1.0 Purpose

To describe a procedure for audit planning, conducting the audit at client premises, preparation of reports and submitting the reposts

2.0 Scope

This procedure covers audit planning, execution of audit and reporting for all types of audits as listed below.

- Stage 1 audit
- Registration or Stage 2 audit
- Verification Audit
- Surveillance audit
- Recertification audit
- Transfer audit

3.0 Responsibility

3.1 Certification Manager and admin officer are responsible for Planning the audit and ensuring the audit reports are received timely in the office and review of the audit reports.

3.2 Audit Team Leaders/Auditors are responsible for execution of audit and preparation of audit and submitting the audit reports.

4.0 Description of Activity

4.1 Introduction

The objective is to provide a professional audit service to all clients. Audit Team leaders and auditors are responsible for ensuring the objectives of their assigned audits are fully met. The various activities needed to be carried out are:

4.1.1 Document review / Site Visit - Stage 1 Audit
4.1.2 Stage 2 Audit
4.1.3 Verification Audit (If Applicable)
4.1.4 Surveillance Audit
4.1.5 Triennial Audit

The term quality management system as applied in this procedure includes management system in accordance with the ISO 17021 standard.

4.2 Audits

4.2.1 The purposes of the audits are to provide assurance that the auditee organization's management system conforms to the requirements of standard applied, as stated in the certification contract and to verify that the documented system has been implemented. The audit also serves to verify that the quality management system is appropriate to auditee organization's activities.

Certification Manager is responsible for selection of the audit team, using the auditor qualification form and summary. Unless required for technical reasons and logistics, care shall be taken to ensure that same auditor does not visit the client more than three consecutive visits. This shall ensure "no bias" and a fresh look at the system. All auditors / subcontractors are responsible for identifying any conflict of interest with the specified client and report to certification Manager . Certification Manager shall review the same and take necessary decisions which may include replacing the person with some other auditor.

4.2.2 The team leader leads the audit in accordance with the referenced instructions. A set of

updated documents pertaining to audit like client details, open non conformances, surveillance plan and comments from prior visits are provided to every audit team. Activities include the opening meeting with the auditee organization, team briefings, audit interviews, nonconformance issuance, auditee organization briefings, and the closing meeting with the auditee organisation. The team leader issues an audit report reflecting the recommendation concerning registration based on the team findings.

If nonconformance is found, the recommendation will be on hold until suitable corrective action has been taken and evidenced.

4.2.3 During the audit if the auditor finds a breach of legislation i.e. legal/regulatory/ statutory requirement not having been followed, the auditor will communicate his finding to the team leader who in turn will notify the auditee organization's management of the violation. The auditor will further investigate the same and check as to why the auditee organization's management has failed to detect and address the same. If and when after proper investigation, it is clear that the auditee organization's management system has short comings, a major/minor nonconformance as appropriate will be raised. Follow-up visits are made to verify that major nonconformance(s) are effectively remedied before registration is granted. In case of legal / statutory / regulatory requirements by the auditee organisation, the following policy shall apply -

In the event of the auditee organisation conducting a violation of the legal requirement, the auditee organisation, as a part of the rules and regulations of Judah Compliance Auditors certification, will inform Judah Compliance Auditors on its own pro-actively and voluntarily. This pro-active information communication by the auditee organisation is not to be confined to onsite-audit activity but is applicable to the complete registration period which the auditee organisation is entitled to by way of Judah Compliance Auditors certification. In case of violation of legal requirements that is observed during a Stage 2 Audit or Surveillance Audit(s), Judah Compliance Auditors audit team will notify the auditee organization's management about the observation. Further the audit team will

conduct a proper investigation on the issue and check as to why the auditee organization's management system has failed to detect and address the same. Based on the investigation of the audit team, if it is established that the management system has shortcomings, a major or minor non-conformance note will be issued.

Additionally, the auditee organisation has to ensure and to provide evidence to that effect to Judah Compliance Auditors that the appropriate authorities have been notified of the violation of legal requirements, as per the prescribed procedure instituted by the relevant authorities. Work instructions for the applicable audit guidelines is also available for the audit team.

In terms of ISO 13485, if the client uses outsourced processes, then JC Auditors will determine and document whether specific competence in the audit team is necessary to evaluate the control of the outsourced process. Annexure D, table D.1 of the IAF MD 9:2022 will be used in determining the audit duration for ISO 13485 audits as well as ISO 13485 audits integrated with ISO 9001 audits.

The audit team shall have the competence for the Technical Area (Annex A in conjunction with relevant knowledge and skills as defined in Annex B) for the scope of audit within the IAF MD 9:2022 document. If the audit is performed for a client that only manufactures parts and offers services (see Table A.1.7 of IAF MD9), the audit team does not have to demonstrate technical competence at the same level as that for a manufacturer providing medical devices.

4.3 Stage 1 audit

Stage 1 Audit is a part of the registration process and not an optional activity. Stage 1 is carried out onsite or by desk /document review, depending on the individual client dynamics as assessed during the contract review. It is not compulsory for the Stage 1

audit to be conducted on site for clients who have been deemed to conform to the RTMS, ISO 39001, ISO 14001, ISO 45001, ISO 22000, ISO 13485, ISO 3834 and ISO 9001 standards, which are administered by the RTMS National Steering Committee, SANS, and other various stakeholders.

