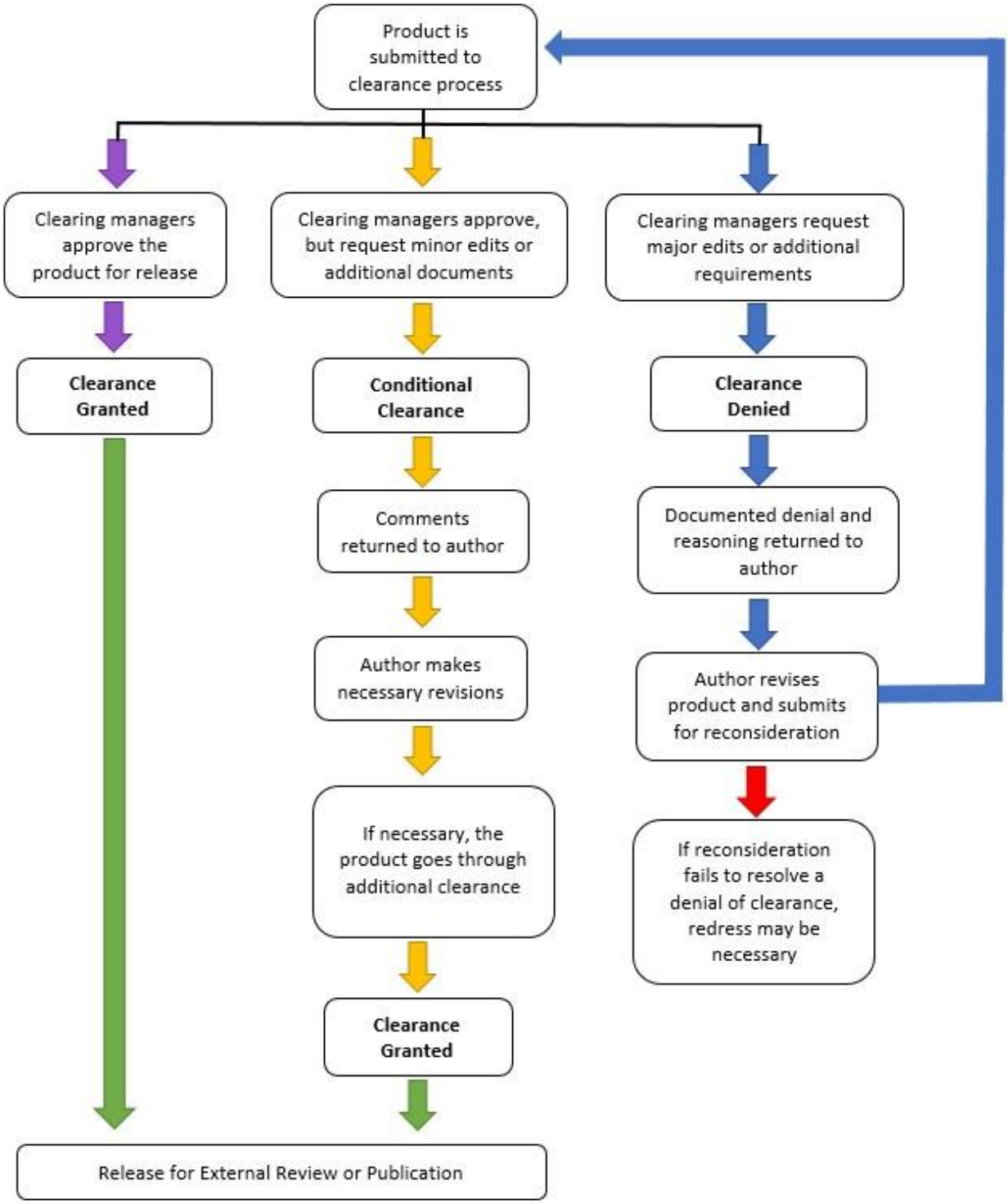


Figure 1. Decision making in clearance

Documentation of Decision

Clearance process decisions and other relevant information should be documented and given to the clearing author who will distribute the information to any coauthors. Managers should clearly document issues and concerns, so that they can be addressed by the author(s). Managers should also be open to discussing the issues that they raise with clearing authors, if needed.

If the comments are substantial, the scientific product may need to be revised and resubmitted for clearance an additional time. If only minor edits are suggested, the scientific product may be given conditional clearance without the need to be resubmitted for clearance. Often, concurrence with comments allows the author to either accept the comment and revise the scientific product or to ignore the comment. Therefore, clearance with comments or with conditions typically indicates that there are minor issues that can be adequately addressed.

- Program-derived best practice: Specify that clearing managers document decisions in the electronic system or on the routing forms, regardless of the decision about releasing the scientific product.
  - Appendix E: Sample Clearance Routing Form for Scientific Products
- Program-derived best practice: Ensure notification is sent to clearing authors when decisions are made by clearing managers. At any point, a clearing author should be able to determine the status of a scientific product in the clearance process.

Documenting decisions makes the clearance process transparent and allows the program, office, or region to hold accountable those in the process. This step also helps identify and minimize the number of reviewers who were unable to examine the scientific product or make a clearance decision in a timely manner.

Programs, offices, and regions should maintain documentation of the clearance process, including the decisions and comments made on the document as it routes through the process.

- Program-derived best practice: Maintain records of all clearance decisions.

Reconsideration

Programs, offices, and regions should establish a reconsideration process for scientific products that have been denied clearance. Reconsideration should allow for a clearing author to resubmit a revised version of a scientific product into clearance at the initial phase (see Figure 1). In some cases, a difference of scientific opinion between a clearing author and a clearing manager may lead to a denial of clearance. Programs, offices, and regions should include reconsideration procedures that attempt to resolve these situations. For example, it may be necessary to assign different or additional clearing managers to the clearance workflow to provide an independent, unbiased evaluation of the scientific product.

- Program-derived best practice: Establish a process for reconsideration that assigns different or additional clearing managers to the clearance workflow.

Appeal

For instances where the clearance procedures were followed, programs, offices, and regions should develop an appeal procedure to resolve a denial of clearance or a differing scientific opinion (see Figure 1). Typically, appeal should occur after reconsideration and give authors the opportunity to express their concerns about a denial of clearance to the next level of management in the clearance chain. Appeal, however, should be considered a last resort. Ideally, authors and managers work together throughout the scientific project's development, thereby addressing potential issues before a scientific product is submitted for clearance. Ultimately, management makes the final decision on clearance based on scientific quality considerations that should be free of political or other types of interference. The Deputy Scientific Integrity Official for the program, office, or region or EPA's Scientific Integrity Official may assist scientists or managers with difficulties during clearance, but should not attempt to referee a differing scientific opinion.

