Center for Devices and Radiological Health Standard Operating Procedure (SOP)

RESOLUTION OF INTERNAL DIFFERENCES OF OPINION IN REGULATORY DECISION-MAKING

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1. PURPOSE

This document sets forth the general policy for the Center for Devices and Radiological Health (CDRH) for resolving internal differences of professional opinion and provides an approach for documentation of associated scientific, clinical and regulatory findings, perspectives and opinions. The procedures in this document apply to all differences of professional opinion within CDRH, except those expressly excluded. This policy implements 21 CFR 10.75 for internal review of CDRH decisions, as it applies to supervisory review of regulatory decisions on the initiative of Center employees in the process of reaching those decisions.

This document supersedes the Standard Operating Procedure (SOP) for Resolution of Internal Differences of Opinion in Regulatory Decision Making, dated October 30, 2009. As with the preceding version, this SOP conforms to the requirements and recommendations of the Staff Manual Guide (SMG) for Scientific Dispute Resolution at FDA (SMG 9010.1 of 01/13/2009). Procedures described in this document are harmonized with similar procedures in other FDA Centers such as the CDER MAPP 4151.1 Rev 1, Scientific / Regulatory Dispute Resolution for Individuals Within a Management Chain, and with the concepts espoused in the draft FDA Staff Manual Guide on Scientific Integrity at FDA. Portions of these procedures were developed with reference to the Nuclear Regulatory Commission Directive 10.159.

2. BACKGROUND

When any regulatory decision or action is considered, CDRH should reach an institutional position after all appropriate scientific and regulatory recommendations and perspectives are obtained, documented, and considered. This process is often complex and may involve multiple staff members and disciplines and may cross organizational boundaries. In most cases, alignment on a decision is achieved through discussion during progress toward a decision. Open and respectful discussions enhance the quality of Center decisions and it is incumbent on all Center employees to maintain an atmosphere of inclusion, professionalism, and mutual respect. In situations where differences of opinion arise during the decision-making process and are resolved through discussion, it is important that the official administrative file captures these differences and the resolution thereof.[1]

Given the complex, multi-layered nature of decision-making and the diversity of expertise of CDRH staff, it is expected that differences of professional opinion will arise in the normal course

[1] Such documentation should conform to the requirements of 21 CFR 10.70, concerning the documentation of significant decisions in the administrative file.

of business. These differences may be scientific, clinical, or regulatory in nature, or some combination of the three. When differences of professional opinion arise between peers or between an individual and their next-level manager or supervisor[2] and cannot be resolved through discussion, and the parties are unable to align with a decision, then the procedures set forth in this policy can be invoked.

3. POLICY

The policy of CDRH is to maintain a working environment that encourages employees to make known their best professional judgments, even though they may differ from the prevailing staff view, disagree with a management decision or policy position, or take issue with proposed or established Center practices. All Center employees are responsible for maintaining an atmosphere of openness, trust, professionalism, and mutual respect. This includes ensuring that staff members who express informal or formal differences of professional opinion are encouraged to express these opinions and are protected from retaliation by their peers, managers, and Center leadership. In addition to this policy, there are fundamental protections provided by the Whistleblower Protection Act of 1989, the Federal Employee Anti-Discrimination and Retaliation (No FEAR) Act of 2002, and various federal laws, regulations and Executive Orders that may apply. Nothing in this document should be interpreted as infringing on these protections.

All individuals involved in reaching a regulatory decision or recommendation are expected to have made reasonable efforts to engage in discussions or other informal means of resolving differences of opinion before initiating the procedures set forth in this document. In some circumstances, an individual may be reluctant to approach members of management about a dispute. In those instances, the individual can discuss the situation with the CDRH Ombudsman and the conversation can be treated as confidential, if desired.

