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# Manual of Standard Operating Procedures and Policies

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## Regulatory Information Systems

### Administrative Handling of Change Requests for Regulatory Review Automated Support Systems

SOPP 8008.1

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#### 1. Purpose

The purpose of this document is to provide guidance to CBER staff on:

- Procedures for requesting modifications to any CBER-wide Regulatory Review Automated Support System
- Responsibilities and procedures of the Change Control Board (CCB) in evaluating and acting on change requests

#### 2. Definitions

##### **Change Request (CR)**

A change request is a request for any kind of modification of or addition to a Regulatory Automated Support System. CRs may include any proposed change in a system, ranging from addition of a field value to creation of another report, screen or even a new system. Requests to fix technical problems or data errors (problem reports) are not considered CRs.

##### **Points of Contact**

The Points of Contact are the office-designated CCB members. The CCB Points of Contact should be knowledgeable about their Office processes in order to facilitate decision making in a timely manner. (See the CCB Public Folder in Outlook for a listing of all current CCB members. The list will be updated as board membership changes.)

##### **Regulatory Automated Support Systems**

Regulatory Automated Support Systems are interactive systems and databases that support the management of the review process. Those currently under the purview of the CCB include:

- **RMS/BLA**
  - Regulatory Management System/Biologics License Applications - Database manages the Centers biologics licensing processes.
- **BRMS**
  - Biologics Regulatory Management System - The legacy licensing management database. Now

accessible Read only.

- **BIMS**

- Biologics IND Management System - Database tracks all regulatory and administrative information on Investigational New Drugs (INDs), Investigational Device Exemptions (IDEs) and Master Files (MFs).

- **NDA**

- New Drug Application System. Manages NDAs and Abbreviated New Drug Applications (ANDAs)

- **CRMTS**

- CBER Regulatory Meetings Tracking System - Database tracks all information related to the regulatory meetings that occur between CBER and the industry.

### 3. **Background**

CBER's Strategic Plan for 2004 has as one of its goals "Interactive Information Systems which are Integral to all CBER Activities." Two strategies to accomplish this goal are to "fully integrate information systems to support a seamless regulatory process" and "support the development and use of interactive databases." Substantial efforts have been made by the Center in adding, improving or replacing existing information systems. Oversight of these efforts has been the responsibility of the Information Management Coordinating Committee (IMCC).

A key component of information system support, during and after development of the databases, is a formal, organized process for change control by the users. Responsibility in this area has varied, particularly for systems in development. Although the BIMS/BRMS Users Subcommittee (BUS) has played a significant role in handling change requests for BIMS and BRMS for a number of years, the expansion of regulatory information systems requires a more formal and visible group to oversee the change control process. The CCB, a sub-committee of the Review Management Coordinating Committee (RMCC), will replace the BUS. The CCB will be chaired by the Director of RIMS. The responsibilities and authority of the CCB are outlined in its Charter (Attachment A).

### 4. **Policy**

The Change Control Board will compile, evaluate and make decisions or recommendations on all change requests for the regulatory automated support systems. Change Requests will be submitted to the CCB through the Regulatory Information Management Staff (RIMS). The CCB will have representation from each office in the Center, and will report to the Review Management Coordinating Committee.

### 5. **Responsibilities**

#### **The CCB is responsible for:**

- Receiving (through RIMS) or initiating all CRs
- Reviewing and discussing the CRs presented to the board
- Determining, in a timely fashion, which CRs should be acted on (with or without modification), which should be rejected, which should be deferred
- Prioritizing and establishing timeframes for CRs to be acted on
- Making recommendations to the RMCC on CRs as necessary, including:
  - Those that require additional resources
  - Those that will have a significant impact on Review Management procedures
  - Those significant CRs that the CCB cannot reach consensus on

#### **RIMS is responsible for:**

- Monitoring and triaging CRs entered into the Access Change Request Database (CRD).
- Acting on minor or urgent CRs that do not require CCB review (generally changes that would have no significant impact on office resources or that are needed to meet and new and immediate tracking need). The CCB will be notified of all such actions.
- Assuring that all other CRs are presented to the CCB for action in a timely manner
- Managing board meetings, including:

- Assuring board meetings are scheduled each month.
  - Scheduling additional board meetings or conducting "virtual" meetings via e-mail as necessary
  - Providing board members lists of CRs for discussion prior to the meetings
  - Assuring that summaries of all meetings are prepared promptly and that they are distributed to board members, the RMCC, and the IMCC.
- Disseminating CCB decisions to appropriate Center staff in a timely manner
- Summarizing approved requests and submitting them to the appropriate development staff
- Tracking and documenting actions on all CRs

**The CCB Chairperson is responsible for:**

- Prioritizing the CCB meeting agendas
- Representing the CCB on the RMCC and IMCC
- Presenting all CR recommendations and issues to the RMCC\IMCC as necessary

**OITM is responsible for:**

- Providing estimated cost/time calculations for changes to help the CCB/RMCC/IMCC determine whether requested changes would be cost beneficial.
- Providing staff and contract support for implementing approved change requests

**The RMCC is responsible for:**

- Making necessary decisions or recommendations on CRs presented to the committee.

