# U.S. Fish and Wildlife Service Information Quality Guidelines and Peer Review

(revised June 2012)

Guidelines issued by the U.S. Fish and Wildlife Service (FWS) for ensuring the quality, objectivity, utility, and integrity of information disseminated by FWS.

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### PART I PURPOSE and LEGAL EFFECT

These guidelines establish FWS policy and procedures for reviewing, substantiating, and correcting the quality of information it disseminates to the public. Persons affected by that information may seek and obtain, where appropriate, correction of information that they believe may be in error. In some limited circumstances, information that is considered "influential" or "highly influential" requires additional independent peer review for additional quality assurance (see Part VI Peer Review).

### LEGAL EFFECT

These guidelines are intended only to improve the internal management of the FWS relating to information quality. Nothing in these guidelines is intended to create any right or benefit, substantive or procedural, enforceable by law or equity by a party against the United States, its agencies, its offices, or another person. These guidelines do not provide, in and by themselves, any right to judicial review.

### PART II BACKGROUND AND APPLICABILITY

In December 2000, Congress required federal agencies to publish their own guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information that they disseminate to the public (44 U.S.C. 3502). The amended language is included in section 515(a) of the P.L. 106-554, HR 5658. The Office of Management and Budget (OMB) published guidelines pursuant to the IQA in the <u>Federal Register</u> on February 22, 2002 (67 FR 8452),

directing agencies to address the requirements of the law. On December 16, 2004, OMB issued their "Final Information Quality Bulletin for Peer Review" (M-05-03).

The first version of the FWS guidelines (interim) were put into effect on December 19, 2006, with the final version in August 2007 and updated in June 2012.

# II-1 <u>To whom do these guidelines apply?</u>

These guidelines apply to all FWS offices that disseminate information to the public.

# II-2 <u>What do these guidelines cover?</u>

These general guidelines (Parts II – V) apply to all information disseminated by the agency to the public if it represents an official view of the FWS or DOI except as described in II-6. This includes information initiated or sponsored by the agency that states that it represents the official position of the FWS. This also includes information from an outside party that is disseminated by the agency in a manner that a reasonable person would likely infer agency endorsement or agreement with the information. In addition, a small subset of the agency information determined to be *influential* information, (*highly influential* assessments are a subset thereof) must meet the stricter elements contained in Part VI Peer Review of these guidelines.

# II-3 <u>What information does not fall under these guidelines</u>?

These guidelines apply only to information that FWS sponsors and disseminates to the public. Examples of information that would generally not meet these criteria are:

- Testimony and information presented to Congress as part of legislative or oversight processes, including drafting assistance in connection with proposed or pending legislation;
- Information accessed via Internet hyperlinks to or from non-FWS sites;
- Opinions that are not FWS positions, where the FWS presentation makes it clear that what is being offered is someone's opinion rather than fact or the views of FWS;
- Petitions from third parties that the FWS is required to evaluate under the Endangered Species Act or other legislation. Such petitions represent the opinions of the petitioners and the Service does not control, endorse, or sponsor information that may be presented to it by petitioning members of the public;
- Correspondence limited to an individual and FWS concerning the status of the individual's particular issue, permit, land, or case is not considered information disseminated to the public (even though such information may be accessible via the Freedom of Information Act);
- Archival records, including library holdings;
- Information intended for distribution only to government employees or FWS contractors or grantees;
- Communications between federal agencies, including management, personnel and organizational information as well as intra- or inter-agency use or sharing of government information, even if the information becomes public at some point (for example, providing comments to another federal agency on its environmental impact statement);
- FWS responses to requests for agency records pursuant to the Freedom of Information Act (FOIA), the Privacy Act, the Federal Advisory Committee Act (FACA), or other similar laws;
- Solicitations (e.g., program announcements, requests for proposals);