The RTMS National Steering Committee and SANS are the national bodies in South Africa who have been responsible for initiating the SANS 1395-1 RTMS, ISO 39001, ISO 14001, ISO 22000, ISO 45001, ISO 13485, ISO 3834 and ISO 9001 standards and have been promoting and administering the RTMS, ISO 39001, ISO 14001, ISO 45001, ISO 22000, ISO 13485, ISO 3834 and ISO 9001 over the last 10 years. These bodies comprises both government and private sector bodies that collectively have an interest in promoting safety, compliance, and efficiency with the road transport arena as well as the environmental and health arenas in South Africa. The RTMS National Committee and SANS include representation from the following bodies:

- National Department of Transport (NdoT)
- KZN Department of Transport
- Council for Scientific & Industrial Research (CSIR)
- Road Traffic Management Corporation (RTMC)
- South African National Roads Agency (SANRAL)
- Cross Border Road Transport Association (CBRTA)
- South African Chamber of Mines
- Road Freight Association (RFA)
- South Africa Sugar Research Institute (SASRI)
- Chemical and Allied Industries Association (CAIA)
- South Africa Bureau of Standards (SABS)

- Standard Bank of South Africa – Asset Finance Division

It has been under the mandate and control of the National RTMS Steering Committee and SANS that JC Auditors has been conducting audits against the RTMS, ISO 39001, and standards since 2007.

4.3.1 Objectives of Stage 1 audit:

During the Stage 1, it is to be established that the requirements of the standard(s) are being met by the auditee organisation. This can be done by review of the available evidence. This evidence may take many forms and some cases need not be "documented". However, this does not alter the need to adhere to the requirements for documentation contained in ISO 17021.

The objective of the Stage 1 audit is to provide:

- To audit the client's management system documentation
- a focus for the planning of the Stage 2 Audit (e.g. resources, time allocation) by review the client's status and understanding regarding the standard w.r.t objectives and operations of the management system, site activities, identification of environmental aspects and associated impacts (for ISO 17021), identification of applicable legislation and licenses matching with site and activities of auditee organization, discussions with client personnel regarding policy, objectives and the state of preparedness of the auditee organisation,
- To evaluate the client's location and site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for the stage 2 audit.

- To collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliance (e.g., quality, environmental, legal aspects of the client's operation, associated risks etc.)
- To review the allocation of resources for stage 2 audit and agreeing with the client on the details of the stage 2 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 system substantiates that the client is ready for the stage 2 audit.
- With regards to SANS 22003 requirements, the objectives of the stage 1 are to provide a focus for planning the stage 2 audit by gaining an understanding of the organization's FSMS and the organization's state of preparedness for stage 2 by reviewing the extent to which:

    a) the organization has identified PRPs that are appropriate to the business (e.g. regulatory, statutory, customer and certification scheme requirements);

    b) the FSMS includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations);

    c) the FSMS includes adequate processes and methods for the identification and implementation of relevant food safety legislation.

    d) the FSMS is designed to achieve the organization's food safety policy.

    e) the FSMS implementation programme justifies proceeding to stage 2.

f) the validation of control measures, verification of activities and improvement programmes conform to the requirements of the FSMS standard.

g) the FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties.

h) there is any additional documentation which needs to be reviewed and/or information which needs to be obtained in advance.

- With regards to ISO 13485 audits, the stage 1 audit will be performed onsite for high-risk medical devices (GHTF C & D) unless extraordinary events or circumstance beyond the control of the organization happen. In such a circumstance, JC Auditors will implement QP13 procedure for the proper maintenance of accreditation and certification

For Companies requiring transferring from another certification body -

- If the company has an accredited certificate by another body, then the process under 4.9 (Pre-transfer review) must be completed.
- If the company has a non-accredited certificate, then Judah Compliance Auditors normal procedures must apply in full.

In terms of ISO 22000, where an organization has implemented externally developed elements of a FSMS, stage 1 shall review the documentation included in the FSMS to determine if the combination of control measures:

- is suitable for the organization.
- was developed in conformity to the requirements of ISO 22000 or other sets of specified FSMS requirements.
- is kept up to date.

The availability of relevant authorizations shall be checked when collecting the information regarding the compliance to regulatory aspects.

For FSMS, stage 1 shall be carried out at the client's premises in order to achieve the objectives stated above. In exceptional circumstances or events, all or part of stage 1 can take place off-site or remotely through the use of ICT and will be fully justified. The evidence demonstrating that stage 1 objectives are fully achieved shall be provided.

The interval between stage 1 and stage 2 shall not be longer than six months. Stage 1 shall be repeated if a longer interval is needed.

4.3.2 Stage 1 audit is intended to -

- Assess that the auditee has a documented management system, which is compliant to applied standard.
- Ensure that the QMS/EMS, FSMS includes an adequate process for identification of the relevant aspects, impacts and determination of their significance.
- Ensure that the system includes a procedure for identification of applicable regulatory requirements and that all the required environmental licenses, permits and approvals are in place.
- Ensure that the management system is designed to achieve defined policy, objectives, and targets.
- Establish that internal audit conforms to the requirements of respective standard and the internal audits are effective and relied upon. Seeking evidence for competence, experience, training & independence of internal auditors (ISO 17021); auditing procedure & methodology; reference & standards; resource availability; organization & planning of audits; checks & reports; timeliness & effectiveness of corrective / preventive action and management of audit follow-up.

