POLICY AND PROCEDURES

OFFICE OF MANAGEMENT

Developing and Issuing MAPPs for CDER

Table of Contents

PURPOSE **1**
BACKGROUND **1**
POLICY **2**
RESPONSIBILITIES **2**
PROCEDURES **5**
REFERENCES **9**
DEFINITIONS **9**
SUMMARY OF CHANGES **11**
EFFECTIVE DATE **11**
CHANGE CONTROL TABLE **11**
ATTACHMENT 1 – MAPP Clearance Flow Chart 12

PURPOSE

This Manual of Policies and Procedures (MAPP) establishes a system for issuing directives (i.e., MAPPs) within the Center for Drug Evaluation and Research (CDER) for the purpose of documenting and disseminating CDER policies and procedures. This MAPP specifies policy, procedures, and responsibilities for the origination, revision, recertification, transfer, clearance, maintenance, and cancellation of MAPPs within CDER.

BACKGROUND

- The Federal Managers Financial Integrity Act of 1982 (FMFIA) requires federal agencies to establish and maintain adequate systems of internal control for accounting and administrative activities.
- U.S. General Accounting Office (GAO) *Standards for Internal Control in the Federal Government* states, "Internal control is a major part of managing an organization. It comprises the plans, methods, and procedures used to meet missions, goals, and objectives, and, in doing so, supports performance-based management."
- Office of Management and Budget (OMB) Circular A-123 requires federal agencies to establish internal control documentation to include policies and procedures, organization charts, manuals, memoranda, flow charts, and related

written materials necessary to describe organizational structure, operating procedures, and administrative practices for accomplishing programs and activities.

- FDA Staff Manual Guide 2020, FDA Quality System Framework for Internal Activities, sets minimum standards for implementation of quality system-controlled directives (including MAPPs) and training (see 5.a.Requirements §0.3(b) and §2.1(c)(2)).
- CDER's MAPP system was established in 1996 and is maintained on the FDA Web site as "Manual of Policies & Procedures (CDER)" at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm.

POLICY

- All office, division, and CDER-wide operating policies and procedures will be published as MAPPs and will remain in effect until they are revised, recertified or canceled.
- The Office of Management will oversee the MAPP system.
- Each MAPP will be reviewed for currency at least every 5 years.
- The system and formats prescribed in this MAPP will be used to issue all MAPPs in CDER.
- Interim MAPPs are temporary (generally effective for 1 year from date of posting) and not publicly available. They are, however, available to CDER staff on the CDER intranet. It is the responsibility of the office that creates the MAPP to ensure that it is still active.

RESPONSIBILITIES

Associate Director for Management in the Office of Management (or designee)

- Clears all MAPPs to ensure adherence to established policies and procedures for MAPP development and review

Director of Regulatory Policy in the Office of Regulatory Policy (or designee)

- Clears Policy MAPPs, as well as Policy and Procedure MAPPs, to ensure adherence to established CDER policies

Super Office or Office Director (or designee)

- Ensures that all office policies and procedures are documented in MAPP format and all employees understand MAPPs relevance to their job performance
- Confirms that all MAPPs originating in the office and subordinate offices remain accurate and current
- Clears all draft MAPPs that:
  - originate in the office
  - originate in other super offices or offices, but reference the office

  - have a CDER-wide impact (clearance occurs at Senior-Staff level)
- Appoints MAPP coordinators or MAPP editors; depending on office procedures, may appoint MAPP authors
- Ensures that interim MAPPs posted on the intranet are reviewed after 1 year and either cancels or clears the MAPP for posting on the public MAPPs Web site
- Ensures an implementation plan is developed that includes appropriate time between the posting date and the effective date for implementation activities to take place when necessary (see MAPP Toolbox on inside.FDA for guidance)
- Communicates the existence of newly posted, revised, recertified, canceled, or transferred MAPPs to employees

CDER MAPP Team (CMT)

The responsibilities of the CDER MAPP Team include supporting, coordinating, and reviewing the development of MAPPs and maintaining the MAPP systems.

