

**FDA STAFF MANUAL GUIDES, VOLUME IV - AGENCY PROGRAM
DIRECTIVES**

GENERAL OR MULTIDISCIPLINE

DISPUTE RESOLUTION

SCIENTIFIC DISPUTE RESOLUTION AT FDA

Effective Date: 01/13/2009

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1. PURPOSE

As part of the ongoing effort to improve the process of internal scientific dispute resolution, and to encourage open communication throughout the agency, this document describes how issues of scientific dispute are managed throughout FDA.

This document sets forth mandatory elements to be included in all scientific dispute resolution processes at the Centers, Office of Regulatory Affairs (ORA) and Office of the Commissioner (OC). In addition, the document provides recommendations for “best practice” activities related to scientific dispute resolution that are either ongoing in Centers, ORA, OC, other agencies or other outside organizations, or that have been suggested by focus groups with FDA employees.

This document also establishes an agency-wide appeals process for internal scientific disputes. Scientific disputes should be resolved whenever possible at the working level within the organization, and after full and frank discussion involving interested parties. When that is not possible, the process contained in this document provides all FDA staff an avenue to further pursue significant scientific disputes that they feel has not been adequately addressed within their Center, ORA or OC.

2. BACKGROUND

The September 2007 Values and Vision all hands broadcast communicated the organizational values that are important to the agency and set the course for the future with a three-part plan to develop leadership, improve processes and enhance resources for a science-led agency, and empower employees through effective communication. In addition, six Agency core values were unveiled: integrity, excellence, accountability, equity, diversity and transparency. The Commissioner, Dr. Andrew von Eschenbach, highlighted the importance to a scientific agency of encouraging and valuing presentation and discussion of differences of opinion. In that spirit, the process of addressing internal differing scientific opinions at FDA is being strengthened.

3. SCOPE AND POLICY

This Staff Manual Guide (SMG) is issued under the following guiding principles:

- FDA encourages the resolution of scientific disputes at the working level in the organization, starting with frontline employees and their immediate supervisors or team leaders.
- The agency's appeals process for scientific disputes is not a replacement for robust and fair Center-level processes.

It is the Agency's policy that all staff should be aware of the paths available to them in case of issues of scientific dispute, that all staff, including initiators of disputes, are treated with openness and respect, and that the agency procedures should not be unnecessarily burdensome.

The FDA Scientific Dispute Resolution (SDR) program is intended to address serious scientific disputes concerning issues that could have a significant impact on public health. They are NOT intended to address issues related to personnel and work environment situations; these types of disputes already have processes in place for their resolution, as do other types of non-scientific disputes.

Every effort will be made to provide FDA staff with an opportunity to resolve scientific disputes internally. The agency-wide program for SDR has two components: agency requirements for the adoption of robust SDR processes at the Centers, ORA and OC (hereafter "Centers"), and an agency-wide process review. Through these processes, the agency will assure that all valid scientific disputes can and, if needed, will receive a full and fair hearing. (see Section Heading 5, sub heading E, for a description of the scope of the review that occurs at the Agency level).

Section 6.1 of this document details FDA's requirements for the minimum standards for scientific dispute resolution processes in the Centers. The Center SDR

requirements serve two purposes. First, robust Center processes foster the principle of resolution at the working levels within the organization. Second, the agency requires that a Center Director will provide a written decision on a case before the Commissioner will address it. These requirements ensure that disputes will be eligible for the agency's appeals process.

Section 6.2 of the document provides a collection of "best practice" SDR activities. The recommendations are not mandatory, but do reflect some of the best ideas for what thoughtful and effective Center SDR processes could include, and may be adopted by Centers as applicable to their own needs.

Section 6.3 of the document describes an appeals process for scientific disputes that are not resolved to the satisfaction of all involved at the Center level. The appeals process provides an avenue to internally resolve disputes by submitting a case for review to the Office of Accountability and Integrity and receiving a final decision from the Commissioner regarding the Centers' compliance with its procedures.

It is the responsibility of all those involved to ensure that all initiators of disputes are protected from any retaliation by their supervisors, peers, leadership and others, related to initiating or engaging in this process. This Staff Manual Guide does not supersede the fundamental protections pursuant to the Whistleblower Protection Act of 1989, the Federal Employee Anti-discrimination and Retaliation (No FEAR) Act of 2002 and all applicable federal laws, regulations and Executive Orders that afford protection under the law.