- Establish that management reviews are conducted and cover continuing suitability, adequacy, and effectiveness of management system.
- Establish that relevant communication from customers / external interested parties is documented and responded.
- Establish that the management system is designed to realize the concept of continual improvement.
- Establish that the proposed scope of registration is appropriate to the auditee organization's business activities.
- Confirm the auditee organization's readiness for registration audit.
- Obtain information about the auditee organization's operations which might have an impact on the stage 2 audit including:
    - Work hours and schedules
    - Special safety requirements
    - Security clearance requirements
    - Logistics
    - Size and complexity of the organization
    - Applicable statutory requirements & licenses
    - Technology expertise necessary
- Prepare a detailed program including audit trails for the upcoming Stage 2 audit.
- Review the adequacy of audit time for Stage 2 audit. Increase or decrease the time duration if required based on the findings of audit; complexity / volume of processes; variation found from the data provided by the client in F59 Application Form. The time for stage 2 may be reduced based on the maturity of the client's system, preparedness for certification, very small sites, complexity of management system and processes conducted at a site, repetitive work, low risk routes etc.

4.3.3 When carrying out a review the auditor shall note his/her areas of concern in the Stage 1

audit report. Special requirements are listed in the Stage 1 audit report for that company i.e., guidance documents, legislation etc. for reference at the audit.

The Document reviews are a part of the stage 1 audit and include at least the following:

- Documentation including procedures with links to related requirements of respective standard. If client has integrated systems (e.g., QMS, OHSMS, FSMS), the documentation shall be reviewed with regards to. interfaces with other systems.
- Description of organization and its on-site processes
- Means and system for realizing continual improvement.
- An overview of applicable regulations and agreements with authorities.
- Internal audit program identified nonconformities and records.
- Records of incidents, breach of regulation and relevant correspondence and QMS/EMS/FSMS related communications with action taken.
- Records for management review
- Details of identified nonconformities and corrective/preventive action taken in last 12 months.

4.3.4 Process steps for Stage 1 audit

The assigned team leader is responsible for managing and documenting the results of the stage 1 audit. However, responsibilities for conducting the document review may be delegated to the other audit team member. The process for the stage 1 audit can be briefly described as follows:

1. Admin officer advises the concerned auditor / TL of the assignment.
2. Admin officer prepares the audit schedule and intimates the client at least a week before the planned audit date. Audit details are communicated to the client via MS Outlook invitation.

3. An opening meeting is held to put the auditee organisation at ease, advise him/ her of objectives of the document review and obtain the auditee organization's cooperation.

4. Generally, only one person is needed to perform the stage 1 audit, but where a team is used or an auditor under training is present, then a team briefing may be necessary.

5. In order to prepare a detailed program for the audit, a tour of the facility to provide familiarization with the auditee's organization is essential.

6. The main objective is to review the auditee organization's readiness with respect to the points listed above. Documents are reviewed only to the level necessary to establish compliance with relevant standard. A record of documents reviewed is made.

7. The auditor shall review for any discrepancy in any information provided in questionnaire and contract review. This shall be reviewed by Certification Manager and may result in change in man-days assigned for the contract.

8. Auditee organisations debrief meeting is held to discuss the areas of concern and obtain any further information necessary to decide on further action.

9. The areas of concern are collated, and an audit report is prepared for the client. On the basis of the areas of concern, a recommendation is made to proceed / defer/ cancel the registration. The auditor shall explain the reason for considering the documentation or system unsatisfactory.

10. The client will be informed by the auditor that any discrepancies not closed out prior to the audit will result in automatic non-conformance notices being raised. The discrepancies include non-completion of scheduled internal audit programmes and management reviews.

11. The Stage 2 audit shall be conducted within 6 months of stage 1 audit for all new client applications. Any further delay shall require stage 1 audit to be carried out again. There is no restriction on minimum time duration.

4.3.5 Non-Conformity and Sentencing of major and minor non-conformances – RTMS, ISO 39001, ISO 14001, ISO 45001, ISO 22000, ISO 13485, ISO 3834 and ISO 9001

A non-conformity is defined as failure to fulfil one or more requirements of the management system standard or a situation that arises serious doubts about a client's management system to achieve its intended output. Nonconformities will be classified in two categories – Minor and Major.

4.3.5.1 During an audit a minor non-conformity shall be deemed present when any activity is not undertaken, and which is stipulated in the client's management system as a requirement or which was undertaken and is relevant but is not controlled within the system and is deemed to be of a minor nature (of little importance to the quality of the firm's product or service). Several non-conformities in any one section, or procedure, shall constitute a major breakdown of the system.

4.3.5.2 A major non-conformance shall be declared when a system or procedure is not working at all, or where there is complete failure to fulfil one or more requirements of the management system, or where there is significant doubt that the client's system can achieve the intended output, or where a serious cumulative number of minor non-conformities are found overall, or when there is a complete lack of system control. Several non-conformities may be grouped together as one major non-conformity.

4.3.5.3 If all non-conformities have been rectified within two months of the audit, then the award will be recommended. If not, a complete re-audit is to be carried out at the discretion of the Certification Manager. If on a follow-up visit it is found that the major nonconformity has not been satisfactorily addressed, then another visit is to be made within two months. If

this fails, then a full re-audit must take place.

4.3.5.4 The client's corrective actions, together with supporting evidence is reviewed by an auditor (or technical expert). If the actions taken and evidence submitted is deemed to adequately address the non-conformance then the reviewer will send an e-mail confirming the same to the administration officer. The administration officer will then formally close out the non-conformance and proceed further with the certification process.