CMT supports:

- Documentation of CDER policies and procedures in MAPP format
- Currency of information in MAPPs by tracking MAPP posting dates and reporting regularly to super offices and offices on the status of MAPPs, including those that are due for review
- MAPP authors, editors, and coordinators in development, editing, and clearance of MAPPs. Additionally, the team reviews proposed MAPPs for consistency with existing authorities (e.g., with FDA Staff Manual Guide)
- Super offices or offices without MAPP editors by providing editorial services (using the CDER Style Guide for editing and The Associated Press (AP) Stylebook to reconcile any issues not addressed in the CDER Style Guide)
- MAPP development by determining the necessary clearance outside the originating office for each MAPP, based on the MAPP's impact on other CDER offices
- Communication strategies to alert CDER staff to the existence of newly posted, revised, recertified, or canceled MAPPs

CMT coordinates:

- CDER-level clearance of proposed and revised MAPPs, including sending received comments to MAPP coordinators
- Timely posting of new, revised, transferred, and interim MAPPs, and timely removal of canceled MAPPs on the CDER MAPP Web page

CMT works with MAPP coordinators by:

- Ensuring that CDER staff are alerted to significant new MAPP postings
- Holding regular CDER-wide meetings with MAPP coordinators as a group to share information and strategies

- Communicating regularly with individual MAPP coordinators to review the status of office MAPPs

CMT maintains:

- MAPP templates and facilitates their use through user training
- The MAPP numbering system
- The MAPP Team SharePoint site, to provide the status of all draft, and current MAPPs
- The MAPP Team SharePoint site advertising newly posted or revised MAPPs
- Copies of all archived MAPPs in Documentum, in accordance with National Archives and Records Administration (NARA) guidance
- CDERMAPPTeam@fda.hhs.gov email and monitors for correspondence related to MAPPs

MAPP Coordinator[1]

- Serves as the point of contact for all MAPP production, recertification, revision, transfer, and cancellation processes in the super office or office
- Assists super office or office management with documenting office policies and procedures in MAPP format
- Establishes office clearance procedures, including documentation of clearance steps, for all MAPPs, with approval from super office or office director (or designee)
- Submits the MAPP initiation form to the CMT at outset of MAPP development to discuss appropriate formatting and clearance procedures and to obtain MAPP number upon submission of the draft MAPP
- Informs CMT, as needed, of status of draft MAPP development, implementation plan, and clearance processes
- Facilitates development and clearance of draft MAPPs, including assisting authors with the use of MAPP templates and planning implementation activities as needed
- Coordinates with authors and editors to reconcile comments on draft MAPPs from CDER subject matter experts and referenced super offices or offices
- Provides super office or office-level-cleared MAPPs to CMT for CDER-level clearance
- Provides authors with CDER-level comments, obtained by CMT during the clearance process, for incorporation into draft MAPPs
- Updates CMT on MAPP status changes, including clearance, cancellation, recertification, and transfer; provides appropriate documentation to CMT (see MAPP Forms for Coordinators under Procedures below)
- Attends MAPP coordinator meetings
- Communicates regularly with CMT to review the status of office MAPPs

[1] Some of the described responsibilities are performed by a MAPP editor, depending on the super office or office

- Coordinates review of each MAPP within their office at least once every 5 years to ensure that MAPPs are current

Author

- Drafts MAPP using the appropriate MAPP template
- Consults with MAPP coordinator and CMT, as needed, to ensure appropriate format and clearance path for draft MAPPs
- Consults, as needed, with appropriate subject matter experts within and outside the originating office for development of MAPPs
- Coordinates and reconciles input with the MAPP coordinator and MAPP editor (if applicable) on draft MAPPs from all subject matter experts and super offices, subordinate offices, or offices that are referenced in the MAPP
- Provides draft MAPPs to the MAPP coordinator to be sent to the MAPP editor (CMT or specific editor for super office or office) for editing in accordance with the CDER Style Guide
- Works with the MAPP coordinator to clear MAPP at the office or subordinate office level, according to office procedures
- Ensures all affected offices are represented in the working group if a working group is involved in the development of a MAPP

