



PHARMADEVILS

IT DEPARTMENT

[Appendix 2c-Template of Vendor Assessment]

Title: Vendor Assessment for <System Name>

Document No.:

<Document No.>

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**Vendor Assessment
For
<System Name>**



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APPROVAL PAGE

Prepared By:

| Name | Designation | Department | Signature | Date |
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| 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:

1.1. OBJECTIVE

Write down the purpose of this Assessment

1.2. SCOPE

Write down the scope of this document.

2.0 COMPUTERIZED SYSTEM DESCRIPTION:

This section will describe the system under assessment

3.0 RESPONSIBILITIES:

This section describes the responsibilities of the concerned person.

4.0 INTRODUCTION:

Identify the type of vendor to be audited i.e. Hardware Supplier, Software Vendor etc. Fill in the relevant sections and questions as determined by the table below:

| Vendor Type | Software | System & Services | Hardware | Hardware | IT Technical | AMC |
|---------------------------------|---------------|--|------------------------------------|-----------------------------|--------------|-------------|
| General information | 5.1 to 5.20 | 5.1 to 5.15/5.17 | 5.1 to 5.20 | 5.13/5.16 to 5.17 | 5.1 to 5.16 | 5.1 to 5.16 |
| Organization & Personnel | 6.1 to 6.10 | 6.1 to 6.10 | 6.1 to 6.10 | 6.1 to 6.10 | 6.1 to 6.10 | 6.1 to 6.10 |
| Infra Structure | 7.1 to 7.16 | 7.2/7.3 to 7.6/7.11 to 7.13 | 7.1 to 7.2/7.4 to 7.7/7.11 to 7.15 | 7.2 to 7.4/7.6/7.11 to 7.15 | 7.1 to 7.11 | 7.1 to 7.5 |
| Security | 8.1 to 8.15 | 8.1/8.4 to 8.10/8.12 to 8.15 | 8.1 to 8.2/8.11/8.13 to 8.15 | 8.10/8.13 to 8.14 | 8.1 to 8.14 | N/A |
| Document Management | 9.1 to 9.8 | 9.1 to 9.8 | 9.1 to 9.3/9.5 to 9.8 | 9.1 to 9.8 | N/A | N/A |
| Quality Management | 10.1 to 10.31 | 10.1 to 10.3/10.5/10.7 to 10.8/10.11/10.20 to 10.24/10.28 to 10.31 | N/A | N/A | N/A | N/A |
| Project Planning and Management | 11.1 to 11.5 | 11.1 to 11.5 | N/A | 11.1 to 11.2/11.4 to 11.5 | N/A | N/A |
| Development | 12.1 to 12.17 | 12.1 to 12.17 | 12.1/12.3 to 12.4/12.8/12.16 | N/A | N/A | N/A |
| Testing | 13.1 to 13.15 | 13.1 to 13.15 | 13.1/13.5 to 13.15 | N/A | N/A | N/A |
| Change Control | 14.1 to 14.10 | 14.1 to 14.10 | N/A | N/A | N/A | N/A |



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| Vendor Type | Software | System & Services | Hardware | Hardware | IT Technical | AMC |
|--------------------------|---------------|-------------------|---------------------------|----------|--------------|--------------|
| Configuration Management | 15.1 to 15.7 | 15.1 to 15.7 | 15.1 to 15.2/15.4 to 15.7 | N/A | N/A | N/A |
| Release Management | 16.1 to 16.12 | N/A | N/A | N/A | N/A | N/A |
| Services & Support | N/A | N/A | N/A | N/A | N/A | 17.1 to 17.7 |

