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[Appendix 2f-Template of GAP Assessment]

Title: GAP Assessment for <System Name>

Document No.:

<Document No.>

Page:1 of 15

**GAP Assessment
for
<System Name>**



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APPROVAL PAGE

Prepared By:

Name	Designation	Department	Signature	Date

Reviewed By:

Name	Designation	Department	Signature	Date

Approved By:

Name	Designation	Department	Signature	Date



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REVISION HISTORY

Revision No.	Effective Date	Reason for Revision
		Initial Document



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1.0 INTRODUCTION:

2.0 PURPOSE:

3.0 SCOPE:

4.0 REFERENCES:

Document Number/ Name	Description

5.0 RESPONSIBILITY:

Role	Responsibility

6.0 DOCUMENT PROCEDURE:

7.0 GAP ASSESSMENT CHECKLIST:

This document consists of check list for below listed items:

1. GAP ASSESSMENT

(Tick mark “✓” whichever / wherever is applicable in this document).



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SECTION-A: GAP ASSESSMENT:

Sr.#	Check Points	Expected Results	Actual Observation	Gaps Found?	Remarks
A1: Availability of Required Documents					
1.	User Requirements Specification (URS)	URS should be available	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2.	Operation Manual/ User's Manual	Operation Manual/ User Manual should be available	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3.	Technical Support	Technical support should be in place from the supplier or principal company for system related problem.	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	



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Sr.#	Check Points	Expected Results	Actual Observation	Gaps Found?	Remarks
4.	Wiring Diagram	Wiring Diagram should be available	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
A2: Availability of Required SOPs					
5.	Change Control Management	Change Control Management SOP should be in place.	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.	System Security/ Access Control	System Security/ Access Control SOP should be in place.	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
7.	Periodic Review of Audit Trail and System Records	Periodic Review of Audit Trail and System records SOP should be in place.	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	



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Sr.#	Check Points	Expected Results	Actual Observation	Gaps Found?	Remarks
8.	Data Backup and Restore	Data Backup and Restore SOP should be in place	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
9.	Record Retention	Record retention SOP should be in place	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
10.	System Operation	System Operation SOP should be in place.	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
11.	Training Procedure	Training Procedure should be in place.	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	



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12.	Disaster Management	Disaster Management SOP should be in place	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13.	Authorization Matrix (User Groups/ Roles/ Access rights)	SOP with defined Authorization Matrix of different user roles and their privileges for the system should be in place	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
14.	Preventive Maintenance	SOP for Preventive Maintenance should be in place	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
A3: System Installation and Operation					
15.	Stable Power utilities with power back up	Uninterrupted Power Supply [UPS] should be installed with battery backup.	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	



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Sr.#	Check Points	Expected Results	Actual Observation	Gaps Found?	Remarks
16.	Trainings	Relevant personnel should be trained on required procedures and training record should be available	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
17.	Printed record/ report	Username, print date and time should appear on printed record/ report	<input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
18.	Communication	The communication between Computer system and Instrument should be indicative to confirm	Communication between Computer system and Instrument is indicative: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
A4: Password and Data Security					
19.	Software Start-up	Software should enforce to enter user name and password at the time of software start-up/ login.	User name and password is: <input type="checkbox"/> Mandatory <input type="checkbox"/> Non Mandatory <input type="checkbox"/> N/A <input type="checkbox"/> Synchronized with Domain	<input type="checkbox"/> Yes <input type="checkbox"/> No	



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Sr.#	Check Points	Expected Results	Actual Observation	Gaps Found?	Remarks
20.	Valid credentials	Software system should accept only valid credentials (User ID./ Name and Password) to access the system function	Software System accepts only valid credentials: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
21.	Minimum password length	System should enforce password length.	Minimum password length should be defined <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
22.	Masking of password entry	Password entry should be masked by the system	Password Entry is masked: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
23.	Duplicate User profile	User Profile (User ID.) should be very unique	User ID. is unique: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	



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24.	Password complexity	System should enforce Password complexity	Password complexity is enforced: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
25.	Password history	System should enforce Password History	Password history is enforced: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
26.	Change Password	System should have provision to change password whenever user intends.	Password change facility is: <input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
27.	Auto expiry password	Auto expiry of password should be available and configured.	Password expiry mechanism is: <input type="checkbox"/> In Place <input type="checkbox"/> Not In Place <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	



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Sr.#	Check Points	Expected Results	Actual Observation	Gaps Found?	Remarks
28.	User account lockout	Software should lock out the User Account after consecutive unsuccessful login attempts.	User Account lock out mechanism [after successive in invalid login attempts] is: <input type="checkbox"/> In Place <input type="checkbox"/> Not In Place <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
29.	User Levels/ Roles and access rights	Software should be available with different user levels/ roles and its rights	Different user level/ roles facility is : <input type="checkbox"/> Available <input type="checkbox"/> Not Available <input type="checkbox"/> N/A Different User Levels Configured in System: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
30.	User administration access (to create, deactivate , Reactivate User profile and change in roles)	Administrator only should be able to perform user administration activities.	Only administrator is able to carry out User Administration activities: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
31.	Audit Trail	An Audit trail should be generated automatically in the system	Audit trail is generated: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	



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Sr.#	Check Points	Expected Results	Actual Observation	Gaps Found?	Remarks
32.	Audit Trail (Date +Time Stamp)	A date and time stamped audit trail should be available for all operator entries and actions.	Audit trail is stamped with date and time: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
33.	Audit Trail (Protection)	Audit trail log record should be protected and stored safely.	Audit trail logging is protected: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Audit Trail is stored safely: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	
34.	System Date and Time	The user [except Administrator] should not be able to change data and time of computer system	User [except Administrator] is not able to change data and time of computer system: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	



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Action Plan for Identified GAPs

Sr. #	Ref. Sr. # of GAP	Check Points/ Actual GAP	Action Plan/ Justification	Responsibility	Completion Date*	Status of GAP [Open/ Close]	Remarks
01							
02							

*All the GAPs will be closed during validation and before approve Validation Summary Report.

Note: This attachment will be a live document, which will be updated as and when the respective gap gets closed during project phase and at the time of Validation Summary Report Preparation, this document will get signed off.

Prepared By (Sign & Date)	Reviewed By (Sign & Date)	Reviewed By (Sign & Date)	Reviewed By (Sign & Date)	Approved By (Sign & Date)

8.0 OVERALL CONCLUSION:



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POST- APPROVAL PAGE

Prepared By:

Name	Designation	Department	Signature	Date

Reviewed By:

Name	Designation	Department	Signature	Date

Approved By:

Name	Designation	Department	Signature	Date