- Press releases, press conferences or similar communications in any medium that announce (including Facebook and Twitter postings), support the announcement, or give public notice of the availability of information FWS has disseminated elsewhere or that summarize recent events or agency actions;
- Distributions of information by outside parties unless a disclaimer is attached explaining that the distribution is being done at the direction or sponsorship of the FWS;
- Draft FWS documents that are disseminated solely for the purpose of soliciting peer review provided that the information contains the following disclaimer: "This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the FWS. It does not represent and should not be construed to represent any agency determination or policy";
- Research by federal employees and recipients of FWS grants, cooperative agreements, or contracts, where the researcher (and not FWS) decides whether and how to publish the research, does so in a manner consistent with academic protocols, and distributes the research with a disclaimer that the research does not represent an official position of the FWS. Distribution of research in this manner is not subject to these guidelines even if FWS retains ownership or other intellectual property rights because the federal government paid for the research;
- Public filings including information submitted by applicants for a permit, license, approval, authorization, grant, or other benefit or permission; information submitted voluntarily as part of public comment during rulemaking;
- Dissemination intended to be limited to subpoenas or information for adjudicative processes, including ongoing criminal or civil action or administrative enforcement action, investigation, or audit;
- Forensic reports issued in connection with ongoing criminal investigations;
- Statements of administration policy; however, any underlying information published by FWS upon which a statement is based may be subject to these guidelines;
- Descriptions of the agency, its responsibilities, ties and its organizational components; and,
- Statements related solely to the internal personnel rules and practices of FWS and other materials produced for FWS employees, contractors, agents or alumni.

# II-4 <u>What happens if information is initially not covered by these guidelines, but FWS</u> <u>subsequently disseminates it to the public</u>?

If a particular distribution of information is not covered by these guidelines, the guidelines may still apply to a subsequent distribution of the information in which FWS adopts, endorses or uses the information to formulate or support a regulation, guidance, or other decision or position.

II-5 <u>When FWS receives a request for information correction under the IQA, can members</u> of the public submit comments or information on that request?

The FWS process, generally, does not include solicitation or acceptance of comments or information from third parties not directly involved in the IQA challenges.

II-6 Who is the official responsible for FWS compliance with the guidelines?

The Director of FWS delegated authority to the Office of the Science Advisor to be the official responsible for compliance with the guidelines. The Senior Science Advisor is the responsible official.

#### PART III DEFINITIONS

III-1 *Information*, in this context, is an encompassing term, meaning any communication or representation of knowledge such as facts or data, in a textual, numerical, graphic, cartographic, narrative, or audiovisual form including digital or electronic formats. Verbal presentations that are not documented by any of these media or forms are exempt from the information definition. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views. For example, a presentation, by a FWS employee in his/her official capacity, that includes interpretation of data would meet the definition of information unless the presentation included a disclaimer that the interpretation was that of the author and did not represent the position of FWS. The term also applies both to documents produced by FWS as well as the underlying data, models, scientific papers and the like that is used by FWS to create that document.

III-2 *Disseminated to the public* means publication (electronic or written) of information to a community or audience. Dissemination does not include distribution limited to government employees (federal, state, tribal or local) or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes, nor does it include information from third parties that is hyper-linked directly or indirectly to or from the FWS web site through the Internet (see II-6).

III-3 *Sponsored information* is information FWS initiates or sponsors for distribution to the public. When information is prepared or submitted by a third party to the FWS and FWS, in turn, distributes that information or uses it to support its viewpoint in a manner that a reasonable person would likely infer FWS endorsement or agreement with it, that information is considered sponsored. For example, FWS may sponsor information that is disseminated to the public to support or represent its viewpoint, formulate or support a FWS regulation or FWS guidance, or otherwise communicate a bureau decision or position

III-4 *Government information* means information created, collected, processed, disseminated, or disposed of, by or for the federal government.

III-5 *Affected persons or organizations* are those who may use, benefit from or be harmed by the disseminated information with a material impact to their interests. An affected person or organization bears the burden of proof that a material impact to their interests has occurred or will occur as a result of information disseminated by FWS.

III-6 *Quality* is an encompassing term that includes the terms utility, objectivity, and integrity. Therefore, the guidelines sometimes refer to these four statutory terms collectively as quality.

III-7 Utility refers to the usefulness of the information to its intended users, including the public.

III-8 *Objectivity* includes whether the disseminated information is presented accurately, clearly, and completely, and in an unbiased manner. Objectivity involves two distinct elements: presentation and substance.

- a) Information disseminated by the FWS will be presented accurately, clearly, and completely.
- b) Information disseminated by the FWS will be treated in an unbiased fashion. In a scientific, financial, or statistical context, we will analyze the original and supporting data and develop our results using sound statistical and research methods to ensure, to the best of our knowledge that our results are not subject to bias. Where a potential for bias is identified, the FWS will address it.
- c) The limitations of the information disseminated by FWS will be explicitly stated.