- Policy-based practice: Provide a procedure for appeal in cases where clearing authors have concerns that the clearance of a scientific product was denied and the applicable clearance procedures were followed.
  - Scientific Integrity Policy, Section IV.B.1

Redress

If clearance procedures are not followed, the clearing author can seek redress by submitting an allegation of a loss of scientific integrity to their Deputy Scientific Integrity Official or to EPA's Scientific Integrity Official or by contacting EPA's Office of Inspector General's hotline.[24] The Deputy or the Scientific Integrity Official will consider whether appropriate clearance procedures were followed but will not attempt to referee a differing scientific opinion.

H. Records Management

Programs, offices, and regions should maintain proper records about a scientific product after it has been cleared. Agency record retention procedures may apply to the documents generated during the clearance process. In addition to the procedures established by the National Archives and Records Administration,[25] procedures may be necessary to standardize where records will be maintained for possible evidentiary use. Documents may include data reports, quality assurance project plans, internal technical review comments, clearance routing forms, comments from clearing reviewers, external peer comments, all responses to comments, and final and summary reports.

Maintaining records of cleared manuscripts is also needed to verify that published manuscripts and underlying datasets become available to the public as called for in the *Plan to Increase Access to Results of EPA-Funded Scientific Research* (see section 1.A).

- Program-derived best practice: Establish a system for filing and archiving electronic copies of final scientific products and documentation about clearance.

I. Training

Programs, offices, and regions can ensure that employees follow technical review and clearance processes by communicating these processes at training sessions or other gatherings and by making them easily accessible on the intranet. Topics that can be covered include: identifying scientific products requiring review and clearance, explaining individuals' roles and responsibilities in the review and clearance processes, and answering questions.

- Program-derived best practice: Deliver regular briefings on the clearance process for managers and staff.

- Program-derived best practice: Post clear and concise procedures online.
  - Appendix H is an example of a clearance procedure for scientific products based on best practices.

[24] Information about the Office of Inspector General is at https://www.epa.gov/oig and the national toll-free number for the OIG hotline is (888) 546-8740.
[25] EPA. 2016. "EPA National Records Management Program." https://www.epa.gov/records

3. Conclusions and Next Steps

The Scientific Integrity Policy supports the free flow of scientific information "to the public, to the scientific community, to Congress, and to the news media by further providing for and protecting the EPA's longstanding commitment to the timely and unfiltered dissemination of its scientific information." Clearance is an integral part of the release of scientific information, but has the potential to slow the process if procedures are ambiguous or inconsistent. Therefore, it is important that programs, offices, and regions have clearance procedures that are transparent, clear, timely, predictable, and consistent. Such procedures should also have the flexibility to ensure both rigorous review and the timely release of information.

Each program, office, and region is expected to consider the best practices in this document to develop or revise its existing clearance procedures as necessary to support its specific needs, while prioritizing transparency, clarity, timeliness, predictability, and consistency. The Scientific Integrity Program is available to assist with this process.

See Appendix H for a sample outline that may be used for developing clearance procedures in a program, office, or region.

4. Summary of Best Practices

This section summarizes the best practices listed throughout the sections of this document. While it may not be necessary for programs, offices, and regions to incorporate all of these best practices, careful consideration should be given to if and how each best practice may help to enhance a program's, office's, or region's clearance procedures.

A. From the Scientific Integrity Policy

- Ensure that reviews of scientific information by Agency managers and other leadership are based only on scientific quality considerations.
- Develop clearance procedures for scientific products.
- Develop time-frames that articulate how many days should be designated for each clearance step.
- Develop a process for redress if clearance procedures are not met.
- Foster a culture of openness by ensuring that clearance procedures allow for the timely release of unfiltered scientific information to the public.
- Encourage communication among project teams and managers to identify any potential issues throughout the clearance process and address them appropriately.

B. Before Clearance: Consideration of EPA Policies and Scientific Review

- Establish criteria for when scientific products may warrant advance notice.
- Establish advance notice procedures for routing products through the appropriate management chain in other programs, offices, or regions.

- If advance notice is anticipated, authors and management should begin conversations about the product as early as possible with the programs, offices, and regions to be notified.
- Specify that highly visible scientific products are submitted along with appropriate communications materials for clearance.
- Remind authors and managers about having and implementing a communications strategy by listing a communications check-in on the clearance routing form.
- Verify that quality system requirements have been reviewed and performed and that any comments have been adequately addressed.
- Authors submit QA documentation along with the scientific product for clearance.
- Ensure that EPA scientists and managers are able to review the scientific content of a proposed Agency document that is based on their scientific activities before its public release.
- Verify that scientific products are in compliance with all applicable EPA standards for human subjects research, public access, and dual-use research of concern, and that any legal concerns have been identified and addressed.
- Provide guidance on the use of ethics and other disclaimers on scientific products and verify that scientific products use the appropriate disclaimers during clearance.
- Create a list of scientific products that are routinely developed by staff and provide guidance on which scientific products need clearance.
- Verify that all applicable scientific review procedures have been followed as appropriate. This includes both internal technical reviews and external peer reviews.
- Authors submit the scientific review record along with the scientific product for clearance.

C. Clearance Process

- Define the roles and responsibilities of a scientific product's authors, clearing managers, and other individuals that contribute to the clearance process.
- Identify an alternate when a clearing manager is unavailable to approve a scientific product for clearance.
- An author should not serve as a technical reviewer or clearance manager on his/her own scientific product.
- Establish a clearance contact to monitor the clearance process and provide guidance to authors and managers.
- Establish clearance workflows for scientific products that need different levels of approval, and provide criteria for determining which workflow is appropriate.
- Encourage project teams and authors to plan for clearance early in the project.
- Include intra-Agency clearance procedures for scientific products that need to be cleared by other EPA programs, offices, or regions.
- Include clearance practices and procedures for scientific products that have external collaborators.
- Encourage employees and external collaborators to plan for the appropriate amount of time that it takes to clear a product before its proposed release and publication date.
- Select a standard method of tracking scientific products through the clearance process that provides real-time tracking, notification, version control, and record keeping. For best results, use an electronic or online tracking system.