4. DEFINITIONS

- A. Agency Scientific Dispute Process Review Board:** The Agency Scientific Dispute Process Review Board (hereafter Board) is a standing committee comprised of representatives of the Office of Accountability and Integrity, Ombudsmen from all Centers and the agency (or officials so designated) and representative(s) from the Office of the Chief Scientist. The Board is chaired by the Chief Scientist. At the discretion of the Chair, additional members may be assigned to the Board on a case by case basis. The Board will assess whether Center processes were followed.
- B. Initiator:** In the Agency dispute process, the initiator is the party that believes that a significant scientific issue has not been adequately addressed by Center dispute resolution processes. The initiator may be an individual, group, or organizational unit (division, office, etc.). Because scientific disputes at the agency might span more than one Center, initiators need not come from the same Center where the decision was made.
- C. Scientific Dispute:** Disputes addressed through this process must be scientific in nature. Eligible disputes may, for example, involve the interpretation of science and decisions taken upon that interpretation. The following disputes are NOT

considered to be scientific disputes and would not be eligible for this process: personnel disputes such as EEO disputes, administrative disputes, labor and employment disputes, enforcement policy disputes and disputes related to the rule-making process.

5. RESPONSIBILITIES

- A. Initiator of SDR process:** The initiator is responsible for submitting the initial documents needed for entry into the SDR appeals process to the Office of Accountability and Integrity (see Section 6.3.C.1 for requirements for complete submission). As soon as it is apparent that Center-level dispute resolution procedures have not resolved the dispute, the initiator should consider the potential public health impact and promptly file a formal SDR request, if appropriate. In addition, the initiator is responsible for fully cooperating with the formal SDR process; this participation may include presenting his or her case to the agency SDR committee(s), providing other documentation as necessary to the case review, and being interviewed by the committees.
- B. Center and agency Ombudsman, or designated official from the Office of the Director:** Ombudsmen at the Centers and agency, or officials so designated, are responsible for being sufficiently familiar with the formal SDR process to effectively counsel potential initiators who approach their offices. At any point in the dispute process, these officials may be approached by the initiator, or any other persons involved in the dispute for consultation. Ombudsmen from the Centers and Agency will serve on the Agency Scientific Dispute Process Review Board. However, the Ombudsman of the involved Center will only participate in presenting the case and the Center's procedures to the Board, but will recuse him/her self from the Board's deliberations.
- C. Center leadership:** Leaders at each Center are responsible for designing a new, or modifying an existing, SDR process for their organization, such that it incorporates all aspects as required by this SMG. Center leaders are also responsible for instituting SDR processes that reflect the guiding principles of openness and resolution of scientific disputes at the lowest organizational level possible. Finally, Center leaders are responsible for communicating the SDR process and training all Center staff on the informal and formal procedures available to resolve scientific dispute internally.
- D. Center Directors:** For each scientific issue under dispute, Center Directors are responsible for ensuring that the SDR process in their organization is documented, communicated, implemented, and conforms to the standards required by the agency (see [21 CFR 10.70](#) and Section 6.1). This responsibility includes maintaining and providing a complete administrative record of the SDR process that was followed for each dispute. They are also responsible for rendering written decisions on disputes that have advanced to them through the scientific dispute resolution processes in their individual organizations. Center Directors are

also responsible for cooperating with the agency's appeals process through interviews, information requests, and presentations to the agency SDR committees, as necessary. Finally, the Center Director is responsible for working closely with the agency SDR committee, the Chief Scientist and the Commissioner throughout an appeal, and carrying out any corrective actions that the Commissioner requires.

- E. Agency Scientific Dispute Process Review Board:** Responsible for conducting full and fair evaluations of the disputes to assess whether the Center's processes were followed, whether the Center considered all relevant evidence bearing on the scientific question at issue, and whether the initiator was provided an opportunity to express his or her concerns at all appropriate levels, prior to and including the Center Director.