4.3.5.5 In terms of ISO 13485 audits, examples of major nonconformities which require the acceptance and the verification of the effectiveness of correction and corrective actions are as follows:

- failure to fully address applicable requirements and implement an entire process for quality management systems (e.g., failure to have a complaint handling or training system)
- failure to implement applicable requirements for quality management systems
- failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects
- products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labelling
- the existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements
- repeated nonconformities from previous audits

4.4 Stage 2 Audit

The objective of the Stage 2 Audit is:

(a) To confirm that the auditee organisation adheres to its own policies, objectives, and procedures.

(b) To conform that the management system of the auditee organisation conforms to all the requirements of the current version of respective standard(s), normative document and achieving the organization's policy & objectives.

(c) To evaluate compliance to applicable legal and regulatory requirements.

4.4.1 The following activities will be carried out to meet the objectives of Stage 2 Audit:

- Assess that the auditee organization's quality management system has been implemented and objective evidence is available to demonstrate its effective implementation in line with its policies, objectives, and procedures.
- Establish that all requirements of the standard are addressed where they apply to the activities covered by the scope of registration.
- Confirm that quality management system is appropriate to the product, process or service provided by the auditee, with the capability of managing and improving performance.
- Encourage auditee organizations to improve their management system on an on-going basis.

While accomplishing this, the registration audit must be conducted to satisfy the needs of the auditee organisation and maintain the integrity of the registration process as a whole. The team leader is responsible for managing and documenting the results of the registration audit. He may delegate specific responsibilities for conduct of audit activities to assigned audit team members.

4.4.2 The Stage 2 audit addresses the implementation of all the elements in the standard and focuses on –

- Procedures to ensure compliance with legal & other requirements.
- Inconsistencies between organization's policy, objectives & targets, and its procedures to achieve them or the results of their application. The registration audit

team shall appreciate that it is for the organization to define the means by which its policy commitment to continual improvement is achieved and to develop processes for achieving / measuring performance.

- Auditee's procedure & application for investigation / development of opportunities for improvement and programs for improvement.
- Auditee's process for achieving continual improvement and its effectiveness.
- Operational control to maintain consistent performance and compliance to procedures.
- Performance monitoring, measuring, reporting & reviewing against the legislative requirement, objectives, and targets.
- Internal auditing, identification / evaluation of non-conformities and completion of effective corrective / preventive actions.
- Management review and management responsibility for quality management system.
- Interfaces and links between policy, aspects & impacts, objectives & targets, responsibilities, programs & procedures, performance data, internal audit, and management review.
- Register of regulatory requirements for the respective standard.
- Seeking evidence for competence, experience, training & independence of internal auditors; auditing procedure & methodology; reference & standards; resource availability; organization & planning of audits; checks & reports; timeliness & effectiveness of corrective / preventive action and management of audit follow-up.
- Staff awareness of the respective management system

If there are combined systems in place, e.g., QMS, FSMS and EMS, then emphasis must be placed to ensure that both standards are adequately addressed and monitored.

Records and auditor notes must demonstrate that adequate time has been given to each standard.

4.4.3 Process steps for Stage 2 Audit

1) Certification Manager or admin officer schedules the audit and informs the Audit team leader (TL). A set of necessary documents like client details, Stage 1 audit report etc. is given to TL. The Admin officer discusses the logistics and audit plan with auditee organisation. Admin Officer prepares the audit Plan and intimates the client normally a week before the planned audit date and the same is agreed upon prior to the audit. In case of any changes in the audit plan during the audit the same is captured as part of the audit report.

2) During the audit planning, the EAC sector specific guidelines and audit trails is used to identify critical processes.

3) Where the assignment is complex (multi-site, has specific technological requirements, and/or utilizes a large audit team etc.), a team briefing may be planned before the scheduled audit date to coordinate details.

4) An opening meeting is held to advise the auditee organisation of the objectives of registration audit, details of the audit and schedule and obtain for the auditee organization's cooperation.

5) Where more than one person has been assigned, daily team meeting may be scheduled after the auditee organisation meeting / site visit to plan the day's strategy and cover any points not included in the pre-visit team meeting.

6) Changes to the auditee organization's documentation since the previous visit is reviewed and outstanding non-conformance(s) followed-up. The auditee organization's management system is assessed according to the schedule and audit trails identified during adequacy audit. Documents reviewed, personnel interviewed, and other pertinent data is recorded in the auditor's note pads. Non-conformances are raised after proper

investigation against activities found non-compliant. The Observations are issued identifying areas of improvement only. The caution will be observed in recording the Observations so that the issues pertaining to non-conformance are not reflected as observations and vice versa. The recording of observations will be strictly confined to areas of improvement only.

7) When audit is for more than a day, daily team debrief meeting is used to discuss findings, followed by auditee organisation debrief to present the findings of day.

8) On the final day of the audit, the team discusses overall performance during the audit and confirm the findings with the client. The team decision to approve or defer registration is recorded in the report. An organization may be recommended only if no major non-conformance is found. In case of a major non-conformance complete the client must submit evidence off corrective actions. Depending on the nature of the evidence of the non-conformance, a verification audit may be required.

9) The visit ends with a Closing Meeting where the recorded findings and team recommendations are formally presented to the auditee. Also, during the Closing Meeting the Team Leader informs the Client to submit the evidence of Corrective Action taken for review and closure of the Non-Conformances identified. In case of major non-conformances identified the client is informed whether a verification audit is necessary depending on the impact of the major non-conformance identified.