III-9 *Integrity* refers to the security and protection of information from unauthorized access or revision to ensure that the information is not compromised through corruption or falsification.

III-10 *Influential*, when used in the phrase "influential scientific, financial, or statistical information," means that we can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policy or private sector decisions, and thus, a decision or action to be taken by the Director, FWS (some may be delegated to Regional or Assistant Directors). We are authorized to define influential in ways appropriate for us, given the nature and multiplicity of issues for which we are responsible. As a general rule, FWS considers an impact clear and substantial when a specific piece of information or body of information is a principal basis for a FWS position (see section VI-5). Information is influential if the same decision would be difficult to arrive at if that information was absent. It should also be noted that the definition applies to "information" itself, not to decisions that the information may support. Even if a decision or action by FWS is itself very important, a particular piece of information supporting it may or may not be "influential."

III-11 *Highly Influential* applies to influential scientific information that the FWS determines to be a scientific assessment that: (i) could have a potential impact of more than \$500 million in any year, or (ii) is novel, controversial, or precedent-setting or has significant interagency interest.

III-12 *Reproducible* means information is capable of being substantially reproduced, subject to an acceptable degree of precision.

### PART IV INFORMATION QUALITY

Each FWS office will incorporate the information quality principles outlined in these guidelines into existing review procedures as appropriate. Offices and Regions may develop unique and new procedures, as needed, to provide additional assurance that the information disseminated by or on behalf of their organizations is consistent with these guidelines.

**Contact Information -** All FWS information (publications, reports, data, web pages, etc.) must contain a contact name/office and a means of contacting the person/office (e.g., email address, mailing address, fax or phone number).

### IV-1 How will FWS determine the "utility" of information?

While assessing the usefulness of information that we disseminate to the public, FWS will consider the uses of the information not only from our perspective, but also from the perspective of the public. "Useful" means that the content of the information is helpful, beneficial, or serviceable to its intended users, or that the information supports the usefulness of other disseminated information by making it more accessible or easier to read, see, understand, obtain, or use.

### IV-2 How will FWS determine "integrity" of information?

Prior to dissemination, FWS information is safeguarded from improper access, modification, or destruction, to a degree commensurate with the risk and magnitude of harm that could result from the loss, misuse, or unauthorized access to or modification of such information.

All electronic information disseminated by FWS adheres to the standards set out in Appendix III, "Security of Automated Information Resources," OMB Circular A-130; the Computer Security Act; and the Government Information Systems Reform Act. Confidentiality of data collected by FWS is safeguarded under legislation such as the Privacy Act and Titles 13, 15, and 22 of the U.S. Code.

#### IV-3 How will FWS determine the objectivity of FWS information?

The FWS definition of objectivity includes whether the disseminated information is presented accurately, clearly, and completely, and in an unbiased manner. To achieve this end, FWS will subject information to review by persons qualified to judge objectivity (as defined by the type of information and the circumstances in which it will be used). Such a "peer review" will be conducted before decision making, unless legal deadlines or other constraints prevent such a timely review. In such cases, the peer review may have to be post hoc. To the extent they are understood, we will explicitly state assumptions, limitations or biases related to the information. Sometimes, supporting documentation must also be disseminated in order to ensure a more clear, complete, and unbiased presentation. In those cases, FWS will identify the sources of supporting information. If data and analytical results have been subjected to formal, independent, peer review, we will generally presume that the information is of acceptable objectivity. However, a request for correction or the FWS may rebut this presumption based on a persuasive showing in a particular instance. If we use peer review to help satisfy the objectivity standard, the review process employed must meet the general criteria for competent and credible peer review (OMB M-05-03, "Final Information Quality Bulletin for Peer Review") and the results of the peer review part of the administrative record (also see VI-7).

Transparency about research design and methods is pivotal to reproducibility. With regard to analytical results, we will generally require sufficient transparency about data and methods that a qualified member of the public could undertake an independent reanalysis. These transparency standards apply to our analysis of data from a single study as well as to analyses that combine information from multiple studies. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.