Specific responsibilities of the Board include the following:

- Collecting all information needed to fairly and objectively review a case
- Consulting all expert opinions that are relevant to the review of each case
- Documenting the findings and rationale behind any recommendations it makes
- Communicating the findings and recommendations to the Commissioner

The Board is also responsible for notifying the Center Director when a decision at their Center is being appealed. In every dispute, members of the Board from Center(s) where disputes arise will recuse themselves from the dispute review process.

- F. Chief Scientist (CS):** The Chief Scientist will chair the Agency Scientific Dispute Process Review Board. The CS will make recommendations to the Commissioner about whether a Center failed to follow its processes and/or did not provide an adequate opportunity to the initiator to express his or her concerns; that all relevant evidence bearing on the scientific question at issue has been considered; and, whether the dispute should be remanded to the Center Director.

- G. FDA Commissioner:** When Center decisions are appealed, the FDA Commissioner will be responsible for rendering a final decision on whether a Center followed its processes, whether the Center provided an adequate opportunity to the initiator to express his or her concerns; whether all relevant evidence bearing on the scientific question at issue has been considered; and whether the dispute should be remanded to the Center Director for corrective action. The Commissioner will work with the Center Director to determine what corrective actions must be taken, if any.

6. PROCEDURES

6.1 REQUIREMENTS FOR SDR PROCESSES AT THE CENTERS

Center management shall create an atmosphere in which consultation and open discussion on controversial issues are encouraged. When disagreements occur, it is necessary to follow appropriate procedures for resolving them. Informal methods, using good management practices for resolving conflict, should be employed prior to instituting the more formal procedures described here. Notwithstanding informal good management practices used to try to resolve the conflict, timely written reviews of the scientific matter in dispute should be completed by all members of a review group, including initiator and supervisors, to enable as open and complete a discussion of the issues as possible at the working level of the organization. If informal attempts fail, requirements for the formal procedures for resolving disagreements at each Center are described below.

A. Requirements for Inclusion in the Formal Scientific Dispute Resolution Process at Each Center

The following requirements should be considered mandatory process inclusions, and must be incorporated into Center activities within Fiscal Year 2008:

1. Required elements of each Center's Standard Operating Procedure (SOP)
 - a. Each Center is required to have an SDR SOP
 - b. If a dispute is not resolved before reaching a Center Director, the Director must render a written opinion on the matter, as this step is a central criterion for advancement to the agency-level appeals process.
 - c. While the scientific dispute resolution process is pending, work on the application and a final regulatory decision will continue unless the Center Director decides that:
 - (1) The appeal raises substantial questions involving a significant risk to the public health, and
 - (2) Postponing the decision would not result in a negative impact on the public health.

Further, center personnel are not expected to postpone regulatory decisions on INDs, IDEs, Food Contact Substance Notices, etc.

- d. Timeframe for rendering a written opinion must be included, and should be developed by each Center consistent with regulatory/statutory timeframes.
 - e. Each SOP must make reference to the agency-level process as the appeals process for a dispute, should the Center-level dispute resolution process be exhausted.
 - f. Timeframes for elevating a dispute to the agency scientific dispute appeals process must be included in the Center SOP.
 - g. Each SOP should include a process by which disputes of sufficient immediacy and scale of impact to public health are able to 'opt-up' to the Center Director in order that he or she can make a decision on the matter within a condensed timeframe.
 - h. SOPs must include certain key messages for SDR
 - (1) SOPs will encourage dispute resolution at the lowest organizational level possible.
 - (2) SOPs will encourage open communication throughout the organization.
 - (3) SOPs will clearly state that initiators will be protected from any repercussion or retaliation by supervisors, Center leadership, and peers.
 - i. Each SOP will make clear the roles and responsibilities of Center staff in the SDR process, including that of the Ombudsman, where one exists.
2. Required communication in each Center's SDR process
- a. Center leadership is responsible for developing and disseminating clear written procedures for internal scientific dispute processes, including the timeline for rendering a written opinion. Center leadership is also responsible for communicating SDR responsibilities to all levels of staff on an annual basis.
 - b. FDA's Administrative Practices and Procedures Regulations provides that all FDA employees responsible for handling a matter are also responsible for insuring the completeness of the administrative file (see 21 CFR 10.70).