MAPP editor (if applicable)

- Edits draft MAPPs originating in his or her super office or office, using the CDER Style Guide, and assists with MAPP clearance according to office procedures
- Coordinates and reconciles input with the MAPP coordinator and author on draft MAPPs from subject matter experts and super offices or offices referenced in the MAPP

PROCEDURES

MAPP Forms

- MAPP Initiation Form – Use this form to initiate a MAPP (also called MAPP Services form).
- MAPP Recertification and Cancellation Form – Use this form to recertify, revise, or cancel a MAPP (also called MAPP Work Request form).
- Clearance Record (FDA Form 2306) (PDF - 360KB) – Use this form to clear new and revised MAPPs.
- Transfer Memo – Use this form to initiate a transfer of MAPP ownership between offices.

MAPP Numbering

- Each super office or office is assigned a range of numbers. CMT will assign individual identification numbers to each MAPP within this range, based on available numbers in proximity to posted MAPPs with similar subject matter. This numbering system consists of a three-part symbol as follows:
  1. the acronym "MAPP"
  2. a four-digit number within the originating office's grouping
  3. the next sequential number, following the decimal point (.X)
- If a MAPP is a revision of a previously posted MAPP, the revision number will be listed immediately following the number (e.g., MAPP 4000.1 Rev. 4).

Format

- All MAPPs will be written in the appropriate MAPP template format. See Definitions for descriptions of MAPPs. The templates, with explanations of each section, are in the MAPP Team SharePoint site. (For access to the site, contact CDERMAPPTeam@fda.hhs.gov.). Information can also be found in the MAPP Toolbox.

Conflict Resolution

- The authors, subject matter experts, and MAPP coordinators will take reasonable steps to reach alignment on MAPP provisions under development.
- The principles of MAPP 4151.8, *Equal Voice*; MAPP 4151.1 Rev.1, *Scientific/Regulatory Dispute Resolution for Individuals Within a Management Chain*; and MAPP 4151.2 Rev. 1, *Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and CDER Director*, are applicable.

Style

- All MAPPs will be written and edited in accordance with CDER Style Guide.

Draft Status

- MAPPs remain in draft status until signed by the Associate Director for Management.
- A draft MAPP will contain the "DRAFT" watermark. CMT will remove the watermark before posting and archiving.

Clearance of new MAPPs at super office or office level by the originating office (see also Attachment 1)

- At the onset of MAPP development, the MAPP coordinator will contact CMT to discuss formatting and clearance, and to obtain a MAPP number.
- For MAPPs involving more than one super office, describe in the purpose section of Form 2306 any implementation activities, such as staff notification or training and the proposed time delay between the MAPP's posting and effective dates to allow the referenced offices to carry out the implementation activities.

- Prior to final clearance by the originating office, a draft MAPP will be cleared by directors of super offices, subordinate offices, or offices referenced in the MAPP, using Form FDA 2306.
- Next, the MAPP will be cleared by the director of the originating office, using Form FDA 2306.
- MAPP coordinators will then submit the cleared MAPP, along with Form FDA 2306, to CMT for clearance at the CDER level.

Clearance at CDER level

- CMT will submit MAPPs affecting CDER-wide operations to Senior Staff for clearance, using the CDER clearance form found in the MAPP Team SharePoint site and the MAPP Tool Box, with a deadline of 10 business days from receipt. Senior Staff may request a deadline extension. Non-response by the deadline signifies concurrence of the MAPP and proposed implementation plan.
- CMT will submit Policy and Procedures MAPPs, as well as Policy MAPPs, to the Director of Regulatory Policy in the Office of Regulatory Policy for clearance.
- CMT will submit all MAPPs to the Associate Director for Management for final clearance.