In situations where public access to data and methods will not occur due to other compelling interests, we will apply especially rigorous checks to analytical results and documents. We will,

however, disclose the specific data sources used, and the specific quantitative methods and assumptions we employed. We will define the type of checks, and the level of detail for documentation, given the nature and complexity of the issues. With regard to analysis of risks, human health, safety, and the environment, we will use or adapt the quality principles applied by Congress to risk information used and disseminated under the Safe Drinking Water Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B)).

# IV-4 <u>How will FWS describe the strengths and weaknesses of the data used in influential</u> <u>scientific information and highly influential scientific assessments?</u>

The preparer of a highly influential assessment or of influential information will document the strengths and weaknesses of the data underlying the assessment/information so that the reader will understand the context for the FWS decision. The narrative will be contained in the administrative record of the issue under consideration. The documentation may be done in a narrative that includes a complete literature cited section, and an assessment of the strengths and weaknesses of the information used for advising the decision at hand. The narrative's form and length is left to the preparer. The following bullet points provide questions to consider in the narrative.

- What types of research studies does the assessment/information rely upon (e.g. experimental studies with controls, statistically designed observational studies that test hypotheses, monitoring studies, information synthesis, professional judgment etc.)?
- How recent is the research?
- What are the sources for the underlying data that support the assessment/information (e.g. peer reviewed article reporting primary data or data synthesis, unpublished peer reviewed reports, on-line publication, textbook, personal communication etc.)?
- Which of the sources were most crucial to the conclusions reached in the assessment/information?
- What type of review did each source receive (anonymous independent peer review, external peer review, agency review, public review and comment, etc.)?
- Were the reviewers independent of the FWS? Were the reviewers independent of individuals or groups advocating a certain course of action by FWS?
- Were the reviews in compliance with OMB M-05-03, "Final Information Quality Bulletin for Peer Review"?

Two examples of how one might provide such a characterization are provided below:

Example 1: (A number of references are listed.) These references were the primary sources of data that provided the basis for the decision. They are peer reviewed studies with an experimental design that includes controls and testable hypotheses. They were completed within the last 5 years and were independently reviewed by non-FWS personnel and published in scientific journals.

Example 2: (A number of references are listed.) These references were articles and sources of data that provided specific data points that were included in the decision document, but by themselves did not primarily contribute to the decision. These citations are a combination of fact sheets, summaries of information, professional judgments, and personal communications that have not been peer reviewed. Most of the data is current (within the last 7 years).

IV-5 <u>How will scientific citations be organized in documents prepared for notice and comment in the Federal Register?</u>

The FWS standard for scientific citations in this circumstance is: *Council of Biology Editors Style Manual: A Guide for Authors, Editors, and Publishers in the Biological Sciences.* CBE Style Manual Committee. 5<sup>th</sup> ed. Council of Biology Editors, 1983.

The FWS usually does not include a literature cited section in the document actually published in the Federal Register because of the cost and our experience that interested persons will contact the FWS to request supporting documents that will include the literature cited section. However, even though the literature cited section does not actually appear in the Federal Register, it must be made available to the public and prepared as a part of the administrative record.

# PART V REQUEST FOR CORRECTION PROCEDURES

Persons seeking correction of information are encouraged to first contact the office or individual identified on an information product before submitting an official request for correction under the IQA procedures outlined below.

**Formal Request for Correction**- If informal requests for correction are not sufficient to resolve the concern, affected persons may also file a challenge with FWS by mail at:

Correspondence Control Unit Attention: <u>Information Quality Correction Request Processing</u> U.S. Fish and Wildlife Service 1849 C Street, NW, Mail Stop 3331-MIB Washington, D.C. 20240

# V-1 Who may request a correction of information?

Any affected person or organization may request a correction of information from FWS pursuant to these guidelines (see website <u>http://www.fws.gov/informationquality/</u>).

V-2 <u>What are the responsibilities of the requester in seeking a request for correction of information?</u>

A request for correction of information should always include the following:

- Statement that the Request for Correction of Information is submitted under FWS Information Quality Guidelines.
- Requester Contact Information. The name of the individual requesting correction, mailing address, telephone number, fax number or email address.
- Description of Information to Correct. The name of the FWS publication, report, or data product; the date of issuance or other identifying information, such as the URL of the contained in that publication, report, or data production for which a correction is being sought.
- Effect of the Alleged Error. Provide an explanation that describes how the requester specifically uses the information, how the alleged error affects the requester in a material way and how a correction would resolve the error.
- A specific description of how the information does not comply with OMB, DOI, and/or FWS Information Quality Guidelines. The requester should cite the specific locations in the text of

the document where the alleged error occurs and should state specifically how the information should be corrected.

