ECI Management Certification Services LLP

Medical Device Quality Management System

ISO 13485

ECI/P-06

Address

Office No. 708, 7th Floor, Rama Equator,
Next to City International School,
Morwadi Road, Pimpri, Pune - 411018,
Maharashtra, India.

Contents

1. PURPOSE

To establish a systematic and uniform methodology for pre-certification activities like application and application review.

2. SCOPE

Management System Certification Schemes

3. REFERENCES

- ISO 17021-1 – Clause 9.1

4. RESPONSIBILITY

CEO, and all personnel of ECI.

5. PROCEDURE

5.1 Application

When a potential client sends an enquiry to ECI for a certification scheme, ECI sends an Application Form ECI/F-01. ECI requires an authorized representative of the potential client to provide the necessary information to enable it to establish the following:

- Name of Organization
- Scope of Certification
- Certification Scheme opted for
- Details of Key Personnel viz. name, email and phone numbers
- Details of Location/s with Contact Details and specific activities carried out at each location
- Details of Outsourced Processes
- Details of Major Technical processes
- Details of statutory & regulatory aspects applicable to product / services / processes within the applied Scope of certification
- Detail bifurcation of manpower – Location and Department wise (full time, part time or contractual)
- Preparedness of the applied QMS
- Applicability of Design to the scope of certification
- Details of consultancy, if taken by the potential client
- Details of Weekly offs
- Details of Multiple Shifts
- Details of Working Hours
- Language to be used during audit
- Details of any availed testing services
- Details of any availed In-house training on any subjects
- Details of any previous or existing certifications, if any
- Details of any Complaints received and action taken (major complaints)
- Details of any current engagement by the potential client with regulatory bodies in respect of legal compliance.
- In case of transfer of certifying body, to provide reasons for seeking the transfer
- Details of Accreditation, if already certified by ECI for applied Standard
- Confirmation on conduct of minimum one round of Internal Audit and Management Review
- Confirmation on compliance to complete cycle of product manufacturing (i.e. batch manufacturing for applied scope).

This information is obtained from the client through Application form.

5.2 Application Review (ECI/F-02):

The client fills up the Application Form and sends it to ECI.

ECI conducts a review of the application and supplementary information (as applicable) and decides whether to accept or decline the application for audit and certification.

ECI conducts application review and establishes following aspects but not limited to:

- Name of Organization
- Certification Standard
- Audit Type
- Scope of Certification
- Location/s and specific activities carried out at each location
- Technical Area
- Applied Accreditation (Single / Dual)
- Availability of Technical area in applied Accreditation scope
- Availability of Auditor or Technical Expert with approved technical area
- Language to be used during conduct of audit
- Determination of Interpreter, if required
- Multi-site sampling if applicable
- Shift Details
- Calculation of effective number of Personnel, based on received detail bifurcation of manpower (full time, part time or contractual)
- Determination of audit duration in terms of man-days required in Stage 1, Stage 2, Surveillance, Recertification and Special Audit. Justification for any increase or decrease in audit duration is recorded.
- Outsourced processes and control established
- Assessment of potential threats to impartiality
- Any specific safety requirement for conduct of audit

The application reviewer can reach to client and consult the ECI code auditor to seek any clarification on information furnished. In addition, review the applicable statutory and regulatory requirement referring to applicant website.
ECI accepts the Application Form based on the positive application review output and ability to conduct audit and certification activity with compliance to review output.
The potential client is formally informed regarding the acceptance of the Application, and Quotation is submitted to the client. A Certification Agreement and Informative Guide are enclosed along with the Quotation.

The audit and certification service may be declined by ECI for the following reasons:

- Non-availability of accredited scope
- Non-availability of audit personnel with approval of specific technical area
- Non-availability of audit personnel to conduct audit in a specific geographical location
- Failure to establish legality of the business activity provided by the potential client
- Any other adverse market information which does not allow audit and certification activity to happen

The applicant organization is formally informed with reasons through a mail about ECI decision to decline the application.

6. RECORDS

- Application form **(ECI/F-01)**
- Application Review **(ECI/F-02)**
- Quotation (**ECI/F-06)**
- Certification Agreement **(ECI/F-05)**

7. REVISION HISTORY

Rev. No.	Effective Date	Details
00	01.01.2025	Initial Issue
01	10.11.2025	Change in the Company Name

ECI Management Certification Services LLP

Medical Device Quality Management System

ISO 13485

ECI/P-07

Address

Office No. 708, 7th Floor, Rama Equator,
Next to City International School,
Morwadi Road, Pimpri, Pune - 411018,
Maharashtra, India.

Contents

1. PURPOSE

To establish a systematic and uniform methodology for planning of audits.

2. SCOPE

Management System Certification Schemes

3. REFERENCES

- ISO 17021-1 – Clause 9.1
- IAF MD9: 2023

4. RESPONSIBILITY

CEO, and all personnel of ECI.

5. PROCEDURE

ECI allots a unique File Number to the applicant organization after review of application.

5.1 Audit Programme:

The audit programme includes full certification cycle to cover the complete management system requirements.
The audit programme for initial certification includes a two-stage initial audit, i.e. Stage 1 and Stage 2.
Surveillance audits are planned in the first and second years following the certification decision.
Recertification audit is planned in the third year, prior to expiry of certification.
The first three-year certification cycle begins with the certification decision. Subsequent cycles begin with the recertification decision.
There may be follow-up audits, special audits (i.e. expanding scope, short notice audits, etc.) which are planned and conducted as applicable and mentioned in the audit programme whenever planned and conducted.
The determination of the audit programme and any subsequent adjustments are done on the basis of following aspects:

- Size of the client
- The scope and complexity of its management system
- Products and processes
- Demonstrated level of management system effectiveness and the results of any previous audits

Where the ECI is taking account of certification already granted to the client and to audits performed by another certification body, ECI shall obtain and retain sufficient evidence, such as reports and documentation on corrective actions, to any nonconformity. The documentation shall support the fulfilling of the requirements of ISO/IEC 17021-1:2015.
The ECI shall, based on the information obtained, justify and record any adjustments to the existing audit programme and follow up the implementation of corrective actions concerning previous nonconformities.
The **Procedure for transfer of Certificates EC/P-22** shall be referred in such case.

Where ECI audits the client for the regulatory scheme that includes or goes beyond the requirements of ISO 13485, it does not need to repeat the audit for conformity with the elements of ISO 13485 previously covered. ECI shall demonstrate all requirements are compiled in the reports.

Where the client operates in multiple shifts, the activities that take place during shift working shall be considered when developing the audit plans
The shifts which are not falling into regular office hours (Third Shift/Night Shift) shall be audited at least once in certification cycle (i.e. during initial or surveillance audits)
If during an audit, these shifts are not audited then justification shall be documented by lead auditor in audit plan/ audit report.
The audit programme shall prepare after stage I and maintained in the report.

Recommended minimum gap between stage 1 and stage 2 audits is 7 days. In determining the interval between stage 1 and stage 2 audits, the audit team gives consideration to the needs of the client to resolve areas of concern identified during the stage 1 audit. The maximum interval between the stage 1 and stage 2 audit shall not

exceed a period of 180 days. In case the period of 180 days is lapsed for conduct of stage 2 audit, then stage 1 audit shall be conducted again.
Note-1: In exemption, reconduct of Stage 1 can be excluded, subject to no change in the organisation's structure and operations concerning the applied scope of certification.
After the successful conduct of stage 2 audit, the certification decision shall be taken within 21 days of the receipt of stage 2 audit report and minor non-conformity corrective action reports (if any). In case there is a major non-conformity in the stage 2 audit, the certification decision shall take 21 days from the date of submission of report for follow up audit, along with the evidences of closure of major non conformity. After the certification decision is done, certificate shall be issued to the client.

Stage I audits can be completed remotely depends on the classification of the medical devices as per GHTF and CDSCO.

Other than Class A Non-sterile Non measuring devices all devices shall be audited on site for the Stage I.

6.2 Audit team nomination:
The audit team is nominated and composed of auditors (and technical experts, as necessary) who, between them, have the totality of the competences identified by ECI for the certification of the applicant organization. The selection of the team is performed with reference to the designations of competence of auditors and technical experts, and may include the use of both internal and external human resources.
Note-1: No audit shall be planned in case the manufacturing facility is non-operational

The auditor is selected from the document **Auditor Competence Matrix.**
The auditors are enlisted in **Auditor Competence Matrix** after thorough approval process as per procedure mentioned in the **Procedure for Competence of Personnel.**
While nominating the audit team, the **Risk Assessment and Mitigation Plan for Third Party Audit and Certification Activity** is duly referred to prevent any perceived risk.
Once the audit team is finalized, the information like File number, type of audit, certification standard, technical area, organization name and addresses of all the locations, the audit team and audit duration are recorded on the "Auditor Nomination".
The audit team members are obliged to report any conflict of interest related to the audit activity to be carried out at client organization and extent of it.

Auditor Nomination is sent to the Client minimum 5 days before. The client has the right to object to any of the proposed audit team members. Objections should be reported by the client within 3 working days of the receipt of audit team information ECI shall discuss this with the client confidentially in order to resolve the matter satisfactorily.
In case if the client does not send back the response of the audit team nomination, ECI considers the nominated audited team as accepted by the client.
The audit team is nominated and composed of auditors (and technical experts, as necessary) who, between them, have the totality of the competences identified by ECI for the certification of the applicant organization. The selection of the team is performed with reference to the designations of competence of auditors and technical experts made, and may include the use of both internal and external human resources.
In deciding the size and composition of the audit team, consideration is given to the following:
a) audit objectives, scope, criteria and estimated audit time;
b) whether the audit is a combined or joint.
ECI does not perform any integrated management systems audit.
c) The overall competence of the audit team needed to achieve the objectives of the audit, taking into account Application Review output considering all aspects as listed under Section 6.2 of Procedure for Pre Certification Activities.
d) certification requirements (including any applicable statutory, regulatory or contractual requirements). In case of specific requirements related to statutory and regulatory requirements, ECI ensures at least one of the audit team members is well aware of the requirements.