The appointment of an individual to a management position within CDRH conveys the authority to make certain regulatory decisions.[3] Regulatory decisions are generally based on input and recommendations of subordinates. Where differing staff opinions exist, the administrative file should document the varying opinions and provide the rationale for the regulatory decision. Prior to reaching a decision, reasonable opportunity should be afforded for discussion and consideration of differing opinions. After a decision has been made, it is incumbent upon the individual who disagrees with the decision to initiate the dispute resolution process. However, as described in SMG 9010.1, progress toward implementation of the decision will continue and Center personnel are not expected to postpone regulatory decisions unless the manager to whom a dispute is referred determines that: (a) the dispute raises substantial questions involving a significant risk to public health; or (b) postponing the decision would not result in a negative impact on the public health or on the ability of the Center to meet specified timelines.

[2] The terms “manager” and “supervisor” are intended to refer to individuals appointed to positions with executive authority. This excludes individuals in leadership positions without executive authority such as team leaders and non-managers who are on temporary assignment to management positions.

[3] See, for example, delegations of authority in SMG 1410.408.

If an individual has reason to believe that resolution of a difference of professional opinion through a stepwise progression through the chain of command will likely result in a significant and immediate negative impact on public health, then the individual should consult with the CDRH Ombudsman to discuss whether to bring the matter to the immediate attention of Center leadership (see section 8 -- Accelerated Review

4. SCOPE

This policy applies to differences of professional opinion regarding scientific, clinical, and/or regulatory issues that arise in the process of reaching a Center decision or action. The formal procedures set forth in this policy should not be invoked until the parties involved have made good faith efforts to resolve differences through informal means.

The following circumstances do not fall within the scope of this policy:

- Personnel disputes, allegations of misconduct, or similar issues that are or could have been appropriately addressed under grievance procedures or personnel appeal procedures;
- Issues that are purely legal in nature (as opposed to issues surrounding how a statute or regulation applies in a scientific or clinical situation);
- Issues that are subject to collective bargaining;
- Process-related issues such as whether appropriate staff members were engaged in the development of a regulatory decision; or
- Issues that have already been considered and addressed or rejected through the appropriate process, unless significant new information has become available.

5. DEFINITIONS

5.1. AdministrativeFile.

Under 21 CFR Part 10, Administrative Practices and Procedures, 21 CFR 10.70 states "FDA employees responsible for handling a matter are responsible for insuring the completeness of the administrative file relating to it. The file must contain appropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes of meetings, and other pertinent written documents." The file must also contain "recommendations and decisions of individual employees, including supervisory personnel, responsible for handling the matter" and "reveal significant controversies or differences of opinion and their resolution." An employee who "has worked on a matter may record individual views on that matter in a written memorandum, which is to be placed in the file."

This policy is intended to conform to the requirements of 21 CFR 10.70, specifically with respect to documentation of significant controversies and differences of opinion. For internal disputes that are significant to a regulatory decision and are resolved informally, the file should contain documentation that reflects the following at a minimum: a description of the nature of the disagreement including disparate viewpoints; a description of the decision made and the basis for the decision; and, a description of the means by which the disagreement was resolved. Disputes that are resolved through the

means provided by this SOP should be reflected in the administrative file by inclusion of relevant documents associated with the dispute, including at a minimum the Initiation Memo (see section 6.1) and the decision of the Next Highest Management Official (see sections 5.4 & 6.3). Note that for disputes involving premarket review files, the Lead Reviewer is responsible for ensuring that the administrative file is complete and the Next Highest Management Official is responsible for providing relevant documents to the Lead Reviewer. For all other disputes, the Next Highest Management Official is responsible for the administrative file.

5.2. Alignment.

The concept of alignment is an expression of general support for a position to be taken or a decision to be made. Alignment does not necessarily imply full agreement by all individuals, disciplines, and organizational components involved in the action. Rather, alignment indicates that all involved individuals agree to support the action to be taken. Alignment should be based on the knowledge that all perspectives, including alternative opinions, and a range of potential options were considered in reaching a decision. Therefore, the action can be considered reasonable even if the action differs from individual opinions or recommendations.

5.3. Initiator.

The initiator of the process described in this procedure is the party who disagrees with the decision made after reasonable efforts have been made to resolve the disagreement informally. Although the term is singular, the initiator may be an individual, group or organizational unit, and may be a line employee, a member of management, or a combination thereof. Documents written by a group of initiators must be signed by all individuals in the group.