10) The report is compiled and emailed to the client. The audit checklist are exclusive notes strictly for use of auditors to carry out the audit and the team leader shall ensure that they are never given out to the auditee.

11) The audit report is submitted only after satisfactory verification of corrective actions taken for the non-conformance(s). The client shall submit the evidence of implementation of corrections and corrective actions of any major nonconformity within 6 months after the last day of stage 2, if this period is lapsed, JC Auditors shall conduct

another stage 2 audit prior to certification being issued. The following process is followed once non-conformances are issued:

1. The client is sent the non-conformances within 5 days of the closing meeting.
2. the client is sent the first reminder of reminder after 60 days of the closing meeting.
3. the client is sent the second reminder after 120 days of the closing meeting.
4. The client is sent the final reminder after 150 days of the closing meeting notifying them that a response is required within 30 days or a stage 2 audit will be conducted.

4.5 Verification Audit

4.5.1 The purpose of verification audits is to conduct the follow-up of non-conformance(s) of an auditee organization's management system, identified during an audit, that were determined to require corrective action. Follow-up audit is required where a major non-conformity is raised. Minor non-conformity does not require formal follow-up visit and may be closed off site based on evidence submitted. The time required for follow-up audit shall be determined based on number and nature of major non-conformities issued.

4.5.2 The Certification Manager will plan and determine the type of follow-up that is required. An off-site follow-up may only be conducted when the corrective action can be objectively evaluated on the basis of documented evidence sent to Judah Compliance Auditors by the auditee organisation. If the follow-up audit is not performed within three months of the stage 2 audit, a partial Re-audit has to be performed. A complete Re-audit will be carried out if the follow-up audit is not performed within 6 months.

4.5.3 The client is then required to submit corrective actions indicating how the non-conformances have been addressed. These corrective actions, together with supporting documents are then reviewed by the auditor and/or certification manager and/or managing member. The auditor and/or certification manager and/or managing member will send an email confirming the evidence is adequate to close out the findings or the auditor and/or certification manager and/or managing member will update the Review of findings (F66) excel spreadsheet to confirm either the non-conformances are closed out or further evidence is required. The non-conformances should be updated to reflect the new status, where the corrective actions are verified. These are reviewed by the team leader and then the Certification Committee. Certification Manager initiate withdrawal/suspension procedures if auditee organisation fails to effectively respond to a corrective action request or if the corrective action is not satisfactory. Audit report for Follow-up audit shall include a closure of the individual non-conformances.

4.6 Surveillance Audit (SA)

The registered management system should continue to meet the requirements of specific standard and should be managed effectively by the auditee organisation. SA is intended to verify the continued effective maintenance of the auditee organization's management system, satisfy the needs of the auditee organisation, and maintain the integrity of the registration process as a whole.

4.6.1 SA is intended to:

- Assess that the auditee organization's registered management system has been maintained.
- Verify that changes to management system subsequent to the previous visit are in compliance with respective standard and that objective evidence is available to substantiate implementation.

- Re-confirm that management system is appropriate to auditee organization's product, process or service provided, with the capability of managing and improving performance.
- Promote the effectiveness of management system.
- Assess major changes in auditee organization's operations, technology that could affect the certification / registration.

4.6.2 The various mandatory elements to be audited at every surveillance are –

- Changes to documented system
- Legal regulatory compliance
- Internal audits
- Document control
- Management responsibility & review
- Use of certificate and logo.
- Corrective & Preventive actions
- Achievement of objectives and Continual improvements
- Appeals / Complaints / communication from external interested parties.
- Effectiveness of management system to achieve auditee organization's policy, objectives & targets.
- Progress of the planned activities and continuing operational.
- Follow-up on identified non-conformities (internal / certifying body)
- Appeals / complaints received by Judah Compliance Auditors

The surveillance audit may be combined with the audits of other management systems. The report should clearly indicate the aspects relevant for each management system.

4.6.3 Process steps for Surveillance Audit

The team leader is responsible for managing and documenting the results of SA. The team leader may delegate specific responsibilities for conduct of audit activities to assigned audit team members. Certification Manager is responsible for review of audit report to assess effectiveness. The process steps for the Surveillance Audit are -

1) Certification Manager or Admin Officer schedules the audit and informs the Audit team leader (TL). Care is taken that the audit is scheduled within 12 months interval – date being last day of Certification Audit. A set of necessary documents like client details, earlier audit report etc. is given to TL.

2) Certification Manager shall review the functions / processes audited in the earlier surveillances before finalizing the audit plan. TL shall ensure that all critical processes are audited at least twice and rest at least once in the three-year period.

3) Where an assignment is particularly complex (i.e., begins at several different locations, has particular technological requirements, and/or utilizes a large number of team members, etc.), it may be beneficial to call a team briefing some time before the scheduled surveillance date to coordinate details.

4) An opening meeting is held to advise the auditee organisation of the objectives of audit, details of the audit and schedule and obtain auditee organization's cooperation. Auditee organisation brief may be conducted if audit extends beyond a day.

5) Where more than one person has been assigned, a daily team meeting is scheduled immediately following the auditee organisation meeting to plan the day's strategy and cover any points not included in the pre-visit team meeting. Changes to the auditee organization's documentation since the previous visit are reviewed and outstanding non-conformances followed-up. The scope on the certificate will be checked against the scope of activities being carried out by the company. If these are

not the same, the auditor will discuss this with the company and inform the Certification Manager or appointed person for further consideration.