After determining the competency, it is also determined to conduct the stage 1 audit on-site or off-site. The sectors where;

Where higher risk medical devices (e.g., GHTF C and D) are concerned, the stage 1 should be performed on-site.

The duration (Stage 1, Stage 2, Surveillance 1, Surveillance 2, Re-certification) audit to be conducted is decided by ECI as per **Manday Guideline.** In case of any deviation (addition / reduction) in the Audit time than the guiding document, the detailed justification shall be recorded.

5.3 Audit pack

After the intimation is sent to the client, an audit pack is sent to the audit team members comprising the Audit plan format and report formats.

5.4 Audit plan

The audit plan for any type of audit is prepared by the nominated Lead auditor appropriate to the objectives and scope of audit.

The audit plan consists of:

Section-A which is filled in by the admin department. This section comprises File No., Audit Date, Type of Audit, Audit Criteria, Client Details, Auditor Details and Scope of Certification.

Section-B is filled in by the Lead Auditor. The Lead Auditor contacts the client authorized representative for logistics arrangement. These details are filled in by the Lead Auditor in the relevant section.

The audit plan refers:

• Audit objectives
• Audit Criteria
• The audit scope, including identification of the organizational and functional units or processes to be audited;
• Dates and all operational sites (i.e. design, manufacture, construction, marketing, installation, servicing or supply of the medical device, etc) to be considered while planning on-site audits also to include temporary sites as appropriate.
• The expected time and duration of on-site audit activities
• The roles and responsibilities of audit team members and accompanying persons.

In case of any deviation (addition / reduction) in the Audit time than as mentioned on the Auditor Nomination, the detailed justification shall be recorded.

The Lead Auditor sends the **Audit Plan** to the client regarding the audit by email. The schedule comprises of approximate timeline for each process to be audited. In case the audit team comprises of more than one personnel, the Lead Auditor allots the processes to the team members with approximate timelines.

The client needs to confirm the details mentioned in the audit plan and communicate back in case any changes in the plan is required. Audit plan shared with client as immediate after audit nomination but not before 3 days of the audit day.

Audit plan may not be prepared in case of off-site Stage-1 audit.

6. RECORDS

- Auditor Nomination (ECI/F-08)
- Manday Guideline (ECI/F-31)
- Audit Plan (ECI/F-07)

7. REVISION HISTORY

Rev. No.	Effective Date	Details
00	01.01.2025	Initial Issue
01	10.11.2025	Change in the Company Name

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Contents

1. PURPOSE

To establish a systematic and uniform methodology for conduct of Stage 1 and Stage 2 audits.

2. SCOPE

Management System Certification Schemes

3. REFERENCES

- ISO 17021-1 – Clause 9.3

4. RESPONSIBILITY

CEO, and all personnel of ECI.

5. PROCEDURE

The initial certification of management system is conducted in two stages: Stage 1 and Stage 2.

5.1 Conduct of Stage 1 Audit

5.1.1 Conducting the Opening Meeting:

ECI audit team conducts a formal opening meeting with the client's management and where appropriate, the personnel responsible for the processes to be audited. The Lead auditor explains how the audit activities will be undertaken.

a. Thank the client for choosing ECI as their certification body and brief introduction of ECI.
b. Confirmation of the language to be used during the audit
c. Introduction of the participants, including an outline of their roles
d. Confirmation of the scope of certification;
e. Confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements with the client, such as the date and time for the closing meeting, interim meetings between the audit team and the client's management;
f. Audit methodology - explain audit methodology to be used to conduct the audit i.e., interviews, observations, verification of records.
g. Audit is based on sampling basis.
h. Confirmation of formal communication channels between the audit team and the client;
i. Confirmation that the resources and facilities needed by the audit team are available;
j. Confirmation of matters relating to confidentiality;
k. Confirmation of relevant work safety, emergency and security procedures for the audit team;
l. Confirmation of the availability, roles and identities of any guides and observers;
m. Confirmation that the audit team leader and audit team representing ECI is responsible for the audit and shall be in control of executing the audit plan including audit activities and audit trails;
n. Method of reporting the areas of concern that could be classified as nonconformity during the stage 2 audit Impact of the areas of concern on certification recommendation
o. Information about the conditions under which the audit may be prematurely terminated;
p. Confirmation of the status of findings of the previous review or audit, if applicable;
q. Confirmation that, during the audit, the client will be kept informed of audit progress and any concerns;
r. Opportunity for the client to ask questions.

5.1.2 Conducting Stage 1 Audit:

In case of on-site stage 1 audit, the attendance of all the concerned members presents in the opening and closing meeting along with the time is recorded.

In case of off-site stage 1 audit, no separate attendance sheet is required in this case.

The stage1 audit is performed:

- to audit the client's management system documentation
- to evaluate the client's location and site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage 2 audit
- to review the client's status and understanding regarding requirements of the standard, in particular with

respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system

- to collect necessary information regarding the scope of management system, processes and location/s of the client, and related statutory and regulatory aspects and compliance (e.g. quality, environmental, legal aspects of client's operation, associated risks etc), wherever necessary refer to the country specific website to ascertain applicability of regulatory requirements.
- to review the allocation of resources for stage 2 audit and agree with the client on the details of the stage2 audit
- to provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the client's management system and site operations in the context of possible significant aspects
- to evaluate if the internal audits and management reviews are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 audit

The above-mentioned objectives are met by conducting stage 1 audit.

The stage 1 audit report captures the following information (but not limited to):

1. Client Name
2. File No.
3. Type and mode of audit (onsite or offsite)
4. Audit criteria (The requirements of the Standard (Eg ISO 9001, ISO 13485, etc.) against which the audit is being conducted.)
5. Dates of conduct of audit: Start date and end date of conduct of audit.
6. Addresses of the client, along with the activity conducted at each site and effective / total number of personnel at each site.
7. Details of the key representatives of the client organization.
8. Applied scope of certification (As stated in the Audit Nomination)
9. Final Scope of Certification (This final scope is agreed upon by the audit team and the client during conduct of stage 1 audit)
10. Nominated audit team and their role in the audit.
11. Audit Summary – This summary specifically captures the sufficiency and readiness of the client for conduct of Stage 2 Audit.
12. Client's introduction detailing the context of the organization, effective / total no. of personnel, needs and expectations of the interested parties
13. Client's Site-Specific conditions including processes and Equipment used, levels of control established (Brief introduction about the client and description of the site in terms of infrastructure, maintenance of infrastructure relevant to the scope of certification.)
14. Client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system
15. Details of applicable regulatory and statutory requirements and compliance status (The audit team specifies whether any there is any applicable regulatory and statutory requirement for the products or services provided. Refer to the country specific website to ascertain applicability of regulatory requirements).
16. Comments on the effectiveness of the internal audits and management reviews – general comment on the internal audit and MRM plans, their conduct and sufficiency with respect to audit criteria.
17. Areas of concern that can be classified as non-conformities in stage 2 audit.
18. Details of the client's management system documented information (Description and reference of Organization charts, Process maps, process flow charts and/or process descriptions, Procedures, Work and/or test instructions, Specifications, Documents containing internal communications, Production schedules, Approved supplier lists, Test and inspection plans, etc.)
19. Non-applicable Clauses / Exclusions claimed with justification
20. Any deviation from the audit plan, along with reasons.
21. Details of any changes observed w.r.t name, man power, scope and address
22. Important points regarding planning of stage 2 audits (recommendations, such as requirement of more than one auditor, more experienced auditors, technical expert or interpreters, audit duration to be increased for some specific process during stage 2 audit, Strong points, weak points, seasonal or weather restrictions, geographical or cultural considerations)

23. Recommendations from the audit team
24. Proposed period for conduct of stage 2 audit.

5.1.3 Communication during the audit:

- During the audit, the audit team shall periodically assess audit progress and exchange information. The Lead Auditor shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.
- Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the Lead Auditor shall report this to the client and, if possible, to ECI to determine appropriate action. The safety risks may include situations like labour unrest at client's location, any major mishaps such as accidents, fire etc., any natural calamity, civil unrest in the geographical location, etc. Other situations may be non-cooperation of auditees with the audit team or evidence of implementation is not available, or there is a major deviation in the scope of certification and actual business activity being carried out at the client premises. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The Lead auditor reports the outcome of the action taken to ECI. This is done through provisions made in the **Stage 1 Audit Report.**
- The Lead auditor shall review with the client any need for changes to the audit scope which becomes apparent as on-site auditing activities progress and report this to the ECI through provisions made in the **Stage 1 Audit report**

5.1.4 Obtaining and verifying information:

During the audit, information relevant to the audit objectives, scope and criteria (including information relating to interfaces between functions, activities and processes) shall be collected by appropriate sampling and verified to become audit evidence.
These evidences should be as per the requirements mentioned in Stage 1 Audit Report.
During the audit, information relevant to audit objectives, scope and criteria is collected by the audit team from the following sources:

- Interviews with employees and other persons
- Observations processes and activities and the surrounding work environment and conditions.
- Review of documentation and records.
- Review company's website (if available)
- Review regulatory website (of country of origin)

5.1.5 Identifying and recording audit findings:

Stage 1 audit findings raised by the audit team and recommendations are recorded in the stage 1 audit report, and communicated to the client by the Lead Auditor, including identification of any areas of concern that could be classified as nonconformity during the stage 2 audit.

5.1.6 Preparing Audit Conclusions:

Under the responsibility of the Lead Auditor and prior to the closing meeting, the audit team shall:

a. Review the audit findings and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and report the areas of concern that could be classified as nonconformity during the stage 2 audit
b) Agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process
c) Agree any necessary follow-up actions
d) Confirm the appropriateness of the audit programme or identify any modification required for future audits (e.g. Scope of certification, audit time or dates, audit team competence).