5.0 GENERAL INFORMATION:

| Sl. | QUESTIONS | RESPONSE | COMMENTS |
|------|--|-----------------|----------|
| 5.1 | Company Name | | |
| 5.2 | Year of establishment | | |
| 5.3 | Location/Address in current city | | |
| 5.4 | Does the Company have other locations? If response is "Yes" then list the relevant locations with brief function of each in the Comments section. | | |
| 5.5 | No. of employees | (all locations) | |
| | | (this location) | |
| 5.6 | Is the company currently involved in any litigation? | | |
| 5.7 | Does the Company have any kind of certification (e.g. ISO, etc.)? If response is "Yes" then list, the certification. If "Yes" provide details of your most recent Certification audit by your certification body (bodies). | (Yes/ No) | |
| 5.8 | How long has the company been involved with the Life Sciences Industry? | ----- years | |
| 5.9 | Does the Company have other locations? If response is "Yes" then list, the relevant locations with brief function of each in the Comments section | | |
| 5.10 | Is the company willing to sign a non-disclosure agreement for the protection of Clients proprietary information? | | |
| 5.11 | Have all persons who are/will be involved in the software development and having access to Clients proprietary information, signed non-disclosure agreements? | | |
| 5.12 | Can you describe the measures that will be taken to ensure the security and confidentiality of Client proprietary information? | | |
| 5.13 | Can you supply a list of people who will have access to client proprietary information including, documentation and information located on servers/clients? | | |
| 5.14 | Can you provide delivery and installation services (technical and other)? | | |
| 5.15 | Can you provide the name and address of the support services available in geographic locations suitable to meet the needs of each software system installation site? | | |



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| Sl. | QUESTIONS | RESPONSE | COMMENTS |
|------|---|----------|----------|
| 5.16 | What is the protection against bankruptcy or the discontinuance of any product? Do you supply source code or is it through an escrow? (if applicable) | | |
| 5.17 | What percentage of the company sales is attributed to the Life sciences Industry? | -----% | |
| 5.18 | Provide a list of products your company currently supplies to, or provides support for, the life sciences and healthcare industries. | | |
| 5.19 | Please supply references we may contact, who have installed or are currently using the services/hardware/software being considered. | | |
| 5.20 | Has the service/product been used in similar regulatory environment before? | | |

| | |
|---|--|
| COMPLIANCE SUMMARY (TO BE COMPLETED BY AUDIT TEAM) | |
| ACCEPTED (A) / CONDITIONAL ACCEPTANCE (CA) / FAILED (F) | |
| COMMENTS / OBSERVATIONS: | |

6.0 ORGANIZATION AND PERSONNEL:

| Sl. | QUESTIONS | RESPONSE | COMMENTS |
|------|--|----------|----------|
| 6.1 | Does the company have a well-defined management structure where roles and responsibilities are clearly defined and understood? | | |
| 6.2 | Provide organizational chart(s) giving the company structure, organization, and the responsibilities of key individuals within the structure (from managing director to personnel responsible for the delivery of the required product/project). | | |
| 6.3 | Are new employees recruited according to job descriptions and job specifications? | | |
| 6.4 | Is there an employee training procedure? Are all employees trained in accordance with this procedure? | | |
| 6.5 | Are training records readily available? If so, are they up to date for all employees? | | |
| 6.6 | Does the training include 21 CFR Part 11 and other relevant industry standards? Does this training include technical training, awareness training, and application specific and regulatory training at a minimum | | |
| 6.7 | Does the Company have a mechanism in place to keep abreast with changes in industry standards and developments in technology sectors? | | |
| 6.8 | Does the Company conduct employee performance evaluation and appraisal at regular intervals? | | |
| 6.9 | Does the training program enforce retraining at regular intervals? | | |
| 6.10 | Does the Company use sub-contractors? Does the | | |



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| | company have a policy or procedure, which they follow when they sub-contract work? Does the company audit the subcontractor to ensure that they meet the company's technical and quality requirements? Are contractors trained on company's policies and procedures in accordance with training guidelines? | | |
|--|---|--|--|

COMPLIANCE SUMMARY (TO BE COMPLETED BY AUDIT TEAM)

ACCEPTED (A) / CONDITIONAL ACCEPTANCE (CA) / FAILED (F)

COMMENTS / OBSERVATIONS:

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7.0 INFRASTRUCTURE

| Sl.No. | Question | Response | Comments |
|---|--|----------|----------|
| 7.1 | Is the development center designed to have appropriate space, lighting, ventilation and environmental controls for the operations being performed? | | |
| 7.2 | Are the facilities maintained properly? | | |
| 7.3 | Does the facility have the necessary licensed operating system and application software? | | |
| 7.4 | Does the facility have the necessary communication infrastructure (phone, network, internet connections, etc.)? | | |
| 7.5 | Are diagnostic tools employed to monitor the health of critical equipment, databases, etc.? | | |
| 7.6 | Are critical systems located in secure locations with controlled | | |
| 7.7 | Do you have written standards and procedures for disaster recovery? | | |
| 7.8 | Do you have written standards and procedures for backup and recovery? | | |
| 7.9 | How is the media, used for backup and recovery controlled? | | |
| 7.10 | How and when are backup and recovery procedures tested? | | |
| 7.11 | Are critical systems connected to UPS and /or Emergency Power? | | |
| 7.12 | Does the facility have reliable power supply? | | |
| 7.13 | Does the facility have alternate power supply in case of a power loss? | | |
| 7.14 | Is there a Fire Alarm and Extinguishing System in place? | | |
| 7.15 | Are all critical equipment covered under a maintenance contract? | | |
| 7.16 | Does the company provide AMC for maintenance? | | |
| COMPLIANCE SUMMARY (TO BE COMPLETED BY AUDIT TEAM) | | | |
| Accepted (A) / Conditional Acceptance (CA) / Failed (F) | | | |
| COMMENTS / OBSERVATIONS: | | | |



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8.0 SECURITY

| Sl.# | Question | Response | Comments |
|---|---|----------|----------|
| 8.1 | Do you have written standards and procedures for physical and logical system security? | | |
| 8.2 | Is there a Burglar Alarm System in place? | | |
| 8.3 | Is logical access to software and networks password protected with hierarchy of access levels? | | |
| 8.4 | Does the Company have a policy for assigning User IDs and passwords, which defines procedure for assigning passwords, assigning access levels, changing passwords and retiring users? | | |
| 8.5 | Does the Company have a software anti-virus policy? | | |
| 8.6 | Is this policy properly communicated to the employees? | | |
| 8.7 | Is anti-virus software installed on all servers and workstations in the facility? | | |
| 8.8 | Is anti-virus software regularly updated for new virus protection? | | |
| 8.9 | Does the Company network have a firewall? | | |
| 8.10 | Is the firewall configured according to Company security policy? | | |
| 8.11 | Are access logs reviewed and action taken on questionable entries? | | |
| 8.12 | Are there security policies and guidelines to configure servers and workstations? | | |
| 8.13 | Are there internal security audit procedures to ensure compliance? | | |
| 8.14 | Are there procedures to handle intrusion attempts and security violations? | | |
| 8.15 | Does the Company use only licensed software? | | |
| COMPLIANCE SUMMARY {TO BE COMPLETED BY AUDIT TEAM} | | | |
| Accepted (A) / Conditional Acceptance (CA) / Failed (F) | | | |
| COMMENTS / OBSERVATIONS | | | |



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9.0 DOCUMENT MANAGEMENT

| SI# | Question | Response | Comments |
|---|--|----------|----------|
| 9.1 | Does the Company have a document management policy? | | |
| 9.2 | Are all documents developed according to documentation standards? | | |
| 9.3 | Are all documents indexed and organized? | | |
| 9.4 | Are all documents reviewed prior to approval and issue? | | |
| 9.5 | Is access to documents and distributions of documents controlled? | | |
| 9.6 | Are document histories maintained? | | |
| 9.7 | Are documents archived for future reference? | | |
| 9.8 | Do all required documents have the appropriate review and approval signatures? | | |
| COMPLIANCE SUMMARY (TO BE COMPLETED BY AUDIT TEAM) | | | |
| Accepted (A) / Conditional Acceptance (CA) / Failed (F) | | | |
| COMMENTS / OBSERVATIONS: | | | |