6) The auditee organization's management system is assessed using the Audit Program. Documents reviewed, personnel interviewed, and other pertinent data is recorded in the auditor's checklists and notes. This information is confidential and not part of the formal audit report. Non-conformances are raised after proper investigation against activities found non-compliant. The observations are issued identifying areas of improvement only. The caution will be observed in recording the observations so that the issues pertaining to non-conformance are not reflected as observations and vice versa.

7) On the final day of the surveillance, the team discusses overall auditee organisation performance and determines the recommendation (registration to continue or follow-up is required). The team prepares the surveillance audit report .

8) The visit ends with a Closing Meeting where the findings and team recommendation are formally presented to the auditee organisation and any follow-up actions agreed upon. The Record of Findings is handed to the auditee organisation and a copy forwarded to Certification manager for review and processing.

9) At least one third of the management system will be checked by the auditor at each surveillance visit. It is essential to ensure that the full system (as a minimum) is covered over a three-year period by surveillances. At each visit complaints, audits, registration marks, documentation changes, and evidence of improvement will be reviewed.

10) The audit report is submitted only after satisfactory verification of corrective actions taken for the non-conformance(s). The client shall submit the evidence of implementation of corrections and corrective actions of any major nonconformity within 6 months after the last day of the audit, if this period is lapsed, JC Auditors will

cancel certification. The following process is followed once non-conformances are issued:

- The client is sent the non-conformances within 5 days of the closing meeting.
- the client is sent the first reminder of reminder after 60 days of the closing meeting.
- the client is sent the second reminder after 120 days of the closing meeting indicating that certification is suspended.
- The client is sent the final reminder after 150 days of the closing meeting notifying them that a response is required within 30 days or certification will be cancelled.

Any auditee organization has to notify Judah Compliance Auditors in writing of any major change in the management system and / or the scope of activities. Certification Manager decides if the verification of changes can be assessed during next surveillance audit or if a special visit has to be scheduled. The performance of the special visit shall be similar to normal surveillance and Certification Manager shall inform the assigned auditor to audit the required changes in system.

In terms of ISO 13485, the surveillance programme shall include a review of actions taken for notification of adverse events, advisory notices, and recalls.

4.6.4 Maintaining of Certificates.

Certificates will be maintained provided that the certified clients continue to satisfy the management system standard and based on positive recommendation from the audit team leader during routine surveillance audits provided that any non-conformity or any other situations which may lead to withdrawal / suspension of certification. In such cases the audit team leader reports to the Certification Committee to initiate a review by competent personnel, independent from those who carried out the audit.

4.7 Recertification (Triennial Audits)

4.7.1 The purpose of the recertification audit is confirm the continued and effective management system as a whole is followed and the continued relevance and applicability of the scope of certification, commitement to enhance and maintain overall effectiveness and improvement of the manageme nt system and whether the operations of a certified client contributes to the achievement of the clients policy and objective.

4.7.2 The following steps should be followed when planning three-year re-approval visits:

- The planning and extent of the visit are in accordance with the certification review committee requirements and that determined at the last surveillance visit. The triennial visit is planned based on client's performance during the certification period, previous surveillance audit reports, trends in NC raised, complaints received during the period and corresponding investigation reports etc.
- Triennial audit may include stage 1, if there is considerable internal / external change in QMS, activities, location, and scope of certification.
- During recertification audit planning the admin officer shall ensure auditor rotation to prevent the complete cycle being carried out by a same auditor.
- Triennial audit shall include review of effectiveness and improvements in the QMS performance.
- The triennial audit is a full audit of the auditee organization's management system follows the same process as the Stage 2 Audit.
- Triennial audits and review follow the same instructions as those for initial audits. Care should be taken for review of changed scope or activities of the client.

4.7.3 Decision on renewing the certificate will be made by Judah Compliance Auditors based on results of recertification audit, review of the certified client's system over the period of certification and any complaints received against the certified client over the certification period.

4.7.4 In accordance with ISO 17021, the triennial audit, closure of all issues and certification committee decision need to be completed prior to expiry date of the current certificate. The new certificate shall then be considered as continuation of certification. In case of situation that corrective action is not submitted in time to complete certification decision, then recertification will not be granted and the validity of the certification will not be extended. The client will be informed and the consequences will be explained. Following expiration of certification, JC Auditors will 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.

The audit report is submitted only after satisfactory verification of corrective actions taken for the non-conformance(s). The client shall submit the evidence of implementation of corrections and corrective actions of any major nonconformity within 6 months after the last day of the audit, if this period is lapsed, JC Auditors shall conduct another stage 2 audit prior to recertification being issued.. The following process is followed once non-conformances are issued:

- The client is sent the non-conformances within 5 days of the closing meeting.
- the client is sent the first reminder of reminder after 60 days of the closing meeting.
- the client is sent the second reminder after 120 days of the closing meeting indicating that certification is suspended.
- The client is sent the final reminder after 150 days of the closing meeting notifying them that a response is required within 30 days or a stage 2 audit will be conducted in order to restore certification.

4.8 Random Audits

4.8.1 Certified clients must continue to comply with the current version of the standard and

any changes to the system must also continue to comply. Also, the scope of registration must continue to be appropriate to the auditee organization's objectives and appropriate for the auditee organization's products and services. If they are repeated non-conformances or serious public compliants then random audits may be conducted.