- c. In addition to documentation required by 21 CFR 10.70, decisions related to the formal SDR process and their supporting rationale will be documented.
- d. At all Centers, decisions related to the formal SDR process and their supporting rationale will be communicated to appropriate parties.

6.2 RECOMMENDATIONS FOR SDR PROCESSES AT THE CENTERS

The following recommendations are offered as FDA's perspective on "best practice" SDR activities. While these recommendations are not considered mandatory, they do reflect some of the best ideas for what a thoughtful and effective Center SDR process could include, and can be adopted by Centers as applicable to their own needs.

A. Best Practices for Formal Scientific Dispute Resolution Processes at the Centers

1. Recommended communication in each Center's SDR process
 - a. Centers could employ various mechanisms to disseminate their SOPs
 - (1) Mechanisms for dissemination could include, but are not limited to, one or more of the following: e-mail, orientation for new staff, workshops, hard copy distribution, online training programs, and an interactive SDR website, interactive SDR slide presentation.
 - (2) Centers may decide to regularly reinforce the importance of SDR via Center retreats or other annualized training programs
 - b. Center SOPs should require that only written documentation of a dispute will trigger a formal dispute resolution process. This step would ensure that the necessary historical record of the dispute is available should it advance to the agency-level appeals process.
 - c. Centers may require each side of the scientific issue under dispute to present their case in writing to enable transparent review at successive steps of the process. It is also considered best practice to document all decisions made at successive levels in the dispute process.

Additionally, in-person meetings with the initiator of the dispute to communicate final decision(s) and rationale may be adopted by Centers as they see fit.
2. Recommended role of the Center Ombudsman, or designated official in the Office of the Director, in the Center's SDR process.

The Center Ombudsman could informally communicate with initiators throughout the SDR process to increase the initiators' comfort with it.

3. Training and mentorship as tools to encourage open communication and the resolution of scientific disputes
 - a. Because supervisors and scientists are often the first level where scientific disputes arise, they may be trained on good management practices, including how to resolve disputes.
 - (1) Centers may institute training programs for all staff on the SDR process and good dispute resolution practices in general.
 - (2) Centers may implement procedures to evaluate supervisors on their management skills and ability to resolve scientific disputes.
 - (3) Centers may enable a "feedback loop" through Center Ombudsmen to counsel individuals (e.g., supervisors or working-level staff) who are frequently involved in formal scientific disputes.
 - b. Mentorship and training programs to encourage open communication
 - (1) Scientists may be paired with non-supervisory mentors.
 - (2) Institute training to produce team norms, process of managing conflict in teams, team charters, etc. for review teams and other groups.
4. Monitoring use of the SDR process

Centers may include questions on annual staff surveys to gauge awareness of and satisfaction with SDR process.
5. Possible formal avenues for scientific dispute resolution apart from chain-of-command mechanisms
 - a. Utilize external experts to seek objective perspective, additional scientific expertise, and practical knowledge. Examples of these are experts from other Centers, ORA and OC, other agencies, and SGEs, who can be used for written consultation.
 - b. Make several avenues available to address scientific issues: regulatory briefings, advisory committees, internal discussions with Center Directors, standing subject matter committees, and multi-disciplinary teams.

