

Policy Development and Review Procedures #190-1 (blue book memo) (Text Only)

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

February 15, 1990

Policy Development and Review Procedures

Purpose.

The purpose of this guidance is to establish a procedure to assure the regular and timely establishment and review of ODE guidance documents and policies.

ODE Management Staff.

Twice each year, prior to two of the designated ODE management staff meetings, each Division, the Program Operations Staff, and the Program Management Office should review the status of ODE guidance memoranda ("Blue Book" memos) to determine whether ODE should consider the issuance of a blue book memo on a topic not yet covered or whether an existing memorandum needs to be updated. The management staff meetings at which the status of ODE guidance documents will be reviewed will be announced in advance. This subject will appear on the agenda for the designated meeting.

In reviewing the status of ODE guidance documents the directors should solicit opinions on the status of ODE policies matter from the division or office supervisors and staff members.

ODE Staff Members.

At any time an ODE staff member may suggest a change in ODE's policies and procedures. This could include the modification or deletion of a current policy or the establishment of a new policy. To do so the staff member should raise the matter with his or her immediate supervisor or the division or office director. Any suggestion should be accompanied by a brief written description of the proposed change, its purpose, and the potential benefits and burdens that may be realized by adopting the policy. The division director should present the suggestion at a weekly division

directors meeting for discussion. Any change in policy that is appropriate will be implemented through the normal "Blue Book" procedures.

Effective Date.

This policy is effective immediately.

More in Guidance Documents (Medical Devices and Radiation-Emitting Products)
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance
(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)