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10.0 QUALITY MANAGEMENT

| Sl.# | Question | Response | Comments |
|-------|---|----------|----------|
| 10.1 | Can you provide up-to-date organization charts of the Quality Management function? | | |
| 10.2 | Can you show a clearly documented Quality Management System (QMS)? Describe. | | |
| 10.3 | Is the QMS certified to a recognized standard? (ISO, CMM etc). | | |
| 10.4 | Does the scope of the certification include all activities in the proposed software, systems & services? | | |
| 10.5 | Are QA/QC organization's responsibilities clearly defined? | | |
| 10.6 | Is the QA/QC function separate from and independent of the project organization? | | |
| 10.7 | Does the company have a policy for maintaining service quality? | | |
| 10.8 | Is the policy for maintaining service quality properly communicated to employees (new and existing)? | | |
| 10.9 | If your product was previously validated, when and where was it validated? | | |
| 10.10 | What documentation can you supply to support validation of the target system? | | |
| 10.11 | Are regular audits done to ensure adherence to the policy? | | |
| 10.12 | Have you ever been audited before? If yes, when and by whom? | | |
| 10.13 | Can you provide proof of corrective actions identified during audits and followed up in a timely manner? | | |
| 10.14 | Does the QA/QC unit review, maintain and enforce all companywide procedures and policies? | | |
| 10.15 | Does the company have procedures to manage all areas of operations? | | |
| 10.16 | Are the standard operating procedures followed/enforced? Are there defined work processes (e.g., work instructions)? | | |
| 10.17 | Is training performed on written procedures? | | |
| 10.18 | Can you provide proof that training of personnel is routinely reviewed? | | |
| 10.19 | Is there a procedure to author, review, revise and approve procedures? | | |
| 10.20 | Are all procedures reviewed periodically? Are measures in place to ensure that procedures reflect current work practices? | | |
| 10.21 | Do all procedures have a revision history? | | |
| 10.22 | Are procedures easily accessible to all employees? | | |
| 10.23 | Are methods in place to ensure that changes to procedures are communicated to personnel responsible for performing the work? | | |
| 10.24 | Do you have standards for user and technical documentation? | | |
| Sl.# | Question | Response | Comments |
| 10.25 | Does QA/QC unit review all GxP project life cycle deliverables including, but not limited to, requirements, specifications and test records? | | |
| 10.26 | Is there a procedure to handle customer bug reports and problems? | | |
| 10.27 | How many customer complaints have been raised/resolved in the last 12 months? Provide details of the process followed to address customer complaints and an example of how a recent customer complaint was addressed? | | |
| 10.28 | Are customer calls logged? How? | | |
| 10.29 | Are troubles shooting guidelines and documentation for the calls | | |



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|---|---|--|--|
| | logged available? | | |
| 10.30 | How are the service turnaround statistics and performance tracking efficient? | | |
| 10.31 | Does the company have a continuous improvement program that uses metrics to evaluate and improve effectiveness of service quality policy? | | |
| COMPLIANCE SUMMARY (TO BE COMPLETED BY AUDIT TEAM) | | | |
| Accepted (A) / Conditional Acceptance (CA) / Failed (F) | | | |
| COMMENTS / OBSERVATIONS | | | |

11.0 PROJECT PLANNING AND MANAGEMENT

| Sl.# | Question | Response | Comments |
|---|---|----------|----------|
| 11.1 | Does the company use quality and project plans (plan detail activities, responsibilities, processes, procedures and timelines) for projects? If "Yes" provide a sample of a recent project plan / quality plan. | | |
| 11.2 | Are these plans reviewed and updated regularly? | | |
| 11.3 | Does the company have a clearly defined (as applicable)? <ul style="list-style-type: none"> ■ Development Life cycle model? ■ Design methodology? ■ Programming standard? ■ Test methodology? | | |
| 11.4 | Is the project structure defined with responsibilities identified? | | |
| 11.5 | Is there a list of deliverables that will be produced for each project? | | |
| COMPLIANCE SUMMARY (TO BE COMPLETED BY AUDIT TEAM) | | | |
| Accepted (A)/ Conditional Acceptance (CA) / Failed (F) | | | |
| COMMENTS / OBSERVATIONS: | | | |

12.0 DEVELOPMENT:

| Sl.# | Question | Response | Comments |
|------|---|----------|----------|
| 12.1 | Does the company have documented requirements specification (user requirements), functional specifications, detailed design specifications, module specifications for projects? | | |
| 12.2 | Do you have written standards and procedures for software, system & services development? (Ex: SDLC) (as applicable) | | |
| 12.3 | Does the company employ traceability techniques to ensure that alt requirements are implemented in design and development? | | |
| 12.4 | Does the company have standards covering the use of programming languages? (e.g.: naming and coding conventions, commenting rules) (as applicable) | | |
| 12.5 | Does the company have standards covering hardware design? (as applicable) | | |
| 12.6 | Does the company have standards for software identification and traceability {e.g.; for each software item: unique name, version, project reference and change history}? | | |
| 12.7 | Does the company apply design reviews and source code reviews? (Checking design, adherence to coding standards, logic, redundant code, identification of critical algorithms) {as applicable) | | |