B. Best Practices for Informal Scientific Dispute and Communication

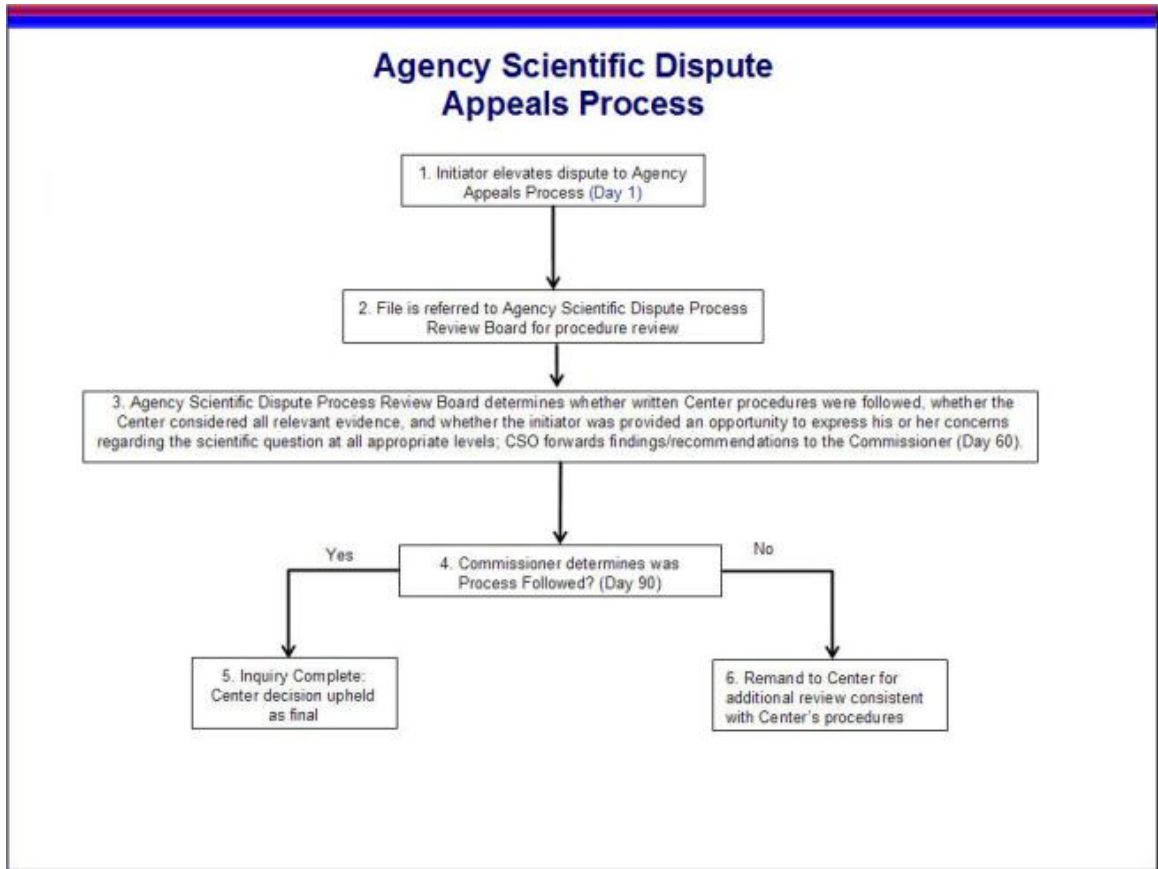
Every effort should be made to informally resolve differences in opinion on scientific matters. There are a variety of methods that Centers and other organizations already employ to foster informal dispute resolution, and still more that were suggested by internal focus groups.

A non-exhaustive list of informal resolution mechanisms includes the following:

1. Institute informal peer review and / or round table discussions. One method could be to institute formalized weekly meetings to informally discuss “hot topics,” or issues of potential dispute.
2. Use [Center Ombudsman](#) (if applicable) for informal perspective and to help filter personnel-related issues.
3. Increase two-way communication within the review process. For example, Centers could choose to have employees meet regularly with their supervisors as a review team to discuss on-going reviews, substantive problems and their recommendations.

6.3 DESCRIPTION OF THE AGENCY’S APPEALS PROCESS FOR SCIENTIFIC DISPUTES

If an initiator is not satisfied after engaging in the scientific dispute resolution process at the Center, this appeals process provides an additional avenue to resolve disputes internally. All scientific disputes under appeal will be reviewed by the Agency Scientific Dispute Process Preview Board, and the Commissioner will make a final decision about the issue under dispute.



A. Description of appeals process for scientific disputes

1. Elevation of disputes to the appeals process marks entry of internal scientific disputes into the formalized agency SDR appeals process. Disputes can advance from the individual Center-level SDR processes into the appeals process if the initiator feels that the dispute has not adequately been addressed / resolved at that level. The initiator must elevate the scientific dispute issue to the agency appeals process within 10 days of receiving the written opinion rendered by the Center.