- Develop time frames that articulate how many days are designated for each clearance step.
- Define what reasonably constitutes "timely" sign-off for each type of scientific product at each clearance stage. This will vary depending on the product type, complexity, length, and potential impact.
- Relay the importance of timely response to EPA personnel at all levels.
- Develop procedures for situations when no response or communication is received from a clearing manager, such as automatically routing the scientific project to an alternate or the next in-line manager or next step in the clearance process.
- Remind authors and managers about having and implementing a communications strategy by listing a communications check-in on the clearance routing form.
- Specify that clearing managers of scientific products should make decisions about release that are based only on scientific quality considerations.
- Develop clearance procedures that explain the next steps that an author can take after clearance is granted.
- Develop clearance documentation that calls a clearing author's attention to any issues that need to be addressed when conditional clearance is given.
- Encourage clearing authors to consult with their first-line supervisors to make sure that the scientific product is ready for clearance initiation.
- Specify that a clearing manager who denies clearance should document his/her reasoning using the electronic system or sign and date his/her reasoning on the clearance routing form.
- Specify that clearing managers document decisions in the electronic system or on the routing forms, regardless of the decision about releasing the scientific product.
- Ensure notification is sent to clearing authors when decisions are made by clearing managers. At any point, a clearing author should be able to determine the status of a scientific product in the clearance process.
- Maintain records of all clearance decisions.
- Establish a process for reconsideration that assigns different or additional clearing managers to the clearance workflow.
- Provide a procedure for appeal in cases where clearing authors have concerns that the clearance of a scientific product was denied and the applicable clearance procedures were followed.
- Establish a system for filing and archiving electronic copies of final scientific products and documentation about clearance.
- Deliver regular briefings on the clearance process for managers and staff.
- Post clear and concise procedures online.

Appendices

Appendix A: Examples of EPA Scientific Products

EPA programs, offices, and regions are encouraged to refer to this Best Practices document as they develop or refine their clearance procedures for scientific products drafted by EPA employees, contractors, grantees (where appropriate) and/or under cooperative agreements. Each program, office, and region should develop clearance workflows (see Appendix F) specific for the scientific products routinely developed by their staff.

The lists below offer examples of Agency scientific products that may need clearance. This list is adapted from the Scientific and Technical Information Clearance System (STICS) used by EPA's Office of Research and Development[26]. It is not meant to be exhaustive, and exclusion from the lists does not mean that the type of scientific product is excluded from the clearance process. Conversely, inclusion on the list does not necessarily mean that type of scientific product requires use of additional clearance, as it may be subject to other forms of agency review and approval.

Examples of EPA Scientific Products

Product Type	Product Subtype	Definition
Book	Book	Technical material prepared as a book or part of a book that has contributing authors in the noted area of expertise.
	Book Chapter	
Conference Proceedings	EPA Proceedings[27]	A written collection of presentations delivered by speakers at an EPA-sponsored conference, workshop, or seminar published by EPA.
	Paper in EPA Proceedings[28]	A manuscript presented at a scientific meeting included as part of an EPA-published proceedings.
	Paper in Non-EPA Proceedings	A manuscript presented at a scientific meeting included as part of a Non-EPA-published proceedings.
Documents	Controlled Document	A document, generated internally, that describes how work must be conducted. Examples of controlled documents are policies, standard operating procedures (SOPs), guidance, blank forms, checklists, and work instructions.
	Guidance	An instructional document or statement that provides directions, suggestions, or guidelines that are intended to assist in implementing a regulation, policy, procedure, method, or requirement.
	Handbook	A collection of information, statistics, data and techniques that are accurate and relevant to a particular subject area.

[26] STICS makes a distinction between highly visible scientific products and other scientific and technical products.
[27] For conference proceedings, EPA would be clearing the collection and not the underlying presentations. Any EPA presentations in the collection would have undergone clearance before the conference, and presentations by non-EPA presenters are not subject to EPA clearance procedures
[28] Footnote 27, *Ibid*.

Product Type	Product Subtype	Definition
	Manual	A series of documented instructions or processes on a specific subject either for internal or external distribution or comprehensive description of a new technology meant to solve an environmental problem. It guides the user through the creation, construction, and maintenance of a technology or technique. User's Guides are also included in this sub-type and explain, step-by-step, how to employ a procedure, piece of equipment, model or program.
	Methods	A collection of procedures and/or scientific techniques, widely accepted for certain applications. A method shows the critical elements for performing an activity and is usually systematically presented in the order in which the elements are to be executed.
	Plans	A document that specifically describes how a system or program is to be implemented. Can be associated with quality, records management, safety and health / environmental management, or computer security.
	Standard Operating Procedure (SOP)	A set of instructions for performing an activity.
Journal Articles	Peer Reviewed	Articles proposed for publication in scientific, peer-reviewed and non-peer reviewed journals. In peer reviewed journals, the journal provides peer review for submitted articles. In non-peer reviewed journals, the journal or magazine has no scientific editorial board and does not provide peer review.
	Non-Peer Reviewed	
Letter to the Editor	Letter to the Editor	Short correspondence of relevance to the audience of a publication usually with the intention of publication to clarify or correct information or state an opinion.
Presentations and Technical Summaries	Abstract	Summary of information to be presented orally, in print, etc.
	Newsletter Article	A piece of informal, though sometimes technical, writing designed to inform and educate the research and technical community of current research status, results, meetings, and publications on a routine basis.
	Poster	A product for display at a scientific meeting, workshop, conference, etc.
	Presentation	Formal talk made to a group of people, e.g., on somebody's recent research or work, often with handouts, diagrams, or other visual aids.
	Technical Fact Sheet	One- or two-page descriptions used to provide detailed information about a high visibility issue, project or activity. They distribute information to a wide variety of audiences, including the Administrator, when warranted, and to the EPA Office of Public Affairs and Programs, Offices, and Regions.
Reports	Extramural Report	A product produced from interagency agreements, cooperative agreements, contracts or grants.

