

FDA Staff Manual Guides, Volume III – General Administration

FDA Official Councils and Committees

FDA Inspectional Affairs Council (IAC)

Effective Date: May 6, 2026

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1. Purpose

The Inspectional Affairs Council (IAC) was formed to serve as a cross-agency governance structure that coordinates strategic decision-making and improves alignment between the Office of Inspections and Investigations (OII) and Centers, Offices, and Program (COP) on enterprise-wide interdependent inspectional matters. The Council serves as a unifying venue to modernize inspectional operations, strengthen inspectional workforce strategies, and streamline agency-wide processes that impact FDA's inspection oversight capabilities in a rapidly evolving global environment. This Staff Manual Guide describes the responsibilities of the council, its membership, and its operating procedures.

2. Background

The FDA's Office of Inspections and Investigations lead all FDA field inspection, investigation, import, and criminal law enforcement activities to protect America's public health and safety.

The Inspectional Affairs Council is established by the Office of the Commissioner and the Office of Inspections and Investigations to address the need for enhanced coordination on enterprise-wide interdependent inspectional matters across FDA. While acknowledging differences in statutory authorities, regulatory frameworks, and existing COP-specific inspectional governance structures, the Council aims to strengthen cross-Agency collaboration, promote consistency where appropriate, and support innovation in inspectional approaches.

The IAC operates under a dual decision-maker governance model with member consensus input and is advisory in nature, not superseding existing statutory authorities or regulatory decision-making responsibilities of individual Center, Office, or Program.

3. Scope

The Council is charged with facilitating accountability, strengthening coordination, enhancing operational efficiency, and ensuring consistent inspectional oversight for enterprise-wide matters across all FDA product areas.

This includes:

Strategic Resource Deployment: Deliver vertical integration and operational excellence, through a right-sized model ensuring science-driven and technical expertise, and risk-based and transparent oversight across the Agency, while aligning inspectional operations, strategic inspectional planning, and workforce investment for enterprise-wide matters.

Improve Operational Capacity: Develop strategies for enhanced collaboration, resource sharing, workforce development, reduced training time for certifications and standardized processes across the Agency where binding interdependencies exist.

Regulatory Predictability: Where appropriate, ensure consistency and standardization across all facility evaluation and inspection activities, globally, while preserving center-specific expertise.

Technology Integration and Modernization: Leverage technology to optimize interagency coordination, unify cross-agency data to streamline inspection processes, and support the implementation of novel assessment technologies to modernize regulatory inspections.

The scope does not include individual inspection decisions; advisory, compliance, or enforcement actions; or operational matters that fall within existing COP authorities.

4. Membership

The IAC operates under a dual co-chair model and includes COP executives.

A. IAC Leadership:

1. **IAC Co-Chair:** Deputy Commissioner for Strategic Initiatives (DCSI) (or delegate in the Office of the Commissioner)
2. **IAC Co-Chair:** Associate Commissioner for Inspections and Investigations, Office of Inspections and Investigations (OII)

B. Core Members:

1. FDA Center Directors - CBER, CDER, CDRH, CTP, CVM
2. Deputy Commissioner for Human Foods
3. Deputy Commissioner for Policy, Legislation, and International Affairs
4. Chief Scientist, Office of the Chief Scientist

C. Advisory Members:

1. Center Deputy Director
2. Principal Deputy Director, Human Foods Program (or designee)
3. Deputy Chief Scientist
4. Principal Deputy Associate Commissioner for Inspections and Investigations (PDACII)
5. Associate Commissioner for Global Policy and Strategy
6. Principal Deputy Chief Counsel, Office of Chief Counsel
7. Chief Financial Officer

D. IAC Support Team:

1. The IAC Support Team will be assigned by the IAC co-chairs.
2. Team consists of OC DCSI and OII Senior Advisors.

E. Additional Attendees:

Additional FDA leaders and/or relevant subject matter experts may be invited to attend meetings on an ad hoc basis. These individuals participate as observers and are not voting members of the IAC.