The following types of recommendations can be given by the Lead Auditor.

Recommendations for Stage 1 audit
Recommended for Stage 2 Audit
Recommended for Stage 2 Audit subjected to submission of Objective Evidence/s against pending or unresolved issues and subsequent offsite verification and acceptance by ECI Lead Auditor
Re conduct of Stage 1 audit

Lead auditor also proposes the date for conduct of stage 2 audit based on the observations raised by the audit team. Copy of these findings and recommendation are also communicated to ECI office.

In determining the interval between stage 1 and stage 2 audits, the audit team gives consideration to the needs of the client to resolve areas of concern identified during the stage 1 audit. ECI also needs to revise its arrangements for stage 2 in case the audit team reports significant changes impacting the management system. The minimum interval between stage 1 and stage 2 audits is 7 days, provided necessary arrangements for conduct of stage 2 audit are done.
The maximum interval between the stage 1 and stage 2 audit shall not exceed a period of 90 days (3 Months). In case the period of 90 days (3 Months) is lapsed for conduct of stage 2 audit, then stage 1 audit shall be conducted again.

5.1.7 Conducting the Closing Meeting:

A formal closing meeting, where attendance shall be recorded, shall be held with the client's management and, where appropriate, those responsible for the functions or processes audited. The purpose of the closing meeting, conducted by the Lead Auditor, is to present the audit conclusions, including the recommendation for stage 2 audit. Any areas of concern that could be classified as nonconformity during the stage 2 audit shall be presented in such a manner that they are understood and the timeframe for responding shall be agreed.

- Thank the client and personnel for their cooperation and general Hospitality
- Reconfirm scope of certification, if there are any changes-explain and provide justification
- Audit Methodology – reconfirmation of audit methodology used during the audit i.e., Interviews, observations verification of records. A statement that audit evidence obtained was based on sample of information and therefore, introducing an element of uncertainty.
- Discuss briefly the audit findings, areas of concern for stage 2 audit.
- The method and time frame of reporting shall be communicated. For e.g. Formal submission of report to the client by way of official email.
- A statement regarding confidentiality of information gathered during the audit
- Give the client opportunity for questions so as to address any queries from client. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved where possible. Any diverging opinions that are not resolved shall be recorded and referred to ECI.
- Declare recommendation
- Information about appeals and complaints handling process.
- A brief explanation about stage 2 audit.
- Distribute attendance sheet for signing of auditors & auditees, collect attendance sheet and thank all.

5.2 Conduct of Stage 2 Audit

5.2.1 Conducting the Opening Meeting:

ECI audit team conducts a formal opening meeting with the client's management and where appropriate, the personnel responsible for the processes to be audited. The Lead auditor explains how the audit activities will be undertaken.

a) Thank the client for choosing ECI as their certification body and brief introduction of ECI
b) Confirmation of the language to be used during the audit
c) Introduction of the participants, including an outline of their roles
d) Confirmation of the scope of certification;

e) Confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements with the client, such as the date and time for the closing meeting, interim meetings between the audit team and the client's management;
f) Audit Methodology - Explain Audit Methodology to be used to conduct the audit i.e., Interviews, observations, verification of records.
g) The audit is based on sampling.
h) Confirmation of formal communication channels between the audit team and the client;
i) Confirmation that the resources and facilities needed by the audit team are available;
j) Confirmation of matters relating to confidentiality;
k) Confirmation of relevant work safety, emergency and security procedures for the audit team;
l) Confirmation of the availability, roles and identities of any guides and observers;
m) Confirmation that the audit team leader and audit team representing ECI is responsible for the audit and shall be in control of executing the audit plan including audit activities and audit trails;
n) Method of Reporting – including any grading of nonconformities (Definition of Major and Minor NC's)
o) Impact of NC's on Certification recommendation
p) Information about the conditions under which the audit may be prematurely terminated;
q) Confirmation of the status of findings of the previous review or audit, if applicable;
r) Confirmation that, during the audit, the client will be kept informed of audit progress and any concerns;
s) Opportunity for the client to ask questions.

5.2.2 Conducting Stage 2 Audit:

The stage 2 audit is performed to evaluate the implementation, including effectiveness of the client's management
system. The stage 2 audit takes place at the site/s of the client. It includes at least the following:

- information and evidence about conformity to all requirements of the applicable management system standard or other normative document;
- performance monitoring, measuring, reporting and reviewing against key performance objectives and targets consistent with the expectations in the applicable management system standard or other normative document;
- the client's management system and performance as regards legal compliance;
- operational control of client's processes
- internal auditing and management review
- management responsibility for the client's policies

The above-mentioned objectives are met by conducting stage 2 audit.
The stage 2 audit report captures the following information (but not limited to) :

1. Client Name
2. File No.
3. Type of audit
4. Audit criteria (The requirements of the Standard (Eg ISO 9001, ISO 13485, etc.) against which the audit is being conducted.)
5. Dates of conduct of audit: Start date and end date of conduct of audit.
6. Addresses of the client, along with the activity conducted at each site and effective / total number of personnel at each site.
7. Details of the key representatives of the client organization.
8. Applied scope of certification (As stated in the Audit Nomination)
9. Final Scope of Certification (This final scope is re-established during the audit and agreed upon by the audit team and the client during conduct of stage 2 audit)
10. Nominated audit team and their role in the audit.
11. Client's introduction detailing the context of the organization, effective/ total no. of personnel, needs and expectations of the interested parties
12. Details of applicable regulatory and statutory requirements and compliance status (The audit team specifies whether any there is any applicable regulatory and statutory requirement for the products

or services provided. Refer to the country specific website to ascertain applicability of regulatory requirements).

13. Audit Summary –This summary specifically captures the overall achievement with respect to Audit Objectives.
14. Strong Points (The audit team captures the strong implementation points w.r.t. the audit criteria)
15. Areas for Improvement
16. Non-Conformities Summary (Number of major and minor non-conformities raised and their reference, i.e. non conformity number/s)
17. Review of operational control of processes including non-applicable clauses identified by the organization and exclusions claimed. (e.g. Description of Management Related, Documented Information, Customer Related, Purchasing, Design and Development, Production and Service Provision, Quality Control, Competence, Training and Awareness, Effectiveness of Internal Audit and Management Review Meeting processes, also Comment parameters like effectiveness of the process, fulfilment of process objectives, whether covered in internal audits and MRM, control of documented information, risk assessment and mitigations if applicable, leadership and commitment, etc. The names of auditee and time of audit of the process is also captured in this section to determine any deviation from the audit plan)
18. Deviations, changes or any unresolved issues (Description of deviation from the audit plan, any significant issues impacting the audit programme, any significant changes that have affected the management system since the last audit, any unresolved issues identified)
19. Changes observed in provided information w.r.t name, man power, scope and address.
20. Recommendations of the audit team
21. Recommendations post closure of Major Non-Conformity, if applicable.

Note-1: Guidelines on Management of Extraordinary Events or Circumstances (Ref. Doc. NABCB Policy on Management of Extraordinary Events or Circumstances Issue 04 Effective dated April 2021)

- ECI may carry out Initial certification audit (Stage-1 & 2) through Remote audits (in part or full) considering the risk factors and based on its risk evaluation process. However, the risk factors may vary for specific schemes and/or scope sectors. ECI will ensure that risk of initial certification audit through Remote is low.
- ECI has process determined for conduct of remote audits (part/complete).
- In case of complete remote Stage-2 audit is conducted, ECI shall perform an additional onsite visit to client site to review the critical manufacturing operations within 6 months of the remote audit, once the current emergency status has been lifted and as soon as travel to restricted areas is possible and businesses are operational or if not possible to do so due to the reasons as stated, ECI shall carry out onsite visit of the client manufacturing operations within a year after the remote audit, provided the situation is conducive for travel with no restrictions and the businesses are operational.

5.2.3 Communication during the audit:

- During the audit, the audit team shall periodically assess audit progress and exchange information. The Lead Auditor shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.
- Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the Lead Auditor shall report this to the client and, if possible, to ECI to determine appropriate action. The safety risks may include situations like labour unrest at client's location, any major mishaps such as accidents, fire etc., any natural calamity, civil unrest in the geographical location, etc. Other situations may be non-cooperation of auditees with the audit team or evidence of implementation is not available, or there is a major deviation in the scope of certification and actual business activity being carried out at the client premises. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The Lead auditor reports the outcome of the action taken to ECI. This is done through provisions made in the **Audit Report**

- The Lead auditor shall review with the client any need for changes to the audit scope which becomes apparent as on-site auditing activities progress and report this to the ECI through provisions made in the **Audit report**

5.2.4 Obtaining and verifying information:

During the audit, information relevant to the audit objectives, scope and criteria (including information relating to interfaces between functions, activities and processes) shall be collected by appropriate sampling and verified to become audit evidence. This evidence shall be recorded within the **Audit Notes** template. Should the auditor use an electronic method of recording audit evidence (i.e. a tablet or laptop), the standard soft copy template of the Auditor notes shall be used.

During the audit, information relevant to audit objectives, scope and criteria is collected by the audit team from the following sources:

• Interviews with employees and other persons
• Observations processes and activities and the surrounding work environment and conditions.
• review of documentation and records.
• review company's website (if available)
• review regulatory website (of country of origin)

5.2.5 Identifying and recording audit findings:

Audit findings summarising conformity and detailing nonconformity and its supporting audit evidence shall be recorded within the Audit Report and **CAR Report respectively.**

Areas / Opportunities for improvement / observations may be identified and recorded

Non-conformances shall not be recorded as areas / opportunities / observations for improvement.