Regular Review

- Each super office, subordinate office, and office will evaluate its currently posted MAPPs at least every fifth year, to ensure they are current and reflective of office and CDER missions. CDER offices and divisions will continually evaluate their existing policies and procedures to ensure they are documented in MAPP format.
- CMT will alert MAPP coordinators 1 year in advance of MAPPs that are approaching their 5-year reevaluation date.
- Each super office, subordinate office, and office will review and finalize interim MAPPs as soon as possible after the MAPP has been posted on the intranet for 1 year.

Recertification

- Super offices or offices will recertify MAPPs that continue to reflect current CDER policy and procedures every 5 years by having the super office or office director sign a recertification memorandum to CMT.
- The recertification memorandum is available in the MAPP Team SharePoint site and the MAPP Tool Box on inside.FDA/CDER. CMT will maintain documentation of such recertification.
- The CMT will insert the recertified date in the footer of the MAPP.

Revision

- Super offices and offices will revise MAPPs needing substantive updating.

- A revised MAPP will be cleared as if it were a new MAPP.
- A revised MAPP will supersede the previous version of the MAPP by the same title (or covering the same subject matter).
- CMT will assign the revised MAPP the same MAPP number as the previous version and will include the revision number listed immediately following the MAPP number (e.g., MAPP 4000.1 Rev. 4).
- Interim MAPPs that are cleared for posting on the MAPPs Web site will retain the MAPP number (no revision number is necessary) because previous iterations were never public.
- Super offices and offices will provide significant changes in the revised MAPP in a numbered list in the Change Control Table on the last page of the MAPP.
- CMT will note the effective dates of all previous versions of the MAPP in the lower left footer of the MAPP in strike-through format.

Non-Substantive Revision

- CDER offices may suggest non-substantive revisions to an existing MAPP at any time; such revision does not require formal clearance.
- MAPP editors, coordinators, or CMT will specify the non-substantive revisions, and CMT will forward changes to the Web team for posting.
- Examples of non-substantive revisions include changes in contact information, office names, Internet addresses, corrections to formatting, and typographical errors.

Transfer

- A MAPP may be transferred from one office to another if an office reorganization occurs. This requires the signatures of the directors of both the transferring and receiving offices.
- Super offices will clear transfers of MAPPs owned by their subordinate offices.
- A transferred MAPP will receive a new MAPP number corresponding to the receiving office.
- The MAPP transfer form is available in the MAPP Team SharePoint site and the MAPP Tool Box.

Cancellation

- Super offices or offices will cancel obsolete MAPPs by a formal memorandum that is signed by the director of the originating office, after consultation with all other super offices, subordinate offices, and offices that are referenced in the MAPP. Super offices will clear cancellations of MAPPs originating in their subordinate offices. The cancellation form is available in the MAPP Team SharePoint site and the MAPP Tool Box on inside.FDA/CDER.
- CMT will alert the CDER Web team to remove a canceled MAPP.

REFERENCES

1. OMB, 2004, Circular A-123, Revised, Management's Responsibility for Internal Control.
2. NARA, 2003, Records Management Handbook.
3. GAO, 1999, Standards for Internal Control in the Federal Government.
4. OMB, Federal Managers Financial Integrity Act of 1982.
5. FDA, 2010, CDER, MAPP 4151.1 Rev. 1: Scientific/Regulatory Dispute Resolution for Individuals Within a Management Chain.
6. FDA, 2006, SMG 2020 FDA Quality System Framework for Internal Activities
7. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.2 Rev. 1: Resolution of Differing Professional Opinions: Review by Ad Hoc Panel and CDER Director.
8. FDA, 2010, Center for Drug Evaluation and Research, MAPP 4151.8 Equal Voice: Discipline and Organizational Component-Collaboration in Scientific and/or Regulatory Decisions.
9. FDA/CDER Style Guide.

DEFINITIONS

Note to reader: The following three definitions are out of alphabetical order for clarity:

Office - An office that reports to the CDER Director and is neither a super office nor a subordinate office.

Super Office - An office that reports to the CDER Director and to which subordinate offices report.

Subordinate Office - An office that reports to a super office.