At this step, the initiator must submit the case, in writing, to the Office of Scientific Integrity (OSI). Receipt of case by OSI will be mark the first day of the agency scientific dispute appeals process. The submission will include:

- Description of how the initiator's position differs from Center's perspective
- Assessment of possible impact to public health should initiator's position not be adopted

- Detailed description of the history of the dispute, including initiator's description of the Center SDR procedures followed and/or not followed, dates of meetings, and decisions rendered throughout the process
 - Action, decision or remedy sought
2. The Agency Scientific Dispute Process Review Board will review the initiator's file, and obtain any other information necessary, to evaluate whether it meets the criteria for review. Other necessary information may include written documentation from the Center. They will assess the information and conclude whether the case meets the following criteria:
- At a minimum, the dispute must be scientific in nature. The Board will not evaluate disputes that are not based on science.
 - The Center Director must have rendered a decision on the scientific issue under dispute.

The Board will notify the Center Director that a scientific dispute has been submitted for appeal.

3. The Board will gather all necessary additional information that will enable a fully-informed recommendation on the case. The Board will obtain the full administrative record of the Center's processes for the dispute and review the Center's published SOP(s). As needed, the Board will conduct interviews with all relevant parties in the dispute, which may include the initiator, team leader, Center Director, and others. They will review the information to determine whether written Center processes were followed

The goal of this review is to determine if the processes followed in the Center fully considered all relevant evidence and provided the initiator with an opportunity to express his or her concerns at all appropriate levels, prior to and including the Center Director. The Board will document findings and recommendations and the Chief Scientist will present his or her recommendations to the Commissioner. Representatives of the involved Center will not participate in this review.

The Board should complete its review by the sixtieth (60) calendar day in the agency SDR appeals process.

4. If the Agency Scientific Dispute Process Review Board determines that the Center's processes and procedures were followed appropriately, that the Center fully considered all relevant evidence and the initiator was provided an opportunity to express his or her concerns regarding the scientific question bearing on the dispute, the Center's decision will be

upheld as final and a written recommendation will be distributed to all internal parties involved in the dispute. The Board findings will be forwarded to the Commissioner and the agency SDR process will be concluded.

5. If the Agency Scientific Dispute Process Review Board finds that the Center's processes and procedures were not followed appropriately, that the Center did not fully consider all relevant evidence and/or the initiator was not provided an opportunity to express his or her concerns regarding the scientific question bearing on the dispute, the Chief Scientist will provide a written recommendation to the Commissioner that the case be returned to the Center for additional review consistent with the Center's procedures. This memo will consist of the Board's rationale for the recommendation, all minority opinions from panelists, and a proposed statement to be used to communicate the Commissioner's decision.
6. The Commissioner will review the Board's recommendation and render a final decision on whether a Center followed its processes, whether the Center provided an adequate opportunity to the initiator to express his or her concerns, and whether the dispute should be remanded to the Center Director for corrective action. The Commissioner will work with the Center Director to determine what corrective actions must be taken, if any.

The Commissioner will communicate this decision, and a short rationale for the decision, in writing to each side of the dispute.

The final decision will be rendered by the Commissioner, by the ninetieth (90) calendar day of the agency SDR appeals process.

B. Anticipated timing of the scientific dispute resolution appeals process

1. From the time that the initiator submits a dispute to the Office of Accountability and Integrity for review, the SDR appeals process will be completed within 90 calendar days.
2. At the discretion of the Commissioner, the process may be accelerated because of statutory or regulatory timelines or urgency of agency decision.

C. Documentation requirements throughout the SDR appeals process

1. Documentation required for entry to the process

The initiator's written case must include the following elements:

- (1) Description of how the initiator's position differs from Center's perspective

- (2) Assessment of possible impact to public health should initiator's position not be adopted
- (3) Detailed description of history of the dispute, including initiator's description of the Center SDR procedures followed and/or not followed, dates of meetings, and decisions rendered throughout the process
- (4) Action, decision or remedy sought

7. EFFECTIVE DATE

The effective date of this guide is January 13, 2009.

8. Document History -- SMG 9010.1, Scientific Dispute Resolution at FDA

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	01/12/2009	N/a	OC/OP/OAI , HF-22	Susan C. Winckler, FDA Chief of Staff
Change	06/19/2019	Sect. 6.3.A.1 change OAI to OSI	OC/OCS/ OSI	Matthew Warren, Director, OC/OCS/OSI

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