A nonconformity shall be raised when a situation represents:

Non-conformity: Non-fulfilment of a standard's requirement

- **Major Non-conformity:** Non-conformity that affects the capability of the management system to achieve the intended results

Non-conformities could be classified as major in the following circumstances:

- if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- a number of minor non-conformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major non-conformity.

- **Minor non-conformity:**
  - Non-conformity that does not affect the capability of the management system to achieve the intended results
  - A finding of nonconformity shall be recorded in the **CAR Report** against a specific requirement of the audit criteria, contain a clear statement of the nonconformity and identify in detail the objective evidence on which the nonconformity is based.
  - Non-conformances shall be discussed with the client to ensure that the evidence is accurate and that the nonconformances are understood.

The audit team leader shall attempt to resolve any diverging opinions between the audit team and the client concerning audit evidence or findings, any unresolved points shall be recorded in the **Audit Report.**

5.2.6 Preparing Audit Conclusions:

Under the responsibility of the Lead Auditor and prior to the closing meeting, the audit team shall:

a) review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the nonconformities
b) agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process
c) agree any necessary follow-up actions
d) confirm the appropriateness of the audit programme or identify any modification required for future audits (e.g. scope of certification, audit time or dates, surveillance frequency, audit team competence). The Lead Auditor along with audit team analyses all information and audit evidence gathered during the stage 1 and stage2 audits to review the audit findings and agree on the audit conclusions.

The following recommendations can be given by the Lead Auditor:

Recommendations for Stage 2 audit
Recommended for Certification in total compliance with applied scope of certification
Recommended for Certification with reduction to applied scope of certification
Recommended for Certification with extension to applied scope of certification
Additional Full Audit Onsite
Additional Limited Audit On-Site
Additional Limited Audit Off-Site

The non-conformities are recorded in "**CAR**" form which is provided along with the audit pack. The Lead auditor, upon receipt of the duly signed **CAR** form from the client shall review the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. The Lead Auditor shall then sign the acceptance of the corrective action plan.
In case of a major nonconformity, the Lead auditor can discuss the same with the client and propose a date to conduct Follow-up Audit. This audit shall be an additional full on-site audit (in case of lapses in core areas where the trail in other processes becomes necessary) or additional limited on-site / off-site audit (on-site incase of situation where the closure compliance need to be verified via onsite demonstration of compliance with participation of auditee and off-site audit in case where the closure compliance can be verified through documentary evidence remotely).

The time frame for submission of correction, identified causes, corrective actions plan is within 7 days from the date of audit. The timeframe for implementing corrective action/s for Major non-conformity is maximum 90 days (3 Months).

The client shall inform and send the evidence of implemented corrective action/s. The Lead Auditor shall decide the date for conducting follow-up audit as per the closure plan and confirmation from Client.

In case of a minor nonconformity, the client needs to submit formal correction, identified root causes, corrective action/s plan within 7 days from the date of audit. Lead Auditor shall check the effective implementation of correction and corrective action in the next subsequent audit, e.g. Surveillance audit.

In Stage 2 audit, the attendance of all the concerned members presents in the opening and closing meeting along with time is recorded.

The Lead Auditor along with audit team analyses all information and audit evidence gathered during the Stage 2 audit to review the audit findings and agree on the audit conclusions.

5.2.7 Conducting the closing meeting

A formal closing meeting, where attendance shall be recorded, shall be held with the client's management and, where appropriate, those responsible for the functions or processes audited. The purpose of the closing meeting, conducted by the Lead Auditor, is to present the audit conclusions, including the recommendation regarding certification. Any nonconformities shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed.

- Thank the client and personnel for their cooperation and general Hospitality
- Reconfirm scope of certification, if there are any changes-explain and provide justification
- Audit Methodology – reconfirmation of audit methodology used during the audit i.e, Interviews, observations, verification of records. A statement that audit evidence obtained was based on sample of information and therefore introducing an element of uncertainty.
- Discuss briefly the audit findings with Positive Observations, Major/Minor NCR's if any.
- Timeframe for the client to present a plan for correction and corrective action for any nonconformities identified during the audit.
- The method and time frame of reporting shall be communicated.
- Confidentiality of information gathered during the audit

- Give the client opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved where possible. Any diverging opinions that are not resolved shall be recorded and referred to ECI
- Declare recommendation
- Certification Approval Process
- Certification approval shall be given by ECI certification decision authority.
- Certificate processing takes (15 - 21 working days) and on certification approval and subsequent compliance by he applicant to contractual obligations, the certificate of approval is released along with relevant certification documents e.g. Instructions to use ECI Prestige Mark and/or Accreditation Mark (as permissible) will be sent along with Certificate.
- Inform Surveillance Frequency
- Complaint and Appeal System – information about appeals system on the conduct or conclusions of audit.
- Address any queries from client
- Distribute attendance sheet for signing of auditors & auditees, collect attendance sheet and thank all.

Lead Auditor is responsible to submit the audit report to ECI certification decision making authority within **5** working days of conduct of audit, along with the audit notes, corrective action request forms (if any), attendance sheet, photographs (if any) and any other relevant document.

6. RECORDS

- Audit Plan (ECI/F-07)
- Auditor Nomination (ECI/F-08)
- Attendance Sheet (ECI/F-11)
- Audit Report (ECI/F-09)
- Corrective Action Request (ECI/F-12)
- Audit Notes (ECI/F-10)

7. REVISION HISTORY

Rev. No.	Effective Date	Details
00	01.01.2025	Initial Issue
01	10.11.2025	Change in the Company Name

ECI Management Certification Services LLP

Medical Device Quality Management System

ISO 13485

ECI/P-09

Address

Office No. 708, 7th Floor, Rama Equator,
Next to City International School,
Morwadi Road, Pimpri, Pune - 411018,
Maharashtra, India.

Contents

1. PURPOSE

To establish a systematic and uniform methodology for surveillance activities.

2. SCOPE

Management System Certification Schemes

3. REFERENCES

- ISO 17021-1
- IAF MD 9

4. RESPONSIBILITY

CEO, all personnel of ECI.

5. PROCEDURE

5.1 Surveillance Activities

Surveillance activities are conducted in a planned manner so as to ensure that the representative areas and functions covered by the scope of the management system are monitored on a regular basis and take into account changes to its certified client and its management system.

Surveillance audits are conducted at least once in a year. The first surveillance audit must be conducted within '12' months from the date of Initial certification decision.

Surveillance activities include on site audits assessing the certified client's management system's fulfilment of specified requirements with respect to the standard to which the certification is granted. Other surveillance activities include:

- enquiries from ECI to the certified client on aspects of certification
- reviewing any client's statements with respect to its operations e.g. promotional material, website
- requests to the client to provide documents and records
- other means of monitoring the certified client's performance such as review of complaints against certified client by interested parties

5.2 Planning Surveillance audit

Surveillance Intimation is sent to client as per audit programme.

This Surveillance Intimation is accompanied with request for filling up the Pre Audit Information Form, to ascertain for any changes in reference to previous audit. ECI conducts a review of the Pre Audit Information Form and supplementary information (as applicable).
If there are changes observed which might significantly impact on mandays, application review form shall be filled and necessary actions shall be taken.

Subsequently, the Administrative Executive communicates the information to the Lead Auditor through Audit Nomination. This is considered by the Lead Auditor while preparing the audit plan. The commercial obligations are informed to the client by Administration Executive and approval of the same is taken from the client. Once the date and commercial terms are confirmed by the client, an intimation is sent to the applicant organization, with **Auditor Nomination.**

Auditor Nomination is sent to the Client. The client has the right to object to any of the proposed audit team members. Objections should be reported by the client within 3 working days of the receipt of audit team information ECI shall discuss this with the client confidentially in order to resolve the matter satisfactorily.
In case if the client does not send back the response of the audit team nomination, ECI considers the nominated audited team as accepted by the client.

5.3 Conducting the Opening Meeting:

ECI audit team conducts a formal opening meeting with the client's management and where appropriate, the personnel responsible for the processes to be audited. The Lead auditor explains how the audit activities will be undertaken.

a) Thank the client for choosing ECI as their certification body and brief introduction of ECI.
b) Confirmation of the language to be used during the audit
c) Introduction of the participants, including an outline of their roles
d) Confirmation of the scope of certification;
e) Confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements with the client, such as the date and time for the closing meeting, interim meetings between the audit team and the client's management;
f) Audit Methodology - Explain Audit Methodology to be used to conduct the audit i.e., Interviews, observations, verification of records.
g) The audit is based on sampling.
h) Confirmation of formal communication channels between the audit team and the client;
i) Confirmation that the resources and facilities needed by the audit team are available;
j) Confirmation of matters relating to confidentiality;
k) Confirmation of relevant work safety, emergency and security procedures for the audit team;
l) Confirmation of the availability, roles and identities of any guides and observers;
m) Confirmation that the audit team leader and audit team representing ECI is responsible for the audit and shall be in control of executing the audit plan including audit activities and audit trails;
n) Method of Reporting – including any grading of nonconformities (Definition of Major and Minor NCs)
o) Impact of NCs on Certification recommendation
p) Information about the conditions under which the audit may be prematurely terminated;
q) Confirmation of the status of findings of the previous review or audit, if applicable;
r) Confirmation that, during the audit, the client will be kept informed of audit progress and any concerns;
s) Opportunity for the client to ask questions.

5.4 Conducting Surveillance Audits:

Surveillance audits are on site audits and are planned together with the other surveillance activities so that ECI can maintain confidence that the certified management system continues to fulfill requirements between recertification audits. The surveillance audit programme includes, at least:

- internal audits and management review
- a review on action taken on non-conformities identified during the previous audit
- Complaints handling procedure
- effectiveness of the management system with regard to achieving the certified client's objectives and intended result of the management system.
- progress of planned activities aimed at continual improvement
- continuing operational control
- review of any changes, and
- Use of marks and/or any other reference to certification.
- In case of MD-QMS, review of actions taken for notification of adverse events, advisory notices, and recalls.