5.4. Next Highest Management Official.

This refers to the manager one level above the organizational level at which the dispute is initiated or contested. If the dispute is between peers or crosses organizational boundaries, the Next Highest Management Official is the individual managing the peers or who oversees all of the organizational units involved in the dispute. Ultimately, this could be the Director of CDRH. When a dispute crosses organizational boundaries such as Division or Office, the affected Directors should attempt to resolve the matter between or among themselves prior to elevating the dispute to the Next Highest Management Official.

6. PROCEDURES

A dispute that cannot be resolved by informal means and that falls within the scope of this document may be brought to the Next Highest Management Official for resolution.

6.1. Initiation.

To invoke the formal process, the initiator writes a statement, called an Initiation Memo, describing the position, concept, opinion, recommendations, or decision with which the Initiator disagrees, the nature of and reasons for the difference in opinion, as well as the

proposed changes and rationale for changes in recommendations and/or conclusions. The Initiation Memo must be submitted to the Ombudsman for review within ten (10) calendar days of the triggering event. In appropriate circumstances the Ombudsman may grant an extension if requested within the ten day initiation period. The Initiation memo should include:

- A summary of the situation in dispute, including: prevailing staff view(s); existing management position, decision or policy; or, established Center practices; and, a brief description of efforts employed to resolve the dispute;
- A description of the Initiator's views and how they differ from the proposed decision or Center action;
- An assessment of the consequences if the Initiator's position is not adopted by the Center; and,
- Copies of, or links to, relevant documents and any other supporting information.

The contents of the Initiation Memo should relate only and specifically to the factual, scientific, clinical, and/or regulatory issues for which there is an internal difference of opinion and should avoid defamatory remarks, undocumented allegations, or irrelevant matters such as personnel issues. A template for the Initiation Memo is attached at the end of this SOP and should be used when the initiator invokes the dispute resolution process.

6.2. Ombudsman Review.

The Initiation Memo is provided by the Initiator to the CDRH Ombudsman who determines within ten (10) calendar days whether the matter in dispute qualifies for resolution under this SOP. If the Ombudsman determines that the issues in dispute, or the circumstances surrounding the difference of professional opinion, disqualifies the matter for consideration under the procedures called out in this document, then the Ombudsman will provide the Initiator with a written response explaining the rationale for the decision to disqualify the dispute. The response may also provide recommendations for alternative means for resolving the dispute. An Initiation Memo that is incomplete may be returned by the Ombudsman to the Initiator seeking additional information to correct the deficiencies.

If the Ombudsman determines that the dispute qualifies for resolution under these procedures, then a memo to that effect is written and is placed in the Administrative File along with the original Initiation Memo. The Ombudsman then transmits the documents relevant to the dispute to the Next Highest Management Official for his or her consideration and resolution.

6.3. Review and Resolution.

The Next Highest Management Official must take differing opinions into consideration and the views of all persons involved in the process will be respected. The manager should ensure that the administrative file documents the differences of opinion. After review, discussion, and consideration of all relevant points of view, the Next Highest Management Official will: make a decision on the matter; write a memorandum stating

and supporting his or her decision; provide a copy to the Initiator; and, place the memorandum in the administrative file.

6.4. Appeal within Center.

If a party to the dispute cannot align with the decision made, then that party may choose to continue the dispute resolution process by presenting the dispute, along with the decision, up the management chain to the Next Highest Management Official, following the same process outlined above. For example, a reviewer may write an Initiation Memo to request that a Division Director review a difference of opinion between the reviewer and his or her Branch Chief. If the Division Director issues a decision supportive of the reviewer, then the Branch Chief may elect to request that the Office Director review the dispute. The Branch Chief then becomes the Initiator by submitting an Initiation Memo with the Ombudsman. This process can be repeated until the dispute ultimately reaches the Director of CDRH, or his or her designee, for consideration and resolution.