4.8.2 Extensions to scope for clients already registered with Judah Compliance Auditors.

- Application form or letter should be completed by the client and returned to Judah Compliance Auditors
- Contract Review will always be carried out by the Certification Manager or appointed person to determine whether an audit or document review is required.

Once the document review is complete then the normal certification review is conducted.

If successful, a new certificate will be issued by Judah Compliance Auditors

Note: After certification, if the client changes anything which significantly affects the registration, then Judah Compliance Auditors must be informed. Judah Compliance Auditors reserves the right to re-assess.

4.8.3 A special visit may be carried out on request of the client for additional certification. Client may request for additional certification any time prior to certification audit or during the three-year period. In case the request is prior to stage 2 audits, the request shall be reviewed by Certification Manager and verified if the client's activities are within the Judah Compliance Auditors scope of accreditation. Stage 2 audit is carried out as described above. If the request is within the three-year period, an additional visit may be required to verify compliance. The commercials shall be communicated with the client. The visit may be merged with planned surveillance. Additional accreditation shall be affected only after successful completion of the audit. The certificate shall be accordingly

amended; however, the expiry date shall be the same. Fees may be charged towards additional accreditation and new certificate issue.

4.8.4 In terms of ISO 13485, Short notice or unannounced audits may be required when:

- external factors apply such as:
  - devices in scope of certification indicate a possible significant deficiency in the quality management system
  - significant safety and performance related information becoming known to JC Auditors
- significant changes occur which have been submitted as required by the regulations or become known to JC Auditors, and which could affect the decision on the client's state of compliance with the regulatory requirements
- when required by legal requirements under public law or by the relevant Regulatory Authority

The following are examples of such changes which could be significant and relevant to JC Auditors 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:

a) QMS – impact and changes:

i. new ownership

ii. extension to manufacturing and/or design control

iii. new facility, site change

1. 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

1. 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. QM management, personnel

1. 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

b. product related changes:

i. new products, categories

ii. addition of a new device 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)

c. QMS & Product related changes:

i. changes in standards, regulations

ii. post market surveillance, vigilance

An unannounced or short-notice audit may also be necessary if JC Auditors has justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements.

In terms of ISO 22000, when JCA conducts unannounced audits as part of surveillance activities, JCA will describe and make known in advance to the certified clients the conditions under which such audits will be organized and conducted.

4.9 Transfers

4.9.1 This applies only to transfers from other accredited certification bodies. Only transfers from companies which have certificates covered by an accreditation of an IAF signatory should be eligible for transfer. Certificates which are not accredited as below shall be treated as new clients.

4.9.2 Pre-transfer review

- Carry out the normal contract review procedure, Quotation Preparation and Staff Allocation, and possibly visit the client. There is no need for a document review unless an extension is involved.
- Check that the client's scope on their certificate is as stated on the questionnaire.
- Confirm the client's certificated activities are compatible with that of Judah Compliance Auditors

- Try to establish the reason for the client wanting to transfer.
- Check that all of the sites that the client wants transferring are covered by their current registration and not just Head Office.
- Check that the certificate is VALID and has not expired and that it is accredited. Certificates that have been suspended or withdrawn or are out of date shall not be considered for transfer. (Note: If the certification body has ceased trading or had its accreditation withdrawn then the transfer can still go ahead on the basis of this review procedure).
- Check the status in their current certificate cycle, take over the surveillance programme or are they due for a triennial re-audit etc. If a triennial is due, we must carry out a full triennial audit including planning and site visits. Any extensions to scope will result in visits.
- Request reports / checklists, non-conformances etc. from the previous certification body. The status of any outstanding non-conformance notices must be known. Non-conformances must be closed out by the previous certification body or sent to Judah Compliance Auditors with evidence of corrective actions taken for Judah Compliance Auditors to close out.
- Request verbal confirmation of the effectiveness of the complaint system. Request details of any major problems.

If no further outstanding problems from the above review are identified, then a certificate may be issued after authorisation by the Certification Committee.

4.9.3 The programme of surveillance visits/triennials is to be adopted from the previous certification body if applicable. Appendix Document is signed by the Chairman of the Certification Committee, Chief Executive and Technical Expert (if applicable) to authorise issue of the certificate.

Note: If, as a result of the review, some of the criteria are not met, then a site audit will be required.

4.10 Opening and Closing Meetings

4.10.1 The Opening and closing meeting are a critical part of the audit process. Opening meeting ensures that all parties understand what is going to happen and how best they can cooperate and coordinate their efforts. Closing meeting ensures that all parties understand the relevance of findings, what they need to do and what happens next. The meeting agenda contains a number of essential requirements which must be advised to the auditee organisation in addition to other useful items which make for a clearer understanding of what is expected from both parties. It is hence essential that all the agenda items listed in the audit meeting checklist is correct.

4.11 Multi-site audits (refer to QP 16 – Procedure for determining audit duration)

4.11.1 This procedure only applies in certain circumstances, e.g.:

- Engaged in distribution, having a number of strategically placed geographic distribution centres; or
- Operating a multi-outlet business; or
- Performing simple, repetitive processing at a number of different sites.

4.11.2 The program may be applied to the whole of the organization under an initial registration, or only part of the total number of sites may be registered initially, with others to be added later at the client's convenience.