The above-mentioned objectives are met by conducting Surveillance audit.

The Surveillance audit report captures the following information (but not limited to):

- Client Name
- File No.
- Type and mode of audit
- Audit criteria (The requirements of the Standard (Eg. ISO 9001, ISO 13485, etc.) against which the audit is being conducted.)

- Dates of conduct of audit: Start date and end date of conduct of audit.
- Addresses of the client, along with the activity conducted at each site and effective / total number of personnel at each site.
- Details of the key representatives of the client organization.
- Certified scope of certification (As stated in the Audit Nomination)
- Final Scope of Certification (Scope is reaffirmed during the audit and agreed upon by the audit team and the client during conduct of surveillance audit)
- Nominated audit team and their role in the audit.
- Client's introduction detailing the context of the organization, effective/ total no. of personnel, needs and expectations of the interested parties
- Details of applicable regulatory and statutory requirements and compliance status (The audit team specifies whether any there is any applicable regulatory and statutory requirement for the products or services provided. Refer to the country specific website to ascertain applicability of regulatory requirements).
- Audit Summary –This summary specifically captures the overall achievement with respect to Audit Objectives.
- Strong Points (The audit team captures the strong implementation points w.r.t. the audit criteria)
- Areas for Improvement
- Non-Conformities Summary (Number of major and minor non-conformities raised and their reference, i.e. non conformity number/s)
- Review of operational control of processes including non-applicable clauses identified by the
- organization and exclusions claimed. (e.g.Description of Management Related, Documented Information, Customer Related, Purchasing, Design and Development, Production and Service Provision, Quality Control, Competence, Training and Awareness, Effectiveness of Internal Audit and Management Review Meeting processes, also Comment parameters like effectiveness of the process, fulfilment of process objectives, whether covered in internal audits and MRM, control of documented information, risk assessment and mitigations if applicable, leadership and commitment, etc. The names of auditee and time of audit of the process is also captured in this section to determine any deviation from the audit plan)
- Use of marks and any other reference to the certification
- Review of actions taken on non-conformances identified in the previous audit.
- Deviations, changes or any unresolved issues (Description of deviation from the audit plan, any significant issues impacting the audit programme, any significant changes that have affected the management system of the client since the last audit took place, any unresolved issues identified)
- Changes observed in provided information w.r.t name, man power, scope and address.
- Recommendations of the audit team
- Recommendations post closure of Major Non-Conformity, if applicable

Note-1: Guidelines on Management of Extraordinary Events or Circumstances (Ref. Doc. NABCB Policy on Management of Extraordinary Events or Circumstances Issue 04 Effective dated April 2021)

- If ECI is unable to complete surveillance audits because of the state of the organization or travel restrictions, then flexibility may be given in Audit dates.
- Surveillance activities must be completed as early as possible once the current emergency status has been lifted and as soon as travel to restricted areas is possible and businesses are operational but should not normally exceed three months from the due date or as announced by NABCB considering the specific extraordinary event or circumstance.
- In case it is not possible to complete the surveillance activities within the timelines as mentioned above, a further extension of another 3 months may be given in case where the remote audit of client cannot be carried out in the initial extension of 3 months, thus allowing a period of maximum 6 months.
- Any extension will be well documented with legitimate reasons for granting extension.

5.5 Communication during the audit:

- During the audit, the audit team shall periodically assess audit progress and exchange information. The Lead Auditor shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.
- Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the Lead Auditor shall report this to the client and, if possible, to ECI to determine appropriate action. The safety risks may include situations like labour unrest at client's location, any major mishaps such as accidents, fire etc., any natural calamity, civil unrest in the geographical location, etc. Other situations may be non-cooperation of auditees with the audit team or evidence of implementation is not available, or there is a major deviation in the scope of certification and actual business activity being carried out at the client premises. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The Lead auditor reports the outcome of the action taken to ECI. This is done through provisions made in the Audit Report.
- The Lead auditor shall review with the client any need for changes to the audit scope which becomes apparent as on-site auditing activities progress and report this to the ECI through provisions made in the Audit report

5.6 Obtaining and verifying information:

During the audit, information relevant to the audit objectives, scope and criteria (including information relating to interfaces between functions, activities and processes) shall be collected by appropriate sampling and verified to become audit evidence. This evidence shall be recorded within the **Audit Notes** template. Should the auditor use an electronic method of recording audit evidence (i.e. a tablet or laptop), the standard soft copy template of the Auditor notes shall be used.

During the audit, information relevant to audit objectives, scope and criteria is collected by the audit team from the following sources:

• Interviews with employees and other persons

- Observations processes and activities and the surrounding work environment and conditions.
- review of documentation and records.
- review company's website (if available)
- review regulatory website (of country of origin)

5.7 Identifying and recording audit findings:

Audit findings summarising conformity and detailing nonconformity and its supporting audit evidence shall be recorded within the Audit Report and **CAR Report respectively.**

Care should be taken to ensure that the Audit Report does not use suggestive words / language but only reflect the situation as observed in the audit process

Areas / Opportunities for improvement / observations may be identified and recorded

Non-conformances shall not be recorded as areas / opportunities / observations for improvement.

A nonconformity shall be raised when a situation represents:

Non-conformity: Non-fulfilment of a standard's requirement

- **Major Non-conformity:** Non-conformity that affects the capability of the management system to achieve the intended results

Non-conformities could be classified as major in the following circumstances:

- if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- a number of minor non-conformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major non-conformity.

- **Minor Non-conformity:**
  - Non-conformity that does not affect the capability of the management system to achieve the intended results

- A finding of nonconformity shall be recorded in the **CAR Report** against a specific requirement of the audit criteria, contain a clear statement of the nonconformity and identify in detail the objective evidence on which the nonconformity is based.
- Non-conformances shall be discussed with the client to ensure that the evidence is accurate and that the nonconformances are understood.

The audit team leader shall attempt to resolve any diverging opinions between the audit team and the client concerning audit evidence or findings, any unresolved points shall be recorded in the **Audit Report.**

5.8 Preparing Audit Conclusions:

Under the responsibility of the Lead Auditor and prior to the closing meeting, the audit team shall:

a) review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the nonconformities
b) agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process
c) agree any necessary follow-up actions
d) confirm the appropriateness of the audit programme or identify any modification required for future audits (e.g. scope of certification, audit time or dates, surveillance frequency, audit team competence).

The following recommendations can be given by the Lead Auditor:

Surveillance
Granted continued certification in total compliance with present scope of certification
Granted Continued Certification with reduction to present scope of certification
Granted Continued Certification with extension to present scope of certification
Additional Full Audit Onsite
Additional Limited Audit On-Site
Additional Limited Audit Off-Site

The non-conformities are recorded in "**CAR**" form which is provided along with the audit pack. The Lead auditor, upon receipt of the duly signed **CAR** form from the client shall review the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. The Lead Auditor shall then sign the acceptance of the corrective action plan.

In case of a major nonconformity, the Lead auditor can discuss the same with the client and propose a date to conduct Follow-up Audit. This audit shall be an additional full on-site audit (in case of lapses in core areas where the trail in other processes becomes necessary) or additional limited on-site / off-site audit (on-site in case of situation where the closure compliance need to be verified via onsite demonstration of compliance with participation of auditee and off-site audit in case where the closure compliance can be verified through documentary evidence remotely).

The time frame for submission of correction, identified causes, corrective actions plan is within 7 days from the date of audit. The timeframe for implementing corrective action/s for Major non-conformity is maximum 90 days (3 Months). The client shall inform and send the evidence of implemented corrective action/s. The Lead Auditor shall decide the date for conducting follow-up audit as per the closure plan and confirmation from Client.

In case of a minor nonconformity, the client needs to submit formal correction, identified root causes, corrective action/s plan within 7 days from the date of audit. Lead Auditor shall check the effective implementation of correction and corrective action in the next subsequent audit, e.g. Surveillance audit. In Surveillance audit, the attendance of all the concerned members presents in the opening and closing meeting along with time is recorded.

The Lead Auditor along with audit team analyses all information and audit evidence gathered during the surveillance audit to review the audit findings and agree on the audit conclusions.

ECI maintains a client's certification based on conclusion by the audit team leader, without any further independent review and decision. The audit team leader can take decision for continuation of

certification. The report and related CAR's shall be sent to ECI for records. In case of a major non conformity observed in the surveillance audit process, the report and related CAR's shall be sent to ECI for decision. Audit team leader shall not take decision for certification continuation in this cases. In such cases, The Technical Reviewer or Decision Maker evaluates the Surveillance audit documents (**Audit Report and CARs)** and any other relevant information (e.g. public information or information related to contractual and legal obligations of the client, complaints received from users of certification). And decision for continuation of Certification, suspension or withdrawal is made.

ECI's Management Representative monitors its surveillance activities, including monitoring the reporting by ECI auditors, to confirm that the certification activity is operating effectively.

5.9 Conducting the Closing Meeting:

A formal closing meeting, where attendance shall be recorded, shall be held with the client's management and where appropriate, those responsible for the functions or processes audited. The purpose of the closing meeting, conducted by the Lead Auditor, is to present the audit conclusions, including the recommendation regarding certification. Any nonconformities shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed.

