


IT STANDARD OPERATING PROCEDURE	DBLGROUP IT DEPARTMENT South Avenue Tower (6th Floor), House-50, Road-3, Gulshan-1, Dhaka, Bangladesh				
TITLE:	Change Management				
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1.0.8 Change Management

1. PURPOSE

The objective of this SOP is to establish a systematic and controlled process for the planning, approval, implementation, and post-implementation review of changes to the IT environment. This process aims to minimize disruptions, enhance system stability, and ensure the security of information systems.

2. SCOPE

This SOP covers all changes to the IT infrastructure, including hardware, software, networks, configurations, and systems, within the organization.

3. ROLES AND RESPONSIBILITIES

3.1 Change Management Board (CMB):

Review and approve or reject change requests.
 Provide oversight and strategic direction for the change management process.
 (See Appendix-A)

3.2 Change Manager:

Oversee the change management process.
 Facilitate communication between stakeholders.
 Ensure compliance with change management policies. (See Appendix-C)

3.3 Change Requesters:

Submit change requests with detailed information.
 Collaborate with IT personnel during the planning and testing phases.
 Provide necessary documentation and justifications.


3.4 IT Administrators:

Participate in the planning and testing of changes.
 Implement approved changes.


4. Change Request Submission:

4.1 Information Required:

Description of the change.
 Justification for the change.
 Impact analysis, including potential risks and mitigations.
 Dependencies on other changes or systems.

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<p>4.2 Submission Process: Change requests must be submitted using a standardized form. (See Appendix-D) Submissions can be made through a designated system or to the Change Manager.</p> <p>4.3 Authorization and Approval: Changes require appropriate authorization based on their impact. The Change Management Board reviews and approves or rejects change requests.</p> <p>5. Change Categorization and Prioritization:</p> <p>5.1 Categorization: Changes are categorized based on their nature (e.g., hardware, software, configuration).</p> <p>5.2 Prioritization: Changes are prioritized based on criticality and impact. Emergency changes are addressed promptly with necessary approvals.</p> <p>6. Change Planning:</p> <p>6.1 Development of Change Plan: Change Requesters collaborate with IT Administrators to develop a detailed change plan. The plan includes resource requirements, timelines, and risk assessments.</p> <p>6.2 Review and Approval: The Change Manager reviews and approves the change plan. The Change Management Board may provide additional input. Procedures:</p> <p>7. Testing and Validation:</p> <p>7.1 Test Environments: Changes must be tested in controlled environments before implementation. System testing and user acceptance testing are conducted.</p> <p>7.2 Validation Criteria: Changes must meet predefined validation criteria before approval. Rollback plans are established in case of testing failures.</p> <p>8. Change Approval:</p> <p>8.1 CAB Meetings: The Change Advisory Board (CAB) meets regularly to review and approve changes. Emergency change approval procedures are followed for urgent changes. (See Appendix-B)</p> <p>9. Change Implementation:</p> <p>9.1 Coordination:</p>					
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IT Administrators coordinate the implementation with relevant teams and stakeholders.

Communication plans are executed to notify affected parties.

9.2 Monitoring:

Changes are monitored during implementation to identify and address issues.

Verification processes ensure the successful completion of changes.

10. Post-Implementation Review:

10.1 Assessment:

A post-implementation review is conducted to assess the success of the change.

Lessons learned are documented for continuous improvement.

10.2 Documentation Update:

System documentation is updated to reflect the implemented changes.

Any improvements to the change management process are documented.

11. Documentation and Record-keeping:

11.1 Change Records:

Comprehensive records of change requests, approvals, and implementations are maintained.

Documentation includes all relevant details, decisions, and communications.

12. Communication:

12.1 Notification:

Stakeholders are notified before, during, and after changes.

A designated communication channel is used for transparency.

13. Training and Awareness:

13.1 Staff Training:


Ongoing training programs are conducted for staff involved in the change management process.

Awareness campaigns emphasize the importance of adhering to change management procedures.

14. Legal and Regulatory Compliance:

14.1 Compliance Check:

The change management process is designed to comply with relevant laws, regulations, and industry standards applicable to the organization.

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ABBREVIATIONS

SOP - Standard Operating Procedure
 IT - Information Technology
 CMB – Change Management Board
 CAB – Change Advisory Board

REVIEW AND REVISION

The SOP is regularly reviewed and updated to incorporate changes in technology and organizational needs.
 Periodic assessments of the change management process are conducted.

COMMUNICATION:

Clearly communicate the SOP to all relevant stakeholders. Ensure that employees are aware of their roles and responsibilities and understand the implications of not adhering to them.

ACCESSIBILITY:


Make the SOP easily accessible to all relevant personnel. This could involve storing it in a central repository, such as an intranet or document management system.

REFERENCES

- FDA's 21 CFR Part 11: Electronic Records; Electronic Signatures
- GAMP 5: A Risk-Based Approach to Compliant GxP Computerized
- Company IT Policies and Procedures
- Industry Best Practices

APPENDICES


APPENDIX-A	Change Management Board (CMB)
APPENDIX-B	Change Advisory Board (CAB)
APPENDIX-C	Change Manager

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APPENDIX-D	Change Request Submission Form						
REVISION HISTORY							
<table border="1" style="width: 100%;"> <tr> <th style="width: 25%;">REVISION DATE</th> <th style="width: 25%;">REVISION NUMBER</th> <th style="width: 50%;">DESCRIPTION OF REVISION</th> </tr> <tr> <td>02 Feb' 24</td> <td>01</td> <td>First edition of the SOP</td> </tr> </table>		REVISION DATE	REVISION NUMBER	DESCRIPTION OF REVISION	02 Feb' 24	01	First edition of the SOP
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APPROVAL		
Prepared by:	Signature	Date
Name: Md. Atiqur Rahman		
Designation: Manager		
Reviewed by:	Signature	Date
Name: Md. Imrul Hasan		
Designation: Sr. Manager		
Approved by:	Signature	Date
Name: Zahidul Alam		
Designation: CIO		
Authorized by:	Signature	Date
Name:		
Designation:		

Distribution: 1. IT Department

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2. HR 3. Related stakeholders (Management Employee)
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