	Internal Report	A report produced when there is a need for a written report in response to a request from an EPA programs, offices, or regions. They will usually be submitted only to the requesting office and will not be reviewed, published or distributed outside of EPA. Whether such reports are placed into a docket or subjected to external peer review is dependent on the intended use of the information.
	Summary	A concise synopsis of the key findings of a research project.
	Technical Report	May be the results of a single major research project, a synthesis of several related research projects, or a special technical report deemed necessary to meet an important information need. The research report normally contains the most authoritative results of a research project on a critical area of interest in which the Agency is involved. These reports do not normally contain large volumes of supporting research data.
	Unpublished Report	A report of technical findings for which a decision has been made that publication would not be in the public interest for one or more of the following reasons: (1) the quality of the work was substandard, misleading, or so inconclusive as to have no scientific value; (2) the results duplicate those of a prior investigation; and/or (3) the results are to be incorporated in subsequent reports (definitely planned), and early publication of partial results would not be cost-effective.
	Database	A collection of related records stored in a software application to organize the data and to enable extraction of desired information.
	Dataset	A meaningful collection or grouping of similar or related data.
	Maps	A graphic representation of an area of land or body of water. Examples include contour and road maps.
	Model	A representation of the behavior of an object or process, often in mathematical or statistical terms. Models can be physical or conceptual.
	These *Best Practices* are focused on the clearance of scientific products developed by an EPA author, or a group of authors including at least one EPA author, as part of his/her official duties that do not routinely undergo an alternate or existing clearance procedure. The above list is exemplary not exhaustive.	

Appendix B: Glossary

Below are definitions to key terms used in this document that are relevant to review and clearance, and individuals that are involved in review and clearance.

Advance Notice: A process for ensuring that senior leadership are made aware of and adequately prepared for the release of scientific products that are highly visible, sensitive, or influential.

Appeal: Ideally led by the program, office, or region, the process for resolving concerns of denial of clearance, when applicable clearance procedures were followed. Typically, appeal occurs after reconsideration efforts have been exhausted.

Approval: The individual authorization for release provided by each manager in the clearance process. Once a scientific product receives approval from all managers in the clearance process, it is considered cleared for release.

Clearance: The "process for obtaining line management approvals prior to a work product's release or publication."[29]

Clearance Contact: A point person at the office-level who is familiar with the clearance process, answers questions about the process, and monitors scientific products and associated documentation as scientific products route through the clearance process.

Clearing Author: Typically, the first-listed author, the point of contact for clearance purposes, and the one who clears the product through his/her management.

Clearing Manager: Any manager involved in the clearance chain that is responsible for approving the scientific product for release.

Communications Lead: When needed, a member of the communications staff who helps prepare the communications strategy for a scientific product.

Deputy Ethics Officials: The employee(s) responsible for overseeing the ethics program in his/her designated office.

Deputy Scientific Integrity Officials: The members of the Scientific Integrity Committee from the programs, offices, and regions.

Dissemination: Agency initiated or sponsored distribution of information to the public (see 5 C.F.R. 1320.3(d), definition of "Conduct or Sponsor" at https://www.whitehouse.gov/omb/fedreg_final_information_quality_guidelines)

[29] EPA. 2015. *Peer Review Handbook*, 4th Edition. https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015

External Peer Review: As defined in the Peer Review Handbook, "a review by non-EPA experts with appropriate knowledge and skills who are independent from the development of the work product. External reviewers may come from other federal agencies, state and local government agencies, academia, industry, nongovernmental organizations, or other outside organizations."[30] External peer review may be convened by the Editor of a scientific journal or by EPA. At EPA, a scientific product should be cleared before it is submitted for journal-convened or EPA-convened external peer review.

Highly Visible Scientific Products: Scientific products that can reasonably be expected to draw the attention of Congress, the scientific community, the media, industry groups, other agencies or governments, or a specific community, or that may significantly impact specific demographic groups or communities more than others. Scientific products that relate to a Presidential initiative or either pending or established policy decisions may also be considered highly visible.

Internal Technical Review: An initial review by independent EPA experts that is done prior to clearance, focusing on the scientific and technical aspects of a scientific product.

Peer Review Coordinator: An employee in the program, office, or region who helps a project manager navigate the Agency's peer review process for scientific products.

Quality Assurance (QA): "An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer. QA is typically applied by managers or technical personnel assigned to a specific oversight role."[31]

Quality Assurance Manager (QAM): A manager who provides written comments to the clearing author documenting any QA issue noted during the QA review. During the clearance process, the QAM may provide verification that scientific products have been appropriately peer-reviewed.

Reconsideration: The process for resubmitting a scientific product that has been previously denied clearance.

Redress: Submission of an allegation of a loss of scientific integrity when clearance is denied and the clearance procedures were not followed.

Release: The distribution of a scientific product that has been subjected to appropriate review.

Review: A process that may include several phases, including scientific quality review, internal technical review, and external peer review.

[30] EPA. 2015. *Peer Review Handbook*, 4th Edition. https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015
[31] EPA, Office of Environmental Information (OEI). 2002. *Overview of the EPA Quality System for Environmental Data and Technology*, EPA/240/R-02/003. https://www.epa.gov/sites/production/files/2015-08/documents/overview-final.pdf

Appendix C: When to Use an Ethics Disclaimer

This section, which has been reviewed by EPA Ethics, explains when to use an ethics disclaimer.

Is an Ethics Disclaimer Needed When Writing in Official Duty?
(with approval of supervisor as part of assigned duties)

IF …	THEN…	AND
For a ***scientific or professional*** *journal*	• Can use official time and resources • Can use subordinates and EPA email address • Can refer solely to EPA position and title • Product must go through office clearance process	• Cannot receive compensation for the work in addition to EPA salary • Does not need a disclaimer for ethics purposes • May still need another type of disclaimer
For a ***non-scientific or non-professional*** journal (e.g., *Life* or *Time* or *Ranger Rick*)	• Can use official time and resources • Can use subordinates and EPA email address • Can refer solely to EPA position and title • Product must go through office clearance process	• Cannot receive compensation for the work in addition to EPA salary • Does not need a disclaimer for ethics purposes • May still need another type of disclaimer

Is an Ethics Disclaimer Needed When Writing in Personal Capacity?