- Whether the information being challenged should be considered influential within the context of the FWS guidelines (see Section VI, below), e.g., how the information constitutes a principal basis for a substantive decision by FWS.
- Supporting Documentary Evidence. Provide any supporting documentary evidence, such as comparable data or research results on the same topic. Wherever possible, the requester should link this supporting evidence to specific locations in the text of the document being challenged so that it is clear how the supporting documentation relates to the challenged information.
- Identification of any other public proceeding, including public comments, legal proceedings, or communications in which the requester has previously or is simultaneously requesting consideration of the same or similar corrections.

# V-3 <u>Will FWS consider all requests for correction of information?</u>

Yes. FWS will consider all requests submitted pursuant to these guidelines, and consider it for correction unless the request itself has been made in bad faith or without justification, or deemed inconsequential, and for which a response would be duplicative of existing processes, unnecessary, or unduly burdensome on the Agency. The burden of proof is on the requester with respect to showing that the information needs to be corrected as well as with respect to the type of correction sought.

# V-4 <u>How will FWS integrate its response to a request for a correction with the rulemaking process?</u>

When the FWS engages in proposed rulemaking, the public should submit comments on the information used in support of the rulemaking as part of the public comment process rather than as a request for correction. If a request for correction is received on a rulemaking, the FWS will respond to the request for correction in the next rulemaking document, which will generally be the final rule. If the FWS determines that an earlier response would not unduly delay issuance of the FWS action and the requester has shown a reasonable likelihood of suffering harm from the unresolved request, the FWS will consider responding to the requester prior to issuing the next rulemaking document.

# V-5 <u>What type of requests would be considered duplicative, unnecessary, or unduly burdensome?</u>

The FWS will not consider a request for correction if it is not from an "affected person". The FWS may choose to simply refer to a parallel process if a request for correction substantially duplicates a previous request. FWS may choose not to invest substantial staff resources to evaluate a request for correction when the information is not influential (e.g., the challenged information is not a principal basis for a FWS position). The Director of the FWS, or designee, reserves the right to judge requests as duplicative, unnecessary or duly burdensome if the requester does not meet the requirements set forth in section V-2.

The federal rulemaking process imposes a legal obligation on federal agencies to conduct a comprehensive public comment process. As such, we must solicit comments on our rulemaking actions, consider all comments received during the public comment period, and

respond to the comments germane to the action. In order to prevent unnecessary delay in the rule making process, if a request is submitted after the comment period closes, the requester must clearly demonstrate that the information in question is pivotal to the decision being made.

# V-6 How will FWS respond to a request for correction of information?

All requests about FWS information quality will be tracked by the Service's Correspondence Control Unit (CCU), which will route requests to the Program or Regional Office responsible for the information. CCU will notify the requester of receipt of the request within 14 calendar days.

If a request for correction of information is appropriate for consideration, FWS will review the request and issue a decision within 90 calendar days from receipt of the challenge. FWS will send the results of this decision to the requester with an explanation for the decision. If the request requires more than 90 calendar days to resolve, the agency will inform the requester that more time is required, indicating the reason(s) why and providing an alternative timeline for reaching a decision. If a request is approved, FWS will take corrective action. The time required for corrective action to be taken will depend on the circumstances of each situation. Corrective measures may include personal contacts via a letter, form letters, press releases or postings on the FWS website to correct a widely disseminated error or address a frequently raised request. Corrective measures, where appropriate, will be designed to provide notice to directly affected persons of any corrections made.

V-7 <u>Will FWS reconsider its decision on a request for the correction of information?</u> Requesters of corrective actions who are dissatisfied with a FWS decision regarding their request may appeal the decision. Appeals for reconsideration must be submitted within 21 calendar days from the date on the decision letter to the requester and should contain the following:

- Indication that the person is seeking an appeal of a FWS decision on a previously submitted request for a correction of information, including the date of the original submission and date of FWS decision;
- Indication of how the individual is an "affected person" under the provisions of these guidelines;
- Name and contact information.
- Explanation of the disagreement with the FWS decision and, if possible, a recommendation of corrective action; and,
- A copy of the original request for the correction of information.