- Thank the client and personnel for their cooperation and general Hospitality
- Reconfirm scope of certification, if there are any changes-explain and provide justification
- Audit Methodology – reconfirmation of audit methodology used during the audit i.e, Interviews, observations, verification of records. A statement that audit evidence obtained was based on sample of information and therefore introducing an element of uncertainty.
- Discuss briefly the audit findings with Positive Observations, Major/Minor NCR's if any.
- Timeframe for the client to present a plan for correction and corrective action for any nonconformities identified during the audit.
- The method and time frame of reporting shall be communicated.
- Confidentiality of information gathered during the audit
- Give the client opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved where possible. Any diverging opinions that are not resolved shall be recorded and referred to ECI.
- Declare recommendation
- Certification continuation Approval Process
- Certification continuation approval shall be given by ECI certification decision authority.
- Report processing takes 10-15 days and on approval and subsequent compliance by the applicant to contractual obligations, the Continuation letter is released along with relevant certification documents e.g.
- Complaint and Appeal System – information about appeals system on the conduct or conclusions of audit.
- Address any queries from client
- Distribute attendance sheet for signing of auditors & auditees, collect attendance sheet and thank all.

6 RECORDS

- Pre Audit Information Form (ECI/F-03)
- Audit Plan (ECI/F-07)
- Auditor Nomination (ECI/F-08)
- Attendance Sheet (ECI/F-11)
- Audit Report (ECI/F-09)
- Corrective Action Request (ECI/F-12)
- Audit Notes (ECI/F-10)

7 REVISION HISTORY

Rev. No.	Effective Date	Details
00	01.01.2025	Initial Issue
01	10.11.2025	Change in the Company Name

ECI Management Certification Services LLP

Medical Device Quality Management System

ISO 13485

ECI/P-10

Address

Office No. 708, 7th Floor, Rama Equator,
Next to City International School,
Morwadi Road, Pimpri, Pune - 411018,
Maharashtra, India.

Contents

1. PURPOSE

To establish a systematic and uniform methodology for recertification.

2. SCOPE

Management System Certification Schemes

3. REFERENCES

- ISO 17021-1
- IAF MD 9

4. RESPONSIBILITY

CEO, all personnel of ECI.

5. PROCEDURE

5.1 Recertification audit planning:

A recertification audit is planned and conducted to evaluate the continued fulfilment of all the requirements of the relevant management system standard or other normative document. The purpose of the recertification audit is to confirm the continued conformity and effectiveness of the management system as a whole, and its continued relevance and applicability for the scope of certification.

This activity shall be completed prior to expiry of existing certificate.
The effective date on the certificate shall be on or after the recertification decision and the expiry date shall be based on existing certificate certification cycle.
An Intimation is sent to the client for recertification subject to the Audit programme.

The details about the client are confirmed through application form. The application form is reviewed by Application reviewer. After the review, a formal quotation along with certification agreement, informative guide is sent to the client for approval.
On receipt of quotation acceptance, certification agreement (duly signed), Legal entity and confirmation of date.

The Application Review may need to have a requirement of conduct of stage 1 audit in situations where there have been
significant changes to the management system such as:

- Change in ownership / constitution
- Change / addition in site location
- Change in business activity
- Change in operational activities, technology

In case there is a need to conduct stage 1 audit while doing recertification, the procedure shall be followed as per procedure of Initial Audits.

Once the date is confirmed by the client for the recertification audit, an intimation is sent to the applicant organization, with Auditor Nomination.

Auditor Nomination is sent to the Client. The client has the right to object to any of the proposed audit team members. Objections should be reported by the client within 3 working days of the receipt of audit team information ECI shall discuss this with the client confidentially in order to resolve the matter satisfactorily.
In case if the client does not send back the response of the audit team nomination, ECI considers the nominated audited team as accepted by the client.

It is ensured that recertification audit is carried out at least 15 days prior to the expiry of the certificate, so that client and ECI gets enough time for closure of all formalities to related to completion of recertification process.

If ECI does not complete the recertification audit or is unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then recertification is not recommended and the validity of the certification is not extended. The client is informed and the consequences are explained.

Following expiration of certification, the certification body can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted. The effective date on the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certification cycle.

5.2 Conducting the opening meeting:

ECI audit team conducts a formal opening meeting with the client's management and where appropriate, the personnel responsible for the processes to be audited. The Lead auditor explains how the audit activities will be undertaken.

a) Thank the client for choosing ECI as their certification body and brief introduction of ECI.
b) Confirmation of the language to be used during the audit
c) Introduction of the participants, including an outline of their roles
d) Confirmation of the scope of certification;
e) Confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements with the client, such as the date and time for the closing meeting, interim meetings between the audit team and the client's management;
f) Audit Methodology - Explain Audit Methodology to be used to conduct the audit i.e., Interviews, observations, verification of records.
g) The audit is based on sampling.
h) Confirmation of formal communication channels between the audit team and the client;
i) Confirmation that the resources and facilities needed by the audit team are available;
j) Confirmation of matters relating to confidentiality;
k) Confirmation of relevant work safety, emergency and security procedures for the audit team;
l) Confirmation of the availability, roles and identities of any guides and observers;
m) Confirmation that the audit team leader and audit team representing ECI is responsible for the audit and shall be in control of executing the audit plan including audit activities and audit trails;
n) Method of Reporting – including any grading of nonconformities (Definition of Major and Minor NCs)
o) Impact of NCs on Certification recommendation
p) Information about the conditions under which the audit may be prematurely terminated;
q) Confirmation of the status of findings of the previous review or audit, if applicable;
r) Confirmation that, during the audit, the client will be kept informed of audit progress and any concerns;
s) Opportunity for the client to ask questions.

5.3 Conducting Recertification audit:

The recertification audit includes an onsite audit that addresses the following:

- The effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification
- Demonstrated competence to maintain the effectiveness and improvement of the management system in order to enhance overall performance
- Whether the operation of certified management system contributes to the achievement of the organization's policy and objectives

The above-mentioned objectives are met by conducting Recertification audit.
The Recertification audit report captures the following information (but not limited to):

- Client Name
- File No.
- Type and mode of audit
- Audit criteria (The requirements of the Standard (Eg. ISO 9001, ISO 13485, etc.) against which the audit is being conducted.)

- Dates of conduct of audit: Start date and end date of conduct of audit.
- Addresses of the client, along with the activity conducted at each site and effective / total number of personnel at each site.
- Details of the key representatives of the client organization.
- Applied scope of certification (As stated in the Audit Nomination)
- Final Scope of Certification (This final scope is agreed upon by the audit team and the client during conduct of Recertification audit)
- Nominated audit team and their role in the audit.
- Client's introduction detailing the context of the organization, effective/ total no. of personnel, needs and expectations of the interested parties
- Details of applicable regulatory and statutory requirements and compliance status (The audit team specifies whether any there is any applicable regulatory and statutory requirement for the products or services provided. Refer to the country specific website to ascertain applicability of regulatory requirements).
- Audit Summary –This summary specifically captures the overall achievement with respect to Audit Objectives.
- Strong Points (The audit team captures the strong implementation points w.r.t. the audit criteria)
- Areas for Improvement
- Non-Conformities Summary (Number of major and minor non-conformities raised and their reference, i.e. non conformity number/s)
- Review of operational control of processes including non-applicable clauses identified by the organization and exclusions claimed. (e.g. Description of Management Related, Documented Information, Customer Related, Purchasing, Design and Development, Production and Service Provision, Quality Control, Competence, Training and Awareness, Effectiveness of Internal Audit and Management Review Meeting processes, also Comment parameters like effectiveness of the process, fulfilment of process objectives, whether covered in internal audits and MRM, control of documented information, risk assessment and mitigations if applicable, leadership and commitment, etc. The names of auditee and time of audit of the process is also captured in this section to determine any deviation from the audit plan)
- Use of marks and any/or any other reference to the certification
- Review of actions taken on non-conformances identified in the previous audit.
- Deviations, changes or any unresolved issues (Description of deviation from the audit plan, any significant issues
- impacting the audit programme, any significant changes that have affected the management system since the
- last audit, any unresolved issues identified)
- Changes observed in provided information w.r.t name, man power, scope and address.
- Recommendations of the audit team
- Recommendations post closure of Major Non-Conformity, if applicable.

Note-1: Guidelines on Management of Extraordinary Events or Circumstances (Ref. Doc. NABCB Policy on Management of Extraordinary Events or Circumstances Issue 04 Effective dated April 2021).

- If a Recertification Audit or other Recertification requirements cannot be completed prior to the expiration of accredited certification, ECI may extend the certification up to '6' months from the date of the expiration of the certification.
- If ECI is unable to gain confidence in the system for which the extension would be granted, then ECI shall decline the client's request for validity extension, including the release of Suspension, if appropriate.
- When ECI successfully completes the recertification activity, the expiration of the renewed certification shall be based on the original recertification cycle. This means not providing the organization an additional '6' months of certification. When the organization is recertified, it will not be for '3' years from the recertification decision, but '3' years from the previous expiration date.

- If it is not possible for ECI to conclude the recertification audits even within this extended '6' months period due to prevailing travel restrictions, ECI may further extend the certificate validity by another '6' months, preferably in intervals of '3' months, i.e. an extension of '12' months in total. However, if this time-frame, from the certification date exceeds '12' months, then ECI shall complete the recertification audit as soon as possible using remote means. In all those cases where the processes cannot be remotely assessed in an effective way to the satisfaction of ECI, the certification scope shall be partially reduced or the certificate shall be completely withdraw, and a new initial audit shall be required. In any case, a decision shall be made taking also into consideration the updated risk associated with the operational control capability of the organization in the extraordinary conditions and the type of certification scheme. In this case, the expiration of the renewed certification shall be based on the original recertification cycle.
- Any extension will be well documented with legitimate reasons for granting extension.