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| 12.8 | Are these design reviews documented, indexed, followed-up and closed? | | |
| 12.9 | Are all the code listings and other code/design review documents identified, controlled and retained with review reports? (as applicable) | | |
| 12.10 | What is the media storage for source code? | | |
| 12.11 | What is the location of on-site media? | | |
| 12.12 | When was the most recent on-site software backup update done? | | |
| 12.13 | When was the most recent off-site software backup update done? | | |
| 12.14 | Are the required software compilers, operating system and utilities available? | | |
| 12.15 | What are the Environmental conditions of software storage locations? | | |
| 12.16 | Do you have Software code retention period policy? | | |
| COMPLIANCE SUMMARY (TO BE COMPLETED BY AUDIT TEAM) | | | |
| Accepted (A) / Conditional Acceptance (CA) / Failed (F) | | | |
| COMMENTS / OBSERVATIONS | | | |
| | | | |

13.0 TESTING

| Sl.# | Question | Response | Comments |
|---|--|----------|----------|
| 13.1 | Does the company have a testing strategy for each stage of the development cycle? | | |
| 13.2 | Do these testing strategies include establishment of a development and testing environment? | | |
| 13.3 | Do test plans exist for this project (unit test, integration test, system test, and acceptance test)? (as applicable) | | |
| 13.4 | Are the tests well designed and structured? (References, unambiguous test descriptions, acceptance criteria and cross-reference to specifications) | | |
| 13.5 | Does the company have formal testing procedures to execute these tests? (Methods of recording test results, retaining raw data, reviewing test results, progressing and resolving test failures) | | |
| 13.6 | Are test procedures formally executed and documented? If "Yes" please provide a sample test script. | | |
| 13.7 | Are test results and associated test documents indexed, organized, maintained and followed-up in case of failure? | | |
| 13.8 | Are there procedures for the recording and handling of test discrepancies? | | |
| 13.10 | Are automated testing tools being used? If so, are there standards for their use? | | |
| 13.11 | Is there evidence that the testing standards are being followed? | | |
| 13.12 | Are all test scripts issued and approved? | | |
| 13.13 | Are test scripts/plans reviewed for accuracy and completeness? | | |
| 13.14 | Are the testers different from the developers? | | |
| 13.15 | Is a test review and approval carried out by a second person? | | |
| COMPLIANCE SUMMARY (TO BE COMPLETED BY AUDIT TEAM) | | | |
| Accepted (A) / Conditional Acceptance (CA) / Failed (F) | | | |
| COMMENTS / OBSERVATIONS: | | | |
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14.0 CHANGE CONTROL:

| Sl.# | Question | Response | Comments |
|---|--|----------|----------|
| 14.1 | Do you have written standards and procedures for change control? | | |
| 14.2 | Is change control applied to? <ul style="list-style-type: none"> ✓ Documentation ✓ Hardware & Software ✓ Configuration data? | | |
| 14.3 | Is the responsibility for approving changes defined? | | |
| 14.4 | Are changes subject to the proper approvals before they are implemented? | | |
| 14.5 | Do the procedures for change control include a method for evaluating the impact of any changes on the application? | | |
| 14.6 | Are there procedures for testing the system after changes have been made? | | |
| 14.7 | Are there suitable security measures in place to prevent unauthorized changes to software, hardware and documentation? | | |
| 14.8 | Is it possible to trace the audit trail from a change request through implementation of the software change? | | |
| 14.9 | Is there evidence of change control being and issued applied to all approved documentation and software? | | |
| 14.10 | Do you have documentation on scope of change and impact on client base? | | |
| COMPLIANCE SUMMARY (TO BE COMPLETED BY AUDIT TEAM) | | | |
| ACCEPTED (A) / CONDITIONAL ACCEPTANCE (CA) / FAILED (F) | | | |
| COMMENTS / OBSERVATIONS: | | | |