IF …	THEN…	AND
For a ***scientific or professional*** publication or book ***related*** to assigned EPA duties, recently assigned duties or ongoing Agency policy, program or operation (whether the employee works on it or not)	• Must gain prior approval of the outside activity • Should not use EPA time or resources in connection with the activity • Cannot use subordinates • Cannot be compensated • Cannot use non-public information • Product does not go through office clearance process	• May refer solely to EPA title or position but must include the following prominent disclaimer that meets requirements of OGC/Ethics: *This work is not a product of the United States Government or the United States Environmental Protection Agency. The author/editor is not doing this work in any governmental capacity. The views expressed are his/her own and do not necessarily represent those of the United States or the US EPA.*

IF …	**THEN…**	**AND**
For a ***scientific or professional*** publication or book on a matter ***unrelated*** to assigned EPA duties, recently assigned duties or ongoing Agency policy, program or operation (whether the employee works on it or not)	• Does not need prior approval • Should not use EPA time or resources in connection with the activity • Cannot use subordinates • Cannot use non-public information • Product does not go through office clearance process	• May refer solely to EPA title or position but must include the prominent disclaimer referenced above
For a ***non-scientific or non-professional*** publication on a matter ***related*** to assigned EPA duties, recently assigned duties or ongoing Agency policy, program or operation (whether the employee works on it or not)	• Must gain prior approval of the outside activity • Should not use EPA time or resources in connection with the activity • Cannot use subordinates • Cannot be compensated • Cannot use non-public information • Product does not go through office clearance process	• May refer solely to EPA title or position but must include the prominent disclaimer referenced above
For a ***non-scientific or non-professional*** publication on a matter ***unrelated*** to assigned EPA duties, recently assigned duties or ongoing Agency policy, program or operation (whether the employee works on it or not)	• May not need prior approval • Cannot use EPA time or resources or subordinates • Cannot refer solely to EPA title or position • Product does not go through office clearance process	• May be able to be compensated • If refer to EPA, then must include several other bio details, with EPA not having any undue prominence • May refer solely to EPA title or position but must include the prominent disclaimer referenced above

Appendix D: Additional Disclaimers

This is a list of additional disclaimers used by EPA. Some are to be used on documents while they are routing through the Agency, and others are to be used on scientific products that have been cleared. In cases where the information is highly relevant to specific policy or regulatory deliberations, the disclaimer should appear on each page of the work product.

If you have questions about when to use an ethics disclaimer, refer to Appendix C of this document. You can also contact the Office of General Counsel or Office of Regional Counsel for assistance.

Internal use only
DO NOT RELEASE – This document is intended for internal Agency use only.

Scientific or Technical Work Product not considered official Agency disseminations (e.g. scientific journal articles)
The views expressed in this [article/presentation/poster] are those of the author(s) and do not necessarily represent the views or the policies of the U.S. Environmental Protection Agency.

Use of trade names (if otherwise unavoidable)
Any mention of trade names, manufacturers, or products does not imply an endorsement by the United States Government or the United States Environmental Protection Agency. EPA and its employees do not endorse any commercial products, services, or enterprises.

Internet communications
Links to Websites outside of the EPA Website are provided for the convenience of the user. Inclusion of information about a Website, an organization, a product, or a service does not represent endorsement or approval by EPA, nor does it represent EPA opinion, policy, or guidance unless specifically indicated. EPA does not exercise any editorial control over the information that may be found at non-EPA websites.

Copyright
This is a work of the U.S. Government and is not subject to copyright protection in the United States.

Work prepared under contract, interagency agreement, or cooperative agreement
The research described in this article has been funded wholly or in part by the United States Environmental Protection Agency [contract, interagency agreement, cooperative agreement] [number] to [Name of Contractor if applicable].

Add one of the following to the above:

- It has not been subject to the Agency's review and therefore does not necessarily reflect the views of the Agency, and no official endorsement should be inferred.
- It has been subjected to review by the Office of ____ and approved for publication. Approval does not signify that the contents reflect the views of the Agency, nor does mention of trade names or commercial products constitute endorsement or recommendation for use.
- It has been subject to the Agency's review, and it has been approved for publication as an EPA document. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

Appendix E: Sample Clearance Routing Form for Scientific Products

Section I. Clearance Initiation *(to be filled out by Clearing Author)*

Clearing Author:	**Date of Clearance Initiation:**
Program/Office/Region:	**Anticipated/Desired Release Date:**
Title/Topic:	**Type of Product:**
Co-Authors and Affiliations	

Official Duties:

☐ This product was developed as part of my official duties.

☐ This product/activity is not part of my official duties, and I understand that I may have additional ethics responsibilities.

Disclaimers: This scientific product may need to have a disclaimer when given to internal technical reviewers and while routing through clearance. An ethics disclaimer may also need to be used when the scientific product is released. Please ensure that your product includes all appropriate disclaimers.

Public Access: Please ensure that this product has a Scientific Data Management Plan in compliance with EPA's Public Access Plan. Documentation of the plan should be attached.

Quality Assurance: Please ensure that this product meets all requirements of [P/O/R]'s Quality Management Plan.

Scientific Review: Please ensure that this product has been through appropriate scientific review. The review record of this product should be attached.

Advance Notice: Does this product need advance notice of [P/O/R] senior leadership or that of other EPA programs, offices, or regions? If yes, please attach the communications plan and internal fact sheet for advance notice procedures ☐Yes ☐No

Human Subjects Research: Does this product contain human subjects research (HSR)? If yes, please attach documentation of HSR approval. ☐Yes ☐No

Dual Use Research: Is there the potential that your scientific findings, work product(s), processes, or results could be misused to cause potential harm? See EPA's Dual-Use Research of Concern Policy for more information. ☐Yes ☐No

Legal Concerns: Does this product raise any potential legal concerns by either the findings presented or a publication agreement? If yes, please attach the document detailing the legal concerns. ☐Yes ☐No

Authorship: Does this product have any authorship issues? ☐Yes ☐No

Communications Check-in: Does this product require a communications plan? ☐Yes ☐No
A communications plan helps to coordinate the release and roll-out of a scientific product. Refer to the communications handbook and staff for support and guidance on developing and implementing a communications plan for this product.