### V-8 How does FWS process requests for reconsideration of FWS decisions?

Requests for reconsideration of FWS decisions related to IQA will be logged and tracked by the CCU. Appellants must limit their request for reconsideration to the FWS' decision on issues raised in the original IQA challenge. Appeals will be reviewed by a panel consisting of Directorate-level officials from the FWS and, when available, another Department of the Interior agency such as the U.S. Geological Survey. The appeals panel will make a recommendation which will be forwarded to the Director of the FWS. The Director of the FWS or his/her designated representative will make the final decision on the appeal within 60 calendar days from receipt of the appeal in FWS.

#### V-9 What is the reporting requirement for oversight of these guidelines?

The Senior Science Advisor, Office of the Science Advisor, will submit reports to the DOI, via the Assistant Secretary-Fish, Wildlife and Parks for consolidated submission to OMB on an annual basis. The report will include the number, nature, and resolution of complaints received by FWS under the provisions of these guidelines in the format requested by OMB.

### PART VI PEER REVIEW

Part VI contains information quality methods and the FWS guidance on peer review of influential information. The guidance in Part VI may also be used for peer review of non-influential information when, at the discretion of FWS managers, such information is judged to warrant it. Part VI does not apply to information submitted by FWS employees to peer-reviewed scientific journals because the FWS accepts the peer review process of these journals as meeting Information Quality Act standards for influential information.

Authors seeking peer review of "influential scientific information" and "highly influential scientific assessments" (hereinafter referred to as influential, unless specified) are responsible for consulting and complying with this and all other guiding documents. The Senior Science Advisor is the single point of contact for the purpose of reporting to the Department about peer review of influential information and coordinating the FWS peer review effort.

Most scientists have a general familiarity with peer review as applied to scientific publication. However, academic peer review is typically carried out anonymously, while peer review for influential information requires at least a listing of the peer reviewers, without attribution of the collective review comments, and maintained in the public record.

Finding independent subject matter experts to be peer reviewers is sometimes a challenge. It may be helpful to request the support of coordinating organizations that have such networks and can manage the review. There are several professional societies such as The Wildlife Society, American Institute of Biological Sciences, Society for Conservation Biology and others as well as a host of private companies, who, under contract can provide valuable management assistance for peer reviews.

The FWS hosts a 5-year (2012-2017), blanket purchase agreement contract with three vendors (EMPSi, AMEC, and Atkins) to provide peer review services, and other science support services, as requested (see FWS homepage website, Science, Peer Review, for more information on how to access these contracts. <u>http://www.fws.gov/informationquality/peer\_review/index.html</u>

When FWS is conducting a peer review of influential information, the reviewers must be both external and independent except in very rare circumstances where no external, independent experts can be found. This section is primarily focused on independent, external review of influential information (although internal review will normally also occur during the process of preparing the information for external, independent review, with the level of effort being scaled to the importance of the problem).

Selecting reviewers--When FWS staff organizes a peer review, time should be spent identifying

and selecting the best, most qualified reviewers with expertise in the subject areas where the review will be focused. Develop criteria for selecting reviewers and to avoid appearance of conflict of interest, review the National Academy of Science's "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports" http://www.nationalacademies.org/coi/

*Review of draft documents--*It is not necessary to wait for a final decision document to be completed before subjecting it to a review of the science on which it is based. For instance, it might be possible to subject critical portions of the scientific materials to review, in advance of a decision. A major advantage of early review is the opportunity to take early corrective action. Most early drafts can be substantially improved through early informal reviews by internal or external experts. Improvements based on these early "friendly" reviews will lead to better products (e.g. study design, sampling method) and more useful comments during more formal peer reviews such as those mentioned above. Soliciting informal reviews by subject matter experts is a good idea (e.g., better products, broadening your scope of professional contacts) even if formal peer review is not applicable.