5. Responsibilities

A. **IAC Co-Chairs.** The IAC co-chairs have joint responsibility for:

1. Ensuring accountability for Council outcomes.
2. Integrating member input into advisory-making processes.
3. Justifying any advisory decisions that significantly diverge from member recommendations.

4. Setting the direction and priorities of the IAC.
5. Determining meeting agendas and facilitating IAC meetings.
6. Promoting balanced participation of all IAC members.
7. Engaging in good-faith deliberation to reach consensus on recommendations.
8. Sharing emerging trends identified by a COP or challenges in inspectional operations.
9. Updating the Office of the Commissioner on inspectional policy.

B. IAC Core Members:

1. Regularly attend meetings, when feasible; presence counts toward quorum. A quorum for the council is a majority of the core members.
2. Actively participate in meetings and review materials in advance.
3. Represent their Center, Office, or Program perspectives on inspectional matters.
4. Share appropriate issues, updates, and decisions within their respective Center, Office, and Program.
5. Engage in good-faith deliberation to reach consensus on recommendations.
6. Lead, delegate, and/or participate in committees and working groups as needed.
7. Share emerging trends identified or challenges in inspectional operations.
8. Submit consensus-based recommendations.

C. Advisory Members:

1. May participate on a consultative and technical basis.
2. Offer counsel and subject matter expertise and guidance.

D. IAC Support Team:

1. Coordinate with subject matter experts from relevant operational divisions to provide technical expertise on specific workstreams.

2. Manage operations and activities of the IAC.
3. Serve as liaison between the IAC and other governance groups.
4. Manage meetings, create agendas, document decisions, and communicate outcomes.
5. Facilitate development of information needed for IAC review.
6. Analyze data related to inspectional operations to inform decision-making.

6. Procedures

Council activities include:

- Advance strategic alignment across OII and Centers, Offices, and Program establishing coordination mechanisms.
- Foster coordination and timely information flow to maintain clear accountability for inspectional outcomes while promoting shared ownership of public health goals.
- Optimize coordination and communication reducing operational redundancy, improved responsiveness, and better alignment between organizations.
- Strengthen communication with industry, international regulatory partners, and other stakeholders on inspectional matters.

Participation in activities of the Council is restricted to the members principals listed in the Membership section. In the limited instances in which the principal listed is unavailable or has changed, a single designee may represent their office in discussions. Members may request topics of which subject matter experts will be invited to present, as warranted.

A. IAC Meetings

1. The IAC will meet monthly or as otherwise decided by Co-chairs.
2. Ad hoc meetings may be scheduled at the discretion of IAC Co-chairs.
3. Committee and working group meetings will occur as needed.
4. Relevant meeting documents will be provided by email in advance of the meeting. Agenda topics selected are intended for FDA internal use only.

5. Meeting minutes with action items will be prepared and distributed by email to all Council members.
6. Agenda topics, meeting minutes and accompanying IAC documentation such as, but not limited to, decisional email correspondence, are for internal use only and part of the deliberative process.

B. IAC Committees and Working Groups

1. Standing committees may be established for specific areas of responsibility.
2. Term-limited working groups may be established to address emerging or urgent concerns.
3. Memoranda will outline the purpose, scope, deliverables, and membership of any committee or working group established.

C. Decision Making

1. Quorum shall be established to ensure engagement to reach consensus for key recommendations. A quorum for the council is a majority of the current voting members.
2. Co-chairs review recommendations and make final decisions within an established timeframe.
3. Decisions are communicated to members in a timely manner, including rationale and impact/effectiveness.

D. Policy Recommendations

1. Policy recommendations promulgated from the IAC will refer to the appropriate COP member.
2. The implementation of new policy or changes in policy will be monitored by the Council.

7. Effective Date

This policy becomes effective on May 6, 2026.

8. Document History – SMG 2010.24 “FDA Inspectional Affairs Council (IAC)”

Status (I,R,C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	05/05/2026	N/A	Strategic Initiatives Special Counsel, OGC Office of Inspections and Investigations (OII)	Lowell Zeta, J.D. Deputy Commissioner Elizabeth Miller, Pharm.D. Associate Commissioner