**The IMCC is responsible for:**

- Making necessary decisions or recommendations on CRs presented to the committee.

**6. Procedures**

**Overview**

CRs will follow the process below. Problem reports (reports of a system or program malfunction, or a data error) will be managed by the Office of Information Technology Management through procedures established by that office.

CRs may originate from any system user, from CCB members, from the coordinating committees, or from Center management.

**Submitting CRs:**

Any proposed CR should first be discussed with the office CCB member(s). The CCB member will enter the CR into CBER's Access Change Request Database (CRD). The CCB member will notify RIMS that a request has been entered.

The request may also be submitted directly to RIMS via e-mail with the following information:

- System and specific screen (e.g., RMS-BLA, Submission Screen).
- Reason for Request (e.g., add a new field).
- Description of change or problem.

**Processing CRs**

For each CR received, RIMS will:

- Assure that the CR has been entered into the CRD.
- Clarify the CR with the requestor or submitting CCB member if necessary.

- Triage the CR. Urgent CRs (e.g., a change is needed to meet a new and immediate tracking need) will be brought to the attention of the CCB Chairperson. Any CRs that are in fact PRs will be directed to the Office of Information Technology Management (OITM).
- Act on the CR if the CR is minor or urgent.
- Schedule any other CR for presentation to the CCB.

### **CCB Review**

CRs scheduled for presentation to the CCB will be prioritized by the CCB Chairperson. The CCB will review and discuss the CRs, and decide by consensus which should be implemented, rejected or deferred. If a consensus can not be reached by the CCB, the Chairperson will present the CR to the RMCC for final resolution.

RIMS will document decisions on the CRs in the CRD, including the reason(s) for the decision. If a CR is rejected or deferred, RIMS will inform the original requestor of the decision. If a CR is accepted for implementation, the Board's decision will be forwarded to OITM for action (see below).

The CCB Chairperson will determine whether the Board's recommendation needs to be presented to the RMCC. If a CR needs RMCC clearance, a summary of the issues and the CCB decision will be prepared by RIMS for presentation.

### **RMCC / IMCC Review**

Any change that would have a significant impact on office information management or review resources or that would require modifications in managed review procedures must be cleared by the RMCC. The RMCC will also review any change requests for which a consensus could not be reached by the CCB.

The RMCC will approve, approve with modifications, defer, or reject each proposed CR presented to it.

If a CR is approved, the committee will determine whether the CR needs to be presented to the IMCC. These CRs will include any which require OITM or contractor resources beyond those allocated for system support and maintenance. A CR that has not yet been decided on by the RMCC may also be presented to the IMCC for consultation. CRs that require review by the IMCC will be presented by the CCB Chairperson.

The IMCC will approve, approve with modifications, defer, or reject each proposed CR presented to it. The reasons for any decision other than approval will be explained to the RMCC. If there is a disagreement about the decision made by the IMCC, the decision will be presented to the office directors for resolution.

### **Follow up and Action on CR decisions**

RIMS will coordinate action on approved CRs. Since most changes will require IT support, RIMS will work with OITM to initiate the change. For those CRs recommended for implementation by the RMCC\IMCC, the CCB Chairperson will provide a proposed time frame and prioritization to OITM. Depending on the scope of the change, specific office CCB members may participate or take the lead in planning and implementing it.

The CRD will be updated by RIMS on all CR decisions and on the status of all approved CRs from the planning period to implementation. Lists of approved CRs pending implementation will be available to the CCB, RMCC, and IMCC via the CCB Public Folder in Outlook. RIMS will also update the CCB on all approved CRs pending action during each monthly CCB meeting.

The CCB will monitor the progress of implementation of approved CRs. Any CR, whether approved, deferred, or rejected may need to be reconsidered at a future time based on changes in the review procedures, system support needs, or available IT resources.

## **7. Appendix**

[CBER Regulatory Information Systems Change Control Board Charter](#)

**8. Effective Date**

April 16, 2001

**9. History**

<b>Written/Revised</b>	<b>Approved</b>	<b>Approval Date</b>	<b>Version Number</b>	<b>Comment</b>
Roger Eastep	Robert Yetter, PhD, Assoc. Dir. for Review Management	April 16, 2001	1	First Issuance of this SOPP

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