5.4 Communication during the audit:

- During the audit, the audit team shall periodically assess audit progress and exchange information. The Lead Auditor shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.
- Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the Lead Auditor shall report this to the client and, if possible, to ECI to determine appropriate action. The safety risks may include situations like labour unrest at client's location, any major mishaps such as accidents, fire etc., any natural calamity, civil unrest in the geographical location, etc. Other situations may be non-cooperation of auditees with the audit team or evidence of implementation is not available, or there is a major deviation in the scope of certification and actual business activity being carried out at the client premises. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The Lead auditor reports the outcome of the action taken to ECI. This is done through provisions made in the Audit Report.
- The Lead auditor shall review with the client any need for changes to the audit scope which becomes apparent as on-site auditing activities progress and report this to the ECI through provisions made in the Audit report

5.5 Obtaining and verifying information:

During the audit, information relevant to the audit objectives, scope and criteria (including information relating to interfaces between functions, activities and processes) shall be collected by appropriate sampling and verified to become audit evidence. This evidence shall be recorded within the Audit Notes template. Should the auditor use an electronic method of recording audit evidence (i.e. a tablet or laptop), the standard soft copy template of the Auditor notes shall be used.
During the audit, information relevant to audit objectives, scope and criteria is collected by the audit team from the following sources:

- Interviews with employees and other persons
- Observations processes and activities and the surrounding work environment and conditions.
- review of documentation and records.
- review company's website (if available)
- review regulatory website (of country of origin)

5.6 Identifying and recording audit findings:

Audit findings summarising conformity and detailing nonconformity and its supporting audit evidence shall be recorded within the Audit Report and **CAR Report respectively.**
Care should be taken to ensure that the Audit Report does not use suggestive words / language but only reflect the situation as observed in the audit process
Areas / Opportunities for improvement / observations may be identified and recorded
Non-conformances shall not be recorded as areas / opportunities / observations for improvement.
A nonconformity shall be raised when a situation represents:

Non-conformity: Non-fulfilment of a standard's requirement

- **Major Non-conformity:** Non-conformity that affects the capability of the management system to achieve the intended results

Non-conformities could be classified as major in the following circumstances:

- if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- a number of minor non-conformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major non-conformity.

- **Minor Non-conformity:**
  - Non-conformity that does not affect the capability of the management system to achieve the intended results
  - A finding of nonconformity shall be recorded in the **CAR Report** against a specific requirement of the audit criteria, contain a clear statement of the nonconformity and identify in detail the objective evidence on which the nonconformity is based.
  - Non-conformances shall be discussed with the client to ensure that the evidence is accurate and that the nonconformances are understood.

The audit team leader shall attempt to resolve any diverging opinions between the audit team and the client concerning audit evidence or findings, any unresolved points shall be recorded in the **Audit Report.**

5.7 Preparing Audit Conclusions:

Under the responsibility of the Lead Auditor and prior to the closing meeting, the audit team shall:

a) review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the nonconformities
b) agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process
c) agree any necessary follow-up actions
d) confirm the appropriateness of the audit programme or identify any modification required for future audits (e.g. scope of certification, audit time or dates, surveillance frequency, audit team competence).

The following recommendations can be given by the Lead Auditor:

Results of Recertification Audit
Recommended for recertification in total compliance with applied scope of certification
Recommended for recertification with reduction to applied scope of certification
Recommended for recertification with extension to applied scope of certification
Additional Full Audit Onsite
Additional Limited Audit On-Site
Additional Limited Audit Off-Site

When during a recertification audit, instance of nonconformity or lack of evidence of conformity are identified ECI defines the time limits for correction and corrective actions to be implemented prior to the expiration of the certification.

The non-conformities are recorded in "CAR" form which is provided along with the audit pack. The Lead auditor, upon receipt of the duly signed CAR form from the client shall review the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. The Lead Auditor shall then sign the acceptance of the corrective action plan.

In case of a major nonconformity, the Lead auditor can discuss the same with the client and propose a date to conduct Follow-up Audit. This audit shall be an additional full on-site audit (in case of lapses in core areas where the trail in other processes becomes necessary) or additional limited on-site / off-site audit (on-site incase of situation where the closure compliance need to be verified via onsit

demonstration of compliance with participation of audittee and off-site audit in case where the closure compliance can be verified through documentary evidence remotely).

The time frame for submission of correction, identified causes, corrective actions plan is within 7 days from the date of audit. The timeframe for implementing corrective action/s for Major non-conformity is maximum 90 days (3 Months). The client shall inform and send the evidence of implemented corrective action/s. The Lead Auditor shall decide the date for conducting followup audit as per the closure plan and confirmation from Client.

These time periods are defined by taking into account that the maximum permissible time period for restoring certification is 6 Months from the date of expiry of Initial certification.

In Recertification audit, the attendance of all the concerned members present in the opening and closing meeting along with time is recorded.

The Lead Auditor along with audit team analyses all information and audit evidence gathered during the Recertification audit to review the audit findings and agree on the audit conclusions.

5.8 Conducting the closing meeting

A formal closing meeting, where attendance shall be recorded, shall be held with the client's management and, where appropriate, those responsible for the functions or processes audited. The purpose of the closing meeting, conducted by the Lead Auditor, is to present the audit conclusions, including the recommendation regarding certification.
Any nonconformities shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed.

- Thank the client and personnel for their cooperation and general Hospitality
- Reconfirm scope of certification, if there are any changes-explain and provide justification
- Audit Methodology – reconfirmation of audit methodology used during the audit i.e, Interviews, observations, verification of records. A statement that audit evidence obtained was based on sample of information and therefore introducing an element of uncertainty.
- Discuss briefly the audit findings with Positive Observations, Major/Minor NCR's if any.
- Timeframe for the client to present a plan for correction and corrective action for any nonconformities identified during the audit.
- The method and time frame of reporting shall be communicated.
- Confidentiality of information gathered during the audit
- Give the client opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved where possible. Any diverging opinions that are not resolved shall be recorded and referred to ECI
- Declare recommendation
- Certification continuation Approval Process
- Certification continuation approval shall be given by ECI certification decision authority.
- Certificate processing takes (15 - 30 days) and on certification approval and subsequent compliance by the applicant to contractual obligations, the certificate of approval is released along with relevant certification documents e.g. Instructions to use ECI Prestige Mark and/or Accreditation Mark (as permissible) will be sent along with Certificate.
- Inform Surveillance Frequency
- Complaint and Appeal System – information about appeals system on the conduct or conclusions of audit.
- Address any queries from client
- Distribute attendance sheet for signing of auditors & auditees, collect attendance sheet and thank all.

Note: ECI shall send the Audit Report within 7 working days from the date of the completion of the audit to the client.

6 RECORDS

- Application Form (ECI/F-01)
- Application Review (ECI/F-02)
- Quotation (ECI/F-06)
- Certification Agreement (ECI/F-05)
- Audit Plan (ECI/F-07)
- Auditor Nomination (ECI/F-08)
- Attendance Sheet (ECI/F-11)
- Audit Report (ECI/F-09)
- Corrective Action Request (ECI/F-12)
- Audit Notes (ECI/F-10)

7 REVISION HISTORY

Rev. No.	Effective Date	Details
00	01.01.2025	Initial Issue
01	10.11.2025	Change in the Company Name

ECI Management Certification Services LLP

Medical Device Quality Management System

ISO 13485

ECI/P-11

Address

Office No. 708, 7th Floor, Rama Equator,
Next to City International School,
Morwadi Road, Pimpri, Pune - 411018,
Maharashtra, India.

Contents

1. PURPOSE

To establish a systematic and uniform methodology for the conduct of Special Audits which include Scope Expansion Audits and Short Notice Audits.

2. SCOPE

Management System Certification Schemes

3. REFERENCES

- ISO 17021-1 – Section 9.6.4
- IAF MD 9

4. RESPONSIBILITY

CEO, all personnel of ECI.

5. PROCEDURE

5.1 Expanding Scope

ECI in response to an application for expansion to the scope of a certification already granted, undertakes a review of the application and determines the necessary audit activities.
The Scope expansion can be a part of Surveillance with additional mandays as applicable or can be a standalone audit.

In most of the cases, the on-site audit activities for expansion of scope are carried out in conjunction with Surveillance Audit. Process to be followed in such cases during surveillance has been detailed in the Procedure for Maintaining Certification.

Once the date is confirmed by the client for the audit, an intimation is sent to the applicant organization, with Auditor Nomination.

Auditor Nomination is sent to the Client. The client has the right to object to any of the proposed audit team members. Objections should be reported by the client within 3 working days of the receipt of audit team information ECI shall discuss this with the client confidentially in order to resolve the matter satisfactorily.
In case if the client does not send back the response of the audit team nomination, ECI considers the nominated audited team as accepted by the client.

Identifying and recording audit findings
Audit findings summarising conformity and detailing nonconformity and its supporting audit evidence shall be recorded within the Audit Report and **CAR Report respectively.**
Care should be taken to ensure that the Audit Report does not use suggestive words / language but only reflect the situation as observed in the audit process
Areas / Opportunities for improvement / observations may be identified and recorded
Non-conformances shall not be recorded as areas / opportunities / observations for improvement.
A nonconformity shall be raised when a situation represents:
Non-conformity: Non-fulfilment of a standard's requirement

- **Major Non-conformity :** Non-conformity that affects the capability of the management system to achieve the intended results

Non-conformities could be classified as major in the following circumstances:
- if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- a number of minor non-conformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major non-conformity.

- **Minor Non-conformity :**
  - Non-conformity that does not affect the capability of the management system to achieve the intended results
  - A finding of nonconformity shall be recorded in the **CAR Report** against a specific requirement of the audit criteria, contain a clear statement of the nonconformity and identify in detail the objective evidence on which the nonconformity is based.
  - Non-conformances shall be discussed with the client to ensure that the evidence is accurate and that the nonconformances are understood.

Preparing Audit Conclusions:
Under the responsibility of the Lead Auditor and prior to the closing meeting, the audit team shall:

a) review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the nonconformities
b) agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process
c) agree any necessary follow-up actions
d) confirm the appropriateness of the audit programme or identify any modification required for future audits (e.g. scope of certification, audit time or dates, surveillance frequency, audit team competence).