Section II. Verification of Review

Quality Assurance Manager	
Has this product been subjected to appropriate QA review?	☐Yes ☐No
Does this product meet all QA requirements as designated by EPA and [P/O/R's] Quality Management Plan?	☐Yes ☐No
Comments:	

Print Name _____ Signature _____ Date _____

Scientific Review Coordinator	
Has this product been subjected to appropriate scientific review?	☐Yes ☐No
Comments:	

Print Name _____ Signature _____ Date _____

(Continued on next page)

Section III. Processing *(to be filled out by clearing management chain)*

First-Line Supervisor	
Decision: ☐ Clearance Granted ☐ Conditional Clearance (must include reason) ☐ Clearance Denied (must include reason)	**Reason for Decision/Comments:**

Does this product use the appropriate disclaimer(s)? If no, then please suggest an appropriate one.	☐Yes	☐No
Does this product have a Scientific Data Management Plan that is in compliance with EPA's Public Access Plan?	☐Yes	☐No
Does this product contain human subjects research (HSR)? If yes, did the HSR receive approval by EPA's Human Subjects Research Review Official?	☐Yes	☐No
Does this product contain potential Dual Research of Concern (DURC)? If yes, please see EPA's DURC Policy.	☐Yes	☐No
Does this product raise legal concerns that need to be further addressed? If yes, please consult with the Office of General Counsel or the Office of Regional Counsel.	☐Yes	☐No
Does this product require advance notice of [P/O/R] senior leadership or other EPA programs, offices, or regions? If yes, please ensure advance notice procedures are followed.	☐Yes	☐No
Upon clearance, should this product be submitted to the Science Inventory?	☐Yes	☐No

I ☐ do / ☐ do not need to see this again before it is released.

Print Name	Signature	Date

(*Continued*)

Clearing Manager	
Decision: ☐ Clearance Granted ☐ Conditional Clearance (must include reason) ☐ Clearance Denied (must include reason)	**Reason for Decision/Comments:**

I ☐ do / ☐ do not need to see this again before it is released.

Print Name _____ Signature _____ Date _____

Clearing Manager	
Decision: ☐ Clearance Granted ☐ Conditional Clearance (must include reason) ☐ Clearance Denied (must include reason)	**Reason for Decision/Comments:**

I ☐ do / ☐ do not need to see this again before it is released.

Print Name _____ Signature _____ Date _____

(Continue form for all clearing managers through final clearance for release by the organizational level director)

Appendix F: Sample Routing Flowcharts for Scientific Products

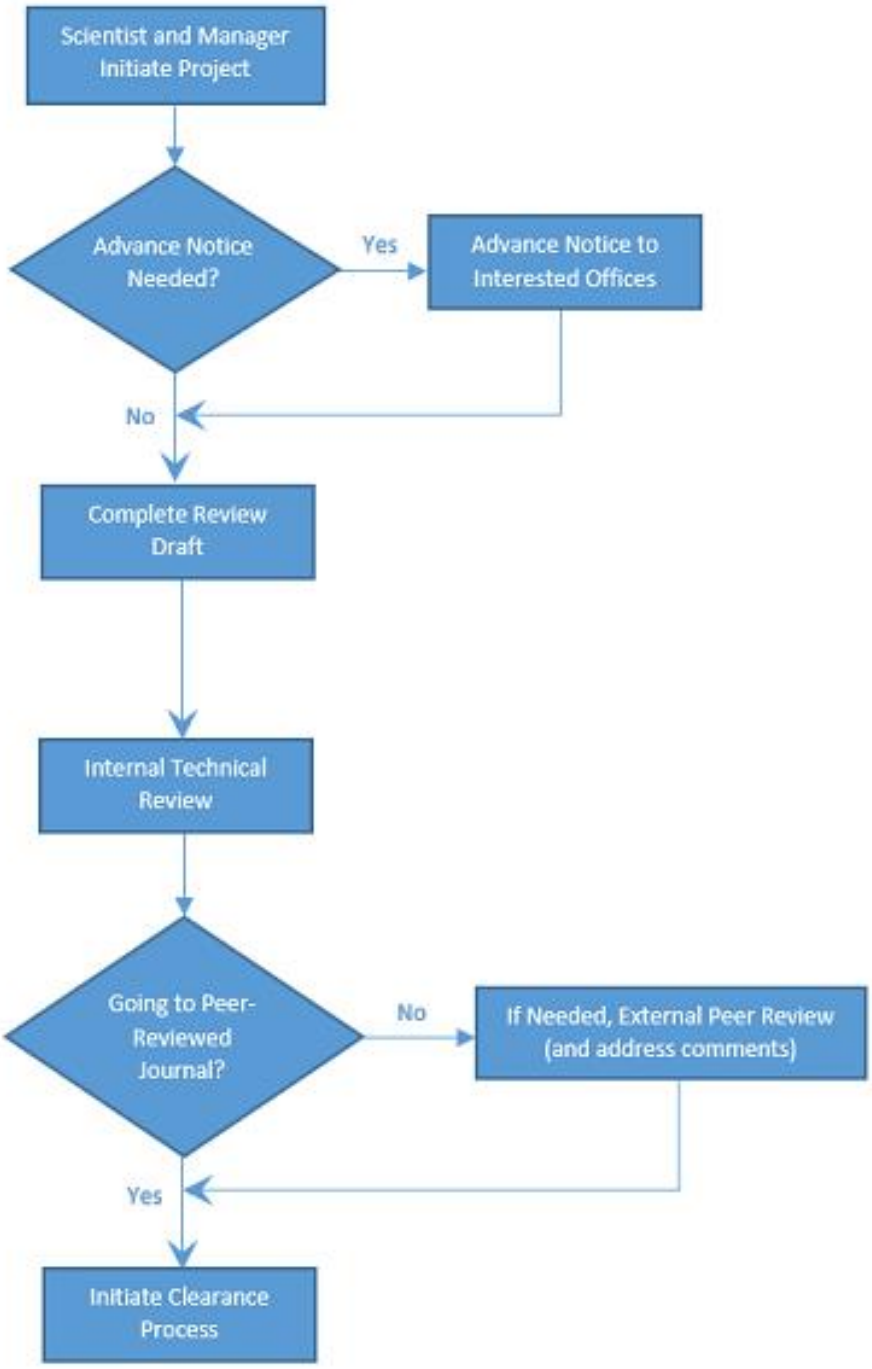
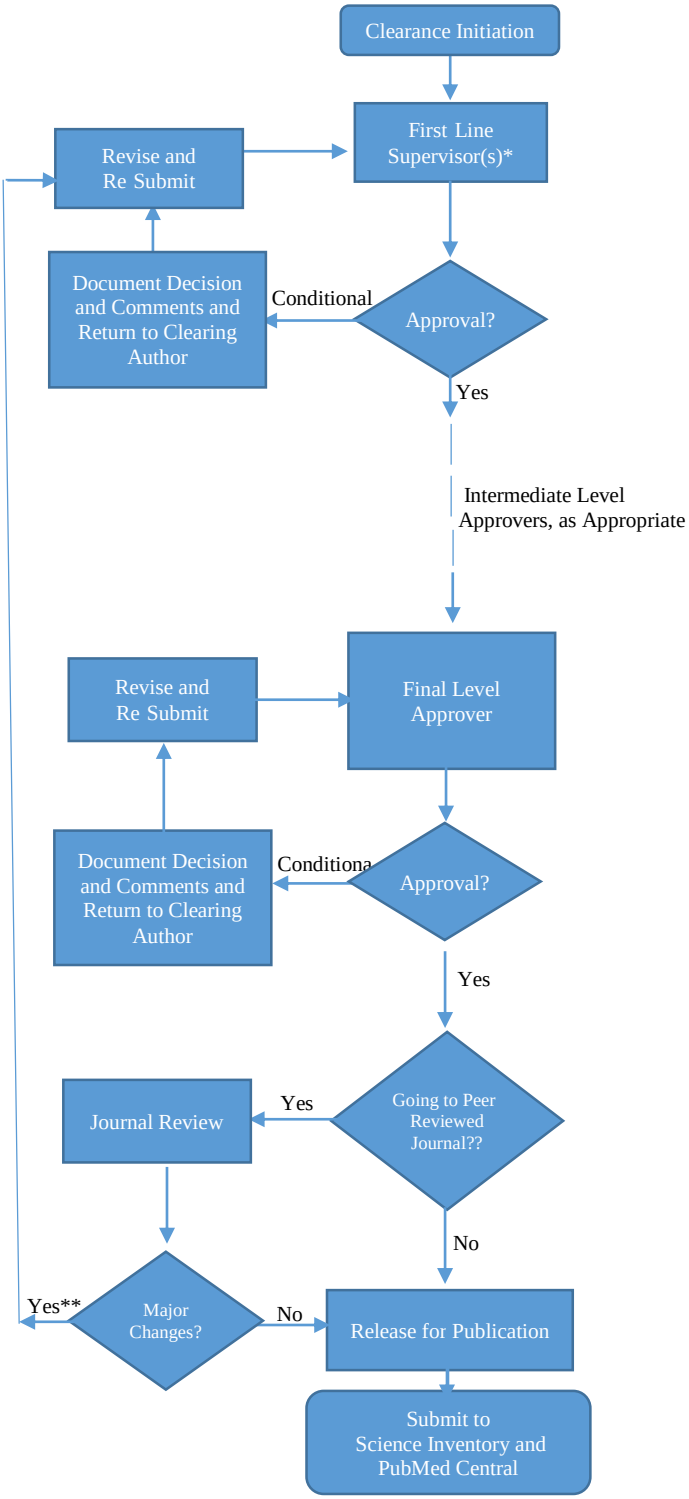