Author – Writer in the originating office with responsibility for drafting or revising a MAPP.

CDER MAPP Team (CMT) – Office of Management (OM) team that assists CDER staff with the development, review, and posting of new MAPPs; manages the system of existing MAPPs; and archives canceled MAPPs.

Interim MAPP – MAPP with a stipulated termination date, usually 1 year from the date of issuance. Because the information contained in an Interim MAPP is temporary, it is not publicly available. An Interim MAPP is posted on the CDER intranet for staff reference.

Manual of Policies and Procedures (MAPP) – Compilation of office policies and procedures, designed to guide staff in the conduct of their work. Each numbered entry is commonly referred to as a "MAPP."

MAPP coordinators – Representative(s) of each office or super office, appointed by their office directors, who coordinate MAPP evaluation, drafting, development, clearance, issuance, revision, recertification, and cancellation. Coordinators for super-offices generally coordinate MAPPs for their subordinate offices. For the name of an office MAPP coordinator, contact the MAPP Team at CDERMAPPTeam@fda.hhs.gov.

MAPP editors – Professional writer/editors located in several offices, super offices, and in CMT. Super-office writer/editors generally edit MAPPs for their subordinate offices.

Originating office – Super office or office that recognizes the need for a MAPP, drafts the MAPP, and coordinates its review within the originating office and other regular, super, or subordinate offices that are referenced in the MAPP. The originating office is responsible for ensuring that the MAPP remains current.

Policy MAPP – Describes a high-level principle or plan to guide decisions and actions in support of CDER goals.

Procedure MAPP – Documents the specific steps necessary to accomplish some aspect of the work of CDER or its component offices or divisions.

Policy and Procedure MAPP – Contains a policy statement and procedures for implementing a Policy and Procedure MAPP.

Program Description MAPP – Identifies and documents the roles, responsibilities, and operational procedures of CDER teams, programs, boards, or committees.

Recertification – Process by which an originating office certifies that an existing MAPP remains current.

Review – Process of reexamination of existing MAPPs by the originating office. Such review will occur at least every fifth year. CMT will remind offices 1 year in advance of the need for review. Following review, MAPPs will be recertified, revised, or canceled.

Revision – Process by which an originating office makes substantive changes to a MAPP. Revisions require the same clearance process as original MAPPs. A MAPP may be revised by the originating office at any time.

Senior Staff clearance – Concurrence by CDER Senior Staff.

Subject matter expert – A CDER staff person with unique knowledge of the content of a MAPP.

Working Group – Representatives of two or more offices coordinating the development of a MAPP.