15.0 CONFIGURATION MANAGEMENT

| Sl.# | Question | Response | Comments |
|---|---|----------|----------|
| 15.1 | Do you have written standards and procedures for configuration management? | | |
| 15.2 | Is there a clear definition of when configuration management starts? | | |
| 15.3 | Is there a clear identification scheme for uniquely identifying each version of the software and code/configuration? (as applicable) | | |
| 15.4 | How is development work coordinated among several programmers and/or designers? | | |
| 15.5 | Are adequate records produced to allow a particular version of system/software to be reliably reconstructed from its component parts? (as applicable) | | |
| 15.6 | Are issued versions of hardware and/or software documentation and archived? | | |
| 15.7 | How are configuration files maintained and documented? Ex: Prepared, by whom, authorization for use? | | |
| COMPLIANCE SUMMARY (TO BE COMPLETED BY AUDIT TEAM) | | | |
| ACCEPTED (A) / CONDITIONAL ACCEPTANCE (CA) / FAILED (F) | | | |
| COMMENTS / OBSERVATIONS: | | | |



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16.0 RELEASE MANAGEMENT

| Sl.# | QUESTION | RESPONSE | COMMENTS |
|---|--|----------|----------|
| 16.1 | Can you provide a market history of products released including initial release notes and update release notes? | | |
| 16.2 | Is there evidence of reviews having been done on all software or designs required by the Project Plan? | | |
| 16.3 | What is the approval process for the release of software/ products to the life sciences and healthcare industries? | | |
| 16.4 | Have all software modules been formally released (conforming to procedures, authorities assigned)? | | |
| 16.5 | Are software listings available? | | |
| 16.6 | Does a sample of the source code conform to the programming standards defined in the Project Plan? | | |
| 16.7 | Do you show evidence that you adequately handle documentation and support for client specific configurations? | | |
| 16.8 | Is there a suitable mechanism to notify clients of problems? | | |
| 16.9 | Is there a description of the signers' responsibility / authority? | | |
| 16.10 | Does the company provide necessary user documentation? (e.g.: user manuals, technical manuals) | | |
| 16.11 | Are source code and documentation available for regulatory inspection? | | |
| 16.12 | Does the company provide the users with customer training whenever applicable? | | |
| COMPLIANCE SUMMARY (TO BE COMPLETED BY AUDIT TEAM) | | | |
| Accepted (A) / Conditional Acceptance (CA) / Failed (F) | | | |
| COMMENTS / OBSERVATIONS: | | | |
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17.0 SERVICES AND SUPPORT

| Sl.# | Question | Response | Comments |
|---|---|----------|----------|
| 17.1 | Does the company have a policy for maintaining service quality? | | |
| 17.1 | Is the policy for maintaining service quality properly communicated to employees (new and existing)? | | |
| 17.2 | Is there a procedure to handle customer bug reports and problems? | | |
| 17.3 | How many customer complaints have been raised/resolved in the last 12 months? Provide details of the process followed to address customer complaints and an example of how a recent customer complaint was addressed? | | |
| 17.4 | Are customer calls logged? How? | | |
| 17.5 | Are troubles shooting guidelines and documentation for the calls logged available? | | |
| 17.6 | How are the service turnaround statistics and performance tracking efficient? | | |
| 17.7 | Does the company have a continuous improvement program that uses metrics to evaluate and improve effectiveness of service quality policy? | | |
| COMPLIANCE SUMMARY (TO BE COMPLETED BY AUDIT TEAM) | | | |
| Accepted (A) / Conditional Acceptance (CA) / Failed (F) | | | |
| COMMENTS / OBSERVATIONS: | | | |

18.0 CONCLUSION:

Write down the conclusion

19.0 SUPPORTING DOCUMENTATION:

Give supporting document (if any)

20.0 ABBREVIATIONS:

This section will describe various abbreviations used in the document.



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POST APPROVAL

Prepared By:

| Name | Designation | Department | Signature | Date |
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Reviewed By:

| Name | Designation | Department | Signature | Date |
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Approved By:

| Name | Designation | Department | Signature | Date |
|------|-------------|------------|-----------|------|
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