Figure F1. Flowchart for Actions Taken Before Clearance of a Scientific Product



*The product should simultaneously be reviewed by all co-authors' first-line supervisors.
**Major external review comments may necessitate going through the review process again.

Figure F2. Clearance Flowchart for Scientific Products

Appendix G: Sample Timeframes for Clearance of Scientific Products

It may be helpful to categorize scientific products, based on the product's level of influence, as explained in the Peer Review Handbook (Section 3.2). The categories may then be used for drafting clearance procedures that include clearance workflows and the personnel that are part of the clearance process, as well as timeframes for completing the clearance process.

These sample timeframes below assume that the scientific product was adequately reviewed and that it meets the requirements of applicable EPA policies and procedures. If authors do not address these before initiating the clearance process, it could significantly delay the release of the product.

Highly Visible Scientific Products

These scientific products are ones that may attract attention from outside parties, including Congress, the scientific community, the media, or the public, or may significantly impact certain communities more than others. Advance notice is typically needed for highly visible scientific products.

Sample timeframes for Highly Visible Scientific Products:

- First-Level Supervisor(s) ≤ 14 days
- Second-Level Supervisor ≤ 7 days
- Other Senior Officials ≤ 7 days
- Approver ≤ 7 - 14 days

Other Scientific and Technical Products

This category includes scientific products that do not fall within the highly visible category, such as routine technical reports and scientific journal articles that do not require the attention of senior leadership. The timeframes below may serve as guidance, but should be adjusted based on the product's type, complexity and length. Optimally, these scientific products should take no more than 30 days to route through clearance.

Sample Timeframes for Other Scientific Products:

- First-Level Supervisor(s) ≤ 7 days
- Second-Level Supervisor (when needed) ≤ 7 days
- Approver ≤ 7 days

Appendix H: Sample Clearance Procedures for Scientific Products Based on Best Practices

The following is an example of clearance procedures that incorporate the best practices listed in this document. P/O/R is used throughout these sample procedures to stand for the relevant program (P), office (O), or region (R). Text contained within {...} identifies sections in the Best Practices document from where text may be drawn.

[Insert P/O/R]
Clearance Procedures for Scientific Products

Applicability

These procedures apply to any scientific product considered based upon work conducted as part of an [P/O/R] employee's official duties that is intended for release.

Roles and Responsibilities

This section explains the roles and responsibilities of individuals who contribute to the [P/O/R] clearance process. {A program, office, or region may adopt text from the earlier section on Roles and Responsibilities, or may adapt this text to reflect conditions specific to the office. The responsibilities of the following individuals should be described in the clearance procedures of the program, office, or region.

- Clearing Author
- Clearance Contact
- Clearing Manager
- Deputy Ethics Official
- Deputy Scientific Integrity Official
- First-line Supervisor
- Human Subjects Coordinator
- Peer Review Coordinator
- Quality Assurance Manager}

Before Clearance: Considerations of EPA Policies and Scientific Review

{The following factors are associated with the clearance of scientific products, should be considered by clearing authors and managers before clearance is initiated, and should be described in an office's clearance procedures. See the section on Before Clearance: Consideration of EPA Policies and Scientific Review for information on each of these factors.

- Identification and Categorization of Scientific Products
- Advance Notice
- Allowing adequate time for clearance; external collaborators
- Communications check-in
- Public access to scientific results
- Quality Assurance
- Human Subjects Research
- Dual-Use Research of Concern

- Legal Concerns
- Quality Assurance
- Authorship
- Disclaimers
- Scientific Review}

Clearance Procedures

All [P/O/R] employees must follow these procedures to obtain approval for the release of a scientific product. A scientific product should not be released outside of the Agency until it has received clearance.