6.5. Appeal to Agency.

If after exhausting the dispute resolution process described in this document a party to the dispute believes that their opinion was not adequately considered or the process was not followed appropriately, or the party disagrees with the Center Director's decision, the party should follow the process described in FDA Staff Manual Guide (SMG) 9010.1 to bring the matter to the attention of the Agency Scientific Dispute Process Review Board and the Commissioner's Office. As provided in the SMG, the dispute must be elevated to the agency appeals process within ten (10) days of receiving the written decision of the Center Director.

6.6. Timing.

The Next Highest Management Official reviewing a dispute should render a decision as soon as feasible, but generally within forty-five (45) calendar days of receipt of the documents relating to the dispute, although disputes referred for outside expertise (see section 7) or involving unusually complex issues may take longer. An Initiator appealing a decision to the next highest level in the supervisory chain should do so within ten (10) calendar days of the date of the decision. However, as mentioned previously, a final regulatory decision will not be delayed pending resolution of an internal dispute except in specific circumstances (see section 3).

7. OUTSIDE EXPERTS

Reference to outside expertise may consist of an advisory panel meeting or a homework assignment to selected Special Government Employees (SGEs) with relevant expertise. In the Initiation Memo, an Initiator may request referral of a dispute to outside expertise. Such a request should include a statement of whether an advisory panel meeting or homework assignment is requested and should provide the rationale for the request. The Next Highest Management Official reviewing the dispute will render and document a decision on the request, and may also, on his or her own initiative, elect to refer the matter to outside expertise as part of reaching a decision. After a dispute has been initiated, additional requests for consultation, including referral of all or part of a dispute for outside expertise, may be submitted by the Initiator to the Next Highest Management Official for consideration. The Next Highest

Management Official will approve or deny the request and will document the reasons for the decision in the final decision document.

8. ACCELERATED REVIEW

As mentioned elsewhere in this document, a matter in dispute that may have a significant and immediate impact on the public health, may qualify for accelerated review by Center leadership up to and including the Center Director. An Initiator who believes that the dispute rises to this level should consult with the CDRH Ombudsman, who will make an initial determination and a recommendation to Center leadership. If a dispute is subject to Accelerated Review, Center leadership should consult with all levels of relevant CDRH management in reaching a decision.

9. DELEGATED AUTHORITY

The Next Highest Management Official may designate a Deputy to review and render a decision on a dispute initiated under the provisions of this policy. In this instance, the decision of the Deputy will have the effect of a decision by the Next Highest Management Official, and any appeal will be referred to the next level in the supervisory chain of command.

10. REFERENCES

Center for Drug Evaluation and Research Manual of Policies and Procedures, MAPP 4151.1 Rev. 1, revised September 16, 2010

FDA Staff Manual Guides, Volume IV, Dispute Resolution, Scientific Dispute Resolution at FDA; SMG 9010.1, dated January 13, 2009

FDA Staff Manual Guides, Volume II, Delegations of Authority, Regulatory – Medical Devices and Radiological Health, Approval, Disapproval, or Withdrawal of Approval of Product Development Protocols and Applications for Premarket Approval, and Humanitarian Device Exemptions for Medical Devices; SMG 1410.408 Rev 1, revised March 23, 2011

FDA Staff Manual Guides, Volume XX, Scientific Integrity at FDA, draft dated August 2, 2011

Nuclear Regulatory Commission Differing Professional Opinions Program Directive 10.159, revised May 16, 2004

11. EFFECTIVE DATE

This document is effective upon publication.

CHANGE CONTROL TABLE

VERSION #	REASON FOR CHANGE	EFFECTIVE DATE	APPROVING OFFICIAL (NAME/TITLE)
1.0	Original	10/30/2009	Jeffrey Shuren, MD, JD

			Director, Center for Devices and Radiological Health
2.0	2-year revision—circulated for Center comments	05/01/2012	Jeffrey Shuren, MD, JD Director, Center for Devices and Radiological Health
2.1	Updated to address comments received	09/04/2012	Jeffrey Shuren, MD, JD Director, Center for Devices and Radiological Health