Be particularly careful when planning audits on multi-site companies to take into consideration the working shifts and those that may require particular expertise. Ensure that the programme caters for a representative sample of the activities undertaken.

It is usual to audit the company Head Office and a sample of sites if all sites are working to the same management system and activities on each site are the same. (Company Head Office is usually where most of the system records are kept but this is not always the case,

each job is to be judged individually.)

4.11.3 There may be situations where sampling is not permitted due to the nature of the work or because the activities on each site are not common to each other. In this situation, the programme would need to allow for visiting each site and would determine the need for a full audit with resulting documentation at each site visited.

If the activities are common and a sample is taken initially, a rolling programme of surveillance visits must be established.

If additional sites need to be added, the client must be able to demonstrate that the new sites are included in a controlled manner. These will normally be treated as an extension to scope. They must be added to the rolling programme, increasing the amount of surveillance time and costs as appropriate.

4.11.4 With large, multi-site companies it is usual to appoint a Project Leader who will be responsible for on-going liaison with the client, arranging dates for surveillances, co-ordinating the rolling programme, and dealing with any day-to-day queries and sorting out extensions to scope. This ensures continuity with the client and that correct sites are visited on rolling programme.

It is not necessary to raise opening and closing meeting for every site visited, but a schedule is to be communicated to the auditors and client rep.

4.12 Multi-site audits

4.12.1 Multiple site audits under the control of a single are carried out in accordance with the following.

All sites will be audited, or the Head Office and a representative number of sites may be sampled by the audit team providing:

a) All sites have been audited in accordance with the internal audit procedures

b) A central management review has been carried out.

4.12.2 The sampling of the sites must include a representative number. The selection of the sites takes into account:

- the results of central and internal audits
- the results of management review
- variations in the size of the sites
- maturity of the system
- existing knowledge of the organisation
- shift patterns
- personnel involved
- repetitiveness of the work
- complexity of the RTMS, ISO 39001, ISO 14001, ISO 45001, ISO 22000, ISO 13485, ISO 3834 and ISO 9001
- complexity of the sites
- variations in working practices
- variations in activities undertaken
- the significance of the aspects
- potential interaction with sensitive environments
- differing legal requirements
- communications from interested parties

These requirements will be considered by the Certification Committee before awarding certificates.

In terms of ISO 22000, if any site has a major nonconformity and satisfactory corrective action have not been implemented in the agreed time frame, certification shall not be granted or maintained for the whole multi-site organization pending satisfactory corrective action.

4.13 Joint audits

4.13.1 Where there is a combined documented system the audits are carried out in accordance with this procedure with the completion of the auditor's reports showing that they have looked at the requirements of ISO 17021 in the areas allotted to them. The auditors assigned to the areas are trained in the requirements of the relevant standard(s) and if

necessary two auditors cover one area to ensure all requirements are addressed.

4.13.2 The audit is carried out according to the audit plan produced at Stage 1 / Document Review, with the Lead Auditor ensuring that the appropriately trained auditors are used for each area and part of the individual standards. Care is taken to ensure that the appropriate amount of time is spent on each area in the company and for ensuring full coverage of the standard requirements. The areas covered are reported on with details of the time spent in the key areas and indications of non-conformances. Where the auditors cover the requirements of more than one standard in one area at the same time during the audit, then the report should indicate this, and examples recorded should show evidence of this.

A plan for surveillance visits is produced at the end of the audit taking into account the time needed for each standard and the expertise for the various surveillance visits as well as the areas to be looked at.

4.13.3 Where a non-conformance is applicable to both standards, only one report is raised and referenced to both standards if appropriate.

4.13.4 If the recommendation is positive for both standards then one audit report is raised. Similarly, if the recommendation is negative for both standards then one audit report is raised. If the recommendation is positive for one standard and negative for the other, two audit reports will be completed separately.

4.13.5 This procedure is followed for surveillance audits with two or more standards being completed in the audit report. The auditor must ensure that sufficient time is allowed in each area to cover the requirements of both standards adequately. The auditor's report must show clearly that the requirements of both standards have been subjected to audit and evidence of compliance recorded.

4.14 Sampling plan and auditing time

4.14.1 As such there is no statistical or mathematical formula to establish the right number of

samples to be taken during an audit. Defining the number of samples to be taken to confirm conformity to the requirements of the standard is not efficient and does not ensure conformity. Adequate sampling would refer to a level of sampling taken during on site interviews and record reviews that give sufficient confidence that the auditee's QMS is implemented and maintained. For a transport operator, a 10% sample (minimum) is taken.

4.14.2 The auditor needs to perform interviews and check records and evidence during interview. The number of samples to be taken depends on the complexity of the processes being audited and the quality of information received from the auditee during the interview. It is also important that the auditor maintains the schedule outlined in the audit plan. At the end of the day the auditor needs to feel comfortable that the samples and the objective evidence seen are representative, in order to draw appropriate conclusions regarding the implementation of RTMS, ISO 39001, ISO 14001, ISO 45001, ISO 22000, ISO 13485, ISO 3834 and ISO 9001.

5.0 Reference

5.1 Work Instruction: Auditor Qualification

5.2 Work Instruction Guidelines for the applicable audits

5.3 ISO 17021 Auditing standard

6.0 Enclosure Nil

7.0 Formats / Exhibits

1. F30 – Audit Notification
2. F31 – Stage 1 Audit Report

F32 – Stage 2 Audit Report