Initiation by Clearing Author

The clearing author is responsible for initiating clearance by either completing and submitting a form or using a designated electronic system. The clearing author must designate the type and category of the product and whether advance notice is necessary {see text on Advance Notice in section 1.A}. Where applicable, the clearing author must submit the following accompanying documents with the scientific product for clearance:

- Scientific review record documenting scientific review activities (internal technical review and external peer review) and responses to reviewers' comments
- Communications strategy that explains how the product will be released once cleared.
- Scientific Data Management Plan
- Documentation that it meets QA requirements

The clearing author should inform management if the scientific product:

- Needs advance notice
- Contains research that qualifies as Human Subjects Research or Dual-Use Research of Concern
- Could raise legal concerns
- Has any authorship issues
- Includes a disclaimer

Routing

Scientific products should be routed through the various levels of [P/O/R] management based upon the product type and category {see Appendix G}. It is crucial that the product route through the clearance process in a timely manner to support the release of scientific information to the public. Scientific products that include authors in other EPA programs, offices, or regions or authors from outside EPA may need to follow additional clearance procedures.

Timeliness

Scientific products should be cleared and released in a timely manner. Example timeframes for the type and category of scientific product are listed {see Appendix G}. If a clearing manager cannot provide a decision in the designated timeframe, he/she should notify the clearing author and either provide the justification for a delayed response or identify an alternate who can provide clearance in his/her absence.

If a clearing manager is unable to provide a decision or communication in the allotted timeframe, the clearing author may elevate the scientific product to the next in-line clearing manager or step in the clearing process. The clearing author should contact the clearance contact and, if necessary, the Deputy Scientific Integrity Official to avoid undue delay.

Intra-Agency Clearance

Scientific products that have collaborators from EPA programs, offices, or regions outside of [P/O/R] require intra-Agency clearance. These products will likely need to be routed through each co-author's line management in his/her program, office, or region for clearance. Scientific products should not be released until cleared by all collaborator programs, offices, and regions.

Interagency Clearance

Scientific products that have [P/O/R] authors in addition to collaborators from other agencies should be cleared by [P/O/R] prior to release. This provision, as well as the procedures of other agencies, should be written into the interagency agreement prior to the initiation of a project.

Verifications by Clearing Managers

Clearance procedures should include a checklist for clearing managers to verify that the scientific product meets requirements of applicable EPA policies and procedures. {See the section, "Before Clearance: Consideration of EPA Policies and Scientific Review" for more information on each item in the checklist.

The checklist should include:

- Advance notification
- Public access to scientific results
- Quality assurance
- Human subjects research
- Dual-use research of concern
- Legal Concerns
- Authorship
- Disclaimers
- Technical review
- Peer review}

Decisions

Each clearing manager involved in the clearing process is responsible for making the decision to clear the product or otherwise explain the rationale for denying clearance. Regardless of the decision made by a clearing manager, it must be documented and the clearing author notified.

Clearance Granted

A decision of "clearance granted" means that the clearing manager approves the scientific product for release and no changes are required. Upon granting clearance, the clearing author should be notified, and the scientific product routed to the next in-line manager or step in the clearance process.

Conditional Clearance

A decision of "conditional clearance" means that the clearing manager individually approves of the scientific product for release only on the condition that any outstanding issues are addressed prior to release. Upon granting conditional clearance, the clearing manager should document the reasons for the decision and notify the clearing author. The clearing manager should designate whether he/she would like to see the revised scientific product before release.

Clearance Denied

A decision of 'clearance denied' means that the clearing manager does not approve the scientific product for release. Upon denying clearance, the responsible clearing manager must document the reasons for denial and send them to the clearing author.

Reconsideration

If a scientific product is denied clearance, the clearing author may resubmit a revised scientific product, beginning at the clearance initiation step. Before resubmitting scientific products, clearing authors should consult with their first-line supervisors to ensure all issues have been addressed.

When initiating reconsideration, clearing authors must designate the scientific product as a resubmission and provide a response to the comments that resulted in the previous denial. The scientific product will then be rerouted through clearance, with two additional clearing managers designated by the clearance contact to provide an unbiased evaluation of the scientific product.

Appeal

Appeal is a procedure for considering release of a scientific product that has been denied clearance, independent of rerouting the product through the clearance personnel chain. If reconsideration fails to resolve a denial of clearance, appeal may be necessary.

Clearing authors should consult with their first-line supervisors when considering appeal. If appeal is appropriate, the clearing author should notify the clearance contact by writing a request for appeal that includes an explanation. The clearance contact is then responsible for reviewing previous clearance records of the scientific product and consulting the appropriate management to address the concerns of the clearing author. If necessary, the clearing author or clearance contact can involve the [P/O/R] Deputy Scientific Integrity Official.

Redress

If clearance procedures are not followed, the clearing author can seek redress by submitting an allegation of a loss of scientific integrity to his/her Deputy Scientific Integrity Official, to EPA's Scientific Integrity Official, or by contacting EPA's Office of Inspector General hotline.

Release and Records Management

Following clearance, the clearing author is responsible for the release of the scientific product in accordance with the communications strategy. As a condition of clearance, clearing authors are responsible for ensuring that the scientific product is submitted for records management, EPA's Science Inventory, and public access.

Records Management

Clearing authors are responsible for following record retention procedures established by the National Archives and Records Administration {see section 2.H} as they apply to scientific products and related documentation that go through clearance.

Science Inventory

After clearance is granted, the clearing author is responsible for submitting the scientific product to the Science Inventory (SI), a searchable repository of EPA scientific activities and products. The Science Inventory increases public access to EPA's science.

Public Access

Consistent with the implementation dates identified in EPA's *Plan for Increasing Access to Results of EPA-Funded Scientific Research* {see text on public access in section 1.A}, the clearing author or the [P/O/R] designee is responsible for depositing the scientific product into NIH's PubMed Central database.

Resources

For Legal and Government Ethics Information:

Office of General Counsel (OGC): General Law Office: http://intranet.epa.gov/ogc/general.htm

OGC Ethics Program: http://intranet.epa.gov/ogc/ethics.htm

For Information about Scientific Integrity:

Scientific Integrity Program: https://intranet.ord.epa.gov/scientific-integrity

To report a concern about the clearance process or a potential loss of scientific integrity:
[P/O/R] Deputy Scientific Integrity Official: https://www.epa.gov/osa/basic-information-about-scientific-integrity

Scientific Integrity Official: https://intranet.ord.epa.gov/scientific-integrity/allegations-and-other-concerns

Office of Inspector General Hotline: https://www.epa.gov/office-inspector-general/epa-oig-hotline