*Review of completed documents--*Often a document (e.g. Critical Habitat Proposal) may be sent to external reviewers for consideration. Each reviewer writes a separate report on the scientific merits and shortcomings, which is then evaluated and addressed by FWS staff. The usefulness of such reviews depends on when the Service submits such material for review. If a completed document is sent out concurrent with the public comment period that provides some assurance of quality and compliance with existing peer review guidance. This approach, however, is essentially a 'final check' approach, and tends to limit the opportunity for early recognition of the need for corrective measures, if such are identified. It may also cause problems when different reviewers have conflicting opinions, and the FWS must choose between them at such a late stage of document development, thus peer review prior to the public comment period should be considered.

*Panel evaluations*--Instead of asking reviewers for their independent opinions, it is sometimes helpful to set up a review panel. Such panels may carry out site-visits (e.g. of FWS facilities) and ask direct questions of the persons preparing the information. It is also possible for such panels to conduct their reviews in a public forum and to write a joint report. Such processes are very powerful in both the public visibility and strength of the scientific record, and in identifying and correcting any scientific weaknesses. Of course panels are also relatively expensive, and need expert management. Note that such panels can meet several times, overseeing any changes that are made, and can even be ongoing in nature. In such circumstances it is important to comply with FACA, and to ensure that these panels restrict their activities to scientific review and individual reviewer advice (allowable under FACA) and not a collective opinion, or comment on any aspect of policy or decision-making (not allowed).

#### VI-1 How does FWS ensure the quality of disseminated information?

FWS ensures the quality of information by using policies and procedures appropriate to the information product. These procedures include senior management oversight and controls, formal and informal peer review, peer editing, product review, internal approval via surname, and error correction. Higher levels of scrutiny are applied to *influential* scientific, financial or

statistical information, which must adhere to a higher standard of quality. Specifically, influential information is to be reproducible (see III-12). Offices that disseminate information to the public will ensure the quality of the information using the appropriate and feasible means, such as but not limited to, internal review, independent peer review, and repeating studies to verify results. FWS will review original information from other sources for adequacy of prior peer review, and for suitability or strength of the information to advise the issues at hand. FWS may conduct a post hoc peer review of original information from other sources when circumstances warrant. For example, an analysis of data may create a result that can be displayed on a map. Such an analysis is also subject to these guidelines. Interactive mapping sites that contain data from non-FWS sources will clearly inform the user of the source of the information.

#### VI-2 <u>How does FWS ensure the quality of "influential" scientific information</u>?

Per OMB's guidelines, FWS facilitates the reproducibility of influential information by also disseminating the study design, methodology and the data sets collected and analyzed is the influential decision-making process.. Independent investigators using the same experimental design and methods should have the capability of reproducing the results of an investigation originally conducted by another researcher or group of researchers with an acceptable degree of imprecision or error. This means that government-funded studies will disseminate the data sets used in the study at the same time as the results of the study are released to the public. Data from studies that were not federally funded, will remain with the private researcher, however, if the private –funded study is significantly relied on as influential information, then the FWS will ensure the quality of the study, including the data, are adequately peer reviewed (see VI-1, VI-4).

In addition, FWS adheres to the OMB Memorandum (M-05-030) "Final Information Quality Bulletin for Peer Review" dated December 16, 2004, to ensure that influential scientific information disseminated to the public is subject to peer review. The Bulletin directs agencies to choose an adequate peer review mechanism considering the complexity and novelty of the science, the relevance of the information to decision making, the significance of the policy decision, the extent of prior peer review and the expected benefits and costs. In addition, the agencies are directed to consider tradeoffs between depth of peer review and timeliness.

For the purpose of implementation of the Interagency Policy for Peer Review in ESA Activities (59 FR 34270, July 1, 1994) by the FWS, the definition of "solicit" in the Policy shall be interpreted as requesting and receiving at least 3 expert opinions regarding pertinent scientific and commercial information and underlying scientific assumptions related to species listings and preparation of species recovery plans.

VI-3 <u>What is the context in which the information deemed "influential" will be changed</u>? FWS will correct errors in influential information in draft documents or proposed management actions before final decisions are made, if possible (see section V-4). Corrections to information in approved management documents typically will be treated as addendums to decision documents or administrative records. The decisions will be revisited according to the regulatory, statutory, or policy guidance for the type of management decision being made, unless circumstances warrant more immediate attention.