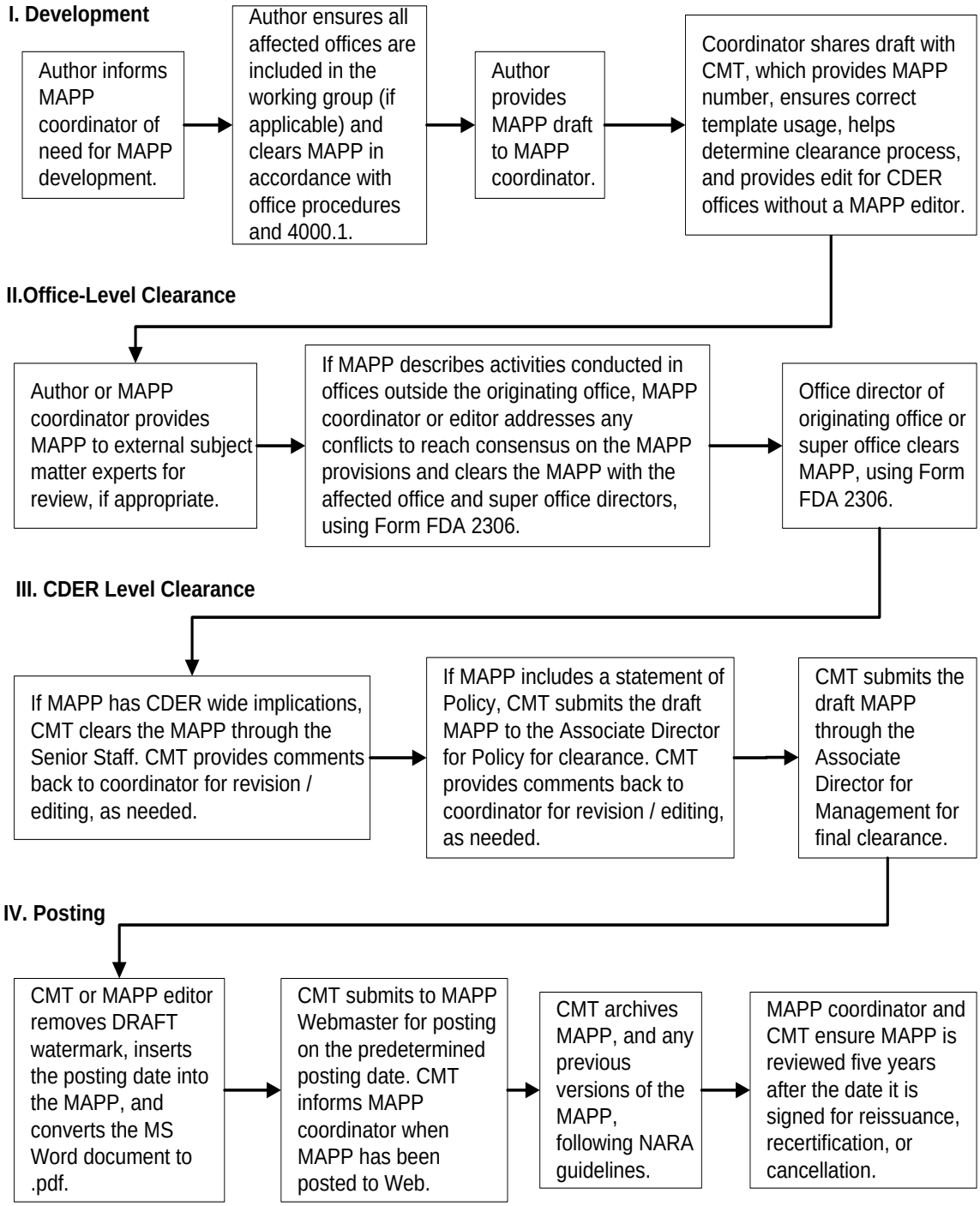
SUMMARY OF CHANGES

1. Reflects responsibility for management of the MAPP system within the Office of Management.
2. Establishes guidelines for MAPP revision, recertification, and cancellation.
3. Requires all MAPPs be recertified every fifth year.
4. Modifies the conflict resolution and clearance process.
5. Updates definitions, responsibilities, and templates.
6. Updates the list of references.
7. Replaces references to eRoom with the MAPP Team SharePoint site.
8. Establishes new responsibilities and procedural steps for developing an implementation plan for MAPPs.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
4/22/96	Initial	n/a
9/24/96	Rev. 1	Adds policy on Interim MAPPs. Identifies new MAPP categories.
3/17/06	Rev. 2	1. Changes a number of definitions, and responsibilities. 2. Shortens CDER-wide clearance period from 15 to 10 days. 3. Attaches template and cover sheet. 4. Adds screen shots of MAPPs on (1996) Internet.
9/26/11	Rev. 3	1. Reflects OM responsibility for the MAPP system. 2. Establishes guidelines for MAPP revision, recertification, and cancellation. 3. Requires all MAPPs be recertified every fifth year. 4. Modifies the conflict resolution and clearance process. 5. Updates definitions, responsibilities, and templates. 6. Adds six references.
9/19/14	Rev. 4	1. Updates the list of references. 2. Replaces references to eRoom with SharePoint site. 3. Establishes new responsibilities and procedural steps for developing an implementation plan (activities and time period) for MAPPs affecting more than one super office.

ATTACHMENT 1 – MAPP Clearance Flow Chart