The following recommendations can be given by the Lead Auditor:

Recommendations for Scope Expansion
Recommended for Certification in total compliance with applied scope of certification
Recommended for Certification with reduction to applied scope of certification
Recommended for recertification with extension to applied scope of certification
Additional Full Audit Onsite
Additional Limited Audit On-Site
Additional Limited Audit Off-Site

When during a scope expansion audit, instance of non-conformity or lack of evidence of conformity are identified, ECI defines the time limits for correction and corrective actions to be implemented prior to the granting of the scope expansion.

5.2 Short Notice / Unannounced Audit
It may be necessary for ECI to conduct Short Notice Audits at certified clients.
In such cases:

a) ECI describes and makes known in advance to the certified clients, the conditions under which such audits will be conducted.
b) ECI exercises additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

Short Notice Audits can be conducted in following situations (but not limited to):

A. Customer of ECI certified client raises concerns/complaints to ECI about certified client. B. During internal surveillance activity, ECI comes across following situations;

B. Misrepresentation of scope or certificate issued by ECI
Available post-market surveillance data known to the ECI on the subject devices indicate a possible significant deficiency in the quality management system of certified client.

C. External factors apply such as:
Devices in the scope of certification indicate a possible significant deficiency in the quality management system

D. Significant safety and performance-related information becoming known to ECI.

E. When required by legal requirements under public law or by the relevant Regulatory Authority
F. Significant changes occur which have been submitted as required by the regulations or become known to ECI, and which could affect the decision on the client's state of compliance with the regulatory requirements. Following are a few of the cases of such changes (but not limited to) that could be significant and relevant to the ECI when considering that a Short Notice audit is required :

The following are examples of such changes which could be significant and relevant to the CAB when considering that a short notice or unannounced audit is required, although none of these changes should automatically trigger a short term or unannounced audit:

QMS – impact and changes:

i. new ownership
ii. extension to manufacturing and/or design control
iii. new facility, site change; modification of the site operation involved in the manufacturing activity (e.g. relocation of the manufacturing operation to a new site or centralizing the design and/or development functions for several manufacturing sites)
iv. new processes, process changes; significant modifications to special processes (e.g. change in production from sterilization through a supplier to an on-site facility or a change in the method of sterilization)
v. QMS Management Personnel - modifications to the defined authority of the management representative that impact:
a) quality management system effectiveness or regulatory compliance
b) the capability and authority to assure that only safe and effective medical devices are released

Product related changes:

i. new products, categories
ii. addition of a new product category to the manufacturing scope within the quality management system (e.g. addition of sterile single use dialysis sets to an existing scope limited to haemodialysis equipment, or the addition of magnetic resonance imaging to an existing scope limited to ultrasound equipment)

QMS & Product related changes:

i. Changes in standards, regulations
ii. Post market surveillance, vigilance

Change of Location / Ownership / Name:

a) The certified organization shall inform ECI of any change in the location of the manufacturing unit.
b) On receipt of such information, ECI shall issue instructions to the certified organization for withdrawal of certification with immediate effect.
c) ECI shall endorse the change of premises on the Certificate.
d) In the event of change of Ownership, the organization shall provide necessary documentary evidence. The new management of the organization shall submit its acceptance to the agreement with ECI and payment of fees. The same process shall be followed as and when an existing applicant undergoes a change in management. Such changes shall not call for a visit to the production site.
e) In case of change of Name, the manufacturer shall inform the change in the name to ECI supported with documentary evidence, and if satisfied ECI shall endorse the Certificate in the new name.

5.4 Scope Reduction

ECI shall reduce the scope of certification to exclude parts of the certified scope.

Certified scope reduction can be done in following scenarios (but not limited to);

- The part of scope not meeting the requirements, when the certified client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification.
- Deletion of a product category from the quality management system scope which client organization is no longer manufacturing.
- Deletion of activity from scope (e.g. Organization previously certified with Manufacturing and Sales activity may reduce the 'Manufacturing' scope and opt only for 'Procurement and Sales' of product)

5.5 Non-conformity and CAR

In special audits mentioned above, the non-conformities are recorded in "CAR Report" form which is provided along with the audit pack. The Lead auditor, upon receipt of the duly signed CAR Report form from the client shall review the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. The Lead Auditor shall then sign the acceptance of the corrective action plan.

In case of a major nonconformity, the Lead auditor can discuss the same with the client and propose a date to conduct Follow-up Audit. This audit shall be an additional full on-site audit (in case of lapses in core areas where the trail in other processes becomes necessary) or additional limited on-site / off-site audit (on-site in case of situation where the closure compliance need to be verified via onsite demonstration of compliance with participation of auditee and offsite audit in case where the closure compliance can be verified through documentary evidence remotely). The time frame for submission of correction, identified causes, corrective actions plan is within 7 days from the date of audit. The timeframe for implementing corrective action/s for Major non-conformity is maximum 90 days (3 Months). The client shall inform and send the evidence of implemented corrective action/s. The Lead Auditor shall decide the date for conducting follow-up audit as per the closure plan and confirmation from Client.

In case of a minor nonconformity, the client needs to submit formal correction, identified root causes, corrective action/s plan within 7 days from the date of audit. Lead Auditor shall check the effective implementation of correction and corrective action in the next subsequent audit, e.g. Surveillance audit or Recertification Audit.

ECI shall send the Audit Report within 7 working days from the date of the completion of the audit to the client.

6 RECORDS

- Application Form (ECI/F-01)
- Appication review (ECI/F-02)
- Quotation (ECI/F-06)
- Audit Plan (ECI/F-07)
- Auditor Nomination (ECI/F-08)
- Attendance Sheet (ECI/F-11)
- Audit Report (ECI/F-09)
- Corrective Action Request (ECI/F-12)
- Audit Notes (ECI/F-10)

7 REVISION HISTORY

Rev. No.	Effective Date	Details
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01	10.11.2025	Change in the Company Name

ECI Management Certification Services LLP

Medical Device Quality Management System

ISO 13485

ECI/P-13

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Morwadi Road, Pimpri, Pune - 411018,
Maharashtra, India.

Contents

1. PURPOSE

To establish a systematic and uniform methodology for the use of Information and Communication Technology (ICT) for Auditing / Assessment Purposes.

2. SCOPE

Auditing / Assessment of Management System Schemes. The use of ICT is not mandatory, but if used as part of the Audit / Assessment methodology, it is mandatory to conform to this document.

3. REFERENCES

- ISO 17021-1
- Section 9 of Quality Manual
- IAF MD4
- IAF MD5
- IAF MD9
- ISOIEC TS 17012

4. RESPONSIBILITY

CEO, and all personnel of ECI.

5. PROCEDURE

5.1. Security and Confidentiality

- Security and Confidentiality shall be maintained for electronic or electronically-transmitted information through ICT for audit / assessment purposes. (Ref. Certification Agreement).
- ECI and Client Organisation shall mutually agree upon use of ICT prior conduct of audit / assessment in accordance with information security and data protection measures and regulations. (Ref. Auditor Nomination).
- In the case of non-fulfilment of the determined measures or non-agreement of information security and data protection measures, ECI shall ascertain the use of other possible methods to conduct the audit / assessment.
- In the case of non-agreement between ECI and Client Organisation for the use of ICT for Audit / Assessment, ECI shall ascertain the use of other possible methods to fulfil the audit / assessment objectives.

5.2 Process Requirements

- ECI shall identify and document the risks and opportunities which may impact audit/assessment effectiveness for each use of ICT under the same conditions, including the selection of the technologies and how they are managed. (Ref. Annex-I to F-01AR Application Review).
- Application Review shall include feasibility check of necessary infrastructure required to support the use of ICT for the audit / assessment activities. (Ref. Annex-I to F-01AR Application Review).
- Considering the risks and opportunities identified, during Application Review ECI shall plan the utilization of ICT and the extent to which ICT will be used for audit/assessment purposes to optimize audit/assessment effectiveness and efficiency while maintaining the integrity of the audit/assessment process.
- ECI shall ensure the nominated Auditor/s understand and utilize the information and communication technologies employed to achieve the desired results of audit(s)/assessment(s). Auditor/s shall be aware of the risks and opportunities of the information and communication technologies used and the impacts that they may have on the validity and objectivity of the information gathered.
- Wherever ICT is used for audit/assessment purposes, ECI shall include necessary additional planning, which contributes to the total audit/assessment time. (Ref. F-01AR Application Review).
- ECI shall record the extent to which ICT has been used in carrying out audit/assessment and the effectiveness of ICT in achieving the audit/assessment objectives in Audit report, Audit plan and supporting documents.

- If any virtual sites included within the scope of audit / assessment, Application Review and relevant audit / assessment documentation shall note that virtual sites are included and the activities performed at the virtual sites shall be identified.

5.3 Definitions:

- Virtual Site:
  - Virtual location where a client organization performs work or provides a service using an on-line environment allowing persons irrespective of physical locations to execute processes.
  - Note 1: A virtual site cannot be considered where the processes must be executed in a physical environment, e.g., warehousing, manufacturing, physical testing laboratories, installation or repairs to physical products.
  - Note 2: A virtual site (e.g. company intranet) is considered a single site for the calculation of audit/assessment time.
- Remote Auditing Method (i.e. ICT Mode Audit)
  - Method used for conducting audit activities from any place other than the location of the auditee
  - Note 1: Remote auditing methods can be used in combination with on-site methods to achieve a full and effective audit.
  - Note 2: Remote auditing methods can be used for virtual locations, i.e. where an organization performs work or provides a service using an online environment, enabling individuals to execute processes irrespective of physical locations.
  - Note 3: Remote auditing methods can be used by the auditor at one site of the auditee to audit another site

6. RECORDS

- Application Review (ECI/F-02)
- Auditor Nomination ICT (ECI/F-08A)
- Certification Agreement (ECI/F-05)

7. REVISION HISTORY

Rev. No.	Effective Date	Details
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