#### VI-4 Does FWS ensure the quality of information from external sources?

The FWS does not take responsibility for the quality of the information produced by other entities unless that information is referenced in FWS documents *and* is a principal basis for a FWS position. In these cases FWS will ensure the quality and transparency of information provided by external sources (e.g., state and local governments). When prior review of information is insufficient, the FWS will conduct peer review of influential scientific information from external sources as appropriate. FWS will accept appropriately peer reviewed, published scientific papers as meeting the quality standards for influential information.

#### VI-5 How will FWS determine whether specific information is "influential?"

Each FWS Program (led by an Assistant Director) must prepare a written policy memo, approved by the Director that identifies the types of information (e.g. categories of documents, models, data, information syntheses etc.) produced within that Program that are classified as influential. Each Assistant Director will base their policy decisions upon application of the criteria in the OMB Information Quality Guidelines (67 FR 8452) and the FWS Information Quality Guidelines. The approved policy memo will be posted on the peer review website of each Program. These policy memos may be revised periodically as necessary. Official determinations for individual pieces of information (documents, models, data, information syntheses etc.) as to whether the information is influential are delegated to the Regional or Assistant Directors, as appropriate. Regional Directors and Assistant Directors must use the guidance provided in the Program memoranda to make such determinations. Before the review of influential information begins, the Region or Program must develop and post a peer review plan on the Region or Program peer review website. The peer review plan must identify an individual by name that has overall responsibility for the review. The specifications of a peer review plan may be found on page 42 of the OMB Peer Review Bulletin: http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf

#### VI-6 Peer Review Agenda

FWS publishes its forecast (updated every 6 months) of influential scientific information and highly influential scientific assessments on its public website as the "Agenda of Peer Review" at http://www.fws.gov/informationquality/peer\_review/index.html Agenda information posted includes title of information document, contact name and contact information, peer review and public review dates and method planned. Each Region and National Program will post (and update every 6 months) their specific forecasted Peer Review Agenda on their respective region/program websites and link to the national FWS Peer Review Agenda website on the national FWS Homepage website.

The FWS must provide an opportunity for the public to comment on each peer review plan. Official public comment periods as announced through the Federal Register are not required for peer review plans, but may be appropriate in some cases. Each plan shall include an electronic mail address or website where such comments can be sent. Comments received should be considered before the peer review plan is implemented, if possible. For example, if a rulemaking is being made available for public comment for 60-90 days, the public notice may call for all comments on the peer review plan to be submitted during the first 20-30 days. At that point, any comments on the peer review plan can be considered and any modifications made. Then the peer review can begin and the peer reviewer comments can be accepted during the open public

comment process. The peer review plan should be updated during the process as needed.

If information is determined not to be influential, the Regional Director or Assistant Director will determine whether or not the information should be peer reviewed to maintain high scientific standards. Regions may delegate the authority to make such determinations to project leaders.

In rare circumstances, a court-ordered deadline for production of decision documents (i.e. rulemaking etc.) may not leave time for an appropriate peer review of information contained in the document prior to submission of the document to the court. Therefore, the peer review may be abbreviated, omitted or alternative methods used if the court's deadline is less than 120 days from the date of the order. Alternative methods such as post hoc peer review are suggested in these circumstances because the FWS is still responsible for the quality of the information contained in the decision document.

# VI-7 <u>How will the results from peer reviews of influential information be made available to the public?</u>

The FWS will not conduct anonymous peer reviews of influential information. Reviewers of influential information will be advised that their independent reviews, including their names and affiliations, and how the FWS responded to their comments will (1) be included in the official record for this review, and (2) once all the reviews are completed, will be available to the public. These documents will either be posted on the Region or Program peer review website or the peer review website will contain a link to the documents.

Peer review plans and other associated documents deemed necessary must remain posted (see VI-6 Peer Review Agenda) until the OMB report to Congress for the year in which that peer review occurred goes to Congress. Generally, for a peer review conducted in FY1, the OMB report to Congress is submitted about the 3<sup>rd</sup> quarter of FY2 but may be later. Contact the Office of the Science Advisor to get the specific dates of the OMB submission of the peer review report to Congress. After the report to Congress has been submitted by OMB, the peer review plan and attendant links may be archived but still should be retrievable for 6 years through some reasonable means if the public seeks a copy of it.